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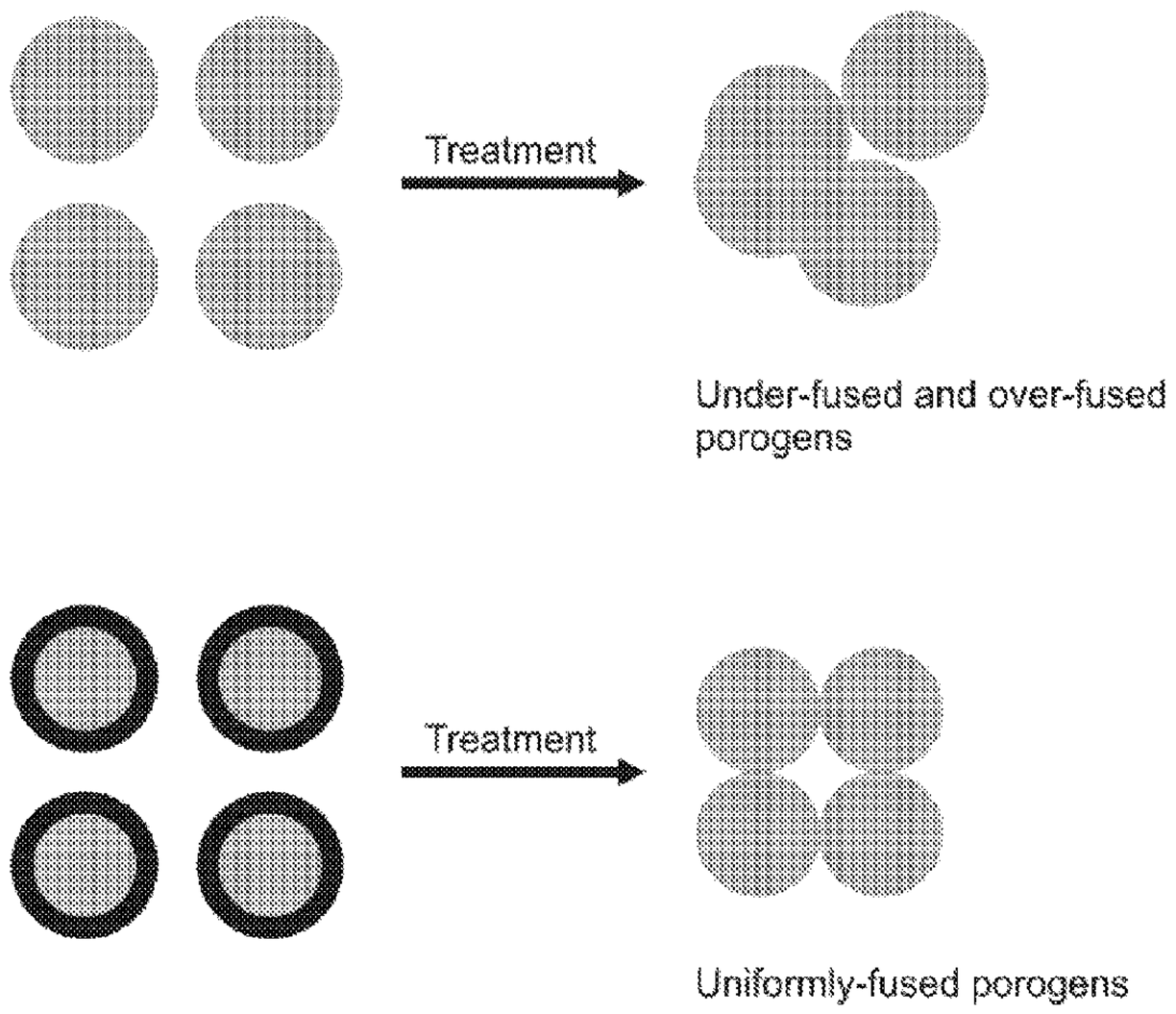
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(54) **Titre : COMPOSITIONS D'AGENTS POROGENES, LEURS PROCEDES DE FABRICATION ET UTILISATIONS**
(54) **Title: POROGEN COMPOSITIONS, METHODS OF MAKING AND USES**



(57) **Abrégé/Abstract:**
The present specification discloses porogen compositions comprising a core material and shell material, methods of making such porogen compositions, methods of forming such porous materials using such porogen compositions, biocompatible implantable devices comprising such porous materials, and methods of making such biocompatible implantable devices

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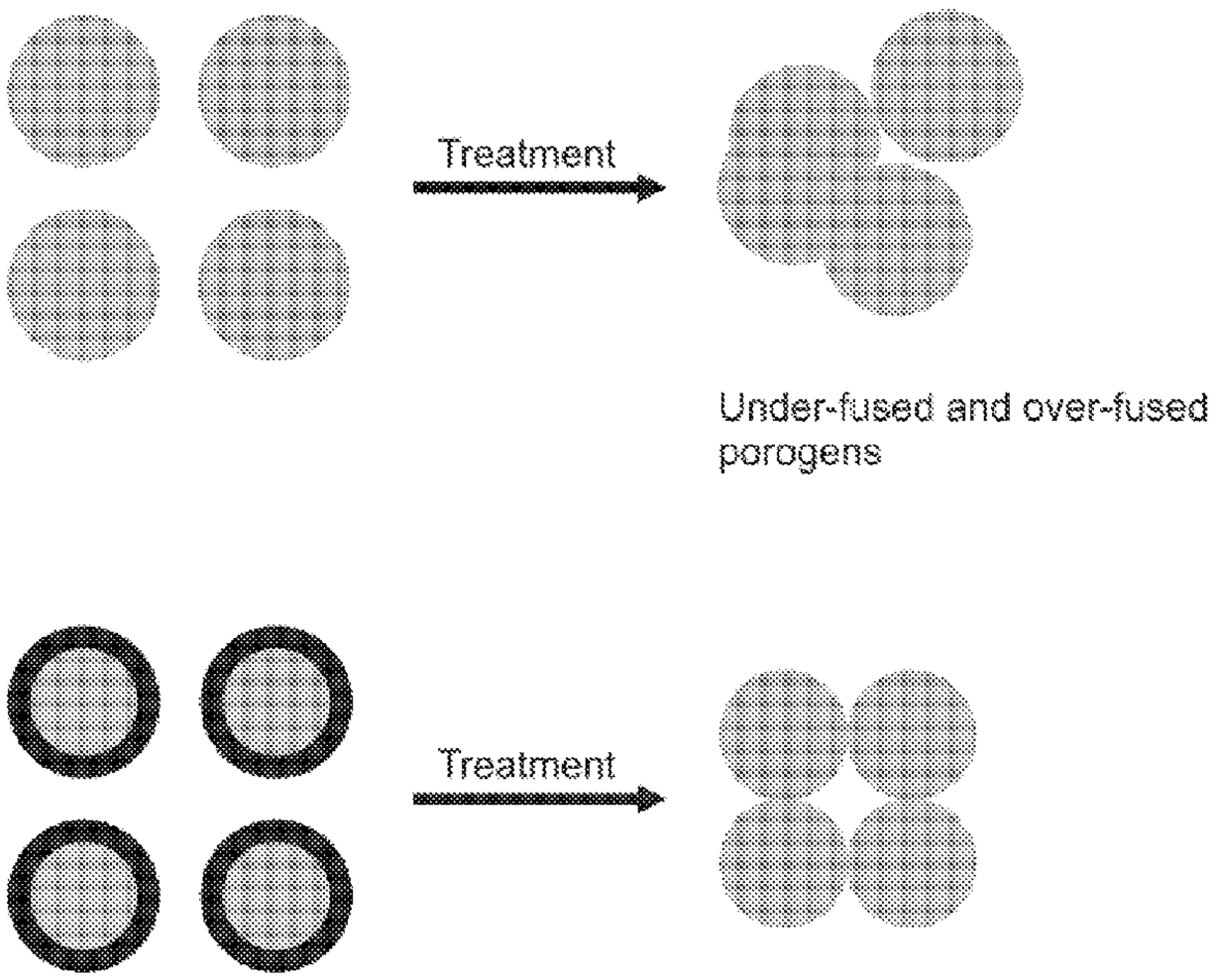
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(54) Title: POROGEN COMPOSITIONS, METHODS OF MAKING AND USES

(57) Abstract: The present specification discloses porogen compositions comprising a core material and shell material, methods of making such porogen compositions, methods of forming such porous materials using such porogen compositions, biocompatible implantable devices comprising such porous materials, and methods of making such biocompatible implantable devices

FIG. 1



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POROGEN COMPOSITIONS, METHODS OF MAKING AND USES

PRIORITY

[01] This patent application claims priority pursuant to 35 U.S.C. § 119(e) to U. S. Provisional Patent Application Serial No. 61/333,599 filed May 11, 2010, and claims priority pursuant to 35 U.S.C. § 120 to U.S. Patent Application Serial No. 13/021,615, filed February 4, 2011, which claims priority benefit to U.S. Provisional Application Serial No. 61/301,864, filed on February 5, 2010;,

INTRODUCTION

[02] Porous materials are widely used in biomedical, industrial, and household applications. In the biomedical field, porous materials have been used as a matrix for tissue engineering/regeneration, wound dressings, drug release matrices, membranes for separations and filtration, sterile filters, artificial kidneys, absorbents, hemostatic devices, and the like. In various industrial and household applications, porous materials have been used as insulating materials, packaging materials, impact absorbers, liquid or gas absorbents, membranes, filters and so forth.

[03] One general method of making a porous material relies on a three-dimensional scaffold used as a negative template. One such example is the porogen scaffold method. In this method, porogens are poured into a mold and treated, such as, e.g., by physical and/or chemical means to fuse the porogens, thereby forming a porogen scaffold comprising fused porogens that are all connected to one another. A material is then poured into the mold to coat the porogen scaffold and this material is then stabilized, such as, e.g., a curing process or a freezing process. After stabilization, the porogen scaffold is removed, leaving behind a porous material. See, e.g., Ma, Reverse Fabrication of Porous Materials, U.S. Patent Publication 2002/0005600; Ratner and Marshall, Novel Porous Materials, U.S. Patent Publication 2008/0075752; Ma and Chen, Porous Materials having Multi-Sized Geometries, U.S. Patent Publication 2007/0036844.

[04] Currently, the porogens used to make the porogen scaffolds are composed of a single material, such as, e.g., gelatin, sucrose, or poly(lactide-co-glycolide). However, the physical and/or chemical treatment to fuse the porogens together does not typically result in a uniform fusion of all porogens to form a well-structured porogen scaffold. For example, most porogens are fused using thermal means where the porogens, in the solid phase, are heated to a temperature above the melting point (or glass transition point). At this temperature, the porogens transition to a liquid phase allowing the porogens to melt together. This process is carefully controlled to allow sufficient melting to form the desired numbers of connections. Too short a thermal treatment will result in an insufficient number of porogen fusions, whereas to long a thermal treatment will result in formation of a solid block. However, even though comprised of the same material, not all porogens melt at the same time. So, even under carefully controlled conditions, the resulted porogen scaffold is not uniformly structured.

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[05] As such, there is a continuing need for porogens that upon physical and/or chemical treatment, a porogen scaffold of uniformly fused porogens is produced. The present application discloses porogen compositions comprising a shell material and a core material and methods of making these porogen compositions. Upon physical and/or chemical treatment the porogen compositions disclosed herein produce porogen scaffold of uniformly fused porogens.

SUMMARY

[06] Thus, aspects of the present specification disclose a porogen composition comprising a shell material and a core material.

[07] Other aspects of the present specification disclose a method of forming a porogen composition, the method comprising the steps of: a) making a particle out of a core material; and b) coating the particle with a shell material.

[08] Yet other aspects of the present specification disclose a method of forming a porous material, the method comprising the steps of: a) fusing porogens disclosed herein to form a porogen scaffold comprising fused porogens; b) coating the porogen scaffold with a material to form an material coated porogen scaffold; c) stabilizing the material coated porogen scaffold; and d) removing the porogen scaffold, wherein porogen scaffold removal results in a porous material, the porous material comprising a matrix defining an array of interconnected pores.

[09] Still other aspects of the present specification disclose a method of forming a porous material, the method comprising the steps of: a) coating porogens disclosed herein with a material to form a material coated porogen mixture; b) treating the material coated porogen mixture to form a porogen scaffold comprising fused porogens and a stabilized material; and c) removing the porogen scaffold fro the stabilized material, wherein porogen scaffold removal results in a porous material, the porous material comprising a matrix defining an array of interconnected pores.

[010]Further aspects of the present specification disclose a method of making a biocompatible implantable device, the method comprising the steps of: a) preparing the surface of a biocompatible implantable device to receive a porous material; b) attaching a porous material to the prepared surface of the biocompatible implantable device. The porous material can be made by the method disclosed in the present specification.

[011] Further aspects of the present specification disclose a method for making a biocompatible implantable device, the method comprising the step of: a) coating a mandrel with an elastomer base; b) curing the elastomer base to form a base layer; c) coating the cured base layer with an elastomer base; d) coating the elastomer base with porogens to form an elastomer coated porogen mixture, the porogens comprise a shell material and a core material as disclosed in the present specification; e) treating the

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elastomer coated porogen mixture to form a porogen scaffold comprising fused porogens and cure the elastomer base; and f) removing the porogen scaffold, wherein porogen scaffold removal results in a porous material, the porous material comprising a non-degradable, biocompatible, elastomer matrix defining an array of interconnected pores. In this method steps (c) and (d) can be repeated multiple times until the desired thickness of the material layer is achieved.

[011A] In an embodiment, there is provided a porogen composition as defined above and herein, wherein the porogen composition comprises about 35% to about 50% sucrose, about 10% to about 15% starch, and about 40% to 50% polyethylene glycol, by weight.

[011B] In an embodiment, there is provided a porogen composition as defined above and herein, wherein the porogen composition comprises about 45% sucrose, about 10% starch, and about 45% polyethylene glycol, by weight.

[011C] In an embodiment, there is provided a porogen composition as defined above and herein, wherein the porogen composition comprises about 40% sucrose, about 15% starch, and about 45% polyethylene glycol, by weight.

[011D] In an embodiment, there is provided a porogen composition as defined above and herein, wherein the porogen composition comprises about 35% to about 50% sucrose, about 10% to about 15% starch, and about 40% to 50% polyethylene glycol, by weight.

[011E] In an embodiment, there is provided a porogen composition as defined above and herein, wherein the porogen composition comprises about 45% sucrose, about 10% starch, and about 45% polyethylene glycol, by weight.

[011F] In an embodiment, there is provided a porogen composition as defined above and herein, wherein the porogen composition comprises about 40% sucrose, about 15% starch, and about 45% polyethylene glycol, by weight.

[011G] In an embodiment, there is provided a method of making porogen composition as defined above and herein, wherein the porogen composition comprises about 35% to about 50% sucrose, about 10% to about 15% starch, and about 40% to 50% polyethylene glycol, by weight.

[011H] In an embodiment, there is provided a method of making a porogen composition as defined above and herein, wherein the porogen composition comprises about 45% sucrose, about 10% starch, and about 45% polyethylene glycol, by weight.

[011I] In an embodiment, there is provided a method of making a porogen composition as defined above and herein, wherein the porogen composition comprises about 40% sucrose, about 15% starch, and about 45% polyethylene glycol, by weight.

BRIEF DESCRIPTION OF THE DRAWINGS

[012] FIG. 1 illustrates the porogens consisting of a single material and porogens comprising a shell material and a core material as disclosed in the present specification. Controlled fusion of porogens consisting of a single material is difficult due to the random timing that each porogen transitions from its solid phase to its liquid phase. As such, fusing porogens under a treatment results in insufficient fusion of the porogens (or under-fusion) and/or too much fusion of porogens (over-fusion). Controlled fusion of porogens can be accomplished using the porogen compositions disclosed in the present specification. Treatment is done under conditions that allow the shell material to transition from its solid phase to its liquid phase, but maintain the core material in its solid phase. As such, fusion of porogen compositions disclosed herein result in a more uniform porogen scaffold.

[013] FIG. 2 illustrates a representative biocompatible implantable device covered with a porous material of the present specification. FIG. 2A is a top view of an implantable device covered with a porous material. FIG. 2B is a side view of an implantable device covered with a porous material. FIG. 2C and 2D illustrate the cross-sectional view of the biocompatible implantable device covered with a porous material.

[014] FIG. 3 illustrates a representative porous material shell of the present specification. FIG. 3A is a top view of a material shell. FIG. 3B is a side view of a material shell. FIG. 3C is a bottom view of a material shell. FIG. 3D illustrate the cross-sectional view of the material shell.

[015] FIG. 4 illustrates a representative biocompatible implantable device covered with a porous material of the present specification. FIG. 4A is a top view of an implantable device covered with a porous material. FIG. 4B is a side view of an implantable device covered with a porous material. FIG. 4C is a bottom view of a biocompatible implantable device covered with a porous material. FIG. 4D illustrates the cross-sectional view of the biocompatible implantable device covered with a porous material.

[016] FIG. 5 shows an analysis of a porous material as disclosed in the present specification. FIG. 5A is scanning electron micrograph image at 50x magnification of the top-view of the porous material. FIG. 5B is scanning electron micrograph image at 50x magnification of the cross-section of the porous material.

[017] FIG. 6 shows an analysis of a porous material as disclosed in the present specification. FIG. 6A is scanning electron micrograph image at 50x magnification of the top-view of the porous material. FIG. 6B is scanning electron micrograph image at 50x magnification of the cross-section of the porous material.

[018] FIG. 7 shows an analysis of a porous material as disclosed in the present specification. FIG. 7A is scanning electron micrograph image at 50x magnification of the top-view of the porous material. FIG. 7B is scanning electron micrograph image at 50x magnification of the cross-section of the porous material.

[019] FIG. 8 shows an analysis of a porous material as disclosed in the present specification. FIG. 8A is scanning electron micrograph image at 50x magnification of the top-view of the porous material. FIG. 8B is scanning electron micrograph image at 50x magnification of the cross-section of the porous material.

[020] FIG. 9 are bar graphs showing data of thickness and disorganization of capsules from various biomaterials, normalized to Textured 1 biomaterial. FIG 9A shows a bar graph of thickness data as normalized mean ± normalized standard deviation. FIG 9B shows a bar graph of disorganization normalized with a standard deviation with upper and lower bounds of confidence intervals.

[021] FIG. 10 is bar graph showing data of collagen content of capsules formed over various biomaterials (n=6). Results are shown as mean ± standard deviation. Asterisks (*) indicates a statistically significant from Texture 1 biomaterial.

[022] FIG 11 is a bar graph showing data from a tissue adhesion test of various biomaterials. Results are shown as mean ± standard deviation.

[023] FIG. 12 is bar graph showing data of stiffness of capsule/ingrowth formed over various tissue expanders at time 0 and at 6 weeks (n=8). Results are shown as mean ± standard deviation.

DETAILED DESCRIPTION

[024] The porogen compositions disclosed herein provide a means to control the degree and amount of fusion that occurs during a treatment. This is accomplished, in part, by providing a shell material and a core material, where the shell material has a lower melting point temperature and/or glass transition temperature relative to the core material. Currently, porogens are composed of a single material. Controlling the fusion of these single material porogens is difficult, due, in part, to the random timing that each individual porogen transitions from its solid phase to its liquid phase. As such, under any given treatment condition designed to cause porogen fusion, there will be a population of porogens that have remained in the solid phase, and yet at the same time, a population of porogens that have completely transitioned into their liquid or rubbery phase (FIG. 1). This unequal or uncontrolled transition from the

solid phase to the liquid or rubbery phase results in a porogen scaffold that comprises regions of insufficient porogen fusion (or under-fusion) and/or too much porogen fusion (over-fusion). The uncontrolled nature of the fusion process produces an un-uniform porogen scaffold that ultimately results in porous materials with a matrix of un-uniform pore sizes and interconnections. Such a disorganized structure can reduce the utility of porous materials. The porogen compositions disclosed herein overcome the uncontrollable fusion rates observed in single material porogens. The compositions disclosed herein comprise porogens comprising a shell material and a core material. Controlled fusion of porogens is achieved because fusion treatment is performed under conditions that allow the shell material to transition from its solid phase to its liquid or rubbery phase, but the core material is maintained in its solid phase. As such, fusion of porogen compositions disclosed herein result in a more uniform porogen scaffold (FIG. 1). Thus, a method of making a porous material that utilizes a porogen composition of the present specification will produce a porous material with a more uniform matrix of pore size and interconnections.

[025] The present specification discloses, in part, a porogen composition. As used herein, the term “porogen composition” or "porogen(s)" refers to any structured material that can be used to create a porous material.

[026] Porogens have a shape sufficient to allow formation of a porogen scaffold useful in making an elastomer matrix as disclosed in the present specification. Any porogen shape is useful with the proviso that the porogen shape is sufficient to allow formation of a porogen scaffold useful in making an elastomer matrix as disclosed in the present specification. Useful porogen shapes include, without limitation, roughly spherical, perfectly spherical, ellipsoidal, polyhedronal, triangular, pyramidal, quadrilateral like squares, rectangles, parallelograms, trapezoids, rhombus and kites, and other types of polygonal shapes.

[027] In an embodiment, porogens have a shape sufficient to allow formation of a porogen scaffold useful in making an elastomer matrix that allows tissue growth within its array of interconnected of pores. In aspects of this embodiment, porogens have a shape that is roughly spherical, perfectly spherical, ellipsoidal, polyhedronal, triangular, pyramidal, quadrilateral, or polygonal.

[028] Porogens have a roundness sufficient to allow formation of a porogen scaffold useful in making a matrix defining an array of interconnected of pores. As used herein, "roundness" is defined as $(6 \times V)/(\pi \times D^3)$, where V is the volume and D is the diameter. Any porogen roundness is useful with the proviso that the porogen roundness is sufficient to allow formation of a porogen scaffold useful in making an elastomer matrix as disclosed in the present specification.

[029] In an embodiment, porogens have a roundness sufficient to allow formation of a porogen scaffold useful in making a matrix defining an array of interconnected of pores. In aspects of this embodiment, porogens have a mean roundness of, *e.g.*, about 0.1, about 0.2, about 0.3, about 0.4, about 0.5, about 0.6, about 0.7, about 0.8, about 0.9, or about 1.0. In other aspects of this embodiment, porogens have a

mean roundness of, *e.g.*, at least 0.1, at least 0.2, at least 0.3, at least 0.4, at least 0.5, at least 0.6, at least 0.7, at least 0.8, at least 0.9, or at least 1.0. In yet other aspects of this embodiment, porogens have a mean roundness of, *e.g.*, at most 0.1, at most 0.2, at most 0.3, at most 0.4, at most 0.5, at most 0.6, at most 0.7, at most 0.8, at most 0.9, or at most 1.0. In still other aspects of this embodiment, have a mean roundness of, *e.g.*, about 0.1 to about 1.0, about 0.2 to about 1.0, about 0.3 to about 1.0, about 0.4 to about 1.0, about 0.5 to about 1.0, about 0.6 to about 1.0, about 0.7 to about 1.0, about 0.8 to about 1.0, about 0.9 to about 1.0, about 0.1 to about 0.9, about 0.2 to about 0.9, about 0.3 to about 0.9, about 0.4 to about 0.9, about 0.5 to about 0.9, about 0.6 to about 0.9, about 0.7 to about 0.9, about 0.8 to about 0.9, about 0.1 to about 0.8, about 0.2 to about 0.8, about 0.3 to about 0.8, about 0.4 to about 0.8, about 0.5 to about 0.8, about 0.6 to about 0.8, about 0.7 to about 0.8, about 0.1 to about 0.7, about 0.2 to about 0.7, about 0.3 to about 0.7, about 0.4 to about 0.7, about 0.5 to about 0.7, about 0.6 to about 0.7, about 0.1 to about 0.6, about 0.2 to about 0.6, about 0.3 to about 0.6, about 0.4 to about 0.6, about 0.5 to about 0.6, about 0.1 to about 0.5, about 0.2 to about 0.5, about 0.3 to about 0.5, or about 0.4 to about 0.5.

[030] A porogen has a thickness sufficient to allow formation of a porogen scaffold. As such, a porogen can be of any thickness, with the proviso that the thickness of the porogen is sufficient to create a porogen scaffold useful for its intended purpose. The thickness of a porogen can be measured base on its shape. For example, for spherical and elliptical porogens, thickness is measured based on the diameter of the core material. For example, for sided-shaped porogens, like polyhedrons, triangles, pyramids, quadrilateral, or polygons, thickness is measured based on the base width of the porogen.

[031] In another embodiment, a porogen comprises mean porogen diameter sufficient to allow formation of a porogen scaffold useful in making a matrix defining an array of interconnected of pores. In aspects of this embodiment, a porogen comprises mean porogen diameter of, *e.g.*, about 50 μm, about 75 μm, about 100 μm, about 150 μm, about 200 μm, about 250 μm, about 300 μm, about 350 μm, about 400 μm, about 450 μm, or about 500 μm. In other aspects, a porogen comprises mean porogen diameter of, *e.g.*, about 500 μm, about 600 μm, about 700 μm, about 800 μm, about 900 μm, about 1000 μm, about 1500 μm, about 2000 μm, about 2500 μm, or about 3000 μm. In yet other aspects of this embodiment, a porogen comprises mean porogen diameter of, *e.g.*, at least 50 μm, at least 75 μm, at least 100 μm, at least 150 μm, at least 200 μm, at least 250 μm, at least 300 μm, at least 350 μm, at least 400 μm, at least 450 μm, or at least 500 μm. In still other aspects, a porogen comprises mean porogen diameter of, *e.g.*, at least 500 μm, at least 600 μm, at least 700 μm, at least 800 μm, at least 900 μm, at least 1000 μm, at least 1500 μm, at least 2000 μm, at least 2500 μm, or at least 3000 μm. In further aspects of this embodiment, a porogen comprises mean porogen diameter of, *e.g.*, at most 50 μm, at most 75 μm, at most 100 μm, at most 150 μm, at most 200 μm, at most 250 μm, at most 300 μm, at most 350 μm, at most 400 μm, at most 450 μm, or at most 500 μm. In yet further aspects of this embodiment, a porogen comprises mean porogen diameter of, *e.g.*, at most 500 μm, at most 600 μm, at most 700 μm, at most 800 μm, at most 900 μm, at most 1000 μm, at most 1500 μm, at most 2000 μm, at most 2500 μm, or at most 3000 μm. In still further aspects of this embodiment, a porogen comprises mean porogen diameter of, *e.g.*, about 300 μm to about 600 μm, about 200 μm to about 700 μm, about 100 μm to about 800 μm, about 500 μm to about 800 μm, about 50 μm to about 500 μm, about 75 μm to about 500 μm,

about 100 µm to about 500 µm, about 200 µm to about 500 µm, about 300 µm to about 500 µm, about 50 µm to about 1000 µm, about 75 µm to about 1000 µm, about 100 µm to about 1000 µm, about 200 µm to about 1000 µm, about 300 µm to about 1000 µm, about 50 µm to about 1000 µm, about 75 µm to about 3000 µm, about 100 µm to about 3000 µm, about 200 µm to about 3000 µm, or about 300 µm to about 3000 µm.

[032] In another embodiment, a porogen comprise mean porogen base sufficient to allow formation of a porogen scaffold useful in making a matrix defining an array of interconnected of pores. In aspects of this embodiment, a porogen comprises mean porogen base of, *e.g.*, about 50 µm, about 75 µm, about 100 µm, about 150 µm, about 200 µm, about 250 µm, about 300 µm, about 350 µm, about 400 µm, about 450 µm, or about 500 µm. In other aspects, a porogen comprises mean porogen base of, *e.g.*, about 500 µm, about 600 µm, about 700 µm, about 800 µm, about 900 µm, about 1000 µm, about 1500 µm, about 2000 µm, about 2500 µm, or about 3000 µm. In yet other aspects of this embodiment, a porogen comprises mean porogen base of, *e.g.*, at least 50 µm, at least 75 µm, at least 100 µm, at least 150 µm, at least 200 µm, at least 250 µm, at least 300 µm, at least 350 µm, at least 400 µm, at least 450 µm, or at least 500 µm. In still other aspects, a porogen comprises mean porogen base of, *e.g.*, at least 500 µm, at least 600 µm, at least 700 µm, at least 800 µm, at least 900 µm, at least 1000 µm, at least 1500 µm, at least 2000 µm, at least 2500 µm, or at least 3000 µm. In further aspects of this embodiment, a porogen comprises mean porogen base of, *e.g.*, at most 50 µm, at most 75 µm, at most 100 µm, at most 150 µm, at most 200 µm, at most 250 µm, at most 300 µm, at most 350 µm, at most 400 µm, at most 450 µm, or at most 500 µm. In yet further aspects of this embodiment, a porogen comprises mean porogen base of, *e.g.*, at most 500 µm, at most 600 µm, at most 700 µm, at most 800 µm, at most 900 µm, at most 1000 µm, at most 1500 µm, at most 2000 µm, at most 2500 µm, or at most 3000 µm. In still further aspects of this embodiment, a porogen comprises mean porogen base of, *e.g.*, about 300 µm to about 600 µm, about 200 µm to about 700 µm, about 100 µm to about 800 µm, about 500 µm to about 800 µm, about 50 µm to about 500 µm, about 75 µm to about 500 µm, about 100 µm to about 500 µm, about 200 µm to about 500 µm, about 300 µm to about 500 µm, about 50 µm to about 1000 µm, about 75 µm to about 1000 µm, about 100 µm to about 1000 µm, about 200 µm to about 1000 µm, about 300 µm to about 1000 µm, about 50 µm to about 1000 µm, about 75 µm to about 3000 µm, about 100 µm to about 3000 µm, about 200 µm to about 3000 µm, or about 300 µm to about 3000 µm.

[033] The present specification discloses, in part, a porogen comprising a shell material. A shell material of a porogen can be made of any material with the proviso that 1) the melting point temperature (Tm) of the shell material is lower than the melting point temperature of the core material; and/or 2) the glass transition temperature (T_g) of the shell material is lower than the glass transition temperature of the core material. As used herein, the term “melting point temperature” or “melting point” refers to the temperature at which the solid and liquid phases of a material exist in equilibrium, at any fixed pressure, and is the temperature at which the first trace of liquid appears. For a material made of a pure substance, the melting, or fusion, process occurs at a single temperature. For a material made of two or more substances, the melting process normally occurs over a range of temperatures, and a distinction is made between the melting point and the freezing point temperature. As used herein, the term “freezing point

temperature" or "freezing point" refers to the temperature at which the solid and liquid phases of a material exist in equilibrium, at any fixed pressure, and is the temperature at which the last trace of solid disappears. The freezing point temperature is usually higher than the melting point temperature in materials made from two or more substances.

[034] Amorphous materials, as well as some polymers, do not have a true melting point temperature as there is no abrupt phase change from a solid phase to a liquid phase at any specific temperature. Instead, amorphous materials and polymers exhibit a gradual change in viscoelastic properties over a range of temperatures. Such materials are characterized by vitrification, or glass transition, the process of converting a material into a glassy amorphous solid that is free from crystalline structure. Vitrification occurs at a glass transition temperature. As used herein, the term "glass transition temperature" refers to the temperature at which the glass and liquid phases of an amorphous material exist in equilibrium, at any fixed pressure, and is the temperature that roughly defined the "knee" point of the material's density vs. temperature graph. The glass transition temperature of an amorphous material is lower than its melting temperature.

[035] A shell material can comprise a natural or synthetic, inorganic or organic material. Exemplary materials suitable as a shell material disclosed in the present specification, include, without limitation, natural and synthetic salt and its derivatives, natural and synthetic ceramic and/or its derivatives, natural and synthetic sugar and its derivatives, natural and synthetic polysaccharide and its derivatives, natural and synthetic wax and its derivatives, natural and synthetic metal and its derivatives, natural and synthetic surfactant and its derivatives, natural and synthetic organic solid and its derivatives, natural and synthetic water soluble solid and its derivatives, and/or natural and synthetic polymer and its derivatives, composites thereof, and/or combinations thereof.

[036] A natural or synthetic salt and its derivatives refer to ionic compounds composed of cations and anions so that the product is electrically neutral. The component ions of a salt can be inorganic or organic, as well as, a monoatomic ion or a polyatomic ion. Common salt-forming cations include, without limitation, Ammonium NH_4^+, Calcium Ca^{2+}, Iron Fe^{2+} and Fe^{3+}, Magnesium Mg^{2+}, Potassium K^+, Pyridinium $C_5H_5NH^+$, Quaternary ammonium NR_4^+, and Sodium Na^+. Common salt-forming anions include, without limitation, Acetate CH_3COO^-, Carbonate CO_3^{2-}, Chloride Cl^-, Citrate $HOC(COO^-)(CH_2COO^-)_2$, Cyanide $C{\equiv}N^-$, Hydroxide OH^-, Nitrate NO_3^-, Nitrite NO_2^-, Oxide O^{2-}, Phosphate PO_4^{3-}, and Sulfate SO_4^{2-}. Non-limiting examples of salts include, cobalt chloride hexahydrate, copper sulfate pentahydrate, ferric hexacyanoferrate, lead diacetate, magnesium sulfate, manganese dioxide, mercury sulfide, monosodium glutamate, nickel chloride hexahydrate, potassium bitartrate, potassium chloride, potassium dichromate, potassium fluoride, potassium permanganate, sodium alginate, sodium chromate, sodium chloride, sodium fluoride, sodium iodate, sodium iodide, sodium nitrate, sodium sulfate, and/or mixtures thereof.

[037] A natural or synthetic ceramic and its derivatives refer to inorganic, non-metallic solids that can have a crystalline or partly crystalline structure, or can be amorphous (e.g., a glass). Ceramics include

oxides, such as, *e.g.*, alumina and zirconium dioxide, non-oxides, such as, *e.g.*, carbides, borides, nitrides, and silicides; and composites comprising combinations of oxides and non-oxides. Non-limiting examples of salts include, alumina, barium titanate, bismuth strontium calcium copper oxide, boron nitride, lead zirconate titanate, magnesium diboride, Silicon aluminium oxynitride, silicon carbide, silicon nitride, strontium titanate, titanium carbide, uranium oxide, yttrium barium copper oxide, zinc oxide, and zirconium dioxide.

[038] A natural or synthetic sugar and its derivatives refer to a compound comprising one to 10 monosaccharide units, e.g.. a monosaccharide, a disaccharide, a trisaccharide, and an oligosaccharide comprising four to ten monosaccharide units. Monosaccharides are polyhydroxy aldehydes or polyhydroxy ketones with three or more carbon atoms, including aldoses, dialdoses, aldoketoses, ketoses and diketoses, as well as cyclic forms, deoxy sugars and amino sugars, and their derivatives, provided that the parent monosaccharide has a (potential) carbonyl group. Oligosaccharides are compounds in which at least two monosaccharide units are joined by glycosidic linkages. According to the number of units, they are called disaccharides, trisaccharides, tetrasaccharides, pentasaccharides, hexasaccharides, heptasaccharides, octasaccharide, nonasaccharides, decasaccharides, etc. An oligosaccharide can be unbranched, branched or cyclic. Non-limiting examples of sugars include, monosacchrides, such as, e.g., trioses, like glyceraldehyde and dihydroxyacetone; tetroses, like erythrose, threose and erythrulose; pentoses, like arabinose, lyxose, ribose, xylose, ribulose, xylulose; hexoses, like allose, altrose, galactose, glucose, gulose, idose, mannose, talose, fructose, psicose, sorbose, tagatose, fucose, rhamnose; heptoses, like sedoheptulose and mannoheptulose; octooses, like octulose and 2-keto-3-deoxy-manno-octonate; nonoses like sialose; and decose; and oligosaccharides, such as, e.g., disaccharides, like sucrose, lactose, maltose, trehalose, cellobiose, gentiobiose, kojibiose, laminaribiose, mannobiose, melibiose, nigerose, rutinose, and xylobiose; trisaccharides like raffinose, acarbose, maltotriose, and melezitose and/or mixtures thereof. Sugars also include sugar substitutes like acesulfame potassium, alitame, aspartame, acesulfame, cyclamate, dulcin, glucin, neohesperidin dihydrochalcone, neotame, saccharin, and sucralose.

[039] A natural or synthetic polysaccharide and its derivatives refer to a polymeric carbohydrate compound comprising more than 10 repeating monosaccharide of disaccharide units joined by glycosidic bonds. A polysaccharide can be linear or contain various degrees of branching. Depending on the structure, these macromolecules can have distinct properties from their monosaccharide building blocks. They may be amorphous or even insoluble in water. When all the monosaccharides in a polysaccharide are the same type the polysaccharide is called a homopolysaccharide, but when more than one type of monosaccharide is present they are called heteropolysaccharides. Non-limiting examples of polysaccharides include, amylose; cellulose; cellulose derivatives (like FICOLL*, alkyl cellulose, carboxy cellulose, methyl cellulose, carboxymethyl cellulose, hemicellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxyethyl methyl cellulose, hydroxypropyl methyl cellulose); chitin; chitosan; dextrans (like dextran 1K, dextran 4K, dextran 40K, dextran 60K, and dextran 70K); dextrin; glycogen; inulin; glycosaminoglycans (like chondroitin sulfates, keratin sulfates, heparin sulfates, alginic acid,

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hyaluronic acid); pectin; pullulan; starch; hetastarch; starch derivatives (like hydroxymethyl starch, hydroxyethyl starch, hydroxypropyl starch, hydroxybutyl starch, and hydroxypentyl starch); xanthan; and salts thereof.

[040] A natural or synthetic wax and its derivatives refer to a type of lipid that contain a wide variety of long-chain alkanes, esters, polyesters and hydroxy esters of long-chain primary alcohols and fatty acids. Waxes are usually distinguished from fats by the lack of triglyceride esters of glycerin (propan-1,2,3-triol) and three fatty acids. Waxes include animal waxes, vegetable waxes, mineral waxes, petroleum waxes, synthetic waxes and/or mixtures thereof. Non-limiting examples of waxes include animal waxes like beeswax, Chinese wax, lanolin (wool wax), shellac wax, spermaceti; vegetable waxes like bayberry wax, candelilla wax, carnauba wax, castor wax, esparto wax, Japan wax, jojoba wax, ouricury wax, rice bran wax, soy wax; mineral waxes like ceresin wax, montan wax, ozokerite, peat wax; petroleum waxes like paraffin wax, microcrystalline wax, petroleum jelly; and synthetic waxes like polyethylene wax, Fischer-Tropsch* wax, esterified wax, saponified wax, substituted amide wax, polymerized α-olefin wax.

[041] A natural or synthetic metal and its derivatives refer to an element, compound, or alloy characterized by high electrical conductivity. An alloy is a mixture of two or more elements in solid solution in which the major component is a metal. A metal can be a base metal, a ferrous metal, a noble metal, or a precious metal. Non limiting examples of metals include alkali metals, like Lithium, Sodium, Potassium, Rubidium, Caesium, and Francium; alkaline earth metals like Beryllium, Magnesium, Calcium, Strontium, Barium, and Radium; transition metals like Zinc, Molybdenum, Cadmium, Scandium, Titanium, Vanadium, Chromium, Manganese, Iron, Cobalt, Nickel, Copper, Yttrium, Zirconium, Niobium, Technetium, Ruthenium, Rhodium, Palladium, Silver, Hafnium, Tantalum, Tungsten, Rhenium, Osmium, Iridium, Platinum, Gold, Mercury, Rutherfordium, Dubnium, Seaborgium, Bohrium, Hassium, Meitnerium, Darmstadtium, Roentgenium, and Copernicium; post-transition metals like Aluminium, Gallium, Indium, Tin, Thallium, Lead, Bismuth, Ununtrium, Ununquadium, Ununpentium, and Ununhexium; lanthanoids like Lanthanum, Cerium, Praseodymium, Neodymium, Promethium, Samarium, Europium, Gadolinium, Terbium, Dysprosium, Holmium, Erbium, Thullium, Ytterbium, and Lutetium; and actinoids like Actinium, Thorium, Protactinium, Uranium, Neptunium, Plutonium, Americium, Curium, Berkelium, Californium, Einsteinium, Fermium, Mendelevium, Nobelium, and Lawrencium.

[042] A natural or synthetic surfactant and its derivatives refer to organic compounds that are amphiphilic and are soluble in both organic solvents and water. A surfactant includes, without limitation, ionic surfactants like cationic surfactants (based on quaternary ammonium cations) and anionic surfactants (based on sulfate, sulfonate or carboxylate anions), zwitterionic (amphoteric) surfactants, and/or non-ionic surfactants. Non-limiting examples of surfactants include anionic surfactants like perfluorooctanoate (PFOA or PFO), perfluorooctanesulfonate (PFOS), sodium dodecyl sulfate (SDS), ammonium lauryl sulfate, and other alkyl sulfate salts, sodium laureth sulfate, also known as sodium lauryl ether sulfate (SLES), alkyl benzene sulfonate, soaps, and fatty acid salts; cationic surfactants like cetyl trimethylammonium bromide (CTAB), also known as hexadecyl trimethyl ammonium bromide, and other alkyltrimethylammonium salts, cetylpyridinium chloride (CPC), polyethoxylated tallow amine (POEA), benzalkonium chloride (BAC), benzethonium chloride (BZT); zwitterionic surfactants like dodecyl

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betaine, cocamidopropyl betaine, coco ampho glycinate; and nonionic surfactants like sucrose monolaurate, sodium cholate, dodecyl dimethylamine oxide, alkyl naphthalene sulfonates (ANS), alkyl poly(ethylene oxide), alkylphenol poly(ethylene oxide), poly(ethylene oxide) and poly(propylene oxide) co-polymers, also known as Poloxamers or Poloxamines including Poloxamer 124 (PLURONIC® L44), Poloxamer 181 (PLURONIC® L61), Poloxamer 182 (PLURONIC® L62), Poloxamer 184 (PLURONIC® L64), Poloxamer 188 (PLURONIC® F68), Poloxamer 237 (PLURONIC® F87), Poloxamer 338 (PLURONIC® L108), and Poloxamer 407 (PLURONIC® F127), alkyl polyglucosides, including octyl glucoside and decyl maltoside, fatty alcohols including cetyl alcohol and oleyl alcohol, cocamide MEA, cocamide DEA, polysorbates including polysorbate 20 (TWEEN® 20), polysorbate 40 (TWEEN® 40), polysorbate 60 (TWEEN® 60), polysorbate 61 (TWEEN® 61), polysorbate 65 (TWEEN® 65), polysorbate 80 (TWEEN® 80), and polysorbate 81 (TWEEN® 81); polyoxyethyleneglycol dodecyl ethers, like BRIJ® 30, and BRIJ® 35; 2-dodecoxyethanol (LUBROL®-PX); polyoxyethylene octyl phenyl ether (TRITON® X-100); sodium dodecyl sulfate (SDS); 3-[(3-Cholamidopropyl)dimethylammonio]-1-propanesulfonate (CHAPS); and 3-[(3-Cholamidopropyl)dimethyl ammonio]-2-hydroxy-1-propanesulfonate (CHAPSO).

[043] A natural or synthetic inorganic solid and its derivatives refer to a mineral not of biological origin. Non-limiting examples of inorganic solids include hydroxyapatite (HAP), carbonated hydroxyapatite, fluorinated hydroxyapatite, various calcium phosphates (CAP), glass, salts, oxides, silicates, and/or the like, and/or mixtures thereof.

[044] A natural or synthetic water-soluble solid and its derivatives refer to any material that can be dissolved in water. Non-limiting examples of inorganic solids include sodium hydroxide and naphthalene.

[045] A natural or synthetic polymer and its derivatives, refer to natural and synthetic macromolecules composed of repeating structural units typically connected by covalent chemical bonds. A polymer includes natural or synthetic hydrophilic polymers, natural or synthetic hydrophobic polymers, natural or synthetic amphiphilic polymers, degradable polymers, partially degradable polymers, non-degradable polymers, and combinations thereof. Polymers may be homopolymers or copolymers. Copolymers may be random copolymers, blocked copolymers, graft copolymers, and/or mixtures thereof. Non-limiting examples of polymers include poly(alkylene oxide), poly(acrylamide), poly(acrylic acid), poly(acrylamide-co-acrylic acid), poly(acrylamide-co-diallyldimethylammonium chloride), poly(acrylonitrile), poly(allylamine), poly(amide), poly(anhydride), poly(butylene), poly(ε-caprolactone), poly(carbonate), poly(ester), poly(etheretherketone), poly(ethersulphone), poly(ethylene), poly(ethylene alcohol), poly(ethylenimine), poly(ethylene glycol), poly(ethylene oxide), poly(glycolide) ((like poly(glycolic acid)), poly(hydroxy butyrate), poly(hydroxyethylmethacrylate), poly(hydroxypropylmethacrylate), poly(hydroxystyrene), poly(imide), poly(lactide), poly(L-lactic acid), poly(D,L-lactic acid), poly(lactide-co-glycolide), poly(lysine), poly(methacrylate), poly(methacrylic acid), poly(methylmethacrylate), poly(orthoester), poly(phenylene oxide), poly(phosphazene), poly(phosphoester), poly(propylene fumarate), poly(propylene), poly(propylene glycol), poly(propylene oxide), poly(styrene), poly(sulfone), poly(tetrafluoroethylene), poly(vinyl acetate), poly(vinyl alcohol), poly(vinyl chloride), poly(vinylidene fluoride), poly(vinyl pyrrolidone), poly(urethane), collagen, gelatin, any copolymer thereof (like

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poly(ethylene oxide) poly(propylene oxide) copolymers (poloxamers), poly(vinyl alcohol-co-ethylene), poly(styrene-co-allyl alcohol, and poly(ethylene)-block-poly(ethylene glycol), and/or any mixtures thereof.

[046] A shell material has a thickness sufficient to allow formation of a porogen scaffold. As such, a shell material can be of any thickness, with the proviso that the amount of shell material is sufficient to create a porogen scaffold useful for its intended purpose. The thickness of the shell material is measured from the interior surface of the shell that is adjacent of the core material to the exterior surface of the shell.

[047] Thus. In an embodiment, a porogen composition comprises a shell material. In an aspect of this embodiment, a porogen composition comprises a shell material having a melting point temperature that is lower than a melting point temperature of the core material. In aspects of this embodiment, a porogen composition comprises a shell material having a melting point temperature that is lower than a melting point temperature of the core material by, *e.g.*, about 1 °C, about 2 °C, about 3 °C, about 4 °C, about 5 °C, about 6 °C, about 7 °C, about 8 °C, about 9 °C, about 10 °C, about 15 °C, about 20 °C, about 25 °C, about 30 °C, about 35 °C, about 40 °C, about 45 °C, or about 50 °C. In other aspects of this embodiment, a porogen composition comprises a shell material having a melting point temperature that is lower than a melting point temperature of the core material by, *e.g.*, at least 1 °C, at least 2 °C, at least 3 °C, at least 4 °C, at least 5 °C, at least 6 °C, at least 7 °C, at least 8 °C, at least 9 °C, at least 10 °C, at least 15 °C, at least 20 °C, at least 25 °C, at least 30 °C, at least 35 °C, at least 40 °C, at least 45 °C, or at least 50 °C. In yet other aspects of this embodiment, a porogen composition comprises a shell material having a melting point temperature that is lower than a melting point temperature of the core material by, *e.g.*, about 5 °C to about 50 °C, about 5 °C to about 75 °C, about 5 °C to about 100 °C, about 5 °C to about 200 °C, about 5 °C to about 300 °C, about 10 °C to about 50 °C, about 10 °C to about 75 °C, about 10 °C to about 100 °C, about 10 °C to about 200 °C, or about 10 °C to about 300 °C.

[048] In an aspect of this embodiment, a porogen composition comprises a shell material having a glass transition temperature that is lower than a glass transition temperature of the core material. In aspects of this embodiment, a porogen composition comprises a shell material having a glass transition temperature that is lower than a glass transition temperature of the core material by, *e.g.*, about 1 °C, about 2 °C, about 3 °C, about 4 °C, about 5 °C, about 6 °C, about 7 °C, about 8 °C, about 9 °C, about 10 °C, about 15 °C, about 20 °C, about 25 °C, about 30 °C, about 35 °C, about 40 °C, about 45 °C, or about 50 °C. In other aspects of this embodiment, a porogen composition comprises a shell material having a glass transition temperature that is lower than a glass transition temperature of the core material by, *e.g.*, at least 1 °C, at least 2 °C, at least 3 °C, at least 4 °C, at least 5 °C, at least 6 °C, at least 7 °C, at least 8 °C, at least 9 °C, at least 10 °C, at least 15 °C, at least 20 °C, at least 25 °C, at least 30 °C, at least 35 °C, at least 40 °C, at least 45 °C, or at least 50 °C. In yet other aspects of this embodiment, a porogen composition comprises a shell material having a glass transition temperature that is lower than a glass transition temperature of the core material by, *e.g.*, about 5 °C to about 50 °C, about 5 °C to about 75 °C, about 5 °C to about 100 °C, about 5 °C to about 200 °C, about 5 °C to about 300 °C, about 10 °C to

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about 50 °C, about 10 °C to about 75 °C, about 10 °C to about 100 °C, about 10 °C to about 200 °C, or about 10 °C to about 300 °C.

[049] In another embodiment, a porogen composition comprises a shell material having a thickness sufficient to allow formation of a porogen scaffold. In aspects of this embodiment, a porogen composition comprises a shell material having a thickness of, *e.g.*, about 1 µm, about 2 µm, about 3 µm, about 4 µm, about 5 µm, about 6 µm, about 7 µm, about 8 µm, about 9 µm, about 10 µm, about 15 µm, about 20 µm, about 25 µm, about 30 µm, about 35 µm, about 40 µm, about 45 µm, or about 50 µm. In other aspects of this embodiment, a porogen composition comprises a shell material having a thickness of, *e.g.*, at least 1 µm, at least 2 µm, at least 3 µm, at least 4 µm, at least 5 µm, at least 6 µm, at least 7 µm, at least 8 µm, at least 9 µm, at least 10 µm, at least 15 µm, at least 20 µm, at least 25 µm, at least 30 µm, at least 35 µm, at least 40 µm, at least 45 µm, or at least 50 µm. In yet other aspects of this embodiment, a porogen composition comprises a shell material having a thickness of, *e.g.*, about 5 µm to about 50 µm, about 5 µm to about 75 µm, about 5 µm to about 100 µm, about 5 µm to about 200 µm, about 5 µm to about 300 µm, about 10 µm to about 50 µm, about 10 µm to about 75 µm, about 10 µm to about 100 µm, about 10 µm to about 200 µm, about 10 µm to about 300 µm, about 15 µm to about 50 µm, about 15 µm to about 75 µm, about 15 µm to about 100 µm, about 15 µm to about 200 µm, or about 15 µm to about 300 µm.

[050] In another embodiment, a shell material comprises an inorganic material. In another embodiment, a shell material comprises an organic material. In another embodiment, a shell material comprises a salt and/or its derivatives, a ceramic and/or its derivatives, a sugar and/or its derivatives, a polysaccharide and/or its derivatives, a wax and/or its derivatives, a metal and/or its derivatives, a surfactant and/or its derivatives, a water soluble solid and/or its derivatives, or a polymer and/or its derivatives.

[051] The present specification discloses, in part, a porogen comprising a core material. A core material of a porogen can be made of any material with the proviso that 1) the melting point temperature (T_m) of the core material is higher than the melting point temperature of the shell material; and/or 2) the glass transition temperature (T_g) of the core material is higher than the glass transition temperature of the shell material. A core material can be of any shape, with the proviso that the shape is useful to create a porogen scaffold. Useful core shapes include, without limitation, roughly spherical, perfectly spherical, ellipsoidal, polyhedronal, triangular, pyramidal, quadrilateral like squares, rectangles, parallelograms, trapezoids, rhombus and kites, and other types of polygonal shapes.

[052] A core material has a thickness sufficient to allow formation of a porogen scaffold. As such, a core material can be of any thickness, with the proviso that the amount of core material is sufficient to create a porogen scaffold useful for its intended purpose. The thickness of a core material can be measured base on its shape. For example, for triangular cores, quadrilateral cores, and any other type of polygonal shape, thickness is measured based on the base width of the core material. For example, for sided-shaped cores, like polyhedrons, triangles, pyramids, quadrilateral, or polygons, thickness is measured based on the base width of the core.

[053] A core material can comprise a natural or synthetic, inorganic or organic material. Exemplary materials suitable as a core material disclosed in the present specification, include, without limitation, natural and synthetic salts and its derivatives, natural and synthetic ceramics and/or its derivatives, natural and synthetic sugars and its derivatives, natural and synthetic polysaccharides and its derivatives, natural and synthetic waxes and its derivatives, natural and synthetic metals and its derivatives, natural and synthetic organic solids and its derivatives, natural and synthetic water soluble solids and its derivatives, and/or natural and synthetic polymers and its derivatives, composites thereof, and/or combinations thereof. Exemplary materials suitable as a core material are described above in the present specification.

[054] Thus, in an embodiment, a porogen composition comprises a core material. In an aspect of this embodiment, a porogen composition comprises a core material having a melting point temperature that is higher than a melting point temperature of the shell material. In aspects of this embodiment, a porogen composition comprises a core material having a melting point temperature that is higher than a melting point temperature of the shell material by, *e.g.*, about 1 °C, about 2 °C, about 3 °C, about 4 °C, about 5 °C, about 6 °C, about 7 °C, about 8 °C, about 9 °C, about 10 °C, about 15 °C, about 20 °C, about 25 °C, about 30 °C, about 35 °C, about 40 °C, about 45 °C, or about 50 °C. In other aspects of this embodiment, a porogen composition comprises a core material having a melting point temperature that is higher than a melting point temperature of the shell material by, *e.g.*, at least 1 °C, at least 2 °C, at least 3 °C, at least 4 °C, at least 5 °C, at least 6 °C, at least 7 °C, at least 8 °C, at least 9 °C, at least 10 °C, at least 15 °C, at least 20 °C, at least 25 °C, at least 30 °C, at least 35 °C, at least 40 °C, at least 45 °C, or at least 50 °C. In yet other aspects of this embodiment, a porogen composition comprises a core material having a melting point temperature that is higher than a melting point temperature of the shell material by, *e.g.*, about 5 °C to about 50 °C, about 5 °C to about 75 °C, about 5 °C to about 100 °C, about 5 °C to about 200 °C, about 5 °C to about 300 °C, about 10 °C to about 50 °C, about 10 °C to about 75 °C, about 10 °C to about 100 °C, about 10 °C to about 200 °C, or about 10 °C to about 300 °C.

[055] In an aspect of this embodiment, a porogen composition comprises a core material having a glass transition temperature that is higher than a glass transition temperature of the shell material. In aspects of this embodiment, a porogen composition comprises a core material having a glass transition temperature that is higher than a glass transition temperature of the shell material by, *e.g.*, about 1 °C, about 2 °C, about 3 °C, about 4 °C, about 5 °C, about 6 °C, about 7 °C, about 8 °C, about 9 °C, about 10 °C, about 15 °C, about 20 °C, about 25 °C, about 30 °C, about 35 °C, about 40 °C, about 45 °C, or about 50 °C. In other aspects of this embodiment, a porogen composition comprises a core material having a glass transition temperature that is higher than a glass transition temperature of the shell material by, *e.g.*, at least 1 °C, at least 2 °C, at least 3 °C, at least 4 °C, at least 5 °C, at least 6 °C, at least 7 °C, at least 8 °C, at least 9 °C, at least 10 °C, at least 15 °C, at least 20 °C, at least 25 °C, at least 30 °C, at least 35 °C, at least 40 °C, at least 45 °C, or at least 50 °C. In yet other aspects of this embodiment, a porogen composition comprises a core material having a glass transition temperature that is higher than a glass transition temperature of the shell material by, *e.g.*, about 5 °C to about 50 °C, about 5 °C to about

75 °C, about 5 °C to about 100 °C, about 5 °C to about 200 °C, about 5 °C to about 300 °C, about 10 °C to about 50 °C, about 10 °C to about 75 °C, about 10 °C to about 100 °C, about 10 °C to about 200 °C, or about 10 °C to about 300 °C.

[056] In another embodiment, a porogen composition comprises a core material having a thickness sufficient to allow formation of a porogen scaffold. In aspects of this embodiment, a porogen composition comprises a core material having a thickness of, *e.g.*, about 10 µm, about 20 µm, about 30 µm, about 40 µm, about 50 µm, about 60 µm, about 70 µm, about 80 µm, about 90 µm, about 100 µm, about 200 µm, about 300 µm, about 400 µm, about 500 µm, about 600 µm, about 700 µm, about 800 µm, or about 900 µm. In other aspects of this embodiment, a porogen composition comprises a shell material having a thickness of, *e.g.*, at least 10 µm, at least 20 µm, at least 30 µm, at least 40 µm, at least 50 µm, at least 60 µm, at least 70 µm, at least 80 µm, at least 90 µm, at least 100 µm, at least 200 µm, at least 300 µm, at least 400 µm, at least 500 µm, at least 600 µm, at least 700 µm, at least 800 µm, or at least 900 µm. In yet other aspects of this embodiment, a porogen composition comprises a shell material having a thickness of, *e.g.*, about 10 µm to about 500 µm, about 10 µm to about 750 µm, about 10 µm to about 1000 µm, about 10 µm to about 2000 µm, about 10 µm to about 3000 µm, about 25 µm to about 500 µm, about 25 µm to about 750 µm, about 25 µm to about 1000 µm, about 25 µm to about 2000 µm, about 25 µm to about 3000 µm, about 50 µm to about 500 µm, about 50 µm to about 750 µm, about 50 µm to about 1000 µm, about 50 µm to about 2000 µm, about 50 µm to about 3000 µm, about 100 µm to about 500 µm, about 100 µm to about 750 µm, about 100 µm to about 1000 µm, about 100 µm to about 2000 µm, or about 100 µm to about 3000 µm.

[057] In another embodiment, a core material comprises an inorganic material. In another embodiment, a core material comprises an organic material. In another embodiment, a core material comprises a salt and/or its derivatives, a ceramic and/or its derivatives, a sugar and/or its derivatives, a polysaccharide and/or its derivatives, a wax and/or its derivatives, a metal and/or its derivatives, a water soluble solid and/or its derivatives, or a polymer and/or its derivatives.

[058] The present specification discloses, in part, a porogen comprising a shell material and a core material, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material.. The melting point temperature or glass transition temperature of any of the shell and core materials is well known to a person of ordinary skill and is publicly available information. See, *e.g.*, Polymer Physics, pp. 454 (Ed. Michael Rubinstein, Edmund T. Rolls, Ralph H. Colby, Oxford University Press, 2003); Inorganic Chemistry, pp. 822 (Ed. Peter Atkins, Duward F. Shriver, Tina Overton, Jonathan Rourke, W.H. Freeman, 2006); and Carbohydrate Chemistry, pp. 96 (B.G. Davis and A.J. Fairbanks, Oxford University Press 2002)..

[059] Thus, in an embodiment, a porogen comprises a shell material comprising an inorganic material and a core material comprising an inorganic material, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass

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transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising an organic material and a core material comprising an inorganic material, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising an inorganic material and a core material comprising an organic material, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising an organic material and a core material comprising an organic material, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material.

[060] In another embodiment, a porogen comprises a shell material comprising a salt and/or its derivatives and a core material comprising a salt and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a ceramic and/or its derivatives and a core material comprising a salt and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a sugar and/or its derivatives and a core material comprising a salt and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a polysaccharide and/or its derivatives and a core material comprising a salt and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a wax and/or its derivatives and a core material comprising a salt and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a metal and/or its derivatives and a core material comprising a salt and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a surfactant and/or its derivatives and a core material comprising a salt and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a water-soluble solid and/or its derivatives and a core material comprising a salt and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a polymer and/or its

derivatives and a core material comprising a salt and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material.

[061] In another embodiment, a porogen comprises a shell material comprising a salt and/or its derivatives and a core material comprising a ceramic and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a ceramic and/or its derivatives and a core material comprising a ceramic and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a sugar and/or its derivatives and a core material comprising a ceramic and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a polysaccharide and/or its derivatives and a core material comprising a ceramic and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a wax and/or its derivatives and a core material comprising a ceramic and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a metal and/or its derivatives and a core material comprising a ceramic and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a surfactant and/or its derivatives and a core material comprising a ceramic and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a water-soluble solid and/or its derivatives and a core material comprising a ceramic and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a polymer and/or its derivatives and a core material comprising a ceramic and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material.

[062] In another embodiment, a porogen comprises a shell material comprising a salt and/or its derivatives and a core material comprising a sugar and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a

shell material comprising a ceramic and/or its derivatives and a core material comprising a sugar and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a sugar and/or its derivatives and a core material comprising a sugar and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a polysaccharide and/or its derivatives and a core material comprising a sugar and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a wax and/or its derivatives and a core material comprising a sugar and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a metal and/or its derivatives and a core material comprising a sugar and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a surfactant and/or its derivatives and a core material comprising a sugar and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a water-soluble solid and/or its derivatives and a core material comprising a sugar and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a polymer and/or its derivatives and a core material comprising a sugar and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material.

[063] In another embodiment, a porogen comprises a shell material comprising a salt and/or its derivatives and a core material comprising a polysaccharide and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a ceramic and/or its derivatives and a core material comprising a polysaccharide and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a sugar and/or its derivatives and a core material comprising a polysaccharide and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a polysaccharide

and/or its derivatives and a core material comprising a polysaccharide and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a wax and/or its derivatives and a core material comprising a polysaccharide and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a metal and/or its derivatives and a core material comprising a polysaccharide and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a surfactant and/or its derivatives and a core material comprising a polysaccharide and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a water-soluble solid and/or its derivatives and a core material comprising a polysaccharide and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a polymer and/or its derivatives and a core material comprising a polysaccharide and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material.

[064] In another embodiment, a porogen comprises a shell material comprising a salt and/or its derivatives and a core material comprising a wax and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a ceramic and/or its derivatives and a core material comprising a wax and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a sugar and/or its derivatives and a core material comprising a wax and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a polysaccharide and/or its derivatives and a core material comprising a wax and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a wax and/or its derivatives and a core material comprising a wax and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a

shell material comprising a metal and/or its derivatives and a core material comprising a wax and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a surfactant and/or its derivatives and a core material comprising a wax and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a water-soluble solid and/or its derivatives and a core material comprising a wax and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a polymer and/or its derivatives and a core material comprising a wax and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material.

[065] In another embodiment, a porogen comprises a shell material comprising a salt and/or its derivatives and a core material comprising a metal and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a ceramic and/or its derivatives and a core material comprising a metal and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a sugar and/or its derivatives and a core material comprising a metal and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a polysaccharide and/or its derivatives and a core material comprising a metal and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a wax and/or its derivatives and a core material comprising a metal and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a metal and/or its derivatives and a core material comprising a metal and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a surfactant and/or its derivatives and a core material comprising a metal and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a water-soluble solid and/or its derivatives and a core material comprising a

metal and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a polymer and/or its derivatives and a core material comprising a metal and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material.

[066] In another embodiment, a porogen comprises a shell material comprising a salt and/or its derivatives and a core material comprising a water-soluble solid and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a ceramic and/or its derivatives and a core material comprising a water-soluble solid and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a sugar and/or its derivatives and a core material comprising a water-soluble solid and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a polysaccharide and/or its derivatives and a core material comprising a water-soluble solid and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a wax and/or its derivatives and a core material comprising a water-soluble solid and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a metal and/or its derivatives and a core material comprising a water-soluble solid and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a surfactant and/or its derivatives and a core material comprising a water-soluble solid and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a water-soluble solid and/or its derivatives and a core material comprising a water-soluble solid and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a polymer and/or its derivatives and a core material comprising a water-soluble solid and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material.

[067] In another embodiment, a porogen comprises a shell material comprising a salt and/or its derivatives and a core material comprising a polymer and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a ceramic and/or its derivatives and a core material comprising a polymer and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a sugar and/or its derivatives and a core material comprising a polymer and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a polysaccharide and/or its derivatives and a core material comprising a polymer and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a wax and/or its derivatives and a core material comprising a polymer and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a metal and/or its derivatives and a core material comprising a polymer and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a surfactant and/or its derivatives and a core material comprising a polymer and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a water-soluble solid and/or its derivatives and a core material comprising a polymer and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material. In another embodiment, a porogen comprises a shell material comprising a polymer and/or its derivatives and a core material comprising a polymer and/or its derivatives, where the core material has a higher melting point temperature or glass transition temperature relative to the melting point temperature or the glass transition temperature of the shell material.

[068] Aspects of the present specification disclose, in part, a porogen comprising a core material and shell material where the shell material is fusible and the core material is non-fusible under a given physical or physicochemical treatment. As used herein, the term “under a given physical or physicochemical treatment” refers to a physical or physicochemical treatment that permits the shell material to transition from its solid phase to its liquid phase, but maintains the core material in its solid phase.

[069] Thus, in an embodiment, a porogen comprises a shell material comprising an inorganic material and a core material comprising an inorganic material, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising an organic material and a core material comprising an inorganic material, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising an inorganic material and a core material comprising an organic material, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising an organic material and a core material comprising an organic material, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible.

[070] In another embodiment, a porogen comprises a shell material comprising a salt and/or its derivatives and a core material comprising a salt and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a ceramic and/or its derivatives and a core material comprising a salt and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a sugar and/or its derivatives and a core material comprising a salt and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a polysaccharide and/or its derivatives and a core material comprising a salt and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a wax and/or its derivatives and a core material comprising a salt and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a metal and/or its derivatives and a core material comprising a salt and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a surfactant and/or its derivatives and a core material comprising a salt and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a water-soluble solid and/or its derivatives and a core material comprising a salt and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a polymer and/or its derivatives and a core material comprising a salt and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible.

[071] In another embodiment, a porogen comprises a shell material comprising a salt and/or its derivatives and a core material comprising a ceramic and/or its derivatives, where under a given physical

or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a ceramic and/or its derivatives and a core material comprising a ceramic and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a sugar and/or its derivatives and a core material comprising a ceramic and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a polysaccharide and/or its derivatives and a core material comprising a ceramic and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a wax and/or its derivatives and a core material comprising a ceramic and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a metal and/or its derivatives and a core material comprising a ceramic and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a surfactant and/or its derivatives and a core material comprising a ceramic and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a water-soluble solid and/or its derivatives and a core material comprising a ceramic and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a polymer and/or its derivatives and a core material comprising a ceramic and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible.

[072] In another embodiment, a porogen comprises a shell material comprising a salt and/or its derivatives and a core material comprising a sugar and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a ceramic and/or its derivatives and a core material comprising a sugar and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a sugar and/or its derivatives and a core material comprising a sugar and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a polysaccharide and/or its derivatives and a core material comprising a sugar and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a wax and/or its derivatives and a core material comprising a sugar and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material

comprising a metal and/or its derivatives and a core material comprising a sugar and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a surfactant and/or its derivatives and a core material comprising a sugar and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a water-soluble solid and/or its derivatives and a core material comprising a sugar and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a polymer and/or its derivatives and a core material comprising a sugar and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible.

[073] In another embodiment, a porogen comprises a shell material comprising a salt and/or its derivatives and a core material comprising a polysaccharide and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a ceramic and/or its derivatives and a core material comprising a polysaccharide and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a sugar and/or its derivatives and a core material comprising a polysaccharide and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a polysaccharide and/or its derivatives and a core material comprising a polysaccharide and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a wax and/or its derivatives and a core material comprising a polysaccharide and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a metal and/or its derivatives and a core material comprising a polysaccharide and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a surfactant and/or its derivatives and a core material comprising a polysaccharide and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a water-soluble solid and/or its derivatives and a core material comprising a polysaccharide and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a polymer and/or its derivatives and a core material comprising a polysaccharide and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible.

[074] In another embodiment, a porogen comprises a shell material comprising a salt and/or its derivatives and a core material comprising a wax and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a ceramic and/or its derivatives and a core material comprising a wax and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a sugar and/or its derivatives and a core material comprising a wax and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a polysaccharide and/or its derivatives and a core material comprising a wax and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a wax and/or its derivatives and a core material comprising a wax and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a metal and/or its derivatives and a core material comprising a wax and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a surfactant and/or its derivatives and a core material comprising a wax and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a water-soluble solid and/or its derivatives and a core material comprising a wax and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a polymer and/or its derivatives and a core material comprising a wax and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible.

[075] In another embodiment, a porogen comprises a shell material comprising a salt and/or its derivatives and a core material comprising a metal and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a ceramic and/or its derivatives and a core material comprising a metal and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a sugar and/or its derivatives and a core material comprising a metal and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a polysaccharide and/or its derivatives and a core material comprising a metal and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a wax and/or its derivatives and a core material comprising a metal and/or its derivatives, where under a given physical or physicochemical treatment the shell material is

fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a metal and/or its derivatives and a core material comprising a metal and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a surfactant and/or its derivatives and a core material comprising a metal and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a water-soluble solid and/or its derivatives and a core material comprising a metal and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a polymer and/or its derivatives and a core material comprising a metal and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible.

[076] In another embodiment, a porogen comprises a shell material comprising a salt and/or its derivatives and a core material comprising a water-soluble solid and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a ceramic and/or its derivatives and a core material comprising a water-soluble solid and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a sugar and/or its derivatives and a core material comprising a water-soluble solid and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a polysaccharide and/or its derivatives and a core material comprising a water-soluble solid and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a wax and/or its derivatives and a core material comprising a water-soluble solid and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a metal and/or its derivatives and a core material comprising a water-soluble solid and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a surfactant and/or its derivatives and a core material comprising a water-soluble solid and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a water-soluble solid and/or its derivatives and a core material comprising a water-soluble solid and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a polymer and/or its derivatives and a core material comprising a water-soluble solid and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible.

[077] In another embodiment, a porogen comprises a shell material comprising a salt and/or its derivatives and a core material comprising a polymer and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a ceramic and/or its derivatives and a core material comprising a polymer and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a sugar and/or its derivatives and a core material comprising a polymer and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a polysaccharide and/or its derivatives and a core material comprising a polymer and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a wax and/or its derivatives and a core material comprising a polymer and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a metal and/or its derivatives and a core material comprising a polymer and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a surfactant and/or its derivatives and a core material comprising a polymer and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a water-soluble solid and/or its derivatives and a core material comprising a polymer and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible. In another embodiment, a porogen comprises a shell material comprising a polymer and/or its derivatives and a core material comprising a polymer and/or its derivatives, where under a given physical or physicochemical treatment the shell material is fusible and the core material is non-fusible.

[078] The present specification discloses methods of making a porogen composition.

[079] In one aspect, methods of making a porogen composition comprise the steps of: a) forming a particle out of a core material; and b) coating the particle with a shell material.

[080] The present specification discloses, in part, forming a particle out of a core material. Suitable core materials are as described above. Forming a particle out of a core material can be accomplished by any suitable means, including, without limitation, pelletization by fluidized bed granulation, rotor granulation, or extrusion-spheronization; grinding by roller mills and sieving; solvent evaporation; or emulsion. Suitable particles of a core material are also commercially available from, *e.g.*, Fisher Scientific (Pittsburgh, PA), Boehringer Ingelheim Pharmaceuticals, Inc. (Ridgefield, CT); and Paulaur Corp., (Cranbury, NJ).

[081] The present specification discloses, in part, coating a particle with a shell material. Suitable shell materials are as described above. Coating a particle with a shell material can be accomplished by any suitable means, including, without limitation, mechanical application such as, *e.g.*, dipping, spraying, filtration, knifing, curtaining, brushing, or vapor deposition; physical adsorption application; thermal application; fluidization application; adhering application; chemical bonding application; self-assembling application; molecular entrapment application, and/or any combination thereof. The shell material is applied to the particle of core material in such a manner as to coat the particle with the desired thickness of shell material. Removal of excess shell material can be accomplished by any suitable means, including, without limitation, gravity-based filtering or sieving, vacuum-based filtering or sieving, blowing, and/or any combination thereof.

[082] The present specification discloses in part, methods of making a porous material using the porogen compositions disclosed in the present specification. The porogens disclosed herein can be used in any methods of making a porous material that utilized previously described porogens. Examples of such methods are described in, *e.g.*, Gates, et al., *Materials Containing Voids with Void Size Controlled on the Nanometer Scale*, U.S. Patent 7,674,521; Hart, et al., *Discrete Nano-Textured Structures in Biomolecular Arrays and Method of Use*, U.S. Patent 7,651,872; Xu and Grenz, *Methods and Devices Using a Shrinkable Support for Porous Monolithic Materials*, U.S. Patent 7,651,762; van den Hoek, et al., *VLSI Fabrication Processes for Introducing Pores into Dielectric Materials*, U.S. Patent 7,629,224; Murphy, et al., *Tissue Engineering Scaffolds*, U.S. Patent 7,575,759; Swetlin, et al., *Polyester Compositions, Methods of Manufacturing Said Compositions, and Articles Made Therefrom*, U.S. Patent 7,557,167; Goodner, et al., *Formation of Interconnect Structures by Removing Sacrificial Material with Supercritical Carbon Dioxide*, U.S. Patent 7,466,025; Xu, *Ultraporous Sol Gel Monoliths*, U.S. Patent 7,439,272; Todd, *Apparatus, Precursors and Deposition Methods for Silicon-Containing Materials*, U.S. Patent 7,425,350; Flodin and Aurell, *Method for Preparing an Open Porous Polymer Material and an Open Porous Polymer Material*, U.S. Patent 7,425,288; Watkins and Pai, *Mesoporous Materials and Methods*, U.S. Patent 7,419,772; Connor, et al., *Porous Composition of Matter, and Method of Making Same*, U.S. Patent 7,368,483; Lukas, et al., *Porous Low Dielectric Constant Compositions and Methods for Making and Using Same*, U.S. Patent 7,332,445; Wu, et al., *Methods for Producing Low Stress Porous Low-K Dielectric Materials Using Precursors with Organic Functional Groups*, U.S. Patent 7,241,704; Yuan and Ding, *Functionalized Porous Poly(Aryl Ether Ketone) Materials and Their Use*, U.S. Patent 7,176,273; Gleason, et al., *Porous Material Formation by Chemical Vapor Deposition onto Colloidal Crystal Templates*, U.S. Patent 7,112,615; Bruza, et al., *Composition Containing a Cross-Linkable Matrix Precursor and a Poragen, and Porous Matrix Prepared Therefrom*, U.S. Patent 7,109,249; Huang, et al., *Nitrogen-Containing Polymers as Porogens in the Preparation of Highly Porous, Low Dielectric Constant Materials*, U.S. Patent 7,087,982; Taboas, et al., *Controlled Local/Global and Micro/Macro-Porous 3D Plastic, Polymer and Ceramic/Cement Composite Scaffold Fabrication and Applications Thereof*, U.S. Patent 7,087,200; Kloster, et al., *Method of Forming a Selectively Converted Inter-Layer Dielectric Using A Porogen Material*, U.S. Patent 7,018,918; You, et al., *Porous Materials*, U.S. Patent 6,998,148; Khanarian, et al., *Porous Optical Materials*, U.S. Patent 6,967,222; Holmes and

Cooper, *Manufacturing Porous Cross-Linked Polymer Monoliths*, U.S. Patent 6,693,159; Ma, *Reverse Fabrication of Porous Materials*, U.S. Patent 6,673,285; Kilaas, et al., *Combined Liner and Matrix System*, U.S. Patent 6,672,385; Chaouk and Meijs, *Hydratable Siloxane Comprising Porous Polymers*, U.S. Patent 6,663,668; Allen, et al., *Porous Materials*, U.S. Patent 6,602,804; Hawker, et al., *Porous Dielectric Material and Electronic Devices Fabricated Therewith*, U.S. Patent 6,541,865; Davankov, et al., *Method of Making Biocompatible Polymeric Adsorbing Material for Purification of Physiological Fluids of Organism*, U.S. Patent 6,531,523; Shastri, et al., *Three-Dimensional Polymer Matrices*, U.S. Patent 6,471,993; Yates, *Photogenerated Nanoporous Materials*, U.S. Patent 6,380,270; Fonnum, *Method for the Manufacture of Amino Group Containing Support Matrices, Support Matrices Prepared by the Method, and Use of the Support Matrices*, U.S. Patent 6,335,438; Chaouk, et al., *Polymers*, U.S. Patent 6,225,367; Chaouk, et al., *High Water Content Porous Polymer*, U.S. Patent 6,160,030; Hawker, et al., *Dielectric Compositions and Method for Their Manufacture*, U.S. Patent 6,107,357; Li, et al., *Polymeric Microbeads and Methods of Preparation*, U.S. Patent 6,100,306; Chaouk, et al., *Process for Manufacture of A Porous Polymer by Use of A Porogen*, U.S. Patent 6,060,530; Li, et al., *Polymeric Microbeads*, U.S. Patent 5,863,957; Frechet and Svec, *Porous Polymeric Material with Gradients*, U.S. Patent 5,728,457; Frechet and Svec, *Pore-Size Selective Modification of Porous Materials*, U.S. Patent 5,633,290; Yen, et al., Ion Exchange Polyethylene Membrane and Process, U.S. Patent 5,531,899; Soria, et al., *Membrane for a Filtration, Gas or Liquid Separation or Pervaporation Apparatus and A Manufacturing Method for Such Membrane*, U.S. Patent 5,066,398; Axisa, et al., *Method of Fabricating A Porous Elastomer*, U.S. Patent Publication 2010/0075056; Liljensten and Persoon, *Biodegradable Ostochondreal Implant*, U.S. Patent Publication 2009/0164014; Favis, et al., *Porous Nanosheath Networks, Method of Making and Uses Thereof*, U.S. Patent Publication 2009/0087641; Hosoya, et al., *Porous Polymer and Process For Producing the Same*, U.S. Patent Publication 2009/0045119; Andersson, *Chitosan Compositions*, U.S. Patent Publication 2009/0022770; Xie, Three-Dimensional Hydrophilic Porous Structures for Fuel Cell Plates, U.S. Patent Publication 2008/0292939; Ratner and Marshall, *Novel Porous Materials*, U.S. Patent Publication 2008/0075752; Ma and Chen, *Porous Materials having Multi-Sized Geometries*, U.S. Patent Publication 2007/0036844; Ma, *Reverse Fabrication of Porous Materials*, U.S. Patent Publication 2002/0005600; Liu, et al., *Porous Materials, Methods of Making and Uses*, Attorney Docket Number 18614 PROV (BRE); and Liu, et al., *Porous Materials, Methods of Making and Uses*, Attorney Docket Number 18707PROV (BRE).

[083] In one aspect, the method of making a porous material comprises the steps of: a) coating porogens comprising a shell material and a core material with a substance base to form a substance coated porogen mixture; b) treating the substance coated porogen mixture to allow fusing of the porogens to form a porogen scaffold and stabilization of the substance; and c) removing the porogen scaffold, wherein porogen scaffold removal results in a porous material, the porous material comprising a substance matrix defining an array of interconnected pores.

[084] In another aspect, a method of making a porous material comprises the steps of a) coating porogens comprising a shell material and a core material with a substance base to form a substance coated porogen mixture; b) packing the substance coated porogen mixture into a mold; c) treating the

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substance coated porogen mixture to allow fusing of the porogens to form a porogen scaffold and stabilization of the substance; and d) removing the porogen scaffold, wherein porogen scaffold removal results in a porous material, the porous material comprising a substance matrix defining an array of interconnected pores.

[085] As used herein, the term “substance base” is synonymous with “uncured substance” and refers to a substance disclosed herein that is in its uncured state. As used herein, the term “elastomer base” is synonymous with “uncured elastomer” and refers to an elastomer disclosed herein that is in its uncured state. As used herein, the term “silicon-based elastomer base” is synonymous with “uncured silicon-based elastomer” and refers to a silicon-based elastomer disclosed herein that is in its uncured state.

[086] The present specification discloses, in part, packing porogens into a mold prior to fusion. Any mold shape may be used for packing the porogens. Porogens can be packed into the mold before coating of a substance base, or can be first coated with a substance base before packing into a mold. If coated first, the substance coated porogen mixture may first have to be devolitalized before packing into a mold. As a non-limiting example, a mold shape can be a shell that outlines the contours an implantable device, such as, *e.g.*, a shell for a breast implant, or a shell for a muscle implant. As another non-limiting example, the mold shape can be one that forms sheets. Such sheets can be made in a wide variety or proportions based on the needed application. For example, the sheets can be made in a size slightly bigger that an implantable device so that there is sufficient material to cover the device and allow for trimming of the excess. As another example, the sheets can be produced as a continuous roll that allows a person skilled in the art to take only the desired amount for an application, such as, *e.g.*, creating strips having a textured surface for control of scar formation. The porogens may be packed into a mold using ultrasonic agitation, mechanical agitation, or any other suitable method for obtaining a closely packed array of porogens.

[087] In an embodiment, a substance coated porogen mixture is packed into a mold. In an aspect of this embodiment, a substance coated porogen mixture is packed into a mold in a manner suitable obtaining a closely packed array of porogens. In other aspects of this embodiment, a substance coated porogen mixture is packed into a mold using sonic agitation or mechanical agitation.

[088] In another embodiment, porogens are packed into a mold. In an aspect of this embodiment, porogens are packed into a mold in a manner suitable obtaining a closely packed array of porogens. In other aspects of this embodiment, porogens are packed into a mold using sonic agitation or mechanical agitation.

[089] As used herein, the term “porogen scaffold” refers to a three-dimensional structural framework composed of fused porogens that serves as the negative replica of a matrix defining an interconnected array or pores. The porogen compositions disclosed herein comprise a shell material and a core material.

[090] The present specification discloses, in part, coating porogens with a substance base to form a substance coated porogen mixture. Coating the porogens with a substance base can be accomplished by any suitable means, including, without limitation, mechanical application such as, *e.g.*, dipping, spraying, knifing, curtaining, brushing, or vapor deposition, thermal application, adhering application, chemical bonding, self-assembling, molecular entrapment, and/or any combination thereof. The substance is applied to the porogens in such a manner as to coat the porogens with the desired thickness of substance. Removal of excess substance base can be accomplished by any suitable means, including, without limitation, gravity-based filtering or sieving, vacuum-based filtering or sieving, blowing, and/or any combination thereof.

[091] Any substance base can be used to coat the porogens with the proviso that the substance base is a suitable material to form a porous material. A substance base can be any organic or inorganic material, composites thereof, and/or combinations thereof. Suitable substance bases include, without limitation, natural and synthetic ceramics and/or its derivatives, natural and synthetic polysaccharides and its derivatives, natural and synthetic metals and its derivatives, natural and synthetic polymers and its derivatives, and/or natural and synthetic elastomers and its derivatives, composites thereof, and/or combinations thereof.

[092] A natural or synthetic elastomer or elastic polymer refers to an amorphous polymer that exists above its glass transition temperature at ambient temperatures, thereby conferring the property of viscoelasticity so that considerable segmental motion is possible, and includes, without limitation, carbon-based elastomers, silicon-based elastomers, thermoset elastomers, and thermoplastic elastomers. As used herein, the term "ambient temperature" refers to a temperature of about 18° C. to about 22° C. Elastomers, ether naturally occurring or synthetically made, comprise monomers usually made of carbon, hydrogen, oxygen, and/or silicon which are linked together to form long polymer chains. Elastomers are typically covalently cross-linked to one another, although non-covalently cross-linked elastomers are known. Elastomers may be homopolymers or copolymers, degradable, substantially non-degradable, or non-degradable. Copolymers may be random copolymers, blocked copolymers, graft copolymers, and/or mixtures thereof. Unlike other polymers classes, elastomers can be stretched many times its original length without breaking by reconfiguring themselves to distribute an applied stress, and the cross-linkages ensure that the elastomers will return to their original configuration when the stress is removed. Elastomers can be a non-medical grade elastomer or a medical grade elastomer. Medical grade elastomers are typically divided into three categories: non-implantable, short term implantable and long-term implantable. Exemplary substantially non-degradable and/or non-degradable, biocompatible, elastomers include, without limitation, bromo isobutylene isoprene (BIIR), polybutadiene (BR), chloro isobutylene isoprene (CIIR), polychloroprene (CR), chlorosulphonated polyethylene (CSM), ethylene propylene (EP), ethylene propylene diene monomer (EPDM), fluorinated hydrocarbon (FKM), fluoro silicone (FVQM), hydrogenated nitrile butadiene (HNBR), polyisoprene (IR), isobutylene isoprene butyl (IIR), methyl vinyl silicone (MVQ), acrylonitrile butadiene (NBR), polyurethane (PU), styrene butadiene (SBR), styrene ethylene/butylene styrene (SEBS), polydimethylsiloxane (PDMS), polysiloxane (SI), and acrylonitrile butadiene carboxy monomer (XNBR).

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[093] Thus, in an embodiment, porogens are coated with a substance base to a thickness sufficient to allow formation of a porous material comprising a matrix defining an interconnected array or pores. In aspects of this embodiment, porogens are coated with a substance to a thickness of, *e.g.*, about 1 μm, about 2 μm, about 3 μm, about 4 μm, about 5 μm, about 6 μm, about 7 μm, about 8 μm, about 9 μm, about 10 μm, about 20 μm, about 30 μm, about 40 μm, about 50 μm, about 60 μm, about 70 μm, about 80 μm, about 90 μm, or about 100 μm. In other aspects of this embodiment, porogens are coated with a substance base to a thickness of, *e.g.*, at least 1 μm, at least 2 μm, at least 3 μm, at least 4 μm, at least 5 μm, at least 6 μm, at least 7 μm, at least 8 μm, at least 9 μm, at least 10 μm, at least 20 μm, at least 30 μm, at least 40 μm, at least 50 μm, at least 60 μm, at least 70 μm, at least 80 μm, at least 90 μm, or at least 100 μm. In yet other aspects of this embodiment, porogens are coated with a substance base to a thickness of, *e.g.*, at most 1 μm, at most 2 μm, at most 3 μm, at most 4 μm, at most 5 μm, at most 6 μm, at most 7 μm, at most 8 μm, at most 9 μm, at most 10 μm, at most 20 μm, at most 30 μm, at most 40 μm, at most 50 μm, at most 60 μm, at most 70 μm, at most 80 μm, at most 90 μm, or at most 100 μm. In still other aspects of this embodiment, porogens are coated with a substance base to a thickness of, *e.g.*, about 1 μm to about 5 μm, about 1 μm to about 10 μm, about 5 μm to about 10 μm, about 5 μm to about 25 μm, about 5 μm to about 50 μm, about 10 μm to about 50 μm, about 10 μm to about 75 μm, about 10 μm to about 100 μm, about 25 μm to about 100 μm, or about 50 μm to about 100 μm.

[094] The present specification discloses, in part, devolitalizing a substance coated porogens. As used herein, the term “devolitalizing” or “devolitalization” refers to a process that removes volatile components from the substance coated porogens. Devolitalization of the substance coated porogens can be accomplished by any suitable means that substantially all the volatile components removed from the substance coated porogens. Non-limiting examples of devolitalizing procedures include evaporation, freeze-drying, sublimination, extraction, and/or any combination thereof.

[095] In an embodiment, a substance coated porogens is devolitalized at a single temperature for a time sufficient to allow the evaporation of substantially all volatile components from the substance coated porogens. In an aspect of this embodiment, a substance coated porogens are devolitalized at ambient temperature for about 1 minute to about 5 minutes. In another aspect of this embodiment, a substance coated porogens are devolitalized at ambient temperature for about 45 minutes to about 75 minutes. In yet another aspect of this embodiment, a substance coated porogens are devolitalized at ambient temperature for about 90 minutes to about 150 minutes. In another aspect of this embodiment, a substance coated porogens are devolitalized at about 18°C to about 22°C for about 1 minute to about 5 minutes. In yet another aspect of this embodiment, a substance coated porogens are devolitalized at about 18°C to about 22°C for about 45 minutes to about 75 minutes. In still another aspect of this embodiment, a substance coated porogens are devolitalized at about 18°C to about 22°C for about 90 minutes to about 150 minutes.

[096] The present specification discloses, in part, treating a substance coated porogen mixture to allow fusing of the porogens to form a porogen scaffold and stabilization of the substance. As used herein, the

term “treating” refers to a process that 1) fuses the porogens to form a porogen scaffold useful to make a porous material comprising a matrix of interconnected array of pore and 2) stabilizes the substance. Non-limiting examples of treating include thermal treating like heating or freezing, chemical treating, catalyst treating, radiation treating, and physical treating. Treating of a substance coated porogen scaffold can be done under any condition for any length of time with the proviso that the treating fuses the porogens to form a porogen scaffold useful to make a porous material comprising a matrix of interconnected array of pore and stabilizes the substance.

[097] Thermal treating a substance coated porogen mixture can be at any temperature or temperatures for any length of time or times with the proviso that the thermal treatment fuses the porogens to form a porogen scaffold and stabilizes the substance base to form a substance matrix as disclosed in the present specification. A non-limiting example of temperatures useful in a thermal treatment are temperatures higher than the glass transition temperature or melting temperature of the porogens, such as between about 5 °C to about 50 °C higher than the glass transition temperature or melting temperature of the porogens. Any temperature can be used in a thermal treatment with the proviso that the temperature is sufficient to cause fusion of the porogens. As a non-limiting example, the thermal treatment can be from about 30 °C to about 250 °C. Increasing the duration of the thermal treatment at a given temperature increases the connection size; increases the sintering temperature, and increases the growth rate of the connections. Any time can be used in a thermal treatment with the proviso that the time is sufficient to cause fusion of the porogens and cures the substance. Suitable times are generally from about 0.5 hours to about 48 hours.

[098] Thus, in an embodiment, a substance coated porogen scaffold is treated by thermal treatment, chemical treatment, catalyst treatment, radiation treatment, or physical treatment where the treatment is sufficient to stabilize a substance. In another embodiment, a substance coated porogen scaffold is treated at a single time, where the treating time is sufficient to stabilize a substance.

[099] In another embodiment, substance coated porogens are thermal treated at a single temperature for a single time, where the treating temperature and time is sufficient to fuse the porogens to form a porogen scaffold and cure the substance to form a substance matrix sufficient to allow tissue growth within its array of interconnected of pores.

[0100] In other aspects of this embodiment, the thermal treatment comprises heating a substance coated porogens for a time at, *e.g.*, about 5 °C higher, about 10 °C higher, about 15 °C higher, about 20 °C higher, about 25 °C higher, about 30 °C higher, about 35 °C higher, about 40 °C higher, about 45 °C higher, or about 50 °C higher than the melting temperature or glass transition temperature of the porogens, where the treating temperature and time is sufficient to fuse the porogens to form a porogen scaffold and cure the substance to form a substance matrix sufficient to allow tissue growth within its array of interconnected of pores. In yet other aspects of this embodiment, the thermal treatment comprises heating a substance coated porogens for a time at, *e.g.*, at least 5 °C higher, at least 10 °C higher, at least 15 °C higher, at least 20 °C higher, at least 25 °C higher, at least 30 °C higher, at least 35

°C higher, at least 40 °C higher, at least 45 °C higher, or at least 50 °C higher than the melting temperature or glass transition temperature of the porogens, where the treating temperature and time is sufficient to fuse the porogens to form a porogen scaffold and cure the substance to form a substance matrix sufficient to allow tissue growth within its array of interconnected of pores. In still other aspects of this embodiment, the thermal treatment comprises heating a substance coated porogens for a time at, *e.g.*, at most 5 °C higher, at most 10 °C higher, at most 15 °C higher, at most 20 °C higher, at most 25 °C higher, at most 30 °C higher, at most 35 °C higher, at most 40 °C higher, at most 45 °C higher, or at most 50 °C higher than the melting temperature or glass transition temperature of the porogens, where the treating temperature and time is sufficient to fuse the porogens to form a porogen scaffold and cure the substance to form a substance matrix sufficient to allow tissue growth within its array of interconnected of pores. In further aspects of this embodiment, the thermal treatment comprises heating a substance coated porogens for a time at, *e.g.*, about 5 °C higher to about 10 °C higher, about 5 °C higher to about 15 °C higher, about 5 °C higher to about 20 °C higher, about 5 °C higher to about 25 °C higher, about 5 °C higher to about 30 °C higher, about 5 °C higher to about 35 °C higher, about 5 °C higher to about 40 °C higher, about 5 °C higher to about 45 °C higher, about 5 °C higher to about 50 °C higher, about 10 °C higher to about 15 °C higher, about 10 °C higher to about 20 °C higher, about 10 °C higher to about 25 °C higher, about 10 °C higher to about 30 °C higher, about 10 °C higher to about 35 °C higher, about 10 °C higher to about 40 °C higher, about 10 °C higher to about 45 °C higher, or about 10 °C higher to about 50 °C higher than the melting temperature or glass transition temperature of the porogens, where the treating temperature and time is sufficient to fuse the porogens to form a porogen scaffold and cure the substance to form a substance matrix sufficient to allow tissue growth within its array of interconnected of pores.

[0101] In another aspect of this embodiment, a substance on a substance coated porogen scaffold is treated at about 30 °C to about 130 °C for about 10 minutes to about 360 minutes, where the treating temperature and time is sufficient to fuse the porogens to form a porogen scaffold and cure the substance to form a substance matrix sufficient to allow tissue growth within its array of interconnected of pores.

[0102] In yet another embodiment, a substance-coated porogens are thermal treated at a plurality of temperatures for a plurality of times, where the treating temperatures and times are sufficient to fuse the porogens to form a porogen scaffold and cure the substance to form a substance matrix sufficient to allow tissue growth within its array of interconnected of pores. In an aspect of this embodiment, substance coated porogens are treated at a first temperature for a first time, and then a second temperature for a second time, where the treating temperatures and times are sufficient to fuse the porogens to form a porogen scaffold and cure the substance to form a substance matrix sufficient to allow tissue growth within its array of interconnected of pores, and where the first and second temperatures are different.

[0103] In aspects of this embodiment, thermal treatment comprises heating the substance coated porogens at a first temperature for a first time, and then heating the porogens at a second temperature for a second time, where the treating temperatures and times are sufficient to fuse the porogens to form a porogen scaffold and cure the substance to form a substance matrix sufficient to allow tissue growth

within its array of interconnected of pores, and where the first and second temperatures are different, and where the first and second temperatures are different. In other aspects of this embodiment, the thermal treatment comprises heating a substance coated porogens for a first time at, *e.g.*, about 5 °C higher, about 10 °C higher, about 15 °C higher, about 20 °C higher, about 25 °C higher, about 30 °C higher, about 35 °C higher, about 40 °C higher, about 45 °C higher, or about 50 °C higher than the melting temperature or glass transition temperature of the substance coated porogens, then heating for a second time the porogens at, *e.g.*, about 5 °C higher, about 10 °C higher, about 15 °C higher, about 20 °C higher, about 25 °C higher, about 30 °C higher, about 35 °C higher, about 40 °C higher, about 45 °C higher, or about 50 °C higher than the melting temperature or glass transition temperature of the porogens, where the treating temperatures and times are sufficient to fuse the porogens to form a porogen scaffold and cure the substance to form a substance matrix sufficient to allow tissue growth within its array of interconnected of pores, and where the first and second temperatures are different. In yet other aspects of this embodiment, the thermal treatment comprises heating a substance coated porogens for a first time at, *e.g.*, at least 5 °C higher, at least 10 °C higher, at least 15 °C higher, at least 20 °C higher, at least 25 °C higher, at least 30 °C higher, at least 35 °C higher, at least 40 °C higher, at least 45 °C higher, or at least 50 °C higher than the melting temperature or glass transition temperature of the porogens, then heating a substance coated porogens for a second time at, *e.g.*, at least 5 °C higher, at least 10 °C higher, at least 15 °C higher, at least 20 °C higher, at least 25 °C higher, at least 30 °C higher, at least 35 °C higher, at least 40 °C higher, at least 45 °C higher, or at least 50 °C higher than the melting temperature or glass transition temperature of the porogens, where the treating temperatures and times are sufficient to fuse the porogens to form a porogen scaffold and cure the substance to form a substance matrix sufficient to allow tissue growth within its array of interconnected of pores, and where the first and second temperatures are different. In still other aspects of this embodiment, the thermal treatment comprises heating a substance coated porogens for a first time at, *e.g.*, at most 5 °C higher, at most 10 °C higher, at most 15 °C higher, at most 20 °C higher, at most 25 °C higher, at most 30 °C higher, at most 35 °C higher, at most 40 °C higher, at most 45 °C higher, or at most 50 °C higher than the melting temperature or glass transition temperature of the porogens, then heating a substance coated porogens for a second time at, *e.g.*, at most 5 °C higher, at most 10 °C higher, at most 15 °C higher, at most 20 °C higher, at most 25 °C higher, at most 30 °C higher, at most 35 °C higher, at most 40 °C higher, at most 45 °C higher, or at most 50 °C higher than the melting temperature or glass transition temperature of the porogens, where the treating temperatures and times are sufficient to fuse the porogens to form a porogen scaffold and cure the substance to form a substance matrix sufficient to allow tissue growth within its array of interconnected of pores, and where the first and second temperatures are different.

[0104] In further aspects of this embodiment, the thermal treatment comprises heating a substance coated porogens for a first time at, *e.g.*, about 5 °C higher to about 10 °C higher, about 5 °C higher to about 15 °C higher, about 5 °C higher to about 20 °C higher, about 5 °C higher to about 25 °C higher, about 5 °C higher to about 30 °C higher, about 5 °C higher to about 35 °C higher, about 5 °C higher to about 40 °C higher, about 5 °C higher to about 45 °C higher, about 5 °C higher to about 50 °C higher, about 10 °C higher to about 15 °C higher, about 10 °C higher to about 20 °C higher, about 10 °C higher to about 25 °C higher, about 10 °C higher to about 30 °C higher, about 10 °C higher to about 35 °C

higher, about 10 °C higher to about 40 °C higher, about 10 °C higher to about 45 °C higher, or about 10 °C higher to about 50 °C higher than the melting temperature or glass transition temperature of the porogens, then heating a substance coated porogens for a second time at, *e.g.*, about 5 °C higher to about 10 °C higher, about 5 °C higher to about 15 °C higher, about 5 °C higher to about 20 °C higher, about 5 °C higher to about 25 °C higher, about 5 °C higher to about 30 °C higher, about 5 °C higher to about 35 °C higher, about 5 °C higher to about 40 °C higher, about 5 °C higher to about 45 °C higher, about 5 °C higher to about 50 °C higher, about 10 °C higher to about 15 °C higher, about 10 °C higher to about 20 °C higher, about 10 °C higher to about 25 °C higher, about 10 °C higher to about 30 °C higher, about 10 °C higher to about 35 °C higher, about 10 °C higher to about 40 °C higher, about 10 °C higher to about 45 °C higher, or about 10 °C higher to about 50 °C higher than the melting temperature or glass transition temperature of the porogens, where the treating temperatures and times are sufficient to fuse the porogens to form a porogen scaffold and cure the substance to form a substance matrix sufficient to allow tissue growth within its array of interconnected of pores, and where the first and second temperatures are different.

[0105] In other aspects of this embodiment, thermal treatment comprises heating the substance coated porogens at a first temperature for a first time, heating the porogens at a second temperature for a second time, and then heating the porogens at a third temperature at a third time, where the treating temperatures and times are sufficient to fuse the porogens to form a porogen scaffold and cure the substance to form a substance matrix sufficient to allow tissue growth within its array of interconnected of pores, and where the first temperature is different from the second temperature and the second temperature is different from the third temperature.

[0106] In other aspects of this embodiment, the thermal treatment comprises heating a substance coated porogens for a first time at, e.g., about 5° C. higher, about 10° C. higher, about 15° C. higher, about 20° C. higher, about 25° C. higher, about 30° C. higher, about 35° C. higher, about 40° C. higher, about 45° C. higher, or about 50° C. higher than the melting temperature or glass transition temperature of the porogens, then heating a substance coated porogens for a second time at, e.g., about 5° C. higher, about 10° C. higher, about 15° C. higher, about 20° C. higher, about 25° C. higher, about 30° C. higher, about 35° C. higher, about 40° C. higher, about 45° C. higher, or about 50° C. higher than the melting temperature or glass transition temperature of the porogens, then heating a substance coated porogens for a third time at, e.g., about 5° C. higher, about 10° C. higher, about 15° C. higher, about 20° C. higher, about 25° C. higher, about 30° C. higher, about 35° C. higher, about 40° C. higher, about 45° C. higher, or about 50° C. higher than the melting temperature or glass transition temperature of the porogens, where the treating temperatures and times are sufficient to fuse the porogens to form a porogen scaffold and cure the substance to form a substance matrix sufficient to allow tissue growth within its array of interconnected of pores, and where the first temperature is different from the second temperature and the second temperature is different from the third temperature. In yet other aspects of this embodiment, the thermal treatment comprises heating a substance coated porogens for a first time at, e.g., at least 5° C. higher, at least 10° C. higher, at least 15° C. higher, at least 20° C. higher, at least 25° C. higher, at least 30° C. higher, at least 35° C. higher, at least 40° C. higher, at least 45° C. higher, or at least 50° C.

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higher than the melting temperature or glass transition temperature of the porogens, then heating a substance coated porogens for a second time at, e.g., at least 5° C. higher, at least 10° C. higher, at least 15° C. higher, at least 20° C. higher, at least 25° C. higher, at least 30° C. higher, at least 35° C. higher, at least 40° C. higher, at least 45° C. higher, or at least 50° C. higher than the melting temperature or glass transition temperature of the porogens, then heating a substance coated porogens for a third time at, e.g., at least 5° C. higher, at least 10° C. higher, at least 15° C. higher, at least 20° C. higher, at least 25° C. higher, at least 30° C. higher, at least 35° C. higher, at least 40° C. higher, at least 45° C. higher, or at least 50° C. higher than the melting temperature or glass transition temperature of the porogens, where the treating temperatures and times are sufficient to fuse the porogens to form a porogen scaffold and cure the substance to form a substance matrix sufficient to allow tissue growth within its array of interconnected of pores, and where the first temperature is different from the second temperature and the second temperature is different from the third temperature. In still other aspects of this embodiment, the thermal treatment comprises heating a substance coated porogens for a first time at, e.g., at most 5° C. higher, at most 10° C. higher, at most 15° C. higher, at most 20° C. higher, at most 25° C. higher, at most 30° C. higher, at most 35° C. higher, at most 40° C. higher, at most 45° C. higher, or at most 50° C. higher than the melting temperature or glass transition temperature of the porogens, then heating a substance coated porogens for a second time at, e.g., at most 5° C. higher, at most 10° C. higher, at most 15° C. higher, at most 20° C. higher, at most 25° C. higher, at most 30° C. higher, at most 35° C. higher, at most 40° C. higher, at most 45° C. higher, or at most 50° C. higher than the melting temperature or glass transition temperature of the porogens, then heating a substance coated porogens for a third time at, e.g., at most 5° C. higher, at most 10° C. higher, at most 15° C. higher, at most 20° C. higher, at most 25° C. higher, at most 30° C. higher, at most 35° C. higher, at most 40° C. higher, at most 45° C. higher, or at most 50° C. higher than the melting temperature or glass transition temperature of the porogens, where the treating temperatures and times are sufficient to fuse the porogens to form a porogen scaffold and cure the substance to form a substance matrix sufficient to allow tissue growth within its array of interconnected of pores, and where the first temperature is different from the second temperature and the second temperature is different from the third temperature.

[0107] In further aspects of this embodiment, the thermal treatment comprises heating a substance coated porogens for a first time at, e.g., about 5° C. higher to about 10° C. higher, about 5° C. higher to about 15° C. higher, about 5° C. higher to about 20° C. higher, about 5° C. higher to about 25° C. higher, about 5° C. higher to about 30° C. higher, about 5° C. higher to about 35° C. higher, about 5° C. higher to about 40° C. higher, about 5° C. higher to about 45° C. higher, about 5° C. higher to about 50° C. higher, about 10° C. higher to about 15° C. higher, about 10° C. higher to about 20° C. higher, about 10° C. higher to about 25° C. higher, about 10° C. higher to about 30° C. higher, about 10° C. higher to about 35° C. higher, about 10° C. higher to about 40° C. higher, about 10° C. higher to about 45° C. higher, or about 10° C. higher to about 50° C. higher than the melting temperature or glass transition temperature of the porogens, then heating a substance coated porogens for a second time at, e.g., about 5° C. higher to about 10° C. higher, about 5° C. higher to about 15° C. higher, about 5° C. higher to about 20° C. higher, about 5° C. higher to about 25° C. higher, about 5° C. higher to about 30° C. higher, about 5° C. higher to about 35° C. higher, about 5° C. higher to about 40° C. higher, about 5° C. higher to about 45° C. higher, about 5° C. higher to about 50° C. higher, about 10° C. higher to about 15°

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C. higher, about 10° C. higher to about 20° C. higher, about 10° C. higher to about 25° C. higher, about 10° C. higher to about 30° C. higher, about 10° C. higher to about 35° C. higher, about 10° C. higher to about 40° C. higher, about 10° C. higher to about 45° C. higher, or about 10° C. higher to about 50° C. higher than the melting temperature or glass transition temperature of the porogens, then heating a substance coated porogens for a third time at, e.g., about 5° C. higher to about 10° C. higher, about 5° C. higher to about 15° C. higher, about 5° C. higher to about 20° C. higher, about 5° C. higher to about 25° C. higher, about 5° C. higher to about 30° C. higher, about 5° C. higher to about 35° C. higher, about 5° C. higher to about 40° C. higher, about 5° C. higher to about 45° C. higher, about 5° C. higher to about 50° C. higher, about 10° C. higher to about 15° C. higher, about 10° C. higher to about 20° C. higher, about 10° C. higher to about 25° C. higher, about 10° C. higher to about 30° C. higher, about 10° C. higher to about 35° C. higher, about 10° C. higher to about 40° C. higher, about 10° C. higher to about 45° C. higher, or about 10° C. higher to about 50° C. higher than the melting temperature or glass transition temperature of the porogens, where the treating temperatures and times are sufficient to fuse the porogens to form a porogen scaffold and cure the substance to form a substance matrix sufficient to allow tissue growth within its array of interconnected of pores, and where the first temperature is different from the second temperature and the second temperature is different from the third temperature.

[0108] In still other aspect of this embodiment, substance coated porogens are treated at about 60 °C to about 75 °C for about 15 minutes to about 45 minutes, and then at about 120 °C to about 130 °C for about 60 minutes to about 90 minutes, where the treating temperatures and times is sufficient to fuse the porogens to form a porogen scaffold and cure the substance to form a substance matrix sufficient to allow tissue growth within its array of interconnected of pores. In a further aspect of this embodiment, substance coated porogen mixture is treated at about 60 °C to about 75 °C for about 15 minutes to about 45 minutes, then at about 135 °C to about 150 °C for about 90 minutes to about 150 minutes, and then at about 150 °C to about 165 °C for about 15 minutes to about 45 minutes.

[0109] The present specification discloses, in part, to form a porogen scaffold. As used herein, the term "porogen scaffold" refers to a three-dimensional structural framework composed of fused porogens that serves as the negative replica of the elastomer matrix defining an interconnected array or pores as disclosed in the present specification.

[0110] The porogen scaffold is formed in such a manner that substantially all the fused porogens in the porogen scaffold have a similar diameter. As used herein, the term "substantially", when used to describe fused porogen, refers to at least 90% of the porogen comprising the porogen scaffold are fused, such as, e.g., at least 95% of the porogens are fused or at least 97% of the porogen are fused. As used herein, the term "similar diameter", when used to describe fused porogen, refers to a difference in the diameters of the two fused porogen that is less than about 20% of the larger diameter. As used herein, the term "diameter", when used to describe fused porogen, refers to the longest line segment that can be drawn that connects two points within the fused porogen, regardless of whether the line passes outside the boundary of the fused porogen. Any fused porogen diameter is useful with the proviso that the fused

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porogen diameter is sufficient to allow formation of a porogen scaffold useful in making an elastomer matrix as disclosed in the present specification.

[0111] The porogen scaffold is formed in such a manner that the diameter of the connections between each fused porogen is sufficient to allow formation of a porogen scaffold useful in making an elastomer matrix as disclosed in the present specification. As used herein, the term "diameter", when describing the connection between fused porogens, refers to the diameter of the cross-section of the connection between two fused porogens in the plane normal to the line connecting the centroids of the two fused porogens, where the plane is chosen so that the area of the cross-section of the connection is at its minimum value. As used herein, the term "diameter of a cross-section of a connection" refers to the average length of a straight line segment that passes through the center, or centroid (in the case of a connection having a cross-section that lacks a center), of the cross-section of a connection and terminates at the periphery of the cross-section. As used herein, the term “substantially”, when used to describe the connections between fused porogens refers to at least 90% of the fused porogens comprising the porogen scaffold make connections between each other, such as, *e.g.*, at least 95% of the fused porogens make connections between each other or at least 97% of the fused porogens make connections between each other.

[0112] In an embodiment, a porogen scaffold comprises fused porogens where substantially all the fused porogens have a similar diameter. In aspects of this embodiment, at least 90% of all the fused porogens have a similar diameter, at least 95% of all the fused porogens have a similar diameter, or at least 97% of all the fused porogens have a similar diameter. In another aspect of this embodiment, difference in the diameters of two fused porogens is, *e.g.*, less than about 20% of the larger diameter, less than about 15% of the larger diameter, less than about 10% of the larger diameter, or less than about 5% of the larger diameter.

[0113] In another embodiment, a porogen scaffold comprises fused porogens have a mean diameter sufficient to allow tissue growth into the array of interconnected porogens. In aspects of this embodiment, a porogen scaffold comprises fused porogens comprising mean fused porogen diameter of, *e.g.*, about 50 μm, about 75 μm, about 100 μm, about 150 μm, about 200 μm, about 250 μm, about 300 μm, about 350 μm, about 400 μm, about 450 μm, or about 500 μm. In other aspects, a porogen scaffold comprises fused porogens comprising mean fused porogen diameter of, *e.g.*, about 500 μm, about 600 μm, about 700 μm, about 800 μm, about 900 μm, about 1000 μm, about 1500 μm, about 2000 μm, about 2500 μm, or about 3000 μm. In yet other aspects of this embodiment, a porogen scaffold comprises fused porogens comprising mean fused porogen diameter of, *e.g.*, at least 50 μm, at least 75 μm, at least 100 μm, at least 150 μm, at least 200 μm, at least 250 μm, at least 300 μm, at least 350 μm, at least 400 μm, at least 450 μm, or at least 500 μm. In still other aspects, an elastomer matrix comprises fused porogens comprising mean fused porogen diameter of, *e.g.*, at least 500 μm, at least 600 μm, at least 700 μm, at least 800 μm, at least 900 μm, at least 1000 μm, at least 1500 μm, at least 2000 μm, at least 2500 μm, or at least 3000 μm. In further aspects of this embodiment, a porogen scaffold comprises fused porogens comprising mean fused porogen diameter of, *e.g.*, at most 50 μm, at most 75 μm, at most 100 μm, at

most 150 µm, at most 200 µm, at most 250 µm, at most 300 µm, at most 350 µm, at most 400 µm, at most 450 µm, or at most 500 µm. In yet further aspects of this embodiment, an elastomer matrix comprises fused porogens comprising mean fused porogen diameter of, *e.g.*, at most 500 µm, at most 600 µm, at most 700 µm, at most 800 µm, at most 900 µm, at most 1000 µm, at most 1500 µm, at most 2000 µm, at most 2500 µm, or at most 3000 µm. In still further aspects of this embodiment, a porogen scaffold comprises fused porogens comprising mean fused porogen diameter in a range from, *e.g.*, about 300 µm to about 600 µm, about 200 µm to about 700 µm, about 100 µm to about 800 µm, about 500 µm to about 800 µm, about 50 µm to about 500 µm, about 75 µm to about 500 µm, about 100 µm to about 500 µm, about 200 µm to about 500 µm, about 300 µm to about 500 µm, about 50 µm to about 1000 µm, about 75 µm to about 1000 µm, about 100 µm to about 1000 µm, about 200 µm to about 1000 µm, about 300 µm to about 1000 µm, about 50 µm to about 1000 µm, about 75 µm to about 3000 µm, about 100 µm to about 3000 µm, about 200 µm to about 3000 µm, or about 300 µm to about 3000 µm.

[0114] In another embodiment, a porogen scaffold comprises fused porogens connected to a plurality of other porogens. In aspects of this embodiment, a porogen scaffold comprises a mean fused porogen connectivity, *e.g.*, about two other fused porogens, about three other fused porogens, about four other fused porogens, about five other fused porogens, about six other fused porogens, about seven other fused porogens, about eight other fused porogens, about nine other fused porogens, about ten other fused porogens, about 11 other fused porogens, or about 12 other fused porogens. In other aspects of this embodiment, a porogen scaffold comprises a mean fused porogen connectivity, *e.g.*, at least two other fused porogens, at least three other fused porogens, at least four other fused porogens, at least five other fused porogens, at least six other fused porogens, at least seven other fused porogens, at least eight other fused porogens, at least nine other fused porogens, at least ten other fused porogens, at least 11 other fused porogens, or at least 12 other fused porogens. In yet other aspects of this embodiment, a porogen scaffold comprises a mean fused porogen connectivity, *e.g.*, at most two other fused porogens, at most three other fused porogens, at most four other fused porogens, at most five other fused porogens, at most six other fused porogens, at most seven other fused porogens, at most eight other fused porogens, at most nine other fused porogens, at most ten other fused porogens, at most 11 other fused porogens, or at most 12 other fused porogens.

[0115] In still other aspects of this embodiment, a porogen scaffold comprises fused porogens connected to, *e.g.*, about two other fused porogens to about 12 other fused porogens, about two other fused porogens to about 11 other fused porogens, about two other fused porogens to about ten other fused porogens, about two other fused porogens to about nine other fused porogens, about two other fused porogens to about eight other fused porogens, about two other fused porogens to about seven other fused porogens, about two other fused porogens to about six other fused porogens, about two other fused porogens to about five other fused porogens, about three other fused porogens to about 12 other fused porogens, about three other fused porogens to about 11 other fused porogens, about three other fused porogens to about ten other fused porogens, about three other fused porogens to about nine other fused porogens, about three other fused porogens to about eight other fused porogens, about three other fused porogens to about seven other fused porogens, about three other fused porogens to about six other

fused porogens, about three other fused porogens to about five other fused porogens, about four other fused porogens to about 12 other fused porogens, about four other fused porogens to about 11 other fused porogens, about four other fused porogens to about ten other fused porogens, about four other fused porogens to about nine other fused porogens, about four other fused porogens to about eight other fused porogens, about four other fused porogens to about seven other fused porogens, about four other fused porogens to about six other fused porogens, about four other fused porogens to about five other fused porogens, about five other fused porogens to about 12 other fused porogens, about five other fused porogens to about 11 other fused porogens, about five other fused porogens to about ten other fused porogens, about five other fused porogens to about nine other fused porogens, about five other fused porogens to about eight other fused porogens, about five other fused porogens to about seven other fused porogens, or about five other fused porogens to about six other fused porogens.

[0116] In another embodiment, a porogen scaffold comprises fused porogens where the diameter of the connections between the fused porogens is sufficient to allow formation of a porogen scaffold useful in making an elastomer matrix that allows tissue growth within its array of interconnected of pores. In aspects of this embodiment, the porogen scaffold comprises fused porogens where the diameter of the connections between the fused porogens is, *e.g.*, about 10% the mean fused porogen diameter, about 20% the mean fused porogen diameter, about 30% the mean fused porogen diameter, about 40% the mean fused porogen diameter, about 50% the mean fused porogen diameter, about 60% the mean fused porogen diameter, about 70% the mean fused porogen diameter, about 80% the mean fused porogen diameter, or about 90% the mean fused porogen diameter. In other aspects of this embodiment, the porogen scaffold comprises fused porogens where the diameter of the connections between the fused porogens is, *e.g.*, at least 10% the mean fused porogen diameter, at least 20% the mean fused porogen diameter, at least 30% the mean fused porogen diameter, at least 40% the mean fused porogen diameter, at least 50% the mean fused porogen diameter, at least 60% the mean fused porogen diameter, at least 70% the mean fused porogen diameter, at least 80% the mean fused porogen diameter, or at least 90% the mean fused porogen diameter. In yet other aspects of this embodiment, the porogen scaffold comprises fused porogens where the diameter of the connections between the fused porogens is, *e.g.*, at most 10% the mean fused porogen diameter, at most 20% the mean fused porogen diameter, at most 30% the mean fused porogen diameter, at most 40% the mean fused porogen diameter, at most 50% the mean fused porogen diameter, at most 60% the mean fused porogen diameter, at most 70% the mean fused porogen diameter, at most 80% the mean fused porogen diameter, or at most 90% the mean fused porogen diameter.

[0117] In still other aspects of this embodiment, a porogen scaffold comprises fused porogens where the diameter of the connections between the fused porogens is, *e.g.*, about 10% to about 90% the mean fused porogen diameter, about 15% to about 90% the mean fused porogen diameter, about 20% to about 90% the mean fused porogen diameter, about 25% to about 90% the mean fused porogen diameter, about 30% to about 90% the mean fused porogen diameter, about 35% to about 90% the mean fused porogen diameter, about 40% to about 90% the mean fused porogen diameter, about 10% to about 80% the mean fused porogen diameter, about 15% to about 80% the mean fused porogen diameter, about

20% to about 80% the mean fused porogen diameter, about 25% to about 80% the mean fused porogen diameter, about 30% to about 80% the mean fused porogen diameter, about 35% to about 80% the mean fused porogen diameter, about 40% to about 80% the mean fused porogen diameter, about 10% to about 70% the mean fused porogen diameter, about 15% to about 70% the mean fused porogen diameter, about 20% to about 70% the mean fused porogen diameter, about 25% to about 70% the mean fused porogen diameter, about 30% to about 70% the mean fused porogen diameter, about 35% to about 70% the mean fused porogen diameter, about 40% to about 70% the mean fused porogen diameter, about 10% to about 60% the mean fused porogen diameter, about 15% to about 60% the mean fused porogen diameter, about 20% to about 60% the mean fused porogen diameter, about 25% to about 60% the mean fused porogen diameter, about 30% to about 60% the mean fused porogen diameter, about 35% to about 60% the mean fused porogen diameter, about 40% to about 60% the mean fused porogen diameter, about 10% to about 50% the mean fused porogen diameter, about 15% to about 50% the mean fused porogen diameter, about 20% to about 50% the mean fused porogen diameter, about 25% to about 50% the mean fused porogen diameter, about 30% to about 50% the mean fused porogen diameter, about 10% to about 40% the mean fused porogen diameter, about 15% to about 40% the mean fused porogen diameter, about 20% to about 40% the mean fused porogen diameter, about 25% to about 40% the mean fused porogen diameter, or about 30% to about 40% the mean fused porogen diameter.

[0118] The present specification discloses, in part, stabilizing a substance. As used herein, the term "stabilizing" refers to a process that exposes the substance base to a element which activates a phase change in the substance base to a more stable state, such as, *e.g.*, by physically or chemically cross-linked components of the substance to one another. Such a stabilization forms, *e.g.*, a substance matrix. Non-limiting examples of stabilizing include curing, such as, *e.g.*, thermal curing, chemical curing, catalyst curing, radiation curing, and physical curing. Stabilizing of a substance coated porogen scaffold can be done under any condition for any length of time with the proviso that the conditions used stabilizes the substance.

[0119] The present specification discloses, in part, removing a porogen scaffold from a treated substance. Removal of the porogen scaffold can be accomplished by any suitable means, with the proviso that removal results in a porous material comprising a matrix defining an array of interconnected pores. Non-limiting examples of porogen removal include solvent extraction, thermal decomposition extraction, degradation extraction, mechanical extraction, and/or any combination thereof. As such, it is beneficial to use shell and core materials that are removable using an extraction method, but such method leaves the porous material intact. In extraction methods requiring exposure to another solution, such as, *e.g.*, solvent extraction, the extraction can incorporate a plurality of solution changes over time to facilitate removal of the porogen scaffold. Non-limiting examples of solvents useful for solvent extraction include water, methylene chloride, acetic acid, formic acid, pyridine, tetrahydrofuran, dimethylsulfoxide, dioxane, benzene, and/or mixtures thereof. A mixed solvent can be in a ratio of higher than about 1:1, first solvent to second solvent or lower than about 1:1, first solvent to second solvent.

[0120] In an embodiment, a porogen scaffold is removed by extraction, where the extraction removes substantially all the porogen scaffold leaving a porous material comprising a matrix defining an array of interconnected pores. In aspects of this embodiment, a porogen scaffold is removed by extraction, where the extraction removes, *e.g.*, about 75% of the porogen scaffold, about 80% of the porogen scaffold, about 85% of the porogen scaffold, about 90% of the porogen scaffold, or about 95% of the porogen scaffold. In other aspects of this embodiment, a porogen scaffold is removed by extraction, where the extraction removes, *e.g.*, at least 75% of the porogen scaffold, at least 80% of the porogen scaffold, at least 85% of the porogen scaffold, at least 90% of the porogen scaffold, or at least 95% of the porogen scaffold. In aspects of this embodiment, a porogen scaffold is removed by extraction, where the extraction removes, *e.g.*, about 75% to about 90% of the porogen scaffold, about 75% to about 95% of the porogen scaffold, about 75% to about 100% of the porogen scaffold, about 80% to about 90% of the porogen scaffold, about 80% to about 95% of the porogen scaffold, about 80% to about 100% of the porogen scaffold, about 85% to about 90% of the porogen scaffold, about 85% to about 95% of the porogen scaffold, or about 85% to about 100% of the porogen scaffold. In an aspect, a porogen scaffold is removed by a solvent extraction, a thermal extraction, a degradation extraction, a mechanical extraction, and/or any combination thereof

[0121] In another embodiment, a porogen scaffold is removed by solvent extraction, where the extraction removes substantially all the porogen scaffold leaving a porous material comprising a matrix defining an array of interconnected pores. In aspects of this embodiment, a porogen scaffold is removed by solvent extraction, where the extraction removes, *e.g.*, about 75% of the porogen scaffold, about 80% of the porogen scaffold, about 85% of the porogen scaffold, about 90% of the porogen scaffold, or about 95% of the porogen scaffold. In other aspects of this embodiment, a porogen scaffold is removed by solvent extraction, where the extraction removes, *e.g.*, at least 75% of the porogen scaffold, at least 80% of the porogen scaffold, at least 85% of the porogen scaffold, at least 90% of the porogen scaffold, or at least 95% of the porogen scaffold. In aspects of this embodiment, a porogen scaffold is removed by solvent extraction, where the extraction removes, *e.g.*, about 75% to about 90% of the porogen scaffold, about 75% to about 95% of the porogen scaffold, about 75% to about 100% of the porogen scaffold, about 80% to about 90% of the porogen scaffold, about 80% to about 95% of the porogen scaffold, about 80% to about 100% of the porogen scaffold, about 85% to about 90% of the porogen scaffold, about 85% to about 95% of the porogen scaffold, or about 85% to about 100% of the porogen scaffold.

[0122] In yet another embodiment, a porogen scaffold is removed by thermal decomposition extraction, where the extraction removes substantially all the porogen scaffold leaving a porous material comprising a matrix defining an array of interconnected pores. In aspects of this embodiment, a porogen scaffold is removed by thermal decomposition extraction, where the extraction removes, *e.g.*, about 75% of the porogen scaffold, about 80% of the porogen scaffold, about 85% of the porogen scaffold, about 90% of the porogen scaffold, or about 95% of the porogen scaffold. In other aspects of this embodiment, a porogen scaffold is removed by thermal decomposition extraction, where the extraction removes, *e.g.*, at least 75% of the porogen scaffold, at least 80% of the porogen scaffold, at least 85% of the porogen scaffold, at least 90% of the porogen scaffold, or at least 95% of the porogen scaffold. In aspects of this

embodiment, a porogen scaffold is removed by thermal decomposition extraction, where the extraction removes, *e.g.*, about 75% to about 90% of the porogen scaffold, about 75% to about 95% of the porogen scaffold, about 75% to about 100% of the porogen scaffold, about 80% to about 90% of the porogen scaffold, about 80% to about 95% of the porogen scaffold, about 80% to about 100% of the porogen scaffold, about 85% to about 90% of the porogen scaffold, about 85% to about 95% of the porogen scaffold, or about 85% to about 100% of the porogen scaffold.

[0123] In still another embodiment, a porogen scaffold is removed by degradation extraction, where the extraction removes substantially all the porogen scaffold leaving a porous material comprising a matrix defining an array of interconnected pores. In aspects of this embodiment, a porogen scaffold is removed by degradation extraction, where the extraction removes, *e.g.*, about 75% of the porogen scaffold, about 80% of the porogen scaffold, about 85% of the porogen scaffold, about 90% of the porogen scaffold, or about 95% of the porogen scaffold. In other aspects of this embodiment, a porogen scaffold is removed by degradation extraction, where the extraction removes, *e.g.*, at least 75% of the porogen scaffold, at least 80% of the porogen scaffold, at least 85% of the porogen scaffold, at least 90% of the porogen scaffold, or at least 95% of the porogen scaffold. In aspects of this embodiment, a porogen scaffold is removed by degradation extraction, where the extraction removes, *e.g.*, about 75% to about 90% of the porogen scaffold, about 75% to about 95% of the porogen scaffold, about 75% to about 100% of the porogen scaffold, about 80% to about 90% of the porogen scaffold, about 80% to about 95% of the porogen scaffold, about 80% to about 100% of the porogen scaffold, about 85% to about 90% of the porogen scaffold, about 85% to about 95% of the porogen scaffold, or about 85% to about 100% of the porogen scaffold.

[0124] In still another embodiment, a porogen scaffold is removed by mechanical extraction, where the extraction removes substantially all the porogen scaffold leaving a porous material comprising a matrix defining an array of interconnected pores. In aspects of this embodiment, a porogen scaffold is removed by mechanical extraction, where the extraction removes, *e.g.*, about 75% of the porogen scaffold, about 80% of the porogen scaffold, about 85% of the porogen scaffold, about 90% of the porogen scaffold, or about 95% of the porogen scaffold. In other aspects of this embodiment, a porogen scaffold is removed by mechanical extraction, where the extraction removes, *e.g.*, at least 75% of the porogen scaffold, at least 80% of the porogen scaffold, at least 85% of the porogen scaffold, at least 90% of the porogen scaffold, or at least 95% of the porogen scaffold. In aspects of this embodiment, a porogen scaffold is removed by mechanical extraction, where the extraction removes, *e.g.*, about 75% to about 90% of the porogen scaffold, about 75% to about 95% of the porogen scaffold, about 75% to about 100% of the porogen scaffold, about 80% to about 90% of the porogen scaffold, about 80% to about 95% of the porogen scaffold, about 80% to about 100% of the porogen scaffold, about 85% to about 90% of the porogen scaffold, about 85% to about 95% of the porogen scaffold, or about 85% to about 100% of the porogen scaffold.

[0125] The present specification discloses, in part, a porous material comprising a substance matrix defining an array of interconnected pores. As used herein, the term “matrix” or “substance matrix” is

synonymous with “treated substance” and refers to a three-dimensional structural framework composed of a substance in its treated or cured state. The porous materials formed by methods using the porogen compositions disclosed herein have a wide range of medical, commercial and household applications. In the medical field, porous materials have been used as a matrix for tissue engineering/regeneration, cell growth supporting matrices, wound dressings, drug release matrices, membranes for separations and filtration, sterile filters, artificial kidneys, absorbents, hemostatic devices, and the like. In various industrial and household applications, porous materials have been used as insulating materials, packaging materials, impact absorbers, liquid or gas absorbents, membranes, filters and so forth.

[0126] Examples of such matrixes and their uses are described in, *e.g.*, Gates, et al., *Materials Containing Voids with Void Size Controlled on the Nanometer Scale*, U.S. Patent 7,674,521; Hart, et al., *Discrete Nano-Textured Structures in Biomolecular Arrays and Method of Use*, U.S. Patent 7,651,872; Xu and Grenz, *Methods and Devices Using a Shrinkable Support for Porous Monolithic Materials*, U.S. Patent 7,651,762; van den Hoek, et al., *VLSI Fabrication Processes for Introducing Pores into Dielectric Materials*, U.S. Patent 7,629,224; Murphy, et al., *Tissue Engineering Scaffolds*, U.S. Patent 7,575,759; Swetlin, et al., *Polyester Compositions, Methods of Manufacturing Said Compositions, and Articles Made Therefrom*, U.S. Patent 7,557,167; Goodner, et al., *Formation of Interconnect Structures by Removing Sacrificial Material with Supercritical Carbon Dioxide*, U.S. Patent 7,466,025; Xu, *Ultraporous Sol Gel Monoliths*, U.S. Patent 7,439,272; Todd, *Apparatus, Precursors and Deposition Methods for Silicon-Containing Materials*, U.S. Patent 7,425,350; Flodin and Aurell, *Method for Preparing an Open Porous Polymer Material and an Open Porous Polymer Material*, U.S. Patent 7,425,288; Watkins and Pai, *Mesoporous Materials and Methods*, U.S. Patent 7,419,772; Connor, et al., *Porous Composition of Matter, and Method of Making Same*, U.S. Patent 7,368,483; Lukas, et al., *Porous Low Dielectric Constant Compositions and Methods for Making and Using Same*, U.S. Patent 7,332,445; Wu, et al., *Methods for Producing Low Stress Porous Low-K Dielectric Materials Using Precursors with Organic Functional Groups*, U.S. Patent 7,241,704; Yuan and Ding, *Functionalized Porous Poly(Aryl Ether Ketone) Materials and Their Use*, U.S. Patent 7,176,273; Gleason, et al., *Porous Material Formation by Chemical Vapor Deposition onto Colloidal Crystal Templates*, U.S. Patent 7,112,615; Bruza, et al., *Composition Containing a Cross-Linkable Matrix Precursor and a Poragen, and Porous Matrix Prepared Therefrom*, U.S. Patent 7,109,249; Huang, et al., *Nitrogen-Containing Polymers as Porogens in the Preparation of Highly Porous, Low Dielectric Constant Materials*, U.S. Patent 7,087,982; Taboas, et al., *Controlled Local/Global and Micro/Macro-Porous 3D Plastic, Polymer and Ceramic/Cement Composite Scaffold Fabrication and Applications Thereof*, U.S. Patent 7,087,200; Kloster, et al., *Method of Forming a Selectively Converted Inter-Layer Dielectric Using A Porogen Material*, U.S. Patent 7,018,918; You, et al., *Porous Materials*, U.S. Patent 6,998,148; Khanarian, et al., *Porous Optical Materials*, U.S. Patent 6,967,222; Holmes and Cooper, *Manufacturing Porous Cross-Linked Polymer Monoliths*, U.S. Patent 6,693,159; Ma, *Reverse Fabrication of Porous Materials*, U.S. Patent 6,673,285; Kilaas, et al., *Combined Liner and Matrix System*, U.S. Patent 6,672,385; Chaouk and Meijs, *Hydratable Siloxane Comprising Porous Polymers*, U.S. Patent 6,663,668; Allen, et al., *Porous Materials*, U.S. Patent 6,602,804; Hawker, et al., *Porous Dielectric Material and Electronic Devices Fabricated Therewith*, U.S. Patent 6,541,865; Davankov, et al., *Method of Making Biocompatible Polymeric Adsorbing Material for Purification of*

Physiological Fluids of Organism, U.S. Patent 6,531,523; Shastri, et al., *Three-Dimensional Polymer Matrices*, U.S. Patent 6,471,993; Yates, *Photogenerated Nanoporous Materials*, U.S. Patent 6,380,270; Fonnum, *Method for the Manufacture of Amino Group Containing Support Matrices, Support Matrices Prepared by the Method, and Use of the Support Matrices*, U.S. Patent 6,335,438; Chaouk, et al., *Polymers*, U.S. Patent 6,225,367; Chaouk, et al., *High Water Content Porous Polymer*, U.S. Patent 6,160,030; Hawker, et al., *Dielectric Compositions and Method for Their Manufacture*, U.S. Patent 6,107,357; Li, et al., *Polymeric Microbeads and Methods of Preparation*, U.S. Patent 6,100,306; Chaouk, et al., *Process for Manufacture of A Porous Polymer by Use of A Porogen*, U.S. Patent 6,060,530; Li, et al., *Polymeric Microbeads*, U.S. Patent 5,863,957; Frechet and Svec, *Porous Polymeric Material with Gradients*, U.S. Patent 5,728,457; Frechet and Svec, *Pore-Size Selective Modification of Porous Materials*, U.S. Patent 5,633,290; Yen, et al., Ion Exchange Polyethylene Membrane and Process, U.S. Patent 5,531,899; Soria, et al., *Membrane for a Filtration, Gas or Liquid Separation or Pervaporation Apparatus and A Manufacturing Method for Such Membrane*, U.S. Patent 5,066,398; Axisa, et al., *Method of Fabricating A Porous Elastomer*, U.S. Patent Publication 2010/0075056; Liljensten and Persoon, *Biodegradable Ostochondreal Implant*, U.S. Patent Publication 2009/0164014; Favis, et al., *Porous Nanosheath Networks, Method of Making and Uses Thereof*, U.S. Patent Publication 2009/0087641; Hosoya, et al., *Porous Polymer and Process For Producing the Same*, U.S. Patent Publication 2009/0045119; Andersson, *Chitosan Compositions*, U.S. Patent Publication 2009/0022770; Xie, Three-Dimensional Hydrophilic Porous Structures for Fuel Cell Plates, U.S. Patent Publication 2008/0292939; Ratner and Marshall, *Novel Porous Materials*, U.S. Patent Publication 2008/0075752; Ma and Chen, *Porous Materials having Multi-Sized Geometries*, U.S. Patent Publication 2007/0036844; Ma, *Reverse Fabrication of Porous Materials*, U.S. Patent Publication 2002/0005600; Liu, et al., *Porous Materials, Methods of Making and Uses*, Attorney Docket Number 18614 PROV (BRE); and Liu, et al., *Porous Materials, Methods of Making and Uses*, Attorney Docket Number 18707PROV (BRE).

[0127] In one aspect, a biocompatible implantable device comprises a porous material formed by methods using the porogen compositions disclosed in the present specification.

[0128] The present specification discloses in part, biocompatible implantable device comprising a layer of porous material as disclosed in the present specification, wherein the porous material covers a surface of the device. See, *e.g.*, FIG. 2, and FIGS. 4-8. As used herein, the term "implantable" refers to any material that can be embedded into, or attached to, tissue, muscle, organ or any other part of an animal body. As used herein, the term "animal" includes all mammals including a human. A biocompatible implantable device is synonymous with "medical device", "biomedical device", "implantable medical device" or "implantable biomedical device" and includes, without limitation, pacemakers, dura matter substitutes, implantable cardiac defibrillators, tissue expanders, and tissue implants used for prosthetic, reconstructive, or aesthetic purposes, like breast implants, muscle implants or implants that reduce or prevent scarring. Examples of biocompatible implantable devices that the porous material disclosed herein can be attached to are described in, *e.g.*, Schuessler, *Rotational Molding System for Medical Articles*, U.S. Patent 7,628,604; Smith, *Mastopexy Stabilization Apparatus and Method*, U.S. Patent

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7,081,135; Knisley, *Inflatable Prosthetic Device*, U.S. Patent 6,936,068; Falcon, *Reinforced Radius Mammary Prostheses and Soft Tissue Expanders*, U.S. 6,605,116; Schuessler, *Rotational Molding of Medical Articles*, U.S. Patent 6,602,452; Murphy, *Seamless Breast Prosthesis*, U.S. Patent 6,074,421; Knowlton, *Segmental Breast Expander For Use in Breast Reconstruction*, U.S. Patent 6,071,309; VanBeek, *Mechanical Tissue Expander*, U.S. Patent 5,882,353; Hunter, *Soft Tissue Implants and Anti-Scarring Agents*, Schuessler, *Self-Sealing Shell For Inflatable Prostheses*, U.S. Patent Publication 2010/0049317; U.S. 2009/0214652; Schraga, *Medical Implant Containing Detection Enhancing Agent and Method For Detecting Content Leakage*, U.S. Patent Publication 2009/0157180; Schuessler, *All-Barrier Elastomeric Gel-Filled Breast Prosthesis*, U.S. Patent Publication 2009/0030515; Connell, *Differential Tissue Expander Implant*, U.S. Patent Publication 2007/0233273; and Hunter, *Medical Implants and Anti-Scarring Agents*, U.S. Patent Publication 2006/0147492; Van Epps, *Soft Filled Prosthesis Shell with Discrete Fixation Surfaces*, International Patent Publication WO/2010/019761; Schuessler, *Self Sealing Shell for Inflatable Prosthesis*, International Patent Publication WO/2010/022130; Yacoub, *Prosthesis Implant Shell*, International Application No. PCT/US09/61045.

[0129] A biocompatible implantable device disclosed herein can be implanted into the soft tissue of an animal during the normal operation of the device. Such implantable devices may be completely implanted into the soft tissue of an animal body (*i.e.*, the entire device is implanted within the body), or the device may be partially implanted into an animal body (*i.e.*, only part of the device is implanted within an animal body, the remainder of the device being located outside of the animal body). A biocompatible implantable device disclosed herein can also be affixed to soft tissue of an animal during the normal operation of the medical device. Such devices are typically affixed to the skin of an animal body.

[0130] The present specification discloses, in part, a porous material that covers a surface of the biocompatible implantable device. Any of the porous materials disclosed herein can be used as the porous material covering a surface of a biocompatible implantable device. In general, the surface of a biocompatible implantable device is one exposed to the surrounding tissue of an animal in a manner that promotes tissue growth, and/or reduces or prevents formation of fibrous capsules that can result in capsular contracture or scarring.

[0131] Thus, in an embodiment, a porous material covers the entire surface of a biocompatible implantable device. In another embodiment, a porous material covers a portion of a surface of a biocompatible implantable device. In aspects of this embodiment, a porous material covers to a front surface of a biocompatible implantable device or a back surface of a biocompatible implantable device. In other aspects, a porous material covers only to, *e.g.*, about 20%, about 30%, about 40%, about 50%, about 60%, about 70% about 80% or about 90% of the entire surface of a biocompatible implantable device, a front surface of a biocompatible implantable device, or a back surface of a biocompatible implantable device. In yet other aspects, a porous material is applied only to, *e.g.*, at least 20%, at least 30%, at least 40%, at least 50%, at least 60%, at least 70% at least 80% or at least 90% of the entire surface of a biocompatible implantable device, a front surface of a biocompatible implantable device, or a

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back surface of a biocompatible implantable device. In still other aspects, a porous material is applied only to, *e.g.*, at most 20%, at most 30%, at most 40%, at most 50%, at most 60%, at most 70% at most 80% or at most 90% of the entire surface of a biocompatible implantable device, a front surface of a biocompatible implantable device, or a back surface of a biocompatible implantable device. In further aspects, a porous material is applied only to, *e.g.*, about 20% to about 100%, about 30% to about 100%, about 40% to about 100%, about 50% to about 100%, about 60% to about 100%, about 70% to about 100%, about 80% to about 100%, or about 90% to about 100% of the entire surface of a biocompatible implantable device, a front surface of a biocompatible implantable device, or a back surface of a biocompatible implantable device.

[0132] The layer of porous material covering a biocompatible implantable device can be of any thickness with the proviso that the material thickness allows tissue growth within the array of interconnected of pores of an elastomer matrix in a manner sufficient to reduce or prevent formation of fibrous capsules that can result in capsular contracture or scarring.

[0133] Thus, in an embodiment, a layer of porous material covering a biocompatible implantable device is of a thickness that allows tissue growth within the array of interconnected of pores of an elastomer matrix in a manner sufficient to reduce or prevent formation of fibrous capsules that can result in capsular contracture or scarring. In aspects of this embodiment, a layer porous material covering a biocompatible implantable device comprises a thickness of, *e.g.*, about 100 μm, about 200 μm, about 300 μm, about 400 μm, about 500 μm, about 600 μm, about 700 μm, about 800 μm, about 900 μm, about 1 mm, about 2 mm, about 3 mm, about 4 mm, about 5 mm, about 6 mm, about 7 mm, about 8 mm, about 9 mm, or about 10 mm. In other aspects of this embodiment, a layer porous material covering a biocompatible implantable device comprises a thickness of, *e.g.*, at least 100 μm, at least 200 μm, at least 300 μm, at least 400 μm, at least 500 μm, at least 600 μm, at least 700 μm, at least 800 μm, at least 900 μm, at least 1 mm, at least 2 mm, at least 3 mm, at least 4 mm, at least 5 mm, at least 6 mm, at least 7 mm, at least 8 mm, at least 9 mm, or at least 10 mm. In yet other aspects of this embodiment, a layer porous material covering a biocompatible implantable device comprises a thickness of, *e.g.*, at most 100 μm, at most 200 μm, at most 300 μm, at most 400 μm, at most 500 μm, at most 600 μm, at most 700 μm, at most 800 μm, at most 900 μm, at most 1 mm, at most 2 mm, at most 3 mm, at most 4 mm, at most 5 mm, at most 6 mm, at most 7 mm, at most 8 mm, at most 9 mm, or at most 10 mm. In still other aspects of this embodiment, a layer porous material covering a biocompatible implantable device comprises a thickness of, *e.g.*, about 100 μm to about 500 μm, about 100 μm to about 1 mm, about 100 μm to about 5 mm, about 500 μm to about 1 mm, about 500 μm to about 2 mm, about 500 μm to about 3 mm, about 500 μm to about 4 mm, about 500 μm to about 5 mm, about 1 mm to about 2 mm, about 1 mm to about 3 mm, about 1 mm to about 4 mm, about 1 mm to about 5 mm, or about 1.5 mm to about 3.5 mm.

[0134] The present specification discloses in part, a method for making biocompatible implantable device comprising a porous material. In an aspect, a method for making biocompatible implantable device comprises the step of attaching a porous material to the surface of a biocompatible implantable device. In another aspect, a method for making biocompatible implantable device comprises the steps of

a) preparing a surface of a biocompatible implantable device surface to receive porous material; b) attaching a porous material to the prepared surface of the device. Any of the porous materials disclosed herein can be used as the porous material attached to a surface of a biocompatible implantable device.

[0135] In yet another aspect, a method for making biocompatible implantable device comprising the step of: a) coating a mandrel with an elastomer base; b) curing the elastomer base to form a base layer; c) coating the cured base layer with an elastomer base; d) coating the elastomer base with porogens to form an elastomer coated porogen mixture, the porogens comprise a shell material and a core material, wherein the shell material as disclosed in the present specification; e) treating the elastomer coated porogen mixture to form a porogen scaffold comprising fused porogens and cure the elastomer base; and f) removing the porogen scaffold, wherein porogen scaffold removal results in a porous material, the porous material comprising a non-degradable, biocompatible, elastomer matrix defining an array of interconnected pores. In this method steps (c) and (d) can be repeated multiple times until the desired thickness of the material layer is achieved.

[0136] The present specification discloses, in part, preparing a surface of a biocompatible implantable device to receive porous material. Preparing a surface of a biocompatible implantable device to receive porous material can be accomplished by any technique that does not destroy the desired properties of the porous material or the biocompatible implantable device. As a non-limiting example, a surface of a biocompatible implantable device can be prepared by applying a bonding substance. Non-limiting examples of bonding substances include silicone adhesives, such as, *e.g.*, RTV silicone and HTV silicone. The bonding substance is applied to the surface of a biocompatible implantable device, the porous material, or both, using any method known in the art, such as, *e.g.*, cast coating, spray coating, dip coating, curtain coating, knife coating, brush coating, vapor deposition coating, and the like.

[0137] The present specification discloses, in part, attaching a porous material to a surface of a biocompatible implantable device. The porous material can be attached to the entire surface of the device, or only to portions of the surface of the device. As a non-limiting example, porous material is attached only to the front surface of the device or only the back surface of the device. Attachment of a porous material to a surface of a biocompatible implantable device can be accomplished by any technique that does not destroy the desired properties of the porous material or the biocompatible implantable device.

[0138] For example, attachment can occur by adhering an already formed porous material onto a surface of a biocompatible implantable device using methods known in the art, such as, *e.g.*, gluing, bonding, melting. For instance, a dispersion of silicone is applied as an adhesive onto a surface of a biocompatible implantable device, a porous material sheet, or both, and then the two materials are placed together in a manner that allows the adhesive to attached the porous material to the surface of the device in such a way that there are no wrinkles on the surface of the device. The silicone adhesive is allowed to cure and then the excess material is cut off creating a uniform seam around the device. This process

results in a biocompatible implantable device comprising a porous material disclosed in the present specification. Examples 2 and 4 illustrate method of this type of attachment.

[0139] Alternatively, attachment can occur by forming the porous material directly onto a surface of a biocompatible implantable device using methods known in the art, such as, *e.g.*, cast coating, spray coating, dip coating, curtain coating, knife coating, brush coating, vapor deposition coating, and the like. For instance, an elastomer base is applied to a mandrel and cured to form a base layer of cured elastomer. The base layer is then initially coated with an elastomer base and then subsequently with porogens to create an elastomer coated porogen mixture. This mixture is then treated as disclosed herein to form a porogen scaffold and cure the elastomer. The porogen scaffold is then removed, leaving a layer of porous material on the surface of the device. The thickness of the porous material layer can be increased by repeated coatings of additional elastomer base and porogens. Examples 5-8 illustrate method of this type of attachment.

[0140] Regardless of the method of attachment, the porous material can be applied to the entire surface of a biocompatible implantable device, or only to portions of the surface of a biocompatible implantable device. As a non-limiting example, porous material is applied only to the front surface of a biocompatible implantable device or only the back surface of a biocompatible implantable device.

[0141] Thus, in an embodiment, a porous material is attached to a surface of a biocompatible implantable device by bonding a porous material to a surface of a biocompatible implantable device. In aspects of this embodiment, a porous material is attached to a surface of a biocompatible implantable device by gluing, bonding, or melting the porous material to a surface of a biocompatible implantable device.

[0142] In another embodiment, a porous material is attached to a surface of a biocompatible implantable device by forming the porous material onto a surface of a biocompatible implantable device. In aspects of this embodiment, a porous material is attached to a surface of a biocompatible implantable device by cast coating, spray coating, dip coating, curtain coating, knife coating, brush coating, or vapor deposition coating.

[0143] In another aspect of this embodiment, forming a porous material on a surface of a biocompatible implantable device comprises coating a cured elastomer base layer with an elastomer base and then coating the uncured elastomer base with porogens to form an elastomer coated porogen mixture. In other aspects of this embodiment, coating a cured elastomer base layer with an uncured elastomer base and then coating the uncured elastomer base with porogens to form an elastomer coated porogen mixture can be repeated, *e.g.*, at least once, at least twice, at least three times, at least four times, at least five times, at least six times, at least seven times, at least eight times, at least nine times, or at least ten times, before the mixture is treated.

[0144] In another embodiment, a porous material is applied to the entire surface of a biocompatible implantable device. In another embodiment, a porous material is applied to a portion of a surface of a biocompatible implantable device. In aspects of this embodiment, a porous material is applied to a front surface of a biocompatible implantable device or a back surface of a biocompatible implantable device. In other aspects, a porous material is applied only to, *e.g.*, about 20%, about 30%, about 40%, about 50%, about 60%, about 70% about 80% or about 90% of the entire surface of a biocompatible implantable device, a front surface of a biocompatible implantable device, or a back surface of a biocompatible implantable device. In yet other aspects, a porous material is applied only to, *e.g.*, at least 20%, at least 30%, at least 40%, at least 50%, at least 60%, at least 70% at least 80% or at least 90% of the entire surface of a biocompatible implantable device, a front surface of a biocompatible implantable device, or a back surface of a biocompatible implantable device. In still other aspects, a porous material is applied only to, *e.g.*, at most 20%, at most 30%, at most 40%, at most 50%, at most 60%, at most 70% at most 80% or at most 90% of the entire surface of a biocompatible implantable device, a front surface of a biocompatible implantable device, or a back surface of a biocompatible implantable device. In further aspects, a porous material is applied only to, *e.g.*, about 20% to about 100%, about 30% to about 100%, about 40% to about 100%, about 50% to about 100%, about 60% to about 100%, about 70% to about 100%, about 80% to about 100%, or about 90% to about 100% of the entire surface of a biocompatible implantable device, a front surface of a biocompatible implantable device, or a back surface of a biocompatible implantable device.

[0145] The layer of porous material applied to a biocompatible implantable device can be of any thickness with the proviso that the material thickness allows tissue growth within the array of interconnected of pores of an elastomer matrix in a manner sufficient to reduce or prevent formation of fibrous capsules that can result in capsular contracture or scarring.

[0146] Thus, in an embodiment, a layer of porous material applied to a biocompatible implantable device is of a thickness that allows tissue growth within the array of interconnected of pores of an elastomer matrix in a manner sufficient to reduce or prevent formation of fibrous capsules that can result in capsular contracture or scarring. In aspects of this embodiment, a layer porous material applied to a biocompatible implantable device comprises a thickness of, *e.g.*, about 100 μm, about 200 μm, about 300 μm, about 400 μm, about 500 μm, about 600 μm, about 700 μm, about 800 μm, about 900 μm, about 1 mm, about 2 mm, about 3 mm, about 4 mm, about 5 mm, about 6 mm, about 7 mm, about 8 mm, about 9 mm, or about 10 mm. In other aspects of this embodiment, a layer porous material applied to a biocompatible implantable device comprises a thickness of, *e.g.*, at least 100 μm, at least 200 μm, at least 300 μm, at least 400 μm, at least 500 μm, at least 600 μm, at least 700 μm, at least 800 μm, at least 900 μm, at least 1 mm, at least 2 mm, at least 3 mm, at least 4 mm, at least 5 mm, at least 6 mm, at least 7 mm, at least 8 mm, at least 9 mm, or at least 10 mm. In yet other aspects of this embodiment, a layer porous material applied to a biocompatible implantable device comprises a thickness of, *e.g.*, at most 100 μm, at most 200 μm, at most 300 μm, at most 400 μm, at most 500 μm, at most 600 μm, at most 700 μm, at most 800 μm, at most 900 μm, at most 1 mm, at most 2 mm, at most 3 mm, at most 4 mm, at most 5 mm, at most 6 mm, at most 7 mm, at most 8 mm, at most 9 mm, or at most 10 mm. In still other aspects of this

embodiment, a layer porous material applied to a biocompatible implantable device comprises a thickness of, *e.g.*, about 100 µm to about 500 µm, about 100 µm to about 1 mm, about 100 µm to about 5 mm, about 500 µm to about 1 mm, about 500 µm to about 2 mm, about 500 µm to about 3 mm, about 500 µm to about 4 mm, about 500 µm to about 5 mm, about 1 mm to about 2 mm, about 1 mm to about 3 mm, about 1 mm to about 4 mm, about 1 mm to about 5 mm, or about 1.5 mm to about 3.5 mm.

[0147] The present specification also discloses a method of implanting a prosthesis, the method comprising the step of implanting the prosthesis in a patient, the prosthesis covered by a porous material disclosed herein; wherein at any time after implantation, if a capsule has formed, the capsule has a thickness of 75 µm or less, has fiber disorganization comprising 50% or more of the fibers that are not parallel to the prosthesis surface, has tissue growth into the biomaterial of the prosthesis of 100 µm or more, has less than 40% collagen content, adheres to tissue with a peak force of at least 8 N and/or and has a stiffness of 20 mmHg/mL or less.

[0148] The present specification also discloses a method of implanting a prosthesis, the method comprising the step of implanting the prosthesis in a patient, the prosthesis covered by a porous material disclosed herein; wherein at any time after implantation, if a capsule has formed, the capsule has a thickness of 50 µm or less, has fiber disorganization comprising 60% or more of the fibers that are parallel to the prosthesis surface, has tissue growth into the biomaterial of the prosthesis of 125 µm or more, has less than 30% collagen content, adheres to tissue with a peak force of at least 9 N and/or and has a stiffness of 15 mmHg/mL or less.

[0149] The present specification also discloses a method of implanting a prosthesis, the method comprising the step of implanting the prosthesis in a patient, the prosthesis covered by a porous material disclosed herein; wherein at any time after implantation, if a capsule has formed, the capsule has a thickness of 25 µm or less, has fiber disorganization comprising 70% or more of the fibers that are not parallel to the prosthesis surface, has tissue growth into the biomaterial of the prosthesis of 150 µm or more, has less than 20% collagen content, adheres to tissue with a peak force of at least 10 N and/or and has a stiffness of 10 mmHg/mL or less.

[0150] The present specification also discloses a method of implanting a prosthesis, the method comprising the step of implanting the prosthesis in a patient, the prosthesis covered by a porous material disclosed herein; wherein at any time after implantation, if a capsule has formed, the capsule has a thickness of about 5 µm to about 75 µm, has fiber disorganization comprising about 50% to about 90% of the fibers that are not parallel to the prosthesis surface, has tissue growth into the biomaterial of the prosthesis of about 100 µm to about 300 µm, has about 5% to about 40% collagen content, adheres to tissue with a peak force of about 8 N to about 11 N, and/or and has a stiffness of about 5 mmHg/mL to about 20 mmHg/mL.

EXAMPLES

[0151] The following examples illustrate representative embodiments now contemplated, but should not be construed to limit the disclosed porous materials, methods of forming such porous materials, biocompatible implantable devices comprising such porous materials, and methods of making such biocompatible implantable devices.

Example 1

A method of making a porous material sheet

[0152] This example illustrates how to make a sheet of porous material using the porogen compositions disclosed in the present specification.

[0153] To coat porogens with a substance, an appropriate amount of porogens comprising a sugar core of about 335 μm and a polyethylene glycol shell of about 15 μm were mixed with an appropriate amount of about 35% (v/v) silicon in xylene (PN-3206-1; NuSil Technology LLC, Carpinteria, CA). In other experiments, the porogen composition used were porogens comprising a sugar core of about 335 μm and a polyethylene glycol shell of about 53 μm, porogens comprising a sugar core of about 390 μm and a polyethylene glycol shell of about 83 μm, or porogens comprising a sugar core of about 460 μm and a polyethylene glycol shell of about 104 μm. The mixture was filtered through a 43 μm sieve to remove the excess silicone and was poured into an about 20 cm x 20 cm square mold coated with a non-stick surface.

[0154] To treat a substance coated porogen mixture to allow fusing of the porogens to form a porogen scaffold and stabilization of the substance, the porogen/silicone mixture was placed into an oven and heated at a temperature of about 75 °C for about 60 min, and then about 126 °C for about 75 minutes. In another experiments, the porogen/silicone mixture was treated by placing into an oven and heated at a temperature of about 126 °C for about 75 minutes, or heated at a temperature of about 145 °C for about 150 minutes, or heated at a temperature of about 126 °C for about 85 min, and then about 30 °C for about 60 minutes. After curing, the sheet of cured elastomer coated porogen scaffold was removed.

[0155] To remove a porogen scaffold from the cured substance, the cured elastomer/porogen scaffold was immersed in hot water. After about 30 minutes, the hot water was removed and the resulting 30 cm x 30 cm x 1.5 mm sheet of porous material was air dried at an ambient temperature of about 18 °C to about 22 °C. This process results in a porous material sheet as disclosed in the present specification.

[0156] A sample from the sheet of porous material can be characterized by microCT analysis and/or scanning electron microscopy (SEM).

Example 2

A method of making a biocompatible implantable device comprising a porous material

[0157] This example illustrates how to make a biocompatible implantable device comprising a porous material formed using the porogen compositions disclosed in the present specification.

[0158] Sheets of porous material comprising an elastomer matrix defining an interconnected array of pores is obtained as described in Example 1.

[0159] To attach a porous material to a biocompatible implantable device, a first porous material sheet is coated with a thin layer of silicone and then placed in the bottom cavity of a mold, adhesive side up. A biocompatible implantable device is then placed on top of the material surface coated with the adhesive. A second porous material sheet is then coated with a thin layer of silicone and applied to the uncovered surface of the biocompatible implantable device. The top piece of the mold cavity is then fixed in place pressing the two material sheets together creating a uniform interface. The silicone adhesive is allowed to cure by placing the covered device into an oven and heated at a temperature of about 126 °C for about 75 minutes. After curing, excess material is trimmed off creating a uniform seam around the biocompatible implantable device. This process results in a biocompatible implantable device **10** as disclosed herein (FIG. 2). FIG. 2A is a top view of an implantable device covered with a porous material **10**. FIG. 2B is a side view of an implantable device covered with a porous material **10** to show a bottom **12** of the implantable device **10** and a top **14** of the implantable device **10**. FIG. 2C and 2D illustrate the cross-sectional view of the biocompatible implantable device covered with a porous material **10** to show an implantable device **16**, a porous material layer **20** including an internal surface **22** and an external surface **24**, where the internal surface **22** is attached to an implantable device surface **18**. Due to the presence of the porous material on the device surface of the biocompatible implantable device there will be a reduction or prevention of the formation of fibrous capsules that can result in capsular contracture or scarring.

[0160] Alternatively, the porous material can be laminated onto a biocompatible implantable device while the device is still on a mandrel. In this process, a first porous material sheet is coated with a thin layer of silicone and then draped over the device on the mandrel in such a way that there are no wrinkles on the surface. After curing the silicone adhesive, as described above, another coating of silicone is applied to the uncovered surface of the biocompatible implantable device and a second porous material is stretched up to cover the back of the device. After curing the silicone adhesive, as described above, the biocompatible implantable device is then taken off the mandrel and the excess porous material is trimmed to create a uniform seam around the device. This process results in a biocompatible implantable device comprising a porous material as disclosed in the present specification. See, *e.g.*, FIG. 2.

Example 3

A method of making a porous material shell

[0161] This example illustrates how to make a porous material shell using the porogen compositions disclosed in the present specification.

[0162] To coat porogens with a substance, an appropriate amount of a porogen composition comprising a sugar core of about 335 µm and a polyethylene glycol shell of about 53 µm are mixed with an appropriate amount of about 35% (v/v) silicon in xylene (PN-3206-1; NuSil Technology LLC, Carpinteria, CA). In other experiments, the porogen composition used are porogens comprising a sugar core of about 335 µm and a polyethylene glycol shell of about 65 µm, porogens comprising a sugar core of about 320 µm and a polyethylene glycol shell of about 30 µm, or porogens comprising a sugar core of about 350 µm and a polyethylene glycol shell of about 50 µm. The mixture is filtered through a 43 µm sieve to remove the excess silicone.

[0163] To pour a substance coated porogen mixture into a mold, the filtered elastomer coated porogen mixture is poured into a mold in the shape of a breast implant shell and the mold is mechanically agitated to pack firmly the mixture. The thickness of the shell is controlled based upon the design of the shell mold.

[0164] To treat a substance coated porogen mixture to allow fusing of the porogens to form a porogen scaffold and cure the elastomer, the porogen/silicone mixture is placed into an oven and is heated at a temperature of about 75 °C for about 45 min, and then about 126 °C for about 75 minutes. In another experiments, the porogen/silicone mixture is treated by placing into an oven and heated at a temperature of about 126 °C for about 75 minutes, or heated at a temperature of about 145 °C for about 60 minutes. After treating, the shell mold is dismantled and the cured elastomer coated porogen scaffold is removed.

[0165] To remove a porogen scaffold from the cured substance, the cured elastomer/porogen scaffold is immersed in hot water. After about 3 hours, the hot water is removed and the resulting shell of porous material is dried in an oven of about 126 °C for 30 minutes. This process results in a porous material shell **10** as disclosed herein (FIG. 3). FIG. 3A is a top view of a material shell **10**. FIG. 3B is a side view of a material shell **10** to show a bottom **12** of the material shell **10** and a top **14** of the material shell **10**. FIG. 3C is a bottom view of a material shell **10** to show a hole **16** from which a biocompatible implantable device may be subsequently inserted through. FIG. 3D illustrate the cross-sectional view of the material shell **10** to show the hole **16**, an internal surface **20** of the material shell **10** and an external surface **22** of the material shell **10**.

[0166] A sample from the sheet of porous material can be characterized by microCT analysis and/or scanning electron microscopy (SEM).

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Example 4

A method of making a biocompatible implantable device comprising a porous material

[0167] This example illustrates how to make a biocompatible implantable device comprising a porous material formed using the porogen compositions disclosed in the present specification.

[0168] A porous material shell comprising a matrix defining an interconnected array of pores is obtained as described in Example 3.

[0169] To attach the porous material shell to a biocompatible implantable device, the surface of the device is coated with a thin layer of silicone. The material shell is then placed over the adhesive coated device in a manner that ensures no wrinkles in the material form. The silicone adhesive is allowed to cure by placing the covered device into an oven and heating at a temperature of 126 °C for 75 minutes. After curing, excess material is trimmed off creating a uniform seam around the biocompatible implantable device. This process results in a biocompatible implantable device comprising a porous material **10** as disclosed herein (FIG. 4). FIG. 4A is a top view of an implantable device covered with a porous material **10**. FIG. 4B is a side view of an implantable device covered with a porous material **10** to show a bottom **12** of the implantable device **10** and a top **14** of the implantable device **10**. FIG. 4C is a bottom view of a biocompatible implantable device covered with a porous material **10** to show a hole **16** and an implantable device **18**. FIG. 4D illustrates the cross-sectional view of the biocompatible implantable device covered with a porous material **10** to show an implantable device **18**, a porous material layer **20** including an internal surface **22** and an external surface **24**, where the internal surface **22** is attached to implantable device surface **19**. Due to the presence of the porous material on the device surface of the biocompatible implantable device there will be a reduction or prevention of the formation of fibrous capsules that can result in capsular contracture or scarring.

Example 5

A method of making an implant comprising a porous material

[0170] This example illustrates how to make an implant comprising a porous material disclosed herein of about 0.5 mm to about 1.5 mm in thickness.

[0171] To preparing the surface of a device to receive a porous material, a base layer of 35% (w/w) silicon in xylene (PN-3206-1; NuSil Technology LLC, Carpinteria, CA) was coated on a mandrel (LR-10), placed into an oven, and cured at a temperature of about 126 °C for about 75 minutes.

[0172] To coat the base layer with a mixture comprising a substance and porogens, the cured base layer was dipped first in about 35% (w/w) silicon in xylene (PN-3206-1; NuSil Technology LLC, Carpinteria, CA) and then air dried for about 3 minutes to allow the xylene to evaporate. After xylene evaporation, the mandrel with the uncured silicone was dipped in a porogen composition comprising a sugar core of about 335 μm and a polyethylene glycol shell of about 53 μm until the maximum amount of

porogens were absorbed into the uncured silicone. In other experiments, the porogen composition used were porogens comprising a sugar core of about 335 μm and a polyethylene glycol shell of about 60 μm, porogens comprising a sugar core of about 390 μm and a polyethylene glycol shell of about 83 μm, or porogens comprising a sugar core of about 460 μm and a polyethylene glycol shell of about 104 μm. The mandrel with the uncured silicon/porogen coating was air dried for about 60 minutes to allow the xylene to evaporate.

[0173] To treat a substance coated porogen mixture to allow fusing of the porogens to form a porogen scaffold and stabilization of the substance, the mandrel coated with the uncured silicone/porogen mixture was placed into an oven and cured at a temperature of about 75 °C for 30 min, and then about 126 °C for 75 minutes. In another experiments, the porogen/silicone mixture was treated by placing into an oven and heated at a temperature of about 126 °C for about 75 minutes, or heated at a temperature of about 145 °C for about 60 minutes.

[0174] To remove porogen scaffold, the cured silicon/porogen scaffold was immersed in hot water. After about 3 hours, the hot water was removed and the resulting implant comprising a porous material of about 0.5 mm to about 1.5 mm was dried in an oven of about 126 °C for 30 minutes. This process resulted in a biocompatible implantable device comprising a porous material as disclosed in the present specification. See, *e.g.*, FIG. 2 and FIG. 4.

[0175] A sample from the implant was characterized by microCT analysis. This analysis revealed that the porous material was about 1.4 mm to about 1.6 mm in thickness with a porosity of about 80%, with open pores comprising at least 80% and close pores comprising at most 0.07%. The mean strut thickness was about 90 μm, with a mean pore size of about 400 μm. The porous material has a compressive modulus of about 20 kPa, elongation at break of about 350%, and a tensile strength of about 14 μPa. Scanning electron analysis of the porous material is shown in FIG. 5.

[0176] To increase the thickness of the porous material covering the base layer, multiple dippings were performed to produce a mandrel coated with multiple layers of an uncured silicone/porogen mixture. Dippings were repeated until the desired thickness is achieved. Examples 4-6 below describe specific examples of this multiple dipping technique.

Example 6

A method of making an implant comprising a porous material

[0177] This example illustrates how to make an implant comprising a porous material of about 1 mm to about 2.5 mm in thickness formed using the porogen compositions disclosed in the present specification.

[0178] A mandrel comprising a base layer of elastomer was prepared as described in Example 3.

[0179] To coat the base layer with a mixture comprising a substance and porogens, the cured base layer was dipped first in about 35% (w/w) silicon in xylene (PN-3206-1; NuSil Technology LLC, Carpinteria, CA) and then air dried for about 3 minutes to allow the xylene to evaporate. After xylene evaporation, the mandrel with the uncured silicone was dipped in a porogen composition comprising a sugar core of about 335 µm and a polyethylene glycol shell of about 53 µm until the maximum amount of porogens were absorbed into the uncured silicone. In other experiments, the porogen composition used were porogens comprising a sugar core of about 335 µm and a polyethylene glycol shell of about 60 µm, porogens comprising a sugar core of about 390 µm and a polyethylene glycol shell of about 83 µm, or porogens comprising a sugar core of about 460 µm and a polyethylene glycol shell of about 104 µm. The mandrel with the uncured silicon/porogen mixture coating was air dried for about 60 minutes to allow the xylene to evaporate. After xylene evaporation, the mandrel coated with the uncured silicone/porogen mixture was dipped first in about 35% (w/w) silicon in xylene, air dried to allow xylene evaporation (about 3 minutes), and then dipped in porogen composition until the maximum amount of porogens were absorbed into the uncured silicone. The mandrel with the second coating of uncured silicon/porogen mixture was air dried for about 60 minutes to allow the xylene to evaporate.

[0180] The mandrel comprising the two coats of uncured silicone/porogen mixture was treating as described in Example 3.

[0181] Removal of the porogen scaffold was as described in Example 5, and the resulting implant comprising a porous material of about 1 mm to about 2.5 mm was dried in an oven of about 126 °C for 30 minutes. This process resulted in a biocompatible implantable device comprising a porous material as disclosed in the present specification. See, *e.g.*, FIG. 2 and FIG. 4.

[0182] A sample from the implant was characterized by microCT analysis. This analysis revealed that the porous material was about 1.0 mm to about 3.0 mm in thickness with a porosity of about 85%, with open pores comprising at least 80% and close pores comprising at most 10%. The mean strut thickness was about 90 µm, with a mean pore size of about 400 µm. The porous material has a compressive modulus of about 20 kPa, elongation at break of about 300%, and a tensile strength of about 14 µPa. Scanning electron analysis of the porous material is shown in FIG. 6.

Example 7

A method of making an implant comprising a porous material

[0183] This example illustrates how to make an implant comprising a porous material of about 2.5 mm to about 4.5 mm in thickness formed using the porogen compositions disclosed in the present specification.

[0184] A mandrel comprising a base layer of elastomer was prepared as described in Example 3.

[0185] To coat the base layer with a mixture comprising a substance and porogens, the cured base layer was dipped first in about 35% (w/w) silicon in xylene (PN-3206-1; NuSil Technology LLC,

Carpinteria, CA) and then air dried for about 3 minutes to allow the xylene to evaporate. After xylene evaporation, the mandrel with the uncured silicone was dipped in a porogen composition comprising a sugar core of about 335 μm and a polyethylene glycol shell of about 53 μm until the maximum amount of porogens were absorbed into the uncured silicone. In other experiments, the porogen composition used were porogens comprising a sugar core of about 335 μm and a polyethylene glycol shell of about 60 μm, porogens comprising a sugar core of about 390 μm and a polyethylene glycol shell of about 83 μm, or porogens comprising a sugar core of about 460 μm and a polyethylene glycol shell of about 104 μm. The mandrel with the uncured silicon/PGLA coating was air dried for about 60 minutes to allow the xylene to evaporate. After xylene evaporation, the mandrel coated with the uncured silicone/porogen mixture was dipped first in about 35% (w/w) silicon in xylene, air dried to allow xylene evaporation (about 3 minutes), and then dipped in the porogen composition until the maximum amount of porogens were absorbed into the uncured silicone. The mandrel with the second coating of uncured silicon/porogen mixture was air dried for about 60 minutes to allow the xylene to evaporate. After xylene evaporation, the mandrel coated with the two layers of the uncured silicone/porogen mixture was dipped first in about 32% (w/w) silicon in xylene, air dried to allow xylene evaporation (about 3 minutes), and then dipped in the porogen composition until the maximum amount of porogens were absorbed into the uncured silicone. The mandrel with the third coating of uncured silicon/porogen mixture was air dried for about 60 minutes to allow the xylene to evaporate.

[0186] The mandrel comprising the three coats of uncured silicone/ porogen mixture was treating as described in Example 3.

[0187] Removal of the porogen scaffold was as described in Example 5, and the resulting implant comprising a porous material of about 2.5 mm to about 4.5 mm was air dried at an ambient temperature of about 18 °C to about 22 °C. This process resulted in a biocompatible implantable device comprising a porous material as disclosed in the present specification. See, *e.g.*, FIG. 2 and FIG. 4.

[0188] A sample from the implant was characterized by microCT analysis. This analysis revealed that the porous material was about 2.0 mm to about 3.0 mm in thickness with a porosity of about 80%, with open pores comprising at least 75% and close pores comprising at most 25%. The mean strut thickness was about 100 μm, with a mean pore size of about 90 μm. Scanning electron analysis of the porous material is shown in FIG. 7.

Example 8

A method of making an implant comprising a porous material

[0189] This example illustrates how to make an implant comprising a porous material of about 3.5 mm to about 5.5 mm in thickness formed using the porogen compositions disclosed in the present specification.

[0190] A mandrel comprising a base layer of elastomer was prepared as described in Example 3.

[0191] To coat the base layer with a mixture comprising a substance and porogens, the cured base layer was dipped first in about 35% (w/w) silicon in xylene (PN-3206-1; NuSil Technology LLC, Carpinteria, CA) and then air dried for about 3 minutes to allow the xylene to evaporate. After xylene evaporation, the mandrel with the uncured silicone was dipped in a porogen composition comprising a sugar core of about 335 µm and a polyethylene glycol shell of about 53 µm until the maximum amount of porogens were absorbed into the uncured silicone. In other experiments, the porogen composition used were porogens comprising a sugar core of about 335 µm and a polyethylene glycol shell of about 60 µm, porogens comprising a sugar core of about 390 µm and a polyethylene glycol shell of about 80 µm, or porogens comprising a sugar core of about 460 µm and a polyethylene glycol shell of about 104 µm. The mandrel with the uncured silicon/porogen mixture coating was air dried for about 60 minutes to allow the xylene to evaporate. After xylene evaporation, the mandrel coated with the uncured silicone/porogen mixture was dipped first in about 35% (w/w) silicon in xylene, air dried to allow xylene evaporation (about 3 minutes), and then dipped in the porogen composition until the maximum amount of porogens were absorbed into the uncured silicone. The mandrel with the second coating of uncured silicon/porogen mixture was air dried for about 60 minutes to allow the xylene to evaporate. After xylene evaporation, the mandrel coated with the two layers of the uncured silicone/porogen mixture was dipped first in about 32% (w/w) silicon in xylene, air dried to allow xylene evaporation (about 3 minutes), and then dipped in the porogen composition until the maximum amount of porogens were absorbed into the uncured silicone. The mandrel with the third coating of uncured silicon/porogen mixture was air dried for about 60 minutes to allow the xylene to evaporate. After xylene evaporation, the mandrel coated with the three layers of the uncured silicone/porogen mixture was dipped first in about 28% (w/w) silicon in xylene, air dried to allow xylene evaporation (about 3 minutes), and then dipped in the porogen composition until the maximum amount of porogens were absorbed into the uncured silicone. The mandrel with the fourth coating of uncured silicon/porogen mixture was air dried for about 60 minutes to allow the xylene to evaporate.

[0192] The mandrel comprising the four coats of uncured silicone/porogen mixture was treating as described in Example 3.

[0193] Removal of the porogen scaffold was as described in Example 5, and the resulting implant comprising a porous material of about 3.5 mm to about 5.5 mm was dried in an oven of about 126 °C for 30 minutes. This process resulted in a biocompatible implantable device comprising a porous material as disclosed in the present specification. See, *e.g.*, FIG. 2 and FIG. 4.

[0194] A sample from the implant will be characterized by microCT analysis. Scanning electron analysis of the porous material is shown in FIG. 8.

Example 9

A method of making a porogen composition

[0195] This example illustrates how to make porogen compositions disclosed in the present specification.

[0196] To make a porogen composition comprising a sugar core material and a polymer shell material, sugar particles suitable for a core material were purchased from Paulaur Corp, (Cranbury, N.J.). These sugar particles were sieved through an about 40 to about 60 mesh to separate particles of about 250 µm to about 450 µm in size. To coat sugar core particles with a polymer, poly(ethylene glycol) was coated onto the sugar core material to a thickness of about 53 µm by fluidization using a fluid bed dryer. The resulting porogen compositions yielded porogens comprising a sugar core material of about 335 µm in diameter and a poly(ethylene glycol) shell material of about 53 µm in thickness.

[0197] To make a porogen composition comprising a polymer core material and a wax shell material, a polycaprolactone (PCL) core material will be made using a solvent evaporation process. Briefly, about 500 mL of a 30% (w/v) solution of PCL in dichloromethane will be poured into 3 L of a 6% (w/v) solution of poly(vinyl alcohol), MW 23000, with constant stirring. The mixture will be continuously stirred for enough time to allow methylene chloride to evaporate. The resulting PCL particles of core material will be filtered to remove debris and then will be washed with deionized water to remove the poly(vinyl alcohol). This process will result in about 100 g of PCL particles of core material with a mean diameter of about 400 µm to about 500 µm. To coat polymer core particles with a wax, paraffin will be coated onto the PCL core material to a thickness of about 50 µm by fluidization using a fluid bed dryer. The resulting porogen compositions will yield porogens comprising a polymer core material of about 450 µm in diameter and a paraffin shell material of about 50 µm in thickness.

[0198] To make a porogen composition comprising a salt core material and a surfactant shell material, sodium chloride particles suitable for a core material will be purchased from a commercial supplier. These salt particles will be sieved through an about 40 to about 60 mesh to separate particles of about 250 µm to about 450 µm in size. To coat salt core particles with a surfactant, polysorbate 20 will be coated onto the salt core material to a thickness of about 15 µm by fluidization using a fluid bed dryer. The resulting porogen compositions will yield porogens comprising a salt core material of about 350 µm in diameter and a polysorbate 20 shell material of about 15 µm in thickness.

[0199] To make a porogen composition comprising a PGLA(50:50) core and a PCL shell material, PGLA (50:50) and polycaprolactone (PCL) were co-dissolved in methylene chloride, where at least 2 parts of PGLA (50:50) and at most at 1 part of PCL were dissolved in methylene chloride. Solvent evaporation was applied to form microparticles. A PGLA(50:50) core with PCL shell was formed by annealing the microparticles at 60 ^{0}C to allow phase separation between PGLA and PCL. About 500 mL of a 30% (w/v) solution of PGLA (50:50) and PCL in dichloromethane was poured into 3 L of a 6% (w/v) solution of poly(vinyl alcohol), MW 23000, with constant stirring until the methylene chloride evaporated.

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The resulting particles in polyvinyl alcohol dispersions were heated at 60 ^{0}C to allow phase separation between PGLA(50:50) and PCL. After cooling down, the microparticles were filtered to remove debris and then washed with deionized water to remove the poly(vinyl alcohol). This process resulted in about 100 g of a PGLA (50:50) core and PCL shell composition with a mean diameter of about 400 μm to about 500 μm.

Example 10

Capsule thickness and disorganization

[0200] In order to measure the thickness and disorganization of capsules formed, disks (1 cm in diameter) of various porous biomaterials were implanted subcutaneously in Sprague-Dawley rats using standard procedures. The biomaterials tested were taken from commercially available implants or experimentally produced as follows: Smooth 1, a biomaterial having a smooth surface (NATRELLE®, Allergan, Inc., Irvine, CA); Smooth 2, a biomaterial having a smooth surface (MEMORYGEL®, Mentor, Inc., Santa Barbara, CA); Textured 1, a biomaterial having a closed-cell textured surface produced from a lost-salt method (BIOCELL®, Allergan, Inc., Irvine, CA); Textured 2, a biomaterial having a closed-cell textured surface produced from an imprinting method (SILTEX®, Mentor, Inc., Santa Barbara, CA); Textured 3, a biomaterial having a closed-cell textured surface produced from either an imprinting or gas foam method (SILIMED®, Sientra, Inc., Santa Barbara, CA); Textured 4, a biomaterial having a closed-cell textured surface produced from an imprinting method (Perouse Plastie, Mentor, Inc., Santa Barbara, CA); Textured 5, a biomaterial having an open-cell polyurethane surface; Textured 6, a biomaterial having an open-cell textured surface produced according to the methods disclosed herein. Samples were harvested at 6 weeks, fixed in formalin, and processed to produce paraffin blocks. The paraffin blocks were sectioned using a microtome at 2 μm thickness and stained with hematoxylin and eosin (H&E).

[0201] Capsules were characterized by measuring the thickness and disorganization of the capsule formed over the porous biomaterials. Capsule thickness was measured by acquiring 2 representative 20x images of the H&E stained biomaterials and measuring the thickness of the capsule at 3 points in the image. Capsule disorganization was evaluated by acquiring 3 representative 20x images of the H&E stained biomaterials, and then drawing a reference vector tangent to the implant surface, as well as, drawing vectors along collagen fibers within the capsule. The angle of each vector relative to the reference vector was then measured, and the standard deviation of the angles was calculated, where greater standard deviations reflected a higher degree of disorganization. All image analysis calculations were performed on the Nikon Elements Advanced Research software.

[0202] All thickness and disorganization measurements were acquired blinded and each measurement was normalized to the data obtained from Textured 1 biomaterial. For the thickness data collected, a one-way ANOVA was run to determine significant effects ($p < 0.05$). If there were any statistically significant effects from the ANOVA analysis, the Tukey's post-hoc test was run for multiple comparisons at $\alpha = 0.05$. For the disorganization data collected, a Levene's Test for Equal Variance was used to determine whether there was a statistically significant difference in disorganization between experimental

groups ($p < 0.05$). Between individual groups, the criteria for non-significance were overlap of confidence intervals (95%), adjusted for the number of groups.

[0203] The capsule thicknesses and disorganization, normalized to the Texture 1 biomaterial within each respective study, are shown in FIG. 9. Smooth Texture 1 and 2 biomaterials, and Textures 1-4 biomaterials (having closed-cell texture) exhibited pronounced capsule formation, and the capsules formed were of equivalent thicknesses of about 100 μm to about 140 μm (FIG. 9A). Texture 5-6 biomaterials exhibited minimal capsule formation with capsules formed having a thickness of less than 10 μm (FIG. 9A). With respect to capsule organization, it was found that Texture 1 biomaterial resulted in a capsule that was more disorganized than Smooth 1 and 2 and Texture 2-4 biomaterials (FIG. 9B). Texture 5 and 6 biomaterials demonstrated extensive ingrowth (about 200 μm) that was interconnected and significantly more disorganized (≥ 50% of fibers were not parallel to implant surface) than Smooth 1 and 2 and Texture 1-4 biomaterials (FIG. 9B). These findings show that Smooth 1 and 2 biomaterials (smooth surface) and Textures 1-4 biomaterials (closed-cell textured surfaces) resulted in a capsule with predominantly organized collagen. Textures 5-6 biomaterials (open-cell textured surfaces), in contrast, induce significant ingrowth that can eliminate capsule and disorganize the tissue at the material-tissue interface.

Example 11

Capsule collagen

[0204] In order to measure the collagen content of capsules formed, disks (1 cm in diameter) of various porous biomaterials were implanted subcutaneously in Sprague-Dawley rats using standard procedures. The biomaterials tested were taken from commercially available implants or experimentally produced as follows: Smooth 1, a biomaterial having a smooth surface (NATRELLE®, Allergan, Inc., Irvine, CA); Smooth 2, a biomaterial having a smooth surface (MEMORYGEL®, Mentor, Inc., Santa Barbara, CA); Textured 1, a biomaterial having a closed-cell textured surface produced from a lost-salt method (BIOCELL®, Allergan, Inc., Irvine, CA); Textured 2, a biomaterial having a closed-cell textured surface produced from an imprinting method (SILTEX®, Mentor, Inc., Santa Barbara, CA); Textured 3, a biomaterial having a closed-cell textured surface produced from an imprinting method (Perouse Plastie, Mentor, Inc., Santa Barbara, CA); Textured 4, a biomaterial having a closed-cell textured surface produced from either an imprinting or gas foam method (SILIMED®, Sientra, Inc., Santa Barbara, CA); Textured 5, a biomaterial having an inverse foam polyurethane-polyethylene glycol surface; Textured 6, a biomaterial having an inverse foam polyurethane-polyethylene glycol surface; Textured 7, a biomaterial having an open-cell polyurethane surface; Textured 8, a biomaterial having a non-woven felt surface. Samples were harvested at 6 weeks, fixed in formalin, and processed to produce paraffin blocks. The paraffin blocks were sectioned using a microtome at 2 μm thickness and stained with aniline blue.

[0205] Capsules were characterized by measuring staining darkness of the capsule formed over the implanted porous biomaterials. The darkness of the capsule was measured from 5 representative 20x images, with overall intensity averaged over the capsules to reflect the depth of staining. To account for

variations in parameters, such as section thickness and precise staining times, all measurements were normalized to the intensity measured within the dermis of the same section, which was utilized as a standard due to the consistent staining that was observed in this region. A one-way ANOVA was run to determine significant effects ($p < 0.05$). If there were any statistically significant effects from the ANOVA analysis, the Tukey's post-hoc test was run for multiple comparisons at $\alpha = 0.05$.

[0206] Figure 10 shows the mean collagen density of capsules and ingrowth formed over smooth and textured biomaterials. It was found that the capsules formed over Smooth 1 and 2 biomaterials and Textured 1-4 biomaterials (closed-cell textured surfaces) showed a statistically significant increase in collagen density over the Texture 5 and 6 biomaterials (inverse foam textured surface), Textured 7 biomaterial (open-cell textured surface), and Textured 8 biomaterial (non-woven felt textured surface). As such, the prevention of capsule formation was shown to be linked to significant ingrowth into an open, interconnected texture, where the ingrowth has a low collagen density.

Example 12
Tissue adhesion

[0207] In order to evaluate the effect of texture on tissue adhesion to a porous biomaterials, strips of various biomaterial were implanted subcutaneously in a Sprague-Dawley rat using standard procedures. The biomaterials tested were taken from commercially available implants or experimentally produced as follows: Smooth 1, n = 38, a biomaterial having a smooth surface (NATRELLE®, Allergan, Inc., Irvine, CA); Textured 1, n = 64, a biomaterial having a closed-cell textured surface produced from a lost-salt method (BIOCELL®, Allergan, Inc., Irvine, CA); Textured 2, n = 6, a biomaterial having a closed-cell textured surface produced from an imprinting method (SILTEX®, Mentor, Inc., Santa Barbara, CA); Textured 3, n = 6, a biomaterial having an inverse foam polyurethane-polyethylene glycol surface; Textured 4, n = 45, a biomaterial having an inverse foam polyurethane-polyethylene glycol surface; Textured 5, n = 45, a biomaterial having an open-cell polyurethane surface; Textured 6, n = 6, a biomaterial having an open-cell polyurethane surface; Textured 7, n = 6,a biomaterial having an open-cell textured surface of 0.8 mm produced according to the methods disclosed herein; Textured 8, n = 6, a biomaterial having an open-cell textured surface of 1.5 mm produced according to the methods disclosed herein. Samples were harvested at 4 weeks, and tissue was pulled from the test strip on a mechanical tester with a pullout speed of 2 mm/second. Adhesion strength was measured as the peak force required to separate the implant from the surrounding tissue. A one-way ANOVA was run to determine significant effects ($p < 0.05$). If there were any statistically significant effects from the ANOVA analysis, the Tukey's post-hoc test was run for multiple comparisons at $\alpha = 0.05$.

[0208] Smooth 1 biomaterial showed little adhesion, as there were no significant protrusions above a micro-scale and had minimal drag on the surrounding tissue (FIG. 11). Textured 1 and 2 biomaterials (closed-cell textured surfaces) exhibited limited amount of tissue interaction and showed greater adhesion than Smooth 1 (FIG. 11). Textured 3 and 4 biomaterials (inverse Foam textured surface) and Textures 5-8 biomaterials (open-cell textured surfaces) showed the highest degree of tissue adhesion (FIG. 11). As

such, Textured 5-8 biomaterials promoted significant tissue infiltration/ingrowth because of the highly porous and interconnected textures.

Example 13
Capsule stiffness

[0209] In order to evaluate stiffness of capsules/ingrowth formed over a porous biomaterials, 7 mL mini-expanders comprising silicone biomaterial of various textures were implanted subcutaneously in a Sprague-Dawley rat using standard procedures. The biomaterials tested were taken from commercially available implants or experimentally produced as follows: Smooth 1, a biomaterial having a smooth surface (NATRELLE®, Allergan, Inc., Irvine, CA); Textured 1, a biomaterial having a closed-cell textured surface produced from a lost-salt method (BIOCELL®, Allergan, Inc., Irvine, CA); Textured 2, a biomaterial having an open-cell textured surface of 0.8 mm produced according to the methods disclosed herein; Textured 3, a biomaterial having an open-cell textured surface of 1.5 mm produced according to the methods disclosed herein. At time 0 (immediately post-implantation) and at 6 weeks, saline was incrementally added to each expander, and the resulting pressure exerted on and by the expander at each step was measured with a digital manometer. Stiffness was calculated by fitting a trend-line to the linear region of the pressure-volume curve and measuring the slope of the line. Increases in the stiffness of the capsule/ingrowth were reflected by increases in the slope. To account for expander-to-expander variability, each stiffness measurement was normalized to the stiffness of the expander itself. A one-way ANOVA was run to determine significant effects ($p < 0.05$). If there were any statistically significant effects from the ANOVA analysis, the Tukey's post-hoc test was run for multiple comparisons at $\alpha = 0.05$.

[0210] Capsules formed over Smooth 1 biomaterial expander showed the greatest stiffness after 6 weeks (FIG. 12). Textured 1 biomaterial expander (closed-cell textured surface) showed lower stiffness than Smooth 1 biomaterial expander but greater stiffness than the Textured 2 and 3 biomaterial expanders (open-cell textured surface) (FIG. 12). This data demonstrates that closed-cell biomaterials result in capsules that are stiffer than those that result from open-cell biomaterials that support ingrowth and prevent capsule formation.

Example 14
Bleeding and capsule response

[0211] In order to identify critical morphological and physical characteristics of the porous biomaterials disclosed herein, disks (1 cm in diameter) of various biomaterials were implanted subcutaneously in a Sprague-Dawley rat using standard procedures and the response to such implantation in terms of capsule formation and bleeding were determined. The morphological and physical characteristics tested for each biomaterial are given in Tables 1 and 2.

Table 1. Morphological Characteristics of Biomaterials					
Biomaterial	**Mean**	**Mean porosity**	**Mean pore**	**Mean**	**Mean**

	thickness (mm)	(%)	size (µm)	interconnections /pore	interconnection size (µm)
Polyurethane 1	2.40 ±0.10	98.0 ±0.4	522 ±87	14.2 ±3.2	166 ±48
Polyurethane 2	2.90 ± 0.01	98.0 ±0.0	488 ±119	14.2 ±1.4	230 ±69
Mesh 1	0.89 ±0.06	72.2 ±1.5	522 ±137	N/A	N/A
Mesh 2	1.38 ±0.10	70.9 ±2.9	560 ±134	N/A	N/A
Fused Porogen 1	0.56 ±0.38	55.6 ±0.5	530 ±150	7.0 ±3.1	325 ±242
Fused Porogen 2	0.79 ±0.06	72.6 ±5.4	458 ±48	7.8 ±1.5	151 ±59
Fused Porogen 3	1.10 ±0.00	77.6 ±1.0	596 ±150	4.6 ±1.9	106 ±42
Fused Porogen 4	1.14 ±0.09	66.4 ±3.2	424 ±68	8.0 ±1.1	111 ±49
Fused Porogen 5	1.32 ±0.02	77.9 ±0.9	408 ±64	7.6 ±2.0	118 ±44
Fused Porogen 6	1.60 ±0.10	77.8 ±1.2	N/D	N/D	N/D
Fused Porogen 7	1.60 ±0.10	81.2 ±1.3	608 ±268	4.9 ±1.9	130 ±85
Fused Porogen 8	1.60 ±0.00	85.3 ±1.4	421 ±48	8.2 ±2.1	128 ±38
Fused Porogen 9	1.61 ±0.03	80.3 ±1.0	456 ±81	7.4 ±1.6	154 ±50
Fused Porogen 10	1.80 ±1.20	80.6 ±0.4	634 ±124	7.5 ±2.6	95 ±33
Fused Porogen 11	1.93 ±0.78	82.8 ±0.5	456 ±65	7.1 ±2.2	133 ±46
Fused Porogen 12	1.95 ±0.19	76.5 ±2.0	431 ±57	7.0 ±1.2	114 ±58
Fused Porogen 13	2.34 ±0.06	74.0 ±0.5	478 ±112	7.1 ±2.0	141 ±47
Fused Porogen 14	2.36 ±0.12	81.1 ±0.5	399 ±93	7.4 ±0.8	126 ±64

Table 2. Physical Characteristics of Biomaterials

Biomaterial	Compressive Response (kPa)			Elongation at Break (%)
	at 5% strain	at 10% strain	at 20% strain	
Polyurethane 1	1.74 ±0.40	2.60 ±0.53	3.38 ±0.52	N/D
Polyurethane 2	1.41 ±0.13	2.63 ±0.03	2.89 ±0.20	454 ±7
Mesh 1	0.07 ±0.01	0.20 ±0.02	0.74 ±0.08	336 ±39
Mesh 2	0.09 ±0.04	0.22 ±0.09	0.74 ±0.39	439 ±56
Fused Porogen 1	0.05 ±0.00	0.18 ±0.01	1.01 ±0.14	N/D
Fused Porogen 2	0.05 ±0.03	0.23 ±0.10	1.59 ±0.46	N/D
Fused Porogen 3	0.04 ±0.01	0.14 ±0.06	0.86 ±0.36	N/D
Fused Porogen 4	0.55 ±0.21	1.55 ±0.50	5.21 ±1.18	287 ±78
Fused Porogen 5	0.13 ±0.02	0.59 ±0.14	3.26 ±0.64	N/D
Fused Porogen 6	0.10 ±0.02	0.38 ±0.11	2.24 ±0.92	N/D
Fused Porogen 7	0.094 ±0.00	0.35 ±0.06	1.86 ±0.36	N/D
Fused Porogen 8	0.04 ±0.01	0.15 ±0.04	0.61 ±0.13	222 ±33
Fused Porogen 9	0.11 ±0.03	0.46 ±0.12	2.00 ±0.26	N/D
Fused Porogen 10	0.14 ±0.01	0.43 ±0.03	1.48 ±0.01	N/D
Fused Porogen 11	0.17 ±0.00	0.64 ±0.01	2.15 ±0.03	N/D
Fused Porogen 12	0.42 ±0.14	1.07 ±0.29	3.17 ±0.61	384 ±20
Fused Porogen 13	0.19 ±0.04	0.84 ±0.16	3.48 ±0.39	N/D
Fused Porogen 14	0.06 ±0.02	0.16 ±0.06	0.61 ±0.10	335 ±11

[0212] Implanted porous biomaterials were harvested, fixed in formalin, and processed to produce paraffin blocks. The paraffin blocks were sectioned using a microtome at 2 µm thickness and stained with hematoxylin and eosin (H&E). Depending on the morphological characteristic being assessed, capsule response was measured by acquiring at least 3 representative 1x, 4x, 20x, or 50x images of sectioned biomaterial, digitally capturing the images, and measuring the characteristic at 3 or more point in each

captured image. All image analysis calculations were performed on the Nikon Elements Advanced Research software. Bleeding response and physical characteristics were measured using routine methods. See, *e.g.*, Winnie, Softness Measurements for Open-Cell Foam Materials and Human Soft Tissue, Measurement Science and Technology (2006).

[0213] The summary of the results obtained from this analysis are given in Table 3. The results indicate that porous biomaterials having a wide range in porosity are well tolerated in that in only a very narrow range of porosity (74-86%) was bleeding observed in some of the biomaterials tested. In terms of capsule formation, increased porosity resulted in decreased capsule formation. Interconnection diameter between pores also influenced the bleeding response in that increased diameter resulted in a decreased bleeding response (Table 3). More strikingly, increasing the number of interconnections per pore decreased both the bleeding response and capsule formation seen in the animals in response to the implanted porous biomaterials (Table 3). Lastly, a fine balance in the stiffness of a porous biomaterial, as measured by compressive forces, was needed to provide the optimal in vivo responses. This is because increased stiffness of a biomaterial resulted in decreased bleeding, whereas decreased stiffness was needed in order to decease capsule formation (Table 3).

Table 3. Bleeding and Capsule Response of Biomaterials

Characteristic	Bleeding Response		Capsule Response	
	No Bleeding	Bleeding	No Capsule	Capsule
Mean thickness (mm)	0.6-2.9	1.6-2.3	0.8-2.9	0.6-2.9
Mean porosity (%)	56-98	74-86	72-98	56-81
Mean pore size (μm)	408-624	456-608	456-641	408-634
Mean interconnections/pore	7-14	4.9-9.5	7.1-14	4.6-9.5
Mean interconnection size (μm)	118-325	130-153	456-641	408-634
Compressive at 5% strain (kPa)	0.05-2.57	0.10-0.20	0.05-1.70	0.00-2.57
Compressive at 10% strain (kPa)	0.18-8.00	0.10-4.20	0.22-4.17	0.10-8.00
Compressive at 20% strain (kPa)	1.00-16.0	1.90-3.50	1.10-7.60	0.90-16.0

[0214] Analyzing all the data obtained from these experiments revealed optimal morphological and physical characteristics for a porous material produced from the porogen method disclosed herein, was as follows: having a porosity of about 80% to about 88%, having an interconnection size of about 110 μm to about 140 μm, having about 7 to about 11 interconnections per pore, having a compressive force of about 0.50 kPa to about 0.70 kPa at 5% strain, having a compressive force of about 1.0 kPa to about 2.0 kPa at 10% strain, and having a compressive force of about 3.5 kPa to about 5.5 kPa at 20% strain. In an aspect of this embodiment, optimal morphological and physical characteristics for a porous material produced from the porogen method disclosed herein, was as follows: having a porosity of about 83% to about 85%, having an interconnection size of about 120 μm to about 130 μm, having about 8 to about 10 interconnections per pore, having a compressive force of about 0.55 kPa to about 0.65 kPa at 5% strain, having a compressive force of about 1.3 kPa to about 1.7 kPa at 10% strain, and having a compressive force of about 4.0 kPa to about 5.0 kPa at 20% strain.

[0215] In closing, it is to be understood that although aspects of the present specification are highlighted by referring to specific embodiments, one skilled in the art will readily appreciate that these disclosed embodiments are only illustrative of the principles of the subject matter disclosed herein. Therefore, it should be understood that the disclosed subject matter is in no way limited to a particular methodology, protocol, and/or reagent, etc., described herein. As such, various modifications or changes to or alternative configurations of the disclosed subject matter can be made in accordance with the teachings herein without departing from the spirit of the present specification. Lastly, the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to limit the scope of the present invention, which is defined solely by the claims. Accordingly, the present invention is not limited to that precisely as shown and described.

[0216] Certain embodiments of the present invention are described herein, including the best mode known to the inventors for carrying out the invention. Of course, variations on these described embodiments will become apparent to those of ordinary skill in the art upon reading the foregoing description. The inventor expects skilled artisans to employ such variations as appropriate, and the inventors intend for the present invention to be practiced otherwise than specifically described herein. Accordingly, this invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described embodiments in all possible variations thereof is encompassed by the invention unless otherwise indicated herein or otherwise clearly contradicted by context.

[0217] Groupings of alternative embodiments, elements, or steps of the present invention are not to be construed as limitations. Each group member may be referred to and claimed individually or in any combination with other group members disclosed herein. It is anticipated that one or more members of a group may be included in, or deleted from, a group for reasons of convenience and/or patentability. When any such inclusion or deletion occurs, the specification is deemed to contain the group as modified thus fulfilling the written description of all Markush groups used in the appended claims.

[0218] Unless otherwise indicated, all numbers expressing a characteristic, item, quantity, parameter, property, term, and so forth used in the present specification and claims are to be understood as being modified in all instances by the term “about.” As used herein, the term “about” means that the characteristic, item, quantity, parameter, property, or term so qualified encompasses a range of plus or minus ten percent above and below the value of the stated characteristic, item, quantity, parameter, property, or term. Accordingly, unless indicated to the contrary, the numerical parameters set forth in the specification and attached claims are approximations that may vary. At the very least, and not as an attempt to limit the application of the doctrine of equivalents to the scope of the claims, each numerical indication should at least be construed in light of the number of reported significant digits and by applying ordinary rounding techniques. Notwithstanding that the numerical ranges and values setting forth the broad scope of the invention are approximations, the numerical ranges and values set forth in the specific examples are reported as precisely as possible. Any numerical range or value, however, inherently contains certain errors necessarily resulting from the standard deviation found in their respective testing

measurements. Recitation of numerical ranges of values herein is merely intended to serve as a shorthand method of referring individually to each separate numerical value falling within the range. Unless otherwise indicated herein, each individual value of a numerical range is incorporated into the present specification as if it were individually recited herein.

[0219] The terms "a," "an," "the" and similar referents used in the context of describing the present invention (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (*e.g.*, "such as") provided herein is intended merely to better illuminate the present invention and does not pose a limitation on the scope of the invention otherwise claimed. No language in the present specification should be construed as indicating any non-claimed element essential to the practice of the invention.

[0220] Specific embodiments disclosed herein may be further limited in the claims using consisting of or consisting essentially of language. When used in the claims, whether as filed or added per amendment, the transition term "consisting of" excludes any element, step, or ingredient not specified in the claims. The transition term "consisting essentially of" limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristic(s). Embodiments of the present invention so claimed are inherently or expressly described and enabled herein.

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CLAIMS

1. A porogen composition useful to form a scaffold for making a porous material, the composition comprising:

a) a shell material; and

b) a core material;

wherein the shell material has a melting temperature that is lower than a melting temperature of the core material.

2. The porogen composition of claim 1, wherein the shell material is a natural or synthetic material.

3. The porogen composition of claim 1, wherein the shell material is an inorganic or organic material.

4. The porogen composition of claim 2, wherein the shell material is a salt or its derivatives, a ceramic or its derivatives, a sugar or its derivatives, a polysaccharide or its derivatives, a wax or its derivatives, a metal or its derivatives, a surfactant or its derivatives, a water soluble solid or its derivatives, a polymer or its derivatives, composites thereof, or combinations thereof.

5. The porogen composition of claim 1, wherein the core material is a natural or synthetic material.

6. The porogen composition of claim 1, wherein the core material is an inorganic or organic material.

7. The porogen composition of claim 5, wherein the core material is a salt or its derivatives, a ceramic or its derivatives, a sugar or its derivatives, a polysaccharide or its derivatives, a wax or its derivatives, a metal or its derivatives, a water soluble solid or its derivatives, a polymer or its derivatives, composites thereof, or combinations thereof.

8. The porogen composition of claim 1, wherein the core material is a sugar and the shell material is a polymer.

9. The porogen composition of claim 1,wherein the shell material is fusible and the core material is non-fusible.

10. The porogen composition of claim 9, wherein the shell material is fusible by a physical state change from solid phase to liquid or rubbery phase.

11. The porogen composition of claim 10, wherein the physical state change is a result of physicochemical treatment comprising heat treatment, or contact of the composition with an organic solvent.

12. The porogen composition of claim 9, wherein the shell material is a natural or synthetic material.

13. The porogen composition of claim 9, wherein the shell material is an inorganic or organic material.

14. The porogen composition of claim 12, wherein the shell material is a salt or its derivatives, a ceramic or its derivatives, a sugar or its derivatives, a polysaccharide or its derivatives, a wax or its derivatives, a metal or its derivatives, a surfactant or its derivatives, a water soluble solid or its derivatives, a polymer or its derivatives, composites thereof, or combinations thereof.

15. The porogen composition of claim 9, wherein the core material is a natural or synthetic material.

16. The porogen composition of claim 9, wherein the core material is an inorganic or organic material.

17. The porogen composition of claim 15, wherein the core material is a salt or its derivatives, a ceramic or its derivatives, a sugar or its derivatives, a polysaccharide or its derivatives, a wax or its derivatives, a metal or its derivatives, a water soluble solid or its derivatives, a polymer or its derivatives, composites thereof, or combinations thereof.

18. The porogen composition of claim 9, wherein the core material is a sugar and the shell material is a polymer.

19. A method of making a porogen composition useful to form a scaffold for making a porous material, the method comprising the steps of:

a) forming a particle out of a core material; and

b) coating the particle with a shell material;

wherein the porogen composition comprises the shell material and the core material, wherein the shell material has a melting temperature that is lower than a melting temperature of the core material.

20. The method of claim 19, wherein the shell material is a salt or its derivatives, a ceramic or its derivatives, a sugar or its derivatives, a polysaccharide or its derivatives, a wax or its derivatives, a metal or its derivatives, a surfactant or its derivatives, a water soluble solid or its derivatives, a polymer or its derivatives, composites thereof, or combinations thereof.

21. The method of claim 19, wherein the core material is a salt or its derivatives, a ceramic or its derivatives, a sugar or its derivatives, a polysaccharide or its derivatives, a wax or its derivatives, a metal or its derivatives, a water soluble solid or its derivatives, a polymer or its derivatives, composites thereof, or combinations thereof.

22. The method of claim 19, wherein the shell material is a salt, a ceramic, a sugar, a polysaccharide, a wax, a metal, a surfactant, a water soluble solid, a polymer, composites thereof, or combinations thereof.

23. The method of claim 22, wherein the core material is a salt, a ceramic, a sugar, a polysaccharide, a wax, a metal, a water soluble solid, a polymer, composites thereof, or combinations thereof.

24. The method of claim 19, wherein the shell material is a polymer.

25. The method of claim 24, wherein the core material is a sugar.

26. A method for making a porous material, the method comprising the steps of:

a) coating porogens with a matrix material to form a matrix material-coated porogen mixture, the porogens comprising a shell material and a core material, wherein the shell material has a melting temperature that is lower than a melting temperature of the core material;

b) treating the matrix material-coated porogen mixture to form a porogen scaffold comprising fused porogens and stabilized matrix material; and

c) removing the porogen scaffold from the stabilized matrix material, wherein porogen scaffold removal results in the porous material, the porous material comprising a matrix defining an array of interconnected pores.

27. The method of claim 26, wherein the shell material is a salt or its derivatives, a ceramic or its derivatives, a sugar or its derivatives, a polysaccharide or its derivatives, a wax or its derivatives, a metal or its derivatives, a surfactant or its derivatives, a water soluble solid or its derivatives, a polymer or its derivatives, composites thereof, or combinations thereof.

28. The method of claim 26, wherein the core material is a salt or its derivatives, a ceramic or its derivatives, a sugar or its derivatives, a polysaccharide or its derivatives, a wax or its derivatives, a metal or its derivatives, a water soluble solid or its derivatives, a polymer or its derivatives, composites thereof, or combinations thereof.

29. The method of claim 26, wherein the shell material is a salt, a ceramic, a sugar, a polysaccharide, a wax, a metal, a surfactant, a water soluble solid, a polymer, composites thereof, or combinations thereof.

30. The method of claim 29, wherein the core material is a salt, a ceramic, a sugar, a polysaccharide, a wax, a metal, a water soluble solid, a polymer, composites thereof, or combinations thereof.

31. The method of claim 26, wherein the shell material is a polymer.

32. The method of claim 31, wherein the core material is a sugar.

33. A method for making a biocompatible implantable device comprising the steps of:

a) coating a mandrel with an elastomer base;

b) curing the elastomer base to form a base layer;

c) coating the cured base layer with an elastomer base;

d) coating the elastomer base with porogens to form an elastomer coated porogen mixture, the porogens comprise a shell material and a core material, wherein the shell material has a melting temperature that is lower than a melting temperature of the core material;

e) treating the elastomer coated porogen mixture to form a porogen scaffold comprising fused porogens and cure the elastomer base, wherein the porogen scaffold comprises a three-dimensional structure where substantially all the fused porogens are each connected to at least four other fused porogens, and wherein the diameter of substantially all the connections between each fused porogen in between about 15% to about 80% of the mean porogen diameter; and

f) removing the porogen scaffold, wherein porogen scaffold removal results in a porous material, the porous material comprising a non-degradable, biocompatible, elastomer matrix defining an array of interconnected pores.

34. The method of claim 33, wherein steps (b) and (c) are repeated at least once.

35. The method of claim 33, wherein steps (b) and (c) are repeated at least twice.

36. The method of claim 33, wherein the shell material is a salt or its derivatives, a ceramic or its derivatives, a sugar or its derivatives, a polysaccharide or its derivatives, a wax or its derivatives, a metal or its derivatives, a surfactant or its derivatives, a water soluble solid or its derivatives, a polymer or its derivatives, composites thereof, or combinations thereof.

37. The method of claim 36, wherein the core material is a salt or its derivative, a ceramic or its derivatives, a sugar or its derivatives, a polysaccharide or its derivatives, a wax or its derivatives, a metal or its derivatives, a water soluble solid or its derivatives, a polymer or its derivatives, composites thereof, or combinations thereof.

38. The method of claim 33, wherein the shell material is a salt, a ceramic, a sugar, a polysaccharide, a wax, a metal, a surfactant, a water soluble solid, a polymer, composites thereof, or combinations thereof.

39. The method of claim 38, wherein the core material is a salt, a ceramic, a sugar, a polysaccharide, a wax, a metal, a water soluble solid, a polymer, composites thereof, or combinations thereof.

40. The method of claim 33, wherein the shell material is a polymer.

41. The method of claim 40, wherein the core material is a sugar.

42. A method for making a biocompatible implantable device comprising a porous elastomeric surface, the method comprising the steps of:
    a) coating a mandrel with an elastomer base;
    b) curing the elastomer base to form a base layer;
    c) coating the cured base layer with an elastomer base;
    d) coating the elastomer base with porogens to form an elastomer coated porogen mixture, the porogens comprise a shell material and a core material, wherein the shell material has a melting temperature that is lower than a melting temperature of the core material;
    e) treating the elastomer coated porogen mixture to form a porogen scaffold comprising fused porogens and cure the elastomer base, wherein the porogen scaffold comprises a three-dimensional structure where substantially all the fused porogens are each connected to at least four other fused porogens, and wherein the diameter of substantially all the connections between each fused porogen is between about 15% to about 80% of the mean porogen diameter; and

f) removing the porogen scaffold, wherein porogen scaffold removal results in a porous material, the porous material comprising a non-degradable, biocompatible, elastomer matrix defining an array of interconnected pores.

43. The method of claim 42, wherein steps (b) and (c) are repeated at least once.

44. The method of claim 42, wherein steps (b) and (c) are repeated at least twice.

45. The method of claim 42, wherein the shell material is a salt or its derivatives, a ceramic or its derivatives, a sugar or its derivatives, a polysaccharide or its derivatives, a wax or its derivatives, a metal or its derivatives, a surfactant or its derivatives, a water soluble solid or its derivatives, a polymer or its derivatives, composites thereof, or combinations thereof.

46. The method of claim 45, wherein the core material is a salt or its derivative, a ceramic or its derivatives, a sugar or its derivatives, a polysaccharide or its derivatives, a wax or its derivatives, a metal or its derivatives, a water soluble solid or its derivatives, a polymer or its derivatives, composites thereof, or combinations thereof.

47. The method of claim 42, wherein the shell material is a salt, a ceramic, a sugar, a polysaccharide, a wax, a metal, a surfactant, a water soluble solid, a polymer, composites thereof, or combinations thereof.

48. The method of claim 47, wherein the core material is a salt, a ceramic, a sugar, a polysaccharide, a wax, a metal, a water soluble solid, a polymer, composites thereof, or combinations thereof.

49. The method of claim 42, wherein the shell material is a polymer.

50. The method of claim 49, wherein the core material is a sugar.

51. The porogen composition of claim 1, wherein the porogen composition comprises about 35% to about 50% sucrose, about 10% to about 15% starch, and about 40% to 50% polyethylene glycol, by weight.

52. The porogen composition of claim 1, wherein the porogen composition comprises about 45% sucrose, about 10% starch, and about 45% polyethylene glycol, by weight.

53. The porogen composition of claim 1, wherein the porogen composition comprises about 40% sucrose, about 15% starch, and about 45% polyethylene glycol, by weight.

54. The porogen composition of claim 1, wherein the porogen composition comprises a mean porogen diameter of about 300 μm to about 650 μm.

55. The porogen composition of claim 54, wherein the porogen composition comprises a mean porogen diameter of about 550 μm.

56. The porogen composition of claim 9, wherein the shell material comprises polyethylene glycol.

57. The porogen composition of claim 9, wherein the porogen composition comprises about 35% to about 50% sucrose, about 10% to about 15% starch, and about 40% to 50% polyethylene glycol, by weight.

58. The porogen composition of claim 57, wherein the porogen composition comprises about 45% sucrose, about 10% starch, and about 45% polyethylene glycol, by weight.

59. The porogen composition of claim 57, wherein the porogen composition comprises about 40% sucrose, about 15% starch, and about 45% polyethylene glycol, by weight.

60. The porogen composition of claim 9, wherein the porogen composition comprises a mean porogen diameter of about 300 μm to about 650 μm.

61. The porogen composition of claim 60, wherein the porogen composition comprises a mean porogen diameter of about 550 μm.

62. A method for forming a breast implant, the method comprising the steps of:

(a) coating a base material with an uncured elastomer base to form an elastomer coated base shell, wherein the uncured elastomer base comprises a silicon-based elastomer and a solvent;

(b) coating the elastomer coated base shell with porogens to form an elastomer coated porogen mixture, wherein each of the porogens comprises a shell material and a core material, wherein the core material comprises at least two compounds, wherein the shell material has a melting temperature that is lower than a melting temperature of the core material;

(c) repeating step (a);

(d) repeating step (b);

(e) treating the elastomer coated porogen mixture such that the porogens are fused to form a porogen scaffold and the uncured elastomer base is cured; and

(f) removing the porogen scaffold, wherein the removing the porogen scaffold results in the base material with porous material.

63. The method of claim 62, wherein the core material comprises sucrose and starch, and the shell material comprises polyethylene glycol.

64. The method of claim 63, wherein the porogen composition comprises about 35% to about 50% sucrose, about 10% to about 15% starch, and about 40% to 50% polyethylene glycol, by weight.

65. The method of claim 64, wherein the porogen composition comprises about 45% sucrose, about 10% starch, and about 45% polyethylene glycol, by weight.

66. The method of claim 64, wherein the porogen composition comprises about 40% sucrose, about 15% starch, and about 45% polyethylene glycol, by weight.

67. The method of claim 62, wherein the porogen composition comprises a mean porogen diameter of about 300 μm to about 650 μm.

68. The method of claim 62, wherein steps (a)-(d) are conducted at about 20°C to about 30°C, and step (e) is conducted in the range of about 100°C to about 150°C.

69. The method of claim 62, wherein steps (a)-(d) are conducted at about 20°C to about 25°C, and step (e) is conducted in the range of about 110°C to about 135°C.

70. The method of claim 62, wherein step (e) is conducted at about 126°C for about 85 minutes.

71. The method of claim 62, further comprises devolitalizing the solvent following step (a), step (b), step (c), step (d), or any combination thereof.

72. The method of claim 62, wherein a devolitalization step follows step (a) for about 15 minutes to about 25 minutes.

73. The method of claim 62, wherein a devolitalization step follows step (b) or step (d) for about 3 minutes to about 6 minutes.

74. The method of claim 62, wherein a devolitalization step follows step (c) for about 20 minutes to about 50 minutes.

75. A method for forming a breast implant with porous material, the method comprising the steps of:

(a) coating a breast implant shell with an uncured elastomer base to form an elastomer coated breast implant shell wherein the uncured elastomer base comprises a silicon-based elastomer and a solvent;

(b) devolitalizing the solvent;

(c) coating the elastomer coated breast implant shell with porogens to form an elastomer coated porogen mixture, wherein each of the porogens comprises a shell material comprising sucrose and starch, and a core material comprising polyethylene glycol, wherein the core material comprises at least two compounds, wherein the shell material has a melting temperature that is lower than a melting temperature of the core material;

(d) devolitalizing the solvent;

(e) repeating step (a);

(f) devolitalizing the solvent;

(g) repeating step (c);

(h) devolitalizing the solvent;

(i) repeating step (a);

(j) devolitalizing the solvent;

(k) repeating step (c);

(l) devolitalizing the solvent;

(m) treating the elastomer coated porogen mixture such that the porogens are fused to form a porogen scaffold and the uncured elastomer base is cured; and

(n) removing the porogen scaffold, wherein the removing the porogen scaffold results in the breast implant with porous material.

FIG. 1

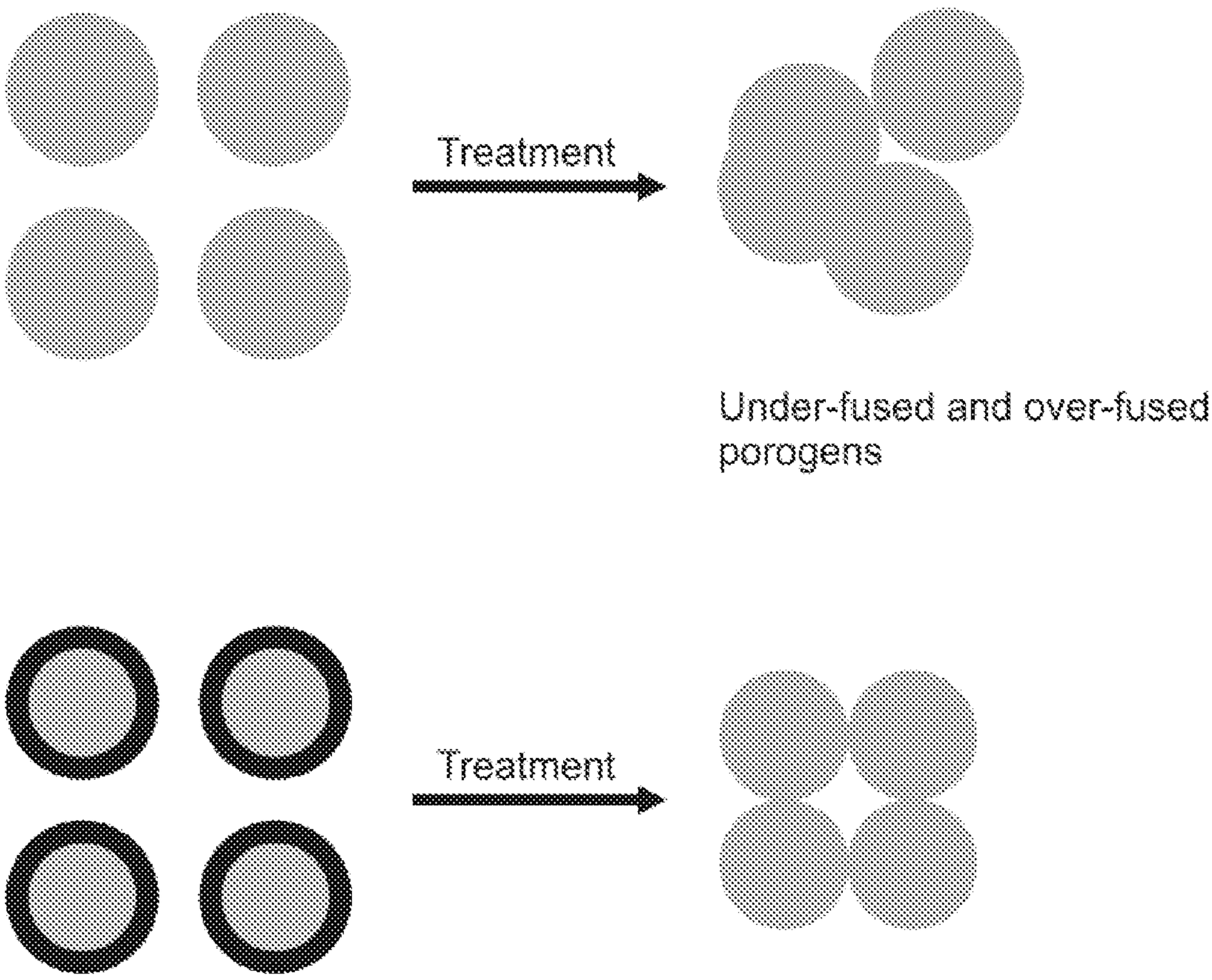

Treatment
Under-fused and over-fused porogens
Treatment
Uniformly-fused porogens

FIG. 2A

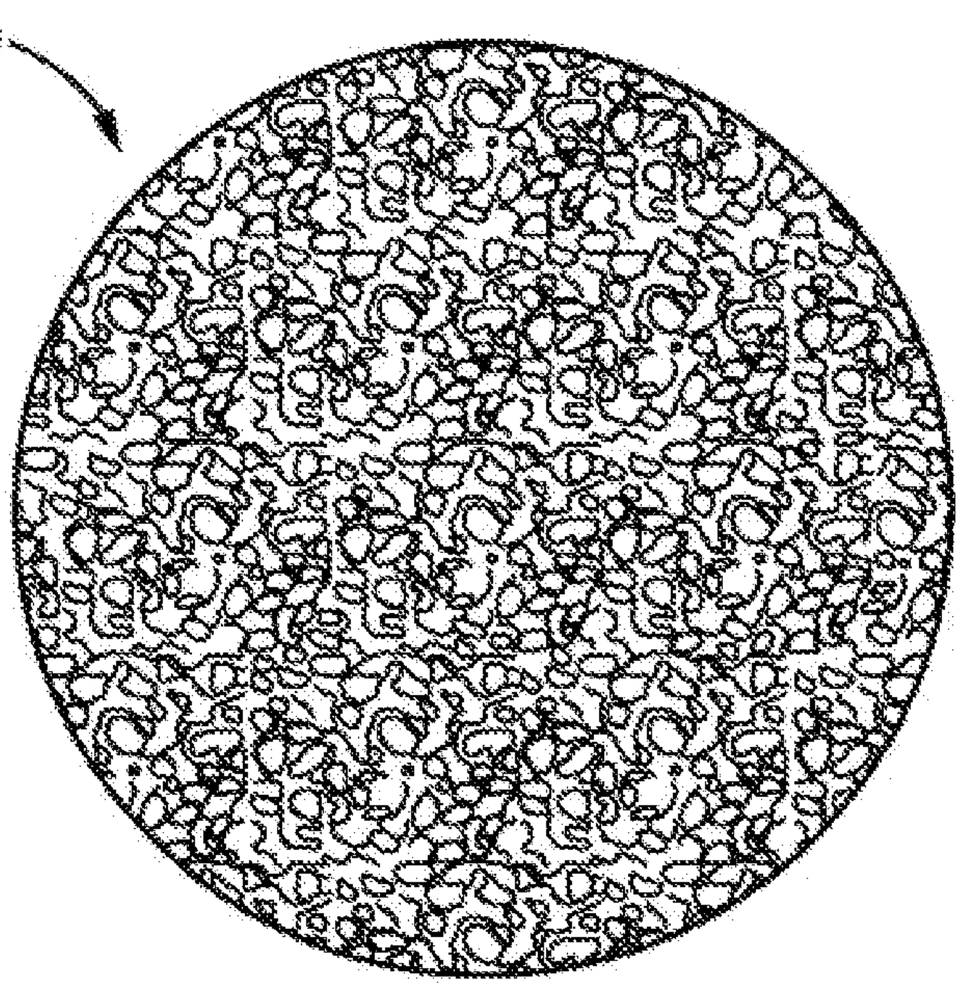


FIG. 2B

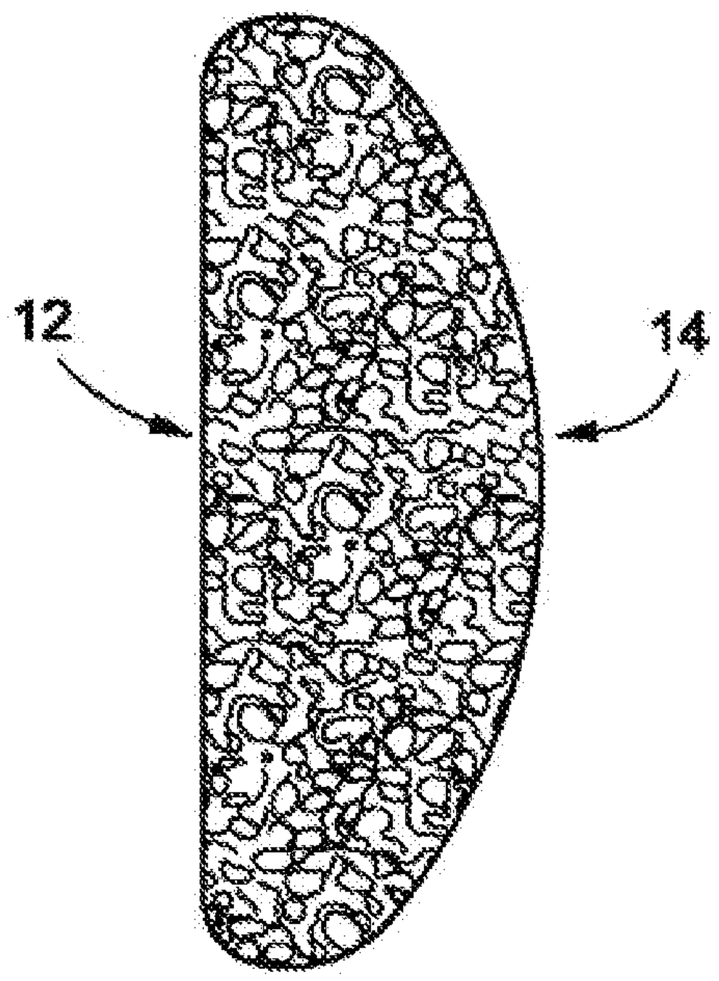


FIG. 2C

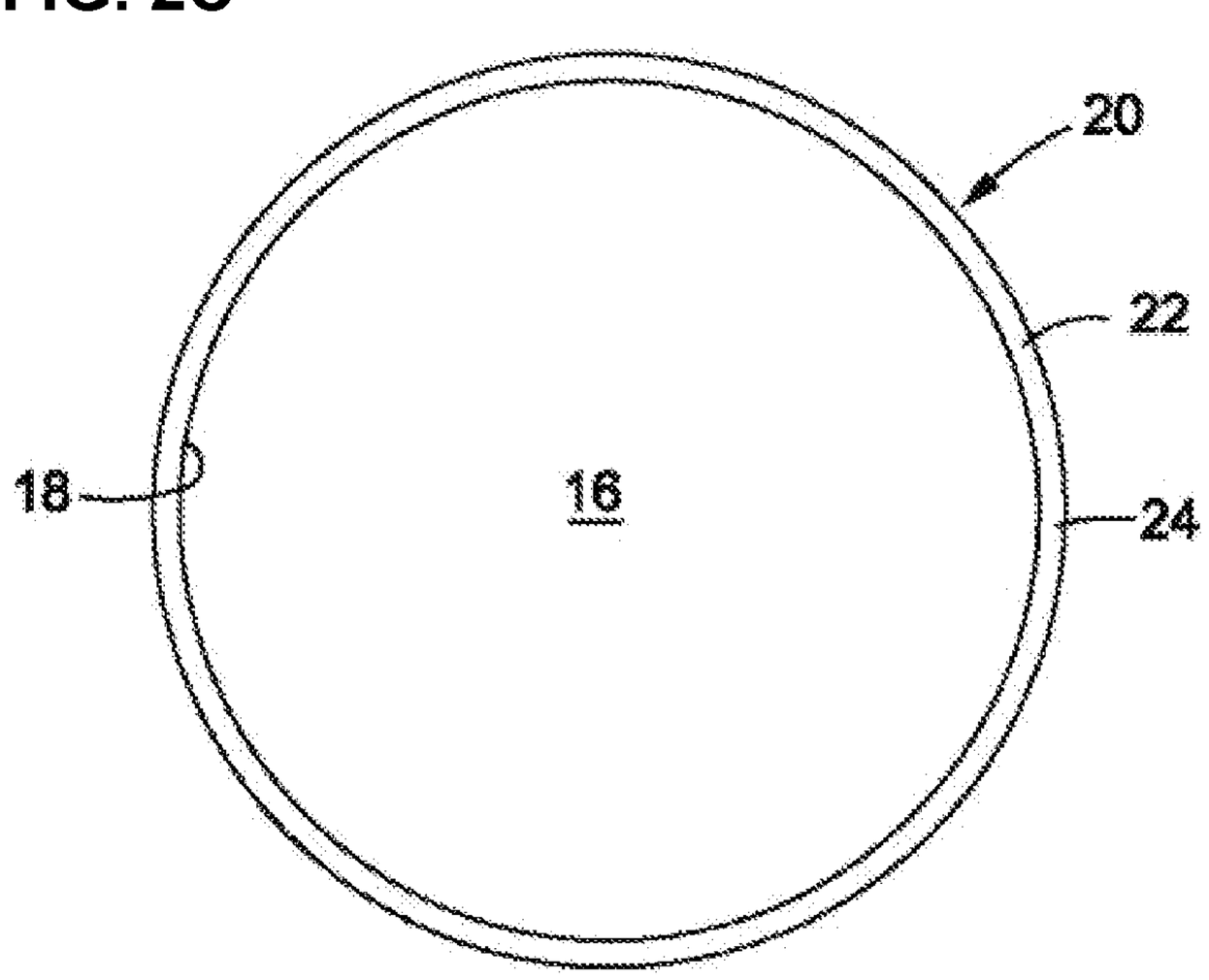


FIG. 2D

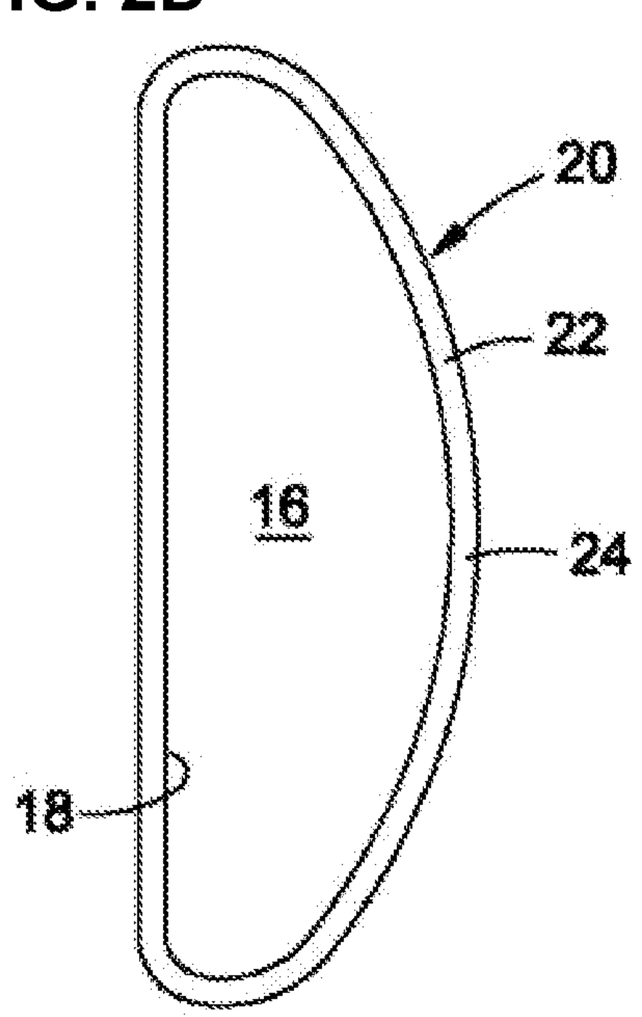


FIG. 3A

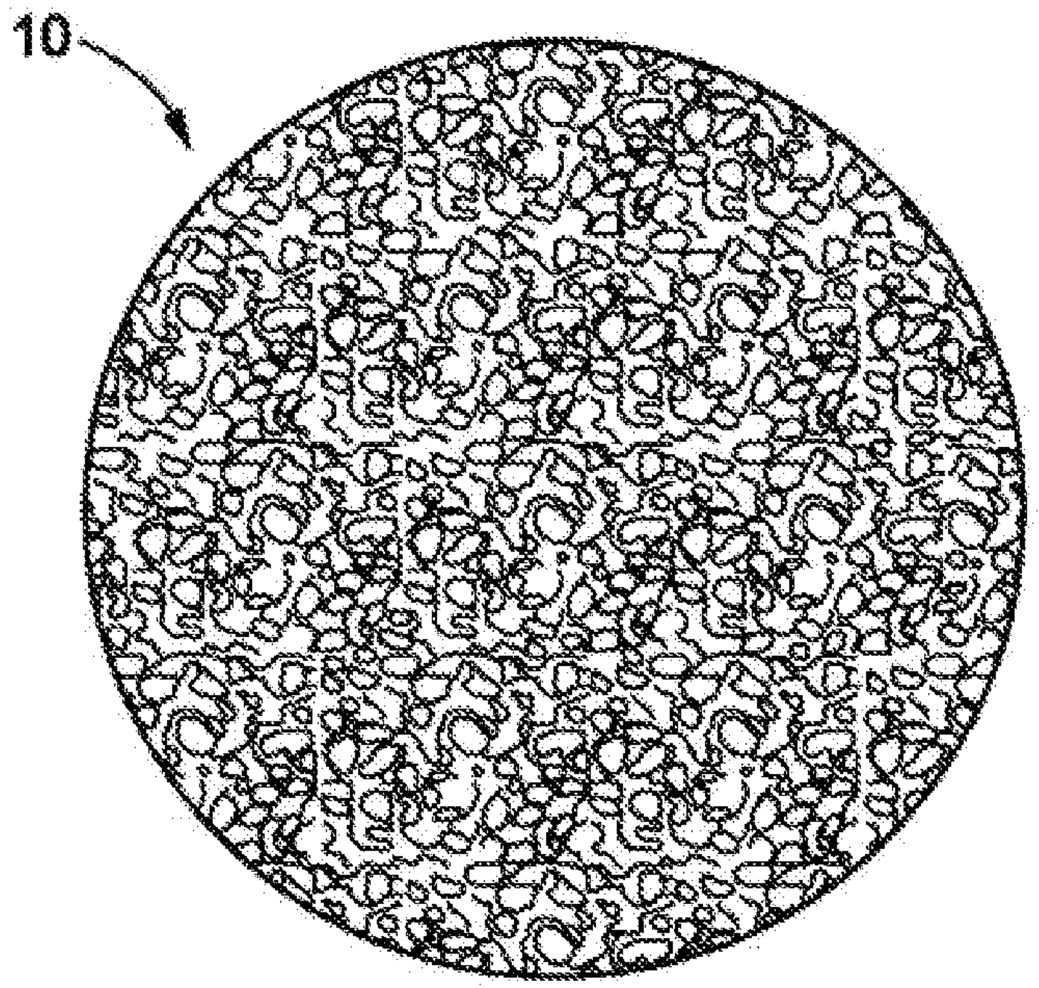


FIG. 3B

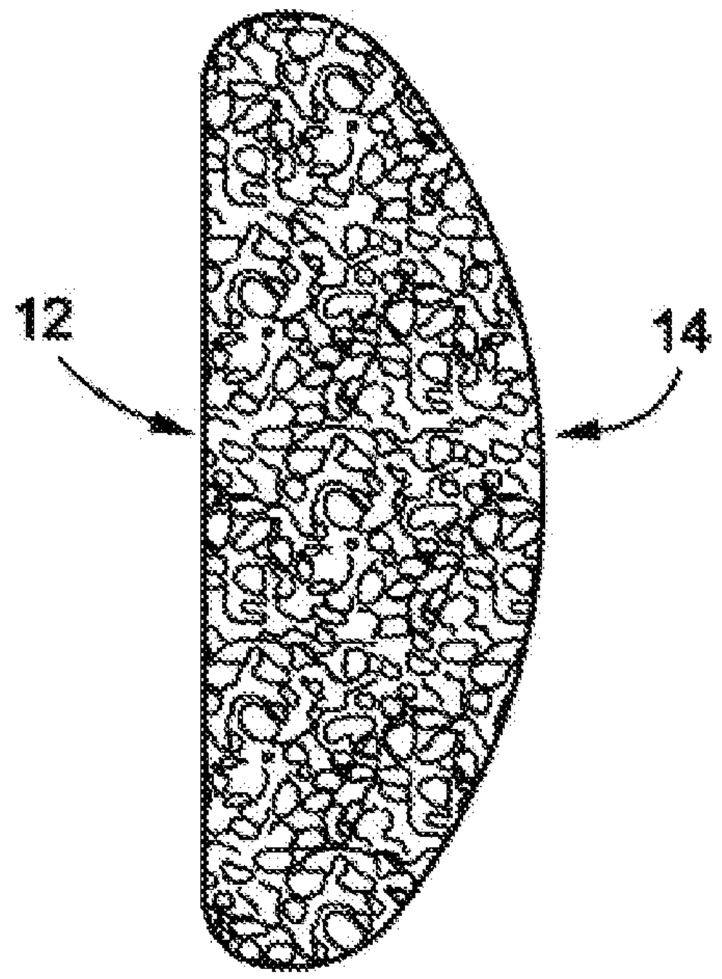


FIG. 3C

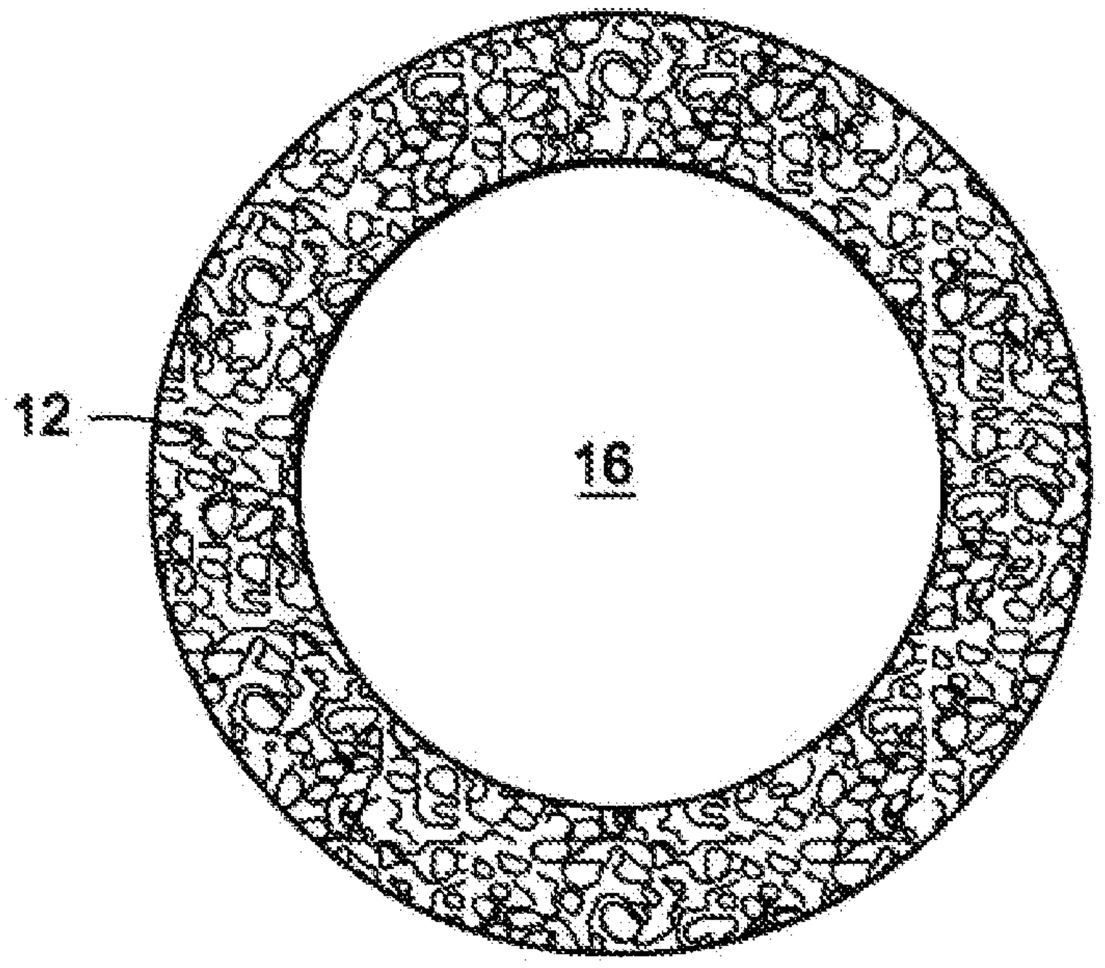


FIG. 3D

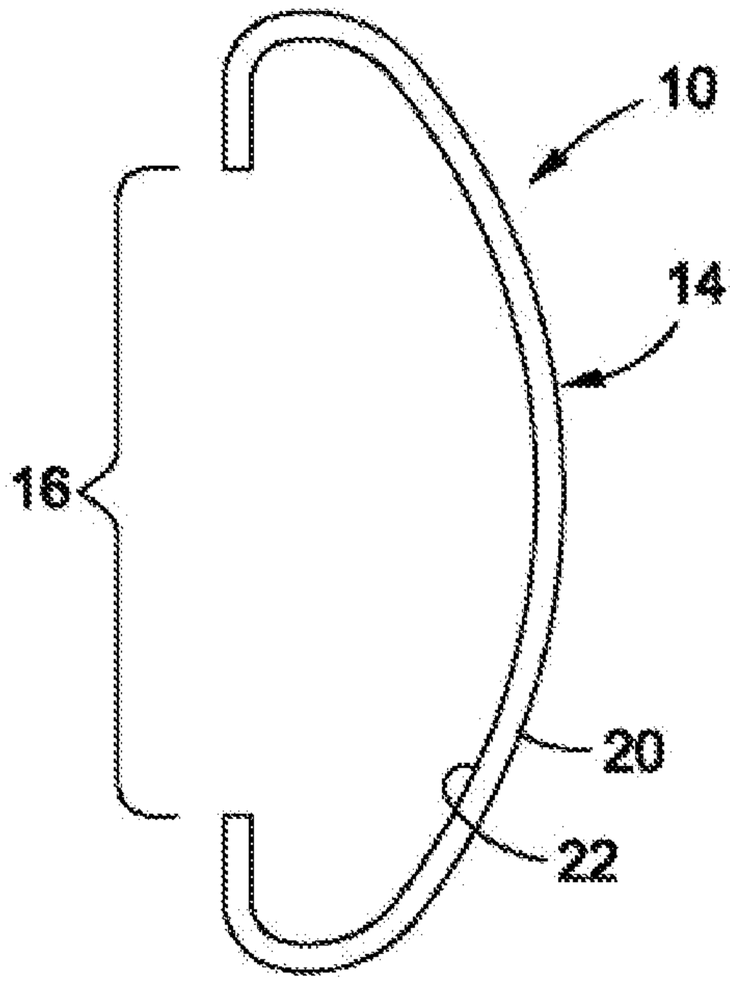


FIG. 4A

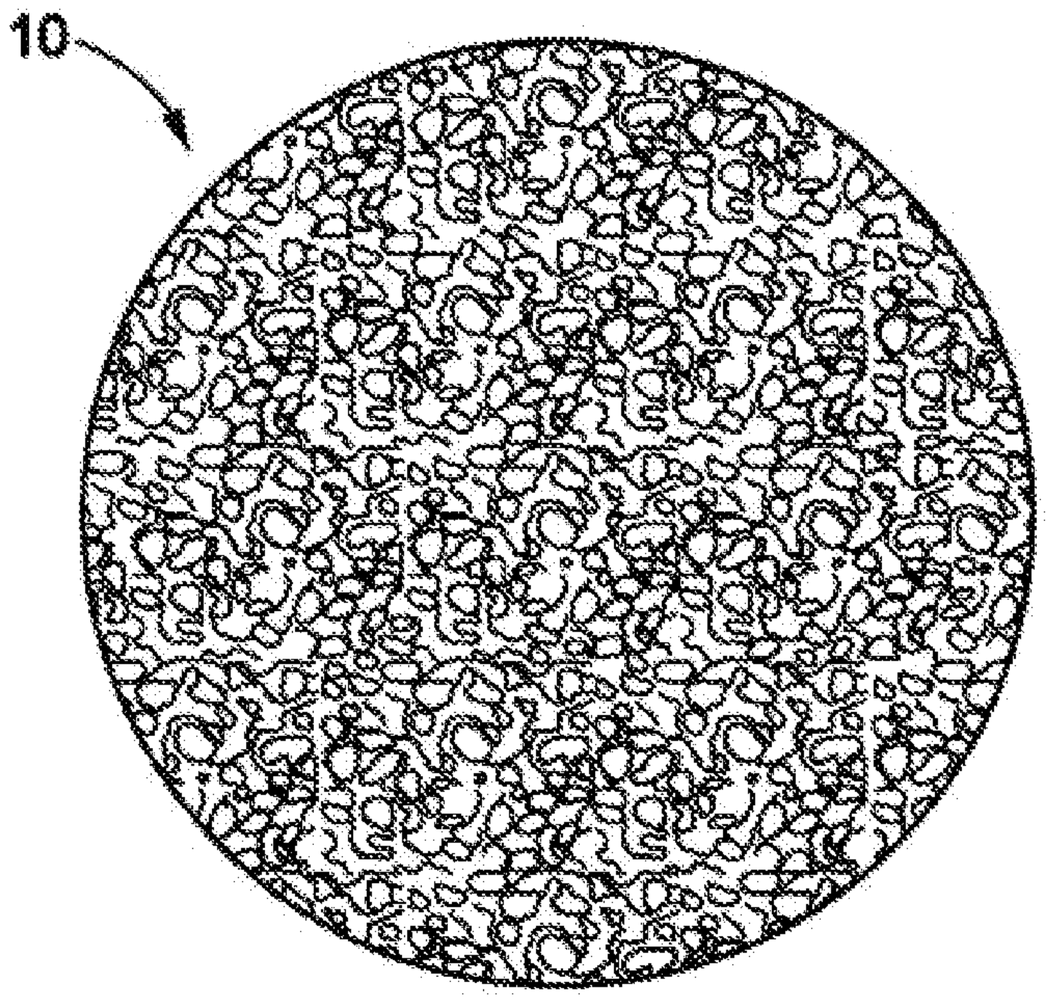


FIG. 4B

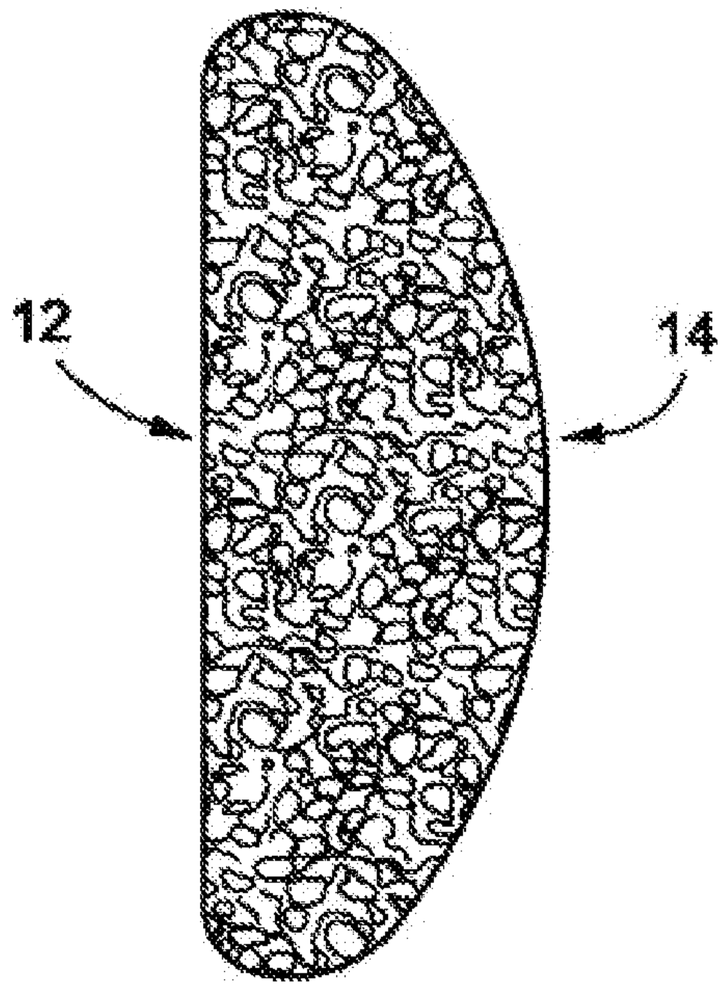


FIG. 4C

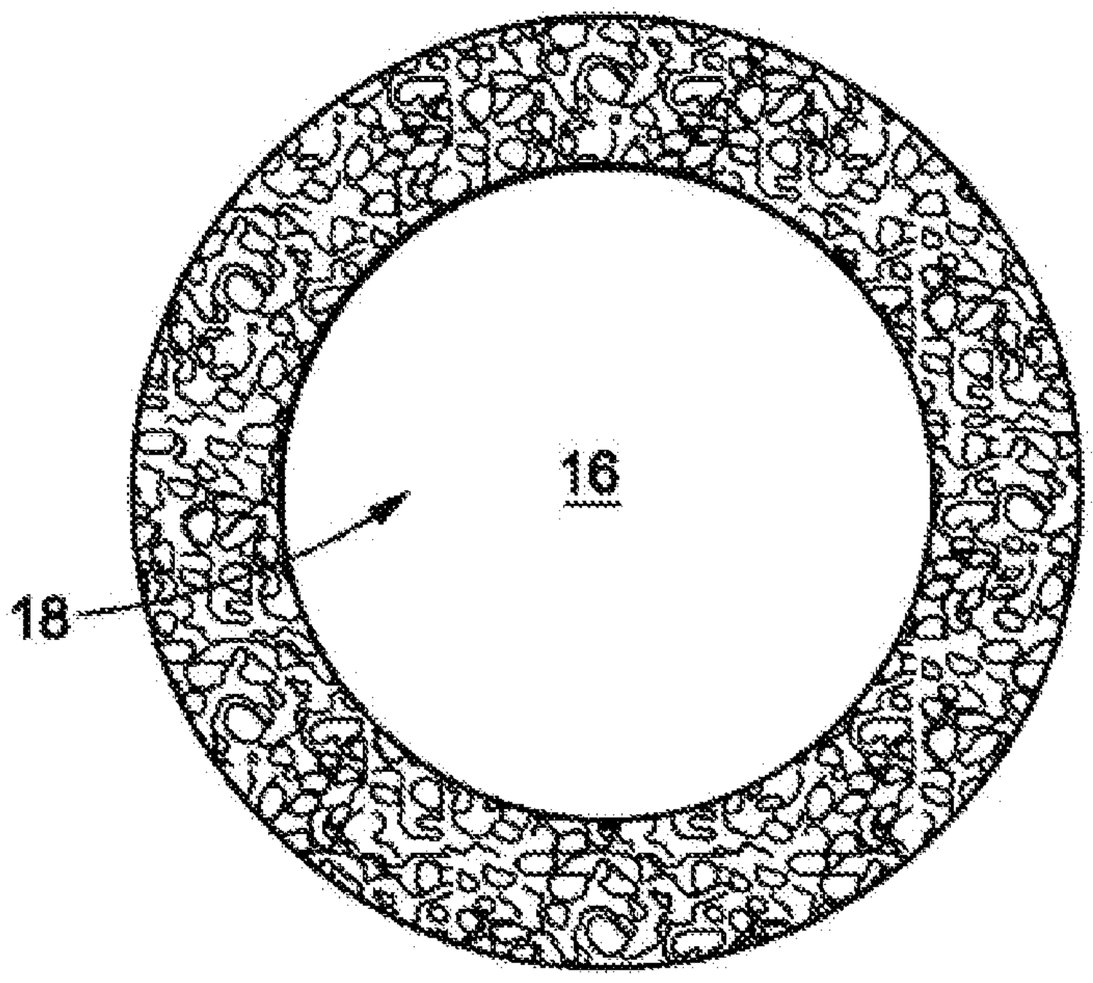


FIG. 4D

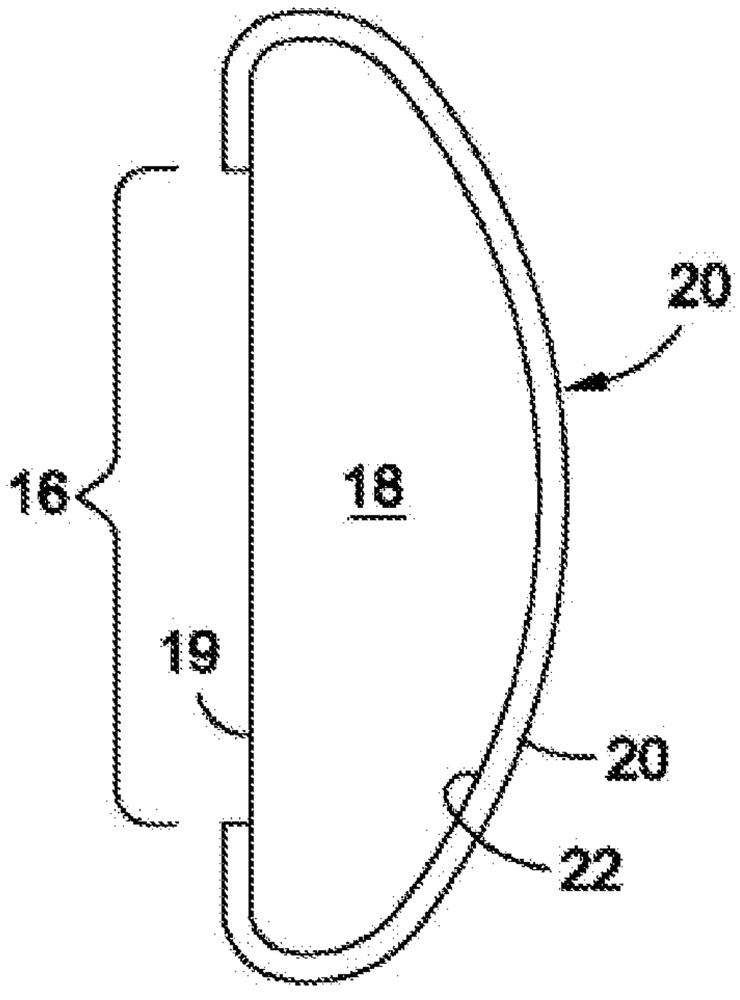


FIG. 5A

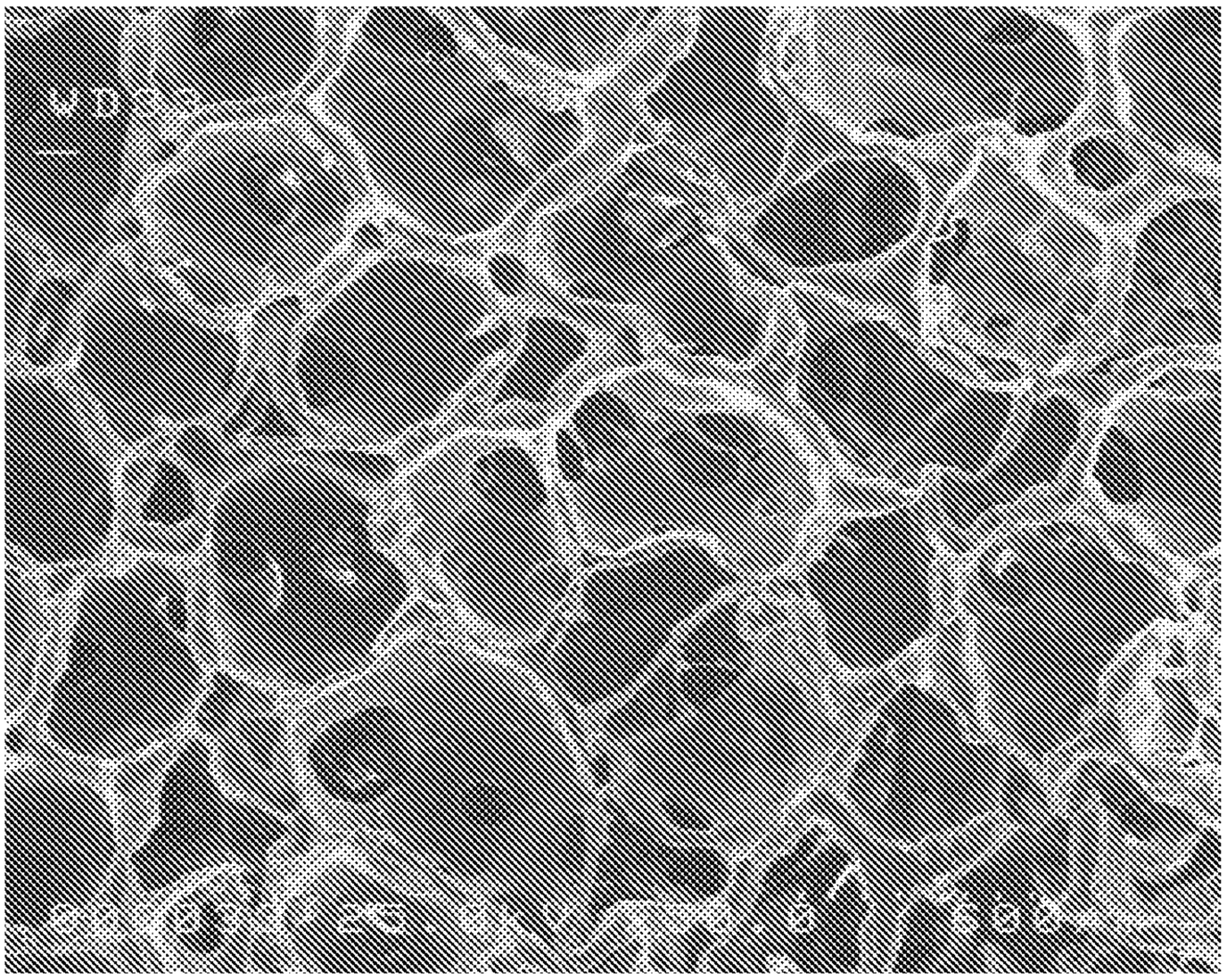


FIG. 5B

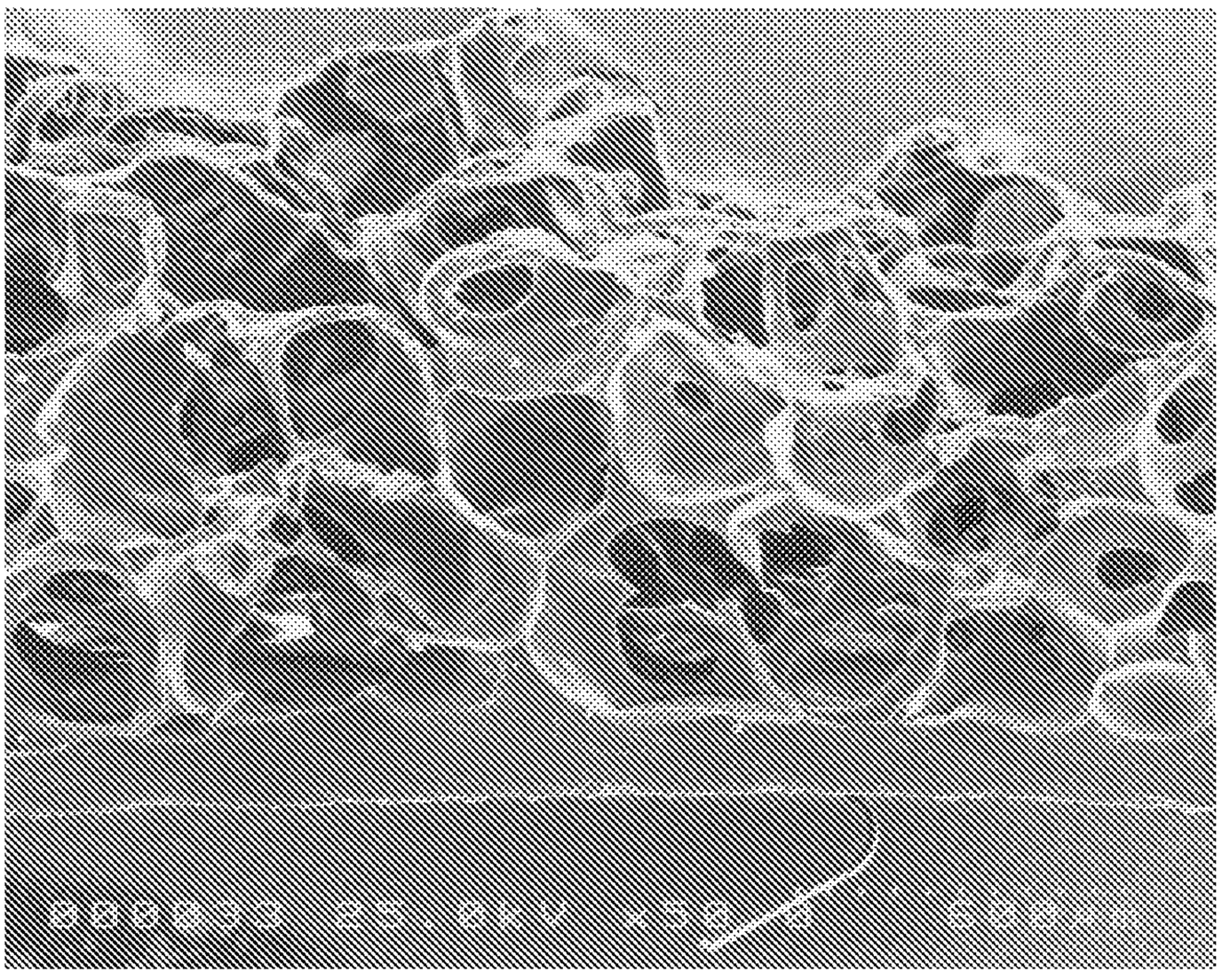


FIG. 6A

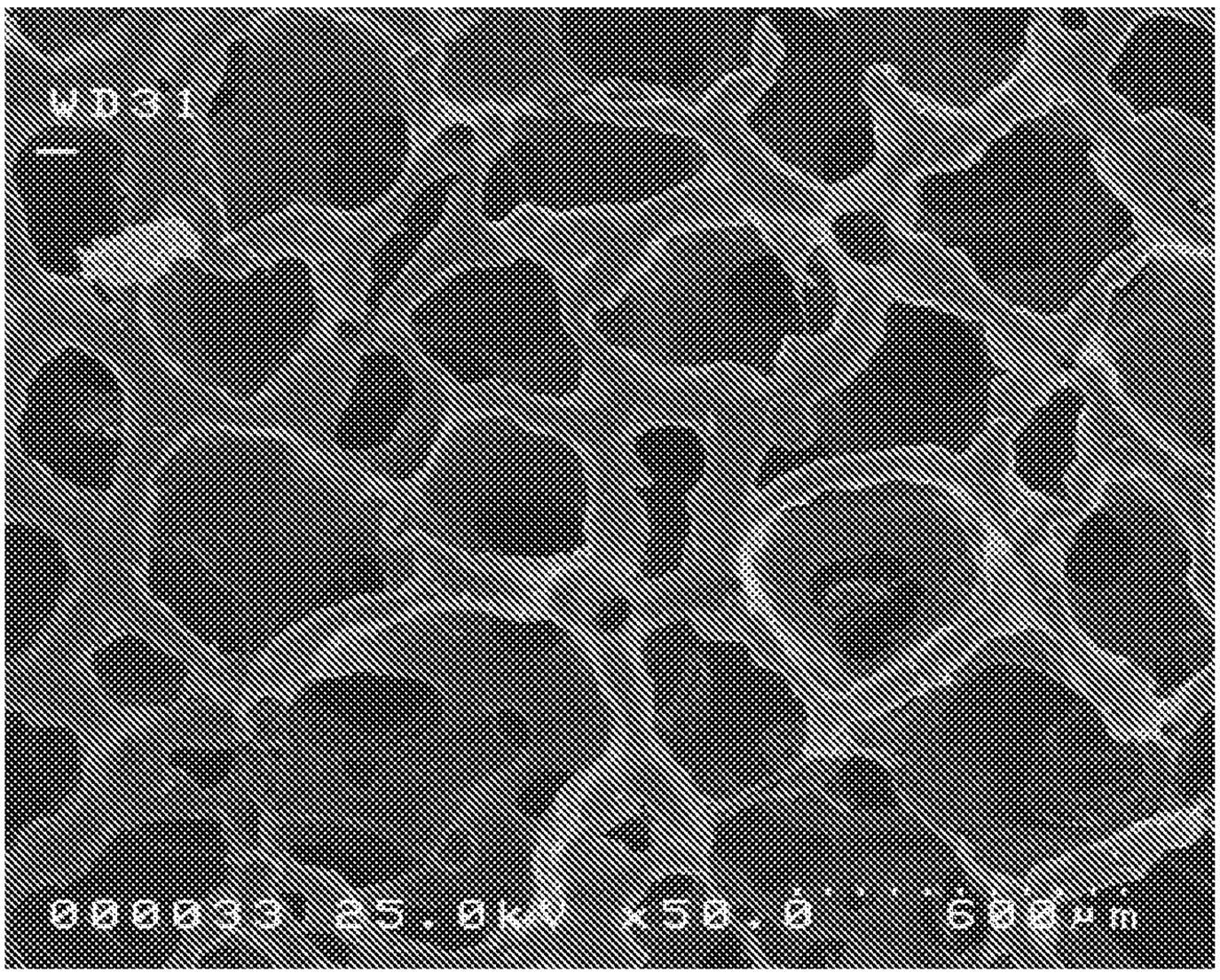

WD31
0000033 25.0kV x50.0 600µm

FIG. 6B

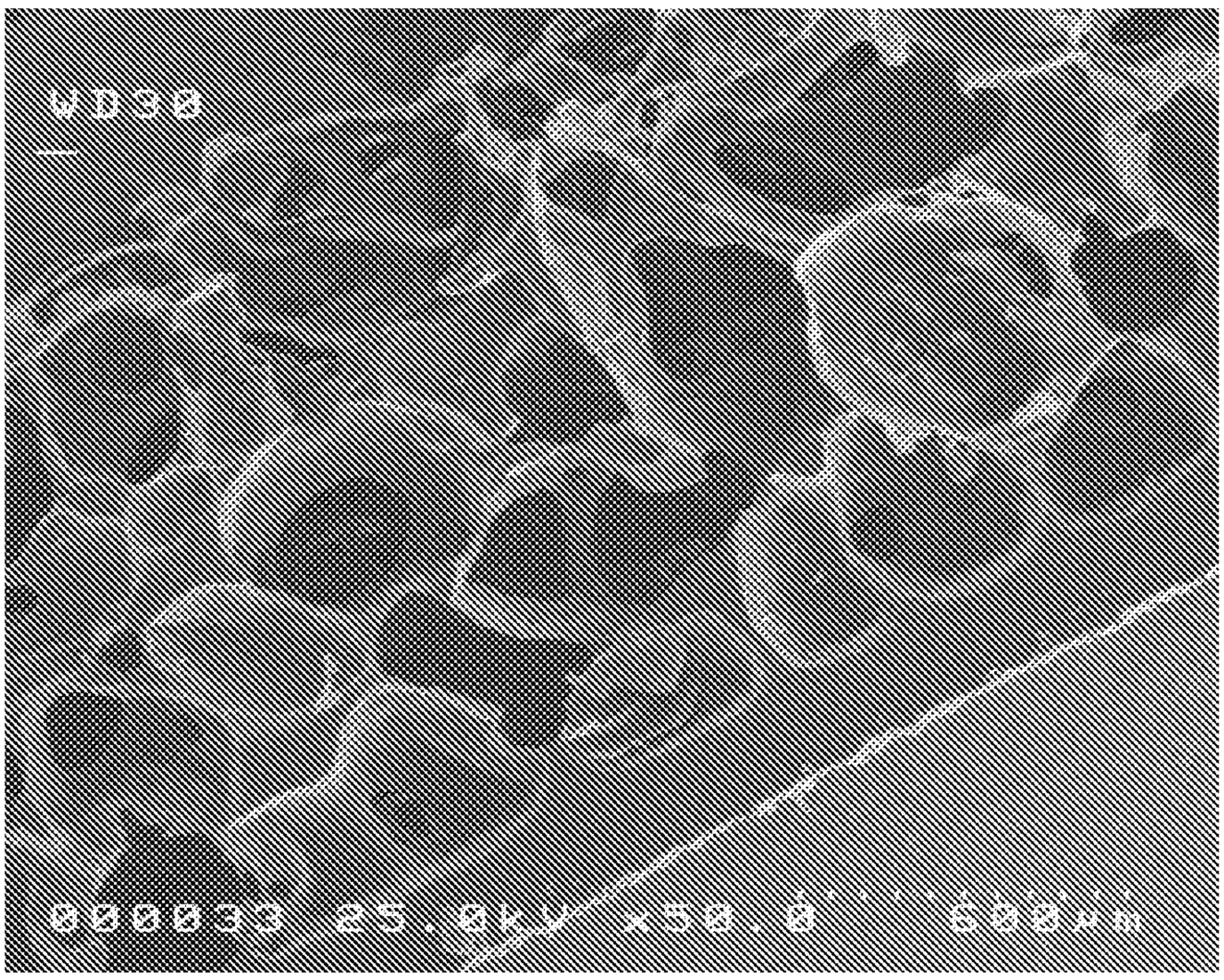

WD30
0000033 25.0kV x50.0 600µm

FIG. 7A

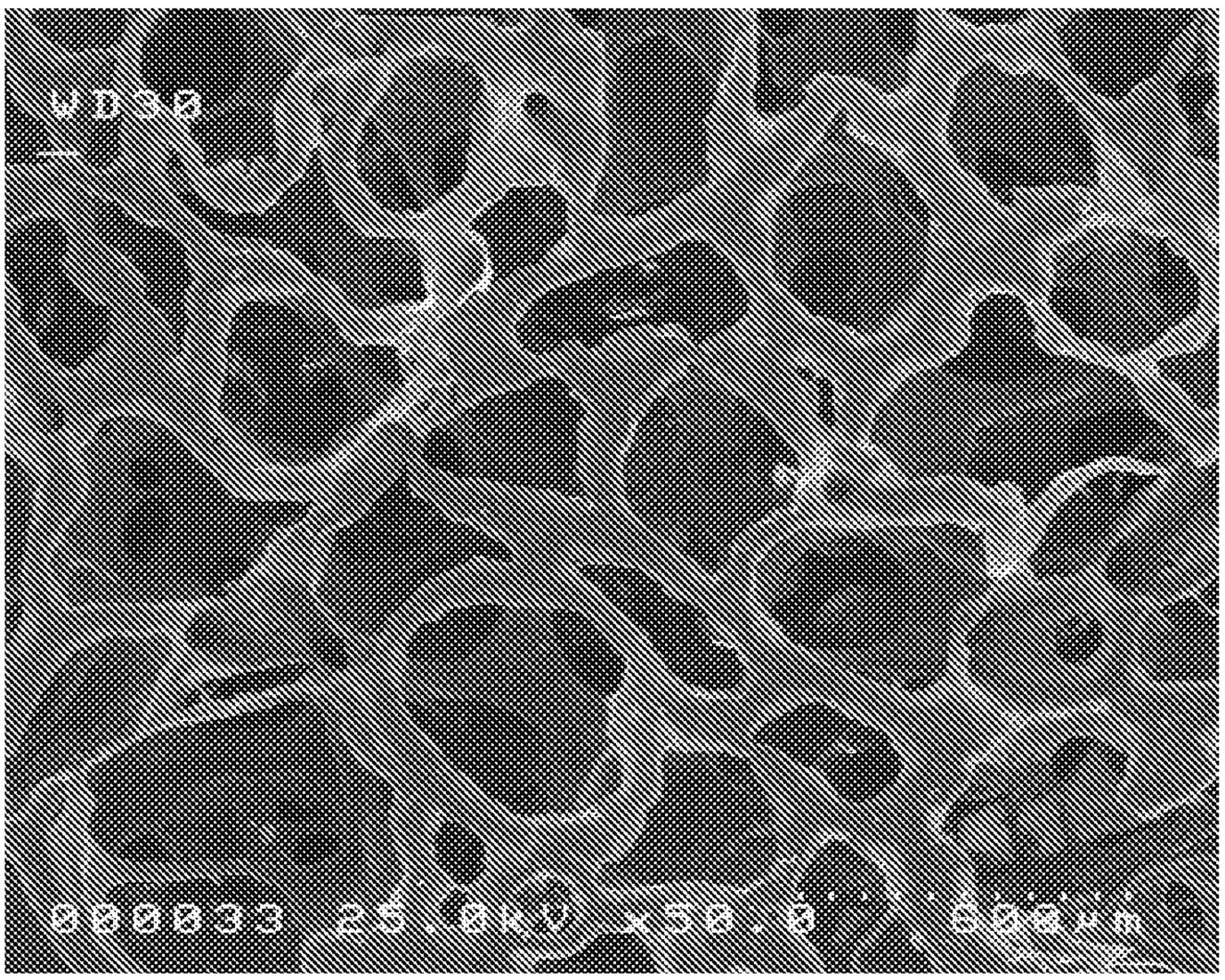


FIG. 7B

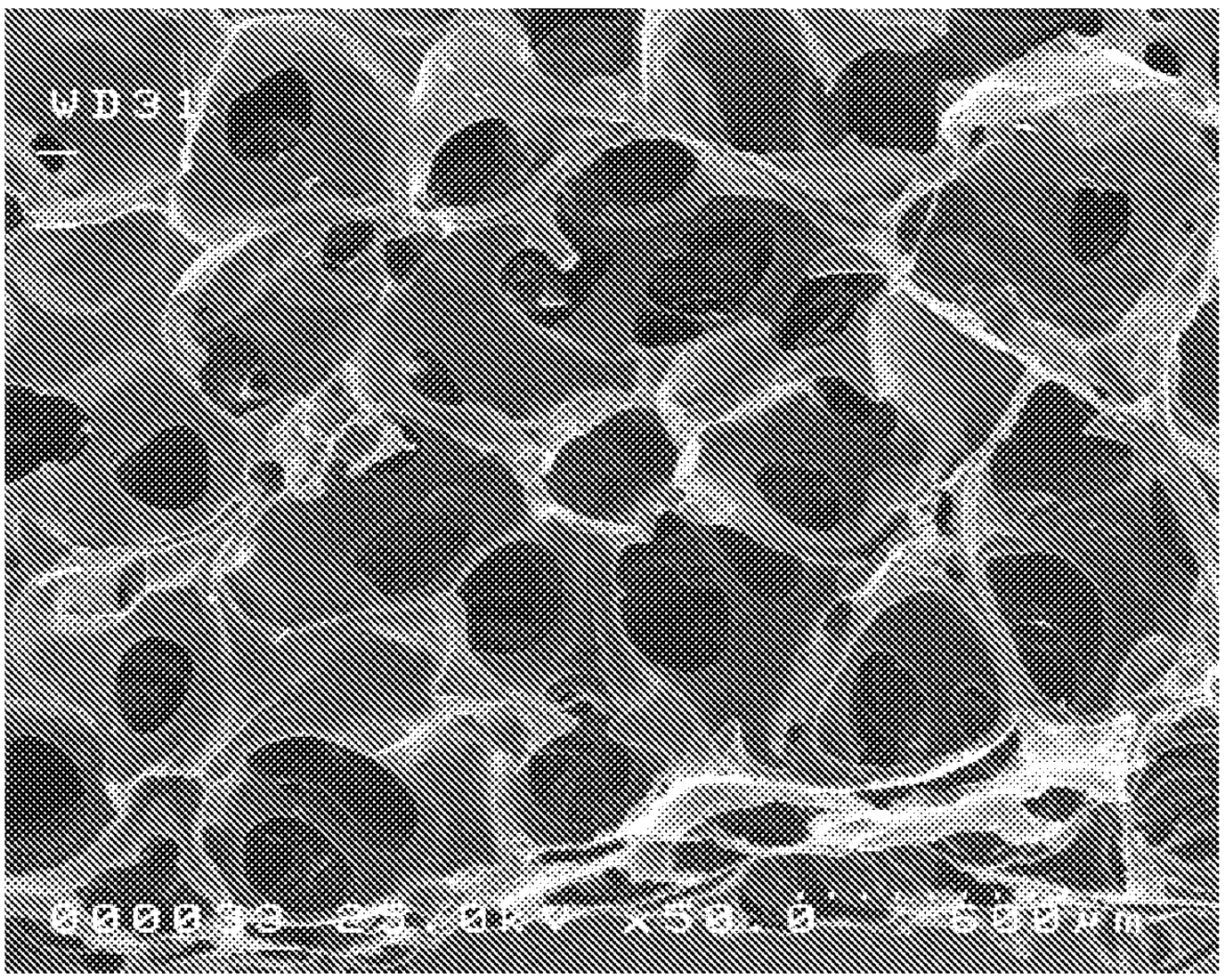


FIG. 8A

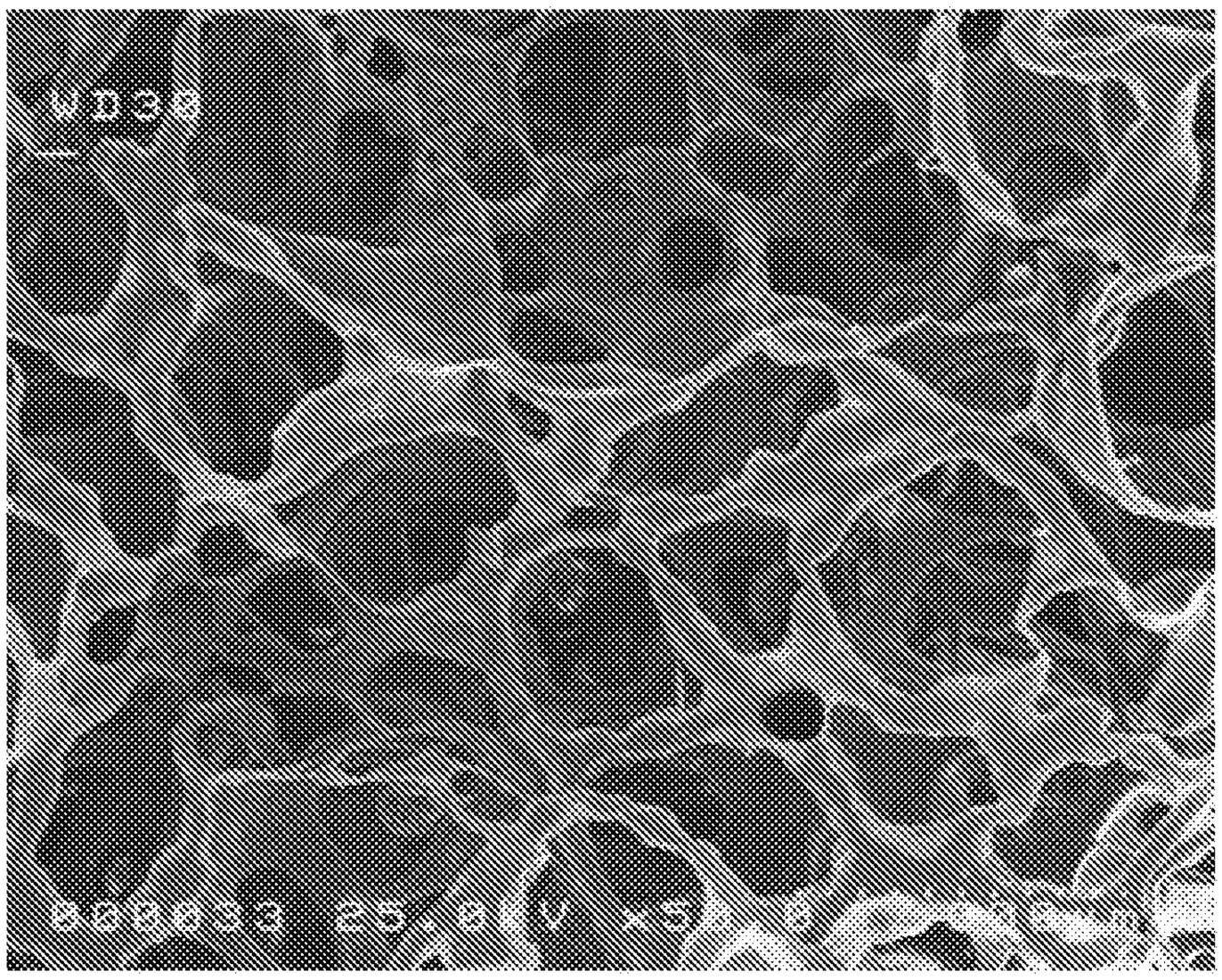
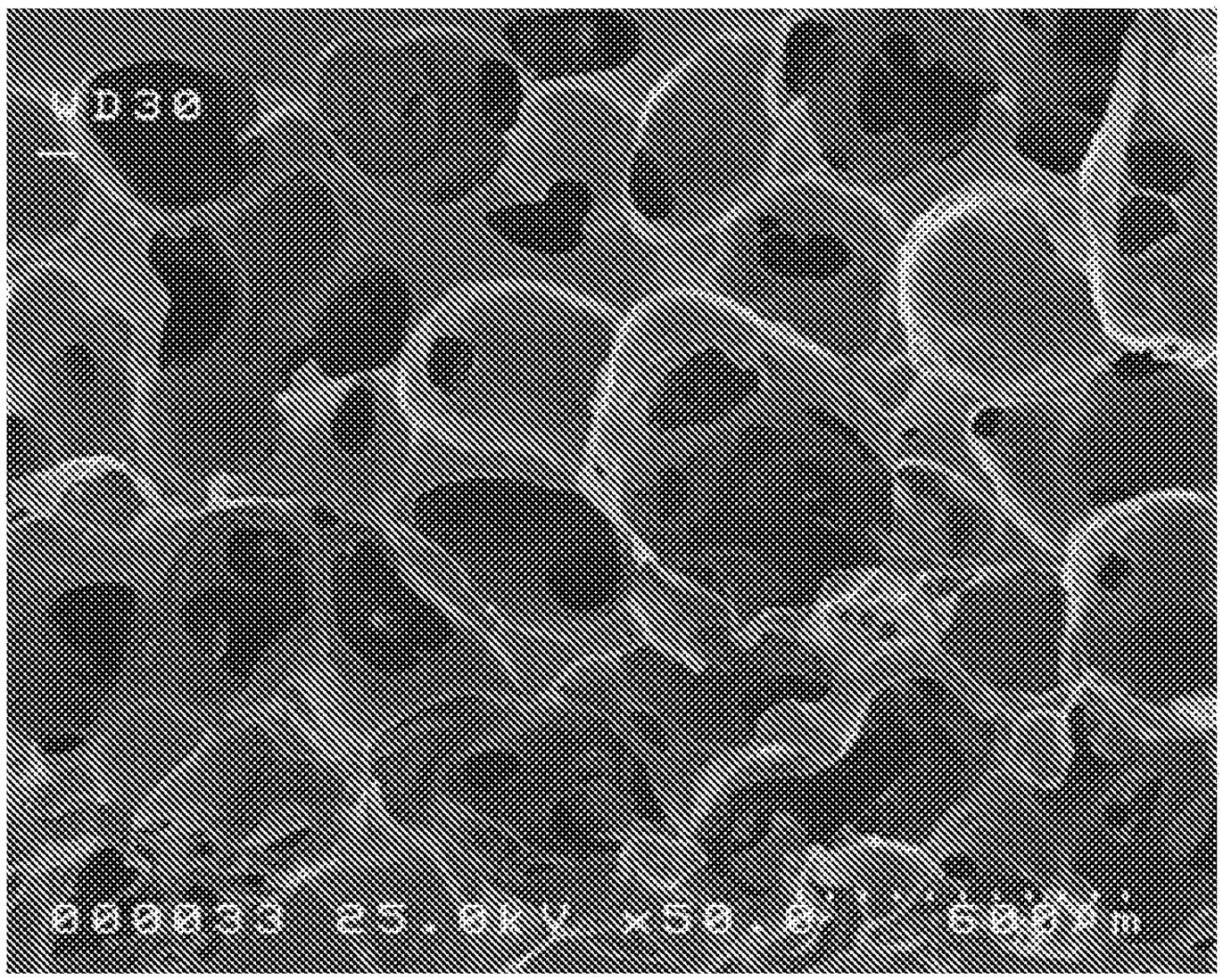


FIG. 8B



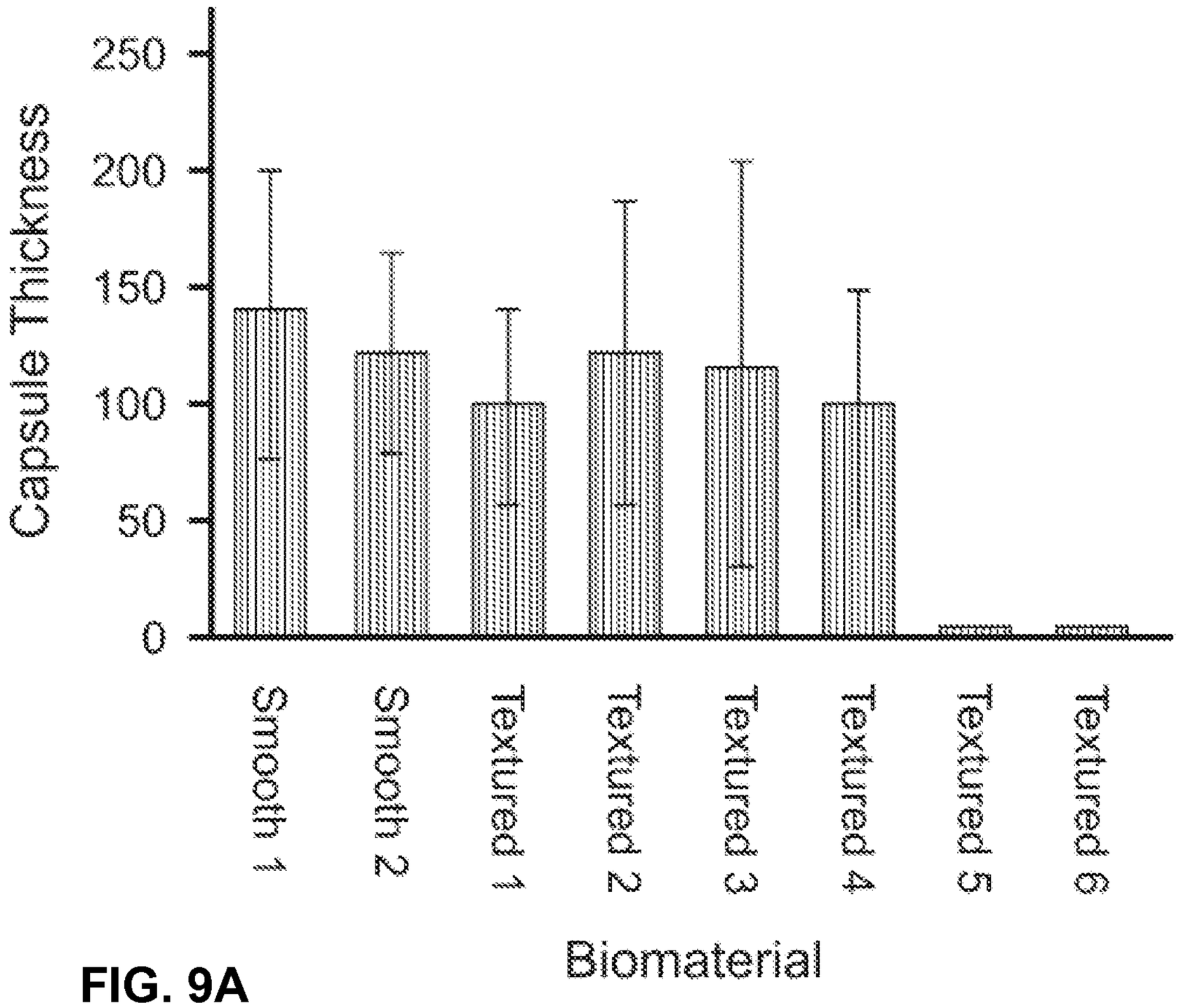

Capsule Thickness
0
50
100
150
200
250
Smooth 1
Smooth 2
Textured 1
Textured 2
Textured 3
Textured 4
Textured 5
Textured 6
Biomaterial

FIG. 9A

FIG. 9B

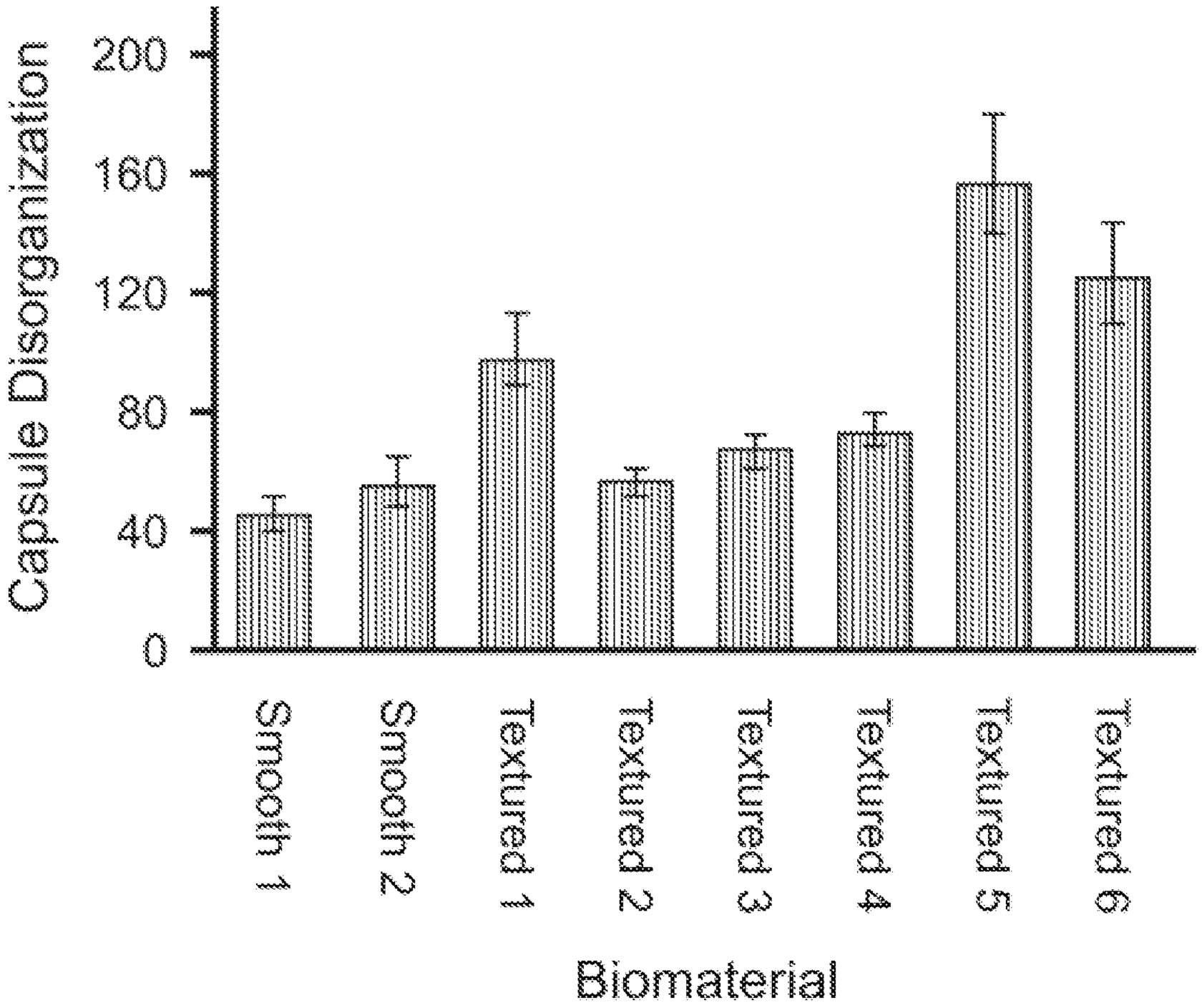

Capsule Disorganization
0
40
80
120
160
200
Smooth 1
Smooth 2
Textured 1
Textured 2
Textured 3
Textured 4
Textured 5
Textured 6
Biomaterial

FIG. 10

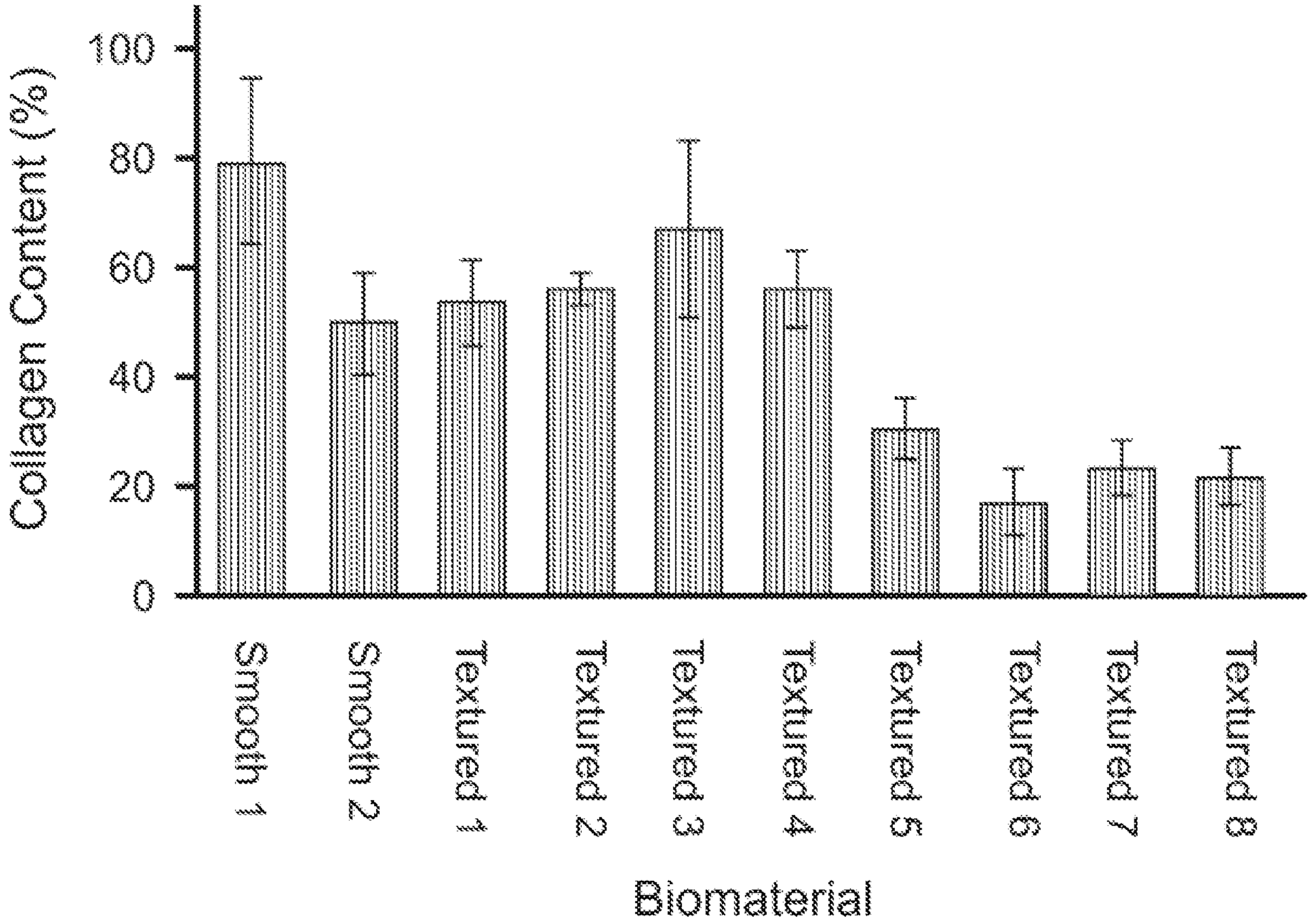

Collagen Content (%)
0
20
40
60
80
100
Smooth 1
Smooth 2
Textured 1
Textured 2
Textured 3
Textured 4
Textured 5
Textured 6
Textured 7
Textured 8
Biomaterial

FIG. 11

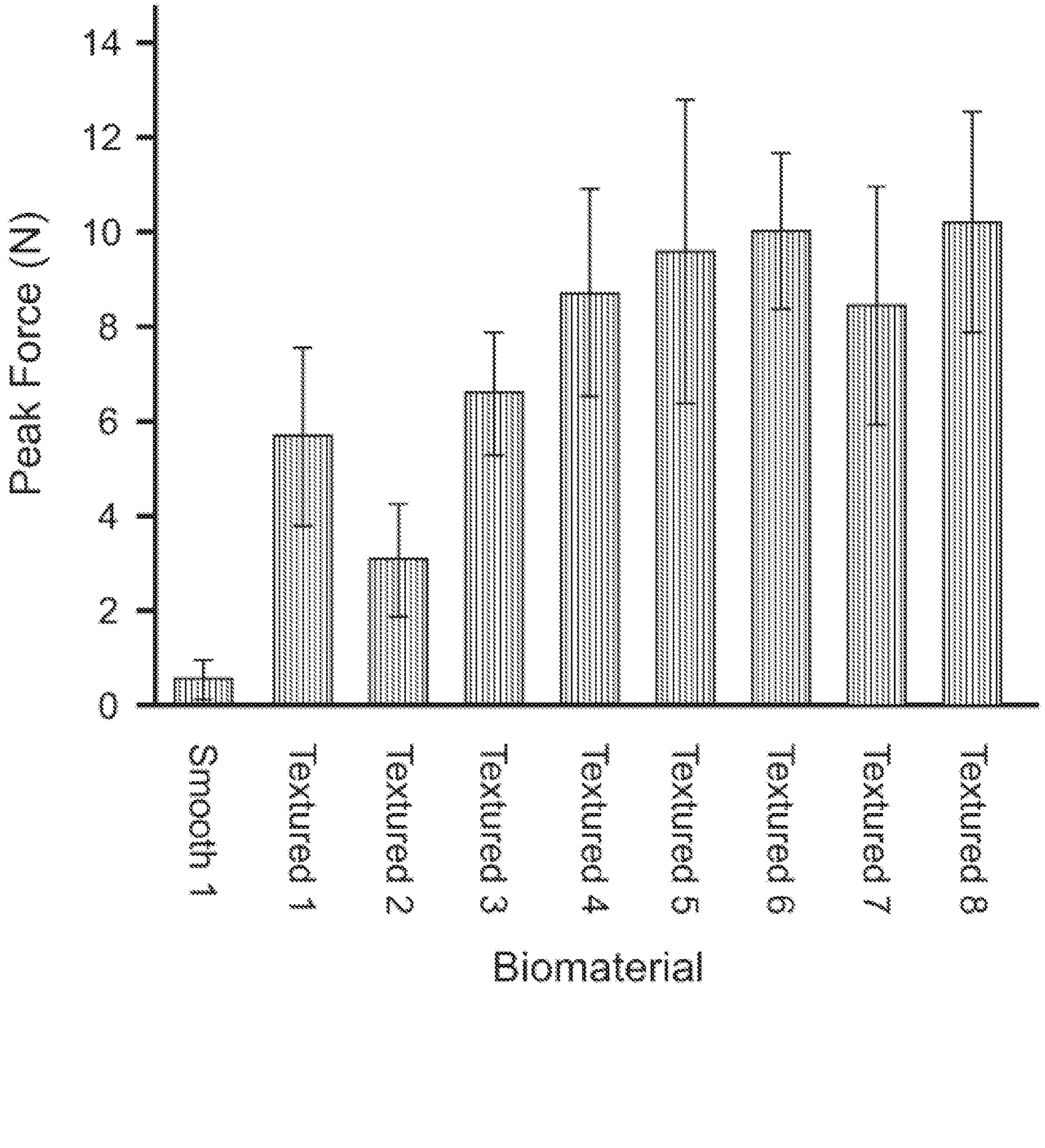
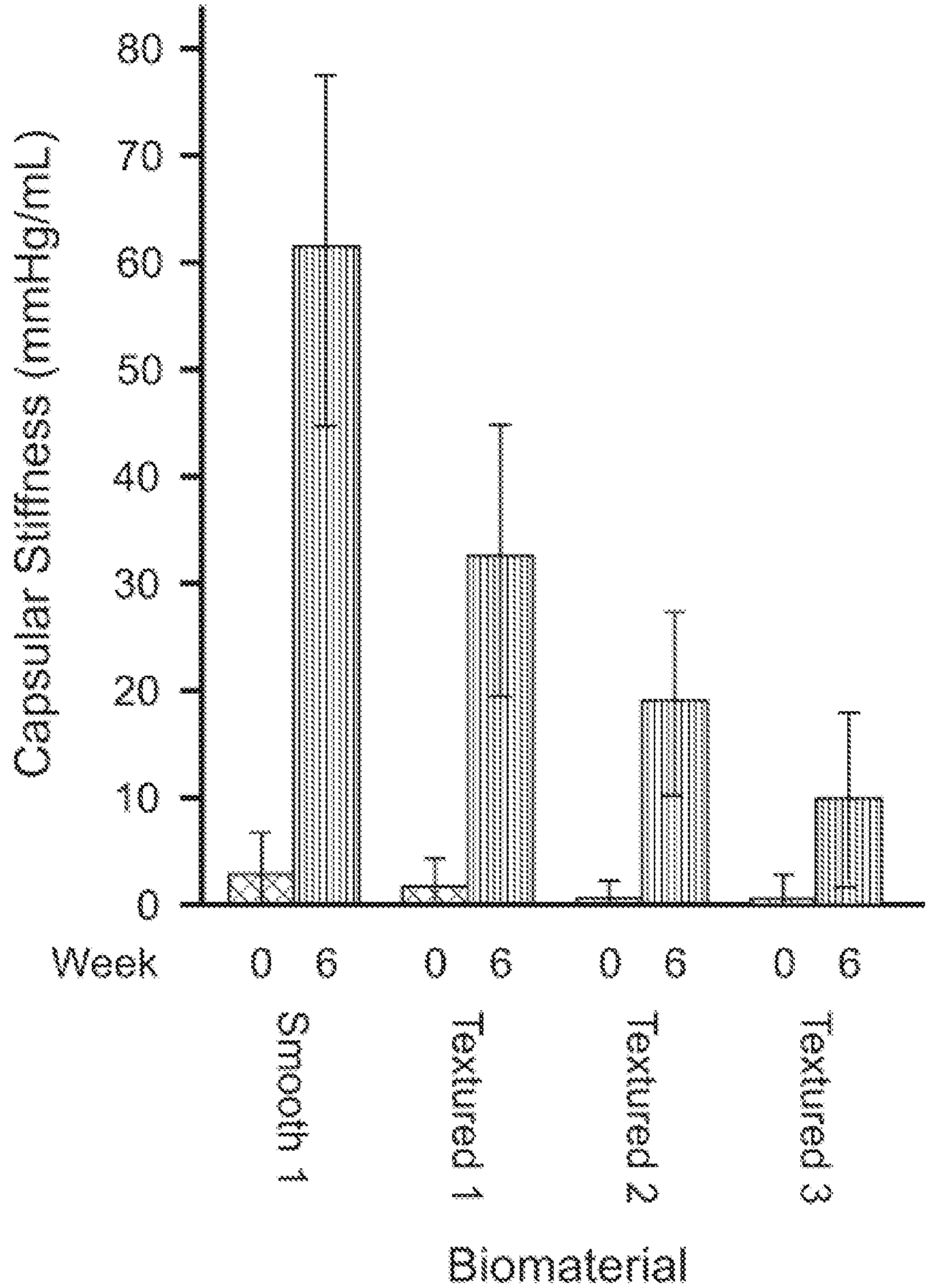
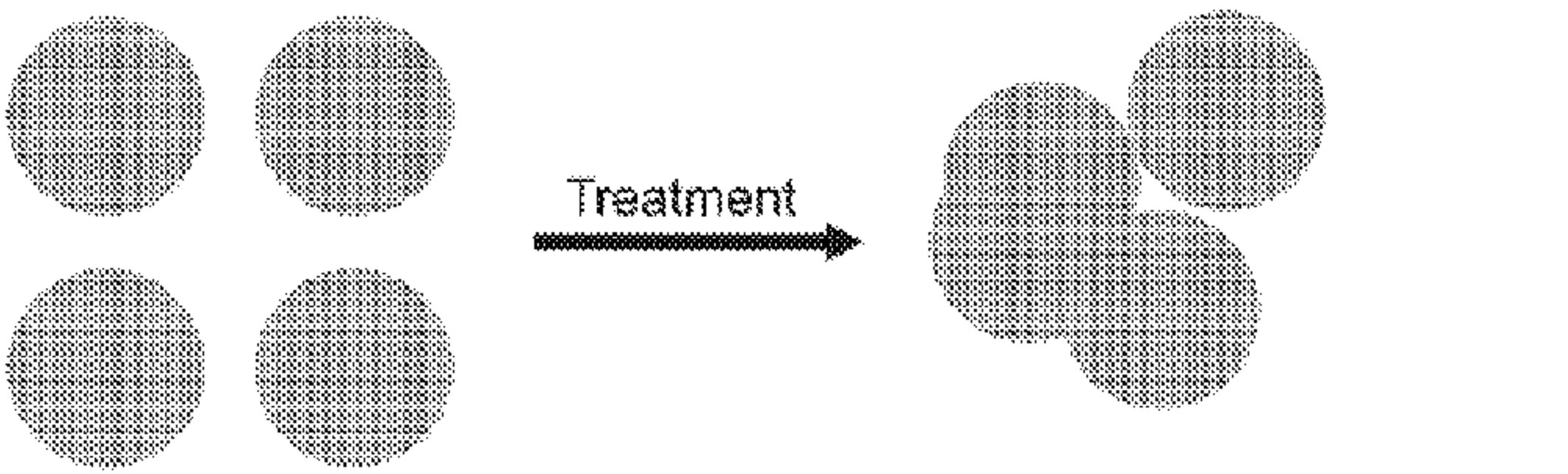
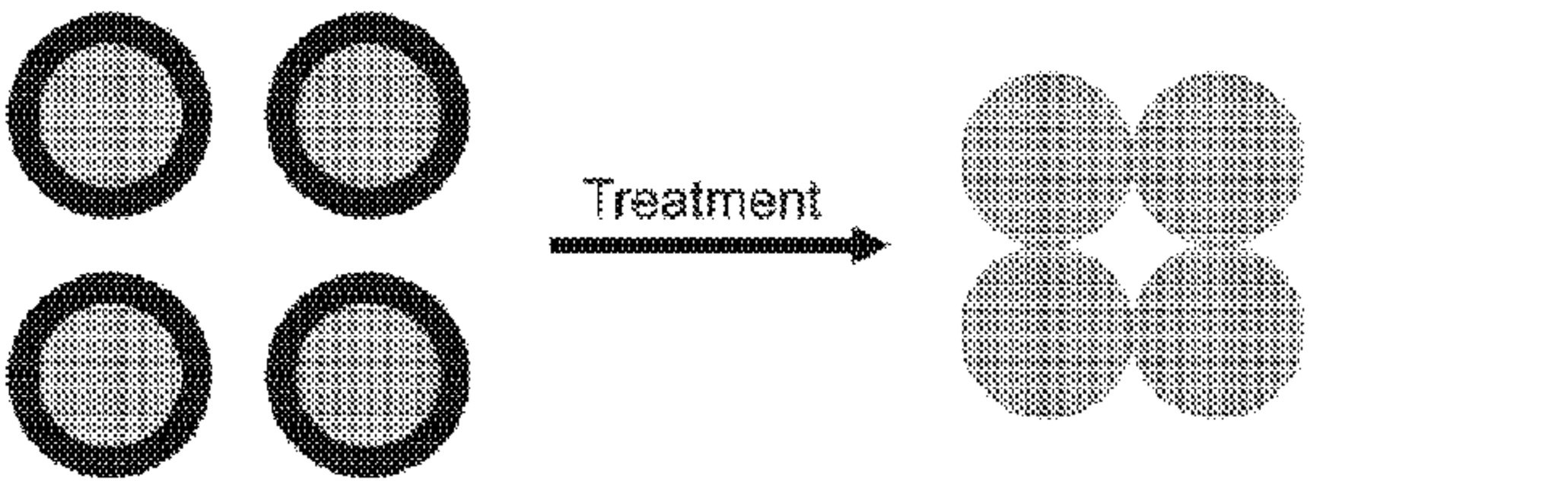

14
Peak Force (N)
0
2
4
6
8
10
12
Smooth 1
Textured 1
Textured 2
Textured 3
Textured 4
Textured 5
Textured 6
Textured 7
Textured 8
Biomaterial

FIG. 12


Capsular Stiffness (mmHg/mL)
0
10
20
30
40
50
60
70
80
Week
0
6
0
6
0
6
0
6
Smooth 1
Textured 1
Textured 2
Textured 3
Biomaterial



Under-fused and over-fused porogens



Uniformly-fused porogens