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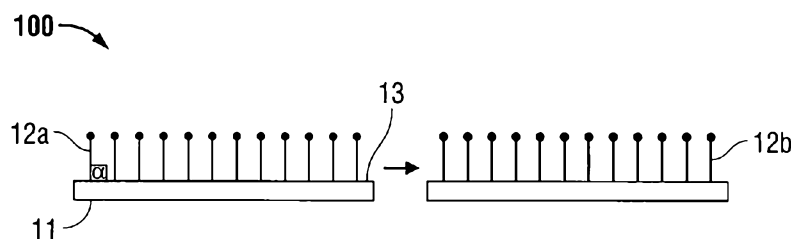


FIG. 1

(57) Abstract: The present disclosure relates to implantable medical devices including swellable tissue gripping elements and methods of forming such devices. The implantable medical device may comprise a biocompatible substrate having a surface comprising at least one swellable grip member. The implantable medical device may take on the form of a surgical mesh, patch, buttress, or pledget and the swellable member may comprise spikes and/or spiked naps. The implantable medical device may also contain a bioactive agent.

IMPLANTABLE DEVICES HAVING SWELLABLE GRIP MEMBERS

BACKGROUND

Technical Field

The present disclosure relates generally to implantable medical devices having at least one tissue gripping element and to methods for forming such devices.

Background of Related Art

Surgical meshes may be used during both laparoscopic and open surgery for repair of many types of defects and injuries. For example, surgical meshes are commonly used in the repair of hernias. The meshes may be used to provide support to surrounding tissue, as well as to supplement standard suturing.

During hernia repair, the mesh may be placed over the entirety of damaged tissue and some of the healthy tissue surrounding the defect. The mesh can be held in place by a fixation device that attaches the mesh to the surrounding tissue. A variety of different fixation devices may be used to anchor the mesh into the tissue. For example, a needled suture may be passed through or around the tissue near the defect to hold the mesh in a position which spans the injured tissue. In other instances, staples, tacks, clips and pins are known to be passed through or around the tissue near the defect to anchor the implant in a position which spans the injured tissue.

Unfortunately, the use of such fixation devices may increase the patient's discomfort and, in certain instances, may weaken the tissue to which the fixation devices are attached. Certain techniques involve placing a mesh against the repair site without the addition of a fixation device. For example, in some instances the mesh may be simply positioned within the abdomen allowing the pressure of the peritoneum to hold the mesh against the posterior side of the

abdominal wall. However, fixation of the mesh may be helpful in order to avoid folding, shrinkage, and migration of the mesh.

Although methods that require the use of fixation devices have been proven effective in anchoring an implant such as a mesh into the tissue, penetration of the tissue by such devices inflicts additional trauma to the damaged tissue or the tissue near the defect and requires additional time for healing. Thus, implantable devices which do not require the use of sutures, staples, tacks, pins, and/or clips is desirable in order to further limit the amount of trauma to healthy tissue surrounding the wound and caused by the fixation devices.

SUMMARY

Accordingly, the present disclosure describes implantable medical devices which include at least one tissue-gripping element, such as a grip member which is partially or completely swellable. In embodiments, the grip member may include a coating which is swellable.

In certain embodiments, the implantable medical devices include a biocompatible substrate having a surface containing at least one swellable grip member. The at least one swellable grip member may protrude perpendicularly from the surface of the biocompatible substrate. In embodiments, a plurality of swellable grip members may be positioned along any portion of the surface of the biocompatible substrate.

In some embodiments, the swellable grip members which may include spiked naps. In other embodiments, the swellable grip members which may include barbs. In still other embodiments, the swellable grip members which may include barbs and spiked naps.

Methods of forming such devices are also disclosed

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing objects and advantages of the disclosure will become more apparent from the reading of the following description in connection with the accompanying drawings, in which:

FIG. 1 is a side view of an implantable medical device having a biocompatible substrate containing swellable grip members according to one embodiment described in the present disclosure;

FIG. 2 is a side view of an implantable medical device having a biocompatible substrate containing swellable grip members according to another embodiment described in the present disclosure;

FIG. 3 is a side view of an implantable medical device having a biocompatible substrate containing swellable grip members according to yet another embodiment described in the present disclosure;

FIG. 4 is a side view of an implantable medical device having a biocompatible substrate containing swellable grip members according to still another embodiment described in the present disclosure;

FIG. 5 is a side view of an implantable medical device having a biocompatible substrate containing swellable grip members according to still another embodiment described in the present disclosure;

FIG. 6 is a top view of an implantable medical device having a biocompatible substrate containing swellable grip members according to still another embodiment described in the present disclosure;

FIG. 7 is a top view of an implantable medical device having a biocompatible substrate containing swellable grip members according to still another embodiment described in the present disclosure;

FIG. 8 is a diagram showing a weave pattern for forming an implantable medical device according to an embodiment described in the present disclosure; and,

FIG. 9 is a diagrammatic side view of a device permitting the formation of swellable grip members on the implantable medical devices in one embodiment described herein.

DETAILED DESCRIPTION

The present disclosure relates to implantable medical devices which display tissue-gripping capabilities. In certain embodiments, the implantable medical devices include at least one swellable grip member. The swellable grip member may attach at least a first portion of the medical device to tissue and/or to at least a second portion of the medical device. Any portion of the grip member may be swellable. In embodiments, the implantable medical devices include swellable grip members which may include at least one barb and/or at least one spiked nap to attach to tissue.

The implantable medical devices include a biocompatible substrate having a surface to which the swellable grip members may be positioned. The biocompatible substrates are often planar in configuration, however, any two-dimensional or three dimensional shapes suitable for implantation may be used. Some examples of suitable biocompatible substrates include films, foams, meshes, buttresses, patches, tapes, pledgets, occlusion devices, and the like. In certain embodiments, the biocompatible substrate is a surgical mesh.

Any biocompatible material may be used to form the biocompatible substrates and/or the filaments described herein. For example, the substrate may be made from natural, synthetic, bioabsorbable or non-bioabsorbable materials. It should of course be understood that any combination of natural, synthetic, bioabsorbable and non-bioabsorbable materials may be used to form the substrates or filaments described herein. The term "bioabsorbable" as used herein is defined to include both biodegradable and bioresorbable materials. By bioabsorbable, it is meant that the materials decompose, or lose structural integrity under body conditions (e.g. enzymatic degradation or hydrolysis) or are broken down (physically or chemically) under physiologic conditions in the body such that the degradation products are excretable or absorbable by the body.

Representative natural bioabsorbable materials include: polysaccharides, such as alginate, dextran, chitin, hyaluronic acid, cellulose, collagen, gelatin, fucans, glycosaminoglycans, and chemical derivatives thereof (substitutions and/or additions of chemical groups, for example, alkyl, alkylene, hydroxylations, oxidations, and other modifications routinely made by those skilled in the art); and proteins, such as albumin, casein, zein, silk, and copolymers and blends thereof, alone or in combination with synthetic polymers.

Synthetically modified natural polymers include cellulose derivatives, such as alkyl celluloses, hydroxyalkyl celluloses, cellulose ethers, cellulose esters, nitrocelluloses, and chitosan. Examples of suitable cellulose derivatives include methyl cellulose, ethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, hydroxybutyl methyl cellulose, cellulose acetate, cellulose propionate, cellulose acetate butyrate, cellulose acetate phthalate, carboxymethyl cellulose, cellulose triacetate, and cellulose sulfate sodium salt. These are collectively referred to herein as "celluloses."

Representative synthetic bioabsorbable polymers include polyhydroxy acids prepared from lactone monomers, such as glycolide, lactide, caprolactone, ϵ -caprolactone, valerolactone, and δ -valerolactone, as well as pluronics, carbonates (e.g., trimethylene carbonate, tetramethylene carbonate, and the like), dioxanones (e.g., 1,4-dioxanone and p-dioxanone), 1,4-dioxepanones (e.g., 1,4-dioxepan-2-one and 1,5-dioxepan-2-one), and combinations thereof. Polymers formed therefrom include: polylactides; poly(lactic acid); polyglycolides; poly(glycolic acid); poly(trimethylene carbonate); poly(dioxanone); poly(hydroxybutyric acid); poly(hydroxyvaleric acid); poly(lactide-co-(ϵ -caprolactone-)); poly(glycolide-co-(ϵ -caprolactone-)); polycarbonates; poly(pseudo amino acids); poly(amino acids); poly(hydroxyalkanoate)s, including polyhydroxybutyrate, polyhydroxyvalerate, poly(3-hydroxybutyrate-co-3-hydroxyvalerate), polyhydroxyoctanoate, and polyhydroxyhexanoate;

polyalkylene oxalates; polyoxaesters; polyanhydrides; polyortho esters; and copolymers, block copolymers, homopolymers, blends, and combinations thereof.

In certain embodiments, the biocompatible substrate may be formed using a combination of bioabsorbable and non-bioabsorbable polymers.

Some non-limiting examples of suitable non-bioabsorbable materials include polyolefins, such as polyethylene and polypropylene including atactic, isotactic, syndiotactic, and blends thereof; polyethylene glycols; polyethylene oxides; ultra high molecular weight polyethylene; copolymers of polyethylene and polypropylene; polyisobutylene and ethylene-alpha olefin copolymers; fluorinated polyolefins, such as fluoroethylenes, including expanded polytetrafluoroethylene (ePTFE) and condensed polytetrafluoroethylene c(PTFE), fluoropropylenes, fluoroPEGs, and polytetrafluoroethylene; polyamides, including Nylon 6, Nylon 6,6, Nylon 6,10, Nylon 11, and Nylon 12; polycaprolactam; polyamines; polyimines; polyesters, such as polyethylene terephthalate, polyethylene naphthalate, polytrimethylene terephthalate and polybutylene terephthalate; aliphatic polyesters; polyethers; polyether-esters, such as polybutester; polytetramethylene ether glycol; 1,4-butanediol; polyurethanes; acrylic polymers and copolymers; modacrylics; vinyl halide polymers and copolymers, such as polyvinyl chloride; polyvinyl alcohols; polyvinyl ethers, such as polyvinyl methyl ether; polyvinylidene halides, such as polyvinylidene fluoride and polyvinylidene chloride; polyacrylonitrile; polyaryletherketones; polyvinyl ketones; polyvinyl aromatics, such as polystyrene; polyvinyl esters, such as polyvinyl acetate; copolymers of vinyl monomers with each other and olefins, such as ethylene-methyl methacrylate copolymers, acrylonitrile-styrene copolymers, ABS resins, and ethylene-vinyl acetate copolymers; alkyd resins; polycarbonates; polyoxymethylenes; polyphosphazene; polyimides; epoxy resins; aramids, rayon; rayon-triacetate; spandex; silicones; and combinations thereof

The biocompatible substrates may be formed using any method within the purview of those skilled in the art. Some non-limiting examples include, weaving, knitting, braiding, crocheting, extruding, spraying, casting, molding, laminating, lyophilization, freeze-drying, and combinations thereof. In some embodiments, the biocompatible substrate may be a two or three dimensional surgical mesh which is woven, knitted, braided, or crocheted from at least one first filament to form the substrate. In certain embodiments, the biocompatible substrate may be a surgical mesh consisting of at least one first filament made of polyethylene terephthalate.

The tissue-gripping elements, i.e., the swellable grip members, may be positioned on at least a portion of the biocompatible substrate. Any portion of the biocompatible substrate may include at least one grip member. Any portion of the grip member may be swellable. For instance, in some embodiments, the entire grip member may include a swellable material (see FIG. 1). In other embodiments, only a portion of the grip member may include a swellable material (see FIG. 2). In certain embodiments, the grip member may be made completely from a swellable material. In other certain embodiments, the grip member may be made from a biocompatible material which includes a swellable coating on at least a portion of the grip member. In still other embodiments, the grip member may be made from a combination of biocompatible material and a swellable material. Examples of suitable, non-limiting examples of biocompatible materials are previously described herein.

In some embodiments, the grip member may be made from at least one second filament. In some embodiments, the second filaments may be made from any swellable material suitable for implantation. In some embodiments, the second filaments may be made from any biocompatible, bioabsorbable, or non-bioabsorbable material, including those described herein. In some embodiments, the first and second filaments may be made from the same materials. In other embodiments, the first and second filaments may be made from different materials. For example, in some embodiments, the biocompatible substrate may be formed from at least one

first filament made from a non-bioabsorbable material, i.e., polypropylene, and the tissue-gripping elements may be formed from at least one second filament made from a bioabsorbable material, i.e., polylactic acid coated with a swellable material, such as a hydrogel.

The swellable portion of the grip member may include any biocompatible swellable material capable of expanding and/or swelling upon implantation of the body. The swellable portion of the grip member may include swellable materials which undergo volumetric expansion in response to exposure to bodily fluids, and/or changes in environmental parameters such as pH, temperature, pressure, and the like. The swellable material may absorb or adsorb water or other bodily fluids such as blood, urine, sweat, tears, bile, and the like. In particular, some suitable materials are able to absorb or adsorb and retain from about 5% to about 95% fluids and other materials absorb or adsorb and retain from about 20% to about 80% fluids.

Some examples of suitable swellable materials include hydrophilic polymers and polymers derived from hydrophilic polymers including hydrogels. Suitable hydrophilic polymers include poly(vinyl alcohol), poly(glycols) such as poly(ethylene glycol) dimethacrylate, poly(ethylene glycol) diacrylate, poly(hydroxyethyl methacrylate), poly(vinyl pyrrolidone), poly(acrylamide), poly(acrylic acid), hydrolyzed poly(acrylonitrile), poly(ethyleneimine), ethoxylated poly(ethyleneimine) and poly(allylamine) as well as, hydrophilic biopolymers and IPNs may also be suitable, such as biopolymers such as chitosan, agarose, hyaluronic acid, collagen and gelatin, (semi) interpenetrating network hydrogels, peptide, protein, and monomers, oligomers, macromers, copolymers and/or other combinations or derivatives of the foregoing.

Some examples of suitable swellable hydrogel materials may be described in any of the following: U.S. Pat. No. 5,162,430 (Rhee et al.), U.S. Pat. No. 5,410,016 (Hubbell et al.), U.S. Pat. No. 5,990,237 (Bentley et al.), U.S. Pat. No. 6,177,095 (Sawhney et al.), U.S. Pat. No. 6,184,266 B1 (Ronan et al.), U.S. Pat. No. 6,201,065 B1 (Pathak et al.), U.S. Pat. No. 6,224,892

B1 (Searle), U.S. Pat. No. 5,980,550 (Eder et al.) and PCT International Patent Publication Nos. WO 00/44306 (Murayama et al.), WO 00/74577 (Wallace et al.).

The swellable material may be combined with the tissue gripping element in any suitable manner. For example, in some embodiments, at least one swellable material may be applied to a portion of the tissue gripping element as a coating or film. In such embodiments, the swellable material may be applied to the tissue gripping elements by dip-coating, spray coating, vapor deposition, extrusion, molding and the like. The swellable material may be combined with a suitable solvent to form a solution or suspension and applied to the tissue gripping element and allowed to dry. Suitable solvents and methods of drying are known to those skilled in the art.

In some embodiments, the tissue gripping element may be formed completely of at least one swellable material. For example, a swellable material such as a hydrophilic polymer which is thermoplastic can be melted and re-solidified without losing its swellable character. In one embodiment, the material is a thermoplastic having a melting temperature in the range from about 70° C to about 200° C. The thermoplastic quality of the swellable material allows for easy processability and end use. Upon melting, the material becomes flowable and can therefore be extruded, pulltruded, injected, shaped, or molded. In particularly useful embodiments, the swellable material may be formed into a second filament suitable for being combined with the first filament of the substrate to form a knitted surgical mesh.

In still other embodiments, at least one swellable material may be combined with a biocompatible polymer to form a bi-component filament. In such embodiments, different portions of the tissue gripping element may swell after implantation.

Referring now to FIG. 1 which illustrates implantable medical device 10 containing biocompatible substrate 11 having surface 13. At least one grip member 12a protrudes from surface 13 of the substrate 11 in a generally perpendicular orientation. As shown in Fig. 1, angle α is about 90° thus illustrating the generally perpendicular relationship between substrate

11 and grip member(s) 12a. Grip member(s) 12a, which is made from a swellable material, is shown in an unexpanded configuration. However, following implantation and/or exposure to bodily fluid, changes in pH, or temperature (depicted by arrow), grip member(s) 12a will swell and become expanded grip member(s) 12b. Although depicted in FIGS. 1 and 2 as generally round-tipped grip members, the grip members are considered spiked naps and capable of penetrating tissue. Thus, grip member 12a is implanted and penetrates a portion of the surrounding tissue before and/or during

In FIG. 2, grip member 22 includes swellable portion 23a and non-swellable portion 24. Thus following implantation and/or exposure to bodily fluid, changes in pH, or temperature (depicted by arrow), only swellable portion 23a which includes a swellable material will swell and become expanded portion 23b. Non-swellable portion 24 remains in an unexpanded configuration. Although swellable portion 23a is shown as the top portion of grip member 22, any portion of grip member 22 may include a swellable material.

In FIGS. 1 and 2, the swellable grip member(s) is shown as a tipped filament, i.e., spiked nap, extending from the surface. However, in some embodiments, such as those shown in FIGS. 3, and 4, the swellable grip members may be barbed spiked naps, and/or barbed loops, respectively. Of course any combination of such grip members may also be envisioned.

As depicted in FIG. 3, implantable medical device 300 includes biocompatible substrate 301 having surface 301a and at least one swellable barbed and spiked nap 302 protruding from the surface of the substrate in a perpendicular manner. Naps 302 are substantially rectilinear in shape and include barbs 303 and spikes 304. At least a portion of naps 302 may include a swellable material. Barbs 303 are bi-directional however unidirectional barbs may also be used. Naps 302 may be formed from barbed loops in which the barbs were oriented in a single direction along the body of the loop. Spikes 304 are slightly greater in width than the remainder of the naps, providing additional tissue gripping capability to the barbed naps.

FIG. 4 illustrates, implantable medical device 400 having biocompatible substrate 401, having surface 401a and at least one swellable barbed loop 402. Swellable barbed loops 402 include a plurality of barbs 403. At least a portion of barbed loop 402 may include a swellable material.

As shown in FIG. 5, 6, and 7, the implantable medical devices described herein may include any number, pattern or concentration of swellable grip members. For example, in FIG. 5, implantable medical device 500 includes biocompatible substrate 501 having at least one swellable barbed loop 502a and at least one swellable barbed and spiked nap 502b. Although shown on opposite sides of substrate 501, it is envisioned that the combination of two or more different tissue-gripping elements may also be positioned on the same side and/or in any combination, concentration or pattern including a combination of swellable and non-swellable grip members.

FIG. 6 illustrates a top view of an implantable medical device 600 that is planar in configuration, having a height, width and length. In this embodiment, swellable gripping elements 601 are a contiguous part of biocompatible substrate 602 and are arranged along an outer perimeter of substrate 602. It is envisioned that in other embodiments the swellable gripping elements may comprise the entire planar surface of the implant. In still other embodiments, the swellable gripping elements may be arranged only at the corners of the implant. In yet another embodiment, the concentration of swellable grip members may vary along different portions of the substrate. Other arrangements of the swellable gripping element are possible and should be apparent to one skilled in the art.

Although the substrate is shown to be generally rectangular, the substrates described herein may be of any shape including elliptical, square, triangular, hexagonal, and circular and the like. In addition, the substrate may include apertures to accommodate the passage of bodily

tissue when implanted. The implant can be shaped and sized during manufacturing or can be cut to a particular size and shape immediately before use.

Turning to FIG. 7, which shows implantable medical device 700 including biocompatible substrate 702 including aperture 706 and flap 703 attached to substrate 702 via interface 705. Swellable grip members 704 are shown positioned on flap 703 which is separate from substrate 702. Swellable grip members 704 may be useful in securing flap 703 to portions of substrate 702. Because swellable grip members 704 do not swell into an expanded state until after implantation, medical device 700 may be rolled and unrolled without swellable grip members attaching flap 703 to substrate 702. Flap 703 is attached to substrate 702 at interface 705 by stitching, welding, adhesive, and stapling or any other suitable method.

In certain embodiments, the implantable medical device may be a surgical mesh which made from a plurality of first and second filaments woven in any suitable manner that allows the filaments to form a substrate and form loops or naps which extend from the surface of said substrate. FIG. 8 diagrams one representative pattern that will form loops in accordance with the present disclosure. The implantable medical device may be made on a warp knitting machine, of the tricot or Raschel type, with at least three sheets or warps of yarn and as many guide bars.

The front and intermediate guide-bars may be threaded with a first set of filaments or yarns. The intermediate bars may be threaded, one guide full, three guides empty, with monofilament or multifilament yarn. This yarn may be made from any suitable biocompatible material; and in some embodiments, may be made from polyethylene terephthalate. This filament or yarn is represented by a broken line and by reference number 811 in FIG. 8. The intermediate bar works in such a way as to obtain a zigzag openwork pattern between the columns of meshes.

The front bar is threaded; one guide full, one guide empty, and works in chain weave with a multifilament or monofilament yarn, represented by number 812 in FIG. 8. The chain

stitch imprisons the monofilament 810 and maintains the knit in length while contributing to the formation of the knit with the intermediate sheet formed by yarn 811.

The rear bar may be threaded, one guide full and one guide empty, with a second filament, i.e., monofilament or multifilament. This second filament or yarn may include a swellable material and optionally any suitable biocompatible material; and in some embodiments, may be made from polylactic acid. The second filament may be woven to form the spiked naps, barbed loops and/or the barbed and spiked naps of the final product.

The diameter of the second filament is over 0.10 millimeter. In practice, this diameter is between 0.14 and 0.18 millimeter and is of the order of 0.15 millimeter. This yarn or filament is represented by reference number 810 and in a solid line in FIG. 8.

The different filaments may be worked according to the following chart:

Warp → Raschel →	Rear bar I Front bar II	Intermediate bar II Intermediate bar II	Front bar III Rear bar III
	7	3	1
	7	2	0
	----	----	----
	3	4	0
	4	5	1
	----	----	
	0	1	
	0	0	
	----	----	
	4	2	
	3	3	

		1	
		0	

		4	
		5	

The rear bar places the yarn in partial weft under the chain stitch and “thrown” onto the needle not forming a chain stitch. For this reason, at the next row, the needle not forming a chain

stitch not being supplied permits escape of the monofilament which forms a loop (see FIG. 9) projecting from the front face of the medical device.

The medical device thus obtained may be a knit provided with loops which are generally perpendicular to one of the surfaces of the substrate. The loops also display the rigidity to hold at about a right angle, which is obtained by the rigidity or nerve of the second filament employed. This rigidity or nerve may be necessary for the subsequent formation of swellable spiked naps, swellable spiked and barbed naps and/or swellable barbed loops which ensure a tissue-gripping function.

Other patterns by which to obtain a knit with loops that protrude from one face should be apparent to one skilled in the art. In embodiments, the second filaments used to form the loops may be coated with a swellable material prior to the knitting of the substrate. In other embodiments, the second filaments used to form the loops may be coated with a swellable material after the knitting of the substrate.

In other embodiments, the second filament used to form the loops can be cut along its length prior to the knitting of the substrate to form barbs. In still other embodiments, the second filaments used to form the loops can first be knitted into the substrate and then may be cut along the length of the loops to form barbs.

FIG. 9 illustrates one method by which loops 901 can be converted into spiked naps 902. In one embodiment, the method includes passing substrate 900 with loops 901 over cylinder 913 containing an electrical heating resistor. Substrate 900 may be pressed flat on cylinder 913 by two pairs of rollers, upstream 915a, 915b and downstream 916a, 916b, respectively, which may be vertically displaceable for controlling the pressing force. This control as well as that of the temperature of the resistor placed in cylinder 913 and of the speed of movement of substrate 900 across cylinder 913 make it possible to melt the head of each of the loops 901 so that each loop

901 forms two spiked naps 902. In some embodiments, the loop may be coated with a swellable material prior to melting to form the barbed and spiked naps of FIG. 3.

Each spiked nap 902 thus has a substantially rectilinear body 904 protruding perpendicularly with respect to the substrate 900. Rectilinear body 904 includes attached end 902a and free end 902b, with free end 902b having spike 903 of greater width than that of the body 904 positioned between attached end 902a and free end 902b. Spike 903 may have the shape of a sphere or mushroom.

In embodiments, any portion of the medical device including the substrate and/or tissue-gripping elements or members can include a bioactive agent. The term “bioactive agent”, as used herein, is used in its broadest sense and includes any substance or mixture of substances that have clinical use. Consequently, bioactive agents may or may not have pharmacological activity per se, e.g., a dye. Alternatively a bioactive agent could be any agent that provides a therapeutic or prophylactic effect, a compound that effects or participates in tissue growth, cell growth, cell differentiation, and an anti-adhesive compound, a compound that may be able to invoke a biological action such as an immune response, or could play any other role in one or more biological processes. It is envisioned that the bioactive agent may be incorporated into the medical device in any suitable form, e.g., films, powders, liquids, gels, and the like.

Examples of classes of bioactive agents, which may be utilized in accordance with the present disclosure include: anti-adhesives; antimicrobials; analgesics; antipyretics; anesthetics; antiepileptics; antihistamines; anti-inflammatories; cardiovascular drugs; diagnostic agents; sympathomimetics; cholinomimetics; antimuscarinics; antispasmodics; hormones; growth factors; muscle relaxants; adrenergic neuron blockers; antineoplastics; immunogenic agents; immunosuppressants; gastrointestinal drugs; diuretics; steroids; lipids; lipopolysaccharides; polysaccharides; platelet activating drugs; clotting factors; and enzymes. It is also intended that combinations of bioactive agents may be used.

Anti-adhesive agents can be used to prevent adhesions from forming between the medical device and the surrounding tissues of the site of implantation of the device. In addition, anti-adhesive agents may be used to prevent adhesions from forming between the implantable medical device and the packaging material. Some examples of these agents include, but are not limited to hydrophilic polymers such as poly(vinyl pyrrolidone), carboxymethyl cellulose, hyaluronic acid, polyethylene oxide, poly vinyl alcohols, and combinations thereof.

Suitable antimicrobial agents which may be included as a bioactive agent include: triclosan, also known as 2,4,4'-trichloro-2'-hydroxydiphenyl ether, chlorhexidine and its salts, including chlorhexidine acetate, chlorhexidine gluconate, chlorhexidine hydrochloride, and chlorhexidine sulfate, silver and its salts, including silver acetate, silver benzoate, silver carbonate, silver citrate, silver iodate, silver iodide, silver lactate, silver laurate, silver nitrate, silver oxide, silver palmitate, silver protein, and silver sulfadiazine; polymyxin, tetracycline; aminoglycosides, such as tobramycin and gentamicin; rifampicin; bacitracin; neomycin; chloramphenicol; miconazole; quinolones such as oxolinic acid, norfloxacin, nalidixic acid, pefloxacin, enoxacin and ciprofloxacin; penicillins such as oxacillin and piperacillin, nonoxynol 9, fusidic acid, cephalosporins; and combinations thereof. In addition, antimicrobial proteins and peptides such as bovine lactoferrin and lactoferricin B may be included as a bioactive agent.

Other bioactive agents, which may be included as a bioactive agent include: local anesthetics; non-steroidal antifertility agents; parasympathomimetic agents; psychotherapeutic agents; tranquilizers; decongestants; sedative hypnotics; steroids; sulfonamides; sympathomimetic agents; vaccines; vitamins; antimalarials; anti-migraine agents; anti-parkinson agents such as L-dopa; anti-spasmodics; anticholinergic agents (e.g., oxybutynin); antitussives; bronchodilators; cardiovascular agents, such as coronary vasodilators and nitroglycerin; alkaloids; analgesics; narcotics such as codeine, dihydrocodeinone, meperidine, morphine and the like; non-narcotics, such as salicylates, aspirin, acetaminophen, d-propoxyphene and the like;

opioid receptor antagonists, such as naltrexone and naloxone; anti-cancer agents; anti-convulsants; anti-emetics; antihistamines; anti-inflammatory agents, such as hormonal agents, hydrocortisone, prednisolone, prednisone, non-hormonal agents, allopurinol, indomethacin, phenylbutazone and the like; prostaglandins and cytotoxic drugs; chemotherapeutics, estrogens; antibacterials; antibiotics; anti-fungals; anti-virals; anticoagulants; anticonvulsants; antidepressants; antihistamines; and immunological agents.

Other examples of suitable bioactive agents, which may be included in the medical device include: viruses and cells; peptides, polypeptides and proteins, as well as analogs, muteins, and active fragments thereof; immunoglobulins; antibodies; cytokines (e.g., lymphokines, monokines, chemokines); blood clotting factors; hemopoietic factors; interleukins (IL-2, IL-3, IL-4, IL-6); interferons (β -IFN, α -IFN and γ -IFN); erythropoietin; nucleases; tumor necrosis factor; colony stimulating factors (e.g., GCSF, GM-CSF, MCSF); insulin; anti-tumor agents and tumor suppressors; blood proteins such as fibrin, thrombin, fibrinogen, synthetic thrombin, synthetic fibrin, synthetic fibrinogen; gonadotropins (e.g., FSH, LH, CG, etc.); hormones and hormone analogs (e.g., growth hormone); vaccines (e.g., tumoral, bacterial and viral antigens); somatostatin; antigens; blood coagulation factors; growth factors (e.g., nerve growth factor, insulin-like growth factor); bone morphogenic proteins; TGF-B; protein inhibitors; protein antagonists; protein agonists; nucleic acids, such as antisense molecules, DNA, RNA, RNAi; oligonucleotides; polynucleotides; and ribozymes.

The implantable medical devices described herein may be formed using any suitable method known to those skilled in the art. In certain embodiments, one such method may include: providing at least one barbed, biocompatible filament; and combining the at least one barbed biocompatible filament with a biocompatible substrate to form barbed loops along a surface of the biocompatible substrate, and coating at least a portion of the barbed loops with a swellable material. In other embodiments, a method may include: providing a biocompatible substrate

having swellable loops protruding perpendicularly from a surface of the biocompatible substrate; and forming barbs on the loops of the medical device.

In addition, the barbed loops may be treated in any manner suitable to separate the barbed loops into two separate barbed and spiked naps. For example, it may be useful to apply a certain amount of heat and/or pressure to melt the barbed loop thereby separating the loop into two separate naps and by melting the material used to form the loop, the ends of each separate nap will include a spike thus creating a spiked and barbed nap. The barbed loops may be treated using any suitable method, including heated rollers or cylinders, lasers, ovens, ultrasonics, and the like.

It will be apparent from the foregoing that, while particular forms of the implantable medical devices have been illustrated and described, various modifications can be made without departing from the spirit and scope of the present disclosure. For example, although particular barb configurations may be illustrated and described herein, any suitable configuration and arrangement may be possible.

CLAIMS:

What is claimed is:

1. An implantable medical device comprising a biocompatible substrate having a surface comprising at least one swellable grip member.
2. The implantable medical device of claim 1 wherein the at least one swellable grip member is oriented perpendicularly to the surface of the biocompatible substrate.
3. The implantable medical device of claim 1 wherein the biocompatible substrate comprises a bioabsorbable material selected from the group consisting of polylactides, poly(lactic acid), polyglycolides, poly(glycolic acid), poly(trimethylene carbonate), poly(dioxanone), poly(hydroxybutyric acid), poly(hydroxyvaleric acid), poly(lactide-co-(ϵ -caprolactone)), poly(glycolide-co-(ϵ -caprolactone)), polycarbonates, poly(pseudo amino acids), poly(amino acids), poly(hydroxyalkanoate)s, polyalkylene oxalates, polyoxaesters, polyanhydrides, polyortho esters, and copolymers, block copolymers, homopolymers, blends, and combinations thereof.
4. The implantable medical device of claim 1 wherein the biocompatible substrate comprises a non-bioabsorbable material selected from the group consisting of at least one of polypropylene, polyethylene terephthalate, expanded polytetrafluoroethylene, condensed polytetrafluoroethylene and combinations thereof.
5. The implantable medical device of claim 1 wherein the biocompatible substrate is selected from the group consisting of a surgical mesh, patch, buttress, and pledget.

6. The implantable medical device of claim 1 wherein the biocompatible substrate comprises a surgical mesh.

7. The implantable medical device of claim 1 wherein the biocompatible substrate further comprises at least one flap.

8. The implantable medical device of claim 7 wherein the at least one flap comprises at least one swellable grip member.

9. The implantable medical device of claim 1 wherein the at least one swellable grip member comprises a swellable material selected from the group consisting of poly(vinyl alcohol), poly(ethylene glycol) dimethacrylate, poly(ethylene glycol) diacrylate, poly(hydroxyethyl methacrylate), poly(vinyl pyrrolidone), poly(acrylamide), poly(acrylic acid), hydrolyzed poly(acrylonitrile), poly(ethyleneimine), ethoxylated poly(ethyleneimine) and poly(allylamine), and combinations thereof.

10. The implantable medical device of claim 1 wherein the at least one swellable grip members comprises a swellable material comprising a hydrogel.

11. The implantable medical device of claim 1 wherein the at least one swellable grip members is completely swellable.

12. The implantable medical device of claim 1 wherein the at least one swellable grip members is at least partially swellable.

13. The implantable medical device of claim 1 further comprising at least one bioactive agent.

14. The implantable medical device of claim 16 wherein the bioactive agent is selected from the group consisting of anti-adhesives, antimicrobials, analgesics, antipyretics, anesthetics, antiepileptics, antihistamines, anti-inflammatories, cardiovascular drugs, diagnostic agents, sympathomimetics, cholinomimetics, antimuscarinics, antispasmodics, hormones, growth factors, muscle relaxants, adrenergic neuron blockers, antineoplastics, immunogenic agents, immunosuppressants, gastrointestinal drugs, diuretics, steroids, lipids, lipopolysaccharides, polysaccharides, platelet activating drugs, clotting factors, enzymes, and combinations thereof.

15. The implantable medical device of claim 1 wherein the at least one swellable grip member comprises a barbed and spiked nap.

16. The implantable medical device of claim 1 wherein the at least one swellable grip member comprises a barbed loop.

17. A method of forming an implantable medical device comprising:
providing at least one swellable filament; and
combining the at least one swellable filament with a biocompatible substrate to form swellable grip members along a surface of the biocompatible substrate.

18. A method of forming an implantable medical device comprising:
providing a biocompatible substrate having at least one grip member protruding perpendicularly from a surface of the biocompatible substrate; and

applying a swellable material to at least a portion of the at least one grip member of the medical device.

19. A method of forming an implantable medical device having swellable barbed and spiked naps comprising:

providing a biocompatible substrate having swellable loops protruding perpendicularly from a surface of the biocompatible substrate;

forming barbs on the swellable loops of the medical device; and

treating a portion of the loops to melt and separate each loop into two swellable barbed and spiked naps.

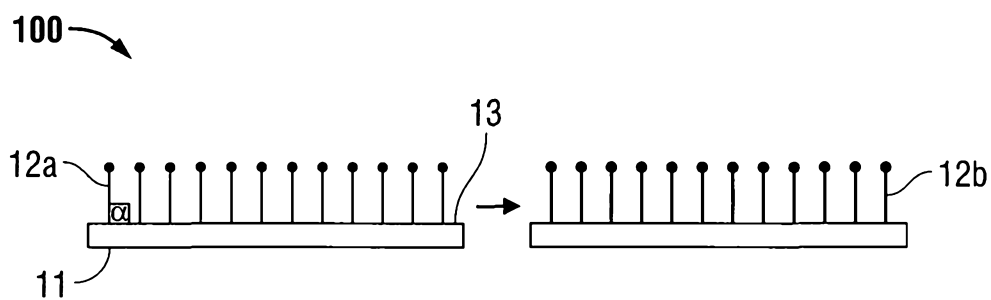
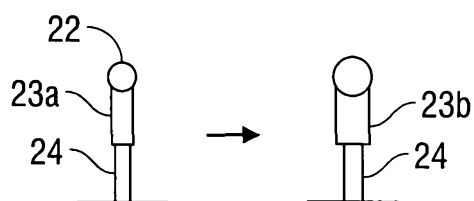
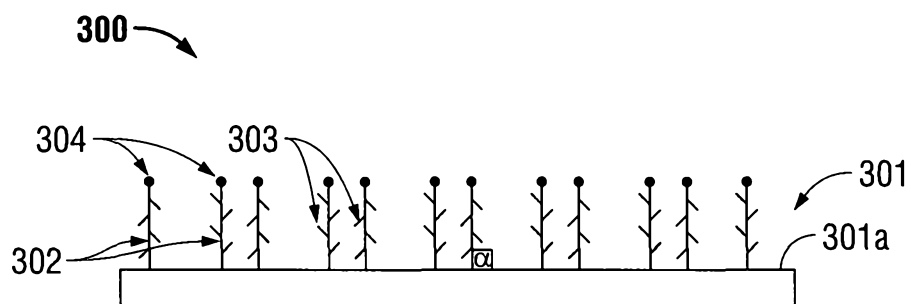
20. A method of forming an implantable medical device having swellable barbed and spiked naps comprising:

providing at least one swellable barbed filament;

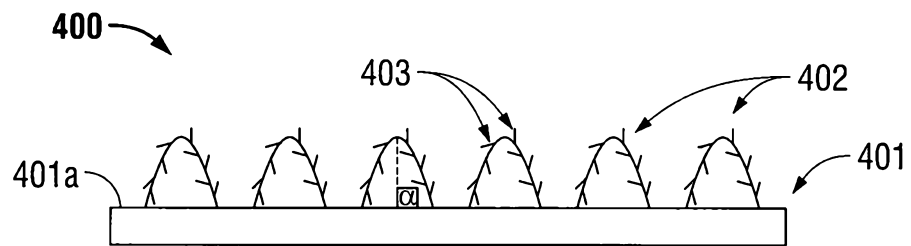
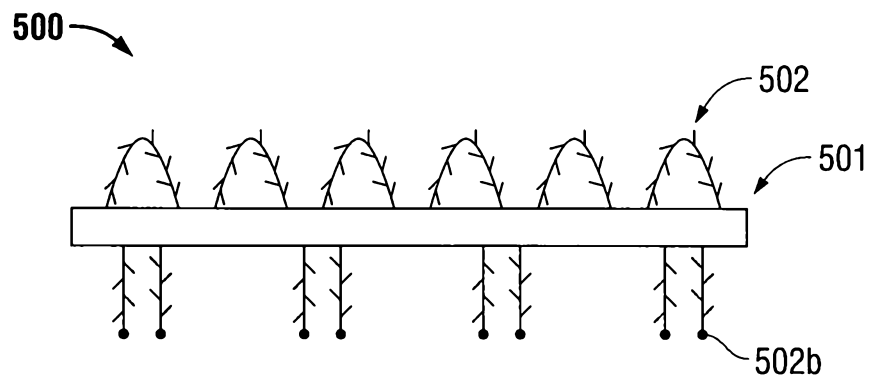
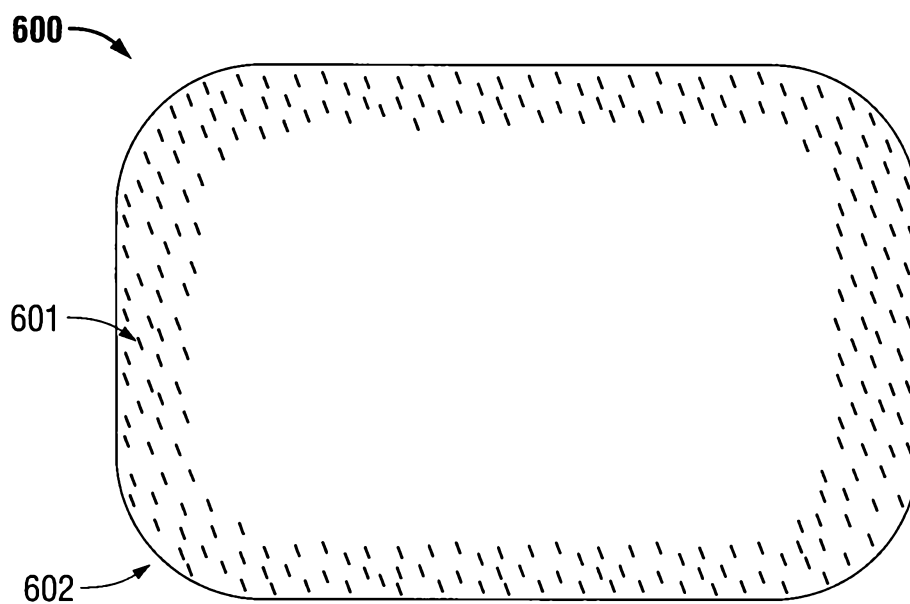
combining the at least one swellable barbed filament with a biocompatible substrate to form at least one swellable barbed looped along a surface of the of the biocompatible substrate; and

treating a portion of the at least one swellable barbed loop to melt and separate each swellable barbed loop into two swellable barbed and spiked naps.

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**FIG. 1****FIG. 2****FIG. 3**

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**FIG. 4****FIG. 5****FIG. 6**

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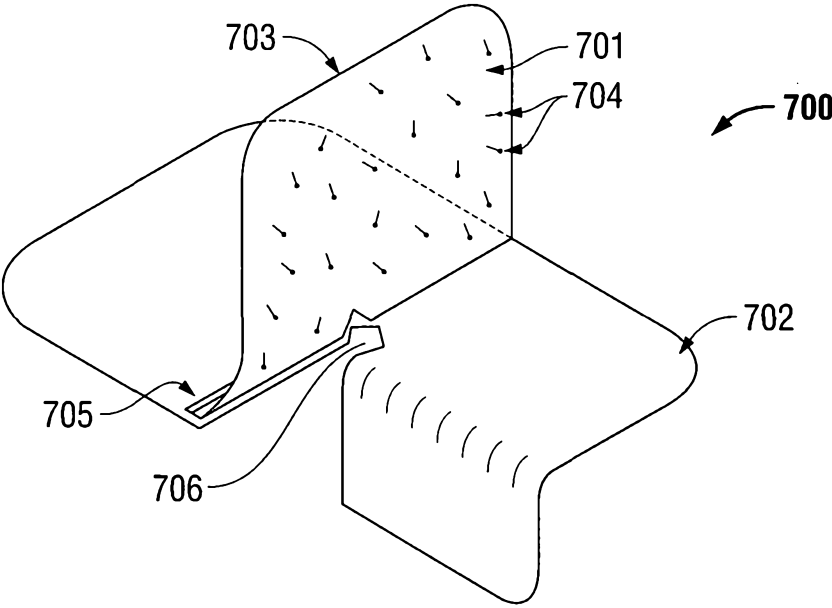


FIG. 7

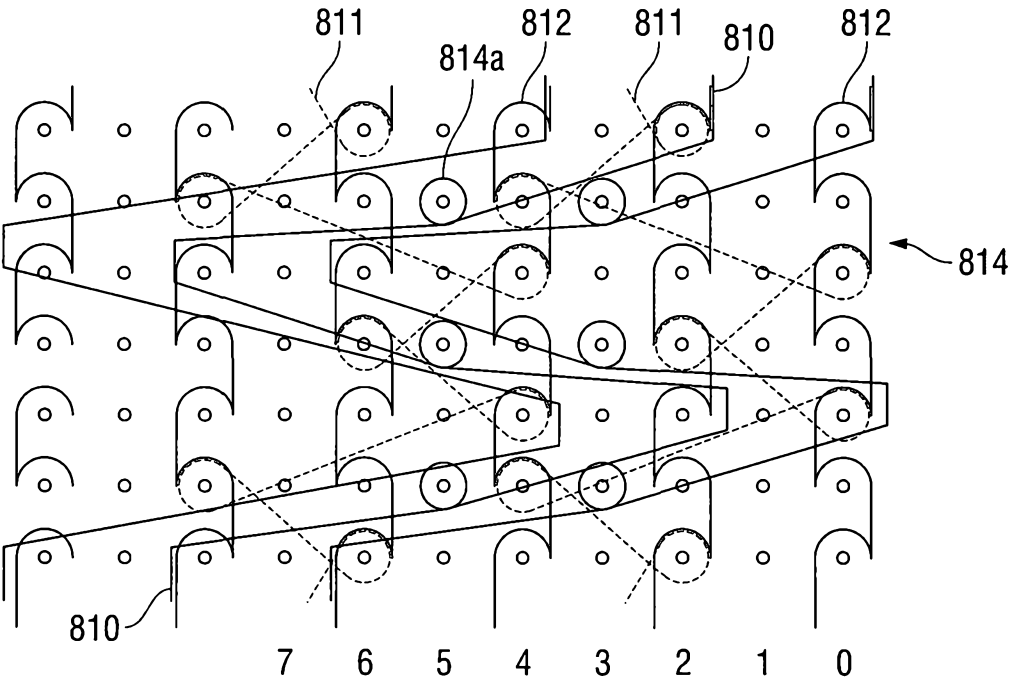


FIG. 8

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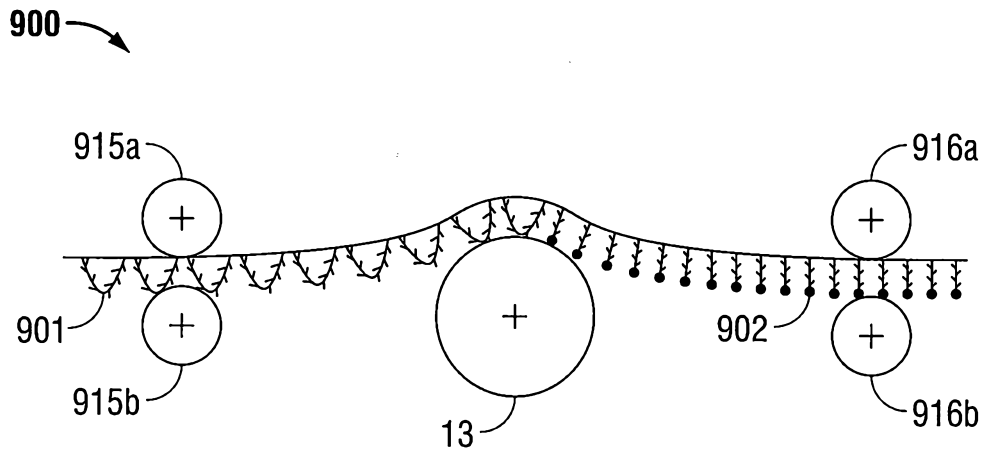


FIG. 9