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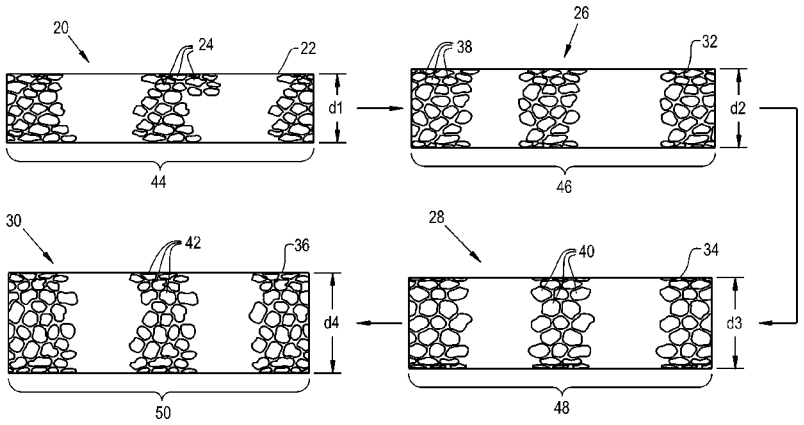


Fig. 2

(57) Abstract: A method of manufacturing a tubular medical implant is provided. The method includes forming a hollow first tube with a first diameter and a first plurality of pores formed thereon and a hollow second tube with a second unstretched diameter and a second plurality of pores formed thereon. The second unstretched diameter is greater than the first diameter. At least a portion of the first tube slides within the second tube to create an overlapped area of the first tube and the second tube. The first tube and second tube are then bonded together in the overlapped area.

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A METHOD OF MANUFACTURING A TUBULAR MEDICAL IMPLANT

Cross Reference To Related Applications

[0001] This is a non-provisional application based upon U.S. provisional patent application serial no. 61/788,738 entitled "POROUS TUBES", filed March 15, 2013, which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] The present invention relates to a method of manufacturing medical implants, and, more particularly, to a method of manufacturing tubular medical implants.

2. Description of the Related Art

[0003] Medical implants are manufactured incorporating various techniques to produce different shapes using biologically compatible materials. One medical implant shape that is commonly used is that of a tubular structure. Tubular medical implants have a wide range of medically useful applications in orthopaedics, cardiology and other areas. One useful feature incorporated into tubular medical implants is a pore pattern on the surface and throughout the implant. By incorporating porosity into the tubular implant, the implant can be given useful properties such as controlled therapeutic release and/or an interface for cell or tissue growth.

[0004] As cell growth mechanics and pharmacokinetics have become better understood, the pore structure of medical implants have become increasingly complex and structured. Such designs requirements of increased complexity have not been met by current production methods, especially in tubular implants that have a relatively high thickness and/or highly variable pore pattern throughout the implant. Of particular difficulty is varying the implant's pore pattern throughout the thickness of the tubular implant.

[0005] One known method of producing tubular medical implants with varied porous structures is to take a base tube, such as a stent, and stretch an elastic, porous graft material over

the stent. When the graft material is properly positioned over the tube, the stretching force is removed which allows the graft material to return to a less stretched state and form a snug fit on the stent. The graft material can then be sewn on to the graft to create a finished stent graft. A problem with this method is that it limits the materials that can be incorporated into the medical implant, is labor intensive and has the risk of permanently changing the pore sizes on the graft material during stretching.

[0006] What is needed in the art is a method that can manufacture tubular medical implants that have complex porous structures from a large variety of materials.

SUMMARY OF THE INVENTION

[0007] The present invention provides a method of creating a tubular medical implant by sliding at least a part of a first porous tube within a second porous tube to create overlapped areas between the first and second porous tubes and then bonding the overlapped areas together.

[0008] The invention in one form is directed to a method of manufacturing a tubular medical implant including the step of forming a hollow first tube with a first diameter and a first plurality of pores thereon. A hollow second tube is formed with a second unstretched diameter and a second plurality of pores formed thereon. The second unstretched diameter is greater than the first diameter. At least a portion of the first tube is slid within the second tube to create overlapped areas between the first tube and the second tube, which are bonded together.

[0009] The invention in another form is directed to a tubular medical implant that includes a first hollow tube, a second hollow tube, and a bonding interface. The first hollow tube includes a first surface with a first plurality of pores formed thereon and the first hollow tube defines a first diameter. The second hollow tube surrounds the first hollow tube and includes a second surface having a second plurality of pores formed thereon. The second hollow tube defines a second unstretched diameter that is greater than the first diameter of the first hollow tube. A bonding

interface is formed between the first hollow tube and second hollow tube to hold the hollow tubes together.

[0010] An advantage of the present invention is that it provides a method to produce tubular medical devices that have complex porous patterns.

[0011] Another advantage is that the method of the present invention allows for precise control of the pore size and distribution in the implant.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] The above-mentioned and other features and advantages of this invention, and the manner of attaining them, will become more apparent and the invention will be better understood by reference to the following description of embodiments of the invention taken in conjunction with the accompanying drawings, wherein:

[0013] Fig. 1 is a perspective view of a porous tube of the present invention;

[0014] Fig. 2 is a perspective step-by-step view of a method of producing a tubular medical implant according to the present invention;

[0015] Fig. 3 is a perspective view of the tubular medical implant produced by the method shown in Fig. 2;

[0016] Fig. 4 is a close-up perspective view of a porous tube of the present invention;

[0017] Fig. 5 is a sectional side view of the porous tube shown in Fig. 4 along line A-A;

[0018] Fig. 6 is a close-up perspective view of another tubular medical implant produced according to the present invention;

[0019] Fig. 7 is a sectional side view of the tubular medical implant shown in Fig. 6 along line A-A;

[0020] Fig. 8 is a close-up perspective view of another porous tube of the present invention;

[0021] Fig. 9 is a sectional side view of the porous tube shown in Fig. 8 along line A-A;

[0022] Fig. 10 is a close-up perspective view of yet another tubular medical implant produced according to the present invention;

[0023] Fig. 11 is a sectional side view of the tubular medical implant shown in Fig. 10 along line A-A;

[0024] Fig. 12 is a close-up perspective view of yet another porous tube of the present invention;

[0025] Fig. 13 is a sectional side view of the porous tube shown in Fig. 12 along line A-A;

[0026] Fig. 14 is a close-up perspective view of yet another porous tube of the present invention;

[0027] Fig. 15 is a sectional side view of the porous tube shown in Fig. 14;

[0028] Fig. 16 a perspective step-by-step view of a method of producing another tubular medical implant according to the present invention; and

[0029] Fig. 17 is a perspective view of the tubular medical implant produced by the method shown in Fig. 16.

[0030] Corresponding reference characters indicate corresponding parts throughout the several views. The exemplifications set out herein illustrate embodiments of the invention and such exemplifications are not to be construed as limiting the scope of the invention in any manner.

DETAILED DESCRIPTION OF THE INVENTION

[0031] Referring now to the drawings, and more particularly to Fig. 1, there is shown a hollow tube 20 which generally includes a tube wall 22 and pores 24 formed in the tube wall 22. As can be seen, the hollow tube 20 has many pores 24 formed through its tube wall 22, but the number of pores 24 can be varied depending on the tube's 20 intended application. The tube wall 22 has

a thickness that can be the same throughout the tube 20 or varied. The tube wall 22 can have any thickness suitable for use at a desired implantation site, including a range from about 0.0001" to greater than 0.04". The tube 20 can be made from any suitable biocompatible material, *e.g.,* titanium, titanium alloys, tantalum, tantalum alloys, cobalt chrome alloys, stainless steel, polyaryletherketone polymers (PAEK), polyetheretherketone (PEEK), polyetherketone (PEK), polyetherketoneketone (PEKK), Ultrapek, polyethylene, polyurethane, alumina and zirconia. Once the tube 20 is formed, the pores 24 can be created in the tube wall 22. The pores 24 can be created by a variety of processes, e.g., chemical etching, photochemical etching, laser cutting, electron-beam machining, conventional machining, stamping, extrusion, rolling and knurling.

[0032] Referring now to Fig. 2, multiple tubes 20, 26, 28, 30 are shown. Each tube 20, 26, 28, 30 has a respective unstretched diameter d1, d2, d3, d4 and a tube wall 22, 32, 34, 36 with pores 24, 38, 40, 42 forming pore patterns 44, 46, 48, 50. The tubes' diameters d1, d2, d3, and d4 vary, with d1<d2<d3<d4. Preferably d1 is not substantially less (>5%) than d2, d2 is not substantially less than d3, and d3 is not substantially less than d4. Each tube wall 22, 32, 34, 36 has a respective thickness that may or may not be equal to the thickness of the other tube walls. Each tube 20, 26, 28, 30 can be made from the same material or different materials, depending on the implant's intended application.

[0033] To produce a finished porous tubular implant 52 (shown in Fig. 3), the tubes 20, 26, 28 with smaller diameters d1, d2, d3 are placed into the tubes 26, 28, 30 with larger diameters d2, d3, d4 sequentially, and bonded together. For example, tube 20 would first be placed within tube 26 to produce a tube (not shown) that has a tube wall thickness substantially equivalent to the thicknesses of tubes 20 and 26 added together. The produced tube also has a 3-dimensional pore architecture that is a combination of pore patterns 44 and 46. Once tube 20 is placed within tube 26, overlapped areas 54 (shown in Fig. 3) of the tubes 20, 26 are created that can be bonded

together to hold tubes 20 and 26 together, if desired, before the intermediate tube is placed within tube 28. Preferably, the diameters d1 and d2 of the tubes 20 and 26 will be relatively similar to each other to allow for a bond interface 56 (shown in Fig. 3) with a negligible thickness or effect on an implant pore pattern 58 of the finished porous tubular implant 52. Once tube 20 is within tube 26, either bonded or not, the tubes 20, 26 are then placed within tube 28, and optionally bonded to tube 28 at overlapped areas. Once tubes 20 and 26 are within tube 28, and optionally bonded, the tubes 20, 26 and 28 are placed within tube 30 and bonded at overlapped areas to form finished tubular implant 52. While finished tubular implant 52 is shown as having the tubes 20, 26, 28 and 30 completely overlapping, it could be desirable to create a tubular implant that has only a partial overlap between some or all of the various component tubes. As previously mentioned, a bond interface 56 is formed between tubes that are bonded together. The bond interface 56 can be formed by the material of tube walls pressing together or be a separable bonding component, such as an adhesive. The method used to bond tubes together can vary based on the tube material(s), but can include, e.g., diffusion bonding, sintering, laser welding, heat staking, thermal processing, ultrasonic welding, mechanical welding and adhesive bonding.

[0034] Figs. 4 and 5 show one embodiment of a section of a tube 60 according to the present invention. Fig. 4 shows a porous microstructure 62 of the section of a porous thin-walled tube 60 of wall thickness *T*. For ease of explanation, tube wall 64 is displayed as flat rather than curved. All pores 66 in this tube wall 64 are through-holes. Struts 68 (which can be referred to as scaffold struts) are defined as the bars of material between the pores 66. Strut width *W* is defined as the smallest dimension of an individual strut 68 on the tube 60 surface. Fig. 5 shows a sectional view of the porous tube 60 in Fig. 4 along line A-A.

[0035] Fig. 6 shows a section of a resulting porous microstructure 70 of porous tubular implant 52 and Fig. 7 shows a section taken along line A-A in Fig. 6. Fig. 7 thus shows one tube wall 72 including four thin-walled tubes 20, 26, 28, 30. The other side of the tube 72 across the diameter of the tube 72 is not shown in Figs. 6 and 7; in other words, the longitudinal axis of the thin-walled tube can be, for example, to the right of the sectional view in Fig. 7, and the longitudinal axis of the assembled tube 72 can be, for example, to the right of the sectional view in Fig. 7.

[0036] Figs. 8 and 9 shows another embodiment of a tube 80 according to the present invention. Figure 8 shows a porous microstructure 82. Fig. 9 shows a portion of a porous thin-walled tube 80 of wall thickness *T*. For ease of explanation, the tube wall 84 is displayed as flat rather than curved. Pores 86 are then created in the tube 80 from both sides 88, 90 of an individual thin-walled tube 80. Different patterns are used to create the pores 86 on each side 88, 90 of the tube 80. A first pore pattern 92 from the outside of the tube 80 transitions to a second pore pattern 94 from the inside of the tube 80 at some location 96 within the tube wall 84. This location 96 is defined as $A*T$, where coefficient A is some fraction of the wall thickness. Coefficient A can range from just greater than 0 to just less than 1. Typically, coefficient A will most likely be on the order of 0.35-0.65.

[0037] To generate a three-dimensional porous tube 100 as shown in Fig. 10, individual thin-walled tubes such as in Fig. 8 are bonded together. In this embodiment of the invention, pore patterns 101, 102, 104, 106 are formed on adjacent sides of adjacent tubes 108, 110, 112 (see Fig. 11). For the three thin-walled tubes 108, 110, 112 bonded together, shown in Fig. 11, tube 108 has pore pattern 101 on a first side 114, and pore pattern 102 on a second side 116. Tube 110 has pore pattern 102 on a first side 118 and pore pattern 104 on a second side 120. Tube 112 has pore pattern 104 on a first side 122 pore pattern 106 on a second side 124. Thus, adjacent thin-walled tubes 108, 110, 112 mate up against identical pore geometries. While the pore

patterns 101, 102, 104, 106 of the thin-walled tubes 108, 110, 112 are shown in Fig. 11 as being aligned to identical pore patterns on adjacent thin-walled tubes 108, 110, 112, the present invention also contemplates mating a tube to another tube with an identical pore pattern on a first side of the tube and a different tube with a non-identical pore pattern on a second side of the tube. The pore patterns 101, 102, 104, 106 can all overlap to create an implant pore (unnumbered) that extends completely through the formed tube wall of porous tube 100.

[0038] Figs. 12 and 13 show another embodiment of a tube 130 according to the present invention. Within a given thin-walled tube 130 of wall thickness T, as can be seen in Fig. 13, the geometry adjacent to a surface 132 can be denoted as a first pore pattern 134. At a thickness of $A*T$, where coefficient A is some fraction of the tube wall thickness T, first pore pattern 134 transitions to a second geometry (pore pattern) 136. Likewise, at a thickness of $B*T$, where coefficient B is some fraction of the tube wall thickness T, second pore pattern 136 transitions to a third geometry (pore pattern) 138. The values of coefficients A and B are such that $0<A<B<1$. The third pore pattern 138 can be different from or identical to the first pore pattern 134.

[0039] The method of the present invention contemplates any number of different geometries being included in a tube wall. Figs. 14 and 15 show a tube wall 140 with five different geometries 142, 144, 146, 148, 150 through a wall thickness T. Geometries 142, 144, 146 and 148 can have respective fraction coefficients A, B, C, D of thickness T that represent the fractional thickness of the corresponding geometry, which can be defined by $0<A<B<C<D<1$. Thus, the thickness of geometry 142 is $A*T$, the thickness of geometry 144 is $B*T$, the thickness of geometry 146 is $C*T$, and the thickness of geometry 148 is $D*T$.

[0040] As described throughout, the number of tubes that can be bonded together according to the present invention to form a porous tubular implant can be varied from a small number (2) of tubes to a large number (>10) of tubes.

[0041] The present invention in one form provides a bone or tissue scaffold including a plurality of layers bonded to one another, each layer having a different pore pattern formed on each side of the layer, adjacent sides of adjacent layers having substantially identical pore patterns which thus align with one another over the course of at least two (for example, two, three, or more) adjacent layers, each layer being formed as a tube, each tube being concentric relative to the other tubes.

[0042] Clinically acceptable bone ingrowth or on-growth surfaces such as BioSync ™ marketed by Sites Medical, beads, plasma spray, or other similar bone or tissue ingrowth or on-growth surfaces can be used.

[0043] The manufacturing method described herein may be used for other purposes as well. One alternative use of this method includes creating a structure that has a layer(s)/tube(s) that is not porous all the way through, or that when aligned (for example, a respective layer) with an adjacent layer a barrier is created to prevent bone or other material, such as a lower melting temperature material, from passing through. In this way, to one side of the barrier, tissue ingrowth can occur; to the other side of the barrier, the lower melting temperature material (which can form a structure beyond the pores) can be retained in the pores.

[0044] Another alternative use of this method includes creating a structure including a layer(s)/tube(s) in the "middle" which has recesses and/or porous sections and including outer layer(s)/tube(s) which are generally solid. The purposes of this include the following: (a) to create a material or product that is lighter by removing material from the wall thickness while leaving the outer or working surfaces unaffected; (b) to create a material or product that has more flexibility and strength in a lighter weight configuration than otherwise possible because of the other size constraints; (c) to provide a method to create regions inside of a product for storage of different materials for a variety of purposes, both medically and non-medically related. While

this method is described in the general application of a tube, this feature can be applied to flat, curved, or other similar geometries.

[0045] Figs. 16 and 17 illustrate a tubular medical implant 160 incorporating porous tubes 162, 164, 166 and a non-porous tube 168. Porous tube 162 is placed within porous tube 164, and optionally bonded together, before being placed within non-porous tube 168. Non-porous tube 168 can act as a barrier to prevent ingrowth of tissues into porous tubes 162 and 164, but can also act as a support tube when placed within porous tube 166 if other tubes (not shown) are being press fitted to porous tube 166. In such a case, non-porous tube 168 can provide strength to resist collapse of porous tube 166 when a pressing pressure and a pressing temperature are applied to the porous tube 166 to press fit another tube on to porous tube 166. Non-porous tube 168 could also be a solid tube acting as a core for porous tubes stacked on top.

[0046] Further, in another embodiment of the present invention, the scaffold of the present invention can be attached (for example, by way of diffusion bonding) to a substrate (such as an implant). The substrate can be an implant and can be made of a variety of materials, including, but not limited to, titanium and/or CoCr.

[0047] While this invention has been described with respect to at least one embodiment, the present invention can be further modified within the spirit and scope of this disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the invention using its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this invention pertains and which fall within the limits of the appended claims.

WHAT IS CLAIMED IS:

1. A method of manufacturing a tubular medical implant, comprising the steps of:

forming a hollow first tube having a first diameter and a first plurality of pores formed thereon;

forming a hollow second tube having a second unstretched diameter and a second plurality of pores formed thereon, said second unstretched diameter being greater than said first diameter;

sliding at least a portion of said first tube within said second tube to create an overlapped area of said first tube and said second tube; and

bonding said first tube to said second tube in said overlapped area.

2. The method according to claim 1, wherein said first plurality of pores forms a first pore pattern and said second plurality of pores forms a second pore pattern.

3. The method according to claim 2, wherein said first pore pattern and said second pore pattern are different patterns.

4. The method according to claim 2, wherein said first pore pattern and said second pore pattern are the same pattern.

5. The method according to claim 2, wherein said bonding step is accomplished using at least one of diffusion bonding, sintering, laser welding, heat staking, thermal processing, ultrasonic welding and adhesive bonding.

6. The method according to claim 2, wherein said bonding step is accomplished by pressing said first tube and said second tube together at a bonding temperature and a bonding pressure.

7. The method according to claim 6, further comprising the step of providing a support rod within said first tube prior to said bonding step.

8. The method according to claim 2, wherein said second tube is in a substantially non-deformed state when sliding over said first tube.

9. The method according to claim 2, further comprising the step of aligning said first pore pattern relative to said second pore pattern prior to said bonding step to form an implant pore pattern.

10. The method according to claim 9, wherein said first tube is composed of at least one of a polymer, a metal and a ceramic and said second tube is composed of at least one of a polymer, a metal and a ceramic.

11. The method according to claim 10, wherein said implant pore pattern includes at least one pore formed through said implantable tubular structure.

12. The method according to claim 10, wherein said first tube and said second tube are aligned such that said first pore pattern and said second pore pattern have no overlap.

13. The method according to claim 2, wherein said first pore pattern and said second pore pattern are created by using at least one of chemical etching, photochemical etching, laser cutting, electron-beam machining, conventional machining, stamping, extrusion, rolling and knurling.

14. A tubular medical implant, comprising:

a first hollow tube including a first tube wall with a first plurality of pores formed thereon, said first hollow tube defining a first diameter;

a second hollow tube surrounding said first hollow tube to form an overlapped area and including a second tube wall with a second plurality of pores formed thereon, said second hollow tube defining a second unstretched diameter that is greater than said first diameter; and

a bonding interface between said first hollow tube and said second hollow tube at said overlapped area.

15. The tubular medical implant of claim 14, wherein said first plurality of pores forms an inner pore pattern and said second plurality of pores forms an outer pore pattern.

16. The tubular medical implant of claim 15, wherein said inner pore pattern and said outer pore pattern together form a plurality of implant pores forming a tubular implant pore pattern.

17. The tubular medical implant of claim 16, wherein a plurality of said implant pores extend entirely through said porous tubular implant.

18. The tubular medical implant of claim 17, wherein at least one of said plurality of implant pores is formed by a partial overlap of one of said first plurality of pores and one of said second plurality of pores.

19. The tubular medical implant of claim 18, wherein said bonding interface is at least one of an adhesive, a deformed material and a melted material.

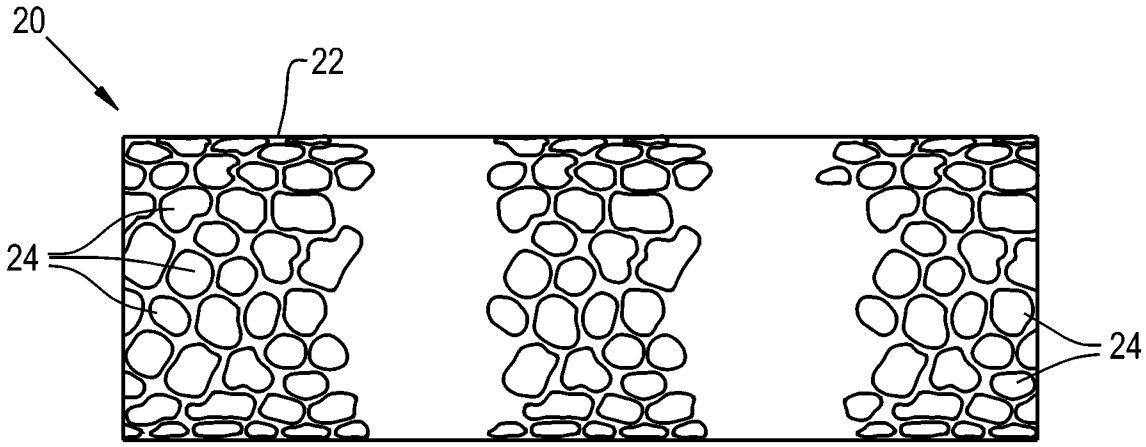


Fig. 1

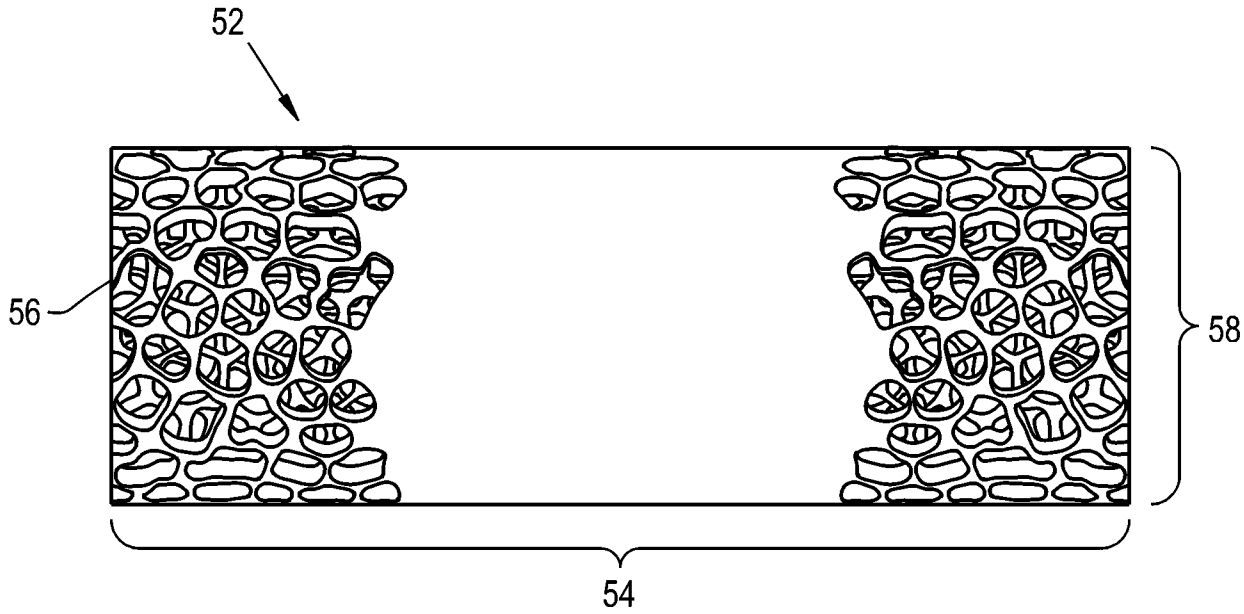


Fig. 3

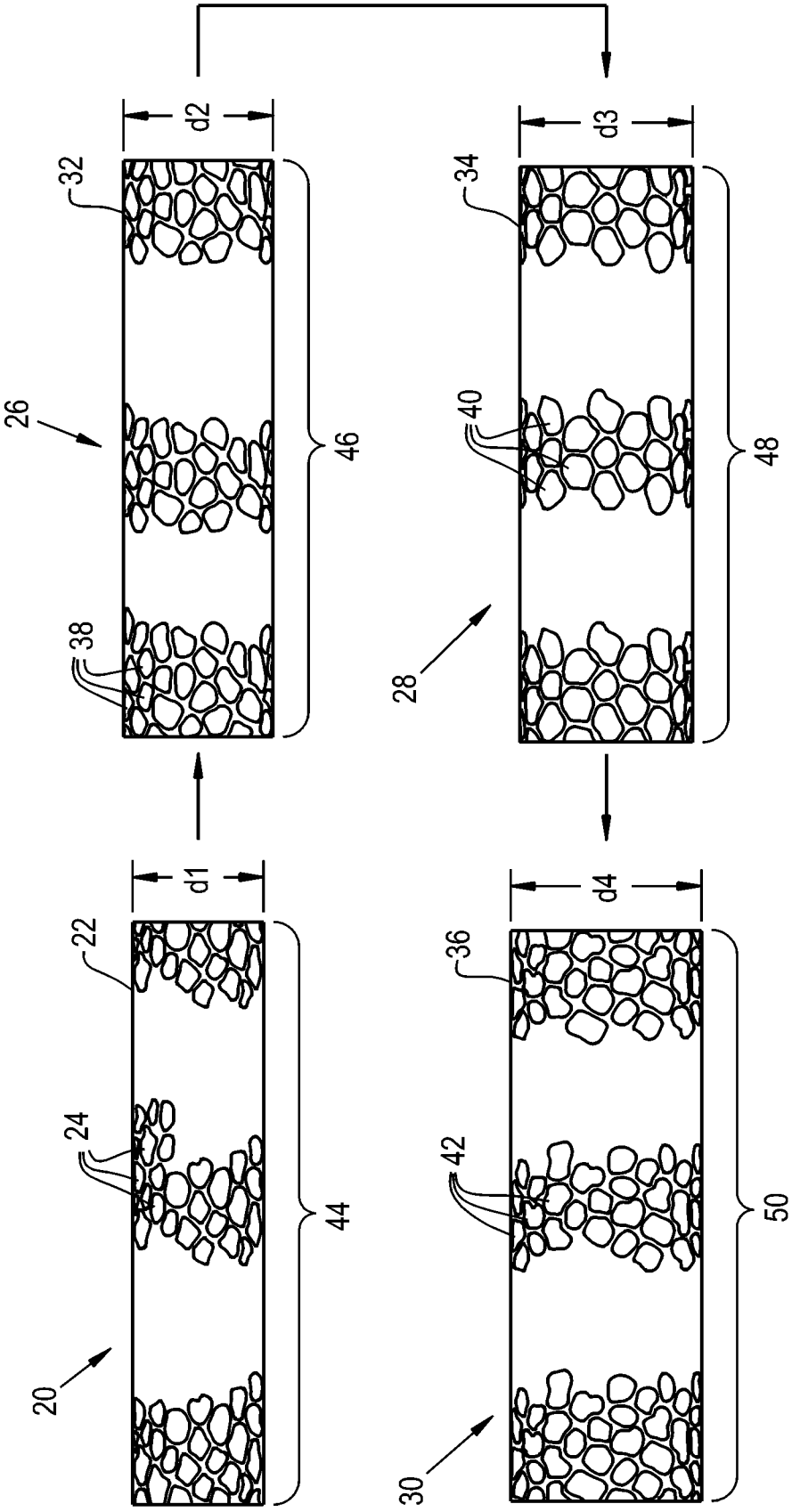


Fig. 2

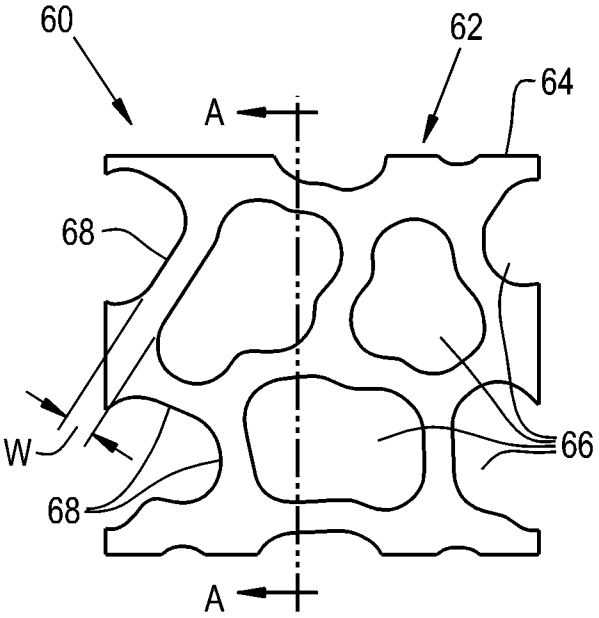


Fig. 4

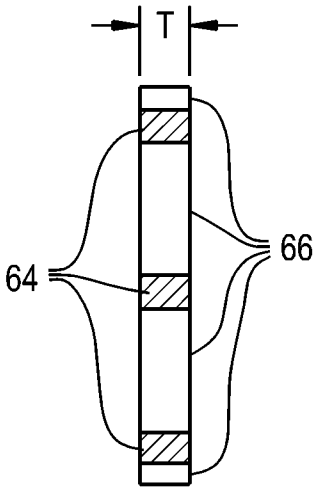


Fig. 5

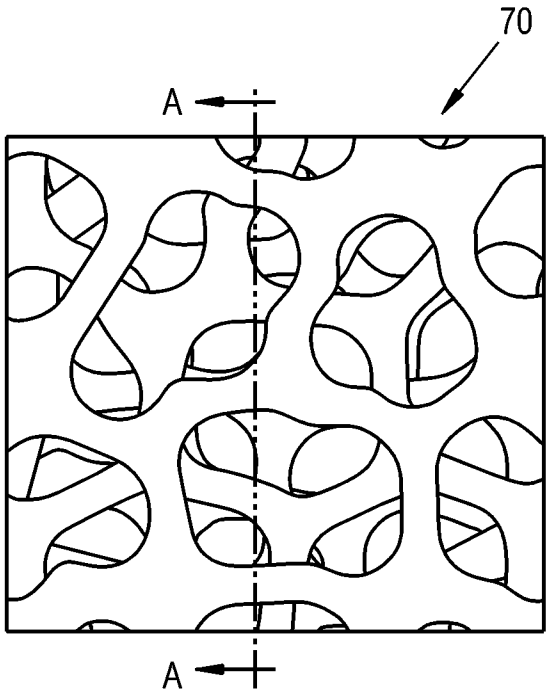


Fig. 6

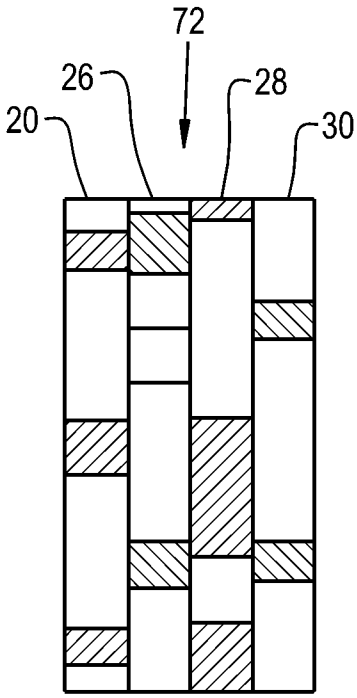


Fig. 7

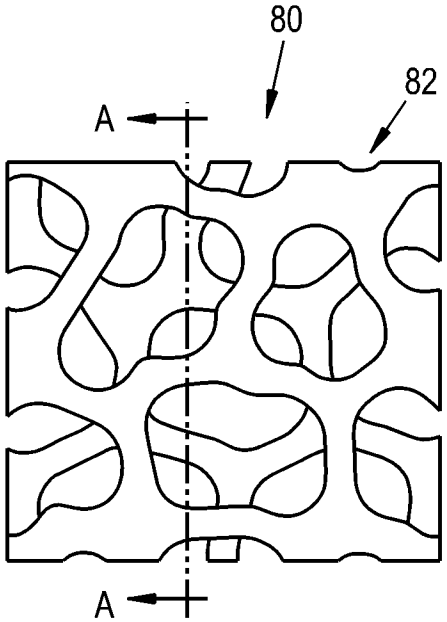


Fig. 8

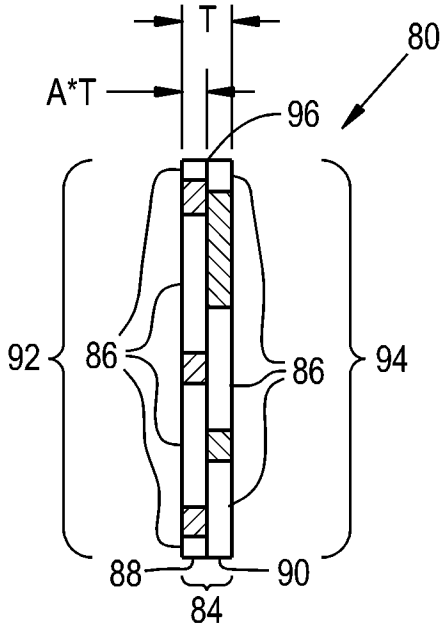


Fig. 9

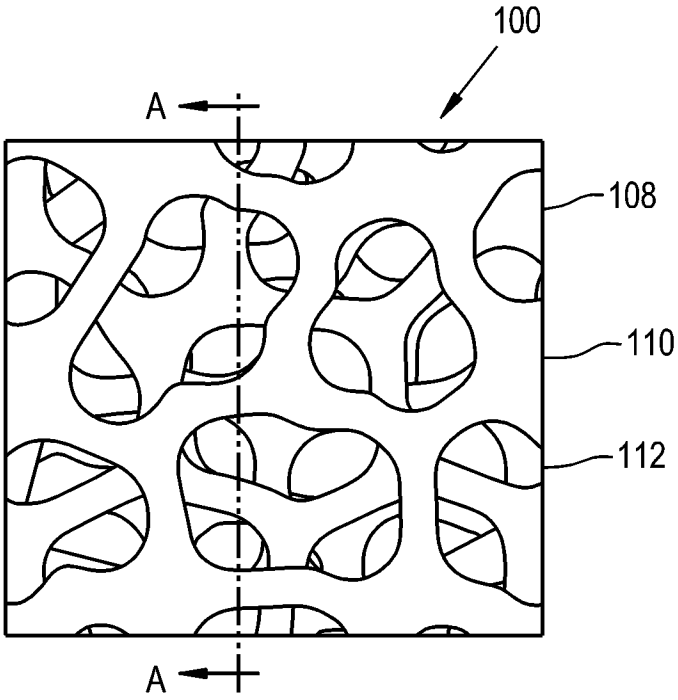


Fig. 10

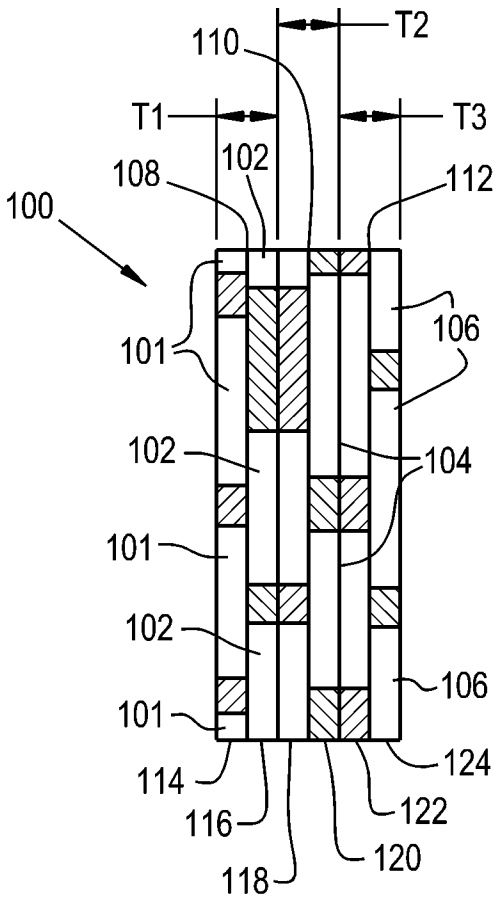


Fig. 11

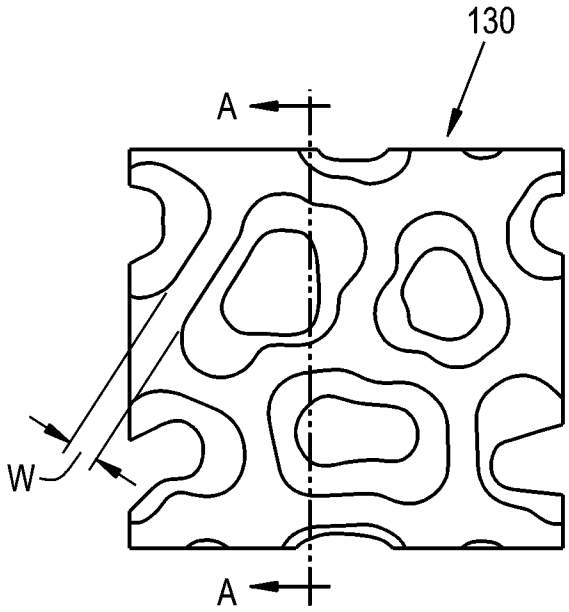


Fig. 12

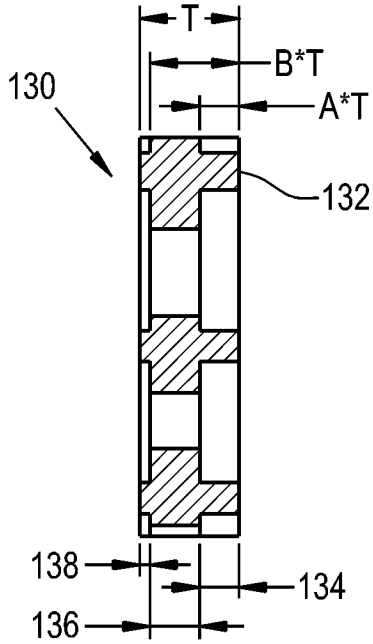


Fig. 13

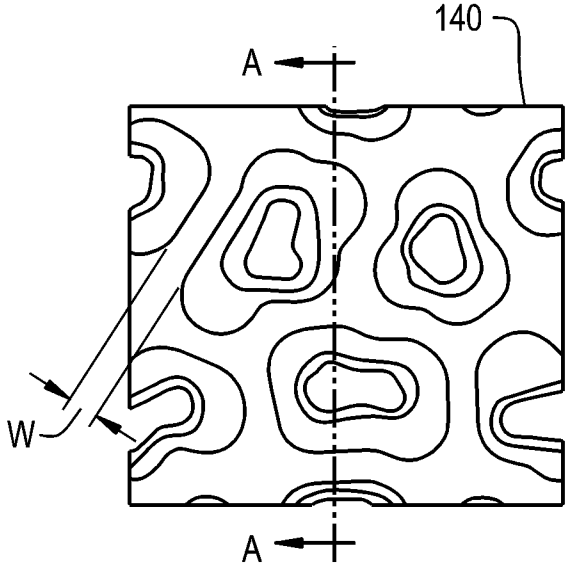


Fig. 14

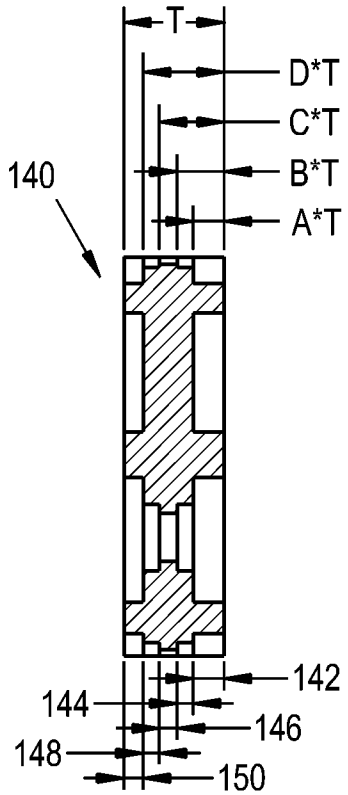


Fig. 15

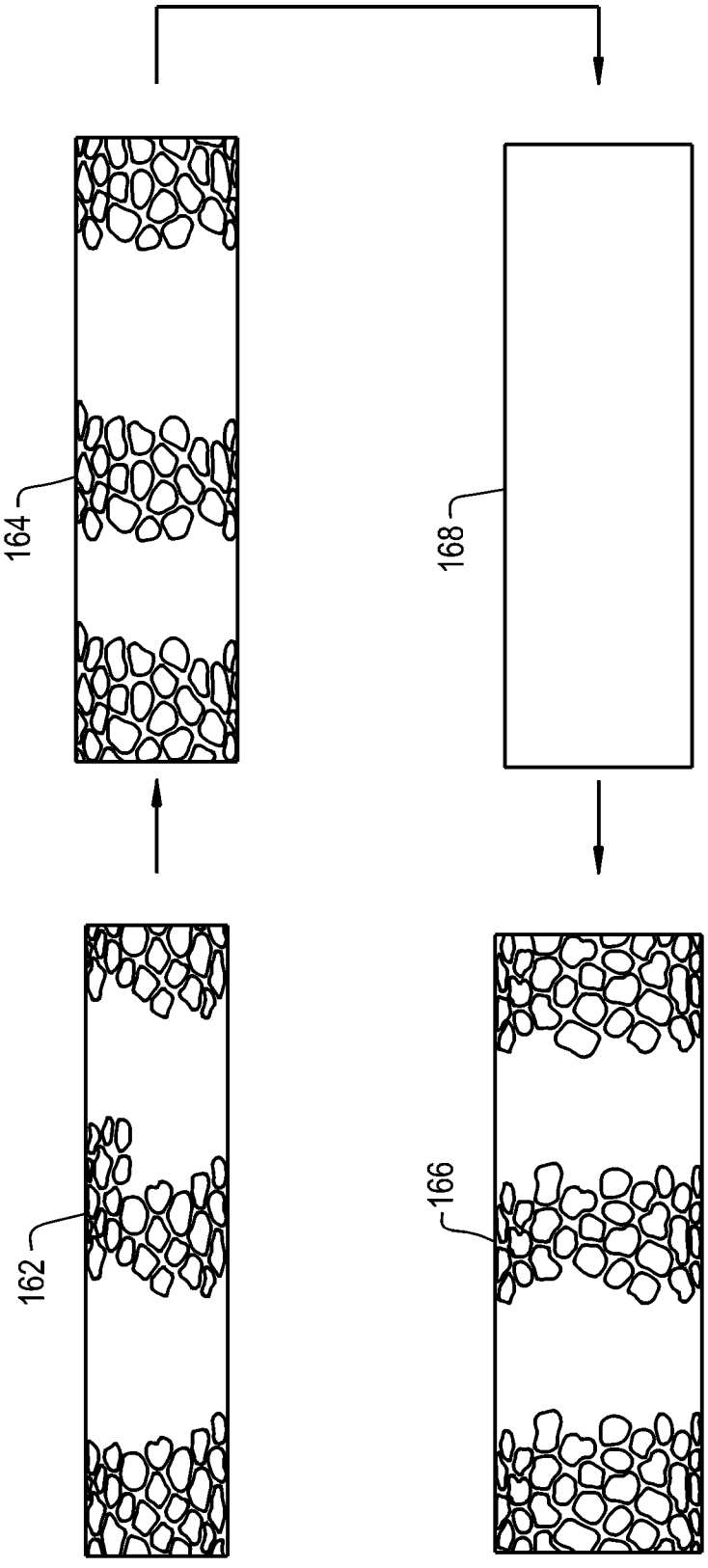


Fig. 16

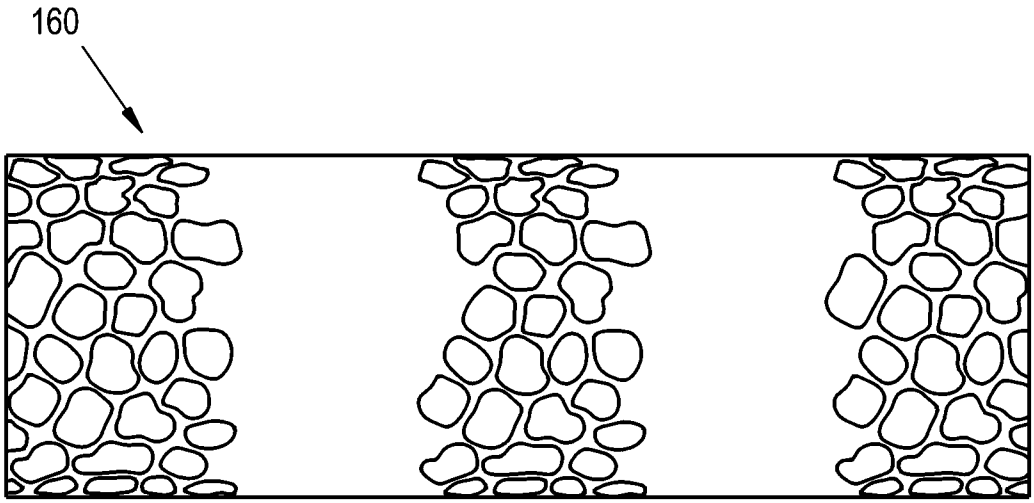


Fig. 17

INTERNATIONAL SEARCH REPORT

International application No.
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A. CLASSIFICATION OF SUBJECT MATTER

A61F 2/04(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F 2/04; A61F 2/06; A61F 2/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: tubular implant, graft, stent, pore, porous, opening, overlap

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003-0130718 A1 (PALMAS, J. C. et al.) 10 July 2003 See abstract; claims 23,30; paragraph [0058]; figures 1-5, 9A-9B.	1-19
A	US 6261320 B1 (TAM, L. A. et al.) 17 July 2001 See abstract; claim 1; column 6, lines 11-64; figures 1-3.	1-19
A	US 5824054 A (KHOSRAVI, F. et al.) 20 October 1998 See abstract; claim 1; column 4, line 54-column 5, line 19; figure 1.	1-19
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A	EP 0938879 A2 (MEDTRONIC AVE, INC.) 1 September 1999 See abstract; claim 1; figure 2.	1-19

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 July 2014 (23.07.2014)	**24 July 2014 (24.07.2014)**

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