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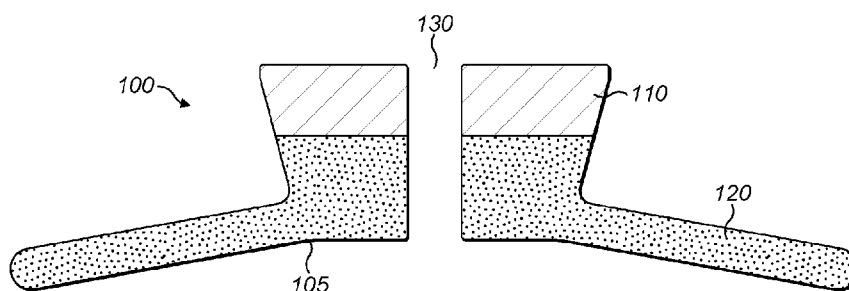


FIG. 1A

(57) Abstract: Described herein is an interface device comprising: a porous member configured to receive soft tissue; wherein the porous member comprises a first and second region arranged about the interface device such that in use the soft tissue is received substantially across the length of the first portion and substantially about the height of the second portion. Preferably, the pore size of the first region is between 300 μ m to 800 μ m, and the height of the second region is substantially the thickness of the received soft tissue. Further described herein, is an interface device comprising a porous member configured to receive soft tissue, wherein the porous member comprises a first and second region arranged about the interface device such that in use the soft tissue is received substantially across the length of the first portion and substantially about the height of the second portion; and a cap portion comprising one or more ports. Preferably, the one or more ports form one or more substantially cylindrical channel through the interface device and each comprising a predefined flange or rim.

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Homeostatic Skin Interface

[0001] The present application relates to a device for maintaining a homeostatic skin interface. In particular, the present invention provides an improved interface device configured
5 for soft tissue integration.

Background

[0002] Percutaneous osseointegrated interface devices have developed to improve coupling with prostheses. Although addressing the patient's need for improved functionality, these
10 systems are prone to infection at the transcutaneous site. To reduce this risk, some of these percutaneous osseointegrated prostheses systems have focussed on forming a seal between the skin of the limb and the implant. Although reducing the risk of infection, these systems have often failed to show long term skin-implant viability or demonstrable mechanical robustness. Similar issues have been known to occur even when these interface devices are
15 configurable for engagement with other types of bone fixation means.

[0003] Additionally, these systems have the major disadvantage of often requiring a patient to undergo multiple surgeries; for example, a patient will normally require a first surgery to create the stump; once this has healed, the patient will be fitted with a threaded bar into the bone; again, its only after this surgery has healed that a further surgery will be scheduled to fit
20 a further bar, mateable with already implanted bar, which protrudes through the skin. It is not uncommon for multiple further corrective surgeries to also be required.

[0004] Further, long term implants are also required for various purposes. For example, for people who require steroid injections to deal with chronic back pain or otherwise, for people who require analyte monitoring, and/or for people who require pacemakers or defibrillators.
25 There is a need to provide these functionalities and/or implants *in vivo* without requiring the user to have multiple procedures and/or face surgical risk (including, by way of example but not limited to, infection, anaesthesia and others) every time something needs adjusting/changing.

[0005] Therefore, there is a need for an improved interface device which addresses the
30 deficiencies in the current state of technology.

[0006] The embodiments described below are not limited to implementations which solve any or all of the disadvantages of the known approaches described above.

Summary

[0007] This Summary is provided to introduce a selection of concepts in a simplified form that are further described below in the Detailed Description. This Summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended to be used to determine the scope of the claimed subject matter; variants and alternative features which facilitate the working of the invention and/or serve to achieve a substantially similar technical effect should be considered as falling into the scope of the invention disclosed herein.

[0008] In a first aspect, there is described an interface device comprising: a porous member configured to receive soft tissue; wherein the porous member comprises a first and second region arranged about the interface device such that in use the soft tissue is received substantially across the length of the first portion and substantially about the height of the second portion.

[0009] In an additional or alternative aspect, there is described an interface device comprising: a porous member configured to receive soft tissue; wherein the porous member comprises a first and second region arranged about the interface device such that in use the soft tissue is received substantially across the length of the first portion and substantially about the height of the second portion, wherein the pore size of the first region is between 300 μm to 800 μm , and wherein the height of the second region is substantially the thickness of the received soft tissue.

[0010] In an additional or alternative aspect, there is described an interface device comprising: a porous member configured to receive soft tissue; wherein the size of the pores of the porous member is between 50 μm to 1.5 mm.

[0011] In an additional or alternative aspect, there is described an interface device comprising: a porous member configured to receive soft tissue, wherein the porous member comprises a first and second region arranged about the interface device such that in use the soft tissue is received substantially across the length of the first portion and substantially about the height of the second portion; and a cap portion comprising one or more ports.

[0012] In an additional or alternative aspect, there is described an interface device comprising: a porous member comprising first and second regions configured to receive soft tissue; wherein the first region is arranged at a position spaced from the second region.

[0013] In an additional or alternative aspect, there is described an interface device for engagement with a device fixable to a bone comprising: a cap portion having a porous

member; wherein the porous member is configured to receive soft tissue; and a collar which when in use abuts the bone.

- 5 **[0014]** In an additional or alternative aspect, there is described an interface device for maintaining a homeostatic barrier, the device comprising: a cap portion; and a porous member configured to receive soft tissue; wherein the porous member extends radially about the cap portion at a predefined distance spaced from the periphery of the cap.

[0015] In an additional or alternative aspect, there is described an interface device comprising: a porous member is configured to receive soft tissue; wherein the porous member comprises a plurality of suture holes.

- 10 **[0016]** Further preferable or optional features of any one or more of the above aspects are described below. It will be appreciated that any one or more of these further preferable or optional features may be combined.

- 15 **[0017]** Preferably, the first and second regions are arranged about the interface device in a substantially non-planar manner. Optionally, the first and second regions are arranged about the interface device at an angle.

[0018] Preferably, the first region is arranged to receive the soft tissue substantially across its length such that the soft tissue substantially rests thereon in use. Preferably, the second region is configured to receive the leading edge of the soft tissue in use. Preferably, the first region is arranged about the interface device at a position spaced from the second region.

- 20 **[0019]** Preferably, the height of the second region, in use, is adaptable. Optionally, the height of the second region, in use, is substantially the thickness of the received soft tissue. Preferably, the height of the second region, in use, is less than the thickness of the received soft tissue. Optionally, the height of the second region, in use, is substantially the thickness of the leading edge of the received soft tissue.

- 25 **[0020]** Preferably, the height of the second region, in use, is less than the thickness of the leading edge of the received soft tissue.

[0021] Preferably, the height of the second region is less than 0.5 mm of the thickness of the received soft tissue or the thickness of the leading edge of the received soft tissue. Optionally, the height of the second region is 4 mm.

- 30 **[0022]** Preferably, the porosity of the pores is variable. Preferably, the first and second portions are arranged about the interface device in a spaced configuration. Optionally, the size of the pores of the porous member is between 200 μm to 1300 μm . Optionally, the

porous member comprises a latticed structure. Optionally, the porous member comprises a square centred latticed structure.

[0023] Preferably, the thickness of the porous member is between less than 1 mm to 6 mm. Preferably, the thickness of porous member is substantially uniform across its length.

- 5 Optionally, the thickness of the porous member is substantially uniform across its length with the periphery of the porous member having a tapered/rounded end. Optionally, the thickness of the porous member is tapered across its length so as to arrive at the periphery at a point, and optionally, where the point may be rounded or pointed.

- 10 **[0024]** Optionally, the combined size of the pores about the porous member is at least 2 times the thickness of the porous member. Optionally, the combined size of the pores about the porous member is at least 3 times the thickness of the porous member. Preferably, the lower bound density of the pores is $1/\text{mm}^3$. Preferably, the thickness and/or pore size of the pores may vary across the porous member. Preferably, the porous member comprises a varying porosity which ranges from a less porous region to a more porous region at its
- 15 periphery.

- 20 **[0025]** Optionally, the surfaces of the pores are smooth. Optionally, the parameters of the porous member are customizable including one or more of the following: the angle (θ), length (l), flange thickness, geometry of the interface surface, number size and location of cross porous member holes, pore structure (size and density), curvature radii and/or relative sizing of sections of the overall profile of the porous member cross-section. Preferably, the porous member is angled in use to be substantially tangential to the natural plane of the soft tissue and/or skin at the implantation site.

- 25 **[0026]** Optionally, the length of the porous member is 5 mm to 35 mm. Preferably, the porous member further comprises reinforcement struts. Optionally, the reinforcement struts secure one or more concentric rings to form a frusto-conical grid or mesh shape. Preferably, the first and second regions are spaced by a solid region. Optionally, the solid region spaces the first and second regions by less than 1 mm to 10 mm. Preferably, the solid region spaces the first and second regions by 3 mm.

- 30 **[0027]** Preferably, the first region is arranged to receive the soft tissue substantially across its length. Preferably, the second region is arranged to receive a leading edge of the soft tissue in use. Optionally, the height of the second region, in use, is adaptable. Preferably, the height of the second region, in use, is substantially the thickness of the received soft tissue. Preferably, the height of the second region, in use, is less than the thickness of the received soft tissue.

[0028] Preferably, the porous member has a substantially uniform shape. Optionally, the shape, dimensions and/or size of the porous member is customizable. Optionally, the shape, dimensions and/or size is adjustable depending on the intended use of the interface device and/or the patient's dimensions. Optionally, adjustable dimensions include one or more of the

5 angle that the porous member protrudes in respect of the interface device, the geometry of connection between the porous member and the interface device including but not limited to the curvature radii of the connection between the porous member and the interface device, the height of the porous member, the relative sizing of profile of the cross-section of the porous member, the length of the porous member and the thickness of the porous member.

10 Preferably, the porosity of the first and second regions is uniform. Optionally, the porosity of the first and/or second regions is non-uniform.

[0029] Preferably, the interface further comprises a collar. Preferably, the collar is load bearing. Optionally, the collar is at least partially porous and/or comprises one or more channels. Optionally, the collar comprises one or more pores have a pore size from 500 μm

15 to 5 mm. Optionally, the pore size is less than 3 mm. Optionally, the collar is cylindrical. Optionally, the collar has tapered sides. Optionally, the collar is substantially conical or frusto-conical. Optionally, the walls of the collar are smooth. Optionally, the walls of the collar have a machined or coarse finish. Optionally, the walls of the collar have a toothed or crenelated arrangement. Optionally, the collar has a non-regular shape. Optionally, the collar has a

20 profile matching the shape of the abutted bone. Optionally, the collar has a 3-D lattice structure.

[0030] Preferably, the interface further comprises a plurality of suture holes. Optionally, the plurality of suture holes are provide spaced about the porous member. Optionally, the suture holes are arranged in pairs. Optionally, a first set of suture holes are provided at a central

25 region of the porous member. Optionally, the first set of suture holes facilitates attachment of the soft tissue onto the porous member. Optionally, a second set of suture holes are provided at the periphery of the porous member. Optionally, the second set of suture holes is used to facilitate fitting or placement of the interface device onto the soft tissue of a patient.

30 Optionally, the first set of suture holes are arranged about the porous member such that in use the soft tissue is affixed to the porous member via a purse string, draw string or peg effect. Optionally, the size of the suture holes are 1 to 5 mm in diameter. Optionally, the diameter of the suture holes is greater than 1.5 mm.

[0031] Preferably, the interface device further comprises a cap portion. Optionally, the cap portion comprises a lower porous surface which in use is arranged to abut soft tissue.

35 Optionally, the lower porous surface extends substantially the entirety of the lower surface of the cap portion. Optionally, the cap portion comprises a substantially solid disk shape with a

specified thickness and a lower porous surface which in use is arranged to abut soft tissue. Optionally, the cap portion comprises a flexible material. Optionally, the flexible material comprises a polymer, and/or optionally, a coated polymer.

- [0032]** Preferably, the interface device further comprises one or more ports. Optionally, the one or more ports extend through the cap portion and/or through the porous member. Optionally, the one or more ports comprise a substantially cylindrical shape. Optionally, the one or more ports comprises a substantially cylindrical channel with a flange or rim. Optionally, the one or more ports comprise a frusto-conical shape. Optionally, the one or more ports have a threaded bore. Optionally, the one or more ports are provided with a surrounding wall or sheathing. Optionally, the sheathing comprises plastic or polymer. Optionally, the sheathing comprises the same material as any tubing, cabling and/or wiring material to pass through the one or more ports. Optionally, the one or more ports may be arranged about the cap portion. Optionally, the one or more ports are arranged to pass through the cap portion and/or the porous region. Optionally, the one or more ports are arranged to pass through the cap portion between the porous region and the soft tissue in use.

- [0033]** Preferably, the cap portion provides at least some surface area not in engagement with soft tissue in use. Optionally, the surface area is adjustable. Optionally, the surface area is adjusted to keep as small as possible whilst providing a surface area for access ports, a collar, and/or any other features. Optionally, one or more tubing, cabling and/or wiring material is provided and is arranged to pass through the one or more ports. Optionally, the one or more cabling and/or wiring is carrying electrical data for control of any device connected to the interface device, optionally via a processor. Optionally, the one or more cabling and/or wiring is internally connected to nerve cuffs or muscle activation sensing electrodes or other electrical connections to or from the nervous system or other internal tissues. Optionally, the one or more cabling and/or wiring connects directly to the biological tissue, and/or connects to one or more internal electronic housings that themselves are connected either directly or via one or more electronic housings to the biological tissue. Optionally, the cap portion further comprises a channel arranged retain/support one or more tubes, cables and/or wires.

- [0034]** Preferably, the cap portion further comprises means for holding/supporting one or more tubes, cables and/or wires. Optionally, the holding/supporting means comprise a frame or support. Optionally, the porous member is integral to the cap portion. Optionally, the porous member and cap portion are mateable. Optionally, mating regions are provided in the porous member and cap portion to facilitate mating.

- [0035]** Preferably, the interface device provides an interface to a means for bone engagement or fixation. Optionally, the interface device provides an interface with an osseointegrated stem, a cemented stem, a smooth press-fitted stem, a plate design and/or any other device suitable for fixation/engagement with a bone.
- 5 **[0036]** Preferably, the interface device maintains a homeostatic barrier. Optionally, the interface device comprises a bio-compatible material. Optionally, the interface device comprises titanium (alloys thereof including Ti6Al4V), stainless steel (and its derivatives), for example having SAE grade 316, high-density polyethylene (HDPE), polylactic acid (PLA), polypropylene (PP) or other polymer or metal, and/or combinations or mixtures thereof.
- 10 **[0037]** The features of each of the above aspects and/or embodiments may be combined as appropriate, as would be apparent to the skilled person, and may be combined with any of the aspects of the invention. Indeed, the order of the embodiments and the ordering and location of the preferable features is indicative only and has no bearing on the features themselves. It is intended for each of the preferable and/or optional features to be interchangeable and/or
- 15 combinable with not only all of the aspect and embodiments, but also each of preferable features.

Brief Description of the Drawings

- [0038]** Embodiments of the invention will be described, by way of example, with reference to the following drawings, in which:
- 20 **[0039]** Figures 1A and 1B are cross-sectional views of interface devices according to exemplary embodiments;
- [0040]** Figure 2 is a cross-sectional view of a prosthetic interface device according to one embodiment;
- 25 **[0041]** Figure 3 is an expanded, cross-sectional view of a portion of the prosthetic interface device of Figure 2;
- [0042]** Figure 4 is a cross-sectional view of a prosthetic interface device according to one embodiment;
- [0043]** Figure 5 is a cross-sectional view of a prosthetic interface device according to one embodiment;
- 30 **[0044]** Figure 6 is a cross-sectional view of a prosthetic interface device according to one embodiment;

- [0045] Figure 7 is a side and bottom view of a prosthetic interface device according to one embodiment;
- [0046] Figure 8A is a cross-sectional view of an interface device according to one embodiment;
- 5 [0047] Figure 8B is a bottom view of the interface device of Figure 6a;
- [0048] Figures 9A, 9B and 9C are cross-sectional views of a prosthetic interface device;
- [0049] Figures 10A, 10B and 10C are cross-sectional views of a prosthetic interface device;
- [0050] Figure 11 is a top view of an interface device according to one embodiment;
- [0051] Figures 12A to 12E are top, side views a prosthetic interface device;
- 10 [0052] Figure 13 is a cross-sectional view of a prosthetic interface device according to one embodiment;
- [0053] Figures 14A and 14B are top view and side view of an interface device, respectively;
- [0054] Figure 15 is a top view of the aperture in the skin when an interface device is being placed there with a preferential suture placement for retaining the soft tissue adjacent to the
- 15 implant edge according to one embodiment; and
- [0055] Figures 16A and 16B are cross-sectional views of a prosthetic interface device and interface device, respectively.
- [0056] Common reference numerals are used throughout the figures to indicate similar features. It should however be noted that even where reference numerals for features used
- 20 throughout the figures vary, this should not be construed as non-interchangeable or distinct. Indeed, unless specified to the contrary, all features referring to similar components and/or having similar functionalities of all embodiments are interchangeable and/or combinable.

Detailed Description

- [0057] Embodiments of the present invention are described below by way of example only.
- 25 These examples represent the best mode of putting the invention into practice that are currently known to the Applicant although they are not the only ways in which this could be achieved. The description sets forth the functions of the example and the sequence of steps for constructing and operating the example. However, the same or equivalent functions and sequences may be accomplished by different examples.

[0058] It should be noted that although exemplary examples, descriptions and/or embodiments are provided under separate headings, these headings should simply serve as a reading aid to provide structure to the description. For the avoidance of any doubt, the features described in any embodiment and/or the embodiments themselves are combinable with the features of any other embodiment and/or any other embodiment unless express statement to the contrary is provided herein. Simply put, the features described herein are not intended to be distinct or exclusive but rather complementary and/or interchangeable.

[0059] Interface geometry

[0060] Figures 1A and 1B are cross-sectional views of interface devices according to exemplary embodiments. The interface devices of these embodiments are designed to maintain a patient's homeostatic barrier. Although these interface devices are configurable for use with osseointegrated stems/devices and/or other means for bone engagement or fixation, they need not be so used. Indeed, it is foreseen that the interface device of these embodiments can have uses with *inter alia* spinal taps, biological monitoring or metering devices as bionic connectors or to provide other passageways; for example, passageways allowing connection of implanted bionic, bioelectronic, electroceutical, neuromodulation, neurostimulation, brain machine interface or brain computer interface devices with an external portion supporting said implanted device(s). The passageway may be used for passing wires or otherwise for power, data, chemical, or optical signals.

[0061] The term "osseointegrated" is used therein is intended to be construed broadly to include use as a cemented stem, a smooth press-fitted stem, a plate design or other means for fixing and/or engaging with a bone including but not limited to any device allowing bone in grow. Therefore, unless specified to the contrary herein, references to the term "osseointegrated" should be considered to be interchangeable with the term "means for bone fixation and/or engagement".

[0062] Figure 1A is cross-sectional view of an interface device according to one embodiment. The interface device 100 of this embodiment is suitable for integration with soft tissue, for example skin. The interface device 100 comprises a cap portion 110 and a surrounding flange 120. In this embodiment, the cap portion 110 and surrounding flange 120 are substantially non-planar, specifically, the cap portion 110 is raised from the surrounding flange 120. It will however be appreciated that the surrounding flange can be substantially planar to and/or extend along a similar path to the cap portion. For example, the surrounding flange can extend substantially from the side of the cap portion 110, preferably such that the surrounding flange 120 is substantially flush with the side of and/or extend along a common path to the cap portion 110. For example, the interface device 100 can be relatively flat and

uniformly round, *e.g.* disc shaped. In alternative embodiments, for example as depicted, the flange 120 may protrude at a downwards trajectory, *e.g.* extending from the side of the cap portion 110 at an angle. The flange 120 may be integral with the cap 120 or may be distinct from but fixable thereto. Although in this embodiment the flange 120 has a substantially uniform shape, it will be understood that this is not required and instead the shape and/or size of the flange 120 may be customizable; for example, the dimensions may be adjusted/able depending on the intended use of the interface device and/or the patient's dimensions.

[0063] Preferably, the flange 120 is designed to allow the patient's soft tissue, such as skin, to grow into it. This configuration enables the homeostatic barrier between internal and external surfaces of the body/patient that is normally provided by the skin to be maintained. In some preferable embodiments, in use, the skin (or other soft tissue) is extended along the length of the flange 120 such that the leading edge of the skin abuts the cap portion 110. It will be appreciated that the skin or other soft tissue need not abut the cap portion 110 to maintain a functional use as a skin fixator between internal and external surfaces of the body, but rather the more coverage the flange 120 provides, the more stabilisation and fixation it provides and hence the less additional artificial means are required to seal the area; for example, by use of surgical glues, grafts, coverings, bandages, etc.

[0064] It will be appreciated that the dimensions of the surrounding flange may be adaptable. The adaptable dimensions may include one or more of the angle that the flange protrudes in respect of the cap portion, the geometry of connection between the flange and the cap portion including but not limited to the curvature radii of the connection between the flange and the cap portion, the height of the porous flange, the relative sizing of profile of the cross-section of the flange, the length of the flange and the thickness of the flange.

[0065] Preferably, the geometry of the flange 120 of the cap portion 110 may be designed to promote soft tissue ingrowth, soft tissue adherence and to minimise stress concentrations (and maximize interface strength) at the skin/device interface when in use (it is also preferably designed to allow long term nutrient supply to the tissues across the length of the flange 120 to maintain long term health).

[0066] A particular advantage has been found as regards the height of the porosity in the area or region where the leading edge of the soft tissue abuts the flange 120 in use. The term "height" in this context is intended to refer to the height as measured in the soft tissue or skin thickness direction, *e.g.* the perpendicular to the flange 120 where it meets the cap 110. Specifically, it has been found that particular advantages arise where the porosity height is substantially equivalent to the thickness of the soft tissue, *e.g.* skin. It has also been found

that these advantages subside where the height of the porosity is larger than the thickness of the skin.

[0067] In one exemplary embodiment, if the skin is expected to be 4.5mm +/- 0.5mm thick, then the height of the porous region where the leading edge of the skin abuts the porous region, it is preferably that the porous region is 4mm tall; such that porosity height is substantially the thickness of the skin but does not exceed it. It will be appreciated that the specific dimensions will be different depending on the patient as well as the intended site of the body. Further detail is provided below, for example as set out in respect of Figures 4A and 4B.

10 **[0068]** For example, the thickness of the flange 120 may be substantially uniform across its length or may vary as will be described in more detail below. In the present embodiment, the thickness of the flange 120 is substantially uniform across its length with the periphery of the flange ending in a tapered/rounded manner. It will however be appreciated that the different configurations may be provided additionally or alternatively. For example, the thickness of the
15 flange might be tapered across its length so as to arrive at the periphery at a point which may be rounded or pointed.

[0069] In the embodiment depicted in Figure 1A, the entirety of the flange and the lower surface 105 (the surface facing the patient in use) of the cap portion 110 is porous. In this embodiment, the cap portion 110 of the interface device 100 comprises a substantially solid
20 disk shape with a specified thickness as its upper portion and a lower or interior surface 105 which is porous. Advantageously, by providing flange 120 which is constructed of an open cell porous material, this enables soft tissue, for example skin tissue to grow into it. Additionally, by providing porous material on the lower surface 105 of the cap portion 110, this enables soft issue, for example muscle tissue, to grow into this interior surface 105 of the interface device
25 100 as well.

[0070] Although in this embodiment, the entirety of the flange and lower surface of the cap comprises a porous material, it will be appreciated that this is not required and only a portion or portions of porosity may be required to achieve the same effect. Not wishing to be bound by theory and as will be discussed in more detail below, it is believed that the more porous
30 the material the more nutrient transfer etc. is facilitated; the flipside being that the more porous the material the weaker the structure. The holes of the porous material are preferably smooth to avoid damage to sutures and/or nutrients flowing through; for example by forming transport capillaries. In the present embodiment, the porous material along the lower surface 105 of the interface device extends along the flange 120/cap portion 110 such

that when the flange receives soft tissue, particularly skin, in use, the soft tissue/skin contacts porous material not only along its inwardly edge, but also at its leading edge.

5 [0071] It will also be appreciated that in alternative embodiments, the cap portion 110 need not comprise a solid disk shape and/or cap shape, but rather could have a rounded shape or any other shape providing surface to allow attachment to the surrounding flange 120, and optionally the osseointegrated or bone fixation device or otherwise, if available.

10 [0072] In the additional or alternative embodiment illustrated in Figure 1B, although the geometrical dimensions of the interface device 150 are substantially congruent to the dimensions of the interface device 100 of Figure 1A, it will be noted that porous material in this embodiment does not extend along the entire lower or inside surface 155 (surface facing the patient in use) of the interface device 150. Instead, the entirety of the flange 170 in this embodiment is porous, as described in respect of Figure 1A, but only a portion of the inside/lower surface 155 of the cap portion 160 is porous. Preferably, and as is depicted, the porous material extends along the flange 170 as well as a portion of the cap portion 160 so that when in use the soft tissue extends along the flange 170 to abut the periphery of the cap portion 160. With this configuration, the leading edge of the skin/soft tissue abuts a porous portion such that the skin/soft tissue can integrate with the porous material on two sides, at the leading edge as well as underneath. Advantageously, the disclosed arrangement affords the benefit of ensuring that all edges/surfaces of the interface device 150 which are in contact with the soft tissue (particularly skin) comprise a porous material, whilst increasing the structural integrity of the interface device 150 and ability to maintain the homeostatic barrier by maintaining a solid or partially solid (e.g. non-porous) core. It will be appreciated that the depicted illustration provides the aforementioned preferable advantage but that alternative arrangements could be envisaged which achieved a substantially similar effect, some such alternative designs being exemplified below.

20 [0073] Although the entirety of the lower surface 155 of the interface device 150 does not comprise porous material, it will be appreciated that this described embodiment still discloses that a majority of the surface area its lower surface 155 comprises porous material. Without wishing to be bound by theory, it is envisaged that the greater the proportion of surface area contact between the lower surface 155 of the interface device 150, the more soft tissue integration during use. In one embodiment, it is preferable that the available porous surface the space that is taken up by holes is at least 3x that of the walls.

30 [0074] Advantages of the aforementioned embodiments, namely where the biological tissue abuts the inner surface of the cap portion, include a minimization of the space between the

interface device 100, 150 and the soft tissue. Without wishing to be bound by theory, it is believed such minimization reduces the risk of infection, edema or internal tissue necrosis.

- [0075]** Preferably, this surface design of the interface device 100, 150 comprises a specified pore size, preferably between 500 μm to 800 μm which, although not wishing to be bound by theory, is based on field wide tissue engineering knowledge of the acceptable range of pore sizes that are viable for cell health. In one exemplary embodiment, the flange 120, 170 comprises a skin compatible surface which may contain pores of the appropriate size further defined herein (for example 200 μm), and a density with a lower bound pore density of $1/\text{mm}^3$ and an upper bound inferred by the pore size.
- [0076]** In one preferable embodiment, the walls are 300 μm thick with 700 μm holes; however, it will be appreciated that the dimensions and porosity may be varied, for example, the thickness of the flange may range from 100 μm to 500 μm thick whilst the pore size may range between 300 μm to 1200 μm , wherein the thickness and/or pore size may vary across the flange.
- [0077]** The interface devices 100, 150 are configured for soft tissue integration. For example, the surrounding flange 120, 170 is configurable to receive soft tissue; for example, the skin and/or muscle of a patient. Advantageously, the interface device 100, 150 in these embodiments, provides mechanical, neural and/or soft tissue integration with a patient. It will be appreciated that the term "patient" should be broadly construed to include both human and animal subjects.
- [0078]** In both Figures 1A and 1B, an access port 130, 180 is disclosed which extends through the interface device 100, 150 to provide a channel or conduit there through. In Figure 1A, the exemplified port 130, extends through the cap portion 110 as well as the flange 120 whereas in view of the alternative construction of the interface device 150 of Figure 1B, the port 180 extends through only the cap portion 160.
- [0079]** Although the access port 130, 180 in these embodiments has a fixed dimension and are located at a predefined position in respect of the interface device 100, 150, namely having a uniform substantially cylindrical shape and extending through substantially the central axis of the interface device 100, 150, this is only exemplary. For example, the port 130, 180 may in fact comprise one or more ports, wherein any one or more of the ports comprise any dimension and shape, uniform or not, and be positioned anywhere on the interface device 130, 180.
- [0080]** Indeed, it will be appreciated that no aperture/port 130, 180 is required.

[0081] The access port 130, 180 may provide access for drainage and/or other biosensing or functionalised materials. The one or more access ports 130, 180 may comprise one or more of the following functions:

[0082] Passage of biosensors for detecting biofilm formation, edema or other conditions;

5 **[0083]** Passage of cables carrying electrical data for control of any device connected to the prosthetic connector, these cables may be internally connected to nerve cuffs or muscle activation sensing electrodes or other electrical connections to or from the nervous system or other internal tissues; equally to allow replacement and/or upgrade of the electronics with minimal disturbance to the body, for example reducing the necessity of major surgery;

10 **[0084]** An aperture through which fluids or gasses can be passed either continuously, periodically or in a single instance either through the port directly or through a conduit that passes through the port for purposes including the promotion and maintenance of tissue health by mechanical stimulation, nutrient flow or other means;

15 **[0085]** Access for surgical procedures including keyhole surgery, this may include for care of the inside of the stump and/or to remove, update, replace and/or reposition internal components of the prosthetic interface device, specifically the nerve cuff; and

[0086] Access for other medical procedures including but not limited to administering of medicines, draining of edema fluid in the stump or care of internal tissues.

20 **[0087]** Additionally or alternatively, the access ports 130, 180 can provide means for additional engagement/integration with a patient. For example, the ports 130, 180 can comprise an integrated or distinct connection means to facilitate mechanical connection between interface device 100, 150 and an osseointegrated device, limb or other physical member, and preferably via an osseointegrated stem portion.

25 **[0088]** The ports 130, 180 can be adapted over time. For example, the ports 130, 180 can be configured to be sealed when implanted, but can be modified in used to open the ports 130, 180 to allow for access as required.

30 **[0089]** Figure 2 is a cross-sectional view of a interface device according to one embodiment. In this exemplary embodiment, the interface device is a prosthetic interface device 200 comprising a cap 210 and a surrounding flange 220. The cap portion 210 in this embodiment is substantially planar and comprises a substantially solid material. However, it will be appreciated that this need not be the case and the cap could have a curved or domed shape nor need the entire portion comprise a solid material. Indeed, it will be appreciated that the

some or all of the properties, dimensions and/or features of the interface device 100, 150 described above could be applied in respect of the present embodiment.

[0090] The surrounding flange 220 of this embodiment extends substantially radially downwards from the cap portion 210 and is substantially porous. In this embodiment, the flange 220 extends from the cap portion 210 specifically extending from the cap at a predefined distance from the periphery or outer edge of the cap 210. The spacing is such that the cap portion 210 extends beyond the point at which the flange 220 engages with or attaches the cap 210, thereby providing a lip or cover. In use, this lip or cover serves as a mechanical or physical means for protecting the soft tissue engaged with the flange 220; advantageously preventing accidental pulling, tension, pressure or otherwise on this area and particularly advantageously providing such protection in respect of the leading edge of the soft tissue.

[0091] The interface device 200 comprises a bio-compatible material. It will be appreciated that it is not essential for the entirety of the interface device 200 or the cap portion 210 to consist of a bio-compatible material, but rather it is preferable that any edges and/or surfaces which in contact with the skin, vascular or muscular tissue of the patient consist substantially thereof. As such, in some embodiments only the surrounding flange 220 or a part thereof and/or the inner surface of the cap portion 210 (i.e. the side of the cap facing the patient in use) or a part thereof may comprise the bio-compatible material. Therefore, although the entire interface device 200 may consist of a bio-compatible material, e.g. only parts of the cap portion 210 in contact with biological tissue will comprise bio-compatible materials. For example, the flange 220 (or any part thereof) and/or a part(s) of the cap portion 210 may comprise titanium (alloys thereof including Ti6Al4V), stainless steel (and its derivatives), for example having SAE grade 316, high-density polyethylene (HDPE), polylactic acid (PLA), polypropylene (PP) or other polymer or metal, and/or combinations or mixtures thereof whether currently known or discovered in future which is found to be suitable for the proposed use.

[0092] The cap portion 200 may comprise a flexible material, for example, but not limited to a polymer which may or may not be coated.

[0093] In this embodiment, the edges of the cap portion 210, specifically where the cap portion 210 meets the flange, are concave for skin integration. This arrangement addresses the need to ensure maintenance of homeostatic barrier which avoids/prevents infection. However, it will be understood that other dimensions, shapes or specifications may be provided.

[0094] As mentioned above, the parameters of the flange 220 which may be customizable including the following: the angle (θ), length (l), flange thickness, geometry of the interface surface, number size and location of cross flange holes, pore structure (size and density), curvature radii and/or relative sizing of sections of the overall profile of the flange cross-section. Preferably, the flange should be angled to be substantially tangential to the natural plane of the soft tissue/skin at the implantation site.

[0095] Although in this example, the flange 220 is at a 45 deg angle to the cap 210, the flange 220 may be angled at any degree, for example at or less than 90 deg, at or less than 80 deg, at or less than 70 deg, at or less than 60 deg, at or less than 50 deg, at or less than 40 deg, at or less than 30 deg, at or less than 20 deg, at or less than 10 deg or any intermediate thereof.

[0096] Preferably, the length of the flange 220 is long enough such that the skin front is shielded from strain under distal skin tension. It will be appreciated that the length of the flange 220 changes dependent on the soft tissue/skin thickness, but that can be simulated in view of the dependence on an orthotropic material property. In some exemplary embodiments, if the thickness of the soft tissue/skin is 4mm thick, the length of the flange should preferably not be less than ~10mm long in order to strain shield the leading edge.

[0097] Although the flange 220 in this embodiment is exemplified as being 15 mm long and 3 mm thick, the flange may be any length including 5 mm, 10 mm, 20 mm, 25 mm, 30 mm to 35 mm or any intermediate thereof and may be any thickness ranging from less than 1 mm, less than 2 mm, less than 3 mm, less than 4 mm, less than 5 mm, less than 6 mm, or any intermediate thereof. It will be appreciated that the length and/or the thickness of the flange 220 need not be uniform and can vary and/or be adjusted to suit. It has been found that a thickness of 3 mm is particular advantageous from a tissue perspective and a thickness of up to 5 mm provides particular advantages in that that flange is strong enough in impact.

[0098] Figure 3 provides an expanded view of a portion of Figure 2 with an optional preferable feature. In this embodiment, the interface device 300 comprises a cap portion 310 and a porous flange 320 extending radially therefrom. As described above, the cap portion 310 comprises a lower surface, or surface facing the patient. As the porous flange 320 is positioned about the lower edge or surface 310 of the cap portion 310, specifically spaced from the edge or periphery of the cap portion 310, an lip or rim 305 is formed at the spaced distance (e.g. between the edge or periphery of the cap portion and the point the flange connects or attached the cap). This lip or rim 305 preferably comprises, at least a portion having a ridged, coarse and/or rough surface/finish. Such finish can be achieved for example during the machining processes before a smoothing process is undertaken. It will be

appreciated that alternative methods of manufacture to achieve a rough or ridged finish maybe achieved. Advantageously, the rough finish of this lower edge portion 305 can aid in securing the soft tissue in use, particularly the leading edge by increasing friction/gripping thereof.

- 5 **[0099]** Although in this embodiment, only a portion of the lower surface of the rim or lip 305 comprises a rough finish, it will be appreciated that any amount of the entire lower surface of the rim or lip 305 can comprise such material for this purpose.

10 **[00100]** It will also be appreciated that the aforementioned preferable arrangement is equally applicable to an interface device, such as those described in respect of Figures 1A and 1B, as well as any homeostatic or prosthetic interface device described herein.

15 **[00101]** Reverting back to the embodiment depicted in Figure 2, the interface device 200 is engaged with an osseointegrated stem portion 230. The osseointegrated stem portion 230 may have any configuration as was known or foreseeable for use in attachment with a bone. As mentioned previously, the stem portion 230 need not be osseointegrated and instead
20 could provide any means suitable for bone engagement or fixation. In this embodiment, the interface device 200 is intended to transmit biomechanical loads from a prosthetic limb into the skeletal system of the patient. In one embodiment, this will be achieved using one or more bone implants that will form the centre of the interface device 200 and will pass through the cap portion 210 as one piece. It will be appreciated that alternative arrangements can be
25 provided. For example, the stem portion 230 need not pass through the cap portion 210, but could be connectable there with by some means of connection, for example via some snap-to-lock or threaded screw arrangement or via used of an adhesive. It will be appreciated that the means for connection may comprise any known arrangement and may be integral to or distinct but additional to the disclosed arrangement.

25 **[00102]** In one embodiment the stem portion 230 comprises a titanium bone implant. However, it will be appreciated that any one or more bone implants can be used and any other material or composition fit for purpose may be used. It will also be appreciated that the stem portion 300 may comprise one or more portions.

30 **[00103]** In alternative embodiments, the bone implant can comprise stainless steel, for example 316 stainless steel, or any other material or composition suitable for being implanted in the bone. The stem portion 230 may further comprise surface coating and may be manufactured in accordance with the state of the art bone integration technology available commercially now or in the future which allows bone integration into the implant.

[00104] When in use, the stem portion 230 may be surgically implanted into the limb of a patient. The stem portion 230 in this embodiment has a tapered edge; however, it will be appreciated that any size and shape which facilitates stable bone integration can be used including arrangements having additional radial or longitudinal ridges or grooves of any size.

5 Indeed, it will be appreciated that the stem portion can be manufactured, having the composition and dimensions, in accordance with the state of the art bone implant technology available commercially now or in the future.

[00105] The stem portion 230 may comprises a protruding bar portion (not shown) that is engageable with cap portion 210 and the prosthetic connector. For example, a bar may be
10 configured such that it directly engages to cap portion 210 and additionally a prosthetic connector which may be adaptable to engage with a particular type of or particular prosthesis, for example in a plug-and-play or key-and-lock attachment manner. In one exemplary embodiment, the top of the bar portion of the stem 230, and/or one or more portions thereof, may comprise a threaded section, compression fitting, bayonet or otherwise to allow for
15 attachment with the prosthetic connector and/or cap portion 210.

[00106] Although the protruding bar portion may be described herein as a bar, it will be appreciated that it need not be a bar or a male connection. Any suitable means configurable or adaptable to connect to the cap portion and a prosthetic connector can be used.

[00107] The prosthetic connector may be a universal connector for attachment by any
20 prostheses and may include but is not constrained by a neural connector. In one preferable embodiment, the bar may comprise two threaded bars, however, it will be appreciated that any means suitable for engaging with the cap portion 210 and the prosthetic connector separately or in unison may be provided.

[00108] By providing an osseointegrated stem portion 230 or other bone fixation means, the
25 interface device 200 is provided with a direct connection to the skeleton, bypassing the soft tissue and reducing the risk of sores often resulting from excessive force of the prosthesis on the skin of the limb. Further, unlike prostheses which are attached to an amputated limb via an osseointegrated device, the present interface device 200 may provide a better mechanical interface between the skin and the device by providing cap portion 230 reducing risk of
30 separation and subsequent infection.

[00109] The interface device 200 discloses a collar 240. In use, it is intended that the collar 240 of the interface device 200 abuts the bone into which the osseointegrated stem 230 is placed. It will be appreciated that although an osseointegrated stem 230 is exemplified herein, in accordance with definition set out previously, it will be appreciated that the stem 230 need
35 not be osseointegrated as such, for example, the device need not be fixated into the bone

itself but may be a cemented stem, a smooth press-fitted stem, a plate design or may comprise any other device suitable for fixation/engagement with a bone. It is envisaged that the collar comprises a smooth face or surface which when fitted sits flush against the bone surface, however, it will be understood that this is not essential and in alternative
5 embodiments a coarse finish is preferable. By providing a load bearing collar, the arrangement affords greater structural integrity and mechanical security of the interface device 200 in use.

[00110] Further, preferably, one or more channels or pores 245 may be provided in the collar 240. Advantageously, these pores 245 can facilitate bone integration by encouraging the
10 bone to grow into them. By allowing the bone to grow into the collar 240, long term stability of the implant is enhanced. Preferably, the size of pores can range from 500 μm to 5 mm. Not wishing to be bound by theory, it is believed that the lower range of pore sizes provides more effective structural bone ingrowth, preferably less than 3 mm. In one exemplary embodiment, the pores are close to 1mm. It will be appreciated that although there are advantages in the
15 lower range of pore sizes, the upper bound may be significantly higher as it is set by the size hole can fit inside the collar as the dimensions of the collar is constrained by the size of the bone and bone canal in use.

[00111] Although in this embodiment the collar 240 has a general cylindrical shape, it will be appreciated that the radius of the collar need not be uniform but rather could have a tapered
20 or substantially conical, or frusto-conical, shape. In some embodiments, it is envisaged that having a larger surface area on the surface where the collar abuts the bone can help with stability whilst extending to a smaller surface area around the cap interface can allow for quicker soft tissue recovery and/or integration underneath the cap.

[00112] Additionally or alternatively, the sides of collar 240 need not be smooth as is depicted. Indeed, the sides could be left expressly with a machined or coarse finish to help
25 facilitate integration. Furthermore, the sides of the collar 240 need not be planar. For example, the sides of the collar 240 could have a toothed or crenelated surface extending along one or more surfaces/edges. This arrangement is particularly advantageous where the collar 240 comprises one or more pores or channels to assist with bone integration. It will also
30 be appreciated that the collar 240 may comprise a non regular shape, for example may have a profile matching the bone face.

[00113] The collar 240 is preferably load bearing. Further discussion regarding the collar may be found at Figure 6 which is equally/additionally applicable here. In some embodiments, the collar has a 3-D lattice structure surrounding a central core, and preferably which is load
35 bearing. The collar 240 may be a 3-D porous load bearing collar (for example as depicted in

Figure 6). By providing a porous structure for the collar, for example with pores that open directly onto the distal cut surface of the bone, supplementary advantages are provided in respect of bone ingrowth.

[00114] It will be appreciated that the radius and/or the surface area of the interface device 200, specifically the cap portion 210 can be any dimension which covers at least a portion of the amputated limb in question. Embodiments include the skin interface device at the full width or partial width of an amputated limb. It has been found that where the interface device 200 is substantially the full surface area of the amputated limb, the surgery is made easier. However, it has also been found that where the interface device 200 has a surface area less than that of the amputated limb, there is less residing of the muscles and any cauterized vessels, for example caused from tissue swelling during/after surgery.

[00115] It will therefore be appreciated that the prosthetic interface device 200 may be designed to cover any amount of the area of the amputated limb; for example, a particular percentage of the limb. In some preferred embodiments, the dimensions of the cap are selected to be as small as possible whilst still providing a surface area for the inclusion of ports, a collar and/or other required features.

[00116] Also, it will be appreciated that not all amputated limbs have the same dimensions and shapes. As such, in certain preferred embodiments, the dimensions of prosthetic interface device 200 may be configurable or adaptable to suit the particular type of limb (e.g. lower leg v. forearm etc.) and/or may be customizable depending on the specifications of the particular patient. For example, as mentioned above, the cap portion 210 of the prosthetic interface device 200 in this embodiment or otherwise need not comprise a disk shape, but instead may comprise a (substantially or semi) conical, (substantially or semi) oblong or any other desired configuration. Furthermore, the cap portion 210, in this embodiment or otherwise, may or may not be rotationally symmetric, particularly advantageous when engaging with limb locations featuring substantially off-centre main bones.

[00117] Not wishing to be bound by theory, it is believed that the larger the surface area of the cap portion 210, the less chance of infection from the wound site, around the skin integration area where the flange 220 adjoins the skin of the amputated limb, spreading to the bone via the osseointegrated device; *i.e.* the more distance between these two features the less chance of infection spreading. Therefore, in one preferred embodiment, the radius of the cap portion 210 is not less than 1 cm and/or the surface area of the cap portion 210 is no less than 10% of the surface area of the amputated limb. However, it will be appreciated that the surface area of the cap portion 210 may be up to 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, or 100% of the surface area of the amputated limb or any percentage therein between.

[00118] Again, not wishing to be bound by theory, it is believed that although there are advantages in providing as large a surface area of the cap portion 210 as possible in respect of the surface area of the amputated limb (for example, to provide distance between the skin integration site and any osseointegrated stem portion), there may be medical challenges in
 5 integrating the cap portion 210 to the amputated limb, specifically the surrounding flange 220 with the skin of the limb where the surface area of the limb is too close to the surface area of the amputated limb.

[00119] The cap portion 220 may comprise titanium, 316 stainless steel, high-density polyethylene (HDPE), polylactic acid (PLA), polypropylene (pp) or other polymer or metal,
 10 and/or combinations or mixtures thereof. In one exemplary embodiment, the cap portion 220 comprises a titanium alloy, optionally a grade 5 alloy such as Ti6Al4V, and could be either 3D printed or machined. Alternative materials include but is not limited to stainless steel (and its derivatives), for example having SAE grade 316 and any other material whether currently known or discovered in future which is found to be suitable for the proposed use.

[00120] Figure 4 is a cross-sectional view of a prosthetic interface device according to one embodiment. The prosthetic interface device 400 of this embodiment comprises each of the features of the prosthetic interface device 200 described above in respect of Figure 2, but for the porosity of the flange 420. It will be appreciated that the specification made in respect of the flange 420 of this embodiment are equally applicable to general soft tissue interface
 15 20 devices such as devices 100, 150 as described in Figures 1A and 1B.

[00121] The flange 420 preferably comprises a biocompatible material, and more preferably a biomimetic surface microstructure as will be described in more detail below. In one additional or alternative embodiment, the material may include porosity at surface, open-celled foam bulk structure, possibility of through-surface pores. Pore sizes may be in the range of 50 μm
 25 to 800 μm . It will be appreciated that the pore size may or may not be uniform and/or the porosity may extend any part or substantially all of the flange 120 and/or cap portion 110. In some embodiments, the pore sizes range from 100 μm to 1300 μm , 150 μm to 700 μm , 200 μm to 650 μm , 250 μm to 600 μm , 300 μm to 550 μm , 350 μm to 500 μm , 400 μm to 450 μm or any combined or intermediate range thereof.

[00122] In one exemplary embodiment, the flange comprises pores having a pore size of 700 μm and a wall thickness of 300 μm . The flange 420 walls may comprise a regular square centred latticed structure so as to have similar properties to soft tissue whilst strengthening the flange. It will be appreciated that although the aforementioned preferable dimensions are exemplified, the dimensions can be adjusted depending the use and/or may vary across the

flange. As will be described in more detail in respect of Figure 8A and 8B, the flange may be provided with reinforcement struts.

[00123] Not wishing to be bound by theory, it is believed that below the lower limit of 50 μm , cells that penetrate are unlikely to survive due to restricted space and lack of nutrients, and above the upper limit of 1.5 mm the strength of the mechanical junction may decrease. The flange may be designed to be porous through substantially its full thickness with the open cell structure.

[00124] The porosity of the flange 420 comprises a varying porosity which ranges from a less porous region where the flange 420 contacts the cap 410 to a more porous region at its periphery. It will be appreciated that the porosity could decrease gradually across the length of the periphery or alternatively there could be distinct portions or zones across the length with different porosities. Not wishing to be bound by theory, it is believed that having a decreased porosity in the region adjacent to the flange joining the cap increases the strength of the flange so it is stronger, where as having an increased porosity nearer the edge improves tissue integration.

[00125] In some preferable embodiments, the flange 420 and/or any other feature comprising a porous material may comprise hydroxyapatite and/or any other material which promotes growth and/or integration of tissue groups.

[00126] Figure 5 is a cross-sectional view of an interface device for use with a bone fixation means according to one embodiment. The interface device 500 of this embodiment comprises each of the features of the prosthetic interface device 200 described above in respect of Figure 2, but for the extent to which the porosity extends along the cap portion 510. It will be appreciated that the interface device 500 need not be configurable to be engaged with a means for bone fixation. As has been mentioned above, it is desirable that each of the surfaces of the interface device 500 which engage with soft tissue are porous. However, it will also be appreciated that introducing porosity also reduces the mechanical strength and stability of the overall structure of the interface device. Therefore, in this embodiment, the porosity extends substantially the length of flange 520. The porosity of the flange 520 can be uniform or non-uniform, as described above in respect of the embodiment of Figure 4 relating interface device 400 and alternative options specified in respect thereof.

[00127] In this embodiment, a further porous portion 515 is provided in the cap 510. In this embodiment, the porous portion 515 is separate or spaced as a distance from, *e.g.* non-adjacent to, the porous flange 520, *i.e.* the porous portions are non-continuous, *e.g.* separated by a solid portion. The porous portion 515 is positioned/arranged on the cap 510 such that in use it is arranged to receive or engage with the leading edge of the soft tissue.

Preferably therefore, the sizing and location of the porous portion 515 is such that it facilitates engagement with the soft tissue whilst ensuring spacing between it and the flange 520.

5 [00128] Preferably, the isolated porous portion at soft tissue/skin front is configured to be equally to, but more preferably less than, the thickness of the soft tissue/skin. For example, the height of this region could be between 4 to 5 mm for pigs and/or 2 to 3 mm for humans. Additional description in this regard has been set out previously in respect of Figure 1.

10 [00129] The width of solid region that separates the two porous sections is preferably around 3 mm but may range from less than 1 mm to 10 mm. Although not wishing to be bound by theory, it is expected that the tissue front may start dying if the thickness of the solid region exceeds this preferred range.

15 [00130] It is believed that by provided spacing or a break between the porous flange and the porous portion (e.g. on the cap) receiving the soft tissue/skin, there is a reducing in the risk of infection caused at the leading edge spreading through the flange whilst maintaining the benefits afforded by embodiments where the soft tissue/skin engages porous material at all surfaces.

20 [00131] Although in this embodiment the porosity is substantially uniform, it will be appreciated that the porosity of the flange 520 and/or the porous portion 515 can have different, non-uniform and/or varying porosities. Furthermore, it should be noted that the specification made in respect of the porous portion 515 of this embodiment is equally applicable to general soft tissue interface devices such as devices 100, 150 as described in Figures 1A and 1B.

25 [00132] Figure 6 is a cross-sectional view of a prosthetic interface device according to one embodiment. The prosthetic interface device 600 of this embodiment comprises each of the features of the prosthetic interface device 200 described above in respect of Figure 2, but for the composition of the collar.

30 [00133] In the prosthetic interface device 200 of Figure 2, collar 240 comprises one or more channels or pores 245 to facilitate bone integration. In this embodiment, collar 640 comprises a porous material for achieving similar effects. Although not wishing to be bound by theory, it is believed that the porous material may facilitate both bone and soft tissue integration. It is believed that the porosity of the collar can be continuous or intermittent and the pore sizes can vary or be uniform. It is also foreseen that the pores and/or channels described above in respect of Figure 2 can also be applied to collar 640 of this embodiment.

[00134] As with the embodiment described above in respect of Figure 2, collar 640 need not have the depicted shape or dimensions, but could be designed to any specification having any dimensions, shape, edge or sides profile.

5 [00135] Figure 7 is a side and bottom view of a prosthetic interface device according to one embodiment. The prosthetic interface device 700 of this embodiment comprises a cap portion 710 and a surrounding flange 720. The interface device 700 further comprises a collar 740 which is configurable to connect with a attachment means for attaching or connecting with a bone. In this embodiment, three side plates 745 are provided which are intended to affix to a bone view screws or other suitable means. The collar 740 is configured to receive the side
10 plates 745 to ensure that the interface device 700 is secured to the bone.

[00136] It will be appreciate that the side plates 745 could be integral with or separate from the collar 740. It will also be appreciated that any means of attachment is available. In alternative embodiments, the side plates 745 could be integral with or connectable directly to the cap portion 710.

15 [00137] Although in the aforementioned embodiment, three side plates 745 are disclosed which are each spaced above the collar 740, it is not essential that three side plates 745 are provided. Indeed, any one or more plates 745 may be provided about the collar 740 and/or cap portion 710. In the present embodiment, the side plates 745 comprise different dimensions and lengths. It will be appreciated that the length and size of any one or more
20 side plate can be adjusted based for example on the type of or size of bone being attached. It is envisaged that this arrangement is particularly preferential for upper arm attachments. Although in this embodiment the side plates 745 are non uniform in length, it will be appreciated that in alternative embodiments the length of each of the side plates 745 may be substantially uniform.

25 [00138] The side plates 745 can provide an alternative or additional means of bone fixation to connection via an osseointegrated device or stem. It will also be appreciated that the plates could in fact comprises a surround ring or cup to encase the bone in use.

[00139] Figures 8A and 8B are cross-sectional and bottom views, respectively, of an interface device according to one embodiment. The interface device 800 of this embodiment comprises
30 a cap portion 810 with a surrounding porous flange 820. In order to provide further mechanical support and/or stability to the flange 820 structure, means 835 for flange reinforcement are provided. In this embodiment, the flange reinforcement means 835 comprises four solid concentric rings spaced about the width of the flange 820. Further solid material bars or struts extending radially outwards from the cap portion 810 are spaced about

the flange 820 and secure the solid concentric rings such that a frusto-conical grid or mesh shape is formed.

[00140] It will be appreciated that the reinforcement means need not have the exemplified shape or dimensions. For example, the means for providing reinforcement or support can comprises any number of rings surrounding the flange and can be any specified width and arrangement; for example, these rings need not be concentric. Additionally, any one or more beams could be provided and can be spaced any point about the cap portion 810. Again, the width and/or the length of these supporting beams can be variable. For example, any one or more beams could extend beyond the outermost ring towards substantially the edge of the flange 620.

[00141] Although in this embodiment, the interface device 820 is a device for soft tissue integration, it will be appreciated that the reinforcement member feature is equally suitable for any device comprising a porous portion or flange, such as for example the prosthetic interface devices of each of Figures 2 through to Figure 5.

15 **[00142]** Ports

[00143] Figures 9A, 9B and 9C are cross-sectional views of a prosthetic interface device depicting ports of various alternative or additional exemplary embodiments. It will be appreciated that the one or more ports illustrated in these embodiments should not be considered to be limiting but rather are exemplary of potential configurations, having particular exemplary dimensions and orientations, which may be used in respect of any interface device and/or prosthetic interface device. Furthermore, it will be appreciated that the any one or more ports described herein may comprise be used in combination with any other one or more ports described herein.

[00144] Figure 9A depicts a cross-sectional view of a prosthetic interface device 900. The one or more ports 930 in this embodiment form a substantially cylindrical channel with a flange or rim around the lower or inner most surface of the interface device 900. In use therefore, the channel formed by the one or more ports 930 will have a wider opening towards the soft tissue of the patient than the outmost opening. Although in this embodiment the lower, wider part of the channel of ports 930 comprises a distinct flange/rim portion, it will be appreciated that a more partially or fully graduated shape may be provided. However, although not wishing to be bound by theory, it is believed that providing a flange, whether inner or outer (although inner is depicted in this embodiment), is preferable for the welding, particularly in the instance of providing a second metal part that seals the port but which optionally may have dedicated electrical contacts passing there through. It will be appreciated that in some alternatives, it is preferably for the flange to be an outer flange, namely in use it faces away

from the person in use. For example, the channel formed from by one or more ports 930 could be substantially frusto-conical in shape. It is envisaged that by providing a larger surface area of the port 930 adjacent to the patient, the port 930 facilitates a great degree and area of access when in use.

5 **[00145]** Figure 9B depicts a cross-sectional view of a prosthetic interface device 900. In Figure 9B prosthetic interface device 900 comprises ports 932 having a threaded bore. Again, it will be appreciated that although in this embodiments, the channels have threaded side walls, the thread can be varied amongst the ports 932. Indeed, the channels need not be substantially cylindrical as is illustrated but as described in respect of 9A may have any
10 desired shape, such as being substantially frusto-conical, or may include a lower flange or rim, either distinct or graduated. By providing a threaded bore, it is believed that the manufacture of the one or more ports 932 is simplified in that a standard drill can be used to produce the ports 932.

[00146] Figure 9C depicts a cross-sectional view of a prosthetic interface device 900. The
15 ports 934 of the prosthetic interface device 900 are substantially cylindrical but are provided with a surrounding wall 936. It will be understood that other shapes or dimensions of the ports 934 are envisaged, for example as those described above. The surrounding wall 936 could be integral to the prosthetic interface device 900 itself or could be distinct therefrom. In additional or alternative embodiments, the surrounding wall 936 could comprise sheathing, for example
20 a plastic material placed in the channel formed by the ports 934 to facilitate ease of use and/or to provide an additional layer to ensure the homeostatic barrier formed by the interface device 900 is substantially intact. For example, the sheathing could be provided with antiseptics or analgesics or otherwise and/or could be positioned during surgery. In some embodiments, this surrounding wall can be replaceable and/or changeable. Again, as with the
25 ports of any other embodiment, although in this embodiment each of the ports 934 comprises the surrounding wall, it will be understood that only one port 934 can be provided in the prosthetic interface device 900 or one or more port types can be provide in the prosthetic interface device 900.

[00147] In one preferable embodiment where sheathing is used, the sheathing may be
30 installed at manufacture and/or be made of such a material (for instance a polymer matching to any tubing cabling and/or wiring material) that could be locally deformed, melted or otherwise to form a seal with the tubing cabling and/or wiring material at the time of device use; and/or any material of choice by the treating clinician.

[00148] Figures 10A, 10B and 10C are cross-sectional views of a prosthetic interface device.
35 It will be appreciated that although the present device is a prosthetic interface device 1000,

the device need not be osseointegrated and/or adaptable to be bone connectable but instead could be a soft tissue interfacing device as described above and herein. Figures 10A, 10B and 10C depict prosthetic interface device 1000 comprising tubing, cabling and/or wiring running through respective ports located at exemplary positions about the prosthetic interface device 1000. It will be appreciated that the (one or more) ports, and respective cabling, may be arranged at any of these exemplary positions, a combination of these locations and/or at alternative locations about the prosthetic interface device 1000.

[00149] Figure 10A is cross-sectional views of prosthetic interface device 1000 wherein the ports 1010 are arranged on the cap 1020 spaced between the flange 1030 and the collar 1040. Any cabling, tubing, wiring etc., extending through the port 1010 channel will pass through the cap 1020 for entry into the soft tissue of the patient in use. It will be understood that although in this embodiment the ports 1010 are radially spaced about the centre point of the cap 1020, the distance need not be uniform. The number and placement of the ports 1010 can be varied as desired.

[00150] By providing a cap portion 1020, spaced from flange 1030, this offers spacing or surface area to allow passage through prosthetic interface device 1000 without having to pass through bone at the same time as ensueing a homeostatic barrier is maintained. This arrangement also has the advantage of limiting the risk of infection getting into the bone or through the channel due to spatial separation as well as reducing interference with the skin leading edge.

[00151] Figure 10B is cross-sectional views of prosthetic interface device 1000 wherein the ports 1012 extend through the cap 1020 and the flange 1030, such that in use any cabling, tubing, wiring etc. passes along the flange into the soft tissue of the patient. It will be appreciated that although in this embodiment the channel formed by the ports 1012 extend the substantially the full length of the flange 1030, the channel need not extend fully, but rather may extend any portion of the flange 1030.

[00152] Figure 10C is cross-sectional views of prosthetic interface device 1000 wherein the ports 1014 are placed about the cap portion 1020 such that the channel formed by the ports 1014 is substantially aligned with the intersection where the skin receiving surface of the flange 1030 engages the lower surface of the cap 1020. In use, any cabling, tubing, wiring etc. extends radially along the skin receiving surface of the flange 1030 for entry into the soft tissue of the patient. This embodiment is particularly advantageous for smaller implants where the cap portion 1020 does not comprise much surface area and therefore it is difficult to find space which does not interfere with the flange and/or an osseointegrated device or collar.

[00153] Although two ports are depicted in each of Figures 10A, 10B and 10C, it will be appreciated that any number of ports may be provided.

[00154] The wires or cables described above may be carrying electrical data for control of any device connected to the interface device, optionally via a processor, may be internally
 5 connected to nerve cuffs or muscle activation sensing electrodes or other electrical connections to or from the nervous system or other internal tissues. It will be appreciated that these wires or cables can connect directly to the biological tissue, for example muscle, without going through any bone (e.g. without needing to go through the stem portion when osseointegrated) and/or these wires or cables can connect to one or more internal electronic
 10 housings that themselves are connected either directly or via one or more electronic housings to the biological tissue, *e.g.* an implanted pulse generator type device.

[00155] These electrodes may comprise a shape, material and/or particular properties, mechanical or otherwise, which are biocompatible and minimize tissue reaction. Additionally, these electrodes may be selected to minimize tissue damage caused from chemical
 15 reactions, toxicity or otherwise. Examples of suitable muscle and/or nerve based electrodes include cuff, needle, sieve or micro array electrodes and/or implantable myoelectric sensors, optical sensors, or similar. Alternative or additional sensors, by way of example only but not limited to, any sensor capable of measuring or receiving neural activity from a neuronal population, any electrode capable of measuring or receiving neural activity from a neuronal
 20 population such as, by way of example only but not limited to, cuff electrodes, paddle electrodes, helical electrodes, book electrodes, lead wire electrodes, stent electrodes, spike array electrodes, conductive polymer electrodes or any other device capable of measuring or receiving neural activity from a neuronal population such as, by way of example only but not limited to, optogenetic sensors. Examples of neural transmitters that may be used in certain
 25 embodiments may be, by way of example only but is not limited to, any electrode capable of controlling or injecting a neural stimulus into a neuronal population, such electrodes may include, by way of example only but not limited to: cuff electrodes, paddle electrodes, helical electrodes, book electrodes, lead wire electrodes, stent electrodes, spike array electrodes, and/or conductive polymer electrodes; or any other apparatus, device or mechanism capable
 30 of controlling and/or injecting or inputting a neural stimulus to a neuronal population such as, by way of example only but not limited to, optogenetic sensors.

[00156] The types of analysis that can be conducted on neural and/or muscular data can include any one or more of: individual nerve and muscle activations; analysis of groups of muscles and nerves; dynamics of firing patterns of nerves or muscles including the timing of
 35 firing such as frequency, rate, interval, shape of firing signal and the distribution pattern across the population of neurons; and the overall changes in electrical potential of the tissue

at one or more sites anywhere within the limb. It should be noted that combinations of any or all of the above may be used simultaneously to improve data quality and that which types of analysis are under use may change dynamically.

5 **[00157]** Figure 11 is a top view of an interface device according to one embodiment. The interface device 1100 comprises four ports 1110 radially spaced about the device. Although in this exemplary embodiment four ports 1110 are illustrated, it will be appreciated that any number of ports 1110 may be provided. Furthermore, it will be appreciated that the one or more ports 1110 need not be spaced uniformly about the interface device 1100.

10 **[00158]** The size and shape of the ports 1110 need not be uniform or similar nor do they need to be circular, creating a substantially cylindrical shaped channel through the interface device. It will be appreciated that one or more of the ports can have any desired shape or dimension.

[00159] Hashed circular lines 1103 and 1105 represent inner and an outermost points, respectively, by which one or more ports 1110 are preferably located. For example, the innermost circular line 1103 for a prosthetic interface device 1110 would preferably be
15 arranged as a location such that the one or more ports 1110 do not interfere with any connection with an osseointegrated stem portion and/or a collar, where applicable. For example, the innermost circle 1103 does preferably not extend further than the outmost edge of the collar and/or the outermost edge of the osseointegrated device. Where the interface device 1110 is not intended for osseointegration, it is foreseen that no innermost circle is
20 required. The outermost circle 1105 defines the outermost points on which one or more ports 1110 are preferably located. This outermost circle 1105 is placed about the device 1110 in line with the intersection between the skin receiving surface of the flange and the cap as per, for example, the port location in Figure 10A. It will be appreciated that if port locations are as detailed in 10B or 10C then the outermost hashed circle 1105 would get larger.

25 **[00160]** Figures 12A to 12E are top, side views a prosthetic interface device depicting additional preferably features. It will be appreciated that although the device 1200 of Figures 12A to 12E are prosthetic interface devices, the teaching is equally applicable to interface devices generally. In these embodiments, various channel specifications are depicted to provide wire or tubing or cabling retaining/supporting means and will accordingly be
30 described. Advantageously, these arrangements protect wire, tubing or cabling protruding from one or more ports by physically protecting and strain shielding the port interface. However, it will be understood that modifications to and/or combinations of any of these embodiments is contemplated herein.

35 **[00161]** Figure 12A illustrates prosthetic interface device 1200 comprising a channel 1280 on the cap portion 1220 extending from the port 1210 configured to receive and/or retain one or

more wires, cables and/or tubing extending therefrom. The channel 1280 may have a uniform depth or may have a slant, sloped or curved depth.

[00162] Figure 12B illustrates an alternative embodiment of prosthetic interface device 1200 wherein the sides of channel 1282 narrow at a point along the channel 1280 such that the one or more wires, cables and/or tubing extending from the port 1210 are retained/secured in place.

[00163] Figure 12C illustrates an alternative embodiment of prosthetic interface device 1200 wherein the channel 1284 has a kink, wriggle or wave so as to secure or retain the one or more wires, cables and/or tubing therein.

[00164] Figure 12D illustrates an alternative embodiment of prosthetic interface device 1200 further comprising a retaining means 1286 extending along side the port 1210 to provide a further mechanical means for holding/supporting the one or more wires, cables and/or tubing. Although in this embodiment, the support or retaining means 1286 comprises a box type structure with a groove or channel for encasing the one or more wires, cables and/or tubing, it will be appreciated that any other suitable shape is possible. For example, the support means 1286 may simply be comprise a frame or support beam to secure the one or more wires, cables and/or tubing along any number of sides; although preferably along at least two sides.

[00165] Figure 12E illustrates an alternative embodiment of prosthetic interface device 1200 wherein the channel 1288 is configured about a post 1290 to enable the one or more wires, cables and/or tubing to wrap around the post for retention thereby.

[00166] Although in each of the aforementioned embodiments the channels are recessed into the cap portion of the interface device, it will be appreciated that this is not necessary and alternatively or additionally could be provided with mechanical means to hold the one or more wires, cables and/or tubing in place.

[00167] Figure 13 is a cross-sectional view of a prosthetic interface device according to one embodiment. In this embodiment, the prosthetic interface device 1300 is modular with each of the component parts configured for engagement with each of the other components. For example, in this embodiment, prosthetic interface device 1300 comprises cap portion or cap 1310 and a porous flange 1320 radially extend from the patient engaging surface of cap 1310. As the present device is a prosthetic interface device 1300, the cap portion 1310 is configured to receive an osseointegrated stem 1350. In this embodiment, the interface device further comprises a collar 1340, which will be understood may be preferable but is not essential. In embodiments where the interface device is not intended for engagement with an osseointegrated stem or bone, it will be appreciated that interface device 1300 need not be

adapted to received a stem portion. Equally, it will be appreciated that prosthetic interface device 1300 can be used in its depicted form even where the device is not intended for use with an osseointegrated stem or bone coupling means, *e.g.* an interface device as otherwise described herein.

5 **[00168]** Mating regions 1330 are depicted in this embodiment are arranged about the cap portion 1310 of the prosthetic interface device 1300. Each of the mating regions 1330 extends through the prosthetic interface device 1300, in this embodiment through the cap portion 1310 and a portion of the osseointegrated stem 1350 specifically, to bolt or otherwise fit the modular components together. It will however be appreciated that the mating regions 1330
10 need not have a thread nor need they go through each of the cap portion 1310 and the osseointegrated stem 1350. Indeed, it will be appreciated that the mating regions 1330 can be placed at any position about the prosthetic interface device 1300 and optionally can be retrofitted once the device has been assembled.

[00169] In this embodiment, the ports 1330 are arranged about the prosthetic interface device
15 1300 in a sunken area 1335 of the cap portion 1310. It will be appreciated that the ports 1330 need not be fitted into recessed portions 1335 of the cap portion 1310.

[00170] Each of the component parts of prosthetic interface device 1300 can be separately modular or can be manufactured as combined pieces; namely the cap portion 1310, the flange 1320, the osseointegrated device 1350 and/or the collar 1340. It will be appreciated
20 that any known means can be used to combine or link the component features. For example, in some embodiments, the modular components can be glued together, in others they can be fastened using fastening means, such as screws, nails, clips or similar, in others, the component parts can be adapted to have mechanical means for attachment, for example a hook and latch, tooth and slot, or any other arrangement operable to combine the component
25 parts.

[00171] In some embodiments, the components could be hinged together to prevent rotation and/or movement about the cap portion 1310 and flange 1320, and collar 1340 and/or osseointegrated stem 1350 where present.

[00172] By providing a prosthetic interface device and/or a interface device that is modular,
30 an increased customisability during placement of the device is afforded. For example, during the placement of the device, the surgeon can select the desired size/shape/type of stem, cap and/or flange independently for that patient and mate the components together in theatre. This means that a wider range of ultimate configurations can be made available for each patient and a decision in this regard can be delayed until such time as the device is being
35 implanted into the patient.

[00173] Suture holes

[00174] Figures 14A and 14B are top view and side view of an interface device, respectively. Interface device 1400 of Figures 14A and 14B comprises a raised cap or cap portion 1410 and a flange 1420 extending radially from the lower or patient engaging surface of the cap 1410. It will be appreciated that although in this embodiment the cap 1410 is raised, the cap 1410 and flange 1420 can be arranged to be substantially planar or follow a substantially conical or other predefined path.

[00175] Around the flange 1420 are sets of holes or apertures. A first series of apertures 1425 are disposed about the flange 1420 substantially adjacent the cap portion 1410. Each of the apertures 1425 is configured in pairs and are spaced around the flange 1420. A second series of apertures 1430 is spaced about the periphery of the flange 1420. Although in this embodiment six pairs for apertures is illustrated on the flange 1410 in respect of each of the first series, adjacent the cap portion 1410, and the second series, adjacent the periphery of the flange 1420, any number of apertures may be provided and may be spaced at any position across the flange 1420. It will be further appreciated that more apertures may be configured about the flange 1420.

[00176] In the present embodiment, it is preferable that the outer, or second series, of apertures 1430, spaced about the periphery of the flange 1420 can be used to facilitate fitting or placement of the interface device 1400 onto the soft tissue of a patient. The inner, or first series, of apertures 1425 surrounding the cap portion 1410 is preferably used to facilitate attachment of the skin or other soft tissue of a patient onto the outer surface of flange 1420. This arrangement is believed to improve placement of the device by improving ease of suturing. However, it will be understood that the apertures 1425, 1430, need not be placed about the flange 1420 as depicted.

[00177] It will be appreciated that although in this embodiment the apertures are set in pairs and are spaced substantially uniformly about the flange 1420, this arrangement is not necessary but is believed to have advantages during surgical fitting of the interface device 1400. Advantageously, by provided spaced pairs, it helps the surgeon keeping track of which holes are being used during suturing and reduces the risk of crossing of skin and muscle sutures.

[00178] These holes or apertures extend through the flange and therefore provide conduits or channels by which nutrients can travel, for example by capillary action or providing space for vascularised tissue to infiltrate.

[00179] Figure 15 is a top view of the aperture in the skin where an interface device is being placed through according to one embodiment. In this embodiment, it is intended that the interface device will be fitted with suture 1550. The suture 1550 in this preferred embodiment is depicted to show a purse string effect to affix the skin around the neck of the flange, e.g. where the flange meets the cap portion of the interface device. Advantageously, this method of affixing the skin about the flange secures the skin in place for healing.

[00180] In one example, the suture 1550 is placed about flange of an interface device such that the suture, string, stands or fibers are threaded or sown through the interface device to stitch the flange of the interface device to the soft tissue of the patient. In this way, the sutures once placed about the flange of the interface device act as a draw string or peg bag to affix the interface device to the respective soft tissue. This arrangement is preferable in that it affixes the soft tissue whilst avoiding tension thereon. It will be understood that an alternative or additional suture arrangement is equally feasible.

[00181] In this embodiment, it is foreseen that the sutures stitching the outer ring or series of apertures (such as those described in Figures 14A and 14B) attach the interface device 1500 to the soft tissue of the patient and preferably provide means for placing or position the device in respect of the patient and the sutures stitching the inner ring or series of apertures (such as those described in Figures 14A and 14B) stitch the skin or other soft tissue of the patient on top of the soft tissue receiving portion of the flange of the interface device 1500.

[00182] Figures 16A and 16B are cross-sectional views of a prosthetic interface device and interface device, respectively. The prosthetic interface device 1600 of Figure 16A and that interface device 1605 of Figure 16B each comprise flange 1620 extending radially from respective caps or cap portions 1610. Flange 1620 comprises channels/suture holes 1625 which extend through the flange.

[00183] The one or more holes, conduits, or channels 1625 pass all the way through the porous flange 1620, at for example regular positions. These holes or conduits may be designed to provide a channel for nutrient flow between, for example, the skin tissues on the outer surface of the flange 1620 and the soft tissue of the patient. It will be appreciated that any number, spacing and size of channels 1625 may be provided.

[00184] It will also be appreciated that such holes or conduits are not required. Indeed, because flange 1620 comprises a porous structure there is the ability for nutrients in fluid to transfer across the flange 1620 such that the skin tissue on the outer surface which in this configuration would ordinarily be isolated from the other tissues can receive nutrients from the bulk muscle tissues abutting the inner surface of the interface device 1600, 1605. However, to further aide in nutrient transfer, it is the intention that in addition to the flange 1620 being

bulk porous that there are specific holes or conduits 1625 that individually cross the full thickness of the flange 1620 so as to allow a freer flow of fluid and nutrients across the flange 1620.

- 5 **[00185]** In one example, the size of the conduits or holes can range from 1 to 5 mm in diameter. However, it will be appreciated that the conduits can be 1 mm, 1.5 mm, 2 mm, 2.5 mm, 3 mm, 3.5 mm, 4 mm, 4.5 mm, 5 mm or any dimension in between. In one preferred embodiment, the diameter of the conduits or holes is 2 mm. Without wishing to be bound by theory, it is believed that diameters under 1.5 mm would suffer from the difficulty that most suture needles would not pass through.
- 10 **[00186]** In one preferred embodiment, the channels, conduits or holes 1625 are formed through flange 1620 by virtue of the apertures (such as those described in Figures 14A, 14B and 15) provided in flange 1620 for suturing purposes. In this preferred embodiment, when the interface device 1605, 1610 is sutured onto the patient, through the apertures (as those described above), channels may still be present around the suture itself. In a preferred
- 15 embodiment, the sutures are biodegradable so that once they have been used to affix the interface device 1605, 1610 onto the soft tissue of the patient, they degrade leaving channels, conduits or holes 1625 to facilitate flow of fluid and nutrients across the flange 1620.

- [00187]** It will be understood that the benefits and advantages described above may relate to one embodiment or may relate to several embodiments. The embodiments are not limited to
- 20 those that solve any or all of the stated problems or those that have any or all of the stated benefits and advantages. Variants should be considered to be included into the scope of the invention.

- [00188]** Any reference to 'an' item refers to one or more of those items. The term 'comprising' is used herein to mean including the method steps or elements identified, but that such steps
- 25 or elements do not comprise an exclusive list and a method or apparatus may contain additional steps or elements.

[00189] Further, as used herein, the term "exemplary" is intended to mean "serving as an illustration or example of something".

- [00190]** Further, to the extent that the term "includes" is used in either the detailed description
- 30 or the claims, such term is intended to be inclusive in a manner similar to the term "comprising" as "comprising" is interpreted when employed as a transitional word in a claim.

[00191] The figures illustrate exemplary methods. While the methods are shown and described as being a series of acts that are performed in a particular sequence, it is to be

understood and appreciated that the methods are not limited by the order of the sequence. For example, some acts can occur in a different order than what is described herein. In addition, an act can occur concurrently with another act. Further, in some instances, not all acts may be required to implement a method described herein.

- 5 **[00192]** It will be understood that the above description of a preferred embodiment is given by way of example only and that various modifications may be made by those skilled in the art. What has been described above includes examples of one or more embodiments. It is, of course, not possible to describe every conceivable modification and alteration of the above devices or methods for purposes of describing the aforementioned aspects, but one of
- 10 ordinary skill in the art can recognize that many further modifications and permutations of various aspects are possible. Accordingly, the described aspects are intended to embrace all such alterations, modifications, and variations that fall within the scope of the appended claims.

Claims

1. An interface device comprising:

a porous member configured to receive soft tissue;

wherein the porous member comprises a first and second region arranged about the
5 interface device such that in use the soft tissue is received substantially across the length of
the first portion and substantially about the height of the second portion.
2. The interface device of claim 1, wherein the first and second regions are arranged
about the interface device in a substantially non-planar manner.
3. The interface device of claim 1 or claim 1, wherein the first and second regions are
10 arranged about the interface device at an angle.
4. The interface device of any preceding claim, wherein the first region is arranged to
receive the soft tissue substantially across its length such that the soft tissue substantially
rests thereon in use.
5. The interface device of any preceding claim, wherein the second region is configured
15 to receive the leading edge of the soft tissue in use.
6. The interface device of any preceding claim, wherein the first region is arranged
about the interface device at a position spaced from the second region.
7. The interface device of any preceding claim, wherein the height of the second region,
in use, is adaptable.
8. The interface device of any preceding claim, wherein the height of the second region,
20 in use, is substantially the thickness of the received soft tissue.
9. The interface device of any preceding claim, wherein the height of the second region,
in use, is less than the thickness of the received soft tissue.
10. The interface device of any preceding claim, wherein the height of the second region,
25 in use, is substantially the thickness of the leading edge of the received soft tissue.
11. The interface device of any preceding claim, wherein the height of the second region,
in use, is less than the thickness of the leading edge of the received soft tissue.

12. The interface device of any preceding claim, wherein the height of the second region is less than 0.5 mm of the thickness of the received soft tissue or the thickness of the leading edge of the received soft tissue.
13. The interface device of claim 12, wherein the height of the second region is 4 mm.
- 5 14. The interface device of any preceding claim, wherein the porosity of the pores is variable.
15. The interface device of any preceding claim, wherein the first and second portions are arranged about the interface device in a spaced configuration.
16. The interface device of any preceding claim, wherein the size of the pores of the porous member is between 200 μm to 1300 μm .
- 10 17. The interface device of any preceding claim, wherein the porous member comprises a latticed structure.
18. The interface device of claim 17, wherein the porous member comprises a square centred latticed structure.
- 15 19. The interface device of any preceding claim, wherein the thickness of the porous member is between less than 1 mm to 6 mm.
20. The interface device of any preceding claim, wherein the thickness of porous member is substantially uniform across its length.
21. The interface device of any of claims 1 to 19, wherein the thickness of the porous member is substantially uniform across its length with the periphery of the porous member having a tapered/rounded end.
- 20 22. The interface device of any of claims 1 to 19, wherein the thickness of the porous member is tapered across its length so as to arrive at the periphery at a point, and optionally, where the point may be rounded or pointed.
- 25 23. The interface device of any preceding claim, wherein the combined size of the pores about the porous member is at least 2 times the thickness of the porous member.
24. The interface device of any preceding claim, wherein the combined size of the pores about the porous member is at least 3 times the thickness of the porous member.

25. The interface device of any preceding claim, wherein the lower bound density of the pores is $1/\text{mm}^3$.
26. The interface device of any preceding claim, wherein the thickness and/or pore size of the pores may vary across the porous member.
- 5 27. The interface device of any preceding claim, wherein the porous member comprises a varying porosity which ranges from a less porous region to a more porous region at its periphery.
28. The interface device of any preceding claim, wherein the surfaces of the pores are smooth.
- 10 29. The interface device of any preceding claim, wherein the parameters of the porous member are customizable including one or more of the following: the angle (θ), length (l), flange thickness, geometry of the interface surface, number size and location of cross porous member holes, pore structure (size and density), curvature radii and/or relative sizing of sections of the overall profile of the porous member cross-section.
- 15 30. The interface device of any preceding claim, wherein the porous member is angled in use to be substantially tangential to the natural plane of the soft tissue and/or skin at the implantation site.
31. The interface device of any preceding claim, wherein the length of the porous member is 5 mm to 35 mm.
- 20 32. The interface device of any preceding claim, wherein the porous member further comprises reinforcement struts.
33. The interface device of claim 32, wherein the reinforcement struts secure one or more concentric rings to form a frusto-conical grid or mesh shape.
- 25 34. The interface device of any preceding claim, wherein the first and second regions are spaced by a solid region.
35. The interface device of claim 34, wherein the solid region spaces the first and second regions by less than 1 mm to 10 mm.
36. The interface device of claim 35, wherein the solid region spaces the first and second regions by 3 mm.
- 30

37. The interface device of any preceding claim, wherein first region is arranged to receive the soft tissue substantially across its length.
38. The interface device of any preceding claim, wherein the second region is arranged to receive a leading edge of the soft tissue in use.
- 5 39. The interface device of any preceding claim, wherein the height of the second region, in use, is adaptable.
40. The interface device of any preceding claim, wherein the height of the second region, in use, is substantially the thickness of the received soft tissue.
41. The interface device of any preceding claim, wherein the height of the second region,
10 in use, is less than the thickness of the received soft tissue.
42. The interface device of any preceding claim, wherein the porous member has a substantially uniform shape.
43. The interface device of any preceding claim, wherein the shape, dimensions and/or size of the porous member is customizable.
- 15 44. The interface device of any preceding claim, wherein shape, dimensions and/or size is adjustable depending on the intended use of the interface device and/or the patient's dimensions.
45. The interface device of claim 44, wherein adjustable dimensions include one or more of the angle that the porous member protrudes in respect of the interface device, the
20 geometry of connection between the porous member and the interface device including but not limited to the curvature radii of the connection between the porous member and the interface device, the height of the porous member, the relative sizing of profile of the cross-section of the porous member, the length of the porous member and the thickness of the porous member.
- 25 46. The interface device of any preceding claim, wherein the porosity of the first and second regions is uniform.
47. The interface device of any of claims 1 to 45, wherein the porosity of the first and/or second regions is non-uniform.
48. The interface device of any preceding claim, further comprising a collar.
- 30 49. The interface device of claim 48, wherein the collar is load bearing.

50. The interface device of any of claims 48 or 49, wherein the collar is at least partially porous and/or comprises one or more channels.
51. The interface device of any of claims 48 to 50, wherein the collar comprises one or more pores have a pore size from 500 μm to 5 mm.
- 5 52. The interface device of claim 51, wherein the pore size is less than 3 mm.
53. The interface device of any of claims 48 to 52, wherein the collar is cylindrical.
54. The interface device of any of claims 48 to 52, wherein the collar has tapered sides.
55. The interface device of any of claims 48 to 52, wherein the collar is substantially conical or frusto-conical.
- 10 56. The interface device of any of claims 48 to 55, wherein the walls of the collar are smooth.
57. The interface device of any of claims 48 to 55, wherein the walls of the collar have a machined or coarse finish.
58. The interface device of any of claims 48 to 55, wherein the walls of the collar have a
15 toothed or crenelated arrangement.
59. The interface device of any of claims 48 to 58, wherein the collar has a non-regular shape.
60. The interface device of any of claims 48 to 59, wherein the collar has a profile matching the shape of the abutted bone.
- 20 61. The interface device of any of claims 48 to 60, wherein the collar has a 3-D lattice structure.
62. The interface device of any preceding claim, further comprising a plurality of suture holes.
63. The interface device of claim 62, wherein the plurality of suture holes are provide
25 spaced about the porous member.
64. The interface device of any of claims 62 or 63, wherein the suture holes are arranged in pairs.

65. The interface device of any of claims 62 to 64, wherein a first set of suture holes are provided at a central region of the porous member.
66. The interface device of claim 65, wherein the first set of suture holes facilitates attachment of the soft tissue onto the porous member.
- 5 67. The interface device of any of claims 62 to 66, wherein a second set of suture holes are provided at the periphery of the porous member.
68. The interface device of claim 67, wherein the second set of suture holes is used to facilitate fitting or placement of the interface device onto the soft tissue of a patient.
69. The interface device of any of claims 65 to 68, wherein the first set of suture holes are
10 arranged about the porous member such that in use the soft tissue is affixed to the porous member via a purse string, draw string or peg effect.
70. The interface device of any of claims 62 to 69, wherein the size of the suture holes are 1 to 5 mm in diameter.
71. The interface device of any preceding claim, wherein the diameter of the suture holes
15 is greater than 1.5 mm.
72. The interface device of any preceding claim, wherein the interface device further comprises a cap portion.
73. The interface device of claim 72, wherein the cap portion comprises a lower porous surface which in use is arranged to abut soft tissue.
- 20 74. The interface device of claims 72 to 73, wherein the lower porous surface extends substantially the entirety of the lower surface of the cap portion.
75. The interface device of claims 72 to 74, wherein the cap portion comprises a substantially solid disk shape with a specified thickness and a lower porous surface which in use is arranged to abut soft tissue.
- 25 76. The interface device of claims 72 to 75, wherein the cap portion comprises a flexible material.
77. The interface device of claim 76, wherein the flexible material comprises a polymer, and/or optionally, a coated polymer.
78. The interface device of claims 72 to 77, further comprising one or more ports.

79. The interface device of claim 78, wherein the one or more ports extend through the cap portion and/or through the porous member.
80. The interface device of claims 72 to 79, wherein the one or more ports comprise a substantially cylindrical shape.
- 5 81. The interface device of claims 72 to 80, wherein the one or more ports comprises a substantially cylindrical channel with a flange or rim.
82. The interface device of claims 72 to 81, wherein the one or more ports comprise a frusto-conical shape.
83. The interface device of claims 72 to 82, wherein the one or more ports have a
10 threaded bore.
84. The interface device of claims 72 to 83, wherein the one or more ports are provided with a surrounding wall or sheathing.
85. The interface device of claims 72 to 84, wherein the sheathing comprises plastic or polymer.
- 15 86. The interface device of claims 72 to 85, wherein the sheathing comprises the same material as any tubing, cabling and/or wiring material to pass through the one or more ports.
87. The interface device of claims 72 to 86, wherein the one or more ports may be arranged about the cap portion.
88. The interface device of claims 72 to 87, wherein the one or more ports are arranged
20 to pass through the cap portion and/or the porous region.
89. The interface device of claims 72 to 88, wherein the one or more ports are arranged to pass through the cap portion between the porous region and the soft tissue in use.
90. The interface device of claims 72 to 89, wherein the cap portion provides at least some surface area not in engagement with soft tissue in use.
- 25 91. The interface device of claim 90, wherein the surface area is adjustable.
92. The interface device of claims 90 or 91, wherein the surface area is adjusted to keep as small as possible whilst providing a surface area for access ports, a collar, and/or any other features.

93. The interface device of claims 72 to 92, further comprising one or more tubing, cabling and/or wiring material arranged to pass through the one or more ports.
94. The interface device of claim 93, wherein the one or more cabling and/or wiring is carrying electrical data for control of any device connected to the interface device, optionally via a processor.
95. The interface device of claims 93 to 94, wherein the one or more cabling and/or wiring is internally connected to nerve cuffs or muscle activation sensing electrodes or other electrical connections to or from the nervous system or other internal tissues.
96. The interface device of claims 93 to 95, wherein the one or more cabling and/or wiring connects directly to the biological tissue, and/or connects to one or more internal electronic housings that themselves are connected either directly or via one or more electronic housings to the biological tissue.
97. The interface device of claims 72 to 96, wherein the cap portion further comprises a channel arranged retain/support one or more tubes, cables and/or wires.
98. The interface device of claims 72 to 97, wherein the cap portion further comprises means for holding/supporting one or more tubes, cables and/or wires.
99. The interface device of claim 98, wherein the holding/supporting means comprise a frame or support.
100. The interface device of claims 72 to 99, wherein the porous member is integral to the cap portion.
101. The interface device of claims 72 to 100, wherein the porous member and cap portion are mateable.
102. The interface device of claims 72 to 101, wherein mating regions are provided in the porous member and cap portion to facilitate mating.
103. The interface device of any preceding claim, wherein the interface device provides an interface to a means for bone engagement or fixation.
104. The interface device of claim 103, wherein the interface device provides an interface with an osseointegrated stem, a cemented stem, a smooth press-fitted stem, a plate design and/or any other device suitable for fixation/engagement with a bone.

105. The interface device of any preceding claim, wherein the interface device maintains a homeostatic barrier.
106. The interface device of any preceding claim, wherein the interface device comprises
5 a bio-compatible material.
107. The interface device of any preceding claim, wherein the interface device comprises titanium (alloys thereof including Ti6Al4V), stainless steel (and its derivatives), for example having SAE grade 316, high-density polyethylene (HDPE), polylactic acid (PLA), polypropylene (PP) or other polymer or metal, and/or combinations or mixtures thereof.
108. An interface device comprising:
10 a porous member configured to receive soft tissue;
wherein the porous member comprises a first and second region arranged about the interface device such that in use the soft tissue is received substantially across the length of the first portion and substantially about the height of the second portion,
15 wherein the pore size of the first region is between 300 μm to 800 μm , and
wherein the height of the second region is substantially the thickness of the received soft tissue.
109. An interface device comprising:
a porous member configured to receive soft tissue;
20 wherein the size of the pores of the porous member is between 50 μm to 1.5 mm.
110. The interface device of claim 109, wherein the size of the pores of the porous member is between 200 μm to 700 μm .
111. The interface device of claim 109 or claim 110, wherein the porous member comprises a latticed structure.
112. The interface device of claim 111, wherein the porous member comprises a square
25 centred latticed structure.
113. The interface device of any of claims 109 to 112, wherein the thickness of the porous member is between less than 1 mm to 6 mm.

114. The interface device of any of claims 109 to 113, wherein the thickness of porous member is substantially uniform across its length.
115. The interface device of any of claims 109 to 114, wherein the thickness of the porous member is substantially uniform across its length with the periphery of the porous member having a tapered/rounded end.
116. The interface device of any of claims 109 to 115, wherein the thickness of the porous member is tapered across its length so as to arrive at the periphery at a point, and optionally, where the point may be rounded or pointed.
117. The interface device of any of claims 109 to 116, wherein the combined size of the pores about the porous member is at least 2 times the thickness of the porous member.
118. The interface device of any of claims 109 to 117, wherein the combined size of the pores about the porous member is at least 3 times the thickness of the porous member.
119. The interface device of any of claims 109 to 118, wherein the lower bound density of the pores is $1/\text{mm}^3$.
120. The interface device of any of claims 109 to 119, wherein the thickness and/or pore size of the pores may vary across the porous member
121. The interface device of any of claims 109 to 120, wherein the thickness and/or pore size of the pores may vary across the porous member.
122. The interface device of any of claims 109 to 121, wherein the surfaces of the pores are smooth.
123. The interface device of any of claims 109 to 122, wherein the parameters of the porous member are customizable including one or more of the following: the angle (θ), length (l), flange thickness, geometry of the interface surface, number size and location of cross porous member holes, pore structure (size and density), curvature radii and/or relative sizing of sections of the overall profile of the porous member cross-section.
124. The interface device of any of claims 109 to 123, wherein the porous member is angled in use to be substantially tangential to the natural plane of the soft tissue and/or skin at the implantation site.
125. The interface device of any of claims 109 to 124, wherein the length of the porous member is 5 mm to 35 mm.

126. The interface device of any of claims 109 to 125, wherein the porous member further comprises reinforcement struts.
- 5 127. The interface device of claim 125, wherein the reinforcement struts secure one or more concentric rings to form a frusto-conical grid or mesh shape.
- 10 128. The interface device of any of claims 109 to 127, wherein the porous member comprises a first and second region arranged about the interface device such that in use the soft tissue is received substantially across the length of the first portion and substantially about the height of the second portion.
129. The interface device of claim 128, wherein the first and second regions are arranged about the interface device in a substantially non-planar manner.
- 15 130. The interface device of claim 128 or claim 129, wherein the first and second regions are arranged about the interface device at an angle.
- 20 131. The interface device of any of claims 128 to 130, wherein the first region is arranged to receive the soft tissue substantially across its length such that the soft tissue substantially rests thereon in use.
132. The interface device of any of claims 128 to 131, wherein the second region is configured to receive the leading edge of the soft tissue in use.
133. The interface device of any of claims 128 to 132, wherein the first region is arranged about the interface device at a position spaced from the second regions.
- 25 134. The interface device of any of claims 128 to 133, wherein the height of the second region, in use, is adaptable.
135. The interface device of any of claims 128 to 134, wherein the height of the second region, in use, is substantially the thickness of the received soft tissue.
- 30 136. The interface device of any of claims 128 to 135, wherein the height of the second region, in use, is less than the thickness of the received soft tissue.
137. The interface device of any of claims 128 to 136, wherein the height of the second region, in use, is substantially the thickness of the leading edge of the received soft tissue.

138. The interface device of any of claims 128 to 137, wherein the height of the second region, in use, is less than the thickness of the leading edge of the received soft tissue.
139. The interface device of any of claims 128 to 138, wherein the height of the second region is less than 0.5 mm of the thickness of the received soft tissue or the thickness of the leading edge of the received soft tissue.
140. The interface device of claim 139, wherein the height of the second region is 4 mm.
141. The interface device of any preceding claim, wherein the porosity of the pores is variable.
142. The interface device of any of claims 128 to 141, wherein the first and second portions are arranged about the interface device in a spaced configuration.
143. The interface device any of claims 128 to 142, wherein the first region is arranged at a position spaced from the second region and/or optionally wherein the first and second regions are spaced by a solid region.
144. The interface device of claim 143, wherein the solid region spaces the first and second regions by less than 1 mm to 10 mm.
145. The interface device of claim 144, wherein the solid region spaces the first and second regions by 3 mm.
146. The interface device of any of claims 128 to 145, wherein first region is arranged to receive the soft tissue substantially across its length.
147. The interface device of any of claims 128 to 146, wherein the second region is arranged to receive a leading edge of the soft tissue in use.
148. The interface device of any of claims 128 to 147, wherein the height of the second region, in use, is adaptable.
149. The interface device of any of claims 128 to 148, wherein the height of the second region, in use, is substantially the thickness of the received soft tissue.
150. The interface device of any of claims 128 to 148, wherein the height of the second region, in use, is less than the thickness of the received soft tissue.
151. The interface device of any preceding claim, wherein the porous member has a substantially uniform shape.

152. The interface device of any preceding claim, wherein the shape, dimensions and/or size of the porous member is customizable.

153. The interface device of any preceding claim, wherein shape, dimensions and/or size is adjustable depending on the intended use of the interface device and/or the patient's dimensions.

154. The interface device of claim 153, wherein adjustable dimensions include one or more of the angle that the porous member protrudes in respect of the interface device, the geometry of connection between the porous member and the interface device including but not limited to the curvature radii of the connection between the porous member and the interface device, the height of the porous member, the relative sizing of profile of the cross-section of the porous member, the length of the porous member and the thickness of the porous member.

155. The interface device of any preceding claim, wherein the porosity of the first and second regions is uniform.

156. The interface device of any of claims 1 to 154, wherein the porosity of the first and/or second regions is non-uniform.

157. An interface device comprising:

a porous member configured to receive soft tissue,

wherein the porous member comprises a first and second region arranged about the interface device such that in use the soft tissue is received substantially across the length of the first portion and substantially about the height of the second portion; and

a cap portion comprising one or more ports.

158. The interface device of claim 157, wherein the one or more ports form one or more substantially cylindrical channels through the interface device, each having a predefined flange or rim.

159. The interface device of claim 158, wherein the flange of rim facilitates connection with and/or ease of welding to further external means.

160. An interface device comprising:

a porous member comprising first and second regions configured to receive soft tissue;

wherein the first region is arranged at a position spaced from the second region.

161. The interface device of claim 160, wherein the first and second regions are spaced by a solid region.
162. The interface device of claim 160 or claim 161, wherein the solid region spaces the first and second regions by less than 1 mm to 10 mm.
163. The interface device of claim 162, wherein the solid region spaces the first and second regions by 3 mm.
164. The interface device of any of claims 160 to 163, wherein first region is arranged to receive the soft tissue substantially across its length.
165. The interface device of any of claims 160 to 164, wherein the second region is arranged to receive a leading edge of the soft tissue in use.
166. The interface device of any of claims 160 to 165, wherein the height of the second region, in use, is adaptable.
167. The interface device of any of claims 160 to 166, wherein the height of the second region, in use, is substantially the thickness of the received soft tissue.
168. The interface device of any of claims 160 to 167, wherein the height of the second region, in use, is less than the thickness of the received soft tissue.
169. The interface device of any of claims 160 to 168, wherein the porous member has a substantially uniform shape.
170. The interface device of any of claims 160 to 169, wherein the shape, dimensions and/or size of the porous member is customizable.
171. The interface device of any of claims 160 to 170, wherein shape, dimensions and/or size is adjustable depending on the intended use of the interface device and/or the patient's dimensions.
172. The interface device of claim 171, wherein adjustable dimensions include one or more of the angle that the porous member protrudes in respect of the interface device, the geometry of connection between the porous member and the interface device including but not limited to the curvature radii of the connection between the porous member and the interface device, the height of the porous member, the relative sizing of profile of the cross-

section of the porous member, the length of the porous member and the thickness of the porous member.

173. The interface device of any of claims 160 to 172, wherein the porosity of the first and second regions is uniform.

5 174. The interface device of any of claims 160 to 172, wherein the porosity of the first and/or second regions is non-uniform.

175. The interface device of any preceding claim, further comprising a collar.

176. The interface device of claim 175, wherein the collar is load bearing.

10 177. The interface device of claim 175 or claim 176, wherein the collar is at least partially porous and/or comprises one or more channels.

178. The interface device of any of claims 175 to 177, wherein the collar comprises one or more pores have a pore size from 500 μm to 5 mm.

179. The interface device of claim 178, wherein the pore size is less than 3 mm.

180. The interface device of any of claims 175 to 179, wherein the collar is cylindrical.

15 181. The interface device of any of claims 175 to 179, wherein the collar has tapered sides.

182. The interface device of any of claims 175 to 179, wherein the collar is substantially conical or frusto-conical.

20 183. The interface device of any of claims 175 to 182, wherein the walls of the collar are smooth.

184. The interface device of any of claims 175 to 182, wherein the walls of the collar have a machined or coarse finish.

185. The interface device of any of claims 175 to 184, wherein the walls of the collar have a toothed or crenelated arrangement.

25 186. The interface device of any of claims 175 to 185, wherein the collar has a non-regular shape.

187. The interface device of any of claims 175 to 187, wherein the collar has a profile matching the shape of the abutted bone.

188. The interface device of any of claims 175 to 187, wherein the collar has a 3-D lattice structure.
189. The interface device of any preceding claim, wherein the porous member extends radially about the cap portion at a predefined distance spaced from the periphery of the cap.
- 5 190. The interface device of claim 189, wherein the spaced predefined distance forms a lip or cover.
191. The interface device of claim 189 or claim 190, wherein the lip or cover serves as a mechanical and/or physical means for protecting the received soft tissue.
192. The interface device of any of claims 189 to 190, wherein the predefined distance of
10 the cap portion comprises at least a portion having a ridged, coarse and/or rough surface/finish.
193. The interface device of claim 192, wherein the course finish provides for secondary engagement with the received soft tissue in use.
194. The interface device of any preceding claim, wherein the porous member comprises
15 a plurality of suture holes.
195. The interface device of claim 194, wherein the plurality of suture holes are provide spaced about the porous member.
196. The interface device of claim 194 or 195, wherein the suture holes are arranged in pairs.
- 20 197. The interface device of any of claims 194 to 196, wherein a first set of suture holes are provided at a central region of the porous member.
198. The interface device of claim 197, wherein the first set of suture holes facilitates attachment of the soft tissue onto the porous member.
199. The interface device of any of claims 194 to 198, wherein a second set of suture
25 holes are provided at the periphery of the porous member.
200. The interface device of claim 199, wherein the second set of suture holes is used to facilitate fitting or placement of the interface device onto the soft tissue of a patient.

201. The interface device of any of claims 194 to 200, wherein the first set of suture holes are arranged about the porous member such that in use the soft tissue is affixed to the porous member via a purse string, draw string or peg effect.
- 5 202. The interface device of any of claims 194 to 201, wherein the size of the suture holes are 1 to 5 mm in diameter.
203. The interface device of any of claims 194 to 202, wherein the diameter of the suture holes is greater than 1.5 mm.
204. The interface device of any preceding claim, wherein the interface device further comprises a cap portion.
- 10 205. The interface device of claim 204, wherein the cap portion comprises a lower porous surface which in use is arranged to abut soft tissue.
206. The interface device of claim 204 or 205, wherein the lower porous surface extends substantially the entirety of the lower surface of the cap portion.
- 15 207. The interface device of any of claims 204 to 206, wherein the cap portion comprises a substantially solid disk shape with a specified thickness and a lower porous surface which in use is arranged to abut soft tissue.
208. The interface device of any of claims 204 to 207, wherein the cap portion comprises a flexible material.
- 20 209. The interface device of claim 208, wherein the flexible material comprises a polymer, and/or optionally, a coated polymer.
210. The interface device of any of claims 204 to 209, further comprising one or more ports.
211. The interface device of claim 210, wherein the one or more ports extend through the cap portion and/or through the porous member.
- 25 212. The interface device of any of claims 210 to 211, wherein the one or more ports comprise a substantially cylindrical shape.
213. The interface device of any of claims 210 to 212, wherein the one or more ports comprises a substantially cylindrical channel with a flange or rim.

214. The interface device of any of claims 210 to 213, wherein the one or more ports comprise a frusto-conical shape.
215. The interface device of any of claims 210 to 215, wherein the one or more ports have a threaded bore.
- 5 216. The interface device of any of claims 210 to 216, wherein the one or more ports are provided with a surrounding wall or sheathing.
217. The interface device of claim 216, wherein the sheathing comprises plastic or polymer.
- 10 218. The interface device of claim 216 or 217, wherein the sheathing comprises the same material as any tubing, cabling and/or wiring material to pass through the one or more ports.
219. The interface device of any of claims 210 to 218, wherein the one or more ports may be arranged about the cap portion.
220. The interface device of any of claims 210 to 219, wherein the one or more ports are arranged to pass through the cap portion and/or the porous region.
- 15 221. The interface device of any of claims 210 to 219, wherein the one or more ports are arranged to pass through the cap portion between the porous region and the soft tissue in use.
222. The interface device of any of claims 210 to 221, wherein the cap portion provides at least some surface area not in engagement with soft tissue in use.
- 20 223. The interface device of any of claims 204 to 222, wherein the surface area is adjustable.
224. The interface device of any of claims 204 to 223, wherein the surface area is adjusted to keep as small as possible whilst providing a surface area for access ports, a collar, and/or any other features.
- 25 225. The interface device of any of claims 210 to 224, further comprising one or more tubing, cabling and/or wiring material arranged to pass through the one or more ports.
226. The interface device of any of claims 210 to 225, wherein the one or more cabling and/or wiring is carrying electrical data for control of any device connected to the interface device, optionally via a processor.

227. The interface device of any of claims 210 to 226, wherein the one or more cabling and/or wiring is internally connected to nerve cuffs or muscle activation sensing electrodes or other electrical connections to or from the nervous system or other internal tissues.
- 5 228. The interface device of any of claims 210 to 227, wherein the one or more cabling and/or wiring connects directly to the biological tissue, and/or connects to one or more internal electronic housings that themselves are connected either directly or via one or more electronic housings to the biological tissue.
229. The interface device of any of claims 204 to 228, wherein the cap portion further comprises a channel arranged retain/support one or more tubes, cables and/or wires
- 10 230. The interface device of any of claims 204 to 229, wherein the cap portion further comprises means for holding/supporting one or more tubes, cables and/or wires.
231. The interface device of claim 230, wherein the holding/supporting means comprise a frame or support.
232. The interface device of any of claims 204 to 231, wherein the porous member is
15 integral to the cap portion.
233. The interface device of any of claims 204 to 232, wherein the porous member and cap portion are mateable.
234. The interface device of claim 234, wherein mating regions are provided in the porous member and cap portion to facilitate mating.
- 20 235. The interface device of any preceding claim, wherein the interface device provides an interface to a means for bone engagement or fixation.
236. The interface device of claim 235, wherein the interface device provides an interface with an osseointegrated stem, a cemented stem, a smooth press-fitted stem, a plate design and/or any other device suitable for fixation/engagement with a bone.
- 25 237. The interface device of any preceding claim, wherein the interface device maintains a homeostatic barrier.
238. The interface device of any preceding claim, wherein the interface device comprises a bio-compatible material.
- 30 239. The interface device of any preceding claim, wherein the interface device comprises titanium (alloys thereof including Ti6Al4V), stainless steel (and its derivatives), for example

having SAE grade 316, high-density polyethylene (HDPE), polylactic acid (PLA), polypropylene (PP) or other polymer or metal, and/or combinations or mixtures thereof.

240. An interface device for engagement with a device fixable to a bone comprising:
a cap portion having a porous member;

5 wherein the porous member is configured to receive soft tissue; and
a collar which when in use abuts the bone.

241. The interface device of claim 240, wherein the collar is load bearing.

242. The interface device of claim 240 or claim 241, wherein the collar is at least partially porous and/or comprises one or more channels.

10 243. The interface device of any of claims 240 to 242, wherein the collar comprises one or more pores have a pore size from 500 μm to 5 mm.

244. The interface device of claim 243, wherein the pore size is less than 3 mm.

245. The interface device of any of claims 240 to 244, wherein the collar is cylindrical.

15 246. The interface device of any of claims 240 to 245, wherein the collar has tapered sides.

247. The interface device of any of claims 240 to 244, wherein the collar is substantially conical or frusto-conical.

248. The interface device of any of claims 240 to 247, wherein the walls of the collar are smooth.

20 249. The interface device of any of claims 240 to 247, wherein the walls of the collar have a machined or coarse finish.

250. The interface device of any of claims 240 to 249, wherein the walls of the collar have a toothed or crenelated arrangement.

25 251. The interface device of any of claims 240 to 250, wherein the collar has a non-regular shape.

252. The interface device of any of claims 240 to 251, wherein the collar has a profile matching the shape of the abutted bone.

253. The interface device of any of claims 240 to 252, wherein the collar has a 3-D lattice structure.
254. The interface device of any of claims 240 to 253, further comprising the features of any preceding claim.
- 5 255. An interface device for maintaining a homeostatic barrier, the device comprising:
- a cap portion; and
- a porous member configured to receive soft tissue;
- wherein the porous member extends radially about the cap portion at a predefined distance spaced from the periphery of the cap.
- 10 256. The interface device of claim 255, wherein the spaced predefined distance forms a lip or cover.
257. The interface device of claim 255 or 256, wherein the lip or cover serves as a mechanical and/or physical means for protecting the received soft tissue.
258. The interface device of any of claims 255 to 257, wherein the predefined distance of
- 15 the cap portion comprises at least a portion having a ridged, coarse and/or rough surface/finish.
259. The interface device of claim 258, wherein the coarse finish provides for secondary engagement with the received soft tissue in use.
260. The interface device of any of claims 255 to 259, further comprising the features of
- 20 any preceding claim.
261. An interface device comprising:
- a porous member is configured to receive soft tissue;
262. The interface device of claim 261, wherein the plurality of suture holes are provide spaced about the porous member.
- 25 263. The interface device of claim 261 or claim 262, wherein the suture holes are arranged in pairs.
264. The interface device of any of claims 261 to 263, wherein a first set of suture holes are provided at a central region of the porous member.

265. The interface device of claim 264, wherein the first set of suture holes facilitates attachment of the soft tissue onto the porous member.
266. The interface device of any of claims 261 to 265, wherein a second set of suture holes are provided at the periphery of the porous member.
- 5 267. The interface device of claim 266, wherein the second set of suture holes is used to facilitate fitting or placement of the interface device onto the soft tissue of a patient.
268. The interface device of any of claims 261 to 267, wherein the first set of suture holes are arranged about the porous member such that in use the soft tissue is affixed to the porous member via a purse string, draw string or peg effect.
- 10 269. The interface device of any of claims 261 to 268, wherein the size of the suture holes are 1 to 5 mm in diameter.
270. The interface device of any of claims 261 to 269, wherein the diameter of the suture holes is greater than 1.5 mm.
- 15 271. The interface device of any of claims 261 to 270, wherein the interface device further comprises a cap portion.
272. The interface device of claim 271, wherein the cap portion comprises a lower porous surface which in use is arranged to abut soft tissue.
273. The interface device of any of claims 261 to 272, wherein the lower porous surface extends substantially the entirety of the lower surface of the cap portion.
- 20 274. The interface device of any of claims 261 to 273, wherein the cap portion comprises a substantially solid disk shape with a specified thickness and a lower porous surface which in use is arranged to abut soft tissue.
275. The interface device of any of claims 261 to 274, wherein the cap portion comprises a flexible material.
- 25 276. The interface device of claim 75, wherein the flexible material comprises a polymer, and/or optionally, a coated polymer.
277. The interface device of any preceding claim, further comprising one or more ports.
278. The interface device of claim 277, wherein the one or more ports extend through the cap portion and/or through the porous member.

279. The interface device of any of claims 277 to 278, wherein the one or more ports comprise a substantially cylindrical shape.
280. The interface device of any of claims 277 to 279, wherein the one or more ports comprises a substantially cylindrical channel with a flange or rim.
- 5 281. The interface device of any of claims 277 to 280, wherein the one or more ports comprise a frusto-conical shape.
282. The interface device of any of claims 277 to 281, wherein the one or more ports have a threaded bore.
283. The interface device of any of claims 277 to 282, wherein the one or more ports are
10 provided with a surrounding wall or sheathing.
284. The interface device of claim 283, wherein the sheathing comprises plastic or polymer.
285. The interface device of claims 283 or 284, wherein the sheathing comprises the same material as any tubing, cabling and/or wiring material to pass through the one or more ports.
- 15 286. The interface device of any of claims 277 to 285, wherein the one or more ports may be arranged about the cap portion.
287. The interface device of any of claims 277 to 286, wherein the one or more ports are arranged to pass through the cap portion and/or the porous region.
288. The interface device of any of claims 277 to 286, wherein the one or more ports are
20 arrange to pass through the cap portion between the porous region and the soft tissue in use.
289. The interface device of any of claims 277 to 288, wherein the cap portion provides at least some surface area not in engagement with soft tissue in use.
290. The interface device of any of claims 277 to 289, wherein the surface area is adjustable.
- 25 291. The interface device of any of claims 277 to 290, wherein the surface area is adjusted to keep as small as possible whilst providing a surface area for access ports, a collar, and/or any other features.
292. The interface device of any of claims 277 to 291, further comprising one or more tubing, cabling and/or wiring material arranged to pass through the one or more ports.

293. The interface device of any of claims 277 to 292, wherein the one or more cabling and/or wiring is carrying electrical data for control of any device connected to the interface device, optionally via a processor.
- 5
294. The interface device of any of claims 277 to 293, wherein the one or more cabling and/or wiring is internally connected to nerve cuffs or muscle activation sensing electrodes or other electrical connections to or from the nervous system or other internal tissues.
- 10
295. The interface device of any of claims 277 to 294, wherein the one or more cabling and/or wiring connects directly to the biological tissue, and/or connects to one or more internal electronic housings that themselves are connected either directly or via one or more electronic housings to the biological tissue.
- 15
296. The interface device of any of claims 271 to 295, wherein the cap portion further comprises a channel arranged retain/support one or more tubes, cables and/or wires.
297. The interface device of any of claims 271 to 296, wherein the cap portion further comprises means for holding/supporting one or more tubes, cables and/or wires.
298. The interface device of claim 297, wherein the holding/supporting means comprise a
- 20
- frame or support.
299. The interface device of any of claims 271 to 298, wherein the porous member is integral to the cap portion.
300. The interface device of any of claims 271 to 299, wherein the porous member and cap portion are mateable.
- 25
301. The interface device of any of claims 271 to 300, wherein mating regions are provided in the porous member and cap portion to facilitate mating.
302. The interface device of any preceding claim, wherein the interface device provides an interface to a means for bone engagement or fixation.
- 30
303. The interface device of claim 302, wherein the interface device provides an interface with an osseointegrated stem, a cemented stem, a smooth press-fitted stem, a plate design and/or any other device suitable for fixation/engagement with a bone.

304. The interface device of any preceding claim, wherein the interface device maintains a homeostatic barrier.
305. The interface device of any preceding claim, wherein the interface device comprises a bio-compatible material.
- 5 306. The interface device of any preceding claim, wherein the interface device comprises titanium (alloys thereof including Ti6Al4V), stainless steel (and its derivatives), for example having SAE grade 316, high-density polyethylene (HDPE), polylactic acid (PLA), polypropylene (PP) or other polymer or metal, and/or combinations or mixtures thereof.
- 10 307. The interface device of any of claims 261 to 306, further comprising the features of any preceding claim.

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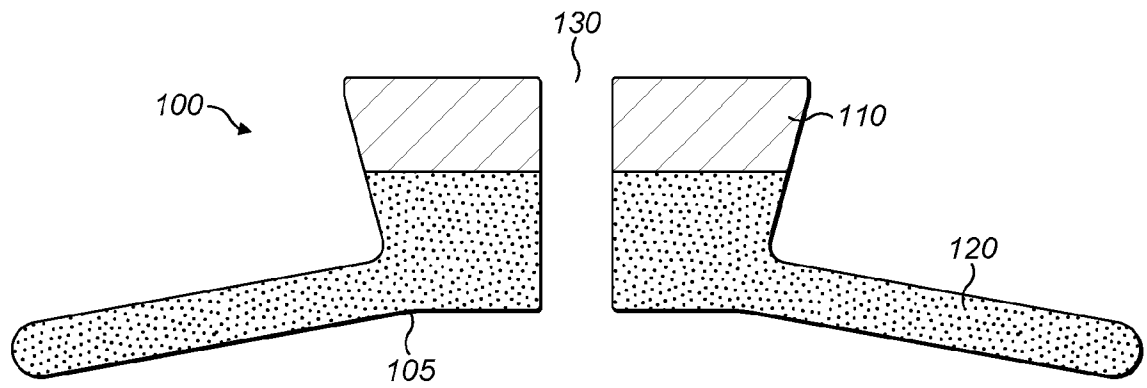


FIG. 1A

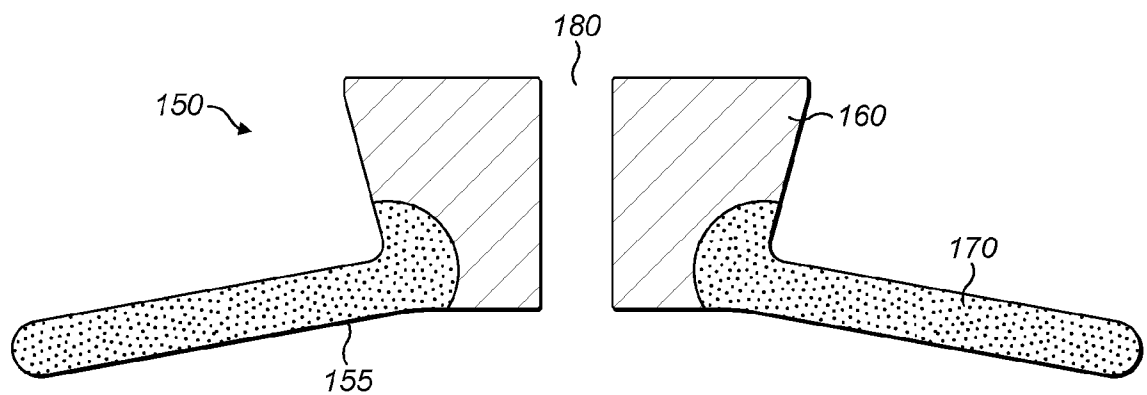


FIG. 1B

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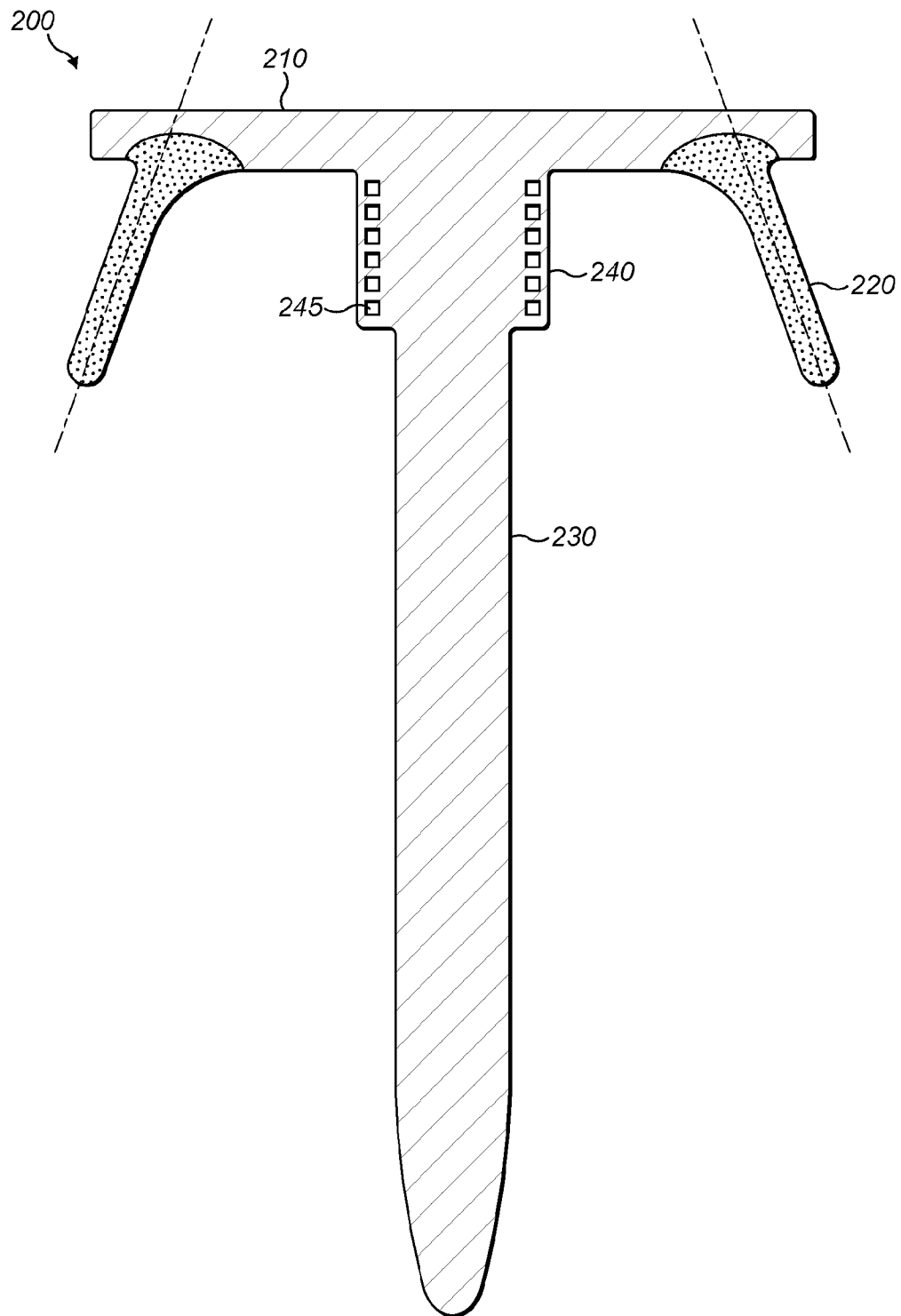
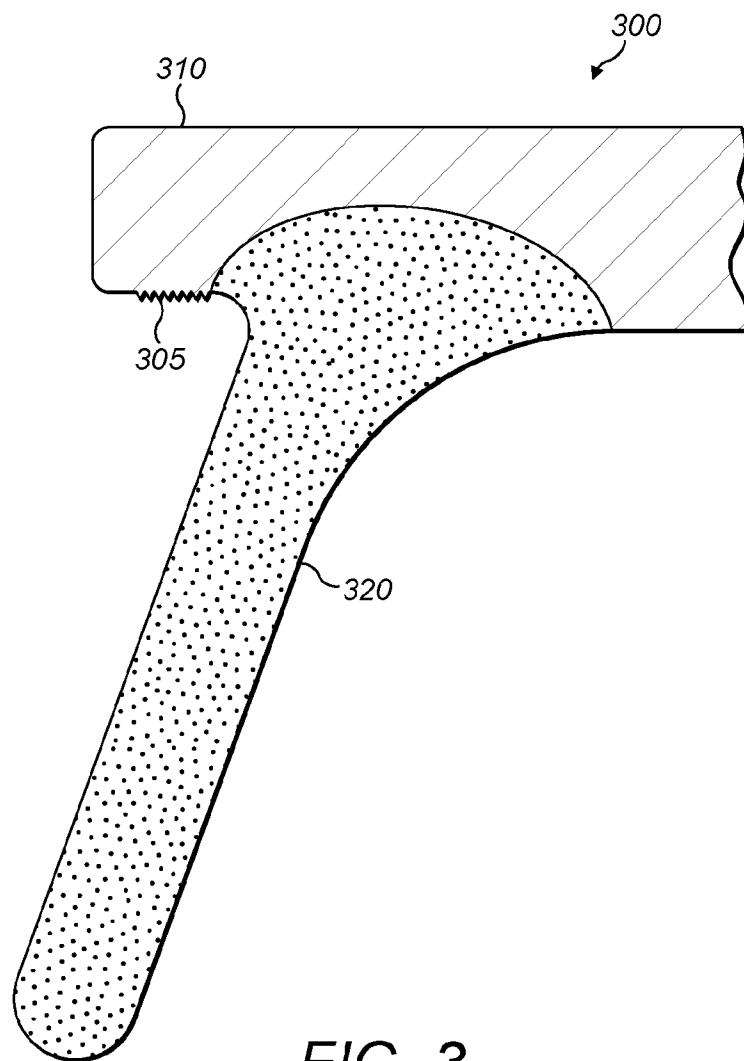
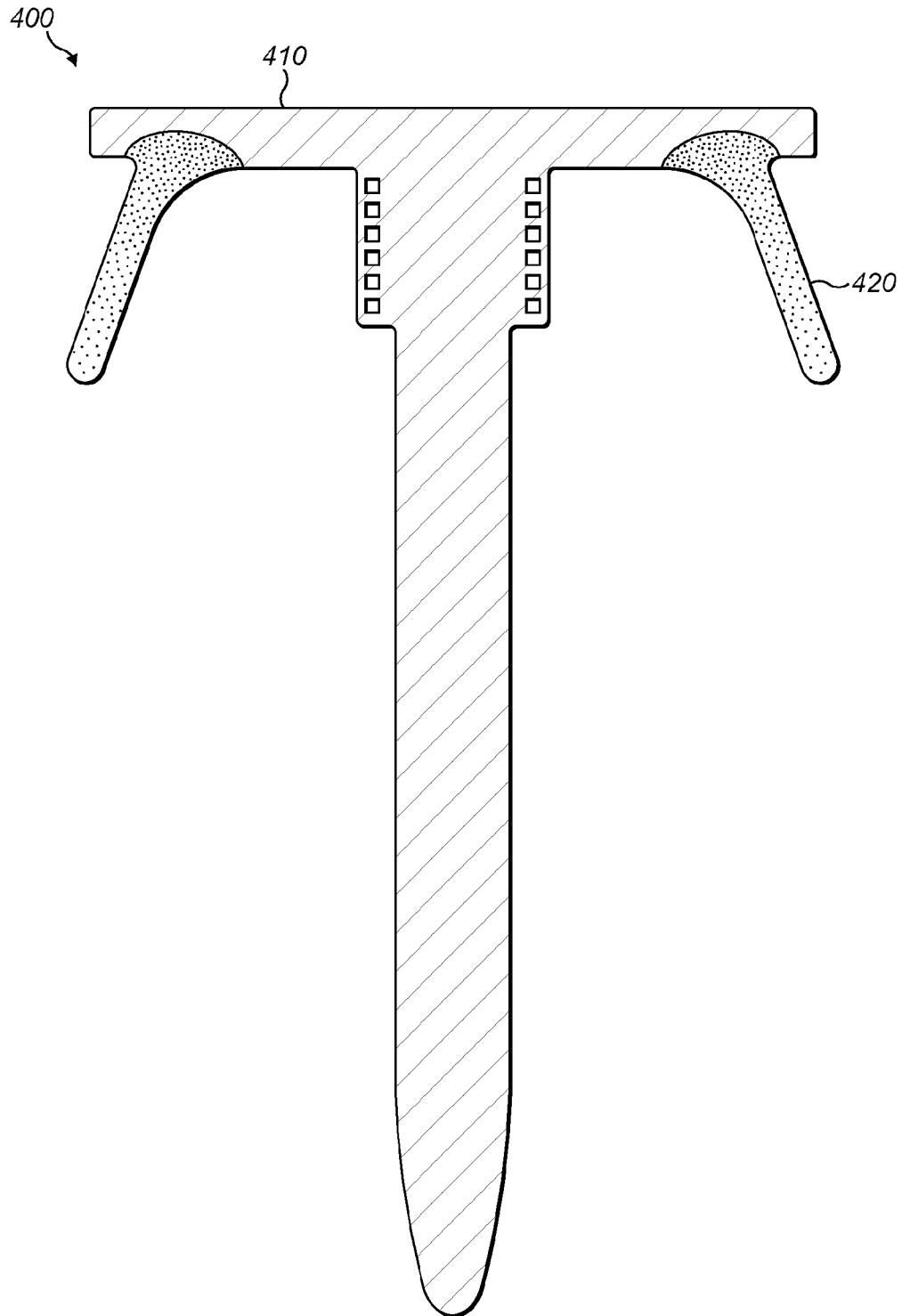


FIG. 2

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**FIG. 3**

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**FIG. 4**

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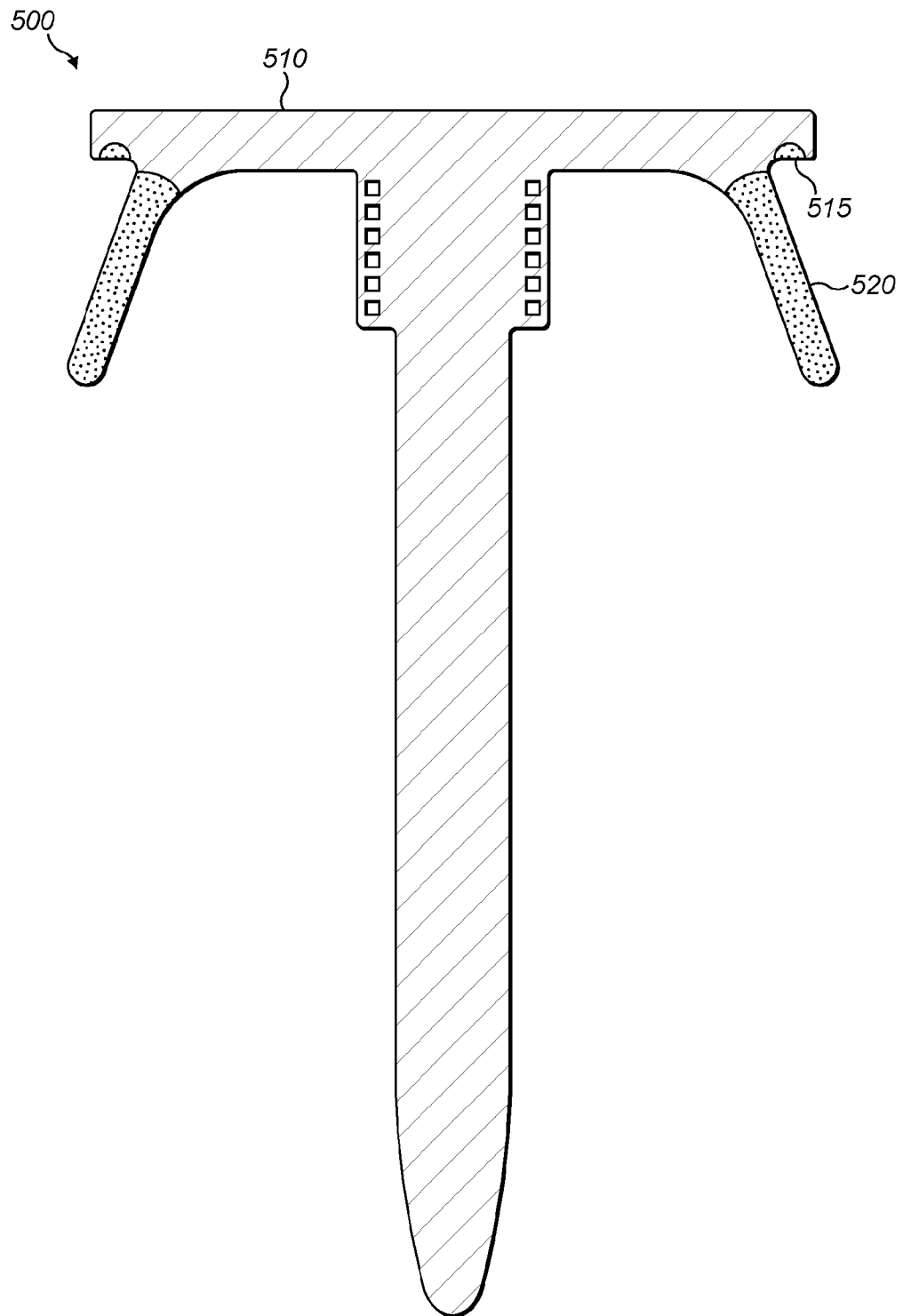


FIG. 5

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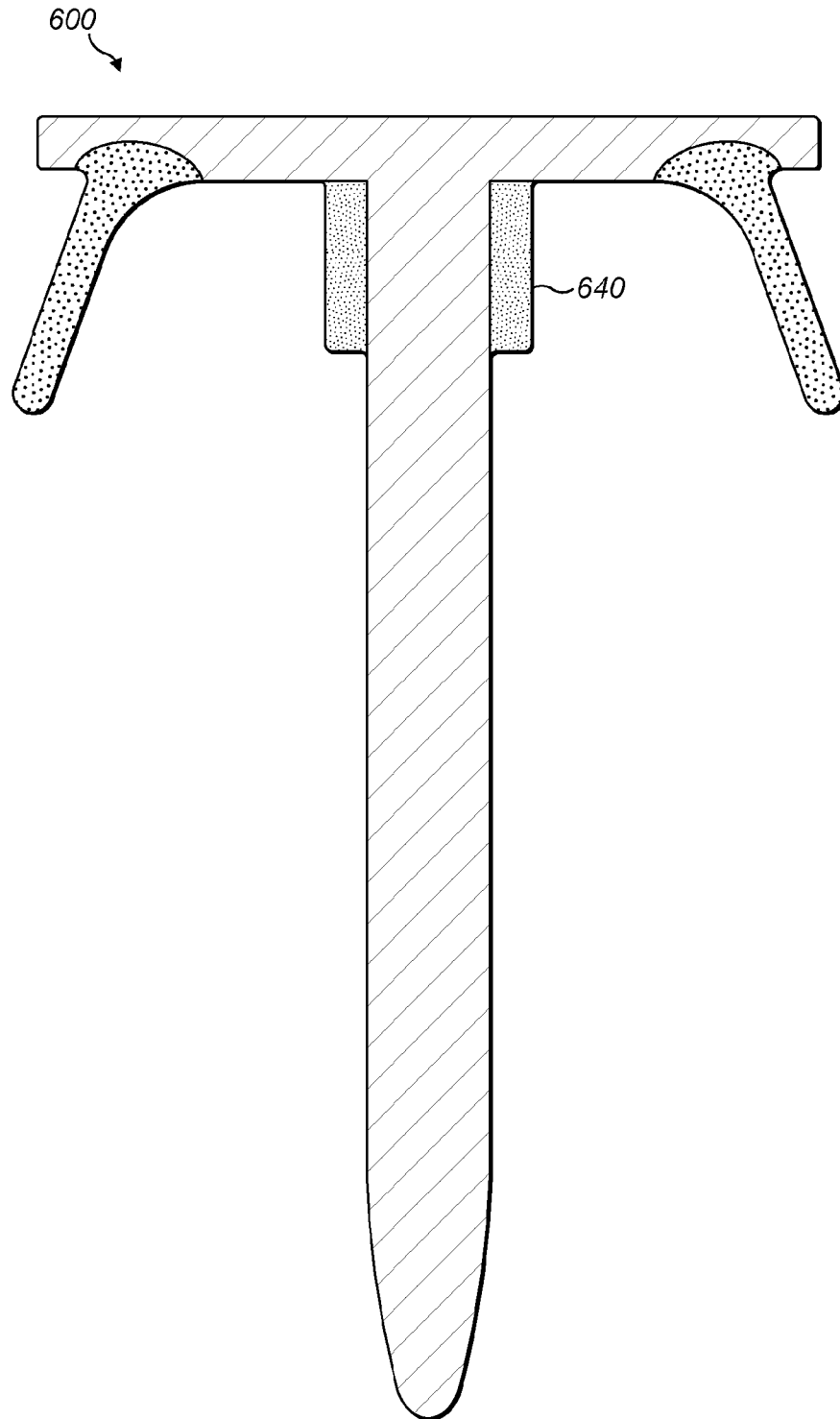


FIG. 6

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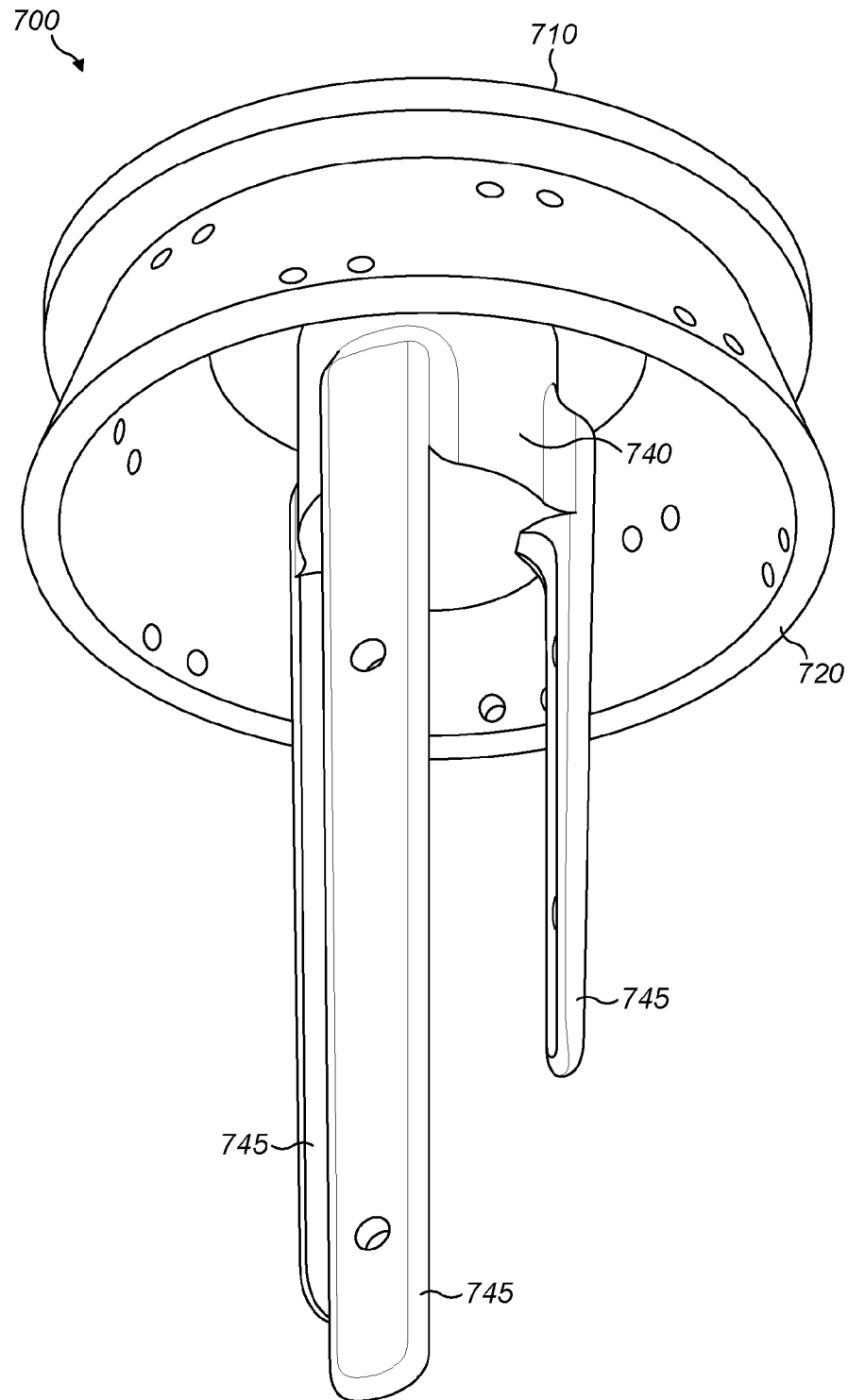


FIG. 7

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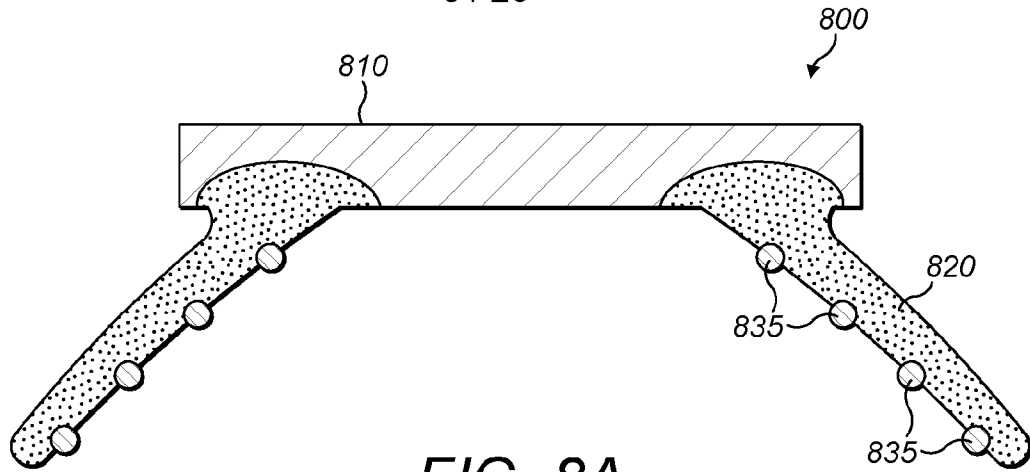


FIG. 8A

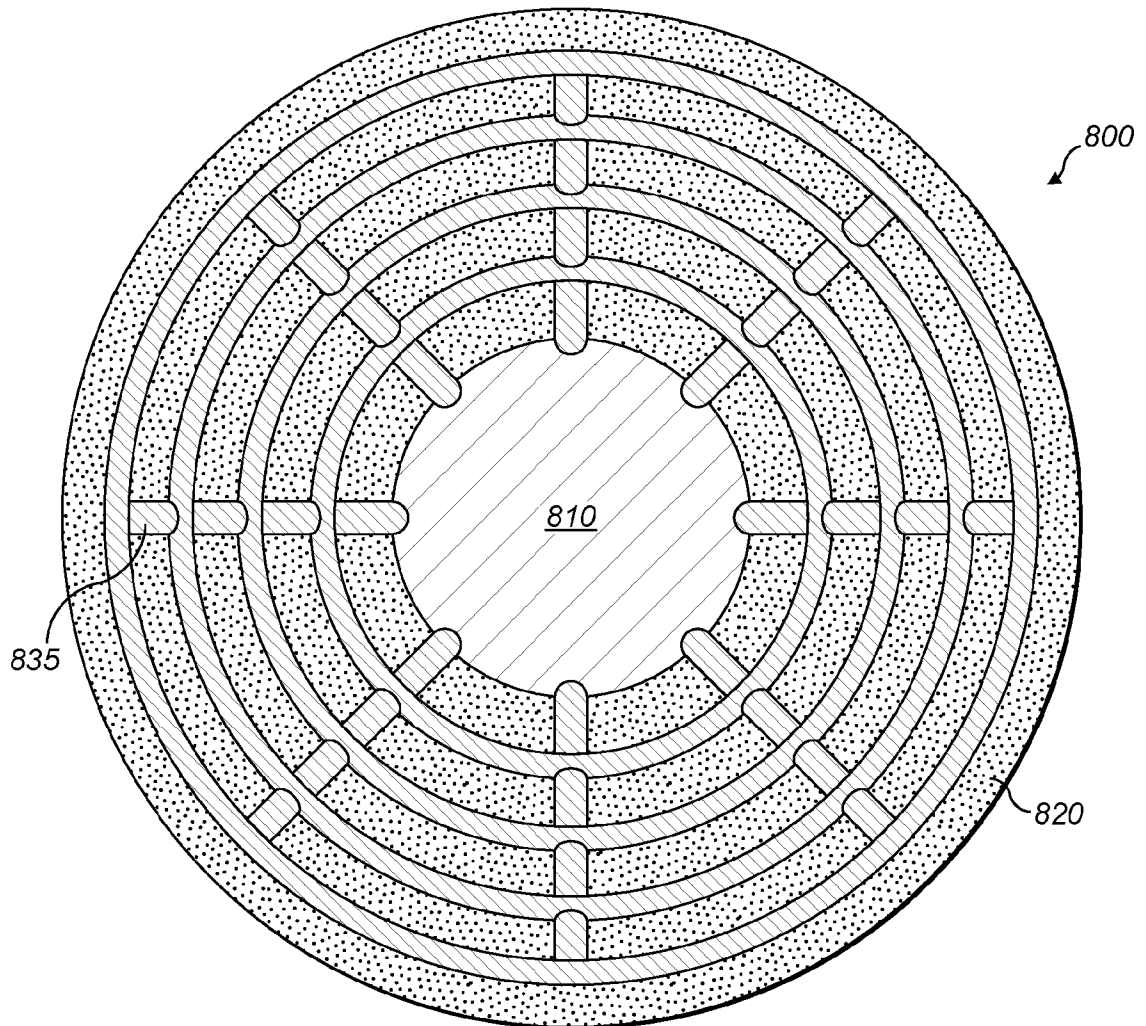


FIG. 8B

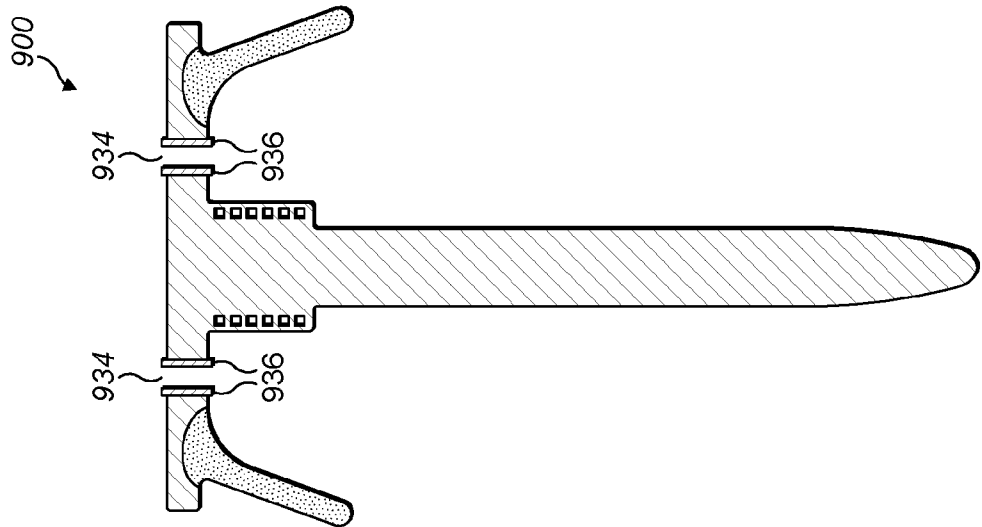


FIG. 9C

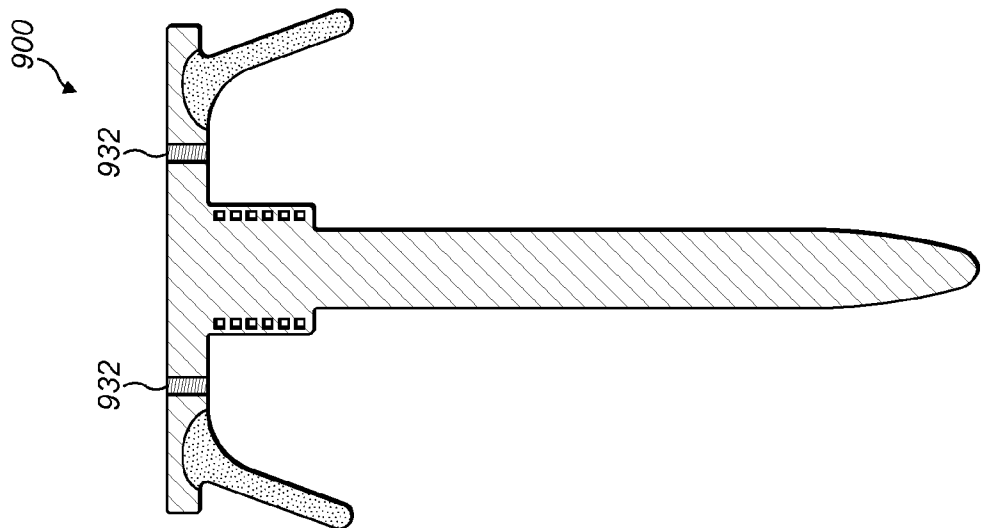


FIG. 9B

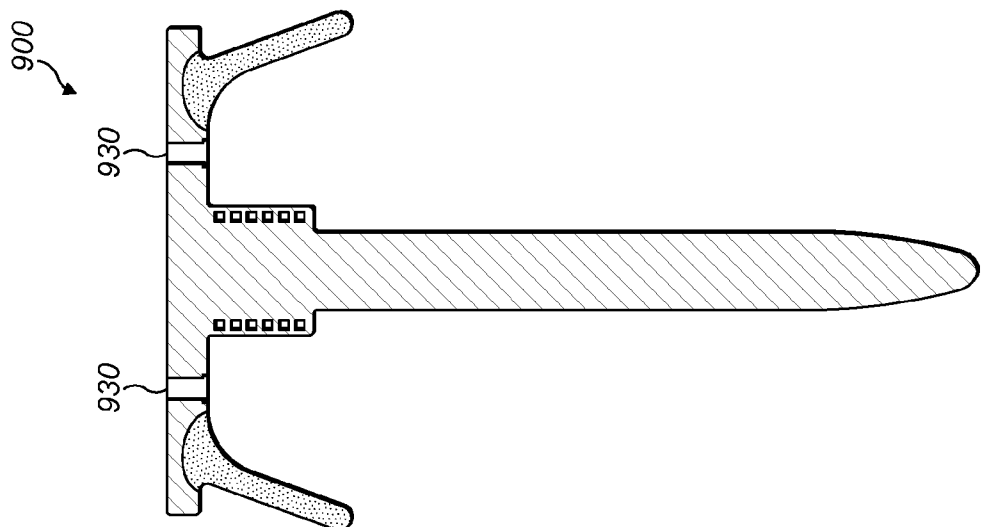


FIG. 9A

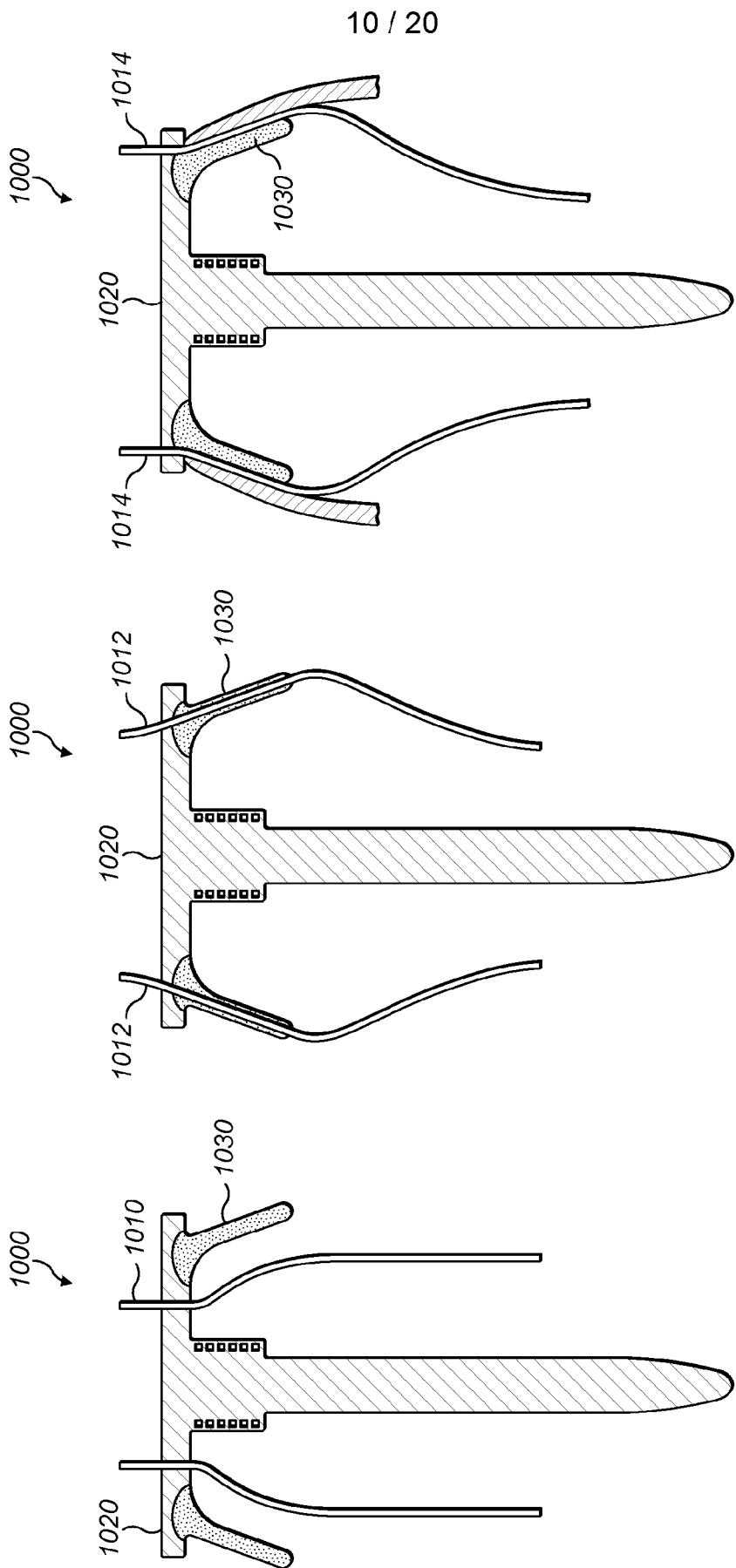


FIG. 10C

FIG. 10B

FIG. 10A

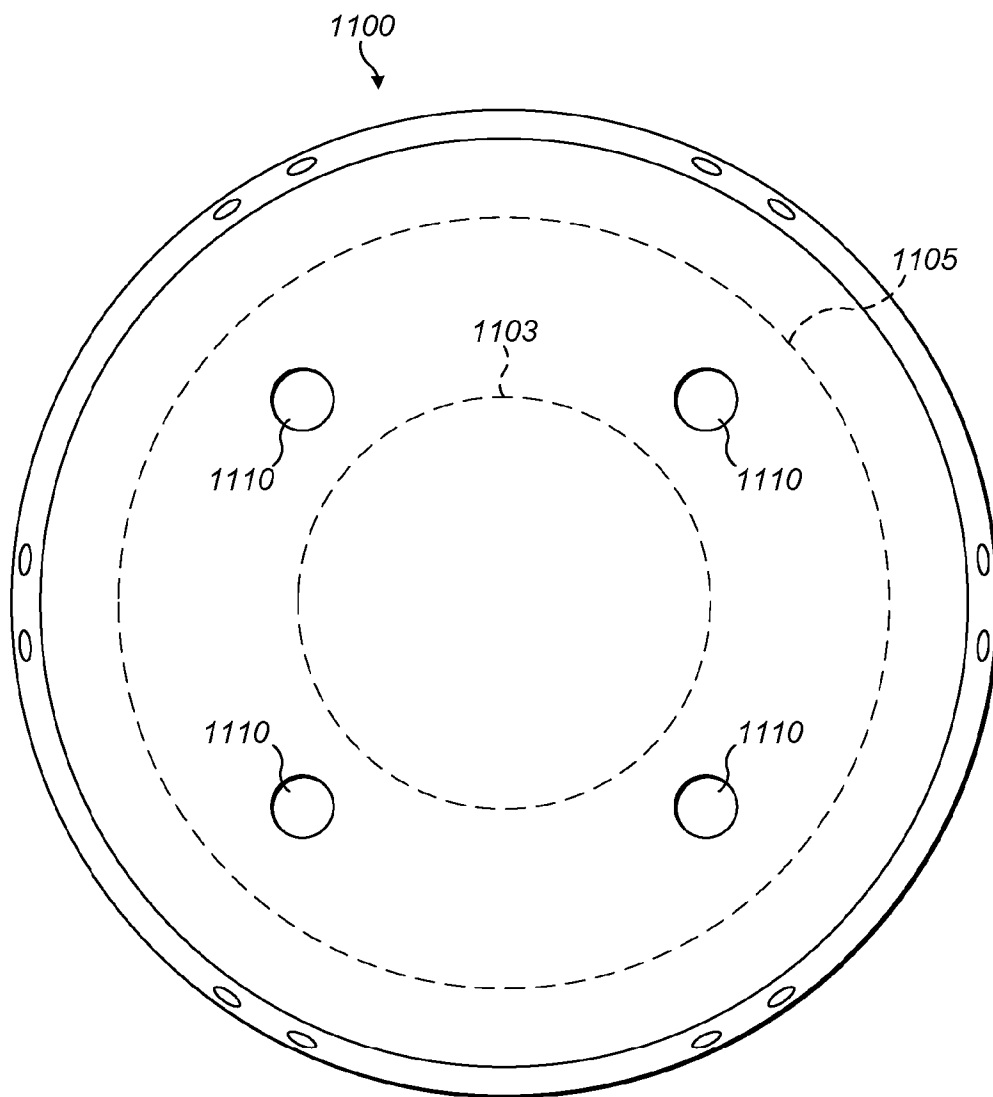


FIG. 11

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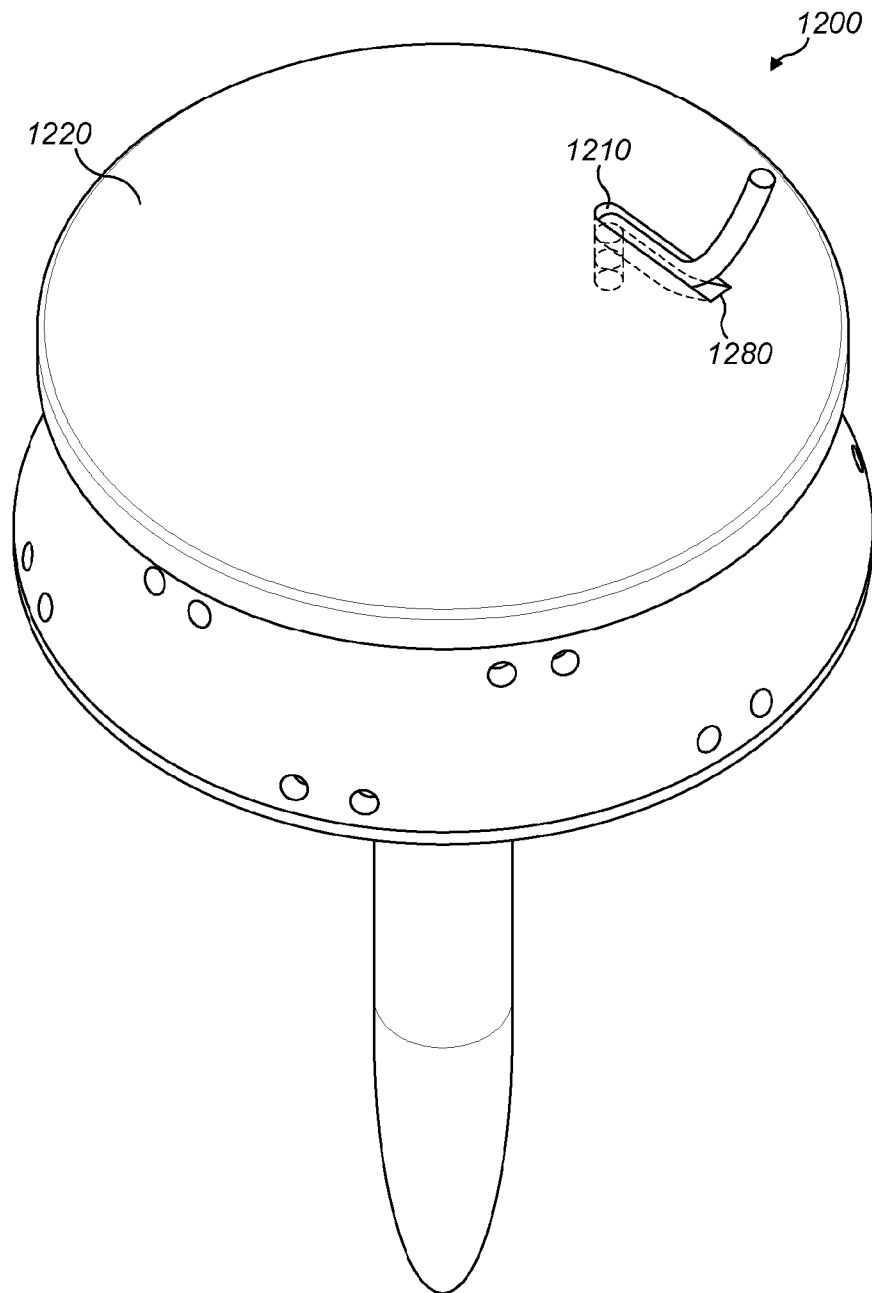


FIG. 12A

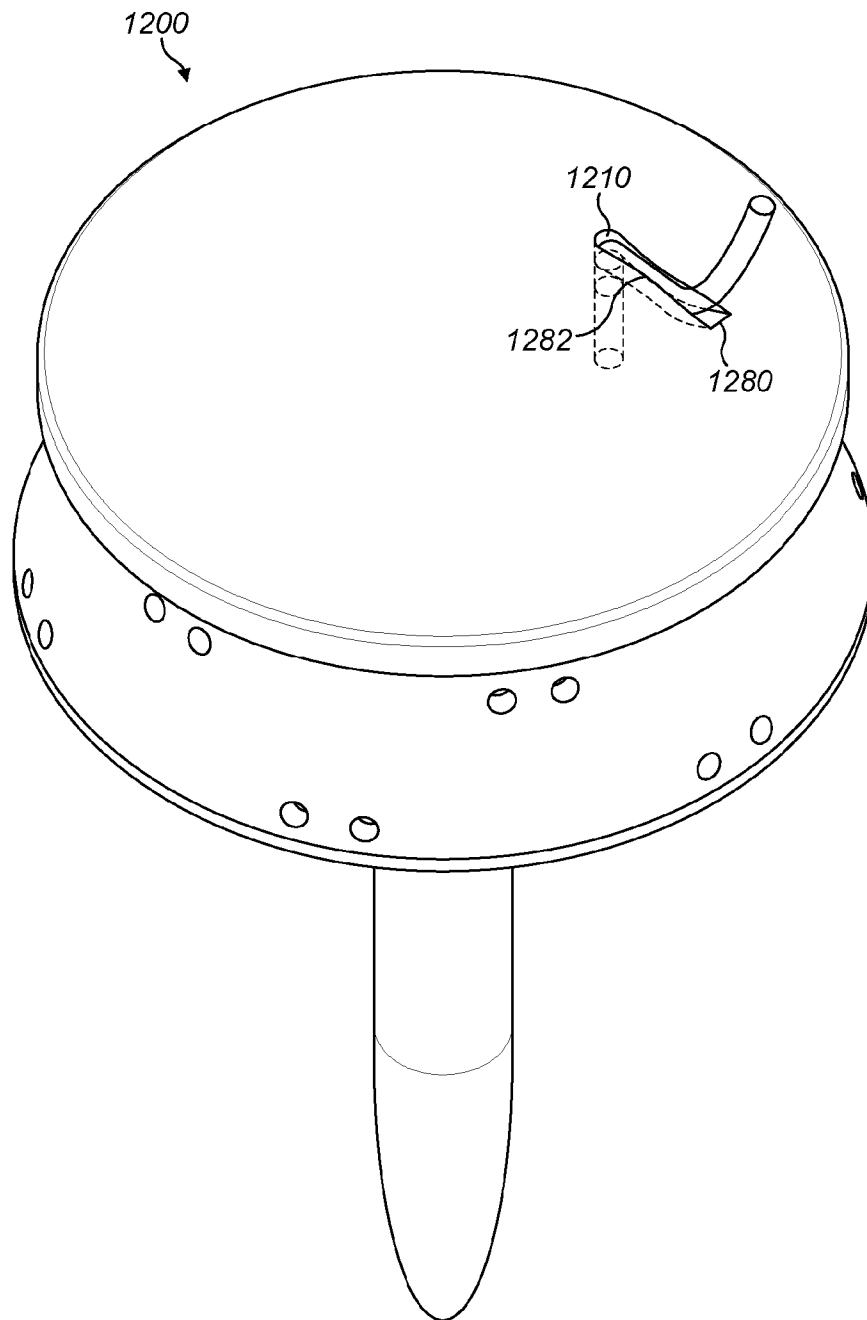


FIG. 12B

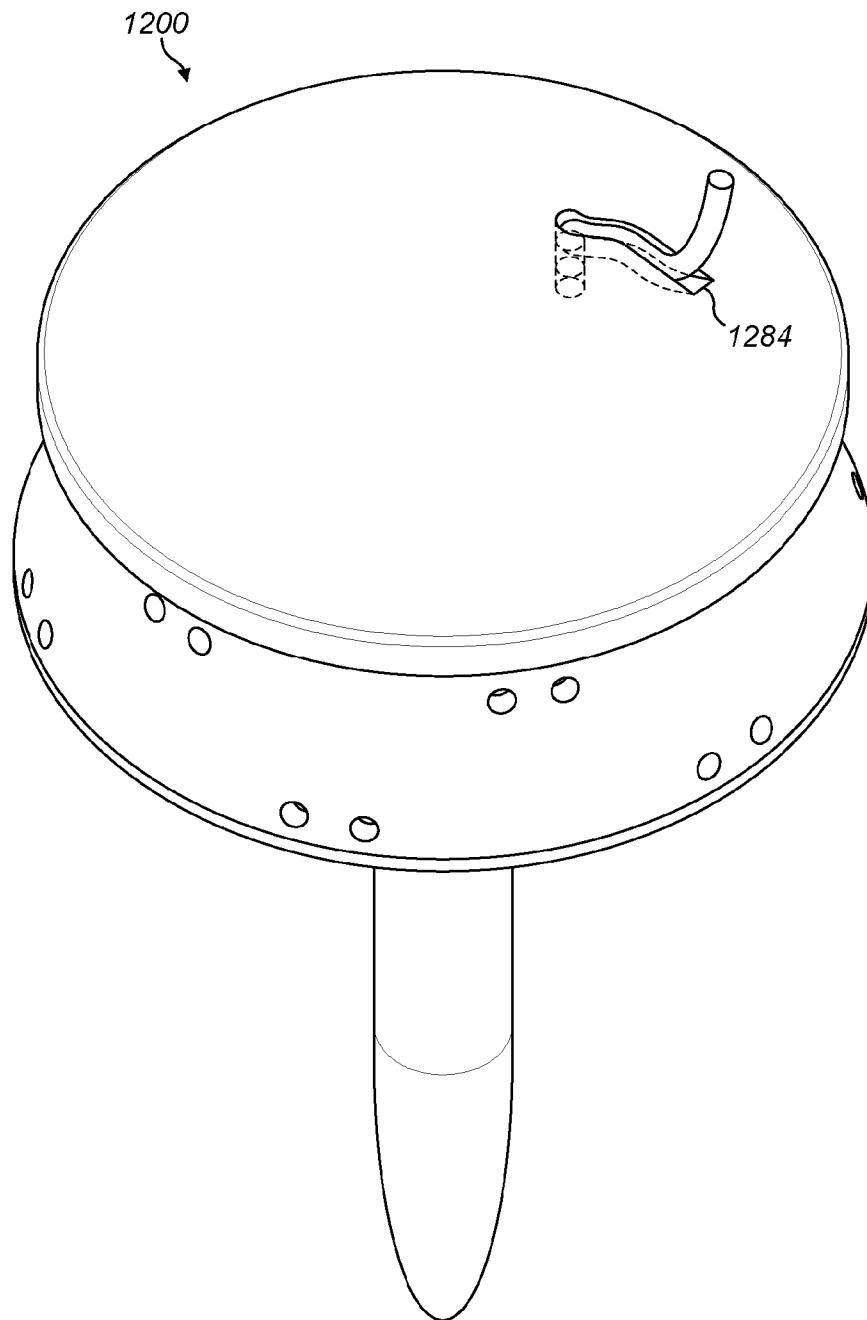


FIG. 12C

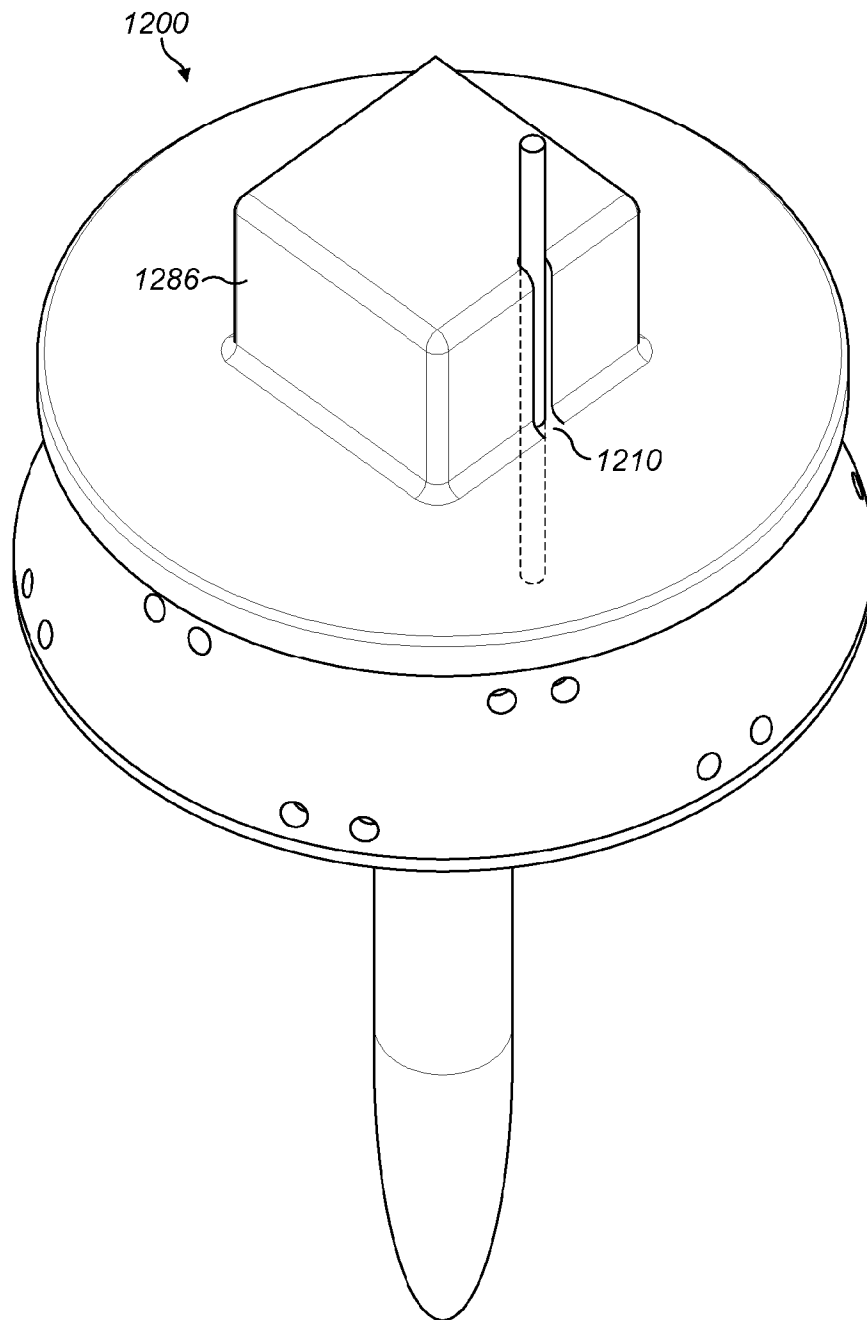


FIG. 12D

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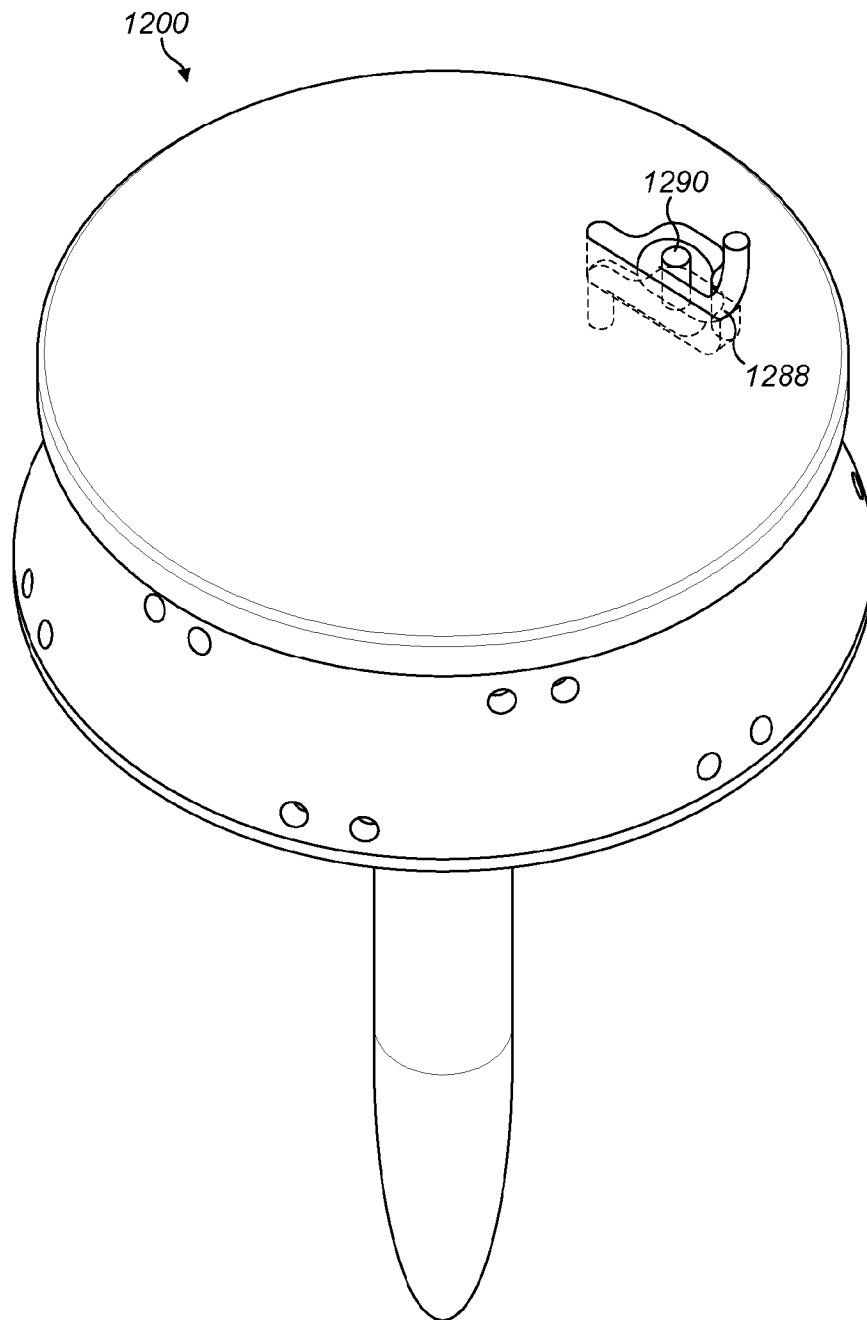


FIG. 12E

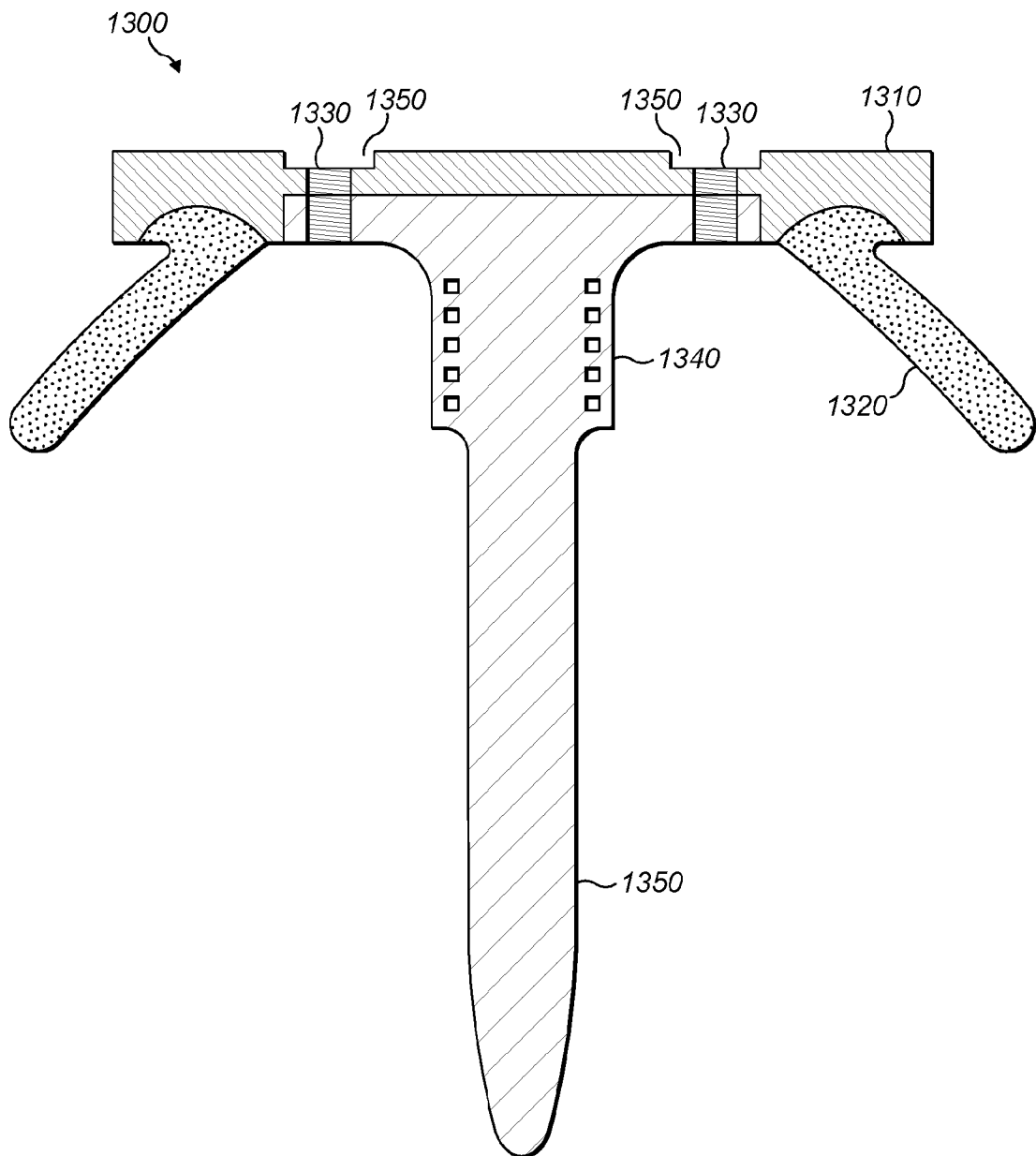


FIG. 13

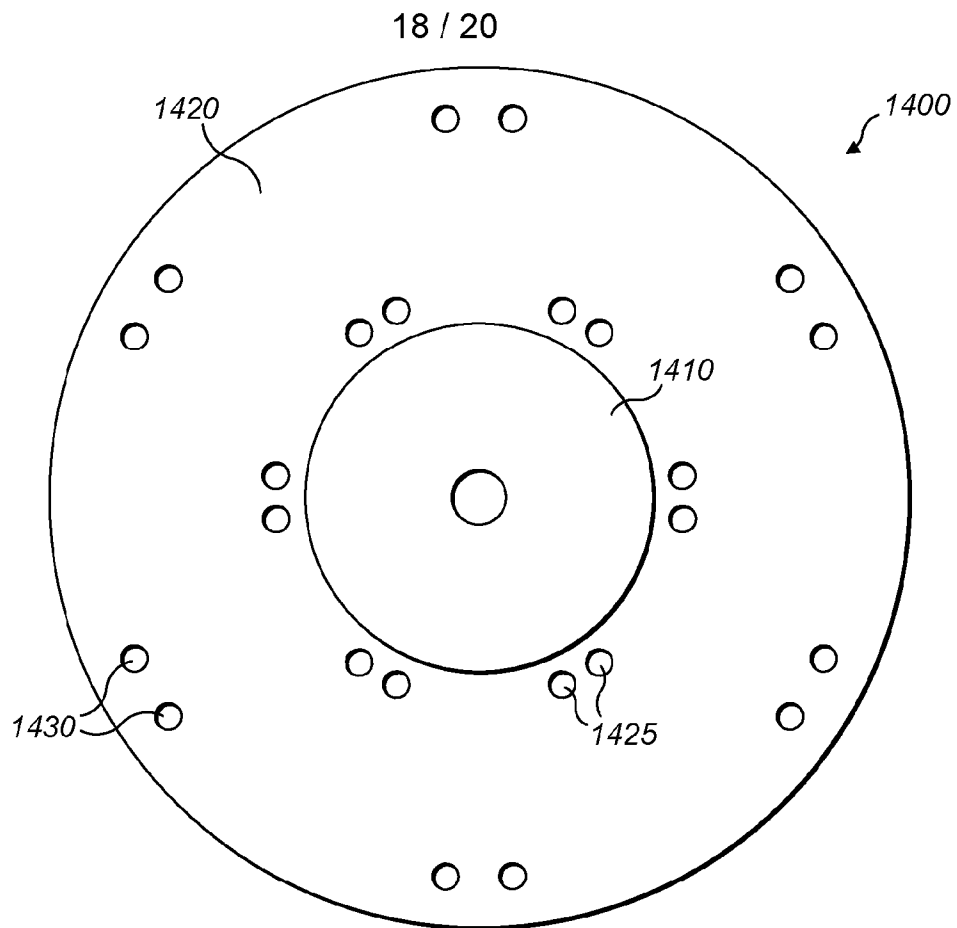


FIG. 14A

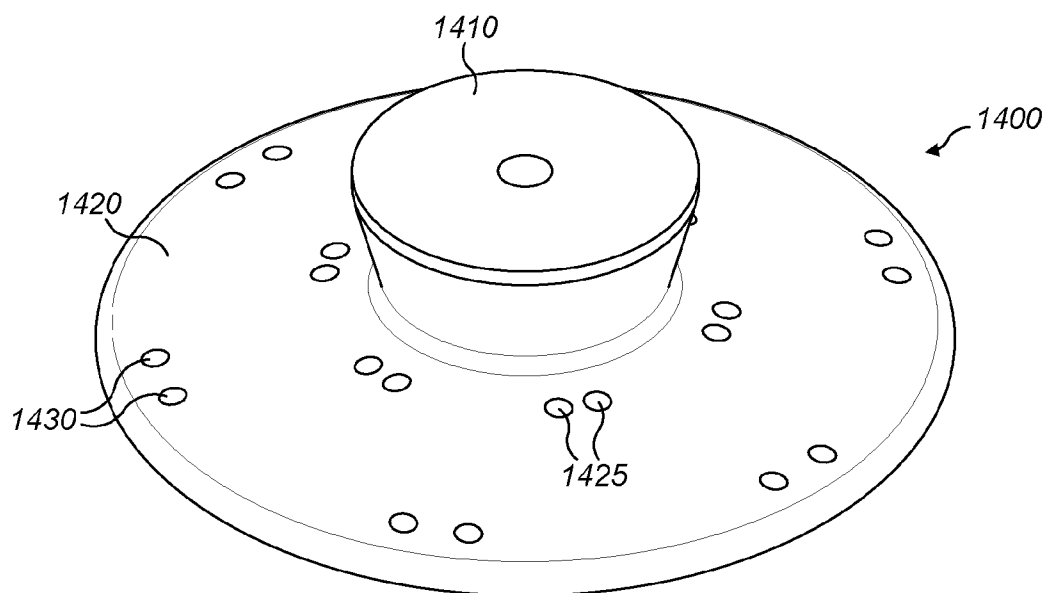
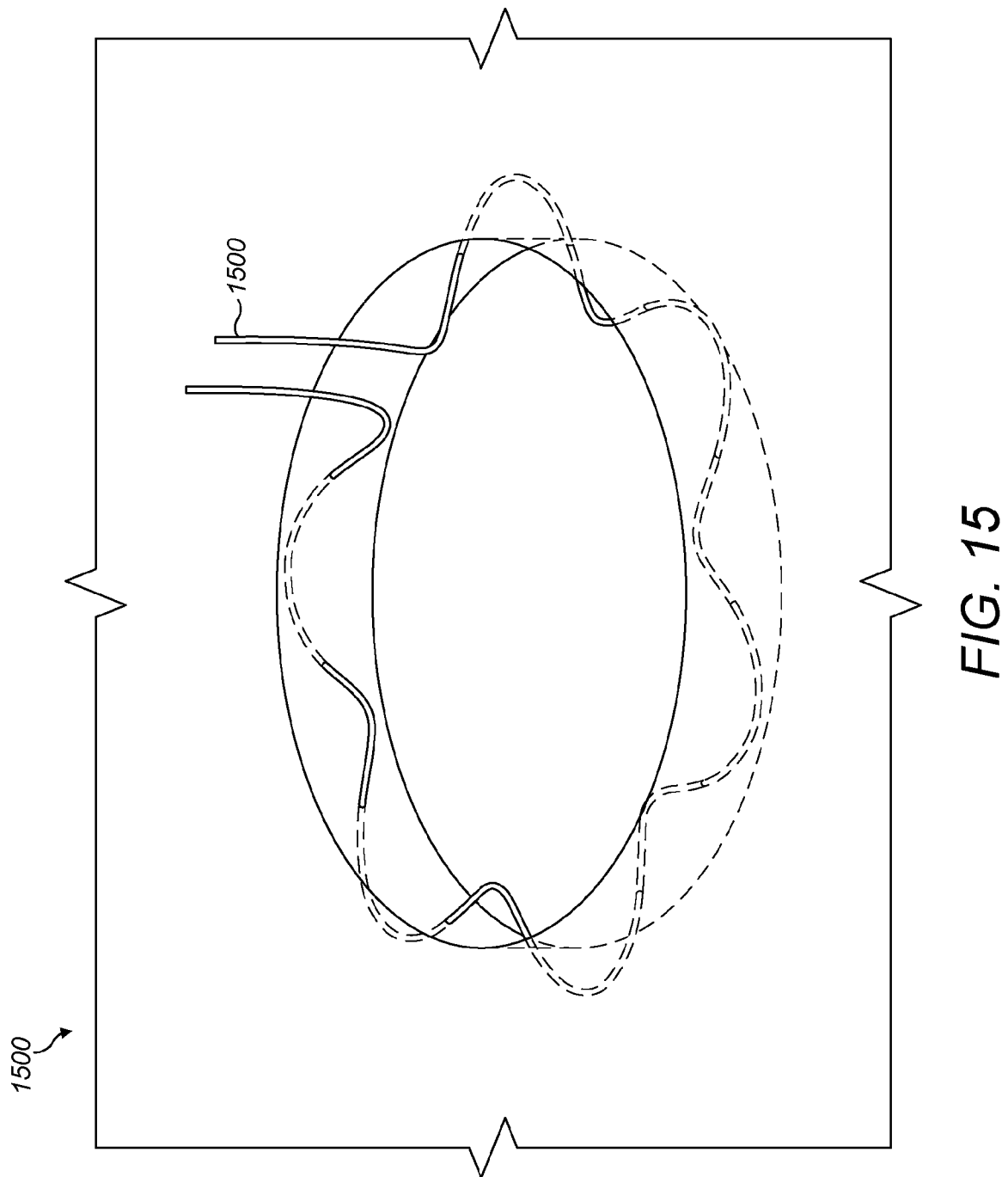


FIG. 14B



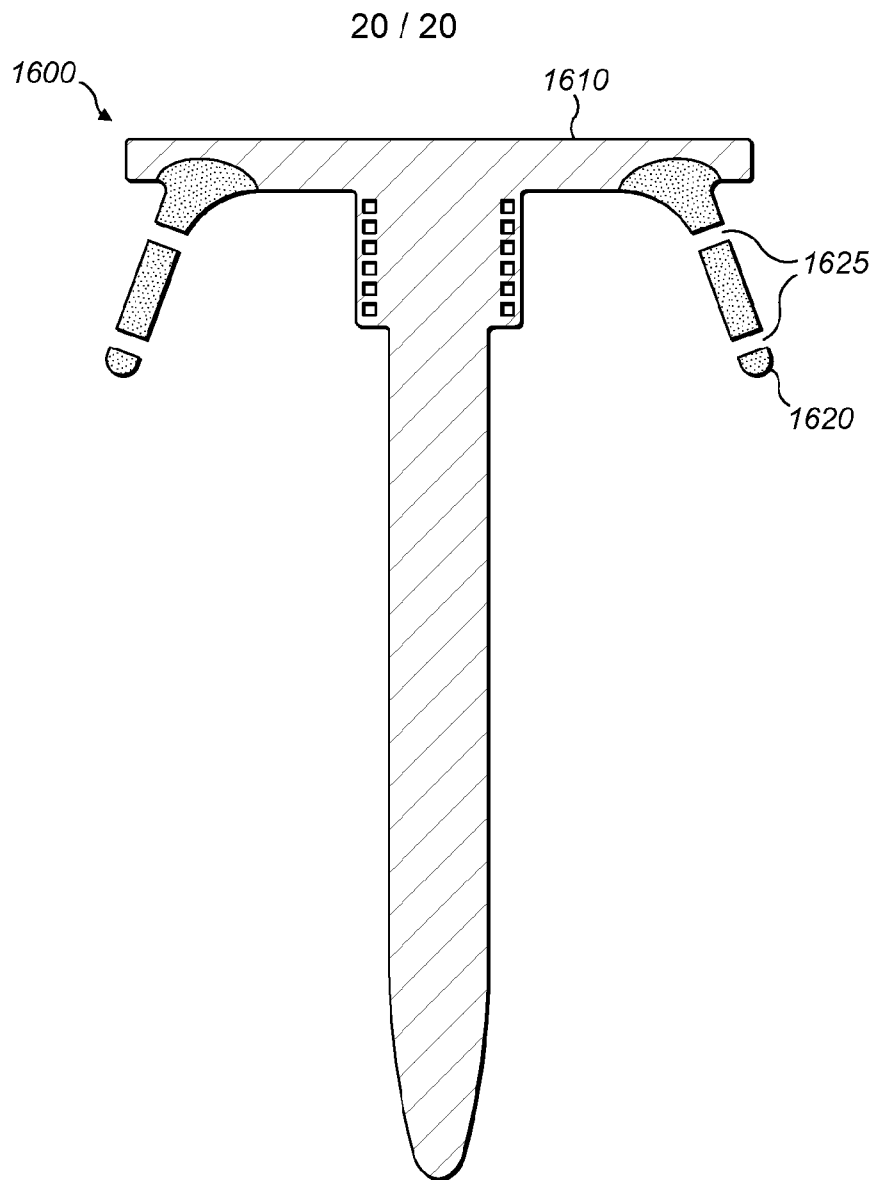


FIG. 16A

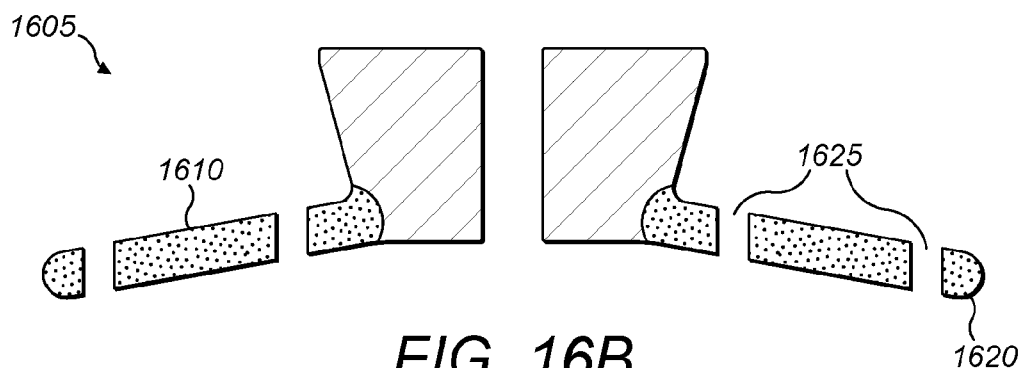


FIG. 16B

INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2019/050871

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M39/02

ADD.

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)

A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 897 081 A (POIRIER VICTOR L [US] ET AL) 30 January 1990 (1990-01-30) column 3, line 3 - column 6, line 56 -----	1-157, 160-307
X	EP 0 174 802 A2 (GORE & ASS [US]) 19 March 1986 (1986-03-19) page 22, line 19 - page 25, line 4 -----	1-307
X	WO 2012/007755 A2 (OSTOMYCURE AS [NO]; EDWIN BJOERN [NO] ET AL.) 19 January 2012 (2012-01-19) page 16, line 11 - page 22, line 3 -----	1-307
X	US 4 668 222 A (POIRIER VICTOR L [US]) 26 May 1987 (1987-05-26) column 2, line 38 - column 6, line 31 ----- -/--	1-157, 160-307



Further documents are listed in the continuation of Box C.



See patent family annex.

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search

22 May 2019

Date of mailing of the international search report

29/05/2019

Name and mailing address of the ISA/

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Authorized officer

Götsch, Stefan

INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2019/050871

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 045 084 A (DUNLOP LTD) 29 October 1980 (1980-10-29) column 1, line 45 - column 3, line 83 -----	1-307

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2019/050871

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4897081	A	30-01-1990	NONE
EP 0174802	A2	19-03-1986	CA 1242369 A 27-09-1988 DE 3574451 D1 04-01-1990 EP 0174802 A2 19-03-1986 GB 2165458 A 16-04-1986 JP H0123141 B2 01-05-1989 JP S61122870 A 10-06-1986 US 4578063 A 25-03-1986
WO 2012007755	A2	19-01-2012	NONE
US 4668222	A	26-05-1987	NONE
GB 2045084	A	29-10-1980	GB 2045084 A 29-10-1980 JP S55143148 A 08-11-1980