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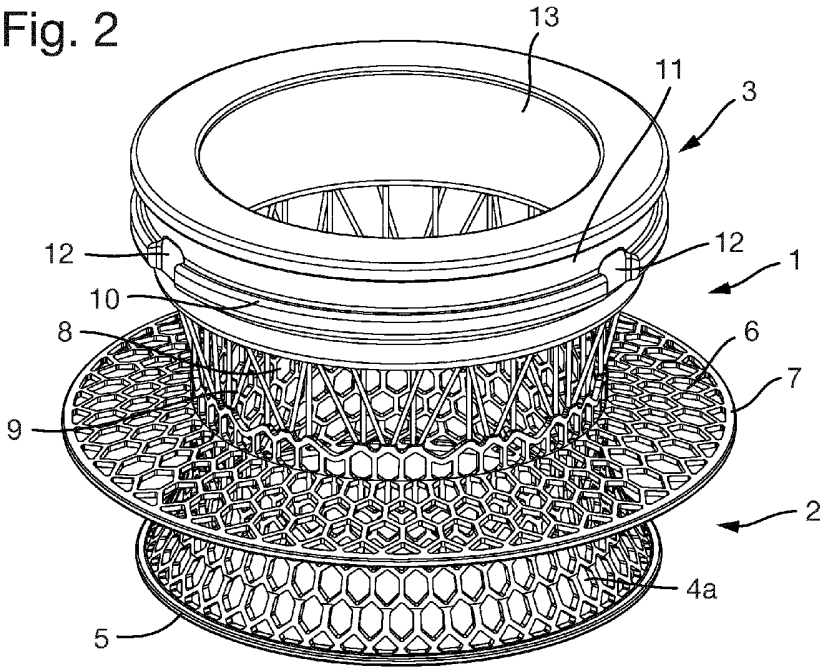
(54) Title: IMPLANT

Fig. 2



(57) Abstract: An implant 1 comprises a tubular interior section 2 for implantation into a patient and an exterior section 3 connected to the interior section 2. A surface of the exterior section 3 comprises a three-dimensional porous structure 13 at its inner circumference.

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Implant

The present invention relates to an implant, particularly a percutaneous ostomy implant, and a surgical method, which may use that implant, preferably for creating a continent reservoir in communication with a percutaneous port.

Ileostomy and colostomy are common operations which may be necessitated, for example, by malignancy or chronic bowel inflammation. The surgery is called an ileostomy if the colon and rectum are removed and a colostomy if the rectum alone is removed. Similarly an abdominal urostomy is created when the urinary bladder has to be removed due to, for example, bladder cancer. In these operations, a stoma is formed in the abdominal wall to which a bowel segment is connected.

Ostomy is a generic term for any such procedure where a stoma is created.

The stoma, in most cases, has to be connected to a bag for the collection of bodily waste. However, instead of a conventional ileostomy, it is possible to make a reservoir known as a "Kock pouch" from the distal part of the ileum. The pouch is formed in such a way that a nipple valve is created which serves to close the reservoir, whilst allowing it to be drained intermittently by means of a catheter. This is an example of a so-called continent ileostomy (CI) and it was formerly an attractive alternative to conventional ileostomy but is now rarely used. The complexity of the procedure and the high potential for complications – most of them related to dysfunction of the continence nipple valve – has deterred many surgeons from adopting the operation today.

The ileopouch anal anastomosis (IPAA) is today the gold standard worldwide for these patients but, as with a CI, this operation is also risky and failures are common, mostly leading to pouch excision with loss of bowel. Conversion of a failed IPAA to a CI would be a preferable option but, again, surgeons are reluctant to perform this complex and unreliable technique. Likewise, conversion of a malfunctional orthotopic neobladder or Bricker urostomy would be desirable.

In its earlier patent application EP 1632201 A1, the present applicant disclosed a percutaneous ostomy implant comprising a solid-walled cylindrical body and an anchoring section in the form of a circular flange. The device was designed to be implanted through the abdominal wall and secured by an anchoring section located below the fascia, above the muscle layer. This section comprised inner and

outer concentric rings interconnected by S-shaped members in order to provide an axially resilient structure which could absorb shear stresses and consequently reduce the risk of tissue damage. Spaces around the S-shaped members and the provision of numerous apertures in the rings allowed for tissue ingrowth and vascularisation. It was proposed to connect the device to the side of the bowel wall and by providing a removable lid on the cylindrical body a continent ostomy could be provided.

US 6017355 discloses another solid-walled implant. This was provided with a fabric coating comprising Dacron velour which was intended to encourage tissue ingrowth.

A development of this implant was disclosed in WO 2007/099500 in which the solid-walled cylindrical body was replaced by an axially outer tubular part spaced from the anchoring section by circumferentially-spaced legs. The tubular part penetrated the skin and formed a ring for connection to a bag or lid. This implant was designed to receive a bowel section drawn up through it; the spaces between the legs allowed the generation of a tissue bond between the inner part of the abdominal wall and the serosal tissue of the bowel in order to provide a more secure, stable, leak-proof and well-vascularised tissue-implant junction. In some embodiments, a circumferential ingrowth mesh was additionally provided. This extended along most of the length of the tubular part with an annular gap being provided between it and the tubular part to facilitate growth of serosal tissue through the mesh.

In a further development, disclosed in WO 2009/024568, the present applicant proposed a cylindrical body formed of two axially-spaced tubular parts. The outer tubular part penetrated the skin and provided a connecting ring. The inner tubular part was attached to an anchoring flange of the type previously described. The two parts were connected together by a "distance means" comprising either radially-spaced legs or a rigid cylindrical ingrowth mesh which allowed for the generation of a tissue bond between the abdominal wall and the bowel. By means of this arrangement, a break was provided in the possible infection path along the implant from the skin.

In a still further development, the applicant disclosed in WO 2010/000851 a percutaneous ostomy implant comprising a cylindrical part for mounting an external detachable device, a cylindrical ingrowth mesh and a circular flange for anchoring the implant. The cylindrical part and circular flange were attached to opposite ends

of the ingrowth mesh, with the mesh extending inside the cylindrical part. The implant was configured such that when it is implanted in the abdominal wall of a patient, abdominal tissue including the epidermis meets the ingrowth mesh and is able to attach therethrough directly to serosal tissue of a bowel segment inside the implant. Thus, it was based on the hypothesis that by allowing the epidermis to attach directly to the serosal tissue, bacterial infection (i.e. bacterial attachment to implant surface and subsequent migration) can be prevented.

However, whilst this implant was found to be effective in ensuring sound attachment of the serosal tissue to the abdominal tissue, it had a drawback in that it became more difficult to ensure a fluid-tight seal between the exterior parts of the implant and the bowel segment. This was because the implant relied upon the bowel segment extending within the cylindrical part and maintaining secure infiltration of serosal tissue through the mesh inside that part to form a good seal to the implant. If the bowel receded below the cylindrical part, a leakage path could be formed through the mesh, even if the bowel segment and abdominal wall remained integrated and the implant remained secure and free of infection.

WO 2011/126724 discloses a stoma stabilising device intended to prevent stomas from constricting over time and hence requiring surgical re-opening. The preferred embodiments comprise a flexible mesh tube with a radially extending mesh anchoring flange. In some variants, multiple layers of mesh may be employed.

In WO 2012/131351, the applicant presented further developments relating to percutaneous ostomy implants comprising a connecting member, a first tubular ingrowth member and a second tubular ingrowth member radially outwardly spaced from the first tubular ingrowth member, a radially-extending dermal anchor to engage the abdominal wall beneath the dermis, and/or a tubular ingrowth member arranged around the connecting member. This implant was formed by a laser cutting process.

However, in trials, this implant was still found to have problems. For example, this implant was fixed to the muscle sheath with an anchor provided at the bottom. This was not ideal with patients adding or losing weight since the implant height was fixed and the thickness of a patient's abdomen could vary over time. There was also insufficient ingrowth at the top of the implant. These factors could lead to skin problems, implant overgrowth, excessive implant protrusion and leakage from the system.

According to one aspect of the invention, there is provided an implant comprising a tubular interior section for implantation into a patient and an exterior section connected to the interior section, a surface of the exterior section comprising a three-dimensional porous structure at an inner circumference thereof. By providing a three-dimensional porous structure at an inner surface of the exterior section, this provides a ingrowth means into which tissue can grow. By providing a three-dimensional structure, this can provide better and more secure ingrowth than previously used two-dimensional ingrowth means. A three-dimensional ingrowth porous structure can provide a "skeleton" structure for tissue ingrowth and creates a physiological need that promotes cellular ingrowth into the structure. Accordingly, in one claimed aspect of the invention, the porous structure is rigid. Furthermore, by providing the three-dimensional porous structure at the exterior section, this can lead to more ingrowth at the outer end of the implant, making it more secure at the exterior end and reducing the possibility of leakage from the system.

Preferably, there is no gap between the three-dimensional porous structure and the rest of the exterior section.

The porous structure is preferably connected to the rest of the exterior section at least at first and second end regions thereof, and/or preferably at a number of points over the height of the porous structure.

Preferably, the porous structure extends to an exterior end (top) of the exterior section. In this way, a bowel segment, for example, may be secured by ingrowth right up to the top end of the implant, thereby providing a more secure implantation of the implant and also reducing the likelihood of leakage. Alternatively, the porous structure may extend to within 1 mm, 2 mm or 3 mm of the exterior end (top) of the exterior section.

The implant may be, for example, an ostomy implant, such as a percutaneous ostomy implant, which is suitable for implantation into the abdominal wall of a patient.

The tubular interior section may be substantially cylindrical but may be of generally any form with an opening along a longitudinal axis thereof. The opening should ideally be large enough for a bowel segment to pass therethrough.

The shape and/or size (e.g. the internal and/or external diameter) of the cross-section of the interior section may vary along its length.

The exterior section may be generally ring-shaped, tubular or cylindrical, for example.

The exterior and/or interior sections may have a substantially circular cross-section.

The exterior section is ideally coaxial with the interior section.

The exterior section may have an outer diameter (measured from its outer edges) of 10-60 mm, more preferably 25-35 mm or 25-30 mm.

The exterior section may have an inner diameter (measured from its inner edges) of 5-55 mm, more preferably 15-30 mm or 20-25 mm.

The interior section may have an inner diameter (measured from its inner edges) at its narrowest point of 5-55 mm, more preferably 15-30 mm or 20-25 mm.

Implants whose exterior and interior sections have a smaller inner diameter (i.e. towards the lower ends of the scales mentioned above) may be particularly useful for urostomies. Implants whose exterior and interior sections have a larger inner diameter (i.e. towards the upper ends of the scales mentioned above) may be particularly useful for colostomies.

The interior and exterior sections may have circular cross-sections or any other shape. Thus, since the cross-sections of these sections need not necessarily be circular, references to "diameter" above refer to the maximum distance measured perpendicularly across the sections.

Preferably, the interior and exterior sections have the same cross-section (e.g. in size and/or shape), at least at the point where the sections meet.

The porous structure is preferably arranged around the entire inner circumference of the exterior section. Alternatively, the porous structure may be provided around at least 70%, at least 75%, at least 80%, at least 85%, at least 90%, at least 95%, at least 97%, at least 98% or at least 99% of the inner circumference of the exterior section. By providing all, or at least a significant part of the inner circumference of the exterior section with a porous structure, this ensures that ingrowth means is provided around all, or at least a significant part, of the inner circumference of the exterior section so secure and sufficient ingrowth may be obtained.

The porous structure preferably has a thickness (or a minimum thickness) of at least 0.5 mm, at least 0.6 mm, at least 0.7 mm, at least 0.8 mm, at least 0.9 mm, at least 1.0 mm, at least 1.1 mm, at least 1.2 mm, or at least 1.25 mm. In preferred embodiments, the porous structure has a thickness of around 1.25 mm or 1.75 mm. By providing a porous structure of at least 0.5 mm (or greater) thick, this means that the porous structure may be formed of a number of layers (e.g. two or three layers)

and helps to ensure secure ingrowth into the porous structure. The thickness of the porous structure may be measured in a radial direction with respect to the longitudinal axis of the implant.

The porous structure should ideally also be thin enough that there is enough space inside the exterior section for a bowel segment to pass through it. Thus, preferably the porous structure has a thickness of 3.0 mm or less, 2.5 mm or less, or 2.0 mm or less. The thickness of the porous structure may be in a range of 0.5 to 2.0 mm, 2.5 mm, or 3.0 mm, for example.

Preferably, the porous structure is completely permeable and has no dead ends. For example, each passage entering the porous structure ideally also has an exit. Alternatively, at least 80%, at least 85%, at least 90%, at least 95%, or at least 97% of the openings into the porous structure have a corresponding exit. This can provide the most secure ingrowth into the ingrowth means.

The thickness of any member forming the porous structure is preferably less than or equal to 500 μm, less than or equal to 450 μm, less than or equal to 400 μm, less than or equal to 350 μm, or less than or equal to 300 μm. The thickness of any member forming the porous structure is preferably greater than or equal to 100 μm, greater than or equal to 125 μm, greater than or equal to 150 μm, or greater than or equal to 200 μm. By providing a porous structure formed of members with such dimensions, this means that the porous structure has dimensions which are biologically comfortable (mimicking coral, for example), thereby creating a physiological need which promotes secure ingrowth of tissue into the porous structure.

For similar reasons, preferably, the maximum diameter of any opening in the porous structure is 500 μm, 450 μm, 400 μm, 350 μm, 300 μm, 250 μm, 200 μm or 150 μm. The minimum diameter of any opening in the porous structure may be 50 μm, 75 μm, 100 μm or 125 μm, for example. The diameters of any openings (or of at least 70%, 75%, 80%, 85%, 90% or 95% of the openings) in the porous structure are preferably in a range of 100 to 400 μm, more preferably, 150 to 350 μm, more preferably 250 to 350 μm, more preferably 275 to 325 μm.

The cross-sections of any members and/or openings in the porous structure may be circular or any other regular or irregular shape such as elliptical, super-elliptical, quadratic with rounded corners, hexagonal, octagonal, polygonal, polygonal with rounded corners, or rectangular with rounded corners, for example. Thus, since the cross-sections of the members and/or openings forming the porous

structure need not necessarily be circular, references to "diameter" above refer to the maximum distance measured perpendicularly across a member and/or an opening in the porous structure.

In further optimised embodiments, both the members forming the porous structure and the openings of the porous structure may vary independently in size and/or shape within one porous structure, in a random or structured (regular) pattern.

The porous structure preferably has a height of at least 3 mm, at least 4 mm, at least 5 mm, or at least 6 mm, where the height is the length of the porous structure measured in a direction parallel to the longitudinal axis of the implant.

The porous structure preferably has a height of less than 10 mm, less than 8 mm, less than 8 mm or less than 7 mm.

Preferably, the height of the porous structure is in a range from 3 to 9 mm, more preferably from 4 to 8 mm, more preferably from 5 to 7 mm, more preferably from 6 to 7 mm.

In a preferred embodiment, the height of the porous structure is 6.35 mm.

The porous structure has a height that is ideally great enough to provide a sufficiently large ingrowth zone, but also small enough that there is limited implant protrusion above skin level (the porous structure being ideally located within the exterior section).

However, in some embodiments the porous structure may extend into the interior section and/or a further porous structure (for example with any of the features discussed in relation to the first porous structure) may be provided in the interior section. Thus, a porous structure with a height of up to around 40 mm may be provided. Such a porous structure could extend from the exterior section into the interior section.

The porous structure may be flexible, semi-flexible or rigid.

The porous structure is preferably integral with the rest of the exterior section. This means that the exterior section, at least, can be formed as a single element (for example with the rest of the implant as well) and there is no need to attach a porous structure inside the exterior section.

The porous structure is preferably made from a biologically acceptable material such as titanium. This helps to prevent patients reacting adversely to the implant. Preferably, a commercially pure titanium is used such as medical grade 2 titanium. Examples of other materials that could be used include titanium grades

according to ASTM F67 (ISO 5832) medical grade 1, 2, 3, 4 or 5, specifically grade 5 Ti64ELI, other biocompatible metals and alloys such as Elgiloy, or a chrome-cobalt-molybdene alloy, biocompatible ceramics and biocompatible polymers.

The porous structure may be formed from interconnecting members. The members may be arranged in layers (e.g. concentric layers), for example. The layers could be connected by connecting members. Accordingly, the connecting members will typically have a radial extent. These are preferably two to four layers, but more preferably three.

The members may form a regular, repeating pattern throughout the porous structure. For example, the porous structure could be formed from a plurality of repeating units.

Alternatively, the porous structure may have an irregular or partly irregular structure.

In either case it will be appreciated that the porous structure is typically porous in multiple directions (i.e. passages through the structure extend in multiple directions) so that a coral-like structure is provided. This is in contra-distinction from conventional mesh which is essentially two-dimensional, with porosity (and passageways) extending in only one direction, relative to the surface of the mesh.

Preferably, the exterior section comprises engagement means (e.g. a engagement mechanism) for engaging with a device. For example, the exterior section may comprise one or more grooves, recesses or indentations into which corresponding attachment means provided on a lid or other device may be attached. Preferably, the engagement means are located on an exterior surface of the implant, or at the very top of the inner surface of the implant, so that tissue inside the implant is not affected when a device is attached to the implant.

Alternative engagement means include: a threaded interface for screwing a device onto the implant, a bayonet attachment, a magnetic interface (i.e. one or more magnets arranged on the implant), a rubber or rubber-like material encompassing the outer perimeter, or like a cork in the inner diameter, for example, of the implant.

In some embodiments, at an inner end, the interior section may comprise a radially extending part, for example in a cone or trumpet-like shape. This can help to secure the implant in a patient's body as it can resist forces acting on the implant in more directions.

Alternatively or additionally, the implant may comprise an anchoring flange extending radially outwardly from the interior section. This can also help to secure the implant in a patient's body.

The anchoring flange may extend to a greater radius than the radially extending part (if both such components are provided).

The anchoring flange may extend perpendicularly from the implant. However, it is preferred that it extends at an angle of less than 90° such that it is sloping towards the interior end of the implant. The anchoring flange may be curved. These features can allow the anchoring flange to follow the general curvature of a patient's body, reducing the likelihood of damage or problems caused by its implantation.

The anchoring flange may be formed of or comprise an ingrowth means (e.g. an ingrowth part) such as a mesh, e.g. a hexagonal mesh. Such an ingrowth means can allow body tissue to grow into the flange and secure the implant in the body.

The interior section preferably extends longitudinally inwardly (i.e. downwardly as shown in the figures) from a point at which the anchoring flange is connected to it. The interior section may additionally or alternatively extend longitudinally outwardly (i.e. upwardly as shown in the figures) from a point at which the anchoring flange is connected to it.

The implant may be flexible, semi-flexible or rigid. In some embodiments the flexibility/rigidity of the implant may vary over its structure. For example, the interior section may be more flexible than the exterior section so that, for example, the interior section is more adapted to the surrounding tissue, but the exterior section is still sufficiently rigid that a lid may be attached to it. This may be achieved by using different materials in different sections of the implant, for example. Such different materials could be joined with welds, glue, friction, threads, or other techniques.

The interior section may be formed of or comprise an ingrowth means (e.g. an ingrowth part) such as a mesh, e.g. a hexagonal mesh. Such an ingrowth means can allow body tissue to grow into the interior section and secure the implant in the body.

The interior section may comprise a plurality of rods, the rods having a diameter of less than or equal to a biologically comfortable length such as 500 µm, 450 µm, 400 µm, 350 µm, 300 µm, 250 µm or 200 µm. The diameter of the rods is

preferably similar to the average diameter of human skin hairs, e.g. 20 to 200 µm. By forming the interior section, or part of the interior section, from such thin components, the amount of material used to form the implant can be minimised, thereby reducing the likelihood of a patient reacting adversely to the implant. Furthermore, since the rods have a diameter of less than or equal to a biologically comfortable length, this reduces the possibility of the patient's body rejecting or reacting adversely to the implant.

This concept is considered to be inventive in its own right, thus, according to a second aspect of the invention, there is provided an implant comprising a tubular interior section for implantation into a patient and an exterior section connected to the interior section, wherein the interior section comprises a plurality of rods and the rods have diameters of less than or equal to 500 µm, less than or equal to 450 µm, less than or equal to 400 µm, less than or equal to 350 µm, less than or equal to 300 µm, less than or equal to 250 µm or less than or equal to 200 µm. The diameters of the rods may be in a range of 100 to 400 µm, 100 to 300 µm, 150 to 250 µm, 100 to 200 µm, 200 to 300 µm, or 250 to 300 µm, for example.

Preferably, the rods have a diameter of greater than or equal to 20 µm, greater than or equal to 50 µm, greater than or equal to 75 µm, or greater than or equal to 100 µm. In a preferred embodiment, the rods have a diameter of 275 µm.

The rods may have a circular cross-section or any other shape. Thus, since the cross-sections of the rods need not necessarily be circular, references to "diameter" above refer to the maximum distance measured perpendicularly across a rod.

The rods are preferably arranged circumferentially around the implant. At least some of the rods may be parallel to the longitudinal axis of the implant, for example.

Depending on the diameter of the rods and the material from which they are made, ideally sufficient rods should be provided to make the implant strong enough to withstand pulling forces acting on it, with a safety margin, for example. The stronger the material used for forming the rods, the smaller the number of rods required. Ideally, the smallest number of rods possible are used to keep the amount of material used to a minimum.

More than 10, 20, 30, 40, 50 or 60 rods may be provided and/or fewer than 150, 140, 130, 120, 110, 100, or 90 rods may be provided.

Preferably, 5 to 150, 20 to 130, 40 to 110, 50 to 100, or 60 to 90 rods are provided.

One or more of the rods is preferably slanted with respect to the longitudinal axis of the implant. This can help to improve the mechanical strength of the implant since such rods can help to withstand torque, shearing and compressing forces acting on the implant. For example, the one or more slanting rods may be arranged at an angle of up to 45°, up to 40°, up to 35°, up to 30°, up to 25°, up to 20°, up to 15° or up to 10° with respect to a longitudinal axis of the implant. Preferably, the one or more slanting rods may be arranged at an angle of at least 5°. In preferred embodiments, one or more slanting rods are arranged at angles of up to 25°.

Rods may be slanted radially inwardly or outwardly from the longitudinal axis of the implant and/or circumferentially or sideways around the implant. The inward or outward radial slant of the rods is preferably less than the circumferential slant. For example, rods may be slanted radially outwards or inwards by an angle of around 15° or less, and/or rods may be slanted circumferentially by an angle of around 25° or less. Rods may be slanted circumferentially in clockwise and/or anti-clockwise directions (when view from the top or exterior end of the implant).

One or more of the rods is preferably parallel with respect to the longitudinal axis of the implant. Such parallel rods can help to withstand axial forces acting on the implant along its longitudinal axis, for example.

Around 30-40%, 30-50%, 40-60%, 50-70% or more of the rods may be slanting.

Around 30-40%, 30-50%, 40-60%, 50-70% or more of the rods may be parallel.

One or more rods may have at least one end located radially inwardly with respect to the implant compared to one or more other rods. Such an arrangement can improve the mechanical strength of the implant, particularly with respect to shear forces. Shear forces may act on an implant, for example, when a patient rises from a chair and contacts a table with the implant, moves sideways and contacts a door-post, or similar situations.

The inner ends of the rods (i.e. the ends of the rods located furthest from the exterior section of the implant) are preferably all located at the same radius of the implant.

The exterior ends of the rods (i.e. the ends of the rods located closest to the exterior section of the implant) may be located at different radii, for example at two

or three different radii. In a preferred embodiment, the exterior ends of the rods are located on three imaginary concentric circles. Preferably, the concentric circles are equally spaced.

The radial distance between the radially innermost exterior ends and the radially outermost exterior ends may correspond to the thickness of the porous structure. For example, the radial distance between the radially innermost exterior ends and the radially outermost exterior ends may be around 1.0 to 2.0 mm or 2.5 mm.

Such arrangements of the rods can result in a very rigid, box-like overall structure, which can help to increase the mechanical strength of the implant and distribute the forces acting on the exterior section of the implant more uniformly into the porous structure.

The rods are ideally long enough that, in use, they can extend through the skin (i.e. the epidermis and the dermis) and also ideally extend partially into the hypodermis. For example, the rods may be at least 1.5 mm, at least 2 mm, at least 2.5 mm, at least 3.0 mm, at least 3.5 mm, at least 4.5 mm or at least 5.0 mm long. The rods may have a maximum length of 8.0 mm, 7.5 mm, 7.0 mm, 6.5 mm, 6.0 mm, 5.5 mm or 5.0 mm. In a preferred embodiment, the rods are around 4.8 mm long. Of course, the slanting rods may be slightly longer than the parallel rods. The lengths referred to in this paragraph may refer to the slanting or the parallel rods.

The interior section may comprise an inner interior section part and an outer interior section part.

The outer interior section part preferably comprises the plurality of rods.

The plurality of rods may connect the inner interior section part to the exterior section.

Preferably, the inner interior section part is connected to the exterior section solely by the plurality of rods. This helps to minimise the amount of material used in the implant.

For similar reasons, the outer interior section part is preferably formed solely from the plurality of rods.

The inner interior section part preferably comprises or is formed of an ingrowth means (e.g. an ingrowth part), preferably in the form of a mesh such as a hexagonal mesh. By providing such an inner interior section part, this can help the implant to be implanted securely into a patient's body.

Various optional features of the aspects described above are considered to be independently inventive.

Thus, according to another aspect of the invention, there is provided an implant comprising an ingrowth means in the form of a three-dimensional porous structure, wherein the porous structure has a thickness of at least 0.5 mm. For example, the porous structure could have a thickness of at least 0.5 mm, at least 0.6 mm, at least 0.7 mm, at least 0.8 mm, at least 0.9 mm, at least 1.0 mm, at least 1.1 mm, at least 1.2 mm, or at least 1.25 mm. In preferred embodiments, the porous structure has a thickness of around 1.25 mm or 1.75 mm. As discussed above, by providing an ingrowth means of at least 0.5 mm thick, this ensures that secure ingrowth into the porous structure can be achieved.

According to another aspect of the invention, there is provided an implant comprising an ingrowth means in the form of a three-dimensional porous structure, wherein the porous structure is completely permeable and has no dead ends.

Preferably, each passage entering the porous structure also has an exit.

According to another aspect of the invention, there is provided an implant comprising an ingrowth means in the form of a three-dimensional porous structure, wherein at least 80%, at least 85%, at least 90%, at least 95%, or at least 97% of the openings into the porous structure have a corresponding exit.

According to another aspect of the invention, there is provided an implant comprising an ingrowth means in the form of a three-dimensional porous structure, wherein the thickness of any member forming the porous structure is less than or equal to 500 µm, less than or equal to 450 µm, less than or equal to 400 µm, less than or equal to 350 µm, or less than or equal to 300 µm.

According to another aspect of the invention, there is provided an implant comprising an ingrowth means in the form of a three-dimensional porous structure, wherein the maximum diameter of any opening in the porous structure is 500 µm, 450 µm, 400 µm, 350 µm, or 300 µm.

The implants of any of the above aspects may be a percutaneous ostomy implant, for example. The implants may comprise a tubular interior section and/or a tubular or ring-shaped exterior section. The interior and exterior sections are preferably co-axial. The ingrowth means may be located in the interior and/or exterior section. Preferably, the ingrowth means extends around the circumference of the interior and/or exterior section.

After an implant has been implanted into a patient, it is important that a bowel segment, for example, or other vessel passing through the implant, is secured so that it can grow into the implant.

There are various ways in which the bowel segment, for example, may be secured or fixated. One conventional method is a surgical procedure referred to as a "turnbull". During this procedure, on a conventional stoma the efferent part of the intestine is wrung inside out and attached to the skin surrounding the stoma. However, after this procedure, the stoma often retracts at skin level, leaving a space and resulting in leakage. Also, it is not possible to perform a conventional turnbull with the implant of the above aspects because this would completely cover and hide the implant. It would then not be possible to use a stabiliser device (to hold the implant in position) during healing and it would also not be possible to monitor the healing and ingrowth of the implant. The risk of bodily waste being caught under the turnbull and around the implant would be great, potentially causing infection, and it would not be possible to clean and wash away such trapped waste. In previous processes with an ostomy implant, the intestine was simply left outside the implant or arranged into a "loose hanging turnbull", not connected to anything, and not secured or fixed.

There is therefore a need for providing a way of securing the bowel segment, for example, to provide a more stable environment for the stoma to heal after an ostomy is performed on a patient.

According to a further aspect of the invention, there is provided an adaptor for securing a bowel segment outside a patient's body after an ostomy has been performed, the adaptor comprising: attachment means (e.g. an implant attachment part) for attaching the adaptor to an implant; and securing means (e.g. a bowel segment securing part) to which a bowel segment may be attached.

By providing such an adaptor, a turnbull procedure may be facilitated and the bowel segment can be secured whilst it heals, thereby reducing the likelihood of it retracting during this process. In addition, when used with an implant according to one of the aspects of the invention described above, the bowel segment can be secured close to the porous ingrowth structure (where this is provided in the exterior section of the implant), which further helps to keep the bowel segment in a fixed position, and thereby provides an optimal peaceful healing situation free from significant movements or mechanical stress.

The adaptor may be referred to as a turnbull adaptor.

The implant itself may also be secured with a stabiliser device to hold it in place during healing.

The adaptor should ideally be easy to attach to the implant with the correct alignment.

Preferably, the attachment means are arranged to prevent the adaptor from moving rotationally, horizontally and vertically with respect to the implant, when the adaptor is attached to the implant. This helps to prevent rotational or other forces acting on the vessel during healing.

Preferably, the attachment means are arranged to attach to an outer surface of the implant, for example in a groove, recess or indentation on an outer surface of the implant. The attachment means may be arranged to engage with one or more corresponding grooves, recesses or indentations on the implant.

In a preferred embodiment, the attachment means comprises one or more resilient members. This is a simple way of allowing the adaptor to be attached to an implant. The one or more resilient members may comprise engagement means (e.g. implant engagement parts), such as protruding parts, for engaging with the implant, for example in one or more corresponding recesses on the implant.

Alternative attachment means could also be used. For example, longer or shorter resilient members could be used with corresponding grooves, recesses or indentations, for example, in a correspondingly lower of higher position on the implant. Different shaped protruding parts could also be used. Other alternatives include: a threaded interface for screwing the adaptor onto the implant, a bayonet attachment, a magnetic interface (i.e. one or more corresponding pairs of magnets on the adaptor and the implant), a rubber or rubber-like material encompassing the outer perimeter of the implant and/or an inner perimeter of the adaptor using only friction forces, a rubber or rubber-like material with a ring-like suction-cup on the adaptor for attaching to a polished top surface, for example, of the implant.

The adaptor preferably has an aperture through which the bowel segment may pass. For example, the adaptor may be substantially ring-shaped. Preferably the aperture has the same shape and/or diameter as the inner shape and/or diameter of the corresponding implant. For example, the adaptor may be substantially ring-shaped or tubular. The aperture may have a diameter of 5-55 mm, more preferably 15-30 mm or 20-25 mm.

The securing means may comprise one or more openings in the adaptor through which sutures may be attached. For example, the adaptor may comprise

one or more radially extending parts in which the one or more openings are provided. The securing means could alternatively comprise one of more hooks to which sutures may be attached.

The adaptor is preferably made of a plastics material such as a medical quality polyamide. Alternatively, the adaptor may be made of medical grade POM, PEEK, or other similar polymer, a semi-rigid or flexible medical grade polymer such as Mediprene or similar, or titanium or other metal or alloy, depending on the attachment mechanism and manufacturing method.

In some embodiments, a biologically degradable material is used to form the adaptor. The adaptor would then "disappear" automatically after a suitable time, as it is dissolved by the surrounding tissue. Such an adaptor could be made of a medical grade polymer such as PGA poly(glycolide), PDO poly(p-dioxanone), LPLG poly(L-lactide-co-glycolide), DLPLG poly(DL-lactide-co-glycolide) or PHB-PHV copolymer (polyhydroxybutyrate-polyhydroxyvalerate), for example.

Different polymers or other materials will degrade at different rates within the body and therefore a polymer or other material should ideally be used which has a suitable release/degradation rate. For example, a material which could form an adaptor that would degrade after a few weeks (e.g. 2-8 or 5-7 weeks) may be suitable. Such an adaptor would remain in the body long enough for the healing process to take place. Also, factors such as mechanical properties, processing properties, possible sterilisation methods, cost and availability of the material, etc. should be considered when selecting a suitable material. The adaptor is preferably arranged to receive the bowel segment therethrough and allow the bowel segment to be reverted back over the adaptor.

According to a further aspect of the invention, there is provided a kit comprising an implant and an adaptor for securing a bowel segment outside a patient's body after an ostomy has been performed, the adaptor comprising: attachment means for attaching the adaptor to the implant; and securing means to which a bowel segment may be attached.

The kit is preferably sterile.

The adaptor in the kit may be as described in relation to the adaptor aspect of the invention or any of its preferred features above.

The implant in the kit may be as described in relation to any of the implant aspects of the invention or any of their preferred features above.

The present invention also extends to a method of performing an ostomy comprising the use of an implant and/or adaptor as described above.

Thus, according to a further aspect there is provided a method of performing an ostomy comprising providing an ostomy implant according to any aspect or any preferred form thereof as described above; providing a suitable opening for the implant in the body of a patient; implanting the implant in the opening and drawing a bowel segment into the implant to provide a stoma. The method is most preferably as described in more detail below.

Viewed from a further aspect, the invention provides a method of performing an ostomy comprising: implanting a percutaneous ostomy implant according to any aspect or any preferred form thereof as described above in the abdomen; drawing a section of vessel (e.g. bowel) into the implant; and securing it to form a stoma. The implant and/or method are preferably as set out herein.

The implant is preferably used or provided in combination with a lid to prevent leakage and/or to protect the stoma. However, it may also be used in combination with a bag or an evacuation device. Thus, viewed from a still further aspect the invention provides an ostomy implant according to any aspect or preferred from described herein, in combination with a mating lid, bag or evacuation device. Mating is typically by means of a part of the lid, bag or evacuation device having a part that in use engages with the exterior section of the implant and preferably connects thereto by means of an engagement means, such as a circumferential groove around the circumference of the exterior section of the implant. However, it is possible for engagement to be wholly or partially with an internal surface of the exterior section.

The invention also extends to a method of performing an ostomy comprising providing an ostomy implant, which is preferably (but not necessarily) according to any aspect or any preferred form thereof as described above; implanting the implant in an opening in the body of a patient; drawing a bowel segment into the implant to provide a stoma; providing an adaptor according to any aspect or any preferred form thereof as described above at an exterior end of the implant; reverting an efferent end of the bowel segment over the adaptor; and securing the efferent end of the bowel segment. The efferent end of the bowel segment may be secured with sutures, for example. The efferent end of the bowl segment is preferably secured to the adaptor.

Preferably, the adaptor is removably attached to the exterior end of the implant, for example with attachment means such as one or more clips.

After a few weeks, for example, when the intestine has grown enough into the implant, the adaptor may be removed.

In order to remove the adaptor, preferably the part of the intestine protruding outside the implant, which has now started to wizen, for example, is cut away. The adaptor may then be removed. The intestine should then reside permanently just at the top of the implant.

The invention also extends to a method of manufacturing an implant, the implant being according to any of the aspects described above. Preferably, the implant is integrally formed. Alternatively, the implant may be made in parts which are subsequently joined together. The parts may be formed from the same material or two or more different materials.

The implant may be formed by a 3D printing process, for example. Preferably, an electron beam or a laser 3D printing process is used. Alternatively, the implant, or parts thereof, may be moulded or conventionally machined and laser or water-jet cut, or produced by etching and/or punching methods.

The method may comprise polishing at least part of the implant (particularly the exterior section, or the outer surface thereof). This can give a smooth finish.

Any of the aspects of the invention described above may comprise any of the features of the other aspects of the invention, even if not specifically stated.

Preferred embodiments of the invention will now be described by way of example only and with reference to the accompanying drawings, in which:

Fig. 1 is a perspective view of an embodiment of an implant;

Fig. 2 is another perspective view of the implant of Fig. 1;

Fig. 3 is a bottom view of the implant of Fig. 1;

Figs. 4(a)-(c) are side views of the implant of Fig. 1;

Fig. 5 is a top view of the implant of Fig. 1;

Fig. 6 is a perspective view of another embodiment of an implant;

Fig. 7 is another perspective view of the implant of Fig. 6;

Fig. 8 is a bottom view of the implant of Fig. 6;

Figs. 9(a)-(c) are side views of the implant of Fig. 6;

Fig. 10 is a top view of the implant of Fig. 6;

Fig. 11 is a perspective view of a porous structure;

Fig. 12 is a part cut-away perspective view of an implant with the porous structure of Fig. 11;

Fig. 13 is a perspective view of an implant with the porous structure of Fig. 11;

Fig. 14 is a bottom view of the implant of Fig. 13;

Fig. 15 is a side view of the implant of Fig. 13;

Fig. 16 is a cross-sectional view of an implant along the line B-B in Fig. 15;

Fig. 17 is a cross-sectional view of an implant along the line A-A in Fig. 15;

Fig. 18 is a top view of the implant of Fig. 14;

Fig. 19 is shows the area labelled C in Fig. 17 in more detail;

Fig. 20 is the area labelled D in Fig. 16 in more detail;

Fig. 21 is another perspective view of the implant of Fig. 13;

Fig. 22 is a perspective view of part of a porous structure;

Fig. 23 is an exploded perspective view of the porous structure of Fig. 22;

Fig. 24 shows a part of another porous structure;

Figs. 25(a)-(c) show parts of the porous structure of Fig. 24 in more detail;

Figs. 26(a)-(f) show top, bottom, bottom perspective, top perspective, front and side views, respectively, of an embodiment of an adaptor;

Fig. 27 is a bottom perspective view of the adapter of Figs. 26(a)-(f) attached to the implant of Fig. 6;

Fig. 28 is a top perspective view of the adapter of Figs. 26(a)-(f) attached to the implant of Fig. 6; and

Fig. 29 is a perspective view of the adapter of Figs. 26(a)-(f) and the implant of Fig. 6 before attachment.

Figs. 1 to 5 show an embodiment of an implant 1.

The implant 1 is formed of an interior section 2 and an exterior section 3. When implanted in a patient, the interior section 2 is located mostly or entirely inside the patient whereas the exterior section 3 is located mostly or entirely outside of the patient.

The interior section 1 is formed of an inner interior section part 4 and an outer interior section part 8.

The inner interior section part 4 is a substantially cylindrical structure formed of an hexagonal mesh. At its lower (as shown in the figures) or inner end, the

cylinder flares radially outwardly in a radially extending part 4a and is terminated by a continuous solid ring 5.

An anchoring flange 6 extends radially outwardly from the inner interior section part 4. This is also made of an hexagonal mesh. The anchoring flange 6 has at its radially outer edge a continuous solid ring 7. The inner interior section part 4 extends both above and below (i.e. outwardly and inwardly from) the anchoring flange 6.

The anchoring flange 6 extends to a greater radius than the radially extending part 4a.

The outer interior section part 8 connects the inner interior section part 4 to the exterior section 3. The outer interior section part 8 is formed from a number of rods 9 extending between the inner interior section part 4 and the exterior section 3. The rods 9 are arranged circumferentially around the implant 1.

Some of the rods 9 are slanted with respect to the longitudinal axis of the implant 1 and others are parallel with it. The slanted rods are angled so that they can withstand rotational forces acting on the implant 1. The rods which are parallel with the longitudinal axis of the implant 1 are for withstanding loads acting on the implant 1 longitudinally.

Some of the rods 9 have an exterior end which is located radially inwardly compared to the exterior ends of other rods 9. The interior ends of the rods 9 are all located at the same radius of the implant 1.

The rods 9 have a maximum diameter of 300 μm and a length of around 4.8 mm. The slanting rods are slightly longer than the parallel rods.

The exterior section 3 is ring-shaped and has an outer circumferential groove 11 to which part of a lid or a connector (e.g. to a bag or other device) or other device may be attached.

The exterior section 3 also has three indentations 12 into which an adaptor (such as the turnbull adaptor described below) or other device may be attached. The indentations 12 are arranged at equally spaced intervals around the outer circumference of the exterior section 3.

The interior surface of the exterior section 3 is formed from a three-dimensional porous structure 13 (not shown in detail here), such as porous structure 213 or 313 described below.

All elements of the implant 1 are integral with each other and made from the same material. The implant 1 is formed entirely of titanium.

The implant 1 is manufactured using a laser 3D printing process. After the implants 1 have been printed using the laser 3D printing process, the outer surface of the exterior section 3 is polished to give a smooth finish.

Alternatively, the implant 1 may be moulded and/or made in parts which are subsequently joined together.

Figs. 6 to 10 show an embodiment of an implant 101 with a larger inner diameter than the implant 1 of Figs. 1 to 5.

However, like the implant 1 of Figs. 1 to 5, the implant 101 is also formed of an interior section 102 and an exterior section 103. The interior section 102 is formed of an inner interior section part 104 and an outer interior section part 108.

The inner interior section part 104 has a radially extending part 104a which is terminated by a continuous solid ring 105.

An anchoring flange 106 extends radially outwardly from the inner interior section part 104 and has at its radially outer edge a continuous solid ring 107.

The outer interior section part 108 is formed of a number of rods 109 extending between the inner interior section part 104 and the exterior section 103.

The exterior section 103 has an outer circumferential groove 111 and three indentations 112. The interior surface of the exterior section 103 is formed from a three-dimensional porous structure 113.

Other features of the implant 1 described above apply equally to the implant 101.

Fig. 11 shows a porous structure 213. As shown in Figs. 12 to 21, the porous structure 213 is in the form of a hollow cylinder or tube located at an inner surface of the exterior section 203.

The implant 201 shown in Figs. 12 to 21 is generally similar to the implants 1 and 101 described above so its structure will not be described in detail. The only difference to implant 1 is that there are no indentations on the exterior section 203.

The implant 201 is formed of an interior section 202 and an exterior section 203. The interior section 201 is formed of an inner interior section part 204 and an outer interior section part 208.

The inner interior section part 204 has a radially extending part 204a which is terminated by a continuous solid ring 205.

An anchoring flange 206 extends radially outwardly from the inner interior section part 204 and has at its radially outer edge a continuous solid ring 207.

The outer interior section part 208 is formed of a number of rods 209 extending between the inner interior section part 204 and the exterior section 203.

The exterior section 203 has an outer circumferential groove 211 but no indentations. The interior surface of the exterior section 203 is formed from the three-dimensional porous structure 213.

The porous structure 213 is completely permeable; there are no dead ends. Every passage entering the porous structure also has an exit. The maximum thickness of any member forming the porous structure is 300 μm and the maximum diameter of any opening is also 300 μm.

Figs. 22 and 23 show a part of the porous structure 213 in more detail. It is formed from interconnecting members 215. The members 215 are arranged in layers 216 which are connected by connecting members 217.

In the embodiment shown, the members 215 and 217 form a regular, repeating pattern throughout the porous structure 213. However, in other embodiments, the porous structure has an irregular structure. The apertures in the porous structure have substantially square, rectangular or cross-shaped cross-sections. However, in alternative embodiments, some or all of the apertures are circular or oval.

Figs. 24 and 25(a)-(c) show an example of another porous structure 313. This porous structure 313 is made up of a number of repeating sub-units 314. Each of the sub-units 314 is formed of four members 315 joined together at a central point of the sub-unit 314 at ends thereof. Six sub-units 314 are joined together to form a generally hexagonal ring or unit 316. The units 316 are then joined together in a regular repeating fashion to form the porous structure 313.

Figs. 26(a)-(f) show an adaptor 500 for securing a bowel segment outside a patient's body after an ostomy has been performed.

The adaptor 500 is formed of a flattened ring 501 with a short cylindrical part 502 protruding in a first direction from an inner diameter of the ring 501. Three resilient members 503 protrude from the ring 501 in an opposite direction to the cylindrical part 502.

The resilient members 503 are arranged equally spaced around the ring 501 and each member 503 has a protruding part 505 located on a radially inward side of the resilient member 503 and towards an end of the resilient member 503 away from the ring 501.

The ring 501 has a number of slot-shaped apertures 504 (in this case, twelve) arranged around it circumferentially.

As shown in Figs. 28 to 30, the adaptor 500 can be attached to the exterior section 103 of an implant 101. The protruding parts 505 of the resilient members 503 fit into the indentations 112, thereby attaching the adaptor 500 to the implant 101 and preventing it from moving both rotationally, transversally and longitudinally with respect to the implant 101.

When attached, the adaptor 500 and the implant 101 have a common axis and the adaptor 500 is sized such that it can fit over and be attached to the implant 101. The inner diameter of the adaptor 500 and the exterior section 103 of the implant 101 are the same.

The adaptor 500 is made entirely of plastic and is fabricated in a laser sintering process from medical quality polyamide powder (PA2200).

The adaptor 500 is sterilised by means of autoclaving and is provided sterile. Alternatively, the adaptor 500 may be sterilised by radiation, gas such as ethylene oxide, plasma or other methods.

The adaptor 500 is provided in different sizes, for example two sizes, to fit different sized implants (i.e. implants with different diameters).

The adaptor 500 is intended to be used during the surgical procedure when implanting an implant such as one described above. When attached to the implant 101, the adaptor 500 can receive the bowel segment therethrough and allow the bowel segment to be reverted back over the adaptor 500.

The adaptor 500 can be used to fix the efferent intestine for around 4 to 6 weeks after implantation, in order to provide best possible stress-free healing and in-growth conditions for the ileum during the integration process with the implant.

The adaptor 500 is attached to the exterior section 103 of the implant 101 at the end of the implantation procedure. It is used to secure the efferent intestine with a few sutures, during the first four to six weeks after implantation. Thereafter, the efferent intestine is cut away and the adaptor 500 is removed.

In order to use the adaptor 500, the following steps are performed:

- Clip the adaptor 500 onto the exterior section 103 of the implant 101. Turn it lightly to ensure it locks correctly in place.
- The efferent end of the intestine is reverted over the adaptor 500 above the implant 101 and secured using sutures through the apertures 504.

- Make sure that the groove 111 around the outside of the exterior section 130 is free from tissue so that it can be used for attachment of a stabiliser device (not shown). (A stabiliser device is a device used to secure the implant 101 in place during the healing period by providing support against tilting or vertical movement of the implant 101. It can be attached to the exterior section 103 of the implant 101, for example, and rests on the skin or a skin barrier.)
- Anchor the intestine to the peritoneum using sutures.

After a few weeks the intestine should have grown enough into the implant 101 for the adaptor 500 to be removed. The part of the intestine protruding outside the implant 101 will now have started to wizen and is cut away. The adaptor 500 is removed and the intestine will reside permanently just at the top of the implant 101.

In order to remove the adaptor 500, the following steps are performed:

- Remove any stoma bag and clean the orifice gently.
- Carefully remove the stabiliser device and the stoma skin barrier.
- Gently rinse around the implant 101 to remove any intestinal content or liquid.
- With a diathermy scalpel, incise the intestine inside of adaptor 500 three millimetres from the top through the entire thickness of the intestine.
- If needed, dissect the intestine down to the base of the adaptor 500 with a forceps. Do not to go beyond the base of the adaptor 500 as this could cause harm to the tissue in-growth into the implant cylinder, resulting in leakage.- With a pointed object, carefully lift the resilient members 503 out of the indentations 112 in the exterior section 103 and remove the adaptor 500 slowly.
- With dissection scissors, trim any excess tissue that remains above the exterior section 103 of the implant 101. If catheterization is needed, do not to touch the inside (interior diameter) of the implant 101.
- Put a new skin barrier, stabiliser and stoma bag in place.

Claims:

1. An implant comprising a tubular interior section for implantation into a patient and an exterior section connected to the interior section, a surface of the exterior section comprising a rigid three-dimensional porous structure at an inner circumference thereof.

2. An implant as claimed in claim 1, wherein the porous structure is integral with the rest of the exterior section; and/or

there is no gap between the porous structure and the rest of the exterior section; and/or

the porous structure is connected to the rest of the exterior section at least at first and second end regions thereof.

3. An implant as claimed in claim 1 or 2, wherein the porous structure extends to within 1 mm, 2 mm or 3 mm of an exterior end of the exterior section.

4. An implant as claimed in claim 1, 2 or 3, wherein the implant is a percutaneous ostomy implant for implantation into the abdominal wall of a patient.

5. An implant as claimed in any preceding claim, wherein the exterior section is ring-shaped.

6. An implant as claimed in any preceding claim, wherein the porous structure is arranged around the entire inner circumference of the exterior section.

7. An implant as claimed in any preceding claim, wherein the porous structure has a thickness of at least 0.5 mm.

8. An implant as claimed in any preceding claim, wherein the porous structure is completely permeable and has no dead ends.

9. An implant as claimed in any preceding claim, wherein each passage entering the porous structure also has an exit.

10. An implant as claimed in any preceding claim, wherein the thickness of any member forming the porous structure is less than or equal to 500 µm.

11. An implant as claimed in any preceding claim, wherein the maximum diameter of any opening in the porous structure is 500 µm.

12. An implant comprising an ingrowth means in the form of a three-dimensional porous structure, wherein the porous structure has a thickness of at least 0.5 mm.

13. An implant comprising an ingrowth means in the form of a three-dimensional porous structure, wherein the porous structure is completely permeable and has no dead ends.

14. An implant as claimed in claim 13, wherein each passage entering the porous structure also has an exit.

15. An implant comprising an ingrowth means in the form of a three-dimensional porous structure, wherein at least 80%, at least 85%, at least 90%, at least 95%, or at least 97% of the openings into the porous structure have a corresponding exit.

16. An implant comprising an ingrowth means in the form of a three-dimensional porous structure, wherein the thickness of any member forming the porous structure is less than or equal to 500 µm , less than or equal to 450 µm, less than or equal to 400 µm, less than or equal to 350 µm, or less than or equal to 300 µm.

17. An implant comprising an ingrowth means in the form of a three-dimensional porous structure, wherein the maximum diameter of any opening in the porous structure is 500 µm, 450 µm, 400 µm, 350 µm, or 300 µm.

18. An implant as claimed in any preceding claim, wherein the porous structure is made from titanium.

19. An implant as claimed in any preceding claim, wherein the porous structure is formed from interconnecting members.

20. An implant as claimed in claim 20, wherein the members are arranged in layers, the layers preferably being arranged concentrically.

21. An implant as claimed in claim 21, wherein the layers are connected by connecting members.

22. An implant comprising a tubular interior section for implantation into a patient and an exterior section connected to the interior section, a surface of the exterior section comprising a three-dimensional porous structure at an inner circumference thereof, wherein the porous structure is formed from a plurality of interconnecting members, preferably arranged concentrically, the layers being interconnected by connecting members.

23. An implant as claimed in claim 19, 20, 21 or 22, wherein the members form a regular, repeating pattern throughout the porous structure.

24. An implant as claimed in any of claims 1 to 22, wherein the porous structure has an irregular structure.

25. An implant comprising a tubular interior section for implantation into a patient and an exterior section connected to the interior section, wherein the interior section comprises a plurality of rods and the rods have a diameter of less than or equal to 500 µm.

26. An implant as claimed in claim 25, wherein the rods are arranged circumferentially around the implant.

27. An implant as claimed in claim 25 or 26, wherein one or more of the rods is slanted with respect to the longitudinal axis of the implant.

28. An implant as claimed in claim 25, 26 or 27, wherein one or more of the rods is parallel with respect to the longitudinal axis of the implant.

29. An implant as claimed in any of claims 25 to 28, wherein one or more rods has at least one end located radially inwardly with respect to the implant compared to other rods.

30. An implant as claimed in any of claims 25 to 29, wherein the rods have a diameter of less than or equal to 450 µm, less than or equal to 400 µm, less than or equal to 350 µm, less than or equal to 300 µm, or less than or equal to 250 µm.

31. An implant as claimed in any of claims 25 to 30, wherein the interior section comprises an inner interior section part and an outer interior section part, wherein the outer interior section part comprises the plurality of rods.

32. An implant as claimed in claim 31, wherein the plurality of rods connect the inner interior section part to the exterior section.

33. An implant as claimed in claim 32, wherein the inner interior section part is connected to the exterior section solely by the plurality of rods.

34. An implant as claimed in any of claims 31 to 32, wherein the outer interior section part is formed solely from the plurality of rods.

35. An implant as claimed in any of claims 31 to 34, wherein the inner interior section part comprises an ingrowth means, preferably in the form of a mesh.

36. An implant as claimed in any preceding claim, wherein at an inner end, the interior section extends radially outwardly.

37. An implant as claimed in any preceding claim, further comprising an anchoring flange extending radially outwardly from the interior section.

38. An implant as claimed in claim 37, wherein the anchoring flange is formed from a mesh.

39. An adaptor for securing a bowel segment outside a patient's body after an ostomy has been performed, the adaptor comprising:

attachment means for attaching the adaptor to an implant; and
securing means to which a bowel segment may be attached.

40. An adaptor as claimed in claim 39, wherein the attachment means comprises one or more resilient members.

41. An adaptor as claimed in claim 39 or 40, wherein the attachment means is arranged to engage with one or more corresponding recesses or other attachment points on an implant.

42. An adaptor as claimed in any of claims 39 to 41, wherein the adaptor has an aperture through which the bowel segment may pass.

43. An adaptor as claimed in any of claims 39 to 42, wherein the adaptor is substantially ring-shaped.

44. An adaptor as claimed in any of claims 39 to 43, wherein the securing means comprises one or more openings in the adaptor through which sutures may be attached.

45. An adaptor as claimed in any of claims 39 to 44, wherein the adaptor is arranged to receive the bowel segment therethrough and allow the bowel segment to be reverted back over the adaptor.

46. An adaptor as claimed in any of claims 39 to 45, wherein the attachment means is arranged such that, when attached to an implant, the adaptor is prevented from rotating with respect to a longitudinal axis of the implant.

47. An adaptor as claimed in any of claims 39 to 46, wherein the attachment means is arranged such that, when attached to an implant, the adaptor is prevented from moving longitudinally and/or transversally with respect to a longitudinal axis of the implant.

48. An adaptor as claimed in any of claims 39 to 47, wherein the adaptor is made of a biologically degradable material.

49. A kit comprising an implant and an adaptor for securing a bowel segment outside a patient's body after an ostomy has been performed, the adaptor comprising:

attachment means for attaching the adaptor to the implant; and

securing means to which a bowel segment may be attached.

50. A kit as claimed in claim 49, wherein the adaptor is as claimed in any of claims 39 to 48.

51. A kit as claimed in claim 49 or 50, wherein the implant is as claimed in any of claims 1 to 38.

52. A implant as claimed in any of claims 1 to 38, in combination with a mating lid, bag and/or evacuation device.

53. A method of performing an ostomy comprising the use of an implant according to any of claims 1 to 38 and/or an adaptor according to any of claims 39 to 48.

54. A method of manufacturing an implant, the implant being according to any of claims 1 to 38.

55. An implant comprising:

a tubular interior section for implantation into a patient, the tubular interior section having first and second ends;

an exterior section having a body for attachment to an adaptor or other removable device, and first and second ends, with the second end of the exterior section connected to the first end of the interior section, with the exterior section having inner and outer surfaces extending between the first and second ends; and

a three-dimensional porous structure configured and dimensioned to fit within the inner surface of the exterior section.

56. An implant comprising:

an exterior section having a body for attachment to an adaptor or other removable device, first and second ends, and inner and outer surfaces extending between the first and second ends, with the second end having a width extending radially between the inner and outer surfaces of the exterior section;

a tubular mesh having first and second ends; and

a plurality of rods joining the second end of the exterior section to the first end of the tubular mesh, wherein the rods are attached at different points on the width and along the circumstance of the second end of the exterior section, and extend to and attach at different points on the circumference of the first end of the tubular mesh, with the rods providing lesser material than the tubular mesh to reduce adverse reactions thereto by a patient who receives the implant.

57. An adaptor for securing a bowel segment outside a patient's body to an implant after an ostomy has been performed, the adaptor comprising:

a tubular body having first and second ends, and being configured and dimensioned to receive an exterior portion of an implant therein;

attachment means for attaching the adaptor to the implant; and

a radially extending part connected to the body that includes securing means for receiving a bowel segment for attachment thereto.

Fig. 1

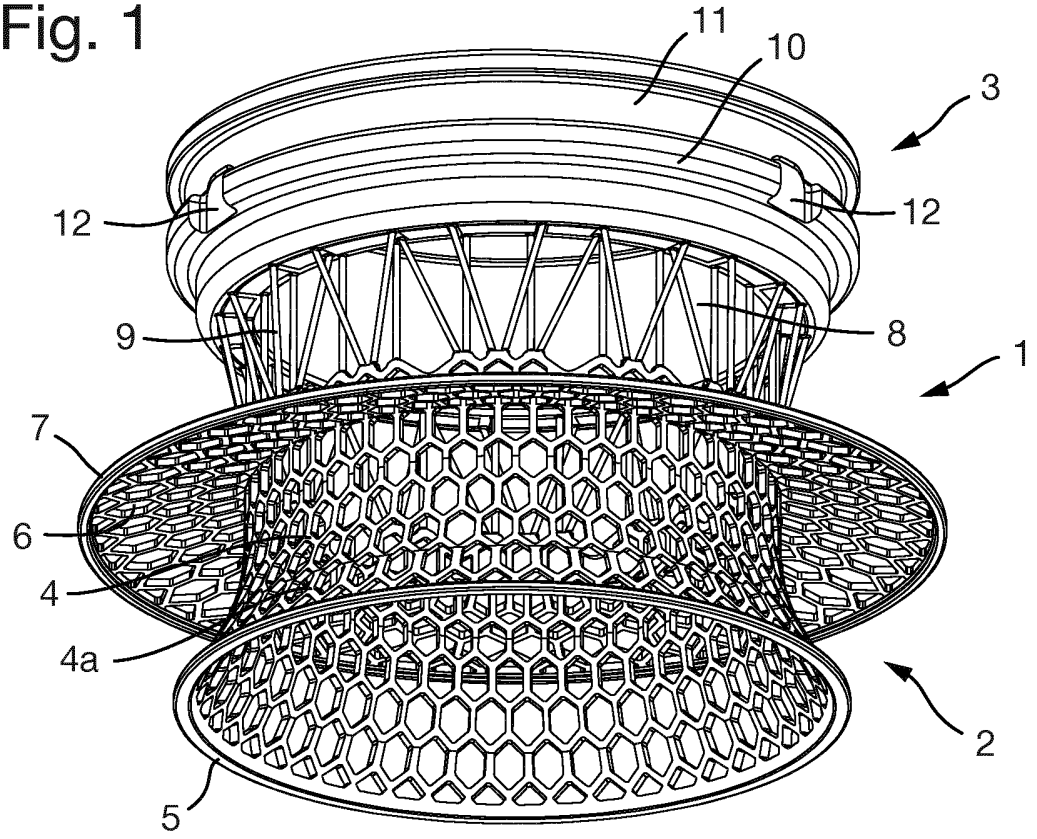

Fig. 2

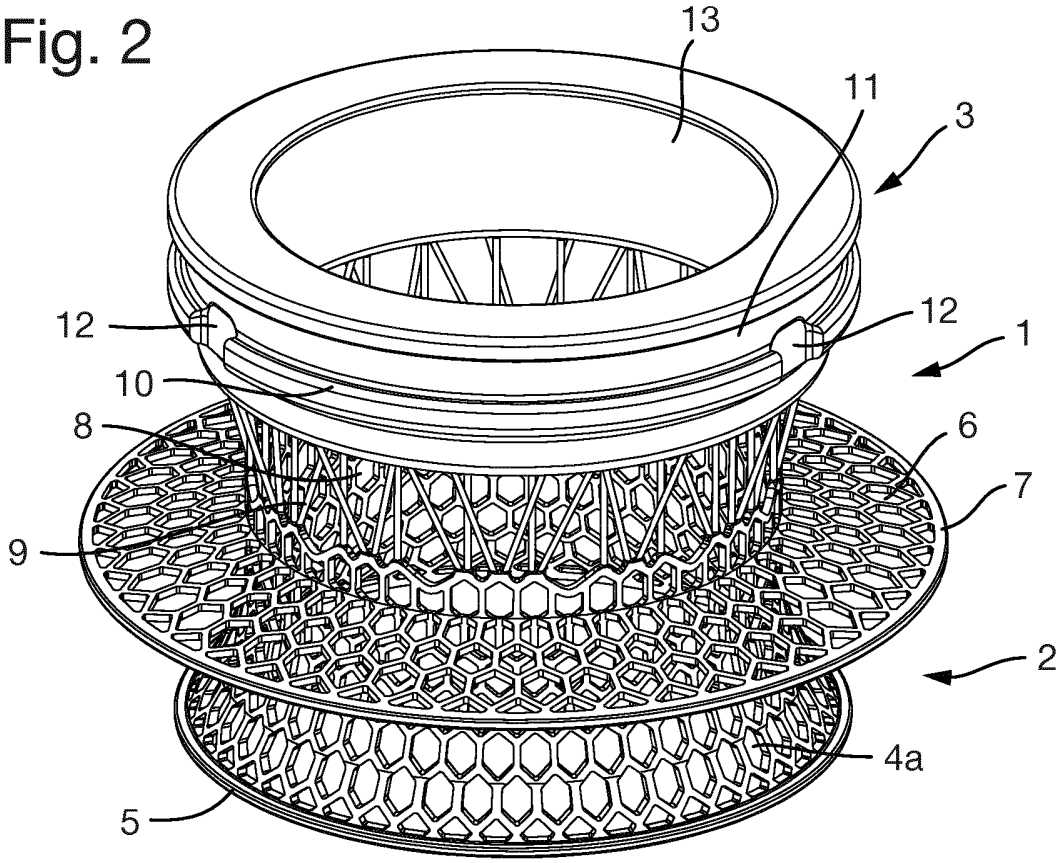

Fig. 3

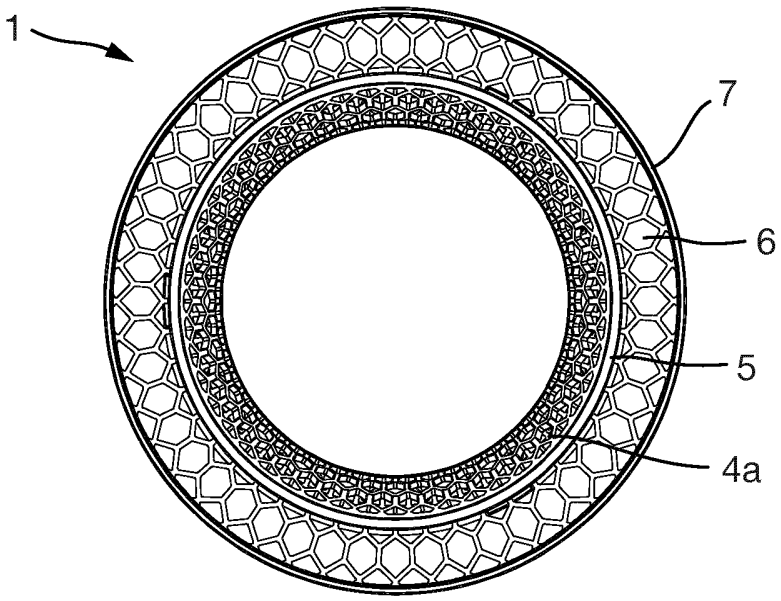

Fig. 5

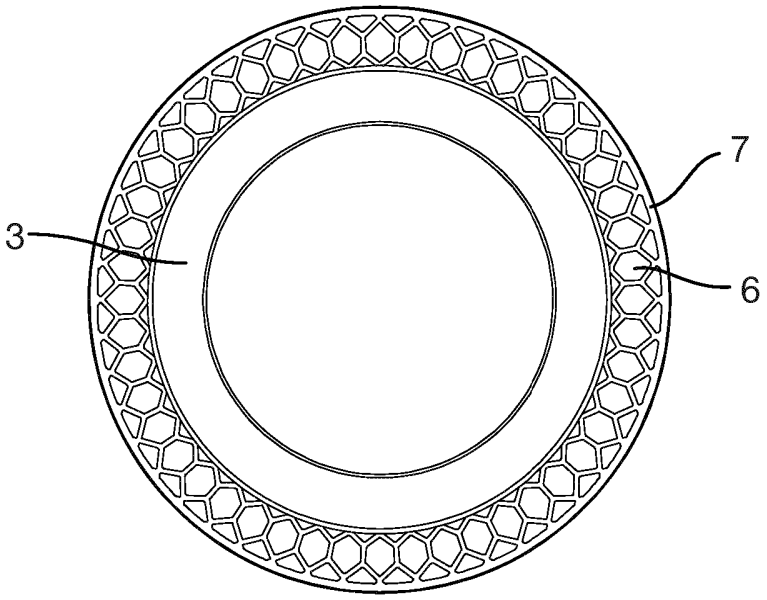

Fig. 4(a)

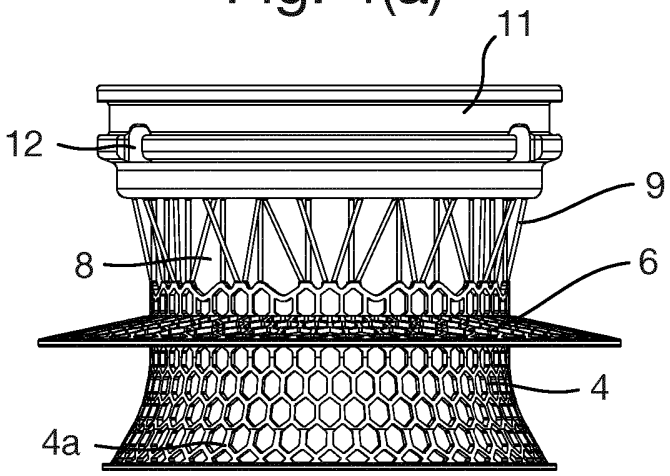

Fig. 4(b)

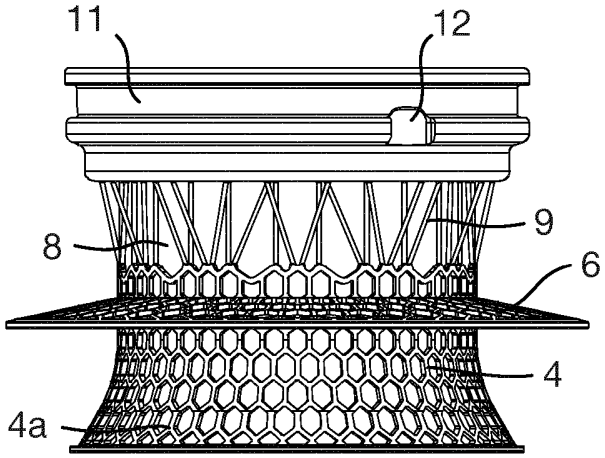

Fig. 4(c)

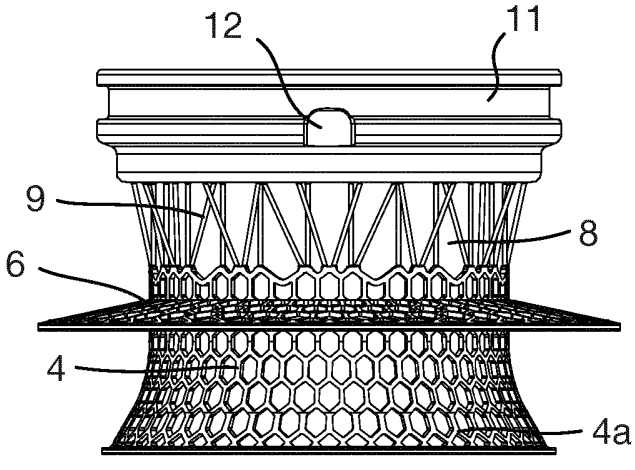

Fig. 6

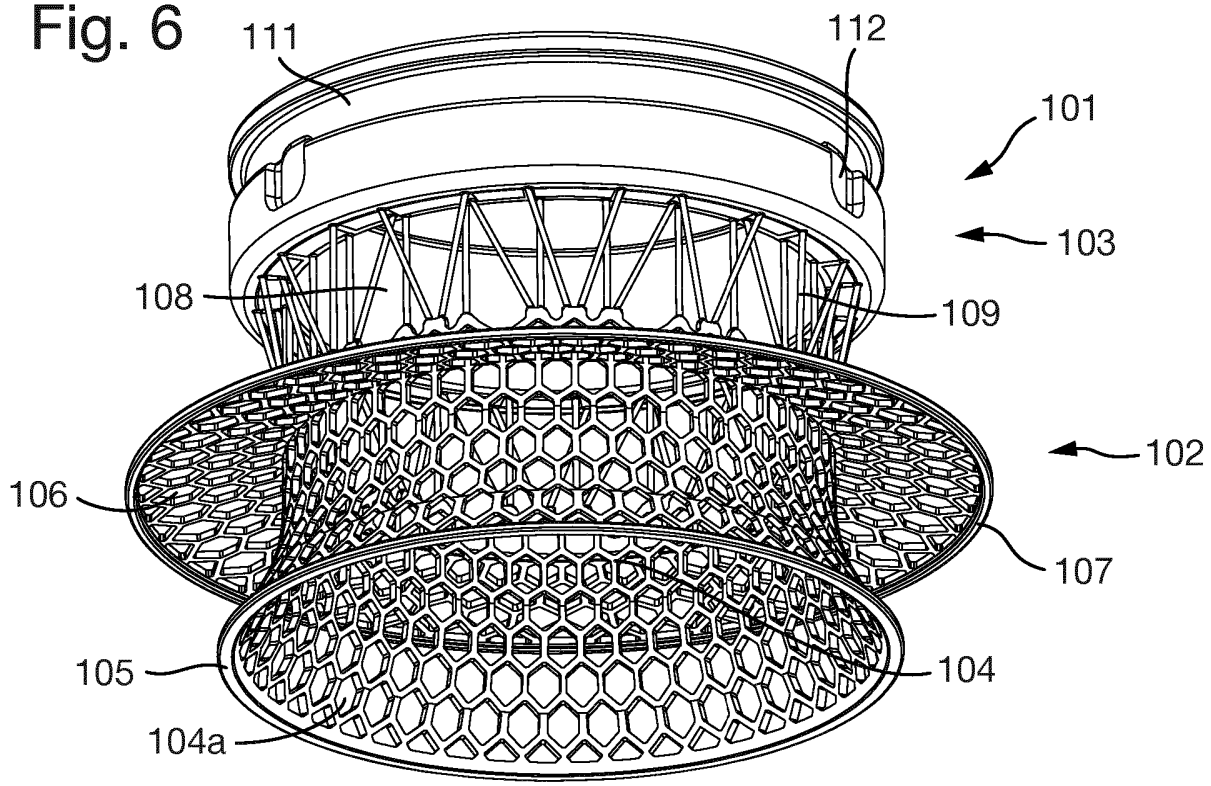
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Fig. 7

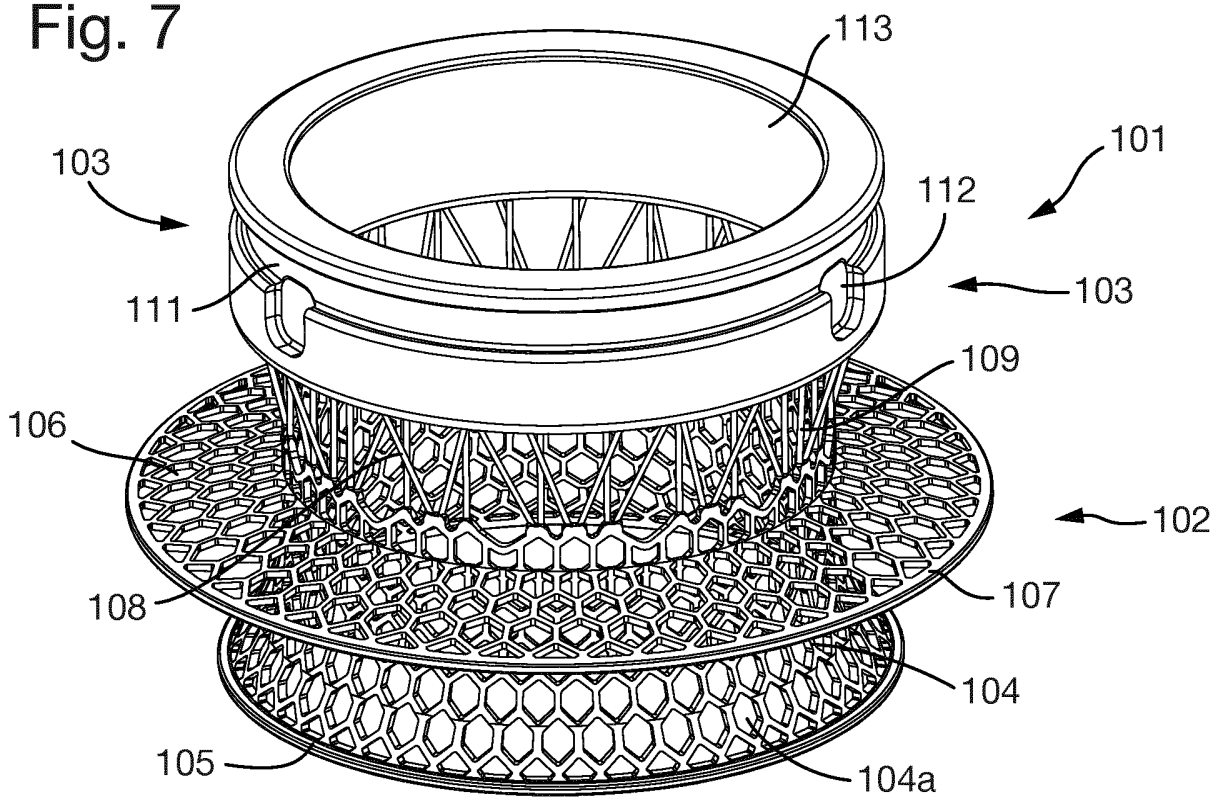
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Fig. 8

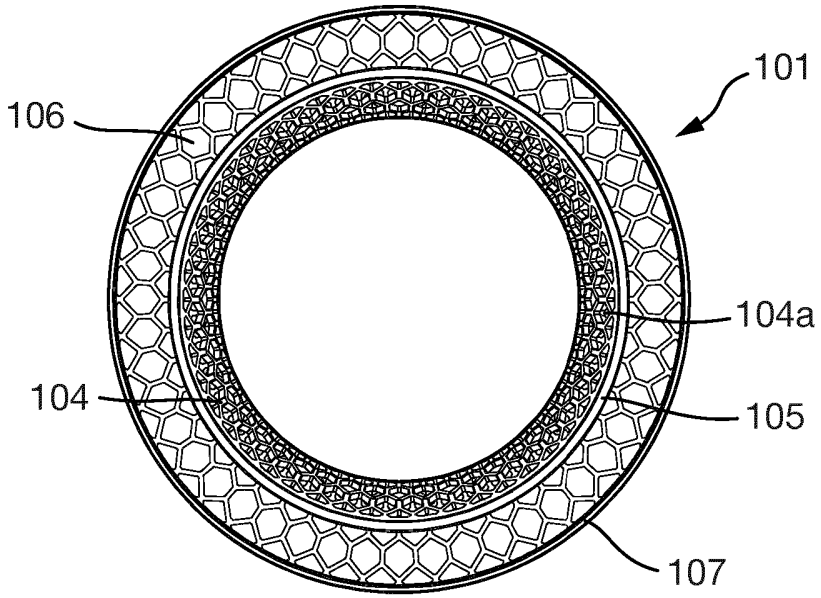


Fig. 10

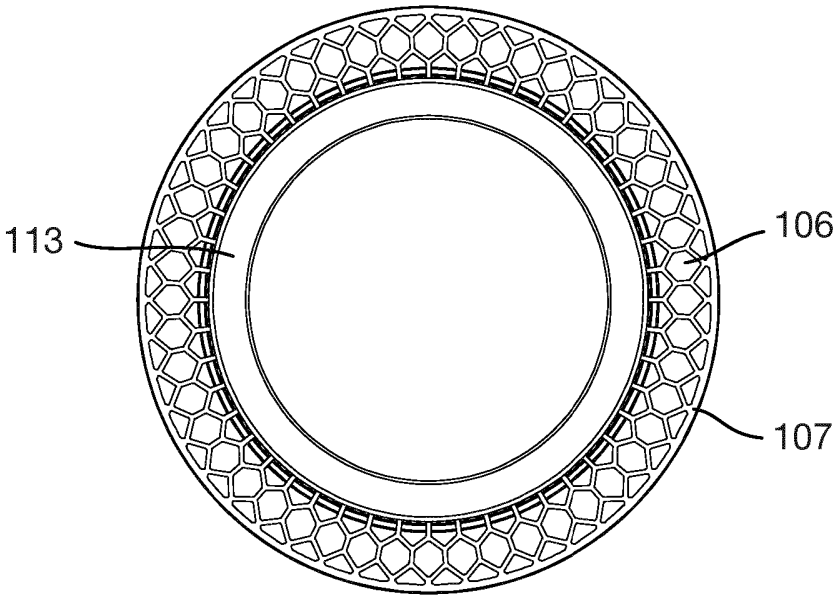


Fig. 9(a)

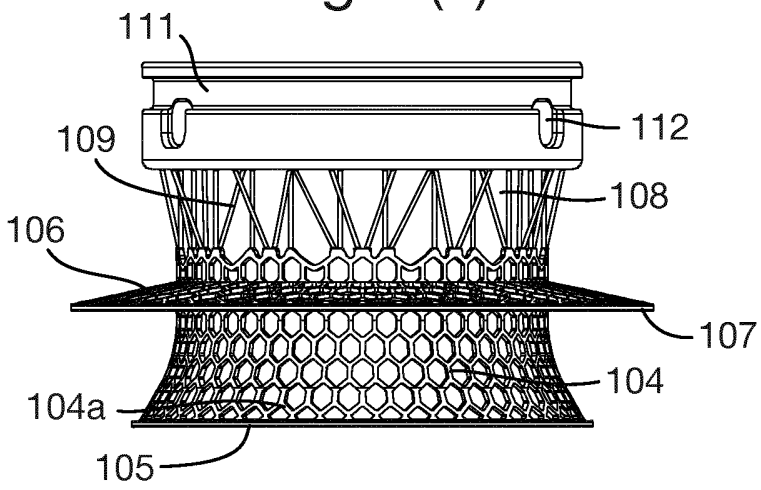


Fig. 9(b)

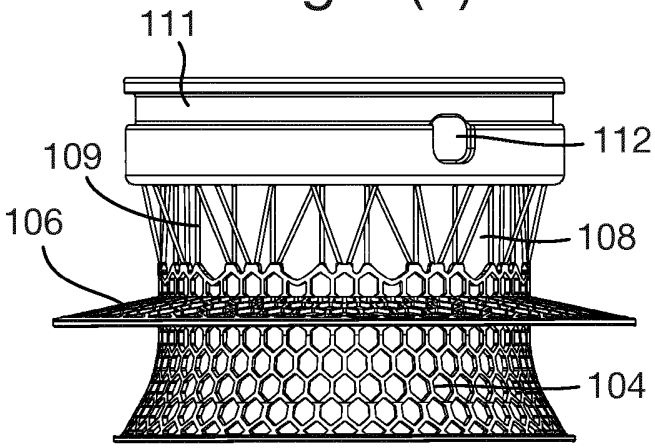


Fig. 9(c)

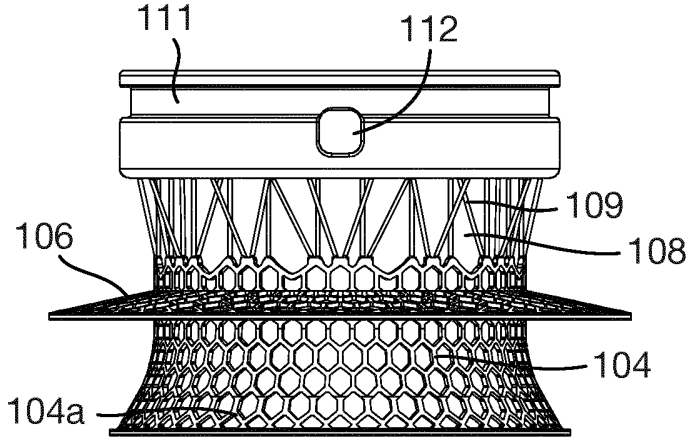


Fig. 11

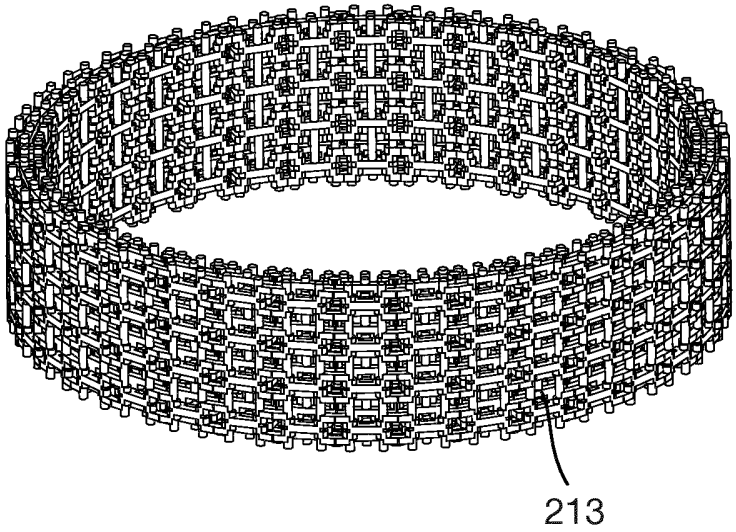


Fig. 12

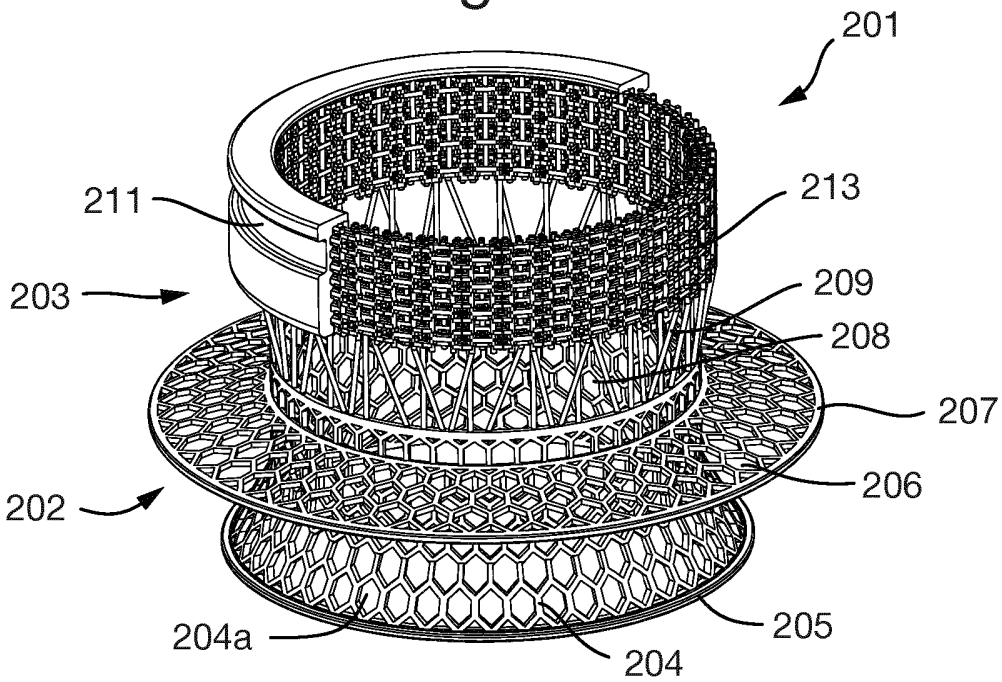


Fig. 13

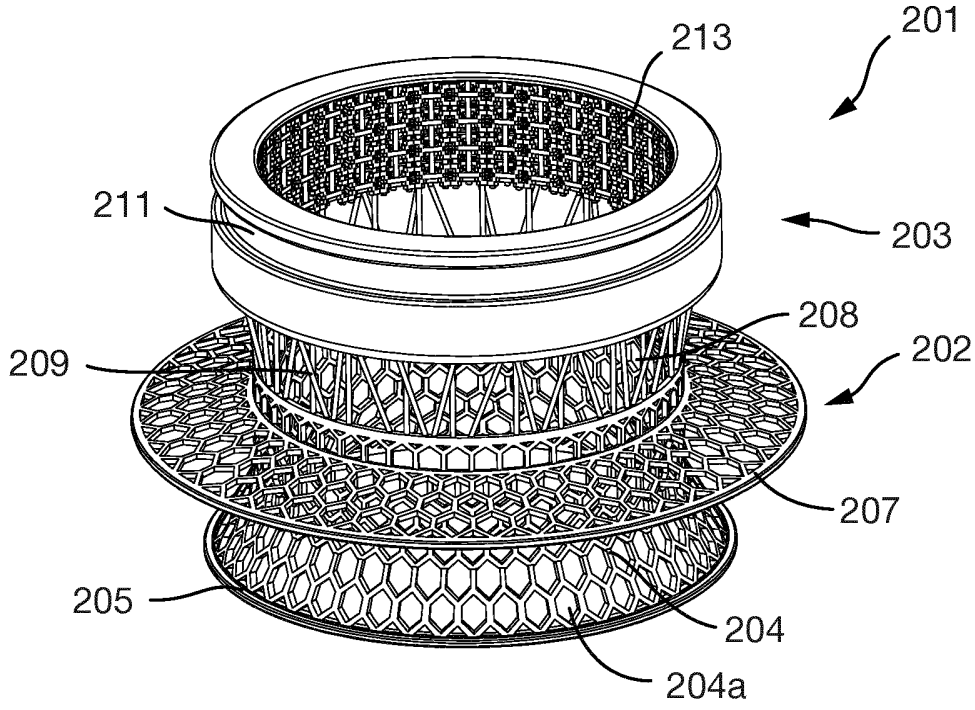


Fig. 14

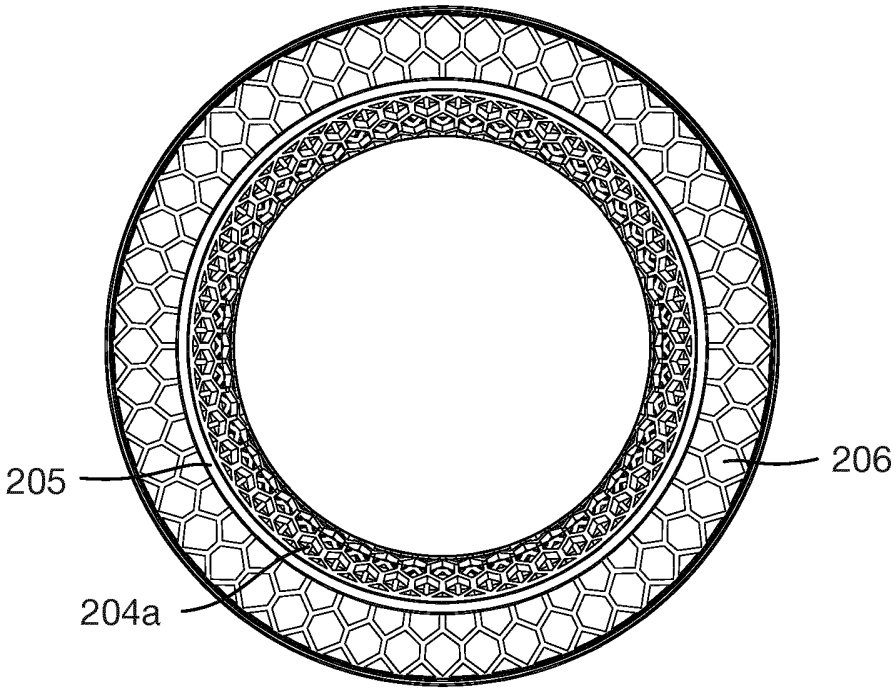


Fig. 15

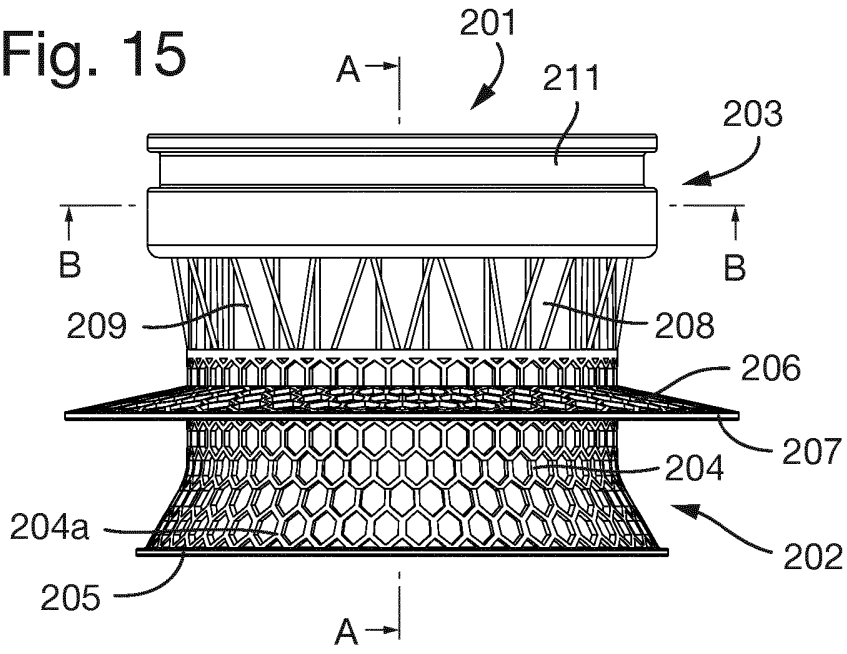


Fig. 16

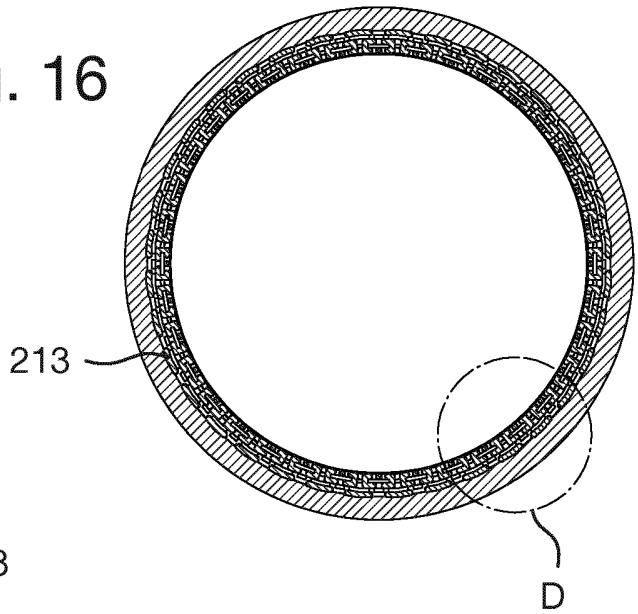


Fig. 17

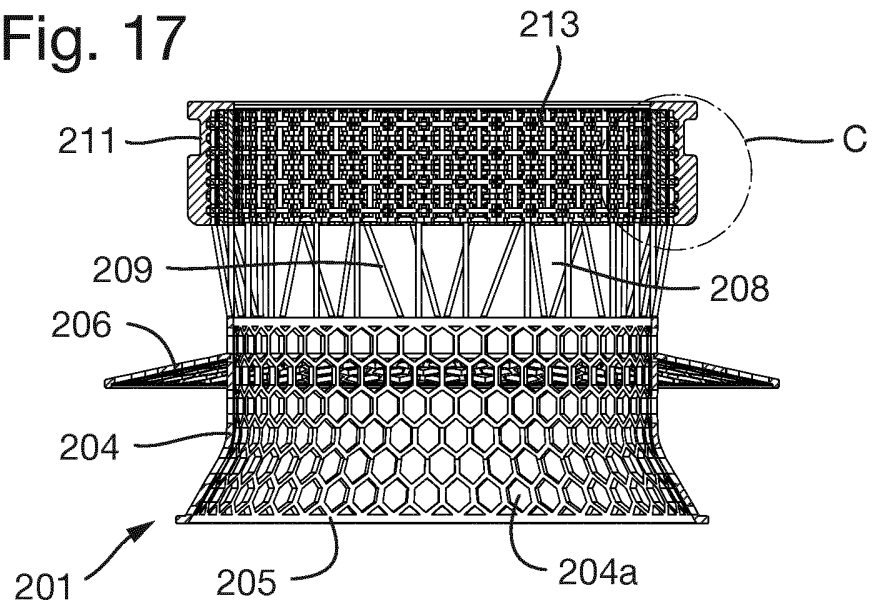


Fig. 18

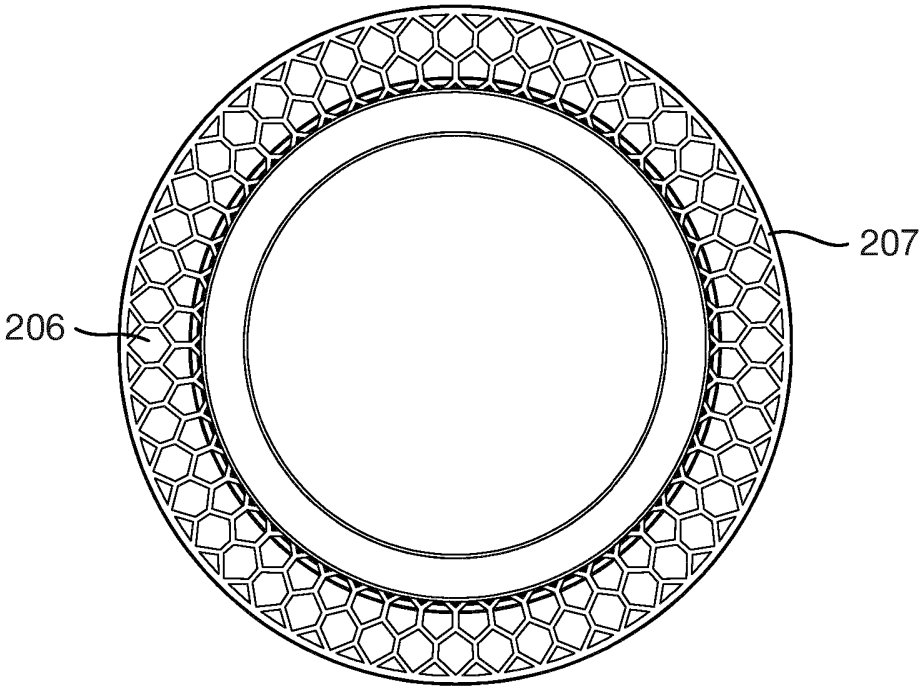


Fig. 19

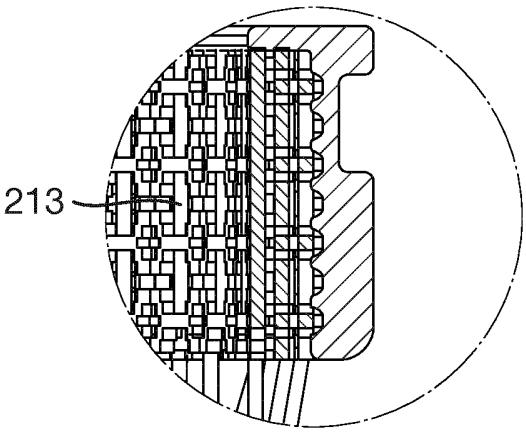


Fig. 20

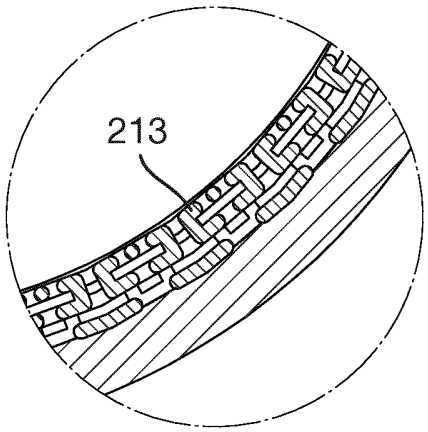


Fig. 21

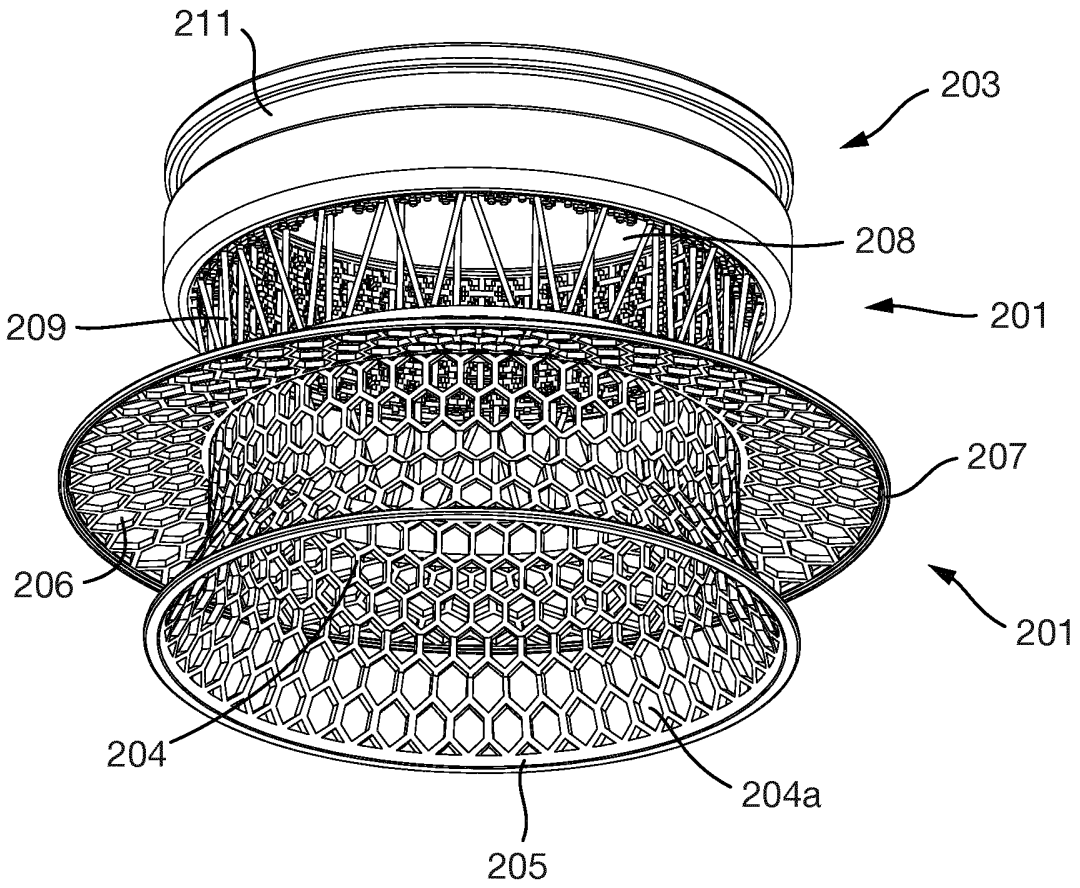


Fig. 22

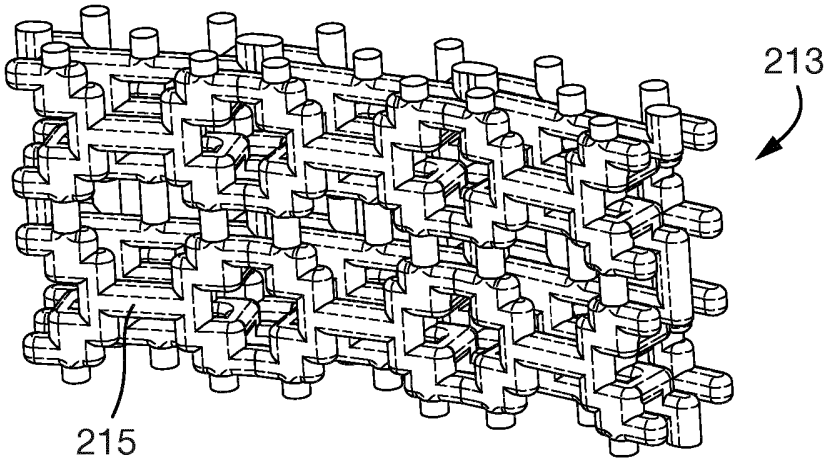


Fig. 23

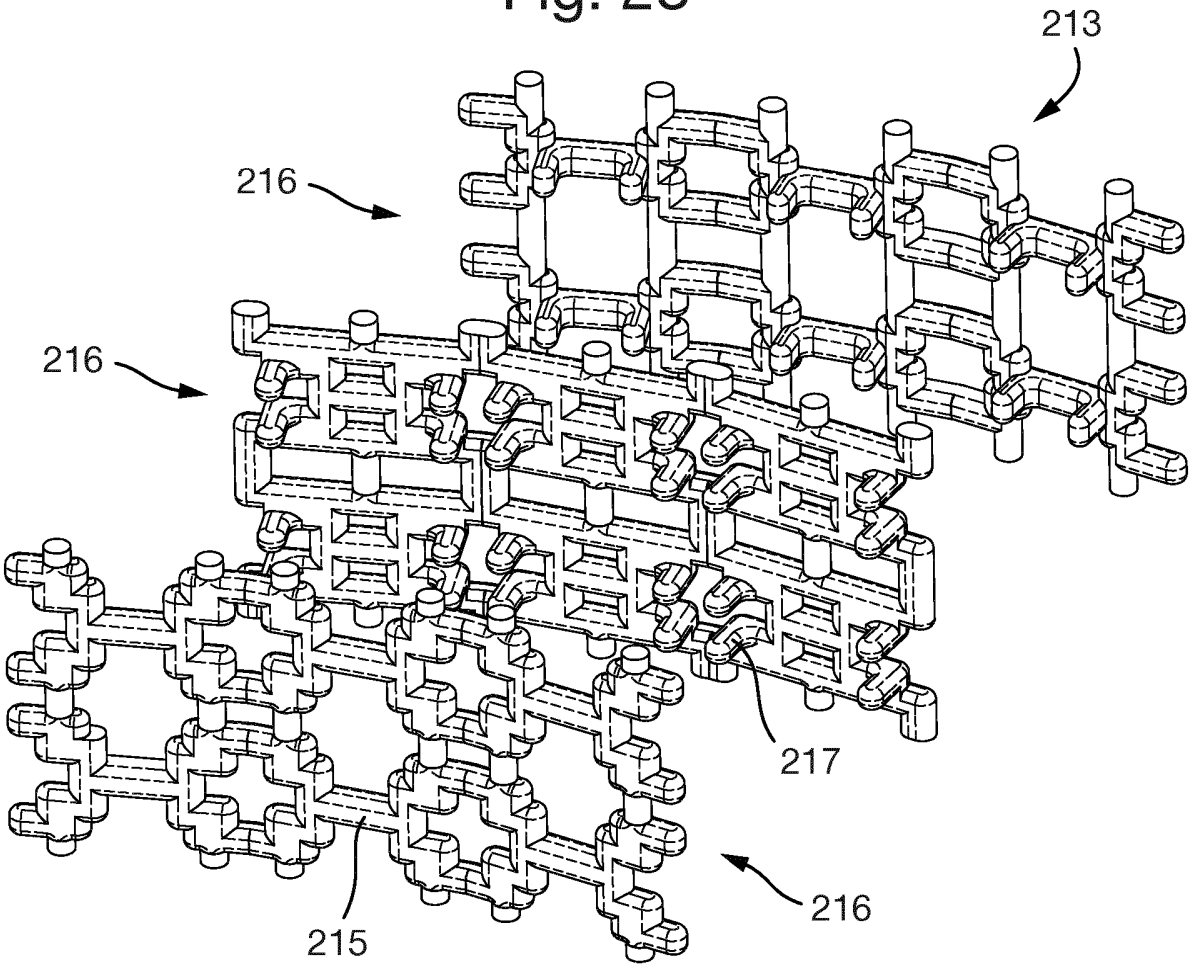


Fig. 24

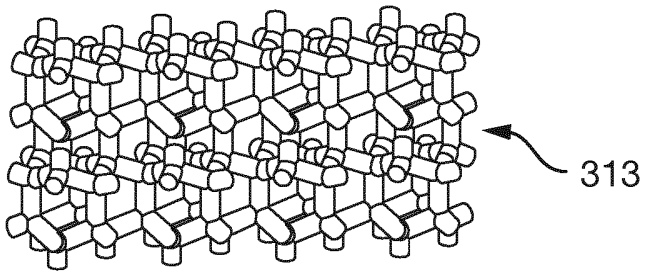


Fig. 25(a)

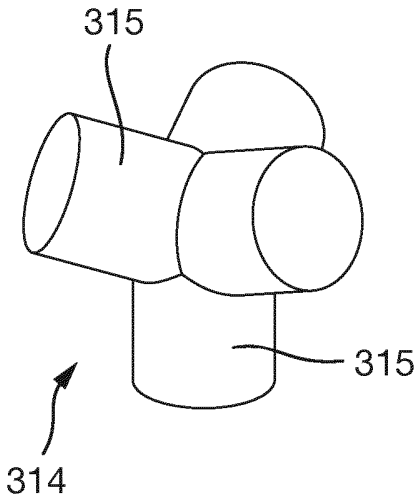


Fig. 25(b)

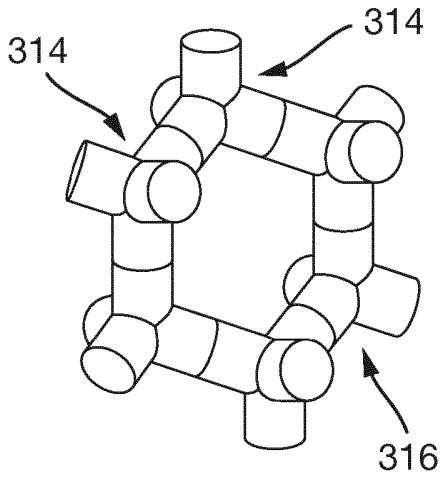


Fig. 25(c)

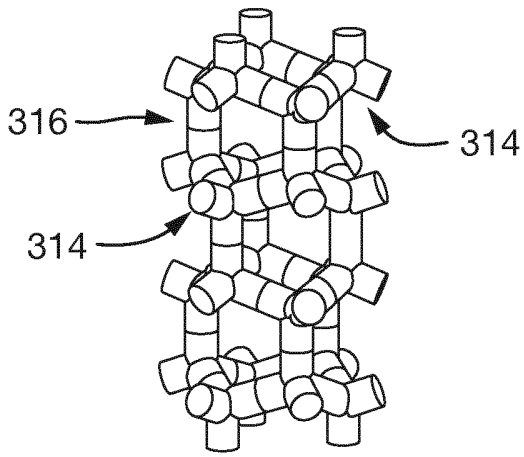


Fig. 26(a)

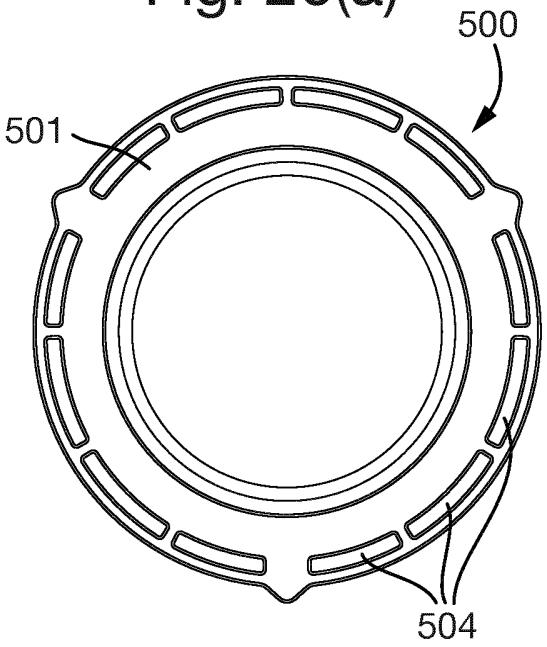


Fig. 26(b)

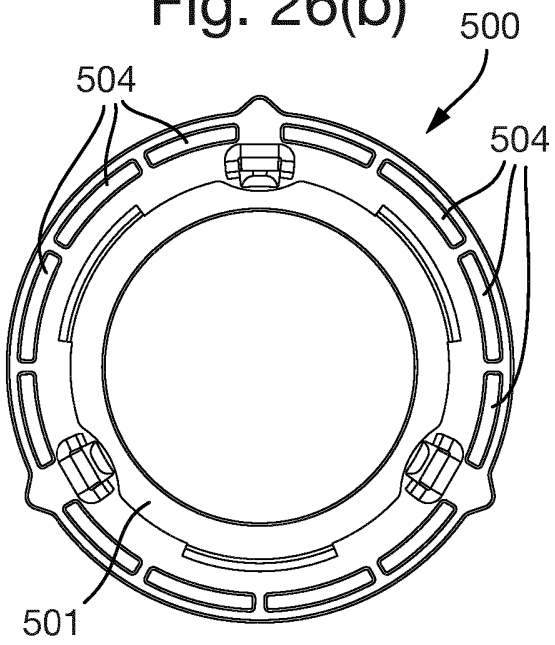


Fig. 26(c)

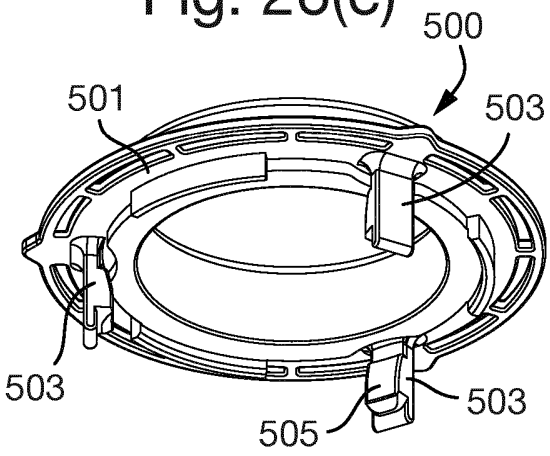


Fig. 26(d)

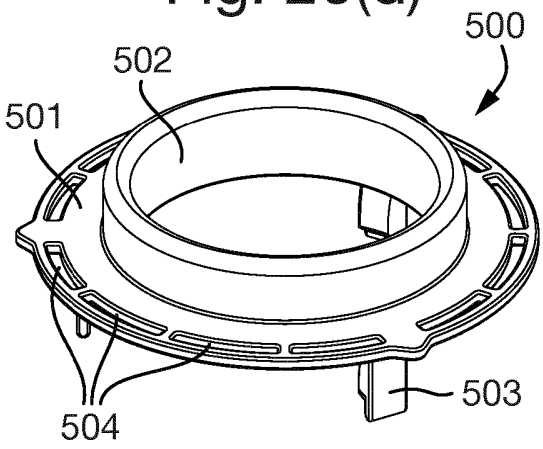


Fig. 26(e)

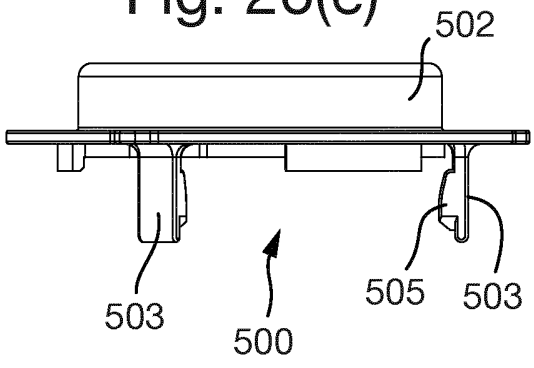


Fig. 26(f)

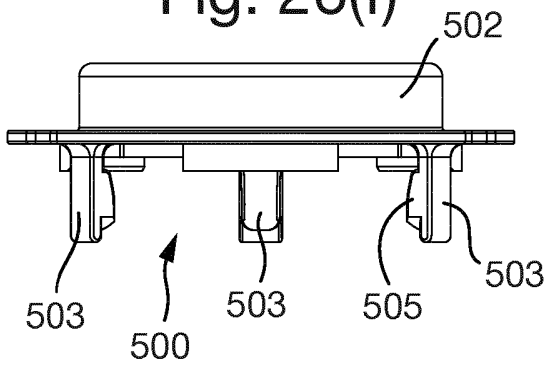


Fig. 27

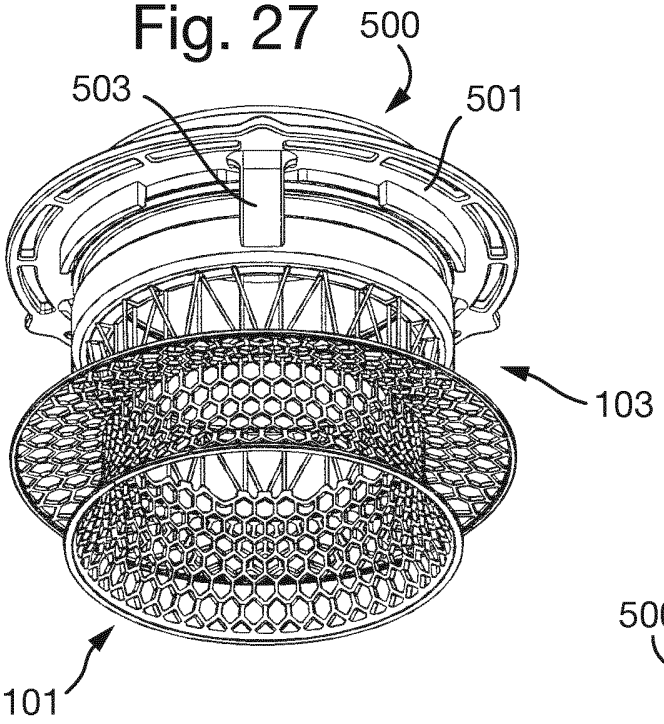


Fig. 28

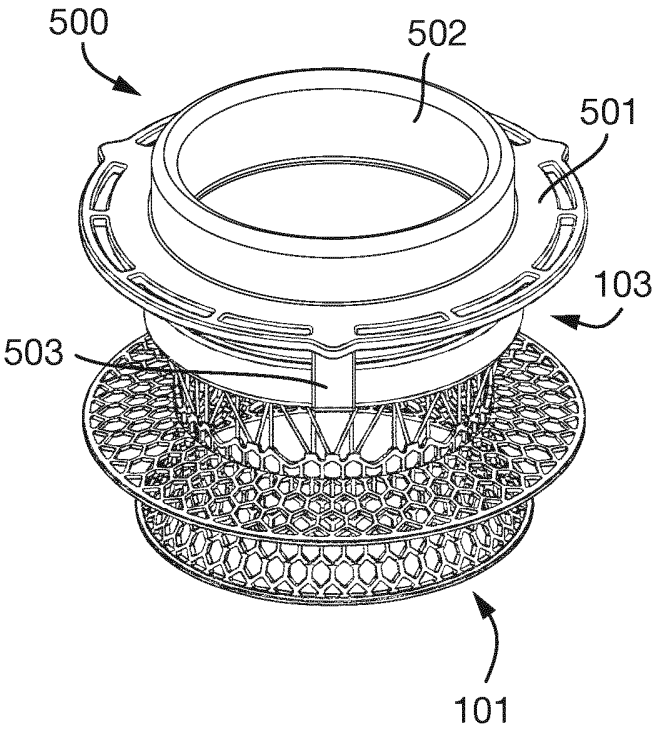
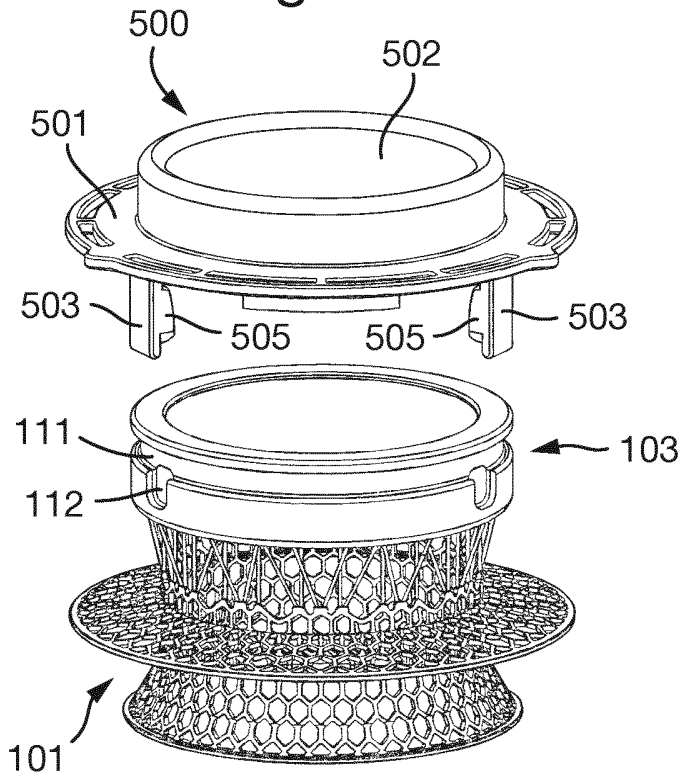


Fig. 29



INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2014/055207

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F5/445
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)
A61F

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	WO 2012/131351 A2 (OSTOMYCURE AS [NO]; JOHANSSON MARTIN [SE]; AXELSSON ROBERT [SE]; AXELS) 4 October 2012 (2012-10-04) figs. 4-6 // page 11, line 3 to page 12, line 16 and page 14, lines 6-8 // claims	1-38,52, 54-56
X	WO 2012/007755 A2 (OSTOMYCURE AS [NO]; EDWIN BJOERN [NO]; THOMSEN PETER [SE]; HULTEN LEIF) 19 January 2012 (2012-01-19) figures	1-38,52, 54-56
X	WO 2011/126724 A1 (DAVINCI BIOMEDICAL RES PRODUCTS INC [US]; VILLANI MARIO [US]; CAPPABIA) 13 October 2011 (2011-10-13) figures	1-38,52, 54-56

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"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

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 July 2014	31/07/2014

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Foged, Søren

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2014/055207

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 183 357 A (BENSON JAMES A [US] ET AL) 15 January 1980 (1980-01-15) fig. 2 // column 5, lines 13-29	1-52, 54-57

X	WO 01/08597 A1 (BIOTAP AS [DK]; HESSEL LASSE L [DK]; MALLING JESPER [DK]) 8 February 2001 (2001-02-08)	39-47, 49,50, 55,57
A	figures	1-38,54, 56

X	WO 92/08499 A1 (GRIFFITH DONALD P [US]) 29 May 1992 (1992-05-29)	39-47, 49,50, 55,57
A	figures	1-38,54, 56

3

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2014/055207

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2012131351 A2	04-10-2012	AU 2012235941 A1	10-10-2013
		CN 103476369 A	25-12-2013
		EP 2688528 A2	29-01-2014
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		US 5290251 A	01-03-1994
		WO 9208499 A1	29-05-1992

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2014/055207

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 53
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[X] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-24, 55(completely); 36-38, 52, 54(partially)

   A medical device in the form of an implant with an interior and exterior section wherein the exterior section comprises a three-dimensional porous structure,
   solving the problem of facilitating ingrowth

   ---

2. claims: 25-35, 56(completely); 36-38, 52, 54(partially)

   A medical device in the form of an implant with an interior and exterior section wherein the interior section comprises a plurality of rods,
   solving the problem of interconnecting the interior and the exterior sections

   ---

3. claims: 39-51, 57

   A medical device in the form of an adaptor for securing a bowel segment outside a patient's body after an ostomy has been performed, the adaptor comprising: attachment means for attaching the adaptor to any implant and securing means to which a bowel segment may be attached,
   solving the problem of allowing a turnbull procedure to be facilitated such that any bowel segment can be secured whilst it heals.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 53

Claim 53 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of this claim (Article 34(4)(a)(I) PCT) which are also not searched, see Rule 39.1(iv) PCT (method for treatment of the human or animal body by surgery and possibly by therapy, in this case a method of performing an ostomy comprising the use of an implant).

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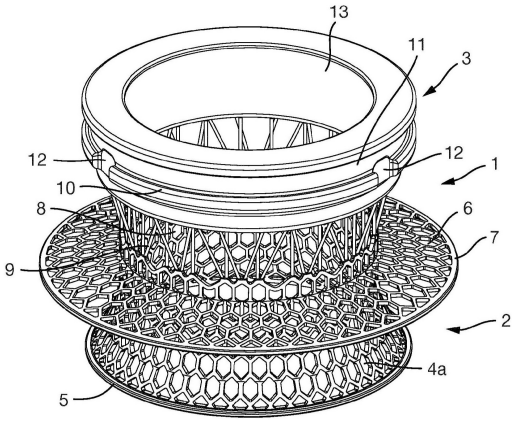
(54)发明名称

植入物

(57)摘要

植入物(1)包括用于植入到患者内的管状内部区段(2)和连接到内部区段(2)的外部区段(3)。外部区段(3)的表面包括在其内周边处的三维多孔结构(13)。



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1.一种植入物,包括用于植入到患者内的管状内部区段和连接到所述内部区段的外部区段,所述外部区段的表面包括在内周边处的刚性三维多孔结构。

2.根据权利要求 1 所述的植入物,其中所述多孔结构与所述外部区段的其余部分成整体 ;和 / 或

在所述多孔结构和所述外部区段的其余部分之间不存在间隙 ;和 / 或

所述多孔结构至少在第一端区域和第二端区域处连接到所述外部区段的其余部分。

3.根据权利要求 1 或 2 所述的植入物,其中所述多孔结构延伸到所述外部区段的外端的 1mm、2mm 或 3mm 内。

4.根据权利要求 1、2 或 3 所述的植入物,其中所述植入物是用于植入到患者的腹壁内的经皮造口术植入物。

5.根据任一项前述权利要求所述的植入物,其中所述外部区段是环形的。

6.根据任一项前述权利要求所述的植入物,其中所述多孔结构布置在所述外部区段的整个内周边周围。

7.根据任一项前述权利要求所述的植入物,其中所述多孔结构具有至少 0.5mm 的厚度。

8.根据任一项前述权利要求所述的植入物,其中所述多孔结构是完全可渗透的,且没有闭端。

9.根据任一项前述权利要求所述的植入物,其中进入所述多孔结构的每一个通路也具有出口。

10.根据任一项前述权利要求所述的植入物,其中形成所述多孔结构的任何构件的厚度小于或等于 500μm。

11.根据任一项前述权利要求所述的植入物,其中所述多孔结构中的任何开口的最大直径是 500μm。

12.一种植入物,包括三维多孔结构的形式的向内生长装置,其中所述多孔结构具有至少 0.5mm 的厚度。

13.一种植入物,包括三维多孔结构的形式的向内生长装置,其中所述多孔结构是完全可渗透的,并且没有闭端。

14.根据权利要求 13 所述的植入物,其中进入所述多孔结构的每一个通路也具有出口。

15.一种植入物,包括三维多孔结构的形式的向内生长装置,其中进入所述多孔结构内的开口的至少 80%、至少 85%、至少 90%、至少 95%或至少 97%具有相应的出口。

16.一种植入物,包括三维多孔结构的形式的向内生长装置,其中形成所述多孔结构的任何构件的厚度小于或等于 500μm、小于或等于 450μm、小于或等于 400μm、小于或等于 350μm,或者小于或等于 300μm。

17.一种植入物,包括三维多孔结构的形式的向内生长装置,其中所述多孔结构中的任何开口的最大直径为 500μm、450μm、400μm、350μm 或者 300μm。

18.根据任一项前述权利要求所述的植入物,其中所述多孔结构由钛制成。

19.根据任一项前述权利要求所述的植入物,其中所述多孔结构由相互连接构件形成。

20.根据权利要求 20 所述的植入物,其中所述构件布置在层中,所述层优选地同心地

布置。

21. 根据权利要求 21 所述的植入物，其中所述层通过连接构件连接。

22. 一种植入物，包括用于植入到患者内的管状内部区段和连接到所述内部区段的外部区段，所述外部区段的表面包括在内周边处的三维多孔结构，其中所述多孔结构由优选地同心地布置的多个相互连接构件形成，这些层由连接构件相互连接。

23. 根据权利要求 19、20、21 或 22 所述的植入物，其中所述构件在整个所述多孔结构中形成规则的重复图案。

24. 根据权利要求 1 至 22 中任一项所述的植入物，其中所述多孔结构具有不规则结构。

25. 一种植入物，包括用于植入到患者内的管状内部区段和连接到所述内部区段的外部区段，其中所述内部区段包括多个杆，且所述杆具有小于或等于 500 μm 的直径。

26. 根据权利要求 25 所述的植入物，其中所述杆围绕所述植入物周向地布置。

27. 根据权利要求 25 或 26 所述的植入物，其中所述杆中的一个或多个相对于所述植入物的纵向轴线倾斜。

28. 根据权利要求 25、26 或 27 所述的植入物，其中所述杆中的一个或多个相对于所述植入物的纵向轴线平行。

29. 根据权利要求 25 至 28 中任一项所述的植入物，其中一个或多个杆与其它杆相比具有相对于所述植入物径向向内定位的至少一端。

30. 根据权利要求 25 至 29 中任一项所述的植入物，其中所述杆的直径小于或等于 450 μm、小于或等于 400 μm、小于或等于 350 μm、小于或等于 300 μm 或小于或等于 250 μm。

31. 根据权利要求 25 至 30 中任一项所述的植入物，其中所述内部区段包括内侧内部区段部分和外侧内部区段部分，其中所述外侧内部区段部分包括所述多个杆。

32. 根据权利要求 31 所述的植入物，其中所述多个杆将所述内侧内部区段部分连接到所述外部区段。

33. 根据权利要求 32 所述的植入物，其中所述内侧内部区段部分仅通过所述多个杆连接到所述外部区段。

34. 根据权利要求 31 至 32 中任一项所述的植入物，其中所述外侧内部区段部分仅由所述多个杆形成。

35. 根据权利要求 31 至 34 中任一项所述的植入物，其中所述内侧内部区段部分包括向内生长装置，优选地为网状物的形式。

36. 根据任一项前述权利要所述的植入物，其中在内端处，所述内部区段径向地向外延伸。

37. 根据任一项前述权利要所述的植入物，还包括从所述内部区段径向地向外延伸的锚固凸缘。

38. 根据权利要 37 所述的植入物，其中所述锚固凸缘由网状物形成。

39. 一种用于在造口术之后固定患者身体外侧的肠段的接合器，所述接合器包括：

用于将所述接合器附接到植入物的附接装置；以及

固定装置，肠段能够被附接到所述固定装置。

40. 根据权利要求 39 所述的接合器，其中所述附接装置包括一个或多个弹性构件。

41. 根据权利要求 39 或 40 所述的接合器，其中所述附接装置布置成与植入物上的一个

或多个相应的凹部或其它附接点接合。

42. 根据权利要求 39 至 41 中任一项所述的接合器，其中所述接合器具有孔，肠段能够穿过所述孔。

43. 根据权利要求 39 至 42 中任一项所述的接合器，其中所述接合器基本上是环形的。

44. 根据权利要求 39 至 43 中任一项所述的接合器，其中所述固定装置包括在所述接合器中的一个或多个开口，缝合线能够附接到所述一个或多个开口。

45. 根据权利要求 39 至 44 中任一项所述的接合器，其中所述接合器布置成接收肠段从中通过，且允许肠段往回返回到所述接合器上。

46. 根据权利要求 39 至 45 中任一项所述的接合器，其中所述附接装置布置成使得当附接到植入物时，所述接合器被防止相对于所述植入物的纵向轴线旋转。

47. 根据权利要求 39 至 46 中任一项所述的接合器，其中所述附接装置布置成使得当附接到植入物时，所述接合器被防止相对于所述植入物的纵向轴线纵向地和 / 或横向地移动。

48. 根据权利要求 39 至 47 中任一项所述的接合器，其中所述接合器由生物可降解的材料制成。

49. 一种成套部件，包括植入物和用于在执行造口术之后固定患者身体外侧的肠段的接合器，所述接合器包括 ：

用于将所述接合器附接到所述植入物的附接装置 ；以及

固定装置，肠段能够被附接到所述固定装置。

50. 根据权利要求 49 所述的成套部件，其中所述接合器为权利要求 39 至 48 中任一项所述的接合器。

51. 根据权利要求 49 或 50 所述的成套部件，其中所述植入物为如权利要求 1 至 38 中任一项所述的植入物。

52. 根据权利要求 1 至 38 中任一项所述的植入物，与匹配盖子、袋子和 / 或排泄装置组合。

53. 一种执行造口术的方法，包括使用根据权利要求 1 至 38 中任一项所述的植入物和 / 或根据权利要求 39 至 48 中任一项所述的接合器。

54. 一种制造植入物的方法，所述植入物为根据权利要求 1 至 38 中任一项所述的植入物。

55. 一种植入物，包括 ：

管状内部区段，所述管状内部区段用于植入到患者内，所述管状内部区段具有第一端和第二端 ；

外部区段，所述外部区段具有用于附接到接合器或其它可移除的装置的主体，并且具有第一端和第二端，所述外部区段的第二端连接到所述内部区段的第一端，所述外部区段具有在第一端和第二端之间延伸的内表面和外表面 ；以及

三维多孔结构，所述三维多孔结构构造成和定尺寸为配合在所述外部区段的内表面内。

56. 一种植入物，包括 ：

外部区段，所述外部区段具有用于附接到接合器或其它可移除的装置的主体、第一端

和第二端，以及在所述第一端和所述第二端之间延伸的内表面和外表面，所述第二端具有在所述外部区段的内表面和外表面之间径向地延伸的宽度；

管状网状物，所述管状网状物具有第一端和第二端；以及

多个杆，所述多个杆将所述外部区段的第二端连接到所述管状网状物的第一端，其中所述杆在所述宽度上的不同点处且沿着所述外部区段的第二端的周边附接，并且延伸到和附接在所述管状网状物的第一端的周边上的不同点，其中所述杆比所述管状网状物提供较少的材料，以减少由接收所述植入物的患者对所述杆的不利反应。

57. 一种用于在执行造口术之后将患者身体外侧的肠段固定到植入物的接合器，所述接合器包括：

管状主体，所述管状主体具有第一端和第二端，并且构造和定尺寸为在所述管状主体中接收植入物的外部部分；

附接装置，所述附接装置用于将所述接合器附接到所述植入物；以及

径向地延伸的部分，该径向地延伸的部分连接到所述主体，包括用于接收肠段与之附接的固定装置。

植入物

技术领域

[0001] 本发明涉及植入物，特别是经皮造口术植入物，和可以使用该植入物的外科手术方法，优选地用于产生与经皮孔口连通的自制性储器。

背景技术

[0002] 回肠造口术和结肠造口术是例如恶性肿瘤或慢性肠炎所需的一般手术。如果结肠和直肠被移除，则外科手术称为回肠造口术，且如果直肠独自被移除，则外科手术称为结肠造口术。类似地，当由于例如膀胱癌而必须移除膀胱时，产生腹壁回肠造口术。在这些手术中，在腹壁中形成人造口，肠段连接到该人造口。

[0003] 造口术是用于产生人造口的任何这种手术的通用术语。

[0004] 在大部分情形中，人造口必须连接到用于收集身体废物的袋子。然而，代替常规回肠造口术，可以自回肠的远端部分制成称为“Kock 贮袋”的储器。该贮袋以产生用于闭合储器同时允许该储器借助于导管间歇地被排出的乳头阀的方式形成。这是所谓的自制性回肠造口术 (CI) 的示例，且其以前是常规的回肠造口术的有吸引力的替代，但是现在已经很少使用。手术的复杂性和高度可能的并发症（它们中的大部分涉及自制性乳头阀的机能障碍）如今已经阻止许多外科医生采用该手术。

[0005] 回肠贮袋肛管吻合术 (IPAA) 如今是这些患者的在世界范围内的黄金标准，但是与 CI 一样，该手术也是危险的且失败是常见的，大部分导致贮袋切除，具有肠的损失。失败的 IPAA 至 CI 的转变将是优选的选择，但是同样地，外科医生并不愿意执行该复杂的且不可靠的技术。同样，故障正位新膀胱或 Bricker 回肠造口术的转变将是值得期望的。

[0006] 在其较早的专利申请 EP 1632201A1 中，本申请人公开了包括实心壁圆柱形主体和为圆形凸缘形式的锚固区段的经皮造口术植入物。该装置设计成穿过腹壁被植入，并通过位于肌肉层上方在筋膜下方的锚固区段来固定。该区段包括由 S 形构件相互连接的内和外同心环，以便提供可以吸收剪切力且因此减少组织破坏的危险的轴向弹性结构。在 S 形构件周围的空间以及在环中设置很多孔允许组织向内生长和血管分布。推荐将该装置连接到肠壁的侧面，并且通过在圆柱形主体上设置可移除的盖子，可以提供自制性造口术。

[0007] US 6017355 公开了另一种实心壁植入物。该植入物设有旨在促进组织向内生长的包括涤纶丝绒的织物涂层。

[0008] 在 WO 2007/099500 中公开了该植入物的发展，其中实心壁圆柱形主体由以周向地间隔开的腿部从锚固区段间隔开的轴向外管状部分替代。管状部分穿透皮肤并形成用于连接到袋子或盖子的环。该植入物设计成接收穿过其拉起的肠区段；腿部之间的空间允许在腹壁的内部部分和肠的浆膜组织之间产生组织结合部，以便提供更牢固的、稳定的、防漏的且良好脉管化的组织 - 植入物联结。在一些实施方式中，周向向内生长的网状物被另外地提供。该网状物沿着管状部分的长度的大部分延伸，在它和管状部分之间提供了环状间隙，以有利于浆膜组织穿过网状物的生长。

[0009] 在 WO 2009/024568 中公开的另外的发展中，本申请人推荐了由两个轴向间隔开

的管状部分形成的圆柱形主体。外管状部分穿透皮肤并提供连接环。内管状部分附接到之前描述的类型的锚固凸缘。该两个部分通过包括允许在腹壁和肠之间产生组织结合部的刚性间隔开的腿部或刚性圆柱形向内生长网状物的“距离装置”连接在一起。借助于该布置，在从皮肤沿着植入物的可能感染路径中提供了隔断。

[0010] 在又一个发展中，本申请人在 WO2010/000851 中公开了一种经皮造口术植入物，其包括用于安置外部可拆卸的装置的圆柱形部分、圆柱形向内生长网状物和用于锚固植入物的圆形凸缘。该圆柱形部分和圆形凸缘被附接到向内生长网状物的相对端，其中网状物在圆柱形部分内延伸。植入物构造成使得当其被植入患者的腹壁中时，包括表皮的腹部组织遇到向内生长网状物，并且能够从中穿过直接地附接到植入物内侧的肠段的浆膜组织。因此，其基于这样的假设，即通过允许表皮直接附接到浆膜组织，可以防止细菌感染（即细菌附着到植入物表面，随后迁移）。

[0011] 然而，尽管该植入物被发现在确保浆膜组织附接到腹部组织的合理附接中是有效的，但是其具有变得更难以确保植入物的外部部分和肠段之间的流体紧密密封的缺陷。这是因为植入物依赖于在圆柱形部分内延伸且维持将浆膜组织穿过在该部分内的网状物的渗入以对植入物形成良好密封的肠段。如果肠缩进圆柱形部分下方，则可穿过网状物形成泄漏路径，即使肠段和腹壁保留完整且植入物保持固定且没有感染。

[0012] WO 2011/126724 公开了旨在防止人造口随时间收缩且因此需要外科手术再开口的人造口稳定装置。优选的实施方式包括具有径向地延伸的网状物锚固凸缘的柔性网状物管。在一些变形中，可采用多层网状物。

[0013] 在 WO 2012/131351 中，申请人提出涉及经皮造口术植入物的另外的发展，其包括连接构件、第一管状向内生长构件和从第一管状向内生长构件径向地向外间隔开的第二管状向内生长构件、在真皮下方接合腹壁的径向延伸的真皮锚固件，和 / 或布置在连接构件周围的管状向内生长构件。该植入物通过激光切割工艺形成。

[0014] 然而，在试验中，该植入物仍被发现具有问题。例如，该植入物利用设置在底部的锚固件固定到肌肉鞘。这对于增加或损失重量的患者是不理想的，因为植入物高度是固定的，而患者腹部的厚度可以随时间改变。在植入物的顶部还存在不充分的向内生长。这些因素可导致皮肤问题、植入物过生长、过量植入物突起和系统泄漏。

发明内容

[0015] 根据本发明的一个方面，提供了一种植入物，包括用于植入到患者内的管状内部区段和连接到内部区段的外部区段，外部区段的表面包括在其内周边处的刚性三维多孔结构。通过在外部区段的内表面处提供三维多孔结构，这提供了组织可以生长到其内的向内生长装置。通过提供三维结构，这可以比之前使用的二维向内生长装置提供更好且更可靠的向内生长。三维向内生长多孔结构可以提供用于组织向内生长的“骨架”结构，并且产生促进细胞向内生长到结构内的生理需要。因此，在本发明的一个要求保护的方面，多孔结构是刚性的。此外，通过提供在外部区段处的三维多孔结构，这可以导致在植入物的外端处的更多向内生长，使得在外端处更牢固且降低了系统泄漏的可能性。

[0016] 优选地，在三维多孔结构和外部区段的其余部分之间不存在间隙。

[0017] 多孔结构优选地至少在其第一端区域和第二端区域处连接到外部区段的其余部

分，和 / 或优选地在多孔结构的高度内的多个点处连接到外部区段的其余部分。

[0018] 优选地，多孔结构延伸到外部区段的外端（顶部）。这样，例如，肠段可以通过向上直到植入物的顶端的向内生长而固定，从而提供植入物的更可靠植入且也减少泄漏的可能性。可替代地，多孔结构可以延伸到外部区段的外端（顶部）内 1mm、2mm 或 3mm。

[0019] 例如，植入物可以是造口术植入物，比如经皮造口术植入物，其适合于植入到患者的腹部内。

[0020] 管状内部区段可以是基本上圆柱形的，但可以是具有沿着其纵向轴线的开口的大体任何形式。开口应理想地足够大以允许肠段从中穿过。

[0021] 外部区段的横截面的形状和 / 或尺寸（例如，内径和 / 或外径）可以沿着其长度变化。

[0022] 例如，外部区段可以是是大体环形的、管状的或圆柱形的。

[0023] 外部区段和 / 或内部区段可以具有大体圆形的横截面。

[0024] 外部区段理想地是与内部区段同轴的。

[0025] 外部区段可以具有 10-60mm，更优选地 25-35mm 或 25-30mm 的外径（从其外边缘测量）。

[0026] 外部区段可以具有 5-55mm，更优选地 15-30mm 或 20-25mm 的内径（从其内边缘测量）。

[0027] 外部区段可以具有在其最窄点处 5-55mm，更优选地 15-30mm 或 20-25mm 的内径（从其内边缘测量）。

[0028] 外部区段和内部区段具有较小内径（即，朝向上述的尺度的下端）的植入物可以对尿道再生术来说是特别有用的。外部区段和内部区段具有较大内径（即，朝向上述的尺度的上端）的植入物可以对于结肠造口术来说是特别有用的。

[0029] 内部区段和外部区段可以具有圆形横截面或者任何其它形状。因此，因为这些区段的横截面不必是圆形的，所以上述对“直径”的参考指垂直地穿过区段测量的最大距离。

[0030] 优选地，内部区段和外部区段具有相同横截面（例如，在尺寸和 / 或形状上），至少在区段相遇的点处具有相同横截面。

[0031] 多孔结构优选地布置在外部区段的整个内周边周围。可替代地，多孔结构可以围绕外部区段的内周边的至少 70％、至少 75％、至少 80％、至少 85％、至少 90％、至少 95％、至少 97％、至少 98％或至少 99％设置。通过给外部区段的内周边的全部或至少大部分设置多孔结构，这确保了向内生长装置围绕外部区段的内周边的全部或至少大部分设置，因此可以获得可靠的且足够的向内生长。

[0032] 多孔结构优选地具有至少 0.5mm、至少 0.6mm、至少 0.7mm、至少 0.8mm、至少 0.9mm、至少 1.0mm、至少 1.1mm、至少 1.2mm 或至少 1.25mm 的厚度（或最小厚度）。在优选的实施方式中，多孔结构具有约 1.25mm 或 1.75mm 的厚度。通过提供至少 0.5mm（或更大）厚度的多孔结构，这意味着多孔结构可以由多个层（例如，两个或三个层）形成，且有助于确保可靠地向内生长到多孔结构。多孔结构的厚度可以相对于植入物的纵向轴线在径向方向上测量。

[0033] 多孔结构应理想地也是足够薄的，以致在外部区段内存在允许肠段从中穿过的足够空间。因此，优选地，多孔结构具有 3.0mm 或更小、2.5mm 或更小或者 2.0mm 或更小的厚

度。例如，多孔结构的厚度可以是在 0.5 至 2.0mm、2.5mm 或 3.0mm 的范围内。

[0034] 优选地，多孔结构是完全可渗透的，没有闭端。例如，进入多孔结构的每一个通路理想地也具有出口。可替代地，进入多孔结构内的开口的至少 80％、至少 85％、至少 90％、至少 95％或至少 97％具有相应的出口。这可以提供进入向内生长装置内的最可靠的向内生长。

[0035] 形成多孔结构的任何构件的厚度优选地小于或等于 500μm，小于或等于 450μm、小于或等于 400μm、小于或等于 350μm 或小于或等于 300μm。形成多孔结构的任何构件的厚度优选地大于或等于 100μm、大于或等于 125μm、大于或等于 150μm 或者大于或等于 200μm。通过提供由具有这种尺寸的构件形成的多孔结构，这意味着多孔结构具有生物上舒适（例如，模仿珊瑚）的尺寸，从而产生促进组织到多孔结构中的牢固向内生长的生理需要。

[0036] 由于类似的原因，优选地，多孔结构中的任何开口的最大直径是 500μm、450μm、400μm、350μm、300μm、250μm、200μm 或 150μm。例如，多孔结构中的任何开口的最小直径可以是 50μm、75μm、100μm 或 125μm。多孔结构中的任何开口（或者开口的至少 70％、75％、80％、85％、90％或 95％）的尺寸优选地在 100 至 400μm 的范围内，更优选地在 150μm 至 350μm，更优选地 250μm 至 350μm，更优选地 275μm 至 325μm。

[0037] 多孔结构中的任何构件和 / 或开口的横截面可以是圆形的或任何其它规则或不规则形状，比如椭圆形的、超椭圆形的、具有圆形角部的四边形、六边形、八边形、多边形、具有圆形角部的多边形或者具有圆形角部的矩形，例如。因此，因为形成多孔结构的构件和 / 或开口的横截面不必是圆形的，所以上述对“直径”的参考指垂直地穿过多孔结构中的构件和 / 或开口测量的最大距离。

[0038] 在另外优化的实施方式中，形成多孔结构的构件和多孔结构的开口两者可以在一个多孔结构内以任意或结构化（规则）图案在尺寸和 / 或形状上独立地变化。

[0039] 多孔结构优选地具有至少 3mm、至少 4mm、至少 5mm 或至少 6mm 的高度，其中高度是在平行于植入物的纵向轴线的方向测量的多孔结构的长度。

[0040] 多孔结构优选地具有小于 10mm、小于 8mm、小于 8mm 或小于 7mm 的高度。

[0041] 优选地，多孔结构的高度是 3 至 9mm 的范围，优选地 4 至 8mm、更优选地 5 至 7mm，更优选地 6 至 7mm 的范围。

[0042] 在优选的实施方式中，多孔结构的高度是 6.35mm。

[0043] 多孔结构的高度理想地足够大以提供足够大的向内生长区，而且也足够小，使得在皮肤水平上方的植入物突出是受限的（多孔结构理想地位于外部区段内）。

[0044] 然而，在一些实施方式中，多孔结构可以延伸到内部区段内和 / 或另外的多孔结构（例如，具有关于第一多孔结构讨论的任何特征）可以设置在内部区段中。因此，具有高达约 40mm 的高度的多孔结构可以被提供。这样的多孔结构可以从外部区段延伸到内部区段内。

[0045] 多孔结构可以是柔性的、半柔性的或刚性的。

[0046] 多孔结构优选地与外部区段的其余部分是一体的。这意味着外部区段至少可以形成为单个元件（例如，也与植入物的其余部分），并且不需要在外部区段内附接多孔结构。

[0047] 多孔结构优选地由诸如钛的生物可接受的材料制成。这有助于防止患者对植入物

的不利反应。优选地，使用商业纯钛，例如医疗 2 级钛。可以使用的其它材料的示例包括根据 ASTM F67(ISO5832) 医疗级 1、2、3、4 或 5 的钛级，尤其是 5 级 Ti64ELI，其它生物相容金属和合金，比如 Elgiloy，或者铬 - 钴 - 钼合金、生物相容陶瓷和生物相容聚合物。

[0048] 多孔结构可以由相互连接的构件形成。构件可以是成层布置（例如，同心层），例如。层可以通过连接构件连接。因此，连接构件通常具有径向延伸。这些优选地是两至四层，但是更优选地是三层。

[0049] 构件可以在整个多孔结构内形成规则的、重复的图案。例如，多孔结构可以由多个重复的单元形成。

[0050] 可替代地，多孔结构可以具有不规则的或部分不规则的结构。

[0051] 在任一种情形中，应理解，多孔结构典型地在多个方向上是多孔的（即，穿过结构的通路在多个方向上延伸），使得提供了珊瑚状结构。这相反地区别于基本上是二维的常规网状物，该常规网状物的孔隙（和通路）相对于网状物的表面仅在一个方向上延伸。

[0052] 优选地，外部区段包括用于与装置接合的接合装置（例如，接合机构）。例如，外部区段可以包括一个或多个凹槽、凹部或缺口，设置在盖子或其它装置上的相应的附接装置可以被附接到该凹槽、凹部或缺口中。优选地，接合装置位于植入物的外表面上，或者在植入物的内表面的正顶部处，使得植入物内的组织在装置附接到植入物时不受影响。

[0053] 可替代的接合装置包括 :用于将装置螺纹连接到植入物的螺纹接口、卡口附接件、磁性接口（即，布置在植入物上的一个或多个磁体）、包围外周界的橡胶或橡胶状材料，或者例如，植入物的内径中的类似软木塞。

[0054] 在一些实施方式中，在内端处，内部区段可以包括径向地延伸的部分，例如，锥形或喇叭状的径向地延伸的部分。这可以有助于将植入物固定在患者身体中，因为其可以抵抗在更多方向作用于植入物的力。

[0055] 可替代地或另外，植入物可包括从内部区段径向向外延伸的锚固凸缘。这也可以有助于将植入物固定在患者身体中。

[0056] 锚固凸缘可以延伸到比径向延伸的部分更大的半径（如果两种这样的部件被提供的话）。

[0057] 锚固凸缘可以从植入物垂直地延伸。然而，优选的是，其以小于 90° 的角度延伸，使得其朝植入物的内端倾斜。锚固凸缘可以是弯曲的。这些特征可以允许锚固特征跟随患者身体的一般曲率，减少由其植入造成的破坏或问题的可能性。

[0058] 锚固凸缘可以由向内生长装置（例如，向内生长部分）比如网状物，例如六边形网状物形成或者包括向内生长装置（例如，向内生长部分）比如网状物，例如六边形网状物。这种向内生长装置可以允许身体组织生长到凸缘内且将植入物固定在身体中。

[0059] 内部区段优选地从锚固凸缘连接到其的点纵向地向内（即，如图中显示的向下地）延伸。内部区段可以另外或可替代从锚固凸缘连接到其的点纵向地向外（即，在图中显示的向上地）延伸。

[0060] 植入物可以是柔性的、半柔性的或刚性的。在一些实施方式中，植入物的柔性 / 刚性可以在其结构内变化。例如，内部区段可以比外部区段更柔性使得，例如内部区段更适合于周围的组织，但是外部区段仍足够刚性的以致盖子可以与之附接。例如，这可以通过在植入物的不同区段使用不同的材料来实现。这种不同的材料可以利用焊料、胶、摩擦、螺纹或

其它技术进行连接。

[0061] 内部区段可以由向内生长装置（例如，向内生长部分）比如网状物，例如六边形网状物形成或者包括向内生长装置（例如，向内生长部分）比如网状物，例如六边形网状物。这种向内生长装置可以允许身体组织生长到内部区段内，且将植入物固定在身体中。

[0062] 内部区段可以包括多个杆，该多个杆的直径小于或等于生物舒适的长度，比如500μm、450μm、400μm、350μm、300μm、250μm或200μm。杆的直径优选地类似于人类皮肤头发的平均直径，例如20至200μm。通过由这种薄的部件形成内部区段，或内部区段的一部分，用于形成植入物的材料的量可以被最小化，从而减少患者与植入物不利地反应的可能性。而且，因为杆的直径小于或等于生物舒适的长度，这减少了患者身体排斥植入物或与植入物不利地反应的可能性。

[0063] 该概念被认为自身是有创造性的，因此，根据本发明的第二方面，提供了一种植入物，包括用于植入到患者内的管状内部区段和连接到所述内部区段的外部区段，其中内部区段包括多个杆且杆的直径小于或等于500μm、小于或等于450μm、小于或等于400μm、小于或等于350μm、小于或等于300μm、小于或等于250μm或小于或等于200μm。例如，杆的直径可以在100至400μm、100至300μm、150至250μm、100至200μm、200至300μm或者250至300μm的范围内。

[0064] 优选地，杆的直径具有大于或等于20μm、大于或等于50μm、大于或等于75μm或者大于或等于100μm。在优选实施方式中，杆具有275μm的直径。

[0065] 杆可具有圆形的横截面或任何其它形状。因此，因为杆的横截面不必是圆形的，所以上述“直径”的参考指垂直地穿过杆材料的最大直径。

[0066] 杆优选地围绕植入物周向地布置。例如，至少一些杆可以平行于植入物的纵向轴线。

[0067] 根据杆的直径和制成杆的材料，理想地足够的杆应被设置，以使植入物足够强来承受作用于其的拉力，具有安全限量，例如。用于形成杆的材料越强，需要的杆的数量越少。理想地，使用可能最少数量的杆，以将使用的材料量保持为最小。

[0068] 多于10、20、30、40、50或60个杆可以被提供，和/或少于150、140、130、120、110、100或90个杆可以被提供。

[0069] 优选地，提供了5至150、20至130、40至110、50至100或60至90个杆。

[0070] 一个或多个杆优选地相对于植入物的纵向轴线倾斜。这可有助于改进植入物的机械强度，因为这种杆可以有助于承受作用于植入物的扭矩、剪切和压缩力。例如，一个或多个倾斜杆可以以相对于植入物的纵向轴线高达45°、高达40°、高达35°、高达30°、高达25°、高达20°、高达15°或者高达10°的角度布置。优选地，一个或多个倾斜杆可以以至少5°的角度布置。在优选的实施方式中，一个或多个倾斜杆可以以高达25°的角度布置。

[0071] 杆可以相对于植入物的纵向轴线径向向内或向外倾斜，和/或围绕植入物周向地或侧向地倾斜。杆的向内或向外径向倾斜优选地小于周向倾斜。例如，杆可以以约15°或更小的角度径向向外或向内倾斜，和/或杆可以以约25°或更小的角度周向地倾斜。杆可以在顺时针和/或逆时针方向（当从植入物的顶端或外端观察时）上周向地倾斜。

[0072] 一个或多个杆优选地相对于植入物的纵向轴线平行。例如，这种平行的杆可以有助于抵抗沿着其纵向轴线作用于植入物的轴向力。

[0073] 杆的约 30-40％、30-50％、40-60％、50-70％或更多可以是倾斜的。

[0074] 杆的约 30-40％、30-50％、40-60％、50-70％或更多可以是平行的。

[0075] 一个或多个杆可以具有与一个或多个其它杆相比相对于植入物径向向内定位的至少一个端部。这种布置可以改进植入物的机械强度，特别是相对于剪切力。例如当患者从椅子起来且使桌子与植入物接触，侧向移动以及接触门柱或类似情形时，剪切力可以作用于植入物。

[0076] 杆的内端（即，杆的距植入物的外部区段最远的端部）优选地全都位于植入物的相同半径处。

[0077] 杆的外端（即，杆的距植入物的外部区段最近的端部）可以位于不同的半径处，例如，位于两个或三个不同的半径处。在优选的实施方式中，杆的外端位于三个假想的同心圆上。优选地，同心圆被相等地间隔开。

[0078] 径向最内的外端和径向最外的外端之间的径向距离可以对应于多孔结构的厚度。例如，径向最内的外端和径向最外的外端之间的径向距离可以是约 1.0 至 2.0mm 或者 2.5mm。

[0079] 杆的这种布置可以导致非常刚性的、盒状的总体结构，这可有助于增加植入物的机械强度，且将作用于植入物的外部区段的力更均匀地分布到多孔结构内。

[0080] 杆理想地足够长，使得在使用中它们可以延伸穿过皮肤（即，表皮和真皮）且也理想地部分地延伸到皮下组织。例如，杆可以是至少 1.5mm、至少 2mm、至少 2.5mm、至少 3.0mm、至少 3.5mm、至少 4.5mm 或至少 5.0mm 长。杆可以具有 8.0mm、7.5mm、7.0mm、6.5mm、6.0mm、5.5mm 或 5.0mm 的最大长度。在优选的实施方式中，杆是约 4.8mm 长。当然，倾斜的杆可以比平行的杆略微长。在该段中提到的长度可以指倾斜的杆或平行的杆。

[0081] 内部区段可以包括内侧内部区段部分和外侧内部区段部分。

[0082] 外侧内部区段部分优选地包括多个杆。

[0083] 多个杆可以将内侧内部区段部分连接到外部区段。

[0084] 优选地，内侧内部区段部分仅通过多个杆连接到外部区段。这有助于最小化在植入物中使用的材料的量。

[0085] 由于类似原因，外侧内部区段部分优选地仅由多个杆形成。

[0086] 内侧内部区段部分优选地包括或由向内生长装置（例如，向内生长部分）形成，优选地网状物的形式，比如六边形网状物。通过提供这种内侧内部区段部分，这可有助于植入物可靠地植入到患者身体内。

[0087] 上述方面的各种任选特征被认为是独立地有创造性的。

[0088] 因此，根据本发明的另一方面，提供了一种植入物，包括三维多孔结构形式的向内生长装置，其中多孔结构具有至少 0.5mm 的厚度。例如，多孔结构可以具有至少 0.5mm、至少 0.6mm、至少 0.7mm、至少 0.8mm、至少 0.9mm、至少 1.0mm、至少 1.1mm、至少 1.2mm 或者至少 1.25mm 的厚度。在优选实施方式中，多孔结构具有约 1.25mm 或 1.75mm 的厚度。如上面所述，通过提供至少 0.5mm 厚的向内生长装置，这确保了可以实现到多孔结构内的可靠向内生长。

[0089] 根据本发明的另一方面，提供了一种植入物，包括三维多孔结构形式的向内生长装置，其中多孔结构是完全可渗透的且没有闭端。

[0090] 优选地，进入多孔结构内的每一个通路也具有出口。

[0091] 根据本发明的另一方面，提供了一种植入物，包括三维多孔结构形式的向内生长装置，其中进入多孔结构内的开口的至少80％、至少85％、至少90％、至少95％或至少97％具有相应的出口。

[0092] 根据本发明的另一方面，提供了一种植入物，包括三维多孔结构形式的向内生长装置，其中形成多孔结构的任何构件的厚度小于或等于500μm、小于或等于450μm、小于或等于400μm、小于或等于350μm或者小于或等于300μm。

[0093] 根据本发明的另一方面，提供了一种植入物，包括三维多孔结构形式的向内生长装置，其中多孔结构中的任何开口的最大直径是500μm、450μm、400μm、350μm或者300μm。

[0094] 上述方面中的任何的植入物可以是经皮造口术植入物，例如。植入物可包括管状内部区段和/或管状或环形外部区段。内部区段和外部区段优选地是同轴的。向内生长装置可以位于内部区段和/或外部区段中。优选地，向内生长装置围绕内部区段和/或外部区段的周边延伸。

[0095] 在植入物已经植入到患者内之后，重要的是，例如穿过植入物的肠段或其它脉管被固定，使得其可以生长到植入物内。

[0096] 存在可以固定或稳固例如肠段的各种方式。一种常规方法是称为“turnbull”的外科手术程序。在该程序期间，在常规的人造口上，肠的传出部分在内侧扭出并且附接到人造口周围的皮肤。然而，在该程序之后，人造口通常在皮肤水平处缩回，留下空间且导致泄漏。而且，不可能利用上述方面的植入物执行常规的turnbull，因为这将完全覆盖和隐藏植入物。然后在治愈期间使用稳定装置（将植入物保持在适当位置）将是不可能的，且监测治愈和植入物的向内生长也将是不可能的。在turnbull下且在植入物周围捕集身体废物的危险将是大的，可能造成感染，且清洁和洗涤这种收集的废物将是不可能的。在利用造口术植入物的之前过程中，肠被简单地留在植入物外侧且布置成“松悬挂的turnbull”，不连接到任何东西，且不被固定或稳固。

[0097] 因此，需要提供例如固定肠段以在对患者执行造口术之后提供用于造口术的更稳定环境以治愈的方式。

[0098] 根据本发明的另外方面，提供了一种用于在已经执行造口术之后固定患者身体外侧的肠段的接合器，所述接合器包括：用于将所述接合器附接到植入物的附接装置（例如，植入物附接部分）；以及固定装置（例如肠段固定部分），肠段能够被附接到该固定装置。

[0099] 通过提供这种接合器，turnbull程序可以被方便化，且肠段可以在其治愈时被固定，从而减少在该过程期间其缩回的可能性。此外，当与上述根据本发明的方面中的一个方面的植入物一起使用时，肠段可以靠近多孔向内生长结构（其中，这设置在植入物的外部区段中）固定，这进一步有助于将肠段保持在固定位置，且从而提供没有明显移动或机械应力的最佳平静的治愈情况。

[0100] 该接合器可以被称为turnbull接合器。

[0101] 植入物自身也可以利用稳定装置固定以在治愈期间将其保持在适当位置。

[0102] 接合器理想地可以容易以正确的对准附接到植入物。

[0103] 优选地，附接装置布置成当接合器附接到植入物时防止接合器相对于植入物旋转

地、水平地和垂直地移动。这有助于防止在治愈期间作用于脉管的旋转力或其它力。

[0104] 优选地，附接装置布置成附接到植入物的外表面，例如，附接到在植入物的外表面上的凹槽、凹部或缺口中。附接装置可以布置成与植入物上的一个或多个相应的凹槽、凹部或缺口接合。

[0105] 在优选实施方式中，附接装置包括一个或多个弹性构件。这是允许接合器附接到植入物的简单方式。一个或多个弹性构件可以包括接合装置（例如，植入物结合部分），比如突出部分，用于与植入物接合，例如接合在植入物上的一个或多个相应的凹部中。

[0106] 也可以使用可替代的附接装置。例如，较长的或较短的弹性构件可以与相应的凹槽、凹部或缺口一起使用，例如，在植入物上的相应较高或较低位置。也可以使用不同的成形的突出部分。其它替代包括：用于将接合器螺纹连接到植入物上的螺纹接口、卡口附接件、磁性接口（即，接合器和植入物上的一个或多个相应对磁体）、仅使用摩擦力包围植入物的外周界和/或接合器的内周界的橡胶或橡胶状材料、在接合器上用于附接到植入物的例如抛光顶表面的具有环状抽吸杯的橡胶或橡胶状材料。

[0107] 接合器优选地具有肠段可以穿过的孔。例如，接合器可以基本上是环形的。优选地，孔具有与相应的植入物的内形状和/或直径相同的形状和/或直径。例如，接合器可以基本上是环形的或管状的。孔可以具有 5-55mm，更优选地 15-30mm 或者 20-25mm 的直径。

[0108] 固定装置可以包括在接合器中的一个或多个开口，缝合线可以穿过该一个或多个开口附接。例如，接合器可以包括一个或多个径向延伸的部分，一个或多个开口设置在该一个或多个径向延伸的部分中。固定装置可以可替代地包括缝合线可以附接到的多个钩子中的一个。

[0109] 接合器优选地由诸如医疗质量聚酰胺的塑料材料制成。可替代地，接合器可以由医疗级 POM、PEEK 或其它类似的聚合物、半刚性或柔性医疗级聚合物比如 Mediprene 或类似物、或者钛或其它金属或合金制成，这取决于附接机制和制造方法。

[0110] 在一些实施方式中，使用生物可降解材料形成接合器。接合器然后将在合适的时间之后自动“消失”，因为其被周围组织溶解。例如，这种接合器可由医疗级聚合物比如 PGA 聚（乙交酯）、PDO 聚（对二氧环己酮）、LPLG 聚 (L- 丙交酯 - 共 - 乙交酯）、DLPLG(DL- 丙交酯 - 共 - 乙交酯）或 PHB-PHV 共聚物（聚羟基丁酸酯 - 聚羟基戊酸酯）制成。

[0111] 不同的聚合物或其它材料将在身体内以不同的比率降解，因此应理想地使用具有合适的释放/降解比率的聚合物或其它材料。例如，能够形成会在几周（例如，2-8 或 5-7 周）之后降解的接合器的材料可以是合适的。这种接合器将在身体中保持足够长以使治愈过程发生。而且，诸如机械性能、处理特性、可能的杀菌方法、材料的成本和可利用性等的因素应在选择合适的材料时被考虑。接合器优选地布置成接收肠段从中穿过，并允许肠段返回到接合器上。

[0112] 根据本发明的另一方面，提供了一种成套部件，该成套部件包括植入物和用于在已经执行造口术之后固定患者身体外侧的肠段的接合器，该接合器包括：用于将所述接合器附接到所述植入物的附接装置；以及固定装置，肠段能够被附接到所述固定装置。

[0113] 成套部件优选地是可杀菌的。

[0114] 成套部件中的接合器可以如关于本发明的接合器方面或其上述优选特征中的任何特征描述的。

[0115] 成套部件中的植入物可以是如关于本发明的植入物方面中的任何或上面它们的优选特征中的任何特征描述的。

[0116] 本发明还涉及包括使用上面描述的植入物和 / 或接合器执行造口术的方法。

[0117] 因此，根据另一方面，提供了一种执行造口术的方法，包括 ：提供根据上述任何方面或其优选形式的造口术植入物 ；在患者身体中提供用于植入物的合适的开口 ；将植入物植入开口中，并且将肠段拉入植入物内以提供人造口。该方法最优选地如在下面更详细描述的。

[0118] 从另一方面来看，本发明提供了执行造口术的方法，包括 ：在腹部中植入根据上面描述的任何方面或其任何优选形式的经皮造口术植入物 ；将脉管的区段（比如，肠）拉入到植入物内 ；以及将它固定以形成人造口。植入物和 / 或方法优选地如本文阐述的。

[0119] 植入物优选地与盖子组合地使用或设置，以便防止泄漏和 / 或保护人造口。然而，其也可以与袋子或排泄装置组合使用。因此，从又一方面来看，本发明提供了与匹配盖子、袋子或排泄装置组合地根据本文描述的任何方面或优选形式的造口术植入物。匹配典型地借助于具有在使用中与植入物的外部区段接合且优选地借助于接合装置（比如在植入物的外部区段的周边周围的周向凹槽）连接至其的一部分的盖子、袋子或排泄装置的一部分。然而，整个地或部分地与外部区段的内表面接合是可能的。

[0120] 本发明还涉及执行造口术的方法，包括 ：提供造口术植入物，其优选地（但非排它地）是根据上面描述的任何方面或其任何优选形式 ；将植入物植入患者身体中的开口内 ；将肠段拉入植入物内以提供人造口 ；在植入物的外端处提供根据上面描述的任何方面或其任何优选形式的接合器 ；将肠段的传出端返回到接合器上 ；以及固定肠段的传出端。肠段的传出端可以利用缝合线固定，例如。肠段的传出端优选地固定到接合器。

[0121] 优选地，接合器可移除地附接到植入物的外端，例如，利用附接装置，比如一个或多个夹子。

[0122] 在几周之后，例如，当肠已经足够地生长到植入物内时，接合器可以被移除。

[0123] 为了移除接合器，优选地，肠的突出到植入物外侧的部分（例如，其现在开始皱缩）被切断。然后可以移除接合器。肠随后应永久地刚好保留在植入物的顶部。

[0124] 本发明还涉及制造植入物的方法，植入物为根据上面描述的任何方面的植入物。优选地，植入物整体地形成。可替代地，植入物可以制成为各部分，这些部分随后连接在一起。各部分可以由相同的材料或者两种或更多种不同的材料形成。

[0125] 植入物可以通过 3D 打印过程形成，例如。优选地，使用电子束或激光 3D 打印过程。可替代地，植入物或其部分可以被模制或常规地机加工和激光或水射流切割，或者通过蚀刻和 / 或冲压方法制作。

[0126] 该方法可以包括抛光植入物的至少一部分（特别是外部区段或其外表面）。这可以给予光滑光洁度。

[0127] 上述本发明的任何方面可以包括本发明的其它方面的任何特征，即使没有明确说明。

附图说明

[0128] 现在将仅举例且参考附图描述本发明的优选实施方式，在附图中 ：

[0129] 图 1 是植入物的实施方式的透视图；

[0130] 图 2 是图 1 的植入物的另一透视图；

[0131] 图 3 是图 1 的植入物的底视图；

[0132] 图 4(a)-(c) 是图 1 的植入物的侧视图；

[0133] 图 5 是图 1 的植入物的俯视图；

[0134] 图 6 是植入物的另一实施方式的透视图；

[0135] 图 7 是图 6 的植入物的另一透视图；

[0136] 图 8 是图 6 的植入物的底视图；

[0137] 图 9(a)-(c) 是图 6 的植入物的侧视图；

[0138] 图 10 是图 6 的植入物的俯视图；

[0139] 图 11 是多孔结构的透视图；

[0140] 图 12 是具有图 11 的多孔结构的植入物的局部剖切透视图；

[0141] 图 13 是具有图 11 的多孔结构的植入物的透视图；

[0142] 图 14 是图 13 的植入物的底视图；

[0143] 图 15 是图 13 的植入物的侧视图；

[0144] 图 16 是沿图 15 中的线 B-B 的植入物的横截面图；

[0145] 图 17 是沿图 15 中的线 A-A 的植入物的横截面图；

[0146] 图 18 是图 14 的植入物的俯视图；

[0147] 图 19 以更多细节显示了图 17 中的标记 C 的区域；

[0148] 图 20 以更多细节显示了图 16 中标记 D 的区域；

[0149] 图 21 是图 13 的植入物的另一透视图；

[0150] 图 22 是多孔结构的部分的透视图；

[0151] 图 23 是图 22 的多孔结构的分解透视图；

[0152] 图 24 显示了另一多孔结构的一部分；

[0153] 图 25(a)-(c) 以更多细节显示了图 24 的多孔结构的部分；

[0154] 图 26(a)-(f) 分别显示了接合器的实施方式的俯视图、底视图、底部透视图、顶部透视图、前视图和侧视图；

[0155] 图 27 是附接到图 6 的植入物的图 26(a)-(f) 的接合器的底部透视图；

[0156] 图 28 是附接到图 6 的植入物的图 26(a)-(f) 的接合器的顶部透视图；以及

[0157] 图 29 是图 26(a)-(f) 的接合器和图 6 的植入物在附接之前的透视图。

具体实施方式

[0158] 图 1 至图 5 显示了植入物 1 的实施方式。

[0159] 植入物 1 由内部区段 2 和外部区段 3 形成。当植入患者内时，内部区段 2 大部分或整个地位于患者内，而外部区段 3 大部分或整个地位于患者外侧。

[0160] 内部区段 1 由内侧内部区段部分 4 和外侧外部区段部分 8 形成。

[0161] 内侧内部区段部分 4 为由六边形网状物形成的基本上圆柱形结构。在其下（如图中显示的）或内端，该圆柱在径向延伸部分 4a 中径向地向外扩展，并且以连续实心环 5 终止。

[0162] 锚固凸缘6从内侧内部区段部分4径向地向外延伸。其也是由六边形网状物制成。锚固凸缘6在其径向外边缘处具有连续的实心环7。内侧内部区段部分4在锚固凸缘6上方和下方（即，向外地和向内地）延伸。

[0163] 锚固凸缘6比径向延伸部分4a延伸更大的半径。

[0164] 外侧内部区段部分8将内侧内部区段部分4连接到外部区段3。外侧内部区段部分8由在内侧内部区段部分4和外部区段3之间延伸的多个杆9形成。杆9周向地布置在植入物1周围。

[0165] 杆9中的一些相对于植入物1的纵向轴线倾斜且其它杆9与植入物1的纵向轴线平行。倾斜的杆成角度使得它们能够承受作用于植入物1上的旋转力。与植入物1的纵向轴线平行的杆用于承受纵向地作用于植入物1的负载。

[0166] 杆9中的一些的外端与其它杆9的外端相比径向地向内定位。杆9的内端都定位在与植入物1的半径相同的半径处。

[0167] 杆9具有300μm的最大直径和约4.8mm的长度。倾斜的杆比平行的杆稍长。

[0168] 外部区段3是环形的且具有外侧周向凹槽11，盖子或连接器的部分（例如，到袋子或其它装置）或其它装置可以附接到外侧周向凹槽11。

[0169] 外部区段3也具有三个缺口12，接合器（比如下面描述的turnbull接合器）或其它装置可以被附接到缺口12内。缺口12以围绕外部区段3的外周边相等间隔开的间隔布置。

[0170] 外部区段3的内表面由三维多孔结构13(此处未详细显示)，比如下面描述的多孔结构213或313形成。

[0171] 植入物1的所有元件彼此成整体且由相同材料制成。植入物1整体由钛形成。

[0172] 植入物1利用激光3D打印过程制造。在植入物1已经利用激光3D打印过程打印之后，外部区段3的外表面被抛光以给予光滑修整。

[0173] 可替代地，植入物1可以以多个部分模制和/或制造，这些部分随后被连接在一起。

[0174] 图6至图10显示了具有比图1至图5的植入物1的内径大的内径的植入物101的实施方式。

[0175] 然而，与图1至图5的植入物1类似，植入物101也由内部区段102和外部区段103形成。内部区段102由内侧内部区段部分104和外侧外部区段部分108形成。

[0176] 内侧内部区段部分104具有由连续的实心环105终止的径向延伸部分104a。

[0177] 锚固凸缘106从内部区段部分104径向地向外延伸并具有在其径向外边缘处的连续的实心环107。

[0178] 外侧外部区段部分108由在内侧内部区段部分104和外部区段103之间延伸的多个杆109形成。

[0179] 外部区段103具有外侧周向凹槽111和三个缺口112。外部区段103的内表面由三维多孔结构113形成。

[0180] 上面描述的植入物1的其它特征同样适用于植入物101。

[0181] 图11显示了多孔结构213。如图12至图21显示的，多孔结构213为定位在外部区段203的内表面处的中空圆柱形圆柱或管的形式。

[0182] 图 12 至图 21 显示的植入物 201 通常类似于上面描述的植入物 1 和 101，因此其结构不详细描述。与植入物 1 的唯一差别在外部区段 203 上没有缺口。

[0183] 植入物 201 由内部区段 202 和外部区段 203 形成。内部区段 201 由内侧内部区段部分 204 和外侧内部区段部分 208 形成。

[0184] 内侧内部区段部分 204 具有由连续的实心环 205 终止的径向延伸部分 204a。

[0185] 锚固凸缘 206 从内部区段部分 204 径向地向外延伸并具有在其径向外边缘处的连续的实心环 207。

[0186] 外侧外部区段部分 208 由在内侧内部区段部分 204 和外部区段 203 之间延伸的多个杆 209 形成。

[0187] 外部区段 203 具有外侧周向凹槽 211 但没有缺口。外部区段 203 的内表面由三维多孔结构 213 形成。

[0188] 多孔结构 213 是完全可渗透的；没有闭端。进入多孔结构的每一个通路也具有出口。形成多孔结构的任何构件的最大厚度是 300μm 且任何开口的最大直径也是 300μm。

[0189] 图 22 和图 23 以更多细节显示了多孔结构 213 的一部分。其由相互连接构件 215 形成。构件 215 布置在由连接构件 217 连接的层 216 中。

[0190] 在所示的实施方式中，构件 215 和 217 在整个多孔结构 213 中形成规则的重复图案。然而，在其它实施方式中，多孔结构具有不规则的结构。在多孔结构中的孔具有基本上正方形的、矩形的或交叉形状的横截面。然而，在可替代的实施方式中，一些孔或所有孔是圆形的或椭圆形的。

[0191] 图 24 和图 25(a)-(c) 显示了另一多孔结构 313 的示例。该多孔结构 313 由多个重复的子单元 314 构成。每一个子单元 314 由四个构件 315 形成，该四个构件的端部在子单元 314 的中心点处连接在一起。六个子单元 314 连接在一起以形成大体六边形环或单元 316。单元 316 然后以规则的重复方式连接在一起，以形成多孔结构 313。

[0192] 图 26(a)-(f) 显示了在已经执行造口术之后用于在患者身体外侧固定肠段的接合器 500。

[0193] 接合器 500 由平坦化的环 501 形成，短的圆柱形部分 502 在第一方向上从环 501 的内径突出。三个弹性构件 503 在与圆柱形部分 502 相反的方向上从环 501 突出。

[0194] 弹性构件 503 布置成围绕环 501 相等地间隔开，且每一个构件 503 具有在弹性构件 503 径向向内侧且朝向弹性构件 503 的背离环 501 的一端布置的突出部分 505。

[0195] 环 501 具有围绕其周向地布置的多个槽形孔 504（在该情形中，12 个）。

[0196] 如图 28 至图 30 所示，接合器 500 可以附接到植入物 101 的外部区段 103。弹性构件 503 的突出部分 505 配合到缺口 112 内，从而将接合器 500 附接到植入物 101 且防止它相对于植入物 101 旋转地、横向地和纵向地移动。

[0197] 当附接时，接合器 500 和植入物 101 具有公共轴线且接合器 500 定尺寸为使得其可以配合在植入物 101 上且附接到植入物 101。接合器 500 的和植入物 101 的外部区段 103 的内径是相同的。

[0198] 接合器 500 整个地由塑料制成且以激光烧结工艺由医疗质量聚酰胺粉末 (PA2200) 制造。

[0199] 接合器 500 借助于高压灭菌法杀菌，且被提供为无菌的。可替代地，接合器 500 可

以通过辐射、气体比如氧化乙烯、等离子体或其它方法杀菌。

[0200] 接合器 500 以不同的尺寸，例如两种尺寸设置，以适合不同尺寸的植入物（即，具有不同直径的植入物）。

[0201] 接合器 500 预期在外科手术期间当植入诸如上述的植入物的植入物时使用。当附接到植入物 101 时，接合器 500 可以接收肠段从中穿过，并且允许肠段在接合器 500 上返回。

[0202] 接合器 500 可用于在植入之后将传出肠固定约 4 至 6 周，以便提供在与植入物结合过程期间用于回肠的最佳可能无应力治愈和向内生长条件。

[0203] 接合器 500 在植入手术结束时附接到植入物 101 的外部区段 103。其用于在植入之后的第一个四到六周期间利用缝合线固定传出肠。此后，传出肠被切断且接合器 500 被移除。

[0204] 为了使用接合器 500，以下步骤被执行：

[0205] - 将接合器 500 夹到植入物 101 的外部区段 103 上。轻微地转动它以确保它正确地锁定在合适位置。

[0206] - 肠的传出端被返回到在植入物 101 上方的接合器 500 上且使用缝合线穿过孔 504 固定。

[0207] - 确保外部区段 130 外侧的周围的凹槽 111 没有组织，使得其可以用于附接稳定器装置（未显示）。（稳定器装置是用于在治愈阶段期间通过提供支撑以抵抗植入物 101 的倾斜或垂直运动而将植入物 101 固定在适当位置的装置。其可以附接到植入物 101 的外部区段 103，例如，且放置在皮肤或皮肤屏障上。）

[0208] - 利用缝合线将肠锚固到腹膜。

[0209] 在几周之后，肠应已经充分生长到植入物 101 内，接合器 500 待移除。突出到植入物 101 外侧的肠的部分现在将已经开始皱缩且被切断。接合器 500 被移除并且肠将仅永久地留在植入物 101 的顶部处。

[0210] 为了移除接合器 500，以下步骤被执行：

[0211] - 移除任何人造口袋子并轻柔地清洁孔口。

[0212] - 仔细地移除稳定装置和人造口皮肤屏障。

[0213] - 温和地冲洗植入物 101 周围以移除任何肠内含物或液体。

[0214] - 利用透热解剖刀切入接合器 500 内侧的肠，从顶部穿过肠的整个厚度三毫米。

[0215] - 如果需要，用钳子解剖肠向下至接合器 500 的基部。不要超出接合器 500 的基部，因为这会对组织到植入物圆柱体内的向内生长有害，导致泄漏。

[0216] - 利用尖状物体，仔细地将弹性构件 503 提升到外部区段 103 中的缺口 112 之外，缓慢地移除接合器 500。

[0217] - 利用解剖剪刀，修剪保留在植入物 101 的外部区段 103 上的任何过量组织。如果需要导管插入术，不要接触植入物 101 的内侧（内径）。

[0218] - 将新的皮肤屏障、稳定器和人造口袋子放置在适当位置。

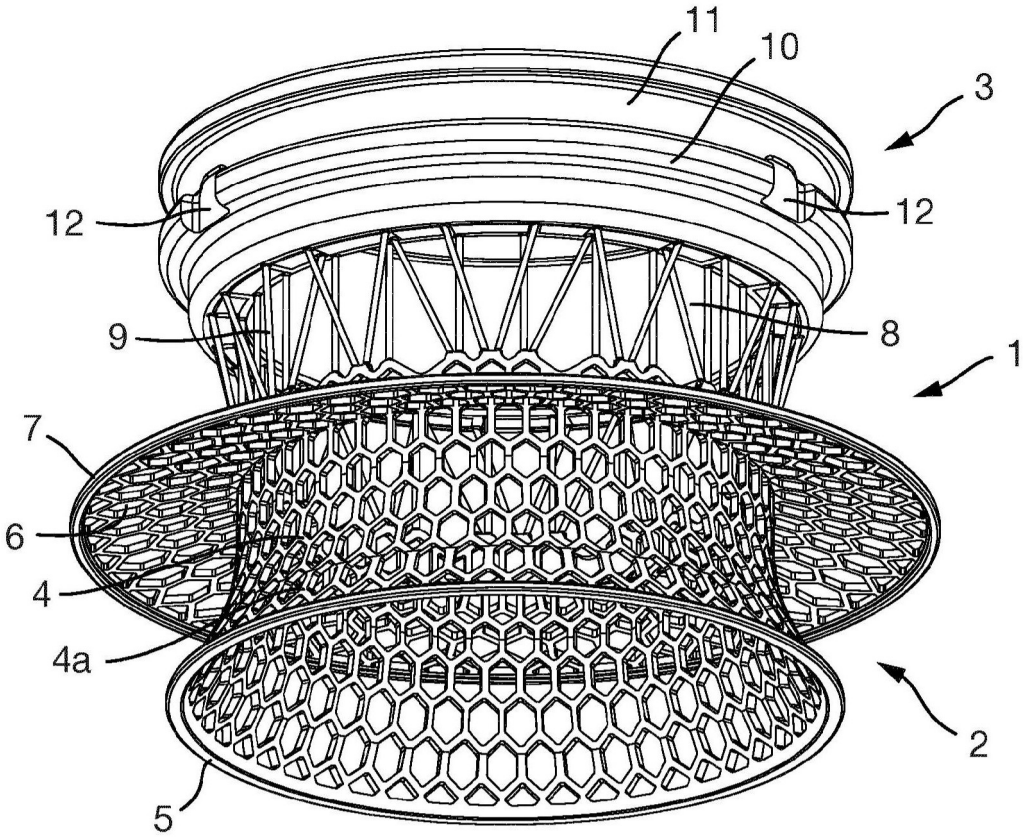


图 1

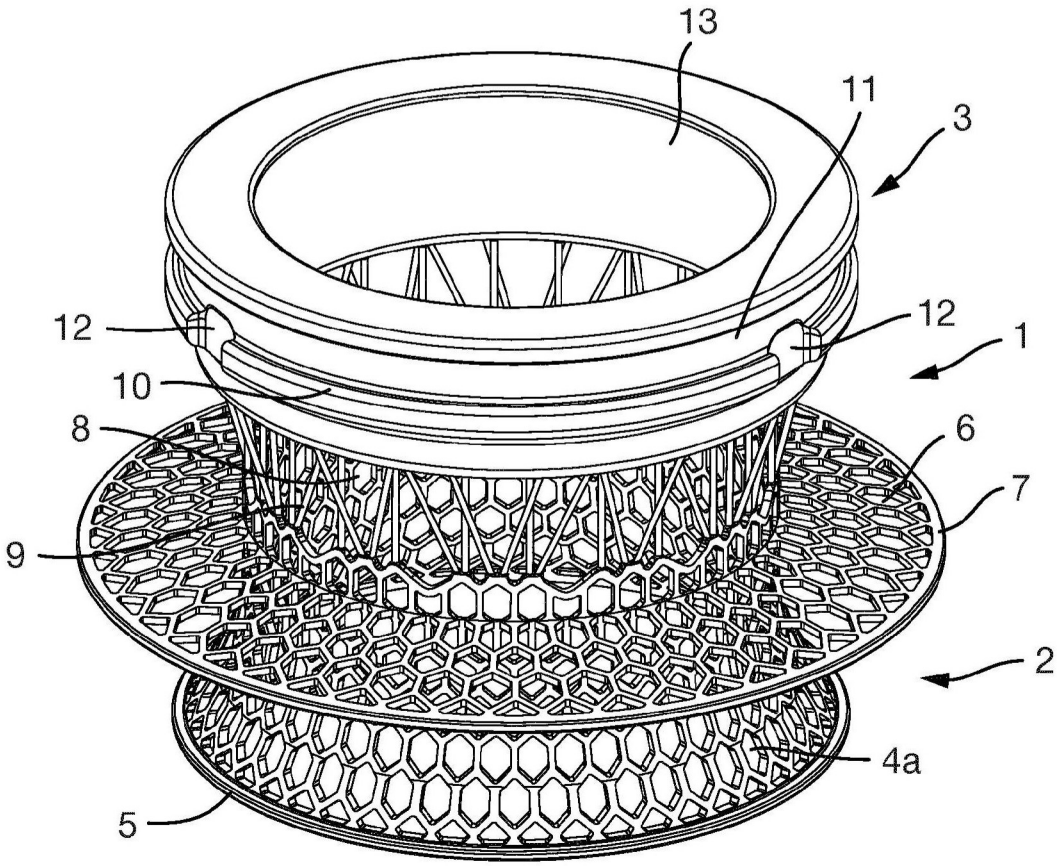


图 2

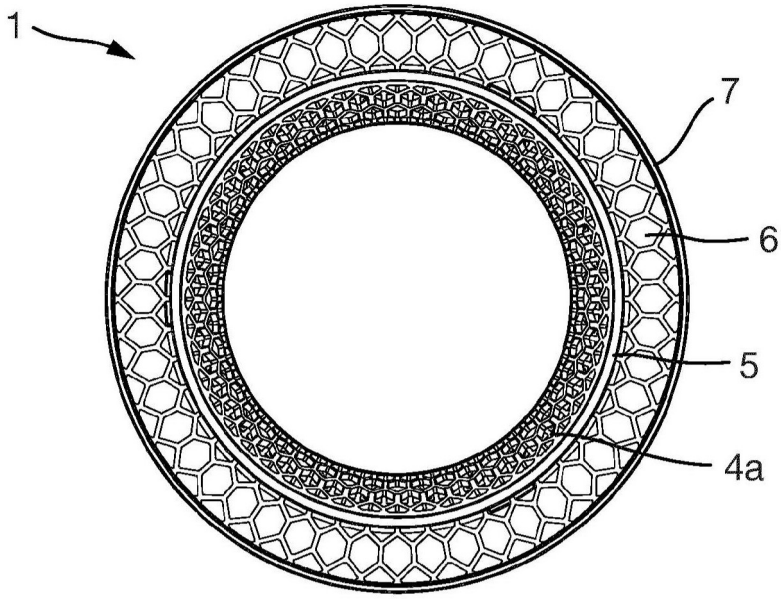


图 3

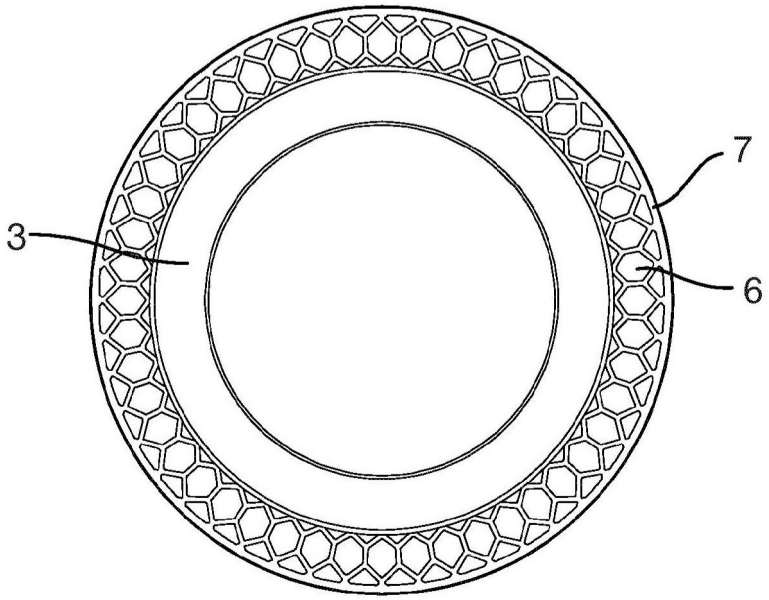


图 5

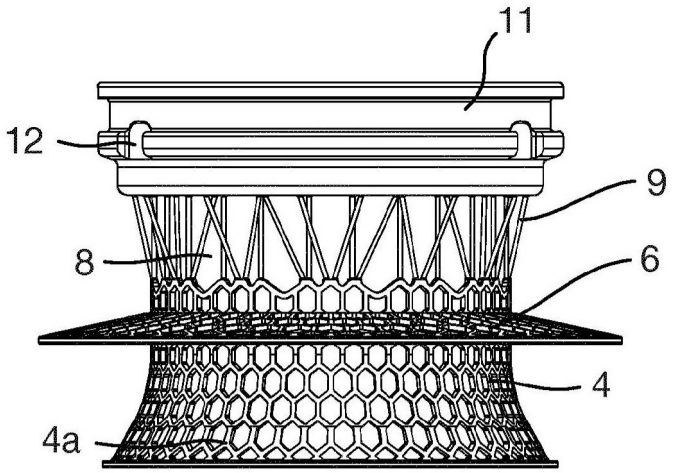


图 4(a)

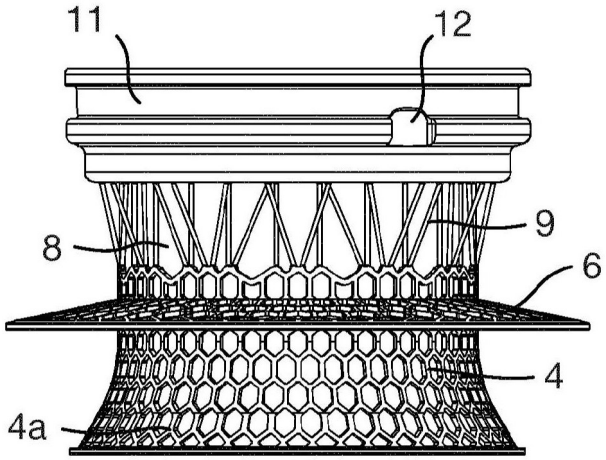


图 4(b)

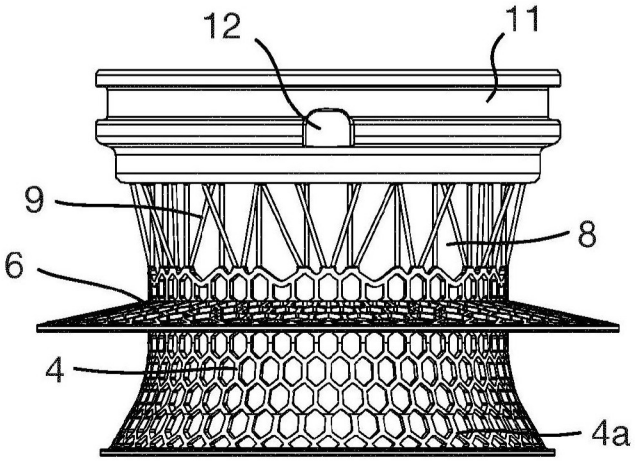
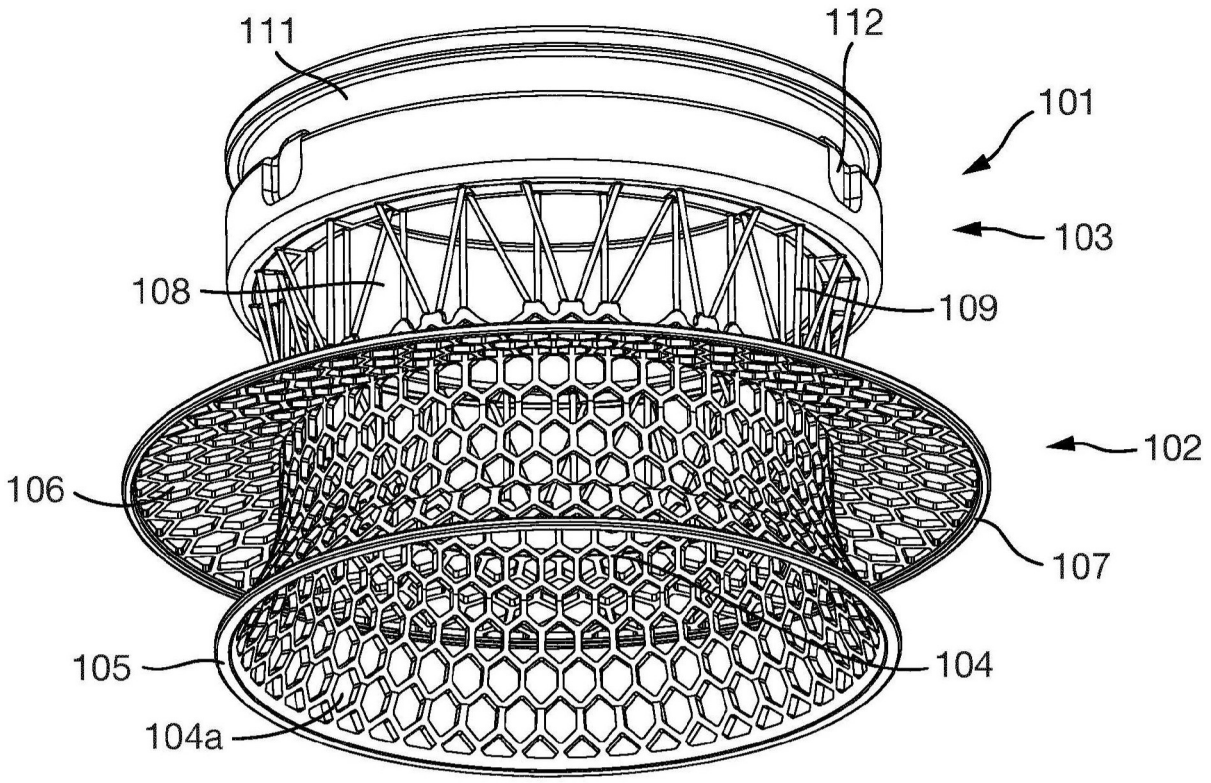


图 4(c)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104a

图 6

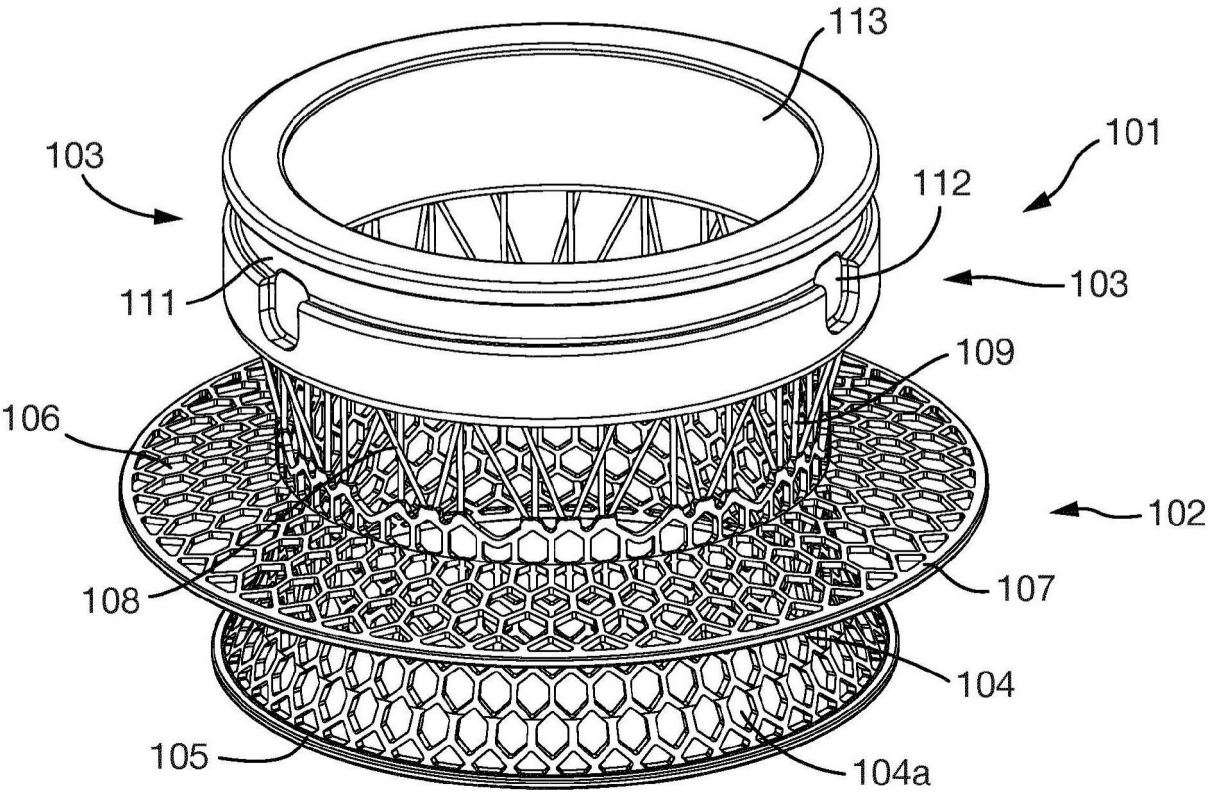
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图 7

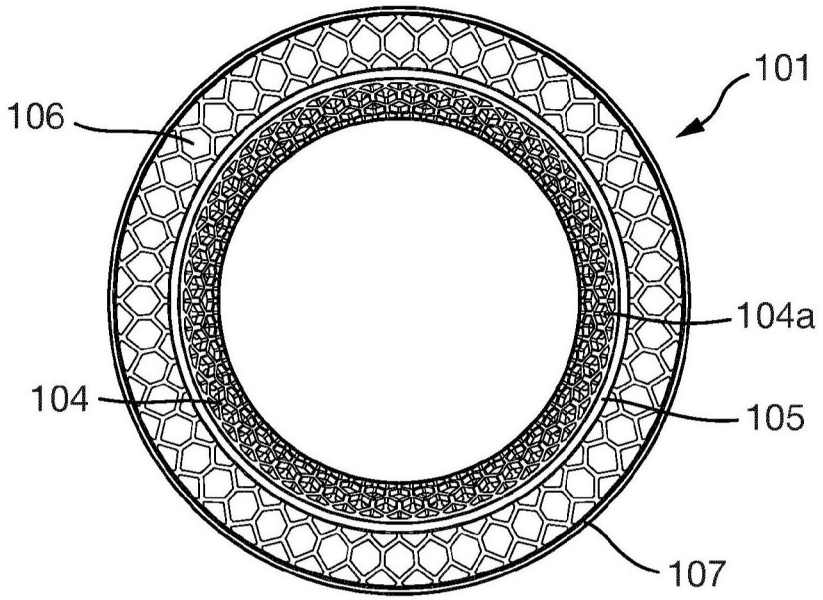

图 8

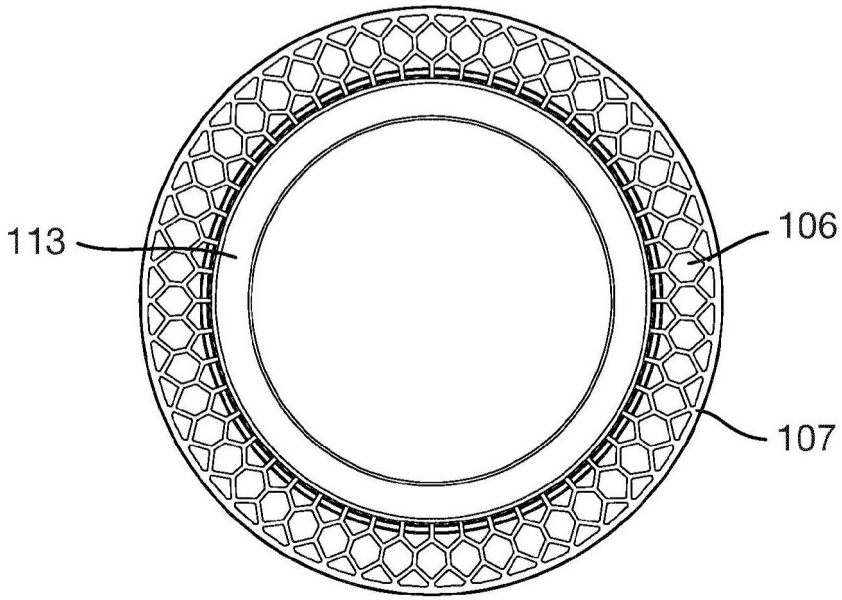

图 10

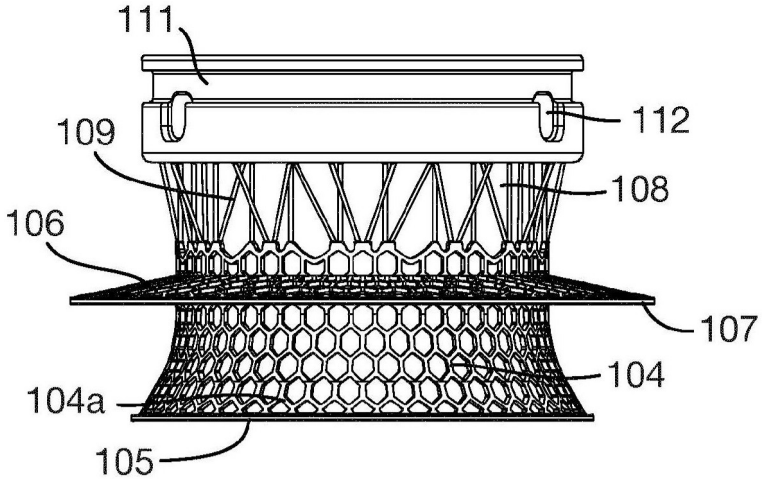
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图 9(a)

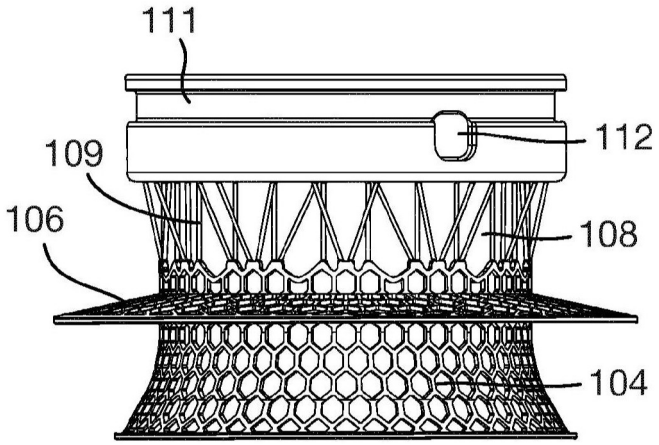
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图 9(b)

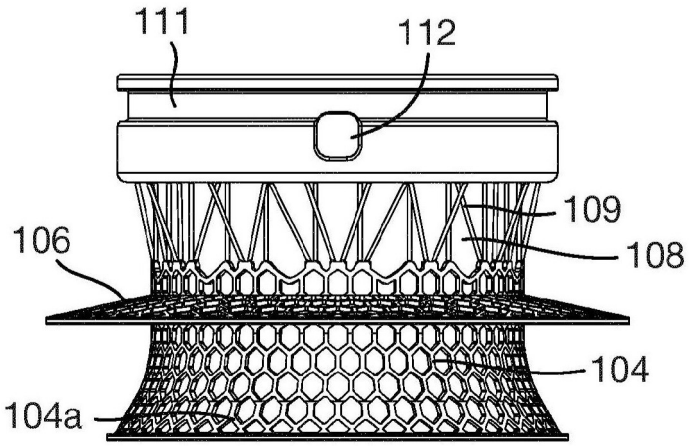
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图 9(c)

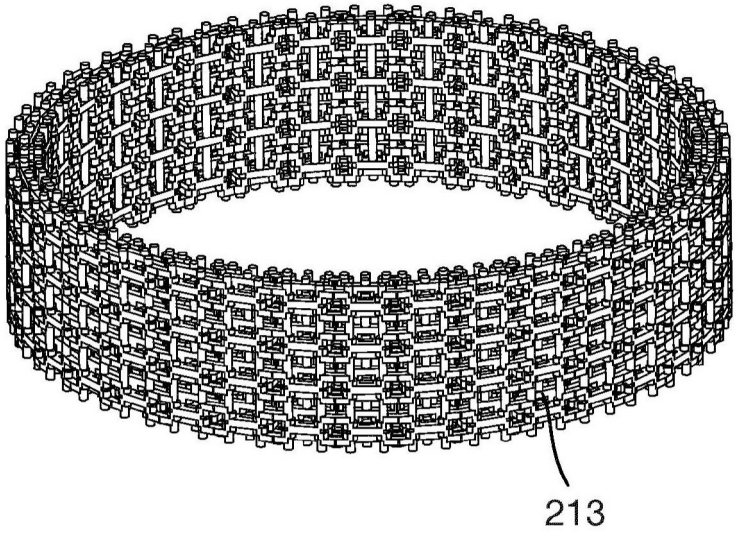


图 11

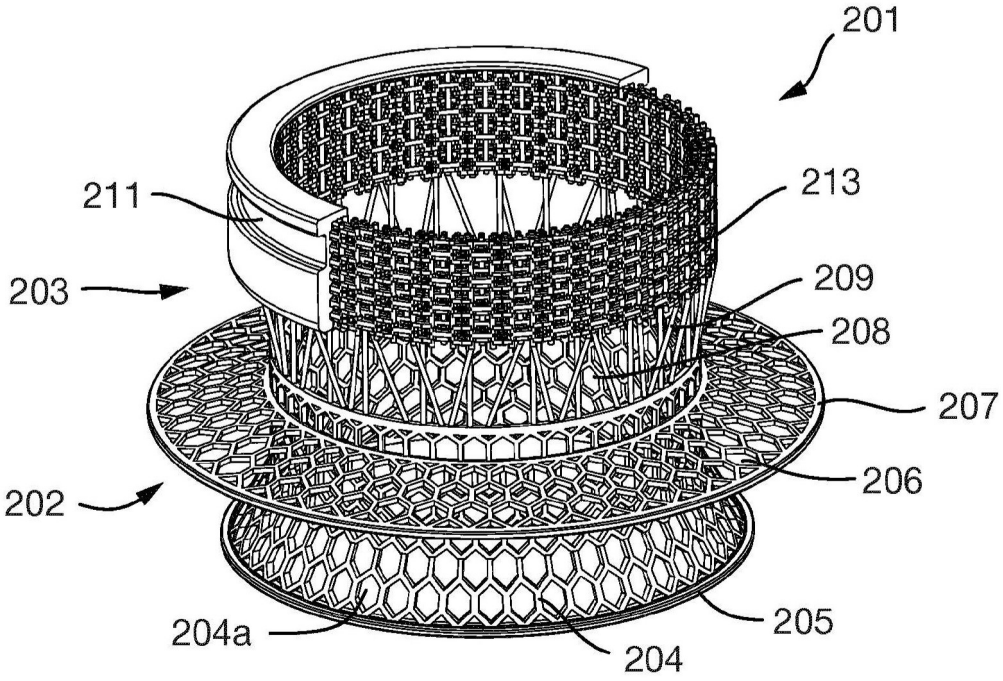


图 12

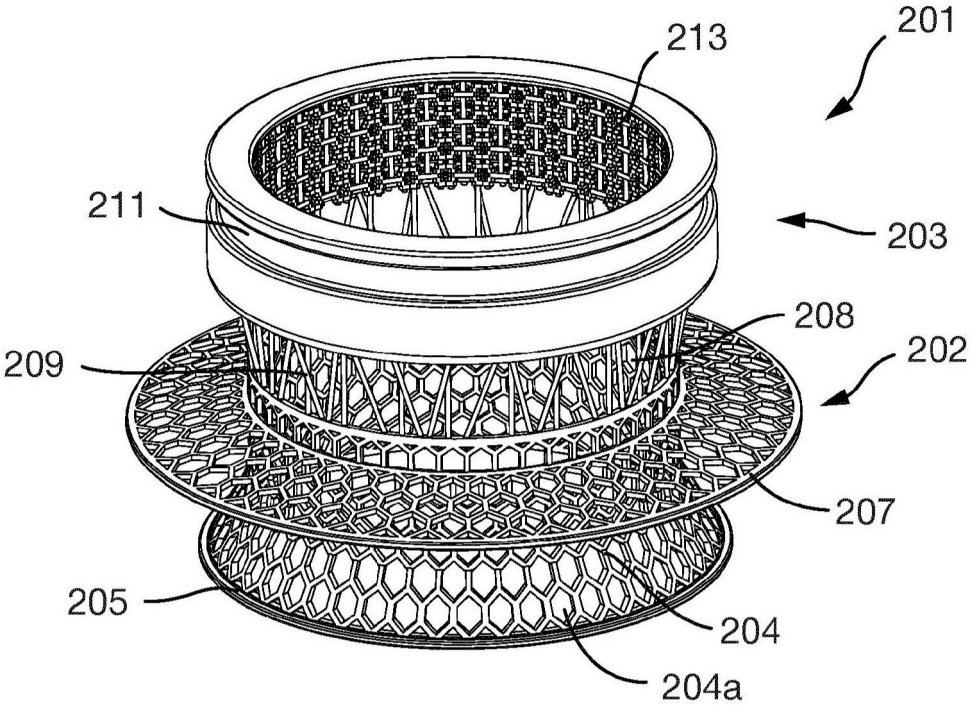


图 13

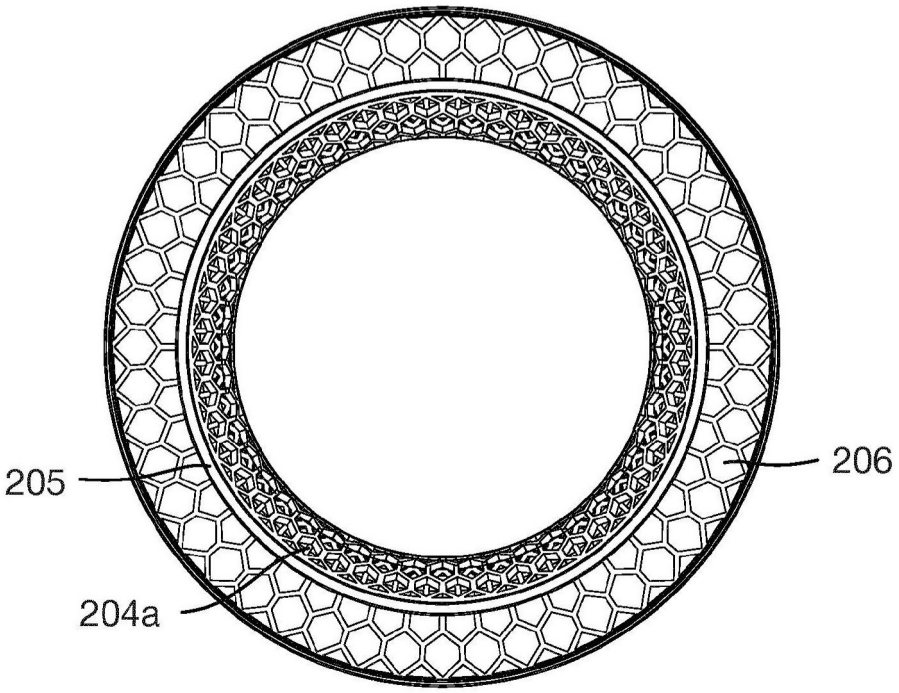


图 14

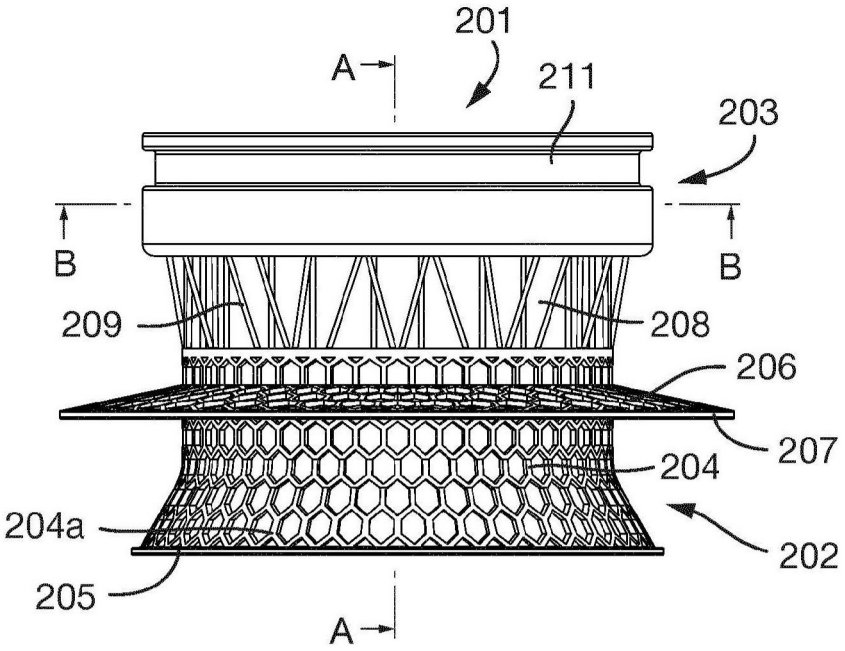


图 15

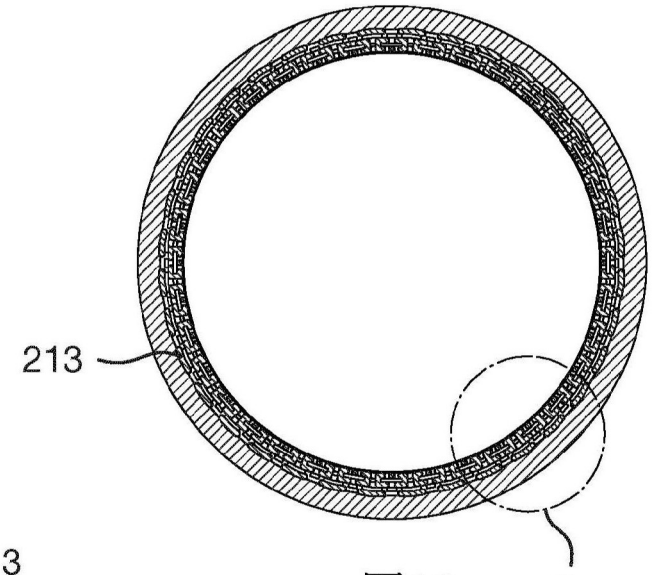


图16

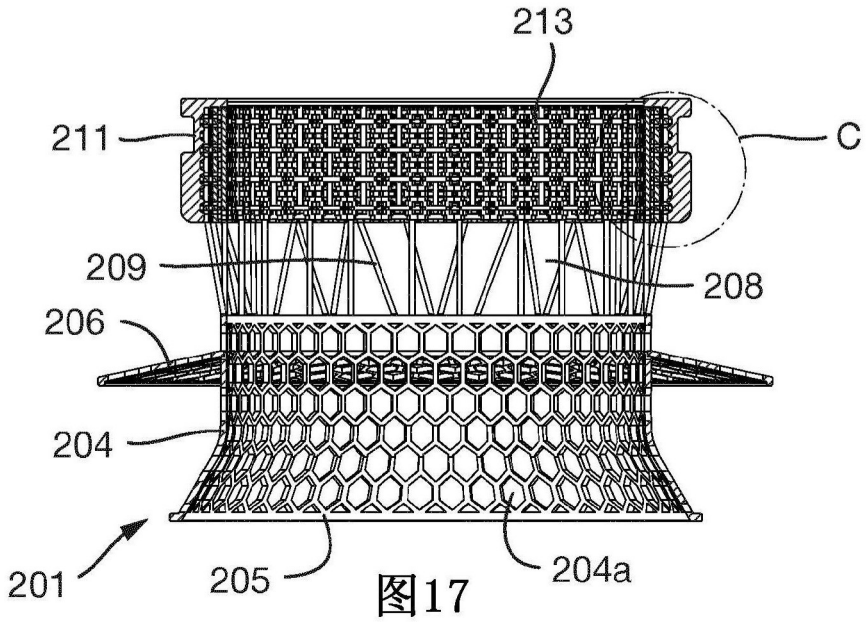


图17

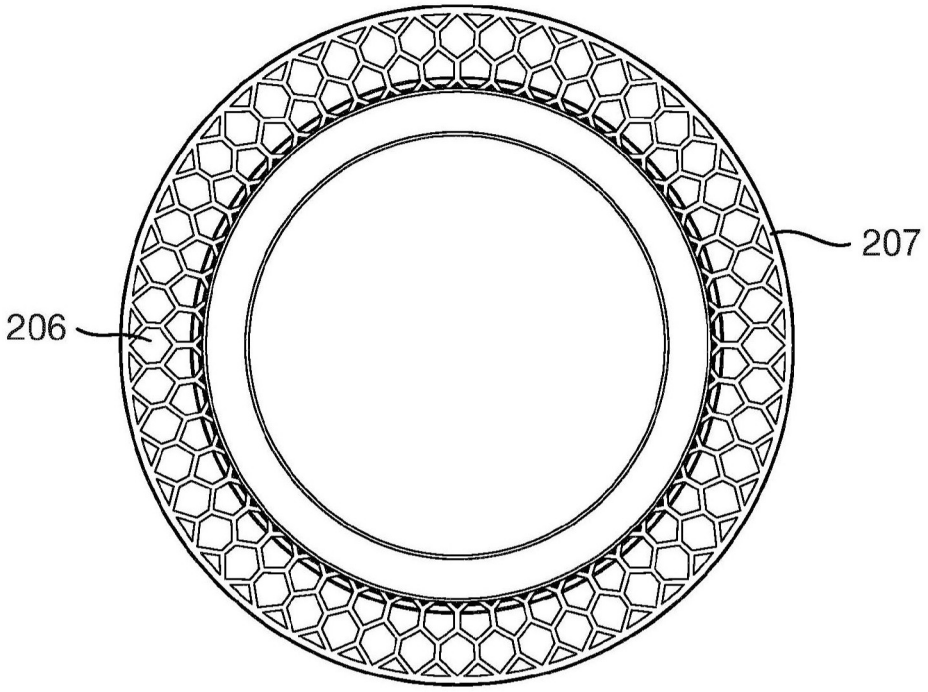


图 18

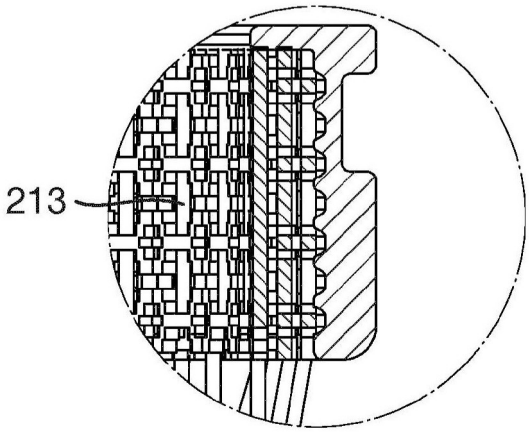


图 19

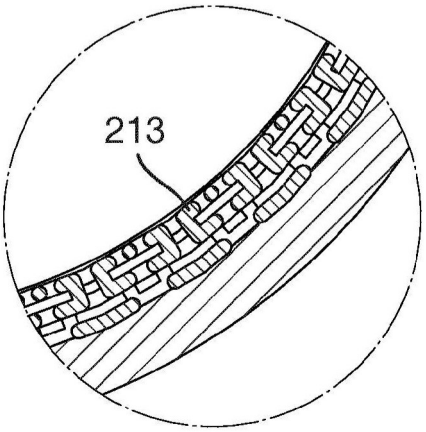


图 20

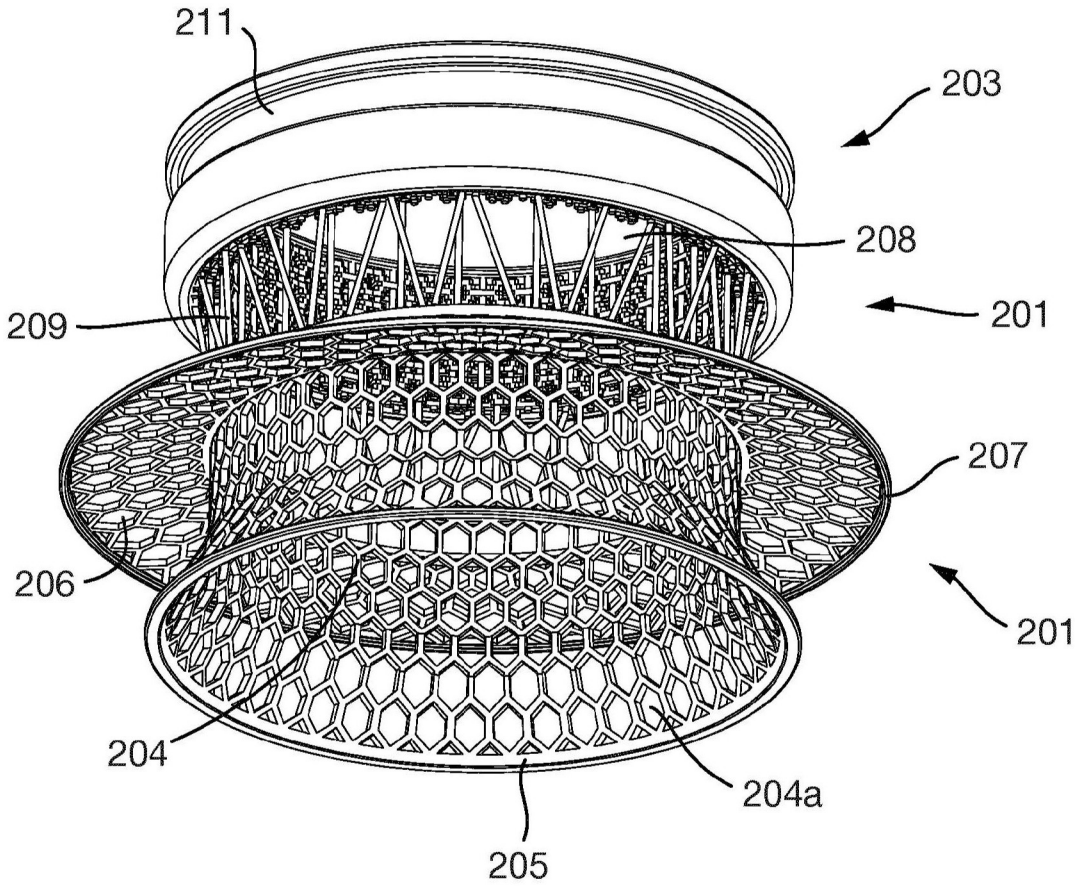


图 21

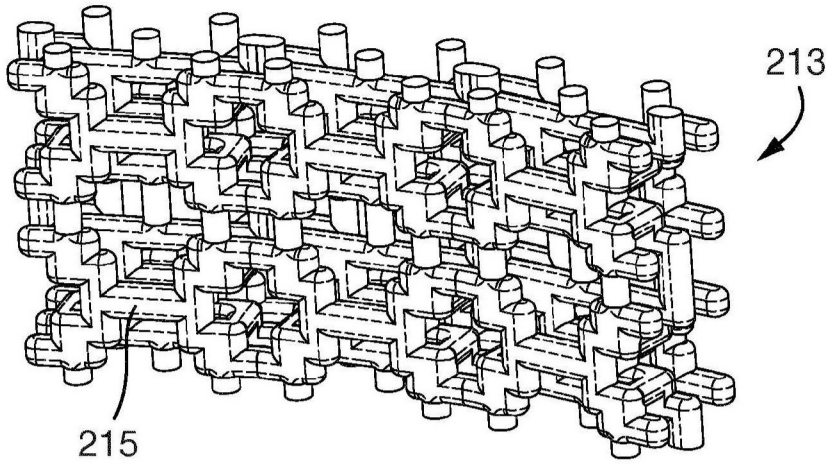


图 22

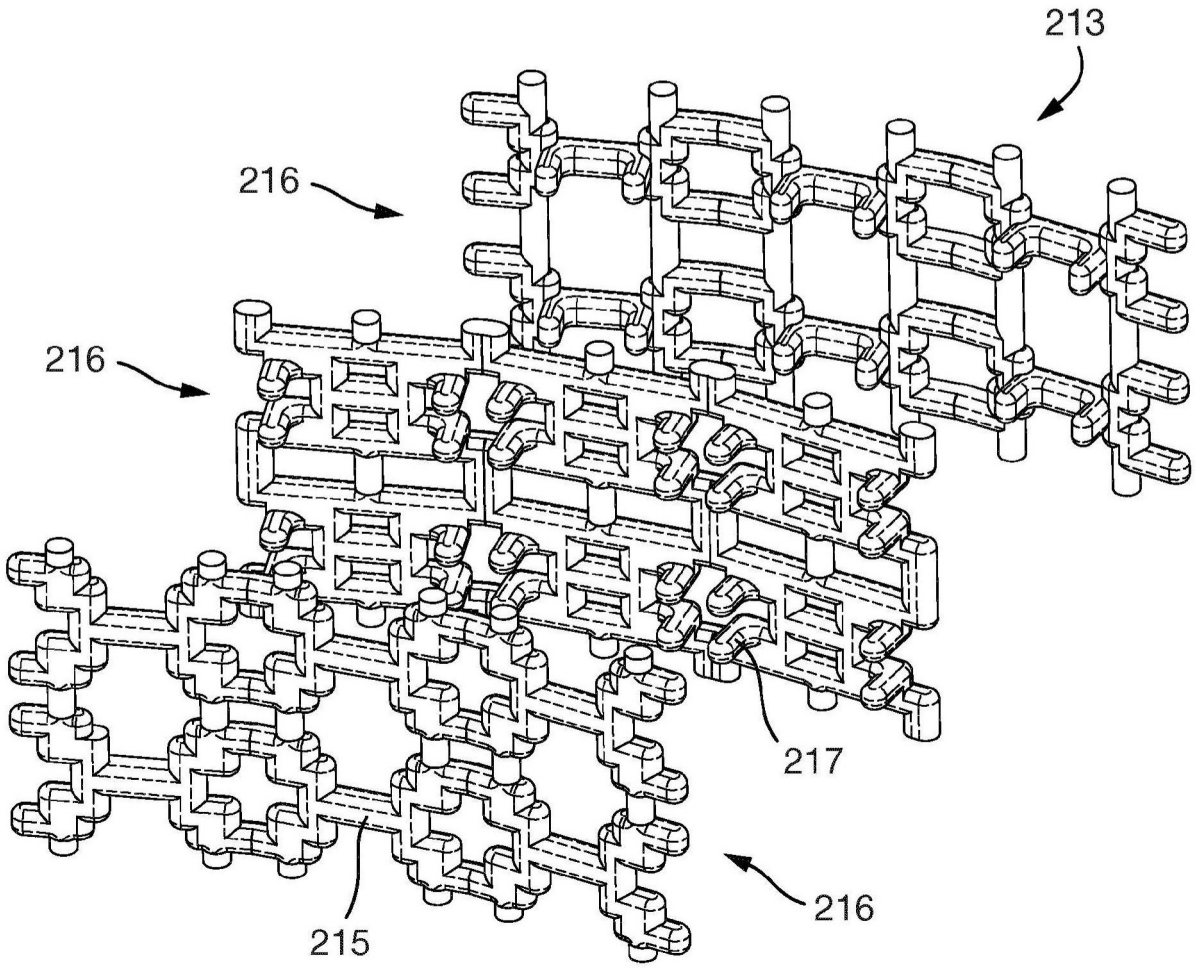


图 23

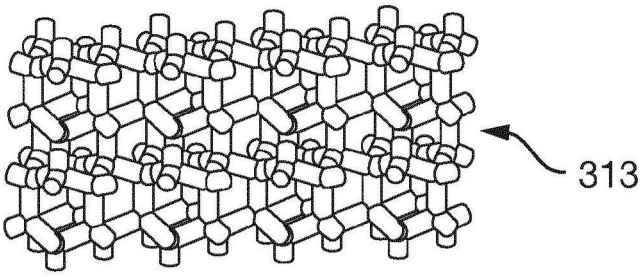


图 24

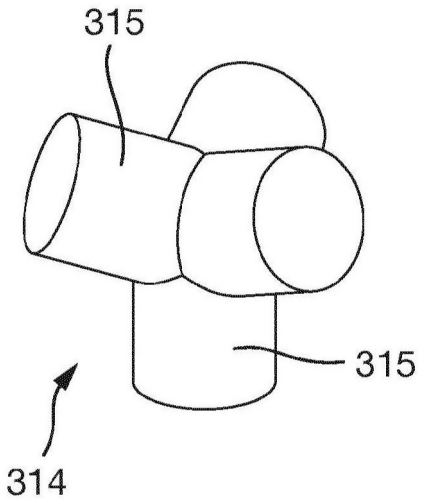


图 25(a)

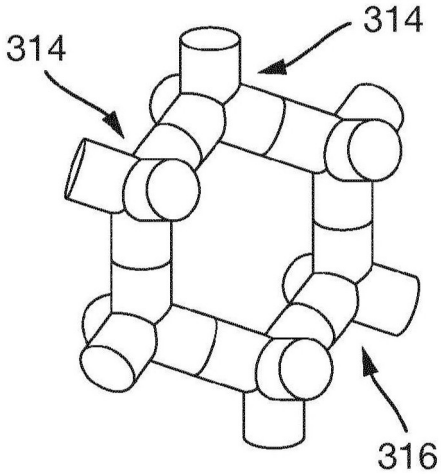


图 25(b)

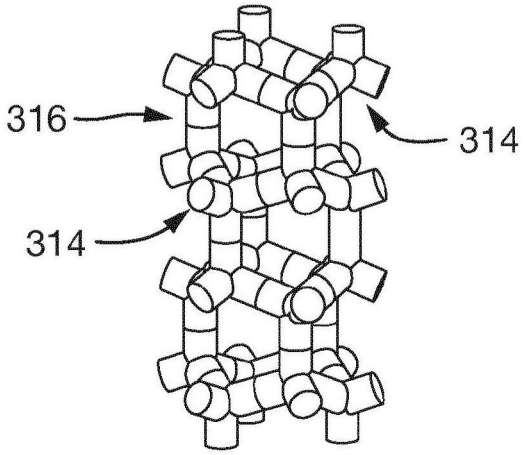


图 25(c)

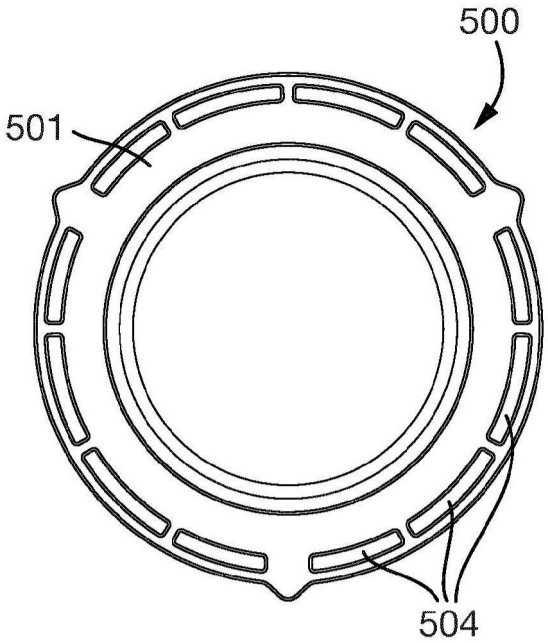


图 26(a)

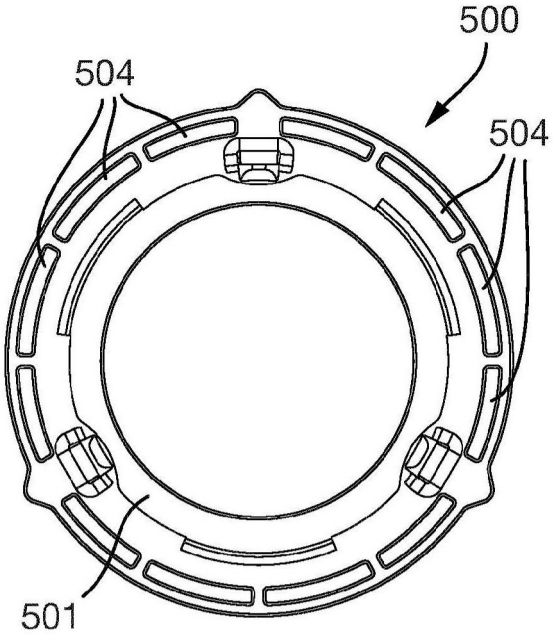


图 26(b)

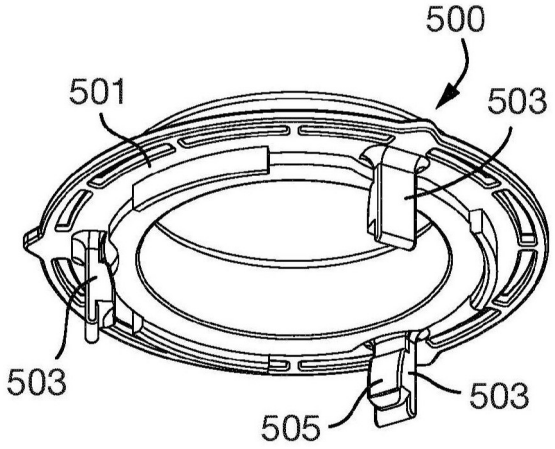


图 26(c)

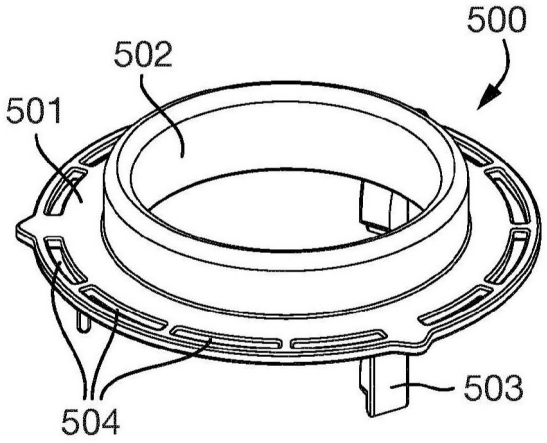


图 26(d)

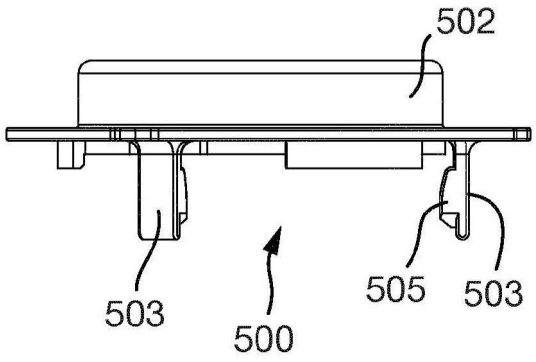


图 26(e)

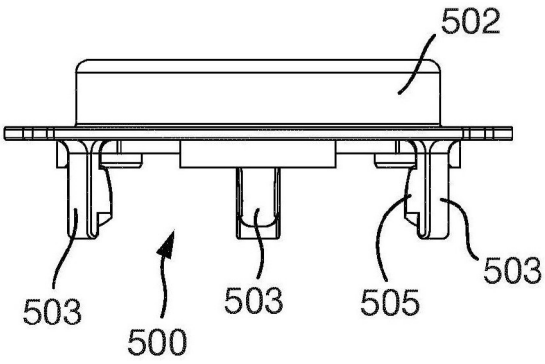


图 26(f)

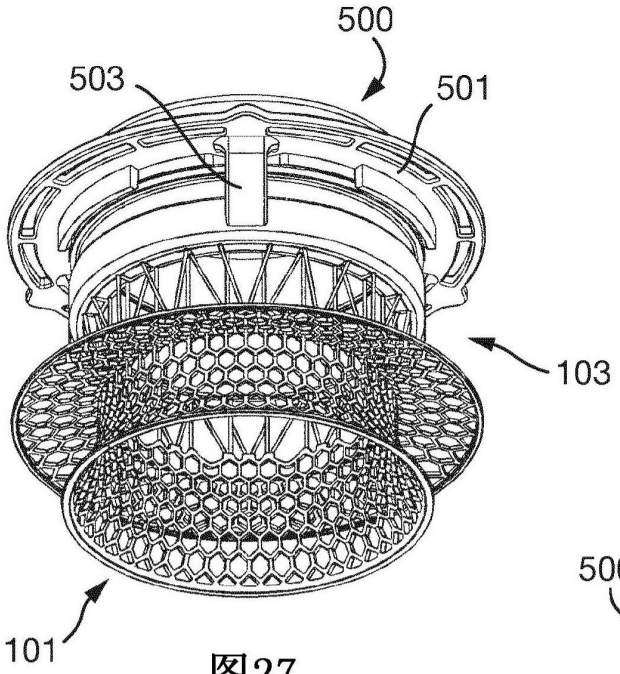

500
503
501
103
101

图27

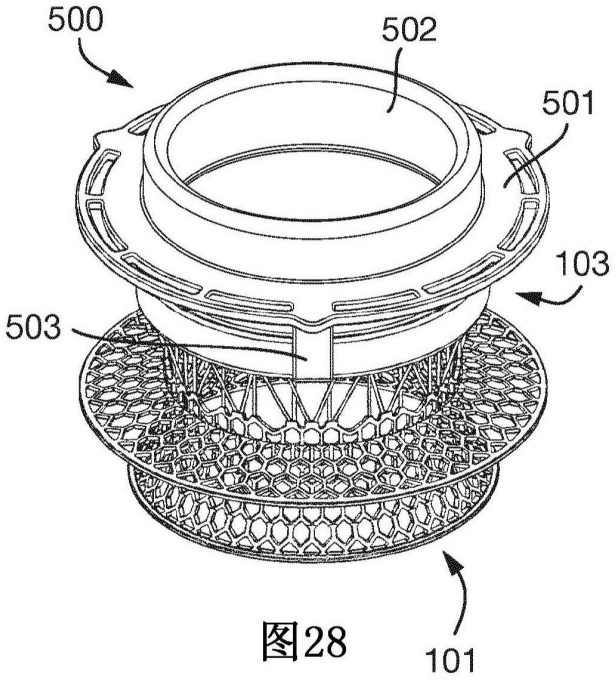
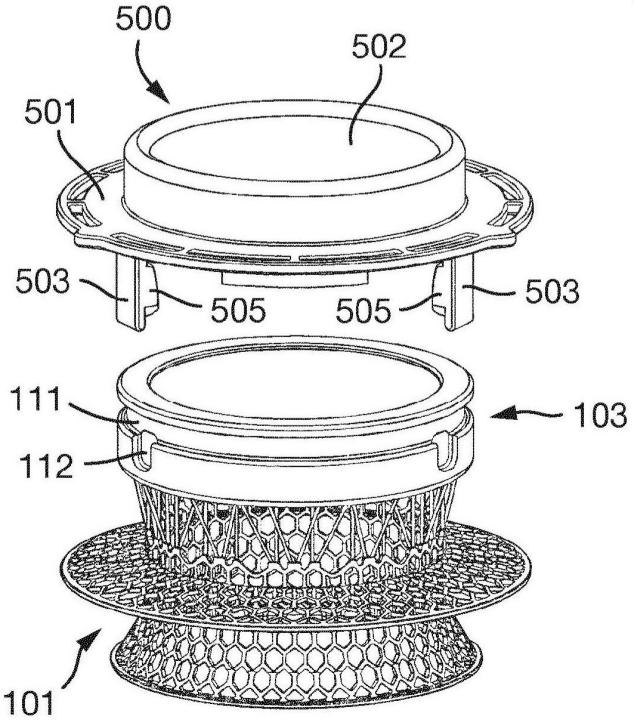

500
502
501
103
503
101

图28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111
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112
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图29

Abstract

An implant 1 comprises a tubular interior section 2 for implantation into a patient and an exterior section 3 connected to the interior section 2. A surface of the exterior section 3 comprises a three-dimensional porous structure 13 at its inner circumference.