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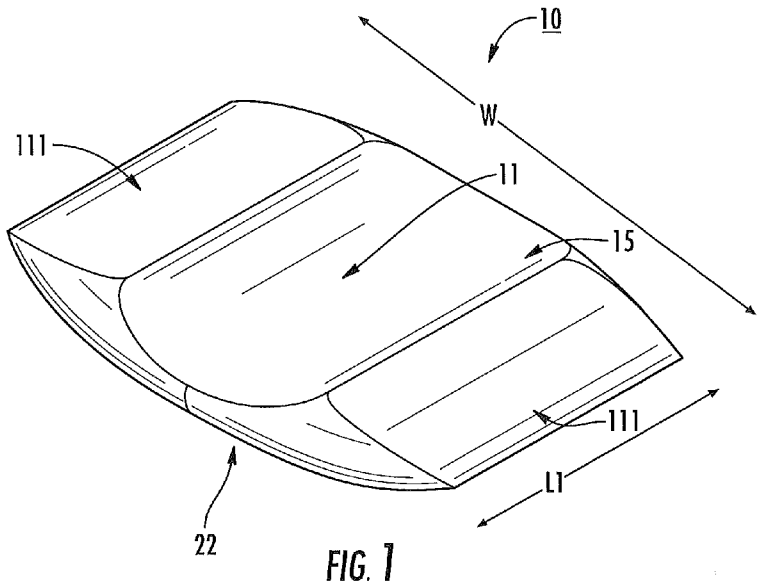

FIG. 1

(57) Abstract: An urogynecologic implant has a curved body that disperses force and reduces the ability of the urethra to expand into the pelvic floor under impulses of abdominal pressure in order to inhibit, reduce or prevent stress urinary incontinence.

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IMPLANTS FOR STRESS URINARY INCONTINENCE TREATMENTS AND RELATED METHODS

RELATED APPLICATIONS

[0001] This application claims the benefit of and priority to U.S. Provisional Application Serial Number 61/665,047, filed June 27, 2012 and U.S. Patent Application No. 13/923,874 filed June 21, 2013, the contents of which are hereby incorporated by reference as if recited in full herein.

FIELD OF THE INVENTION

[0002] The present invention relates to surgical implants to treat urinary incontinence.

BACKGROUND

[0003] Stress incontinence is the involuntary leakage of urine due to increased abdominal pressure such as during a cough. This is particularly prevalent in women and has been shown to degrade the quality of life. In the past, transvaginal slings, transobturator tape, and a single-incision mini-slings have been used to attempt to treat this condition. Generally stated, these devices include a surgical mesh that is placed around the mid-urethra to form a hammock-like structure, anchoring it to the pubic bone to attempt to prevent the leakage of urine.

[0004] However, the transvaginal and transobturator slings require three incisions and the surgery is performed in a hospital operating room, making it inconvenient and expensive. The mini-sling only requires a single incision, but it has been associated with a lower effectiveness and a higher risk of complications, which have recently come under FDA review.

SUMMARY OF EMBODIMENTS OF THE INVENTION

[0005] Embodiments of the present invention provide minimally invasive surgical implants that can inhibit or prevent stress urinary incontinence.

[0006] The implants can be placed and/or implanted to operate in a non-restrictive way to increase the ease of implantation and prevent voiding complications.

[0007] Embodiments of the invention are directed to three dimensional rigid or semi-rigid urogynecologic implants having a defined three dimensional self-supporting shape sized and configured to reside between a urethra and an anterior vaginal wall of a patient.

[0008] Embodiments of the invention are directed to stress incontinence implants. The implants have a rigid or semi-rigid urogynecologic implant comprising a first primary surface with a curved medial portion and a second primary surface underlying the first primary surface.

[0009] The implant can have a monolithic porous polymer body.

[0010] The implant can have s a hollow interior compartment.

[0011] The implant can be sized and configured for transvaginal placement.

[0012] The implant can have a width dimension and a length dimension and the width dimension can be greater than the length dimension.

[0013] The width dimensions can be about 50% greater than the length dimension.

[0014] The second primary surface can be curved and can have a radius of curvature that is greater than a radius of curvature of the first primary surface medial portion.

[0015] The first primary surface can have a medial portion that merges into outer ramped end portions. The second primary surface can have an arc configuration with opposing ends and a respective ramped end portion can meet a respective arc end portion to define a respective short end edge of the implant.

[0016] The short end edges can reside closer to the first primary surface than the second primary surface.

[0017] The implant can be configured to reside between an anterior vagina wall and an outer surface of a lower to middle portion of a urethra.

[0018] The implant can be held in position without mechanical fixation between the vagina wall and the urethra.

[0019] The first primary surface medial portion can merge into outer ramped end portions that incline down toward second primary surface. The implant can include mesh extending out from the respective ramped end portions.

[0020] The implant can be sized and configured to surround only about 180 degrees or less of a female urethra and can have a maximum thickness that is between about 1 mm to about 5 mm.

[0021] The implant can have a width that is between about 15-30 mm and a length that is between about 7-10 mm and a maximum thickness that is between about 1 mm and 5 mm.

[0022] The implant can have a silicone body.

[0023] The implant can have a porosity of at least one of: (i) a matrix of pores, (b) spaced apart or intersecting channels; or (c) pores and channels. At least some of the pores or channels can have a diameter or cross-width dimension between about 125 mm and 250 mm.

[0024] The implant can have a biodegradable body.

[0025] The implant can be provided in a plurality of different sizes according to severity of stress urinary incontinence and/or urethra size, wherein at least one of implant width or implant thickness increases for implants for severe stress urinary incontinence and large urethra size, relative to implants for mild or moderate stress urinary incontinence and small or medium urethra size.

[0026] Other embodiments are directed to methods of treating urinary incontinence. The methods include: (a) placing a three-dimensional shaped rigid or semi-rigid implant between a urethra and anterior vagina wall of a female patient; then (b) distributing forces from a first side of the implant facing the urethra to a longer second side of the implant adjacent the anterior vagina wall in response to impulses of abdominal pressure stress to thereby inhibit urinary incontinence.

[0027] The placing can be carried out via entry in a single incision in the vaginal wall.

[0028] Still other embodiments are directed to methods of fabricating a urinary incontinence implant. The methods include forming a rigid or semi-rigid three dimensional implant body having a three-dimensional shape including a first radius of curvature associated with a medial portion of a first primary surface and a second radius of curvature associated with an arc of an underlying second primary surface.

[0029] The method can include forming pores in the implant body during or after the molding.

[0030] The forming the pores can include directing laser light into the molded implant body to form through channels.

[0031] Before the forming step, the method can include providing a flowable material of the moldable material that can be combined with a porogen in the mold or prior to introducing into the mold, then after the forming step, the porogon can be removed from the molded implant body leaving a porous implant body.

[0032] The forming step can include injection molding implant material in a mold having a cavity that defines the first and second radii of curvature.

[0033] The implant material can include silicone.

[0034] Still other embodiments are directed to molds for a medical stress incontinence implant. The molds include a mold body having an internal volumetric cavity with walls that are configured with first and second radii of curvature that are configured to form a rigid or semi-rigid three dimensional implant body having a three-dimensional shape including a first radius of curvature associated with a medial portion of a first primary surface and a second radius of curvature associated with an arc of an underlying second primary surface.

[0035] It is noted that aspects of the invention described with respect to one embodiment, may be incorporated in a different embodiment although not specifically described relative thereto. That is, all embodiments and/or features of any embodiment can be combined in any way and/or combination. Applicant reserves the right to change any originally filed claim or file any new claim accordingly, including the right to be able to amend any originally filed claim to depend from and/or incorporate any feature of any other claim although not originally claimed in that manner. These and other objects and/or aspects of the present invention are explained in detail in the specification set forth below.

[0036] Other systems and/or methods according to embodiments of the invention will be or become apparent to one with skill in the art upon review of the following drawings and detailed description. It is intended that all such additional systems, methods, and/or devices be included within this description, be within the scope of the present invention, and be protected by the accompanying claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0037] Other features of the present invention will be more readily understood from the following detailed description of exemplary embodiments thereof when read in conjunction with the accompanying drawings.

[0038] **Figure 1** is a top perspective view of one example of a surgical implant according to embodiments of the present invention.

[0039] **Figure 2** is a side view along one long edge of the implant shown in **Figure 1**.

[0040] **Figure 3** is a side view along one short edge of the implant shown in **Figure 1**.

Figure 4 is a top view of the implant shown in **Figure 1.**

[0041] **Figure 5** is a top perspective view illustrating an exemplary implant with mesh attachments according to some embodiments of the present invention.

[0042] **Figures 6A-6C** are schematic illustrations of a response of the pubourethral system to a cough without the present invention.

[0043] **Figures 7A-7C** are schematic illustrations of the response of the pubourethral system to a cough with the present invention according to embodiments of the present invention.

[0044] **Figure 8** is an enlarged schematic illustration of an implant in position according to embodiments of the present invention.

[0045] **Figures 9A-9C** are schematic illustrations of a sequence of surgical steps that can be used to place urogynecologic implants according to embodiments of the present invention.

[0046] **Figures 10A-10C** are illustrations of exemplary dimensions and radii according to particular embodiments of the present invention.

[0047] **Figure 11** is a side section view (taken inward of one long edge) of the implant shown in **Figure 1** illustrating a hollow interior cavity according to embodiments of the present invention.

[0048] **Figure 12** is a side view (along one long edge) of an exemplary implant illustrating different end configurations and that the implant may include one or more pores or apertures according to embodiments of the present invention.

[0049] **Figure 13** is a perspective view of an implant similar to that shown in **Figure 1** illustrating that the implant can have sufficient pores to allow fluid transport therethrough according to embodiments of the present invention.

[0050] **Figure 14** is a schematic illustration of different size implants selected to accommodate different size urethras according to embodiments of the present invention.

[0051] **Figure 15** is a schematic illustration of different size implants selected to accommodate different degrees of severity of urinary stress incontinence according to embodiments of the present invention.

[0052] **Figure 16A** is a side perspective view of an exemplary mold for fabricating an implant according to embodiments of the present invention.

[0053] **Figure 16B** is a section view of the mold shown in **Figure 16A** according to embodiments of the present invention.

[0054] **Figure 17** is a schematic illustration of a method/system for forming pores in a stress incontinence implant according to some embodiments of the present invention.

[0055] **Figure 18** is a schematic illustration of another embodiment of a method/system for forming pores in a stress incontinence implant according to some embodiments of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

[0056] The present invention now is described more fully hereinafter with reference to the accompanying drawings, in which embodiments of the invention are shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art.

[0057] Like numbers refer to like elements throughout. In the figures, the thickness of certain lines, layers, components, elements or features may be exaggerated for clarity. Broken lines illustrate optional features or operations unless specified otherwise. One or more features shown and discussed with respect to one embodiment may be included in another embodiment even if not explicitly described or shown with another embodiment.

[0058] The terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. As used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, integers, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, integers, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items. As used herein, phrases such as "between X and Y" and "between about X and Y" should be interpreted to include X and Y. As used herein, phrases such as "between about X and Y" mean "between about X and about Y." As used herein, phrases such as "from about X to Y" mean "from about X to about Y."

[0059] Unless otherwise defined, all terms (including technical and scientific terms) used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. It will be further understood that terms, such as those

defined in commonly used dictionaries, should be interpreted as having a meaning that is consistent with their meaning in the context of the specification and relevant art and should not be interpreted in an idealized or overly formal sense unless expressly so defined herein. Well-known functions or constructions may not be described in detail for brevity and/or clarity.

[0060] It will be understood that when an element is referred to as being "on", "attached" to, "connected" to, "coupled" with, "contacting", etc., another element, it can be directly on, attached to, connected to, coupled with or contacting the other element or intervening elements may also be present. In contrast, when an element is referred to as being, for example, "directly on", "directly attached" to, "directly connected" to, "directly coupled" with or "directly contacting" another element, there are no intervening elements present. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[0061] Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if the device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[0062] It will be understood that, although the terms first, second, etc. may be used herein to describe various elements, components, regions, layers and/or sections, these elements, components, regions, layers and/or sections should not be limited by these terms. These terms are only used to distinguish one element, component, region, layer or section from another region, layer or section. Thus, a first element, component, region, layer or section discussed below could be termed a second element, component, region, layer or section without departing from the teachings of the present invention. The sequence of

operations (or steps) is not limited to the order presented in the claims or figures unless specifically indicated otherwise.

[0063] The term "about" means that the recited number or value can vary by +/- 20%.

[0064] The term "sterile" means that the noted device or material meets or exceeds defined medical guidelines of cleanliness and is substantially (if not totally) without contaminants so as to be suitable for medical uses.

[0065] The term "urogynecologic implant" refers to implants targeted for use between a urethra and vagina of female patients. The implants may be acutely or chronically placed. The implants may be for medical or veterinarian uses, e.g., for human or animals, but are particularly suitable for human use.

[0066] In contrast to conformally configured slings, the term "semi-rigid" means that the implant is flexible, typically elastically flexible in at least one dimension, but has sufficient rigidity to be self-supporting and able to maintain its three-dimensional shape outside a target body in a non-loaded, free-standing configuration. The implant can also be configured so as to be able to substantially maintain a non-loaded pre-implanted 3-D external shape while in position in the body, typically even when under normal, non-stress related loading in the body.

[0067] Referring now to **Figures 1-4**, there is shown an implant **10** having a rigid or semi-rigid curved shape. The implant **10** has two opposing primary surfaces **15, 22**. The first primary surface **15** can be curved, typically in a direction facing a urethra **23** (**Figure 7A, 8**). In the orientation shown, the first primary surface **15** is a top surface. The first primary surface **15** can include a medial portion that is curved or has a relatively wide groove **110** that merges into two downwardly-curved or linearly tapered end portions **111** that can terminate at an outermost edge **111e** (which may be sharp, blunt or rounded). The other primary surface **22** can also be upwardly curved (or curved in a direction facing the urethra **23**) and meet the upper primary surface **15** at the edge **111e**. The second primary surface **22** may also be substantially planar (not shown). Other configurations of the implant may be used.

[0068] The implant **10** can have a width "W" that is about the size of a diameter of an average urethra (e.g., about 20 mm). The length dimension "L" is typically less than the W dimension, typically between about 40-60% less, such as about 50% less. The length L1 (at the ends) can be about 1/3 the length of an average lower end length of a urethra, e.g., about 10 mm. The maximum length dimension L2 may be at the center and be greater than the length L1at the ends **111** as shown in **Figure 10C** and this may be about 14 mm.

[0069] The maximum thickness (average) can be between about 1 mm to about 10 mm, typically 1 mm to 9 mm, including between about 1- 6 mm, such as about 1. 5 mm, about 2 mm, about 2.5 mm, about 3 mm, about 3.5 mm, about 4 mm, about 4.5 mm or about 5 mm.

[0070] The surface area of the curved surface or groove **110** can be about 50% of the longer surface **22** as shown in **Figures 1** and **10C**. However, this relationship can vary and it is contemplated that a less incontinent woman may use an implant where the groove or curved surface **110** is closer in area to the longer second primary surface **22** while a more incontinent woman may use an implant where the shorter curved or groove surface **110** has an area that is even less than about 50% than the longer surface to provide increased support.

[0071] In some embodiments, the implant **10** can be sized and configured to surround only about 180 degrees or less of a female urethra, typically between about 60-120 degrees, and can have a maximum thickness that is between about 1 mm to about 6 mm, typically about 1.5 mm to about 5 mm, and in some embodiments about 2 mm, about 2.5 mm, about 3 mm, about 3.5 mm, about 4 mm, about 4.5 mm or about 5 mm.

[0072] In some embodiments, the implant **10** can have a width W that is between about 15-30 mm, a length L that is between about 7-10 mm and a maximum thickness that is between about 1 mm and about 5 mm.

[0073] **Figures 10A-10C** illustrate exemplary radii and dimensions (and reflect average dimensions) of the implant **10**. As shown, the implant **10** can include three different radii, a first radius R1 defining the curvature of the groove or middle portion **110** of the upper surface **15**, a second radius R2 defining the curvature of the lower or second primary surface **22** and an optional third radius R3 for defining the interface between the surfaces **15, 22**. The first radius R1 can have a dimension that is about 10 mm measured from a centerline (marked as "C/L" as shown in **Figure 10A**). The second radius R2 can be at least about double the first, such as about 27 mm. The third radius R3, where used, can be the largest radius, typically about 30-50% greater than R2, and may be about 39.4 mm. The edge **111e** may reside closer to the first primary surface **15** than the second **22**, e.g., at about 1.8 mm on a side having an overall thickness of about 2 mm.

[0074] The shapes and size of the implant **10** can vary from that shown. Also, as shown in **Figures 14** and **15**, the implant **10** can be provided in a range of different sizes for different anatomical and/or functional requirements or fit. For example, the implants **10** can be provided in a plurality of defined ranges, such as "small," "medium" and "large" with

different lengths, widths and/or potentially thicknesses and/or differing degrees of rigidity. The middle portion **110** of the surface **15** may change as the ratio R of a shorter to longer surface **15:22** changes. Also, the thickness of the implant and overall shape (and rigidity) may vary according to other factors such as the degree of pelvic prolapse.

[0075] **Figure 14** illustrates that the maximum width W (the width of the longest side dimension) is typically 10-25% greater than the outer diameter of the lower to mid portion of the urethra, at the location the implant **10** is to be positioned. As shown, for a small urethra, e.g., about a 1.4 cm diameter urethra, the longest length of a suitable implant can be about 1.6 cm or about 1.7 cm; for a medium size urethra, e.g., about a 1.7 cm diameter urethra, the maximum outer length of the implant can be about 2.0 cm; and for a large urethra, e.g., about a 2.0 cm diameter urethra, a 2.4 cm implant may be appropriate. The thickness dimension (measured at the centerline) of the implant 10 can vary, including between about 2.5 mm to about 6 mm, typically between about 3 mm to about 5 mm, on average, measured at the centerline C/L.

[0076] **Figure 15** illustrates that the size/configuration of an implant **10** can be selected according to the severity of the stress urinary incontinence, e.g., mild (Mi), moderate (Mo) or severe Sv, with the width dimension W being wider in that order, such as from about 1. 6 cm, to about 2.0 cm, to about 2.4 cm, or other size demarcations of increasing widths. Again, the thickness and/or rigidity of the implant may also vary according to a rated severity of the condition.

[0077] The curvatures of primary surfaces **15** and **22** can be shaped to fit about adjacent surrounding anatomy. In position, the first primary surface **15** can contact an outer surface of a lower to mid-portion of the urethra **23** (**Figure 7A, 8**) while the bottom or lower primary surface **22** rests on top of an outer surface of the (anterior) vaginal wall **26**, as shown in **Figures 7A** and **8**.

[0078] The curved surface typically curves upward toward the urethra as shown in **Figures 7A-7C**. In other embodiments, the implant **10** can have planar primary surfaces or can include one planar and one curved primary surface. In yet other embodiments, the curvature can be reverse that shown in **Figures 7A-7C**, e.g., the primary surface may project out toward the urethra rather than curve away from the urethra.

[0079] The primary surfaces **15** and **22** can be completely smooth to reduce stress on tissue and inhibit complications such as erosion or extrusion. The term "smooth" means that there is a smooth (rather than rough) tactile feel so that its surface finish is non-irritating to

adjacent tissue. The primary surfaces **15** and **22** can be continuous solid closed outer surfaces, and, at least for the portions contacting local tissue, may have a constant continuous and uninterrupted line (radius).

[0080] In some embodiments, the surface area of the curved middle portion or groove **110** of the first primary surface **15** can be smaller than the surface area of the rear or second primary surface **22**. The radius of curvature of surfaces of the outer segments **111** can be greater than that of both **110** and **22** in order to create a disparity between the contact area of the groove (**110**) and urethra **23**, and the contact area of the bottom surface (**22**) and vaginal wall **26**. The two primary surfaces **15**, **22** can meet at edges **111e** and at outer rounded ends or shoulders **122** (**Figure 3**).

[0081] In some embodiments, the implant **10** can be a rigid or semi-rigid molded body. The implant **10** can be formed of a biocompatible (inert) material or materials such as a biocompatible polymer(s) or rubber that provides sufficient rigidity to be able to provide the force distribution. In some embodiments, the implant **10** can have a Young's modulus between about 2 and about 10 MPa, substantially corresponding to the range of elasticity between healthy and weakened vaginal wall tissue.

[0082] The implant **10** can have a porous body (**Figure 13**) or a solid hollow body with a hollow interior **20** (**Figure 11**) or combinations of same. The implant **10** can be a monolithic molded body of a biocompatible (non-cytotoxic) material that has a defined three-dimensional shape. In some embodiments, the implant **10** can be a solid, porous and/or hollow monolithic molded body of a plurality of biocompatible materials that define the three-dimensional shape. In some embodiments, the implant **10** comprises polypropylene. In some embodiments, the implant **10** comprises silicone. In some embodiments, the implant **10** is rigid or semi-rigid and comprises a combination of materials and may be formed of a material(s) that is/are radio-opaque or biodegradeable over time, such as, but not limited to, polycaprolactone and poly-L-lactone.

[0083] The implant **10** may be coated, impregnated, painted, sprayed, dipped or otherwise formed to include (externally and/or internally) a radio-opaque material, such as barium sulfate, to allow in-vivo imaging. The implant **10** may be coated, impregnated or otherwise formed with a biocompatible (non-cytotoxic) material, such as collagen, to reduce the risk of infection. The implant **10** can incorporate therapeutic agents or drugs that are released to local tissue over time. The term "drug" is used interchangeably with "therapeutic agent" and refers to an agent (e.g., an organic compound, an inorganic compound, a

biomolecule, etc.) that has a beneficial effect on a subject/patient, which beneficial effect can be complete or partial. "Biomolecule" as used herein refers to a protein, a polypeptide, a nucleic acid (e.g., a deoxyribonucleic acid and/or a ribonucleic acid), and/or a fragment thereof. Exemplary drugs include, but are not limited to, analgesics such as non-steroidal anti-inflammatory drugs and opioids; antibiotics; anti-scarring agents; steroids; anti-inflammatory agents such as steroids, salicylates, ibuprofen, naproxen, dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine and mesalamine; bisphosphonates; anti-thrombotic agents such as heparin, heparin derivatives, urokinase, and PPack (dextrophenylalanine proline arginine chloromethylketone); antineoplastic/antiproliferative/anti-miotic agents such as paclitaxel, 5-fluorouracil, cisplatin, vinblastine, vincristine, epothilones, endostatin, angiostatin, angiopeptin, and thymidine kinase inhibitors; anesthetic agents such as lidocaine, bupivacaine and ropivacaine; vascular cell growth promoters such as transcriptional activators, and translational promoters; vascular cell growth inhibitors such as growth factor inhibitors, growth factor receptor antagonists, transcriptional repressors, translational repressors, replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, bifunctional molecules consisting of a growth factor and a cytotoxin, bifunctional molecules consisting of an antibody and a cytotoxin; protein kinase and tyrosine kinase inhibitors (e.g., tyrphostins, genistein, quinoxalines); antimicrobial agents such as triclosan, cephalosporins, aminoglycosides and nitrofurantoin; cytotoxic agents, cytostatic agents and cell proliferation affectors; vasodilating agents; antibodies (e.g., monoclonal antibodies and/or polyclonal antibodies); growth factors; cytokines; hormones; vitamins; minerals; or any combination thereof.

[0084] Referring now to **Figure 5**, a length or section of macroporous surgical mesh **130** may be optionally attached to both ends **111** of the implant **10**. This may encourage tissue integration and improve device fixation over a long period of time. The mesh segments **130** can be configured from any suitable material and may optionally comprise small, interwoven threads of polypropylene. The mesh **130** can be rigid, semi-rigid or flexible. The mesh ends **130** can be tucked into surrounding tissue (rather than locked together). They can be positioned with about a 137 degree angle between them, and can extend towards the obturator membrane.

[0085] Referring now to **Figures 6A-6C**, a section of the pubourethral anatomy is shown. This anatomy includes a pubic bone **21**, urethra **23**, and pelvic floor **22** which is comprised of the vaginal wall **26**, rectum, and levator ani. **Figures 6A-6C** display the

response of a stress incontinent pubourethral system without the invention to a sudden impulse of abdominal pressure **30**. Generally stated, the pubic bone **21** is fixed in place, but the increase in intra-urethral force causes the urethra **23** to exert a downward force **24** on the pelvic floor **22**. The result **31** can be that the urethra **23** expands and sinks into the pelvic floor **22**, thus allowing leakage to occur.

[0086] In contrast, as shown in **Figures 7A-7C**, the implant **10**, when positioned in the pubourethral anatomy, can inhibit urine leakage. The surface contact area between the urethra **23** and medial portion or groove **110** is smaller than the contact area between the pelvic floor and lower or second primary surface **22**. Thus, during an impulse of abdominal pressure **32**, the downward force **26** of the urethra is dispersed (distributed) across a greater area and the associated pressure is reduced. The result **33** is that the pelvic floor becomes better able to resist the urethral expansion and inhibit, reduce or prevent leakage. The implant **10** may also optionally be configured to act as a shock absorber to be able to reduce the degree of force transmitted.

[0087] **Figure 8** illustrates the implant **10** in position. The implant **10** can be "free-floating" or self-restraining to be held in position once placed. This is because the holding space that the implant is placed an artificial sub-urethral space due to the surgery (this area is typically filled with fascia and connective tissue). Thus, it is unlikely that the implant **10** will migrate. These two tissue compartments can hold the implant **10** in position without requiring positive fixation. Optionally, sutures or surgical glue may be used to attach the device to the pubourethral fascia to facilitate fixation. Over time, the implant **10** may be encapsulated by fibrous tissue or in-growth which can connect or attach it to the urethra and/or vaginal wall.

[0088] **Figures 9A-9C** illustrate an exemplary sequence of steps for placing the implant **10**, typically with a single, transvaginal incision. However, laparoscopic or other surgical pathways can be used. A urethral catheter **200** can be used with clamps **210** to hold the vagina open. The urethra can be palpated with a finger, then the insert can be inserted into the appropriate space between the urethra and vagina wall as shown in **Figure 8**. If the implant **10** with mesh ends **130** is placed, then a trochar may be used to place or position the mesh. Ultrasound or another imaging modality may be used to facilitate proper placement or confirm placement of the implant **10**.

[0089] **Figure 11** illustrates another embodiment of an implant **10**. In this embodiment the implant **10** has a hollow interior compartment **20**. This compartment **20** may

include a different material such as a resilient material or the compartment **20** can include air (non-pressurized). In some embodiments, an internal pressurized bladder may reside in the interior compartment and may comprise saline or other inert fluid. In some embodiments, the implant **10** includes an outer casing that does not require a bladder (it may be sufficiently air or fluid tight) and can have a pressurized compartment of air, saline or other material.

[0090] **Figure 12** illustrates that the implant **10** can include a different profile shape on the upper or first primary surface **10**.

[0091] **Figure 12** also illustrates that the implant **10** can include a plurality of spaced apart apertures **40** (shown as through apertures, but closed ones may also be used). The apertures **40** may allow fluid transfer and/or tissue ingrowth. The apertures **40** can extend in a common direction, top to bottom and/or side to side, and can be parallel or may intersect or be discrete spaced apart channels.

[0092] **Figure 13** shows the implant can include pores **40p** that may be in a regular or irregular pattern and that may be discrete or interconnected as a matrix to provide channels for fluid flow or exchange through the implant **10**. The pores **40p** and/or apertures **40a** can be sized and configured to allow for white blood cell migration and/or tissue integration. The pores **40p** and/or apertures **40** can be configured to provide between about 10-60% porosity, typically between about 10-40% porosity, with aperture and/or pore diameters ranging between about 10 mm to about 300 mm, such as between about 125 mm and 250 mm, including about 125 mm, about 130 mm, about 140 mm, about 150 mm, about 160 mm, about 170 mm, about 180 mm, about 190 mm, about 200 mm, about 210 mm, about 220 mm, about 230 mm, about 240 mm and about 250 mm.

[0093] **Figures 16A** and **16B** illustrate an exemplary mold **210** that can be used to form the implant **10**. The mold **210** includes a mold cavity **210c** that has an internal shape that corresponds to the curvature of the implant **10** with defined radii such as discussed with respect to embodiments shown in **Figures 1**, **4**, and **10A-10C**, for example. The mold **210** can be configured as an injection molding mold **210**. The mold **210** can be a single compartment mold or a multiple compartment mold block with discrete mold cavities for fabricating a plurality of discrete implants concurrently. The mold and mold materials may be sterile or aseptic or the mold can be sterilized after it is fabricated.

[0094] **Figure 17** illustrates an example of a fabrication system/method **200** that can be used to form a porous implant **10**. In this embodiments, a mold material **205** (e.g., silicone) can be mixed with a soluble porogen **208**, which is molded together in the mold **210**

and integrated into the molded body in a pre-form body **10a**. The mold material and porogen can be premixed and introduced into the mold cavity or can be mixed while or after introduced into the mold cavity. The term "porogen" refers to a material that is able to be removed from the primary moldable material after molding in sufficient amounts to create apertures, pores or channels. The pre-form body **10a** is then rinsed, sprayed, dipped, chemically reacted or otherwise processed to remove or dissolve away the porogen **208** to thereby form a porous molded body **10b**. This can form a sponge-like body with interconnecting pores **40p**. The porogen can comprise a salt-leeching material.

[0095] **Figure 18** illustrates a different example of a fabrication system/method **250**. Here, the system **250** includes a laser **260** with a laser power source **265** and head **270** that is configured to form pores **40p** in a molded body **10a**, typically as vertical channels **40ch** that extend through the implant **10**. The pore channels **40ch** can be substantially parallel and may have diameters as described above, e.g., between about typically between about 125 mm and 250 mm.

[0096] The methods/systems for forming the porosity described herein are by way of example only and non-limiting to the implants contemplated by the present invention. For example, the mold cavity **210c** can include disposable or permanent inserts that extend in the mold to provide the apertures, pores and/or channels **40a, 40p, 40ch** (not shown).

[0097] The implants **10** contemplated by embodiments of the invention can have a much smaller area than conventional slings and can optionally be implanted through a single transvaginal incision in a less invasive manner than current incontinence slings. Once fitted under the urethra, the implant **10** will typically not need to be adjusted. There is no tension on the implant itself, so the procedure is much easier to learn and reproduce consistently. The implants do not require (and can be devoid of) barbed fixation tips that may otherwise present a bleeding risk. Unlike the sling, the implants **10** do not restrict the urethra. The implants **10** can inhibit, reduce or prevent urinary leakage by dispersing or distributing force to inhibit or prevent a sudden expansion associated with stress incontinence. The surfaces of the implant can be smooth and minimize the risk of tissue erosion or organ perforation. Thus, embodiments of the present invention provide urogynecologic implants that reduce, inhibit or prevent stress incontinence by reducing the displacement of the urethra into the pelvic floor during impulses of pressure.

[0098] While the foregoing written description of the invention enables one of ordinary skill to make and use what is considered presently to be the best mode thereof, those

of ordinary skill will understand and appreciate the existence of variations, combinations, and equivalents of the specific embodiment, method, and examples herein. The invention should therefore not be limited by the above described embodiment, method, and examples, but by all embodiments and methods within the scope and spirit of the invention as claimed.

THAT WHICH IS CLAIMED:

1. A stress incontinence implant, comprising:

a three dimensional rigid or semi-rigid urogynecologic implant having a defined three dimensional self-supporting shape sized and configured to reside between a urethra and an anterior vaginal wall of a patient.

2. The implant of Claim 1, wherein the implant comprising a first primary surface with a curved medial portion and a second primary surface underlying the first primary surface.

3. The implant of Claim 1, wherein the implant comprises a monolithic porous polymer body.

4. The implant of Claim 1, wherein the implant comprises a hollow interior compartment.

5. The implant of Claim 1, wherein the implant has a body with a Young's modulus between about 2 MPa and about 10 MPa

6. The implant of Claim 1, wherein the implant has a width dimension and a length dimension, with the width dimension being greater than the length dimension.

7. The implant of Claim 6, wherein the width dimensions is about 50% greater than the length dimension.

8. The implant of Claim 2, wherein the second primary surface is curved and has a radius of curvature that is greater than a radius of curvature of the first primary surface medial portion.

9. The implant of Claim 2, wherein the first primary surface medial portion merges into outer ramped end portions and the second primary surface has an arc configuration with opposing ends, and wherein a respective ramped end portion meets a respective arc end portion to define a respective short end edge of the implant.

10. The implant of Claim 8, wherein the short end edges reside closer to the first primary surface than the second primary surface.

11. The implant of Claim 1, wherein the implant is configured to reside between the anterior vaginal wall and an outer surface at of a lower to middle portion of a urethra.

12. The implant of Claim 11, wherein the implant is sized and configured to be held in position between the vaginal wall and the urethra without mechanical fixation.

13. The implant of Claim 1, wherein the implant has a first primary surface with a curved medial portion that is sized and configured to face a urethra, the medial portion merging into respective opposing outer ramped end portions that incline down toward a second primary surface.

14. The implant of Claim 1, further comprising mesh extending out from the implant.

15. The implant of Claim 1, wherein the implant is sized and configured to surround only about 180 degrees or less of a female urethra and has a maximum thickness that is between about 1 mm to about 5 mm.

16. The implant of Claim 1, wherein the implant has a width that is between about 15-30 mm, a length that is between about 7-10 mm and a maximum thickness that is between about 1 mm and 5 mm.

17. The implant of Claim 1, wherein the implant comprises a rigid or semi-rigid silicone body.

18. The implant of Claim 1, wherein the implant has a porosity provided by of at least one of: (i) a matrix of pores, (b) spaced apart or intersecting channels; or (c) pores and channels, wherein at least some of the pores or channels have a diameter and/or width between about 125 mm and 250 mm.

19. The implant of Claim 1, wherein the implant is provided in a plurality of different sizes according to severity of stress urinary incontinence and/or urethra size, wherein at least one of implant width or implant thickness increases for implants for severe stress urinary incontinence and large urethra size, relative to implants for mild or moderate stress urinary incontinence and small or medium urethra size.

20. A method of treating urinary incontinence, comprising:

distributing forces from a three-dimensional shaped rigid or semi-rigid implant residing between a urethra and anterior vaginal wall of a female patient from a first side of the implant facing the urethra to a longer second side of the implant adjacent the anterior vagina wall in response to impulses of abdominal pressure stress to thereby inhibit urinary incontinence.

21. A method of fabricating a urinary incontinence implant, comprising:

forming a rigid or semi-rigid three dimensional implant body having sufficient rigidity to define a self-supporting three-dimensional shape.

22. The method of Claim 20, wherein the forming step is carried out by molding the implant body to include a first radius of curvature associated with a first primary surface and a second radius of curvature associated with an arc of an underlying second primary surface.

23. The method of Claim 20, wherein the forming is carried out by molding the implant body, the method further comprising forming pores in the implant body during or after the molding.

24. The method of Claim 23, wherein the forming the pores comprises directing laser light into the molded implant body to form through channels.

25. The method of Claim 21, wherein before the forming step, a flowable material of the moldable material is combined with a porogen in the mold or prior to introducing into the mold, then after the forming step, the porogen is removed from the molded implant body leaving a porous implant body.

26. The method of Claim 22, wherein the forming step comprises injection molding implant material in a mold having a cavity that defines the first and second radii of curvature.

27. The method of Claim 25, wherein the forming is carried out by molding the implant body using silicone to form a rigid or semi-rigid silicone implant body.

28. A mold for a medical stress incontinence implant, comprising:

a mold body having an internal volumetric cavity with walls that are configured to form a rigid or semi-rigid three dimensional implant body having a three-dimensional shape sized and configured to reside between a urethra and anterior vaginal wall.

29. The mold of Claim 28, wherein the cavity walls are configured to define first and second radii of curvature in the implant body, including a first radius of curvature associated with a first primary surface and a second radius of curvature associated with an arc of an underlying second primary surface.

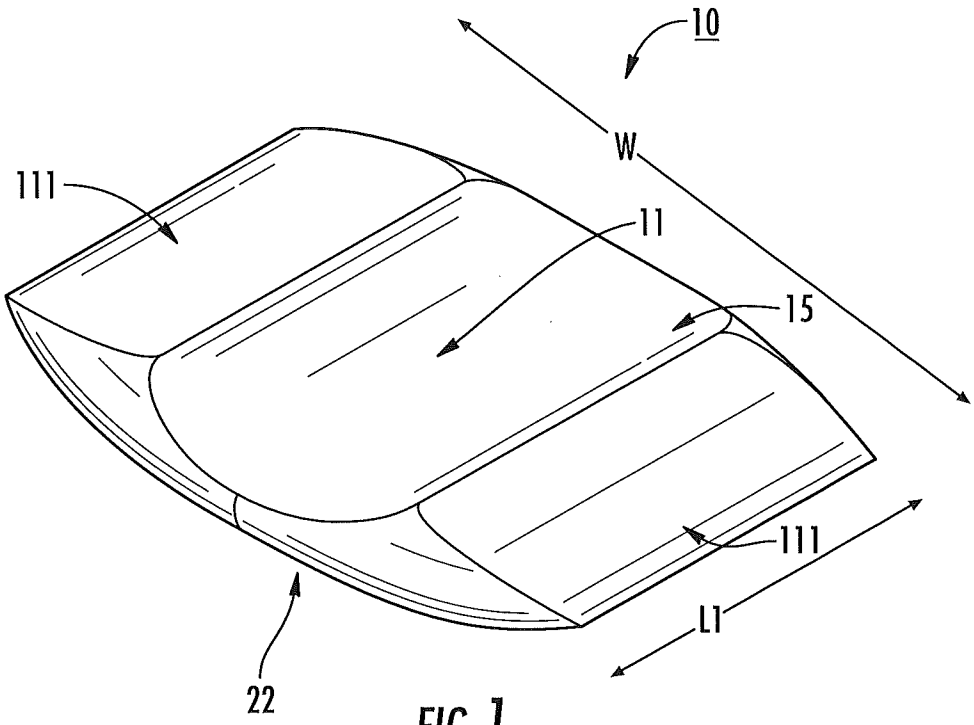

FIG. 1

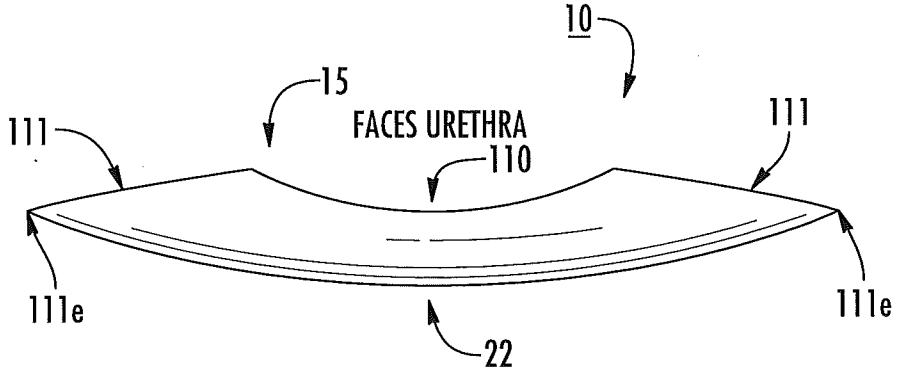

FIG. 2

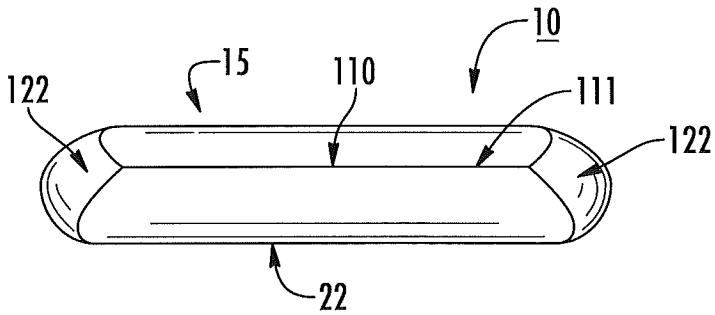

FIG. 3

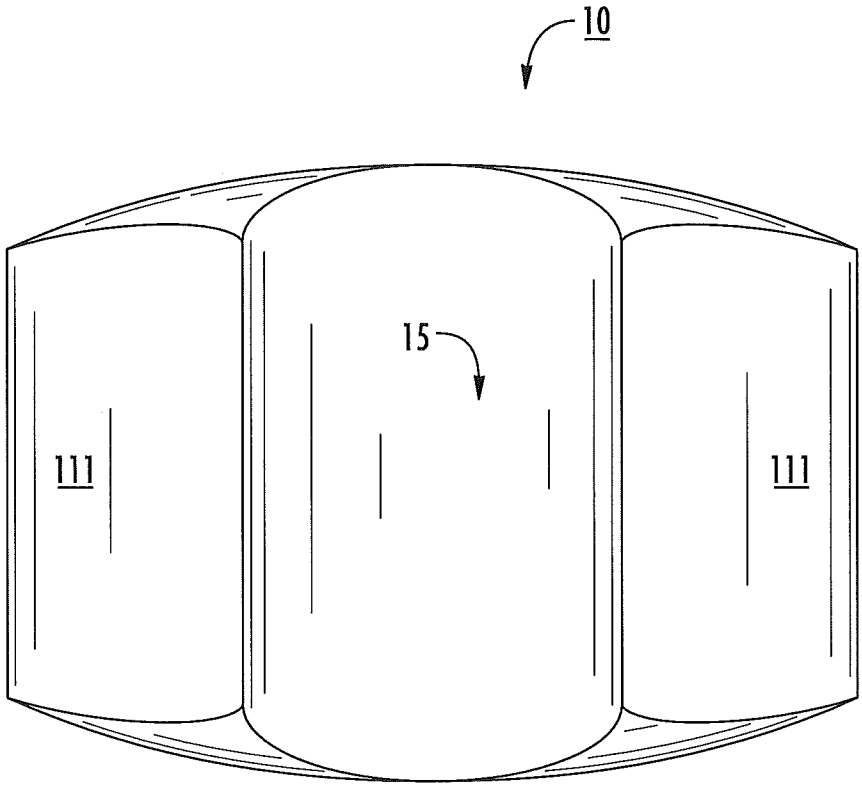

FIG. 4

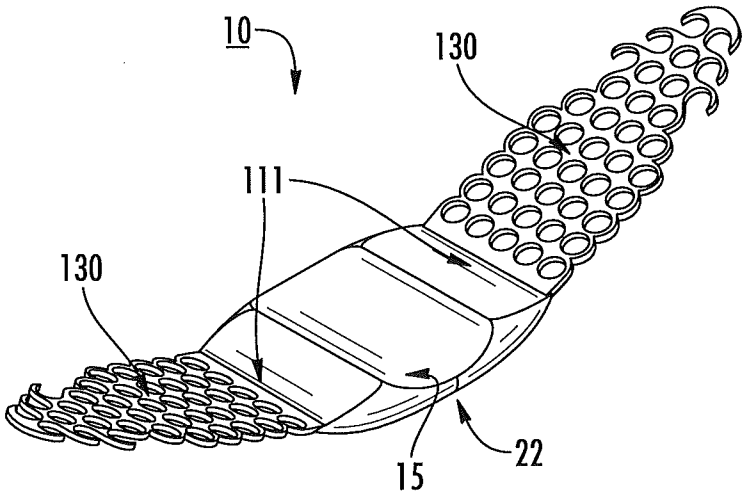

FIG. 5

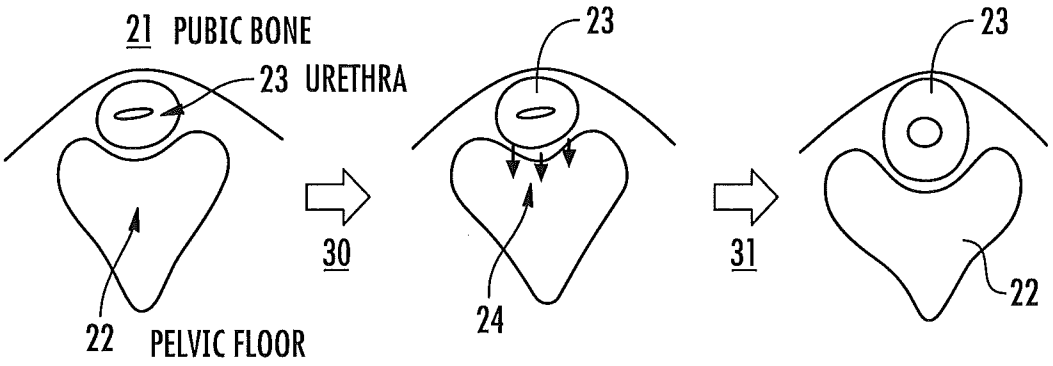

FIG. 6A FIG. 6B FIG. 6C

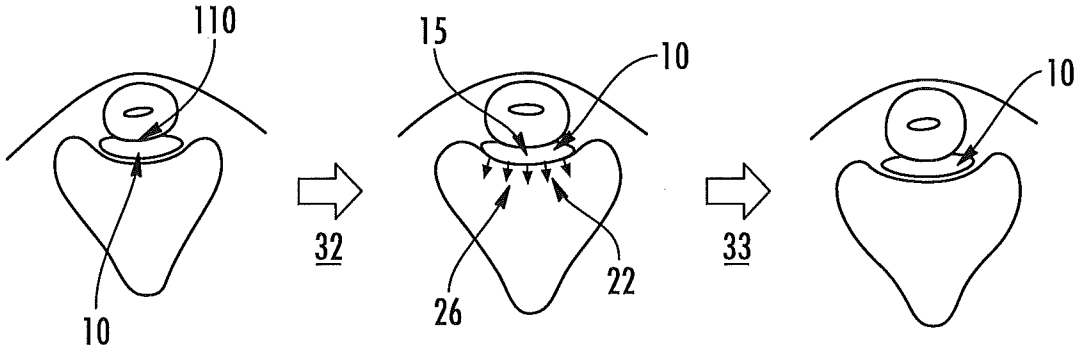

FIG. 7A FIG. 7B FIG. 7C

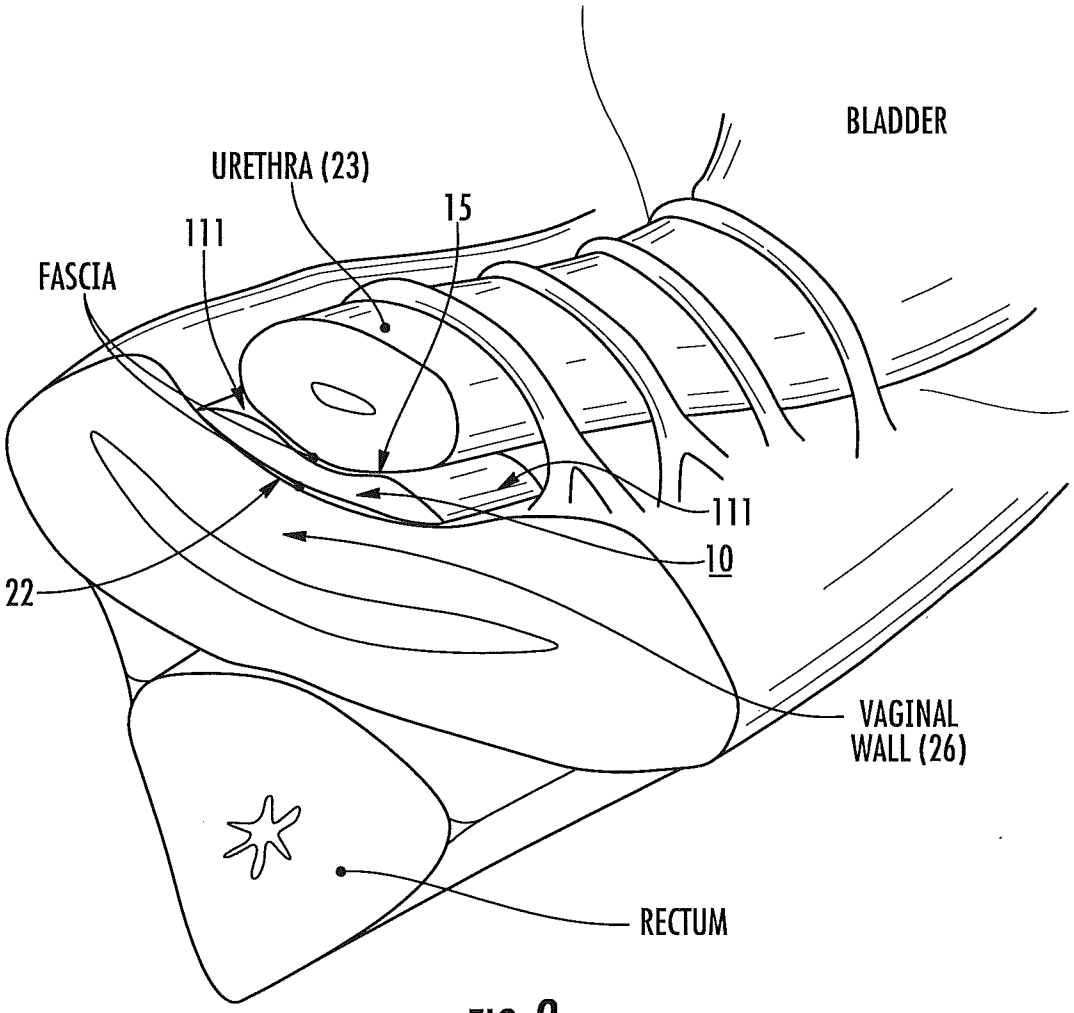
BLADDER
URETHRA (23)
15
111
FASCIA
111
10
22
VAGINAL
WALL (26)
RECTUM

FIG. 8

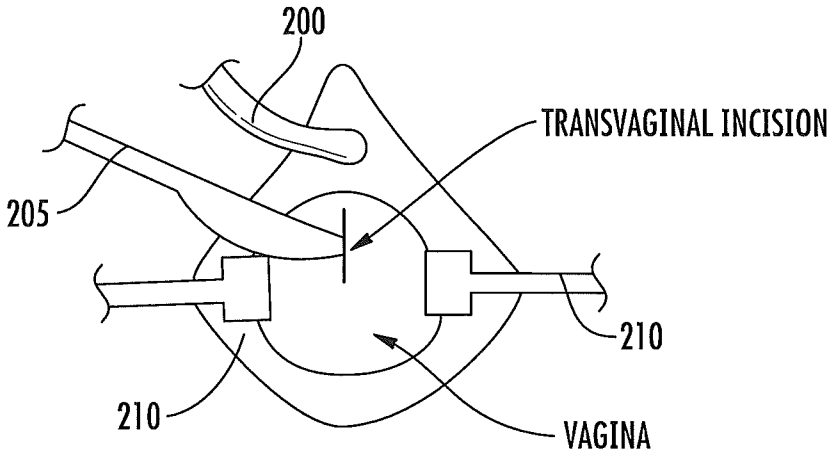

FIG. 9A

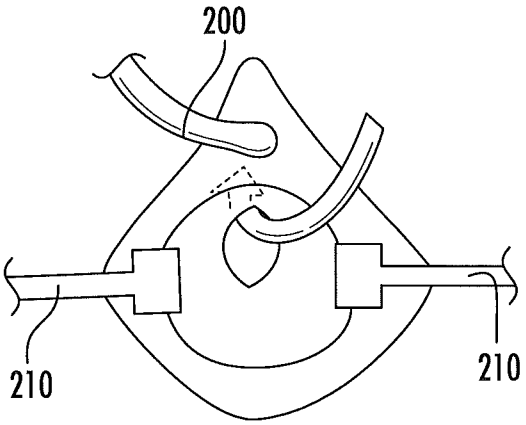

FIG. 9B

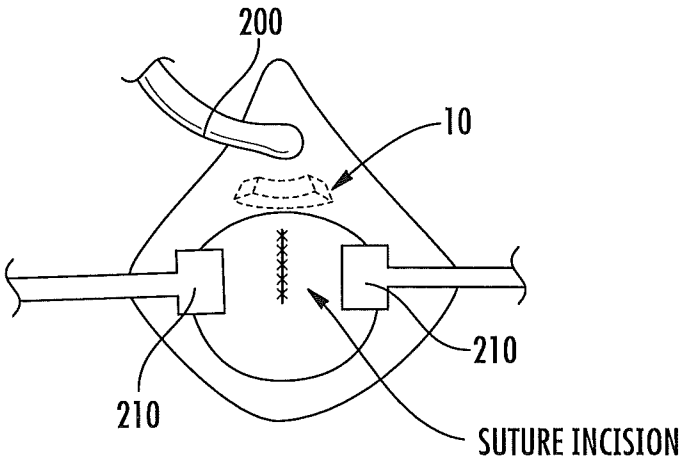

FIG. 9C

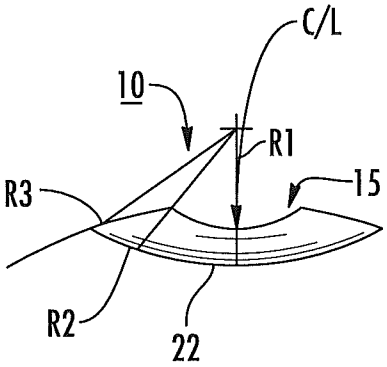

FIG. 10A

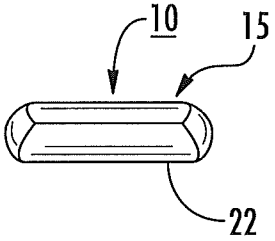

FIG. 10B

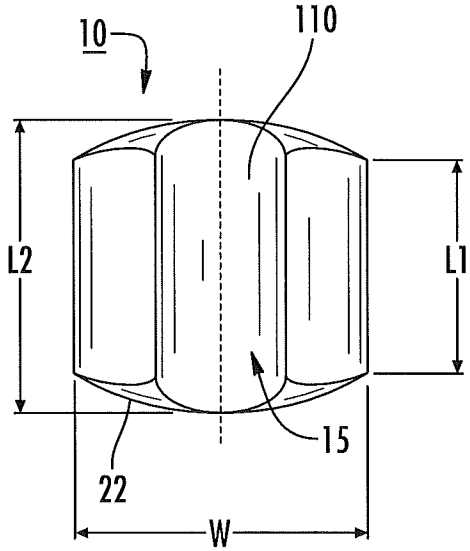

FIG. 10C

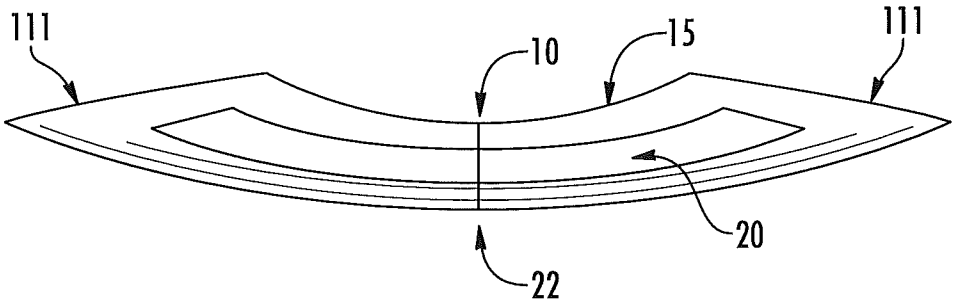

FIG. 11

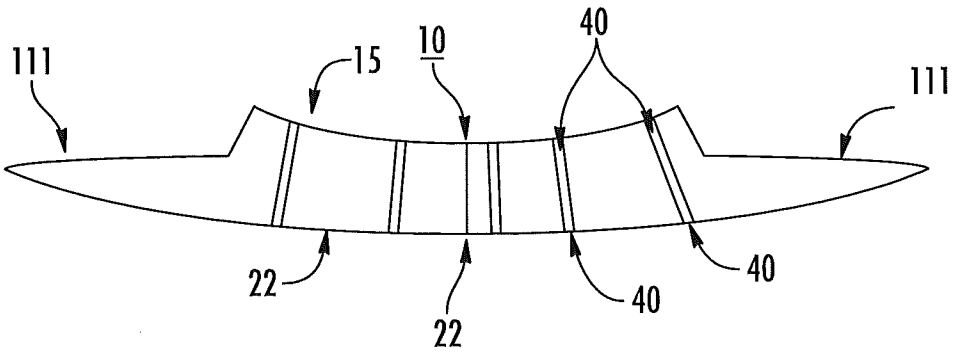

FIG. 12

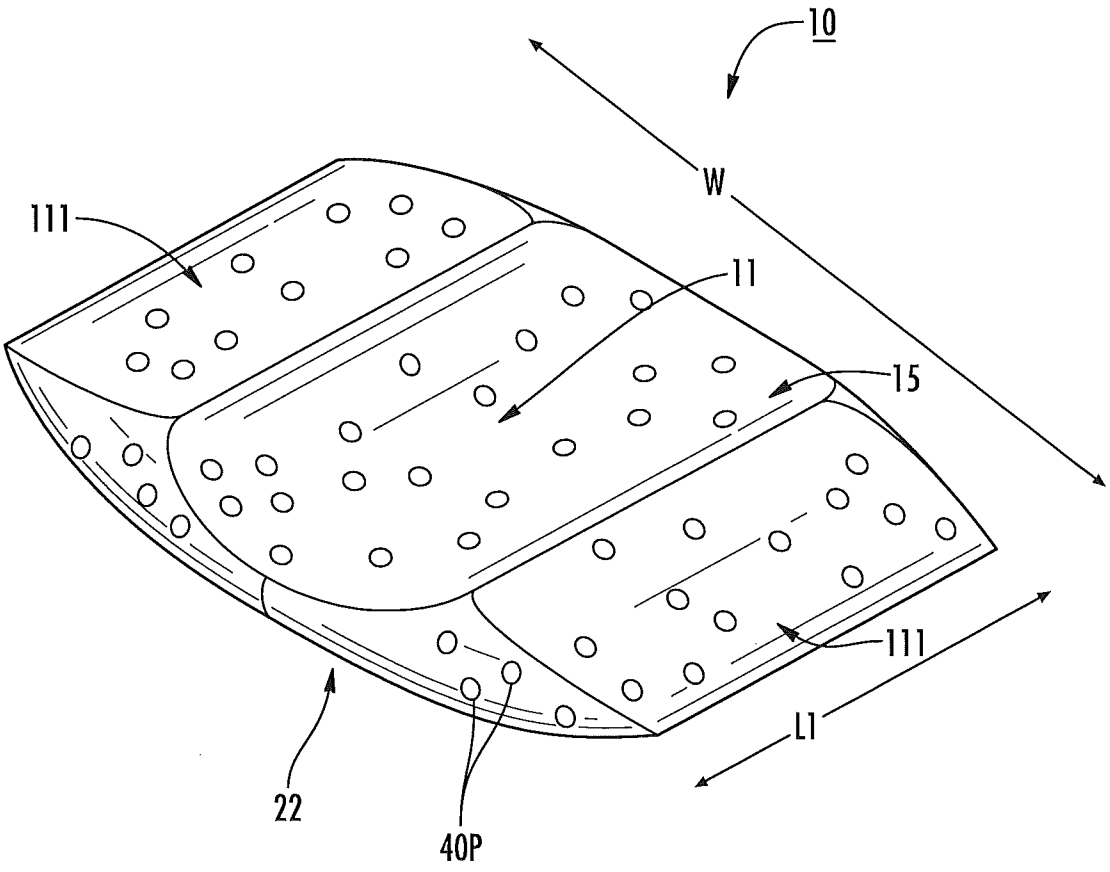

FIG. 13

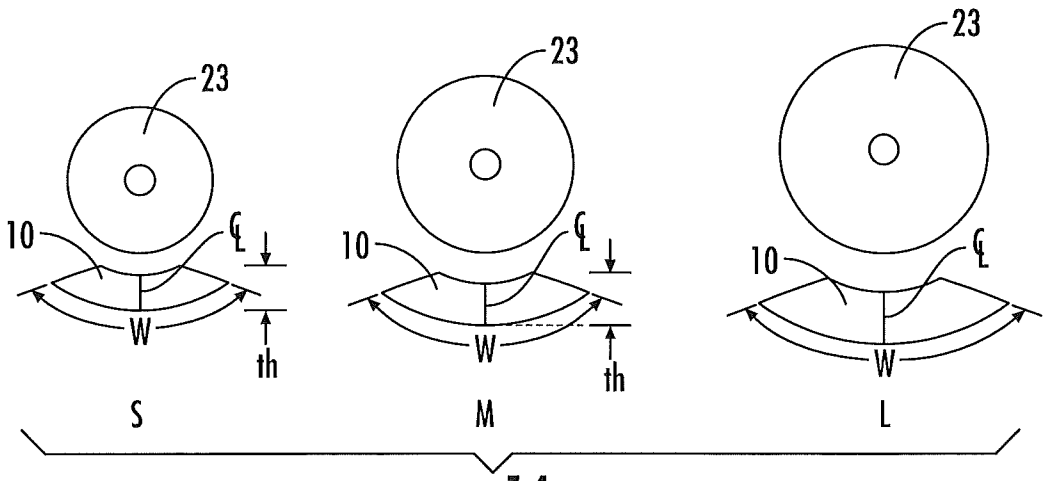

FIG. 14

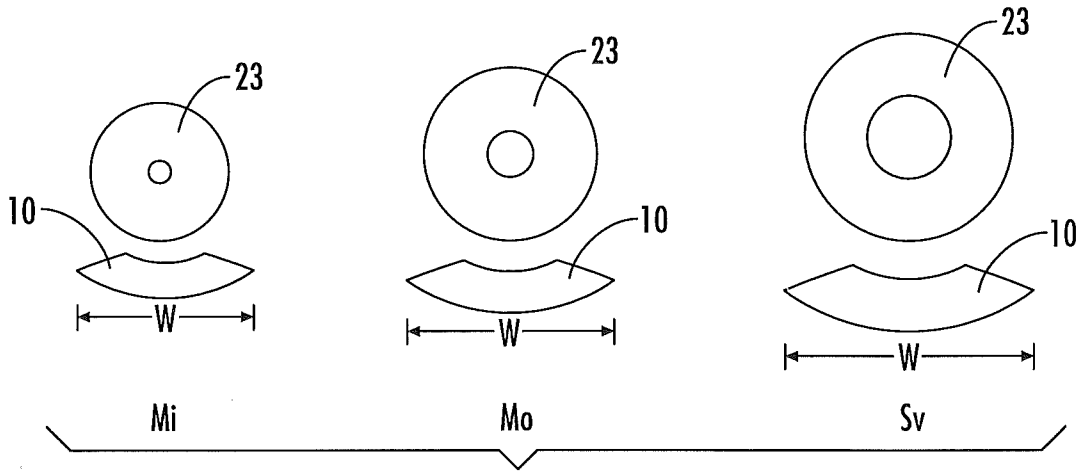

FIG. 15

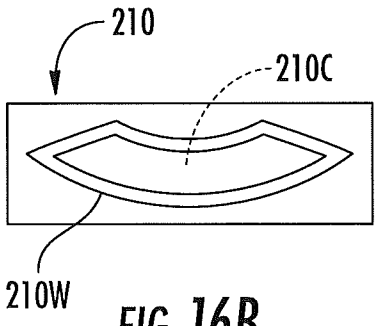

FIG. 16B

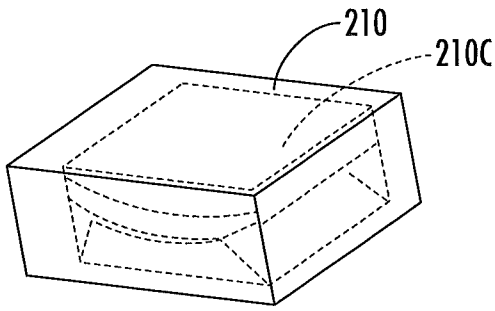

FIG. 16A

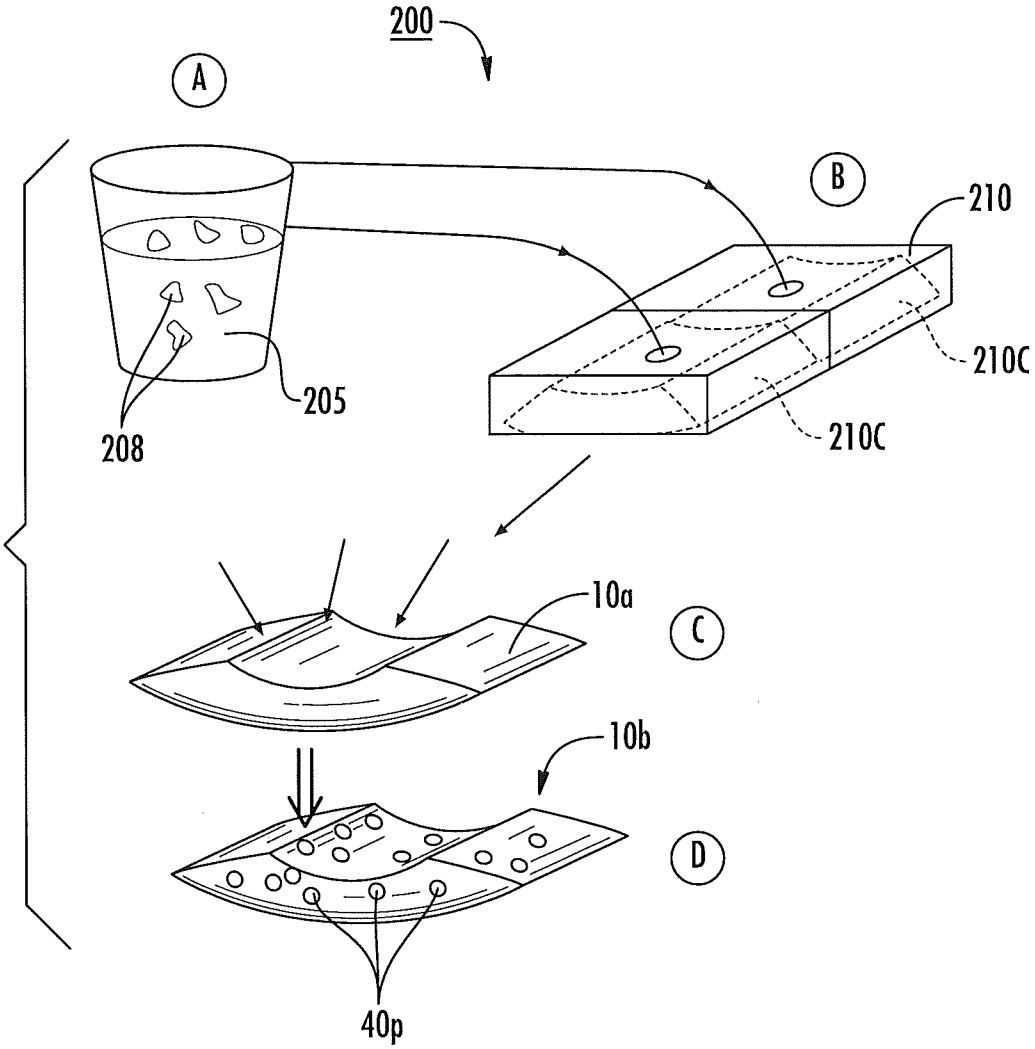

FIG. 17

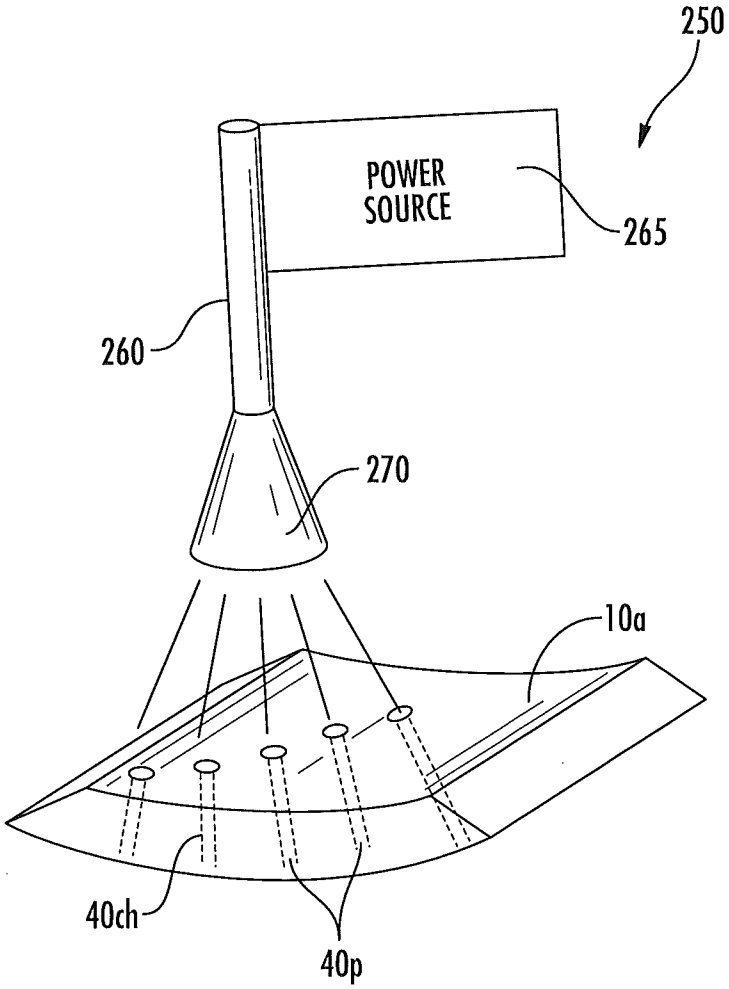

FIG. 18

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/047567

A. CLASSIFICATION OF SUBJECT MATTER

A61F 2/00(2006.01)i, A61F 2/04(2006.01)i, A61B 17/00(2006.01)i, A61L 27/14(2006.01)i, A61L 27/56(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F 2/00; A61F 6/06; A61F 2/02; A61B 17/03; B05D 3/10; A61F 2/04; A61B 17/00; A61L 27/14; A61L 27/56

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & keywords: incontinence, rigid, urogynecologic, urethra, vaginal wall, porous

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 8033982 B2 (WEISER, M. F.) 11 October 2011 See abstract; column 5, lines 47-53; column 12, lines 6-23; column 18, lines 1-18; claims 1, 10; and figures 1, 4.	1,2,4-17,19,21,22,25,26(1)
Y		3,18,23,24,26-28
Y	US 2012-0010636 A1 (BOEY, Y. C. F. et al.) 12 January 2012 See abstract; paragraphs [0035], [0040], [0043], [0044], [0072].	3,18,23,24,26-28
A		1,2,4-17,19,21,22,25,26(1)
A	US 2011-0190574 A1 (MAURETTE, N. L.) 4 August 2011 See abstract; paragraphs [0067], [0068]; and figures 7-11.	1-19,21-28
A	US 7713188 B2 (BOUFFIER, B.) 11 May 2010 See column 11, lines 53-64; figure 17.	1-19,21-28

☒ Further documents are listed in the continuation of Box C. ☒ 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 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
08 October 2013 (08.10.2013)	**08 October 2013 (08.10.2013)**

Name and mailing address of the ISA/KR
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea
Facsimile No. +82-42-472-7140

Authorized officer
HAN In Ho
Telephone No. +82-42-481-3362

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/047567

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 7601118 B2 (SMITH, D. J. et al.) 13 October 2009 See claim 1; figure 1. * Note : Claim 26 of this application are not numbered consecutively in Arabic numbers, since claim 26 is found twice (PCT Rule 6.1(b)). For the claim 26(1), the claim is renumbered by the authority because the claim 26 is found twice.	1-19,21-28

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/047567

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. ☒ Claims Nos.: 20
because they relate to subject matter not required to be searched by this Authority, namely:
Claim 20 pertains to method for treatment of the human and thus relates to a subject-matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.

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:

1. ☐ As all required addtional 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 fee, this Authority did not invite payment of any additional fee.

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.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2013/047567

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