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(54) Title: VAGINAL STENTS, VAGINAL DILATORS, AND METHODS OF FABRICATING THE SAME

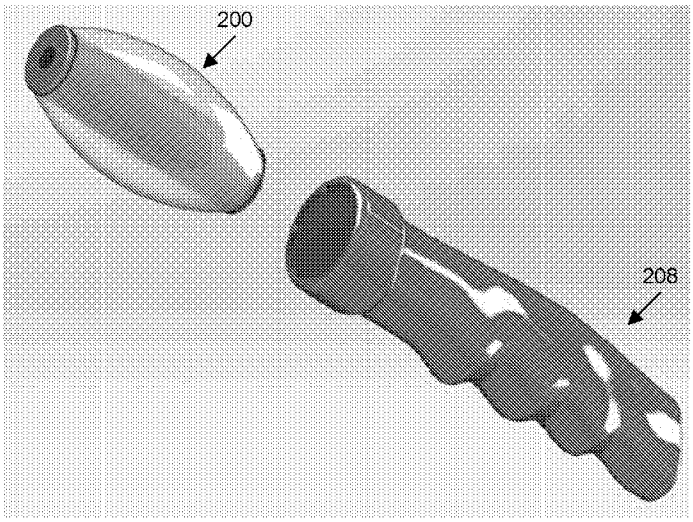


FIG. 2C

(57) Abstract: One aspect of the invention provides a vaginal stent system including: an inflatable vaginal stent and a removable handle. The inflatable vaginal stent include includes: an elastomeric exterior wall and a first fitting located at a base of the inflatable vaginal stent. The removable handle is adapted and configured for insertion, inflation, and removal of the inflatable vaginal stent from a subject's vagina. The removable handle includes a second fitting complementary to the first fitting and adapted and configure to form substantially fluid tight coupling when the handle is coupled to the inflatable vaginal stent. Another aspect of the invention provides a method of fabricating a customized vaginal stent or dilator. The method includes: generating a 3D model of a vaginal stent or dilator; and controlling a 3D printer to fabricate a vaginal stent or dilator according to the 3D model.

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VAGINAL STENTS, VAGINAL DILATORS, AND METHODS OF FABRICATING THE SAME

CROSS-REFERENCES TO RELATED APPLICATIONS

This application claims priority to U.S. Provisional Patent Application Serial No. 62/147,285, filed April 14, 2015, and U.S. Provisional Patent Application Serial No. 62/300,295, filed February 26, 2016. The entire contents of each of these applications is hereby incorporated by reference herein.

BACKGROUND OF THE INVENTION

Vaginal dilators and stents are used after surgical neovagina creation in order to maintain the caliber of the newly created vagina and to avoid restenosis after surgery or radiation. Neovaginal creation is necessary in girls born with Mayer-Rokitansky-Küster-Hauser (MRKH) syndrome (1/4,500), vaginal agenesis (1/5,000-7,000), cloacal anomalies, Congenital Adrenal Hyperplasia or other congenital anomalies. Additional uses include any women with vaginal stenosis from pelvic radiation or gynecology-oncology related cancer surgeries.

Currently available stents and dilators exist only in adult vaginal sizes that cannot be used safely or comfortably in the pediatric population or oncologic patients who have undergone vaginal brachytherapy.

SUMMARY OF THE INVENTION

One aspect of the invention provides a vaginal stent system including: an inflatable vaginal stent and a removable handle. The inflatable vaginal stent include includes: an elastomeric exterior wall and a first fitting located at a base of the inflatable vaginal stent. The removable handle is adapted and configured for insertion, inflation, and removal of the inflatable vaginal stent from a subject's vagina. The removable handle includes a second fitting complementary to the first fitting and adapted and configure to form substantially fluid tight coupling when the handle is coupled to the inflatable vaginal stent.

This aspect of the invention can have a variety of embodiments. At least one of the inflatable vaginal stent and the removable handle can include one or more magnets. The inflatable vaginal stent can include a magnetically-actuatable valve adapted and configured to deflate the inflatable vaginal stent when the removable handle is placed in proximity to a base of

the inflatable vaginal stent. The one or more magnets can have sufficient strength to remove the inflatable vaginal stent from a subject's vagina by placing the removable handle proximate to the subject's perineum.

Another aspect of the invention provides a vaginal dilator system including: a vaginal dilator and a removable handle. The vaginal dilator includes: an exterior wall and a hollow channel extending the length of the vaginal stent. The removable handle is adapted and configured for insertion and removal of the inflatable vaginal stent from a subject's vagina.

This aspect of the invention can have a variety of embodiments. At least one of the vaginal dilator and the removable handle can include one or more magnets. The one or more magnets can have sufficient strength to remove the inflatable vaginal stent from a subject's vagina by placing the removable handle proximate to the subject's perineum.

Another aspect of the invention provides a method of fabricating a customized vaginal stent or dilator. The method includes: generating a 3D model of a vaginal stent or dilator; and controlling a 3D printer to fabricate a vaginal stent or dilator according to the 3D model.

BRIEF DESCRIPTION OF THE DRAWINGS

For a fuller understanding of the nature and desired objects of the present invention, reference is made to the following detailed description taken in conjunction with the accompanying drawing figures wherein like reference characters denote corresponding parts throughout the several views.

FIG. 1 depicts a method 100 of fabricating a vaginal stent or dilator according to an embodiment of the invention.

FIGS. 2A-2C depict perspective views of a vaginal stent according to an embodiment of the invention.

FIGS. 3A-3E depict various views of a core for a vaginal stent according to an embodiment of the invention.

FIGS. 4A-4D depict vaginal dilators according to embodiments of the invention.

DEFINITIONS

The instant invention is most clearly understood with reference to the following definitions.

As used herein, the singular form "a," "an," and "the" include plural references unless the context clearly dictates otherwise.

Unless specifically stated or obvious from context, as used herein, the term "about" is understood as within a range of normal tolerance in the art, for example within 2 standard deviations of the mean. "About" can be understood as within 10%, 9%, 8%, 7%, 6%, 5%, 4%, 3%, 2%, 1%, 0.5%, 0.1%, 0.05%, or 0.01% of the stated value. Unless otherwise clear from context, all numerical values provided herein are modified by the term about.

As used in the specification and claims, the terms "comprises," "comprising," "containing," "having," and the like can have the meaning ascribed to them in U.S. patent law and can mean "includes," "including," and the like.

Unless specifically stated or obvious from context, the term "or," as used herein, is understood to be inclusive.

Ranges provided herein are understood to be shorthand for all of the values within the range. For example, a range of 1 to 50 is understood to include any number, combination of numbers, or sub-range from the group consisting 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, or 50 (as well as fractions thereof unless the context clearly dictates otherwise).

DETAILED DESCRIPTION OF THE INVENTION

Methods of Fabricating Vaginal Stents or Dilators

Referring now to FIG. 1, one aspect of the invention provides a method 100 of fabricating a vaginal stent or dilator.

Optionally in step S102, one or more measurements are obtained. The measurements can relate to the current dimensions of a subject's vagina or desired dimensions for various medical reasons. In some embodiments, the dimensions can be assessed visually by a healthcare provider. Additionally or alternatively, one or more imaging devices such as an inflatable cavity imager (*e.g.*, as described in U.S. Patent Application Publication Nos. 2014/0272221,

2014/0276005, and 2014/0276105) or various ultrasound, magnetic resonance, computed tomography, and/or X-ray devices and techniques can be utilized.

In step S104, a 3D model of a vaginal stent or dilator is generated. The 3D model can be generated based on the one or more measurements obtained in step S102 or can be generated from one or more templates or patterns. The 3D model can be generated using computer-aided design (CAD) software and can be manipulated by a healthcare provider to have a desired shape and/or dimensions. In some embodiments, a stent has an uninflated dimension of about 7 cm in length by about 2 cm in width or about 6 cm in length by about 1 cm in width. In some embodiments, dilators can have lengths and diameters as small as about 0.5 cm.

In step S106, a 3D printer is controlled to fabricate a vaginal stent or dilator according to the 3D model generated in step S104. A variety of 3D printers are available from a variety of sources. One suitable 3D printer is the OBJET30 PRO™ 3D printer from Stratasys Ltd. of Eden Prairie, Minnesota, which deposits layers of liquid photopolymers. One exemplary photopolymer is OBJET RGD525 acrylic photopolymer also available from Stratasys Ltd. Other suitable photopolymers include acrylonitrile butadiene styrene (ABS), polypropylene, rubber, and the like. Suitable fused deposition modeling (FDM) thermoplastics include acrylonitrile butadiene styrene (ABS), acrylonitrile styrene acrylate (ASA), nylon, polycarbonate (PC), PC-ABS blends, polylactic acid (PLA), polyvinyl alcohol (PVA), thermoplastic elastomers (TPEs), high impact polystyrene (HIPS), and the like. Other suitable extrudable materials include silicone.

Fabrication of vaginal stents and dilators can provide customized devices to fit a particular subject's anatomy and medical needs without the delays associated with manufacturing and shipping. Additionally, customized fabrication can avoid the need to purchase multiple devices that may not fit the patient's anatomy or needs, and can reduce patient frustration, pain, and non-compliance.

In addition to 3D printing one or more components of a vaginal stent or dilator, 3D printing can also be utilized to produce negative molds of one or more components that can then be used to mold or more components. For example, a negative of an uninflated exterior wall as described further herein can be printed using a 3D printer and then used to cast the exterior wall, *e.g.*, with an elastomer such as polyurethane.

Vaginal Stents

Referring now to FIG. 2A, another aspect of the invention provide a vaginal stent 200 that can be inserted into a subject's vagina and inflated to a desired size to achieve a medical goal. The vaginal stent 200 includes an elastomeric exterior wall 202 and a fitting 204 located at the base of the vaginal stent 200. When inflated, the stent 200 can be rigid enough to retain shape and vaginal wall support despite movement and valsalva. The stent 200 can be inserted intraoperatively, remain *in situ*, and be progressively inflated until removal at a later date when healing occurs.

The fitting 204 can be adapted and configured to receive a fluid (either gas or liquid) to inflate the elastomeric exterior wall 202 to a desired level and/or shape. In one embodiment, the fitting 204 is a Luer-lock-style fitting.

A central core 206 can maintain the length of and facilitate insertion of the stent 200 into the subject's vagina prior to inflation. The central core 206 can be pliable, while also having rebound and shape memory. The central core 206 can be fabricated from rubbers, plastics, or metals. In one embodiment, the central core 206 has a plurality of holes to facilitate flow of fluid into the region bound by the elastomeric exterior wall 202. In some embodiments, the inner core 206 is perforated or is a plastic mesh.

Insertion and removal of vaginal stents can be challenging and/or uncomfortable for many patients and particularly for children and adolescents. In order to address this discomfort, embodiments of the invention can utilize a removable handle 208 as depicted in FIG. 2B. One or more of the removable handle 208 and the vaginal stent 200 can include one or more magnets (*e.g.*, 4 or 8) such as rare-earth magnets. In some embodiments, the magnets can have sufficient strength to pull the vaginal stent 200 from the subject's vagina when the subject holds the removable handle 208 adjacent or proximal to the subject's perineum. Without being bound by theory, it is believed that between about 0 pounds and about 26 pounds of force (*e.g.*, between about 0 pounds and about 5 pounds, between about 5 pounds and about 10 pounds, between about 10 pounds and about 15 pounds, between about 15 pounds and about 20 pounds, between about 20 pounds and about 26 pounds, and the like) would be sufficient to remove a deflated vaginal stent from a typical subject's vagina and that sufficient force can be generated across the perineum using magnets.

In order to further minimize user discomfort, the removable handle can facilitate inflation and/or deflation of the magnetic stent. For example, the vaginal stent 200 can include one or more fittings located on a base that engages with the removable handle 208 and the removable handle 208 can include a complementary second fitting. For example, the fittings can be located centrally to a plurality of radially-arranged magnets and/or ferromagnetic materials so that fittings will be aligned by magnetic forces. Once the vaginal stent 200, the removable handle 208, and the fittings therein are engaged, fluid can flow from the removable handle into the vaginal stent 200 for inflation. One or more valves (*e.g.*, one-way or check valves) can seal the vaginal stent 200 against fluid leakage. In one embodiment, one or more of the one or more valves can be magnetically-actuated, preferably at a relatively low magnetic force so that the vaginal stent 200 will deflate as the removable handle 208 approaches the perineum and prior to the application of sufficient forces to move and extract the vaginal stent 200. In some embodiments, the removable handle 208 can include a pressure gauge to provide feedback to the subject regarding the degree of inflation of the coupled vaginal stent.

Referring now to FIGS. 3A and 3B, side and top views of the core 206 are provided showing the perforations in the outer wall and the hollow center and ends that allow for passage of vaginal secretions. FIGS. 3C-3E provide cross-sectional views of the core. FIG. 3E provides exemplary dimensions in millimeters.

Vaginal Dilator

Referring now to FIG. 4A, another aspect of the invention provides vaginal dilators 400a, 400b, 400c that can be composed of a rigid, durable plastic material shaped as a tapered hollow capsule. Various sizes can be produced. For example, dilator 400a has a diameter of about 20 mm and a length of about 70 mm, dilator 400b has a diameter of about 15 mm and a length of about 65 mm, and dilator 400c has a diameter of about 10 mm and a length of about 60 mm. Any of the vaginal dilators disclosed herein may comprise a hollow channel for extrusion of fluid from the vagina as shown in FIG. 4A. In certain embodiments, the channel runs along the entire length of the vaginal dialator. The diameter of the channel is not restricted to any particular diameter, but should be sufficient for fluid to enter the channel and, in certain embodiments, to pass through the dilator.

Referring now to FIGS. 4B and 4C, in some embodiments, the vaginal dilator(s) 400 include or are compatible with the use of magnets 410 for engagement with a removable

handle 208 for insertion and/or removable. The arrangement of four magnets 410 at 90° radial intervals is depicted in FIG. 4D. In some embodiments, the removable handle 208 is compatible with both the vaginal stents 200 and the vaginal dilators 400.

EQUIVALENTS

Although preferred embodiments of the invention have been described using specific terms, such description is for illustrative purposes only, and it is to be understood that changes and variations may be made without departing from the spirit or scope of the following claims.

INCORPORATION BY REFERENCE

The entire contents of all patents, published patent applications, and other references cited herein are hereby expressly incorporated herein in their entireties by reference.

CLAIMS

1. A vaginal stent system comprising:

an inflatable vaginal stent comprising:

an elastomeric exterior wall; and

a first fitting located at a base of the inflatable vaginal stent; and

a removable handle adapted and configured for insertion, inflation, and removal of the inflatable vaginal stent from a subject's vagina, the removable handle including a second fitting complementary to the first fitting and adapted and configure to form substantially fluid tight coupling when the handle is coupled to the inflatable vaginal stent.

2. The vaginal stent of claim 1, wherein at least one of the inflatable vaginal stent and the removable handle include one or more magnets.

3. The vaginal stent of claim 2, wherein the inflatable vaginal stent includes a magnetically-actuatable valve adapted and configured to deflate the inflatable vaginal stent when the removable handle is placed in proximity to a base of the inflatable vaginal stent.

4. The vaginal stent of claim 2, wherein the one or more magnets have sufficient strength to remove the inflatable vaginal stent from a subject's vagina by placing the removable handle proximate to the subject's perineum.

5. A vaginal dilator system comprising:

a vaginal dilator including:

an exterior wall; and

a hollow channel extending the length of the vaginal stent; and

a removable handle adapted and configured for insertion and removal of the inflatable vaginal stent from a subject's vagina.

6. The vaginal dilator system of claim 5, wherein at least one of the vaginal dilator and the removable handle include one or more magnets.

7. The vaginal dilator of claim 6, wherein the one or more magnets have sufficient strength to remove the inflatable vaginal stent from a subject's vagina by placing the removable handle proximate to the subject's perineum.

8. A method of fabricating a customized vaginal stent or dilator, the method comprising:
generating a 3D model of a vaginal stent or dilator; and
controlling a 3D printer to fabricate a vaginal stent or dilator according to the 3D model.

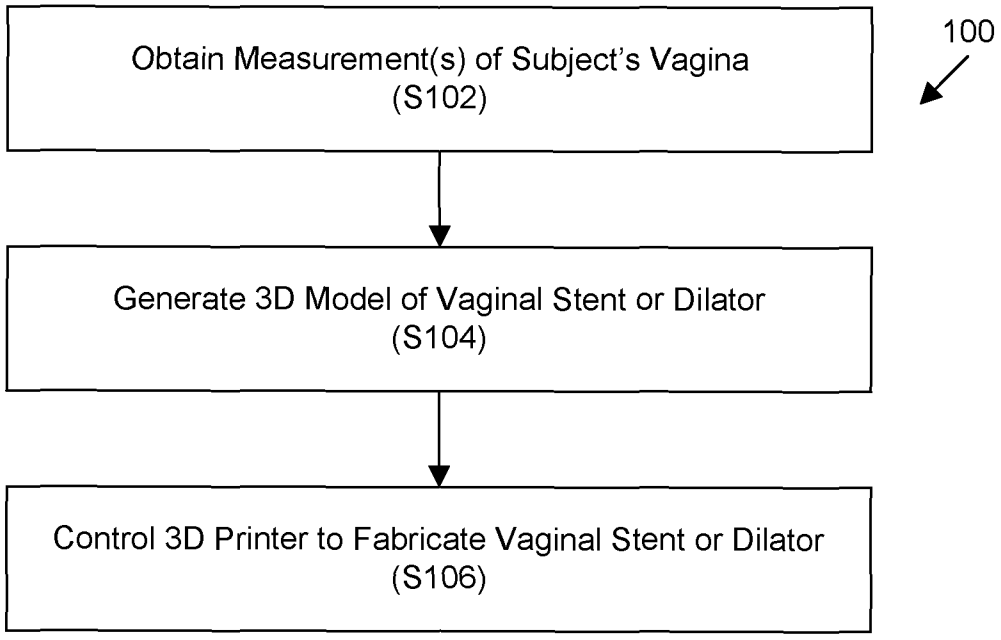

Obtain Measurement(s) of Subject's Vagina
(S102)
100
Generate 3D Model of Vaginal Stent or Dilator
(S104)
Control 3D Printer to Fabricate Vaginal Stent or Dilator
(S106)

FIG. 1

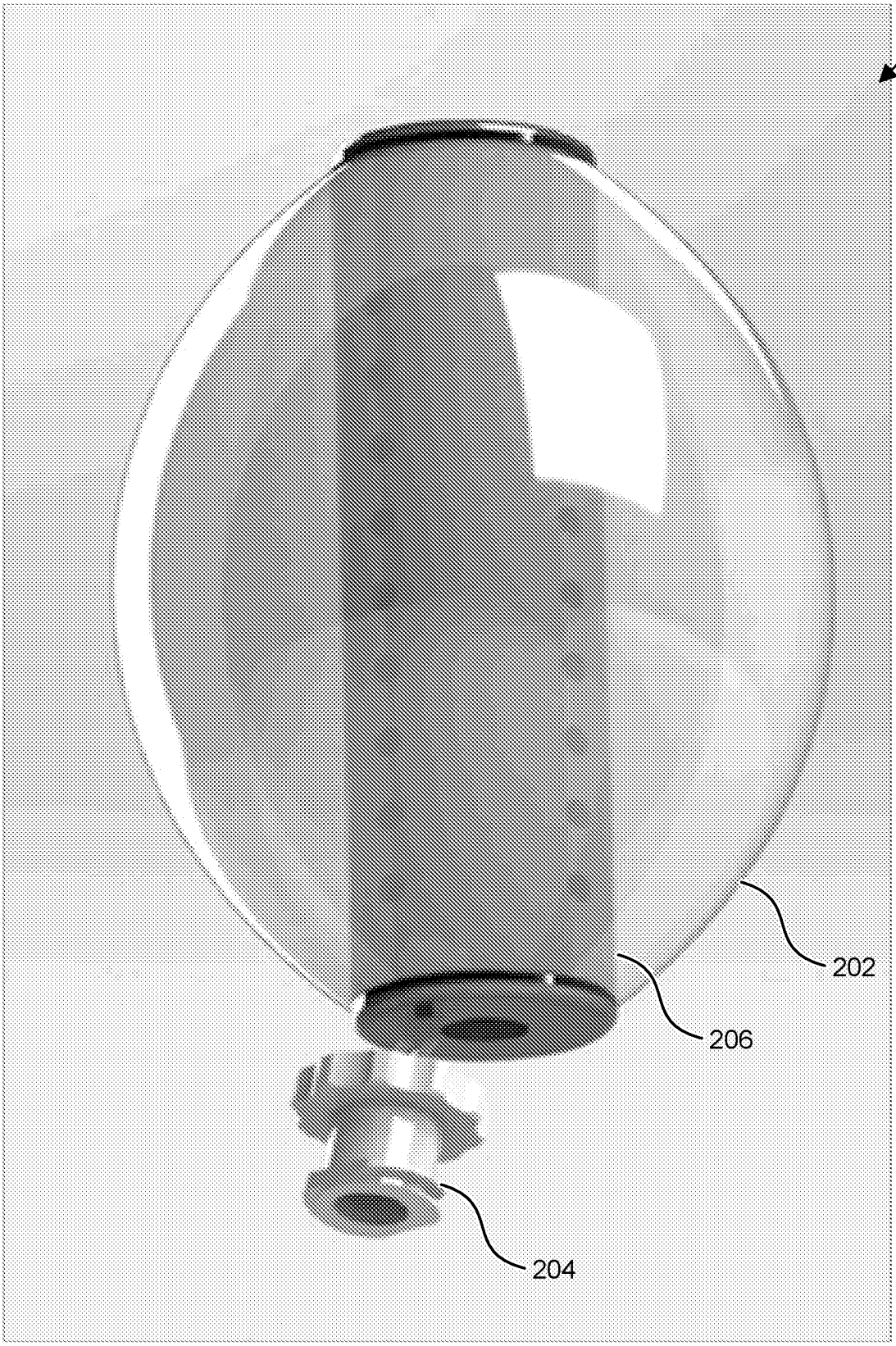


FIG. 2A

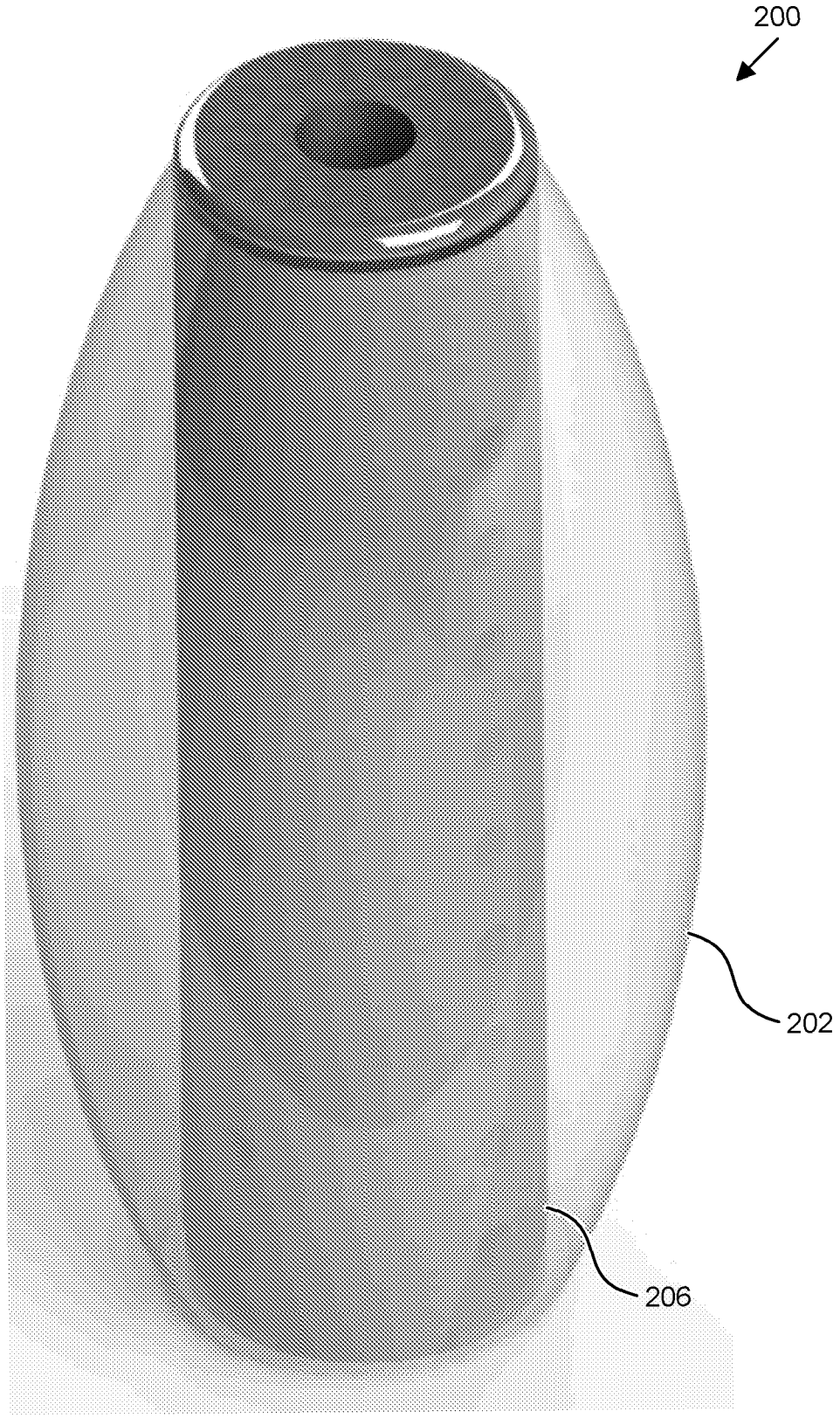


FIG. 2B

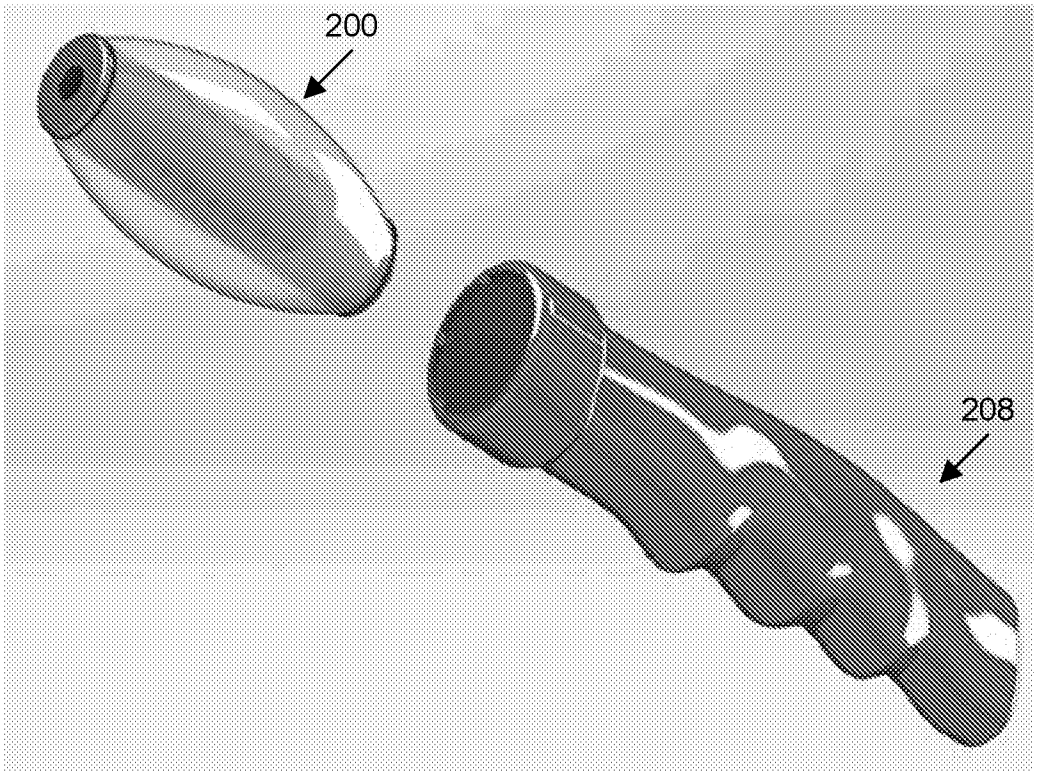


FIG. 2C

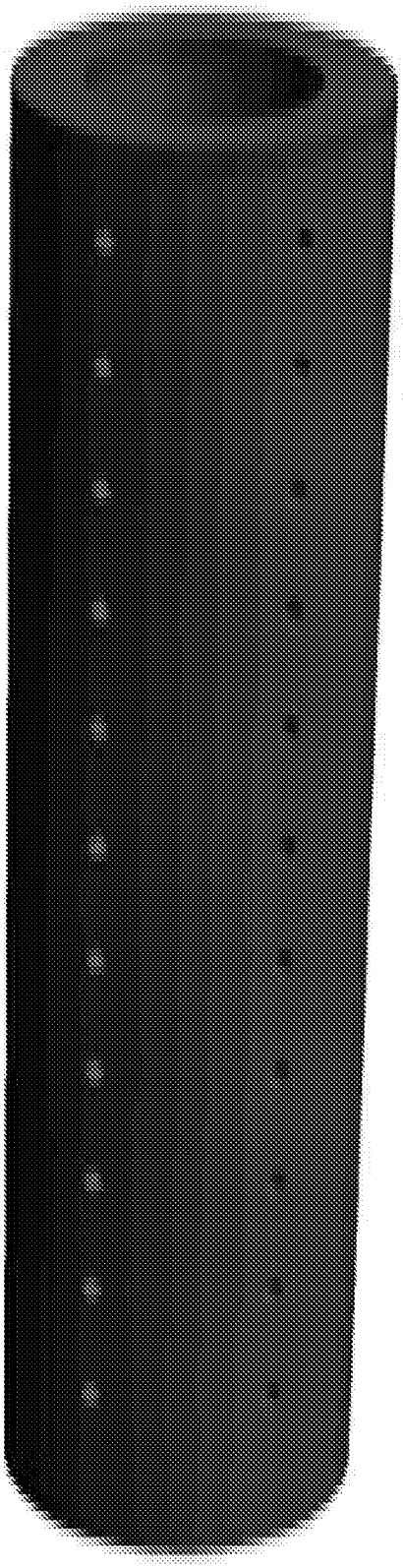


FIG. 3A



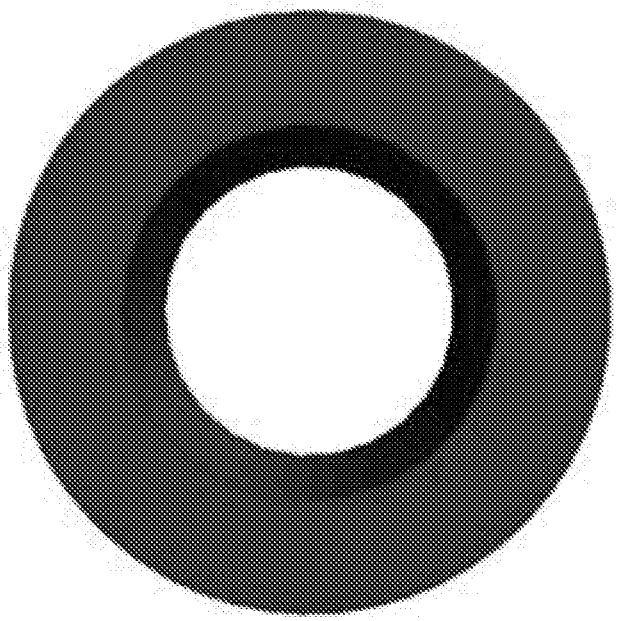


FIG. 3B

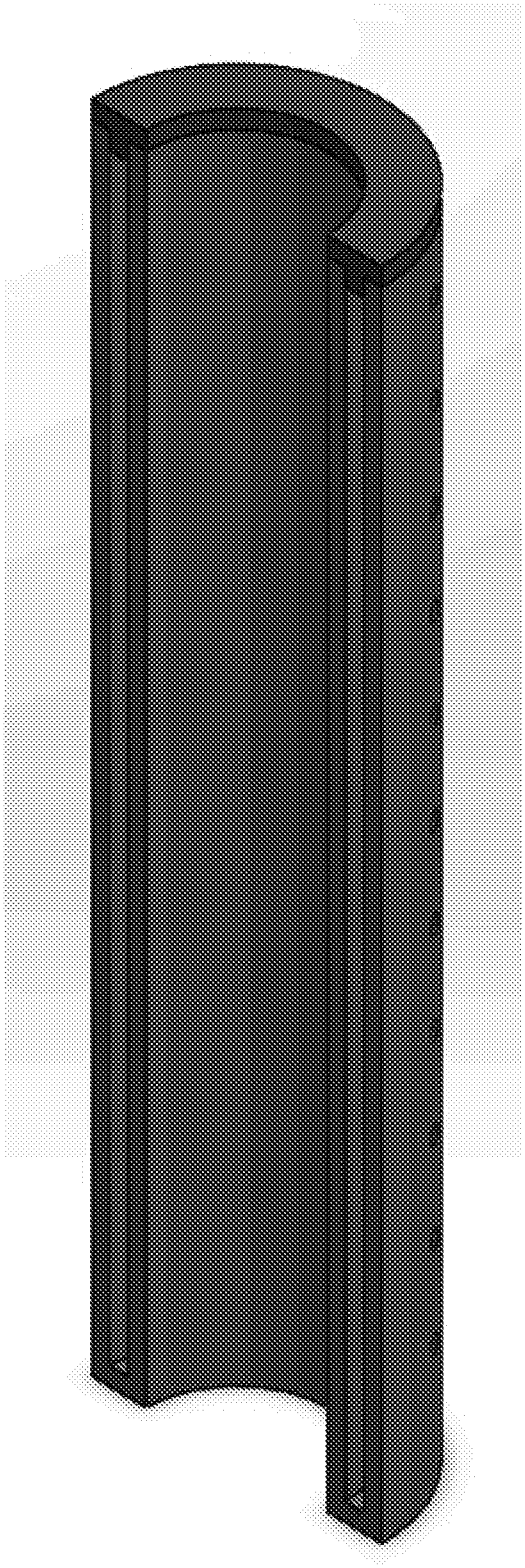


FIG. 3C

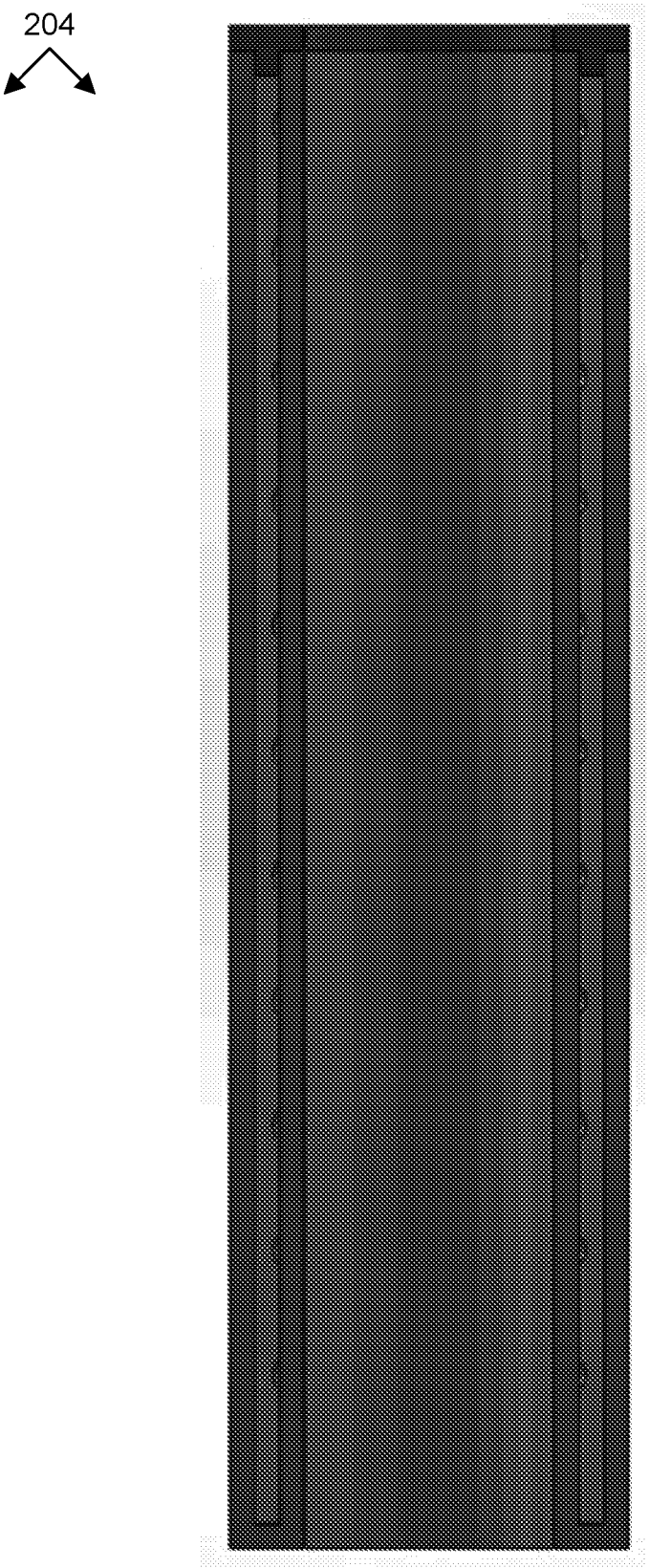


FIG. 3D

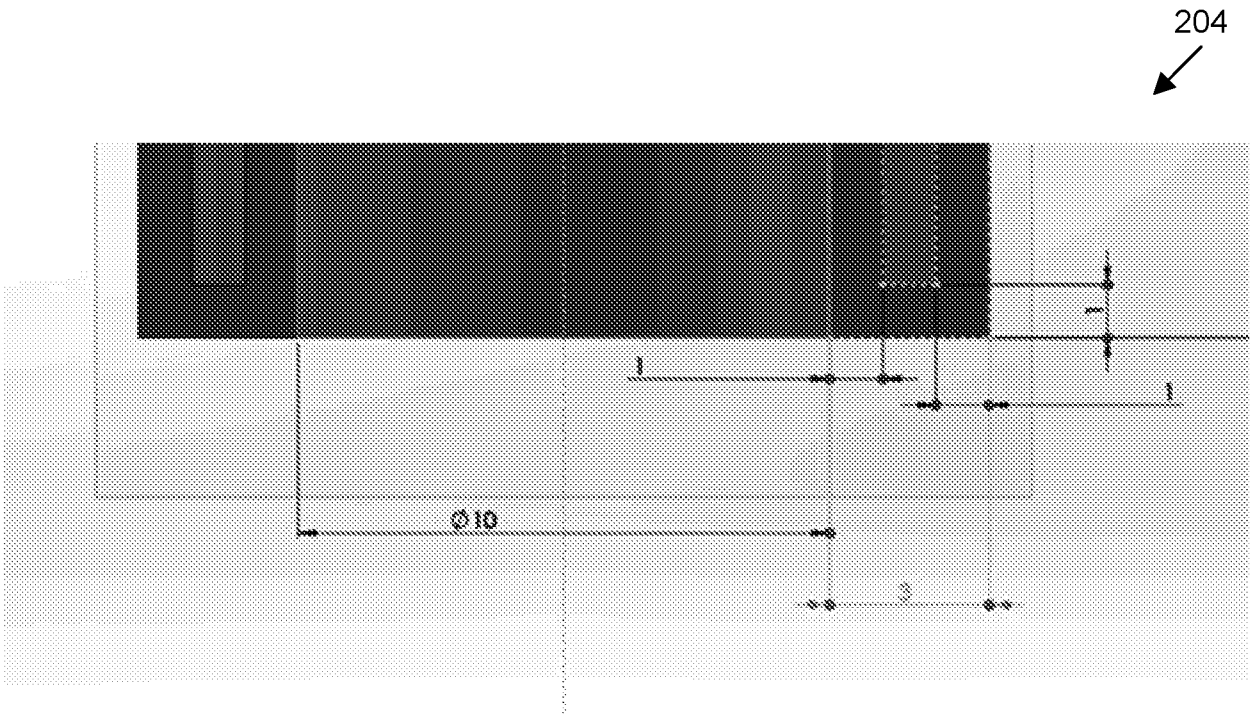


FIG. 3E

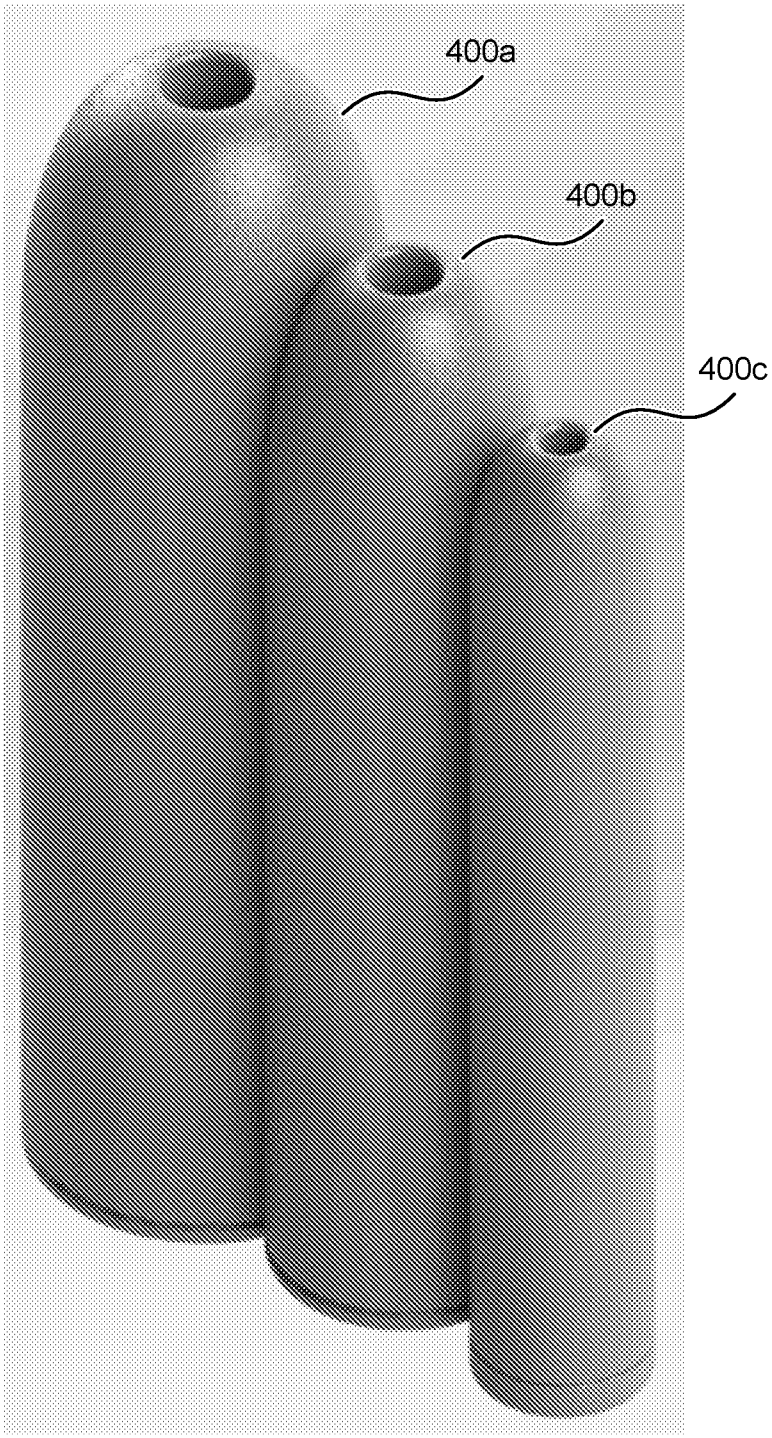


FIG. 4A

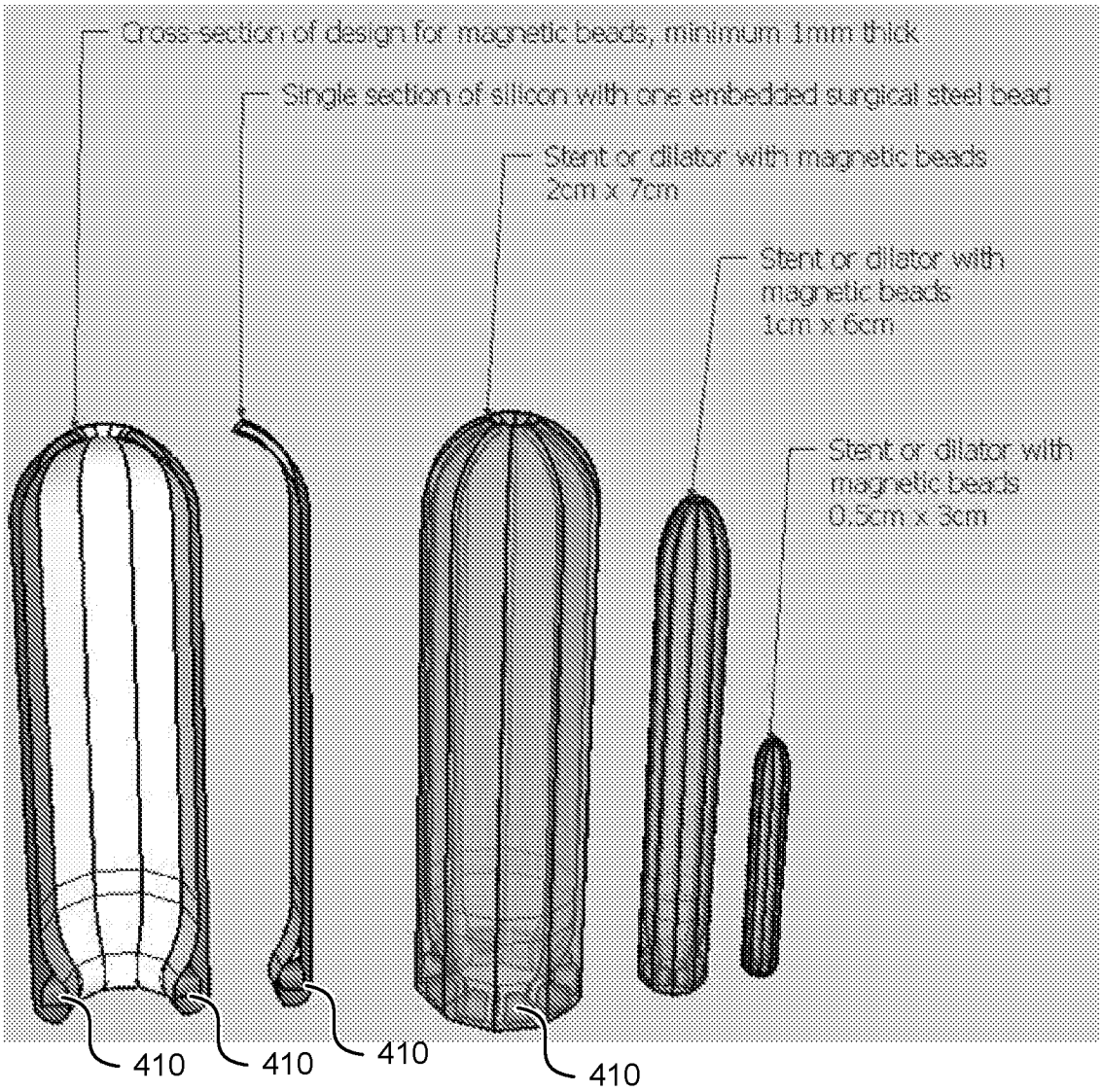

Cross-section of design for magnetic beads, minimum 1mm thick
Single section of silicon with one embedded surgical steel bead
Stent or dilator with magnetic beads
2cm x 7cm
Stent or dilator with
magnetic beads
1cm x 6cm
Stent or dilator with
magnetic beads
0.5cm x 3cm
410
410
410
410

FIG. 4B

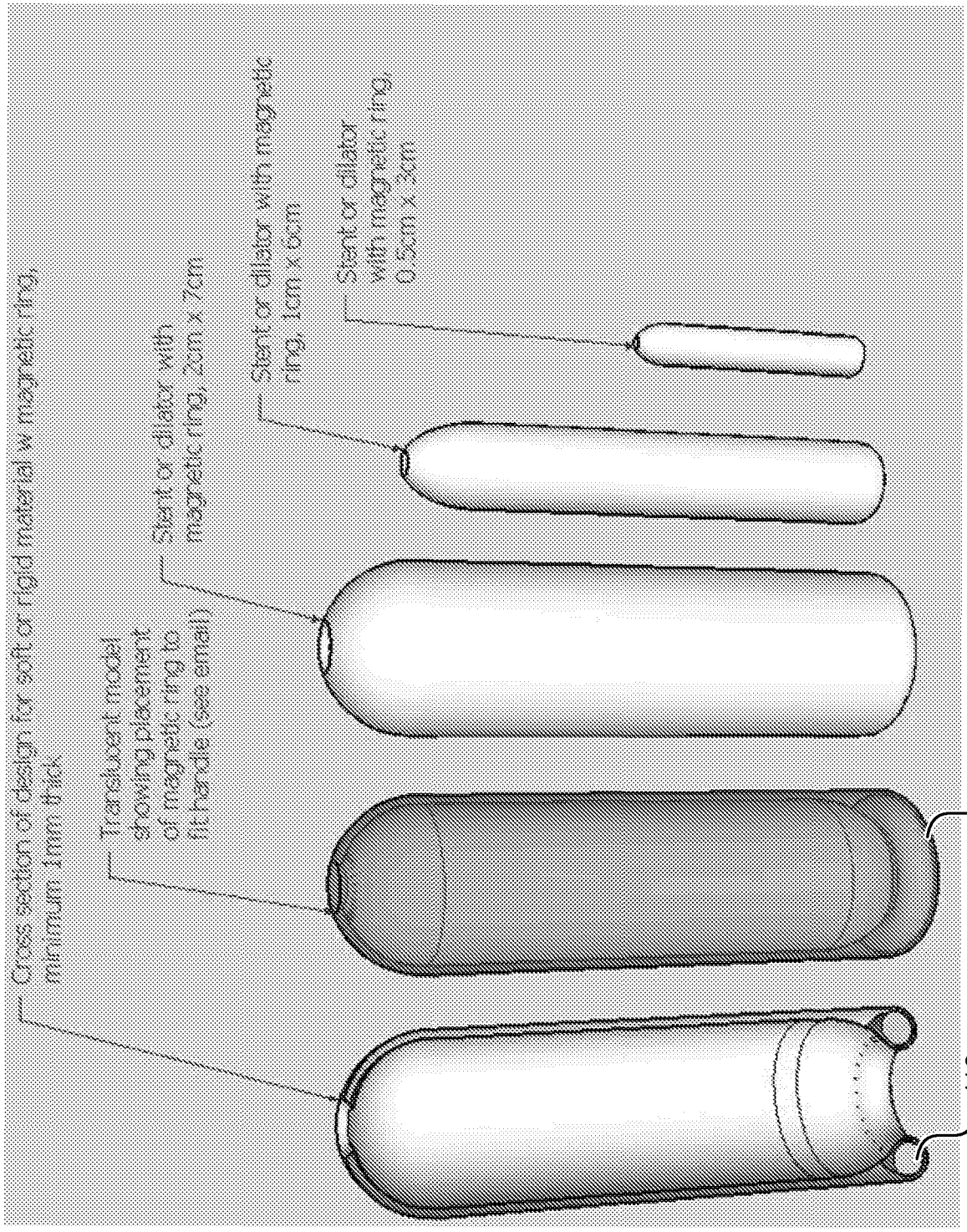

Cross section of dilator or sheath of rigid material with magnetic ring, minimum 1mm thick
Translucent model showing placement of magnetic plug to fit handle (see email)
Stent or dilator with magnetic ring, 20cm x 7cm
Stent or dilator with magnetic ring, 1cm x 6cm
Stent or dilator with magnetic ring, 0.5cm x 3cm
410
410

FIG. 4C

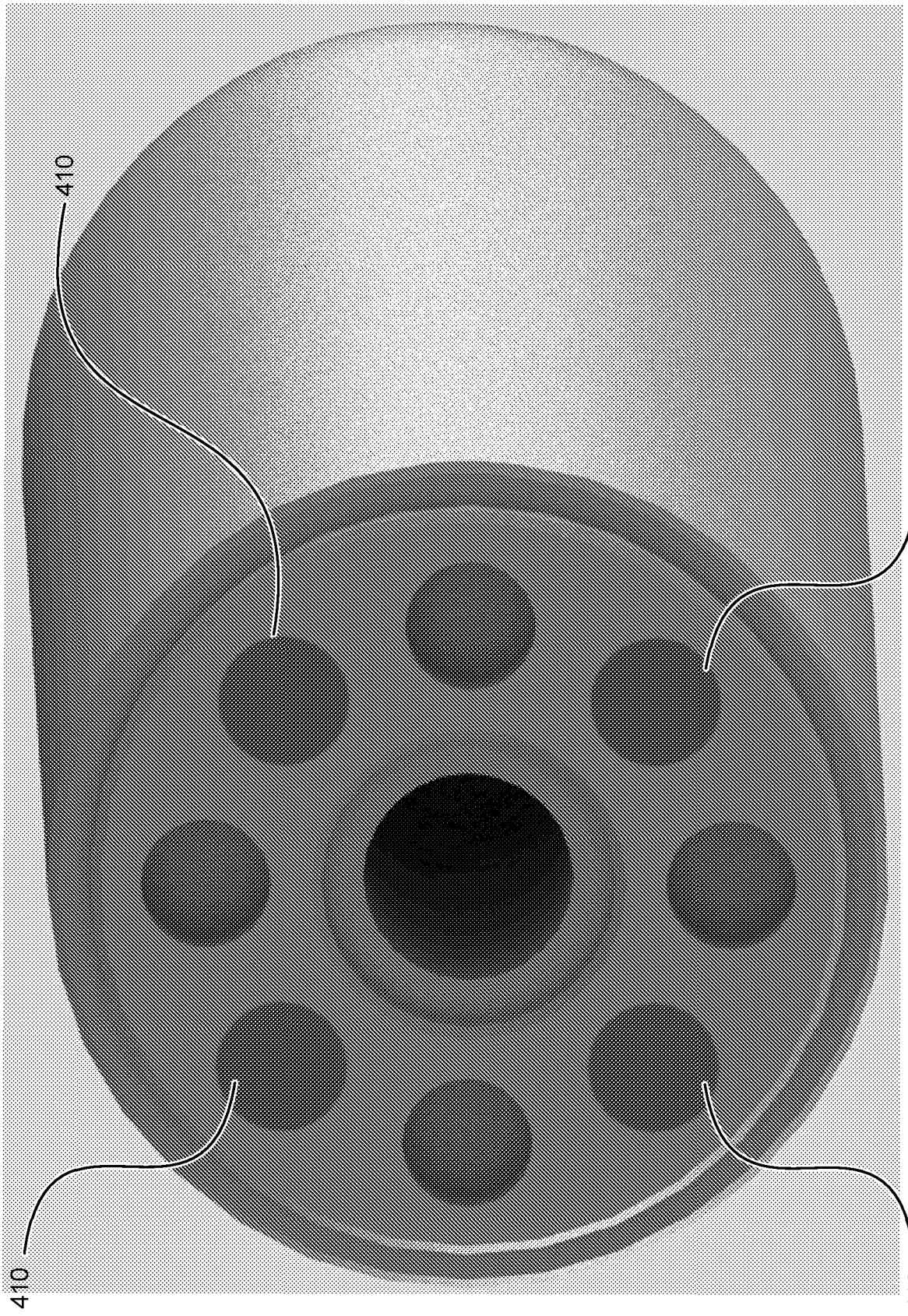


FIG. 4D

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/25826

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 29/02 (2016.01)
CPC - A61M 29/02
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)
IPC(8) : A61M 29/02 (2016.01)
CPC : A61M 29/02

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC(8) : A61M 29/00; A61B 17/00, 17/42 (2016.01)
CPC: A61M 29/00; A61B 17/00, 17/42

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Patbase, Google Patent, Google Scholar: vagina, stent, dilator, splint, balloon, attach, remove, detach, couple, join, handle, grip, inflate, pneumatic, magnet, valve, 3d printing, rapid prototyping, customized

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	DE 3800744 C1 (KAMPMANN) 03 May 1989 (03.05.1989) see especially col 2, ln 60 to col 3, ln 4, col 3, ln 20-54, fig 1, 2 and machine translation	1, 5 --- 2-4, 6-7
X --- Y	US 2005/0021069 A1 (FEUER et al) 27 January 2005 (27.01.2005) see especially para [0045], [0058], [0071], [0076], [0077], [0097], [0098], fig 12A-C, 16A-C	5 --- 1
X	WO 2015/013716 A1 (THE REGENTS OF THE UNIVERSITY OF CALIFORNIA) 29 January 2015 (29.01.2015) see especially para [0017], [0020], [0064], [0092], [0100], [0111], fig 16, 20	8
Y	US 2010/0082057 A1 (BORKON) 01 April 2010 (01.04.2010) see especially para [0033]	1
Y	US 2007/0043388 A1 (GREENWOOD) 22 February 2007 (22.02.2007) see especially para [0051], [0064], [0082], fig 5	2-4, 6-7
Y	US 2014/0200605 A1 (JONES et al) 17 July 2014 (17.07.2014) see especially para [0119]	3
A,P	US 2015/0170416 A1 (McGREGOR et al) 18 June 2015 (18.06.2015) see whole document	1-8
A	US 2004/0030352 A1 (McGLOUGHLIN et al) 12 February 2004 (12.02.2004) see whole document	1-8
A	US 6,224,580 B1 (CHRISTENSEN) 01 May 2001 (01.05.2001) see whole document	1-8
A	US 5,716,329 A (DIETER) 10 February 1998 (10.02.1998) see whole document	1-8

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

* 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
19 May 2016	22 JUL 2016
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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