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(54) Title: URETHRAL IMPLANT

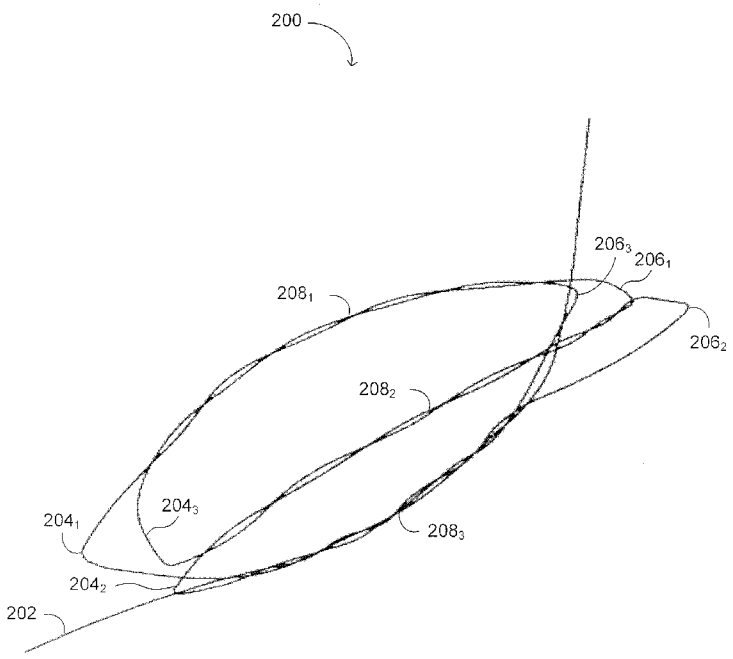

FIG. 3

(57) Abstract: A urethral-implant configured to be implanted within a restricted location of a urethra, the urethral-implant, forming at least one closed-shape by coiling ends of the single wire section on each other, the closed-shape including a distal section, a proximal section and two lateral sections extending between the proximal section and the distal section, the closed-shape exhibiting an expanded configuration and foldable into a compressed configuration, the urethral-implant further configured to extend from the compressed configuration to the expanded configuration such that the distance between sections of the wire increases, relative to the distance between the sections of the wire in the compressed configuration, the urethral-implant being for applying continuous pressure on surrounding tissue thereby applying continuous radial pressure on at least one of a urethral wall and tissue surrounding the urethral wall, the radial pressure being sufficient to cause either a widening effect, extending a urinal passage or inducing infarction.

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[Continued on next page]

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URETHRAL IMPLANT

FIELD OF THE DISCLOSED TECHNIQUE

The disclosed technique relates to implants, in general, and to urethral implants produced from a single wire section, in particular.

BACKGROUND OF THE DISCLOSED TECHNIQUE

The urethra is the tube that carries the urine from the bladder to the external urethral orifice, to remove the urine from the body. In some cases, the urethra may be partially or fully blocked due to conditions such as prostate enlargement or urethral stricture, resulting in conditions such as Benign Prostatic Hyperplasia (BPH), prostatic Bladder Neck Obstruction (BNO) and the like, and the flow of fluids in the urethra is restricted and even blocked. Such a partial or full block of the urethra may cause discomfort and pain and may even result in infections.

Transurethral incision of the prostate (TUIP) is an endoscopic procedure usually performed under general anaesthetic in which a surgeon employs an instrument (e.g., a scalpel, a laser beam generator and an electrical current actuator) inserted into the urethra for making incisions in the bladder neck where the prostate meets the bladder (i.e., more specifically in the midline to the level of the verumontanum). Incising the muscles in the bladder neck area relieves the obstructive effect of the prostate on the bladder neck and prostatic urethra and relaxes the opening of the bladder, thus decreasing resistance to the flow of urine out of the bladder. It is noted that, no tissue is removed during TUIP.

Infarction is a process resulting in a macroscopic area of necrotic tissue in some organ caused by loss of adequate blood supply. The inadequate blood supply can result from pressure applied to the blood vessels. Even by applying a relative small but continuous pressure on a

tissue, one can block the tiny blood vessels within the tissue and induce infarction.

Know in the art are implants which are inserted through the urethral orifice, in a compressed state to the blocked section of the urethra. When positioned in the blocked section of the urethra, the implant expands and widens the blocked section thus enabling the flow of fluids through the urethra. PCT Patent Application Publication WO 2006/040767 A1, to Kilemnik, and entitled "Prostate Treatment Stent" is directed at a tissue dissecting implant. The implant is spring-shaped and includes a plurality of rings elastically coupled there-between. Adjacent rings apply pressure on tissues caught between the rings, thereby pinching the caught tissues and inducing necrosis.

US Patent Application Publication No. 2011/0276081 to Kilemnik, and entitled "Radial Cutter Implant" is directed at an implant for applying radial forces on the tissues surrounding it. The implant includes wires for applying radial pressure on the surrounding tissues. Each of the wires extends in a different radial direction, and therefore, each wire applies pressure on different tissues. The implant can further include a longitudinal central tube, such that the wires are coupled with a proximal end and a distal end of the tube. The tube supports the wires and provides structural stability to the implant. The distal end of the wires is positioned within the bladder of the subject, and may irritate the bladder.

US Patent No. 5,209,725 issued to Roth, and entitled "Prostatic Urethra Dilatation Catheter System and Method", is directed to an instrument for performing a transurethral balloon dilatation procedure of the prostate. The balloon dilatation instrument includes a hollow catheter and optical viewing means. The hollow catheter includes a shaft, an inflatable optically transparent balloon, and at least one suitable visible marking. The distal end portion of the shaft is made of an optically transparent material. The inflatable optically transparent balloon is

coupled with the distal end portion of the shaft, and is sized to dilate the prostatic urethra. The at least one suitable visible marking is positioned on the catheter proximally to the balloon, such that the marking can be visualized relative to a predetermined anatomical landmark (e.g., verumon tanum). In this manner, proper positioning of the balloon, relative to the prostatic urethra, is performed prior to and during the dilation of the prostatic urethra. The optical viewing means, is slidable within the catheter, for visibly viewing the marking intra-luminally from within the catheter. The balloon is correctly located relative to the prostatic urethra. The balloon is inflated so as to dilate the prostatic urethra without damaging the external sphincter at the apex of the prostate.

US Patent No. 5,499,994 issued to Tihon et al., and entitled "Dilation Device for the Urethra", is directed to a dilation device for opening a portion of an obstructed urethra. The dilation device includes an inner hollow tubular core and an outer confining covering. The inner hollow tubular core defines a lumen therein. The lumen is a conduit of sufficient diameter to permit urine to flow freely there-through from the bladder. The core is substantially non-collapsible. The outer confining covering is capable of expanding radially outwardly to a predetermined extent. The covering has a length of at least partially that of the obstructed portion of the urethra. The dilation device can further include retractable spikes for anchoring the device in its intended position.

SUMMARY OF THE PRESENT DISCLOSED TECHNIQUE

A urethral implant configured to be implanted within a restricted location of a urethra. The urethral implant, forms at least one closed shape by coiling ends of the single wire section on each other. The at least one closed shape includes a distal section, a proximal section and two lateral sections extending between the proximal section and the distal section. The at least one closed shape exhibits an expanded configuration and is foldable into a compressed configuration. The urethral implant further being configured to extend from the compressed configuration to the expanded configuration such that the distance between sections of the wire increases, relative to the distance between the sections of the wire in the compressed configuration. The urethral implant being for applying continuous pressure on surrounding tissue, thereby applying continuous radial pressure on at least one of a urethral wall and tissue surrounding the urethral wall in the restricted location. The radial pressure being sufficient to cause at least one of, a widening effect, extending a urinal passage, and inducing infarction.

BRIEF DESCRIPTION OF THE DRAWINGS

The disclosed technique will be understood and appreciated more fully from the following detailed description taken in conjunction with the drawings in which:

Figure 1 is a schematic illustration of a urethral implant, constructed and operative in accordance with an embodiment of the disclosed technique;

Figure 2 is a schematic illustration of a urethral implant, constructed and operative in accordance with another embodiment of the disclosed technique;

Figure 3 is a schematic illustration of a urethral implant, constructed and operative in accordance with a further embodiment of the disclosed technique;

Figure 4 is a schematic illustration of a urethral implant, constructed and operative in accordance with another embodiment of the disclosed technique;

Figures 5A-5C are schematic illustrations of deployment of a urethral, operative in accordance with a further embodiment of the disclosed technique;

Figures 6A-6E are schematic illustrations of a urethral implant, constructed and operative in accordance with another embodiment of the disclosed technique; and

Figures 7A-7C are schematic illustrations of a urethral implant, constructed and operative in accordance with another embodiment of the disclosed technique.

DETAILED DESCRIPTION OF THE EMBODIMENTS

The disclosed technique overcomes the disadvantages of the prior art by providing a urethral implant for applying continuous pressure on the surrounding tissue, thereby causing ischemia, which results in necrosis. The urethral implant is made of a single wire section, forming at least one closed shape which includes a distal section, a proximal section and two lateral sections extending between the proximal section and the distal section. The closed shape exhibits an expanded configuration and is foldable into a compressed configuration. The urethral implant is further configured to extend from the compressed configuration to the expanded configuration such that the distance between sections of said wire increases, relative to the distance between these sections in the compressed configuration. The urethral is configured to be implanted within urethra. For example, the urethral implant may be implanted at a urethral stricture location, for applying pressure on the surrounding tissue (i.e., the inner wall) of the urethra, thereby causing ischemia at the stricture location, which results in necrosis and the widening of the urethra, allowing fluid to flow through the urethra. The urethral implant may include at least two closed shapes where each closed shape has a proximal section, a distal section and two lateral sections extending between the respective proximal section and the distal section. Adjacent pairs of the at least two closed shapes share at least one common lateral section.

Reference is now made to Figure 1, which is a schematic illustration of a urethral implant, generally referenced 100, constructed and operative in accordance with an embodiment of the disclosed technique. Urethral implant 100 is made of a single wire section 102, forming a closed shape, which includes a distal section 104, a proximal section 106 and two lateral sections 108_1 and 108_2 extending between distal section

104 and the proximal section 106. Urethral implant 100 is formed by creating the closed shape with wire 102 and then coiling wire 102 on itself.

Reference is now made to Figure 2, which is a schematic illustration of a urethral implant, generally referenced 150, constructed and operative in accordance with another embodiment of the disclosed technique. Urethral implant 150 is made of a single wire section 152, forming two closed shapes. The first closed shape includes a distal section 154_1, a proximal section 156_1 and two lateral sections 158_1 and 158_2 extending between distal section 154_1 and the proximal section 156_1. The second closed shape includes a distal section 154_2, a proximal section 156_2 and two lateral sections 158_2 and 158_3 extending between distal section 154_2 and the proximal section 156_2. Lateral section 158_2 is a common lateral section between the two closed shapes. Urethral implant 150 is formed by first creating the first closed shape with wire 152 and then coiling wire 152 on itself. Coiling wire 152 on itself creates to wire end extensions of wires section 152. Then, the second closed shape is formed from the two wire end extensions of wire 152 and coiling the two wire end extensions of wire 152 one with the other.

Reference is now made to Figure 3, which is a schematic illustration of a urethral implant, generally referenced 200, constructed and operative in accordance with a further embodiment of the disclosed technique. Urethral implant 200 is made of a single wire 202, forming three closed shapes. The first closed shape includes a distal section 204_1, a proximal section 206_1 and two lateral sections 208_1 and 208_2 extending between distal section 204_1 and the proximal section 206_1. The second closed shape includes a distal section 204_2, a proximal section 206_2 and two lateral sections 208_2 and 208_3 extending between distal section 204_2 and the proximal section 206_2. The third closed shape includes a distal section 204_3, a proximal section 206_3 and two lateral sections 208_3 and 208_1 extending between distal section 204_3 and the

proximal section 206_3. Thus, lateral section 208_1 is common to the first and the third closed shapes. Thus, lateral section 208_2 is common to the first and the second closed shapes and lateral section 208_2 is common to the second and the third closed shapes.

Urethral implant 200 is formed by first creating the first closed shape with wire 202 and then coiling wire 202 on itself forming lateral sections 208_1 and 208_2 similar to as described above in conjunction with Figure 1. Then, the second closed shape is formed with the wire end extensions of wire 202 and coiling the two extensions of wire 202 one with the other, similar to as described above in conjunction with Figure 2, thus forming lateral section 208_3. The third closed shape is formed with the two wire end extensions of wire 202, by coiling the two wire end extension of wire 202 on lateral section 208_1.

Reference is now made to Figure 4, which is a schematic illustration of a urethral implant, generally referenced 250, constructed and operative in accordance with another embodiment of the disclosed technique. Urethral implant 250 is similar in construction form and functionality to urethral implant 200 (Figure 3).

Each of the single wire urethral implants 100, 150, 200 and 250 described hereinabove is made from materials such as stainless steel or Shape Memory Alloy (SMA), such as Nickel Titanium alloy (Nitinol). The transition between the compressed configuration to the expanded configuration occurs due to the elastic (i.e., spring like) characteristics of the material. Each of the single wire urethral implants 100, 150, 200 and 250 described hereinabove may be wider at the proximal end than at the distal end thereof for preventing said removable implant from moving in the distal direction. Alternatively, Each of the single wire urethral implants 100, 150, 200 and 250 described hereinabove may be wider at the distal end than at the proximal end thereof for preventing said removable implant from moving in the proximal direction. According to yet another

alternative, each of the single wire urethral implants 100, 150, 200 and 250 described hereinabove may be narrower at the middle thereof than at the distal and proximal portions thereof, for preventing said removable implant from moving in the proximal direction and in the distal direction. According to yet another alternative, each of the single wire urethral implants 100, 150, 200 and 250 described hereinabove may exhibit the shape of a butterfly wing.

Reference is now made to Figures 5A-5C which are schematic illustrations of deployment of a urethral implant 300, operative in accordance with a further embodiment of the disclosed technique. Initially, urethral implant is in a compressed configuration and is located within an overtube 302 also referred to as a restrainer. Overtube 302, with urethral implant 300 compressed therein is inserted into the urethra 304, until urethral implant 300 is aligned with a stricture 306 (Figure 5B). Thereafter, overtube 302 is pulled over urethral implant 300. Once overtube 302 is removed from over urethral implant 300, urethral implant 300 expands to the expanded configuration thereof (Figure 5C). As urethral implant extends from the compressed configuration to the expanded configuration, urethral implant 300 applies a force on stricture 306. As a result, urethral implant 300 applies pressure on the necrosis or scar tissue at stricture 306 thereby dissecting the necrosis or scar tissue and widening urethra 304 at the stricture location. After the treatment, the implant may be pulled out of urethra 304 by reinserting overtube 302 and pulling on lead wire 308 to reinsert urethral 304 into over tube 302. Over tube 302 is then pulled out of urethra. Alternatively, urethral implant 300 may be pulled out of urethra 304 directly by pulling on lead wire 308 (i.e., without reinserting overtube 302). In Figures 5A-5C, urethral implant 300 includes a concave portion in at least one of the lateral sections thereof. In the expanded configuration, tissue fills this concave portion, thereby anchoring urethral implant in position.

The exemplary urethral implants described hereinabove are made of a single wire and exhibit a "closed loop configuration". In a "closed loop configuration", all the lateral sections are connect to both the proximal and the distal sections. However, the urethral implants according to the disclosed technique may also exhibit an "open loop configuration", where at least one of the lateral sections is connected only to the proximal section or only to the distal section. Also, the urethral implants according to the disclosed technique may be cut out of a metal sheet or tube.

Reference is now made to Figures 6A-6E, which are schematic illustrations of a urethral implant, generally referenced 320, constructed and operative in accordance with another embodiment of the disclosed technique. Urethral implant 320 includes three lateral sections 322, 324 and 326 arranged in a closed loop configuration (i.e., lateral sections 322, 324 and 326 are connected to proximal section and the distal section of urethral implant 320). Urethral implant 320 is cut out from a metal sheet or tube. Figure 6A depicts a top view of urethral implant 320 in a compressed configuration. Figure 6B, depicts cross-section B-B of urethral implant 320 in the compressed configuration. Figure 6C depicts an isometric view of urethral implant 320 in a compressed configuration. Figure 6D depicts an isometric view of urethral implant 320 in an expanded configuration. Figure 6E, depicts cross-section A-A of urethral implant 320 in the expanded configuration.

Reference is now made to Figures 7A-7C, which are schematic illustrations of a urethral implant, generally referenced 350, constructed and operative in accordance with a further embodiment of the disclosed technique. Urethral implant 350 includes three lateral sections 352, 354 and 356 arranged in an open loop configuration (i.e., where at least one of the lateral sections is connected only to the proximal section or only to the distal section). Figure Urethral implant 350, lateral section 356 is

connected only to the proximal section. Urethral implant 350 is also cut out from a metal sheet or tube. Figure 7A depicts a top view of urethral implant 350 in a compressed configuration. Figure 7B depicts an isometric view of urethral implant 350 in an expanded configuration. Figure 7c depicts a side view of urethral implant 350 in the expanded configuration.

It will be appreciated by persons skilled in the art that the disclosed technique is not limited to what has been particularly shown and described hereinabove. Rather the scope of the disclosed technique is defined only by the claims, which follow.

CLAIMS

1. A urethral implant configured to be implanted within a restricted location of a urethra, said urethral implant, forming at least one closed shape by coiling ends of said single wire section on each other, said at least one closed shape including a distal section, a proximal section and two lateral sections extending between the proximal section and the distal section, said at least one closed shape exhibiting an expanded configuration and is foldable into a compressed configuration, said urethral implant further being configured to extend from said compressed configuration to said expanded configuration such that the distance between sections of said wire increases, relative to the distance between said sections of said wire in said compressed configuration, said urethral implant being for applying continuous pressure on surrounding tissue thereby applying continuous radial pressure on at least one of a urethral wall and tissue surrounding the urethral wall in said restricted location, said radial pressure being sufficient to cause at least one of, a widening effect, extending a urinal passage, and inducing infarction.

2. The urethral implant according to claim 1, wherein the shape of at least one of said at least two closed shapes is selected from the list consisting of:

the shape of said at least one closed shape being wider at the proximal end than at the distal end thereof for preventing said removable implant from moving in the distal direction;

the shape of at least one closed shapes being wider at the distal end than at the proximal end thereof for preventing said removable implant from moving in the proximal direction;

the shape of at least one closed shapes being narrower at the middle thereof than at the distal and proximal portions thereof for

preventing said removable implant from moving in the proximal direction and in the distal direction; and

a butterfly wing.

3. The urethral implant according to claim 1, further including another lateral section, connected to one of said distal section and proximal section.

4. The urethral implant according to claim 1, wherein said at least one closed shape includes two adjacent closed shapes with a common lateral section, a first closed shaped is formed by said coiling ends of said single wire section on each other thus creating wire end extensions and thus forming a first lateral section and a second lateral section, a second closed shape is formed by coiling said two wire end extensions one with the other thus forming a third lateral section, said second lateral section being said common lateral section.

5. The urethral implant according to claim 1, wherein said at least one closed shape includes three adjacent closed shapes with common lateral sections, a first closed shaped is formed by said coiling ends of said single wire section on each other thus creating wire end extensions and thus forming a first lateral section and a second lateral section, a second closed shape is formed by coiling said two wire end extensions one with the other thus forming a third lateral section, a third closed shape is formed by coiling said two wire end extension on said first lateral section of said first shape.

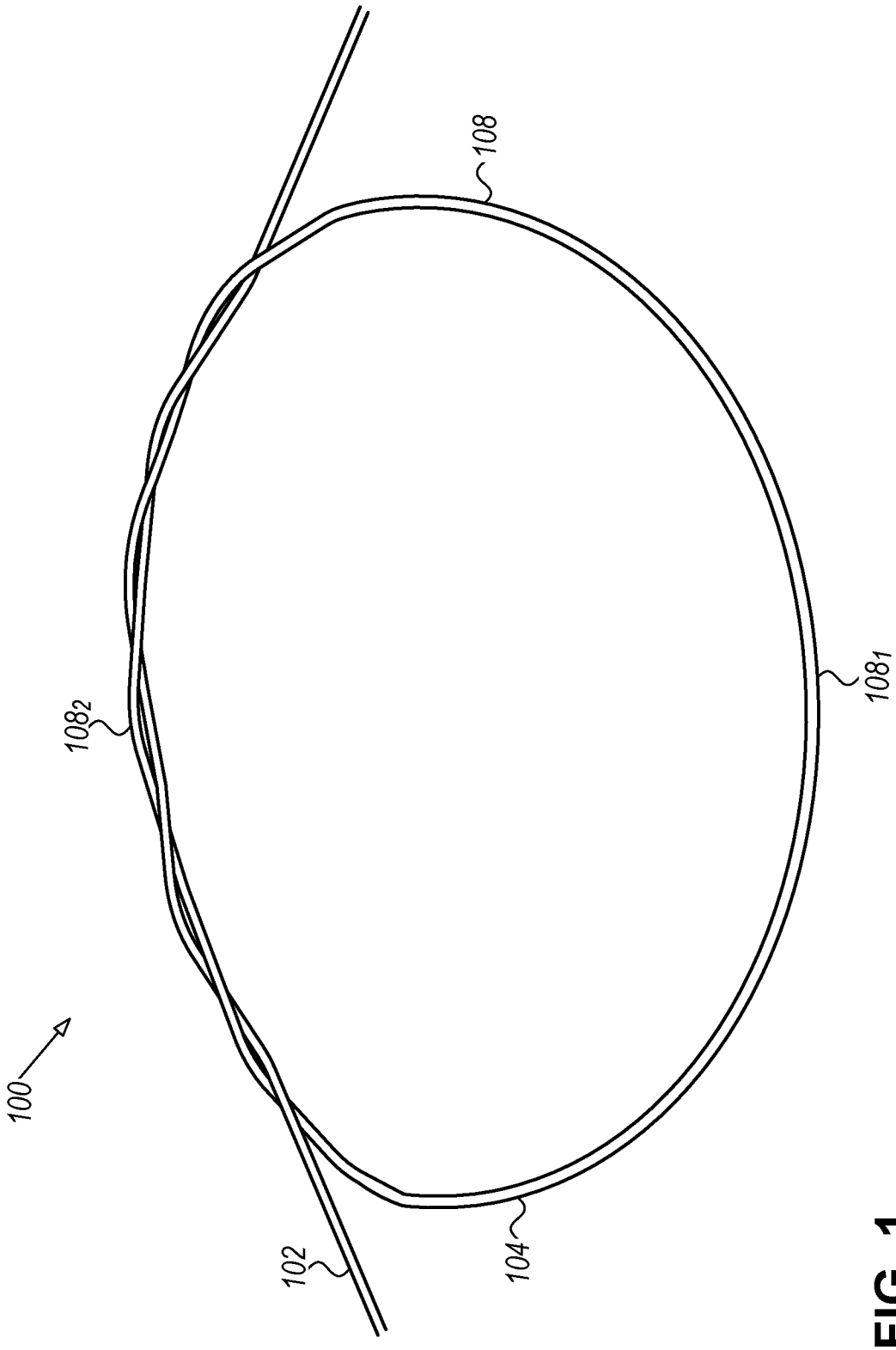

FIG. 1

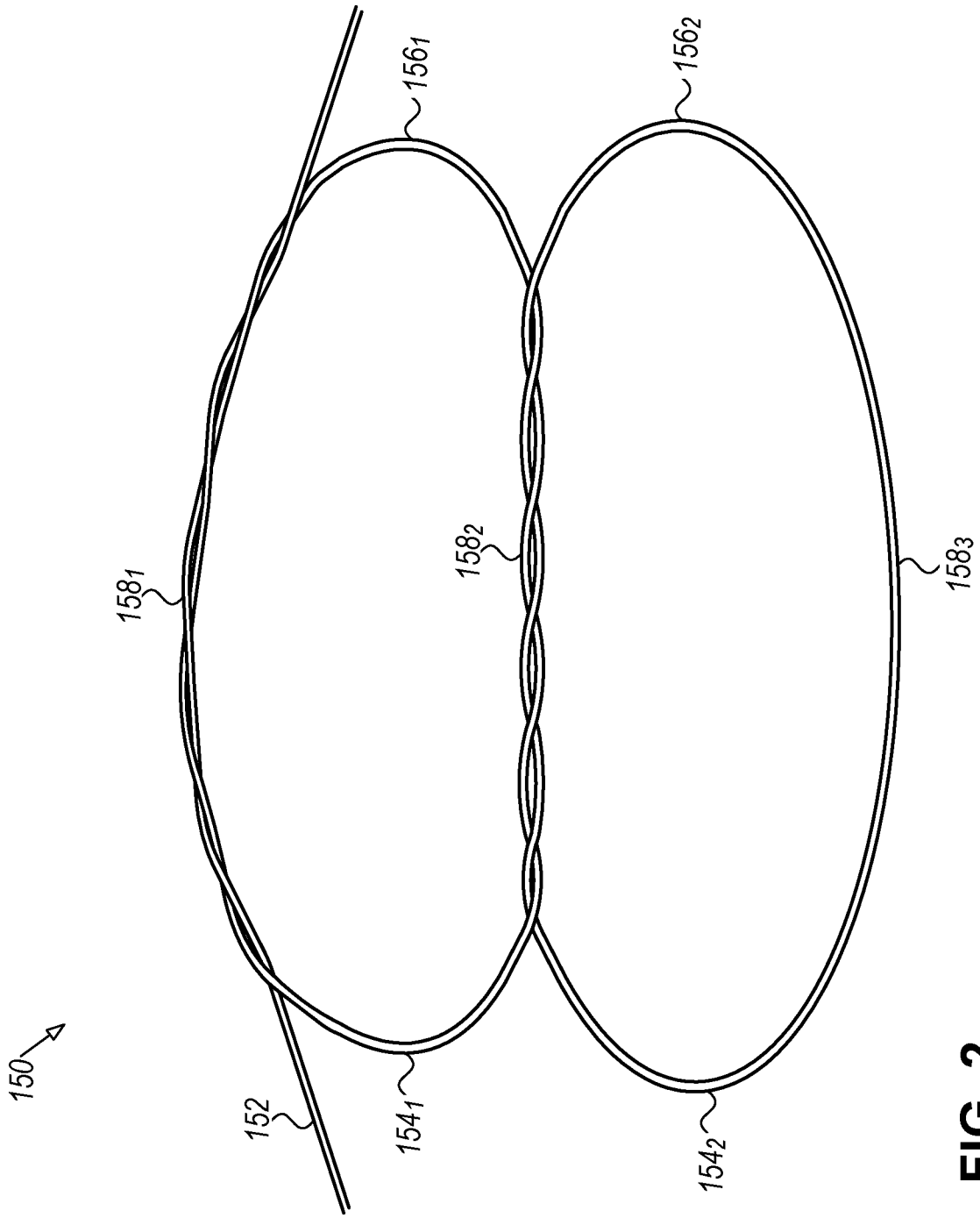

FIG. 2

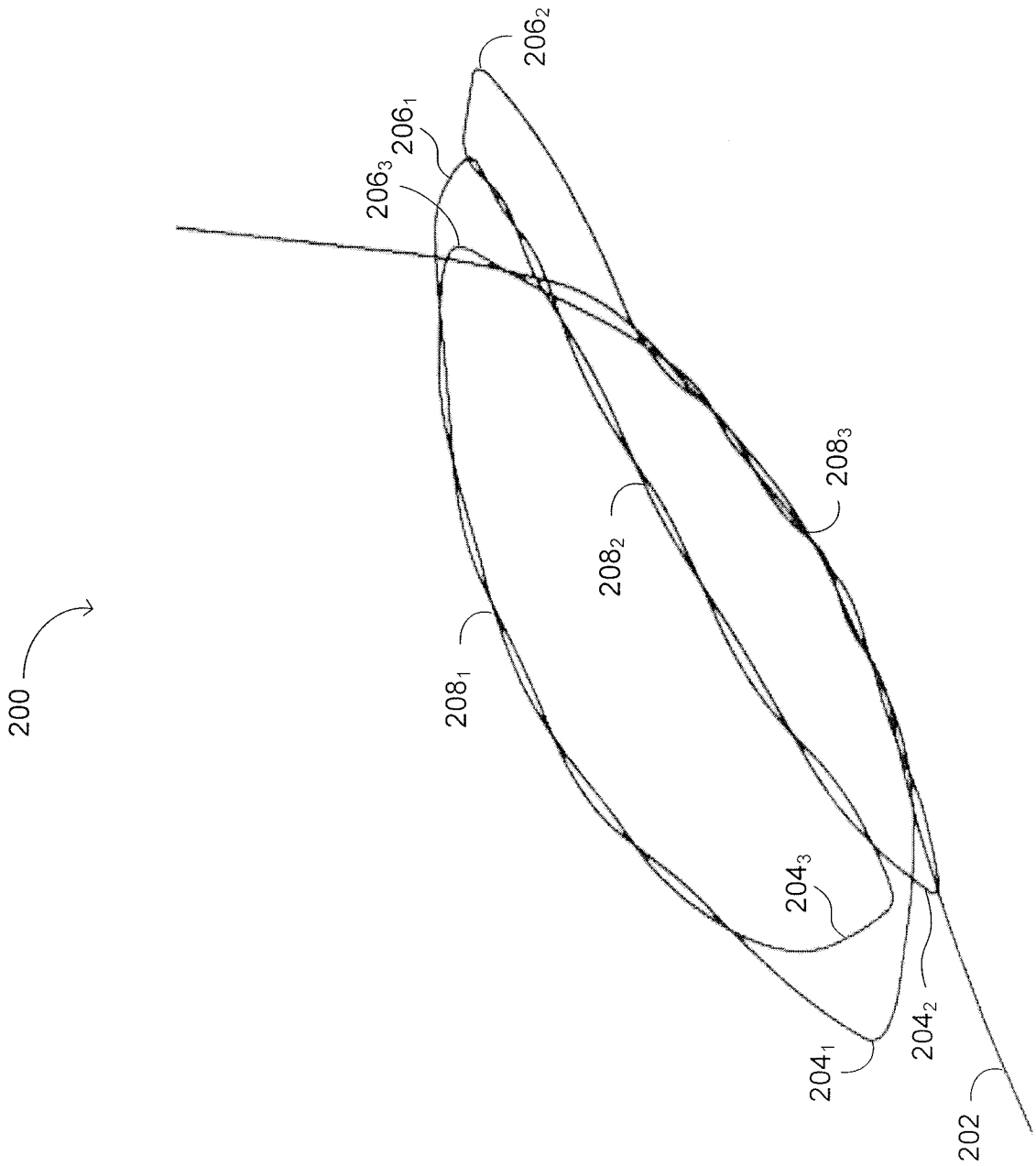

FIG. 3

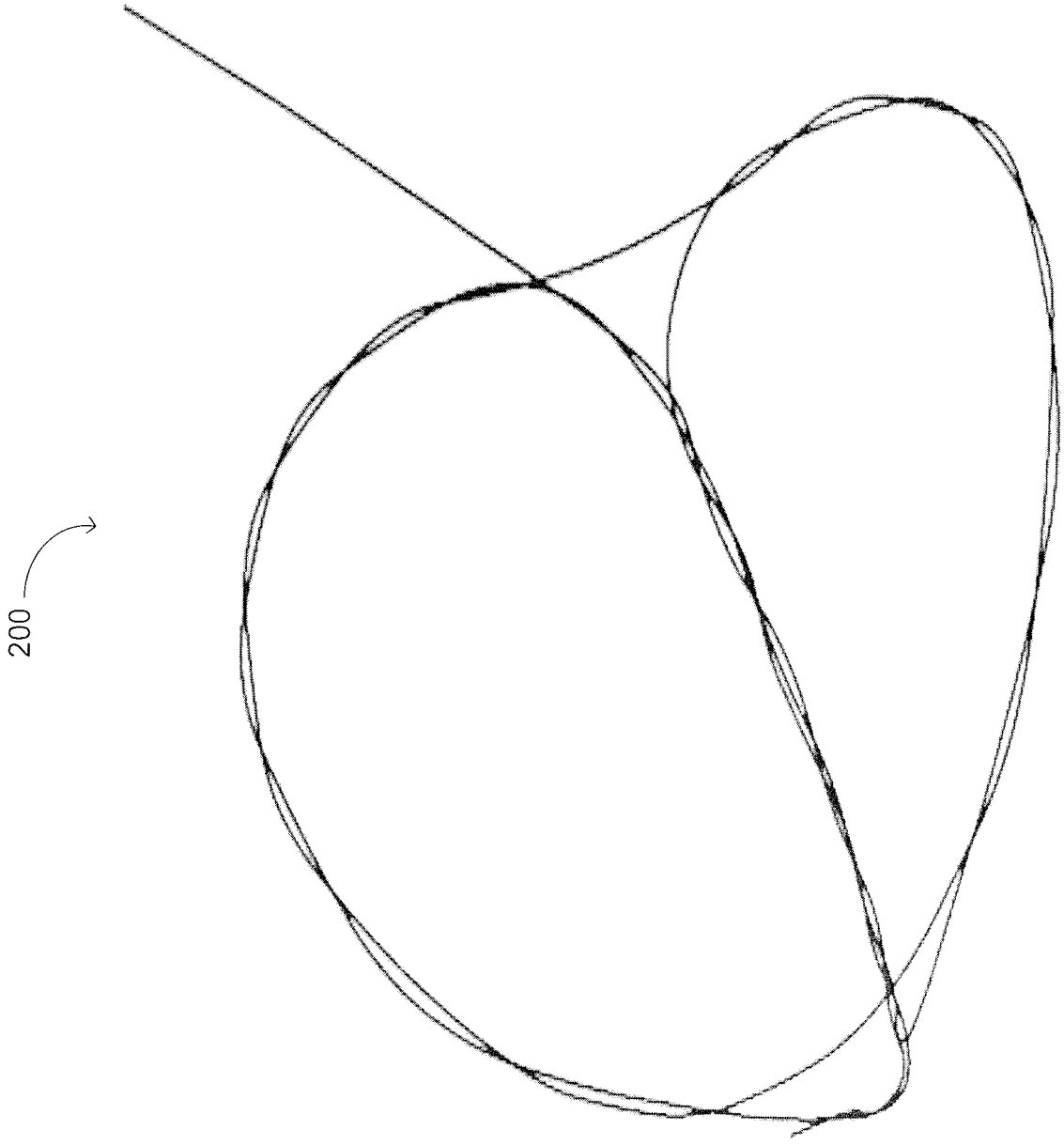

FIG. 4

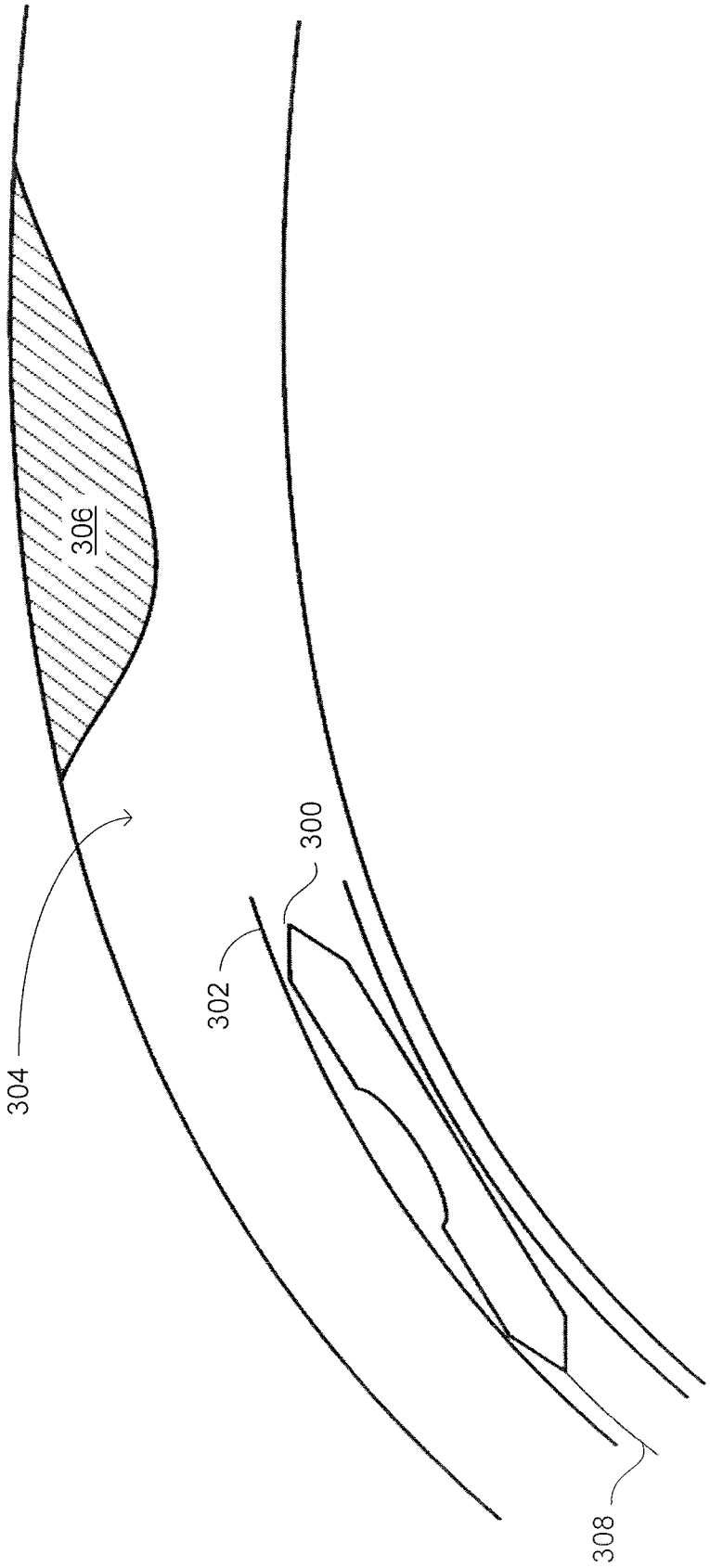

FIG. 5A

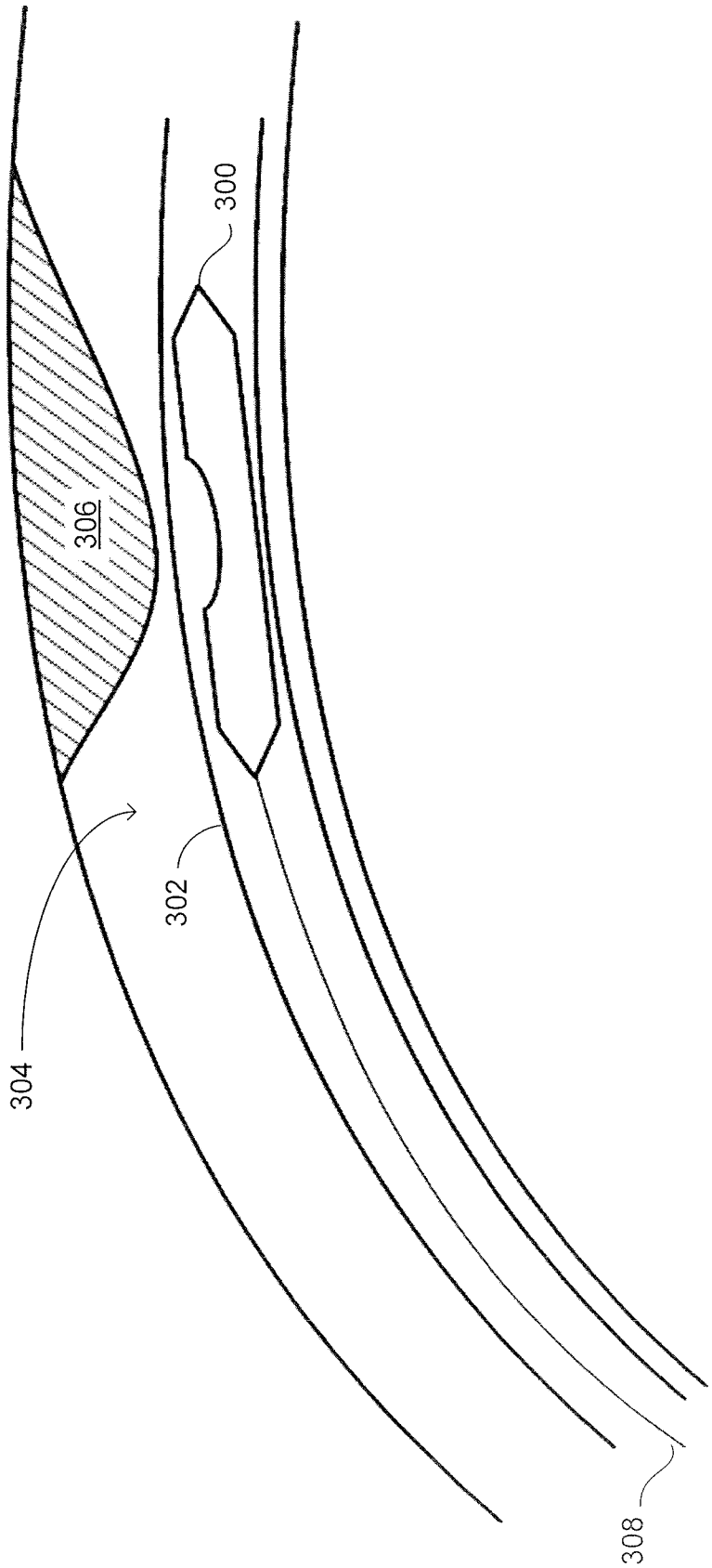

FIG. 5B

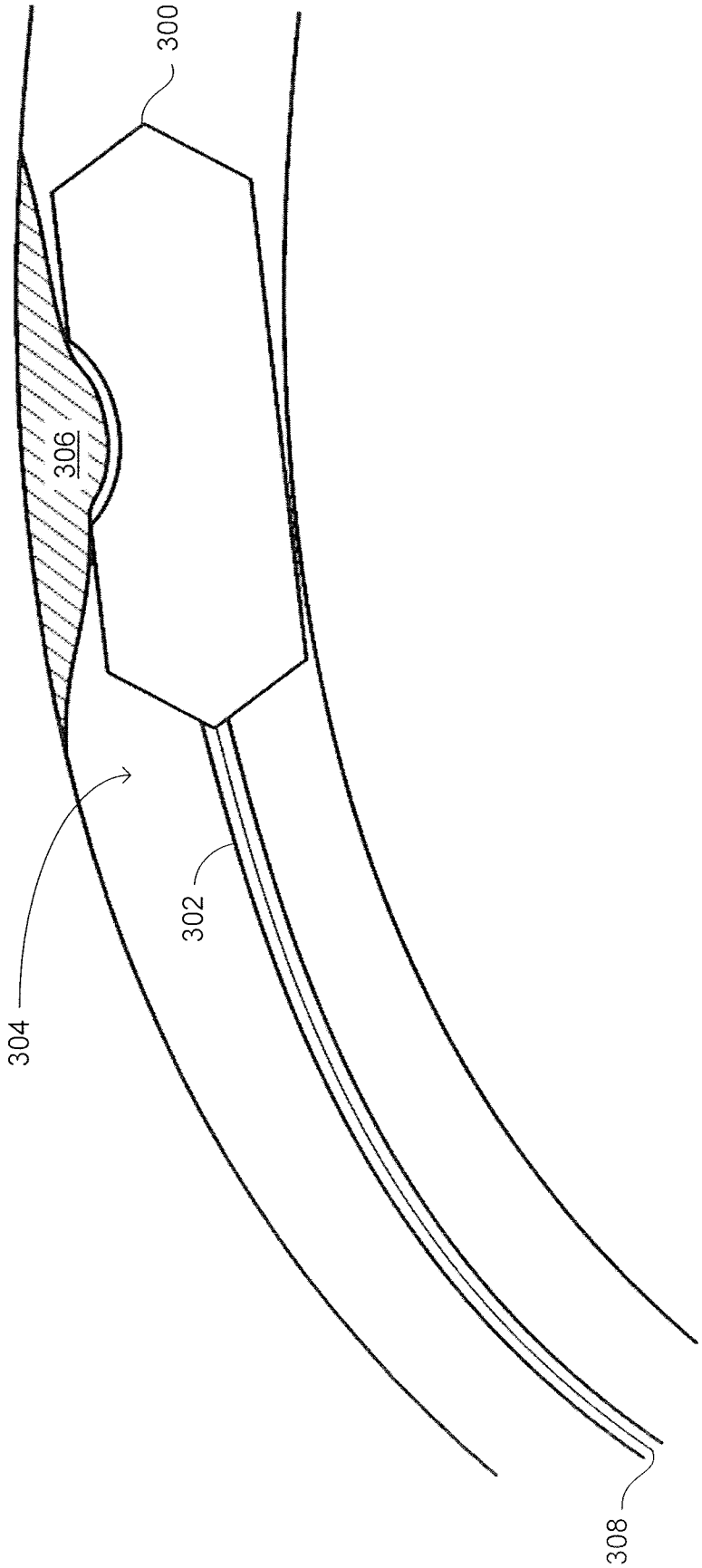

FIG. 5C

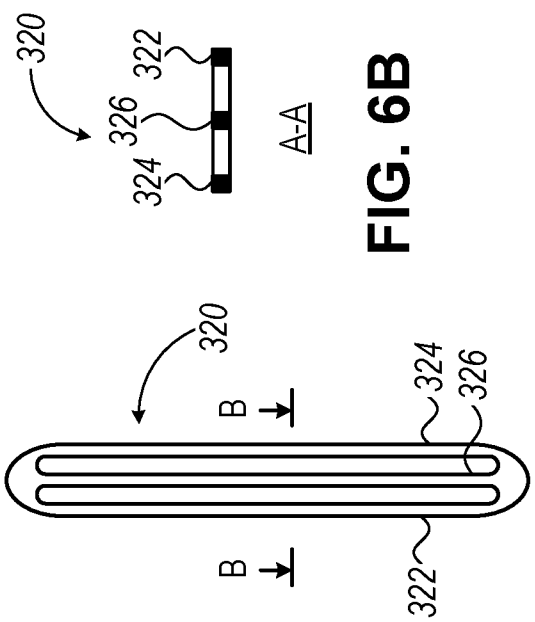

FIG. 6A

FIG. 6B

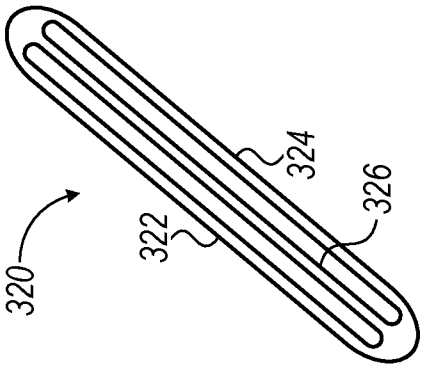

FIG. 6C

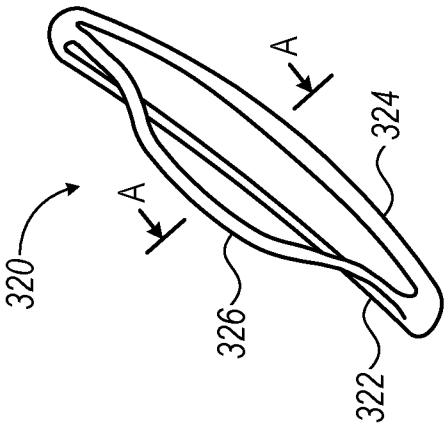

FIG. 6D

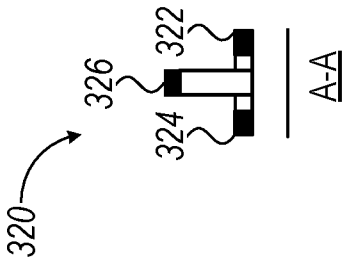

FIG. 6E

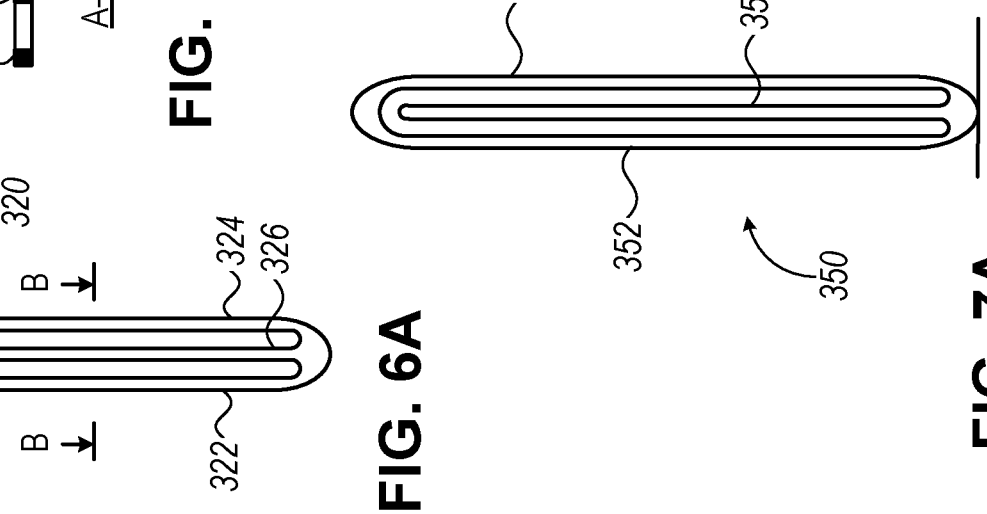

FIG. 7A

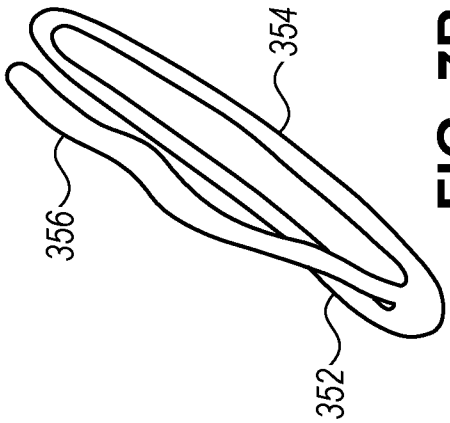

FIG. 7B

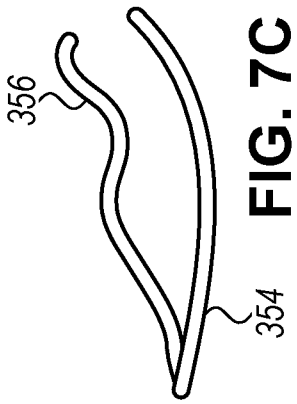

FIG. 7C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2019/050727

A. CLASSIFICATION OF SUBJECT MATTER
IPC (20190101) A61F 2/04, A61F 2/02, A61F 2/86, A61M 27/00
CPC (20130101) A61F 2/04, A61F 2230/0004, A61F 2230/0091, A61F 2/02, A61F 2002/047, A61F 2/86, A61M 27/008
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 (20190101) A61F 2/04, A61F 2/02, A61F 2/86, A61M 27/00
CPC (20130101) A61F 2/04, A61F 2230/0004, A61F 2230/0091, A61F 2/02, A61F 2002/047, A61F 2/86, A61M 27/008

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)
Databases consulted: Google Patents, Derwent Innovation, Orbit

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2017000598 A1 BUTTERFLY MEDICAL LTD 05 Jan 2017 (2017/01/05) Abstract; [0014], [0017], [0025], [0026], [0082], [0088], [0092]; Figs. 1A, 1B, 3B;	1-4
Y		5
X	EP 3167845 A1 College of the Holy and Undivided Trinity of Queen Elizabeth near Dublin 17 May 2017 (2017/05/17) Abstract; Col 9 - lines 7-11, Col 10 - lines 15-20; Figs. 1, 3	1
A	Entire document	2-5
Y	US 2016317180 A1 MEDI-TATE LTD 03 Nov 2016 (2016/11/03)	5
A	US 2011276081 A1 MEDI TATE LTD 10 Nov 2011 (2011/11/10) Entire document	1-5

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
29 Oct 2019	29 Oct 2019

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