

(12) STANDARD PATENT
(19) AUSTRALIAN PATENT OFFICE

(11) Application No. AU 2014374936 B2

(54) Title
An incising implant for the prostatic urethra

(51) International Patent Classification(s)
A61M 29/00 (2006.01)

(21) Application No: **2014374936** (22) Date of Filing: **2014.12.02**

(87) WIPO No: **WO15/101975**

(30) Priority Data

(31) Number	(32) Date	(33) Country
62/077,331	2014.11.10	US
PCT/IL2014/051015	2014.11.23	IL
61/921,590	2013.12.30	US

(43) Publication Date: **2015.07.09**

(44) Accepted Journal Date: **2019.12.05**

(71) Applicant(s)
Medi-Tate Ltd.

(72) Inventor(s)
Kilemnik, Ido

(74) Agent / Attorney
AJ PARK, Level 24, Tower 2, Darling Park 201 Sussex St, Sydney, NSW, 2000, AU

(56) Related Art
US 20100137893 A1
US 20110276081 A1

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization

International Bureau



(10) International Publication Number

WO 2015/101975 A1

(43) International Publication Date

9 July 2015 (09.07.2015)

(51) International Patent Classification:

A61M 29/00 (2006.01)

(21) International Application Number:

PCT/IL2014/051045

(22) International Filing Date:

2 December 2014 (02.12.2014)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/921,590 30 December 2013 (30.12.2013) US

62/077,331 10 November 2014 (10.11.2014) US

PCT/IL2014/051015

23 November 2014 (23.11.2014) IL

(71) Applicant: MEDI-TATE LTD. [IL/IL]; PO Box 226, 9 Hahadas St., 3060000 Or Akiva (IL).

(72) Inventor: KILEMNIK, Ido; 35 Derech Harishonim, 4286500 Haniel (IL).

(74) Agents: KORAKH & CO. ADVOCATES AND PATENT ATTORNEYS et al.; P.O.B. 58100, 6158002 Tel Aviv (IL).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

(54) Title: AN INCISING IMPLANT FOR THE PROSTATIC URETHRA

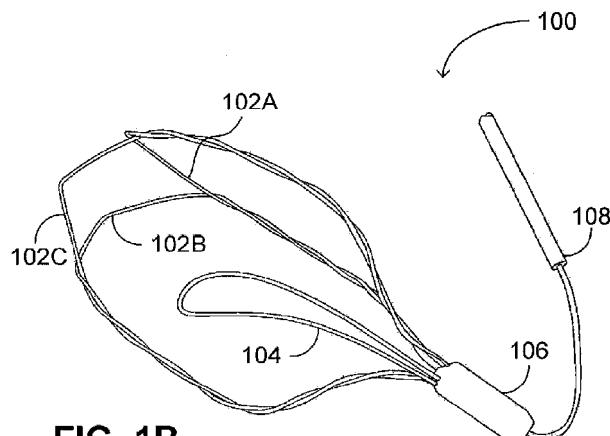


FIG. 1B

(57) Abstract: An incising implant for creating incisions in the prostatic urethra of a subject, the implant including at least two closed-shaped wires, each of the wires having a proximal section, a distal section and two lateral sections extending between the proximal section and the distal section, each of the closed-shaped wires being elastic thereby being compressible into a compressed configuration, each of the lateral sections of each of the wires being adjoined with another lateral section of another one of the wires.

14 Nov 2019

2014374936

AN INCISING IMPLANT FOR THE PROSTATIC URETHRA

5

FIELD OF THE DISCLOSED TECHNIQUE

The disclosed technique relates to systems and methods for relieving a prostate enlargement (e.g., as a result of benign prostatic hyperplasia), in general, and to systems and methods for creating incisions in the inner wall tissues of the prostatic urethra.

10

BACKGROUND OF THE DISCLOSED TECHNIQUE

The prostate is a walnut-sized gland that forms part of the male reproductive system. The prostate is located in front of the rectum and just below the bladder, where urine is stored. The prostate surrounds a portion of the urethra (hence referred to as the prostatic urethra), the canal through which urine passes out of the body. Prostate enlargement can result from a number of medical problems such as Benign Prostatic Hyperplasia (BPH), prostatic Bladder Neck Obstruction (BNO) and the like. The enlarged prostate applies pressure on the urethra (i.e., on the prostatic urethra and possibly on neighboring areas, such as the bladder neck and damages bladder function.

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.

PCT Patent Application Publication No. 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, 5 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 10 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.

In this specification where reference has been made to patent 15 specifications, other external documents, or other sources of information, this is generally for the purpose of providing a context for discussing the features of the invention. Unless specifically stated otherwise, reference to such external documents or such sources of information is not to be construed as an admission that such documents or such sources of 20 information, in any jurisdiction, are prior art or form part of the common general knowledge in the art.

SUMMARY OF THE DISCLOSED TECHNIQUE

It is an object of the disclosed technique to provide an incising implant for creating longitudinal incisions in a prostatic urethra of a subject. In accordance with a first aspect of the invention, there is thus provided an incising implant for creating incisions in a prostatic urethra of a subject. The incising implant includes at least two wires being closed-shaped. Each of the wires has a proximal section, a distal section and a plurality of longitudinal sections extending between the proximal section and the distal section. Each of the closed-shaped wires is elastic, and thereby compressible into a compressed configuration. Each of the longitudinal sections of each of the wires is adjoined with another longitudinal section of another one of the wires. The wires are configured for applying radial pressure on surrounding tissues of said prostatic urethra thereby creating longitudinal incisions along a longitudinal axis of said prostatic urethra in an open configuration of said incising implant.

In accordance with an embodiment of the disclosed technique, there is thus provided a method for implanting an incising implant within a prostatic urethra of a subject. The method includes the steps of enfolding the incising implant within a sheath and inserting the sheath into a urethra of the subject. The incising implant is elastic. When the implant is enfolded within the sheath the implant is compressed such that the implant conforms to a diameter of the sheath. The sheath is inserted into the urethra until a distal end of the sheath extends into a bladder of the subject. The method further includes the steps of pushing the incising implant within the sheath until the incising implant exits the distal end of the sheath into the bladder, and pulling the incising implant until the incising implant is implanted within the prostatic urethra.

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:

5 Figures 1A, 1B and 1C are schematic illustrations of an incising implant for creating incisions in the inner wall tissues of the prostatic urethra, constructed and operative in accordance with an embodiment of the disclosed technique;

10 Figures 2A, 2B and 2C are schematic illustrations of an incising implant for creating incisions in the inner wall tissues of the prostatic urethra, constructed and operative in accordance with another embodiment of the disclosed technique;

15 Figure 3 is a schematic illustration of an incising implant for creating incisions in the inner wall tissues of the prostatic urethra, constructed and operative in accordance with a further embodiment of the disclosed technique;

Figures 4A and 4B are schematic illustrations of a proximal niche of a proximal cap of an incising implant, constructed and operative in accordance with yet another embodiment of the disclosed technique; and

20 Figures 5A-5L are schematic illustrations of a method for deploying and for extracting an incising implant, operative in accordance with yet a further embodiment of the disclosed technique.

DETAILED DESCRIPTION OF THE EMBODIMENTS

The disclosed technique overcomes the disadvantages of the prior art by providing an incising implant to be implanted in the prostatic urethra (or at the vicinity thereof, for example, in the bladder neck). The 5 incising implant includes wires which apply radial force on the surrounding inner wall tissues of the prostatic urethra. Over time, the wires induce infraction and thereby produce longitudinal incisions in the surrounding tissues. The incisions relieve constriction of the prostatic urethra.

In accordance with an embodiment of the disclosed technique, 10 the incising implant is formed by three closed-shape wires (or more). The shape of each wire can be roughly divided into a proximal section, a distal end section and two longitudinal sections extending between the proximal and the distal sections. Each wire is made of an elastic material allowing it to be compressed into a sheath, and to assume its original shape when 15 released from the sheath.

The longitudinal sections of each wire are adjoined with longitudinal sections of adjacent wires. Thereby, the wires are coupled to each other to form a frame of wires. Each wire forms a face of the wire frame, and the adjoined longitudinal sections form the edges of the wire 20 frame. The edges of the wire frame apply radial pressure on the inner wall tissues of the prostatic urethra, thereby creating longitudinal incisions that relieve urethral constriction and increase the urinal passage.

The wires, when applying pressure on the surrounding tissues, are pressed against one another (i.e., each wire is pressed against adjacent 25 wires to which it is adjoined at the respective longitudinal sections). Thereby, the wires support each other. In other words, when a wire applies a force on a tissue, the tissue applies an opposite force having the same magnitude (in accordance with Newton's third law). The wire is thus pressed against adjoined adjacent wires. These adjoined wires, in turn, are pushed 30 against other tissues. In this manner, the wire frame is self-supporting,

obviating the need for an additional supporting element, such as a central support tube. Additionally, each edge of the wire frame is formed by two adjoined wires, doubling the pressure applied on the tissues and allowing for thinner wires.

5 In accordance with another embodiment of the disclosed technique, there is thus provided a method for deploying an incising implant in the prostatic urethra of the subject. The method involves enfolding the incising implant within a sheath. The implant is elastic and thereby conforms to the circumference of the enfolding sheath which is smaller than the 10 circumference of the implant. The sheath is inserted into the urethra and is pushed until its distal end extends into the bladder of the subject. The implant is pushed within the sheath until it extends from the distal end of the sheath. Once released from the sheath the elastic implant resumes its original, extended, configuration.

15 The implant can include a proximal cap having a proximal niche (or a proximal protrusion). The proximal niche is a non-round niche that can transfer rotary motion from a corresponding pin (or in case of a proximal protrusion – a corresponding niche). Thereby, the user can rotate the implant within the bladder to a desired rotary orientation.

20 Thereafter, the implant is pulled back in the proximal direction until it is positioned within the prostatic urethra (and/or the bladder neck). The implant remains within the prostatic urethra for a period of time (e.g., several hours or several day), during which the implant creates longitudinal 25 incisions in the surrounding inner wall tissues of the urethra for relieving urethral constrictions. After the period of time passes, a sheath is inserted into the urethra and enfolds the implant, thereby compressing the implant back to a compressed configuration. Following this, the implant is removed from the urethra via the sheath.

30 The terms pressure and force (e.g., applying radial pressure or applying radial force) are employed interchangeably herein below, to

describe the operation of the wires of the implant on the surrounding tissues. That is, the wires are described as applying pressure on the tissues, or as applying force on the tissues. Herein below, the terms proximal and distal refer to directions relative to implantable device and the delivery system. In particular, the distal end is the end of the device (or of the system) that is inserted into the body of the patient first and reaches the deepest. The proximal end is the end closer to the exit from the body of the patient.

Reference is now made to Figures 1A, 1B and 1C, which are schematic illustrations of an incising implant, generally referenced 100, for creating incisions in the inner wall tissues of the prostatic urethra, constructed and operative in accordance with an embodiment of the disclosed technique. Figure 1A depicts the incising implant from a top-view perspective (i.e., as would be seen in case the observer is located distally to the implant), and Figures 1B and 1C depict the incision implant from opposite isometric perspectives. Incising implant 100 includes three closed-shaped wires 102A, 102B and 102C (also referred to herein below, together, as wires 102), an anchoring leaflet 104, a proximal cap 106, and an extraction string 108.

The closed shape of each of wires 102 can roughly be divided into a proximal section, a distal section and two longitudinal sections extending between the proximal section and the distal section. For example, the proximal section can be a U-shaped proximal end, from which the longitudinal sections extend. The distal section is the section connecting the longitudinal sections. Each of wires 102 is coupled with adjacent ones of wires 102 on either side thereof. Specifically, the longitudinal sections of each of wires 102 are coupled with longitudinal sections of adjacent wires. For example, one longitudinal section of wire 102A is coupled with a longitudinal section of wire 102B, and the other longitudinal section of wire 102A is coupled with a longitudinal section of wire 102C. The other

longitudinal section of wire 102B (not coupled with 102A) is coupled with the other longitudinal section of wire 102C (that is also not coupled with 102A). Proximal cap 106 holds the proximal ends of wires 102 together. Extraction string 108 is coupled with wires 102, or with proximal cap 106.

5 The following paragraphs describe the use of incising implant 100. Thereafter, the components of incising implant 100 would be elaborately described. Incising implant 100 is temporary implanted in the prostatic urethra for creating longitudinal incisions in the inner wall tissues of the prostatic urethra, thereby relieving urethra constriction.

10 Incising implant 100 is implanted by employing a sheath (not shown) for inserting the implant into the urethra. Implant 100 is compressed within the sheath such that the diameter of the circumference of implant 100, illustrated by dotted circle 110, conforms to the inner diameter of the sheath. Wires 102 are made of elastic material, such that when released 15 from the enfolding sheath they regain their original, extended, shape (and the original circumference diameter of implant 100). When positioned in the prostatic urethra, implant 100 is bound by the inner diameter of the urethral walls surrounding it.

20 Wires 102 push against the surrounding tissues (i.e., apply a radial outward force on the tissues). Over time, the force applied by wires 102 impairs the blood (and oxygen) supply to the tissues in contact with wires 102, thereby inducing tissues necrosis and creating infarcted 25 incisions. Over time, the incisions become deeper until wires 102 reach their full extent (i.e., until implant 100 regains its original circumference diameter as illustrated by dotted circle 110). It is noted however, that implant 100 can be removed before fully regaining its original shape, in case the incisions are determined to be sufficiently deep to relieve the constriction of the urethra.

30 Implant 100 is implanted such that wires 102 are aligned with the longitudinal direction of the urethra. Therefore, wires 102 create longitudinal

incisions in the inner wall tissues of the prostatic urethra. That is, the longitudinal incisions are incisions running along the longitudinal axis of the urethra. Put another way, longitudinal incisions are incisions running along (and not across) the urinary passage.

5 The period of time required for creating incisions that are sufficient to relieve urethra constriction depends on various factors, such as the level of constriction, the materials of wires 102, the original fully extending shape of wires 102, and the like. Implant 100 can remain in the prostatic urethra for a predetermined period of time. Alternatively, implant
10 100 can remain implanted until the constriction is sufficiently relieved, as determined by a physician, according to tests (e.g., observations of the implant effect over time), or by the subject himself (e.g., according to what the subject feels when urinating). For example, implant 100 can be implanted for a time period ranging between a one hour and several weeks.
15 The incisions created by implant 100 are created over time without causing pain or bleeding to the subject. After implant 100 is implanted, the subject can be released and resume his regular lifestyle, without any hindrances. After the required period of time, implant is removed from the subject.

20 Incising implant 100 is implanted within the prostatic urethra to relieve constriction of the urethra, caused for example by prostatic enlargement. Implant 100 can be positioned in other, or in additional, areas of the urinal passage, such as the bladder neck. Alternatively, implant 100 can be implanted in any tubular organ that requires relief of a constriction, such as tubular organs of the digestion system, blood vessels, and the like.

25 Wires 102 (i.e., wires 102A, 102B and 102C) are closed-shaped wires made of elastic material. The material of wires should be elastic enough to allow wires to be compressed within a sheath, and to conform to the inner diameter of the sheath, during insertion into the urethra. The wires should regain their original, extended, shape (and the original circumference diameter) once released from the sheath. Additionally, the
30

wires should be strong enough to apply a force on the surrounding tissues to induce necrosis in the tissues (e.g., a force of 0.5 Newton), and thereby to create infarcted longitudinal incisions. Wires 102 can be made, for example, from Nickel Titanium alloy (Nitinol). Alternatively, implant 100 is 5 made of biodegradable materials, such that there is no need to remove implant 100 from the body of the patient.

The closed shape of wires can be roughly divided into three sections, a proximal section (referenced by elliptical broken line), a middle section consisting of two longitudinal sections, and a distal section 10 (referenced by polygonal broken line). The proximal section (or proximal end) is U-shaped. The longitudinal sections extend from the arms of the U-shaped proximal end and are connected via the distal section (or distal end). The distal section serves as a support crosspiece connecting the longitudinal sections of the wire. Exemplary closed shapes of the wires are 15 illustrated in Figures 1A-1C, 2A-2C, 3, and 4.

The longitudinal sections of each of wires 102 are the sections in contact with the surrounding tissues. That is, the longitudinal sections are the sections pushing against the tissues for creating the incisions. The longitudinal sections of each of wires 102 are coupled (i.e., adjoined) with 20 longitudinal sections of adjacent wires. For example, a first longitudinal section of wire 102A is adjoined with a first longitudinal section of wire 102B, a second longitudinal section of wire 102A is adjoined with a first longitudinal section of wire 102C, and a second longitudinal section of wire 102B is adjoined with a second longitudinal section of wire 102C. In this 25 manner, the adjoined wires form together a supporting wire frame, such that each closed-shape wire forms a face of the frame, and each adjoined pair of longitudinal sections of adjacent wires forms an edge of the frame.

When the longitudinal sections of wires 102 are pushed against the surrounding tissues (i.e., as implant 100 tries to regain its original shape 30 while being bound by the urethra inner walls), the surrounding tissues apply

an opposite force on wires 102 in accordance with the third law of Newton. Each of wires 102 is pushed against the adjacent wires to which it is adjoined. The wire frame increases the structural stability of implant 100 and allowing implant 100 to apply sufficient force for creating the incisions 5 in the surrounding tissues. Thus, the wire frame obviates the need for an additional support element, such as a central support tube.

In the example set forth in Figures 1A-1C, wires 102 are adjoined together by being wound (i.e., twisted) around each other. That is, the first 10 longitudinal section of wire 102A and the first longitudinal section of wire 102B are wound around each other; the first second longitudinal section of wire 102A and the first longitudinal section of wire 102C are wound around each other; and the second longitudinal section of wire 102B and the second longitudinal section of wire 102C are wound around each other. The twist coupling of wires 102 further provides structural solidity to implant 100. 15 Thereby, each of wires 102 can be made thinner without compromising the robustness of implant 100. For example, each of wires can be as thin as 0.5 millimeters (i.e., the cross section of each of the wires is 0.5 millimeters).

The wounding of wires 102 can be achieved, for example, by twisting the longitudinal sections around each other and thermally treating 20 implant 100 for stabilizing the winding. Wires 102 can be wound around each other by being placed in a mold having rotating elements that grab the longitudinal sections and wound them around each other.

In the example set forth in Figures 1A-C there are three wound wires, each consisting of two longitudinal sections of two adjacent wires, 25 wound around each other. Thus, the wire frame has three longitudinal edges creating three longitudinal incisions. In accordance with an alternative embodiment of the disclosed technique, the implant can include other numbers of closed-shaped wires, such as a single wire, two wires, (for a wire frame of two longitudinal edges creating two longitudinal

incisions), four wires (for a wire frame of four longitudinal edges creating four longitudinal incisions), five wires, and the like.

5 Proximal cap 106 is coupled with the proximal ends of wires 102 for coupling wires 102 together. Thereby, the wire frame is further strengthened. Put another way, proximal cap 106 helps to maintain the structure of implant 102 (i.e., increases the structural stability) by further adjoining wires 102 to each other.

10 In the example set forth in Figures 1A-1C, proximal cap 106 encases the proximal ends of wires 102. Thereby, proximal cap 106 shields tissues of the urethra from getting caught in the proximal ends of wires 102. Additionally, proximal cap 106 serves to prevent wires 102 from unwinding.

15 Proximal cap 106 can include a proximal non-round niche (e.g., niche 502 of Figures 4A and 4B). The non-round proximal niche of proximal cap 106 is configured to receive a corresponding non-round pin, and to transfer rotary motion of the pin to implant 100. Thereby, the user can rotate implant 100 when implant is located within the bladder of the subject, as would be detailed further herein below with reference to Figures 4A-4B and 5A-5L.

20 Anchoring leaflet 104 serves as a one-way stopper allowing implant to move from the bladder into the prostatic urethra and preventing implant 100 from migrating back toward the bladder by being stuck against one of the urethral sphincters. Leaflet 104 can be a wire leaflet (e.g., as depicted in Figures 1A-1C), or any other form allowing it to slice across the urethral sphincters in the proximal direction and preventing it to slide across 25 the urethral sphincters in the distal direction. For example, leaflet can be bar-shaped. Leaflet can be coupled to implant elastically or via an axis, or another coupling mechanism configured to enable leaflet to serve as a one-way stopper for movement across the urethral sphincters. Alternatively, other or additional anchoring elements can be employed for anchoring

implant in its place (moving in the proximal direction, the distal direction, or both), such as barbs on wires 102.

Extraction string 108 enables the physician to extract implant 100. Specifically, the distal end of string 108 is coupled with implant 100, and the proximal end of string 108 extends outside of the body of the subject. The physician can insert an extraction sheath into the urethra along string 108 for enfolding implant 100. The physician can extract the enfolded implant by pulling string 108. String 108 is strong enough for pulling implant 100 without being torn (e.g., the thickness and materials of string 108 allow pulling implant 100 via string 108). String 108 can be a single strand or a woven bundle of strands for further fortifying it.

Incising implant 100 is deployed such that it does not extend distally beyond the bladder neck of the subject (i.e., does not extend into the bladder). Specifically, wires 102 do not come into contact with the tissues of the bladder itself. Thereby, implant 100 does not irritate the bladder of the patient.

In accordance with an embodiment of the disclosed technique, the incising implant is colored in such a manner that enables the physician to easily position it in order. For example, the wires of the implant are color coded such that sections that should be positioned on top are colored blue, and sections that should be positioned on the bottom are colored white. The physician can observe the implant in the bladder via a cystoscope, and rotate the implant to the desired orientation according to the colors of the implant.

Reference is now made to Figures 2A, 2B and 2C, which are schematic illustrations of an incising implant, generally referenced 100, for creating incisions in the inner wall tissues of the prostatic urethra, constructed and operative in accordance with another embodiment of the disclosed technique. Figure 2A depicts the incising implant from an isometric perspective, Figure 2B depicts the incising implant from a top-view

perspective, and Figure 2C depicts a closed-shaped wire of the implant. Incising implant 200 includes three closed-shaped wires 202A, 202B and 202C (also referred to herein below, together, as wires 202), and an anchoring leaflet 204. The components of implant 200 are similar to those of implant 100, and for the sake of brevity only the differences are elaborated herein below.

The closed shape of each of wires 202 is depicted in Figure 2C. The closed shape is truncated at the distal end thereof. That is, the distal end of each of wires 202 is substantially perpendicular to the longitudinal axis of implant 200. Thereby, the wires do not come into contact with the tissues of the bladder, for avoiding bladder irritation.

Wires 202 are not wound around each other. Instead, wires 102 can be adjoined to one another (i.e., the longitudinal sections are adjoined to longitudinal sections of adjacent wires) by various manners. For example, the wires are welded together, glued together, or coupled by a coupling mechanism or element (e.g., coupling thread binding the longitudinal sections together).

In the example set forth in Figures 2A-2C (and in Figure 3 herein below), the incising implant is depicted without a proximal cap and an extraction string. It is noted however, that the implant can include any of the proximal cap, the extraction string, or both.

Reference is now made to Figure 3, which is a schematic illustration of an incising implant, generally referenced 300, for creating incisions in the inner wall tissues of the prostatic urethra, constructed and operative in accordance with a further embodiment of the disclosed technique. Incising implant 300 includes three closed-shaped wires 302A, 302B and 302C (also referred to herein below, together, as wires 302) and an anchoring leaflet 306. The components of implant 300 are similar to those of implant 100, and for the sake of brevity only the differences are elaborated herein below. Implant 300 is depicted from a bottom-view

perspective (i.e., as seen by a proximally located observer). The closed shape of wires 302 is triangular, such that together wires 302 form a triangular-pyramid wire frame with the proximal ends of the wires forming the apex of the pyramid, and the distal ends forming the base of the 5 pyramid. The adjoined longitudinal sections of wires 302 form the longitudinal edges of the triangular pyramid.

Reference is now made to Figures 4A and 4B, which are schematic illustrations of a proximal niche, generally referenced 402, of a proximal cap of an incising implant, constructed and operative in 10 accordance with yet another embodiment of the disclosed technique. The proximal cap is detailed herein above with reference to proximal cap 106 of Figures 1A-1C. The niche has a non-round shape for allowing it to transfer rotary motion from the corresponding pin inserted into the niche. Thereby, the physician can rotate the incising implant from afar (e.g., when the 15 implant is in the bladder). In the example set forth in Figure 4A, the shape of niche 402 is rectangular, and in the example set forth in Figure 4B, the shape of niche 402 is hexagonal. Alternatively, the niche can have any shape allowing it to transfer rotary motion (i.e., rotations around the central axis of the proximal cap), such as non-round shapes, a slit, an array of 20 niches (e.g., two holes), and the like.

Reference is now made to Figures 5A-5L, which are schematic illustrations of a method for deploying and for extracting an incising implant, operative in accordance with yet a further embodiment of the disclosed technique. With reference to Figure 5A, an extraction string 510 (shown in 25 Figure 5J) extends from the proximal end of implant 500. Implant 500 includes a proximal cap having a non-round proximal niche (both not shown). A guidewire 506 includes a distal head (i.e., distal pin), which shape corresponds to the proximal niche of the proximal cap of implant 500; and an inner channel (not show). The distal head of guidewire 506 is inserted 30 into the proximal niche of the proximal cap of implant 500. Extraction string

510 runs through the inner channel of guidewire 506. At the proximal end of extraction string 510 a proximal knot 512 (shown in Figure 5J) holds guidewire 506 attached to implant 500. Incising implant 500 is attached to the distal end of deployment sheath 502, such that guidewire 506 (and 5 extraction string 510 running therethrough) runs through sheath 502.

With reference to Figure 5B, a physician removes protective cover 504 from implant 500, thereby implant 500 expands to its original open configuration (as seen in any of drawings 1A-1C, 2A-2C, and 3). A protective cover 504 keeps implant 500 sterile during storage prior to use.

10 With reference to Figure 5C, while holding guidewire 506, the physician pushes sheath 502 over implant 500 thereby enfolding implant 500 within sheath 502 for delivery into the urethra.

With reference to Figure 5D, the physician inserts a rigid cystoscope 508 (e.g., size 20French) into the urethra, for example, as in a 15 routine urethral catheterization procedure. With reference to Figure 5E, the physician inserts sheath 502, including compressed implant 500 therewithin, into cystoscope 508. The physician continues pushing implant 500 through cystoscope 508 by pushing guidewire 506, until implant 500 extends through the distal end of cystoscope 508. With reference to Figure 20 5F, the physician removes sheath 502 from implant 500 and out of cystoscope 508. With reference to Figure 5G, once released from sheath 502 and from cystoscope 508, implant 500 expands (i.e., regains its original extended shape).

With reference to Figure 5H, the physician rotates implant 500 to 25 the desired orientation by rotating guidewire 506 (and its distal head inserted into the proximal niche of implant 500). An anchoring leaflet of implant 500 (e.g., leaflet 104 of Figures 1A-1C) should be positioned posteriorly. The wires of implant 500 can be color coded, such that the sections that should be positioned on the top are colored, for example, blue; 30 and the sections that should be positioned on the bottom are colored, for

example, white. The physician rotates implant as detailed further herein above with reference to proximal cap 106 of Figures 1A-1C, and proximal cap 400 of Figures 4A-4B.

With reference to Figure 5I, while holding implant 500 in place by using guide wire 506, the physician retracts cystoscope 508. Thereafter, the physician pulls implant 500 via guidewire 506 until the anchoring leaflet of implant 500 slides over a urethral sphincter and implant is positioned within the prostatic urethra. With reference to Figure 5J, the physician cuts knot 512 at the proximal end of extraction string 510, and retracts guidewire 506 from the urethra.

Thereby, implant 500 is implanted within the prostatic urethra and starts applying radial outward force on the surrounding tissues of the inner walls of the urethra for creating longitudinal incisions. Implant 500 is left within the prostatic urethra for a selected time period (e.g., ranging between one hour and several weeks. Thereafter implant 500 is removed as would be detailed below. Alternatively, implant 500 is made of biodegradable materials and simply dissolves after a selected time period.

With reference to Figure 5K, the physician inserts cystoscope 508 through the urethra toward implant 500 over extraction string 510. Alternatively, the physician can insert sheath 502 instead of cystoscope 508. The physician pushes cystoscope 508 until it enfolds implant 500. With reference to Figure 5L, the physician extracts implant 500 enfolded within cystoscope 508 by pulling implant via extraction string 510. Then, the physician extracts cystoscope 508 from the urethra.

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.

The term 'comprising' as used in this specification and claims means 'consisting at least in part of'. When interpreting statements in this

specification and claims which include the term 'comprising', other features besides the features prefaced by this term in each statement can also be present. Related terms such as 'comprise' and 'comprised' are to be interpreted in a similar manner.

CLAIMS

1. An incising implant for creating incisions in a prostatic urethra of a subject, the incising implant including:

5 at least two wires being closed-shaped, each of said wires having a proximal section, a distal section and a plurality of longitudinal sections extending between said proximal section and said distal section, each of said closed-shaped wires being elastic thereby being compressible into a compressed configuration, said longitudinal sections of each of said wires being adjoined with another longitudinal section of another one of said wires, wherein said wires are configured for applying radial pressure on surrounding tissues of said prostatic urethra thereby creating longitudinal incisions along a longitudinal axis of said prostatic urethra in an open configuration of said incising implant.

15

2. The incising implant of claim 1, wherein each of said longitudinal sections of each of said wires being wound around said another longitudinal section of said another one of said wires.

20

3. The incising implant of claim 1, further including a proximal cap coupled with said proximal section of each of said wires, said proximal cap configured to hold said wires together.

25

4. The incising implant of claim 3, wherein said proximal cap including a proximal non-round niche configured to accept a corresponding pin, and configured to transfer rotary motion of said pin to said incising implant.

5. The incising implant of claim 1, further including an extraction string configured to couple with said incising implant, said extraction sting being arranged to allow pulling said incising implant out of said subject.

5 6. The incising implant of claim 1, further comprising an anchor for preventing said incising implant from moving in the direction of a bladder of said subject.

10 7. The incising implant of claim 1, wherein said wires form together a wire frame having a proximal apex formed by said proximal section of each of said wires, and having a distal base formed by said distal ends of each of said wires.

15 8. The incising implant of claim 1, wherein said wires are selected from the group consisting of: Nickel Titanium alloy (Nitinol), and biodegradable materials.

9. The incising implant of claim 1, wherein said closed-shaped of said at least two wires are triangular.

20 10. The incising implant of claim 3, configured to be used with a guidewire configured for insertion into a proximal niche of said proximal cap of said incising implant.

25 11. The incising implant of claim 1, wherein said incising implant is enfolded in a sheath in said compressed configuration.

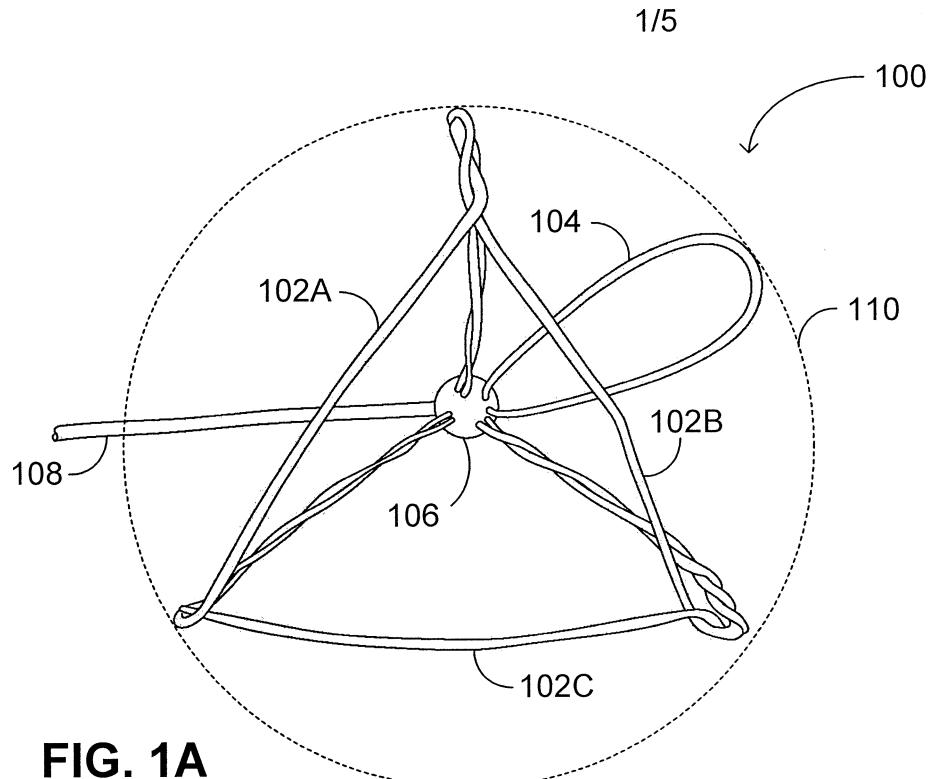


FIG. 1A

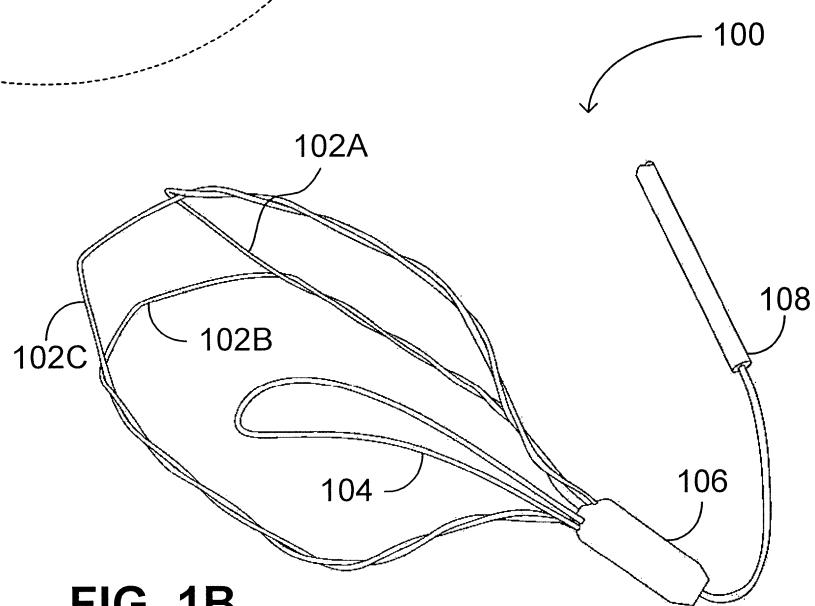


FIG. 1B

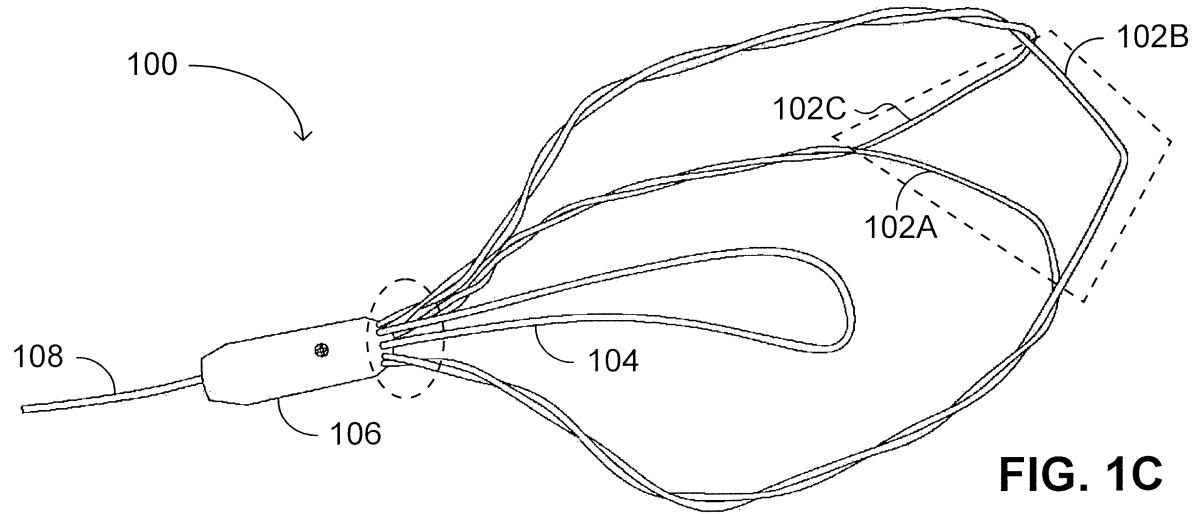
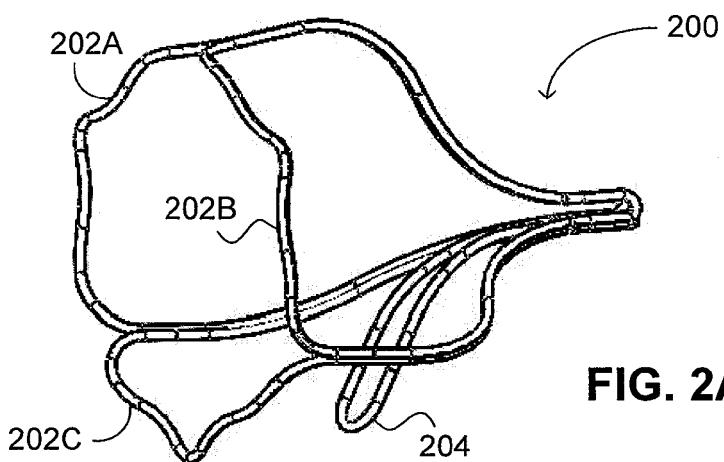
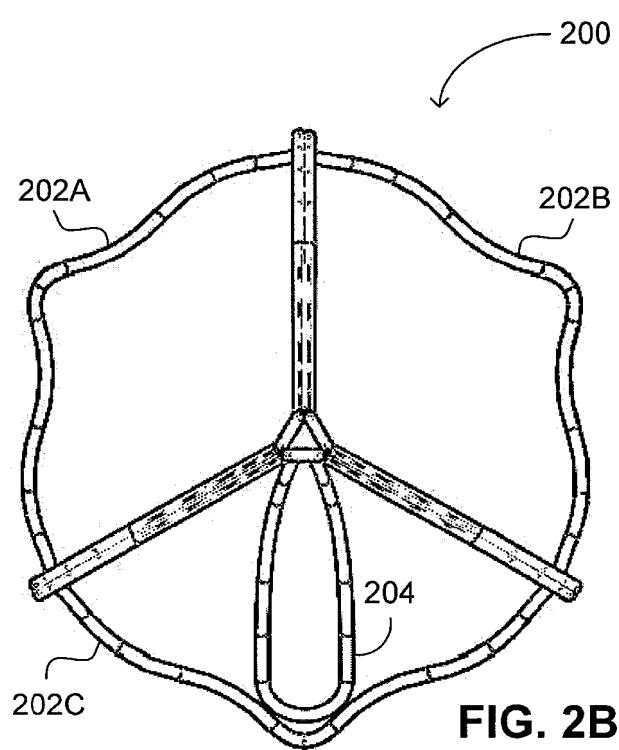
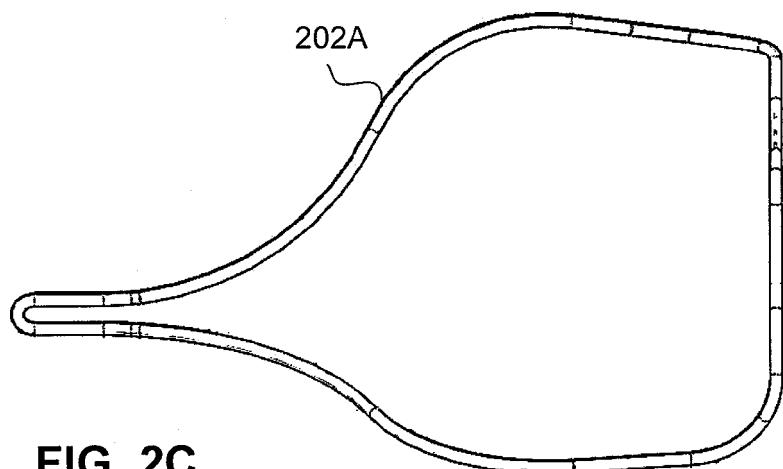
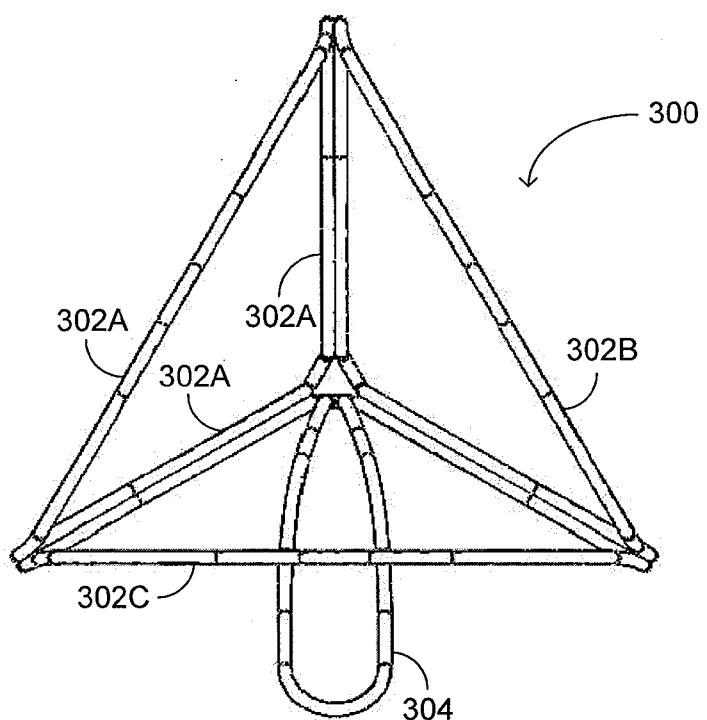
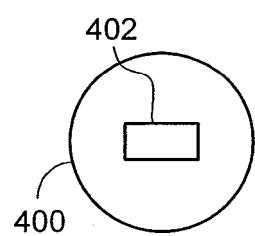
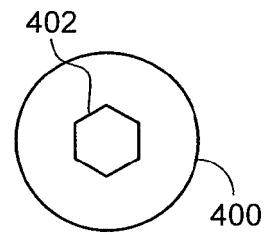
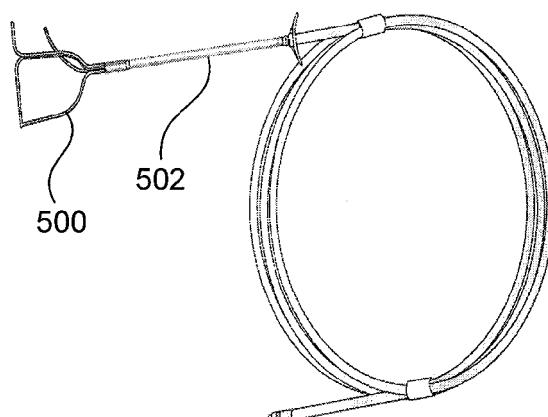
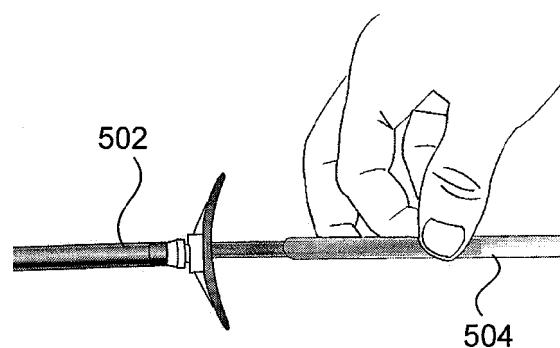
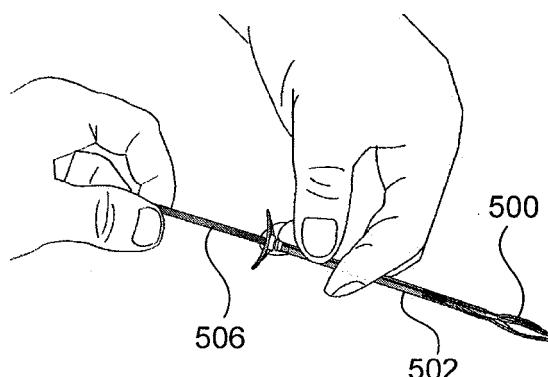
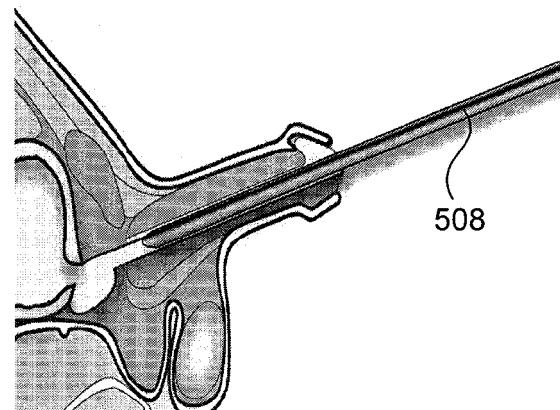
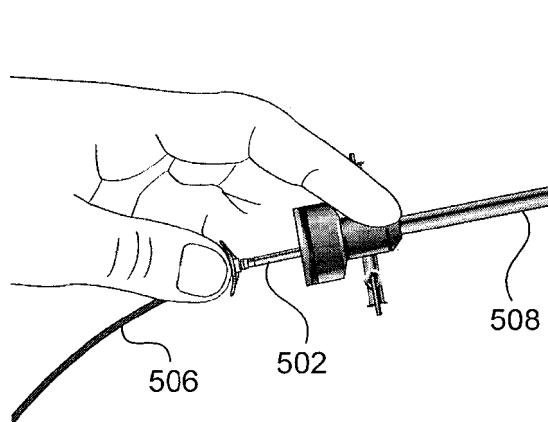
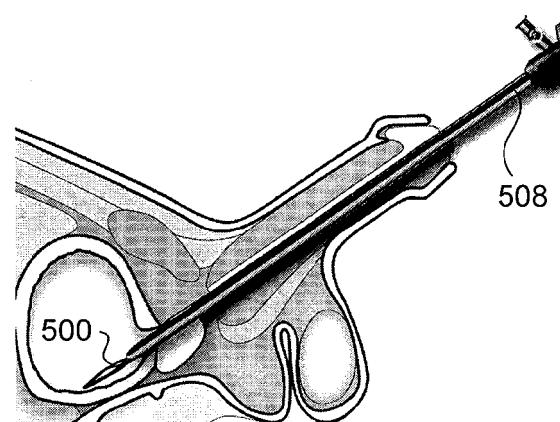
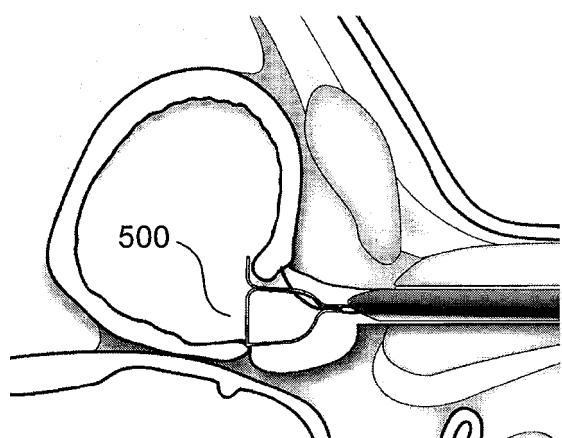
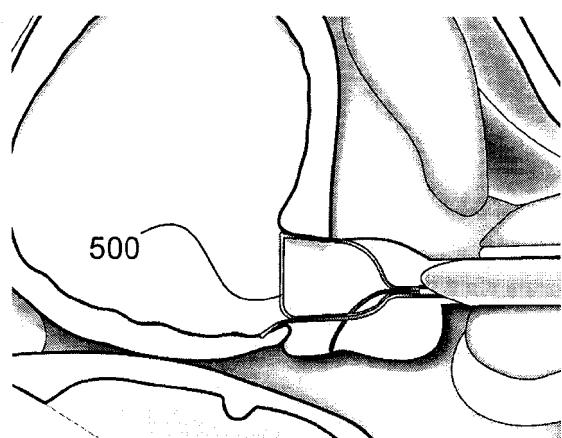
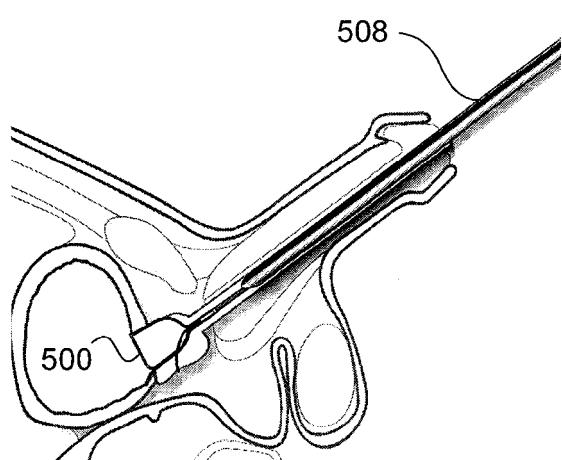
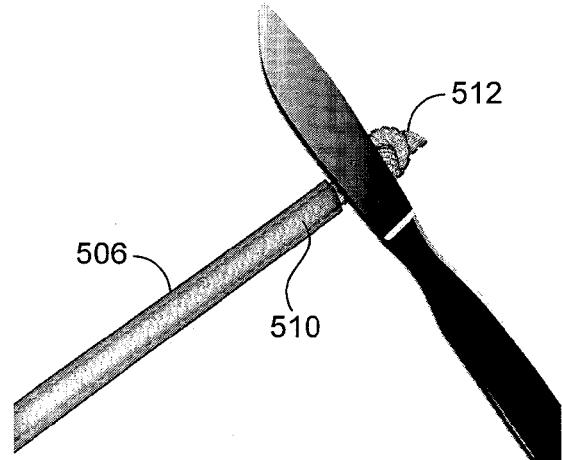
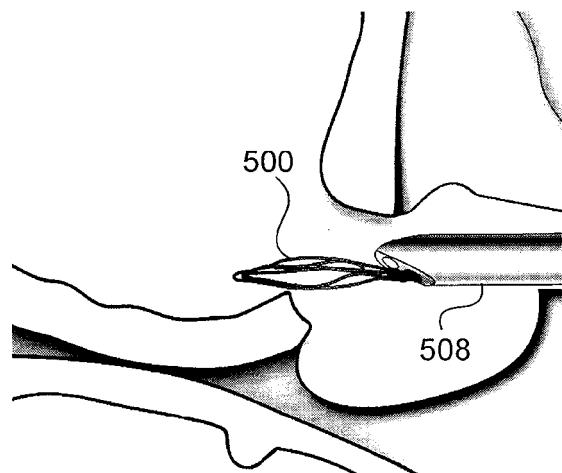
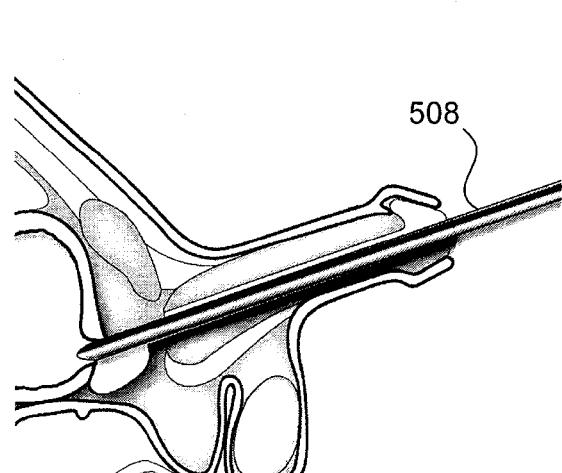


FIG. 1C

**FIG. 2A****FIG. 2B****FIG. 2C**

**FIG. 3****FIG. 4A****FIG. 4B**

**FIG. 5A****FIG. 5B****FIG. 5C****FIG. 5D****FIG. 5E****FIG. 5F**

**FIG. 5G****FIG. 5H****FIG. 5I****FIG. 5J****FIG. 5K****FIG. 5L**