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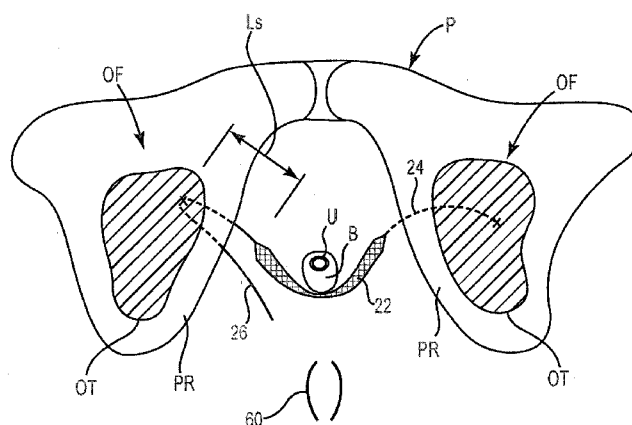


Fig. 3A

(57) Abstract: An incontinence treatment device includes a urethral support and first and second connectors. The urethral support extends between a first end and a second end and has porosity that is configured to allow tissue in-growth through the urethral support. The first connector is attached to the first end of the urethral support and the second connector is attached to the second end of the urethral support. At least one of the first connector and the second connector is a cross-linked polymer connector having a glass transition temperature between 40-70 degrees Celsius. The cross-linked polymer connector has an initial length that is elongated to an implant length that is greater than the initial length. Means for heating the cross-linked polymer connector from an extracorporeal location through intact skin is provided, thereby shortening the cross-linked polymer connector.



INCONTINENCE TREATMENT DEVICE AND METHOD OF TREATING INCONTINENCE

Background

5 Devices for treating urinary incontinence include slings, supports, and other scaffold-like devices that are implanted in a patient's body to support the urethra.

 One incontinence treatment device is a sub-urethral sling that is surgically implanted under the urethra. The implanted sling supports the urethra, which inhibits urine from leaking out of the urethra particularly during a provocative event
10 (e.g., coughing or sneezing).

 Implanting an incontinence treatment device and anatomically securing the device can be difficult and time-consuming. In addition, imperfect anatomical fixation or adjustment in the tension of the device relative to the urethra has the potential to produce suboptimal results in the treatment of urinary incontinence.

15 Other urinary incontinence treatment devices, such as injected bulking liquids, provide beneficial effects, but the beneficial effects of bulking liquids can potentially decrease over time, for example as the liquid is absorbed into the body.

 Improved incontinence treatment devices and methods of implantation of the devices would be welcomed by both the patient and the surgical staff.

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Summary

 One aspect provides an incontinence treatment device including a urethral support and first and second connectors. The urethral support extends between a first end and a second end and has porosity that is configured to allow tissue in-
25 growth through the urethral support. The first connector is attached to the first end of the urethral support and the second connector is attached to the second end of the urethral support. At least one of the first connector and the second connector is a cross-linked polymer connector having a glass transition temperature between 40-70 degrees Celsius. The cross-linked polymer connector has an initial length that is

elongated to an implant length that is greater than the initial length. Means for heating the cross-linked polymer connector from an extracorporeal location through intact skin is provided, thereby shortening the cross-linked polymer connector.

One aspect provides a device adapted to treat incontinence in a patient. The device includes a support having a first end and a second end; a first connector attached to the first end of the support and a second connector attached to the second end of the support; a first anchor coupled to the first connector and a second anchor coupled to the second connector; and a ferromagnet. At least one of the connectors is a cross-linked polymer connector. The device is implantable such that the anchors are fixed within a pelvis of the patient and tissue is grown through the support. The ferromagnet is attached around each cross-linked polymer connector between a midpoint of the cross-linked polymer connector and its respective anchor. The device includes means for shortening, through intact skin from an extracorporeal location, a length of the cross-linked polymer connector between the midpoint of the cross-linked polymer connector and its respective anchor.

One aspect provides a method of treating incontinence in a patient that includes implanting a support by suspending the support from a pair of connectors attached to tissue thereby supporting a urethra of the patient with an implanted support and a pair of implanted connectors. The method additionally includes evaluating the patient for incontinence, and reducing the incontinence of the patient by shortening a length of one of the pair of implanted connectors through intact skin from a location extracorporeal of the patient.

One aspect provides a method of treating incontinence in a patient that includes implanting in a healthcare setting a device having a support supporting a urethra of the patient, a cross-linked polymer connector extending between the support and an anchor attached to pelvic tissue of the patient, and a ferromagnet attached around the cross-linked polymer connector between a midpoint of the cross-linked polymer connector and the anchor. The method additionally includes evaluating the patient for incontinence after discharging the patient from the

healthcare setting, and reducing incontinence of the patient by applying energy through intact skin of the patient thereby heating and shortening the cross-linked polymer connector between the midpoint of the cross-linked polymer connector and the anchor.

5

Brief Description of the Drawings

The accompanying drawings are included to provide a further understanding of embodiments and are incorporated in and constitute a part of this specification. The drawings illustrate embodiments and together with the description serve to
10 explain principles of embodiments. Other embodiments and many of the intended advantages of embodiments will be readily appreciated as they become better understood by reference to the following detailed description. The elements of the drawings are not necessarily to scale relative to each other. Like reference numerals designate corresponding similar parts.

15 Figure 1A is a top view of one embodiment of an incontinence treatment device including a support and connectors extending from the support.

Figure 1B is a cross-sectional view of one of the connectors of the device illustrated in Figure 1A.

20 Figure 1C is a cross-sectional view of the connector of Figure 1A including an insulating sheath.

Figure 2A is a perspective view of one embodiment of a process for extruding a strand suitable for use as one of the connectors illustrated in Figure 1B.

Figure 2B is a side view of one embodiment of a length of the strand illustrated in Figure 2A being irradiated to cross-link molecules of the strand.

25 Figure 2C is a side view of the cross-linked strand illustrated in Figure 2B stretched to orient the molecules in the cross-linked strand and provide the strand at an appropriate implant length.

Figure 2D is a side view of the stretched strand illustrated in Figure 2C heated to relax the oriented molecules in the cross-linked strand and shrink the strand from the implant length to a shorter length.

Figure 3A is a schematic view of the incontinence treatment device
5 illustrated in Figure 1A implanted in a patient.

Figure 3B is a schematic view of the implanted incontinence treatment device adjusted from an extracorporeal location through intact skin of the patient.

Figure 4 is a perspective view of one embodiment of an incontinence treatment device including a ferromagnet placed around a heat-shrinkable
10 connector.

Figure 5A is a perspective view, Figure 5B is an axial cross-sectional view, and Figure 5C is a longitudinal cross-sectional view of the ferromagnet illustrated in Figure 4.

Figure 6A is a schematic view of the incontinence treatment device
15 illustrated in Figure 4 implanted in a patient.

Figure 6B is a schematic view of the incontinence treatment device illustrated in Figure 6A adjusted from an extracorporeal location through intact skin of the patient.

Figure 7 is a top view of one embodiment of an incontinence treatment
20 device including a pair of trans obturator arms, each provided with a connector and a ferromagnet, and a pair of suprapubic arms.

Figure 8 is a schematic view of the incontinence treatment device illustrated in Figure 7 implanted in a patient.

Figure 9 is a flow diagram of one embodiment of a method of treating
25 incontinence in a patient.

Detailed Description

In the following Detailed Description, reference is made to the accompanying drawings, which form a part hereof, and in which is shown by way of

illustration specific embodiments in which the invention may be practiced. In this regard, directional terminology, such as “top,” “bottom,” “front,” “back,” “leading,” “trailing,” etc., is used with reference to the orientation of the Figure(s) being described. Because components of embodiments can be positioned in a number of different orientations, the directional terminology is used for purposes of illustration and is in no way limiting. It is to be understood that other embodiments may be utilized and structural or logical changes may be made without departing from the scope of the present invention. The following detailed description, therefore, is not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims.

It is to be understood that the features of the various exemplary embodiments described herein may be combined with each other, unless specifically noted otherwise.

Tissue includes soft tissue, which includes dermal tissue, sub-dermal tissue, ligaments, tendons, or membranes. As employed in this specification, the term “tissue” does not include bone.

In this application, skin is defined to be an organ including an epidermis upper layer, a hypodermis lower layer, and a dermis layer between the epidermis and hypodermis layers. Intact skin means skin in which the dermis layer is not compromised, which includes, as two illustrative examples, a dermis layer that has been incised but has healed post-surgically and a naturally occurring dermis layer that has not been incised in a surgical procedure.

In this application, “extracorporeal” means from outside of the body. The expression of acting on an implant from “an extracorporeal location through intact skin” means that the implant is adjusted from outside the patient without surgically accessing the implant or cutting into the skin.

People who are incontinent may be segregated into two groups: those with hyper-mobile urethras and those whose urethras are not hyper-mobile. A hyper-mobile urethra will translate into alignment with an exit of the bladder, thus creating

a “straight-shot” pathway from the bladder that allows urine to escape from the bladder and out of the urethra. Physicians have developed an evaluation to determine if the patient has a hyper-mobile urethra. The evaluation entails the placement of an indicator stick into the longitudinal axis of the urethra such that a
5 portion of the indicator stick extends distally out of the patient’s body (those of skill in the art refer to the evaluation as the “Q-tipTM test”). The patient is prompted to initiate a provocative event, for example a cough or a tightening of the abdominal muscles, and the physician observes the indicator stick for movement (this evaluation is sometimes referred to as the “cough test”). Movement of the indicator
10 stick indicates that the longitudinal axis of the urethra is moving, which is indicative of the patient having a hyper-mobile urethra.

The urethra is normally supported by connective and other tissues. Over time, and particularly with parous women, the support of the urethra erodes, giving rise to hyper-mobility of the urethra. As described above, hyper-mobile urethras are
15 susceptible to the undesirable leaking of urine during provocative events such as sneezing, laughing, or coughing (which is sometimes referred to as stress urinary incontinence).

The implant described herein supports the urethra to treat incontinence. In addition, the implant described herein is adjustable post-implant without surgically
20 accessing the implant (e.g., from outside of the patient’s body) to modify/increase the support provided to the urethra from the implant over time.

Figure 1A is a top view of one embodiment of an incontinence treatment device 20 including a urethral support 22 and a pair of connectors 24, 26. In one embodiment, the urethral support 22 extends between a first end 34 and a second
25 end 36, and the first connector 24 is connected to the first end 34 and a second connector 26 is connected to the second end 36 of the urethral support 22.

The urethral support 22 is selected to be tissue compatible for implantation into a human body and is configured to allow tissue ingrowth through its structure to anchor the support 22 in the body after implantation and healing. Suitable material

for the support 22 includes autograft material (the patient's own tissue), allograft material (tissue from a cadaver), xenograft material (tissue from another species), or synthetic materials such as woven fabrics, meshes, nonwoven fabrics, meshes, fibrillated fibers, or spun and fibrillated fibers that are provided with voids (pores) configured to allow tissue ingrowth into the support. The pores are generally larger, on average, than 75 μm .

The support 22 is suitably shaped as a rectangular sling, a multi-arm support having an X-shape with four arms extending from a body, a T-shaped sling having two transverse arms and one longitudinal body, or other pelvic support shapes.

In one embodiment, the support 22 is a knitted monofilament polypropylene mesh having a mass per area between approximately 15-35 g/m^2 with a pore size between approximately 500-1500 μm and a thickness of approximately 260 μm . This mesh is thin and light weight (i.e., the basis weight is less than approximately 35 g/m^2) to provide a thin and comfortable mesh that is less likely to erode tissue that contacts the mesh and less likely to be sensed through the tissue layers by the patient. Other suitable materials for the support 22 include fabrics formed from polyester, polyethylene, silicone, urethanes, polyurethanes, copolymers, or block copolymers of these or suitably similar polymeric materials. Suitable such knitted monofilament polypropylene mesh is available from Coloplast Corp., Minneapolis, MN. Other suitable woven polypropylene mesh material is available from, for example, HerniaMesh, Chivasso, Italy.

The connectors 24, 26 are provided as strands that are employed to suspend the urethral support 22 in a patient's body to support the urethra (female) or to elevate and compress the urethra (male). In one embodiment, at least one of the connectors 24, 26 is provided as a cross-linked polymer connector having a glass transition temperature between 40-70°C. The cross-linked polymer connector, for example connector 26, is provided as an amorphous polymer that is initially irradiated to cause internal cross-linking of the polymer molecules. The cross-linking sets the molecules in a preferred orientation. The cross-linked polymer

connector 26 is stretched from an initial length to a stretched, final product length. When the stretched cross-linked polymer connector is heated, or energy is otherwise provided to overcome the stretched orientation of the molecules, the molecules relax and return to the cross-linked, preferred orientation associated with the initial length
5 of the cross-linked connector 26. In this manner, the cross-linked polymer connector 26 is heat-shrinkable between its stretched, final product length and its initial length.

Figure 1B is a cross-sectional view of the cross-linked polymer connector 26. In one embodiment, the cross-linked polymer connector 26 includes an
10 amorphous polymer 40 that is cross-linked and metal particles 42 that are doped or otherwise dispersed into the polymer 40. The metal particles 42 can be heated, and when heated, cause the polymer 40 to be heated above its glass transition temperature to allow the oriented molecules relax to their initial cross-linked state. In one embodiment, the metal particles 42 are ferromagnetic and respond to
15 induction heating, for example as provided by an inductive heat source producing an alternating current field.

Suitable amorphous polymers 40 that are configured for cross-linking include nylon 12, high density polyethylene, and polyester, as three examples. In one example, an amorphous nylon 12 polymer is selected having a glass transition
20 temperature between 40-70°C. The nylon 12 is irradiated with an electron beam source to cross-link the molecules of the nylon 12. The nylon 12 is stretched and the cross-linked molecules are stretched and oriented. At temperatures below 40°C, the nylon 12 is stable to local temperatures (the temperature of a healthy human body is approximately 37° C). For temperatures above 40° C., approaching 70° C.,
25 the nylon 12 has sufficient molecular mobility to allow the oriented molecules to move or relax from the stretched and oriented state back to the initial cross-linked orientation, thus shrinking in length when heated.

In one embodiment, the metal particles 42 are provided in the polymer 40. The metal particles 42 are configured to be heated and conduct the heat to the

polymer 40 to transition the polymer 40 between the stretched / oriented state back to the initial cross-linked (short) state. Suitable materials for the metal particles 42 include metal elements and alloys of metal, for example iron, or an iron alloy including NiCu, or an iron alloy including CoPd.

5 The metal particles 42 are provided to conduct heat to the polymer 40. Figure 1C illustrates an embodiment where the cross-linked polymer connector 26 is co-axially extruded, for example, or otherwise coated to include a co-axial sheath 43 of a low thermal conductivity material provided to insulate the cross-linked polymer connector 26, when heated, from adjacent tissue. Suitable materials having low
10 thermal conductivity include foams (for example polyolefin foam) or polymer sheaths that are not doped with metal particles. Thus, in one embodiment the illustrated cross-linked polymer connector 26 is provided with an insulating exterior cover / sheath 43 of a material having a thermal conductivity that is lower than the thermal conductivity of the polymer 40 / particle 42 system.

15 Figure 2A is a perspective view of one embodiment of a process 50 for forming a strand 51 suitable for use as one of the cross-linked polymer connectors 26. In one embodiment, the strand 51 is formed by an extruder 53 that delivers amorphous polymer through a fiber-forming spinnerette 52.

 Figure 2B is a side view of one embodiment of the strand 51 being irradiated
20 by an irradiation source 54 to cross-link molecules of the strand 51. The radiation causes the strand 51 to retain a memory of its initial length L1.

 Figure 2C is a side view of the strand 51 stretched to a stretched implant length Ls to form the cross-linked connector 26. The energy or the force that is employed to stretch the cross-linked connector 26 from its initial length L1 to the
25 stretched length Ls (e.g., the implant length Ls) overcomes the energy of the cross-linked molecular orientation to orient (or re-orient) the molecules in the connector 26 at the desired implant length Ls.

 Figure 2D is a side view of the stretched strand / connector 26 heated to relax the oriented molecules in the cross-linked strand / connector 26. When the

connector 26 is heated, from a heat source or energy source 56 such as an inductive energy source, the molecules relax and the connector 26 shrinks to a shortened length L2 (shorter than the implant length Ls). Additional applied energy or continuous heating will shrink the connector 26 back to the cross-linked orientation associated with the un-stretched, initial length L1 (Figure 2B). Suitable energy sources 56 are those that are able to penetrate the human body through intact skin and include microwave energy sources or inductively coupled devices that provide an alternating current field that couples with the metal particles 42 (Figure 1B) to heat the metal particles 42, thus heating and shrinking polymer 40.

As mentioned above, in one embodiment the connector 26 is fabricated from an amorphous polymer 40 that is doped with metal particles 42. The above discussion applies to connectors or strands formed from a cross-linkable amorphous polymer, such as nylon 12 that does not include metal particles. An un-doped cross-linked polymer system, when irradiated, stretched, and suitably heated (e.g., via radiation or convection), will behave as described above. In one embodiment, the metal particles 42 are incorporated into the amorphous polymer 40 to allow the connector 26 to receive extracorporeal heat sources such as microwaves, inductors, and other wireless energy transmitters and become heated.

Figure 3A is a schematic view of the incontinence treatment device 20 attached to tissue to support a urethra U of the patient. In one embodiment, the device 20 is attached between opposing obturator membrane tissue OT of opposing obturator foramen OF, although the device is acceptably attachable to other pelvic tissue. The urethral support 22 is generally placed against bulbous spongiosum tissue B of the urethra to decrease possible erosion of the urethra itself. The connectors 24, 26 extend from the support 22 around a portion of the pubic ramus PR bones and are terminated in the obturator membrane tissue OT. In one embodiment, the patient is a female and the incontinence treatment device 20 supports the urethra U without compressing the urethra U. In one embodiment, the

patient is a male and the incontinence treatment device 20 supports the urethra U by elevating and compressing at least a portion of a bulb the urethra U.

In one embodiment, the incontinence treatment device 20 is introduced through a single perineal incision 60 along an inside out pass that places the
5 connectors 24, 26 around a portion of the pubic ramus PR. For example, the surgeon places the connectors 24, 26 either digitally with a finger or with a tool into the incision 60 and guides the each connector 24, 26 inwardly for termination with pelvic tissue, for example a ligament or the membrane tissue OT of the obturator foramen OF.

10 The incontinence treatment device 20 is implanted in the patient such that the support 22 is suspended under the urethra U in contact with the bulbous spongiosum tissue B, and the connectors 24, 26 are terminated into tissue. When implanted, the connector 26 extends between the support 22 and the membrane tissue OT and has the stretched implant length Ls. The device 20 is initially
15 adjusted during the implantation surgery to ensure that an appropriate level of support is provided to the urethra U to reduce or eliminate the incontinent condition of the patient. Thereafter, the surgeon closes the minimally invasive incision 60 according to acceptable practices. The incontinence treatment device 20 provides the patient with a level of continence immediately after implantation due to the
20 suspension provided by the support 22 to the urethra, or due to the elevation and compression (in males) that is provided to the urethra U.

Figure 3B is a schematic view of the implanted incontinence treatment device 20. The patient, through the healing process or other activities, might eventually experience a reduced level of continence characterized by leaking of
25 urine from the urethra. The prior solution, in such cases, would be to schedule the patient for surgery, incise tissue of the patient, and adjust the tension of the support or the connectors manually inside of the body. In contrast, the implanted incontinence treatment device 20 provides the patient and the surgeon with the ability to adjust the connector 26 from an extracorporeal location through intact skin

S by shortening the cross-linked polymer connector 26 from the implanted length L_s (Figure 3A) to a shorter length L_2 . The shortened connector 26 “tightens” and applies increased beneficial support to urethra U to reduce or eliminate the patient’s incontinence.

5 In one embodiment, the surgeon adjusts the connector 26 in a clinical setting by applying an extracorporeal energy source, for example an inductive heating device providing alternating current energy through the patient’s skin S, without forming an incision, and the energy is directed to the connector 26. The metal particles 42 (Figure 1B) are inductively heated and cause local heating of the
10 polymer 40. Heating of the polymer 40 relaxes the orientation of the molecules of the connector 26 and allows the molecules to return toward the initial orientation associated with the cross-linked state having initial length L_1 (Figure 2B). In this manner, the connector 26 heat shrinks from the final stretched implant length L_s (Figure 3A) to a shorter length L_2 (Figure 2D). The shorter length L_2 is less than
15 the stretched implant length L_s , such that the connector 26 shrinks in response to local heating to provide additional urethral support and improved continence. If the energy source is applied for a sufficiently long duration of time, the connector 26 will heat shrink from the final product length, or stretched implant length L_s , all the way back to the initial length L_1 .

20 Figure 4 is a perspective view of one embodiment of an incontinence treatment device 80. The device 80 includes a support 82, connectors 84, 86 extending from the support 82, anchors 88, 90 attached to the connectors 84, 86, respectively, and a ferromagnetic unit 92 attached to the connector 86.

 The support 82 is similar to and suitably fabricated from the materials
25 described above for support 22.

 In one embodiment, at least one of the connectors 84, 86 is fabricated to provide a cross-linked polymer connector having a glass transition temperature between 40-70°C. In one embodiment, the first connector 84 is provided as a standard polypropylene suture material and the second connector 86 is provided as a

heat shrinkable cross-linked polymer connector as described above for connector 26.

In one embodiment, the anchors 88, 90 are adjustable anchors that move relative to the connectors 84, 86, respectively. In one embodiment, at least one of the anchors 88, 90 is fixed relative to its respective connector 84, 86.

The ferromagnetic unit 92 is provided to receive energy and be heated, and conduct the heat to the connector 86, which allows the connector 86 to heat shrink as the molecules in a cross-linked polymer connector 86 relax in response to the heat energy. For example, in one embodiment energy is delivered to the patient's body from an extracorporeal location from an induction heating device. The ferromagnetic unit 92 couples with the field from the induction heating device and becomes heated. The heated ferromagnetic unit 92 conducts heat to the connector 86, allowing the connector 86 to be heated to a temperature above its glass transition temperature, which relaxes the molecules in the connector 86 to permit heat shrinking of the connector 86.

The heat delivered to the connector 86 is proportional to the length of the ferromagnetic unit 92. It has been discovered that the amount of shrinkage delivered to the connector 86 is a function of the length of the ferromagnetic unit 92. With this in mind, in one embodiment the ferromagnetic unit 92 is placed around less than half of the implant length L_s of the connector 86. In one embodiment, the ferromagnetic unit 92 is placed around the connector 86 closer to the second anchor 90 than to the support 82. That is to say, in one embodiment the ferromagnetic unit 92 is placed on the connector 86 between a midpoint M_p of the connector 86 and the anchor 90 to heat and shorten that portion of the connector 86. In one embodiment, the ferromagnetic unit 92 has a length between 0.5–6.0 cm, and preferably the ferromagnetic unit 92 has a length of approximately 2 cm.

In one embodiment, the ferromagnetic unit 92 is placed on the connector 86 between a midpoint M_p of the connector 86 and the anchor 90 to heat and shorten

that portion of the connector 86 and not heat the length of the cross-linked polymer connector 86 between the midpoint Mp of the connector 86 and the support 82.

Figure 5A is a perspective view, Figure 5B is an axial cross-sectional view, and Figure 5C is a longitudinal cross-sectional view of the ferromagnet unit 92. In one embodiment, the ferromagnetic unit 92 is provided as a cylinder having an axial hole 94 extending the length of the cylinder. The axial hole 94 is sized to receive and fit snugly around the connector 86 in a heat-conducting configuration.

In one embodiment, the ferromagnetic unit 92 includes a core 96 of material and a thermal insulator 98. The core 96 of material is configured to respond to induction heating, and in one embodiment is provided as an alloy of NiCu or an alloy of CoPd. The ferromagnetic unit 92 is heatable to heat the connector 86, and is preferably tailored to minimize overheating and/or heating of the adjacent tissue. For example, in one embodiment the core 96 is selected to have a Curie temperature that is higher than the glass transition temperature of the connector 86. In this configuration, the ferromagnetic unit 92 would cease to heat once it becomes paramagnetic as it reaches its Curie temperature. In this manner, the ferromagnetic unit 92 is self-regulating and is designed to have a ceiling temperature above which it will not heat. For example, in one embodiment the connector 86 has a glass transition temperature of between 40-70°C and the ferromagnetic unit 92 is fabricated to have a Curie temperature of between 60-75° C. As an example, in one embodiment the cross-linked polymer connector 86 is heat shrinkable at a temperature above 43 degrees Celsius, and the ferromagnetic unit 92 has a Curie temperature of approximately 60 degrees Celsius such that the ferromagnetic unit 92 will inductively heat to a temperature of 60 degrees Celsius or less to effectively heat the connector 86 without undesirably over heating the surrounding tissue.

The thermal insulator 98 is provided around the core 96 to ensure that the temperature of the ferromagnetic unit 92 does not become so hot as to deleteriously affect the patient. In one embodiment, the thermal insulator 98 is provided as a

ceramic or a pyrolytic carbon sleeve disposed around an exterior surface of the core 96.

Figure 6A is a schematic view of the incontinence treatment device 80 implanted in a patient. The anchors 88, 90 are fixed into tissue T and the connectors 84, 86 extend to the support 82 to suspend it under the urethra in contact with the bulbous spongiosum B tissue. The ferromagnetic unit 92 is closer to the second anchor 90 than it is to the support 82 such that a distance D1 is established between an end of the support 82 and the tissue T. In one embodiment, the incontinence treatment device 80 is implanted through a minimally invasive incision and suspended between the membranes of the opposing obturator foramen of the patient.

The device 80 is adjusted by the surgeon during surgery to ensure that an appropriate level of support is provided to the urethra U to reduce or eliminate the incontinent condition of the patient. Thereafter, the surgeon closes the minimally invasive incision according to acceptable practices. The incontinence treatment device 80 provides the patient with a level of continence immediately after implantation due to the suspension provided by the support 82 to the urethra, or due to the elevation and compression (in males) that is provided to the urethra U.

The implanted incontinence treatment device 80 provides the surgeon with the ability to adjust the connector 86 from an extracorporeal location through intact skin of the patient, thereby shortening the cross-linked polymer connector 86 and applying increased beneficial support to urethra U.

Figure 6B is a schematic view of the incontinence treatment device 80 as implanted and adjusted from an extracorporeal location through intact skin of the patient. There can be times when the patient discovers the presence of stress urinary incontinence, and the device 80 is configured to treat the stress urinary incontinence in a clinical setting. In one approach, the patient meets with the surgeon to discuss the incontinence, and the surgeon evaluates the level of incontinence, for example with the "cough test" described above. If the surgeon determines that stress urinary incontinence is present, the connector 86 is shortened from a location extracorporeal

from the patient, without an incision, to reduce or eliminate the stress urinary incontinence.

In one embodiment, the surgeon applies an energy field through the intact skin of the patient, and the energy heats the ferromagnetic unit 92. The heated
5 ferromagnetic unit 92 transfers heat to the connector 86, which warms a portion of the connector 86 above the glass transition temperature of the cross-linked polymer connector 86, thus allowing the molecules of the connector 86 to relax and shrink the connector 86 from the distance D1 (Figure 6A) to distance D2.

Small changes in the length of the connector 86 will result in increased
10 support to urethra U. In this regard, the length of the connector 86 need not be adjusted from the stretched implant length Ls all the way back to the much shorter initial length L1. The surgeon, as guided by experience, will briefly apply the energy to the connector 86, repeat the cough test, and iterate this process until a suitable level of continence for the patient is achieved.

15 In one embodiment, the ferromagnetic unit 92 has a length between 0.5-4 cm and is inductively heatable through intact skin to heat and thereby shorten only that portion of the connector 86 that is under the ferromagnetic unit 92 and that portion of the connector 86 that is within one length of the ferromagnetic unit 92.

Figure 7 is a top view of one embodiment of an incontinence treatment
20 device 100. The device 100 includes a support body 102, a pair of trans obturator arms 104, 106 extending from the support body 102, a pair of suprapubic arms 108, 110 extending from the support body 102 and connectors 114, 116, 118, 120 each extending from a respective one of the arms. The support body 102 and the arms 104, 106, 108, 110 are each suitably fabricated from the materials described above
25 for the support 22 (Figure 1A).

In one embodiment, the connectors 114, 116 are provided with anchors 124, 126, respectively. The anchors 124, 126 include anchors that are fixed to the respective connectors, anchors that are movable relative to their connectors, or combinations of fixed and adjustable anchors.

One or more of the connectors 114, 116, 118, 120 is configured to be heat shrinkable consistent with the embodiment described above in Figure 1A including the cross-linked polymer that is doped with metal particles or the embodiment described above in Figure 4 including the cross-linked polymer provided with a ferromagnet. For example, in one embodiment the connectors 114, 116 are each provided as a cross-linked polymer connector have a glass transition temperature between 40-70°C and include a ferromagnetic unit 134, 136, connected around a respective one of the connectors 114, 116. In another embodiment, all of the connectors 114, 116, 118, 120 are provided as heat shrinkable connectors (anchorless or with anchors as determined to be suitable for the surgical application).

In one embodiment, the incontinence treatment device 100 is surgically implanted into a patient via a single, minimally invasive incision in which the anchors 124, 126 are attached to a membrane extending over an opposing one of the obturator foramen to suspend the trans obturator arms 104, 106 across the pelvis, and the suprapubic arms 108, 110 are tunneled and terminated subcutaneously within the patient suprapubically. In one embodiment, the suprapubic arms 108, 110 are provided with optional removable sleeves 138, 140, respectively, that are employed to assist in the placement of the suprapubic arms 108, 110 suprapubically. The sleeves 138, 140 are removed from the arms 108, 110 after the arms are placed suprapubically within a patient.

Figure 8 is a schematic view of the incontinence treatment device 100 implanted in a male patient. The illustration presents a sub-dermal view of the location of the support body 102 relative to the ventral urethral bulb B of the patient. The trans obturator arms 104, 106 extend between membranes covering the obturator foramen OF. The suprapubic arms 108, 110 are tunneled and terminated subcutaneously within the patient suprapubically.

The tension in the connectors 114, 116 is adjustable surgically via the anchors 124, 126 that tension the support body 102 to elevate and compress the

ventral urethral bulb B of the patient. The suprapubic arms 108, 110 are tunneled subcutaneously to compress the perineal urethra U. The surgeon adjusts the tension / elevation of the support body 102 via the anchors 124, 126, and adjusts the compression of the support body 102 against the ventral urethral bulb B of the patient by selectively tightening the suprapubic arms 108, 110. This surgical adjustment of the two pairs of arms may be done incrementally until the surgeon achieves the desired coaptation of the urethra U through the elevation and compression of the ventral urethral bulb B of the patient.

Thereafter, the tension in the connectors 114, 116 is adjustable post-operatively through the intact skin of the patient (without forming an incision) to address instances of recurring incontinence post-surgically consistent with the embodiments described above.

Figure 9 is a flow diagram 150 of one embodiment of a method of treating incontinence in a patient. The method includes implanting the device at 152 and adjusting one or more connectors of the device during surgery at 154. Consistent with the surgical implantation of a medical device, the patient is discharged from a hospital or day care surgery center and allowed to heal at 156. The patient, for various reasons, may experience the recurrence of undesirable discharge of urine from the urethra (incontinence). The method provides means for addressing postsurgical incontinence by evaluation of the continence of the patient at 158 by a medical professional, for example through conducting a cough test or other suitable test. One example of the cough test includes an indicator, such as an absorbent stick, placed in the patient's urethra prior to the patient being prompted to cough or otherwise voluntarily stress the abdominal area. The indicator is observed for movement (which indicates hypermobility of the urethra) and urine discharge from the urethra. If the medical professional determines that the patient does not have a hypermobile urethra or urine discharge, the patient is deemed to be continent at 160. Alternatively, urine discharged from the urethra indicates incontinence at 162. Embodiments described herein provide for the adjustment of a connector or of

the support of the urinary incontinence device at 164 from an extracorporeal location as applied through intact skin in an office setting to adjust/elevate/compress or otherwise provide improved support to the urethra.

Although specific embodiments have been illustrated and described herein, it
5 will be appreciated by those of ordinary skill in the art that a variety of alternate
and/or equivalent implementations may be substituted for the specific embodiments
shown and described without departing from the scope of the present invention.
This application is intended to cover any adaptations or variations of medical
devices as discussed herein. Therefore, it is intended that this invention be limited
10 only by the claims and the equivalents thereof.

WHAT IS CLAIMED IS:

1. An incontinence treatment device comprising:
 - a urethral support extending between a first end and a second end and having porosity configured to allow tissue in-growth through the urethral support;
 - a first connector attached to the first end of the urethral support and a second connector attached to the second end of the urethral support, at least one of the first connector and the second connector comprising a cross-linked polymer connector having a glass transition temperature between 40-70 degrees Celsius, the cross-linked polymer connector having an initial length, the cross-linked polymer connector elongated to an implant length that is greater than the initial length; and
 - means for heating the cross-linked polymer connector from an extracorporeal location through intact skin thereby shortening the cross-linked polymer connector.
2. The incontinence treatment device of claim 1, wherein the cross-linked polymer connector is doped to include metal particles and the means for heating the cross-linked polymer connector comprises an induction heating source configured to inductively couple with the metal particles.
3. The incontinence treatment device of claim 1 or 2, wherein the cross-linked polymer connector is one of nylon and polyolefin.
4. The incontinence treatment device of claim 1, 2 or 3, wherein the cross-linked polymer connector comprises an insulating sheath having a thermal conductivity that is lower than a thermal conductivity of the cross-linked polymer connector.

5. The incontinence treatment device of any one of the claims 1 – 4, further comprising:
 - a ferromagnetic unit placed around less than half of the implant length of the cross-linked polymer connector, the ferromagnetic unit inductively heatable through intact skin to heat and thereby shorten less than half of the implant length of the cross-linked polymer connector.
6. The incontinence treatment device of claim 5, wherein the cross-linked polymer connector is heat shrinkable at a temperature above 40 degrees Celsius, and the ferromagnetic unit comprises a Curie temperature of approximately 60 degrees Celsius.
7. The incontinence treatment device of claim 5 or 6, wherein the ferromagnetic unit comprises a cylinder defining an axial hole that is sized to receive the connector.
8. The incontinence treatment device of claim 5, 6 or 7, wherein the ferromagnetic unit has an outer surface insulator provided to minimize heating of tissue that is adjacent to the cross-linked polymer connector.
9. The incontinence treatment device of any one of the claims 5 – 8, further comprising:
 - a first anchor coupled to the first connector and a second anchor coupled to the second connector.
10. The incontinence treatment device of claim 9, wherein the ferromagnetic unit is placed around the second connector nearer to the second anchor than to the urethral support.

11. The incontinence treatment device of claim 9 or 10, wherein the ferromagnetic unit is placed around the second connector between a midpoint of the second connector and the second anchor.
12. The incontinence treatment device of claim 9, 10 or 11, wherein the first and second anchors each comprise an adjustable anchor that is movably attached along a respective one of the first and second connectors.
13. The incontinence treatment device of any one of the claims 9 – 12, wherein the first anchor is fixed in place relative to the first connector and the second anchor is an adjustable anchor that is movably attached along the second connector.
14. The incontinence treatment device of any one of the claims 9 – 13, wherein the first anchor is fixed in place relative to the first connector and the second anchor is fixed in place relative to the second connector, and the incontinence treatment device further comprises:
 - a ferromagnetic unit disposed around the first connector at a location nearer to the first anchor than to the urethral support.
15. The incontinence treatment device of any one of the claims 5 – 14, wherein the ferromagnetic unit has a length and is inductively heatable through intact skin to heat and thereby shorten only that portion of the connector that is under the ferromagnetic unit and that portion of the connector that is within one length of the ferromagnetic unit.
16. A device adapted to treat incontinence in a patient, the device comprising:
 - a support having a first end and a second end;

a first connector attached to the first end of the support and a second connector attached to the second end of the support, at least one of the connectors comprising a cross-linked polymer connector;

a first anchor coupled to the first connector and a second anchor coupled to the second connector, the device implantable such that the anchors are fixed within a pelvis of the patient and tissue is grown through the support;

a ferromagnet attached around each cross-linked polymer connector between a midpoint of the cross-linked polymer connector and its respective anchor; and

means for shortening, through intact skin from an extracorporeal location, a length of the cross-linked polymer connector between the midpoint of the cross-linked polymer connector and its respective anchor.

17. The device of claim 16, comprising means for shortening, through intact skin from an extracorporeal location, only the length of the cross-linked polymer connector between the midpoint of the cross-linked polymer connector and its respective anchor.

18. The device of claim 16 or 17, comprising heating, through intact skin from an extracorporeal location, the length of the cross-linked polymer connector between the midpoint of the cross-linked polymer connector and its respective anchor and not heating a length of the cross-linked polymer connector between the midpoint of the cross-linked polymer connector and the support.

19. The device of claim 16, 17 or 18, comprising selectively shortening only that portion of the cross-linked polymer connector that is between the midpoint of the cross-linked polymer connector and its respective anchor.

20. A method of treating incontinence in a patient, the method comprising:

implanting a support by suspending the support from a pair of connectors attached to tissue thereby supporting a urethra of the patient with an implanted support and a pair of implanted connectors;

evaluating the patient for incontinence post-implantation of the support; and

reducing the incontinence of the patient by shortening a length of one of the pair of implanted connectors through intact skin from a location extracorporeal of the patient.

21. The method of claim 20, wherein suspending the support from a pair of connectors attached to tissue comprises securing a first anchor that is attached to a first connector into tissue and securing a second anchor that is attached to a second connector to tissue, each of the first and second connectors extending from an opposing end of the support.

22. The method of claim 21, comprising anchoring the first anchor to a membrane of a first obturator foramen and anchoring the second anchor to a membrane of a second obturator foramen.

23. The method of claim 20, 21 or 22, wherein shortening a length of one of the pair of implanted connectors comprises inductively heating a ferromagnet that is disposed around a cross-linked polymer connector causing the cross-linked polymer connector to shrink.

24. The method of claim 23, wherein the ferromagnet is disposed around the cross-linked polymer connector at a segment that is closer to where the connector is attached to the tissue than to the support, and causing the cross-linked polymer connector to shrink comprises causing only the segment of the cross-linked polymer connector to shrink.

25. The method of claim 23 or 24, wherein inductively heating a ferromagnet comprises placing an alternating current source outside the patient, directing the alternating current source to the ferromagnet, and heating the ferromagnet.
26. The method of claim 25, wherein an exterior surface of the ferromagnet comprises a thermal insulator such that heating the ferromagnet heats the tissue surrounding the urethra of the patient by less than 10 degrees Celsius.
27. The method of any one of the claims 20 – 26, wherein shortening a length of one of the pair of implanted connectors comprises inductively heating a cross-linked polymer connector that is doped with metal particles, heating the metal particles and heating the cross-linked polymer connector thus causing the cross-linked polymer connector to shrink.
28. The method of any one of the claims 20 – 27, wherein supporting a urethra of the patient comprises positioning the support in contact with bulbous spongiosum tissue surrounding a urethra of the patient.
29. The method of any one of the claims 20 – 28, wherein evaluating the patient for incontinence post-implantation of the support comprises conducting a cough test of the patient and observing for urine discharge from the urethra.
30. The method of any one of the claims 20 – 29, comprising reducing the incontinence of the patient by shortening a length of both of the implanted connectors.
31. A method of treating incontinence in a patient, the method comprising:
implanting in a healthcare setting a device having a support supporting a urethra of the patient, a cross-linked polymer connector extending between the

support and an anchor attached to pelvic tissue of the patient, and a ferromagnet attached around the cross-linked polymer connector between a midpoint of the cross-linked polymer connector and the anchor;

evaluating the patient for incontinence after discharging the patient from the healthcare setting; and

reducing incontinence of the patient by applying energy through intact skin of the patient thereby heating and shortening the cross-linked polymer connector between the midpoint of the cross-linked polymer connector and the anchor.

32. The method of claim 31, wherein the ferromagnet is attached around the cross-linked polymer connector adjacent to the anchor, and heating and shortening the cross-linked polymer connector comprises heating and shortening a segment of the cross-linked polymer connector adjacent to the anchor.

33. The method of claim 31 or 32, comprising heating and shortening less than one-fourth of the cross-linked polymer connector.

34. The method of claim 31, 32 or 33, wherein an exterior surface of the ferromagnet comprises a thermal insulator configured to reduce heating of the support.

35. An incontinence treatment device for use in the treatment of incontinence in a patient, wherein the treatment comprises the method according to any one of the claims 20 – 34.

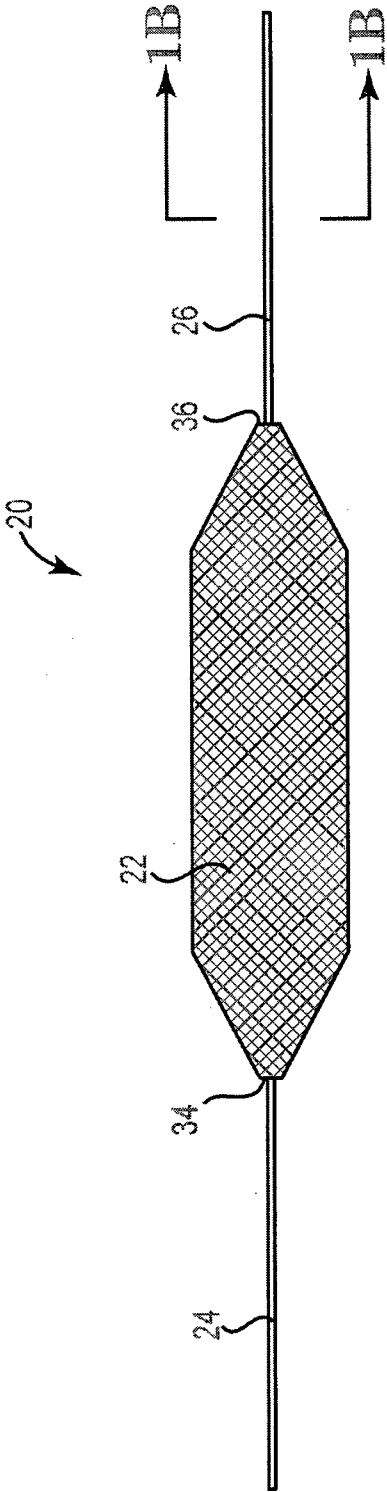
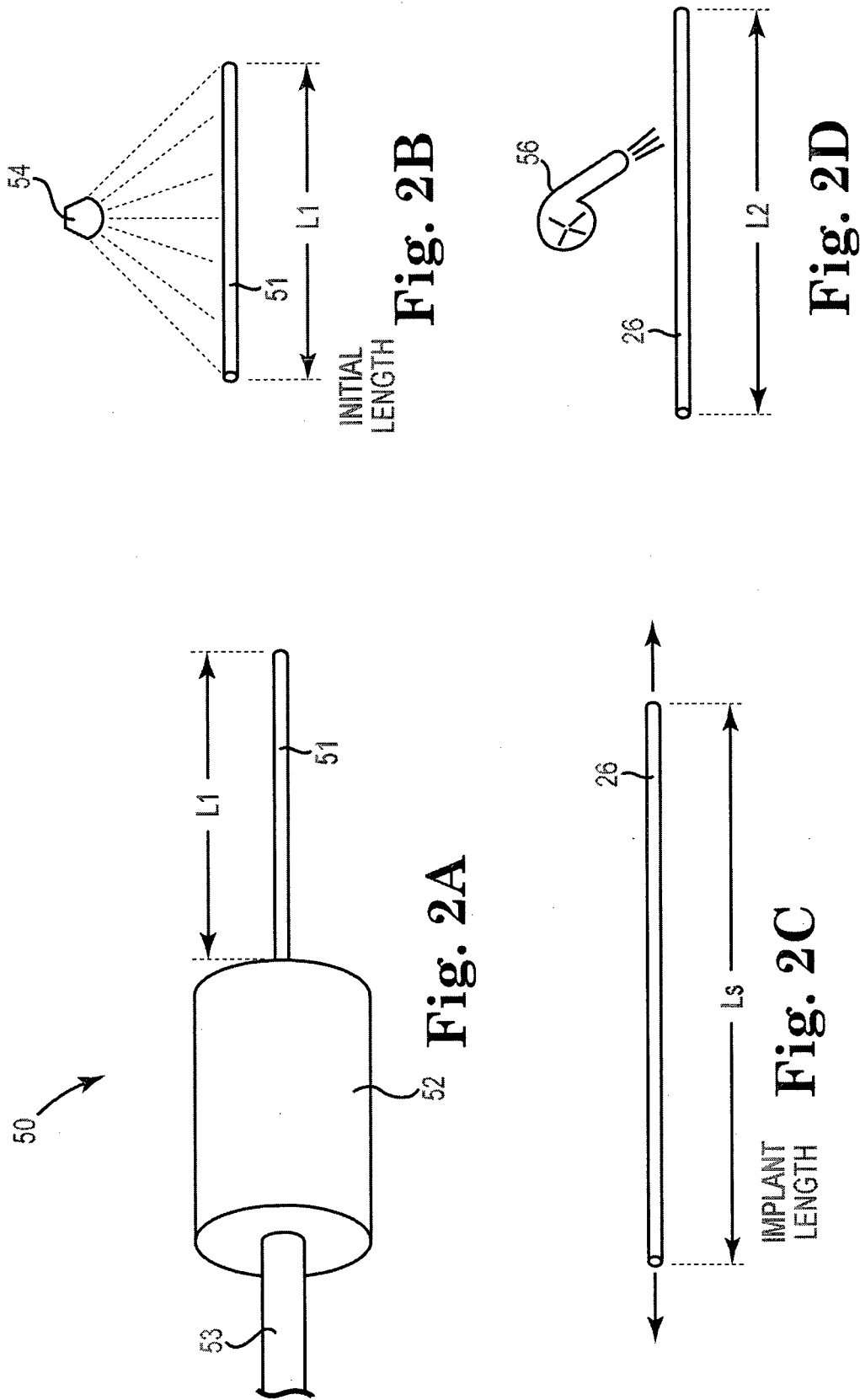


Fig. 1A



Fig. 1B

Fig. 1C



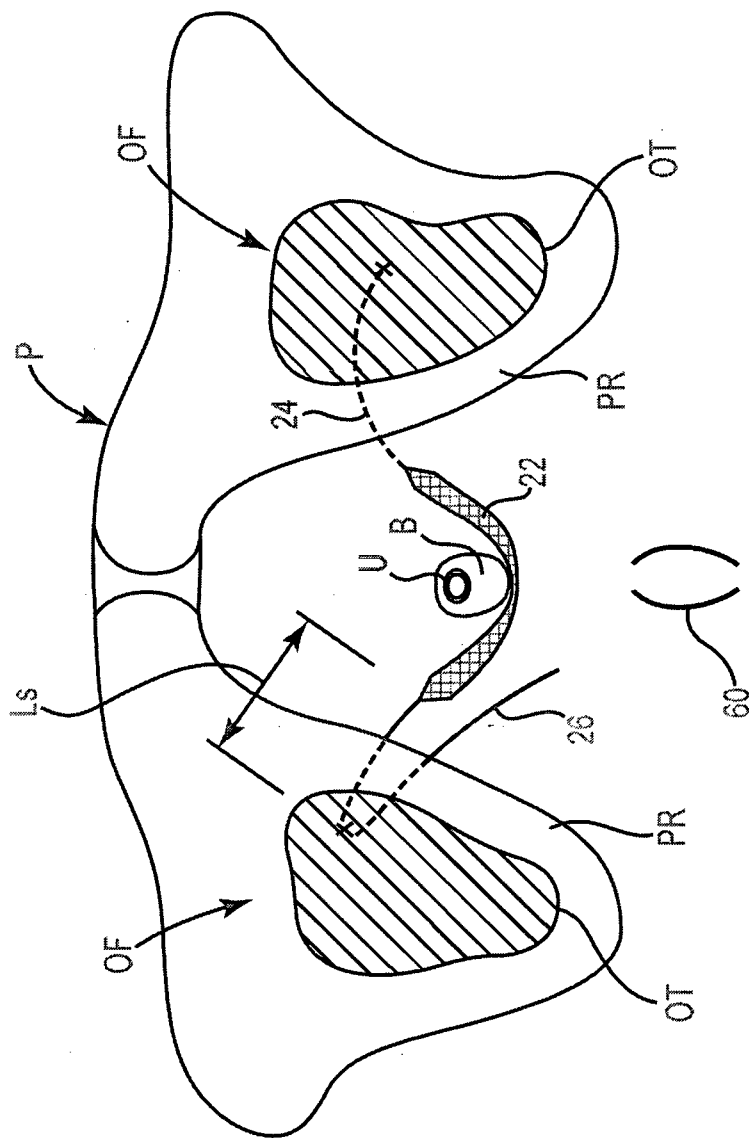
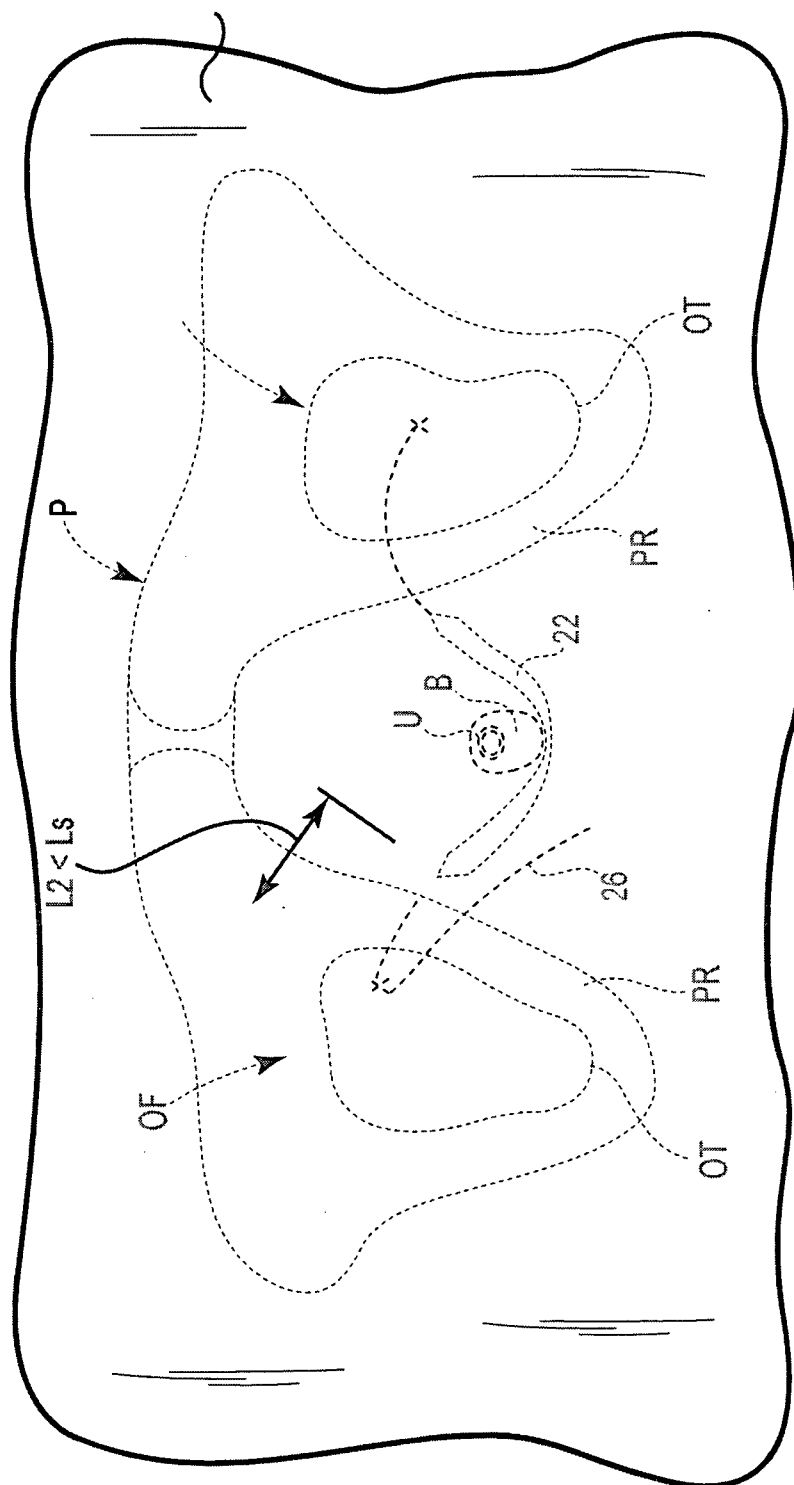


Fig. 3A



Fi. 3B

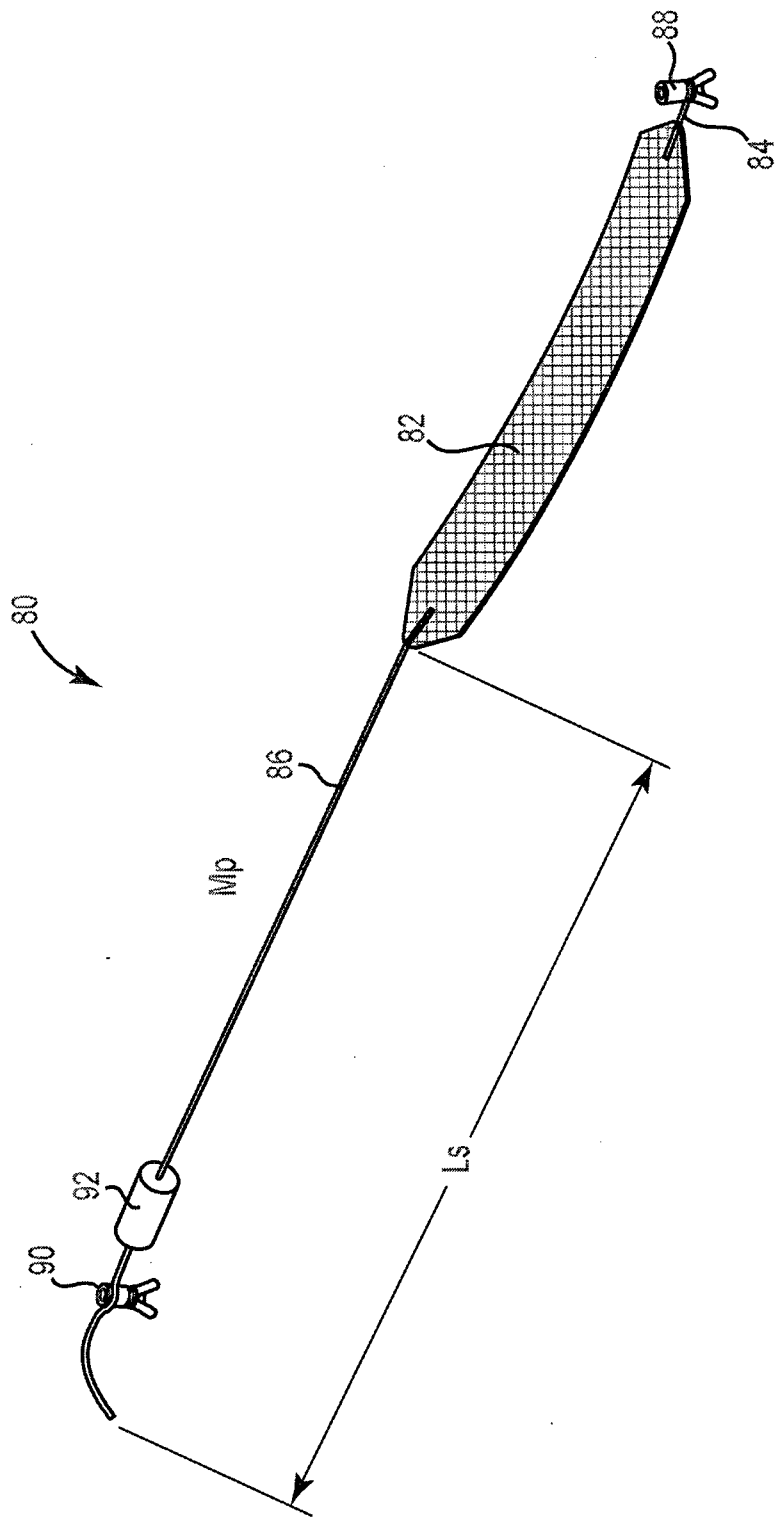


Fig. 4

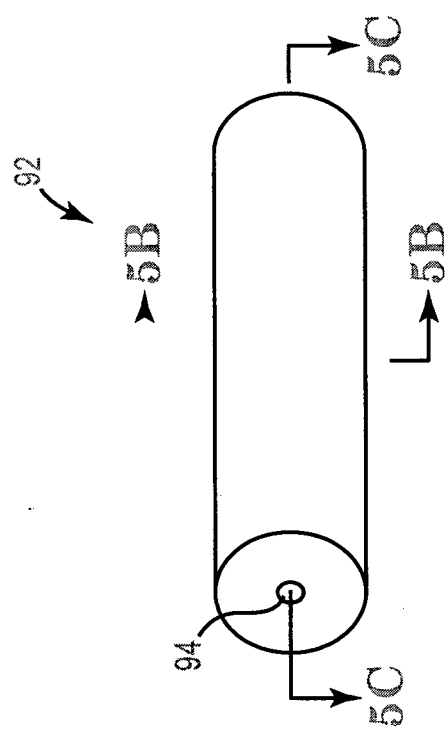


Fig. 5A

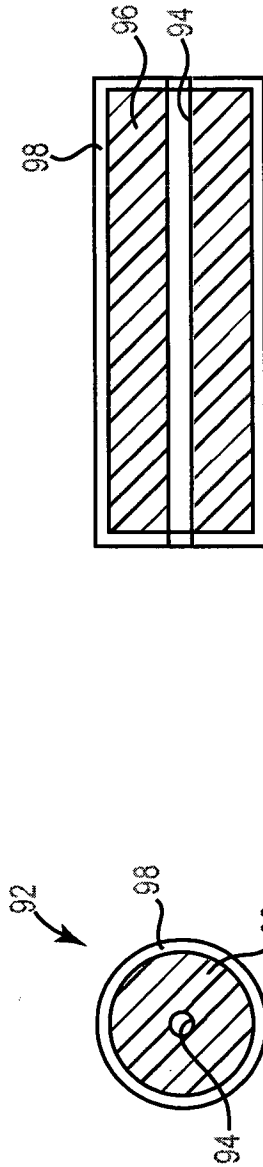


Fig. 5B Fig. 5C

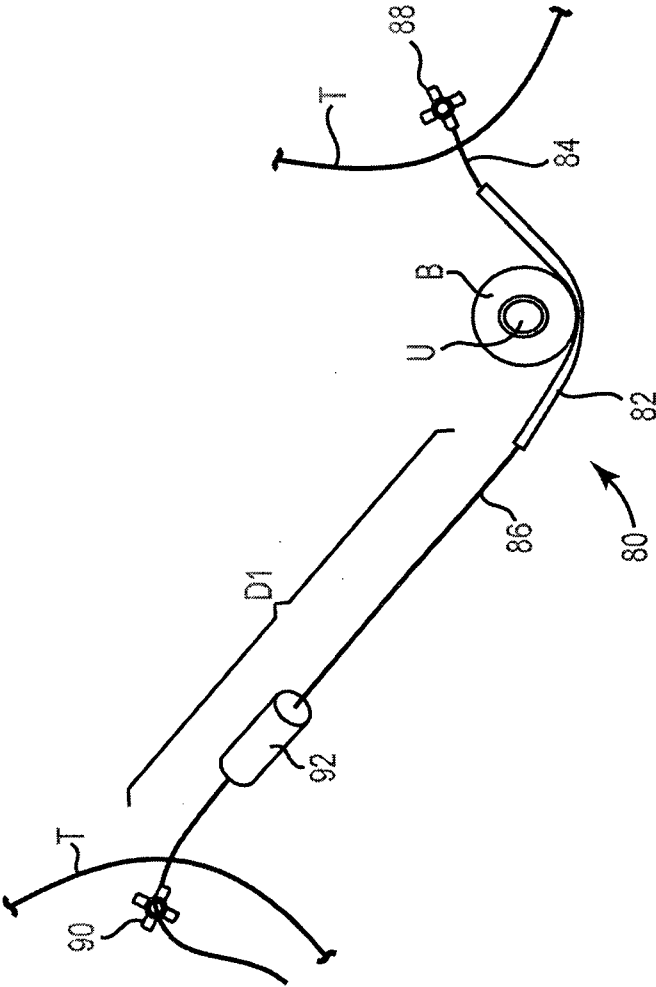
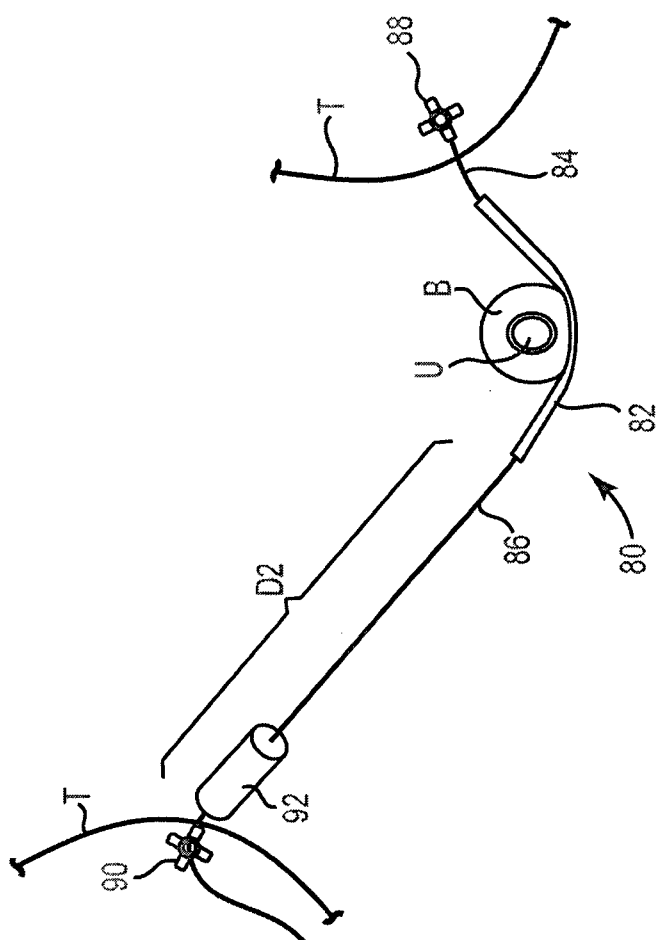


Fig. 6A



Fi. 6B

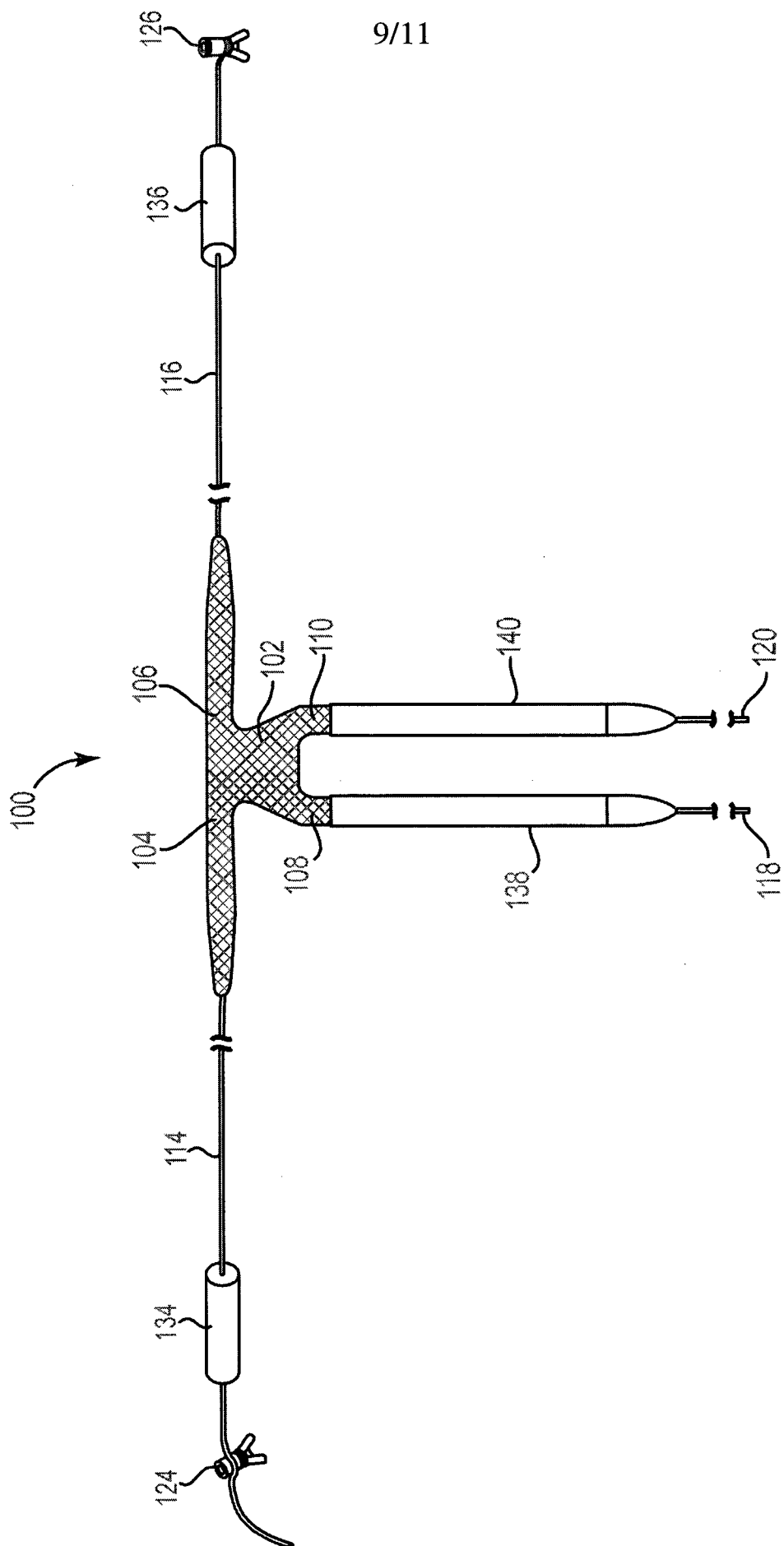


Fig. 7

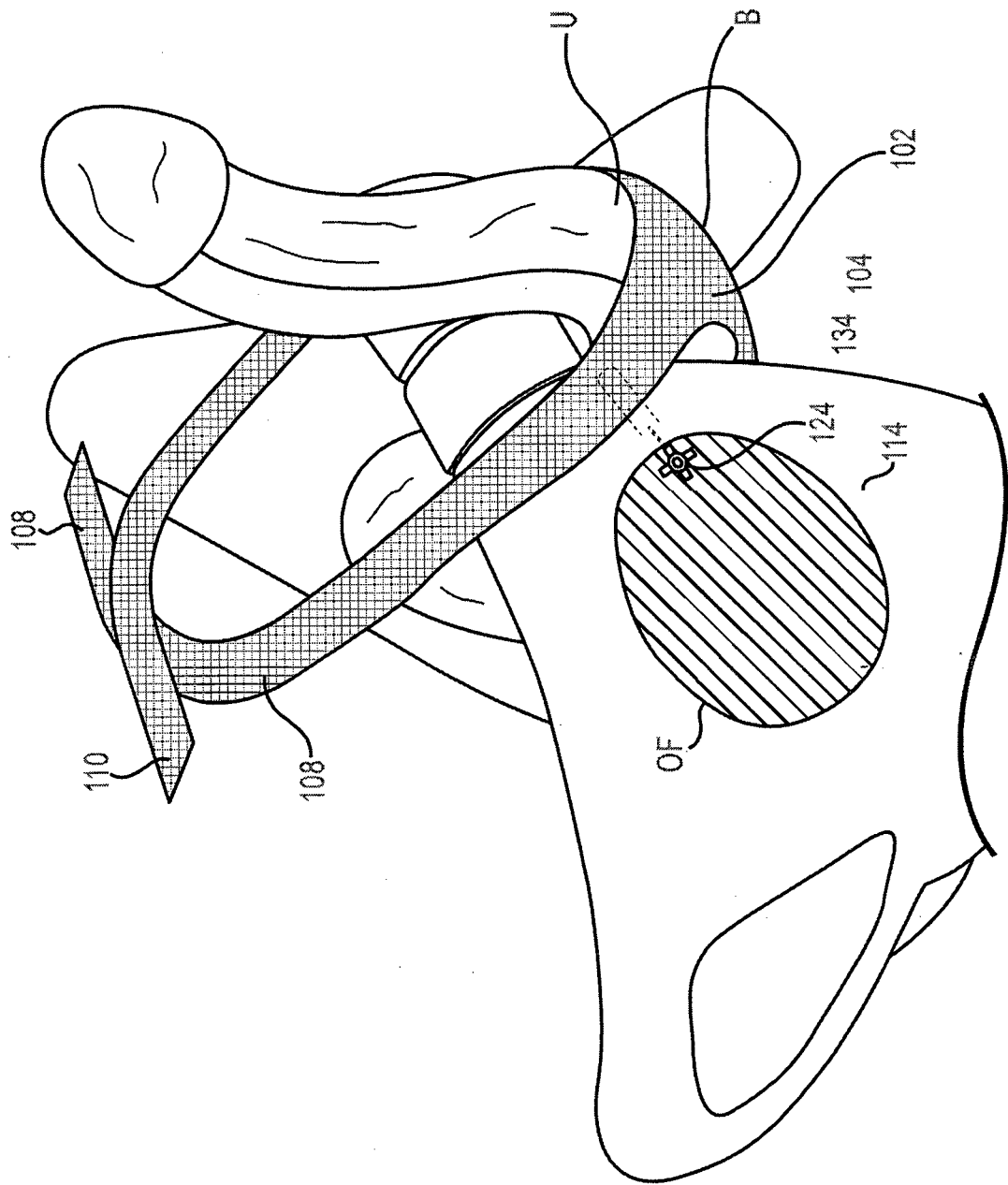
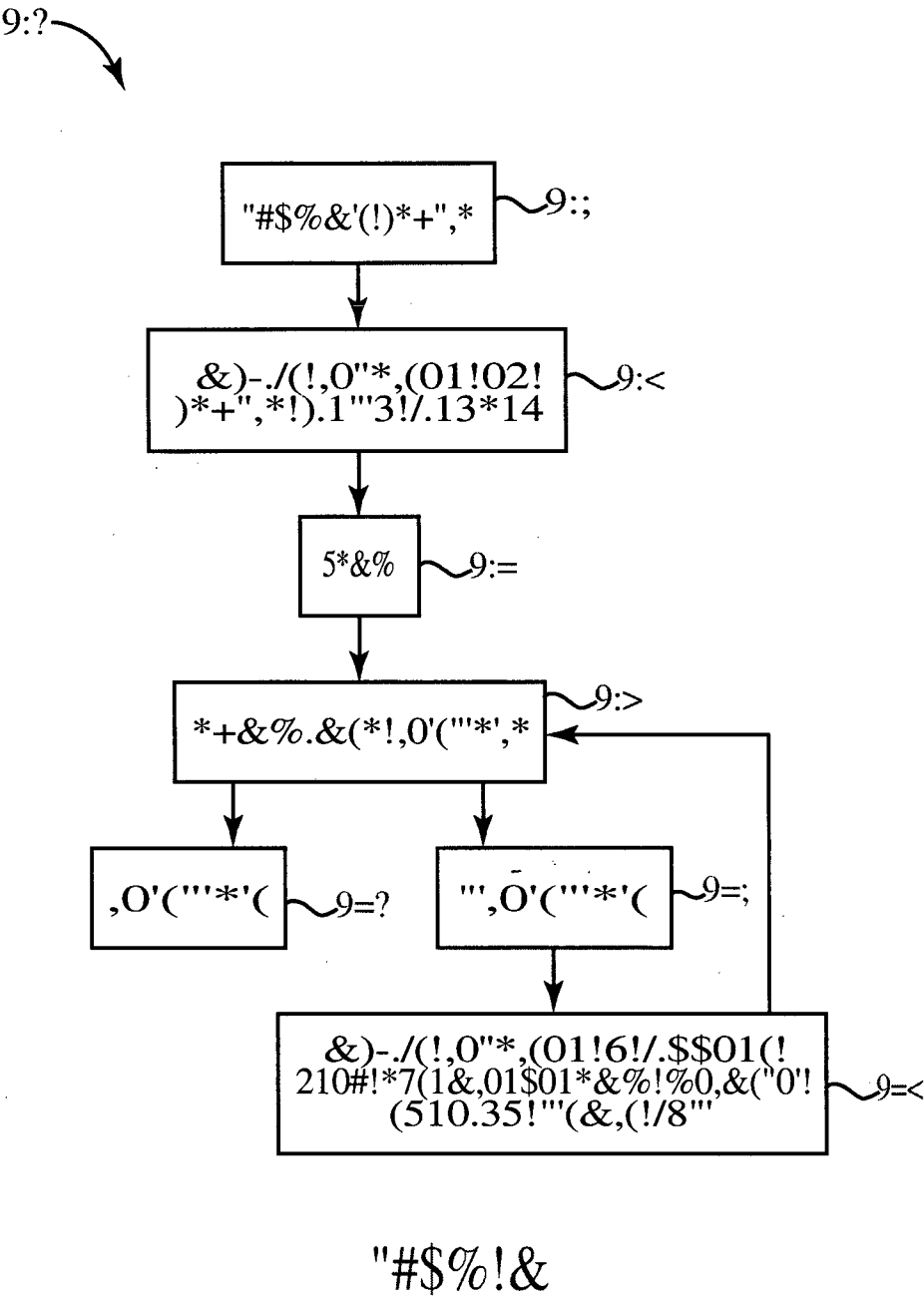


Fig. 8

11/11



INTERNATIONAL SEARCH REPORT

International application No

PCT/DK2011/050213

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F2/00 A61F7/12
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2007/149555 A2 (AMS RES CORP [US]; LUND ROBERT E [US]; OGDahl JASON W [US]; ROLL JESSI) 27 December 2007 (2007-12-27)	1-4
A	paragraphs [0009], [0024], [0105] - [0109]; figures 12,13	16
Y	US 2008/249245 A1 (MATHER PATRICK T [US] ET AL) 9 October 2008 (2008-10-09)	1-4
A	paragraphs [0003], [0004], [0024], [0028], [0035]; figure 3	16
A	US 2008/269548 A1 (VECCHIOTTI RICHARD G [US] ET AL) 30 October 2008 (2008-10-30)	1,16
	paragraph [0087] - paragraph [0090]; figures 8-10	



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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

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"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

2 August 2011

Date of mailing of the international search report

09/08/2011

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK2011/050213

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

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

1. ☒ Claims Nos.: 20-35
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/DK2011/050213

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2007149555	A2	27-12-2007	
		AU 2007261254 A1	27-12-2007
		CA 2654294 A1	27-12-2007
		EP 2049039 A2	22-04-2009
		JP 2009540937 A	26-11-2009
		KR 20090023470 A	04-03-2009
		US 2010261950 A1	14-10-2010
		US 2011124954 A1	26-05-2011
		WO 2007149593 A2	27-12-2007

US 2008249245	A1	09-10-2008	
		AT 498648 T	15-03-2011
		AU 2003300377 A1	04-05-2004
		CA 2501549 A1	22-04-2004
		EP 1558671 A1	03-08-2005
		JP 4530990 B2	25-08-2010
		JP 2006503172 A	26-01-2006
		WO 2004033539 A1	22-04-2004
		US 2007135578 A1	14-06-2007
		US 2004122174 A1	24-06-2004

US 2008269548	A1	30-10-2008	
		AU 2008246135 A1	06-11-2008
		CA 2686136 A1	06-11-2008
		EP 2144575 A1	20-01-2010
		JP 2010524635 A	22-07-2010
		WO 2008134064 A1	06-11-2008
