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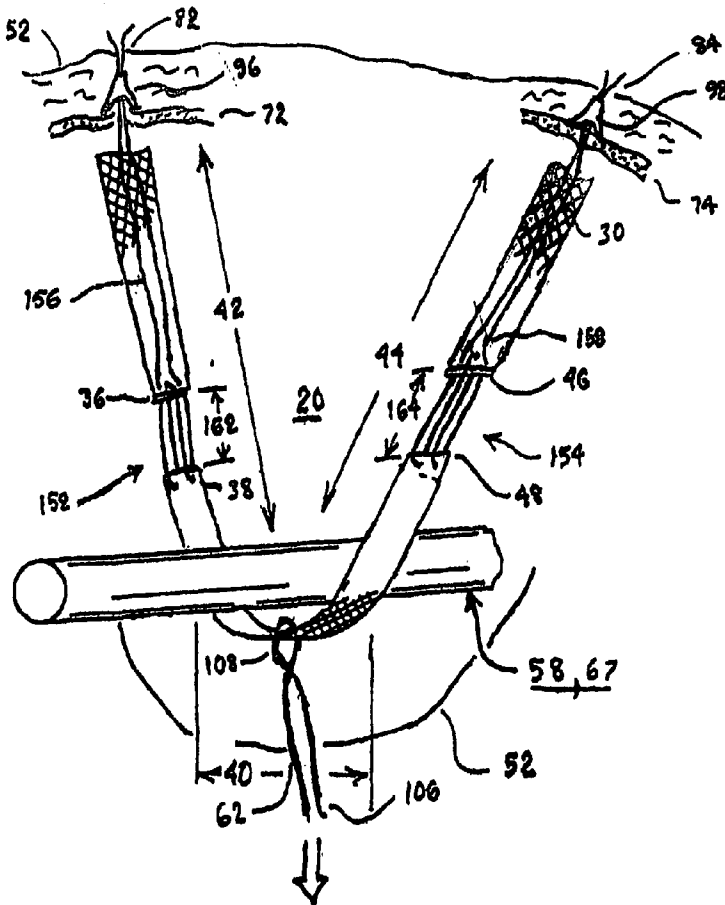
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(54) Title: ADJUSTABLE TENSION INCONTINENCE SLING ASSEMBLIES



(57) Abstract: Systems for providing support to body tissue to alleviate incontinence are disclosed that comprise an elongated incontinence sling having a central support portion adapted to be positioned to support any one of the urethra or anus and first and second sling end portions extending from the central support portion through body tissue and a tension adjustment mechanism acting on or within one or both of the sling end portions. The sling tension adjustment mechanism is attached to and extends through an adjustment spacing between sling intermediate ends within at least one sling end portion. The adjustment spacing is lengthened to decrease sling tension and shortened to increase sling tension

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ADJUSTABLE TENSION INCONTINENCE SLING ASSEMBLIES

RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application Serial No 60/805,544 filed June 22, 2006, and U.S. Provisional Application Serial No 60/806,664 filed July 6, 2006, the entire contents of which are incorporated herein by reference.

TECHNICAL FIELD

[0002] The present invention pertains to improved methods and apparatus providing support to a portion of the urethra or rectum or anus to alleviate urinary or fecal incontinence and particularly to elongated slings having mechanisms for selectively adjusting the tension applied through the sling to body tissue.

BACKGROUND

[0003] Urinary incontinence is a condition characterized by involuntary loss of urine, beyond the individual's control, due to the loss or diminution of the ability to maintain the urethral sphincter closed as the bladder fills with urine. Male or female stress urinary incontinence (SUI) occurs when the patient is physically or emotionally stressed. Such patients may also experience urge incontinence.

[0004] Fecal incontinence is a condition characterized by involuntary defecation or passage of feces through the anal canal due to injury to or weakness of one or more of the internal anal sphincter, the external anal sphincter, and the levator ani.

[0005] Implantable urethral and anal prosthetic sphincter systems have been disclosed in the prior art to treat incontinence that comprise an inflatable balloon that is either pillow or cuff shaped, a balloon reservoir/pressure source filled with a fluid, a pump, and interconnecting tubing. The balloon is implantable beneath or surrounding the urethral tract (at or near the bladder neck in female patients) or around the anal sphincter and is coupled through

tubing to the balloon reservoir/pressure source and pump that are implanted subcutaneously. The pump may be manually actuated to inflate the balloon compress the urethral tract to prevent incontinence and to deflate the balloon to allow voiding. Examples of such prosthetic sphincter systems are disclosed in U.S. Patent Nos. 4,222,377, 4,571,749, and 5,562,598, and one such system comprises the AMS-800 Urinary Control System available from American Medical Systems, Inc.

[0006] Urethral tapes or slings have been developed that are implanted in a urethral sling procedure in which the urethral sling is inserted beneath the urethra and advanced in the retro pubic space, perforating the abdominal fascia. In one procedure, peripheral or end portions of the elongated urethral sling are affixed to bone or body tissue, and a central support portion of the elongated urethral sling extends under the urethral or bladder neck to provide a platform that compresses the urethral sphincter, limits urethral distention, and pelvic drop, and thereby improves coaptation. Elongated "self-fixating" slings have also been clinically introduced for implantation in the body that do not require that the end portions be physically attached to tissue or bone and that rely upon tissue ingrowth into sling pores to stabilize the sling as disclosed, for example, in commonly assigned U.S. Patent Nos. 6,382,214, 6,612,977, 6,641,524, 6,648,921, 6,652,450, 6,702,827, 6,802,807, and 6,911,003 and publications and patents cited therein.

[0007] The above-described slings comprise a central portion that is adapted to support the urethra, two end portions bracketing the support portion, a protective sheath or sheaths encasing at least the end portions, and connectors at the ends of the sling. Various ways of attaching a sleeve end and sling mesh end to a connector are detailed in the above-referenced '450 patent, for example. Further ways of attaching sling ends to sling implantation tools are disclosed in U.S. Patent Application Publication Nos. 2004/0087970, 2005/0245787, and 2005/0250977. The sling implantation tools are employed to form tissue pathways extending from a vaginal incision to two abdominal skin incisions and to draw the sling end portions through the pathways to dispose the sling free ends out of the skin incisions and the central portion

around the urethra. The connectors are detached from the sling ends, and the sheaths are drawn out of the skin incisions, allowing the incisions to be closed.

[0008] Sling tension is typically adjusted at implantation sufficiently to take up any slack in the sling and impart at least a degree of increased tension to the urethra with the bladder empty. A surgical instrument may be placed between the sling central portion and the urethra, the sling ends drawn to tension and fully close the urethral tract, and the instrument withdrawn so that the urethra is relaxed sufficiently to function. Alternative tension adjustment mechanisms that may be employed during implantation are disclosed in the above-referenced commonly assigned '827 and '921 patents.

[0009] Typically, such urethral tapes or slings are fabricated of a loose weave sling fabric or mesh that acutely engages tissue and encourages tissue ingrowth along the pathway through mesh pores to achieve chronic stabilization or "self-fixation. Tissue ingrowth takes about 2-3 weeks in the typical patient in the absence of any significant intentional or unintentional movement of the mesh. During this post-operative time, the patient monitors the degree of success achieved in ameliorating leakage and any discomfort that might occur if the applied tension is so high as to unduly slow voluntary urination.

[0010] If any such problems occur, it may be necessary to reopen the incisions to access and pull on the sling ends to tighten the sling central portion around the urethra or to reopen the vaginal incision to pull on the sling central portion to loosen the sling central portion around the urethra. Several approaches have been taken to simplify or reduce the need for such post-operative adjustments.

[0011] One tension adjustment complication arises from the fact that the loose weave sling mesh inherently stretches and elongates when tension is applied at the ends or central support portion to overcome resistance of the tissue bearing against the sling mesh along the tissue pathway. It is difficult to judge just how much tension to apply to achieve adequate tightening or loosening in

the central support portion. In one approach to overcoming this complication disclosed, for example, in the above-referenced '450 patent, an elongated repositioning means, e.g., an elongated inextensible tensioning member, is incorporated extending in or along the sling mesh from near the sling ends to or through the sling central portion. Tension applied to the repositioning means is transmitted along the length of the sling so the sling mesh does not substantially stretch during initial positioning and any repositioning during the acute healing phase.

[0012] In another approach disclosed, for example, in U.S. Patent Application Publication 2006/0058574 (FIGs. 4a – 4f), an expandable member or container is incorporated on or in the sling central support portion that can be inflated or deflated with bulking agent to apply more or less tension to the urethra. As stated therein, optionally, the container has a touchable internal valve element to permit the surgeon to palpate the area prior to injecting or removing the bulking agent. Alternatively, the bulking agent may be injected and removed via a two-way external port. When a bulking agent is injected into the container, the tissue between the mesh and urethra will expand. This results in two effects; a simple vertical lifting due to expansion and a vertical lifting due to stretching the outside of the mesh. A suitable bulking agent may be water or saline. A similar approach is disclosed in U.S. Patent Nos. 4,019,499 and 6,786,861.

[0013] Other approaches that enable increasing tension of the sling central portion against the urethra involve shortening the lengths of the sling end portions as described, for example in the above-referenced, commonly assigned '921 patent. Mesh folds are formed in the sling end portions using filaments that extend through vaginal incisions externally of the body. Depending on the embodiment, the mesh folds can be released to decrease sling tension or be tightened to increase sling tension by pulling on the filament ends following the initial implantation procedure. In other embodiments, filaments are extended substantially through the lengths of the sling end portions and extend from the vaginal incisions. The filaments may

be gripped and pulled to tighten the mesh in the sling end portions to increase overall sling tension.

[0014] In still another approach disclosed, for example, in U.S. Patent Application Publication 2006/0058574 (FIGs. 5a – 5c), the mesh sling or tape is further modified to include a mechanical adjustment means to adjust the length of the tape in the end portions on either side of the central portion after the tape has been implanted in the tissue pathways. The mechanical adjustment means incorporate a tie-wrap mechanism or sutures and one-way suture retaining devices of the type disclosed in U.S. Patent No. 5,669,935 located along the tape on either side of the central portion. In each case, one suture end is affixed to the tape and extends along it and through a suture retaining device affixed to the tape closer to the central portion. The sutures or tie-wrap are not tensioned at implantation, and the tie-wrap or suture free ends extend through the vaginal incision. If the tension on the urethra is too light as determined during the acute healing phase, the surgeon may grasp and pull on the tie-wrap or suture free ends to shorten the lengths of the tape end portions and thereby increase sling tension. The exposed suture or tie-wrap ends may be severed during chronic implantation.

[0015] In yet another approach, tape or sling ends or the end of a tensioning cable coupled to a urethral support mechanism are coupled to an adjustment mechanism that is chronically implanted subcutaneously and can be accessed to adjust sling tension. See, for example, commonly assigned U.S. Patent No. 4,969,892 and further U.S. Patent Nos. 5,474,518 and 6,117,067 and the REMEEX® readjustable sling by Neomedic, Intl. (www.remeex.com). Ratchet or gear adjustment mechanisms that are accessed using a driver inserted through the skin and thereby rotated to increase or decrease sling tension are disclosed in the '892 and '518 patents. An inflatable/deflatable elastic chamber, adjustment mechanism that incorporates a fill port that is penetrable by a syringe needle advanced through the skin is disclosed in the '067 patent. The adjustment forces are applied to the sling ends and must be transmitted through the sling to effect any change in tension along the sling central portion adjacent the urethra.

[0016] Further sling tension adjustment mechanisms and techniques involve adding tensioning filaments to the sling free ends and extending the elements through the skin incisions and into engagement with buttons or pads implanted subcutaneously engaging a muscle or rectus fascia layer and/or having tissue engaging elements or anchors along the filament or at the sling ends that engage subcutaneous tissues as disclosed, for example, in U.S. Patent No. 6,911,002 and in U.S. Patent Application Publication Nos. 2005/0004576 and 2006/0089525.

[0017] Although effective in alleviating SUI, further improvements in urethral and anal slings to post-operatively adjust tension applied to the urethra and anus are desirable.

SUMMARY

[0018] The preferred embodiments of the present invention incorporate a number of inventive features that address the above-described problems that may be combined as illustrated by the preferred embodiments or advantageously separately employed.

[0019] The present invention involves improvements in an elongated incontinence sling, or simply sling, comprising a central support portion and end portions extending from the central portion to sling ends. Herein, use of the term sling or the expression "incontinence sling" without further qualification shall embrace urethral slings adapted to be placed through a tissue pathway disposing the central support portion between the urethra or bladder neck (hereafter collectively referred to as the urethra for convenience) and the vaginal wall to alleviate urethral incontinence and fecal slings adapted to be placed through a tissue pathway disposing the central support portion inferior to the anus, the anal sphincter or the lower rectum (hereafter collectively referred to as the anus for convenience) to alleviate fecal incontinence. Certain embodiments employ tensioning filaments or lines or sutures that are referred to as sutures for convenience.

[0020] In accordance with the present invention, such slings are improved to enhance post-operative sling adjustment of the tension applied to the urethra or anus to enhance efficacy and patient comfort. Several categories of the invention are disclosed herein. The various embodiments disclosed herein are applicable to both males and females, to address issues of incontinence in both, to address issues of prolapse repair in female and perineal floor descent, as well as fecal incontinence in both. Also surgical techniques such as forming suprapubic, retropubic, transobturator, inside out, outside in tissue pathways between two skin incisions, or a tissue pathway formed from a single incision through the vagina or perineal floor (in male or female patients) are also contemplated for passage of a sling therethrough.

[0021] In various embodiments, sling tension adjustment mechanisms join separate sling pieces forming part of the sling mesh with the sling end portions such that the sling tension adjustment mechanisms are interposed between and attached to sling intermediate ends that are spaced apart by an adjustment spacing. Various adjustment actuators and techniques are employed to adjust the sling tension adjustment mechanisms to decrease or increase the adjustment spacing between the sling intermediate ends to thereby shorten or lengthen, respectively, the overall length of the sling end portions and to thereby increase or decrease, respectively, the tension applied by the central support portion to the urethra or anus. The sling tension adjustment mechanisms are disposed along the sling end portions so as to be disposed at tissue pathway locations that are proximate the patient's skin to enable application of the external adjustment actuator against the skin or through the skin and underlying tissues to operate the sling tension adjustment mechanisms.

[0022] In one embodiment, sutures are threaded back and forth through mesh pores adjacent the intermediate ends and across the respective adjustment spacings of each sling end portion. The suture ends are adapted to be extended through the skin incisions to function as adjustment actuators in the manner of draw strings for later adjustment of the adjustment spacings during the acute healing phase. The suture ends may be grasped and pulled to pull

the sling intermediate ends closer together to decrease the adjustment spacing and thereby decrease the sling length and increase tension applied by the center support portion to the urethra or anus.

[0023] In a variation of this embodiment, the tensioning sutures are passed through suture or tissue anchors that engage subcutaneous muscle, the rectus fascia or the transobturator membrane and extend through the skin incisions employed to form the tissue pathway that the sling extends through. Alternatively, the tensioning sutures are passed through suture or tissue anchors that engage subcutaneous muscle, the rectus fascia or the transobturator membrane and extend through other skin incisions to be grasped and pulled on to adjust tension. For convenience, such subcutaneous muscle, the rectus fascia or the transobturator membrane or other membranes and fascia are collectively referred to as tissue layers herein.

[0024] In another embodiment, the external adjustment actuator comprises a signal transmitter that is employed to generate a sling adjustment command that passes transcutaneously (through the intact skin), and the adjustment mechanism comprises a receiver for receiving the transmitted commands and increases or decreases the adjustment spacing. In yet further embodiments, the external adjustment actuator is a magnetic field generator or permanent magnet that is employed to generate a magnetic field representing a sling adjustment command that passes transcutaneously through the skin, and the adjustment mechanism comprises a magnetic field responsive element that responds by increasing or decreasing the adjustment spacing. In still further embodiments, the sling tension adjustment mechanism comprises a temperature responsive element responsive to heat or cold applied transcutaneously by an external thermal heater or cooler to heat or cool the adjustment mechanism to thereby increase or decrease the adjustment spacing. In yet further embodiments, the sling tension adjustment mechanism comprises light responsive elements responsive to certain wavelengths of light that can be generated by an external adjustment actuator and

transmitted transcutaneously to the sling tension adjustment mechanism to thereby increase or decrease the adjustment spacing.

[0025] In still another embodiment, the external adjustment actuator is inserted percutaneously (penetrating the skin) to engage and operate the sling tension adjustment mechanism to increase or decrease the adjustment spacing. Various sling tension adjustment mechanisms are provided that can be rotated by the external adjustment actuator in one direction to draw the sling intermediate ends together to increase sling tension and that can be rotated in the other direction to allow the sling intermediate ends to separate apart to decrease sling tension.

[0026] In yet another embodiment, the external adjustment actuator is a syringe or the like that is inserted percutaneously to engage a port of a fluid retaining chamber of the sling tension adjustment mechanism, whereby the adjustment spacing is adjusted by injecting or withdrawing fluid from the fluid chamber to increase or decrease the adjustment spacing. In certain variations, the sling tension adjustment mechanism comprises a fluid reservoir to be implanted just below the skin, a fluid chamber disposed in the adjustment spacing and coupled to the intermediate ends, and a tube extending between the fluid reservoir and the fluid chamber in each sling end portion. The fluid reservoir has a fluid delivery/withdrawal port that may be percutaneously accessed to introduce fluid into the fluid reservoir or to withdraw fluid from the fluid reservoir following implantation of the sling to thereby adjust the amount of fluid in the fluid chamber and adjust the length of the adjustable spacing.

[0027] In certain embodiments, the fluid chamber comprises a single action hydraulic cylinder disposed in the adjustment spacing coupled to one sling intermediate end, the cylinder containing a fluid operated piston within an elongated chamber, the cylinder coupled to a sling adjustment rod that is in turn coupled to the other sling intermediate end. The fluid volume introduced into the fluid chamber determines the piston location in the cylinder and the resulting length of the adjustment spacing. In a variation, a dual action hydraulic cylinder having a pair of opposed pistons in the fluid chamber are

each coupled to rods that are in turn coupled to sling intermediate ends governs the adjustment spacing.

[0028] In these embodiments, the fluid chambers are preferably empty of fluid when the sterile sling is supplied in the sterile package from the manufacturer. Implantation of the sling through body pathways may be simpler and easier with the fluid chambers empty. The fluid, e.g., a sterile saline or other biocompatible hydraulic fluid, may be introduced through the fluid delivery port(s) while the port(s) are still accessible. The amount of fluid necessary to effect blockage of the urethral tract may be checked by draining and filling the patient's bladder through the urethral tract, determining efficacy, and adding or withdrawing fluid to adjust the applied urethral pressures in the pressurized and ambient pressure fluid distribution states. Similar procedures may be employed to effect constriction of the anal canal.

[0029] In further embodiments the external adjustment actuator comprises an elongated gear drive instrument having a shaft extending between a handle and an engaging end shaped to be percutaneously advanced through the skin. The adjustment mechanism comprises a driven gear means engageable by the engaging end the gear drive for operating the spacing adjustment means to increase or decrease the adjustment spacing.

[0030] Optionally, sling end tissue anchors may be provided on sling ends to engage tissues, e.g., the rectus fascia or the obturator membrane to fix the sling ends and aid in tension adjustment of the sling end portions.

[0031] Optionally, a sling adjustment mechanism may be incorporated into the sling central support portion to enable the separate tensioning of the sling central support portion.

[0032] This summary of the invention has been presented here simply to point out some of the ways that the invention overcomes difficulties presented in the prior art and to distinguish the invention from the prior art and is not intended to operate in any manner as a limitation on the interpretation of

claims that are presented initially in the patent application and that are ultimately granted.

BRIEF DESCRIPTION OF THE DRAWINGS

[0033] These and other advantages and features of the present invention will be more readily understood from the following detailed description of the preferred embodiments thereof, when considered in conjunction with the drawings, in which like reference numerals indicate identical structures throughout the several views, and wherein:

[0034] FIG. 1 is a schematic view of an exemplary sling assembly enclosing a sling adapted to be modified in accordance with the invention to function as an adjustable tension urethral or fecal sling;

[0035] FIG. 2 is a schematic illustration of the sling of FIG. 1 adapted to be modified in accordance with the invention to provide an adjustable tension function;

[0036] FIG. 3 is a schematic illustration of a urethral sling of FIG. 2 implanted in a female patient's body in relation to the urethra or bladder neck;

[0037] FIG. 4 is a schematic illustration of a fecal sling of FIG. 2 implanted in a female patient's body in relation to the anus and rectum;

[0038] FIG. 5 is a schematic illustration of the relation of the sling central support portion and sling end portions to the urethra or anus;

[0039] FIG. 6 is a schematic illustration of a generic embodiment of an adjustable tension sling of the present invention having sling tension adjustment mechanisms formed in gaps or spaces in the sling mesh forming the sling end portions such that the sling tension adjustment mechanisms are interposed between and attached to sling intermediate ends that are spaced apart by an adjustment spacing;

[0040] FIG. 7 is a schematic illustration of the generic embodiment of FIG. 6 having optional tissue anchors extending from the sling ends to aid in the operation of the sling tension adjustment mechanisms;

[0041] FIGs. 8 and 9 are schematic illustrations of an embodiment of an adjustable tension sling, wherein sliding locks that engage intermediate ends or loops of the sling mesh are incorporated into the sling end portions to increase and/or decrease the sling tension;

[0042] FIG. 10 is a schematic illustration of a further embodiment of an adjustable tension sling, wherein sling tension adjustment sutures bridge adjustment spacings in the sling end portions and extend through the skin to increase and/or decrease the sling tension;

[0043] FIG. 11A is a schematic illustration of a variation of the adjustable tension sling of FIG. 10, wherein the sling tension adjustment sutures extend through or around tissue anchors and extend through the skin to be available to increase and/or decrease the sling tension;

[0044] FIG. 11B is a schematic illustration of a further variation of the adjustable tension sling of FIG. 10, wherein the sling ends incorporate tissue anchors passed through and engaging tissue layers and the tension adjustment sutures extend through or around further tissue anchors and extend through the skin to be available to increase and/or decrease the sling tension;

[0045] FIGs. 12 and 13 are schematic illustrations of further preferred embodiments of an adjustable tension sling having sling tension adjustment mechanisms bridging adjustment spacings in the sling end portions adapted to be adjusted by commands transcutaneously transmitted from an external adjustment actuator to increase and/or decrease the tension applied locally to the urethra;

[0046] FIGs. 14 - 17 are schematic illustrations of further preferred embodiments of an adjustable tension sling having sling tension adjustment mechanisms bridging adjustment spacings in the sling end portions

comprising serpentine roller adjustment mechanisms that adjusts the length of an adjustment spacing in response to an externally applied command;

[0047] FIG. 18 is a schematic illustration of a further preferred embodiment of an adjustable tension sling, wherein the adjustment mechanism is adjusted by an external adjustment actuator comprising an external adjustment actuator having an engaging end at the end of a shaft adapted to be percutaneously advanced into engagement with the adjustment mechanism to adjust the length of an adjustment spacing between intermediate sling ends in the sling end portions;

[0048] FIG. 19 is a schematic illustration of one embodiment of the sling tension adjustment mechanisms of FIG. 18 employing a rotatable bobbin, a fixed catch and detents around the bobbin circumference;

[0049] FIGs. 20 - 22 are schematic illustrations of the adjustment mechanism of FIG. 19 that adjusts the length of an adjustment spacing in response to an externally applied external adjustment actuator;

[0050] FIG. 23 is a schematic view in section of a variation on the embodiment of FIG. 19, wherein the adjustment mechanism housing supports a rotatable bobbin surrounded by a fixed detent ring providing an increased range of adjustments;

[0051] FIGs. 24 - 26 are schematic plan illustrations of a further embodiment of the adjustment mechanism of FIG. 18, wherein a dual cam assembly having a first cam operates to decrease the adjustable spacings from the neutral length illustrated in FIG. 24 to the contracted length of FIGs. 25A - 25D and a second cam operates to increase the adjustable spacings to the extended length of FIGs. 26A - 26D;

[0052] FIG. 27 is a schematic illustration of a further preferred embodiment of the adjustable tension sling, wherein the adjustment mechanism is adjusted by an external fluid delivery/withdrawal syringe adapted to be percutaneously advanced into engagement with a fluid port of the adjustment mechanism to

adjust the length of the adjustment spacing between intermediate sling ends in the sling end portions;

[0053] FIGs. 28 - 31 are schematic plan side or top views illustrating one, single action, hydraulic cylinder, adjustment mechanism of FIG. 27 having a fluid chamber adapted to be filled or be emptied of fluid using the syringe of FIG. 27 to adjust the length of the adjustment spacing between intermediate sling ends in the sling end portions;

[0054] FIGs. 32 - 36 are schematic perspective, side or top views in partial section illustrating a further single action, hydraulic cylinder, adjustment mechanism of FIG. 27 having a fluid chamber adapted to be filled or be emptied of fluid using the syringe of FIG. 27 to adjust the length of the adjustment spacing between intermediate sling ends in the sling end portions;

[0055] FIGs. 37 - 40 are schematic perspective or top views illustrating a still further single action, hydraulic adjustment mechanism of FIG. 27 having a fluid chamber adapted to be filled or be emptied of fluid using the syringe of FIG. 27 to adjust the length of the adjustment spacing between intermediate sling ends in the sling end portions;

[0056] FIG. 41 is a schematic illustration of a further preferred embodiment of the adjustable tension sling, wherein the adjustment mechanism is adjusted by an external fluid delivery/withdrawal syringe adapted to be percutaneously advanced into engagement with a fluid port of a subcutaneously implantable fluid reservoir coupled to the adjustment mechanism to adjust the length of the adjustment spacing between intermediate sling ends in the sling end portions;

[0057] FIGs. 42 - 44 are schematic perspective views in partial section illustrating a single action, hydraulic cylinder, adjustment mechanisms of FIG. 41 having fluid chambers adapted to be filled or be emptied of fluid using the syringe of FIG. 41 to adjust the length of the adjustment spacing between intermediate sling ends in the sling end portions;

- [0058]** FIG. 45 is a perspective view in partial section of a further single action, hydraulic cylinder, adjustment mechanism adapted to be employed as depicted in FIG. 41 having fluid chamber portions adapted to be filled or be emptied of fluid using a syringe to add or withdraw fluid from subcutaneously implanted fluid reservoirs coupled to the fluid chamber portions to adjust the length of the adjustment spacing between intermediate sling ends in the sling end portions;
- [0059]** FIG. 46 is a perspective view in partial section of a dual action, hydraulic cylinder, adjustment mechanism adapted to be employed as depicted in FIG. 41 having fluid chamber portions adapted to be filled or be emptied of fluid using a syringe to add or withdraw fluid from subcutaneously implanted fluid reservoirs coupled to the fluid chamber portions to adjust the length of the adjustment spacing between intermediate sling ends in the sling end portions;
- [0060]** FIGs. 47 and 48 are schematic plan views in partial section illustrating one form of locking mechanism incorporated into the single action hydraulic cylinder adjustment mechanism of FIGs. 28 - 31;
- [0061]** FIGs. 49 and 50 are schematic plan views in partial section illustrating another form of locking mechanism incorporated into the single action hydraulic cylinder adjustment mechanism of FIGs. 28 - 31;
- [0062]** FIG. 51 is a schematic illustration of a miniaturized, single action, hydraulic cylinder, adjustment mechanism incorporating the locking mechanism illustrated in FIGs. 47 and 48;
- [0063]** FIG. 52 is a side plan view of the miniaturized, single action, hydraulic cylinder, adjustment mechanism of FIG. 51;
- [0064]** FIG. 53 is a top plan view in partial section of the miniaturized, single action, hydraulic cylinder, adjustment mechanism of FIG. 51;

- [0065]** FIG. 54 is a schematic illustration of a miniaturized, mechanical gear, adjustment mechanism that is adjusted by a gear drive extended temporarily through the patient's skin;
- [0066]** FIG. 55 is a schematic expanded view in partial section illustrating the gear drive components within the adjustment mechanism of FIG. 54;
- [0067]** FIG. 56 is a schematic illustration of a further miniaturized, mechanical gear, adjustment mechanism that is adjusted by a gear drive external adjustment actuator extended percutaneously through the patient's skin to engage the gear drive and adjust sling tension;
- [0068]** FIG. 57 is a schematic illustration of a still further miniaturized, mechanical gear, adjustment mechanism that is adjusted by a rack and pinion gear drive extended temporarily through the patient's skin; and
- [0069]** FIGs. 58A - 58D are schematic views in partial section illustrating adjustment of sling tension through use of the rack and pinion gear drive extended temporarily through the patient's skin to adjust the miniaturized, mechanical gear, adjustment mechanism of FIG. 57.
- [0070]** The drawing figures are not necessarily to scale.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

- [0071]** The various embodiments of the present invention are implemented in slings suitable for and methods of implanting such slings in the treatment of male and female urinary and fecal incontinence and to effect pelvic floor, perineal floor, and pelvic prolapse repairs employing a variety of surgical approaches. For example, female pelvic floor repair slings may be implanted by techniques that involve transvaginal, transobturator, suprapubic, pre-pubic, or transperineal exposures or pathways, and male urinary incontinence slings may be implanted by techniques that involve transobturator, suprapubic, or transperineal pathways. Any of the disclosed embodiments can be used as fecal incontinence slings which may be implanted by techniques that involve transvaginal, transobturator, suprapubic or via perineal floor pathways. In

fecal incontinence applications, the disclosed embodiments can be used to correct the anorectal angle in the rectum to re-establish continence in patients. The above methods can, but are not necessarily limited to, utilize helical needles of the type described in U.S. Patent No. 6,911,003 or C-shaped needles or elongate needles of the type used to perform suprapubic procedures.

[0072] Referring to FIG. 1, an exemplary embodiment of an elongated sling assembly 10 is depicted in which the embodiments of the present invention may be advantageously implemented. The elongated sling assembly 10 contains a sling 20 that may be implanted in any of the above-described manners and pathways through which at least end portions of the elongated sling assembly 10 is drawn to dispose a central support portion 40 of sling 20 in operative relation to the urethral or bladder neck or around the anal sphincter or elsewhere in the pelvic region. The sling assembly 10 comprises the sling 20 coupled to sling end connectors 12 and 14 and encased in protective sheaths 22 and 24.

[0073] The depicted exemplary sling assembly 10 thus extends between sling end connectors 12 and 14 that engage with the free ends of right hand and left hand sling implantation tools of the types described above, for example. The sling end connectors 12 and 14 are shaped to dilate the right and left passages or pathways through body tissue formed by the curved needles of the right and left hand implantation tools in the above-described trans-vaginal or transobturator procedures, for example.

[0074] In this example, the sling 20 is enclosed within protective sheaths 22 and 24 extending from the sling end connectors, 12 and 14, respectively, to respective free and open sheath ends 26 and 28. Preferably, the protective sheaths 22 and 24 are constructed of a flexible thin transparent plastic film that enables visual examination of the sling 20 and is sufficiently lubricious that it passes easily through the tissue pathways of the patient formed using the right hand and left hand sling implantation tools of the types described above or otherwise created. The sheaths 22 and 24 can include sheath indicia or tear scores, perforations or holes for assisting the surgeon in

properly orienting sling 20 relative to the urethra. Embodiments of the present invention are contemplated that involve modifying the sheaths 22 and 24.

[0075] The sling 20 that is left in place chronically (following implantation and removal of sheaths 22 and 24 and end connectors 12 and 14) comprises an elongated, rectangular (in this depicted embodiment) braided or preferably knitted, mesh strip or simply mesh 30 as shown in FIG. 2. The sling 20 and mesh 30 are subdivided into a central support portion 40 that is adapted to be placed through a pathway extending between the urethra or bladder neck and the vaginal wall. Proximal end portions 42 and 44 of sling 20 extend from the central support portion 40 to the mesh ends 32 and 34. In FIGs. 1 – 5, the mesh 30 extends between mesh ends 32 and 34 and may be continuous throughout the length of the sling 20 between mesh ends 32 and 34. However, it will be understood that the central portion 40 of sling 20 may be formed of other materials such that the central portion 40 is physically attached to the end portions 42 and 44. In certain embodiments, the central portion 40 may be formed of any tissue-compatible synthetic material or any natural biocompatible material, including, but not limited to, treated autologous, allograft, or xenograft tissues, porcine dermis, a tissue engineered matrix, or a combination thereof.

[0076] The sling 20 of sling assembly 10 is therefore similar to those the disclosed in the above-referenced '450 and '003 patents but is modified herein to incorporate one or more of the aspects of the present invention. It will be understood that the mesh 30 may be dimensioned shaped in a variety of ways known in the art for implantation in the treatment of male and female urinary and fecal incontinence and to effect pelvic floor, perineal floor, and pelvic prolapse repairs employing a variety of surgical approaches. For example, the sling 20 may comprise more than two end portions 42 and 44 coupled to connectors and extending at a variety of angles from a particularly shaped center portion 40.

[0077] In the implantation procedures described in the above-referenced '214, '450, and '524 patents and U.S. Patent Application Publication Nos. 2005/0043580 and 2005/0065395, the sling connector ends 12 and 14 are

fitted to the implantation tools and the proximal end portions 42 and 44 are drawn through the body passageway or pathway. The central support portion 40 is adapted to drawn against tissue to support the urethra or bladder neck or the anal sphincter or elsewhere in the pelvic region after the proximal end portions 42 and 44 are drawn through body pathways. The sling connector ends 12, and 14 are drawn out of the skin incision and detached from the implantation tool needle ends. The mesh 30 and sheaths 22 and 24 are severed just proximate to the connector ends 12 and 14, respectively. The remaining portions of the protective sheaths 22 and 24 are withdrawn over the mesh 30 and through the skin incisions. The sling 20 then remains in place, and tension adjustments are made to provide sufficient urethral or anal resistance to leakage. The incisions are closed upon completion of the tests, and tissue ingrowth into the pores of the mesh 30 takes place in a matter of weeks.

[0078] Before describing the embodiments of the invention, attention is directed to a step illustrated in FIG. 3 of one such sling implantation procedure that results in the sling 20 extending through a tissue pathway created in a female (for example) patient 50 extending around the urethra 58. In preceding steps, the tissue pathway was formed by passing needles through a vaginal skin incision 62 just adjacent to the vagina 60 through soft tissue between urethra 58 and vagina 60 and along each side of urethra 58 through layers of fat, muscle, and fascia and between pubic bone 54 and bladder 56 to first and second skin incisions through skin 52. Any of the known tissue pathways may be formed in this generally described manner. In a related embodiment, a sling is implanted via a single incision (vaginal incision 62) with the sling being pushed up into the transobturator or retro pubic space. The end connectors 12 and 14 of the sling assembly 10 were attached to the same or other needles to draw the sling assembly 10 through the tissue pathway to dispose the end connectors outside the patient's skin 52. As shown in FIG. 3, the connectors 12 and 14 and sheaths 22 and 24 were removed after being drawn out of the skin incisions, leaving the sling 20 in place. In a related embodiment, connectors 12 and 14 are eliminated.

[0079] Referring to FIG. 4, a schematic illustration of an incontinence sling implanted in a female (for example) patient's body for treating fecal incontinence is depicted. In this illustration, the sling central portion 40 extends underneath the anus or anal sphincter 67 or inferior portion of the rectum 65 (hereafter collectively referred to as the anus 67 for convenience) to correct the anorectal angle in the patient. Various surgical approaches can be used to implant sling 20 to correct fecal incontinence including suprapubic, transobturator, retropubic, prepubic, transperineal and transvaginal (including a single incision approach transvaginally or transperineally).

[0080] At this point, the tension T that sling 20 applies against the urethra 58 or anus 67 is adjusted as schematically illustrated in FIG. 5. Since the procedure may be performed using a local anesthesia, the patient 50 is able to provide feedback to the surgeon during adjustment of sling tension. In the procedure illustrated in FIG. 3, typically, the bladder 56 is filled with saline using a catheter, and the patient is requested to cough. The surgeon is able to determine whether leakage occurs and may adjust the tension on the sling 20 by pulling on the exposed sling ends 32 and 34 to increase tension of the center support portion 40 against the urethra 58 or by pulling on center support portion through the vaginal incision to decrease the tension of the center support portion 40 against the urethra 58. The exposed end sections of the end portions 42 and 44 are trimmed away, and the abdominal incisions and the vaginal incision (as well as the labia fold incisions for the transobturator approach) are closed. In the various embodiments of the present invention, such slings as sling 20 are improved to enhance post-operative sling adjustment of the tension T applied to the urethra 58 or the anus 67 to enhance efficacy and patient comfort.

[0081] While not essential to the practice of the present invention, it may be desirable to provide mechanisms incorporated into or that act on the sling central support portion 40 to facilitate the adjustment of the tension T applied to the urethra 58 or the anus 67. For example, a sling central portion adjustment mechanism may be provided to increase and/or decrease the tension applied locally to the urethra 58 or the anus 67. The sling central

portion adjustment mechanism is associated directly or indirectly with the sling central support portion 40 and is distinct from the sling tension adjustment mechanisms incorporated in the sling end portion or portions.

[0082] For example, as shown in FIG. 10, the sling central portion tension adjustment may simply comprise a suture 108 extending around the sling central portion and passing through the skin incision to provide post-operative tension adjustment of the sling central portion 40 by pulling on sling ends 106. Adjustments may be made until the suture is withdrawn through the skin 52 or is absorbed by the body.

[0083] Longer-term post-operative adjustment of the sling central portion tension may be accomplished with sling central portion adjustment mechanisms that remain in place. In one approach, the mechanism may be accessed for tension adjustment employing an external adjustment actuator that is percutaneously advanced through the skin 52 to engage the sling central portion adjustment mechanism. For example, one such approach involves injecting or withdrawing fluid from a fluid chamber of a pillow of the sling central portion adjustment mechanism applying pressure to the urethra 58 or the anus 67.

[0084] In certain more complex embodiments of the second category, sling tension adjustment mechanisms are formed in gaps in the sling mesh forming the sling end portions such that the sling tension adjustment mechanisms are interposed between and attached to sling intermediate ends that are spaced apart by an adjustment spacing. Various mechanisms and techniques are employed to adjust the sling tension adjustment mechanisms to decrease or increase the adjustment spacing between the sling intermediate ends to thereby shorten or lengthen, respectively, the overall length of the sling end portions and to thereby increase or decrease, respectively, the tension applied by the central support portion to the urethra. The sling tension adjustment mechanisms are disposed along the sling end portions so as to be disposed at tissue pathway locations that are proximate the patient's skin to enable access to or application of the external adjustment actuator against the

skin or through the skin and underlying tissues to operate the sling tension adjustment mechanisms.

[0085] Turning to FIGs. 6 and 7, in accordance with embodiments of the present invention, a sling tension adjustment mechanism is incorporated into or on a section of one or preferably both of the sling end portions 42 and 44 proximal to but spaced from the central support portion 40 that can be adjusted at least in the acute post-operative healing phase. A first sling end portion tension adjustment mechanism 102 is schematically depicted extending between and coupled to sling intermediate ends 36 and 38 of sling end portion 42. The gap or adjustment spacing 162 between sling intermediate ends 36 and 38 is shortened to increase tension or lengthened to decrease tension in sling end portion 42. Similarly, a second sling end portion tension adjustment mechanism 104 is schematically depicted extending between and coupled to sling intermediate ends 46 and 48 of sling end portion 44. The gap or adjustment spacing 164 between sling intermediate ends 46 and 48 is shortened to increase tension or lengthened to decrease tension in sling end portion 44. The spacing of each sling tension adjustment mechanism 102 and 104 from the central support portion 40 is selected in relation to the anatomy for either male or female fecal or urinary incontinence slings and the implantation route or technique to facilitate access or engagement with an externally applied adjustment actuator or an actuator element extending percutaneously from a skin incision. The adjustment mechanisms are generally adjusted to adjust the length and/or tension of the end portions 42 and 44 to thereby tension the center support portion 40 and draw it closer to the urethra 58 or anus 67 to relax tension of the center support portion 40 to release pressure on the urethra 58 or anus 67.

[0086] As shown in FIG. 7, it may be desirable to stabilize the sling ends 32 and 34 in tissue by optionally providing sling tissue anchors 92 and 94 extending from the sling ends 32 and 34. The anchors 92 may take any of the forms disclosed in the above-referenced U.S. Patent Application Publication No. 2005/0004576, for example. Generally speaking such tissue anchors 92 and 94 can be readily drawn through tissue in the direction away from the

sling ends 32 and 34, respectively, but resist retraction back through the tissue. Advantageously, the sling tissue anchors 92 and 94 may be extended through and bear against the rectus fascia or the transobturator to stabilize the sling ends 32 and 34 to set sling tension and to resist being drawn toward the sling tension adjustment mechanisms 102 and 104 when tension is increased.

[0087] In certain particular embodiments of the invention depicted in FIGs. 8 and 9, the end portion tension adjustment mechanisms comprise sliding locks 132 and 134 (FIG. 8) or 142 and 144 (FIG. 9) that engage the end portions 42 and 44 of the sling mesh 30. In one variation shown in FIG. 16, sections of the sling mesh 30 are looped and passed through channels of sliding locks 132 and 134. In the other variation shown in FIG. 9, the sling intermediate ends are drawn through channels of the sliding locks 142 and 144. It will be understood that the depicted slings 20 are disposed in the patient's body the manner depicted in FIG. 3 or FIG. 4. The loops 136, 138 or free ends 146, 148 function as actuator elements that can be grasped through the skin incisions 82 and 84 (or through a vaginal incision if a single incision approach is chosen) and pulled upon with respect to the sliding locks 132, 134 or 142, 144 to shorten the lengths of the end portions 42, 44 and increase tension on the urethra 58.

[0088] Sliding locks 132, 134 and 142, 144 operate similar to zip-tie locks. It will be understood that the depicted loops 136, 138 and the free ends 146, 148 can comprise sutures or zip-lock tapes fastened to intermediate ends of the sling mesh 30 so that the sutures or zip-lock tapes are drawn through channels of the sliding locks 132, 134 and 142, 144.

[0089] A further specific embodiment of the present invention is depicted in FIG. 10, wherein the end portion 42 is severed at intermediate ends 36 and 38 to form a gap or adjustment spacing 162, and the end portion 44 is severed at intermediate ends 46 and 48 to form a gap or adjustment spacing 164. Sutures 156 and 158 are threaded back and forth through mesh pores adjacent the intermediate ends 36,38 and 46, 48, respectively, and across the respective adjustment spacings 162 and 164, to function as draw strings for

later adjustment of the adjustment spacings 162 and 164 during the acute healing phase. The suture 156 and adjustment spacing 162 comprise sling end portion tension adjustment mechanism 152 of end portion 42, and the suture 158 and adjustment spacing 164 comprise sling end portion tension adjustment mechanism 154 of end portion 44.

[0090] In this embodiment, the suture ends 166 and 168 of respective sutures 156 and 158 extending from the skin incisions 82 and 84 during implantation of the sling 20 function as the adjustment actuators. The suture ends 166 and 168 may be grasped and pulled to shorten the adjustment spacings 162 and 164 to thereby shorten the sling end portions 42 and 44 and thereby decrease the sling length and increase tension applied by the center support portion 40 to the urethra 58 (or anus).

[0091] A further adjustment suture 108 (optionally formed of biodegradable material) is optionally placed around the sling mesh 30 and extended through the vaginal skin incision 62 to enable manual tension adjustment. The suture ends 106 may be grasped and pulled to function as an actuator element and pull the sling mesh away from the urethra 58 to release tension applied by the center support portion 40 to the urethra 58 (or anus).

[0092] In the absence of adjustment suture 108, the sling central support portion 40 may be accessed by reopening the vaginal incision 62 to pull on the sling 20 to draw the sutures 156 and 158 back through the mesh pores, thereby increasing the sling length and decreasing tension applied by the center support portion 40 to the urethra 58 (or anus).

[0093] Optionally, a biodegradable sheath may be placed over the adjustment mechanisms 152 and 154 and at least a portion of the sling mesh to inhibit tissue ingrowth into the mesh pores and adjustment spacings 162 and 164 and thereby ease adjustment of the sling 20 until the sheath is absorbed and tissue ingrowth encapsulates and immobilizes sling mesh 30.

[0094] The suture ends 166, 168, and 106 may be severed at the respective incisions 82, 84, and 62 following final adjustment.

[0095] Certain sling implantation procedures for urethral and fecal slings involve employing implantation instruments having needles that are advanced from a first skin incision to a second skin incision to form first and second or right and left (non-suprapubic) tissue pathways around the urethra 58 or the anus 67. The instruments or other instruments are then employed to push or pull the sling end portions 42 and 44 through the first and second pathways to dispose the sling ends near or through the skin incisions 82 and 84 as shown in FIGs. 3 and 4. The above-described embodiments contemplate implantation in such tissue pathways.

[0096] Other sling implantation procedures for urethral and fecal slings have sling ends configured to engage sling implantation tool needle ends to be pushed from a single incision adjacent the urethra 58 (or the anus 67) through first and second tissue pathways to dispose the sling end portions extending away from the urethra 58 (or anus 67). The skin incisions 82 and 84 are not necessarily made, and the sling ends are disposed at subcutaneous locations.

[0097] In a variation of this embodiment of the invention depicted in FIG. 11A, the sutures 156 and 158 are drawn through tissue anchors 96 and 98 that are passed through and bear against subcutaneous tissue layers 72 and 74, respectively. Generally speaking, the tissue anchors 96 and 98 have channels or bores that one or both of the sutures 116 and 118 are passed through that grip the sutures with sufficient force to maintain sling tension. The suture retaining force may be overcome by manipulation of the suture and tissue anchor to increase or decrease sling tension during post-operative recuperation. The suture ends extending through the skin incisions 82 and 84 are placed under the skin 52, and the incisions are closed. During chronic implantation, adjustments of sling tension may take place by reopening the skin incisions 82 and 84 to access the suture ends and the tissue anchors 96 and 98.

[0098] In this embodiment, the suture 156 passes through a slidable bore of the tissue anchor 96 and through the same skin incision 82 that the tissue pathway is created for the sling 20. Similarly, the suture 158 is depicted extending through a slidable bore of the tissue anchor 98 and through the

same skin incision 84 that the tissue pathway is created for the sling 20. For example, the tissue pathway may extend through the right and left transobturator membranes (tissue layers 72 and 74) that the tissue anchors 96 and 98 are passed through and bear against.

[0099] In a further variation of this embodiment of the invention depicted in FIG. 11B, tissue anchors 632 and 634 are coupled to the sling ends 32 and 34, respectively, and the sutures 156 and 158 are passed through the tissue anchors 96 and 98. In the implantation procedure, the tissue anchor 632 and the sling end portion 42 are pushed from a single skin incision below the urethra 58 or anus 67 through a first tissue pathway such that the tissue anchor 632 is passed through and bears against tissue layer 72. Similarly, the tissue anchor 634 and the sling end portion 43 are pushed from the skin incision below the urethra 58 or anus 67 through a second tissue pathway such that the tissue anchor 634 is passed through and bears against tissue layer 74.

[00100] The suture 156 and tissue anchor 96 are pushed through a further tissue pathway such that the tissue anchor 96 is passed through and bears against a separate tissue layer 76 and then through a skin incision 86. Similarly, the suture 158 and tissue anchor 98 are pushed through a further tissue pathway such that the tissue anchor 96 is passed through and bears against a separate tissue layer 76 and then through a skin incision 88. Alternatively, the sutures 156 and 158 can first be passed by themselves through the skin incisions 86 and 88, respectively, and the tissue anchors 96 and 98 can be applied over the sutures 156 and 158 to bear against the tissue layers 76 and 78, respectively. In a related embodiment, the various sling embodiments can be used without tissue anchors.

[00101] Tension can be applied by pulling on the suture ends of sutures 156 and 158, respectively while applying pressure against the subcutaneous tissue anchors 96 and 98, thereby decreasing the spacings 162 and 164. Tension on sutures 156 and 158 can be release to lengthen spacings 162 and 164 by exposing and manipulating the tissue anchors 96 and 98.

[00102] It will be understood that the tissue layers 72, 74, 76, and 78 may comprise a muscle layer, fascia or transobturator membrane. Tissue layers 72 and 76 may be the same or a different tissue layer, and tissue layers 74 and 78 may be the same or a different tissue layer. The particular locations of skin incisions 86 and 88 and the respective tissue anchors 96 and 98 may include obturator, abdominal, pelvic, perineal and rectal regions.

[00103] The tissue anchors 632, 634, 96, and 98 may take any of the forms disclosed in the above-referenced '002 patent and in U.S. Patent Application Publication Nos. 2005/0004576 and 2006/0089525.

[00104] A wide variety of other specific embodiments of the invention employing adjustment mechanisms bridging a gap between the sling intermediate ends 36, 38 and 46, 48 to adjust spacings 162 and 164 are contemplated. In the following embodiments, the adjustment actuator acts upon the sling end portion adjustment mechanisms 102 and 104 by percutaneous direct access to an adjustment tool or transcutaneous transmission of adjustment commands to an adjustment control of the adjustment mechanism. In these embodiments, both shortening and lengthening of the length of the adjustment spacings 162 and 164 for increasing and decreasing sling tension are contemplated by these embodiments.

[00105] Referring to FIG. 12, adjustment mechanism 202 is disposed across the adjustment spacing 162 and affixed to sling intermediate ends 36 and 38, and adjustment mechanism 204 is disposed across the adjustment spacing 164 and affixed to sling intermediate ends 46 and 48. An external adjustment actuator 200 is depicted brought into proximity to or applied against the skin 52 for generating an adjustment command 210 that is communicated transcutaneously through the skin 52 and underlying fat, tissue and fascia to adjustment mechanism 204. It will be understood that the external adjustment actuator 200 may also be brought into proximity to the skin 52 for generating a similar adjustment command communicated transcutaneously through the skin 52 and underlying fat, tissue and fascia to adjustment mechanism 202. The adjustment mechanisms 202 and 204 comprise electro-mechanical

systems or elements or materials that respond to the transmitted command 210 to effect the adjustment in length of the adjustable spacings 162 and 164. In a related embodiment, mechanisms 202 and 204 are shape memory alloy (e.g. nitinol) elements that contract in size and expand in size depending on the stimulus.

[00106] In one variation of this embodiment depicted in FIG. 13, the external adjustment actuator 200 is an RF signal generator that generates an RF signal 210 through antenna 206 applied to the patient's skin as command 210. The adjustment mechanisms 202 and 204 each incorporate an RF antenna 216 that receives the RF signal and apply the received signal to internal electro-mechanical drive mechanism 218 for extending or contracting the length of the adjustment mechanisms 202 and 204.

[00107] Alternatively, the RF signal 210 is a power signal that is received by antenna 216 to generate a current that is applied to resistive heating elements or heat responsive elements forming the electro-mechanical drive mechanism 218 of each of adjustment mechanisms 202 and 204. For example, the electro-mechanical drive mechanism 218 of the adjustment mechanisms 202 and 204 may comprise chambers holding a heat responsive fluid that expands as heat is applied, and the expanded fluid drives pistons in the chambers to increase the overall length of the adjustment mechanisms 202 and 204. Or, the electro-mechanical drive mechanism 218 may comprise a heat responsive bi-metal strip that is heated by the received current and expands or contracts in length to expand or contract the length of the adjustment mechanisms 202 and 204.

[00108] Alternatively, the external adjustment actuator 200 generates a pulsed or steady magnetic field as the command 210. The adjustment mechanisms 202 and 204 incorporate magnetic responsive switches, e.g., reed switches or MAGFETs within the electro-mechanical drive mechanism 218 that switch states and operate the electro-mechanical drive mechanism 218 to extend or contract the length of the adjustment mechanisms 202 and 204.

[00109] Alternatively, the external adjustment actuator 200 is simply a heating or chilling pad that is applied to the skin to locally heat or cool the underlying tissue and the adjustment mechanisms 202 and 204 to expand or contract a heat responsive element or material that is incorporated into the adjustment mechanisms 202 and 204. The heating and/or cooling of the heat responsive element or material extends and/or or contracts the length of the adjustment mechanisms 202 and 204.

[00110] Alternatively, the sling tension adjustment mechanisms 202 and 204 comprise light responsive elements, and the external adjustment actuator 200 comprises a light source (laser or diode) that emits light pulses of a light frequency capable of penetrating the skin and underlying fat layers and fascia as the command 210 that the light responsive elements are capable of detecting. An electro-mechanical drive mechanism 218 responds to the output signals of the light detectors to adjust the length of the adjustment mechanisms 202 and 204.

[00111] FIGs. 14 - 17 are schematic illustrations of a serpentine roller that may be incorporated into the adjustment mechanisms 202 and 204 to adjust the length of the adjustment spacings 162 and 164. The intermediate ends 36, 38 and 46, 48 are attached to ends of a band 230 that extends through a channel 226 of the housing 220, the channel 226 including two chambers 222 and 224. The band 230 extends around roller 232 disposed in chamber 222 and roller 234 disposed in chamber 224. The lengths of the adjustment spacings 162, 164 depend on the location of the rollers 232 and 234 in the respective channels 222 and 224.

[00112] A maximum length of the adjustment spacings 162, 164 is obtained with the rollers 232 and 234 disposed substantially out of the respective channels 222 and 224 as shown in FIG 16. A minimum length of the adjustment spacings 162, 164 is obtained with the rollers 232 and 234 disposed fully within the respective channels 222 and 224 as shown in FIG 17. An intermediate or neutral length of the adjustment spacings 162, 164 is obtained with the roller 232 disposed fully within the respective channels 222 and the roller 234 disposed substantially out of the respective channel 224 as

shown in FIG 15. The sling 20 would be implanted with the rollers 232 and 234 disposed in the neutral position of FIG. 15, and later adjustments to the position of FIG. 16 or FIG. 17 would be made with an external adjuster applied to the patient' s skin 52. It is contemplated that movement of the rollers 232 and 234 would be controlled by an electro-mechanical interface between the rollers 232 and 234 and any mechanism responsive to commands 210 generated by the external actuator 200 as described above.

[00113] In further embodiments illustrated schematically in FIG. 18, the external adjustment actuator 310 has an actuator-engaging end 312 at the end of a shaft 314. The tension adjustment mechanisms 302 and 304 are shaped with actuator end receptacles 306 and 308, respectively, that can be manually palpated through the skin 52. The actuator engaging end 312 and shaft 314 can be inserted percutaneously through skin incisions 64 and 66 to fit the actuator engaging end 312 into the actuator end receptacles 306 and 308. The external adjustment actuator 310 is depicted in engagement (at separate times) with both actuator end receptacles 306 and 308 in FIG. 18. Various rotatable mechanisms within the tension adjustment mechanisms 302 and 304 are contemplated that can be rotated by manual rotation of the external adjustment actuator 310 in one direction to shorten the sling end portions 42 and 44 together to increase sling tension and that can be rotated by manual rotation of the external adjustment actuator 310 in the other direction to lengthen the sling end portions 42 and 44 to separate apart to decrease sling tension. The actuator engaging end 312 is shaped to both penetrate tissue and to have mating surfaces for engaging the end receptacles 306 and 308 to enable rotation in both directions.

[00114] The tension adjustment mechanisms 302 and 304 depicted in FIGs. 19 - 22 each comprise a bobbin 316 mounted for rotation in a receptacle of a housing 320 fixed at one end to the sling intermediate end 36, 46, the bobbin 316 shaped with the actuator end receptacles 306, 308 extending axially into one side of the bobbin 316. A band or strand 330 extends from a fixed connection with the other sling intermediate end 38, 48 into a channel 322 in housing 320 and around a groove of the bobbin 316 to a fixed coupling with

the bobbin 316. The bobbin 316 is formed with three detents 332, 334, 336 spaced apart around its circumference, and the free end of a catch 324 fixed at its other end to housing 320 engages one of the detents 332, 334, 336.

[00115] In this embodiment, the actuator end receptacles 306, 308 have a five sided socket shape, and the engaging end 312 of the shaft 314 of external adjustment actuator 310 is also shaped as a mating five-side wrench having a distal point and is shown poised to be inserted into the actuator end receptacle 306, 308 in FIG. 19. The neutral position of the bobbin 316 at the time that the sling 20 is implanted is depicted in FIG. 20. At a later date, the external adjustment actuator 310 can be used to engage and rotate the bobbin 316 to either increase or decrease the amount of the band or strand 330 taken up on the bobbin groove and to thereby shorten or extend, respectively, the adjustment spacing 162, 164, and tighten or loosen, respectively, the sling 20 and increase or decrease, respectively, tension applied by the sling central support portion 40 to the urethra 58 (or anus).

[00116] As shown in FIG. 21, a minimum length of the adjustment spacing 162, 164 is obtained by clockwise rotation of the bobbin 316 to move the catch end 324 out of detent 334 and along the outer edge of the bobbin 316 until the catch end engages detent 336. As shown in FIG. 22, a maximum length of the adjustment spacing 162, 164 is obtained by counter-clockwise rotation of the bobbin 316 to move the catch end 324 out of detent 334 and along the outer edge of the bobbin 316 until the catch end engages detent 332.

[00117] An alternative detent arrangement of the bobbin and housing is depicted in FIG. 23. In this variation, the housing 340 supports a rotatable bobbin 346 surrounded by a fixed detent ring 342. The actuator-engaging receptacle 348 is shaped to receive an actuator end shaped like a three-sided Keith needle. A first band or strand 350 extends from a fixed end about a portion of the circumference of the bobbin 346 and is coupled at its other end to the intermediate end 36, 46 of the sling 20 formed of mesh 30. A second band or strand 352 extends from a fixed end about a portion of the circumference of the bobbin 346 and is coupled at its other end to the intermediate end 38, 48 of the sling 20. The rotatable bobbin 346 and fixed

detent ring 342 further comprise a plurality of flexible tabs or teeth that interlock like gear teeth.

[00118] Again, a neutral position of the bobbin 346 is established at the time that the sling 20 is implanted is depicted. At a later date, the Keith needle style external adjustment actuator 310 can be used to engage the receptacle 348 and rotate the bobbin 346 clockwise to decrease or counterclockwise to increase the amount of the bands or strands 350, 352 taken up on the bobbin grooves. The clockwise and counterclockwise bobbin rotations thereby extend or shorten, respectively, the adjustment spacing 162, 164, and loosen or tighten, respectively, the sling 20 and decrease or increase, respectively, tension applied by the sling central support portion 40 to the urethra 58.

[00119] An alternative dual cam adjustment mechanism 362, 364 is depicted in FIGs. 24, 25A - 25D, and 26A - 26D disposed in the adjustable spacings 162, 164. The tension adjustment mechanisms 362, 364 each comprise a dual cam assembly 370 comprising a first cam 372 coupled to first tether 374 and a first cam follower 376 and a second cam 382 coupled to a second tether 384 and second cam follower 386. The ends of the first and second tethers 374 and 384 are coupled to the sling intermediate ends 36, 46, and 38, 48 respectively. The first cam 372 rotated with respect to cam follower 376 operates to decrease the adjustable spacings 162, 164 from the neutral length of FIG. 24 to the contracted length of FIG. 25A as shown in FIGS. 25B - 25D. The second cam 382 rotated with respect to cam follower 38 operates to increase the adjustable spacings 162, 164 from the neutral length of FIG. 24 to the contracted length of FIG. 26A as shown in FIGS. 26B - 26D. The external adjustment actuator 310 (FIG. 18) is operated to engage either the first or the second cam 372 or 382 to increase or decrease sling tension, respectively. Any suitable socket and actuator configuration may be employed for effecting selective rotation of the cams.

[00120] In yet further embodiments of the second category depicted schematically in FIG. 27, the external adjustment actuator is a syringe 410 or the like that is inserted percutaneously through a skin incision to engage a

port 406, 408 of a fluid retaining chamber of the sling tension adjustment mechanism 402, 404.

[00121] In the embodiment depicted in FIGs. 28 - 31, the port 406, 408 comprises a penetrable, resealable septum, and a needle stop may be included within the fluid chamber opposite the resealable septum to prevent needle perforation of the wall of the fluid retaining chamber within the outer housing 415. The port 406, 408 is coupled to sling intermediate end 36, 46, and a rod 420 is coupled at its free end to the sling intermediate end 38, 48. The port 406, 408 accesses a cylinder within housing 422 so that the fluid delivered through the septum of the port 406, 408 is also delivered into the cylinder. A piston coupled to the rod 420 (which may simply be an enlarged diameter end of rod 420) is also enclosed within the cylinder of housing 422. Rod 420 extends through a C-shaped opening 417 in the end of outer housing 415 that guides but does not inhibit movement of rod 420. The adjustment spacing 162, 164 is adjusted by injecting or withdrawing fluid from the fluid chamber to laterally extend or retract the piston mounted rod 420 to increase or decrease the adjustment spacing 162, 164 as shown in FIGs. 29 - 31.

[00122] A variation on this embodiment is depicted in FIGs. 32 - 36, wherein a sling tension adjustment mechanism 432, 434 is substituted for the sling tension adjustment mechanism 402, 404 of FIGs. 27 - 31. In this variation, the port 436 is formed with a syringe needle interlock 443, and the syringe 410 has a special interlocking tip 442 that opens and enters the interlock 443 to deliver or withdraw fluid from or to the syringe chamber 416. The port 436 is coupled to a housing 446 enclosing a cylinder or fluid chamber 444 that the fluid is delivered into. The interlock 443 is spring loaded by spring 440 within the port chamber 445. A piston 448 is also enclosed within the housing 446 and coupled to a rod 450 extending from the housing end. The port 436 is coupled to sling intermediate end 36, 46, and the rod 450 is coupled at its free end to the sling intermediate end 38, 48.

[00123] The volume of fluid delivered into the fluid chamber 444 dictates the position of the cylinder 448 within the chamber 444 and the extension of the rod 450. The adjustment spacing 162, 164 is therefore adjusted by injecting

or withdrawing fluid from the fluid chamber 444 to laterally extend or retract the piston 448 and rod 450 to increase or decrease the adjustment spacing 162, 164 as shown in FIGs. 35 - 36.

[00124] The sling tension adjustment mechanisms 402, 404 and 432, 434 depicted in FIGs. 27 - 36 comprise single action, hydraulic pistons, wherein the fixed housing is coupled to one sling intermediate end and the movable rod end is coupled to the other intermediate sling end. It will be understood that the sling tension adjustment mechanisms 402, 404 and 432, 434 depicted in FIGs. 27 - 36 may be modified to function as dual action, hydraulic pistons having axially aligned and opposed pistons coupled to respective rods, and the rod free ends of each mechanism coupled to the sling intermediate ends 36, 46 and 38, 48.

[00125] A still further variation on this embodiment of the second category illustrated in FIG. 27 is depicted in FIGs. 37 - 40, wherein a sling tension adjustment mechanism 462, 464 is substituted for the sling tension adjustment mechanism 402, 404 of FIGs. 27 - 31. In this dual action variation, the external adjustment actuator is the syringe 410 or the like that is inserted percutaneously through a skin incision to engage a port 406, 408 of a fluid chamber 470 of the sling tension adjustment mechanism 462, 464. The port 406, 408 comprises a penetrable, resealable septum, and a needle stop may be included within the fluid chamber opposite the resealable septum to prevent needle perforation of the wall of the fluid chamber 470.

[00126] The S-shaped chamber housing 472 enclosing the fluid chamber 470 is shaped with opposed spiral arms 466 and 468 respectively coupled to sling intermediate end 36, 46 and end 38, 48. The housing 472 is formed of a material that is expandable as fluid volume and pressure increases as shown in FIG. 39 and contractible as fluid volume and pressure decreases as shown in FIG. 40. The adjustment spacing 162, 164 is therefore adjusted by injecting or withdrawing fluid from the fluid chamber 470 to laterally extend or retract the opposed spiral arms 466 and 468 to increase or decrease the adjustment spacing 162, 164 as shown in FIGs. 37 - 40.

[00127] In a further alternative variation (not shown), the arms 466 and 468 may be corrugated with one or more corrugation to function in the manner of bellows. In such case, the arms 466 and 468 may be spiral as depicted or extend in axial alignment and away from one another to increase or decrease the adjustable spacing 162, 164.

[00128] In certain further embodiments of the second category of the invention depicted schematically in FIG. 41, the sling tension adjustment mechanisms 502 and 504 comprise fluid reservoirs 512 and 514, housings 522 and 524, respectively, and tubes 532 and 534 extending between the fluid reservoirs 512 and 514 and housings 522 and 524, respectively, alongside the sling end portions 42 and 44, respectively. The housings 522 and 524 are coupled to the sling intermediate ends 36, 38 and 46, 48, respectively, and define the adjustment spacings 162 and 164, respectively.

[00129] The fluid reservoirs 512 and 514 are adapted to be implanted just below the skin 52 adjacent the skin incisions 82 and 84, respectively. Alternatively, the tubes 532 and 534 may extend through the skin incisions 82 and 84 to dispose the fluid reservoirs 512 and 514 outside the skin during the healing phase. In that case, the tubes 532 and 534 may be pulled upon to detach their distal ends from tube fittings on the housings 522 and 524 after tissue ingrowth into the mesh pores has secured the sling 20 in position. Tissue ingrowth should maintain the adjustment spacings 162, 164 even if the hydraulic fluid (saline) then escapes from fluid cylinders and chambers within the housings 522 and 524.

[00130] The fluid reservoirs 512 and 514 have respective fluid delivery/withdrawal ports 516 and 518 that may be percutaneously accessed by needle tip 412 of syringe 410 to introduce fluid into the fluid reservoir 512, 514 or to withdraw fluid from the fluid reservoir 512, 514 following implantation of the sling 20 to thereby adjust the amount of fluid in the fluid chambers of housings 522 and 524 and adjust the length of the adjustable spacings 162 and 164.

[00131] It will be understood that the housings 522, 524 may incorporate any of the adjustment mechanisms 402, 404 or 432, 434 or 462, 464 and variations thereof described above with the tubes 532, 534 and fluid reservoirs 512 and 514 substituted for the above-described fluid delivery/withdrawal ports.

[00132] In FIGs. 42 - 45, alternative forms of adjustment housings 522 and 524 of the adjustment mechanisms 502, 504 and 502', 504' containing fluid chambers, pistons, and connecting rods are depicted in greater detail. The housing 522, 524 encloses a fluid chamber 526, a piston 528 and a rod 530 extending axially from one end of the housing 522, 524. In the particular single action cylinder designs depicted in FIGs. 42 - 45, the housing 522, 524 is elliptical in lateral cross-section having a major ellipse axis corresponding generally to the width of the mesh 30 of sling 20 so that the minor ellipse axis minimizes overall thickness of the sling 20. The housing wall 542, fluid chamber 526, and piston 528 may be shaped more oblong than elliptic as shown in FIG. 46. The sling intermediate end 36, 46 is coupled by thermoplastic rivets or sutures or the like to the stationary end of housing 522, 524, and the sling intermediate end 38, 48 is coupled by thermoplastic rivets or sutures or the like to the movable free end of rod 530 in each housing 522, 524. It will be understood that the piston 528 is formed with a ring or rings that provide a tight seal with the housing wall 542 defining the fluid chamber 526 to minimize fluid loss.

[00133] In the variation of this embodiment of adjustment mechanism 502, 504 depicted in FIGs. 42 - 44, the tubes 532 and 534 extend from the end of the housing 522, 524 opposite the rod 530 and centrally along the axes of the mesh 30 of each of the end portions 42 and 44, respectively, to the fluid reservoirs 512 and 514, respectively, to supply fluid to or withdraw fluid from the chamber portion defined by the housing interior wall 536 and the piston head 538. In the variation of adjustment mechanism 502', 504' depicted in FIG. 45, the tube 532, 534 extends offset from the axis of the sling mesh 30.

[00134] A dual action hydraulic cylinder form of an adjustment mechanism 552 similar to adjustment mechanisms 502, 504 and 502', 504' is depicted in FIG. 46. An oblong shape of the piston 558, the housing 562, and fluid chamber

556 is also depicted in FIG. 46 that may be substituted for the elliptical shapes of the piston 528, housing 522, 524, and fluid chamber 526, respectively, of FIGs. 42 - 45.

[00135] The dual action adjustment mechanism 552 requires two subcutaneously implantable fluid reservoirs (not shown) or a dual action fluid reservoir and tubes 572 and 574 extending alongside the sling mesh to subcutaneous implantation sites. The housing 562 encloses a fluid chamber 556, piston 558 and rod 560 extending through an opening in one end of the housing 562. The fluid chamber 556 comprises a contracting chamber 568 coupled to tube 572 on one side of piston 558 and an extending chamber 570 coupled to tube 574 on the other side of the piston 558.

[00136] In use, the adjustment mechanism 552 is substituted for the adjustment mechanisms 502 and 504 of FIG. 41 to define the adjustment spacings 162 and 164 as a function of the position of the piston 558 in the fluid chamber 556. The adjustment spacing 162, 164 is lengthened if fluid is introduced into chamber portion 570 from the first fluid reservoir through tube 574 while fluid is simultaneously withdrawn from chamber portion 568 into the second fluid reservoir through tube 572. Conversely, adjustment spacing 162, 164 is shortened if fluid is introduced into chamber portion 568 from the second fluid reservoir through tube 572 while fluid is simultaneously withdrawn from chamber portion 570 into the first fluid reservoir through tube 574.

[00137] Any of the above-described single action hydraulic adjustment mechanisms can be modified in this fashion to function as a dual action hydraulic adjustment mechanism. It may be desirable to provide a locking mechanism to maintain the adjusted position of the piston and rod of the single or dual action hydraulic adjustment mechanisms disclosed herein after setting the adjustment spacing. Leakage and blow-by of the pressurized hydraulic fluid may occur causing the adjustment spacing to change before tissue ingrowth into the sling mesh pores stabilizes the sling.

[00138] FIGs. 47 and 48 illustrate one form of locking mechanism 405 incorporated into a single action hydraulic cylinder adjustment mechanism

402, 404 of the type shown in FIGs. 28 - 31. In the depicted single action, hydraulic cylinder, adjustment mechanism 402', 404', upper and lower lines of serrations, or teeth 421 and 423 extend along the rod 420. The rod 420 extends from the cylinder 455 within housing 422 and passes through a locking ring 425 mounted to slightly rock or pivot on axle 427 supported by the outer housing 415. A counterweight rod 429 also extends from the axle within the outer housing 415. Serrations or teeth are also formed on the inner wall of the locking ring 425 in alignment and engagement with the upper and lower lines of serrations or teeth 421 and 423.

[00139] The frictional engagement of the serrations of the locking ring 425 and the upper and lower lines of serrations or teeth 421 and 423 function as the locking mechanism 405 and tend to inhibit movement of the rod 420, but the engagement force is overcome when fluid is added to or removed from the cylinder. The piston and rod 420 can therefore move between its limits due to the change in fluid pressure. If fluid pressure gradually decreases due to leakage, the counterweight rod 429 tends to cause the locking ring 425 to pivot on axle 427 to engage the teeth together to resist movement of the rod 420. It will be understood that the outer housing 415 may extend completely around the locking ring 425 and the housing 422 to isolate them from body tissue.

[00140] FIGs. 49 and 50 illustrate another form of locking mechanism 435 incorporated into a single action hydraulic cylinder adjustment mechanism 402, 404 of the type shown in FIGs. 28 - 31. In the depicted single action hydraulic cylinder adjustment mechanism 402", 404", the locking mechanism 435 comprises modifications to the rod 420 providing reduced diameter sections 437, 439, and a laterally extending pin 441, a pair of springs 447, 449 disposed around rod sections 437, 439, and a rotatable sleeve 457 disposed over the rod 420. The rotatable sleeve 457 surrounding rod 420 extends through the C-shaped opening 417 in housing 415. A spiral slot 451 with a plurality of notches 453 is formed in the rotatable sleeve 457, and the pin 441 extends through the spiral slot 451 and can be engaged in a notch 453.

[00141] The adjustment spacing 162, 164 is adjusted by injecting or withdrawing fluid from the fluid chamber to laterally extend or retract the piston mounted rod 420 to increase or decrease the adjustment spacing 162, 164. In the process, rod 420 is moved within cylinder 455 against the spring force of one or the other of the springs 447, 449 and the outwardly extending pin 441 travels along the spiral slot 447, rotating the sleeve 457. The spring force functions as a detent by lodging the pin 441 into engagement with the closest notch 453. The engagement resists any change in rod position that might otherwise occur due to loss of fluid from the cylinder. However, the engagement force can be overcome when fluid is added to or removed from the cylinder. It will be understood that the outer housing 415 may extend completely around the pin 441 and the housing 422 to isolate them from body tissue.

[00142] These locking mechanisms may be incorporated into the various single and dual action hydraulic cylinder adjustment mechanisms disclosed herein.

[00143] A further miniaturized single action hydraulic cylinder adjustment mechanism 402', 404' is depicted in FIGs. 51 - 53 that may be substituted for the above-described adjustment mechanism 502, 504 of FIG. 41. In this embodiment, the width and height or diameter of the modified housing 415' is sized to correspond generally to the width of the sling mesh 30 of sling 20. The locking mechanism 405 described above is incorporated into the modified housing 415' although locking mechanism 435 may be substituted for locking mechanism 405. The cylinder 455 is directly coupled to a tube coupling 419 that the end of the tube 532, 534 is affixed to. The syringe 410 is employed to penetrate the septum of the fill port 512, 514 to add or remove fluid from cylinder 455 and adjust the rod 420 to adjust the adjustable spacing as described above with respect to FIG. 41. As noted above, the tube distal end may be detached from the fluid coupling 419 when tissue ingrowth immobilizes the sling mesh 30. It will be understood that the outer housing 415' may extend completely around the locking ring 425 and the housing 422' to isolate them from body tissue.

[00144] The adjustable mechanism of the second aspect of the sling 20 of the present invention may also comprise miniaturized mechanical mechanisms that are adjustable outside the patient's skin or percutaneously through the patient's skin during the healing phase. In certain embodiments the external adjustment actuator comprises an elongated gear drive instrument having a shaft extending between a handle and an engaging end shaped to be percutaneously advanced through the skin. The adjustment mechanism comprises a driven gear means engageable by the engaging end the gear drive for operating the spacing adjustment means to increase or decrease the adjustment spacing.

[00145] A miniaturized gear driven adjustment mechanism 802, 804 is depicted in FIGs. 54 and 55 that may be substituted for the above-described adjustment mechanisms 502 and 504 of FIG. 41. An adjustment mechanism housing 822 is attached at one end to the intermediate sling end 36, 46 and encloses a gear chamber 826 and a rod chamber 824. A driven gear 828 is enclosed within the gear chamber 826, and a rod 820 having a spiral thread 834 extending around its circumference extends through the rod chamber 824 and out of housing end opening 832. The spiral thread 834 engages gear threads within the bore of the driven gear 828. One end of the rod 820 is coupled to the intermediate sling end 38, 48.

[00146] A gear drive 810 comprises an elongated drive shaft 812 extending through a sheath lumen 814 of a drive sheath 816 to a drive gear 830 within the gear chamber 826 of an outer housing 822. The teeth of the drive gear 830 and the driven gear 828 are in engagement. The drive sheath 816 extends through the skin incisions following implantation to enable adjustment of the length of the rod 820 within the rod chamber 824. The gear drive handle 818 may be grasped and rotated to rotate the drive shaft 812 and the drive gear 830. Rotation of the driven gear 828 around the rod 820 in one direction drives the rod 820 out of the rod chamber 824 and lengthens the adjustment spacing 164, 166, whereas rotation of the driven gear 828 around the rod 820 in the other direction drives the rod 820 into the rod chamber 824 and shortens the adjustment spacing 164, 166.

[00147] The distal end of drive shaft 812 may be shaped to detachably engage axially with the drive gear 830 so that the drive sheath 816 and shaft 812 may be axially pulled upon from their proximal ends outside the skin to detach from the housing 822 and drive gear 830, respectively, and be drawn out through the skin incision after tissue ingrowth into the mesh pores has secured the sling 20 in position.

[00148] An alternative, miniaturized, gear driven adjustment mechanism 852, 854 is depicted in FIG. 56 that may be substituted for the above-described adjustment mechanisms 302 and 304 of FIG. 18. An adjustment mechanism housing 872 is attached at one end to the intermediate sling end 36, 46 and encloses a gear chamber 876 and a rod chamber 874. A driven gear 878 is enclosed within the gear chamber 876, and a rod 870 having a spiral thread 884 extending around its circumference extends through the rod chamber 874 and out of housing end opening 832. The spiral thread 884 engages gear threads within the bore of the driven gear 878. One end of the rod 870 is coupled to the intermediate sling end 38, 48.

[00149] A gear driver 860 comprises an elongated drive shaft 866 having a spiral drive gear 880 at the distal end of the drive shaft 866 and a handle 868 at the proximal end of the drive shaft 866. The distal end of the gear drive 860 may be shaped to be percutaneously advanced through the patient's intact skin at pre-made incisions to interact with the driven gear 878. The distal end of the drive shaft 866 is extended through an opening in the housing 872 and into engagement with the drive gear 880 to adjust of the length of the rod 870 within the rod chamber 874. The teeth of the drive gear 880 and the driven gear 878 are depicted in engagement in FIG. 56. The gear drive handle 868 may be grasped and rotated to rotate the drive shaft 866 and the drive gear 880. Rotation of the driven gear 878 around the rod 870 in one direction drives the rod 870 out of the rod chamber 874 and lengthens the adjustment spacing 164, 166, whereas rotation of the driven gear 878 around the rod 870 in the other direction drives the rod 870 into the rod chamber 874 and shortens the adjustment spacing 164, 166.

[00150] It will be understood that alternatively, the gear drive may take the form of gear drive 810 of FIG. 54 that is temporarily left extending through the skin incisions following implantation of the sling. In that case, the distal end of drive shaft 812 may be shaped to detachably engage axially with the drive gear 880 so that the drive sheath 816 and shaft 812 may be axially pulled upon from their proximal ends outside the skin to detach from the housing 872 and drive gear 880, respectively, and be drawn out through the skin incision after tissue ingrowth into the mesh pores has secured the sling 20 in position.

[00151] A still further alternative, miniaturized, mechanical drive mechanism 902, 904 is depicted in FIG. 57 that may be substituted for the above-described adjustment mechanisms 502 and 504 of FIG. 41. In this embodiment, the adjustment spacing 164, 166 is adjusted by a rack and pinion gear drive 910 extended temporarily through the patient's skin or implanted under the patient's skin and accessed percutaneously with an external adjustment actuator 310 shaped to engage the pinion gear drive 910 similar to external adjustment actuator 310 shown in FIG. 18.

[00152] In the embodiment depicted in FIG. 57, the gear drive 910 comprises an elongated drive shaft 912 extending through a sheath lumen 914 of a drive sheath 916 from a gear drive housing 918 to the mechanical drive mechanism 902, 904. The proximal end of the sheath 916 is coupled to the gear drive housing 918. The gear drive housing 918 encloses a gear chamber 926 in which a rack 930, coupled at one end to the proximal end of the drive shaft 912, is disposed for lateral movement, and a pinion 928 is positioned for rotary movement. The teeth of the rack 930 and the pinion 928 are in engagement. A hex shaped recess 932 is formed in the pinion to be engaged by a hex wrench to rotate the pinion 928 and laterally move the rack 930 within the gear chamber 926.

[00153] The distal ends of the sheath 916 and the drive shaft 912 are coupled to one end of the housing 906 of the drive mechanism 902, 904. The housing 906 takes the form of the housing 415' of FIGs. 51 - 53 and is depicted without a cover to expose the rod chamber 908 and the rod 920 and locking mechanism 905 disposed therein. Locking mechanism 905 corresponds to

locking mechanism 405 described above and may take other forms or may not be provided in this embodiment.

[00154] Rotation of the pinion 928 in one direction drives the rack 930 and the drive shaft 912 in one direction to drive rod 920 out of the rod chamber 908 and lengthen the adjustment spacing 164, 166. Rotation of the pinion 928 in the other direction drives the rack 930 and the drive shaft 912 in the other direction to pull rod 920 into the rod chamber 908 and shortens the adjustment spacing 164, 166.

[00155] A still further alternative, miniaturized, mechanical drive mechanism 952, 954 is depicted in FIGs. 58A - 58D that may be substituted for the above-described adjustment mechanisms 502 and 504 of FIG. 41. In this embodiment, the adjustment spacing 164, 166 is also adjusted by a rack and pinion gear drive 910 extended temporarily through the patient's skin or implanted under the patient's skin and accessed percutaneously with an external adjustment actuator 310 shaped to engage the rack and pinion gear drive 910 as described above with respect to FIG. 57.

[00156] In this embodiment, the housing 956 is coupled at one end to the sling intermediate end 36, 46, and encloses a rack chamber 958 and a driven rack 962 within the rack chamber 958. The driven rack 962 in rack chamber 958 is coupled at one rack end to the end of the drive shaft 914 and at the other rack end to the sling intermediate end 38, 48. A pivotally mounted catch 964 is shaped to engage rack teeth 962 and to guide movement and help maintain rack 960 in a selected position in the rack chamber 958 to define the adjustment spacing 162, 164.

[00157] Rotation of the pinion 928 in one direction drives the drive rack 930 and the drive shaft 912 in one direction to move drive rack 962 out of the rack chamber 958 and lengthen the adjustment spacing 164, 166 as shown in FIG. 58B. Rotation of the pinion 928 in the other direction moves the rack 930 and the drive shaft 912 in the other direction to pull rod 920 into the rack chamber 958 and shortens the adjustment spacing 164, 166, as shown in FIG 58D.

[00158] It will be understood that the gear drive housing 918 can be implanted under the skin. It will also be understood that each gear drive housing 918 can be temporarily left extending through the skin incisions following implantation of the sling. In this case, the distal end of drive shaft 912 may be shaped to detachably engage axially with the rod 920, and the distal end of the sheath 916 may detachably engage with the end of the housing 906 or 956. After tissue ingrowth into the mesh pores has secured the sling 20 in position, the drive sheath 916 and shaft 912 may be axially pulled upon from their proximal ends outside the skin to detach from the housing 906 or 956 and rod 920 or rack 960, respectively, and be drawn out through the skin incision.

[00159] With respect to the embodiment of FIGs. 58A - 58D, it will be understood that the drive pinion 928 can alternatively be integrated into the rack chamber 958 in lieu of or alongside the pivoting catch 964. In this variation, the gear drive 910, sheath 916, and the shaft 912 would be eliminated, and the pinion 928 located if the rack chamber 958 could be accessed by the percutaneously inserted hex wrench 310 in the manner described above with respect to FIGs. 18 - 23.

[00160] It will be understood that the above-described embodiments of the second category of the sling of the invention may be modified by substituting other support materials than open pore mesh 30, particularly in the central support portion 40, e.g., homograft or allograft materials or nonporous synthetic materials. Moreover, other materials and structures may be substituted for the mesh 30 in the sections of constituting one or both of the end portions extending from the intermediate ends 38 and 48 to the ends of the central support portion 40. For example, one or more straight or spiral suture may be substituted for all or part of such sections.

[00161] While the above-described embodiments of adjustable tension slings depict methods and apparatus for adjusting sling tension in each end portion, it will be understood that in each case only one adjustment mechanism may be provided acting on or within one sling end portion (or alternatively on both end portions 1).

[00162] It will also be understood that all of the above-described embodiments of the urethral or fecal slings may optionally incorporate a sling central portion adjustment mechanism, e.g., suture 108 illustrated in FIGs. 10 and 11 or as otherwise described herein.

[00163] Furthermore, it will be understood that all of the above-described embodiments of the urethral or fecal slings illustrated in FIGs. 12 through 58 may optionally incorporate tissue anchors coupled to the sling ends extending from or incorporated into the sling ends 32 and 34. For example the sling anchor 92 illustrated extending from sling end 32 in FIG. 11 could be incorporated into a suture extending from the sling ends 32 and 34 in each such embodiment to assist in tensioning the sling end portions 42 and 44 during adjustment of the tension adjustment mechanisms.

[00164] Many of the embodiments described herein can be used in connection with prolapse and pelvic floor repairs (men and women) that may require post-operative adjustment of the implanted mesh or graft or sling. They may also be used in connection with prostatectomies or hysterectomies and to support any other body tissue within the pelvic area or other parts of the body including but not limited to, hernia repair, and shoulder and abdominal repairs. Examples of meshes, grafts and prolapse repairs are described in U.S. Publication Nos. 2004-0039453 A1, 2005-0250977 A1, and 2005-0245787 A1, which are hereby incorporated by reference in their entirety.

[00165] All patents and publications referenced herein are hereby incorporated by reference in their entireties.

[00166] It will be understood that certain of the above-described structures, functions and operations of the above-described preferred embodiments are not necessary to practice the present invention and are included in the description simply for completeness of an exemplary embodiment or embodiments. It will also be understood that there may be other structures, functions and operations ancillary to the typical surgical procedures that are not disclosed and are not necessary to the practice of the present invention.

[00167] In addition, it will be understood that specifically described structures, functions and operations set forth in the above-referenced patents can be practiced in conjunction with the present invention, but they are not essential to its practice. It is therefore to be understood, that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described without actually departing from the spirit and scope of the present invention.

CLAIMS:

1. A system for providing support to body tissue to alleviate incontinence comprising:

an elongated incontinence sling having a central support portion adapted to be positioned to support any one of the urethra or anus having first and second sling end portions extending from the central support portion through body tissue;

a tension adjustment mechanism acting on or within one or both of the sling end portions, wherein the sling tension adjustment mechanism is attached to and extends through an adjustment spacing between sling intermediate ends within the sling end portion intermediate the sling end and the sling central portion and comprises spacing adjustment means for changing the adjustment spacing; and

external adjustment actuator means for actuating the sling tension adjustment mechanism to change the adjustment spacing between the sling intermediate ends and thereby change tension in the sling central portion applied to the urethra or anus.

2. The system of Claim 1, wherein the external adjustment actuator means extends through the patient's skin for adjustment.

3. The system of Claim 1, further comprising at least one tissue anchor coupled to at least one sling end adapted to be passed through body tissue to anchor the sling end against the body tissue to stabilize the sling end and facilitate adjustment of sling tension.

4. The system of Claim 1, wherein:

the tension adjustment mechanism comprises a portion of a suture extending across the adjustment spacing between the sling intermediate ends within the sling end portion intermediate the sling end and the sling central portion to form the spacing adjustment means; and

the external adjustment actuator means comprises a portion of the suture extending from the spacing adjustment means between the sling intermediate ends and adapted to be extended through a skin incision for manipulation to change the adjustment spacing between the sling intermediate ends and thereby change tension in the sling central portion applied to the urethra or anus.

5. The system of Claim 1, wherein:

the sling tension adjustment mechanism comprises a portion of a suture extending the across the adjustment spacing between the sling intermediate ends within the sling end portion intermediate the sling end and the sling central portion to form the spacing adjustment means; and

the external adjustment actuator means comprises:

a portion of the suture extending from the spacing adjustment means between the sling intermediate ends and adapted to be extended through a tissue pathway through body tissue; and

a tissue anchor having a bore receiving the portion of the suture extending through body tissue, the tissue anchor adapted to be manipulated to anchor against the body tissue and to the change the adjustment spacing between the sling intermediate ends and thereby change tension in the sling central portion applied to the urethra or anus.

6. The system of Claim 5, wherein the sling further comprises at least one tissue anchor coupled to at least one sling end adapted to be passed through body tissue to anchor the sling end against the body tissue to stabilize the sling end and facilitate adjustment of sling tension.

7. The system of Claim 1, wherein:

the external adjustment actuator comprises a transmitter adapted to be brought into proximity to or applied against the skin and operated to generate a spacing adjustment command that is communicated transcutaneously through the skin and body tissue to the adjustment mechanism; and

the adjustment mechanism comprises means responsive to the transcutaneously communicated commands for operating the spacing adjustment means to increase or decrease the adjustment spacing.

8. The system of Claim 7, wherein:

the external adjustment actuator comprises a RF signal transmitter that is employed to generate a RF sling adjustment command transmitted through the patient's skin; and

the adjustment mechanism comprises a RF receiver for receiving the transmitted commands, and the spacing adjustment means is responsive to the received RF signal to increase or decrease the adjustment spacing.

9. The system of Claim 7, wherein:

the external adjustment actuator comprises is a magnetic field generator or permanent magnet that is employed to generate a magnetic field representing a sling adjustment command that passes transcutaneously through the patient's skin; and

the spacing adjustment means comprises a magnetic field responsive element that responds to the magnetic field by increasing or decreasing the adjustment spacing.

10. The system of Claim 7, wherein:

the external adjustment actuator comprises an external thermal heater or cooler adapted to be applied to the patient's skin; and

the spacing adjustment means comprises a temperature responsive element responsive to heat or cold applied transcutaneously through the patient's skin to heat or cool the adjustment mechanism to thereby increase or decrease the adjustment spacing.

11. The system of Claim 7, wherein:

the external adjustment actuator comprises an external light source adapted to be applied to the patient's skin and to generate a light wavelength that is transmittable through skin and body tissue; and

the spacing adjustment means comprises light responsive elements responsive to the wavelength of light generated by the external adjustment actuator and transmitted transcutaneously to the sling tension adjustment mechanism to thereby increase or decrease the adjustment spacing.

12. The system of Claim 1, wherein:

the external adjustment actuator comprises an elongated instrument having a shaft extending between a handle and an engaging end shaped to be percutaneously advanced through the skin; and

the adjustment mechanism comprises means engageable by the engaging end of the external adjustment actuator for operating the spacing adjustment means to increase or decrease the adjustment spacing.

13. The system of Claim 12, wherein:

the engageable means comprises:

a housing coupled to one sling intermediate end; and

a rotatable bobbin supported by the housing having a receptacle shaped to receive the engaging end of the elongated instrument to enable rotation of the bobbin; and

the spacing adjustment means comprises a strand coupled to the other sling intermediate end and extending around the bobbin that is adapted to be wound onto the bobbin to decrease the adjustment spacing or to be unwound from the bobbin to increase the adjustment spacing.

14. The system of Claim 12, wherein:

the engageable means comprises:

a housing having a chamber bounded by a fixed detent ring of tabs extending into the chamber; and

a rotatable bobbin supported by the housing within the chamber having a receptacle shaped to receive the engaging end of the elongated instrument to enable rotation of the bobbin and an array of flexible tabs extending radially outward of the bobbin in engagement with the tabs of the fixed detent ring; and

the spacing adjustment means comprises a first strand coupled to the first sling intermediate end and extending around the bobbin in a first

direction and a second strand coupled to the second sling intermediate end and extending around the bobbin in an opposite direction,

whereby the first and second strands are wound onto the bobbin by rotation of the bobbin in a first direction to shorten the adjustment spacing and the first and second strands are unwound from the bobbin by rotation of the bobbin in a second direction to shorten the adjustment spacing.

15. The system of Claim 12, wherein:

the engageable means comprises:

a housing having a chamber;

a dual cam assembly supported by the housing within the chamber comprising a first cam having a first receptacle shaped to receive the engaging end of the elongated instrument and a second cam having a second receptacle shaped to receive the engaging end of the elongated instrument;

a first cam follower mounted to the housing and bearing on the first cam; and

a second cam follower mounted to the housing and bearing on the second cam; and

the spacing adjustment means comprises a first tether coupled to the first sling intermediate end and extending around the first cam in a first direction and a second tether coupled to the second sling intermediate end and extending around the second cam in an opposite direction,

whereby the first tether is wound onto the first cam by rotation of the first cam in a first direction into engagement with the first cam follower to shorten the adjustment spacing and the second tether is unwound from the

second cam by rotation of the second cam in the first direction into engagement with the second cam follower to shorten the adjustment spacing.

16. The system of Claim 1, wherein:

the external adjustment actuator comprises a syringe having a syringe chamber adapted to be filled with fluid and a syringe needle having a needle bore extending from the syringe chamber to the needle tip, the syringe needle adapted to be percutaneously passed through the patient's skin;

the tension adjustment mechanism comprises a housing enclosing a fluid retaining chamber having a port penetrable by the syringe needle tip enabling adding or withdrawing fluid from the fluid retaining chamber; and

the spacing adjustment means is coupled to the fluid retaining chamber,

whereby the adjustment spacing is adjusted by passing the syringe needle tip through the port and injecting or withdrawing fluid from the fluid retaining chamber to increase or decrease the adjustment spacing.

17. The system of Claim 16, wherein:

the housing comprises a piston chamber, a piston within the chamber, and a piston rod extending from the piston chamber;

the housing is coupled to the first intermediate end; and

the piston rod is coupled to the second intermediate end,

whereby the piston is moved within the piston chamber to increase the adjustment spacing upon adding fluid through the port to the piston chamber and to decrease the adjustment spacing upon withdrawing fluid through the port to the piston chamber.

18. The system of Claim 16, wherein:

the housing is formed of a flexible material in having opposed first and second spiral arms extending away from the port;

the first intermediate end is coupled to the first spiral arm; and

the second intermediate end is coupled to the second spiral arm,

whereby the arcuate arms straighten to increase the adjustment spacing upon adding fluid through the port.

19. The system of Claim 1, further comprising

a fluid reservoir adapted to be subcutaneously implanted having a penetrable port and enclosing a reservoir chamber and further comprising a tube extending from the reservoir chamber to a tube end; and wherein:

the external adjustment actuator comprises a syringe having a syringe chamber adapted to be filled with fluid and a syringe needle having a needle bore extending from the syringe chamber to the needle tip, the syringe needle adapted to be percutaneously passed through the patient's skin and through the port into the reservoir chamber;

the tension adjustment mechanism comprises a housing enclosing a fluid retaining chamber coupled to the tube end; and

the spacing adjustment means is coupled to the fluid retaining chamber,

whereby the adjustment spacing is adjusted by passing the syringe needle tip through the port and injecting or withdrawing fluid from the reservoir chamber and the fluid retaining chamber to increase or decrease the adjustment spacing.

20. The system of Claim 19, wherein:

the housing comprises a piston chamber, a piston within the chamber, and a piston rod extending from the piston chamber;

the housing is coupled to the first intermediate end; and

the piston rod is coupled to the second intermediate end,

whereby the piston is moved within the piston chamber to increase the adjustment spacing upon adding fluid through the port to the piston chamber and to decrease the adjustment spacing upon withdrawing fluid through the port to the piston chamber.

21. The system of Claim 20, wherein the fluid retaining chamber comprises a single action hydraulic cylinder or a dual action hydraulic cylinder.

22. The system of Claim 1, wherein:

the external adjustment actuator comprises an elongated gear drive instrument having a shaft extending between a handle and an engaging end shaped to be percutaneously advanced through the skin; and

the adjustment mechanism comprises a driven gear means engageable by the engaging end the gear drive for operating the spacing adjustment means to increase or decrease the adjustment spacing.

23. The system of Claim 22, wherein:

the driven gear means comprises:

a housing coupled to the first sling intermediate end enclosing a gear chamber and a rod chamber;

a threaded rod extending through the rod chamber and attached at one end to the second sling intermediate end; and

a rotatable driven gear supported by the housing and in engagement with the threaded rod,

whereby the driven gear is rotatable by engagement with and rotation of the drive gear in a first direction to extend the threaded rod from the rod chamber to increase the adjustment spacing and is rotatable by engagement with and rotation of the drive gear in a second direction to draw the threaded rod into the rod chamber to decrease the adjustment spacing

24. The system of Claim 22, further comprising:

a gear drive adapted to be subcutaneously implanted having a receptacle, and an elongated drive shaft extending through a sheath lumen of a drive sheath to a drive shaft end, and wherein:

the external adjustment actuator comprises an elongated gear drive instrument having a shaft extending between a handle and an engaging end shaped to be percutaneously advanced through the skin into engagement with the receptacle; and

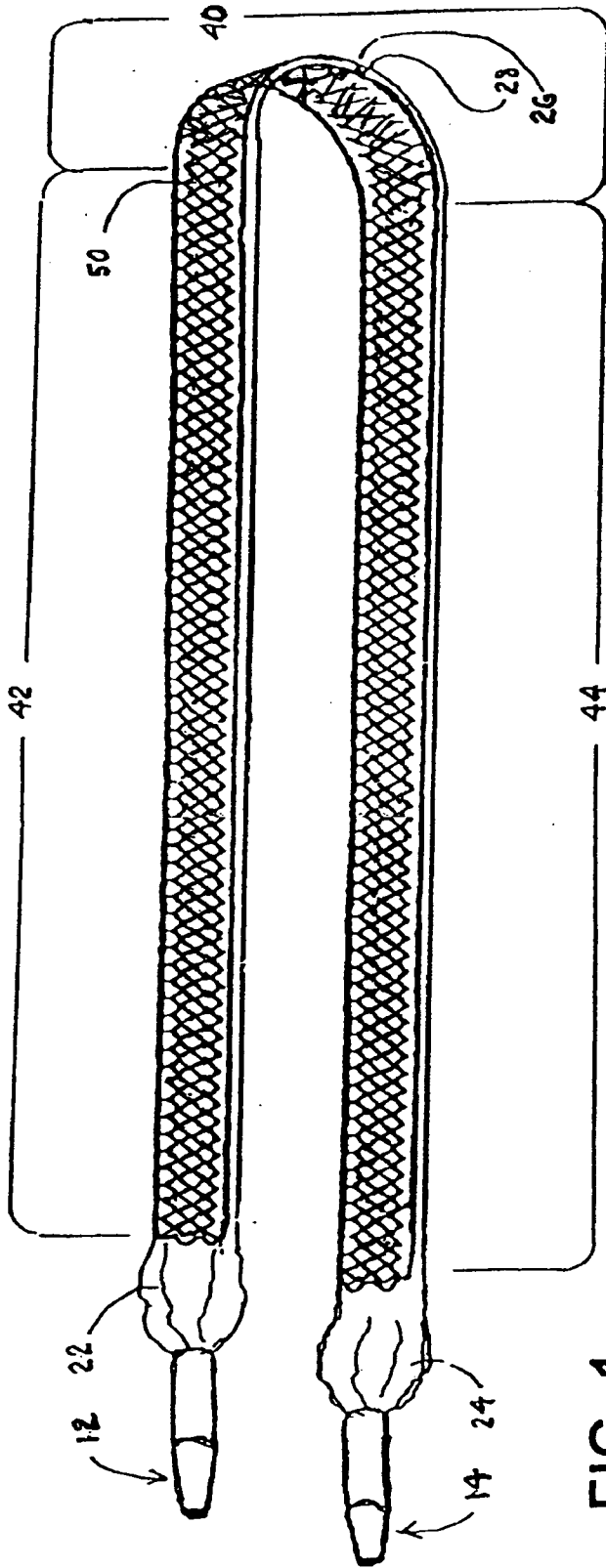
the adjustment mechanism comprises a driven gear means engageable by the drive shaft end for operating the spacing adjustment means to increase or decrease the adjustment spacing.

25. A method of providing support to body tissue to alleviate incontinence comprising:

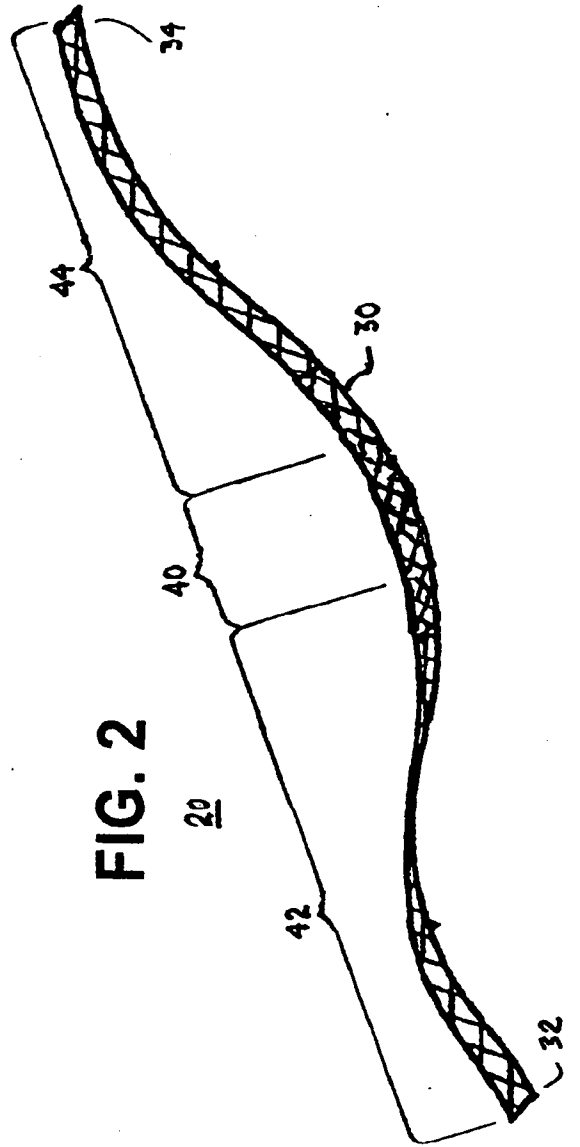
providing an elongated incontinence sling having a central support portion adapted to be positioned to support any one of the urethra or anus having first and second sling end portions extending from the central support portion through body tissue and a tension adjustment mechanism acting on or within one or both of the sling end portions, wherein the sling tension adjustment mechanism is attached to and extends through an adjustment spacing between sling intermediate ends within the sling end portion intermediate the sling end and the sling central portion and comprises spacing adjustment means for changing the adjustment spacing;

implanting the incontinence sling disposing the central support portion in operative relation to the one of the urethra or anus; and

actuating the sling tension adjustment mechanism to change the adjustment spacing between the sling intermediate ends and thereby change tension in the sling central portion applied to the urethra or anus.



10



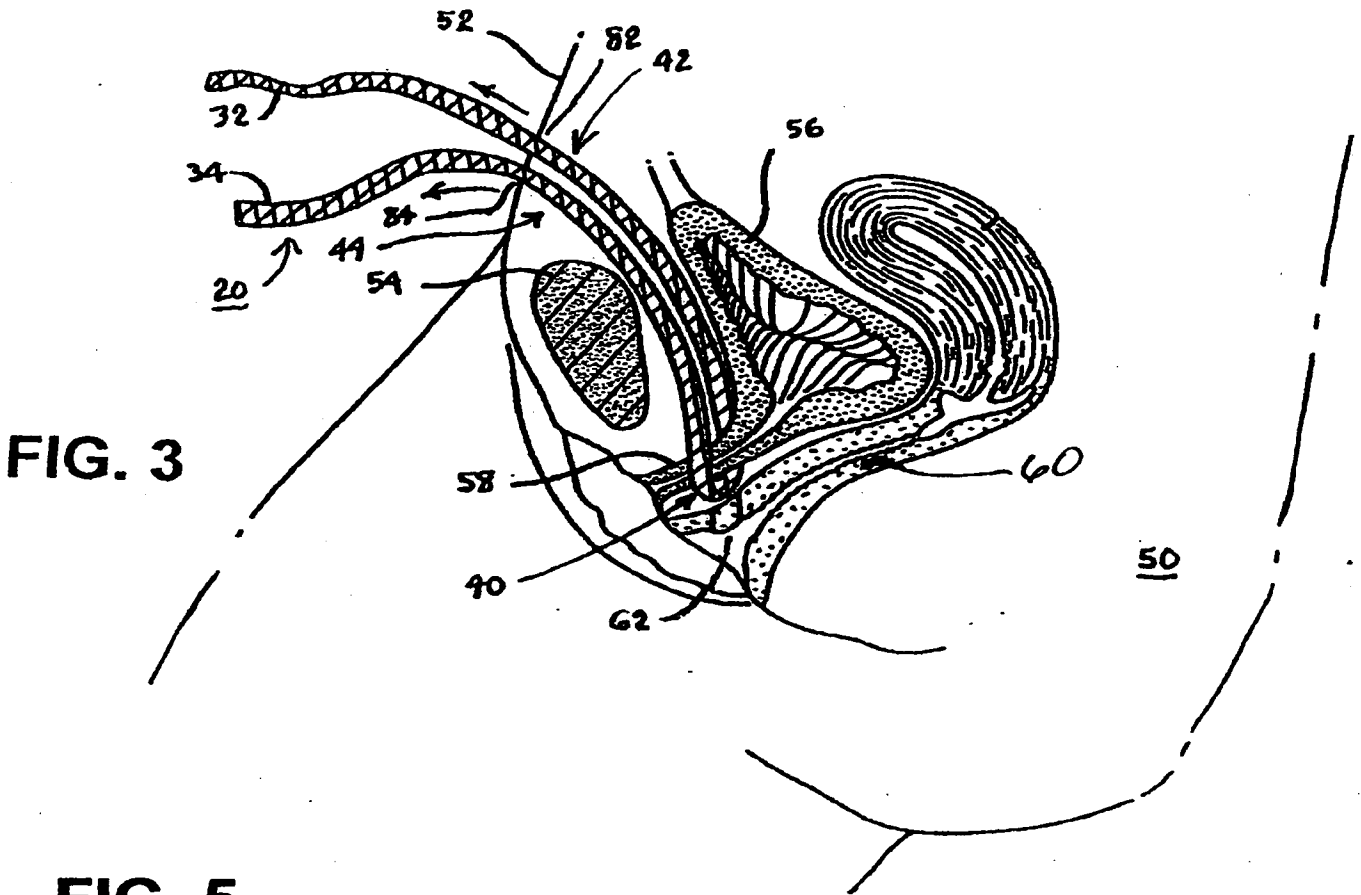


FIG. 5

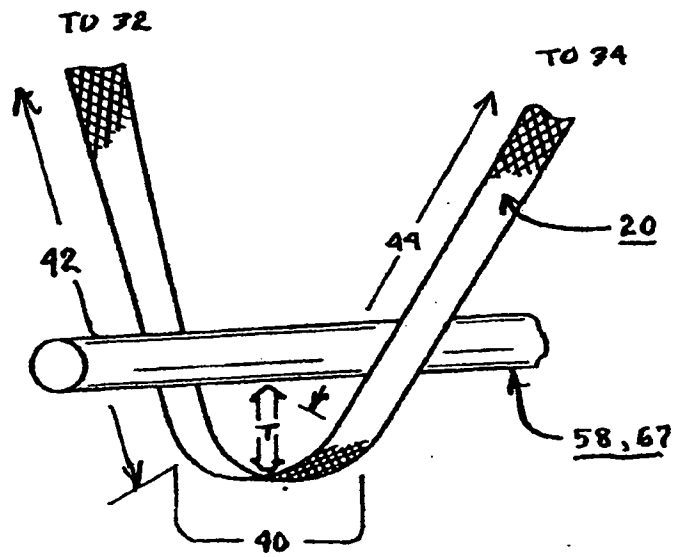
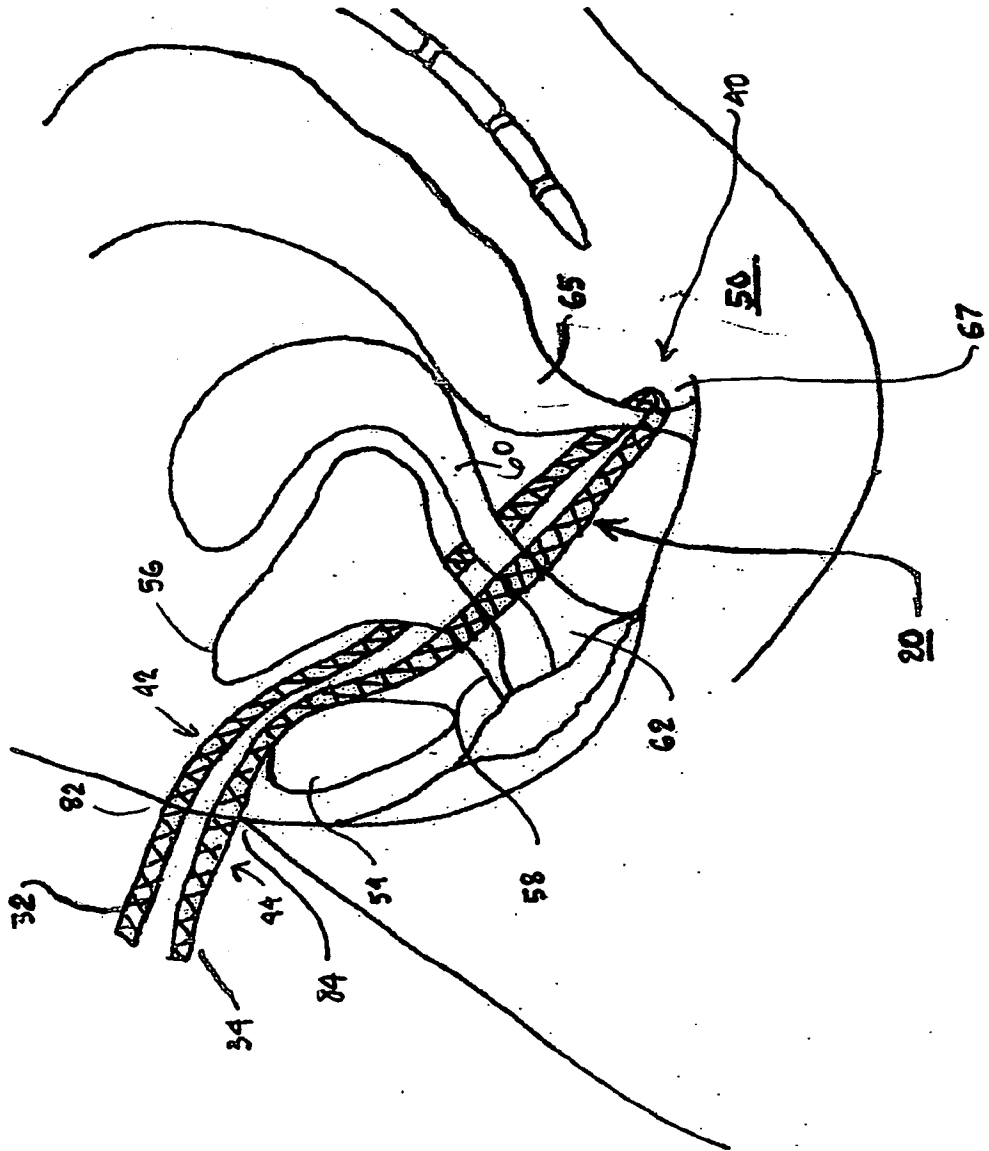


FIG. 4



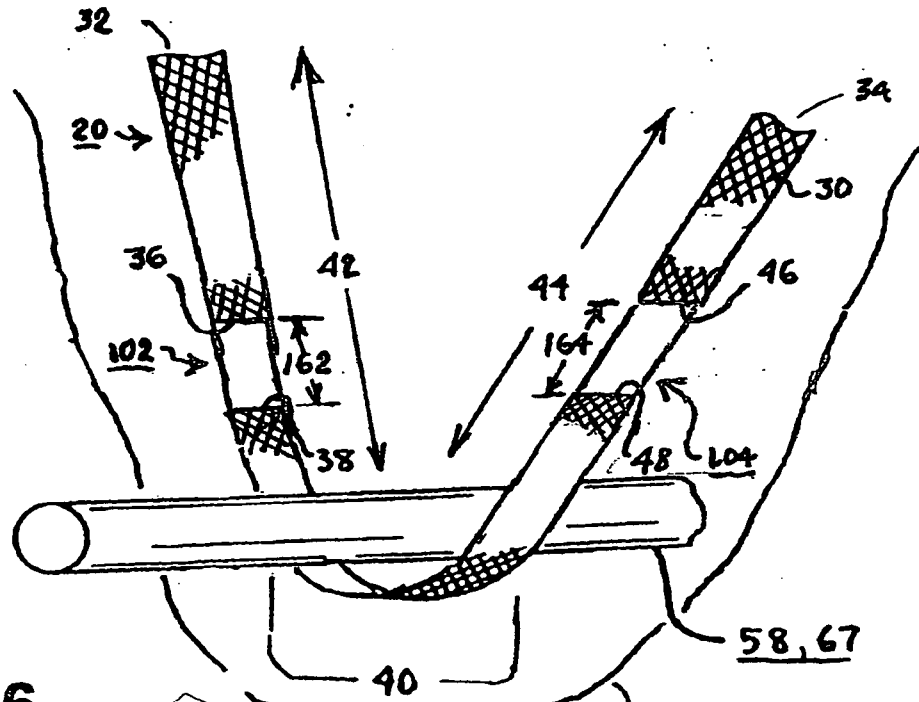


FIG. 6

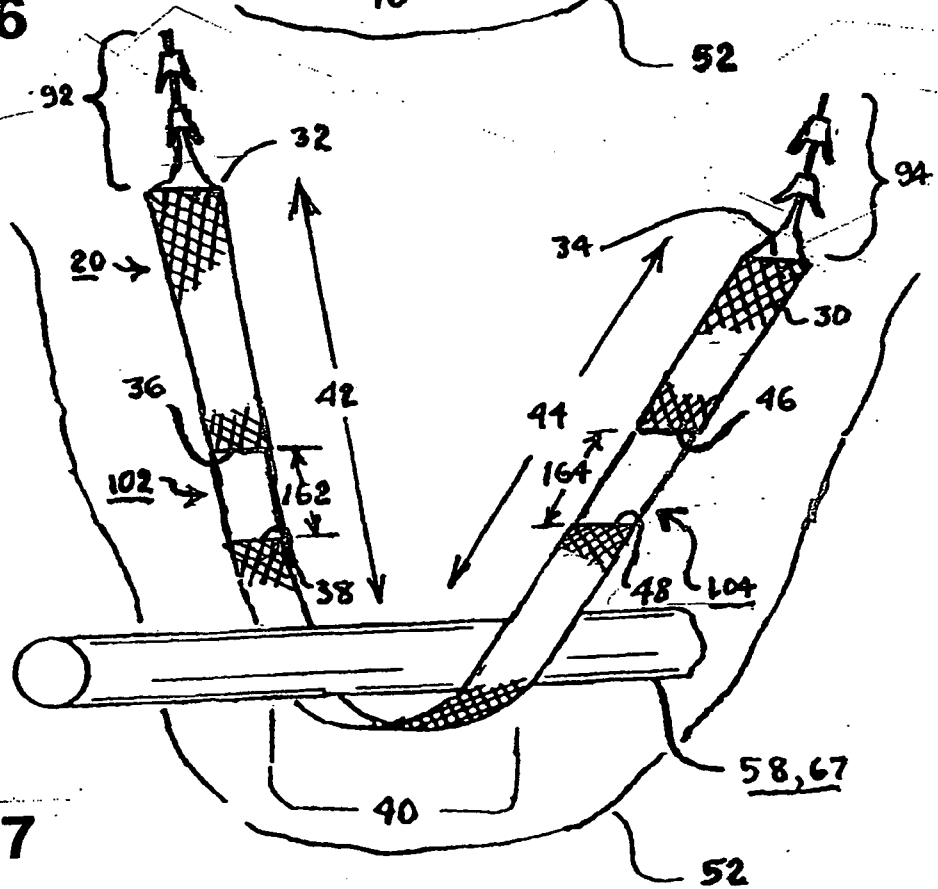


FIG. 7

FIG. 8

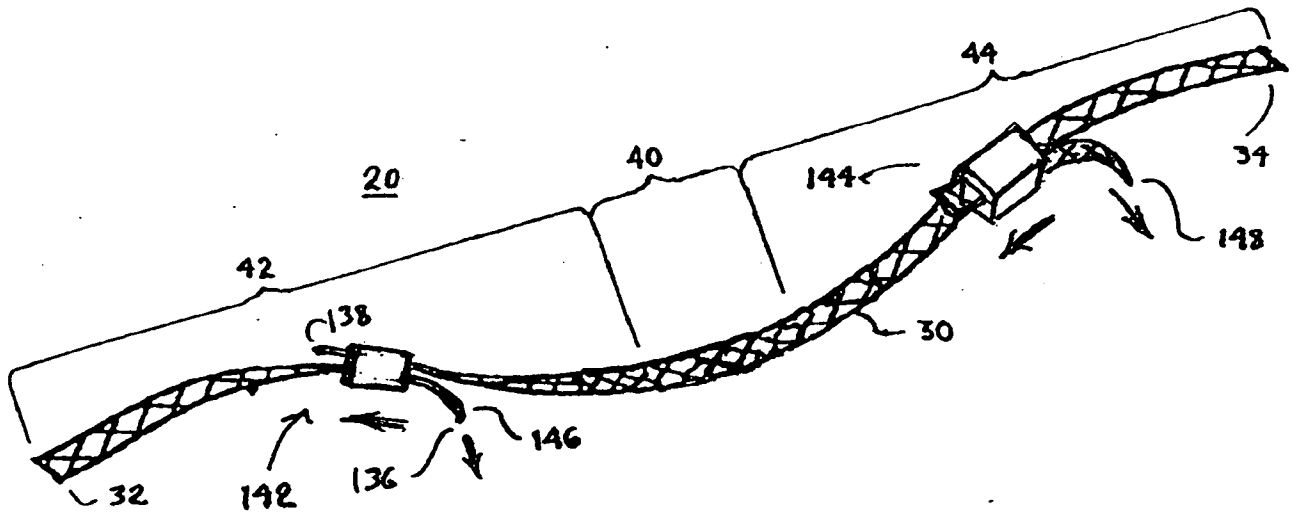
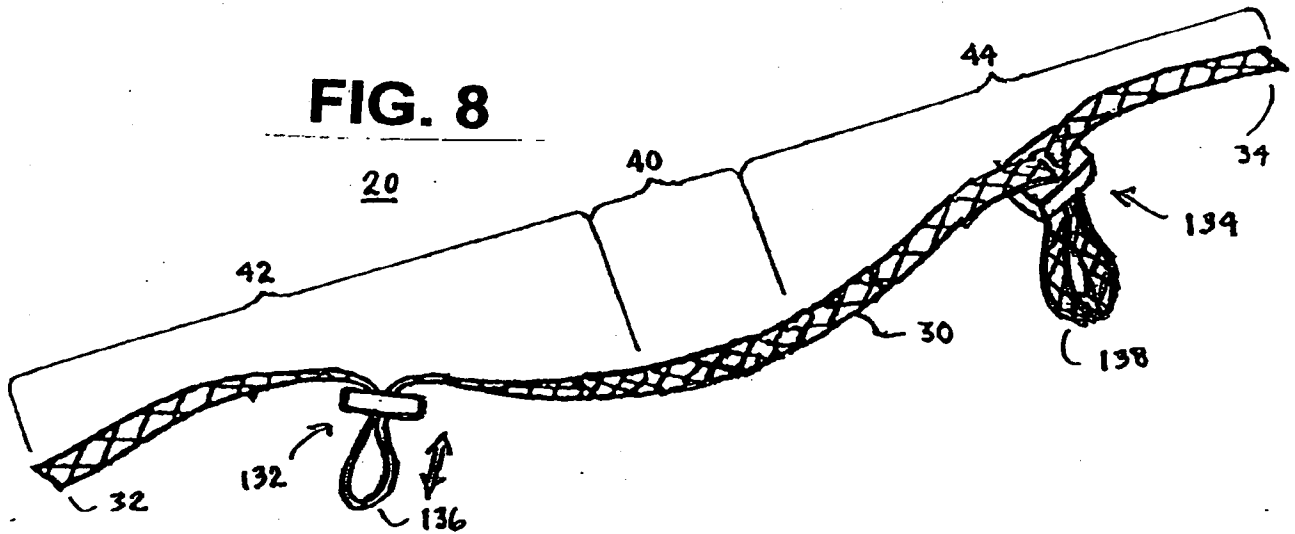


FIG. 9

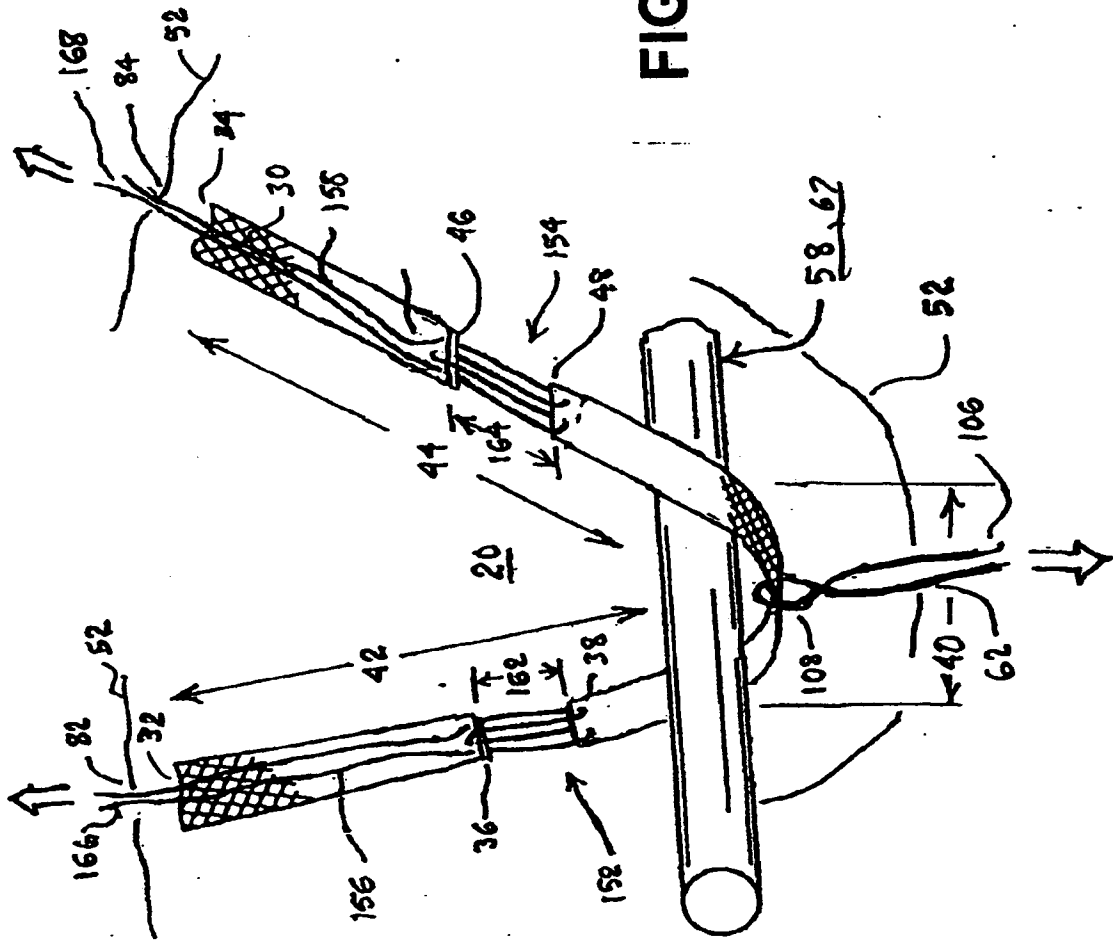


FIG. 10

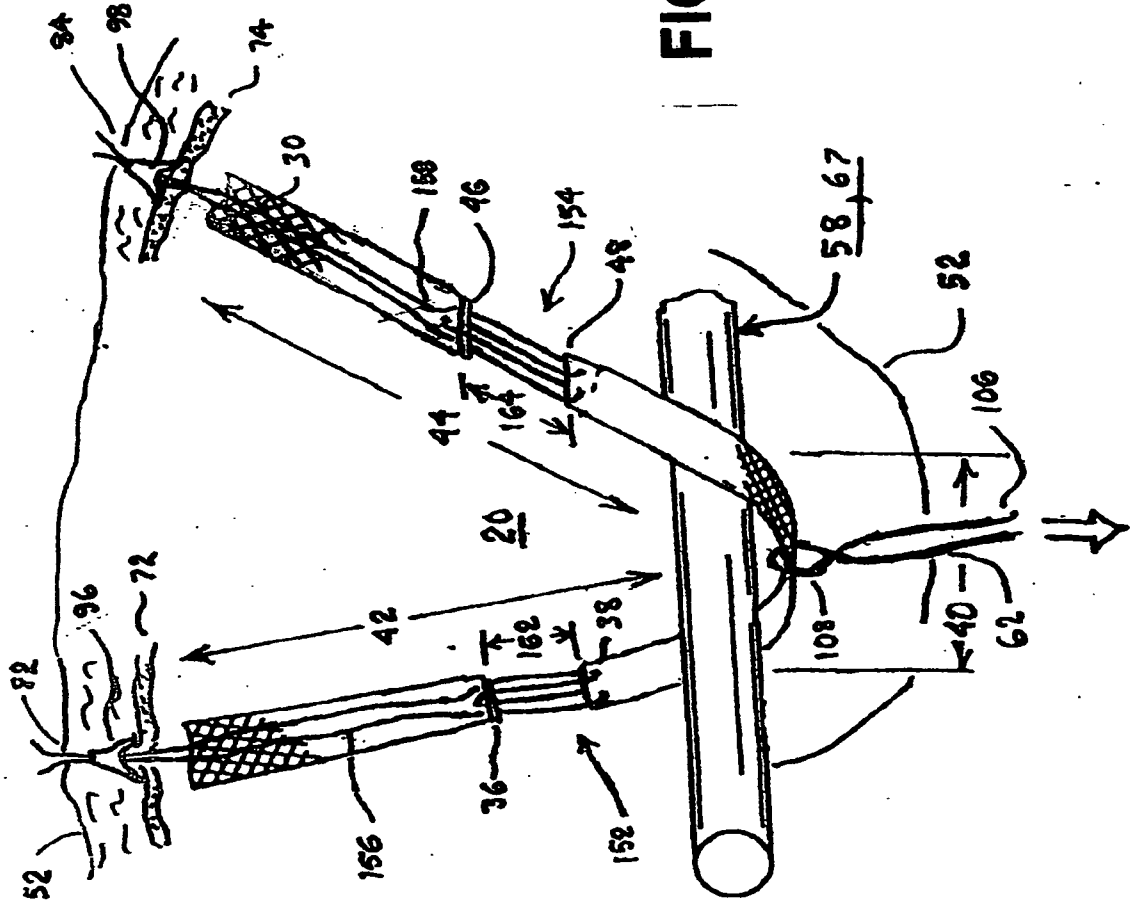


FIG. 11A

FIG. 12

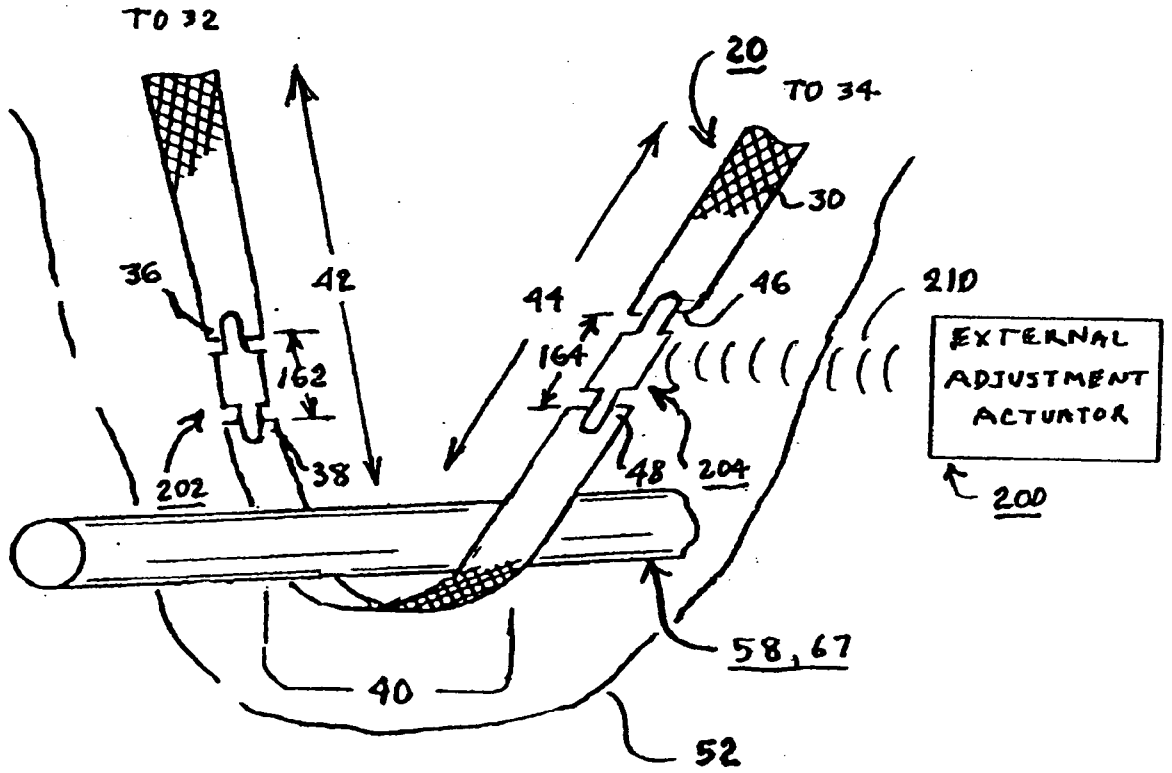
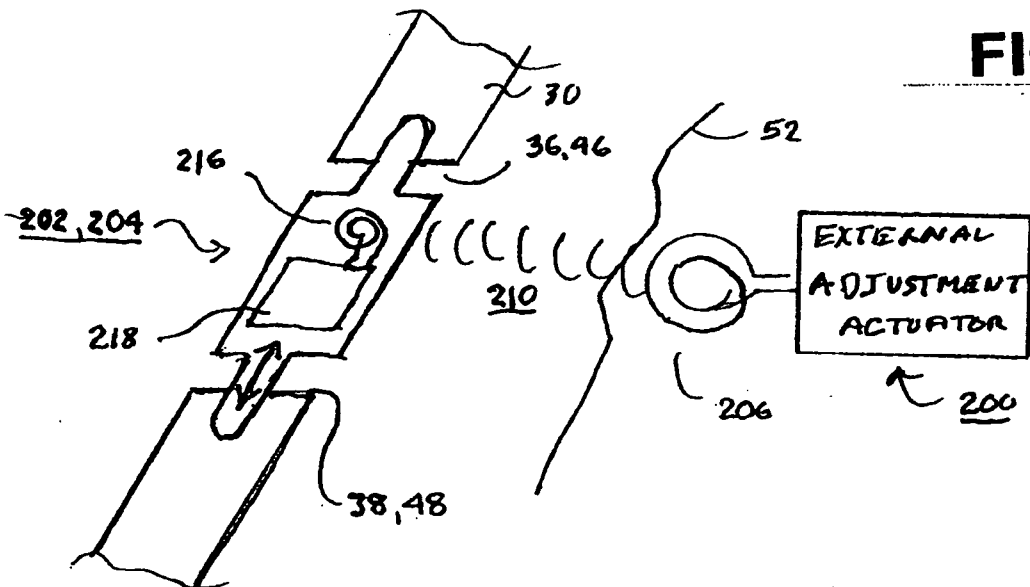


FIG. 13



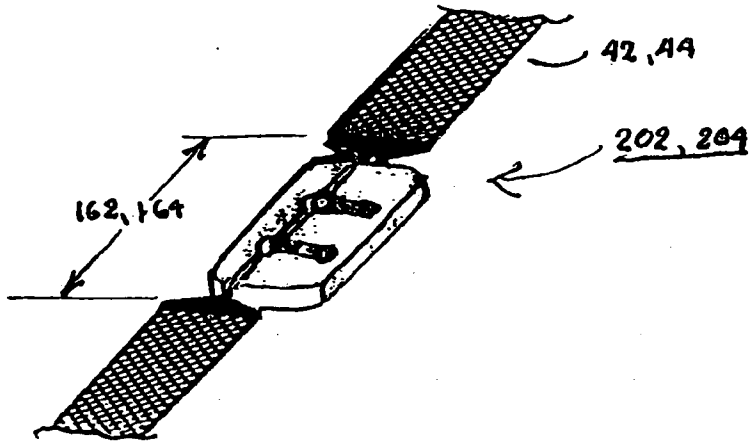


FIG. 14

FIG. 15

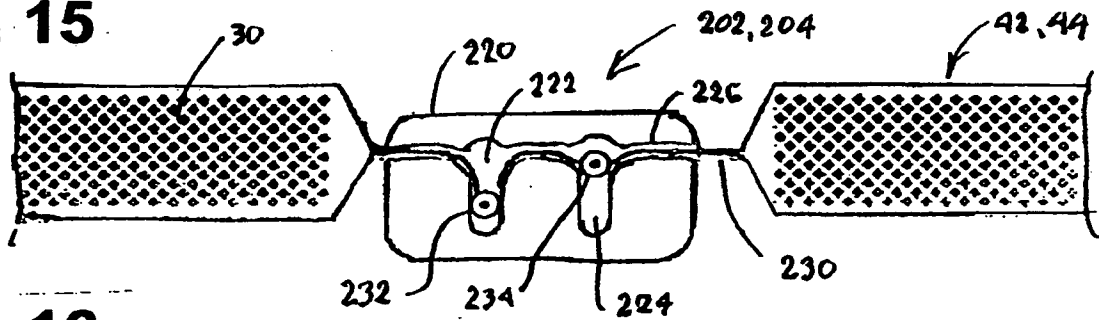


FIG. 16

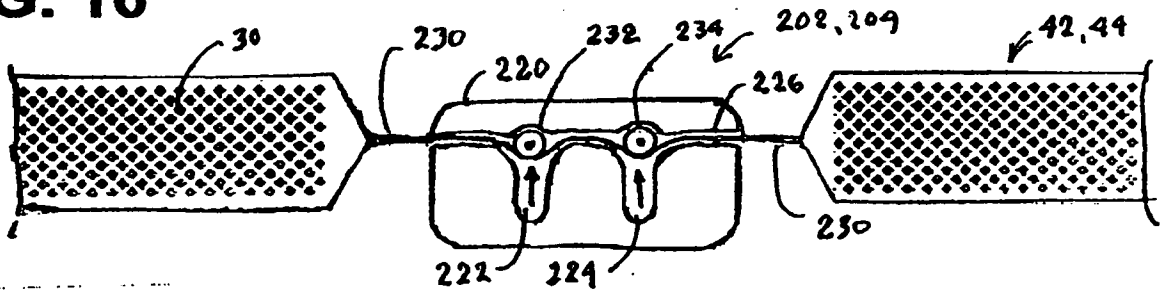
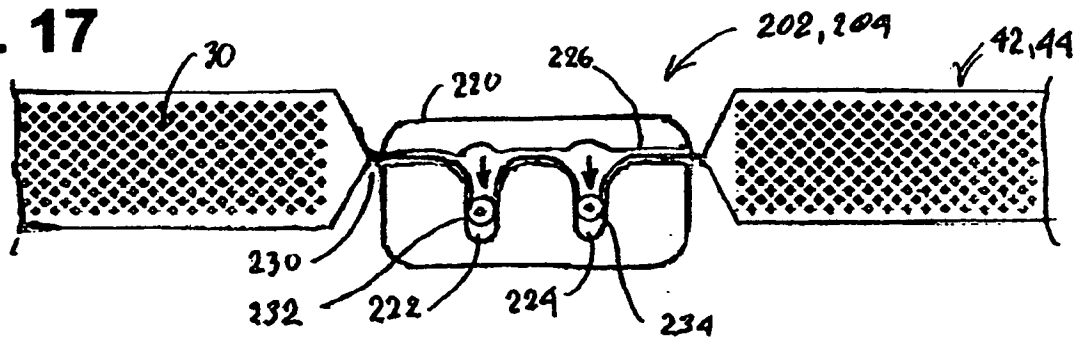


FIG. 17



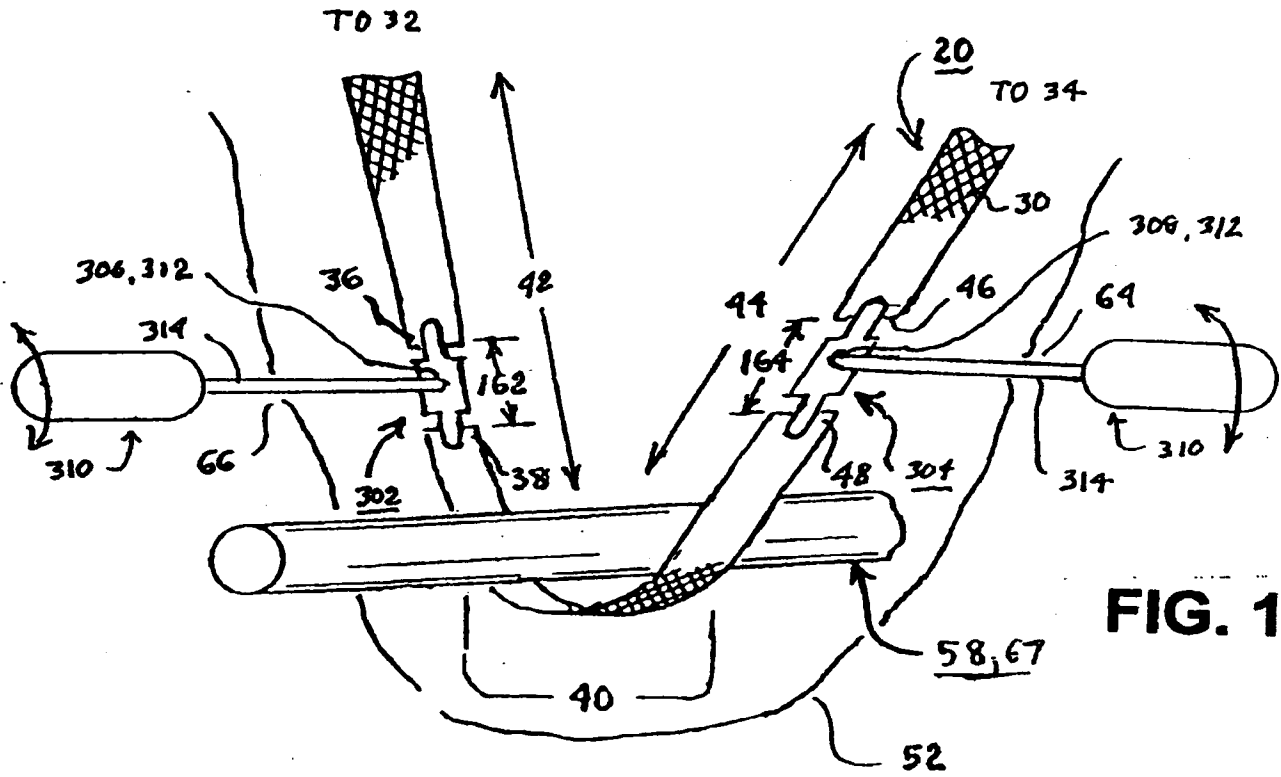


FIG. 18

FIG. 19

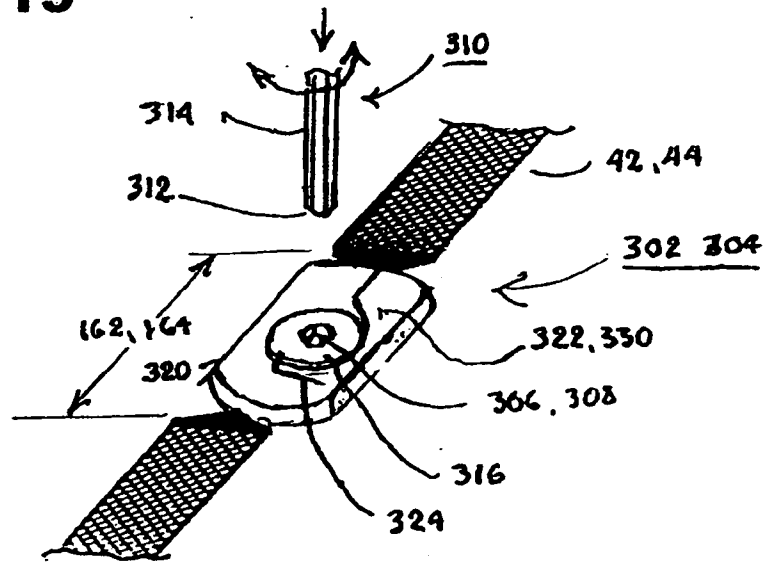


FIG. 20

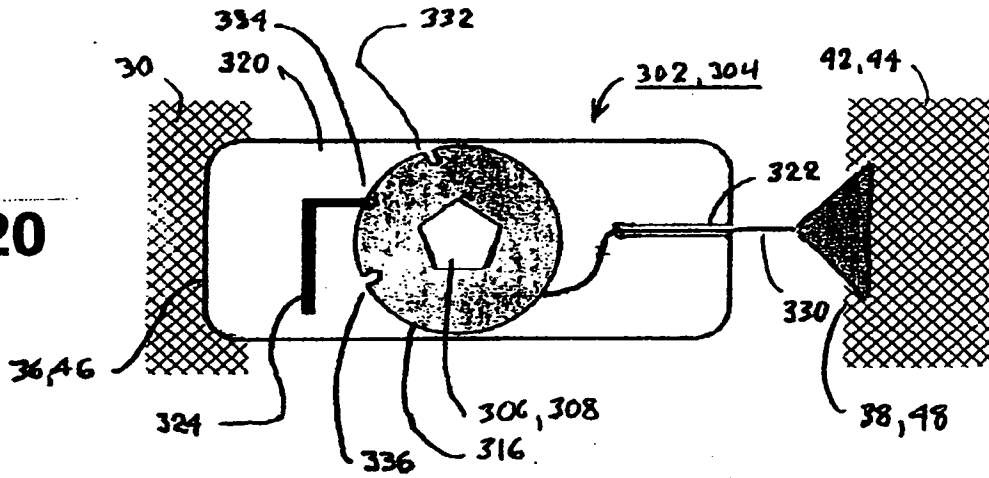


FIG. 21

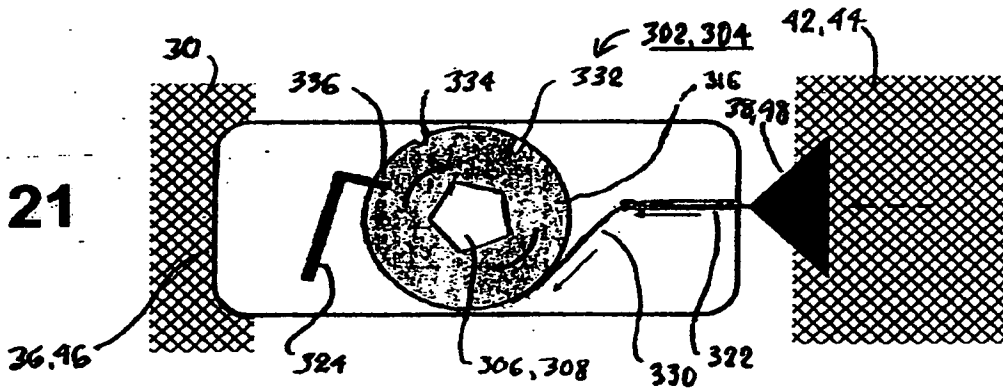
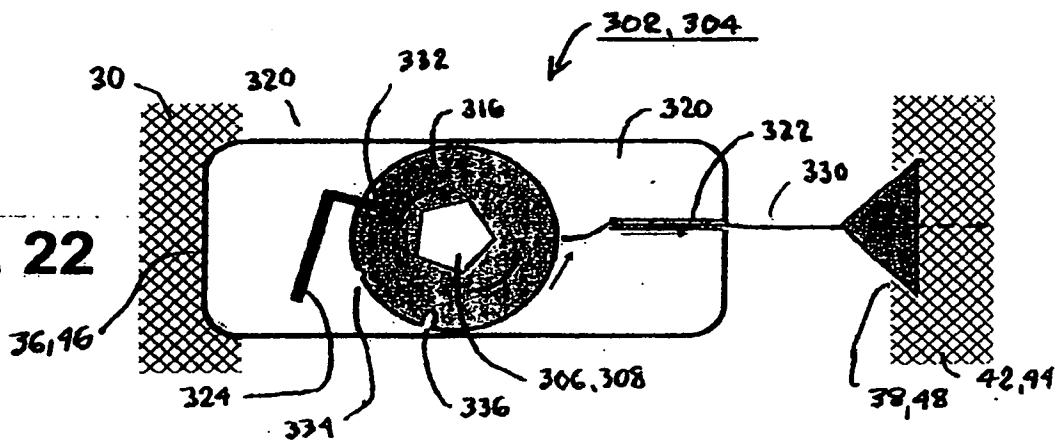


FIG. 22



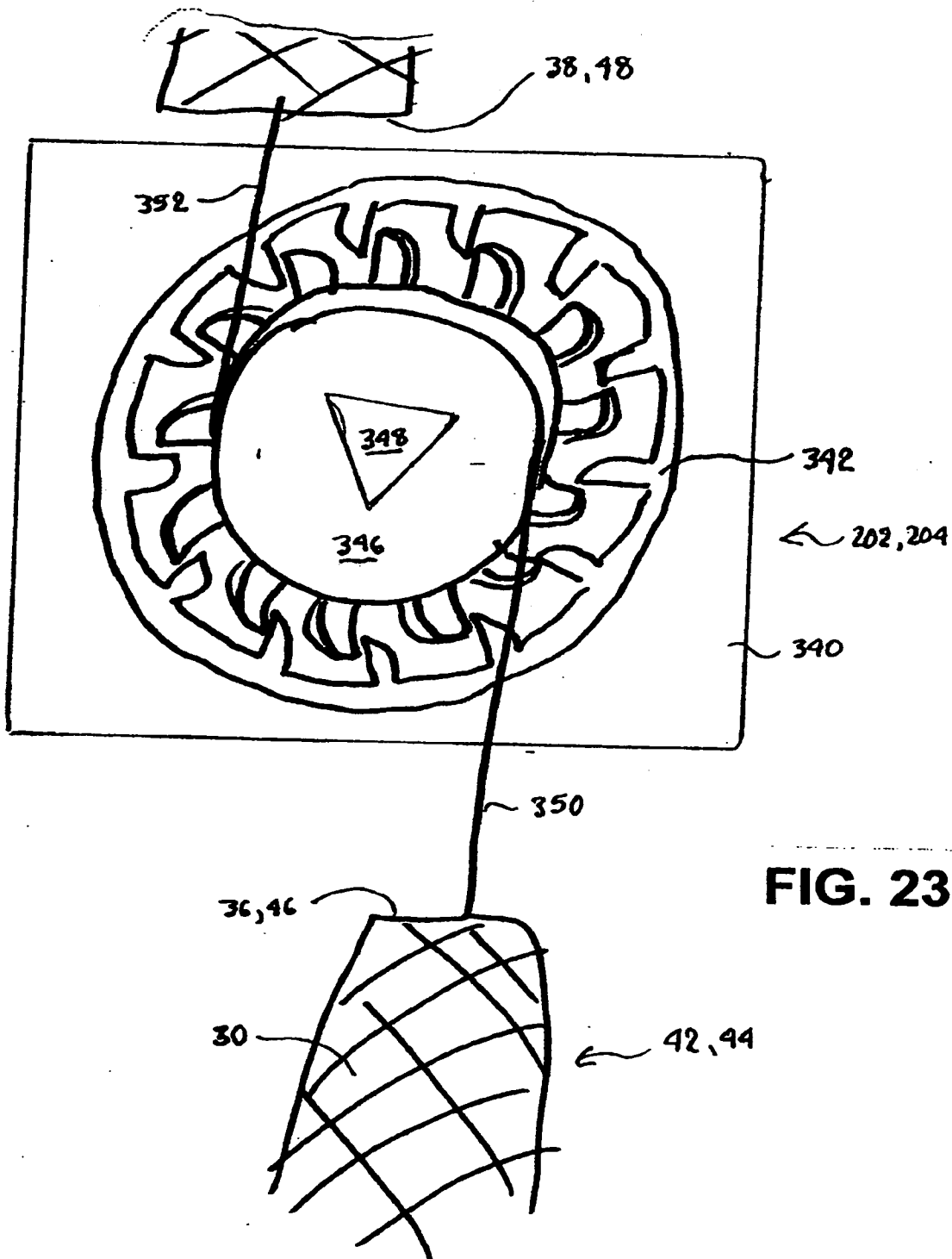


FIG. 23

FIG. 24

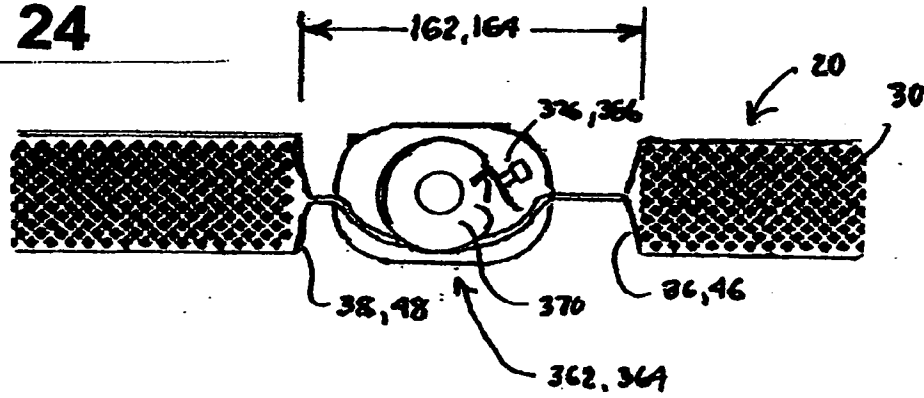


FIG. 25A

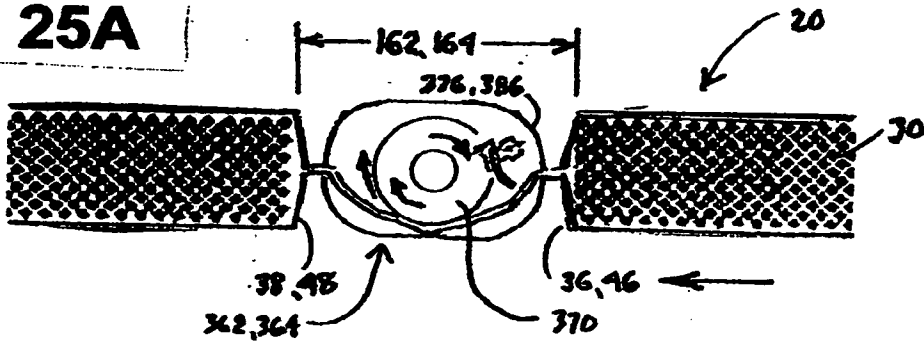


FIG. 26A

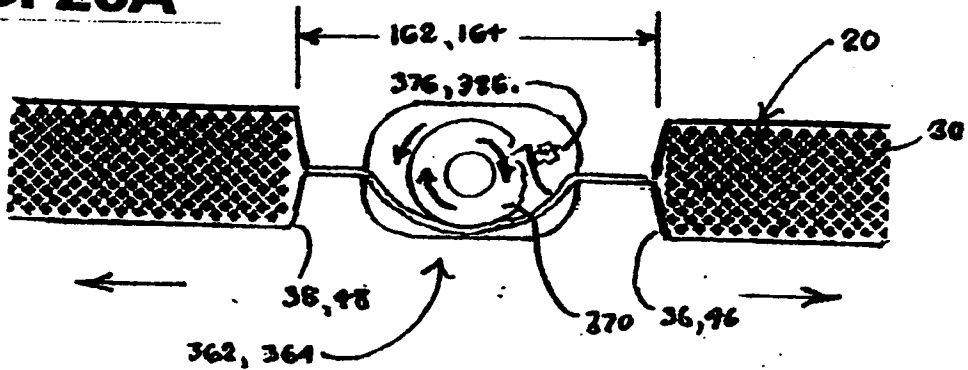


FIG. 25B

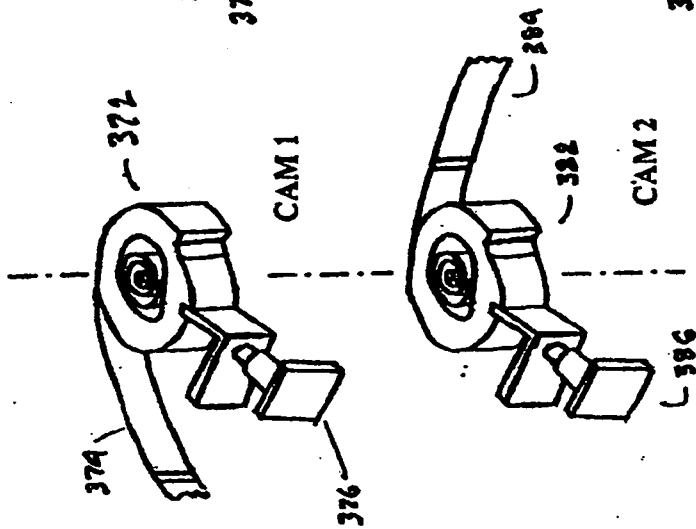


FIG. 25C

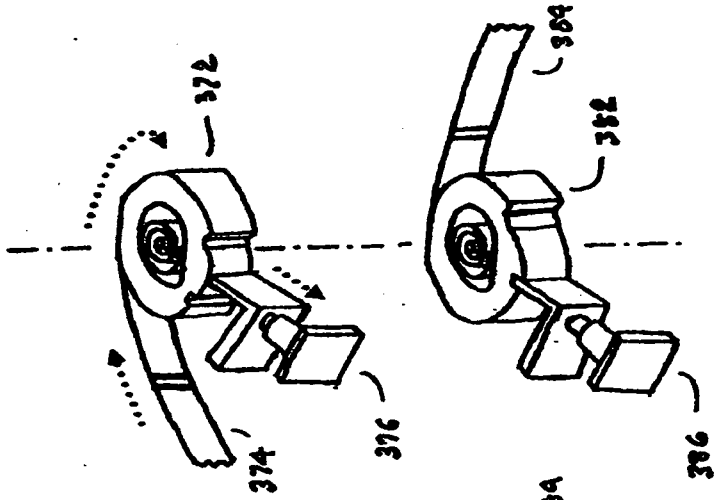
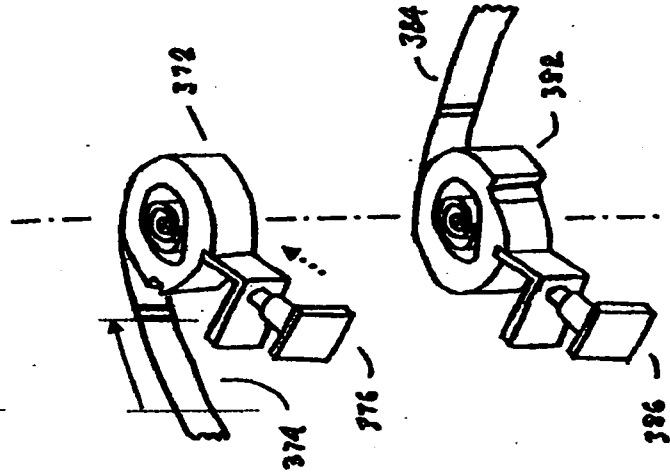


FIG. 25D



CAM 1 Actuator Releases
Lock Allowing Rotation Over
Cam and Wrapping Tether
Around Cam Shortening Tether

CAM 1 Actuator Locks
Preventing Further Rotation

FIG. 26B

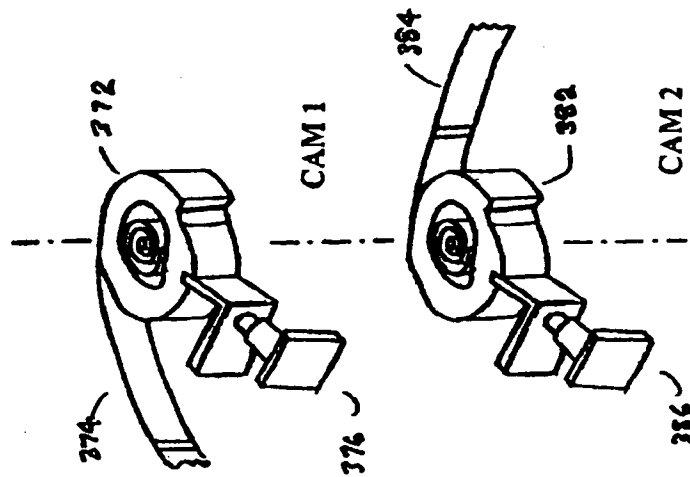
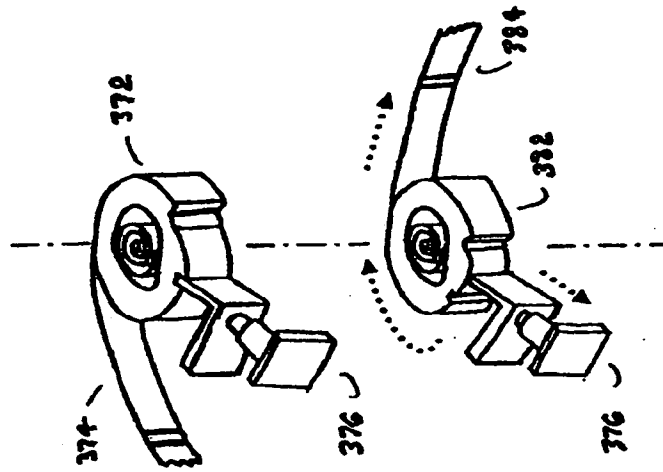
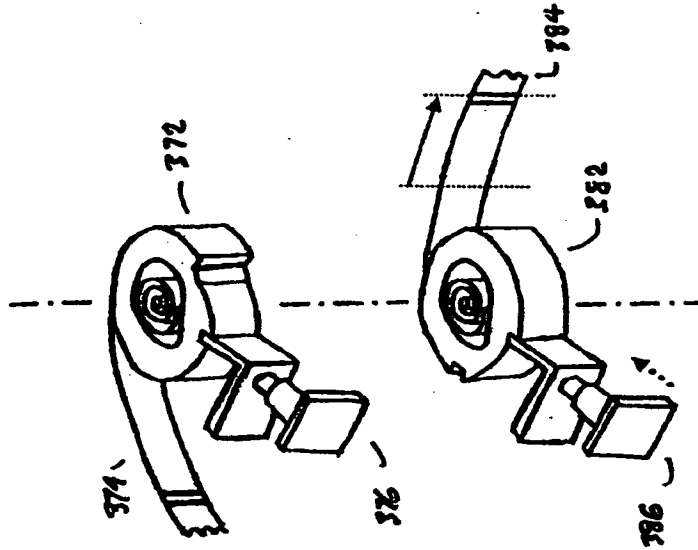


FIG. 26C



CAM 2 Actuator Releases
 Lock Allowing Rotation Over
 Cam and Unwrapping Tether
 From Cam Lengthening Tether

FIG. 26D



CAM 2 Actuator Locks
 Preventing Further Rotation

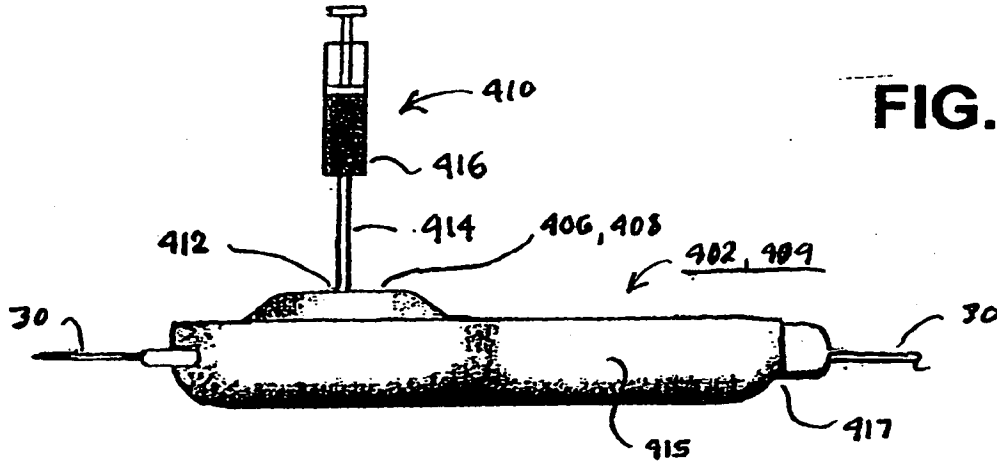


FIG. 28

FIG. 29

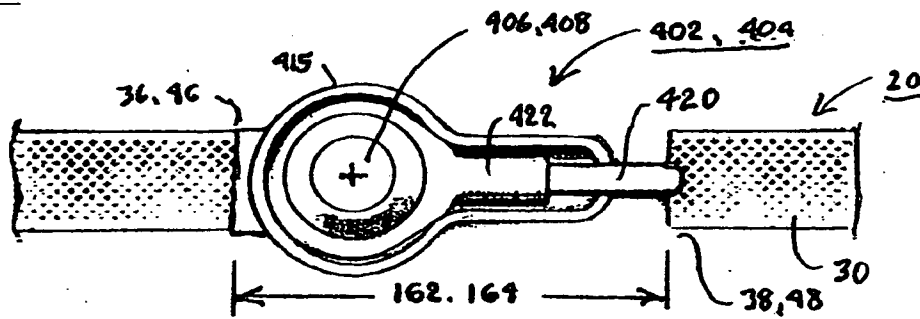


FIG. 30

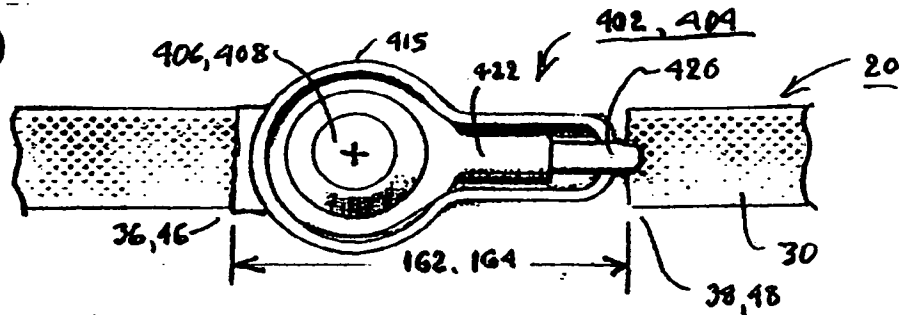
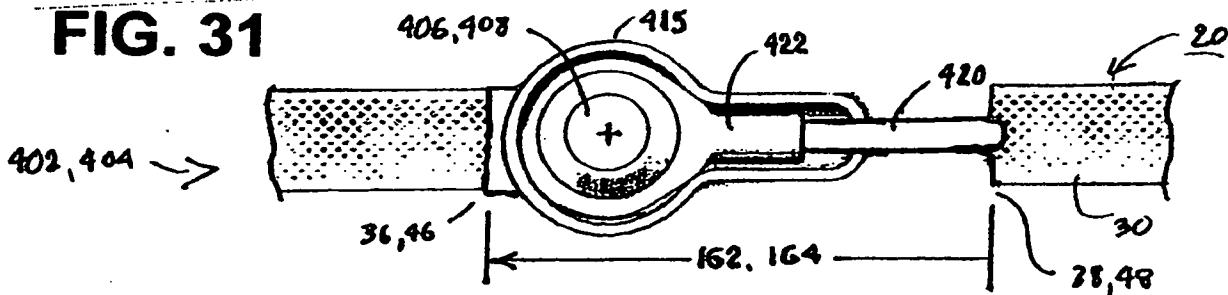


FIG. 31



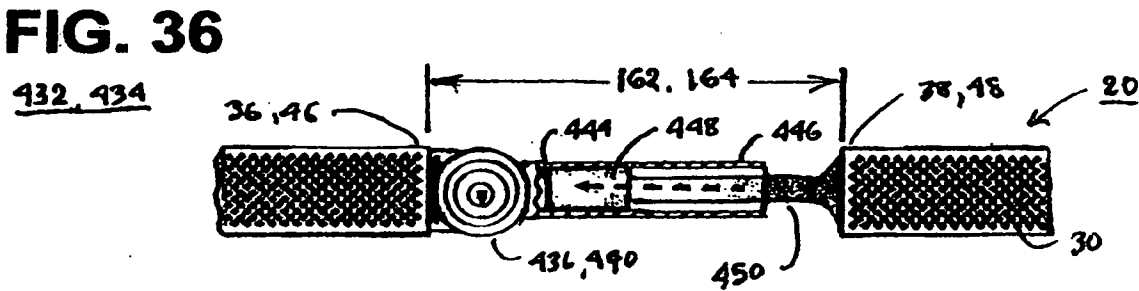
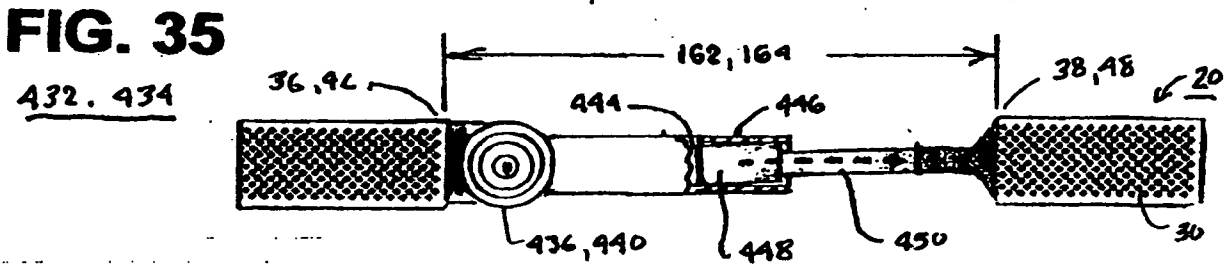
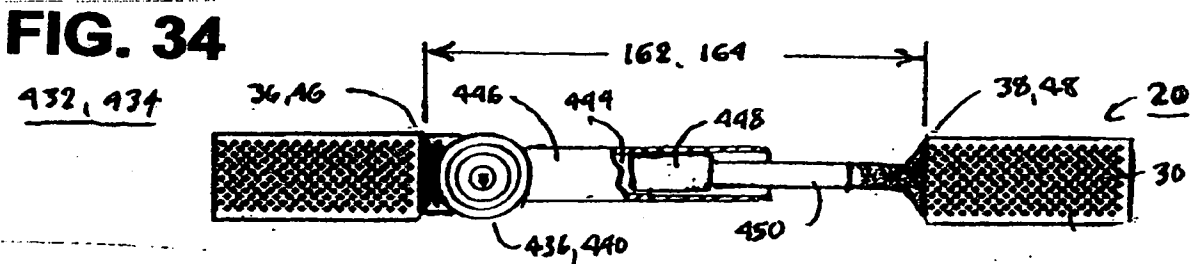
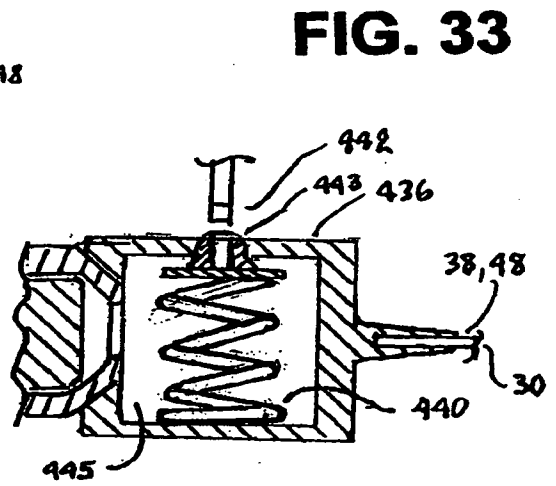
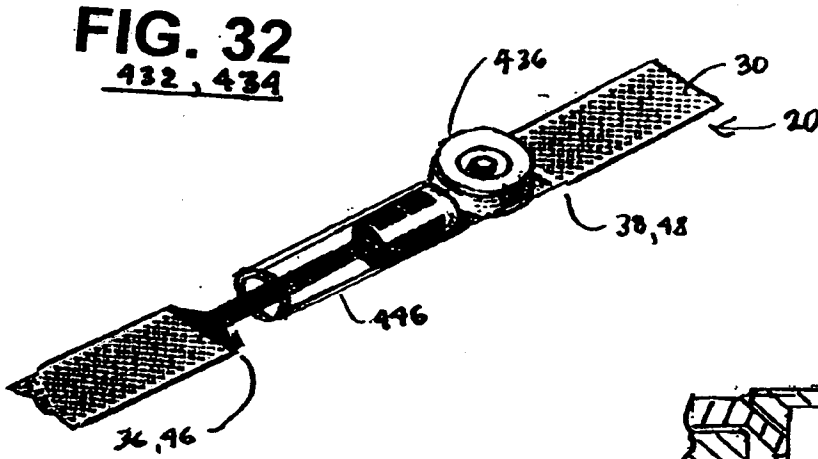


FIG. 37

462, 464

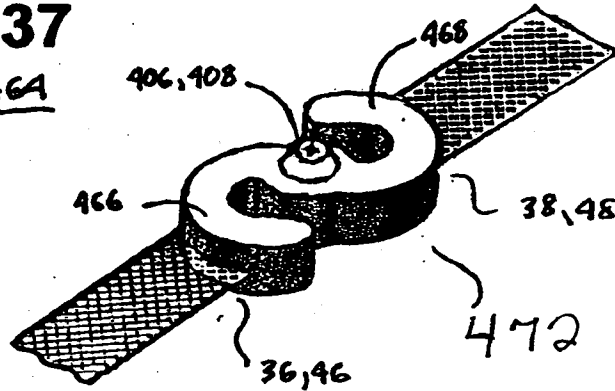


FIG. 38

462, 464

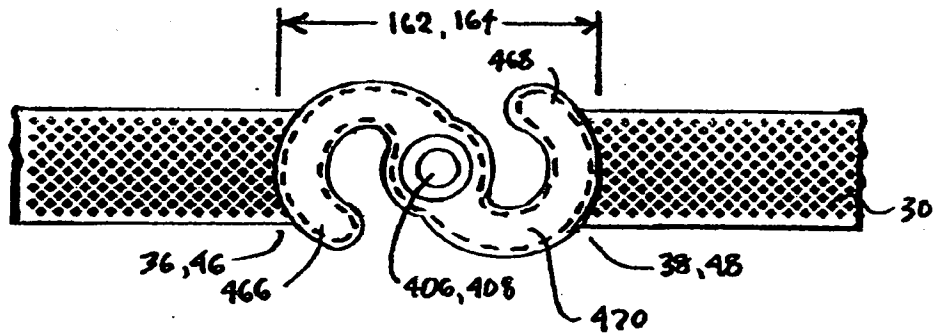


FIG. 39

462, 464

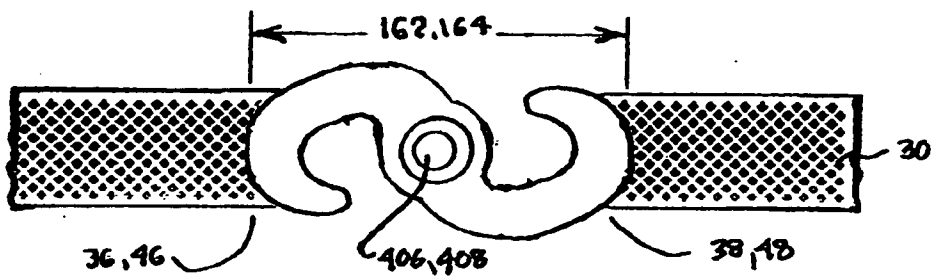
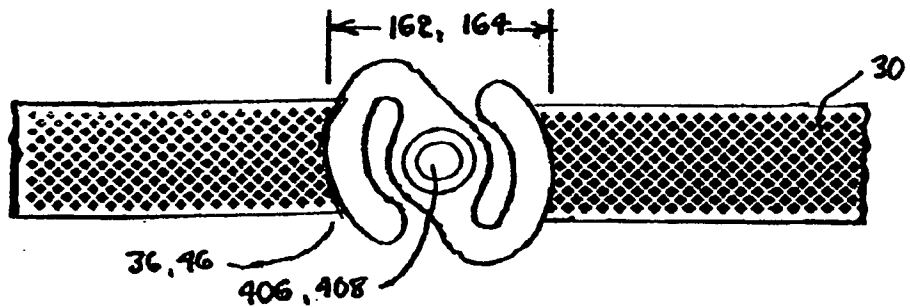


FIG. 40

462, 464



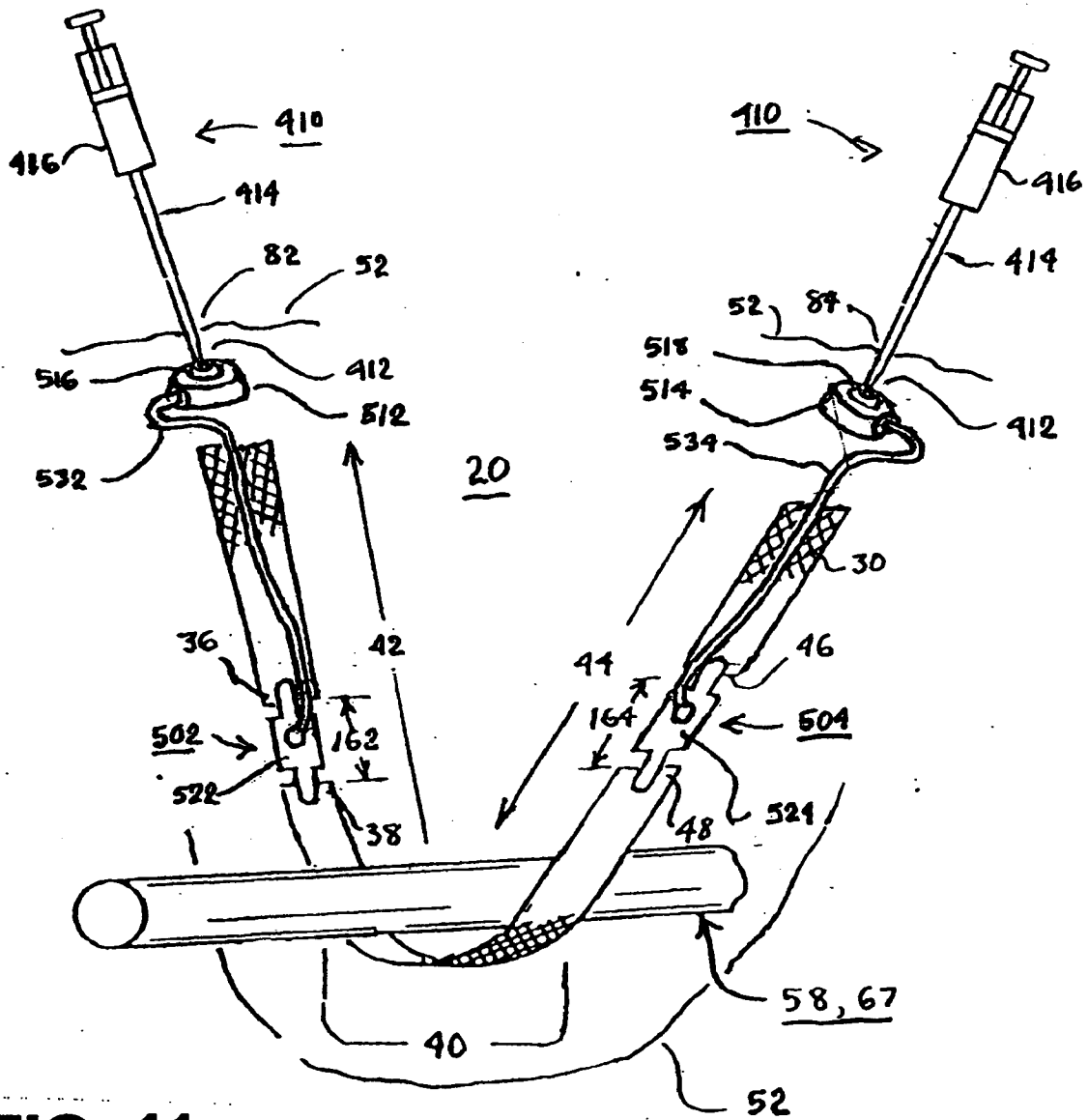


FIG. 41

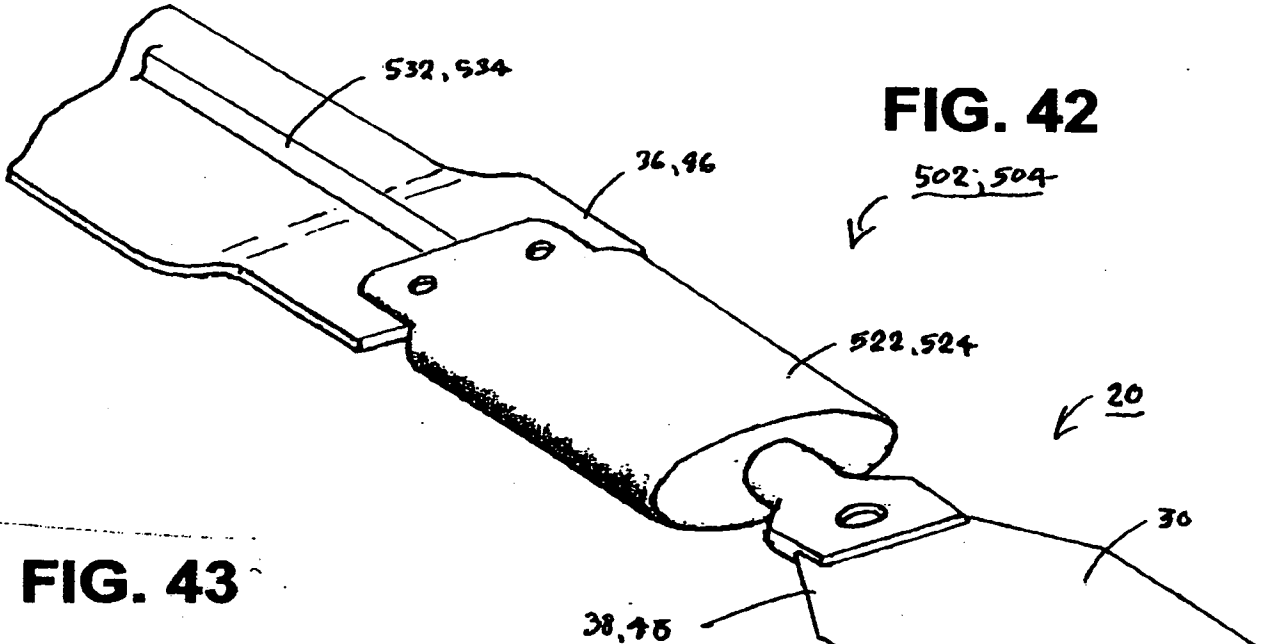


FIG. 43

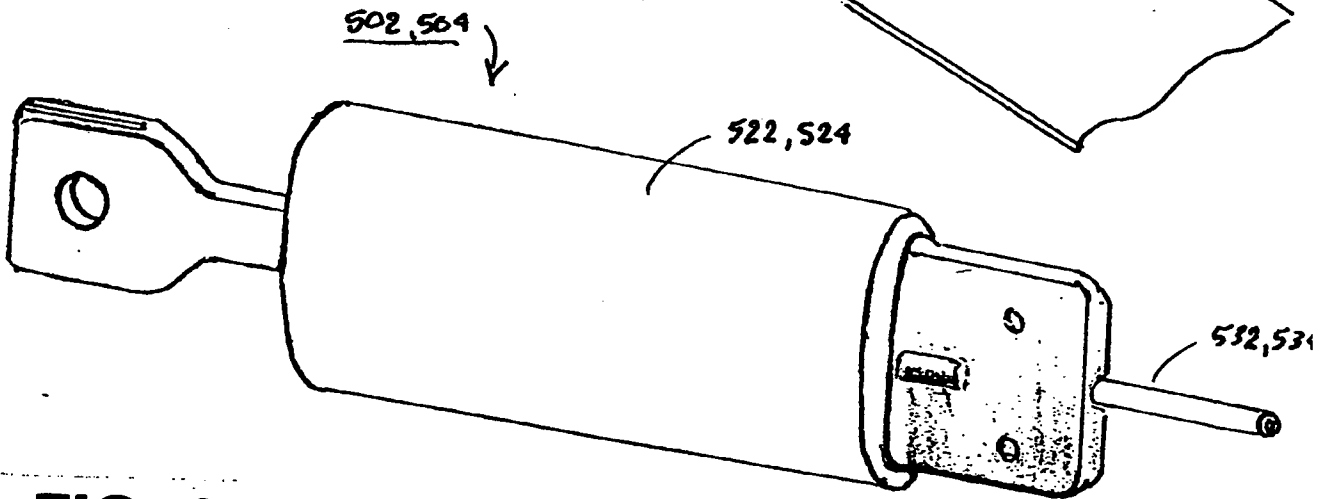


FIG. 44

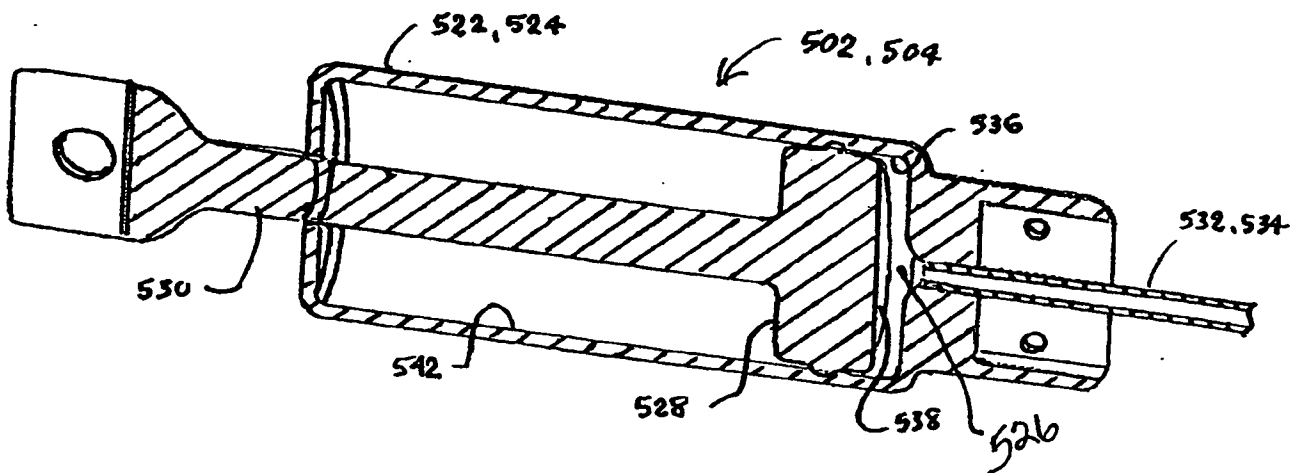


FIG. 47

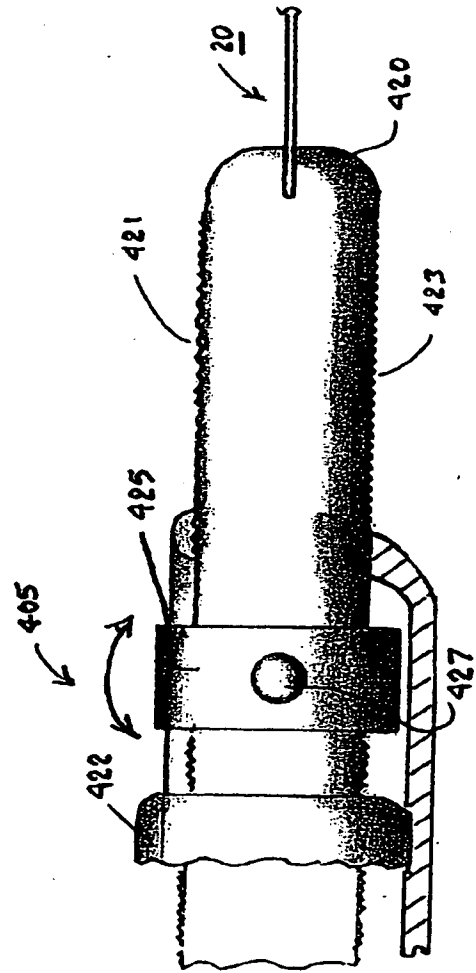
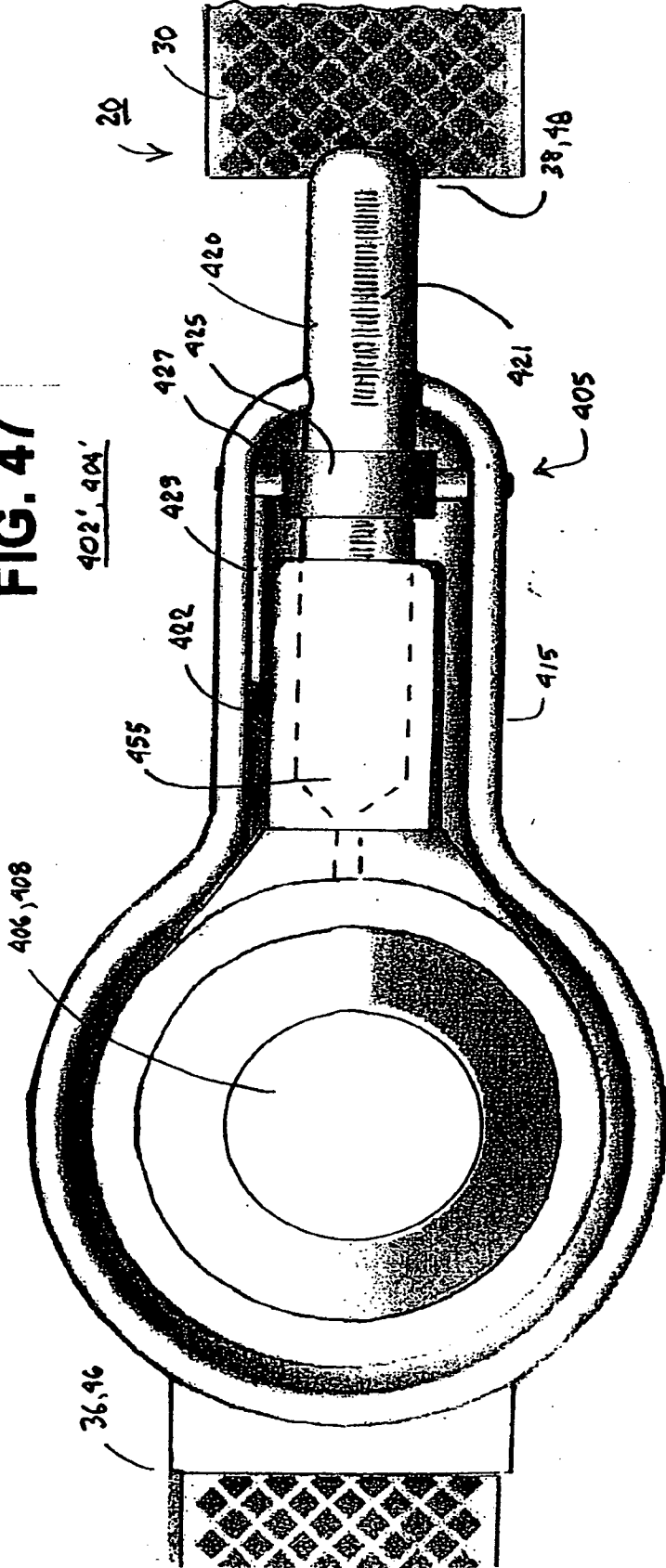


FIG. 48

FIG. 49

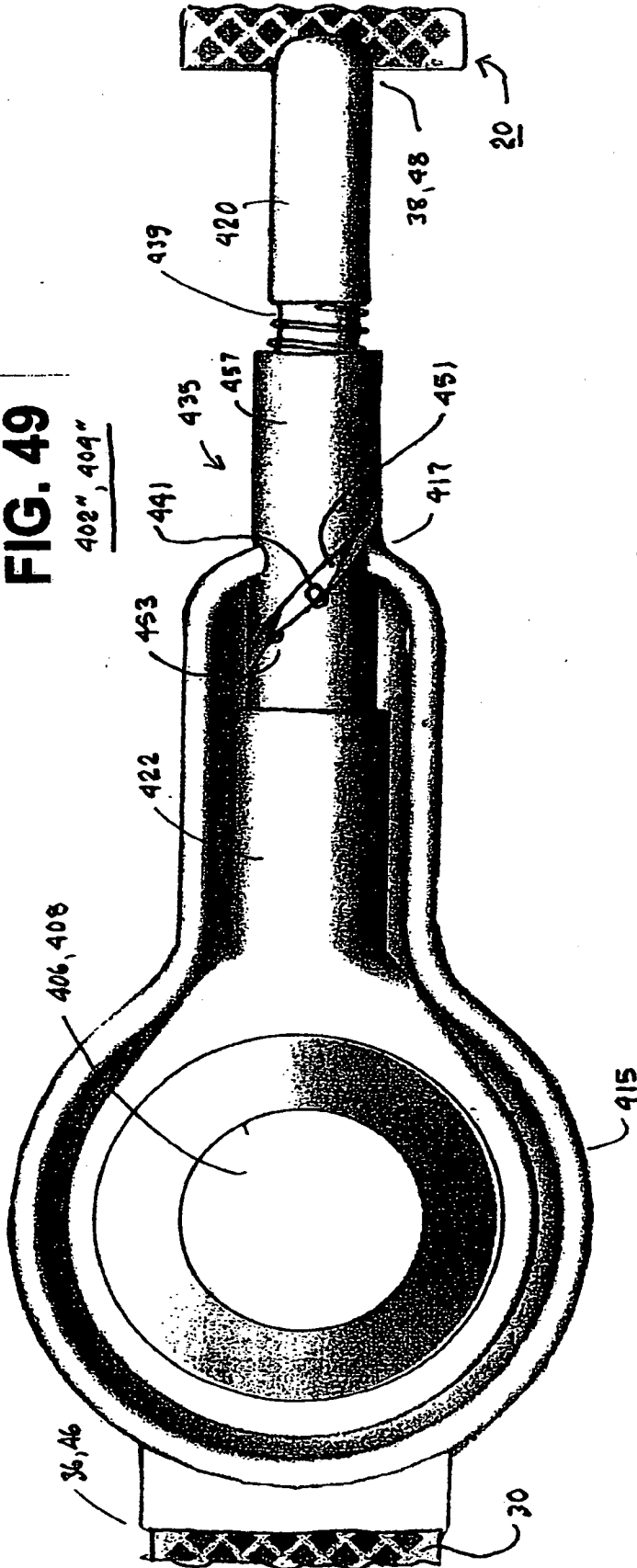


FIG. 50

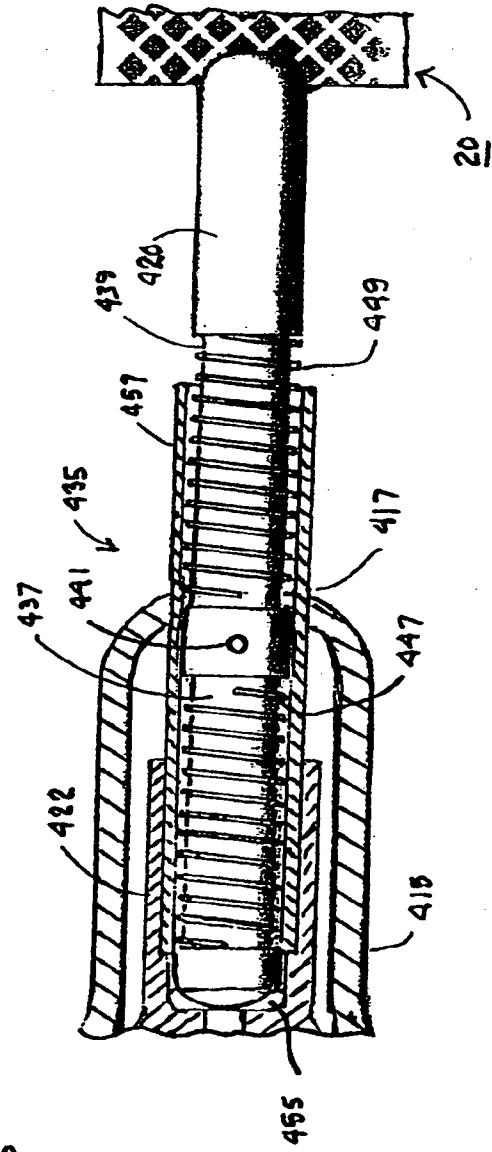


FIG. 51

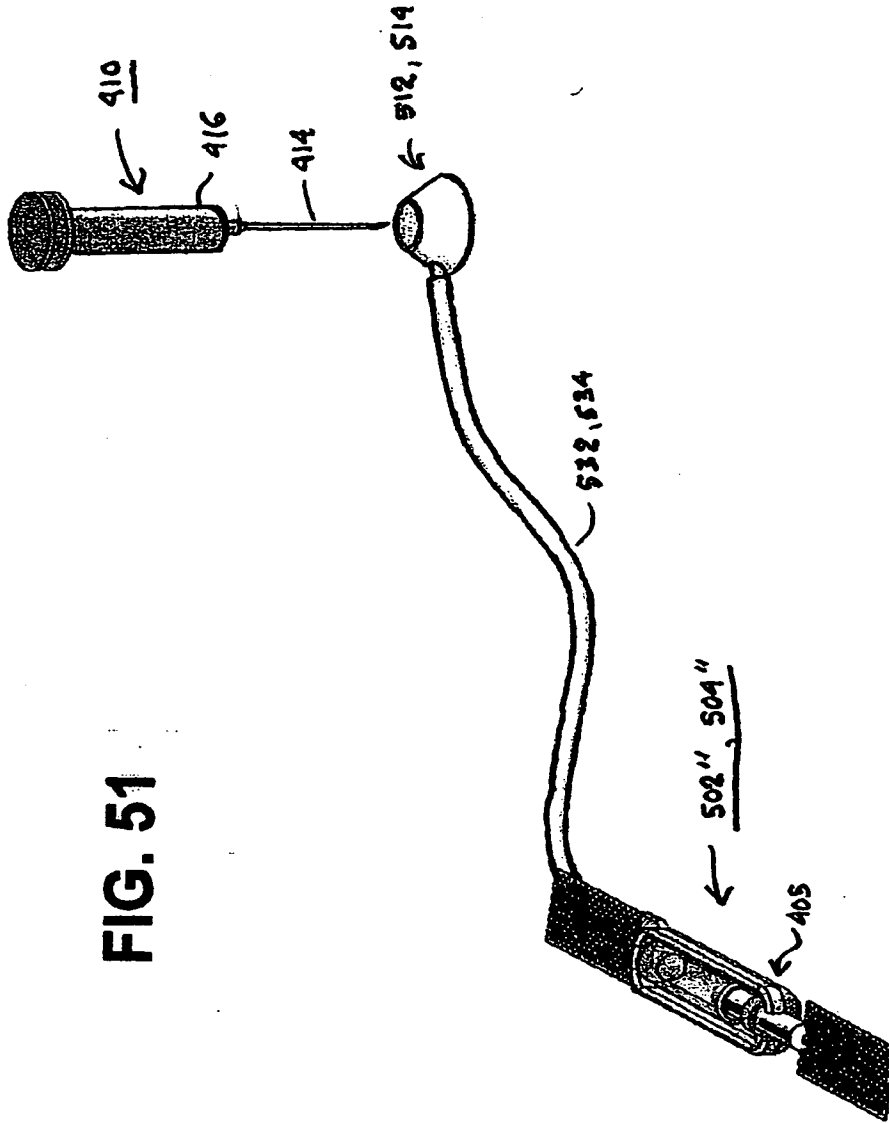


FIG. 52

502", 504"

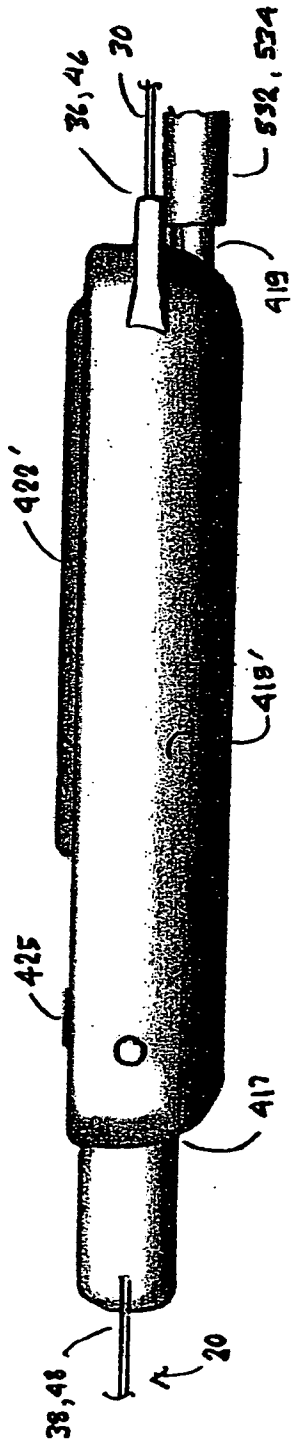


FIG. 53

502", 504"

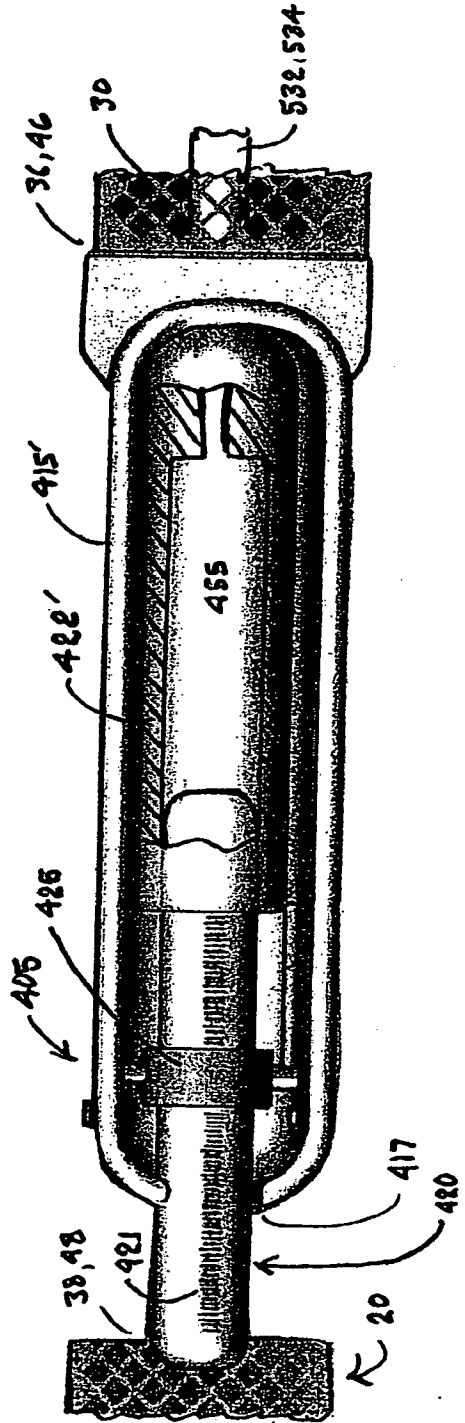


FIG. 57
902, 904

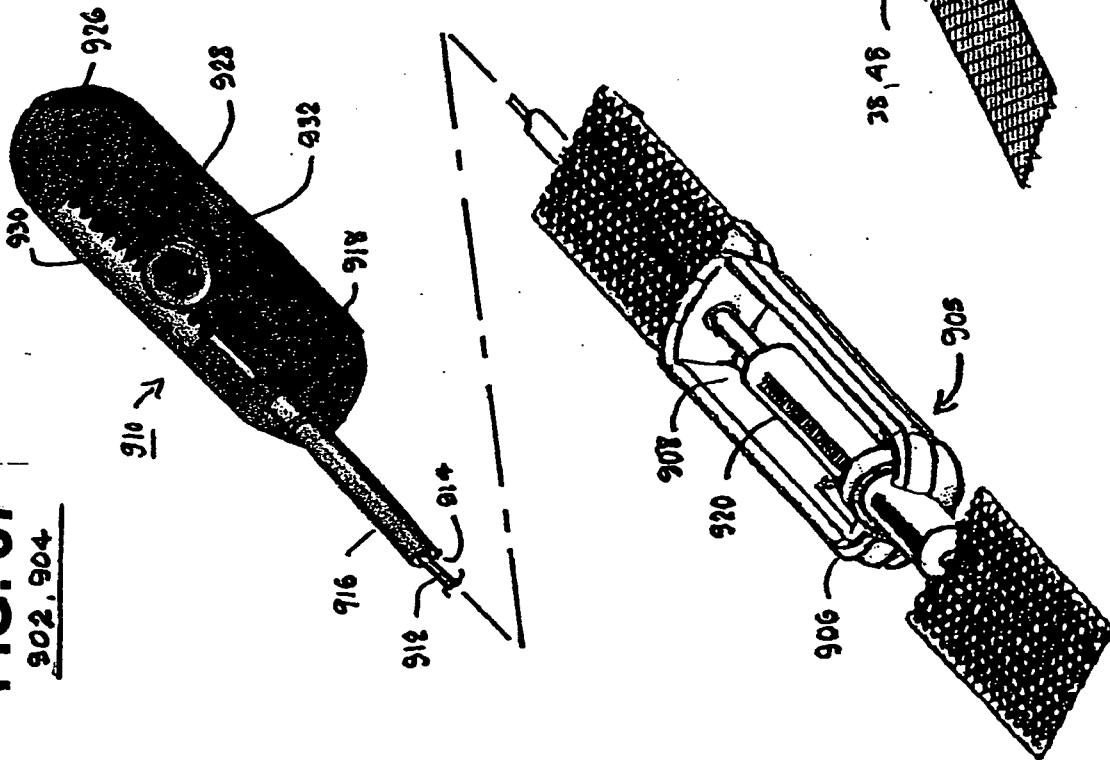


FIG. 56
852, 854

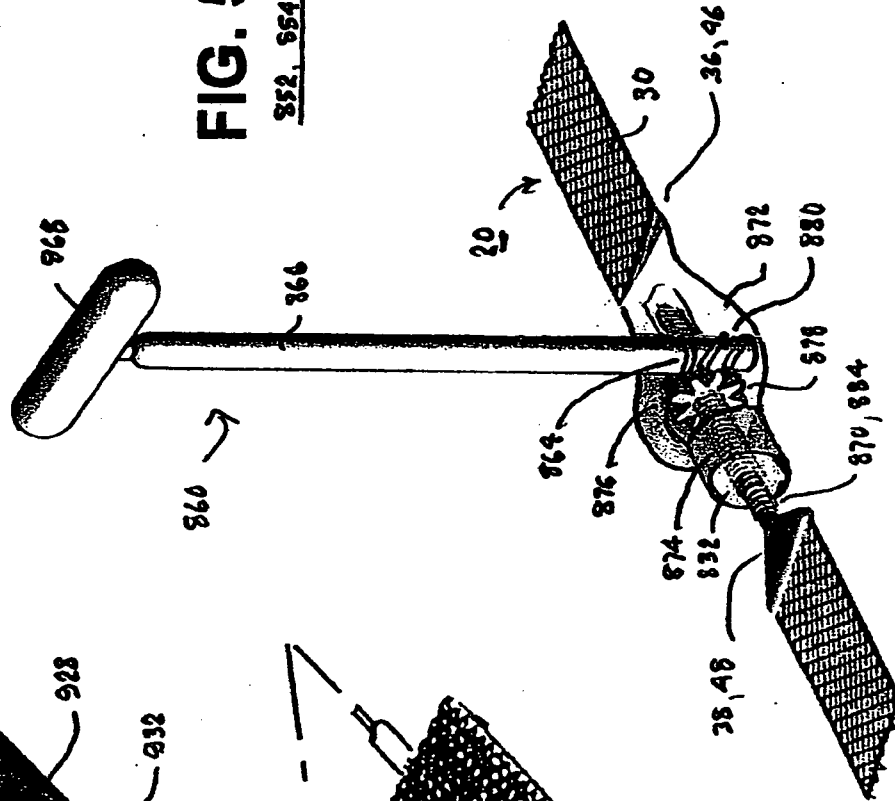


FIG. 58A

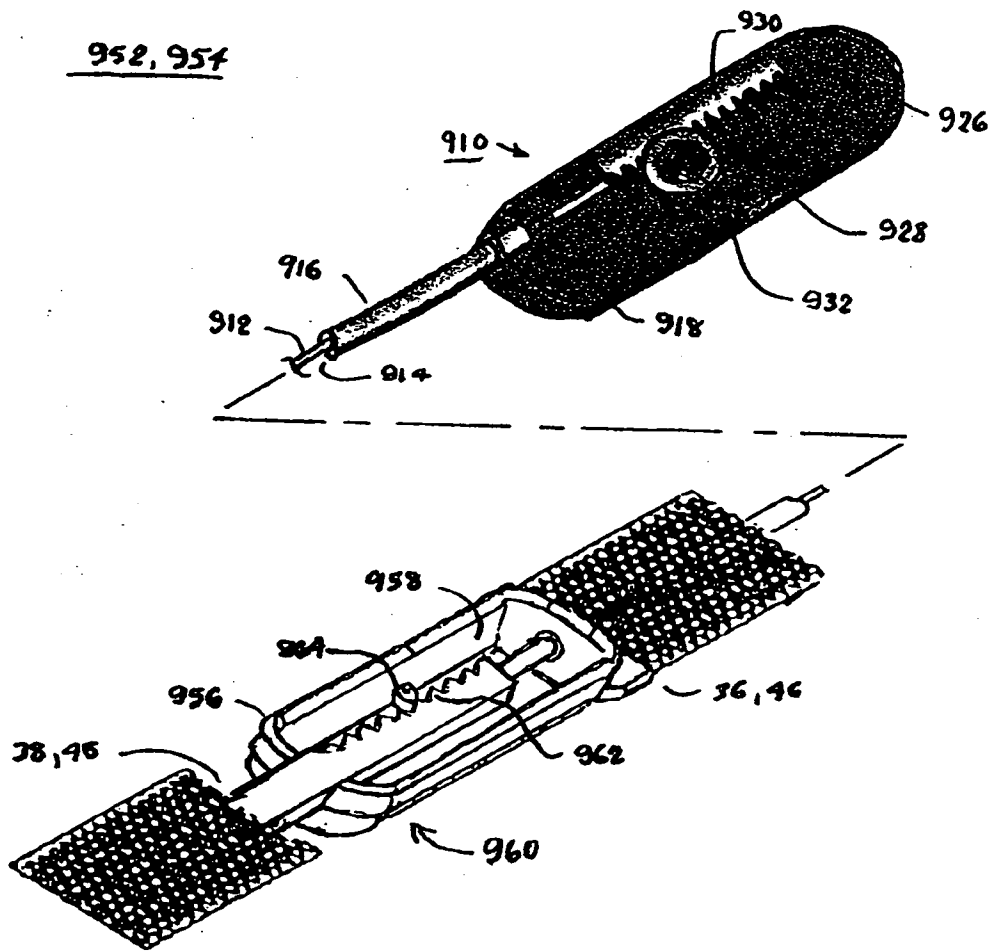


FIG. 58B

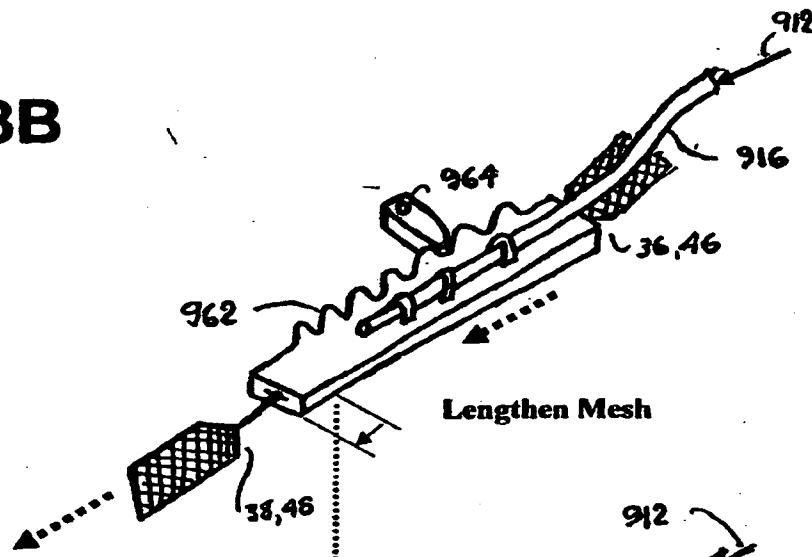


FIG. 58C

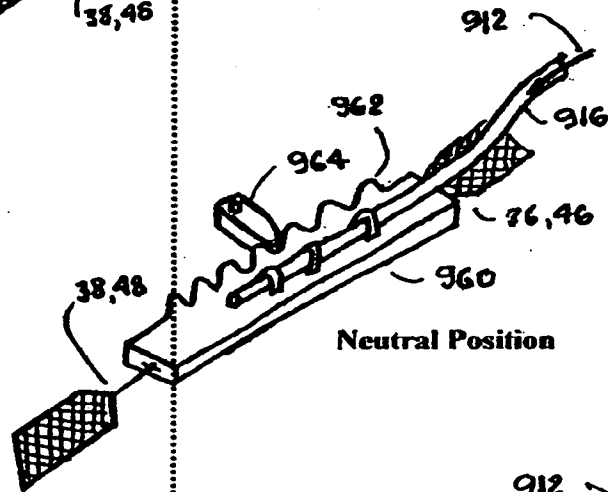


FIG. 58D

