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(54) **SURGICAL APPARATUS AND METHODS FOR DELIVERY OF A SLING IN THE TREATMENT OF FEMALE URINARY INCONTINENCE**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 40 days.

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(51) **Int. Cl.**⁷ **A61B 17/00**

(52) **U.S. Cl.** **600/30**

(58) **Field of Search** 600/29-31, 37; 128/DIG. 25, 897, 898; 604/272-274, 263; 606/139, 144, 148, 145, 151

(57) **ABSTRACT**

Surgical apparatus for treating female stress urinary incontinence include a pair of curved delivery needles, each defining a distal end and a proximal end and adopted to be inserted into the abdomen of a female and to be positioned on either side of the bladder neck so as to define a delivery path for a tape which may be removably attached to the proximal ends of the delivery needles through the vagina for implantation into the abdomen to provide support for the urethra. A pair of curved delivery sheaths, each adapted to be inserted into the abdomen around one of the delivery needles, allow withdrawal of the delivery needles from the abdomen such that the tape is conducted along the delivery path. In the preferred embodiment, the delivery needles also allow simultaneous introduction of a local anesthetic into the abdominal tissues. Methods for treatment of stress urinary incontinence utilizing the surgical apparatus are also disclosed.

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30 Claims, 8 Drawing Sheets

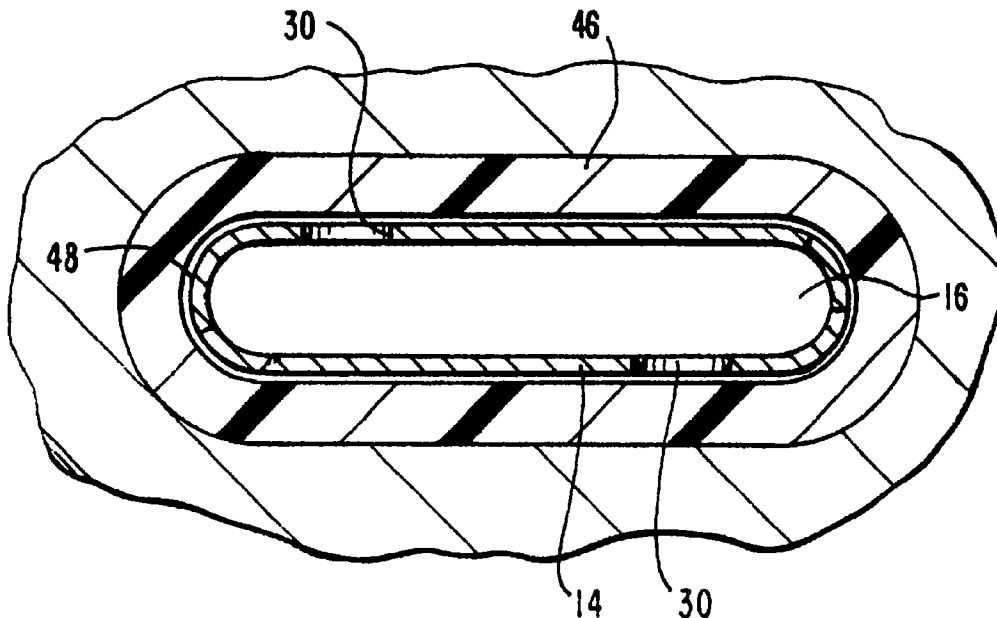


FIG. 1

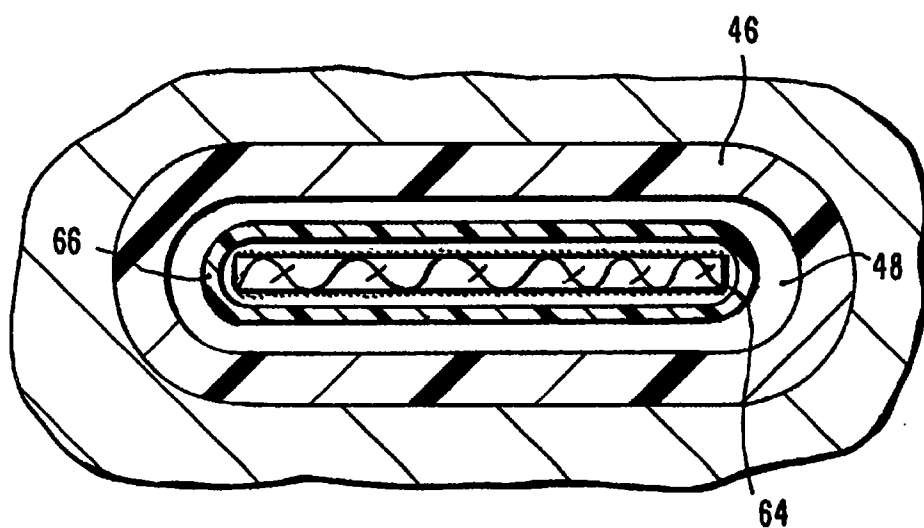
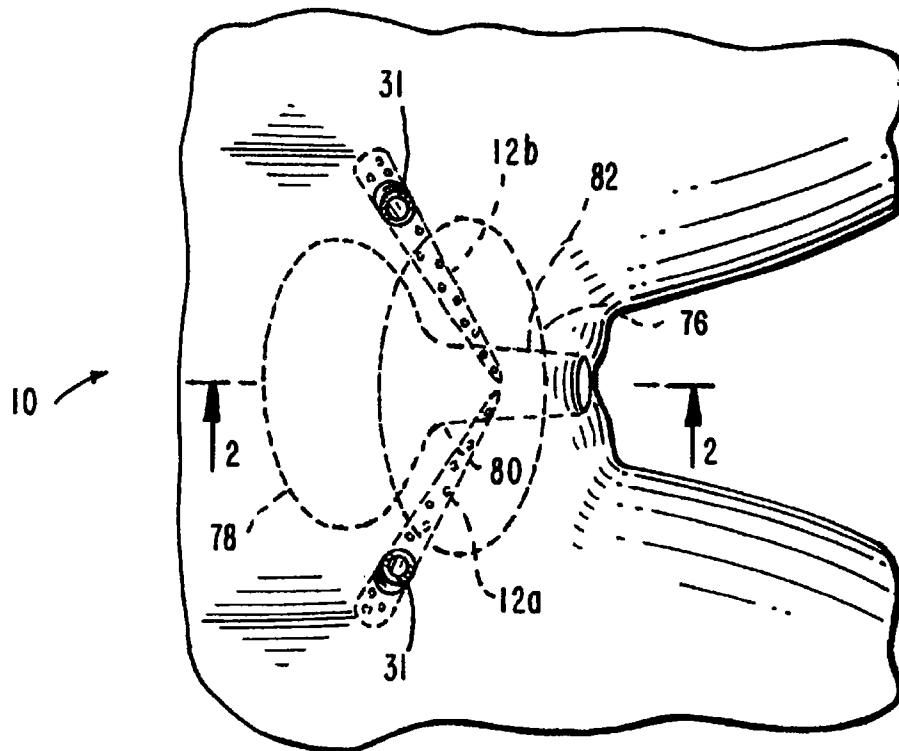


FIG. 10

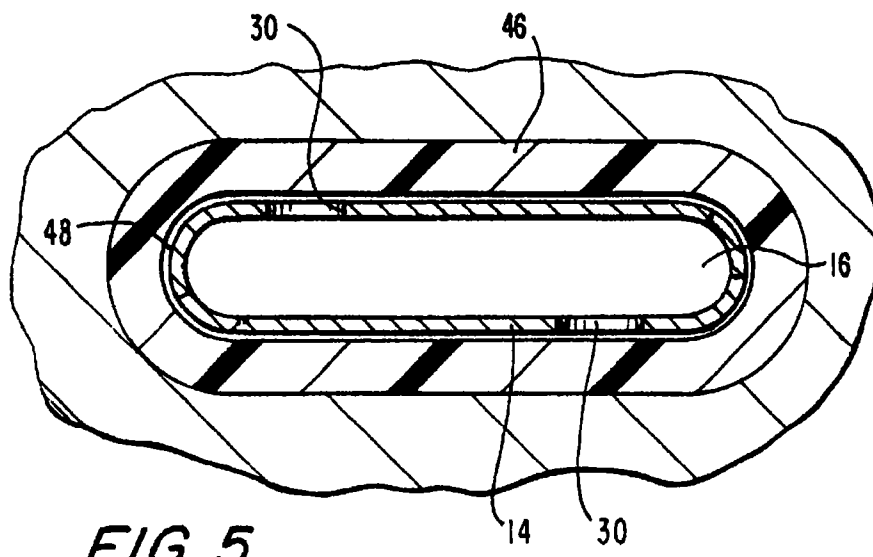
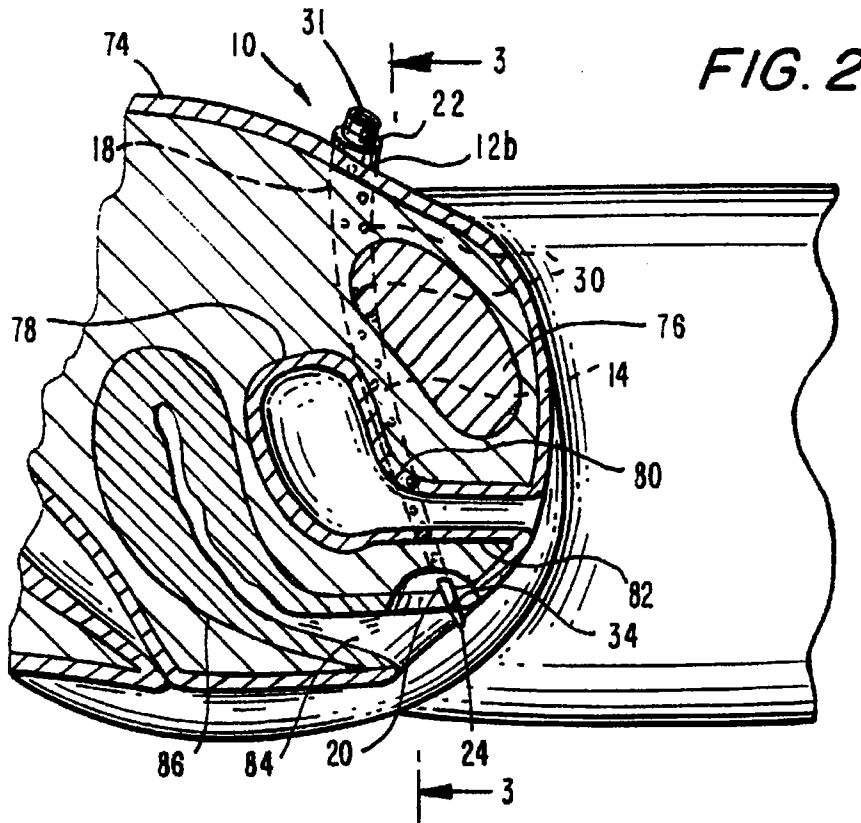


FIG. 3

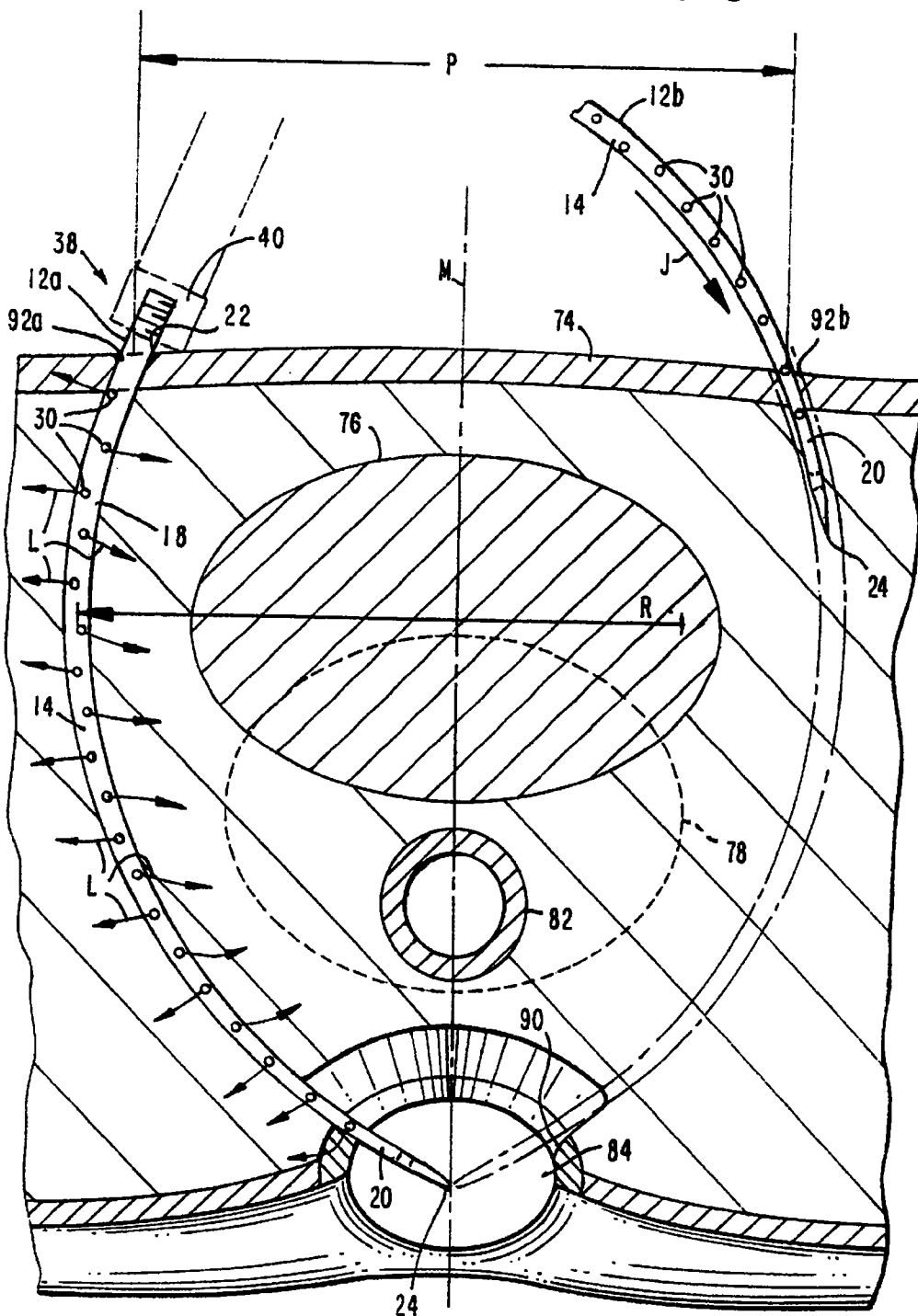
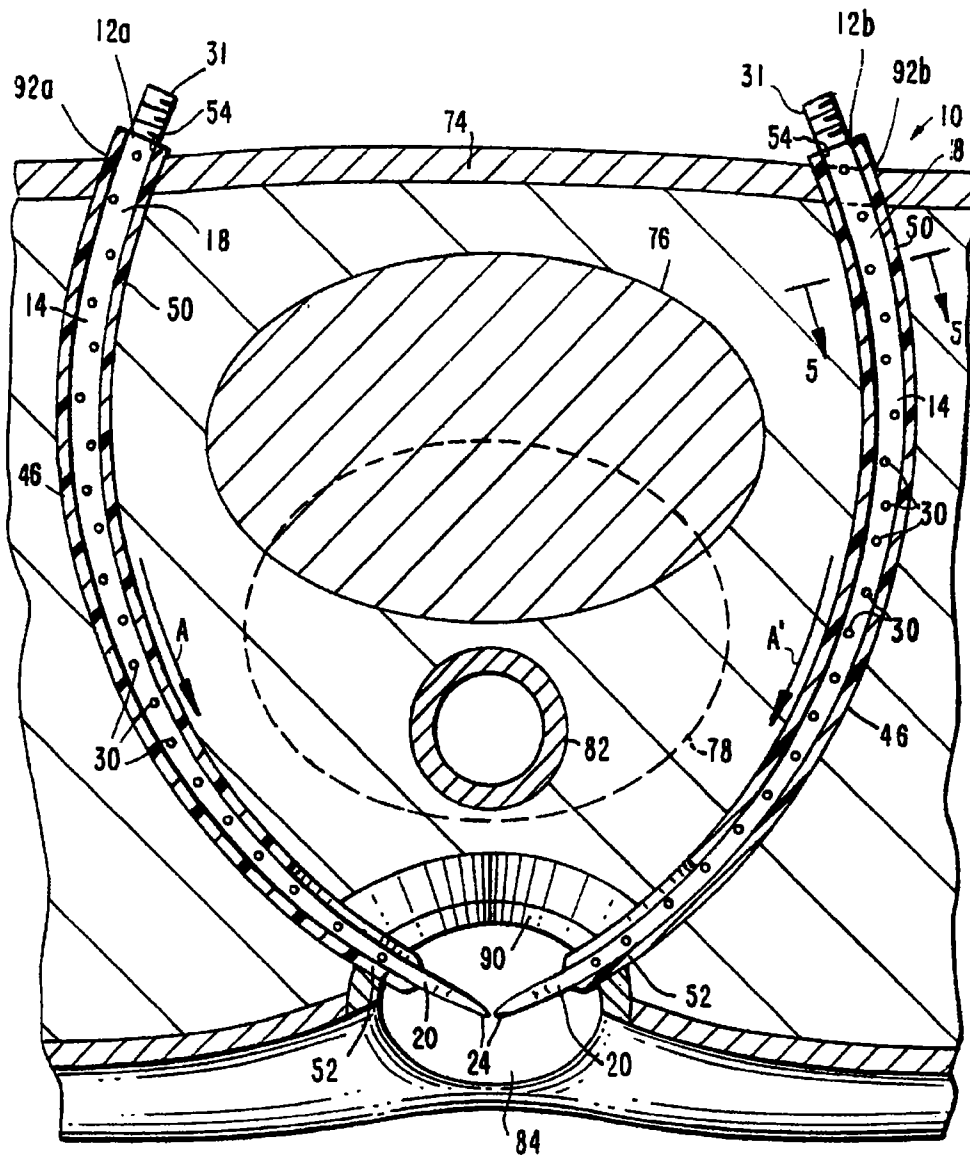
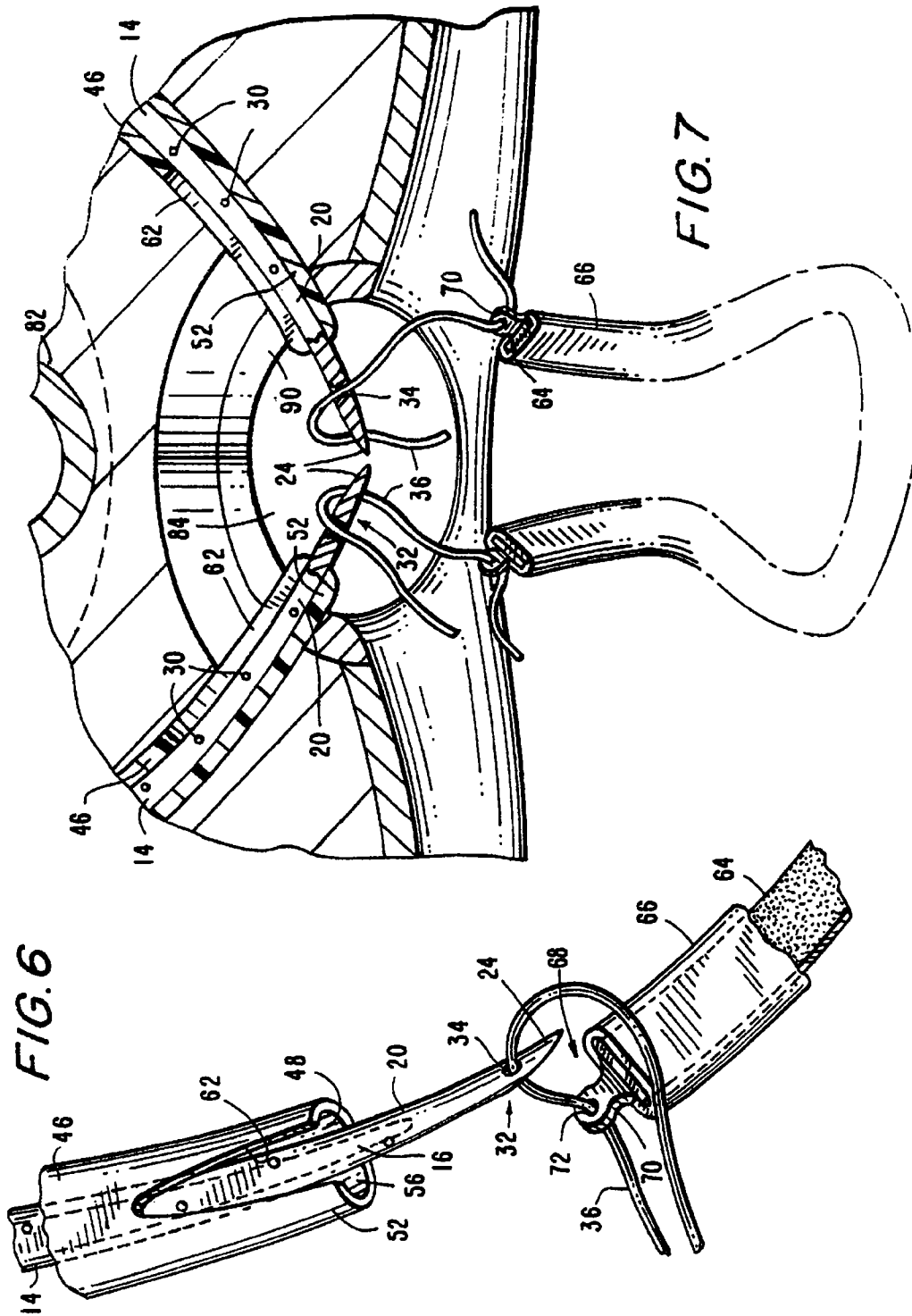


FIG. 4





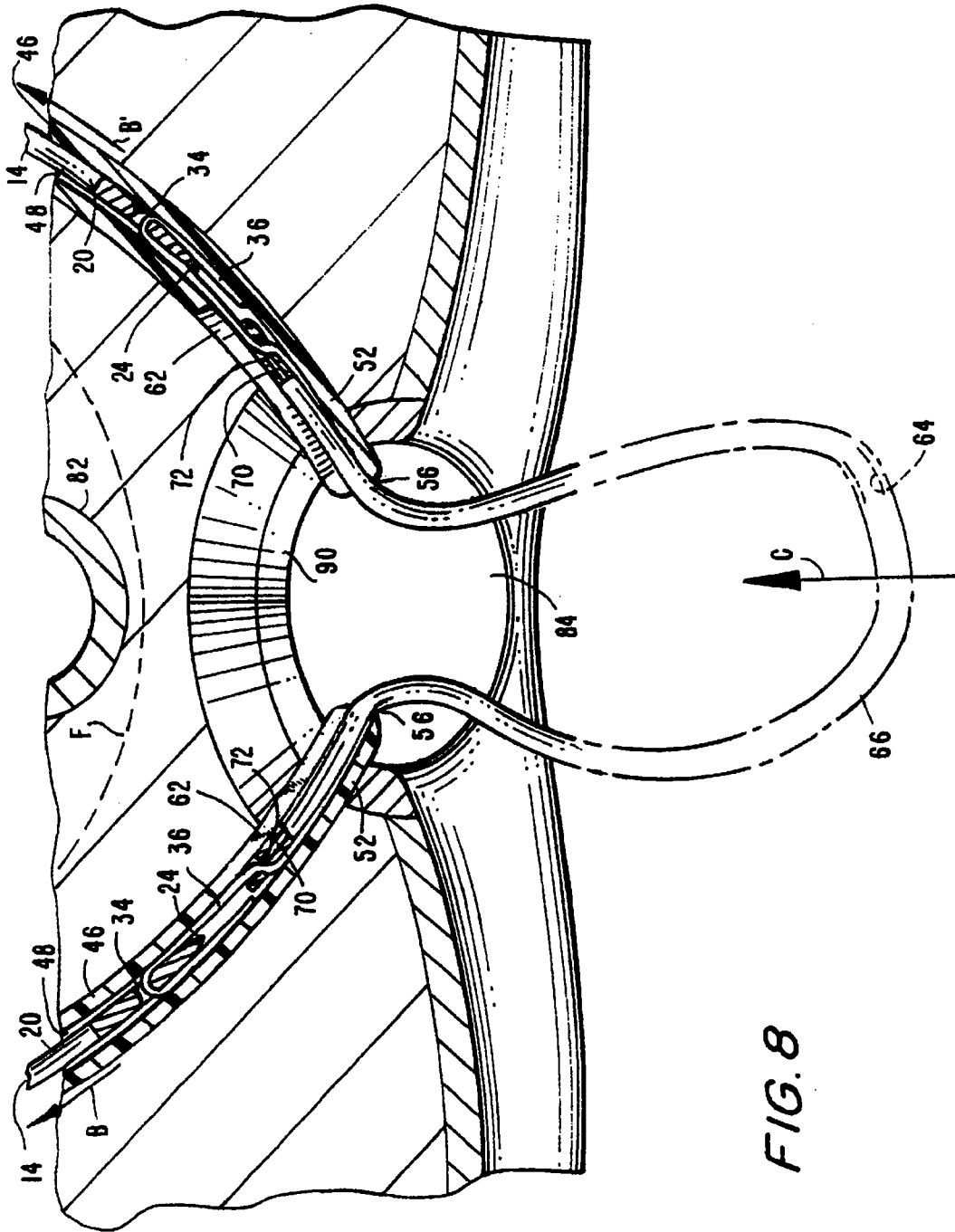
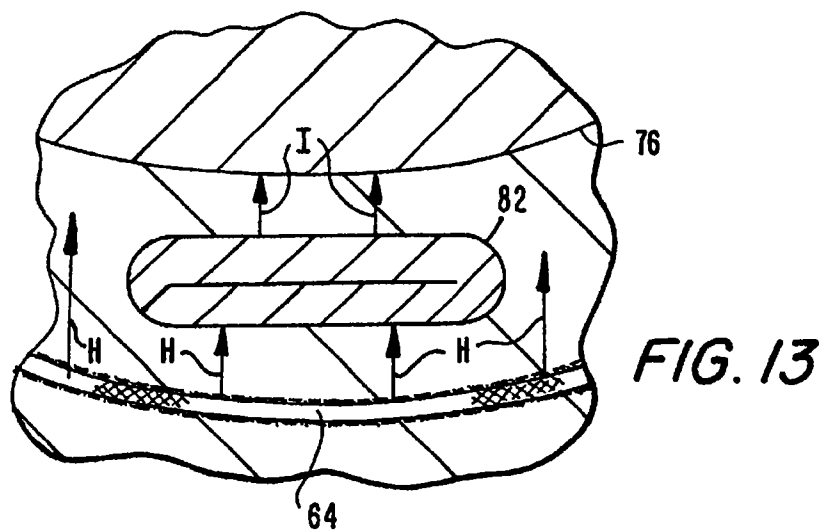
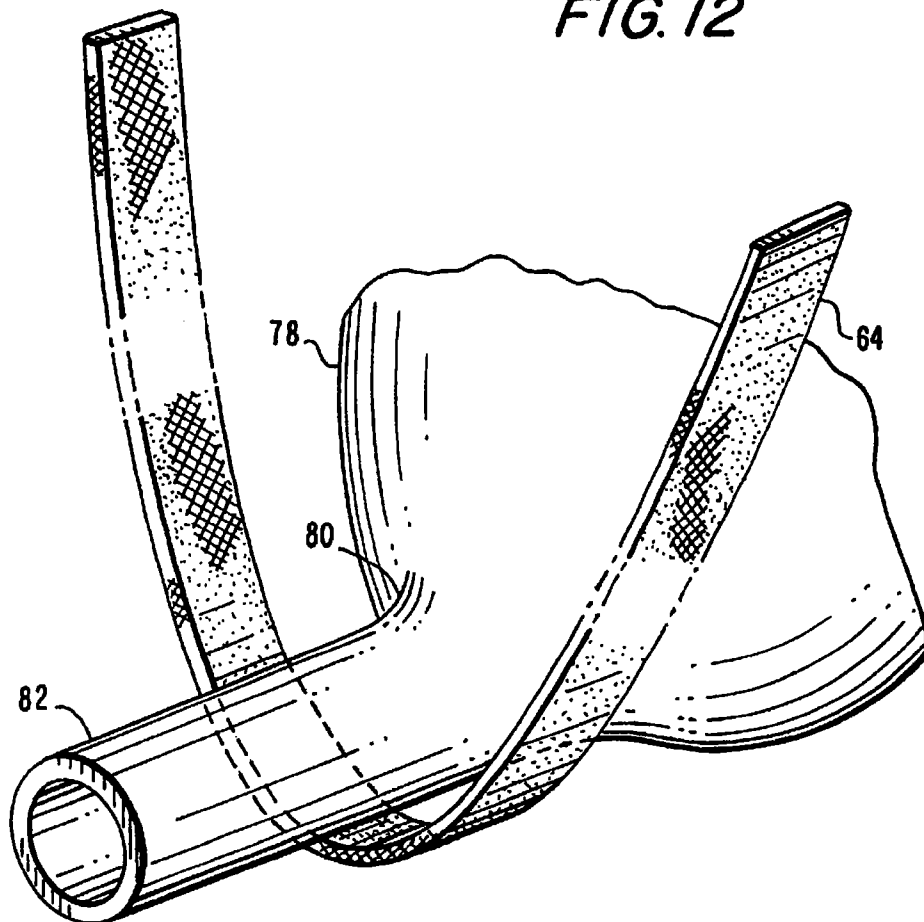


FIG. 8

FIG. 12



**SURGICAL APPARATUS AND METHODS
FOR DELIVERY OF A SLING IN THE
TREATMENT OF FEMALE URINARY
INCONTINENCE**

REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of prior copending U.S. Provisional Patent Application Ser. No. 60/235,438, filed Sep. 26, 2000.

TECHNICAL FIELD

The present invention relates broadly to the field of human health care, and in particular, to the treatment of a certain type of urinary incontinence in human beings. More specifically, this invention relates to surgical apparatus and methods for treating stress urinary incontinence in human females.

BACKGROUND OF THE INVENTION

Many women suffer from leakage of urine when they cough, laugh, sneeze or engage in various types of physical exercise. This condition is called stress urinary incontinence ("SUI") and is related to weakness of the muscles within the pelvis that provide support for the urethra and the bladder neck. SUI may be caused by a functional defect of the tissue or ligaments connecting the vaginal wall with the pelvic muscles and pubic bone. Common contributory factors include repetitive straining of the pelvic muscles, childbirth, loss of pelvic muscle tone, and estrogen loss. Such a defect results in an improperly functioning urethra, but unlike other types of urinary incontinence, SUI is not a problem of the urinary bladder.

Non-operative treatment options for patients with SUI can be attempted, by instructing such patients to perform pelvic exercises, known as Kegel exercises, with the intention of strengthening the supporting muscles. However, when these exercises fail to reverse SUI, surgical repair is advised.

Among the many surgical options for SUI that have been described in the medical literature, the introduction into the abdominal cavity of a pubovaginal "sling" has emerged in the past decade as the most effective. In this surgical procedure, a tape-like material, shaped like a flat ribbon, is passed through pelvic tissue and is positioned around the urethra and the bladder neck, forming a loop located between the urethra and the vaginal wall and thereby creating a supportive "hammock" or sling effect. The tape is extended over the pubis and through the abdominal wall and is tightened, after which the surplus tape is cut and removed, and the tape is left implanted in the patient's abdominal cavity.

The tape provides a structure means for tissue ingrowth and thereby provides a newly created body tissue supporting means for the urethra. When pressure is exerted upon the lower abdomen, such as during a cough or sneeze, the sling provides support to the urethra, allowing it to keep its seal and prevent the unwanted discharge of urine.

Three sources for sling materials are available: autologous fascia (a muscle cover that is obtained from the patient's own body, but at least one additional incision is required in order to retrieve the fascia), cadaveric fascia (a muscle cover obtained from a tissue bank, but which may be associated with infectious and immunological side effects) and non-biological synthetic tapes. By using a synthetic material, there is no need for surgical retrieval of autologous fascia and therefore the surgical time, as well as the resulting pain

and recovery time for the patient, are reduced when compared with utilizing autologous fascia, while the safety concerns inherent in using cadaveric fascia are avoided.

Nevertheless, significant post-operative complications have been observed when synthetic materials are used, although such complications have not arisen when a new procedure that was recently developed in Sweden is used. In this procedure, a woven synthetic tape material, fabricated of polypropylene mesh and initially protected with a plastic cover that is subsequently removed, is implanted around the urethra via a small vaginal incision, and is delivered into both sides of the pelvis through two tiny incisions in the lower abdomen. This outpatient surgery is termed Tension free Vaginal Tape ("TVT") and can be accomplished with local anesthesia and intravenous sedation, thus making it very attractive for both patients and surgeons for many reasons, not the least of which is that the tension of the tape can be adjusted by the surgeon based upon feedback provided by the patient.

The main (and perhaps the only) drawback of this TVT procedure is the use of two relatively thick, elongated pointed shafts (known as "trocars") that are introduced seriatim into the pelvis through the vagina in order to deliver the synthetic tape, each end of which is initially attached to one of the trocars. The insertion of these sizeable trocars is inherently a "blind" procedure and it can therefore lead to injuries to pelvic structures, such as the urinary bladder, blood vessels, muscles and nerves. Because of these potential complications, the bladder needs to be emptied by catheter each time the trocars and the synthetic tape are passed inside the pelvis. The catheter is placed in the bladder and the surgeon then inserts a metal guide into the catheter which is used to push the bladder away from the surgical tract within the pelvis where the large trocars used for TVT will pass. This requires repeated catheterizations, with insertions of the guide and eventual removal of both the guide and the catheter. In addition, repeated cystoscopic examinations (insertion of an endoscopic device that visualizes the inside of the bladder) must be performed in order to detect injuries to the bladder (bladder perforations). These repeated maneuvers are cumbersome, and they prolong the surgical time required to perform TVT.

Moreover, despite these precautionary manipulations, bladder perforations and bleeding inside the pelvic area from vascular injuries resulting from the TVT procedure of the prior art have been described in the medical literature. The reports of these complications, and the need for repeated preventive manipulations during the surgery, have led to a desire among surgeons who are performing (or who plan to perform) TVT to simplify and to improve the safety of the delivery system. The present invention is directed to meeting the aforesaid desirable objective, by providing a new delivery system with which TVT can become a simpler and safer procedure.

SUMMARY OF THE INVENTION

The invention overcomes the deficiencies of the prior art and provides for improved apparatus and methods for the treatment of female stress urinary incontinence. The invention provides an improved apparatus in the form of a tape delivery assembly which is preferably disposable after a single use, and which can be used not only to deliver a synthetic mesh tape intended to be implanted within the patient's abdominal cavity and to function as a pubovaginal sling, but also, in a preferred embodiment, to introduce a local anesthetic into the adjacent abdominal tissue at the same time.

The tape delivery assembly includes a pair of curved delivery needles, each of which has a varying diameter, but each of which is narrower than the prior art trocars. In the preferred embodiment, each delivery needle comprises a hollow needle body defining an interior needle body passageway and further defining a proximal end and a distal end, the distal end having an opening therein in fluid communication with the passageway; the needle body further defining a plurality of spaced openings disposed circumferentially around the needle body along substantially its entire length, the plurality of spaced openings also in fluid communication with the needle body passageway. The tape delivery assembly further includes means for removably attaching the proximal end of each delivery needle to separate ends of the tape intended to be implanted within the abdominal cavity. In the preferred embodiment, the tape delivery assembly also includes, for each delivery needle, means connected to the distal end of the needle body for removably attaching the needle body to a source of local anesthetic.

The tape delivery assembly further includes, for each delivery needle, a curved delivery sheath, also of varying diameter, and defining an interior sheath passageway for removably receiving a delivery needle therein, and further defining first and second ends having first and second openings therein, respectively, each opening in communication with the sheath passageway, the first opening allowing the delivery needle to be introduced into the sheath passageway, and the second opening allowing the delivery needle to be withdrawn from the sheath passageway.

In practice, the curved delivery needles are introduced into the patient's abdominal cavity via two small incisions made in the lower abdominal wall, and while (in the preferred embodiment) local anesthetic is continuously introduced through each needle body, the delivery needles are inserted into and through the pelvic tissue such that the needle bodies are ultimately positioned with their proximal ends adjacent one another and extending through the vaginal wall (via an incision previously made therein), and with the adjacent portions of the needle bodies positioned on opposite sides of the bladder neck adjacent the urethra, thereby defining a delivery path for the tape to be implanted in the patient's abdominal cavity. A delivery sheath is then inserted around each delivery needle through the abdominal incision, such that the delivery sheath envelops the delivery needle along substantially its entire length, except for the proximal end thereof, and such that the delivery sheaths are situated along the delivery path defined by the delivery needles.

The tape to be implanted within the patient's abdominal cavity is then introduced via the vagina, and each end of the tape is attached to the proximal end of one of the delivery needles via the attachment means. The delivery needles are then withdrawn from the delivery sheaths, thereby pulling or conducting the tape into the delivery sheaths, and the tape ends are thereafter detached from the delivery needles, leaving the tape disposed along the delivery path within the delivery sheaths. The delivery sheaths are then withdrawn, and the tape remains, already positioned appropriately for completion of the TVT procedure in accordance with the prior art. Thus, the invention also provides an improved method for the treatment of stress urinary incontinence in which the improved apparatus of the invention is utilized.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other aspects, features, objects and advantages of the present invention will become more apparent from the

following detailed description of the presently most preferred embodiment thereof (which is given for the purposes of disclosure), when read in conjunction with the accompanying drawings (which form a part of the specification, but which are not to be considered limiting in its scope), wherein:

FIG. 1 is a schematic view of the torso of a human female patient, viewed from above, depicting portions of the preferred embodiment of the present invention in place within the abdominal cavity;

FIG. 2 is an enlarged cross-sectional view, taken substantially along the lines 2—2 of FIG. 1;

FIG. 3 is a further enlarged cross-sectional view, taken substantially along the lines 3—3 of FIG. 2;

FIG. 4 is a view similar to that of FIG. 3, but showing additional portions of the preferred embodiment of the present invention;

FIG. 5 is a still further enlarged cross-sectional view, taken substantially along lines 5—5 of FIG. 4;

FIG. 6 is an enlarged plan view depicting the illustrative attachment means of the present invention;

FIG. 7 is a view, partially in cross-section, depicting the manner in which a synthetic tape is introduced into the abdominal cavity through the vagina;

FIG. 8 is a view similar to that of FIG. 7, showing the manner in which the tape is towed into the abdominal cavity in accordance with the present invention;

FIG. 9 is a view similar to that of FIG. 8, depicting the tape after it is delivered into the abdominal cavity;

FIG. 10 is an enlarged cross-sectional view, similar to FIG. 5, but taken substantially along the lines 10—10 of FIG. 9;

FIG. 11 is a view similar to that of FIG. 9, showing the tape in its final position within the abdominal cavity;

FIG. 12 is a schematic perspective view, also depicting the tape in its final position within the abdominal cavity, where it serves as a pubovaginal sling around the urethra; and

FIG. 13 is a cross-sectional view, illustrating the function of the tape in restoring urinary continence to the patient.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The preferred embodiment of the present invention will now be further described with reference to the accompanying drawings, wherein like reference numerals designate like or corresponding parts throughout the several views. Referring first to FIGS. 1—6, the tape delivery assembly of the present invention is generally designated 10. Assembly 10 includes a pair of elongated, generally tubular, arcuate delivery needles 12a, 12b. Delivery needles 12a, 12b are fabricated from a material that is compatible with the human body, preferably a rigid metal material that is conventionally used for surgical instruments, such as stainless steel, and may be generally smooth, preferably polished, on their exterior to facilitate penetration of soft tissue.

Delivery needles 12a, 12b each comprise a needle body 14 which is generally hollow and which defines an interior needle body passageway 16. Needle body 14 further defines a distal needle end 18 and a proximal needle end 20, the proximal needle end 20 terminating in a needle tip 24, while the distal needle end 18 terminates (in the preferred embodiment) in a distal needle opening 22 that is in fluid communication with the needle body passageway 16. Needle body passageway 16 preferably extends substan-

