US 20050004576A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2005/0004576 A1**

**Benderev** (43) **Pub. Date: Jan. 6, 2005**

(54) **SYSTEM FOR SECURING SUTURES, GRAFTS AND SOFT TISSUE TO BONE AND PERIOSTEUM**

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(21) Appl. No.: **10/841,594**

(22) Filed: **May 7, 2004**

**Related U.S. Application Data**

(63) Continuation-in-part of application No. 10/679,131, filed on Oct. 3, 2003, which is a continuation-in-part of application No. 10/466,330, filed on Jul. 30, 2003, which is a continuation-in-part of application No. 09/733,455, filed on Dec. 8, 2000, which is a continuation-in-part of application No. 09/197,938, filed on Nov. 23, 1998, now Pat. No. 6,200,330.

(30) **Foreign Application Priority Data**

Feb. 8, 2001 (JP) ..... 2001-32280

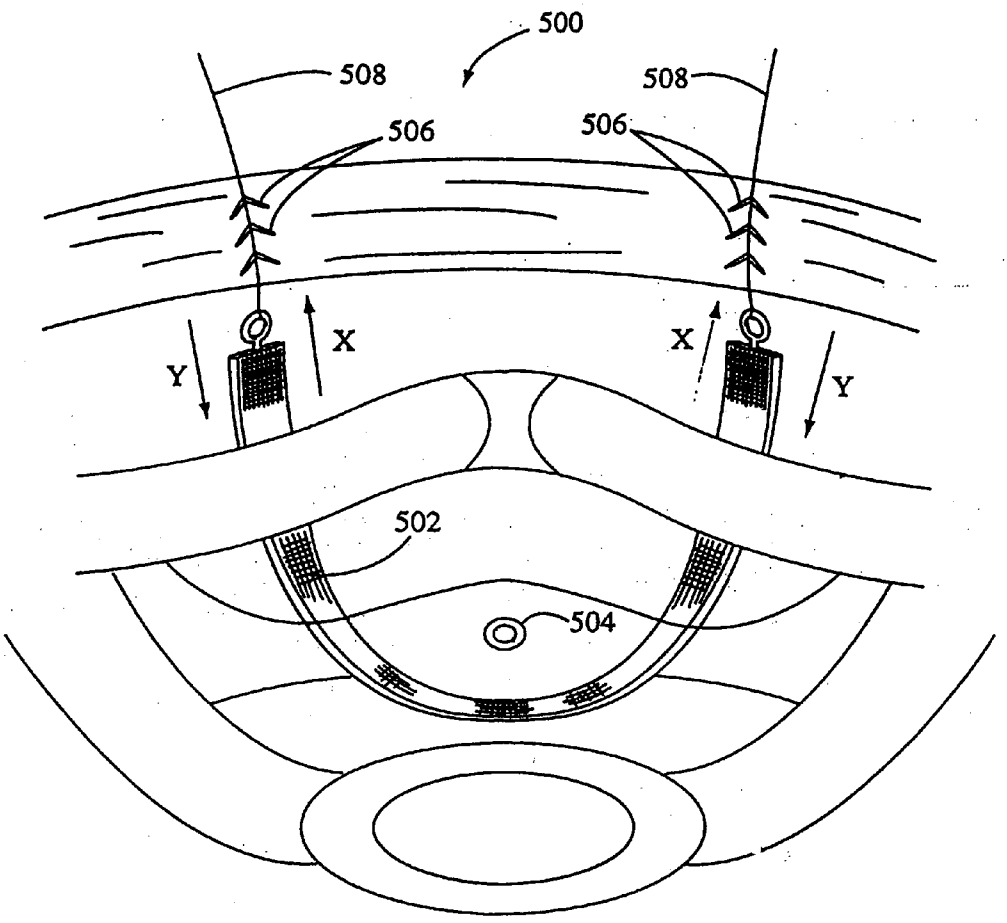
**Publication Classification**

(51) **Int. Cl.**[7] ..... **A61B 17/56**

(52) **U.S. Cl.** ..... **606/72**

(57) **ABSTRACT**

Self-anchoring slings and deployment mechanisms for use therewith in selectively positioning a sling into position within the body. According to a preferred embodiment, the sling comprises an elongate sling portion having opposed ends. Formed upon each respective opposed end is an anchor member operative to be percutaneously advanced through soft tissue at a selected target site in a first direction but resist movement in an opposed direction. Such anchor members are operative to extend in opposed directions to thus enable a sling to be securely affixed into position and resist sag or otherwise lose its ability to support a given structure.



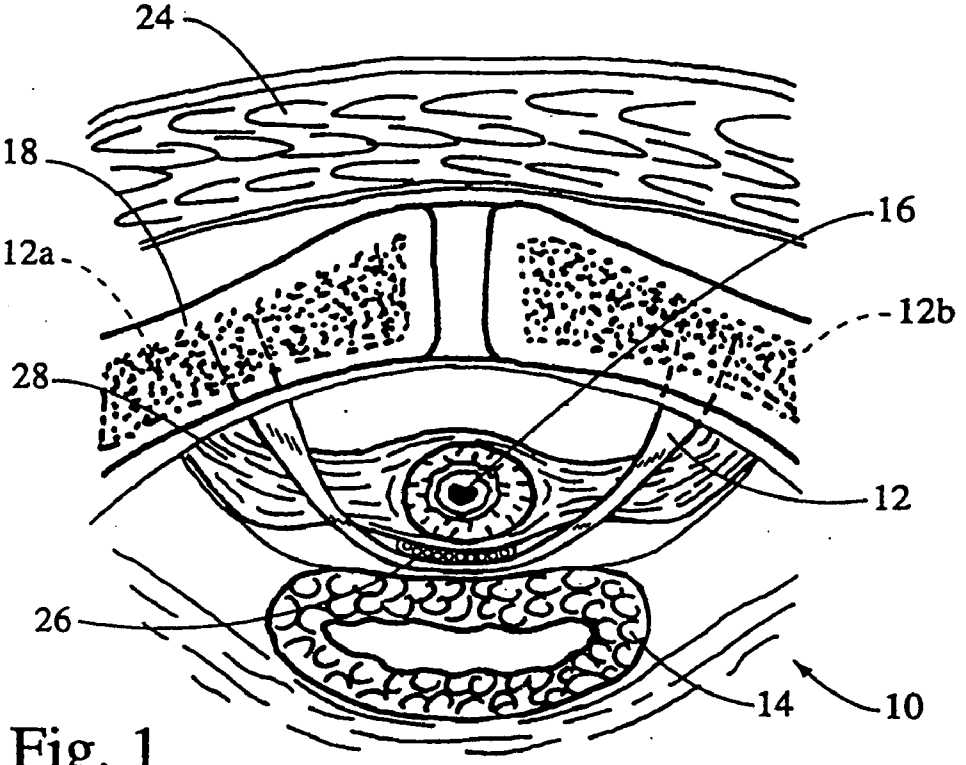



Fig. 1

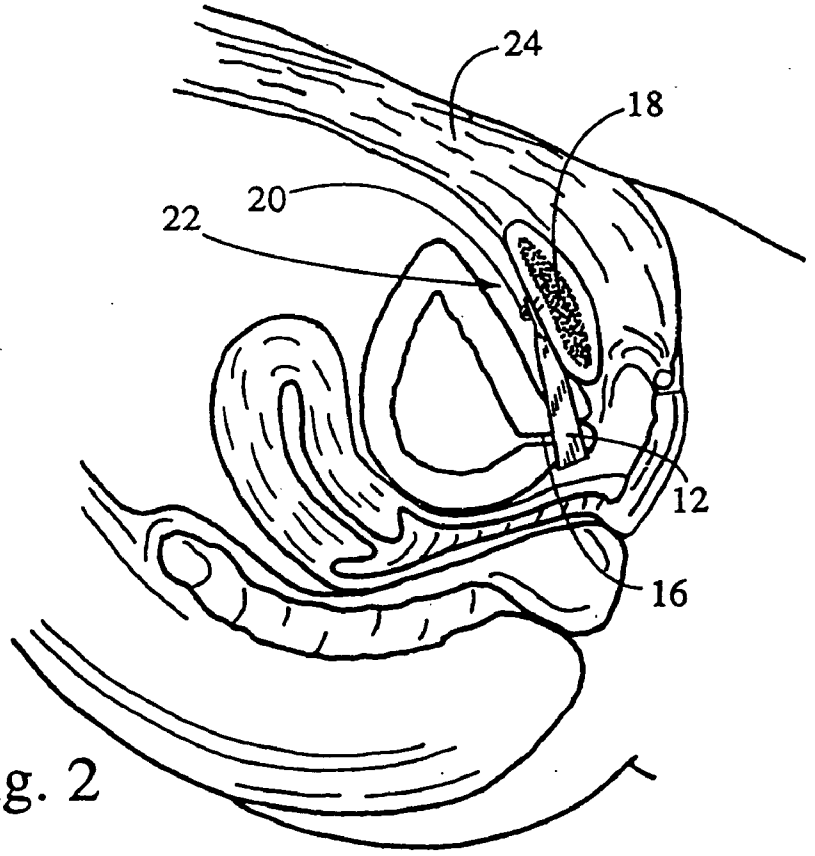



Fig. 2

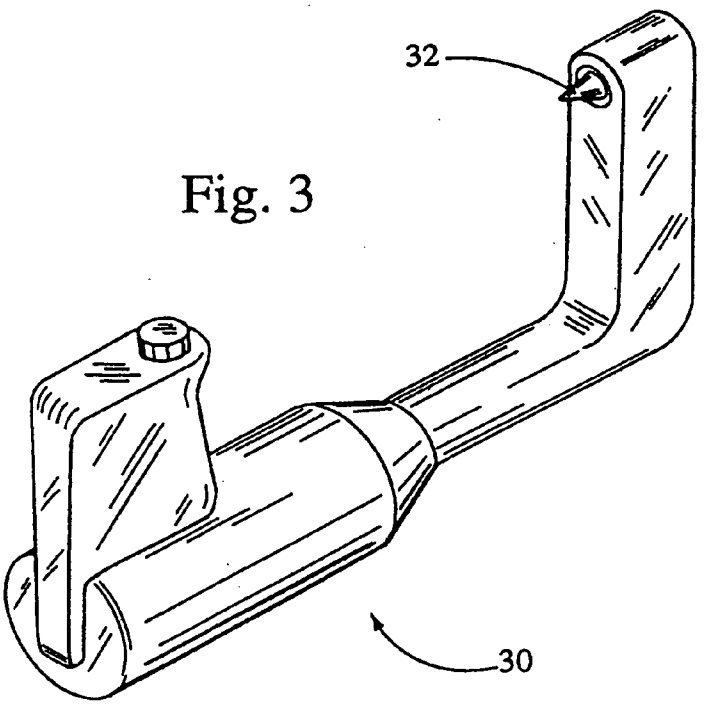



Fig. 3

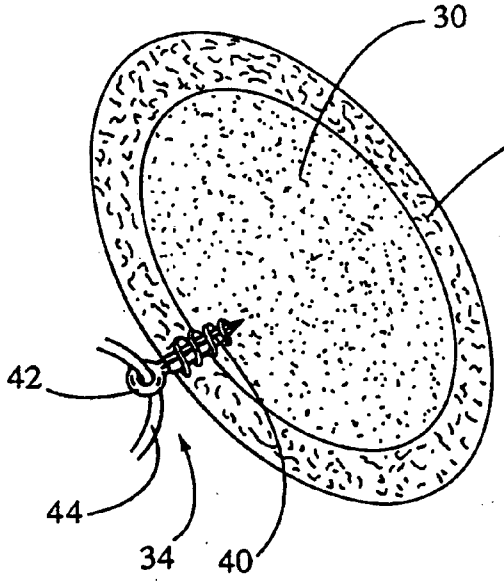



Fig. 4

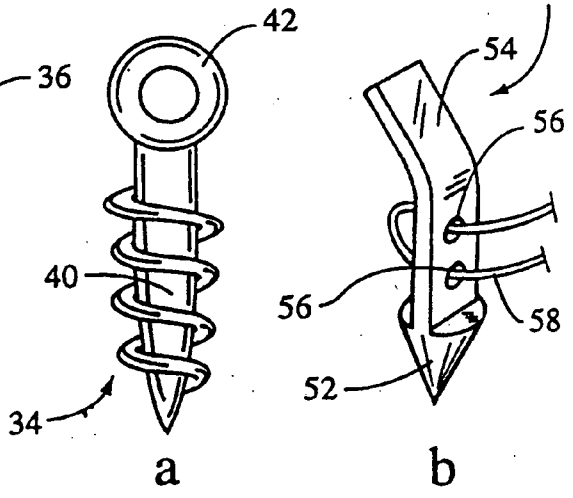



Fig. 5

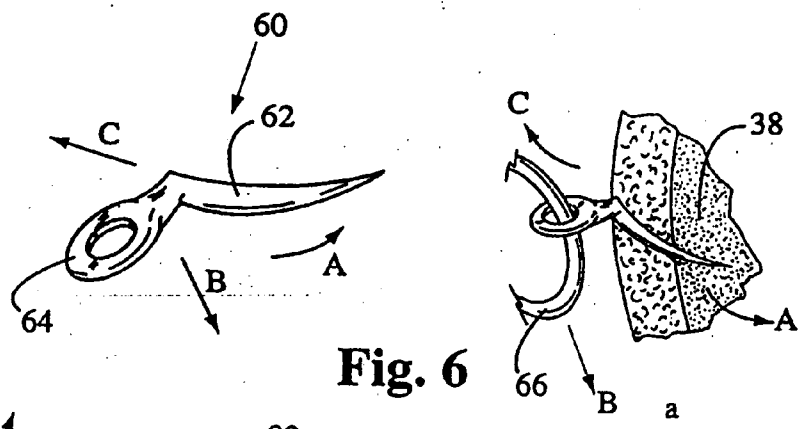



Fig. 6

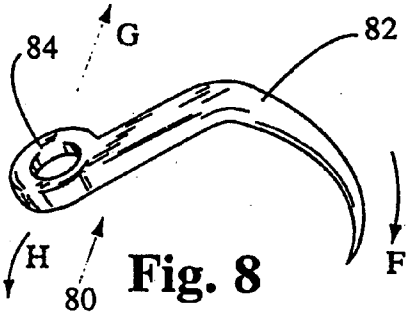



Fig. 8

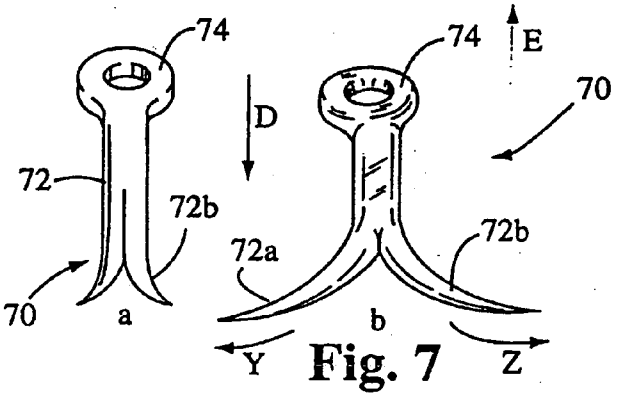



Fig. 7

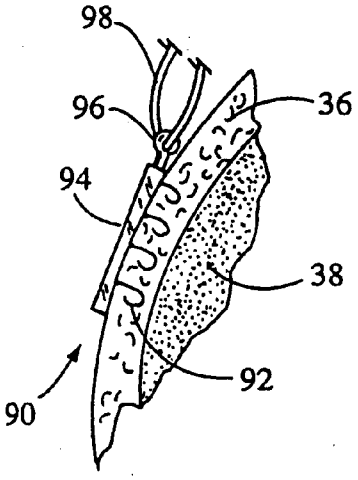



Fig. 9

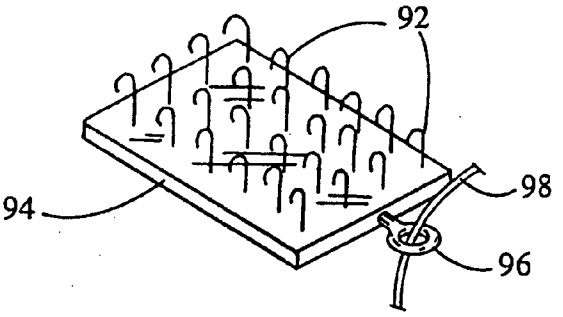



Fig.10

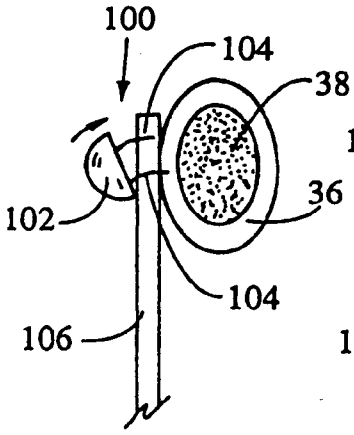



Fig. 11

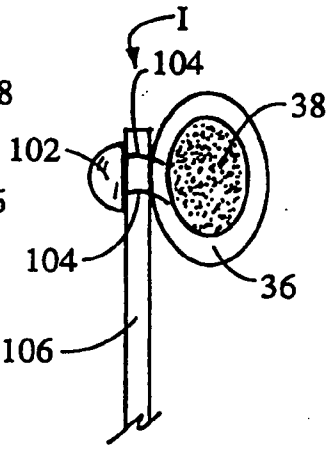



Fig. 12

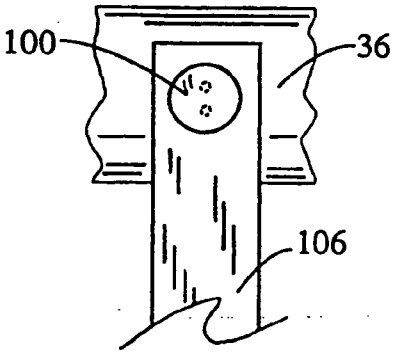



Fig. 13

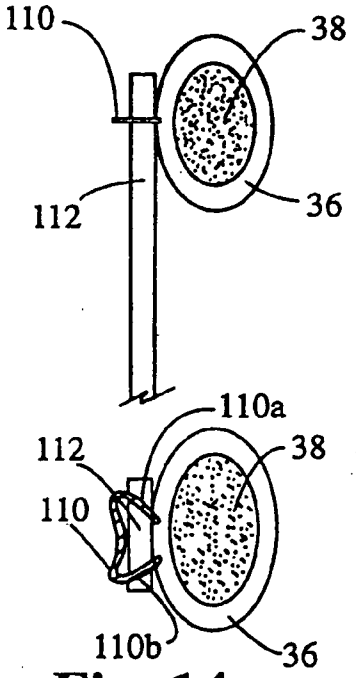



Fig. 14

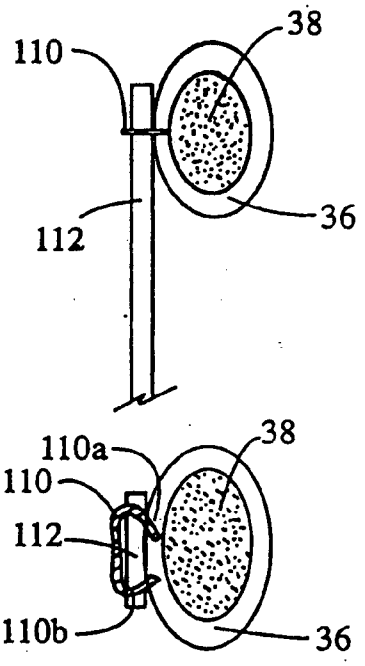



Fig. 15

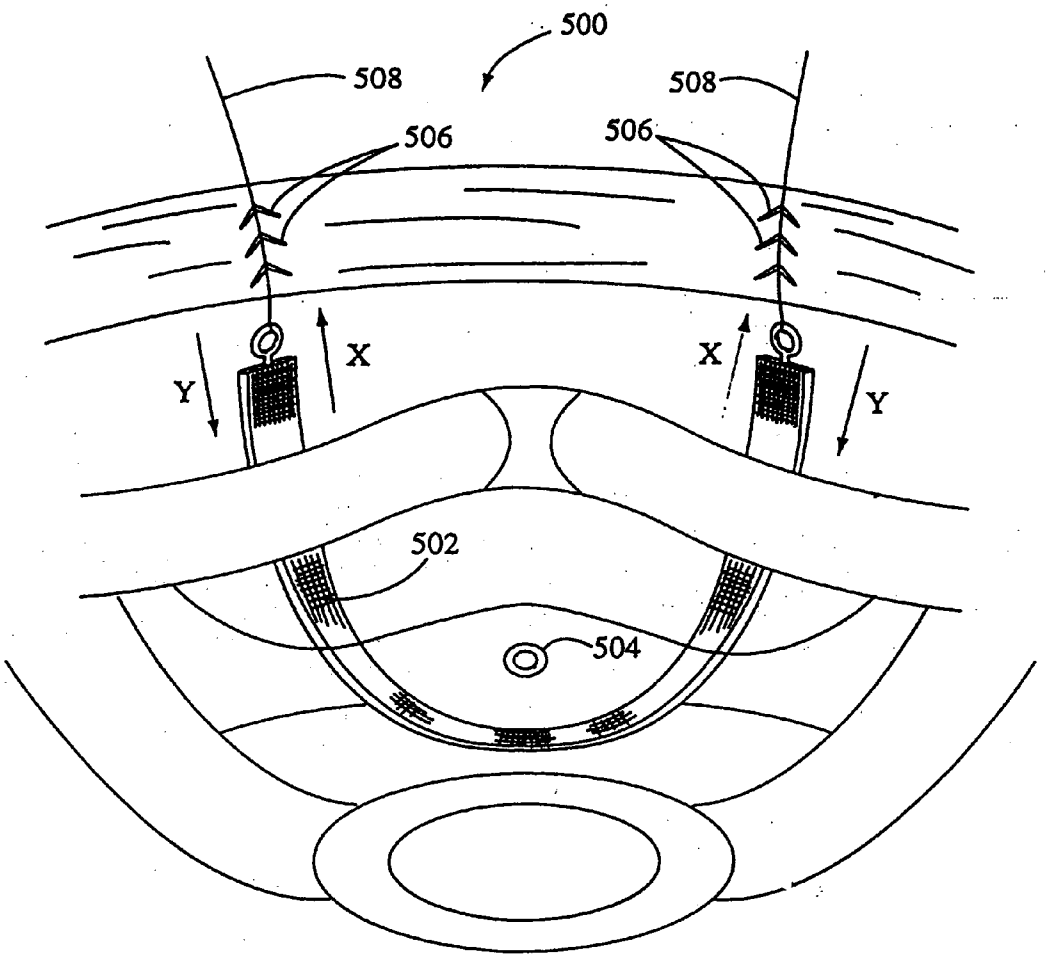



Fig.16

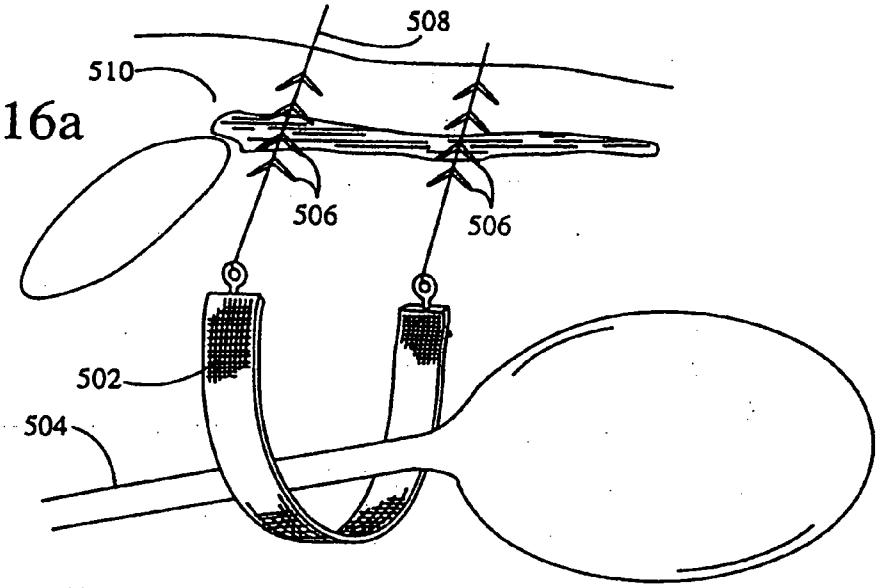



Fig. 16a

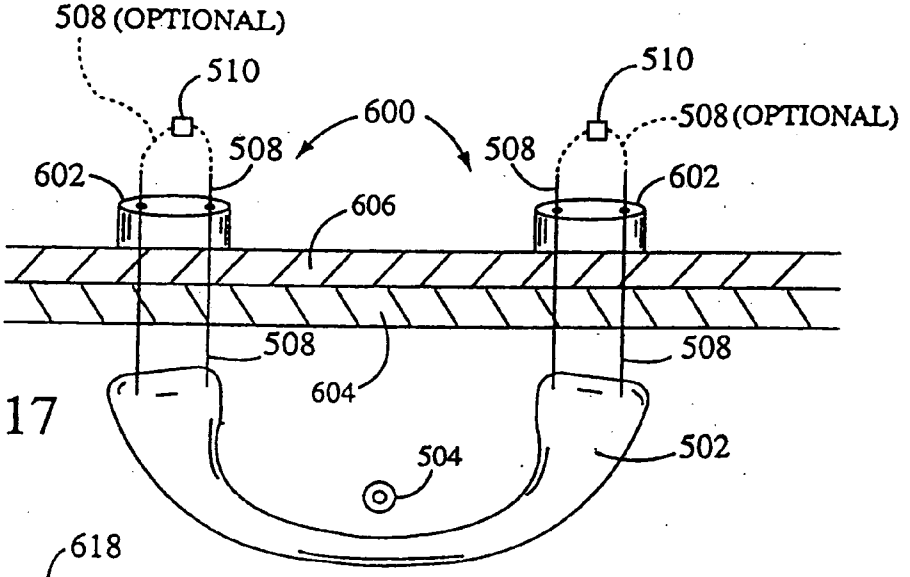



Fig. 17

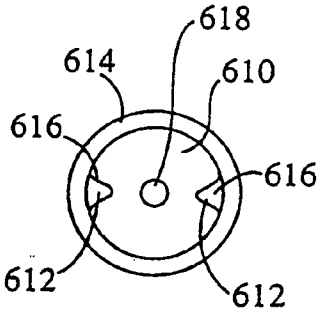



Fig. 17a

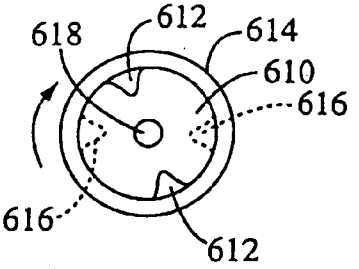



Fig. 17b

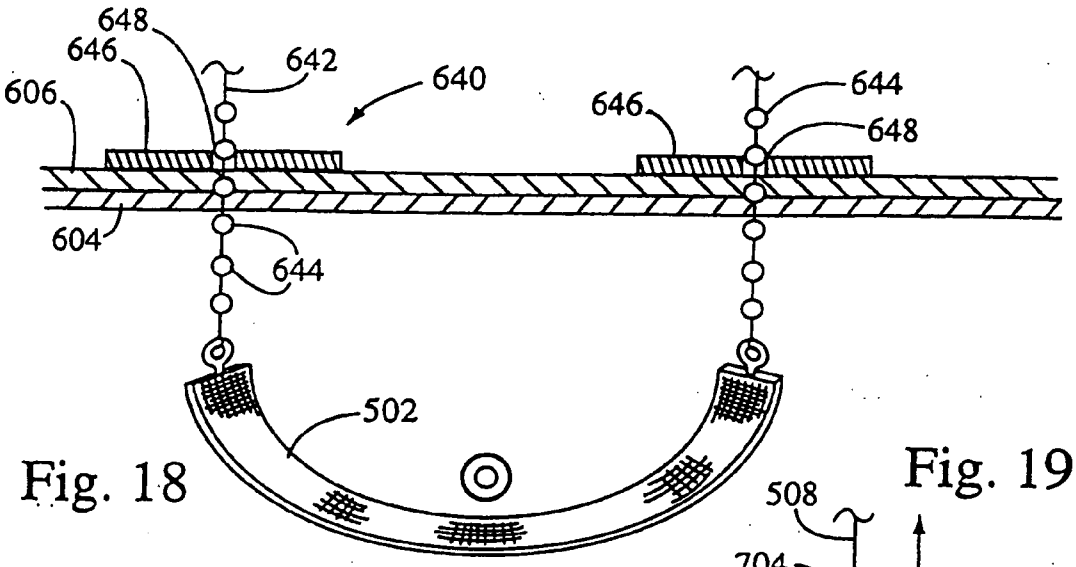



Fig. 18

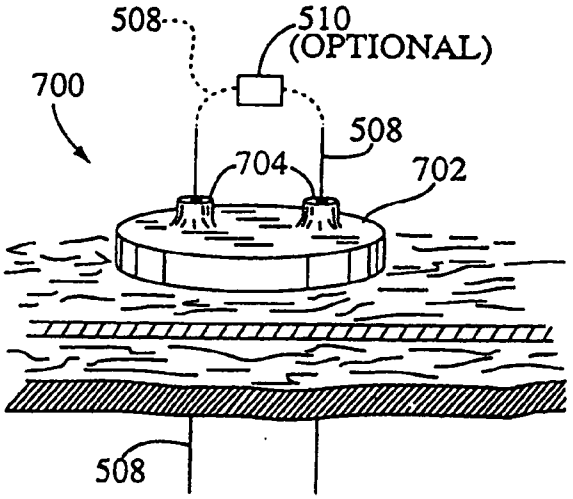



Fig. 19

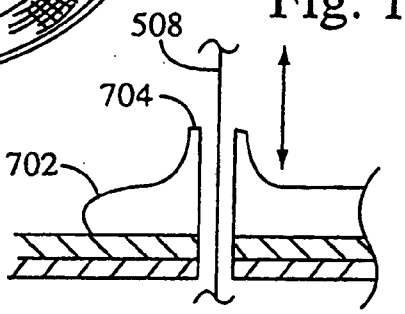



Fig. 19a

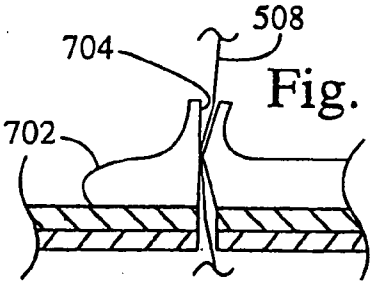



Fig. 19b

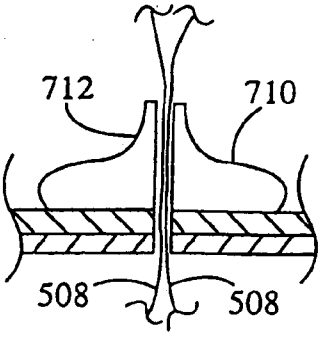



Fig. 19c

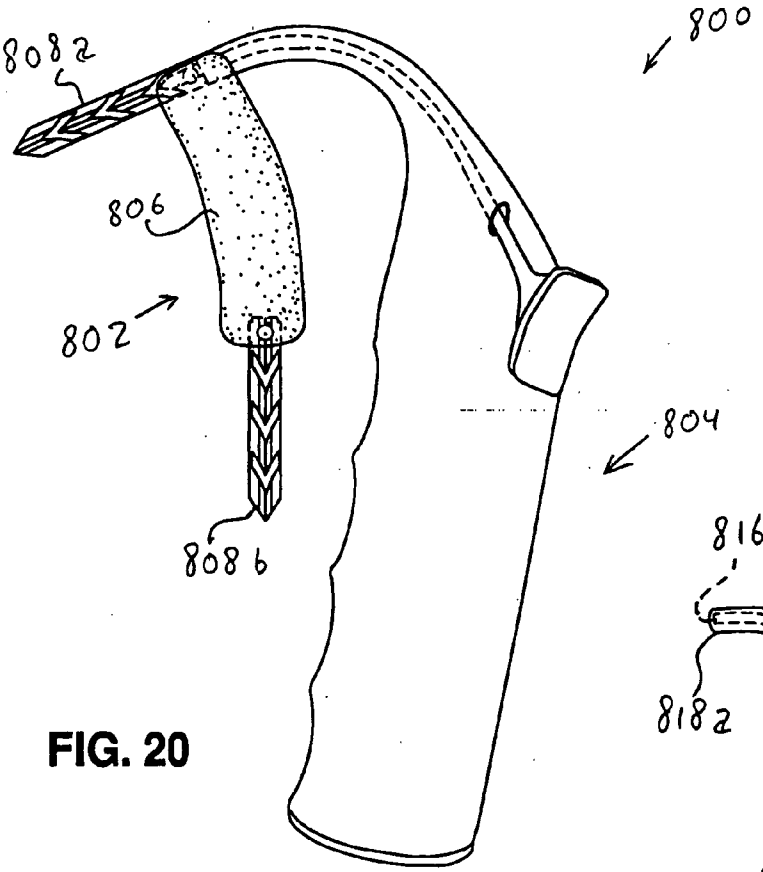



FIG. 20

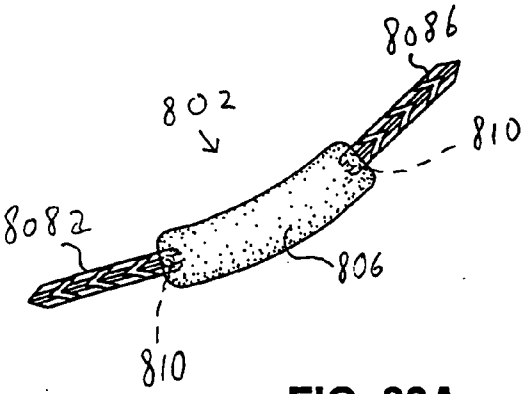



FIG. 20A

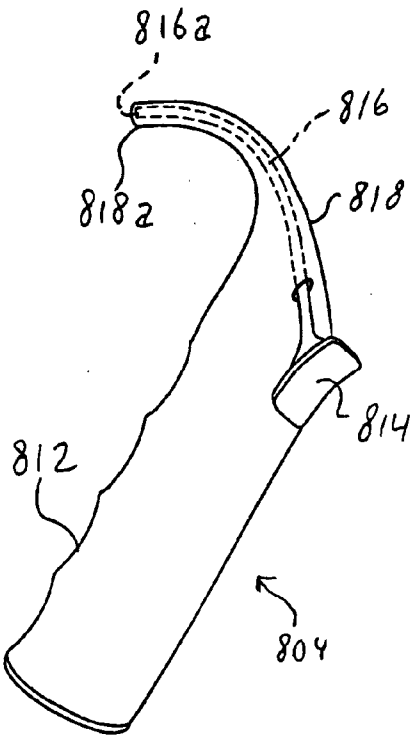



FIG. 20B

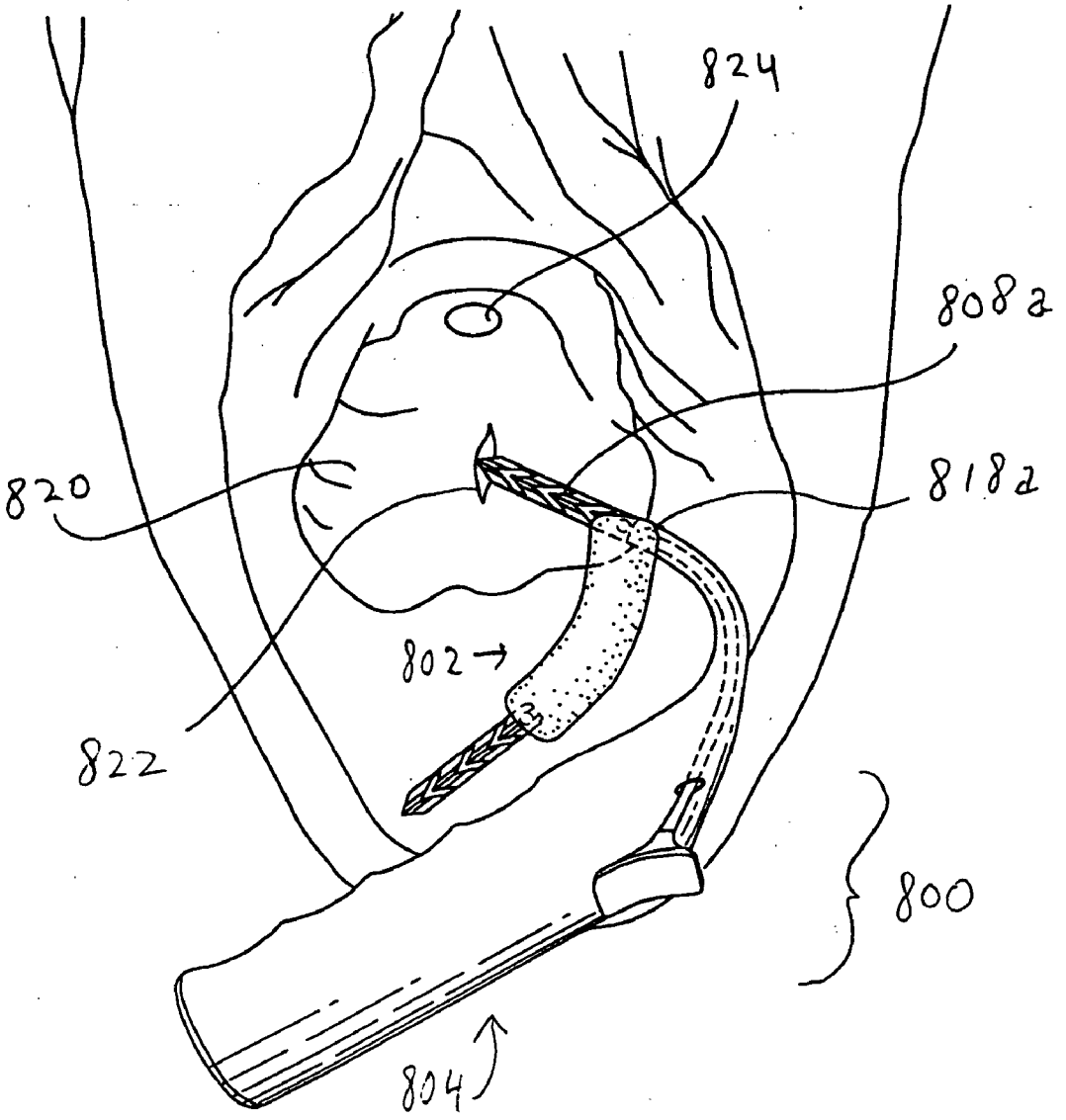



FIG. 21

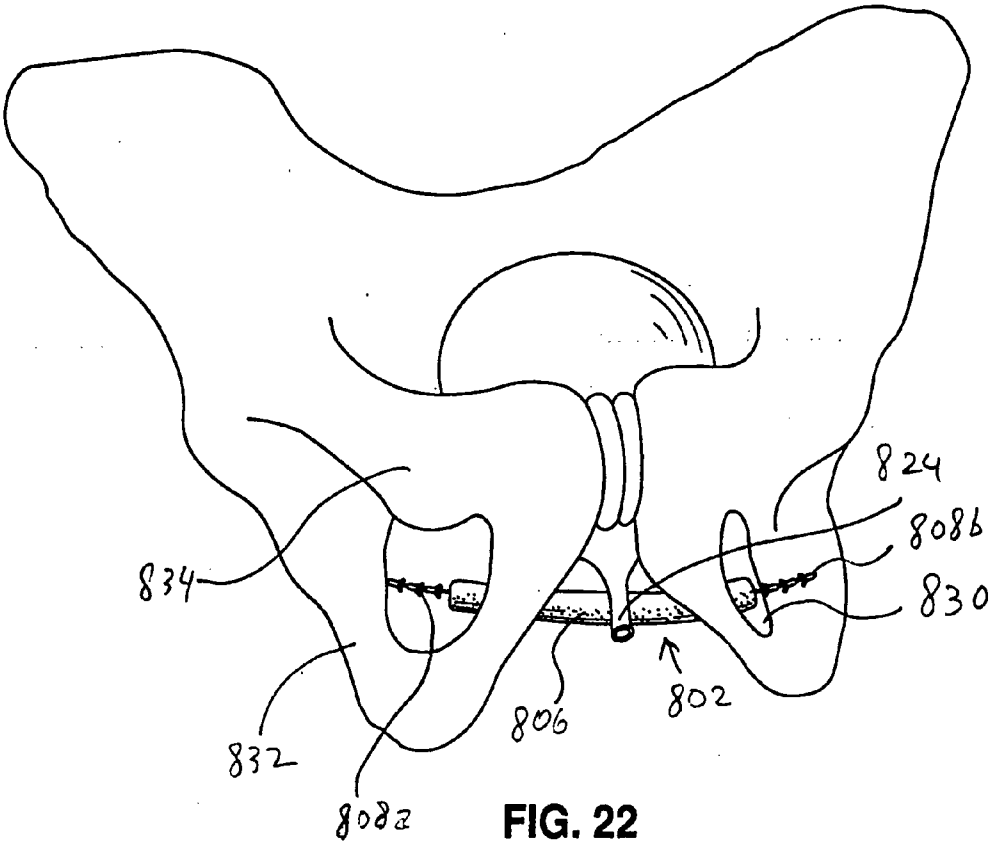



FIG. 22

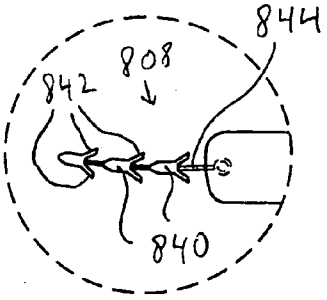



FIG. 22A

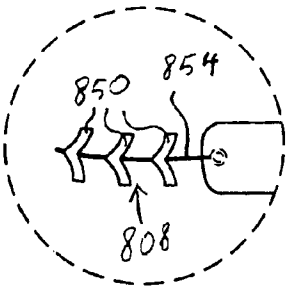



FIG. 22B

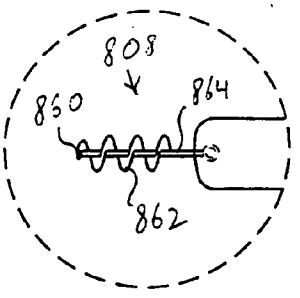



FIG. 22C

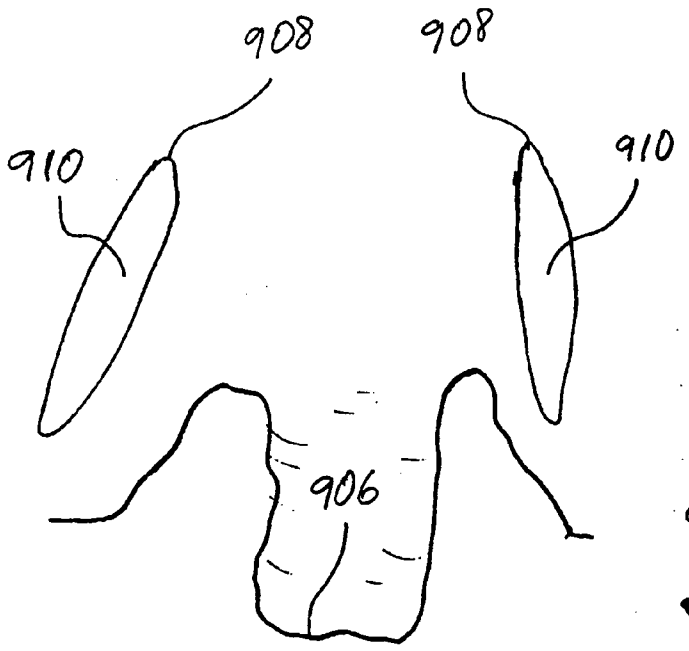



Fig. 23

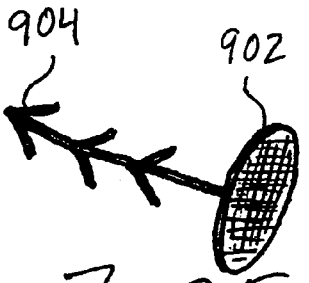



Fig. 25

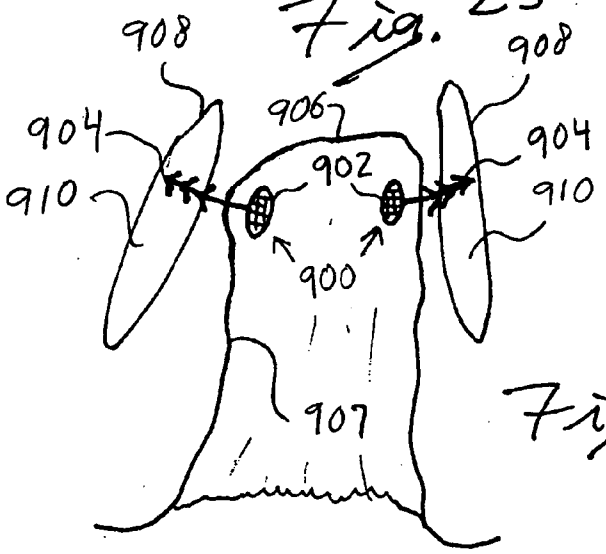



Fig. 24

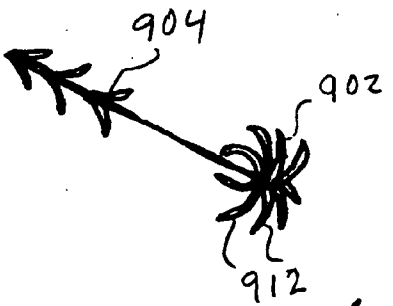



Fig. 26

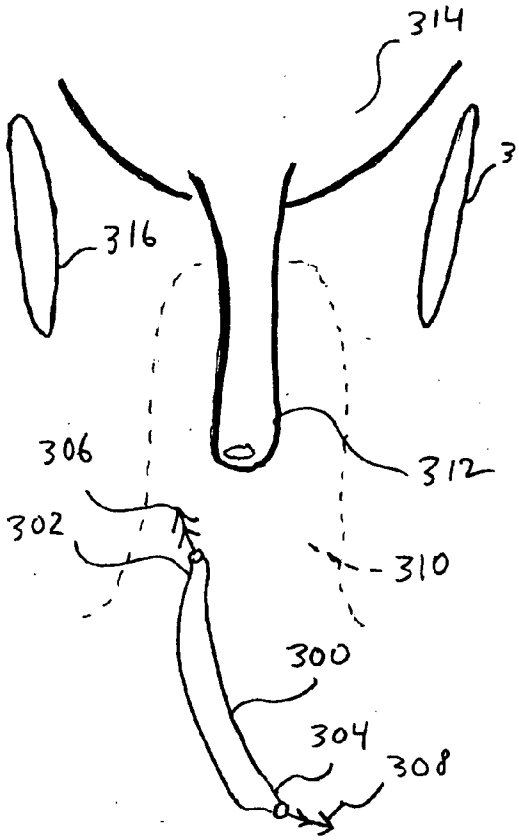



Fig. 27

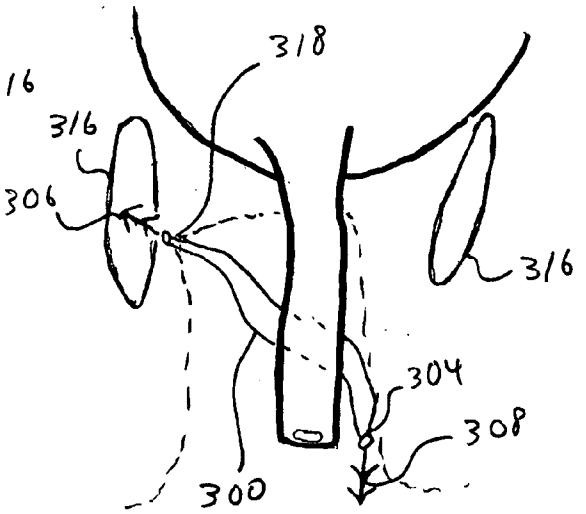



Fig. 28

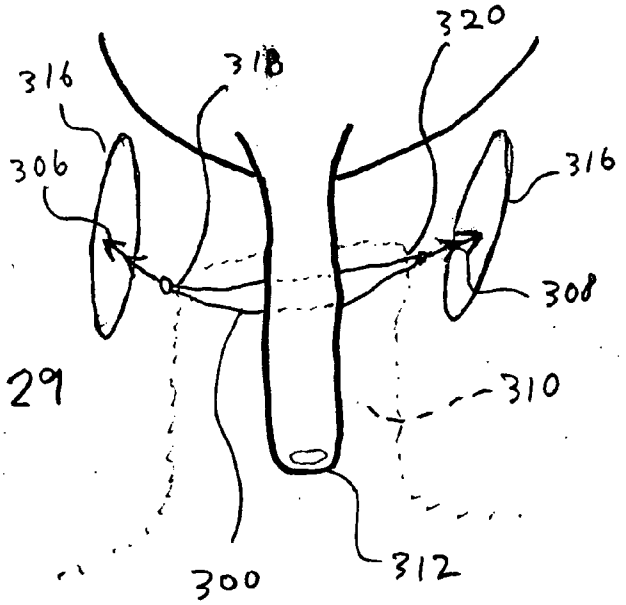



Fig. 29

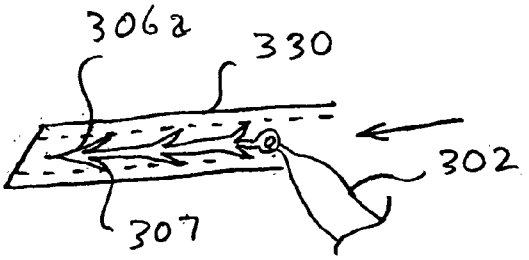



Fig. 30

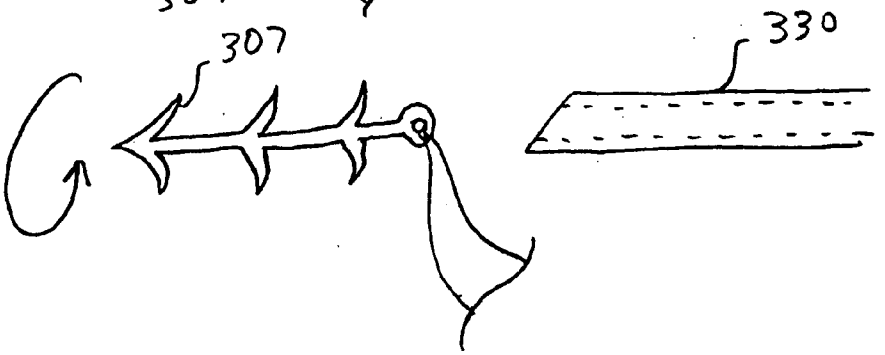



Fig. 31

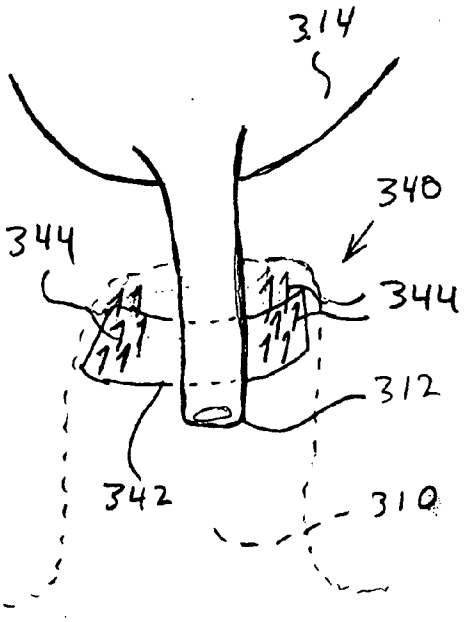



Fig. 32

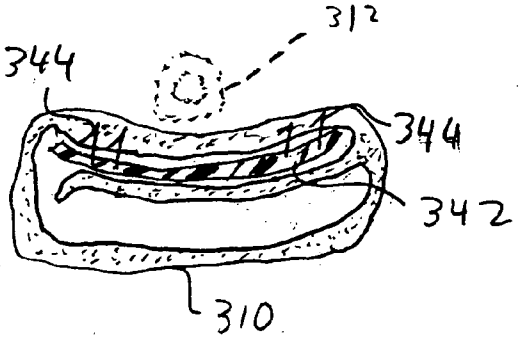



Fig. 32a

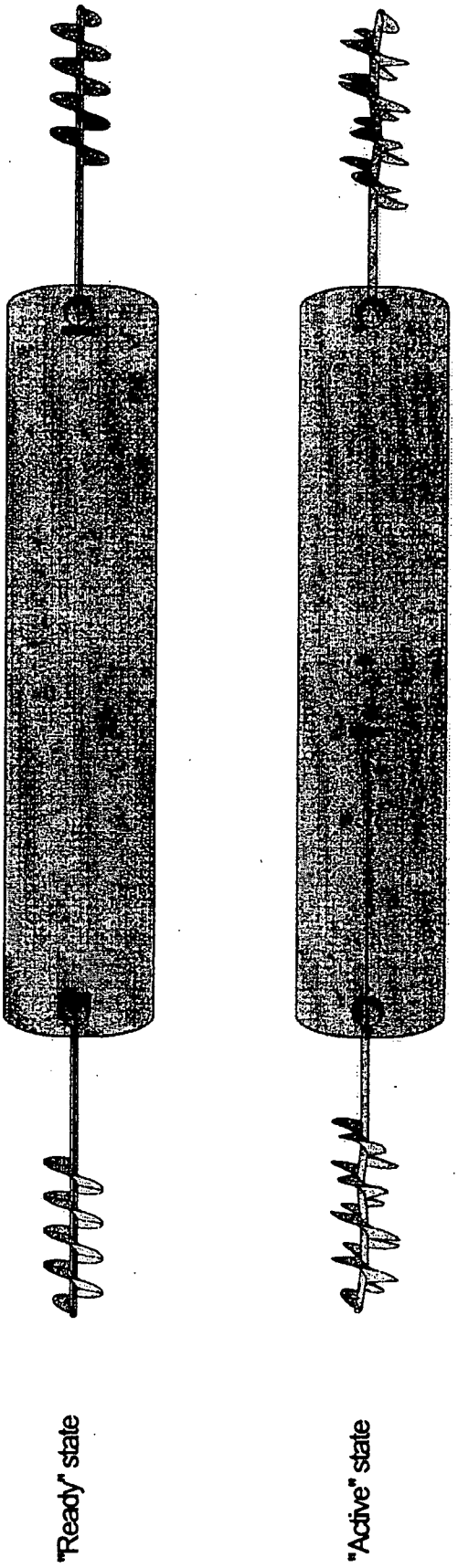



Fig. 33

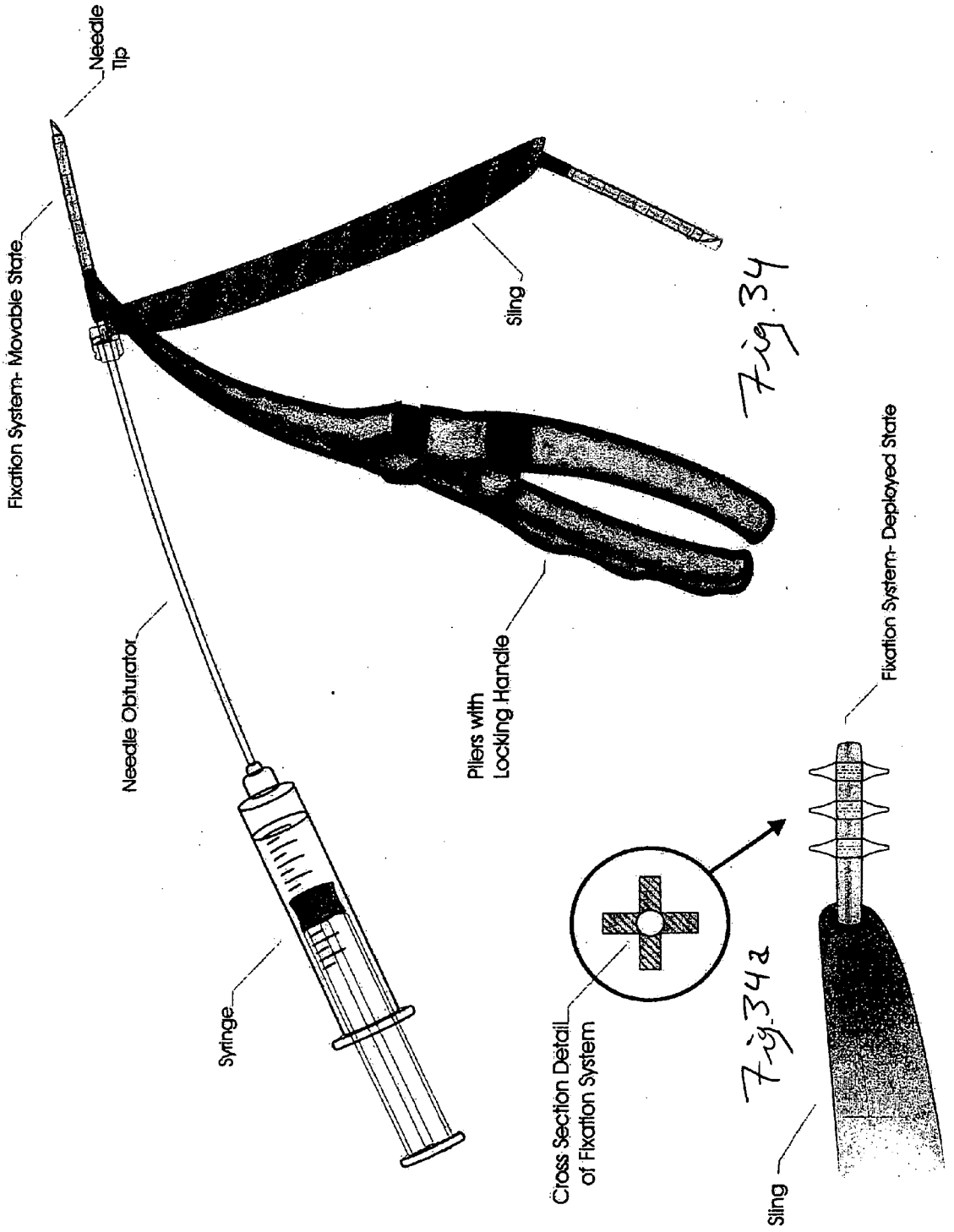



Fig. 34

Fig. 34a

# SYSTEM FOR SECURING SUTURES, GRAFTS AND SOFT TISSUE TO BONE AND PERIOSTEUM

## CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The following patent application is a continuation-in-part of U.S. patent application Ser. No. 10/679,131, entitled SYSTEMS FOR SECURING SUTURES, GRAFTS AND SOFT TISSUE TO BONE AND PERIOSTEUM, filed on Oct. 3, 2003, which is a continuation-in-part of U.S. patent application Ser. No. 10/466,330 entitled SYSTEMS FOR SECURING SUTURES, GRAFTS AND SOFT TISSUE TO BONE A PERIOSTEUM, filed Aug. 23, 2003, which is a continuation-in-part of U.S. patent application Ser. No. 09/733,455 entitled SYSTEM AND METHOD FOR SECURING SUTURES TO BONE AND TISSUE, filed Dec. 8, 2000, which is a continuation-in-part of U.S. patent application Ser. No. 09/197,938 entitled SYSTEMS FOR SECURING SUTURES, GRAFTS AND SOFT TISSUE TO BONE AND PERIOSTEUM, now issued as U.S. Pat. No. 6,200,330, and further relies upon Disclosure Document No. 547,586 entitled Percutaneous Dart, filed Feb. 17, 2004; Disclosure Document No. 463,908 entitled Transvaginal Rectus-Fascia Anchor, filed Oct. 21, 1999; Disclosure Document No. 479243 entitled Adjustable Soft Tissue Attachment Device and System, filed Sep. 5, 2000; Disclosure Document entitled Transvaginal Rectus-Fascia Attachment, filed Mar. 1, 2000, disclosure document number not assigned; Disclosure Document entitled Transvaginal Attachment Delivery Tool, filed on or about Mar. 1, 2000, disclosure document number not assigned; Disclosure Document No. 463,825 entitled Transvaginal Anchor Delivery Tool, filed on Oct. 21, 1999; Disclosure Document No. 458,659 entitled Transvaginal Adjustable System, filed Jul. 6, 1999; and Disclosure Document No. 480,805 entitled Adjustable Suture Soft Tissue Attachment System, filed Oct. 6, 2000, the teachings of all of which are incorporated herein by reference.

## STATEMENT RE: FEDERALLY SPONSORED RESEARCH/DEVELOPMENT

[0002] Not Applicable

## BACKGROUND OF THE INVENTION

[0003] The use of surgical suture anchors for use in attaching soft tissue to bone is well known in the art. In this regard, such anchoring mechanisms have found widespread applicability for a number of surgical procedures, and in particular orthopedic, gynecologic and urologic procedures. Exemplary of such devices include bone screws or anchors that are implantable within bone which further have formed thereon an eyelet or other type of assembly to which may be affixed suture lines or a segment of soft tissue. Exemplary of such devices include those devices disclosed in U.S. Pat. Nos. 5,370,662, and 5,443,482 to Stone, et al. and U.S. Pat. No. 4,738,255 to Gobel, et al.

[0004] Generally, prior art anchor systems take one of two forms. The first configuration typically comprises a self-tapping bone screw, typically made of titanium, having an eyelet formed thereon to which the sutures or other material may be attached. In the alternative prior art configuration, the device comprises an anchor member, which may take the form of an arrowhead or similar conical configuration, which further includes a shaft or attachment member extending therefrom, the latter being formed to have one or more apertures to which the sutures or other material may be attached.

[0005] With respect to the surgical installation of such devices, bone-screw mechanisms must necessarily be screwed in position, typically by a battery-powered screw driver, at a target site upon a particular bone. Anchor devices of the other aforementioned variety typically must be "shot" into position at a particular site within a bone, typically via a spring-loaded delivery mechanism. Exemplary of such bone-anchor insertion devices include the In-Fast and In-Tac bone screw and bone anchor fixation devices previously produced by Influence, Inc. of San Francisco, Calif., now a division of American Medical Systems, Inc.

[0006] Although such prior art anchor devices generally provide sufficient support to the various sutures and grafts affixed thereto, such fixation devices suffer from numerous drawbacks. In this regard, it is difficult for the surgeon to accurately deploy the insertion device such that the anchor is correctly inserted at the target site. Moreover, substantial difficulty arises in removing and adjusting such devices. This latter task is especially problematic with respect to bone-screw devices insofar as the surgeon attempting to remove the same must take great care to insure that the removal device, also typically comprising a battery-powered screw driver, properly unscrews the anchor member from its seated position. Other prior art anchor devices are even further problematic insofar as the same are often irretrievable once deployed, especially in situations where the same are deployed too deeply into the bone mass.

[0007] Additional problems exist with prior art bone fixation systems insofar as the same have a tendency to become dislodged over time from their seated position. In this regard, due to the repetitive application of stress or strain upon the bone anchor via the suture or soft tissue attached thereto, such anchors can eventually become loose and slip out of engagement from their fixed position. This tendency is especially likely to the extent repetitive and persistent application of strain and stress is applied in one specific direction or orientation. In this regard, many fixation techniques are susceptible to failure with misplacement or pull-out of anchors and eventual dislodgement of the structure/graft supported thereby with coughing, vomiting or other violent activity. Moreover, even to the extent such bone anchoring systems remain securely in position, recent study tends to indicate that such bone fixation devices may actually have a tendency to cut the sutures sought to be held thereby.

[0008] Separate and apart from the drawbacks associated with the use of prior art bone anchoring systems is the fact that often times anchor systems provide far more structural support than is necessary for a given surgical application. In this respect, numerous surgical procedures requiring the fixation of sutures and/or soft tissue require only a minimal degree of tension. Exemplary of, and perhaps most well-known of such procedures include pelvic prolapse surgery, also known as colpopexy, colporrhaphy or vaginofixation, and transvaginal sling surgery, the latter of which is performed to treat incontinence. The former procedures typically involve the anchoring of all or a portion of the

prolapsed vagina to adjacent or nearby structures such as the sacrum whereas sling surgery essentially involves the formation of a graft positioned beneath the urethra with the opposed ends thereof being secured to either one of the abdominal fascia, Cooper's ligament or pubic bone. While such slings typically require little to no tension once fixed into position, due to the lack of alternative means for affixing the opposed ends of such sling into position relative to the pubic bone, such prior art bone anchor devices must necessarily be deployed.

[0009] As a result, time spent in surgery is increased and the patient undergoing such procedures in subjected to a far more traumatic experience and has a possibly greater susceptibility of becoming infected by virtue of the deployment of such anchor devices than would otherwise occur to the extent alternative, less traumatic affixation devices could be deployed. Along these lines, a substantial risk exists simply by utilizing a retropubic route to gain access to the surgical site where such sling is affixed into position. In this regard, accessing such surgical site via a retropubic route can increase the risk of bleeding and/or intestinal injury due to the proximity of blood vessels existing within and above the pubocervical fascia and the intestines.

[0010] Accordingly, there is a need in the art for systems, devices and methods for affixing sutures, grafts, soft tissues, synthetic materials, and the like to bone and soft tissue that are easier to deploy, manipulate and can remain more firmly seated into position than prior art devices, especially in the performance of suburethral sling, colporrhaphy and colpopexy procedures. There is additionally a need for such devices that can be utilized in a wide variety of surgical applications and may be further customized for use for particular applications such that an optimal degree of support or leverage can be provided thereby. There is further a need in the art for affixation systems, devices and methods that can provide for means for affixing sutures, grafts, soft tissues, synthetic materials, and the like into position that are less traumatic, easier to deploy and adjust, and may be readily removed and repositioned at a particular site than prior art systems and devices. There is yet additionally a need in the art for systems and methods that, in certain applications, such as urinary incontinence, can easily and readily enable a sling to be surgically deployed and secured into position percutaneously, and especially within the epithelium of a body cavity, such as vaginal epithelium, that can thus enable such procedures to be performed in a medical office setting, as opposed to a surgical center or hospital.

## BRIEF SUMMARY OF THE INVENTION

[0011] The present invention specifically addresses and alleviates the above-identified deficiencies in the art. In this regard, the present invention is directed to novel devices, systems and methods for the attachment of sutures, grafts and other types of tissues and materials to bone, periosteum, ligaments, fascia and other soft tissue as may be warranted in a given surgical procedure. The devices of type present invention are particularly well suited for the secure placement of one or both of the opposed ends of a suburethral sling for use in suburethral sling surgery, but are by no means limited to such particular application.

[0012] In a first preferred embodiment, the invention comprises an implant implantable within bone, ligaments, fascia and other soft tissue at a desired location. The implant comprises a piton portion designed to pierce into and engage with the bone, or tissue, and a support structure coupled therewith, the latter of which may take the form of a post, hook or eyelet to which the suture, graft, or tissue may be attached. The implants of the present invention may further include a handle member formed thereon to facilitate the insertion and removal of the implant from its fixed or seated position within the bone/tissue.

[0013] The piton portion of the implant is specifically designed to become more firmly embedded within the bone or other tissue when pressure is applied to the support structure in a first direction, but may be dislodged or removed when the implant is pulled in an opposed or second direction. The piton member may be further selectively sized and adapted for use in a particular application, and may be particularly designed to penetrate up to certain depths and/or be capable of supporting a specific quantity of mass or weight. In this regard, the implants may be designed to have two or more piton members, that each respectively provide means for securely attaching such implant to a desired side. Such implants may be further configured such that multiple implants may be deployed upon a length of a suture, such that the suture may be selectively pulled and anchored into position along a desired pathway. In this respect, the piton members may be formed such that the same are operative to facilitate movement through tissue in one direction, yet perform an anchoring function in an opposite direction.

[0014] Such embodiment further advantageously allows for post-operative adjustment whereby the suture with piton members attached thereto can be selectively pulled along the desired pathway to the extent necessary to adjust the suture position and/or introduce a greater degree of tension thereto. Along these lines, such embodiment has the additional advantage of being completely removable from the patient's body by virtue of its ability to selectively move through and out of tissue.

[0015] In a second preferred embodiment, the invention comprises a disc anchoring system that is operative to serve as a platform to which sutures, graphs and the like may be secured or, alternatively, serve as a support for forming a suture "bridge". According to one preferred version, the affixation device comprises a disc or anchor plate which is positionable upon a layer to tissue, such as a layer of muscle, fascia, or ligament, and in particular, the rectus fascia layer. The anchoring plate is preferably formed to be generally circular in nature and comprised of an inner plate member encased within an annular outer plate member. The inner and outer plate members are further preferably formed such that at least one, and preferably two, diametrically opposed apertures are formed respectively therein for receiving suture lines insertable therethrough. The inner plate and outer annular member are formed relative one another such that the inner plate is rotational relative the outer annular ring and operative to transition between a first open configuration, wherein said apertures formed upon the respective plates are open to receive suture lines therethrough and a second closed configuration, wherein rotation of the inner plate relative to the annular ring causes the apertures to close and lock, (i.e., crimp) any suture line extending therethrough to become rigidly secured in position. To the extent desired,

those portions of the sutures extending through the anchor plate may be affixed to one another to thus form a bridge or adjoining suture link.

[0016] In an alternative configuration, the disc anchoring system comprises a disc or anchor plate which is likewise positionable upon a layer of tissue (e.g., muscle, fascia, or ligament) that includes at least one, and preferably two to four, channels for receiving suture lines insertable therethrough. The channel or channels are configured such that the same are crimpable such that when the suture line or lines are ideally positioned therein or impart the necessary degree of support to an object (i.e., sling, graft, etc.), the crimping of such channel or channels affixes such length of suture or sutures into position. To achieve that end, it is contemplated that any of a variety of conventional crimping devices may be deployed to impart the necessary crimp in the channel or channels. As per the aforementioned embodiment, to the extent multiple suture lines extend through such plate, the same may be tied, linked, crimped or otherwise joined to one another to form a suture bridge.

[0017] The disc anchoring system may further take the form of a system whereby a suture, having a plurality of protuberances formed therealong, is engageable with an anchor plate, the latter having an aperture formed therein for receiving the suture line. As respective ones of the protuberances extend through and rest against the anchor plate, the suture line may thus be maintained in a fixed position relative a desired target site. Such embodiment advantageously provides for post-operative adjustment should it become necessary to reposition the suture or increase the tension within the suture line secured by the disc anchoring system.

[0018] In all embodiments, the disc anchoring systems are particularly well suited for the use in pubovaginal sling surgery where it is necessary to secure a sling such that the sling extends a desired distance from the urethra or exerts a desired degree of supportive pressure thereto, which thus necessitates that such sling be selectively secured into position via the suture extending through the anchor plate. It will be recognized, however, that such disc anchoring systems may be utilized for a wide variety of medical applications and further, may be formed to be permanently affixed into position or formed from a bio-absorbable material to the extent such anchoring systems need only remain resident for a limited duration. Still further, it is contemplated that each of the aforementioned disc anchoring system may incorporate a load-bearing object, such as a washer, mesh or other like structure, as part of or in conjunction with the disc anchoring system to facilitate the distribution of stress and strain imparted thereto. As with the disc system, such load distributing apparatus may be formed to be permanently secured into position or formed from an absorbable material.

[0019] In a third preferred embodiment, the invention comprises an affixation device designed to secure sutures, grafts, tissues, synthetic materials, and the like to periosteum (i.e., the thick fibrous membrane covering the surface of bones) and other soft tissue. According to a preferred embodiment, the affixation device includes a backing or base member having at least one, and preferably a multiplicity of hook members that are sized and adapted to hook into and ensnare with the periosteum or tissue. The hook members may be specifically designed to become partially embedded within the periosteum tissue, to thus provide relatively loose connection that is easier to remove, or adjust, and may be designed to penetrate deeper within the periosteum tissue to thus provide a more secure method of attachment. An attachment member formed upon the base member is further provided to which may be attached a suture or a portion of a graft.

[0020] In an alternative preferred embodiment, the invention comprises an implantable tack consisting of a hub member having at least one, and preferably two or more hook members formed thereon, the latter being designed to extend through the graft or tissue and become ensnared with and embedded in the periosteum such that the graft or tissue becomes interposed between and affixed into position relative the tack and periosteum. The affixation devices according to such embodiments are specifically designed for selective attachment and detachment, and are further designed to provide more atraumatic means for the attachment of the suture or graft to a target location via the periosteum and soft tissue. Such a fixation device, however, may be adapted such that the same are designed to pierce into and become embedded with the bone, as per the other aforementioned embodiments.

[0021] In yet another embodiment of the present invention, there is provided a novel surgical staple that is also designed to secure a graft or other types of tissues and materials to the bone, periosteum, or other soft tissue at a specific site or location. The staples of the present invention are preferably formed from plastically deformable materials having opposed ends that are designed to penetrate through the graft/tissue and hook into the bone, periosteum or soft tissue at a selected site of fixation. Once secured in position, the staples are operative to assume an expanded configuration such that the hooks formed thereby become more firmly embedded within the bone/tissue at the target site of fixation to thus further secure attachment of the graft thereto. Preferably, such staples may be fabricated from a shape-memory material, such as nitinol, which thus enables the staple to assume the compressed configuration when at room temperature, but transition to the operative, expanded configuration when warmed to body temperature, as will occur when the device is deployed. Such materials further enable the staples of the present invention to be removed, as may be necessary, during a given procedure or later procedures. Conversely, such staples may be formed from material that enable the same to compress or contract once secured into position to thus provide for a more secure means of attachment.

[0022] The present invention further comprises novel surgical approaches for the secure placement of a transvaginal sling during transvaginal sling surgery. More particularly, such surgical procedure involves securing such sling into position, namely, beneath the urethra, with the opposed ends thereof being secured to the posterior portion of the pubic bone, whether it be either the pubic bone itself or the periosteum surrounding the same, in the retropubic space. The opposed ends of the sling may be attached to either the periosteum over the pubic bone or to the pubic bone itself using the novel affixation devices of the present invention. Advantageously, such surgical procedure eliminated the needs to form an abdominal incision, which typically must be made utilizing conventional surgical procedures. The novel affixation method of the present invention during such

surgery further provides for the ingrowth of the opposed ends of the graft to a target site near or on the pubic bone or the periosteum thereabout that eliminates any intervening pelvic fascia that would otherwise become interposed between the anchor and opposed ends of the sling sought to be secured into position.

[0023] As an alternative to the aforementioned approaches, the present invention further comprises novel systems and surgical techniques that can deploy anchoring systems for the placement of radio opaque markers, such as the TINED lead system of radio opaque markers produced by Medtronic, Inc., and pelvic floor reconstruction for support of pelvic organs, such as through the use of slings affixed thereto, that are fixed into position via trans-obturator placement, as opposed to conventional retropubic surgical placement. Such surgical techniques, devices and systems utilized therewith are positioned utilizing a single percutaneous incision made in the vaginal epithelium which enables a sling to be anchored into position in a target tissue, such as rectus and/or pubocervical fascia, via sling placement toward or through the obturator foramen. To achieve that end, there is preferably provided a deployment system operative to selectively deploy and securely place into position a self-anchoring sling comprised of an elongate sling having opposed ends. Formed on each opposed end of such sling are dedicated anchor mechanisms that are each operative to penetrate into and become embedded within a target site of soft tissue, such as the obturator membrane situated within or around the obturator foramen.

[0024] Each respective anchor mechanism is operatively configured such that each anchor mechanism is advanceable in a first direction through the soft tissue at the target site but selectively adjustable to resist movement in an opposed direction, (i.e., such anchor mechanisms are configured such that the opposed ends of the sling are capable of being advanced in opposed directions but resisting or preventing contraction or other similar type of motion drawing the ends towards one another). To facilitate such movement, it is contemplated that the anchor mechanisms may take the form of screws, arrowheads, prongs, and in particular generally Y-shaped or chevron shaped prongs, or any other structure that is capable of being advanced in one direction yet resists or is biased against movement in an opposed direction. In further refinements such anchor mechanisms may further be selectively configured to penetrate to a desired depth within a tissue mass, as well as may be selectively configured to assume a first compressed or deployment configuration such that the same will be operative to be positioned within a specific target site, and a second operative configuration whereby the anchor mechanism expands or otherwise assumes a locking configuration that enables the anchor to become affixed into position. In this regard, it is contemplated that the anchor mechanism may be formed to have an outwardly expanding spring bias such that once released from a confined position automatically expands or anchors in an automatic fashion.

[0025] With respect to the deployment of such slings, it is contemplated that the same will be deployed through a manually operable deployment mechanism. Preferably, such deployment mechanism will include a handle having a deployment member extending distally therefrom. With respect to the latter, the deployment member will preferably be configured for insertion through and under the vaginal wall to thus enable the slings with anchor mechanisms formed thereon to be deployed via a trans-obturator or other route. To facilitate that end, it is contemplated that the deployment member may be provided with a sharpened distal end capable of forming an incision within the vagina and thereafter be extensable under the vaginal wall to thus deploy the slings of the aforementioned variety within or near the obturator foramen. In use, the sling having the anchoring mechanisms formed upon the opposed ends thereof will be coupled to or mounted upon the deployment member such that a respective one of the anchor mechanisms can be positioned by the deployment member at a specified site within the target tissue (e.g., the pubocervical fascia or within the obturator foramen). In this regard, it is contemplated that the deployment member may be configured such that the anchor mechanisms will be deployed in a sequential manner such that a first anchor is deployed in one target site and the other opposed anchor member deployed at a second site such that the sling disposed intermediate the anchor members can be selectively positioned to provide an optimal degree of support to the urethra. In order to manipulate such device, it is contemplated that the deployment system will include an actuation member that enables the surgeon to manually direct the advancement of the anchor mechanism coupled with or mounted upon the deployment member of the mechanism to thus enable the self-anchoring sling to be controllably fixed into position. To facilitate such placement, it is contemplated that the deployment member may be selectively curved or shaped to gain access more readily within a particular anatomical site, such as the obturator foramen.

[0026] There is further disclosed herein novel systems and surgical techniques that advantageously allows for the percutaneous deployment of a sling, to thus provide for very rapid, secure and atraumatic sling placement. In the first of two such preferred techniques, an elongate implant or sling having opposed ends with anchoring mechanisms formed thereon, which may comprise any of the aforementioned variety that are operative to assume an insertion configuration and anchoring configuration, is surgically implanted by merely deploying the anchoring mechanisms percutaneously with the sling portion extending externally across from the respect points at which the opposed ends are percutaneously anchored. In one specific application, particularly well suited for the treatment of urinary incontinence, the anchoring mechanisms formed upon opposed ends of such sling will each be percutaneously driven through a target site within the vaginal wall anchored within a mass of soft tissue, such as into the obturator foramen. In this respect, the anchoring mechanisms will be percutaneously driven across the upper vaginal wall such that the sling portion extends thereacross and in a generally perpendicular orientation relative to the urethra, extending thereabove. Such externally extending portions of the sling will be operative to provide the necessary degree of urethral support. Advantageously, however, such sling need only extend across the external surface of the vaginal wall and need not be surgically embedded, as per prior art surgical techniques. Presently, it is contemplated that such externally extending sling portion will eventually be completely or partially encompassed by tissue ingrowth and thus safely remain implanted within the patient. Alternatively, it is contemplated that such sling may be caused to erode through the epithelium more rapidly into place, such as through electrocauterization The

sling may also be treated with a suitable antimicrobial agent to ensure that the same minimizes the risk of infection.

[0027] In a second preferred embodiment of such novel percutaneous surgical technique, a sling-like implant or support is provided having opposed ends, the latter having one or more anchor mechanisms formed on the opposed ends thereof, that are designed to be placed either under the vaginal epithelium or over the epitheleium and allowed to erode or pass therethrough. With respect to the latter two, such process can be facilitated by the application of an electrocauterizing current, radiofrequency energy or any other treatment known in the art that will facilitate the penetration or ingrowth of such strip. As per the aforementioned embodiment, such suburethral strip is deployed and anchored into position percutaneously, thus eliminating the need to surgically implant the sling internally and in closer proximity to the urethra. In this second embodiment, the ends of the sling containing the anchors can be pulled out from the tissue and moved if initial adjustment becomes necessary.

[0028] Such novel percutaneous surgical techniques and systems utilized therewith are further believed to be operative for any of a variety of conditions, such as prolapse In this regard, any type of surgical procedure whereby a sling or fixation system is deployed to support a given anatomical structure, that utilizes one or more anchoring mechanisms that can be percutaneously secured into position with the sling portion providing the necessary support extending externally from such percutaneous anchoring sites, can be deemed to fall within the scope of the present invention.

[0029] Related to the foregoing techniques and further encompassed within the scope of the present invention are surgical techniques, slings and anchoring devices for performing vaginal reconstruction surgery, such as vaginal prolapse surgery. According to such technique, the prolapsed vagina in inverted such that the same attains its proper anatomical orientation and, as per the aforementioned technique regarding the deployment of anchoring mechanisms within the obturator foramen, at least one, and preferably an opposed pair of anchoring mechanisms are deployed through the vaginal wall and into the obturator foramen, thus causing the vaginal wall to remain anchored in its proper anatomic orientation. To that end, it is contemplated that the anchoring mechanisms are operative to penetrate into and become embedded within a target site of soft tissue within or around the obturator foramen in a second platform or mesh portion which remains embedded or compressed against the vaginal wall to thus support and retain such structure into position. To facilitate that end, it is contemplated that such anchor members will include a platform surface formed from mesh or other like material to thus provide sufficient surface area to support the vaginal wall into proper positioning.

[0030] It is therefore an object of the present invention to provide surgical implantation devices to facilitate the attachment of sutures, grafts, tissues and the like to bone, periosteum and soft tissue that are easier to implant and remove than prior art devices, and are further capable of providing greater support or leverage to the structures coupled therewith than prior art devices.

[0031] Another object of the present invention is to provide surgical implantation devices for the attachment of sutures, grafts, tissues and the like to bone, periosteum and soft tissue that can be utilized in a wide variety of surgical procedures, and in particular colpopexy, colporrhaphy, suburethral sling or other pelvic support surgery, and that may be further designed to provide an optimal degree of support for a given quantity of mass or weight as may be necessary for a given surgical procedure.

[0032] Another object of the present invention is to provide devices for the affixation of sutures, grafts, tissues and the like to periosteum and soft tissue at a specific site or location that does not require any anchoring mechanism to be inserted into the bone.

[0033] Another object of the present invention is to provide devices for the attachment of sutures, grafts, tissues and the like to bone, periosteum and soft tissue at a specific location that are less traumatic than other prior art affixation devices.

[0034] Another object of the present invention is to provide devices for the attachment of sutures, grafts, tissues and the like to bone periosteum and soft tissue at a specific location that are easily attachable to and detachable from a point of fixation than prior art devices and re-attachable as may be necessary for a given procedure or future procedures.

[0035] Still further objects of the invention include methods and devices for securing sutures, grafts, tissues and the like to bone, periosteum and soft tissue that are of simple construction, may be easily and readily utilized for a variety of surgical procedures, may be readily adapted for use in a wide variety of surgical procedures, and provide an equal, if not greater degree of support or leverage than prior art devices.

[0036] Another object of the present invention is to provide a self-anchoring sling that enables the sling to be securely affixed into position within a site of soft tissue such that the same resists sag or otherwise lessens its ability to provide support that can further preferably be deployed via a trans-obturator route, and preferably via a system and method that enables the same to be deployed via a single access route, such as a single vaginal incision, to thus eliminate risks associated with sling delivery via a retropubic route.

[0037] Another object of the present invention to provide a novel surgical procedure for the formation and affixation of a suburethral sling whereby the opposed ends of the sling are secured near or at the posterior side of the pubic bone in the retropubic space with the opposed ends of the sling being secured to either the periosteum, Cooper's ligament, fascia or the pubic bone itself.

[0038] It is another object of the present invention to provide a novel surgical procedure for performing vaginal prolapse surgery, as well as provide devices for performing vaginofixation such that the vagina is surgically positioned according to its proper physiological orientation by anchoring the same in or around a target site of soft tissue, preferably situated at or near the obturator foramen.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0039] These, as well as other features of the present invention will become more apparent upon reference to the drawings wherein:

[0040] **FIG. 1** is a frontal, cross-sectional view of the rectus fascia, pubic bone, urethra and vagina further depicting a sling member positioned about the urethra or in which the respective ones of opposed ends of the sling are secured to the pubic bone.

[0041] **FIG. 2** is a side cross-sectional view of the anatomical structures depicted in **FIG. 1** and further depicting the fastening arrangement by which the sling is anchored to the posterior portion of the pubic bone.

[0042] **FIG. 3** is a prior art surgical instrument utilized to secure the anchor member depicted in **FIG. 2** to the posterior of the pubic bone.

[0043] **FIG. 4** is a cross-sectional view of the pubic bone having a prior art anchor device secured thereto.

[0044] **FIGS. 5***a* and **5***b* are perspective views of prior art anchor devices.

[0045] **FIG. 6** and **6***a* are a perspective view of a surgical implant constructed in accordance with a preferred embodiment of the present invention for use in attaching sutures, grafts, tissues and the like to bone, periosteum, and soft tissue, and a side view of the same being inserted into bone.

[0046] **FIG. 7***a* is a perspective view of a surgical implant constructed in accordance with a second preferred embodiment of the present invention for use in attaching sutures, grafts, tissues and the like to bone, periosteum, and soft tissue. Such figure depicts the surgical implant assuming a pre-insertion configuration.

[0047] **FIG. 7***b* is a perspective view of the surgical implant of **FIG. 7***a* with the implant assuming an expanded, anchoring configuration.

[0048] **FIG. 8** is a perspective view of a surgical implant constructed in accordance with a third preferred embodiment of the present invention for use in attaching sutures, grafts, tissues and the like to bone, periosteum, and soft tissue.

[0049] **FIG. 9** is a cross-sectional view of the pubic bone and periosteum thereof having an affixation device affixed with the latter, said affixation device being constructed in accordance with a fourth preferred embodiment of the present invention useful for securing sutures, grafts, tissues and the like to bone, periosteum and soft tissue.

[0050] **FIG. 10** is a perspective view of the affixation device depicted in **FIG. 9**.

[0051] **FIG. 11** is a cross-sectional view of the pubic bone and periosteum formed thereabout having an opposed end of a graft being secured thereto with an implantable tack, the latter being constructed in accordance with a fifth preferred embodiment of the present invention.

[0052] **FIG. 12** is a cross-sectional view of the pubic bone and periosteum formed thereabout showing the graft depicted in **FIG. 11** being secured thereto via the implantable tack.

[0053] **FIG. 13** is a frontal view of the graft depicted in **FIGS. 11 and 12** as secured to the periosteum via the implantable tack of the present invention.

[0054] **FIG. 14** is a cross-sectional view further depicting an expanded view of the pubic bone with periosteum formed thereabout having an opposed end of the surgical sling affixed to the periosteum via a surgical staple, the latter being constructed in accordance with a sixth preferred embodiment of the present invention, the staple assuming a first insertion mode.

[0055] **FIG. 15** is a side-view depicting the surgical staple depicted in **FIG. 14** securing an opposed end of the sling to the periosteum, the staple assuming a second, affixation configuration.

[0056] **FIG. 16** is a cross-sectional view of a suture having a plurality of affixation devices secured thereto, the latter constructed in accordance with a preferred embodiment of the present invention, for use in securing the suture along a desired pathway through tissue.

[0057] **FIG. 16***a* is a perspective side view of **FIG. 16**.

[0058] **FIG. 17** is a frontal, partially cross-sectional view of a sling being secured beneath a urethra and selectively secured into position to layers of muscle/rectus fascia via an anchoring plate fixation device as constructed in accordance to a preferred embodiment of the present invention.

[0059] **FIGS. 17***a* and **17***b* are top views of the fixation device utilized in **FIG. 17**, the fixation device being shown in a first operative configuration in a second locking or closed configuration.

[0060] **FIG. 18** is a perspective view of an anchoring system constructed in accordance with another preferred embodiment of the present invention.

[0061] **FIG. 19** is a perspective view of an anchoring system constructed in accordance with another preferred embodiment of the present invention.

[0062] **FIG. 19***a* is a partial cross-sectional view of the system depicted in **FIG. 19** shown with a suture line extending through a channel defined thereby.

[0063] **FIG. 19***b* is the cross-sectional view of **FIG. 19***a* wherein the channel of said anchoring system is shown in a crimped configuration, the crimp maintaining the suture disposed within the channel in fixed position.

[0064] **FIG. 19***c* is a cross-sectional view of the anchoring system depicted in **FIG. 19** with one channel extending therethrough, said channel having two suture lines extended therethrough.

[0065] **FIG. 20** is a perspective view of a sling deployment system comprised of a self-anchoring sling member comprised of an elongate sling having anchoring mechanisms formed on the opposed sides thereof, a respective one of the anchoring mechanisms being coupled with a manually operable sling deployment mechanism constructed in accordance with a preferred embodiment of the present invention.

[0066] **FIG. 20***a* is a perspective view of the sling member depicted in **FIG. 20**.

[0067] **FIG. 20***b* is a perspective view of the sling deployment mechanism depicted in **FIG. 10**.

[0068] **FIG. 21** is a perspective illustration of the sling deployment system and components thereof as depicted in **FIGS. 20, 20***a* and **20***b* wherein a respective anchor mechanism of the sling component is advanced into an incision made in a vaginal wall.

[0069] **FIG. 22** is a perspective view of the self-anchoring sling depicted in FIGS. **20, 20**(*a*) and **21** as positioned within the obturator foramen and operative to support the patient's urethra.

[0070] **FIG. 22***a* is a perspective view of an embodiment anchoring mechanism as incorporated within the self-anchoring slings of the present invention as constructed in accordance with a preferred embodiment.

[0071] **FIG. 22***b* is a perspective view of an embodiment anchoring mechanism as incorporated within the self-anchoring slings of the present invention as constructed in accordance with another preferred embodiment.

[0072] **FIG. 22***c* is a screw-type anchor for use with the self-anchoring slings of the present invention as constructed in accordance with yet a further preferred embodiment.

[0073] **FIG. 23** is a frontal view of a prolapsed vagina and the positioning of the obturator foramen relative thereto.

[0074] **FIG. 24** depicts the vaginofixation of the prolapsed vagina in **FIG. 23** utilizing a fixation device constructed in accordance with a preferred embodiment of the present invention.

[0075] **FIG. 25** is an enlarged perspective view of the fixation device depicted in **FIG. 24**.

[0076] **FIG. 26** is a perspective view of the fixation device of **FIG. 25** as constructed in accordance with an alternative preferred embodiment of the present invention.

[0077] **FIG. 27** is a perspective view of a percutaneously deployed sling for use in supporting the urethra for purposes of treating incontinence whereby the sling is delivered and deployed within the vagina.

[0078] **FIG. 28** is a perspective view of the sling of **FIG. 27** wherein one end of the sling is shown percutaneously anchored within the obturator foramen through the vaginal wall.

[0079] **FIG. 29** is a perspective view of the sling of **FIGS. 27 and 28** wherein each respective end of the sling is percutaneously secured to the obturator foreman with the sling positioned across the vaginal wall and underneath the urethra.

[0080] **FIG. 30** is a side perspective view of a preferred percutaneous anchoring mechanism for percutaneously securing an end of a sling depicted in **FIGS. 27-29** wherein the anchor is shown positioned within the lumen of a needle or cylinder and assuming a first compressed configuration.

[0081] **FIG. 31** is a side perspective view of the anchoring mechanism of **FIG. 30** wherein said anchoring mechanism is shown delivered through the lumen of the needle or over the needle and assuming a second anchoring configuration.

[0082] **FIG. 32** is a perspective view of a suburethral support shown deployed within and anchored to the vaginal wall and operative to support the urethra extending thereabove.

[0083] **FIG. 32***a* is a perspective view of the suburethral support of **FIG. 31** shown under the vaginal epithelium to provide support to the urethra extending thereover.

[0084] **FIG. 33** is a top perspective view of a sling having preferred anchoring mechanisms formed thereon shown with the anchoring mechanisms assuming a first insertion or ready state and a second anchoring or active state.

[0085] **FIG. 34** is a perspective view of a syringe shown deploying a sling, the latter having anchoring mechanisms formed thereon one of which is mounted atop the distal end of the needle in a first insertion configuration and also shown in a second deployed state, an enlarged view of which is shown in **FIG. 34***a*.

## DETAILED DESCRIPTION OF THE INVENTION

[0086] The detailed description as set forth below in connection with the appended drawings is intended as a description of the presently preferred embodiments of the invention, and is not intended to represent the only form in which the present invention may be constructed or utilized. The description sets forth the functions and sequences of steps for constructing and operating the invention in connection with the illustrated embodiments. It is understood, however, that the same or equivalent functions and sequences may be accomplished by different embodiments and that they are also intended to be encompassed within the scope of this invention.

[0087] Referring now to the drawings, and particularly **FIGS. 6-15**. there are shown various embodiments of the devices and systems of the present invention for securing sutures, grafts, tissues and synthetic materials, and the like to bone, periosteum and other soft tissue. As is well known in the practice of medicine, a wide variety of surgical procedures often necessitate the use of anchoring devices for purposes of attaching suture lines and grafts to bone. Exemplary of such anchoring devices include those disclosed in U.S. Pat. Registration Nos. 5,370,662 and 5,443,482, the teachings of which are expressly incorporated herein by reference as frequently deployed in orthopedic, gynecologic, and urologic surgical procedures.

[0088] Among the more well-known surgical procedures incorporating the use of such anchoring devices include transvaginal sling surgery. As illustrated in **FIGS. 1 and 2**, such surgical procedure **10** involves the formation of a sling **12**, which may comprise a harvested graft from a donor, or the patient's own tissue or an elongate strip of fabricated synthetic material or some combination thereof, that is introduced via an opening made to the vaginal wall **14** selectively positioned beneath the urethra **16**. Once properly positioned, the sling **12** is secured into position. Unlike conventional transvaginal sling surgery, however, the sling **12** as depicted in **FIGS. 1 and 2** is secured within the retropubic space via an anchoring mechanism **20**, more clearly depicted in **FIG. 2**. As will be appreciated by those skilled in the art, the method by which the opposed ends **12***a*, **12***b* of the sling **12** are secured, namely to the posterior side of the pubic bone **18**, represents a novel approach insofar as such sling **12** is stitched into position in the retropubic space **22**, as opposed to the suprapubic space which is conventionally utilized. Unlike alternative methods of performing suburethral sling procedures, such transvaginal sling surgi-

cal procedure advantageously dispenses with the need to form an incision in the patient's lower abdomen **24** to thus enable the surgeon to gain access to the various anatomical structures, such as the abdominal fascia, pubic bone, or Cooper's ligament, to which the opposed ends of such sling are to be attached. As is well known, performing such abdominal incision increases operative time, increases the chances of infection, delays recovery time, and leaves undesirable scarring. Moreover, such sling procedure as depicted does not require that the sutures or opposed ends of the grafts be caused to penetrate through the intervening pubocervical fascia **28**, depicted in **FIG. 1**, present in the retropubic space **22** which, as will be appreciated by those skilled in the art, prevents ingrowth of the opposed ends **12***a*, **12***b* of the sling **12** sought to be secured in position.

[**0089**] As a result of the support imparted by the sling **12** to the urethra **16** during such times as the patient makes provocative gestures, as occurs during coughing, such sling **12** serves as support that prevents incontinence occurring during such provocative event. To insure that the sling **12** is positioned such that the same imparts an optimal degree of support to the urethra **16**, it is contemplated that a tension/pressure monitor **26**, as depicted in **FIG. 1**, may be utilized during the performance of such surgical procedure. Such tension/pressure monitors **26** may take any of a variety of forms such as those disclosed in Applicant's co-pending U.S. patent application Ser. No. 09/157,466, the teachings of which are expressly incorporated herein by reference.

[**0090**] In order to provide an anchoring mechanism necessary to secure the sling into position during transvaginal sling procedures, however, there must be deployed the aforementioned anchoring device **20**. As depicted in **FIG. 3**, there is shown one such anchor deployment device **30**, also known in the practice of medicine as a bone screw inserter, which allows for bone-screw fixation. Perhaps the most well-known of such devices include the In-Fast and In-Tac bone screw and bone anchor fixation devices previously produced by Influence, Inc. of San Francisco, Calif. Such affixation devices are formed to have a generally "U" shape as shown that enables the distal-most end **32** thereof to be easily inserted into the vagina and be correctly positioned on the posterior portion of the pubic bone. As will be appreciated by those skilled in the art, the distal-most end **32** of such fixation deployment devices **30** are designed to deploy an anchoring device by screwing or embedding the same into bone at a specific site.

[**0091**] As more clearly seen in **FIG. 4**, once deployed, the anchor devices **34** are advanced through the periosteum **36** and become embedded into the bone. To provide means for affixing the suture lines or grafts thereto, there is typically formed on the anchor devices a post, hook or eyelet, as shown. Among the more well-known designs of such anchoring devices currently in use include those depicted in **FIGS. 5***a* and **5***b*. The first such prior art device **34** depicted in **FIG. 5***a* comprises a self-tapping bone screw **40**, typically made of titanium, having an eyelet **42** formed thereon to which the sutures **44** or other material may be attached, as shown in **FIG. 4**. In the alternative prior art configuration **50** depicted in **FIG. 5***b*, the anchor fixation device comprises an anchor portion **52**, which may take the form of a conical member having a shaft or attachment member **54** extending therefrom, the latter being formed to have one or more apertures **56** thereon to which sutures **58** or other material may be attached. Such devices are typically "shot" into position via spring-loaded insertion devices, such as the In-Tac device discussed above.

[**0092**] Although such prior art anchor devices, such as those depicted in **FIGS. 5***a* and **5***b*, generally provide sufficient support to the various sutures and grafts affixed thereto, such fixation devices **34**, **50** suffer from numerous drawbacks. With respect to the bone-screw fixation devices **34**, such devices are difficult to deploy and fix into position. In this regard, such screw fixation devices **34** require the battery-operated inserters **30** depicted in **FIG. 3** that must necessarily drill the fixation device **34** into position. Removing such devices **34** is further problematic insofar as the same must necessarily be unscrewed from their position, which as those skilled in the art will appreciate requires meticulous precision.

[**0093**] Anchor devices **50** are also problematic insofar as the same are not only difficult to deploy, typically via a spring-loaded gun mechanism, but are often times irretrievable once deployed. In this regard, once such fixation device **50** is sufficiently embedded within the bone, the anchor portion **52** thereof cannot be reversibly extracted from its embedded position within the bone. As such, to the extent such anchoring devices **50** have been inappropriately deployed (e.g., deployed at a wrong location), there is little, if any, recourse to retrieve the same. Additionally, such prior art bone screws **34** and anchors **50** have the ability to become loosened and dislodged from their position once a sufficient amount of pressure is applied thereto over time. The probability of becoming dislodged is further increased in those situations where a persistent strain is applied to such devices in a single direction, as can occur when a suture or graft is hung upon the anchoring device. In such circumstances, surgical intervention is necessary to not only retrieve the dislodged screw or anchor, but also deploy yet another of such devices as per the original surgical procedure.

[**0094**] Referring now to **FIGS. 6-8**, there are shown three embodiments **60**, **70**, **80** of a surgical implant insertable into bone (as well as periosteum, ligaments, and other soft tissue) which are useful in providing means to secure sutures, grafts, tissues, synthetic materials, and the like to bone, as may be necessary for a given surgical procedure. Each of the embodiments depicted have the advantage of being easy to insert and remove, as well as provide an equal, if not greater, degree of support than prior art devices. Such novel implants further have the ability to remain more firmly seated into position once embedded in bone than such prior art devices.

[**0095**] Referring now to **FIG. 6**, there is shown a first embodiment **60** of the surgical implant. As illustrated, the implant **60** comprises a piton member **62** having an eyelet **64** formed thereon. The piton member **62** preferably comprises an arcuate blade having proximal and distal ends, the latter being designed to be inserted into bone such that as the same is advanced therein, there is defined a penetration pathway as indicated by the latter "A". Once inserted into the bone tissue at the target site of fixation, the eyelet portion **64** of the implant will extend therefrom as illustrated in **FIG. 6***a*, which will thus provide the necessary structure to which the sutures **66**, grafts and the like may be attached. Although the embodiment shown depicts the use of an eyelet **64**, it will be recognized that other substitute support or attachment struc-

tures, such as posts, hooks and the like, including even sledged-on fixation of the suture or graft to the piton, may be utilized as may be necessary for a given application.

[0096] As will be appreciated by those skilled in the art, by inserting the implant in the direction indicated by the letter "A", it will be appreciated that to the extent a force is applied thereto, such as by suture **60** or graft, via a vector having an orientation in the general direction of letter "B", such force will necessarily cause the implant to wedge deeper and become more secure into position within the bone **38**, and will thus cause the same to become more rigidly affixed into position unlike prior art devices which have a tendency to become loose and potentially dislodged with the application of greater amounts of pressure and strain thereto.

[0097] Such implant further provides the advantage of being easy to remove. In this regard, due to its orientation within the bone, to the extent a pulling force is applied to the implant in the direction indicated by the letter "C", such implant **60** will be caused to become easily dislodged from its seated position to the extent it becomes necessary to remove and/or reposition such implantable fixation device. Such ease of removal advantageously provides for a simpler, less traumatic procedure than those procedures involving prior art screw and anchor fixation devices.

[0098] Referring now to **FIGS. 7***a* and **7***b,* there is shown a second embodiment **70** of a surgical implant designed to be embedded within bone or soft tissue to which may be attached sutures, grafts and the like. Such embodiment **50**, similar to the embodiment **60** depicted in **FIG. 6**, is specifically designed such that the same becomes more firmly seated into position within the bone to the extent a force is applied in a first direction, as indicated by the letter "D". **FIG. 7***a* depicts the surgical implant **70** assuming an insertion configuration which enables the same to be implanted into bone at a target site selected by the surgeon. Such implant is provided with a piton member **72** having opposed flanges **72***a,* **72***b* formed at the distal end thereof that are designed to spread apart in the directions "Y" and "Z" and become more deeply embedded within the bone to the extent a pressure is applied in a direction indicated by the letter "D". Although the specific embodiment **70** shown depicts that the opposed flanges **72***a,* **72***b* flare outwardly, it is to be understood that such flanges can be designed to curve inwardly. Moreover, although such embodiment depicts two opposed flanges, it should be recognized that such implant may have three or more flanges and that each respective flange may be designed to flare outwardly, as shown, or hook inwardly as may be needed to a specific application.

[0099] Once firmly embedded within the bone, the eyelet portion **74** of such implant may be utilized to attach sutures and the like. Of additional advantage, similar to the embodiment shown in **FIG. 6**, is the fact that such implant **70** may further be easily removed to the extent a pulling or opposed force is applied in the direction indicated by the letter "E". As such, to the extent it becomes necessary to remove or otherwise reposition such anchoring device, such anchoring device **70** may be easily dislodged by application of such force. As will be appreciated, such design allows for easier and less traumatic removal than prior art anchor and screw fixation devices.

[0100] Referring now to **FIG. 8**, there is shown a third embodiment **80** of a surgical tissue implant useful as a fixation device to attach sutures, tissues, and grafts to bone, periosteum, and soft tissue. As per the other embodiments, such implant **80** includes a piton member **82**, preferably formed as a sickle-shaped member, having an eyelet **84** formed on the proximal end thereof. Such implant **80** is designed to be embedded into the bone or other tissue in the direction indicated by the letter "F". Once so secured into position, forces may be applied thereto, via eyelet **84** in the direction indicate by the letter "G", which will thus work to further embed the piton member **82** into the bone via the penetration pathway defined by the distal end of the piton member **82** so that the implant becomes more secure therewithin. Likewise, to the extent it becomes necessary to remove such device **80**, such device may be removed by pulling or otherwise rearwardly retracting the implant in the direction indicated by the letter "H" which, as discussed in the other embodiments, provides for simpler and less traumatic procedure than prior art methodology.

[0101] Although each of the aforementioned embodiments **60, 70, 80** are particularly well-suited for insertion into bone, it should be recognized by those skilled in the art that the same may be utilized to affix sutures, grafts, tissues, synthetic materials and the like to connective tissue, and in particular, periosteum as per the further embodiments discussed more fully below. In this respect, each of the aforementioned embodiments **60, 70, 80** may be designed such that the piton portion thereof pierces into and becomes embedded within such tissue and remains firmly seated thereat so that the attachment mechanism formed thereon can provide a service to which the sutures, grafts and the like may be attached.

[0102] As will further be appreciated, in each of the embodiments **60, 70, 80** depicted in **FIGS. 6-8**, the orientation of each of the implants as the same are embedded into the bone or tissue is crucial for the necessary operation thereof. In this regard, it will be appreciated that the implant must be oriented such that the resultant tension or strain applied thereto will cause the piton portion thereof to advance in the penetration pathway defined thereby. Otherwise, to the extent tension is applied in an opposed direction, such implant may be caused to dislodge from its seated position. As a consequence, it will be appreciated that the implants of the present invention must be selectively positioned, and that the surgeon must take great care in making certain that the ultimate tension applied thereto is oriented to facilitate the attachment of the implant to the bone, as opposed to casing the same to become dislodged therefrom.

[0103] Referring now to drawings **16** and **16***a,* there is shown an additional surgical tissue implant **500** useful as a fixation mechanism to attach sutures, tissues, and grafts to soft tissue. In the embodiment depicted, which is shown being deployed for use in securing a sling **502** into position to provide support to a urethra **504**, the implant **500** comprises a plurality of dual-prong anchoring mechanisms **506** disposed linearly about a suture-like cord or line **508**, which enables such line to advance through the tissue in one direction, but resists rearward movement in the opposite direction. As shown, the implants can be configured to have a generally V-orientation such that the suture **508** bisects such implant and extends therethrough. As will be recognized, each respective implant will have an eyelet or other aperture through which the suture, which may be a suture line or suture-like cord, may be extended. As will be further

recognized, although depicted as having a generally V-orientation, it will be appreciated that the anchoring mechanisms **506** may be arranged in a staggered configuration, extend along only one side of the suture **508**, or otherwise be radially disposed about a length of the suture **508**. Accordingly, it will be recognized that numerous other designs are contemplated that fall within the scope of the present invention.

[**0104**] By linearly disposing the implants along the suture line, the suture line may be advanced in a direction indicated by the letter "X", but yet resist movement in the direction indicated by the letter "Y". Advantageously, such arrangement enables the suture line **508** to be pulled into a desired position such that the sling **502** supported thereby can be caused to provide a selective degree of support to the urethra **504** or otherwise maintain a desired distance therefrom. Furthermore, to the extent the suture line **508** with implants **506** or the sling **502** supported thereby are inappropriately positioned, it will be recognized by those skilled in the art that, if necessary, the suture line **508** can be cut and the suture with implants affixed thereto extracted completely from the patient's body (and replaced, if necessary or desired). Such design further advantageously permits for the adjustment of the suture line and/or the sling supported thereby not only intro-operatively, but also post-operatively insofar as the suture line **508** can be extended further, for example, in the direction indicated by the letter "X", as may be desired to the extent it is necessary to add extra tension to the suture line **508**. Moreover, as discussed above, the suture line **508** can be removed entirely from a patient's body. In such circumstances, a second suture line **508** having such implants attached can be substituted in its place.

[**0105**] An example of the application of such system is illustrated in the side-perspective view of **FIG. 16***a*. As illustrated, the sling **502** is positioned about the urethra **504** and supported upwardly by the suture-like cord **508** having the fixation devices **506** linearly disposed upon the length thereof. In this regard, each respective suture, cord, etc. **508** supporting each respective side of the sling **502** may be selectively caused to remain securely embedded at a desired position within the rectus fascia **510** or other soft tissue. As will be appreciated by those skilled in the art, due to the ability of the suture lines or suture-like cords **508** with the novel implant fixation devices **506** affixed thereto, the surgeon can incrementally increase the pressure exerted by the sling **502** against the urethra **504** or the distance by which the sling **502** extends from the urethra **504** merely by incrementally advancing the suture line/cord **508** through the rectus fascia **510**. As will be appreciated, there has not heretofore been available any mechanism available which provides a surgeon with the ability to merely advance a suture through tissue and have the same remain firmly secured into position. Rather, and as discussed more fully in the background, surgeons have had to identify a target site to which such sling can be anchored and thereafter tie the same into position such that the sling maintains the desired degree of support or distance from the urethra. As is widely recognized, malposition of the sling has been deemed the cause for creating a significant problem and substantially high morbidity for those patients having undergone sling surgery.

[**0106**] In a similar, yet further advanced variation of the embodiment depicted in **FIGS. 16 and 16***a*, there is shown in **FIGS. 20-22***c* a system **800** comprised of the combination of a deployment mechanism **804** and surgical implant **802**, the latter being configured as per tissue implant **500** that enables a sling portion **806** to be secured into position via the use of anchor mechanisms **808***a*, **808***b*, the latter of which are operative to advance through tissue in one direction but resist rearward movement in an opposite direction. In this regard, and as more clearly depicted in **FIG. 20***a*, implant **802** will preferably be comprised of an elongate sling portion **806**, which as those skilled in the art will appreciate may take any of a variety of natural tissues, synthetic material or some combination thereof operative to become implanted within the body and support a specified anatomical structure. Affixed on the opposed ends of the sling **806** are dedicated anchor mechanisms **808***a*, **808***b* which are affixed to the respective ends of the sling **806** via a coupling apparatus **810**, which may likewise comprise any of a variety of attachment mechanisms known in the art.

[**0107**] Each respective anchor mechanism **808***a*, **808***b* may be configured per a variety of embodiments, discussed more fully below, that can enable each mechanism to be advanced into a target site of tissue in one direction yet resist movement when pulled in an opposed direction. In this regard, each respective anchor mechanism **808***a*, **808***b*, will be preferably formed upon the opposed ends of the sling **806** such that the anchor mechanisms **808***a*, **808***b* can be advanced through a target site of tissue in dissimilar directions, such as opposed directions, to thus enable the sling **806** to stretch beneath and ultimately support the target anatomical structure as previously discussed above with reference to **FIGS. 1 and 16** (as well as **FIG. 22** more fully below). To achieve that end, anchor mechanisms **808***a*, **808***b* may be provided with generally arrowhead-shaped members, V-shaped members, Y-shaped members, or any structure well-known in the art that facilitates the ability of the anchor mechanisms **808***a*, **808***b* to cut through and become positioned or embedded within a target site of tissue such that the same can become resident or fixed in position. In this regard, it is contemplated that the anchor mechanisms **808***a*, **808***b*, may be provided with a textured surface or otherwise be provided with materials to facilitate the ingrowth of tissue about the same to thus enable the anchor mechanisms to remain firmly seated into position once implanted into the body. Illustrative of such an embodiment would include the use of a mesh material cut such that the strands of the fabric of such mesh facilitate movement when advanced in a first direction but resist rearward movement due to the frayed, outwardly-flaring strands of the mesh that would be oriented to cause such loose ends to resist or become biased against rearward movement.

[**0108**] To facilitate the ability of the implant **802** to be accurately and securely placed into position within the body, a deployment mechanism **804**, more clearly depicted in **FIG. 20***b*, may be utilized. Although the implant **802** may be surgically implanted into position utilizing a variety of well-known surgical techniques, it is believed that deployment mechanism **804** may be useful to more quickly, accurately and atraumatically position and securely affix such implant **802** into position. As illustrated, the mechanism **804** comprises a manually operable handle **812** having a deployment member **818** extending distally therefrom. An actuator mechanism **814** is disposed within the handle **812** and includes an elongate shaft portion **816** disposed axially within the deployment member **818** such that the distal-most

end thereof **816***a* is caused to selectively protrude through a distal-most opening **818***a* of the deployment member **818**. The actuator **814**, and more particularly the shaft **816** thereof may be selectively coupled to an anchor mechanism such as **808***a* depicted in **FIG. 20** to thus direct and position the anchor mechanism **808***a* at a target site within the body. Such deployment member **818** may be configured to have a variety of sizes and shapes, and may be specifically configured for deployment of an implant **802** at a particular target site within the body. For use in deploying implants, such as **802**, to provide suburethral support for the treatment of incontinence, it is contemplated that the deployment member **818** will have a generally arcuate shape and may further be preferably configured to deploy the implant **802** within the obturator foramen of a patient via a trans-obturator route, discussed more fully below.

[**0109**] To facilitate the interconnection between the implant **802**, and more particularly an anchor mechanism **808** thereof, with the deployment mechanism **804**, it is contemplated that such anchor mechanism **808** may be pre-loaded in a cartridge, not shown, the latter being selectively inter-connectable with the deployment member **818**. In such embodiment, it is contemplated that such cartridge will be operative to form a rigid casing about the anchor mechanism **808** to thus enable the anchor mechanism to be easily affixed into position on the deployment member **818** and thereafter surgically guided into position such that once a target site has been accessed, the anchor mechanism **808** can be selectively deployed from the cartridge. To help enable the cartridge to reach such desired target site, it is contemplated that such cartridge may be provided with a cutting apparatus or sharpened cutting edge to thus enable the same to cut and advance through tissue. To that end, it will be readily appreciated by those skilled in the art that many possible designs and configurations will be readily apparent to effectuate that end.

[**0110**] Referring now to **FIG. 21**, there is shown the use of the system **800** to deploy the implant **802** via the deployment mechanism **804**. In the procedure illustrated, such implant **802** is being deployed through an incision **822** formed within the vaginal wall **820** to thus enable a urethra **824** to ultimately become supported thereby. To that end, it is contemplated that such deployment may take one of two forms. According to a first embodiment, the anchor mechanisms **808** housed within the deployment mechanism are compressed to assume a first deployment configuration and, once released therefrom, assume an expanded configuration that enables the same to remain fixed in position. Alternatively, the anchor mechanisms may simply assume a single state and deploy directly into tissue at a desired surgical site. As will be appreciated, however, other techniques will be readily apparent to those skilled in the art for use in deploying the anchor mechanisms of the present invention.

[**0111**] In this regard, the procedure depicted in **FIG. 21** represents deployment of a suburethral sling via a trans-obturator route. As is well-known, most slings are currently delivered via a retropubic route, and although the implants **802** and deployment mechanisms **804** can readily be adapted and utilized for such procedures, current methodology suggests that implant or sling deployment made via a trans-obtruator route substantially minimizes well-known risks associated with bleeding and/or intestinal or bladder injury associated with surgical sling implant procedures utilizing a retropubic route to gain access to the surgical site. In this regard, current medical literature strongly suggests that a trans-obturator route substantially avoids the blood vessels existing within and above the pubocervical fascia, bladder and the intestines. Moreover, securing slings into position according to conventional methodology utilizing retropubic access often times results in sling dislodgement or misplacement, especially so when conventional sling anchoring fails due to the pull or dislodgement of anchors and/or mesh when the patient engages in a violent provocative event, such as coughing, vomiting or some other violent activity.

[**0112**] As shown, the deployment mechanism **804** is selectively positioned such that an anchor mechanism **808***a* of the sling is advanced into the incision **822** via distally-extending deployment member **818**. The actuator **814**, and more particularly the shaft **816** extending therefrom, is operative to advance the anchor member **808***a* away from the distal end **818***a* of the member and through the soft tissue until the same becomes within a target site of tissue. To facilitate the ability of the mechanism to gain access to the target site, it is contemplated that the distal-most end **818***a* of deployment member **818** may be provided with a sharpened cutting surface to thus enable the same to be advanced through tissue via single incision **822**. In an alternative approach, the distal-most end **818***a* will cooperate with anchor mechanism **808***a* to thus enable the implant to be advanced into and positioned through percutaneous incision **822** made in the vaginal wall **820**. Along these lines, it is contemplated that once an anchor mechanism **808***a* is sufficiently positioned, the second anchor mechanism **808***b* will be affixed to the distal-most end of the deployment member **818** of mechanism **804** and likewise be secured into position by selectively advancing the anchor mechanism **808***b* through the same incision but in an opposed direction relative the first anchor mechanism **808***a*, the latter having been secured into position and thus operative to resist rearward movement.

[**0113**] As will be readily appreciated by those skilled in the art, by merely advancing the anchor mechanisms **808***a*, **808***b*, in generally opposed directions, the anchor mechanisms will thus be operative to stretch out the sling portion **806** such that the same can selectively and accurately be positioned about a target anatomical structure. In this respect, it is contemplated that the sling portion **806** can be positioned such that the same maintains a specified degree of tension or support to an anatomical structure, such as the urethra **824** or some part of the vagina as in a colporrhaphy or colpopexy, or may otherwise be positioned such that the same maintains a desired spatial relationship and orientation relative an anatomical structure. Of additional advantage is the fact that each respective opposed anchor mechanism **808** of the implant **802** can be positioned within the body via a single incision or point of access, which thus eliminates the need for a second incision or access point to be formed in the body, as is known per conventional sling placement which typically requires that separate access points or incisions be made for each fixation point, (i.e., the points at which the opposed ends of the sling are fixed into position within the body).

[**0114**] As a consequence, and shown more clearly in **FIG. 22**, the implant **802** may be selectively positioned such that the sling **806** component thereof properly supports the urethra **824** as is desired to achieve a favorable outcome. In the placement of the implant **802** as depicted, however, the

same illustrates the fixation of the implant **802**, and more particularly the sling **806** thereof, within the obturator foramen of pelvis **830**, as defined by the pubis **834** and ishium **832** regions thereof. In this regard, each respective anchor mechanism **808***a*, **808***b* becomes embedded within a target tissue site, such as the pubocervical fascia, toward or through the obturator foramen and ultimately positioned in the desired locale relative the bladder **828** and, more particularly, urethra **824** extending therefrom.

[**0115**] As discussed above, anchor mechanisms **808***a*, **808***b* will preferably be formed or attached to the opposed ends of the sling **806** to thus enable the opposed ends to be stretched out and positioned in the desired manner. To achieve that end, it is important that the anchor mechanisms **808***a*, **808***b* be configured to thus enable the same the be easily advanced into position, to thus achieve the desired goal of fast, accurate and atraumatic placement, but at the same time provide the necessary degree of anchoring support to thus define a secured point of fixation from which the sling **806** can extend and ultimately impart the desired degree of support. **FIGS. 22***a*-**22***c* depict various embodiments of the anchor mechanism **808** that are contemplated to achieve those objectives.

[**0116**] Referring now to **FIG. 22***a,* there is shown an enlarged view of an anchor mechanism **808** similar to that depicted in **FIG. 22**. As illustrated, the anchor mechanism comprises a plurality of anchor bodies **840** each having opposed, outwardly extending anchor members or arms **842** which thus define a generally Y-shaped body. Each respective anchor mechanism **840** is disposed upon elongate cord **844**, which may take the form of a suture or other implantable material well-known to those skilled in the art. To facilitate the ability to manipulate anchor mechanism **808**, elongate cord **844** may be formed to have a desired stiffness, and may be formed as a cable having reinforced material therein operative to provide some structural rigidity as may be desired in some applications.

[**0117**] **FIG. 22***b* represents a similar embodiment whereby a plurality of generally chevron-shaped anchor members **850** are disposed upon the length of an elongate cord **854**. Each respective chevron-shaped member **850** is provided with outwardly-extending members or arms **852** that provide a means to anchor the same into tissue. Both the embodiments depicted in **FIG. 22***a* and **22***b,* similar to those discussed above in relation to the embodiment depicted in **FIG. 16** and **16***a,* essentially comprise a plurality of dual-pronged anchor mechanisms disposed linearly about a cord-like suture of various malleability to thus enable the same to advance through tissue in one direction, either by pushing or pulling, but resist rearward movement in an opposite direction. In this respect, the generally Y-shaped and generally chevron-shaped embodiments depicted in **FIGS. 22***a* and **22***b* are similar to the generally V-oriented embodiment depicted in **FIGS. 16 and 16***a* to thus enable a plurality of anchoring members to be disposed upon a length of cord, suture and the like, to be linearly disposed there along. It will be recognized, however, that numerous other designs are contemplated that fall within the scope of the present invention. As discussed above, such anchor mechanism may comprise selectively oriented segments of mesh material that are selectively oriented such that the loose or frayed fiber ends of the mesh extend in a rearward configuration to thus resist rearward movement.

[**0118**] Referring now to **FIG. 22***c,* there is shown a similar type embodiment whereby the anchor mechanism **808** is defined by a screw mechanism **862**, having a distal-most end **860** operative to advance into tissue along a central axis **864**, the latter of which may be a cord or cable having a requisite stiffness. Alternatively, screw mechanism **862** and central axis **864** may comprise a firm yet malleable material suitable for implantation within the body. In such embodiment, it is contemplated that the screw-anchor mechanism **862** can be advanced into a target site of tissue by either blunt advancement or rotational advancement, the latter being facilitated by use of a deployment system **804** whereby the deployment member **818** is operative to selectively position the same within a tissue mass.

[**0119**] As will be appreciated, alternative anchoring mechanisms are contemplated and will be readily known to those skilled in the art. Along these lines, it is contemplated that the anchor mechanisms may be formed to be operatively transitional between a first compressed state whereby one or more of the anchor members, and more particularly the outwardly extending prongs thereof as depicted in **FIGS. 22***a, 22b* are advanced into position within a target site of soft tissue and a second operative configuration whereby the anchor members and/or prongs thereof expand to become fixed into position at the appropriate target site of soft tissue. **101201** Although not shown, in order to achieve such selective placement of the anchoring mechanisms capable of operatively transitioning between such first and second configurations, it is contemplated that such anchor mechanisms may be selectively positioned via the use of conventional deployment techniques and devices, such as catheters, needles, and/or guide wires. Exemplary of the latter, as utilized to position such operatively transitional anchor mechanisms for use in sling surgery, would be accomplished via the introduction of the guide wire through and then under the vaginal wall and then into the tissue adjacent to the vagina. Once properly positioned, an expansion is then effectuated along the guide wire within the vaginal, via the use of conventional coaxial or balloon systems or other well-known spreading devices that, following deployment, are thereafter removed. As per the procedures discussed above, it is understood that once a first anchor mechanism is deployed, a similar procedure must necessarily be followed to deploy the second respective anchor mechanism such that the sling disposed therebetween is operatively positioned to impart the desired support or positioning at a specified anatomical site.

[**0120**] Another example for use in deploying such operatively transitional anchor mechanisms would include the use of an elongate sheath that is focused as a portion of the deployment member **818** is operative to retain a multiplicity of anchor mechanisms, and in particular a plurality of anchor bodies, such as **840** depicted in **FIG. 2**, within an elongate lumen thereof. It is contemplated that such sheath will have a sharpened distal end to thus enable the same with anchor bodies retained therein to be selectively positioned such that the prongs or other attachment elements thereof do not cut, engage with or otherwise become prematurely deployed. Along these lines, it is contemplated that such sheath deployment member would ideally be utilized to selectively position a multiplicity of anchor members positioned along a suture line or other cord-like structure, and may further include mechanisms to facilitate the deployment of such anchor mechanisms to either extend from or be withdrawn

within the lumen of such sheath. It is likewise contemplated that such sheath can be used to deploy a plurality of linearly-arranged radio opaque markers, such as the TINED lead system of radio opaque markers produced by Medtronics, Inc. which have a configuration similar to that of the anchor bodies depicted in **FIG. 22A**. In use, it is contemplated that such sheath may be provided with an elongate slot formed along a portion the length thereof that enables the cord-like structure having one or more anchor mechanisms formed thereon to be pulled or pushed into the sheath as well as allow the sheath to be removed following the placement of the anchor mechanism deployed thereby.

[**0121**] Referring now to **FIGS. 27-34***a*, and initially to **FIG. 27**, there is shown yet a further novel surgical implant **300** and method of deploying the same that advantageously allows for the percutaneous attachment of such implant into position to thus enable an anatomical structure to be properly supported thereby yet without having the need to surgically place the implant entirely within a patient's body. As illustrated, the implant **300** will comprise an elongate sling of the aforementioned variety having first and second ends **302**, **304**. Attached to each respective end **302**, **304** are anchoring mechanisms **306**, **308**, which may take any of the aforementioned configurations discussed herein, and in particular those embodiments depicted in **FIGS. 11-16***a* and **FIGS. 20-22***c* and **FIGS. 23-26**. In this regard, such anchoring mechanisms are preferably configured such that the same are operative to be inserted and advanced through tissue in a first direction yet resist rearward movement when pulled in an opposed direction. Such anchoring mechanisms **306**, **308** will further preferably be provided with a sharpened distal tip to facilitate the ability of the same to be positioned percutaneously, as discussed below and in other embodiments disclosed herein.

[**0122**] Unlike prior art slings, the implant **300** as shown in **FIG. 27**, is operative to be anchored into position percutaneously, and is specifically illustrated in **FIG. 27** for the purpose of providing suburethral support. To that end, a respective one of the ends **302** of the implant **30** will be advanced into the vagina **310**, which extends underneath and in generally parallel relation to the urethra **312** extending from bladder **314**. Once sufficiently advanced into the vagina, the anchoring mechanism **306** will be pierced through the vagina through percutaneous entry site **318** and allowed to anchor within a soft tissue mass, bone, or periosteum, as per any of the aforementioned embodiments. In one particularly preferred embodiment, the anchoring mechanism **306** will be advanced through the vagina **310** to a point sufficient to where the same can be secured within the obturator foreman **316**. As will be readily appreciated by those skilled in the art, the term percutaneous or percutaneously, as used herein, is meant to encompass anything passing through the skin, and in particular epithelium, and expressly includes the epithelium of any particular body cavity, such as the vaginal epithelium as referenced in the drawings.

[**0123**] The respective other anchor mechanism **308** attached to the other respective end **304** of implant **300** is similarly pierced the vaginal wall at percutaneous entry site **320** and likewise advanced therethrough to where the same preferably can be anchored within the obturator foreman **316**, as illustrated in **FIG. 29**.

[**0124**] As further illustrated in **FIG. 29**, once secured into place, the implant **300** will thus have the opposed ends **302**, **304** thereof anchored via dedicated anchoring mechanisms **306**, **308** in a percutaneous manner. The elongate strip or sling portion of the implant **300**, however, will extend across the vaginal wall and exterior to the points at which the implant **300** are secured into position. As such, the sling can be secured into position and thereafter provide suburethral support without the main body of the implant **300** having to be surgically implanted within the patient. In this regard, the suburethral support is provided by that portion of the implant **300** extending across the vaginal wall itself.

[**0125**] As will be readily appreciated by those skilled in the art, by securing the implant **300** in such a manner advantageously allows for very rapid affixation that substantially minimizes the trauma, bleeding, time and precise surgical skill necessary to the extent the implant **300** were to be secured into position via prior art surgical techniques. Accordingly, it is contemplated at the present time that the implant **300**, by virtue of its percutaneous attachment mechanism, can be secured into position in a medical office based setting, as opposed to the need for a hospital or surgical facility where sling implantation must typically be performed. In addition, anesthesia may be administered locally at the site of implantation of the anchoring mechanism to avoid general or regional anesthesia.

[**0126**] With respect to the implant **300**, the same may be fabricated as per any conventional sling, graft, support as is currently practiced in the art or developed hereafter. Along these lines, the implant **300** can be formed from mesh, wire, synthetic material, absorbable material, natural material (i.e., tissues harvested from the patient or donor), or any other material well-known to those skilled in the art. Along these lines, it is contemplated that the implant **300** may be modified to facilitate the ingrowth of tissue to thus enable the same to be permanently seated in position, or may be scarred in place, which can be accomplished by a wide variety of techniques known in the art, such as through electrocauterization. With respect to the latter, the electrocautery energy will likely cause the implant **300** to cut or pass into or through the vaginal epithelium.

[**0127**] Referring now to **FIGS. 30 and 31**, there is shown a preferred embodiment of a percutaneous anchor mechanism for use in the implants discussed above with respect to **FIGS. 27-29**. Per the other types of anchoring mechanisms disclosed in the present application, it is contemplated that the percutaneous anchoring mechanism **306***a*, depicted in **FIG. 30**, will be operative to be advanced in one direction and resist movement in a rearward direction. One preferred method of deploying such anchoring mechanism **300***a* is through delivery by needle or cylinder whereby the anchoring mechanism **306***a* is disposed within the lumen of the needle **330** such that the prongs **307** thereof are shown assuming a compressed or retracted configuration. Once the needle **330** is sufficiently advanced to the target site to which the anchoring mechanism **306***a* is to be deployed, the anchoring mechanism **306***a* is deployed from the needle **330** which thus enables the prongs **307** to assume a second, expanded anchoring configuration, as shown in **FIG. 31**. To achieve that end, it is contemplated that the prongs **307** of anchoring mechanism **306***a* may be formed from a plastic deformable material or possibly formed from a transitional metal such as nitinol, which is operative to transition to a

second configuration upon exposure to a higher temperature, such as regular body temperature, as discussed above.

[0128] In addition to being disposed and delivered through a needle or cylinder, it is contemplated that the anchor mechanism may be designed to be deployed over a needle or through a needle, as depicted in **FIG. 34**. In this regard, a respective one of anchor mechanisms will be deployed over a needle and released therefrom. In such embodiment, as depicted in **FIG. 34***a,* the end of such anchoring mechanism may be caused such that the prongs or other attachment devices formed on such anchor mechanism spring open upon release from the needle.

[0129] When the anchoring mechanism **306***a* assumes its expanded configuration, as shown in **FIG. 31**, the extended nature of the prongs **307** can further preferably function as a screw, such that when rotated in the direction shown, provides yet a further post-delivery mechanism to enable the anchor **306***a* to advance in a forward or rearward direction by merely twisting or screwing the anchor in one direction or the other. As will be readily appreciated by those skilled in the art, there has not heretofor been available any type of anchoring mechanism that is operative to be selectively adjusted in both forward and rearward directions once implanted within the body, especially within soft tissue.

[0130] In a similar embodiment depicted in **FIG. 33**, each respective anchoring mechanisms formed upon the sling can be formed to have a first screw-type configuration shown in the top portion of **FIG. 33**, which depicts a ready state or insertion configuration. While in such configuration, the same may be selectively advanced forwardly or rearwardly within a mass of soft tissue by simply rotating such anchoring mechanism. To the extent the same has been secured at a target site, the same may be caused to assume an active state, shown in the lower portion of **FIG. 33**, which thus enables the anchoring mechanisms to deform in such a manner whereby the same remains secured into position. Such transition between the ready state and active state can be accomplished by a variety of means, such as by the use of a transitional metal, such as nitinol or by physically deforming the anchor mechanisms, such as pulling or retracting the anchor mechanisms such that the same deform as shown.

[0131] Referring now to **FIGS. 32 and 32***a,* there is shown a second embodiment of a percutaneously delivered support mechanism operative to impart urethral support for the treatment of incontinence. As illustrated, the implant **340** is comprised of an elongate backing or sling portion **342** having anchoring mechanisms or elements **344** formed on the respective ends thereof. As per the embodiment discussed with respect to **FIGS. 27-31**, the implant **340** is positioned within the vagina and underneath the urethra extending thereabove. The anchoring elements **344** are thus percutaneously compressed into the vagina which causes the implant **340**, and more importantly the support portion **342** thereof to remain secured into position and provide support to the urethra **312**. With respect to such anchoring mechanisms **344**, the same may take any of those anchoring mechanisms disclosed herein suitable for such procedure, and in particular those disclosed in **FIGS. 9 and 10**. As will be readily appreciated by those skilled in the art, the implant **340** can thus enable a suburethral support to be quickly and accurately secured into position without ever having to form any type of incision within the patient, which thus dispenses with the traditional surgical procedures associated with performing sling surgery and the like.

[0132] To better facilitate the ability of the implant **340** to remain in position and provide the desired degree of support, there is shown in **FIG. 32***a* the surgical implantation of the implant within the vaginal epithelium. In this regard, an incision is made in the vaginal epithelium whereby the backing **342** with anchoring mechanisms **344** formed thereon is inserted therewithin such that the anchoring mechanisms extend within and become attached to the upper vaginal epithelium. The lower epithelium will, in time, scar over and grow about the backing **342** thus causing the same to remain in its seated position indefinitely. To the extent desired, it is contemplated that backing **342** may be operative to receive an electrocauterizing current to thus facilitate the ability of the same to cause scarring to thus facilitate the ability of the backing **342** to remain secured within the vaginal epithelium.

[0133] With respect to both of the preferred embodiments discussed above with respect to **FIGS. 27-32***a,* it is contemplated that the same may not be utilized only for the use in treatment of incontinence, but can be used in other parts of the body. Similarly, it is contemplated that in such embodiments, and in particularly the embodiment depicted in **FIGS. 27-29**, can be used in the treatment of prolapse. Accordingly, it is contemplated that such percutaneously anchored sling may be utilized in a significant number of medical procedures.

[0134] Referring now to **FIG. 17**, there is shown yet another embodiment of a device **600** for attaching sutures, grafts, tissues and the like into position in the human body. As illustrated, such embodiment comprises an anchoring disc or plate **602** which may be secured to or rest upon an anatomical structure, and more particularly a layer of muscle **604** or rectus fascia **606** as shown. As illustrated, which again is in the context of securing a sling **502** into position such that the urethra **504** is supported thereby, suture lines or suture-like cords **508** on each opposed end of the sling **502** are secured by dedicated anchoring plates **602**, the latter being supported by a layer of muscle and/or layer of rectus fascia. As shown, the anchoring plates **602** are operative to secure the suture lines **508** into position such that the same are allowed to selectively advance therethrough and remain secured in position thereby without requiring that the sutures **508** be ties (i.e., at the fascia level **606**).

[0135] To achieve that objective, there is shown in **FIGS. 17***a* and **17***b* the mechanism by which the anchoring plate **602** is operative to secure the suture lines **508** thereto. As shown in **17***a,* the anchoring plate **602** comprises the combination of a first inner plate member **610** having at least one, and preferably two diametrically opposed apertures **612** formed therein. Encased about the first plate member **610** is a second annular plate member **614** which also includes at least one, and preferably two, apertures **616** formed therein, such apertures **616** being selectively alignable with the apertures **612** formed upon the first inner plate **610**. The first inner plate member **610** is rotationally mounted within the outer anchoring plate member **614**, such that the same is operative to transition between a first open configuration, wherein the apertures **612** of the first inner plate **610** are alignable with those formed on the outer annular plate **614**,

and a second closed configuration, as shown in **FIG. 17***b*, wherein the apertures formed on the inner and outer plates **612**, **615**, respectively, are not aligned with one another, such that a closure is formed.

[**0136**] In use, the anchoring plate **602** may be secured into position, via prongs or some other type of anchoring mechanism (not shown) to a desired site. Alternatively, it will be appreciated that such anchoring plate **602** may only need be placed on the rectus fascia and, as discussed more fully below, due to the downward force exerted upon the anchoring plate **602** via the sutures held thereby, such anchoring plate will be caused to remain resident at the desired deployment site. Once positioned, the inner and outer plate members **610**, **614** are maintained in the first operative configuration such that the apertures **612**, **616**, respectively formed thereon form the opening or openings through such anchoring plate **602**. The suture lines **508** may then be extended through apertures defined by the first and second plate members such that the sling **502** held thereby is maintained in a desired orientation or provides a desired degree of support to the urethra **504**. Once so positioned, the inner and outer plate members **610**, **614** are rotated relative one another such that second closed configuration is maintained, which thus serves to secure the suture lines **508** into position. To facilitate that end, a knob **618** or other turning mechanism formed upon the inner plate may be provided to facilitate the insertionability to secure the suture lines **508** into position. As discussed above, such design advantageously dispenses with the need to tie down the suture lines or cords at the fascia level. To the extent desired, such anchoring system further enables the suture lines, and more particularly the suture lines extending through the anchor plate, to be secured to one another to thus form a suture "bridge". As shown in phantom, each respective suture line extending through the anchor plate can be linked to one another as shown. To achieve that end, it will be appreciated that such suture lines may be either tied, fused, crimped, linked or joined to one another via any of a wide variety of methods and devices well known to those skilled in the art.

[**0137**] Referring now to **FIG. 18**, there is shown a further refinement of the system utilized to secure a suture line at a desired location such that a sling, graft or other object supported thereby is maintained at a desired location. As illustrated, such system **640** comprises the combination of a suture-like cord **642** having a plurality of protuberances **644** formed therealong and an anchoring plate **646**. The suture-like cord **642** with protuberances **644** is formed such that the same is extensible through tissue. As will be appreciated by those skilled in the art, attached to an opposed end of such suture-like cord **642** with protuberances **644** is a graft, sling **502** or some other object to be held thereby. The suture-like cord **642** is extensible through the anchoring plate **646**, the latter being secured at a desired target site, which may include a bone, periosteum, soft tissue, or a layer of rectus fascia **606** as shown. The suture **642** is extensible through such anchoring plates **646** such that respective ones of the protuberances **644** engage with a locking aperture **648** formed on such plate **646**. As illustrated, each respective protuberance **644** can be pulled through such aperture **648** and thereafter caused to lock the suture **642** into position. As will be appreciated, as the sutures **642** pull through the anchoring plate **646**, the suture line **642** will become progressively shorter and thus raise the object (i.e., sling **502**) held thereby to the desired location. Advantageously, such system accommodated movement in both directions, and by pulling the suture in the rearward direction can cause the suture to experience an increase in slack, which thus consequently can lower or lessen the tension in the object supported thereby. As per the embodiment depicted in **FIG. 17**, these suture-like cords with protuberances, to the extent multiple cords are utilized, may be linked to one another to thus form a suture bridge, as may be desired for certain applications.

[**0138**] Referring now to **FIGS. 19-19***c*, and initially to **FIG. 19**, there is shown an additional embodiment **700** of an anchoring system for securing a suture-like cord or line **508** at a desired location. As per the embodiments depicted in **FIGS. 17 and 18**, the embodiment shown includes an anchor plate **702** having at least one, and preferably two to four, channels **704** extending therethrough for receiving suture-like cords **508**. As per the aforementioned embodiments, the anchor plate **702** may likewise be secured into position with a fastener mechanism or, alternatively, merely be positioned at a desired site upon fascia or soft tissue with the ultimate tension imparted thereto by the sutures **508** held thereby causing the same to remain resident at such site. As to the embodiment shown, the anchoring plate **702**, once positioned, is operative to receive the suture line or lines **508** through the channels **704** defined thereby. As more clearly illustrated in the cross-sectional view of **FIG. 19***a*, the suture-like cord **508** can be pulled upwardly or downwardly until the same attains the desired position and/or imparts the desired tension to an object held thereby. Once such proper position and/or tension is attained, the channel **704** within which the suture-like cord **508** is disposed may be crimped, as depicted in **FIG. 19***b*, such that the suture line **508** is compressively held thereby. As will be appreciated by those skilled in the art, the channel **704** defined by the anchor plate **702** will be formed from a suitable deformable material well-known to those skilled in the art which can not only be easily crimped, but once so crimped, will impart the necessary compressive force to hold the suture **508** in position. It will likewise be recognized that the crimp made to the channel **704** may be formed by any of a variety of surgical crimping mechanisms well-known and commercially available.

[**0139**] In an alternative configuration depicted in **FIG. 19***c*, the anchor plate **710** is designed such that the same only has one channel **712** formed therethrough through which one or more suture-like cords **508** may be received. As may be desired for certain procedures, particularly where it is advantageous to simplify such procedures, the channel **712** defined in the anchor plate **710** will preferably be centrally disposed upon the anchor plate such that the same is adapted to receive multiple suture-like cords therethrough (e.g., four (4) suture lines to accommodate two (2) opposed ends of a sling). Once the cord or cords **508** have been received therethrough and optimally positioned, the channel **712** may be crimped such that the cords are compressively held as desired. Any length of the sutures extending therethrough may be linked or connected to one another to thus form a suture bridge, which is again in phantom in **FIG. 19**.

[**0140**] As will be recognized by those skilled in the art, by providing such a simplistic, atraumatic mechanism for securing sutures, grafts and the like into position substantially reduces suture erosion, greatly minimizes operative time, patient recovery time and further minimizes the risk of

infection by minimizing the degree of invasiveness typically associated with securing slings and the like into an optimal position.

[0141] As will further be readily appreciated by those skilled in the art, the aforementioned anchoring systems, particularly those mechanisms depicted in **FIGS. 17-19***c*, such may be formed from a bio-absorbable material, such that the anchoring system becomes absorbed over time. As will be appreciated by those skilled in the art, to the extent the anchoring system is fabricated to become absorbed over time, the aforementioned discussion regarding the suture bridge may be deemed optimal should it become necessary to maintain the suture lines at a desired location following absorption of such anchoring system.

[0142] Alternatively, the anchoring systems may be formed from a non-absorbable material such that the same remains permanently embedded within the body. Moreover, it will be recognized that those mechanisms depicted in **FIGS. 17-19***c* may further incorporate a tension spreading mechanism, such a washer or mesh of fabric, that may be deployed with or integrated as part of such anchoring system. In this respect, it will be appreciated that due to the fact that the suture holding mechanisms depicted in **FIG. 17-19***c* will necessarily have a stress and strain imparted thereto via the sutures held thereby, such plate may dissipate the stress and strain over a larger surface area via the incorporation of such tension spreading mechanism. As per the anchor plates themselves, such tension spreading mechanism may be formed from an absorbable or non-absorbable material and may be formed integral with or separate from the anchor plate.

[0143] Referring now to remaining drawings **9-15**, and initially to **FIG. 9**, there are depicted further embodiments of the present, invention that are directed to devices for attaching sutures, grafts, tissues and the like to periosteum **36** (i.e., the thick fibrous membrane covering the surface of bones), as well as other types of soft tissue. In this regard, each of the embodiments herein preferably do not penetrate or otherwise become embedded within the bone **38**, but rather are attachable to the periosteum **36** at a specific site thereof. However, it should be expressly understood that such embodiments may be modified or otherwise adapted to penetrate and become embedded within the bone **38**, as may be necessary or ideal for a given medical procedure.

[0144] As will be appreciated by those skilled in the art, a wide variety of surgical procedures requiring fixation of sutures, grafts and the like, such as transvaginal sling surgery, particularly when performed in accordance with the procedure depicted in **FIGS. 1 and 2**, frequently do not necessitate the use of devices, such as those depicted in **FIG. 5**, that must necessarily be screwed or anchored within the bone. Quite unexpectedly, it has recently been reported at a meeting sponsored by the American Uro-Gynecologic Society that by utilizing the periosteum **36** as a point of affixation, such affixation can be made more or equally secure than prior art bone screws and anchors, but at the same time achieving satisfactory, if not superior, structural support. In this regard, deployment of such prior art bone-screw/anchor devices is generally considered an excessive measure insofar as such devices are known to frequently provide an excess amount of support than what is typically required or suitable for such particular purpose. However, due to the fact that no feasible alternative had been available until now, such bone screw and anchor devices are utilized, which can substantially complicate such surgical procedures as well as cause the patient to endure unnecessary trauma, possibly delayed recovery time, and possibly higher risk of infection.

[0145] In the first of such embodiments depicted in **FIGS. 9 and 10**, there is provided an affixation device **90** comprised of at least one, and preferably a multiplicity of piton members **92** mounted upon a base member. Each one of the multiplicity of pitons **92**, which may take the form of a hook as shown, is designed to ensnare with and become embedded in a target site of soft tissue of the periosteum **36**, as depicted in **FIG. 9**, but not penetrate or otherwise disrupt the outer surface of the bone **38** therebeneath. In this respect, the piton members **92** may be designed such that with light pressure the same only penetrate within a certain limited depth of the periosteum **36** or tissue, such that the same provide a moderate degree of fixation and can be easily removed, or with greater pressure the same penetrate deeper so that the device **90** can become more securely embedded within the periosteum **36** or tissue to thus provide for a more secure base or attachment. Formed on the base member **94** is an attachment means, which may comprise a post or eyelet **96** as shown, to which may be attached the suture **98** or graft. As will be appreciated, the affixation device **90** need only be placed against the periosteum **36** at a target location such that the piton members **92** thereof become embedded there within. Because the piton members **92** of the affixation device are caused to only become embedded within the periosteum **36**, such novel fixation device may be easily removed and repositioned as may be necessary in a given surgical procedure to insure that an optimal degree of support or positioning is attained.

[0146] Once so optimally positioned, the suture **98** or graft may be attached to the device **90** as per conventional surgical procedures. Alternatively, due to the ease by which the affixation device **90** may be detached and reattached, the surgeon is provided with the option of securing the suture **98** or graft to such affixation device **90** and thereafter positioning the affixation device **90** at a target site for best positioning. Advantageously, although the affixation device **90** is specifically designed to provide for easy dislodgment and repositioning, it is believed that once the same is secured into position, due to the eventual overgrowth of tissue about such device **90**, the affixation device will continue to provide firmer and stronger support over time.

[0147] Referring not to **FIGS. 11-13**, there is shown another embodiment **100** of an affixation device useful in the attachment of sutures, grafts, tissues and the like to periosteum, soft tissue, and bone. In the embodiment shown, such affixation device **100** comprises a tack member having a hub portion **102** and at least one, and preferably two or more, prong members **104** formed thereon. As illustrated, the implantable tack **100** may be utilized to affix a graft **106** or other like tissue to the periosteum **36** by merely interposing the graft **106** between the periosteum and the tack **100** and compressing such tack **100** there against such that the prongs **104** thereof extend therethrough and become embedded in the periosteum **36** as systematically shown in **FIGS. 11 and 12**.

[0148] As will be recognized, the prong portions **104** of such tack **100** will be specifically designed and configured to

extend through a given layer of tissue or graft material **106** and become embedded into the periosteum **36**, but not otherwise extend to or penetrate the bone **38** lying therebeneath (although the embodiment may be modified for such applications). It will further be appreciated that such prongs **104** may vary in number and may take any of a variety of shapes and configurations necessary to achieve that end. As discussed above, it is contemplated that the prong members **104** may be designed to penetrate within the soft tissue, periosteum **36**, or even bone **38** at specified depths to thus provide for selective degrees of attachment thereto. In this regard, it is specifically contemplated that such prong members **104** may be formed to have a straight, hook or arcuate shape such that the same facilitate the affixation of a graft **106** to the target site of fixation. For example, in **FIG. 12** it will be recognized that due to the arcuate shape of the prong members **104** of the implantable tack **100**, when a force is applied in a direction indicated by the letter "I", such force will actually cause the prong members **104** of such implantable tack **100** to penetrate further within the periosteum **36** to thus cause the affixation to become more secure with increased tension. Furthermore, by utilizing a hub member **102** as part of the implantable tack **100**, as illustrated in **FIG. 13**, such implantable tack **100** can be easily accessed and removed in later surgical procedures. To facilitate such removal, a grip, protrusion or an aperture formed upon the hub may be provided. For example, it is contemplated that an attachment material, such as a synthetic mesh "extension" or sleeve, may be formed upon the hub **102**.

**[0149]** Referring now to **FIGS. 14 and 15**, there is shown yet another preferred embodiment **110** of the present invention that comprises a novel surgical staple for securing sutures, tissues or grafts **112**, to the periosteum **36**. As illustrated, the staple **110** is operative to penetrate through a segment of tissue or graft **112** and become embedded within the periosteum **36** such that the graft or tissue is caused to become affixed therewith. As illustrated in the top view portion of **FIG. 14**, the staple is operative to assume a first insertion configuration whereby the prongs **110***a*, **110***b* or such staple **110** are advanced through the graft **112** and ultimately into the periosteum **36**. Thereafter, as illustrated in the top view of **FIG. 15**, the prongs **110***a*, **110***b* are caused to embed within the periosteum **36** to enhance the attachment therewith. As may be necessary for a certain application, such prongs **110***a*, **110***b* may even be caused to embed within the bone **38** lying there underneath to thus provide a more secure attachment.

**[0150]** To facilitate the ability of the staple **110** to secure the graft **112** to the periosteum **36** in the aforementioned manner, it is contemplated that such staple **110** may be formed of resilient, self-expanding or self-contracting material which is biased to the operative configuration shown in **FIG. 15** such that when unconstrained, the opposed ends of the staple **110** will become further embedded into the periosteum. Similarly, such staple may be fabricated from a plastically deformable material which is initially formed to assume the insertion configuration depicted in **FIG. 14**, but can subsequently be deformed to assume the operative configuration depicted in **FIG. 15**. As a still further alternative, such staple **110** may be formed from a shape-memory material, such as nitinol, which thus enables the staple to assume the insertion configuration depicted in **FIG. 14** when at room temperature, but transition to the operative, more secure configuration depicted in **FIG. 15** when warmed to body temperature, as will occur such staple is deployed. As a further advantage, to the extent it becomes necessary to remove or otherwise reposition such staple **110**, it will be recognized by those skilled in the art that removal of such staple **110** may be facilitated by merely cooling the same down by any of a variety of well-known methods, including applying cold saline thereto.

**[0151]** All of the affixation devices discussed herein, although having widespread applicability and substantial advantage over prior art anchor devices, and more particularly bone screws and bone anchors, are particularly well suited in gynecologic, urologic and orthopedic surgical applications. It is believed that such affixation devices are particularly well suited for transvaginal sling surgery insofar as much of the medical literature tends to indicate that in a vast majority of patients, the sling that is utilized in such procedures should be placed with little to no tension at all, with the tension vector emanating therefrom being oriented in a direction well-suited to the piton portion of those embodying as depicted in **FIGS. 6-8**. Indeed, considerable authority exists that optimal placement of the sling in transvaginal sling surgery occurs when the sling merely comes near or into contact with the urethra. Affixation by attaching the sling merely to the periosteum and not to the bone is thus believed to provide more than sufficient leverage or support to the sling in such applications, but yet have the further advantage of being exceptionally easy to secure and re-secure into position in a much less traumatic manner than the prior art devices.

**[0152]** Exemplary of such applications, as illustrated in **FIGS. 23-26** is the use of the anchor mechanisms disclosed herein in vaginofixation. Such procedure, also known as colpopexy or colporrhaphy is closely related to the aforementioned surgical techniques related to transvaginal sling placement insofar as the same relies upon fixation devices, anchors and various sling-like materials that are operative to position and maintain the vagina in its proper orientation. In this regard, **FIG. 23** illustrates vaginal prolapse whereby the vaginal apex **906** is shown extending outwardly from the vagina of a patient. Such Figure further illustrates the relative positioning of the obturator foramen **908**, and more particularly the membrane **910** extending about the obturator foramen **908**, the latter as discussed above now being widely considered as the optimal zone within which to anchor slings and the like for the treatment of urinary incontinence.

**[0153]** Referring now to **FIG. 24**, there is shown the use of an anchor mechanism **900** constructed in accordance with a preferred embodiment of the present invention shown positioning the vagina according to its proper orientation whereby the apex of the vagina **906** is shown extending upwardly within the body. To achieve that end, the fixation device **900** is shown securing the vaginal wall **907** to the membrane **910** extending about the obturator foramen. To accomplish that end, the fixation device **900** is provided with a harpoon or barbed portion **904** operative to extend through the vaginal wall **907** and into a mass of soft tissue, such as membrane **910**. To secure vaginal wall **907** in proximity to such soft tissue, there is preferably provided a large platform or head portion **902** that preferably possesses sufficient surface area to hold the vaginal wall **907** according to its proper orientation such that the vaginal apex **906** remains properly positioned within the patient's body. As will be appreciated by those skilled in the art, the barbed portion

**904** will be configured as per any of the aforementioned embodiments such that the barb **904** will be operative to be inserted into a mass of soft tissue into a first direction but resist rearward movement when pulled in the opposite direction. It is further contemplated that such fixation device **900** may be deployed through any surgical technique known in the art whether it be manually or by deployment via a surgical instrument such as those discussed above or otherwise known in the art. For example, such fixation device **900** may be deployed via a coaxial system whereby a conventional guide wire is first deployed to identify the location the obturator membrane with the device **900** being deployed thereafter. Advantageously, such procedure eliminates the risks associated with blindly deploying such fixation device **900**.

[**0154**] With respect to the preferred embodiments of such anchoring mechanism **900** for use in vaginofixation, two such embodiments are depicted in **FIGS. 25 and 26** respectively. Referring initially to **FIG. 25**, (which is an enlarged figure of the fixation device depicted in **FIG. 24**), such fixation device includes a head portion **902** having a sufficient surface area operative to compress and hold a portion of vaginal wall tissue. As will be appreciated by those skilled in the art, such head portion **902** may preferably be formed from mesh or other biocompatible material to facilitate the ability of the device to secure a tissue mass (i.e., vaginal wall) securably into position. The anchor portion **904**, as discussed above, may take any of a variety of self-anchoring mechanisms discussed herein. As depicted, such anchor portion **904** includes a plurality of linearly-arranged arrows or V-shaped members operative to extend into tissue in a first direction but resist movement in an opposite direction.

[**0155**] Referring now to **FIG. 26**, there is depicted an alternative embodiment whereby the head portion **902** is comprised of a plurality of wire or claw members operative to grab and securably hold a portion of soft tissue. The anchor portion **904** is configured as per the embodiment discussed above with respect to **FIG. 25** and may include any anchoring mechanism operative to be advanced into tissue in a first direction but resist movement in an opposite direction, as would be achieved by the linearly arranged arrow members as depicted. As should be readily understood, however, the head portion **902** depicted in **FIGS. 25 and 26** may take a variety of alternative configurations as will be readily appreciated by those skilled in the art. In this respect, so long as the anchor portion **902** is operative to attach to and securably hold a mass of soft tissue, the same should be deemed to fall within the scope of the present invention. Also, head portion **902** may further include a member formed thereon, such as a post, eyelet, or other structure, to facilitate manipulation or attachment thereto.

[**0156**] Although the invention has been described herein with specific reference to a presently preferred embodiment thereof, it will be appreciated by those skilled in the art that various modifications, deletions, and alterations may be made to such preferred embodiment without departing from the spirit and scope of the invention. For example, it will be recognized that the piton portion of any of the surgical implants disclosed herein may take any of a variety of forms such that the same are caused to become more thoroughly seated in a position via the application of force in one direction, but yet become more easily withdrawn when pulled rearwardly in a second direction. It is further contemplated that such embodiments may be formed from plastically deformable or shape-memory material to thus facilitate fixation of such devices at a selected target site. Moreover, it should be recognized that the affixation devices disclosed herein designed to affix sutures, grafts, tissues, synthetic materials, and the like to periosteum may further be modified so that the same additionally penetrate into and become embedded within the bone lying thereunderneath. Specifically, with respect to the embodiment depicted in **FIG. 10**, one or more of the hooks may be sized and adapted to penetrate into the bone, similar to the prongs formed on the implantable tack depicted in **FIGS. 11-13**. Likewise, the prongs of the staple element depicted in **FIGS. 14 and 15** may be designed to penetrate and embed within the bone. Accordingly, it is intended that all reasonably foreseeable additions, modifications, deletions and alterations be included within the scope of the invention as defined in the following claims.

What is claimed is:

**1**. An implant for providing support to an anatomical structure comprising:

a) an elongate segment of material having first and second opposed ends.; and

b) at least one anchor mechanism formed upon a respective one of said ends of said segment of material, said anchor mechanism being operatively configured such that said anchor mechanism is percutaneously advanceable through a soft tissue mass in a first direction and selectively positionable at a target site therewithin and resistant to movement in an opposite direction.

**2**. The implant of claim 1 wherein said implant includes two anchor mechanisms attached to said segment of material, each anchor mechanism being formed on a respective one of said opposed ends of said segment of material and percutaneously advanceable through soft tissue.

**3**. The implant of claim 2 wherein said first and second anchor mechanisms are operatively positioned to be advanced through a mass of soft tissue in generally opposed or generally parallel directions relative one another.

**4**. The implant of claim 1 wherein said segment of material comprises a sling.

**5**. The implant of claim 4 wherein said sling is fabricated from a material selected from the group consisting of synthetic material, natural material, tissue harvested from a host, and combinations thereof.

**6**. The implant of claim 3 wherein each respective anchor mechanism is operatively transitional from a first insertion configuration and second anchoring configuration wherein said second anchoring configuration.

**7**. A system for securing a sling into affixed position within a target site of soft tissue within the body comprising:

a) a sling comprised of an elongate segment of material having first and second opposed ends, each respective opposed end having an anchor mechanism formed thereon such that each respective anchor mechanism is percutaneously advanceable through said soft tissue at said selected target site in a first direction and resistant to movement in a direction dissimilar from said first direction; and

b) a needle for positioning said anchor mechanisms of said implantable sling within said target site of said soft

tissue, said needle being detachably fastenable to a respective one of said anchor mechanisms of said implantable sling.

**8**. The system of claim 7 wherein said segment of material is selected from the group consisting of synthetic material, metal, natural material, tissue harvested from a host, or combinations thereof.

**9**. A method for implanting a sling for supporting an anatomical structure comprising the steps:

a) providing a sling comprised of an elongate segment of material having first and second opposed ends, each respective opposed end having an anchor mechanism formed thereon such that each respective anchor mechanism is percutaneously advanceable through said soft tissue at said selected target site in a first direction and resistant to movement in an opposite direction;

b) percutaneously advancing a respective one of said anchor mechanisms toward a selected site, such that said anchor mechanism becomes embedded within a first mass of soft tissue;

c) percutaneously advancing said respective other anchor member toward a selected site, such that said respective other anchor member becomes embedded within a second mass of tissue; and

d) wherein said first and second tissue masses are located such that said sling extends about a portion of said anatomical structure and is supported thereby.

**10**. A urethral support comprising:

a) an elongate segment having first and second opposed ends;

b) a first anchoring mechanism formed upon a respective one of said ends of said support and a second anchoring mechanism formed upon the respective other end of said support; and

c) wherein said backing is operatively positionable within the vagina and said first and second anchoring mechanisms are operative to imbed within a portion of said vaginal epithelium.

**11**. The system of claim 10 wherein said backing and anchor mechanisms formed thereon are operative to be surgically implanted under the vaginal epithelium.

**12**. The method of claim 7 wherein said anchor mechanism is detachably fastenable within said needle.

**13**. The method of claim 7 wherein said anchor mechanism is detachably fastenable upon the exterior distal tip of said needle.

**14**. The implant of claim 6 wherein each respective anchor mechanism comprises a spiral-shaped screw when said anchor mechanism assumes said first insertion configuration.

**15**. The implant of claim 6 wherein each respective anchor mechanism comprises a spiral-shaped screw when said anchor mechanism assumes said first configuration and can be deformed to assume said second insertion configuration to secure the anchor mechanism in position.

**16**. The implant of claim 1 wherein said implant is operative to provide vaginofixation to a prolapsed vagina.

**17**. The method of claim 9 wherein in step d), said anatomical structure comprises a prolapsed vagina.

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