Title: METHODS AND APPARATUS FOR TREATING PELVIC FLOOR PROLAPSE

Abstract: This invention relates to a surgical implant system for repairing pelvic prolapse in a patient. In particular, the present invention relates to an implant, a delivery device and a method for implanting and securing the implant to tissue structures in the pelvic region of the body.
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
METHODS AND APPARATUS FOR TREATING PELVIC FLOOR PROLAPSE

FIELD OF THE INVENTION

This invention relates to a surgical implant system for repairing pelvic floor prolapse in a patient. In particular, the present invention relates to an implant, a delivery device and a method for implanting and securing the implant to tissue structures in the pelvic region of the body.

BACKGROUND OF THE INVENTION

Pelvic floor disorders are a type of abnormality that affects the pelvic region and is a painful and dangerous condition whereby delicate anatomical structures can shift and even protrude into other pelvic structures such as the bladder, rectum and vagina. Typical pelvic floor disorders include vaginal vault; whereby the vagina prolapses on itself usually following hysterectomy, rectocele; a protrusion of the rectum into the posterior vaginal wall, enterocele; a protrusion of the small bowel into the posterior vaginal space, uterocele; a collapse of the support for the uterus and subsequent falling into the vagina and urethrocele; a collapse of the bladder and/or the urethra into the anterior vaginal wall. This displacement from a normal position of these organs is caused by damage or stretching of complex supporting structures such as ligaments or muscles. Once these supporting structures are compromised, artificial methods must be utilized to restore these anatomical structures to their proper position and provide long term securement in place. This condition is often treated by systems that position a surgical implant, often a mesh, into the pelvic cavity. This mesh requires some fixation through deep structures such as ligaments or muscles or through the skin. The mesh implants often have straps that fix in anterior and posterior structures. The straps are positioned using various needle assemblies that create pathways in tissue that extend from the pelvic cavity to the skin. These needle assemblies pass from outside the body into the pelvic cavity to collect the straps whereby they may be pulled outside the body and secured.
Alternatively these straps may be secured by needles that create pathways in tissue which are passed from inside the pelvic cavity and pass in the opposite direction to the skin outside the body. The passage of these long needles requires considerable skill so that the needles do not damage nerves or blood vessels present in the needle pathways. The passage of these needles is performed without direct visualization so considerable skill on the part of the surgeon is required to avoid these critical structures and to place the implant correctly. In some procedures these mesh implants are secured directly to the pelvic region using staples or suture and these can pull out over time and are often the cause of considerable pain and discomfort for the patient.

Thus there is a need for an improved device and method for the treatment of pelvic floor disorders that eliminates the passage of these needles through delicate structures and avoids sutures or staples. A device that can deliver and secure a strap to the pelvic region from within the pelvic floor region without requiring long needle passes through the skin is needed.

**SUMMARY OF THE INVENTION**

The present invention generally describes systems and methods to treat pelvic floor disorders, particularly pelvic prolapse conditions and/or urinary incontinence using single incision techniques through the vaginal wall. In this type of procedure, access to the pelvic floor cavity is made through the anterior or posterior vaginal wall so that supporting structures such as slings or mesh implants may be introduced and secured to support the urethra, bladderneck, vagina, bladder and pelvic floor. Access through the vagina may be used to insert, position, tension and fixate an implant to the pelvic floor without requiring dangerous blind procedures described previously. Devices and methods that utilize single incision surgery may be safer, quicker and less traumatic for the patient.

One aspect of the invention is an apparatus for treating pelvic floor disorders. The invention includes an implant that has at least one arm extending from the implant. The implant arm is adapted to secure the implant to a tissue structure by generally passing through or around the tissue. The invention also includes a delivery device to deliver the apparatus to the treatment...
area and may have a housing with a passer disposed inside. The passer may be configured to
penetrate pelvic tissue structures in a generally circular path when it is advanced from the
housing. The passer may be further adapted to couple to the implant and pull the arm
through the path when it is retracted.

In another embodiment of the invention, the delivery device may have the arm detachably
coupled to the housing and the arm may be positioned to intersect the expected path of the
passer such that a distal end of the passer contacts and couples to the arm before the passer is
retracted. The arm may also be preloaded onto the housing before insertion into the pelvic
floor region of the body.

In another embodiment, the arm may be positioned independently from the implant. A
connector may be configured to detachably couple the arm to the implant such that the arm
may be first secured to a tissue structure, then the implant is introduced and the arm may be
coupled to the implant. This may allow strap placement before the implant is introduced and
secured.

Another aspect the arm may have an inner portion and an outer portion with the two
portions detachably joined together end to end with a removable cord. This cord may be
removed or severed so that the distal portion separates from the proximal portion.

Another aspect of the invention is a delivery device for securing an arm extending from an
implant to a tissue structure. This delivery device may have a housing with a passer disposed
within. This passer may be configured to penetrate at least a portion of the tissue structure to
form a generally circular path when it is advanced from the housing. This advancement may
be in a plane orthogonal to the housing's longitudinal axis and the passer may have a
connector adapted to couple to the arm after penetrating the tissue structure. The passer may
be used to pull the arm back through the path when it is retracted. This delivery device may
also include a pivot and an actuator that is coupled to the passer and this passer may have a
circular radius and be configured such that as the actuator is advanced, the passer rotates
about the pivot in the generally circular path. In general the circular path may encircle various
ligaments or pelvic tissues such as the sacrospinous ligament or the arcus tendineus.

In one embodiment the connector described is a magnetic coupler and in another the
connector is mechanical coupler. The delivery device may be rigid or it may be flexible and may have a preset or flexible shape.

In another embodiment the passer may be made from a super elastic alloy that has a pre-set radius and the passer may be confined to a straightened condition by an outer tube and configured such that as the passer is advanced from the tube it penetrates tissue in a generally circular path.

Another aspect of the invention is an apparatus for securing an arm of a surgical implant to a tissue structure. The apparatus may have a tubular housing that contains a guide and the guide maybe adapted to penetrate the tissue in a substantially circular path when advanced from the open distal end of the housing. The apparatus may further include a strap tube that is connected to the arm and disposed about the guide. Additionally a pusher may be disposed about the guide in a proximal position to the strap tube and the pusher may be adapted to push the strap tube along the guide.

A further embodiment of the invention is a surgical kit for treating pelvic prolapse including an implant arm with at least one arm, a delivery device for securing the arm to the pelvic tissue and a funnel. The funnel may have an attached drape and a retention ring adapted to retain the funnel in an incision.

Another aspect of the invention is a method of securing an implant having at least one arm to the pelvic cavity of a patient. The steps may include making an incision in the vaginal wall, positioning a delivery device into the incision, advancing a passer and penetrating adjacent tissue, coupling the passer to the arm, retracting the passer and pulling the coupled arm back through the tissue and withdrawing the delivery device and the arm from the incision.

The method may further include positioning the delivery device using a finger or an endoscope coupled to a distal end of the device. The method may further include positioning a funnel in the incision, introducing the implant through the funnel and pulling a free end of the arm back through the funnel.

Another embodiment of the invention is a method of securing an implant having at least one arm to the pelvic floor of a patient including the steps of making an incision in the vaginal wall,
positioning a delivery device into the incision, advancing a guide through tissue, advancing a strap tube along the path of the guide by using a pusher, withdrawing the guide and pusher into the housing and removing the delivery device.

It is understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention as claimed. The accompanying drawings illustrating an embodiment of the invention and together with the description serve to explain the principles of the invention.

**BRIEF DESCRIPTION OF THE DRAWINGS**

Figure 1A is a cutaway view of a normal pelvic cavity;
Figure 1B is a cutaway view of a pelvic cavity having urethrocele;
Figure 1C is a cutaway view of a pelvic cavity having rectocele;
Figure 1D is a cutaway view of a pelvic cavity having enterocele;
Figure 2 is a perspective view of an embodiment of a surgical implant;
Figure 3 is a cutaway view of a pelvic cavity with the device supporting the bladder;
Figure 4A is a perspective view drawing of an embodiment of the present invention showing an apparatus for securing an arm to a pelvic tissue structure;
Figure 4B is a perspective view drawing of an embodiment of the present invention showing an alternate apparatus for securing an arm to a pelvic tissue structure;
Figure 4C is a perspective view drawing of an embodiment of the present invention showing another alternate apparatus for securing an arm to a pelvic tissue structure;
Figure 5A is a perspective view of a delivery device for securing an arm to a pelvic tissue structure;
Figure 5B is a perspective view of the delivery device of FIG 5A showing a passer having a generally circular path around a tissue structure;
Figure 5C is a perspective view of the delivery device of FIG 5B showing the arm being pulled by the passer;
Figure 6A is a perspective view of an embodiment of a delivery device for securing an arm
showing a passer with a connector and an arm with a receiver;
Figure 6B is a perspective view of a delivery device of FIG 6A showing a passer and arm connected using the connector and receiver;
Figure 6C is a perspective view of a passer with a threaded connector and an arm with a threaded tube;
Figure 7A is a perspective view of an embodiment of a delivery device for seeming an amni to a tissue structure;
Figure 7B is a perspective view of the device of Figure 7A showing a deployed passer;
Figure 7C is perspective view of the device of Figure 7B with a pusher and strap tube deployed;
Figure 7D is perspective view of the device of Figure 7C with the passer and pusher withdrawn;
Figure 8A is a drawing of an alternative shape of a delivery device for securing an arm showing a substantially straight shape;
Figure 8B is a drawing of an alternative delivery device for securing an arm showing an offset straight shape;
Figure 8C is a drawing of an alternative delivery device for securing an arm showing a curved shape;
Figure 8D is a drawing of a flexible delivery device for securing an arm;
Figure 9A is a perspective view of a delivery device for securing an arm having a finger loop;
Figure 9B is a perspective view of a delivery device for securing an arm having an endoscope attached;
Figure 10 is a perspective view of an embodiment of a surgical implant showing a funnel and drape.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS
Although many different devices and several different methods of accessing and repairing pelvic floor disorders such as fecal or urinary incontinence, vaginal vault prolapse, vaginal hernia, rectocele, enterocele, uterocele, and urethrocele or combinations of these disorders have been tried, including surgical and laparoscopic procedures, a better device and method are needed. Particularly a device that can be easily implanted and secured to pelvic floor structures without requiring dangerous and highly skilled needle passes through the skin is necessary. An implant and implantation method that permit introduction of a delivery device to which is attached a surgical implant to the pelvic cavity using a small incision, that can be implanted and secured without exceptional skill by the surgeon or risk to the patient may lead to better outcomes.

Although the repair of pelvic floor disorders is particularly referenced, it is anticipated that the apparatus and methods described herein maybe used for other surgical or laparoscopic procedures whereby a tissue structure of the human body requires strengthening or supporting. The delivery devices described are applicable to pelvic floor disorders but maybe used wherever a strap, cord, arm or suture needs to be passed through a tissue of the body.

Referring to Figure IA, there is shown a cross-sectional view of a normal, pelvic region of a female body. The pelvic region includes the uterus 1, pubic bone 2, bladder 3, urethra 4, vagina 5, fallopian tube 6, ovary 7, small bowel 8 and the rectum 9. These organs and structures are shown for a healthy female without any pelvic floor disorders. The organs such as the bladder 3, vagina 5, ovary 7 and fallopian tube 6 are shown properly supported by ligaments and connective tissue such that these organs are in their correct anatomical location. Figures IB-ID illustrate various conditions of pelvic floor prolapse where the present invention may be useful for treatment. Figure IB shows a pelvic floor afflicted with urethrocele, or a collapse of the bladder 3 and/or urethra 4 into the anterior vaginal wall 10.

This protrusion of the urethra and bladder in this figure illustrates how the vagina of the patient may become compromised and cause pain and discomfort to the patient. Figure IC shows a pelvic floor afflicted with rectocele, or a collapse of the rectum 9 into the posterior vaginal wall 12. Figure ID shows a pelvic floor afflicted with enterocele, or a collapse of the small bowel 8 into the upper portion of the posterior vaginal wall 14. The proper return of
these organs to their proper orientation and location in the pelvic cavity is one of the objects of this invention.

Referring now to Figure 2, there is shown a surgical implant 28 comprised of an implant 30 and having at least one flexible arm 32A-E extending from the side of the implant. The implant 30 may be constructed of a solid or a permeable material. The implant 30 may have various shapes. An example of a permeable material is a mesh that may be receptive to tissue ingrowth. Suitable materials for making the mesh may be: polypropylene mesh such as that distributed by CR, Bard, Inc. of Murray Hill, NJ. under the trade name "Marlex"; a polyethylene mesh material of the type distributed by E. I. Du Pont de Nemours and Company of Wilmington, Del. under the trade name "Alathon"; and a Dacroii mesh material or a Nylon mesh material of the type distributed by E. I. Du Pont de Nemours and Company of Wilmington, Del. Additionally the mesh may be constructed from a metallic mesh or a polymer mesh having interwoven metallic filaments. These filaments may provide additional strength to the mesh or make the mesh radiopaque for later visualization. The mesh may be a single layer or have a multilayer construction. The mesh may have one or more layers constructed from a bioabsorbable material such that the mesh may be reabsorbed by the body over time. The mesh may have one or more layers constructed from a layer having anti-adhesion properties such that ingrowth or attachment of tissue to the mesh is inhibited. One or more layers may also be coated with an anti-adhesional coating that is applied to a surface to inhibit tissue attachment. These anti adhesional characteristics may be particularly useful for those implant surfaces that are exposed to the internal viscera of the abdominal cavity. In this situation it may be helpful to inhibit potential attachment of various organs to the implant. One example of an adhesion resistant material is, for example, a thread of polytetrafluoroethylene polymer material of the type sold under the trade name "Gore-Tex" by W. L. Gore & Associates, Inc.

The implant 30 may be made initially oversized compared to the size of the pelvic disorder. The implant may be sized substantially larger than the area of the disorder and the implant 30 may be trimmable so that the implant may be trimmed in situ to fit the size of the interventional need, hi this way one implant size may be provided to the user and then the
implant custom trimmed to fit the surgical conditions.

The arm 32A-E may be used to secure the implant 30 to the pelvic cavity and if more than one arm 32 is used then they are preferably symmetrically arranged around the perimeter of the implant 30. Although five arms 32A, 32B, 32C, 32D, and 32E are shown in Figure 2, this is for descriptive purposes only. The apparatus 28 may use one, two, four or more anus. The placement of the arm maybe at an apex of the implant 30 or evenly spaced around the perimeter. The arm maybe integrally formed as an extension of the implant 30 or may be a separate piece that is formed from the same material as the implant 30. The arm and the implant 30 may also be constructed from different materials.

The arm may be identified with unique identifying characteristics called differentiators so that one arm may be discerned from another. In this way an arm corresponding to a particular location on the implant may be identified and the anatomical position of the arm can be discerned. By way of example that is not meant to be limiting, each arm may have a different color coding so that when the implant is inside the pelvic space, the orientation of the implant may be discerned and correct positioning of the arms to avoid entanglement can be realized. The arm may be further differentiated from other arms by degrees of radiopacity, by an identifying structure such as interwoven threads, by a printed number on the arm itself, or by differences in materials. Other means of differentiation are possible and these examples are not intended to be limiting.

The arm may have different configurations and the device 28 may utilize one configuration only for a particular implant or multiple configurations maybe utilized on a single implant. However the arm is generally flexible and not rigid. While other prior art devices utilize stiff and rigid engagement type arms and especially rigid placement needles or trocars, the present invention is flexible. The arms are adapted to pass through or in some case around pelvic tissue structures such as the sacrospinous ligament or the arcus tendineus.

Arm 32A is shown as a woven mesh that is integrally formed as an extension of the implant mesh 30. In this configuration the arm 32A is a mesh strap that may extend 2-20 inches from the perimeter of the implant 30. As can be shown the arm 32A has a tapered end 33 that reduces the width of the strap. The end of the arm may have a piercing element 34 attached at
the end of the arm.

Arm 32B, having an inner end 35 and an outer end 36, is shown coupled to the implant 30 at inner end 35. Inner end 35 is located interiorly from the perimeter of the implant 30. This attachment location may facilitate trimming the implant area at the interventional site because the attachment point is set apart from the edge that might be trimmed. The attachment location could be located anywhere on the implant and is not limited to a particular location. Secondly, arm 32B is not integral to the implant 30 but is a separate arm. Arm 32B is attached to the implant with a connector 37 at the end 35 of the arm 32B. This arm may be deployed as part of the implant or may be decoupled from the implant and re-coupled later.

This configuration of implant allows separate placement of the arm and implant, in some situations it may be preferable to position the arm 32B prior to insertion of the implant. In other situations it may be preferable to position the arm after the implant is positioned. The connector 37 maybe any type of mechanical connector, magnetic connector, adhesive or other connector. Some examples of mechanical connectors are hooks, snaps, threaded sections, bayonet fastener, hook and loop type fastener, snares, buttons, suture, or clamps although any type of connector may be suitable and this list is not meant to be limiting.

Arm 32B also has a detachment zone 38 that is the coupling zone for the inner portion 32B and the outer portion 40. Outer portion 40 has inner and an outer ends 41 and 42. The inner end 41 of the outer portion 40 is coupled to the outer end 36 with the use of cord 44. The cord 44 may be a thread, suture or other similar material configured so that the two described ends 36 and 41 can be coupled by loosely tying them together. An end of the cord 46 may extend outside the body. Together the arm 32B and the outer portion 40 provide a long enough length of strap so that the combination can be used to tension the implant by pulling the outer portion 40 from outside the body. However, once the implant is tensioned properly any excess arm is unnecessary and is often removed so that the end of the arm can be positioned inside the incision. Therefore the excess maybe cut away but the optimal cutting point may be deep inside the pelvic cavity and difficult to reach especially with a small incision.

Therefore the detachment zone 38 is intended to provide a remote method of detaching unnecessary length of the arm that is inside the incision. The cord 44 may be severed at the
detachable zone 38 with a blade or may be released by pulling on the cord end 46 from outside the body. In another embodiment of the invention the arm 32B terminates at outer end 36 and outer portion 40 is not present. However cord 44 may still be threaded through the outer end 36 only. Tension may be applied to the arm by pulling on the cord 44. After proper positioning and tensioning of the implant 30, the cord may be removed from the arm 32B by pulling on the cord end 46 so that the outer end 36 remains inside the pelvic cavity.

In another embodiment of the arm 32C, the width of the arm is reduced to facilitate pulling the arm through various tissue structures. The reduced lateral profile may reduce friction and the resultant force required to pull or push the arm. The arm 32C profile may be reduced by spinning, forming or winding the arm 32C material into a smaller diameter and thereby forming a cord or leader. The arm 32C profile may be reduced by the use of a sleeve 50 disposed around the arm. Such a sleeve 50 may be made of polyethylene, polypropylene, nylon, silicone or other suitable polymer that may be useful to reduce the friction as the arm passes through tissue structures. The sleeve 50 may be made from a shrink tubing. Arm 32C may have all or a part of its length comprised of a leader 52. This leader may be made of suture, cord, string, wire or other suitable flexible material. This leader 52 may be coupled directly to the implant 30 or may comprise a portion of the arm 32C and a piercing member may or may not be attached at the end.

The outer end of the arm may also terminate with an anchor 54 or 56 attached to amis 32D and 32E. Arms 32D and 32E may be positioned in a tissue structure either by pushing or pulling the arms as will be shown. These arms' outer ends enter tissue structures and then anchor into the tissue to secure the arm to the tissue. Various anchor designs are anticipated and the anchors 54 and 56 are not meant to be limiting. Anchor 54 is shown having lateral barbs 55 that may have a fixed configuration or these barbs maybe deployable after positioning. The anchor 56 is a barbed hook which may pass easily into tissue and then inhibit reverse movement to prevent pullout of the anchor and arm.

Referring now to Figure 3, shown is a cross-sectional view of a pelvic floor with an example of an implant 72 positioned to support the urethra and bladder for the treatment of urethrocele. An incision 70 has been made along the anterior wall 10 of the vagina 5 to
provide access to the bladder 3 and the urethra 4. The incision is positioned to maximize the exposure to the prolapsed area. The implant has been positioned around the bladder and urethra to maximize support of these two organs. As can be seen by comparing Figure 3 to Figure 1B, the bladder and the urethra have been moved to their proper positions as shown in Figure 1A. The implant 72 is shown as a mesh having open cells and two arms at one end 74a-b and two arms at the opposite end 75a-b. These arms are secured to pelvic tissue (not shown) to secure the implant. This is shown as an illustration only and many other implant sizes, materials and securement methods may be used. The implant may be placed through the incision in the anterior vaginal wall 70 as shown and then the delivery devices removed, the mesh positioned where needed and then the incision is closed to complete the procedure. Referring to Figures 4A-C, three embodiments of a delivery device to position an arm are illustrated. Such a delivery device and method maybe used to position an arm in a tissue structure through a confined space with little visibility such as found in the incision and small spaces of the pelvic cavity. An intended benefit of the described delivery device and method is to position an arm as previously described through a smaller incision as with other devices. Another intended benefit is that the positioning, securement and tensioning of the arm attached to an implant can be performed from inside the cavity without the need to pass anchoring straps outside the body and without having to insert large needles or trocars into the pelvic region from outside the body.

The delivery device 100 includes a housing 102 having a cavity 104 disposed at its distal end 106. A curvilinear passer 108 having an inner end 109 and an outer end 110 is disposed inside the housing 102. The outer end 110 is sharpened to facilitate passage through tissue structures. The inner end 109 is coupled to the housing 102 at a rotating pivot 112 so that the passer can rotate about this pivot in a generally circular pathway. The passer 108 is rotatably linked to an actuator 114 at linkage 116 and the actuator is slidably disposed inside the housing. The outer end 110 of the passer may also have a connector 118 that is adapted to couple to an arm.

As shown in Figures 5A-C, the delivery device 100 of Figure 4A is positioned at the delivery site with the cavity facing the direction of activation. As the actuator 114 is moved toward the
distal end 106, the passer 108 is driven through the linkage 116 and pivots around the pivot
112. The passer then moves in a generally circular pathway that conforms to the shape of the
passer into or around tissue structures 117 located inside or adjacent the cavity. The
mechanism maybe useful to drive the passer 108 around tissue structures 117 such as
tendons, bone, ligaments or other pelvic structures. As the passer traverses in a generally
circular pathway, it couples with an end of an arm 119 that is positioned along the generally
circular path of the passer using the connector 118. The connector 118 shown is a barbed
hook that penetrates the mesh of the arm 119. The arm 119 maybe loaded onto the housing
such that the generally circular travel of the passer intersects an end portion of the arm 119.
The arm may be preloaded onto the housing prior to insertion of the delivery device into the
pelvic cavity. This arm may be captured and temporarily coupled to the delivery device. In
this method, the arm of an implant would first be positioned onto a housing and then the arm
and the housing could be delivered together into the pelvic cavity.
Once the arm 119 is coupled to the connector 118, the actuator may be retracted away from
the distal end 106 which also retracts the passer 108. This movement pulls the arm 119 along
the generally circular pathway of the passer, and back into the housing. The delivery device
100 may be withdrawn in the direction of the arrow, pulling the arm through or around the
tissue structures. In the case of pelvic prolapse repair, the delivery device 100 maybe used to
position the arms in or around various tissue structures such as the sacrospinous ligament,
arcur tendineus, bone or other pelvic structures.
An alternate delivery device 130 is shown in Figure 4B including a housing 132 having a
tapered end 133 with a passer 134 slidably disposed inside. The passer 134 may have a
sharpened end 136 and a connector 138 to couple with an engagement device. The passer is
made from a curved superelastic alloy such as Nitinol. The passer 134 is restrained inside the
housing and when advanced outside the housing, the passer assumes a curved shape. The
passer is driven through tissue structures as it is further advanced from the housing traversing
a generally circular pathway. The connector 138 located at the sharpened end 136 is adapted
to couple with an arm such that as the passer is retracted inside the housing 132, the arm (not
shown) is pulled through the generally circular pathway of the passer. The mechanism may
be useful to drive the passer around tissue structures such as tendons, bone, ligaments or other pelvic structures. The delivery device 130 may be withdrawn pulling the arm through the tissue structures. In the case of pelvic prolapse repair, the delivery device 130 maybe used to position the arms in various tissue structures such as the sacrospinous ligament or the arcus tendineus.

An alternate delivery device 140 is shown in Figure 4C having a passer 142 comprising an elongate hollow housing 144 coupled with a steerable end portion 146. Disposed inside the hollow housing are at least two controlling wires 147a-b that extend to the proximal end. These controlling wires are attached to the steerable end portion 146 such that by relaxing one wire and pulling another the steerable end portion may be actuated to steer the steerable end portion 146 in a particular direction. As can be seen, if the wires are positioned next to a tissue structure and actuated to form a curved configuration, as the passer 142 is advanced the passer will traverse through a generally circular pathway. The passer may have a sharpened end 148 and a connector 149 located at the end. The connector 149 is adapted to couple with an arm such that as the passer 142 is retracted and the steerable end portion is straightened, the arm (not shown) is pulled through the generally circular pathway. The delivery device 140 maybe withdrawn pulling the arm through the tissue structures. In the case of pelvic prolapse repair, the delivery device 140 maybe used to position the arms in various tissue structures such as the sacrospinous ligament or the arcus tendineus.

Alternate connectors are illustrated in Figures 6A-C that may be useful to connect a previously described passer with an arm. A connector 150 is shown attached to a passer 152 similar to those discussed. The connector 150 maybe a magnet tip that is configured to mate with a magnetic receiver 154 attached to an arm 155. As the magnetic tip passes through tissue structures and approaches the magnetic receiver 154, a magnetic coupling occurs and the arm 155 is detachably joined to the connector and passer. The magnetic coupling should be strong enough to maintain the coupling as the passer is withdrawn pulling the arm 155 through tissue structures. Rare earth magnets may be used in this example. Also shown is connector 160 attached to a passer (not shown) similar to those discussed. The connector 160 maybe a threaded rod 162 that is configured to mate with a similarly threaded
tube 164 attached to an arm 165. As the threaded rod 162 passes through tissue structures and approaches the threaded tube 164, the two may be coupled by screwing the two together and the arm 165 is detachably joined to the connector 160. The threaded coupling should be strong enough to maintain the coupling as the passer is withdrawn pulling the arm 165 through tissue structures.

In addition to these connector examples shown, the passer 152 may utilize any number of mechanical connectors such a barb, a spear, a threaded connector, a snap, a bayonet system, a latch, a clamp, hook and loop type fasteners or a jaw. Any connector that can couple an end portion of the arm with the passer tip maybe used. Likewise any number of magnetic couplers as well as adhesives maybe utilized. The list of potential couplers is large and any number of suitable connectors known by those skilled in the art maybe successfully employed.

An alternate embodiment of an arm delivery device 200 is shown in Figures 7A-D having an elongate hollow body 201 enclosing an elongate tubular housing 202 that may freely slide along the transverse axis of the body 201. The housing 202 has a guide 204 comprising an elongate flexible curvilinear rod disposed therein. The guide 204 is adapted to assume a generally circular shape when not constrained inside the housing. The guide 204 has a tip 206 configured to penetrate tissue structures of the body. The delivery device 200 further comprises a strap tube 208 and a tubular pusher 210 disposed coaxially about the outside of the housing such that both may slide along the transverse axis of the housing. The strap tube 208 has distal 210 and proximal 211 end portions with the distal end portion configured to couple to a catch 212 located at an opening 214 in the body. The catch is adapted to secure the strap tube to the body 201 as will be shown. The strap tube 208 has an arm 216 attached to the proximal end 211.

In use, the body 201 is introduced into the pelvic cavity through an incision in the vaginal wall and the guide 204 is extended from the housing 202 such that the guide makes a generally circular pathway through and around tissue structures 218 and enters the opening 214 in the body 201. Alternatively other sites other than the vaginal example given may be used to insert the delivery device into the pelvic cavity. If this is used outside the pelvic
region, then other suitable entry sites may be used. The housing 202 is then extended from the body and the strap tube 208 is pushed from the housing along the guide 204 by the pusher 210. The strap tube 208 is pushed through tissue structures 218 while following the guide until it enters the opening 214 and is captured by the catch 212. At this point the strap tube is coupled to the body 201. The guide, pusher and housing are retracted back into the body and the body removed from the pelvic space. As can be seen, as the body is withdrawn, the arm 216 is positioned through and around tissue structures 218.

The device of Figures 5, 6 and 7 may be positioned and used in such a way that the arm 119, 155 or 216 respectively is secured to pelvic tissue structures. As shown in Figures 8A-D, the various delivery devices previously described may be made with various shapes and rigidities to facilitate placement of the delivery device in the pelvic space. The delivery device 230 is a generally straight and rigid device with a handle 231 connected at the proximal end. Delivery device 232 has an angular offset bend along its length that may be useful in certain anatomical conditions and delivery device 234 has a general curvilinear shape. Alternatively the delivery device 236 may be flexible and not rigid or may be steerable by the operator.

The delivery devices previously described may be placed in the pelvic cavity using positioning aids to guide and direct the placement of the arms. These aids may utilize tactile or visual feedback to the operator so that tissue structures such as arteries, veins, nerves, bone, ligaments or tendons in the body can be identified and the placement of the arm may be properly directed compared to a blind approach. Referring to Figures 9A-C, the delivery device may have a finger loop 250 configured at the distal end such that an operator may place a finger into the loop and utilize tactile feeling in the finger to guide placement of the delivery device end. The finger loop 250 may be attached to the delivery device at point 251 using adhesive or mechanical attachments. The finger loop 250 may also be integrally formed as part of the delivery device. Similarly, the delivery device 252 may have a light source 254 attached to the outer body of the delivery device 252. This light source may be an LED light source and be adapted to radiate a generally confined narrow beam of light. This light maybe
directed such that the light may be seen through the skin. In this way the operator can utilize the light as a marker to guide positioning as described. In another embodiment the delivery device maybe constructed with loops 260 to couple an endoscope 262 to the delivery device. In this way the placement and delivery of arms using the delivery device may be controlled through direct visualization by the operator. Multiple arms maybe used to secure an implant in the pelvic space. These arms may have cords or leaders that extend from the distal ends of the arms that may be used to tension the implant. Keeping these ends organized and identified maybe challenging. Additionally the sterility of all of these loose ends and the implant must be maintained in a crowded surgical site. To organize and identify the various cords coming from the arms, the leaders themselves or the arms may be color coded, shape coated or in some other way uniquely identified with differentiators so that an individual arm and its location to the implant and the pelvic cavity can be determined.

A device to organize the method of implanting the implant and providing a large sterile barrier is illustrated in Figure 10. A funnel 300 is shown positioned in the incision of a posterior vaginal wall. The hourglass shaped funnel 300 has a wide opening 302 and a narrow opening 304 positioned in the incision and a narrowed neck in between. The funnel may have a straight taper configuration or other configurations as well. The narrow opening 304 may have a retention ring 308 that has an outer diameter greater than the narrow opening 304. The retention ring 308 outer diameter is sized so that once placed into the incision, it retains the funnel 300 in the incision and prevents inadvertent dislodgement of the funnel from the incision. A drape 310 is attached to the wide opening 302 and extends radially outward from the opening. The drape and funnel may be packaged sterile and the drape is sized to cover an extended surgical area. As can be appreciated when the narrow opening 304 of a sterile funnel is inserted into an incision and the drape extended, an effective sterile barrier is created so that an implant having multiple arms may be inserted through the funnel and into the pelvic space in a sterile, organized manner. Furthermore the arms or leaders attached to the ends of the arms maybe threaded back through the funnel after positioning into a tissue structure. When the end of an arm is pulled to apply tension to the implant the inside of the
retention ring 304 may act as a fulcrum point and protect the incision edge from abrasion from the arm. The excess length of the arm may be removed, the funnel and drape removed and the incision closed to complete the operation. The excess length may be particularly removed by severing or removing the cord 44 located in a detachment zone 38 as shown in Figure 2.

This invention has been described and specific examples of the invention have been portrayed. The use of those specifics is not intended to limit the invention in any way.

Additionally, to the extent that there are variations of the invention, which are within the spirit of the disclosure or equivalent to the inventions found in the claims, it is our intent that this patent will cover those variations as well.
What is claimed is:

1. An apparatus for treating pelvic floor disorders comprising:
   an implant having at least one arm extending from the implant that is adapted to secure the implant to a tissue structure,

2. The apparatus of claim 1, wherein the arm is detachably coupled to the housing and positioned to intersect an expected path of the passer such that a distal end of the passer couples to the arm before the passer is retracted.

3. The apparatus of claim 1, wherein the arm is preloaded to the housing.

4. The apparatus of claim 1 further comprising a mesh formed from a material selected from a group consisting of a synthetic material, a biological material and a combination of synthetic and biological materials.

5. The apparatus of claim 2, wherein the arm comprises a strap, cord, suture or mesh with the arm having an inner and an outer end.

6. The apparatus of claim 5, wherein the inner end of the arm includes a connector configured to detachably couple the arm to the implant enables the arm to be first secured to the tissue structure and thereafter coupled to the implant.

7. The apparatus of claim 6, wherein the arm further comprises differentiators enabling differentiation of one arm of the implant from another arm of the implant.

8. The apparatus of claim 7, wherein the differentiators are configured to differentiate arm color, shape, radiopacity, materials of construction and physical structure.

9. The apparatus of claim 6, wherein the connector comprises a mechanical fastener, hook and loop type fastener, button, suture, magnetic fastener, adhesive or clamp.

10. The apparatus of claim 5, wherein the arm is tapered between the ends and further comprises a tapered sleeve, the sleeve being adapted to reduce frictional drag as the
arm is secured to the tissue structure.

11. The apparatus of claim 5, wherein the arm further comprises an inner portion and an outer portion, the two portions detachably joined together end to end with a removable cord such that when the cord is removed or cut the distal portion separates from the proximal portion.

12. A delivery device for securing an arm extending from an implant to a tissue structure comprising:
   a housing;
   a passer disposed within said housing, the passer being configured to penetrate at least a portion of the tissue to form a generally circular path when advanced from the housing in a plane orthogonal to the longitudinal axis of the housing, said passer having a connector adapted to couple to the arm after penetrating the tissue structure, said passer being further adapted to pull the arm back through the path when retracted.

13. The delivery device of claim 12, further comprising a pivot and an actuator coupled to the passer, said passer having a circular radius and configured such that as the actuator is advanced, the passer rotates about the pivot in the generally circular path.

14. The delivery device of claim 13, wherein the arm is disposed about the housing such that the generally circular path of the passer intersects a portion of the arm.

15. The delivery device of claim 12, wherein the circular ocular path is selected to encircle a sacrospinous ligament.

16. The delivery device of claim 12, wherein the circular path is selected to encircle the arcus tendineus.

17. The delivery device of claim 12, wherein the connector couples to the arm using a magnetic coupler.

18. The delivery device of claim 12, wherein the connector couples to the arm using a mechanical coupler.

19. The delivery device of claim 18, wherein the mechanical coupler further comprises a barb, a spear, a threaded connector, a snap, a bayonet system, a latch, a clamp or a jaw.
20. The delivery device of claim 12, wherein the housing is flexible and has a preset or flexible shape.

21. The delivery device of claim 12, wherein the passer is made from a super elastic alloy having a pre-set radius, the passer being confined to a straightened condition by an outer tube and configured such that as the passer is advanced from the tube in a plane orthogonal to the housing longitudinal axis, a sharpened distal end penetrates tissue in the generally circular path.

22. The delivery device of claim 21, wherein the path is selected for encircling a sacrospinous ligament, an arcus tendineus, or other tissue structure.

23. The delivery device of claim 12, further comprising a finger holder configured to retain a finger of an operator for enabling tactile feel of the operator to guide the delivery device to an anatomical position.

24. An apparatus for securing an arm of a surgical implant to at least a portion of a tissue structure, the apparatus comprises:

- a tubular housing containing a guide, said guide adapted to penetrate the tissue structure in a substantially circular path when advanced from the open distal end of the housing,
- a strap tube connected to the arm and disposed about the guide, and
- a pusher disposed about the guide in a proximal position to the strap tube, said pusher being adapted to push the strap tube along the guide.

25. The apparatus of claim 24, wherein the substantially circular path initially extends away from the housing and thereafter returns to intersect the housing.

26. The apparatus of claim 19, wherein the path is selected for encircling a sacrospinous ligament, arcus tendineus, or other tissue structure.

27. The apparatus of claim 25, wherein the housing comprises a catch to retain the strap tube after the strap tube is moved along the guide by the pusher.

28. The apparatus of claim 24, wherein the guide is a guidewire.

29. A surgical kit for treating pelvic prolapse comprising:

- an implant arm having at least one arm extending therefrom, and
a delivery device for securing said arm to a portion of pelvic tissue comprising a passer configured to penetrate at least a portion of the pelvic tissue in a generally circular path when advanced, said passer having a connector adapted to couple to the arm after penetrating the pelvic tissue, said passer being adapted to pull the arm through the path when retracted.

30. The kit of claim 29, wherein the delivery device further comprises a pivot and an actuator coupled to the passer, said passer having a circular radius and configured such that as the actuator is advanced, the passer rotates about the pivot in a generally circular path.

31. The kit of claim 29, wherein the path is selected for encircling a sacrospinous ligament, arcus tendineus, or other pelvic tissue structure.

32. The kit of claim 29, further comprising a funnel having a wide and a narrow opening and an attached drape, the wide opening forming an opening in the drape and the narrow opening being sized for placement into a surgical incision, said funnel being further adapted to receive the implant.

33. The kit of claim 32, wherein the funnel further comprises a retention ring formed at the narrow opening configured to retain the funnel in the incision, said funnel being configured to hold the incision open and to allow the arm to pass through the narrow neck after passing through the portion of the vaginal wall.

34. The kit of claim 32, wherein said funnel is sized to permit at least partial closure of the incision and is configured to allow the arm to pass through the narrow neck so that the tension of the implant maybe adjusted by pulling on the arm against the narrow neck.
## A Classification of Subject Matter

- IPC(8) - A61 F 2/00; A61 F 13/00 (2008.04)
- USPC - 600/37

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

## B Fields Searched

- Minimum documentation searched (classification system followed by classification symbols) IPC(8) - A61 F 2/00; A61 F 13/00 (2008.04)
- USPC - 600/37

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched IPC(8) - A61 F 2/00; A61 F 13/00 (2008.04)
- USPC - 600/37; 126/897, 698; 600/29,30; 606/1 19,139,149,151

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used):
- PubMed: US PAT, US PGPUB, US OCR, EPO; Google Scholar; Keywords: pelvic, pelvis, implant, implanted, implantable, prosthetic, prostheses, probe, surgical tool, floor disorder, circular path, trocar, cannula, strap, cord, mesh, barb, latch, clamp, bayonet, threaded connector, spear, synthetic, biological, biodegradable

## C Documents Considered to be Relevant

<table>
<thead>
<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>US 2002/0028880 A1 (THIERFELDER et al.) 07 March 2002 (07.03.2002) para [0015], [0017], [0018], [0020], [0022], [0025], [0026], [0028], [0061], [0068], [0067], [0073], [0089][0091], [0094], [0123], and [0134][0141]</td>
<td>1-34</td>
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<tr>
<td>Y</td>
<td>US 2006/0258898 A1 (MONTPETIT et al.) 16 November 2006 (16.11.2006) para [0048], [0049], [0054], [0055], [0059], [0061], [0062], and [0067]; FIG. 1</td>
<td>1-34</td>
</tr>
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<td>Y</td>
<td>US 2007/0270890 A1 (MILLER) 22 November 2007 (22.11.2007) para [0011], [0021], [0024], and [0027], [0039] and FIGS. 5a-5d</td>
<td>13-16, 22, 25-27, 30, 31</td>
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<tr>
<td>Y</td>
<td>US 2004/0054353 A1 (TAYLOR) 18 March 2004 (18.03.2004) para [0003], [0006], [0067], [0071]; FIG. 4</td>
<td>32-34</td>
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</tbody>
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## D Further Documents are listed in the continuation of Box C

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

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