Abstract: A prosthesis for addressing pelvic organ prolapse in females comprises a frame fabricated from a shape memory material that supports a thin, flexible mesh sheet in a stretched condition when the frame is unconstrained. The mesh sheet is formed with two finger receiving pockets proximate its posterior periphery to be used by the surgeon in steering the prosthesis to a desired disposition within the pelvic basin. The frame is shaped so as to conform to and be supported by bone structures and muscle tissue in the pelvic basin while providing needed support to pelvic organs to maintain them in a proper position. The use of a shape memory material allows the prosthesis to be rolled or folded into a reduced size for ease of placement through a small incision in the wall of the vagina, but that springs back to its memorized shape following deployment from a delivery sheath.
Declarations under Rule 4.17:

— as to applicant’s entitlement to apply for and be granted a patent (Rule 4.17(H))

— as to the applicant’s entitlement to claim the priority of the earlier application (Rule 4.17(m))

— with international search report (Art. 21(3))
APPARATUS AND METHOD FOR PELVIC FLOOR REPAIR
IN THE HUMAN FEMALE

Background of the Invention

I. Cross-Reference To Related Application: This application is a continuation-in-part of U.S. application serial no. 12/716,323, filed March 3, 2010, which is a continuation-in-part of U.S. application serial no. 12/564,179 filed September 22, 2009, which is a continuation-in-part of U.S. application serial no. 12/421,116, filed April 9, 2009.

II. Field of the Invention: This invention relates generally to a surgically implantable prosthesis for hernia repair, and more particularly to an implantable device especially designed for pelvic floor repair.

III. Discussion of the Prior Art: The following definitions apply to terminology used in the present specification and claims:

Genital prolapse or pelvic organ prolapse (POP) refers to a loss of fibromuscular support of the pelvic viscera that results in vaginal protrusion. The prolapse is usually described according to the area of the vagina in which it occurs.

An anterior vaginal prolapse (or anterior pelvic compartment prolapse) generally involves the bladder (cystocele), and often involves hypermobility of the urethrovesical junction as well (cystourethrocele).

A posterior vaginal prolapse (or posterior pelvic compartment prolapse) often involves protrusion of a loop of the rectum into the vaginal canal (rectocele) and/or protrusion of a loop of small bowel in a peritoneal sac (enterocele).

Procidentia refers to a complete protrusion of the uterus and vagina.

The term vaginal vault prolapse refers to a complete or partial inversion of the vaginal vault, most commonly occurring in patients who have had a hysterectomy.

The term pseudorectocele describes an inadequate or defective perineum resulting in exposure of the mid-portion of the posterior vaginal wall. It mimics the appearance of a rectocele, but does not involve creation of a rectal pouch that incorporates both rectal and vaginal walls with loss of vaginal rugation.
An enterocele is the herniation of a peritoneal sac (usually filled with small bowel) through the vaginal apex. An enterocele may be further classified as a traction enterocele or a pulsion enterocele.

A traction enterocele is a protrusion of the posterior cul-de-sac that is pulled down by the prolapsing cervix or vaginal cuff.

A pulsion enterocele is a protrusion of the cul-de-sac through the vagina resulting from chronically increased intra-abdominal pressure. Pulsion enteroceles are frequently large and always contain small bowel. Enteroceles are usually encountered as a dissect through the rectal-vaginal septum, but may also occur in the space between the bladder and the anterior vaginal wall.

Factors which predispose women of all ethnic groups to the development of POP include injuries to the pelvic tissues during vaginal delivery followed by chronic increases in intra-abdominal pressure, obesity, advancing age and estrogen deficiency. Pelvic trauma and pelvic surgery may damage the neuromuscular structures, connective tissue and muscles of the pelvic floor, and vaginal delivery leads to stretching, dislocation, tearing and avulsion of pelvic tissues. Neurological injury to the pudendal nerve may also occur, as has been demonstrated in women with stress incontinence and pelvic organ prolapse. Chronic straining, as through heavy lifting, may also damage the pudendal nerve and lead to subsequent pelvic floor dysfunction by compromising neuromuscular function.

Post-hysterectomy vaginal vault prolapse is a distressing and increasingly common problem. It may occur following vaginal or abdominal hysterectomy and often results from inattention to the proper reconstruction of vaginal apex support following removal of the uterus.

POP can present many symptoms, depending on the organs involved. The most frequent symptom is a complaint of a protrusion or bulge felt within or appearing from the vagina that worsens with prolonged standing or walking. In some cases, the prolapse may be large enough to impair ambulation. Other common symptoms include low back pain, urinary incontinence, bladder and rectal voiding difficulty and sexual dysfunction. Changes in the vaginal epithelium are frequently
present in women with prolapse. In younger women, the vaginal skin may be hypertrophic, but in older women it will be atrophic, particularly if they are not receiving estrogen replacement therapy. Sexual dysfunction may also be present in women with prolapse due to alterations in vaginal anatomy and pelvic organ function.

In the human female, the endopelvic fascia condensations are responsible for pelvic organ support along with the muscular pelvic diaphragm, attaching the bladder, uterus, vagina and rectum to the pelvic sidewalls. It is subdivided into the parametrium and paracolpium. The parametrium consists of the uterosacral-cardinal ligament complex of condensed endopelvic fascia, which provides part of the structural support of the uterus. These so-called "ligaments" are really only two different parts of a single mass of loose tissue. The paracolpium attaches the upper two-thirds of the vagina to the pelvic wall and is continuous with the parametrium when the uterus is in situ. It helps suspend the vaginal apex after hysterectomy.

The vagina has three main levels of support:

Level I support includes the vagina apex and the paracervical vagina and consists of the long connective tissue fibers of the superior paracolpium.

The mid-portion of the vagina (Level II) is attached laterally, stretching between the bladder and the rectum and supported by the inferior portion of the paracolpium. At this level, the anterior vaginal wall and the endopelvic fascia merge to form the pubocervical fascia, which underlies the bladder and prevents protrusion of the bladder into the vaginal lumen. Posteriorly, the endopelvic fascia merges with the posterior vaginal wall to form the rectovaginal fascia or septum. This layer prevents the rectum from protruding through the posterior vaginal wall.

The lowest portion of the vagina (Level III) is found at the vaginal introitus and has no intervening paracolpium to suspend it. At this level, the vagina fuses directly with the levator ani muscles laterally, the urethra anteriorly and the perineum posteriorly.

Injury to the suspensory fibers of the upper paracolpium (Level I support) may result in uterine and vaginal vault prolapse with enterocele. Damage to the pubocervical fascia or rectovaginal fascia (the supportive fibers of Level II) leads to...
the development of cystocele and rectocele, respectively. Injury often occurs at both levels and results in a combination of defects.

Another important component of the pelvic floor is the levator ani muscles, critical in pelvic floor support. These muscles maintain a constant basal tone that maintains the uterus and vagina in place. Above the levator ani, the ligaments and fascia stabilize the organs in position. Constant adjustments in muscular activity prevent the stretching of the pelvic ligaments. Contraction of the pubovisceral muscle pulls the rectum toward the pubic bone, closing the urogenital hiatus and compressing the urethra, vagina and uterus. The pelvic floor should be seen as a dynamic trampoline that is constantly expanding and contracting in response to changing stimuli rather than a static slab. The levator muscles contract reflexively during periods of increased intra abdominal pressure (coughing, sneezing, etc.). In this process, the urethra, vagina and rectum are compressed against the levator plate, maintaining their normal positions in the pelvis. Any stretching or laceration of the levator muscles or endopelvic fascia can result in widening of the urogenital hiatus and a rotation in the axis of the levator plate with the subsequent development of a predisposition to uterine or vaginal prolapse.

The first meaningful advance in the treatment of POP was the development of vaginal pessaries that functioned as trusses. Generally speaking, a pessary is a device that can be inserted into the vagina to support sagging organs. Their use gained considerable popularity in the mid-19th century and they continue to be used when surgical risk is unacceptable or where the patient prefers this option. During the 20th century, advances in the understanding and surgical treatment of POP progressed at an increasing rate.

In 1909, Dr. George White of Georgia was one of the first to report a cystocele repair using a transvaginal paravaginal approach. His correct assessment of what is now referred to as "Level II" pelvic organ support by the attachment of the pubocervical fascia to the Arcus Tendineous of the pelvic sidewalls was rediscovered by mainstream workers in the field in the 1950's. This procedure involves difficult and specialized suturing techniques.
In the 1950's Dr. Milton McCall of Louisiana emphasized the importance of uterosacral ligaments in the so-called "Level I" support of the vaginal vault after hysterectomy.

More recently, in the 1990's, emphasis has been placed on the hernia nature of POP, leading to a change from absorbable suture material to permanent suture.

Again, in the 1990's, pelvic anatomist, John DeLancey of Michigan, published "A Biomechanical Analysis of Normal Vaginal Anatomy". This work identified specific surgical goals for each of the three levels of support. These are proximal vaginal suspension (Level I support), mid-vaginal lateral attachment (Level II support) and distal vaginal fusion to the perineum and urogenital fascia. These are the basic concepts that contemporary pelvic surgeons must satisfy to complete a pelvic herniation surgery.

For much of the 20th century, surgical repair of pelvic floor hernias was based upon the assumption by the influential pelvic surgeon, Howard Kelly of Johns Hopkins Hospital, and other workers in the field, that fascial attenuations of the vaginal walls were the cause of these hernias. Middle, anterior and posterior vaginal wall fascial plication, otherwise known as anterior and posterior colporrhaphy, respectively, generally with absorbable suture material (chronic catgut), was the mainstay of surgical treatment for most of these hernias.

The high recurrent herniation rates, particularly that of cystocele formation with this approach, led to intensive clinical research into the exact defects involved in the pelvic floor hernia formation. These defects were considered by these researchers to be due to injuries sustained during childbirth and to be specific in site as opposed to simple attenuation. Such anatomic site specific damage lends itself to the concept of pelvic reconstructive surgery. Dr. A. Colin Richardson of Georgia classified damage to the pubocervical fascia between the bladder and anterior wall as proximal, distal, central and lateral. Other workers, such as Dr. David Nichols of Rhode Island, encouraged gynecologists to both identify and repair each of these defects and to return support attachments to their original anatomic location. This includes, for example, repair of a paravaginal hernia by reattaching with suture the pubocervical...
fascia to the Arcus Tendineus. Such pelvic reconstructive surgery is heavily
dependent for success upon the training, skill and expertise of individual surgeons. It
frequently demands relatively long operative times.

Thus a need exists for a surgically implantable device that will rely less upon
the attributes of individual surgeons for success and that will involve a shorter
operating time. At the same time, such new devices must exhibit improved results
over prior art methods of pelvic floor repair, both in terms of function and reduced
complication rates.

Furthermore, a need exists for a surgically implantable device having the
ability to repair damage, and thus restore normal function, to crucial level II
supporting mechanisms without the need for difficult and specialized suturing
techniques.

A further need exists for a surgically implantable prosthesis having the ability
to restore level I support that can be rapidly positioned and held in place with a
minimum of suturing.

Ideally, a single, easily implantable device should be created that addresses
synchronously Level I, II and III support as espoused by the pelvic anatomist, John
DeLancey, without the need for difficult and specialized suturing techniques.

With advances in biomaterial technology has come the development of
lightweight polypropylene meshes, biodegradable, biocompatible and shape memory
copolymers and biological grafts. Such materials have all been utilized in pelvic floor
repair in the last decade with varying degrees of success. Improved function with
reduced complication rates has been seen particularly in the advances made in ultra-
lightweight polypropylene mesh technology.

The evolution of surgical implantation methods of these materials has been
rapid in recent years. It has included the development of multiple proprietary kits that
purport to facilitate repair using synthetic and biosynthetic graft implants in minimally
invasive fashion. They entered the market so quickly that the scientific literature
lagged behind with data to confirm improved safety and efficiency as compared to
previous methods. These systems were heavily marketed in the U.S. and globally, and
included the Apogee and Perigee systems (American Medical Systems, Minnetonka, MN), Avaulta (Bard Urological, Covington, GA) and the Gynecare Prolift (Ethicon, Somerville, NJ).

They utilize the blind passage of four long curved needles through the obturator space for anterior repair with fixation of the graft or patch by four mesh arms and two needle passages for posterior repair. Once again, results are dependent to a large degree on surgical expertise. Large scale studies have been limited and conducted by surgical experts and authorities in the field with typically low complication rates. For optimal use, these kits are still heavily dependent upon surgical skill, particularly with regard to the accuracy of the needle passage and avoidance of excess tension on the mesh arms.

The present invention avoids the use of such needles and mesh arms. In addition it fully satisfies the need for Level I, II and III support and ensures the implanted patch remains flat without folds and crinkling.

SUMMARY OF THE INVENTION

The foregoing needs are satisfied by the present invention that relates to an implant for pelvic floor repair. The implantable prosthesis consists of an expandable frame for holding open a sheet of a suitable biological graft or a synthetic mesh material. The device is designed to be held in place in the pelvis by low level recoil forces imposed between the device frame and the pelvic walls. With regard to anterior pelvic floor repair, such recoil forces include, but are not limited to, those between the frame and the fibromuscular pelvic sidewalls in close proximity to the so-called "plane of maximum dimension". Anatomical structures on each side of the pelvis, known as the Arcus Tendineous Fascia Pelvis laterally, the Sacrospinous Ligament posteriorly and the Inferior Pubic Ramus anteriorly, will be in close proximity to the plane of the frame.

Broadly stated, the implantable device of the present invention may comprise a sheet of mesh fabric or graft material of a predetermined shape configuration along with a support frame for maintaining the sheet in its predetermined shape configuration following implantation of the device proximate the pelvic floor of a
female patient. The support frame is affixed to the sheet of mesh fabric or graft material and includes first and second wing portions that are bilaterally symmetrical about a central axis of the device. The wing portions include rounded wing tip portions at first ends thereof that are adapted to abut the pelvic wall in proximity to the Sacrospinous Ligaments, when implanted in a female patient, said wing tip portions on the first and second wing portions being integrally joined to one another by a concave, arcuate segment. End portions of the first and second wing portions that are opposite to the wing tip portions are dimensioned to rest upon the posterior surface of the pubic rami and/or Symphysis Pubis of said female when the wing tip portions engage the patient's posterior pelvic wall proximate to the sacrospinous ligament.

The frame itself is preferably formed from a biodegradable polymer exhibiting shape memory properties but may also comprise a Nitinol wire.

Because of the shape memory property of the frame, it is capable of being rolled or otherwise folded into a tubular configuration of a relatively small radial dimension for delivery through a surgical incision through the vaginal wall in its low profile configuration, but once inside the body, proximate the pelvic floor, will unfurl to its predetermined desired shape.

In accordance with a further embodiment, the sheet of mesh fabric or biological graft material may have closed-ended pockets formed proximate the wingtip members on the posterior edge of the material configured to accommodate the index finger and middle finger of a medical professional to facilitate the placement of the posterior edge on the female patient's sacrospinous ligament. When placed in the pockets, the fingers can be spread to create a V and used to tactilely sense the ischial spine such that when the fingers are removed from the pockets, the posterior edge of the prosthesis will engage the sacrospinous ligament.

DESCRIPTION OF THE DRAWINGS

The foregoing features, objects and advantages of the invention will become apparent to those skilled in the art from the following detailed description of a preferred embodiment, especially when considered in conjunction with the
accompanying drawings in which:

Figure 1 is a plan view of a first embodiment when in an expanded, unconstrained condition;

Figure 2 shows the device of Figure 1 in a rolled, low profile condition adapted to be delivered into the pelvic compartment via a vaginal incision of approximately 3 cm in length;

Figure 3 is a superior view of the female pelvic diaphragm showing placement of the device of the present invention in treating pelvic floor herniation;

Figure 4 is a plan view of an alternative embodiment when in an expanded, unconstrained condition;

Figure 5 is a plan view of a further alternative embodiment when in an expanded, unconstrained condition;

Figure 6 is a cross-sectioned view taken through the frame of the embodiment of Figure 5;

Figure 7 is an anatomical skeletal drawing illustrating an anterior view of the female pelvis showing placement of the device of Figure 4 in treating pelvic organ prolapse;

Figure 8 is a sagittal section view showing approximate placement of the prosthesis of the present invention for addressing pelvic organ prolapse;

Figure 9 is a schematic sagittal view illustrating cystocele;

Figure 10 is a view like Figure 9 but showing placement of the prosthesis in treatment of cystocele;

Figure 11 is a plan view of yet another embodiment when in an expanded, unconstrained condition;

Figure 12 is a plan view of still another embodiment in its expanded condition;

Figure 13 is an enlarged plan view of the prosthesis of the present invention especially shaped for addressing posterior paravaginal compartment defects;

Figure 14 is a plan view of the prosthesis of the present invention especially shaped for addressing anterior paravaginal compartment defects;

Figure 15 is a view like that of Figure 13, but where the frame is removable;
Figure 16 is a view like that of Figure 14, but where the frame is removable; Figure 17 is a view like that of Figure 13, but with an alternative frame construction; Figure 18 is a view like that of Figure 14, but an alternative frame construction; Figure 19 is a further embodiment incorporating anchors for attachment and an alternate frame construction for addressing anterior paravaginal compartment defects; and Figure 20 is an embodiment like that of Figure 19, but shaped for addressing posterior paravaginal compartment defects.

DESCRIPTION OF THE PREFERRED EMBODIMENT

This description of the preferred embodiments is intended to be read in connection with the accompanying drawings, which are to be considered part of the entire written description of this invention. In the description, relative terms such as "lower", "upper", "horizontal", "vertical", "above", "below", "up", "down", "top" and "bottom" as well as derivatives thereof (e.g., "horizontally", "downwardly", "upwardly", etc.) should be construed to refer to the orientation as then described or as shown in the drawings under discussion. These relative terms are for convenience of description and do not require that the apparatus be constructed or operated in a particular orientation. Terms such as "connected", "connecting", "attached", "attaching", "join" and "joining" are used interchangeably and refer to one structure or surface being secured to another structure or surface or integrally fabricated in one piece, unless expressly described otherwise.

Referring first to Figure 1, it shows a plan view of the pelvic floor repair patch constructed in accordance with a first embodiment of the present invention. It is seen to comprise a sheet of mesh fabric 12 having a predetermined shape configuration. Without limitation, the sheet of mesh fabric may be formed from polypropylene or PTFE, both of which have been used in the past in constructing implantable medical prostheses. While such mesh fabrics are preferred, it is also contemplated that the sheet 12 may comprise a xenograft, such as appropriately
treated porcine dermis tissue.

The sheet material 12 is provided with a support frame 14 for maintaining the sheet 12 in its predetermined shape configuration following placement of the patch 10 proximate the pelvic floor of a female patient.

As seen in Figure 1, the support frame 14 used in this embodiment is affixed to the sheet 12, such as by closely spaced stitches 16. The support frame 14 comprises first and second wing portions 18 and 20 that are preferably bilaterally symmetrical about an imaginary central axis 21 of the device. Each of the wing portions 18 and 20 includes rounded wing tip portions 22 and 24 at first ends thereof and these wing tip portions on the first and second wing portions 18 and 20 are integrally joined to one another by a concave, arcuate segment 26.

In the embodiment of Figure 1, the ends of the wing portions 18 and 20 opposite the wing tip portions 22 and 24 are generally rounded as at 28 and 30. Convex arcuate segments 29 and 31 join the wing tips 22 and 24 to their respective opposite ends 28 and 30.

The support frame 14 may comprise one or more strands of a shape memory material, multiple strands will be wound together as a cable. Without limitation, the strands may be made from a shape memory metal, such as Nitinol, or alternatively, from a suitable biodegradable polymer having elastic properties.

The particular polymer to be used as a biomaterial in forming the frame is one that will match the mechanical properties and the time of degradation to the needs of the application. The ideal polymer for this application will not evoke an inflammatory/toxic response, is able to be metabolized in the body after fulfilling its purpose and one that leaves no significant trace, is sterilizable and can readily be processed into the desired configuration.

Polydioxanone is a bio-degradable polymer having a glass transition temperature in a range of from -10°C and 0°C and a crystallinity of about 55%. The presence of an ether oxygen group into the backbone of the polymer chain gives the material a good flexibility. It also exhibits a shape memory property. A monofilament of polydioxanone loses about 50% of its initial breaking strength after
three weeks and is absorbed within six months. This provides ample time for tissue ingrowth into the mesh to take place.

As further seen in Figure 1, the sheet 12 generally follows the contour of the frame member, but with the border of the sheet material 12 extending laterally beyond the support frame.

To prevent unraveling of the multiple strands comprising the cable frame 14, it has been found expedient to apply a tubular ferrule 32 to the free ends of the strands to form a closed loop. Where the frame comprises multiple strands of Nitinol wire twisted together as a cable, the ferrule 32 may be laser beam welded in place surrounding the opposed ends of the strands. Where the frame comprises a polymer, the free ends may be fused together by melting and then allowed to solidify. In either case, fraying of the multiple strands is prevented.

With the frame 14 being fabricated from an elastic material, it is possible to roll up the device from the configuration shown in Figure 1, which is generally planar, to a tubular configuration as shown in Figure 2. As such, the device may then be inserted through an incision 2-3 cm in length in the wall of the vagina into the pelvic cavity where it is allowed to unfurl by elastic recoil and thus reassume the shape configuration shown in Figure 1. The surgeon may then use his or her fingers to position the device in the appropriate pelvic plane described previously to best address the type and degree of organ prolapse that the surgery is intended to correct. Because of the inherent property of the frame, it reduces bunching or crinkling of the mesh due to uneven suturing of prior art patch materials used in pelvic floor repair. Such bunching or crinkling commonly results in dyspareunia during coitus.

If it is desired to remove a metal frame 14 following placement of the sheet 12 and before closing the incision in the vaginal wall, the sheet may be formed so as to include a plurality of spaced-apart "belt-loop" like appendages thereon through which the frame 14 is strung. After being appropriately spaced, bio-degradable anchoring tacks can be used to hold the sheet 12 in place, the frame 14 can be stripped out from the belt loop appendages and removed from the patient. Of course, if the frame 14 comprises a bio-degradable polymer, there is no need to remove it because it will be
absorbed by the body following tissue ingrowth through the sheet material during the period of three months or so post-surgery.

Referring next to Figure 3, there is shown a superior view of the female pelvic diaphragm showing placement of the device of the present invention in treating pelvic floor herniation. When appropriately placed, the rounded wing tip portions 22 and 24 on the prosthesis frame 14 are arranged to rest against the pelvic wall in the region of the Sacrospinous Ligament 34 that extends between the sacral spine 36 and the sacrum 38. The opposite end portions 28 and 30 yieldingly engage the region of the lower symphysis and adjacent inferior pubic rami 40. When the device is so positioned, the convex arcuate portions of the frame 29 and 31 will be supported by the pelvic sidewalls in the region of the Arcus Tendineous Fasciae Pelvis 42. This placement results in the anterior end portion of the concave arc segment 26 looping around the vagina at the level of the cervix, C. The concave segment connecting ends 28 and 30 provides clearance for the urethra, U.

Figure 4 is an alternative embodiment of the device for addressing repair of Level I and Level II support. It comprises a frame member 100 supporting a biocompatible sheet, such as a polypropylene mesh or a treated porcine dermis material 102.

As in the embodiment of Figure 1, the frame is again bilaterally symmetrical about an imaginary central axis 104. It is comprised of a plurality of generally circular arcs that are integrally joined to form a pair of wing-shaped members 106 and 108 on opposite sides of the axis 104.

The arcs define wingtip portions 110 and 112 that when placed in a female patient are arranged to abut the region of the sacrospinous ligaments. These wingtip portions are joined to one another by a concave, arcuate segment that is sized and shaped so as not to interfere with the rectum, R, and providing support to the vagina at the level of the cervix, C. The concave, arcuate portion 116 allows engagement of the implant with the lower Symphysis Pubis inferior pelvic rami. The convex arcuate segments 118 and 120 are designed such that they resiliently engage the pelvic sidewalls in a plane located slightly above the ischial spine, which is proximate the
pelvic plane of the greatest dimensions.

In the embodiment of Figure 4, the frame 100 is preferably molded from a biocompatible, bio-degradable polymer exhibiting shape memory properties. Polyurethanes formed from a high molecular weight poly(e-caprolactone) and a high weight fraction of hard-segment-determining blocks exhibit a high shape-memory property. Block copolymers made with polyethylene terephthalate and polyethylene oxide is also a potential candidate as are copolymers of polyglycolide (PGA) and polylactide (PLA). Another potential candidate for the frame material is a polymer called polynorbornene. Readers desiring additional information on shape memory polymers exhibiting bio-degradable properties are referred to an article entitled "Shape-Memory Polymers" authored by Andreas Lendlein and Steffen Kelch, Angew. Chem. Int. Ed. 2002, 41, pages 2034-2057, the contents of which are hereby incorporated by reference.

Turning next to Figure 5, there is shown a further embodiment in which the sheet 102 has fibers interwoven in the mesh so as to stimulate tissue ingrowth when the prosthesis is to be used for repairing Level I as well as Level II vaginal support. In the area of the wingtips 110 and 112, the mesh sheet 102 is interwoven with fibers of polyethylene terephthalate (PET) as identified by numeral 126, a material known to induce fibrosis, whereby the mesh sheet 102 becomes secured prior to the loss of resiliency in the frame due to biodegradation with time.

As a further option, to reduce the possibility of patient discomfort due to pressure of the resilient frame with pelvic tissue prior to its being absorbed, the frame may be formed in a molding operation to exhibit a cross section such as depicted in Figure 6 hereof. The polymer frame member 100 is integrally molded to exhibit a cushioning layer 122 formed of a soft, deformable foam material. The cushioning layer 122 need only span the arcuate portions 118 and 120 of the frame member 100. The cushioning layer 122 is sufficiently resilient that it can deform to spread the contact force over a greater area, thereby reducing the contact pressure between the frame structure and the tissue that it abuts. The embodiment of Figure 5 and the cross-section of Figure 6 also show that the cushioning layer 122 may have raised tread-like
projections as at 128 extending radially from the surface thereof which aid in fixing the frame in fibromuscular tissue of the pelvic side walls. These projections may be integrally molded with the cushion layer 122.

Figure 7 is an anterior view of the skeletal female pelvis on which the prosthesis of the present invention has been added to generally illustrate the placement of the prosthesis when addressing forms of pelvic organ prolapse. The anterior portion of the frame 100 is made to engage the inferior pubic symphysis as best seen in Figure 8 while the wingtip portions 110 and 112 thereof abut the Sacrospinous Ligament proximate the joint between the third and fourth sacral segments. As the name suggests, the Sacrospinous Ligament is a thin, triangular ligament attached by its apex to the ischial spine, and medially, by its broad base, to the lateral margins of the sacrum and coccyx. When the prosthesis is so positioned, the convex arcuate segments 118 and 120 of the prosthesis are somewhat elevated relative to the ischial spine and engage the region of the Arcus Tendineous Fascia Pelvis.

Figure 9 is a schematic illustration of the condition known as cystocele in which the posterior wall of the bladder prolapses into the vaginal space due to a defect in the anterior vaginal wall fascia. In Figure 9, the pubic symphysis is identified by numeral 200 and the ischial spine by numeral 202. The urethra 204 leads to the urinary bladder 206 exhibiting a cystocele 208 or protrusion into the vaginal canal 210 leading to the uterus 212. The rectum is identified by numeral 214.

The bladder and urethra are separated from the vagina by the pubocervical fascia. Intact fascia prevents the bladder from bulging down into the vagina. Females with cystocele have a defect or weakness in this fascia.

Figure 10 is a view like that of Figure 9 but with the prosthesis of the present invention deployed as previously described so as to provide lateral support to the bladder 206 and repairing the cystocele. In this view, the cross-section of the frame 100 is displayed with its anterior portion engaged with the pubic symphysis or inferior rami and its posterior wingtip portions abutting the region of the sacrospinous ligaments identified in Figure 10 by numeral 216.

In the event that it is desired to remove the frame from the pelvic floor repair
device following proper positioning of the mesh sheet for the particular prolapse mode encountered, the pelvic floor repair device of the present invention can be configured as illustrated in Figure 11. Like in the previously described embodiments, it comprises a sheet of mesh fabric 11 of a predetermined shape configuration where the mesh sheet is preferably a woven ultra lightweight polypropylene material, such as, Smartmesh™, by Mpathy Medical Devices Limited of Glasgow, Scotland.

As in the previous embodiments, the mesh fabric is cut so as to exhibit a pair of wing-shaped members 13 and 15, each exhibiting a wing-tip 17 and 19. The wing members 13 and 15 are generally bi-laterally symmetrical with respect to an imaginary centerline 21.

Generally regularly spaced along the perimeter of the mesh sheet 11 is a plurality of loops, as at 23, which may be integrally formed with the mesh sheet 11 or added thereto in a sewing operation.

The implantable pelvic floor repair device further includes a support frame 25 for maintaining the sheet 11 in its predetermined shape configuration following implantation of the device proximate the pelvic floor of a female patient. The frame 25 differs from that used in the earlier described embodiments in that it comprises two separate segments 27 and 33, each being a shape memory material such as Nitinol. The segments 27 and 33 may be single strands or may comprise multiple fine strands twisted together as a cable.

As seen in Figure 11, the frame segment 27 extends through the loops 23 on the wing member 13 and frames segment 33 extends through the loops 23 of the wing member 15. The frame segments 27 and 33 overlap one another in a zone 31 proximate the centerline 21, but do not join to one another. The frame segments 27 and 33 are heat treated so as to maintain the shape configuration illustrated in Figure 11 when unconstrained. The wing portions 13 and 15 including the wingtip portions 17 and 19 at a first end thereof are adapted to abut the sacrospinous ligaments when implanted in a female patient and are joined to one another by a concave arcuate segment defined by the predetermined portions of the first and second separate segments 27, 33 that extend from the wingtip ends 17 and 19 to the overlapping zone.
35. The convex curved end portions that lie opposite from the wingtip portions are adapted to rest upon the inferior pubic rami of the female patient when the wingtip portions are in engagement with the sacrospinous ligaments.

With continued reference to Figure 11, the frame segments 27 and 33 terminate in a tail-like extension 37 that is adapted to extend through a surgically created slit in a wall of the vagina when the device has been appropriately positioned to address a particular type of vaginal prolapse. The tail portions 37 may comprise a single strand and, as such, are of greater flexibility than the rest of the frame 25. In a matter of three days or so, early tissue ingrowth through the mesh material has taken place sufficient to fixate and stabilize patch 11. A medical professional may extract the frame by passing a pair of forceps up the vaginal canal via a vaginal speculum and grasping the tail end 33 of the frame segments 27 and 33 and remove them, one at a time, by pulling the frame segments out from the loops 23 and out beyond the vaginal opening.

As with the earlier described embodiments, the device of Figure 11 can be readily rolled or otherwise folded to a reduced profile for passage through the surgically created slit formed in the vaginal wall and because of the shape memory property of the frame, it will readily unfurl to allow placement in the manner earlier described.

Figure 12 shows still another alternative embodiment of the invention disposed in situ for pelvic floor repair. As in the earlier described embodiments, the prosthesis comprises a sheet of flexible synthetic mesh or biological graft material. An example of the former is the ultra lightweight polypropylene mesh known as Smartmesh™, a product of Mpathy Medical Devices Ltd. The sheet is fixed to a frame 14 comprising a monofilament of a shape memory material.

In the embodiment of Figure 12, the frame 14 forms an open loop having a first free end portion 44 of a length allowing that end to protrude through a surgically created opening in the vaginal wall. The second free end 46 of the frame member 14 remains disposed on the sheet of mesh material 11. It is to be further noted that in the embodiment of Figure 12, the mesh material 11 extends beyond the loop frame 14.
preferably about one centimeter, forming a skirt generally encircling the frame member 14.

Without limitation, the mesh sheet 11 may be temporarily affixed to the frame using a pair of suitable suture threads 48 that spirally wrap about the frame 14 along the length thereof while passing through the mesh, the pair of threads being joined by a knot. In this fashion, the frame can subsequently be removed once the mesh has been appropriately deployed so as to address the particular prolapse condition encountered. In the case of the synthetic mesh, removal of the frame may be carried out approximately 72 hours after surgery to deploy the mesh. The suture thread 38 will have a free end thereof extending beyond the knot into the vaginal canal where it can be grasped by a forceps and pulled so as to unwind from the frame and mesh once the pair of threads is cut along the knot. To facilitate removal even further, two pairs of suture threads may be used, the first pair extending over the left half of the prosthesis as shown in Figure 12 and the second pair being wound about the right half of the prosthesis. Frame removal can be carried out in an office surrounding.

A further feature of the embodiment of Figure 12 is the inclusion of finger-receiving pockets formed in the mesh 11 as identified by numerals 50 and 52 in Figure 12. The pockets 50 and 52 may be preformed and attached to the mesh sheet by stitching or, alternatively, pockets may be formed in a suitable molding operation, given the fact that the mesh material 11 is preferably a thermoplastic, e.g., polypropylene. The pockets are generally placed on opposite sides of the device center line 21 so as to receive the practitioner's forefinger and middle finger when the two fingers are splayed to form a V. With his or her fingers inserted in the pockets, the prosthesis can be manipulated until the practitioner tactiley detects the ischial spine projections in the female patient's pelvis and thereby identifying that the wingtips of the prosthesis abut the sacrospinus ligament for purpose of fixation of the prosthesis to that structure.

Figures 13-19 are included herein to comply with the "best mode" requirements of § 112 of the Patent Act. Specifically, they depict the best mode contemplated for fabricating and shaping prostheses for addressing POP.
Figure 13 illustrates an embodiment of the invention especially advantageous for use in treating paravaginal posterior compartment prolapse. Rather than exhibiting convex, arcuate wings, as in the devices of Figures 11 and 12, the mesh 11 is more V-shaped, but with a more gently rounded apex 60. Further, the mesh is formed to provide finger pockets 50, 52 projecting from the posterior wingtips 22 and 24 of the mesh. It has been found beneficial to provide additional webbing at the end portions 62 and 64 of the finger pockets to provide greater holding power to sutures 66 and 68 which are used to affix the prosthesis to a patient’s sacrospinus ligament when providing Level I support to the vaginal vault, i.e., the vaginal wall proximate the cervix. The frame member 70 may comprise a biodegradable elastic polymer material formed as a closed loop and generally following the shape configuration of the mesh 11 on which it is attached, as by interweaving or sewing.

The mesh 11 is adapted to be attached to the perineal body by sutures 72, 74 and when the prosthesis is thus attached, it provides Level III support for posterior paravaginal compartment prolapse.

Using a biodegradable material for the somewhat oval-shaped frame 70, after a period of about 10 to 12 weeks, the frame is completely absorbed and this occurs after the mesh is completely endothelialized and thus anchored in its desired shape configuration originally established by the frame.

Figure 14 illustrates a prosthesis like that of Figure 13, but designed to address anterior paravaginal compartment prolapse. As can be seen, it differs slightly in its shape configuration, being somewhat more rounded. Like the embodiment of Figure 13, it has finger-receiving pockets 50', 52' extending beyond a posterior wingtip region 22', 24', where the ends of the pockets 50', 52' are reinforced, as at 62', 64', whereby sutures, as at 66', 68' can be used to affix the pocket ends to the patient's sacrospinus ligament to yield Level I support to address cystocele resulting from anterior pelvic compartment prolapse.

A biodegradable elastic frame 70', when unconstrained, maintains the synthetic mesh 11' somewhat planar and when appropriately disposed between the bladder and vagina, provides Level II support. Level III support is achieved when the anterior end
of the prosthesis is sutured to the patient’s pubocervical fascia by sutures shown as at 72' and 74'.

The embodiments of Figures 15 and 16 are designed for the same purpose as the embodiments of Figures 13 and 14, respectively, but instead of employing a biodegradable frame, a Nitinol or other shape memory alloy wire frame is employed. The wire frame 80 is designed to be removed, once the prosthesis has been installed and tissue ingrowth has anchored the mesh, usually within about 72 hours post placement.

The frame is temporarily affixed to the mesh by sutures 82, 84 formed as a loop and woven through the mesh and about the wire frame as shown. The frame can be separated from the mesh by first snipping the suture loop above the knots 86, 88 and pulling the sutures 82, 84 out through the surgically created slit 90 that had been formed through the vaginal wall when the prosthesis was first implanted. Once the suture strips are removed, the frame wire 80 can be pulled out through the same surgical opening 90.

Figures 17 and 18 illustrate alternative constructions of prostheses for treating posterior and anterior compartment prolapse, respectively. The mesh 11 is of the same shape configuration as in the earlier embodiments of Figures 13 and 14, but the support frame is modified. Rather than a loop, as in Figures 13 and 14, the frame in the embodiment of Figure 17 comprises linear stiffeners 90, 92 placed along the edges of the mesh between the wingtips 22”, 24” and mesh extension ears 94, 96.

In the embodiment of Figure 18, the stiffener members 98, 100 are arcuate, rather than linear, to generally match the shape of the mesh border.

The stiffeners 90, 92 in Figure 17 and 98, 100 in Figure 18 are preferably an elastic biodegradable plastic such as polydioxonone. In accordance with the earlier disclosed embodiments, the stiffeners can be Nitinol or other alloy exhibiting shape memory properties such that it can be folded or rolled into a small profile for delivery through a vaginal wall incision, but will unfurl to a predetermined shape configuration when unconstrained.

The extension ears are tabs 94, 96 and 94', 96' in the embodiments of Figures
17 and 18, respectively, provide a way that the mesh 11 may be affixed by sutures to the pubocervical fascia (Figure 17) and the perineal body (Figure 18), when the respective devices are used in treating posterior and/or anterior compartment paravaginal prolapse.

Figure 19 illustrates yet another implementation of an implantable device for pelvic floor repair in human females. It is seen to comprise a sheet of an ultra lightweight polypropylene mesh material 110 of the type commercially available from Mpathy Medical, Inc. of Raynham, Massachusetts, under that company's trademark, Smartmesh®. The mesh may be of a predetermined shape configuration, here shown as being somewhat circular and having a pair of closed ended fingertip receiving portions 112 and 114. The pocket 112 is designed to receive the distal phalanx of either a surgeon's middle finger of his/her right hand while pocket 114 will receive the distal phalanx of the surgeon's middle finger if right handed or index finger if left handed.

The entry opening to the closed ended pockets is identified by a border or edge 116. The mesh distal of the edge 116 is interwoven with additional reinforcing strands of polypropylene. Affixed to the reinforced closed ends of the pockets 112 and 114 are attachment members 118, preferably in the form of finger insertable tacks having a broad head 120 affixed at the closed ends of the finger pockets and a pointed, barbed shaft 122.

Formed along the perimeter of the mesh sheet 110 are a plurality of loops, as at 124, and threaded through the loops is a frame member 126 fabricated from a shape memory material designed to be rolled up or folded for passage through a surgically created slit 128 in the vaginal wall and that will deploy or unfurl the mesh when unconstrained within the pelvic space. The frame is preferably formed as a cable comprising a plurality of fine strands of a nickel-titanium alloy such as Nitinol®. Rather than being a closed loop, the frame 126 is formed so that in its austenite state, it follows the contour of the mesh 110 as it passes through the loops 124 and with opposed ends 130 and 132 unconnected. The end 130 passes out through the slit 128, allowing a medical professional to remove the frame by pulling on the end 130 once
tissue ingrowth into the mesh has occurred to anchor it in place, usually within about six days, post-surgery.

In use, the barbed tacks 118 are used to anchor the finger pockets into the sacrospinous ligaments by application of fingertip force against the tack heads 120.

Figure 20 is substantially identical to Figure 19 except is of a slightly different shape configuration more conducive to treating posterior paravaginal compartment defects. Rather than having a somewhat circular shape, the mesh and frame in Figure 20 are more oblong or oval in shape.

A method for the surgical repair of anterior vaginal wall prolapse, or cystocele, is described with reference to Figures 7 through 12. The surgical procedure involved will, in its general description, be well recognized by workers in the field. A concomitant procedure for stress urinary incontinence (SUI), both occult and overt, may be carried out under the same anesthetic.

After standard preoperative preparation of the patient has been completed in an optimal manner, she will receive appropriate anesthesia and be placed in the so-called modified lithotomy position. She will then be prepped and draped in the standard manner. This will include insertion of an indwelling bladder catheter using standard aseptic technique to allow identification of the urethra and also application of anti-thromboembolic pneumatic sequential compression stockings to the lower limbs. A weighted vaginal retractor or other suitable form of retractor such as the "Lone Star" (tm) is used.

Two pairs of Allis Forceps, or similar, are then applied, in the sagittal plane about 5 cms apart, to the cystocele. The inferior pair of such forceps is placed proximate to the bladder neck. The intervening vaginal wall of the cystocele is placed on traction between the clamps and infiltrated, using a 22 gauge needle, with an adequate volume of saline containing suitable local anesthetic and vasoconstrictor agents. This will facilitate optimal hydrodissection and hemostasis.

While maintaining opposing traction on the Allis Forceps, a small incision with a maximum length of approximately 3 cms is made in the vaginal wall commencing in the region of the bladder neck and proceeding in the midline in a
cephalad direction toward the vaginal apex. The use of hydrodissection allows the incision to be deep enough to reach the bladder fascia (pubocervical fascia) in a safe manner and thus minimize failure of wound healing with subsequent mesh extrusion.

Initial sharp then blunt dissection technique with the fingertip - well known to workers in the field, is then used to separate the bladder from the anterior vaginal wall and reach and identify in turn, the ischial spine and sacrospinous ligaments on both sides of the pelvis.

The invention shown in the several disclosed embodiments is then passed in a closed and circularly folded configuration completely through the vaginal incision in the midline toward the sacrum, between the vagina and the bladder. The device is then allowed to unfold by inherent elastic recoil and digitally positioned into the desired anatomical location previously described. On each side of the pelvis, the posterior frame of the invention will be positioned just above and proximate to the ischial spine and be gently fixed by short projections, incorporated into the polymer frame as previously described into the fibromuscular tissues of the coccygeus muscle.

Alternative embodiment and method of fixation of the mesh into the sacrospinous ligament complex include, for example, biodegradable barbs suitable for fingertip compression.

As previously described, if it is desired to remove the frame from the patient following proper placement of the mesh sheet, the embodiment of Figure 12 allows uncoupling of the mesh sheet from its frame by first drawing the threads 48 out through the surgically created incision in the vaginal wall and that is followed by removal of the frame itself by grasping the free end 44 with forceps and pulling the now-released frame out through the opening in the vaginal wall.

Using the embodiments of the present invention, the pelvic repair procedures can be carried out with a minimum of suturing. The frame structure will hold the mesh fabric or sheet of graft material in its deployed state and only a few biodegradable anchor pins will be required to prevent movement of the mesh until tissue fixation occurs about three days after surgery. Alternatively, a Capio ligature device from Boston Scientific Corporation may be used to suture the mesh in place prior to
frame withdrawal.

This invention has been described herein in considerable detail in order to comply with the patent statutes and to provide those skilled in the art with the information needed to apply the novel principles and to construct and use such specialized components as are required. However, it is to be understood that the invention can be carried out by specifically different equipment and devices, and that various modifications, both as to the equipment and operating procedures, can be accomplished without departing from the scope of the invention itself.

What is claimed is:
Claims

1. An implantable device for pelvic floor repair comprising:
   (a) a thin, flexible sheet having a predetermined shape configuration;
   (b) a support frame for maintaining said sheet in its predetermined shape configuration following implantation of said device proximate the pelvic floor of a female patient; and
   (c) said support frame being affixed to said sheet and including first and second wing portions that are bilaterally symmetrical about a central axis of the device, the wing portions including rounded wingtip portions at first ends thereof adapted to abut the sacrospinous ligaments when implanted in a female patient, said wingtip portions on the first and second wing portions being integrally joined to one another by a concave, arcuate segment, with end portions of the first and second wing portions opposite the wingtip portions, being dimensioned to rest upon the inferior pubic rami of said female patient when the wingtip portions engage the sacrospinous ligaments.

2. The implantable device as in claim 1 wherein said support frame comprises a plurality of strands of a shape memory material wound together as a cable.

3. The implantable device as in claim 2 wherein the shape memory material comprises Nitinol.

4. The implantable device as in claim 1 wherein the support frame comprises at least one strand of a shape memory material.

5. The implantable device as in claim 4 wherein the shape memory material is a bio-degradable polymer.

6. The implantable device as in claim 5 wherein the support frame further includes a cushion layer over a predetermined portion of the first and second wing positions.

7. The implantable device as in claim 6 wherein the cushion layer is separated from the at least one strand of the shape memory material by an air gap.
8. The implantable device as in claim 6 wherein the cushion layer has radially extending anchoring projections thereon.

9. The implantable device as in claim 1 wherein the end portions of the first and second wing portions opposite from the wingtip portions each being V-shaped, spaced-apart and disconnected from one another.

10. The implantable device as in claim 1 wherein said sheet comprises a synthetic mesh.

11. The implantable device as in claim 10 wherein the synthetic mesh comprises one of polypropylene and PTFE.

12. The implantable device as in claim 1 wherein the sheet is a xenograft material.

13. The implantable device as in claim 9 and further including tubular ferules bonded to end portions of the first and second wing portions to prevent fraying of said cable.

14. The implantable device as in claim 13 wherein said frame includes convex arcuate segments extending between said rounded wingtip portions and said end portions of said first and second wing portions.

15. The implantable device as in claim 1 wherein said sheet and frame can be rolled into a reduced-profile, cylindrical configuration for delivery through a surgically created opening in the patient's body.

16. The implantable device of claim 1 wherein the sheet includes a plurality of loops affixed to the periphery thereof at regularly spaced intervals.

17. The implantable device of claim 16 wherein the support frame comprises first and second separate segments, each generally spanning about one-half of the perimeter of the sheet and passing through predetermined ones of the plurality of loops.

18. The implantable device as in claim 17 wherein said support frame comprises a plurality of strands of a shape memory material wound together as a cable.

19. The implantable device as in claim 18 wherein the shape memory
material comprises Nitinol.

20. The implantable device as in claim 16 wherein the support frame comprises at least one strand of a shape memory material.

21. The implantable device as in claim 20 wherein the shape memory material is a bio-degradable polymer.

22. The implantable device as in claim 1 wherein the end portions of the first and second wing portions, opposite from the wingtip portions, each terminate in extensions adapted to extend through a surgically created slit in a wall of the female vagina when the device is positioned as stated in paragraph (c) of claim 1.

23. The implantable device as in claim 1 wherein the synthetic mesh comprises one of polypropylene and PTFE.

24. The implantable device as in claim 22 wherein said frame includes convex arcuate segments extending between said rounded wingtip portions and said extensions on said first and second wing portions.

25. The implantable device as in claim 1 wherein said sheet and frame can be folded into a reduced-profile configuration for delivery through a surgically created opening in the vaginal wall.

26. The implantable device of claim 17 wherein the support frame can be removed from the loops following placement of the device proximate the pelvic floor by grasping said extensions one at a time and pulling the first and second segments free from the loops of the mesh sheet and out the vaginal opening of the patient.

27. An implantable device for pelvic floor repair, comprising:
   (a) a flexible, mesh sheet having a predetermined shape configuration and with a pair of closed ended pockets projecting from a posterior edge of the sheet, one pocket being sized to receive a distal phalanx of an index finger and the other pocket a distal phalanx of a middle finger of a surgeon therein;
   (b) a support frame for maintaining the mesh sheet in said predetermined shape configuration where unconstrained and following implantation of the device proximate floor of a female patient, said support frame comprising at
least one segment of a material exhibiting a shape memory property removably 
attached to the mesh sheet; and

(c) attachment members affixed to the closed ends of each of the 
pair of closed ended pockets and deployable by the surgeon for securing the ends of 
the pockets to the sacrospinous ligaments of the female patient.

28. The implantable device of claim 27 wherein the attachment members 
comprise pointed barbed projections extending outward of said closed ends of the 
pockets.

29. The implantable device of claim 28 and further including a head 
member on a proximal end of the barbed projection adapted for engagement by the 
surgeon's forefinger and index fingers to facilitate pressing of the pointed, barbed 
projection into the sacrospinous ligament.

30. The implantable device of claim 27 wherein the predetermined shape 
configuration is generally circular and the support frame surrounds said mesh sheet 
and is secured to the mesh sheet by a passing through a plurality of radially extending 
loops on the perimeter of the mesh sheet.

31. The implantable device of claim 27 wherein the predetermined shape 
configuration is generally oblong and the support frame surrounds said mesh sheet 
and is secured to the mesh sheet by a passing through a plurality of radially extending 
loops on the perimeter of the mesh sheet.

32. The implantable device of claim 29 wherein the head member and the 
pointed barbed projection are of a biodegradable polymer.

33. The implantable device of claim 27 wherein the material exhibiting 
shape memory properties is a nickel-titanium alloy.

34. The implantable device of claim 27 wherein the support frame 
comprises first and second generally straight stiffening segments affixed to the mesh 
sheet and extending from anterior to posterior end portions thereof along opposed side 
edges of the mesh sheet.
INTERNATIONAL SEARCH REPORT

A  CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/00 (2010.01)
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) - A61F 2/00 (2010.01)
USPC - 600/29, 30, 31, 37

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Pathbase, Google Scholar

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>
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D  Further documents are listed in the continuation of Box C

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Date of the actual completion of the international search
06 May 2010

Date of mailing of the international search report
20 MAY 2010

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