

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
7 February 2008 (07.02.2008)

PCT

(10) International Publication Number  
**WO 2008/015722 A1**

(51) International Patent Classification:  
A61F 2/00 (2006.01)

(21) International Application Number:  
PCT/IT2007/000560

(22) International Filing Date: 2 August 2007 (02.08.2007)

(25) Filing Language: Italian

(26) Publication Language: English

(30) Priority Data:  
RM2006A000413 2 August 2006 (02.08.2006) IT

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(81) Designated States (unless otherwise indicated, for every  
kind of national protection available): AE, AG, AL, AM,

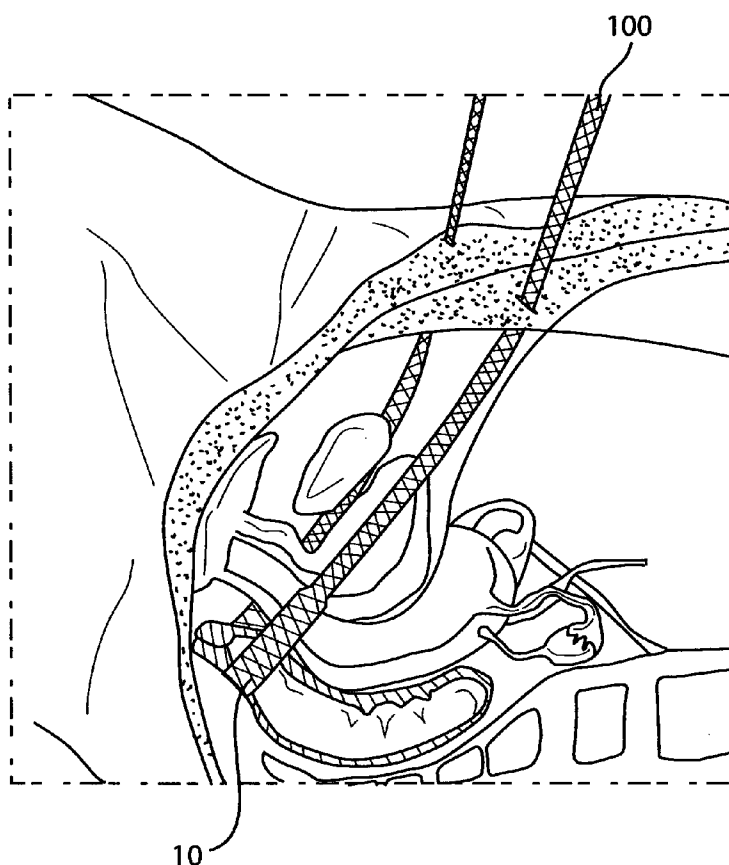
AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH,  
CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG,  
ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL,  
IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK,  
LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW,  
MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL,  
PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY,  
TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA,  
ZM, ZW.

(84) Designated States (unless otherwise indicated, for every  
kind of regional protection available): ARIPO (BW, GH,  
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,  
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),  
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,  
FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL,  
PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM,  
GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

- with international search report
- before the expiration of the time limit for amending the  
claims and to be republished in the event of receipt of  
amendments

(54) Title: PROSTHESIS FOR USE IN THE SURGICAL TREATMENT OF RECTAL AND PELVIC PROLAPSE AND FAECAL INCONTINENCE AND RELATED SURGICAL KIT



(57) Abstract: The invention concerns a prosthesis (100) for use in the surgical treatment of rectal and pelvic prolapse and faecal incontinence, and related surgical kit, comprised of a net band, made up of material suitable to surgical implant, comprising a wider central body (10) and two more narrow arms (20, 20'), said central body (10) being suitable to be applied in correspondence of rectum, thus surrounding ano-rectal canal behind, above and close to the raphe ano-coccygeus, said arms (20, 20') being suitable to bilaterally pass through obturator foramen, respective ends of said arms (20, 20') not coupled with said central body (10) being suitable to be anchored to the subcutaneous tissue, so that said central body exerts a suspension action on anal sphincters and on rectum, thus re-creating a fascia support hammock stabilising pelvic pavement. The invention further concerns a prosthetic kit for implanting a prosthesis according to the invention for use in the surgical treatment of rectal and pelvic prolapse and faecal incontinence, comprising the same prosthesis and one or more curved needles suitable to implant said prosthesis.

PROSTHESIS FOR USE IN THE SURGICAL TREATMENT OF  
RECTAL AND PELVIC PROLAPSE AND FAECAL INCONTINENCE  
AND RELATED SURGICAL KIT

5           The present invention relates to a prosthesis for use in the surgical treatment of rectal and pelvic prolapse and faecal incontinence, and related surgical kit.

          More particularly, the invention refers to a prosthesis suitable to be employed at the same time in surgical therapy of rectal and pelvic  
10       prolapse and faecal incontinence, thus permitting solving both problems by a single surgical intervention. Present invention further relates to a prosthetic kit suitable to be used in surgical therapies of rectal and pelvic prolapse (Syndrome Perineum Descendent) and of Faecal Incontinence.

Functional Anatomy of the Pelvic Floor

15       Introduction

          An adequate understanding of continence regulating mechanisms in the general context of pelvic floor components cannot prescind from a similarly adequate and comprehensive knowledge of the anatomy of such region.

20       Muscles, nerves and fascias constituting the same must be known in addition to anatomo-functional peculiarity thereof also as a complex but intriguing integrated unit, thus characterising the morph-functional unit of pelvic floor.

          Diagnosis of malfunctioning level of one of above-mentioned  
25       components can be considered as exhaustive only when any anatomical or dysfunctional problem is considered.

Anatomy of Pelvic Support

          Pelvic floor must be considered as a whole consisting of three compartments in close interdependent relationship as to dynamics and  
30       functionality:

          anterior compartment, comprising urethra, vesical neck and bladder;

          upper compartment comprising uterus, vaginal vault (for hysterectomy), and Douglas' pouch;

35       posterior compartment comprising rectum, anal canal and perineum.

          The correction of any defect must carefully be estimated taking into account the functional integrity economy with two others.

### Urethra

Female urethra is an about 4 cm long virtual duct, which, in its passage through urogenital diaphragm and perineal membrane, describes S pathway. Urethral epithelium is disposed in various folds and supplied with numerous glands opening in all length thereof. Epithelium is stratified squamous within distal portion while it becomes transitional near the bladder, respectively. It is supported by lamina propria and fibro-elastic connective tissue. Urethral closing pressure depends on the striated and smooth musculature tone and collapse of vascular plexus to form a perfect mucosal barrier.

### Urethral musculature

Urethra consists of longitudinal and oblique smooth and circular musculature at 8:1 ratio; which already explains intrinsic miopragia of this apparatus in comparison to male one wherein this ratio is almost inverted. Longitudinal fibres whose function is to narrow and widen the urethral lumen during the urination, while the circular fibres representing so-called striated sphincter located at the level of urogenital diaphragm contribute for resting urethral resistance. Urethral and periurethral striated musculature located in the middle third constitutes the so-called extrinsic sphincter mechanism, consisting of two components: an inner urethral wall adjacent and an external portion consisting of striated muscular fibres of the pelvic diaphragm. All these muscular components act as a single functional unit named: urogenital striated sphincter. It is composed primarily of small diameter "slow twitch" fibres assuring tone within the urethral lumen during an extended time period. Also "fast twitch" fibres are present whose function is to increase the urethral closure under load or interrupt voluntarily urine flow by means a reflex muscular contraction. Histochemistry and electromyography studies have evidenced that the reflex contraction occurs 200 msec before the increase of abdominal pressure raising at higher than 100% percentage of pressor transmission in the distal urethral quarter.

### Pubourethral ligaments and midurethral complex

Pubourethral ligaments connect midurethral third with the lower margin of the pubic bone and provide support and stability to the urethra and frontal vaginal wall. The weakness of these fascial thickenings favours a back- and downwardly movement of middle urethra, but it does not

support the vesical neck effectively. In front of these ligaments muscular striated bundles of urethra external sphincter are located.

Pubourethral ligaments divide urethra in three portions: proximal third, comprising vesical neck and the intra-abdominal portion, middle urethra with striated musculature, and distal third. Within proximal third, only 1,5-2 cm long, the mechanism of passive continence is performed, while middle urethra is responsible for the active continence and acts with compensative function in the presence of a proximal urethra incompetence. Urethral distal third acts exclusively as a duct for urines and it does not perform any sphincter function.

The accumulation of striated fibres at urethral middle level, makes most substantial this portion as to thickness; muscular fibres are localised in upper and lateral position with respect to the urethra according to half moon shape, being rather deficient below.

#### Urethropelvic Fascia

It covers urethra for all length thereof on vaginal side and fusing with endopelvic fascia, constitutes the so-called "urethral bed" together with the pubourethral ligaments, suspending middle urethra within tendinous arc of pelvic fascia. This structure is named urethropelvic ligament, constituting primary supporting means of the neck and urethra proximal to the sidewall of pelvis. The contraction of levator or obturator muscles results in an increment of tensile strength of urethropelvic ligaments, thus increasing continence. On the contrary the weakness of levator plate and urethropelvic ligaments (minor with respect to separation or elongation of urethropelvic fascia) will result in hyper-mobility of the urethra and vesical neck, resulting in lowered continence efficiency of proximal urethra. The confirmation in biopsy tests of smooth musculature, nervous tissue and elastin in addition to collagen, within the pubourethral, uterosacral and superolateral ligaments of the vagina, provided new evidences about what believed, it is to say that the muscles and fascial thickenings concur to the same objective, i.e. the perfect "dynamic retention" indispensable for the involved organs to perform a perfect operation (Petros 2000).

#### Vesicopelvic Fascia

The vesicopelvic ligaments are the structures responsible for the bladder support to lateral pelvic wall and must be consider the prosecution of urethropelvic ligaments.

The portion of fascia that is interposed between vaginal wall and bladder is named pubocervical fascia; traumas to which this structure is subjected during the delivery or hormonal deficiency together with secondary atrophy of the pelvic plane and consequent relaxation, result in supporting defects classified based on involved areas as central (defect of pubocervical fascia), lateral or paravaginal (defect of the vesicopelvic ligaments) or combined defects. However recently the presence of a real connective fascia, histologically different from underlying connective below the vaginal wall.

#### Cardinal ligaments

Cardinal ligaments play a fundamental role in addition to the uterus support also for the bladder and they extend from the isthmus of uterus to lateral pelvic wall in correspondence of ischiatic spine. They have triangular shape and contain branches of uterine artery; posteriorly they fuse with sacral-uterine ligaments, while anteriorly they fuse with endopelvic fascia. Failed medialization of these ligaments during hysterectomy and delivery traumas involve a concentric damage to vaginal support and elongation of same ligaments.

#### Uterus and vagina support mechanisms

Generally the pelvic organ support is provided through pelvic musculature interaction (levator group) and connective structures. During most physiological events the pelvic musculature is the primary support for pelvic organs. Connective tissue on the other hand stabilises pelvic organs in the correct position in order to receive the maximum support from the musculature. During two main functional events, i.e. urination and evacuation, only connective tissue and ligaments thereof support pelvic organs during the muscular relaxation. Female vagina with normal anatomy lies in horizontal plane with respect to upper third thereof. This results from the join of the cervix and uterus to the pelvic wall by means of the complex of cardinal and uterosacral ligaments (parametrium). This tissue extends downwardly in upper vaginal portion and it is joined to the pelvic wall (paracolpium) and consists of an upper portion of fibres laterally extending along the pelvic wall (De Lancey level I). At this level there are also muscular dysmorphologies, which additionally join upper vaginal third to the levator medial wall ("levator attachment"). In the vagina middle portion paracolpium still anchors vagina laterally to the white line or tendinous arc of pelvic fascia (level II). This attachment assures transverse

pathway of the vagina between bladder and rectum. Distal portion (level III) of vagina forms a 45° angle with respect to the vertical and fuses anteriorly with urethra, posteriorly with perineal body and laterally with anus levator.

5                   Pelvic diaphragm

All pelvis support means originate from unique scaffolding, represented from bone structures constituting the same.

The pelvic diaphragm and perineal musculature, mainly coccygeal and anus levator muscles, constitute the floor thereof.

10                   Anus levator muscle and fascia thereof originate: laterally from pelvic portion of pubic bone and obturator fascia thickening, called arc line (tendinous arc of anus levator), from symphysis, and most inner surface of ischiatic spine, respectively.

15                   The three branches constituting the levator muscle, pubococcygeal, ileococcygeal and ischiococcygeal, represent the lower support for urethra, vagina and rectum going there through according to U shaped hiatus in the frontal portion. Some muscular digitations of pubococcygeal muscle reach urethra and concur to form external sphincter. Fibres which on the other hand fuse anteriorly and laterally to  
20                   the rectum participate to perineal support and concur to form the anus external sphincter.

                  Anus levator acts as a whole even if it consists of two main components: diaphragmatic (coccygeal and ileococcygeal muscles) and pubovisceral (pubococcygeal and puborectal muscles) portions,  
25                   respectively. Coccygeal muscles pass laterally from coccyx to sacrum to ischiatic spine and have sacralspinal ligaments as tendinous components. Ileococcygeal muscles originate laterally to pubic symphysis, go across the pelvic wall and fuse laterally to the tendinous arc of the anus levator and joining on the median line at level of the ano-coccygeal raphe, they  
30                   form levator plate. Puborectal muscles form a sling posteriorly to the rectum and contribute to anal continence. The space between the levators, through which rectum, vagina and urethra pass, is called genital hiatus. S2-S4 sacral metameres assure innervation of this important functional district.

35                   Although problems involving continence and genital prolapse increase in parallel with age, in the life of a woman no time exists, like during delivery, during which these structures are more vulnerable; the

vaginal delivery represents in fact a factor increasing by 4-11 times the risk to develop a genital prolapse.

5 In fact, delivery traumatism, mainly if repeated, involves the widening of U shaped hiatus delimited from levator bundles, but already during pregnancy support means of the pelvic organs lose their typical consistency due to relaxin, placental hormone reaching significant levels in the first trimester and that would result in collagen modifications with secondary increment of the elasticity and tensile strength reduction.

10 Levator covering fascia constitutes endopelvic fascia whose thickenings form ligament structures assigned to the correct "dynamic support" of pelvic organs. This fascia originates from pelvis sidewall and subsequently it is divided in two leaves encircling urethra, vesical neck and bladder

15 At urethral level it originates pubourethral and urethropelvic ligaments which in their front to behind pathway continue in vesicopelvic ligaments assigned to the bladder suspension. On the contrary bladder floor and uterine cervix are supported from cardinal and uterosacral ligaments.

#### Anal sphincters

20 The support structure of posterior compartment consist of anal sphincters.

25 Inner sphincter consists of smooth musculature, terminal layer of intestinal lining one and has tonic contractile activity largely controlled by intrinsic innervation. The nervous centre is situated in the lumbosacral marrow and a damage of hypogastric or sacral nerves determines an anal pressure decrease. Anaesthesia of ano-rectal region does not effect its tone. The inner sphincter is responsible mainly for the basal continence and its dysfunction determines "soiling" (anal dirtying).

30 The external sphincter consists of striated musculature. This musculature presents continuity with support structure of the pelvic floor through the puborectal muscle, which, as it is, determines 80 % ano-rectal angulation. This muscle possesses a step-wise activity and it is voluntarily manageable and, by creating high pressure zone, controls anal continence.

35 Puborectal muscle is closely involved in this activity in a reflex way. The reflex origin is spinal but it remains under medullary control; in

fact a voluntary contraction is possible for a period not longer than 1-2 minutes.

#### Continence mechanisms

##### Urinary continence

5           Urinary continence is the result of an equilibrium among various components: the closing pressure of urethra, anatomical and functional length thereof, ability of pelvic floor and urethra to increase the peripheral resistances during the stress and correct anatomical localisation of the sphincter unit. These components are organised resulting in, as defined by  
10       Raz, the UCLA Theory of urinary female continence, wherein U indicates the urethra modifications under stress, C represents the function of urethra closure, L indicates the anatomical and functional length of urethra and A indicates the anatomy.

          When the sphincter mechanism does not compensate  
15       adequately the abdominal pressure increases, the typical situation of stress urinary incontinence occurs, characterised by the involuntary loss of urine concurrently to a defecation manoeuvre or anyway involving sudden increases of abdominal pressure.

##### Faecal continence

20           Alterations of the external sphincter function result in defecation urgency up to faecal incontinence. Innervation dysfunctions cause hypotonic myotrophy of this sphincter unit causing effective damages in addition to the incontinence function also to the support structure of the pelvic floor with both posterior and total pelvic prolapse.

25           Structural alterations can result frequently from chronic costiveness and delivery. Posterior prolapse occurs with a lowering of the anal orifice level with respect to the intergluteus sulcus to the exit of the same rectum through the anus for several centimetres also.

          The posterior vaginal wall and the function of pelvic floor  
30       support.

          Fascia support consists of pre-rectal and para-rectal fascias while muscular support planes are:

- pelvic floor (levator, especially in pubococcygeal portion thereof)
- 35       - urogenital diaphragm comprising bulbocavernosus, superficial transverse muscle of perineum
- external anal sphincter

- central fibrous nucleus of perineum.

Urogenital diaphragm is localised under the lower portion of the levators. Between anus and vagina, on the median line, a tendinous structure, perineal fibrous body, is localised, which constitutes the point of musculo-fascial central insertion. A line joining the ischiatic tuberosities divides the perineum as two triangles, i.e. anterior urogenital and posterior anal.

In the woman the urogenital triangle is divided by clitoris, urethra and vaginal vestibule in two halves. Just below the subcutaneous fascia a musculo-membranous layer is present; it is here that two symmetrical bulbo-cavernous muscles passing from every side of the vestibulum to below labia maiora between clitoris anteriorly and the perineal body posteriorly are found. Following at perineal fibrous body the two transverse superficial perineum muscles reaching bilaterally both ischiatic tuberosities are inserted.

On the contrary the anal canal is the only viscus of the posterior perineal triangle. The muscular fibres of the superficial anal sphincter encircle anus and pass between the ano-coccygeal ligament and the perineal body. Deep anal sphincter encircles on the contrary the anal canal and it is fused upwardly with inferomedialis fibres of anus levator (puborectal\pubococcygeal). In the patients with relaxation of pelvic floor, the normal anatomical support is defective: the levator plane relaxes (turning from horizontal to convex); the levator hiatus widens and the medium-vaginal normal angulation of 110° disappears. Vagina distal half is found at approximately 45° from the vertical line. Vagina then turns downwardly and posteriorly and not more in upper well supported horizontal position; from above it results the rectum herniation.

In the patients with second level damage of muscular support (perineal or urogenital diaphragm), the introitus is wider and the distance from urethra to posterior fork is increased. Various degrees of perineal lesion can be observed, from a minimum, with only a small lesion of the perineum to a severe one, wherein the perineal structures are disappeared and the vaginal reach the anterior wall of rectum.

Like in the anterior vaginal wall, where the central can coexist with lateral defects, similarly it occurs posteriorly, where the defects at the same time can interest the pelvic floor and perineum; the disarranging of the pre-rectal fascia at level of the rectovaginal septum, the widening of

the levator hiatus resulting in lacking of the separation between middle vagina region and rectum together with weakening of the perineal musculature are most frequently detected defects.

#### Uro-Genital prolapse

5 Urogenital prolapse, with reference to female pelvis physiology, generally means the downwardly movement of the uterus, bladder and intestinum rectum associated with the vagina walls.

During his biological evolution, the human being has assumed an erect position which, from an anatomical point of view, resulted in the  
10 upsetting of the viscera position within the so-called pelvic cavity.

In particular, the female pelvis was in such position that it must bear the ponderal load of endo-abdominal apparatuses, without an adequate counterbalance by pelvic structures thereof.

15 In this context, the above reported urogenital prolapse can result from several causes, among which all those phenomena aggravating endo-abdominal pressure on the female pelvis are to be pointed out, like the hard duties, traumatic sport activity, long time standing, cough, obesity and so on.

Further the prolapse is promoted in the women who have had  
20 many deliveries but also wherein weakness and hypotonia of the uterus support structures, also in nullipara.

Consequences of a less or more pronounced prolapse involve a general worsening of the life quality and result in local circulatory disorders, swelling of external genitalia, backache, heaviness feeling in the  
25 lower venter and, in severe cases, ulcerations and exudations.

Moreover, an important consequence of prolapse is represented from stress urinary incontinence, in many cases associated to lowering of the vagina anterior wall, urethra and vesical neck.

There are various urogenital prolapse types, depending on the  
30 involved region, its position in this region and downwardly reached position, i.e. first degree if the lower extremity of the uterus neck lies on the upper extremity of the vaginal canal without not reaching the vulvar slit, second degree when the uterus neck appears at the vulvar slit and third degree when the lower extremity of the uterus neck comes out of  
35 vulva.

When the uterus lowering results on its turn in the lowering of the anterior vaginal wall, in the course of this movement urinary bladder

and urethra are dragged. In these cases the phenomenon is indicated with cystocele and/or urethro-cystocele term.

On the contrary when the posterior vaginal wall is involved, the downwardly movement thereof is together with the anterior wall of the rectum intestine. In these cases the phenomenon is indicated with the term rectocele and involves the formation of a bulging in correspondence of the mucosa, sub-mucosa and muscular involved fascias, sizing up to 10 cm.

Cystocele can occur for a separation of lateral, transverse or mixed endopelvic fascia (central-lateral).

#### Therapy

These different situations are faced by means of aimed and sometimes different surgical approaches.

Fascia repair operations for the lateral separations abdominally ("paravaginal repair") or vaginally, by surgically coupling four points of the anterior vaginal wall using four pairs of non-absorbable threads then suspended in the retropubic area, according to the so-called "four corner" technique.

In the central separations the approach consists of so-called medialization of the vagina adjacent structures, i.e. levator muscles and fascias, in order to raise the vagina, bladder and sometimes also uterus.

As to rectocele, the surgical approach comprises so-called posterior colporrhaphy, that is the anchorage of the interested tissues to the medial branches of the anus levator ("Levator Myorrhaphy"), or endoanal treatment.

In spite of this variety of surgical therapies allowing to face the urogenital prolapse also in premature phase, contrasting the same in several modalities of occurrence, the results obtained are not satisfactory because relapse phenomena in high percentage, up to 30%, have been evidenced, during a period from six months to one year after the operation.

Further it is very frequent the case wherein a patient subjected for a repair of a determined region develops at a distance a *descensus* of the not previously treated segment.

The reason of the recidivations is to be searched mainly in the fact that whichever repair operation needs, in the period of cicatrization, stabilisation and strengthening resulting from the assigned connective

structures. In effect, in many of these cases, neoformed collagen tissue constitutes the requirement for the successive lowering of the surgically treated structures.

5 In fact, the connecting tissue is weakened above all because, in the prolapse typical age like in the predisposed subjects, the hormonal order, expecting an oestrogen decrease and in particular menopause, favour the formation of more weak type collagen tissue.

10 The rectal prolapse is surgically treated trans-anally or abdominally with variable successful percentage depending on used technique with not secondary effects on continence function and with high relapse percentages.

15 It is object of the present invention that of providing a prosthesis permitting obviating to the above mentioned drawbacks, with reference to the known surgical techniques for pelvic and rectal prolapse and faecal incontinence.

20 It is therefore specific object of the present invention a prosthesis for use in the surgical treatment of rectal and pelvic prolapse and faecal incontinence, and related surgical kit, comprised of a net band, made up of material suitable to surgical implant, comprising a wider central body and two more narrow arms, said central body being suitable to be applied in correspondence of rectum, thus surrounding ano-rectal canal behind, above and close to the raphe ano-coccygeus, said arms being  
25 suitable to bilaterally pass through obturator foramen, respective ends of said arms not coupled with said central body being suitable to be anchored to the subcutaneous tissue, so that said central body exerts a suspension action on anal sphincter and on rectum, thus re-creating a fascia support hammock stabilising pelvic pavement.

30 Preferably, according to the invention, said material suitable to the surgical implant is a non-reabsorbible material.

Preferably, according to the invention, said material suitable to the surgical implant is a partially reabsorbible material.

35 Preferably, according to the invention, said material suitable to the surgical implant is a biological material.

Preferably, according to the invention, said arms ends are suitable to be anchored to the subcutaneous tissue once freed, e.g. by a Velcro® effect.

5 Preferably, according to the invention, said arm ends are suitable to be anchored by suture stitches.

Preferably, according to the invention, said arms are, on said respective ends, provided with means for hooking curved surgical needles, preferably disposable curved surgical needles.

10 Preferably, according to the invention, said hooking means are of the not recoverable kind.

Preferably, according to the invention, said net band has a bi-directional elastic extensibility and a traction resistance higher than 10 kg/cm<sup>2</sup>.

15 Preferably, according to the invention, said net band has a thickness between 0.5 mm and 0.9 mm.

Preferably, according to the invention, said net band net has a thickness of about 0.7 mm.

20 Preferably, according to the invention, said net band is comprised of a polypropylene net, particularly a stereoisomer isotactic of polypropylene (e.g. PROLENE®, manufactured by Ethicon® Inc.).

Preferably, according to the invention, said net is centrally comprised of biological tissue and its arms are comprised of synthetic tissue.

25 Preferably, according to the invention, in correspondence of intersections of net wires, said wires are connected each other so that the net can be cut according to every direction without fraying.

Preferably, according to the invention, transverse dimensions of the meshes are between 1 mm and 3 mm, said meshes preferably having a rhomboid shape.

30 Preferably, according to the invention, said central body has an extension between 4 cm and 10 cm according to longitudinal direction of connection of arms.

35 Preferably, according to the invention, said central body has an extension between 4.5 cm and 5.5 cm according to longitudinal direction of connection of arms, and respective connection zones with said arms are provided having a length between 1.5 cm and 2.5 cm, and having a width varying from the central body width to the arms width.

Preferably, according to the invention, said central body has an extension between 2 cm and 3 cm, particularly 2.5 cm, according to longitudinal direction of connection of arms.

5 Preferably, according to the invention, said arms have a width between 1.2 cm and 1.7 cm, particularly 1.5 cm.

Preferably, according to the invention, ends of said arms are provided with quick anchoring means to the subcutaneous tissue.

10 Preferably, according to the invention, said quick anchoring means to the subcutaneous tissue are comprised of three-dimensional undulations at the ends of said arms, preferably ogive shaped undulations, and then a free net.

Preferably, according to the invention, said net band comprises longitudinal reinforcing wires extending parallel to its edges according to its extension direction.

15 Preferably, according to the invention, said net band comprises second reinforcement wires in its central body, said second transverse wires being transverse to its extension direction.

20 It is further object of the present invention a prosthetic kit for implanting a prosthesis use in the surgical treatment of rectal and pelvic prolapse and faecal incontinence, comprising the following components:

a prosthesis as defined in the present invention;

one or more curved needles suitable to implant said prosthesis.

25 Preferably, according to the invention, said curved needles have a handle, and have a metallic element with a multiple curvature specular shape.

Preferably, according to the invention, said curved needles have a first portion straight, a second portion rising with respect to the prolongation of the first portion and having a slight curvature, and a third portion with a bigger curvature and ending with an eye.

30 The present invention will be now described, for illustrative but not limitative purposes, according to its preferred embodiments, with particular reference to the figures of the enclosed drawings, wherein:

figure 1a shows an embodiment of the prosthesis according to the present invention;

35 figure 1b shows a possible end of prosthesis of figure 1a;

figure 2a shows anatomical positioning of prosthesis according to the invention with respect to the inner zone of male perineum;

figure 2a shows anatomical positioning of prosthesis according to the invention with respect to the inner zone of female perineum;

figure 3 shows positioning of prosthesis according to the invention with respect to organ group;

5 figure 4a shows an embodiment of the prosthesis according to the present invention;

figure 4b shows a further embodiment of the prosthesis according to the present invention;

10 figure 5 shows an example of a couple of needles (a) and (b) according to the invention;

figure 6 shows identical end of the two needles according to the invention.

15 Making reference to the above limits of the presently available surgical therapies, it has been realised an intervention technique providing the use of a particular needle/prosthesis kit studied to solve the above problems.

20 Solution idea on which the present invention is based is that of using, as prosthetic assembly, a synthetic material (not reabsorbible or partially reabsorbible material) or a biological material that can be transperineally applied bilaterally passing through obturator foramen (see figures 2a and 2b), so as to exert a suspension action of ano-sphincters and of rectum (see figure 3), thus re-creating a fascia support hammock stabilising pelvic pavement.

25 Prosthesis will extend along a major portion of the directional line of puborectal muscle, surrounding ano-rectal canal behind, above and close to the raphe ano-coccygeus, and, moving forward, it will be bilaterally anchored to the obturator foramen, presuming that pelvic diaphragm is supported, substantially following anatomical reperi of puborectal muscle.

30 Synthetic material (e.g. Prolene®) or biological material band of prosthesis according to the invention is for example preferably comprised of a central portion long 5 – 6 cm and high 2.5 – 4 cm, bilaterally degrading at 1.5 cm within a distance of 2 cm, and prolongs with two arms, each one long 25 cm and high 1.5 cm, ending with a series of  
35 ogives, followed by a further portion of free net, that will be introduced through needle eye.

Preferably, but not necessarily, central part in contact with rectum wall is coated with biological material (collagen) in order to reduce at most possible erosive phenomenons.

Two arms of net band will be thus passed through two obturator foramens by two curved needles bilaterally passing through obturator membrane, taking care of centrally positioning central part of prosthesis behind rectum.

#### Surgical Technique

After having put patient in a pushing lithotomic position and having before hand disinfected perineum and anus-rectal and vaginal) cavities (after a suitable intestinal preparation), a vertical incision is made long about 2 – 3 cm, laterally beyond 3 cm from anal coetaneous folds, on the left side of the patient at 3 hour (or on the right side in case technician is left-handed). Once unglued subcutaneous tissue by an acute and rounded way, a tunnel is made by digitoclasys about anus-rectal channel, thus entering in a virtual space between rectum rear wall and raphe ano-coccygeus.

Two point-shaped cutaneous incisions are made by lancet, at the level of the lower edge of obturator foramen, having as bilateral repere ischial tuberosities.

Thus curved needle is introduced, passing through obturator membrane, and thus it is brought by a combined action (through vagina for a woman – through rectum for a man) until exiting from the surgical opening already realised.

It is thus hooked distal end of band exiting from skin. This action is repeated from the opposed part, coupling needlepoint behind rectum wall.

Now, two arms of band are pulled by a combined action of hand index within anal channel in order to evaluate tension of central part of the same.

Now, it is considered the retraction condition of perineum in order to eventually loosening or pulling said band. Two band ends can be let free within subcutaneous tissue, thus exploiting the so-called Velcro® effect of synthetic material, or they can be fixed by a quick hooking system, or anchored by two not-reabsorbible mono-filament suture stitches, or even self-support thanks to a silicone ogives or similar material system, as shown in figure 1b and explained more specifically in the

following. Now, cutaneous openings are closed after having cut the exceeding net.

Detailed description of prosthesis

5 Main advantage of the prosthetic assembly according to the present invention is an increase of production of connective tissue between surgically implanted net meshes, naturally creating a not-reabsorbible and elastic support providing an efficient support and preventing a subsequent descent of pelvic structures subjected to prolapse.

10 Furthermore, surgical application of said prosthetic assembly that can be carried out both in a premature phase or in an advanced phase of prolapse or incontinence can correct both faecal incontinence and rectum and pelvic prolapse.

15 Making reference to figures 1 – 3, it is represented a prosthetic assembly of the kind suitable to be used in surgical treatments of urogenital prolapse, substantially divided into two different prosthesis. A first prosthesis 100 of the prosthetic assembly is represented in figures 1a and 1b, particularly suitable for surgical therapy of faecal incontinence and rectal prolapse.

20 In figure 1a, first prosthesis is comprised of a not-reabsorbible synthetic net 3.

Said synthetic net 3, which obviously is sterile and inert, has a bi-directional elasticity and a traction resistance higher than  $10 \text{ kg/cm}^2$ , with a thickness between 0.5 mm and 0.9 mm, preferably about 0.7 mm.

25 In correspondence of intersections 4 between wires 5, said wires 5 are coupled each other in such a way that net 3 can be cut according to every direction without fraying.

Transverse dimensions of meshes 6 are between 1 mm and 3 mm, said meshes having a substantially rhomboid shape.

30 Each wire 5 is a not-reabsorbible monofilament wire comprised of polypropylene  $(\text{C}_3\text{H}_6)_n$ , particularly an isotactic stereoisomer of polypropylene.

35 A kind of particularly suitable net for this kind of use is a net comprised of a monofilament manufactured by Ethicon®, Inc., and marketed under the trade name of PROLENE® polypropylene Net.

As alternative to the above described not-reabsorbible net, it is possible using with the same effect a partially reabsorbible net or a biological tissue.

Prosthesis 100 according to the invention has a central body 10, which, in the longitudinal direction along which arms 20, 20' connect, has an extension between 4 and 10 cm, more preferably between 4.5 and 5.5 cm. They are further provided connection zones 30, 30' with said arms having a length between 1.5 and 2.5 cm, and a width varying between the central body 10 width and the arms 20, 20' width.

Said central body has an extension between 2 cm and 3 cm, particularly 2.5 cm, according to longitudinal direction of connection of arms.

Said arms 20, 20' have a width between 1.2 cm and 1.7 cm, particularly 1.5 cm.

At the ends 40, 40' of said arms 20, 20' anchoring means are provided for curved needles for implanting prosthesis 100.

An example of end 50 of arms 20, 20' is shown in figure 1b, said end being undulated so as to permit a quick anchoring of subcutaneous tissue. Three-dimensional undulation defines ogives 51, acting in sub-cutaneous tissue as hooks, thus keeping prosthesis according to the invention under tension.

Since prosthesis cannot be more rigid, being it necessary adapting the same to tissues on which a traction is exerted, it is preferred providing the net with suitable reinforcements, so that net does not tightens during traction, making pressure only on a portion of its surface, usually centrally.

Making now reference to figure 4a, an example of reinforcement is comprised of wires 60 made up of a more resistant material, extending parallel to the prosthesis edges. Still, making reference to figure 4b, reinforcements can be wires 61 that are transverse to the larger extension direction of central body 10. it is evident that different combinations of the two kind of reinforcements can be provided.

#### Detailed description of needles

Making reference to figures 5 and 6, two needles 200, 200' according to the invention have a specular shape. Needle (a) is used by right hand, while needle (b) is used by left hand.

A metallic element 202, 202' is connected to the handle, and has a multiple curvature. In fact, after a first portion straight 203, 203', it is provided a second portion 204, 204', rising with respect to the prolongation of the first portion and having a slight curvature, and a third portion 205, 205' with a bigger curvature and ending with an eye.

Opening on the tip of needle (eye) is clearly shown in figure 6, for fixing band according to the invention.

Main advantage of the prosthetic assembly, thanks to the prosthesis and the kit according to the invention, is that it is possible offering to those suffering of rectal and pelvic prolapse a solution to most of daily life problems due to this pathology, not being any more necessary wearing hygienic napkins, with the consequent problems. Defecation is possible thanks to a proper positioning of the above kit, or to simple microclisms in case a pushing traction of prosthesis has been done during the surgical intervention.

The present invention has been described for illustrative but not limitative purposes, according to its preferred embodiments, but it is to be understood that modifications and/or changes can be introduced by those skilled in the art without departing from the relevant scope as defined in the enclosed claims.

## CLAIMS

1. Prosthesis (100) for use in the surgical treatment of rectal and pelvic prolapse and faecal incontinence, and related surgical kit, comprised of a net band, made up of material suitable to surgical implant, comprising a wider central body (10) and two more narrow arms (20, 20'), said central body (10) being suitable to be applied in correspondence of rectum, thus surrounding ano-rectal canal behind, above and close to the raphe ano-coccygeus, said arms (20, 20') being suitable to bilaterally pass through obturator foramen, respective ends of said arms (20, 20') not coupled with said central body (10) being suitable to be anchored to the subcutaneous tissue, so that said central body exerts a suspension action on anal sphincters and on rectum, thus re-creating a fascia support hammock stabilising pelvic pavement.
2. Prosthesis according to claim 1, characterised in that said material suitable to the surgical implant is a non-reabsorbible material.
3. Prosthesis according to claim 1, characterised in that said material suitable to the surgical implant is a partially reabsorbible material.
4. Prosthesis according to claim 1, characterised in that said material suitable to the surgical implant is a biological material.
5. Prosthesis according to one of claims 1 - 4, characterised in that said arms (20, 20') ends (50) are suitable to be anchored to the subcutaneous tissue once freed, e.g. by a Velcro® effect.
6. Prosthesis according to one of claims 1 - 5, characterised in that said arm (20, 20') ends (50) are suitable to be anchored by suture stitches.
7. Prosthesis according to one of claims 1 - 6, characterised in that said arms (20, 20') are, on said respective ends, provided with means (40, 40') for hooking curved surgical needles, preferably disposable curved surgical needles.
8. Prosthesis according to claim 7, characterised in that said hooking means (40, 40') are of the not recoverable kind.
9. Prosthesis according to one of claims 1 - 8, characterised in that said net band has a bi-directional elastic extensibility and a traction resistance higher than 10 kg/cm<sup>2</sup>.
10. Prosthesis according to one of claims 1 - 9, characterised in that said net band has a thickness between 0.5 mm and 0.9 mm.

11. Prosthesis according to one of claims 1 - 9, characterised in that said net band net has a thickness of about 0.7 mm.

12. Prosthesis according to one of claims 1 - 11, characterised in that said net band is comprised of a polypropylene net, particularly a stereoisomer isotactic of polypropylene (e.g. PROLENE<sup>®</sup>, manufactured by Ethicon<sup>®</sup> Inc.).

13. Prosthesis according to one of claims 1 - 12, characterised in that said net is centrally comprised of biological tissue and its arms are comprised of synthetic tissue.

14. Prosthesis according to one of claims 1 - 13, characterised in that in correspondence of intersections (4) of net wires(5), said wires (5) are connected each other so that the net (3) can be cut according to every direction without fraying.

15. Prosthesis according to one of claims 1 - 14, characterised in that transverse dimensions of the meshes (6) are between 1 mm and 3 mm, said meshes preferably having a rhomboid shape.

16. Prosthesis according to one of claims 1 - 15, characterised in that said central body (10) has an extension between 4 cm and 10 cm according to longitudinal direction of connection of arms (20, 20').

17. Prosthesis according to claim 16, characterised in that said central body (10) has an extension between 4.5 cm and 5.5 cm according to longitudinal direction of connection of arms (20, 20'), and respective connection zones with said arms are provided having a length between 1.5 cm and 2.5 cm, and having a width varying from the central body width to the arms (20, 20') width.

18. Prosthesis according to one of claims 1 - 17, characterised in that said central body (10) has an extension between 2 cm and 3 cm, particularly 2.5 cm, according to longitudinal direction of connection of arms (20, 20').

19. Prosthesis according to one of claims 1 - 18, characterised in that said arms (20, 20') have a width between 1.2 cm and 1.7 cm, particularly 1.5 cm.

20. Prosthesis according to one of claims 1 - 19, characterised in that ends (50) of said arms (20, 20') are provided with quick anchoring means (50, 51) to the subcutaneous tissue.

21. Prosthesis according to one of claims 1 - 20, characterised in that said quick anchoring means (50, 51) to the subcutaneous tissue are

comprised of three-dimensional undulations at the ends of said arms (20, 20'), preferably ogive shaped undulations, and then a free net.

22. Prosthesis according to one of claims 1 - 21, characterised in that said net band comprises longitudinal reinforcing wires (60) extending parallel to its edges according to its extension direction.

23. Prosthesis according to one of claims 1 - 22, characterised in that said net band comprises second reinforcement wires (61) in its central body (10), said second transverse wires (61) being transverse to its extension direction.

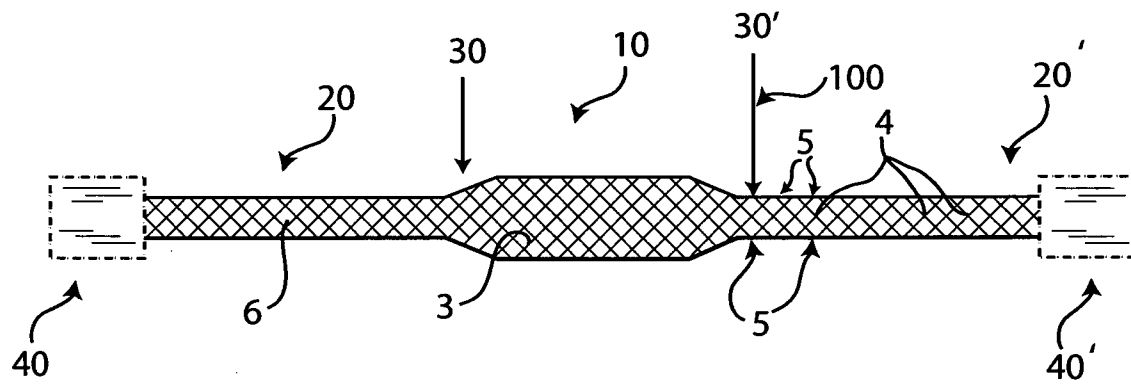
24. Prosthetic kit for implanting a prosthesis use in the surgical treatment of rectal and pelvic prolapse and faecal incontinence, comprising the following components:

a prosthesis as defined in each one of claims 1 - 23;  
one or more curved needles (200, 200') suitable to implant said prosthesis.

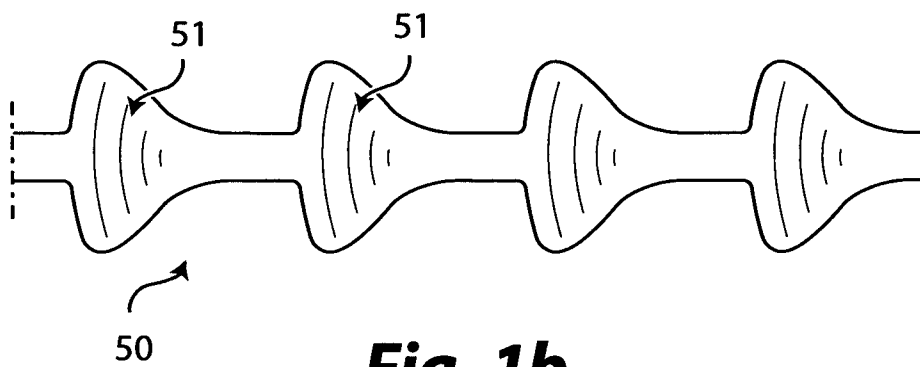
25. Prosthetic kit according to claim 24, characterised in that said curved needles (200, 200') have a handle (201, 201'), and have a metallic element (202, 202') with a multiple curvature specular shape.

26. Prosthetic kit according to claim 25, characterised in that said curved needles (200, 200') have a first portion straight (203, 203'), a second portion (204, 204') rising with respect to the prolongation of the first portion and having a slight curvature, and a third portion (205, 205') with a bigger curvature and ending with an eye.

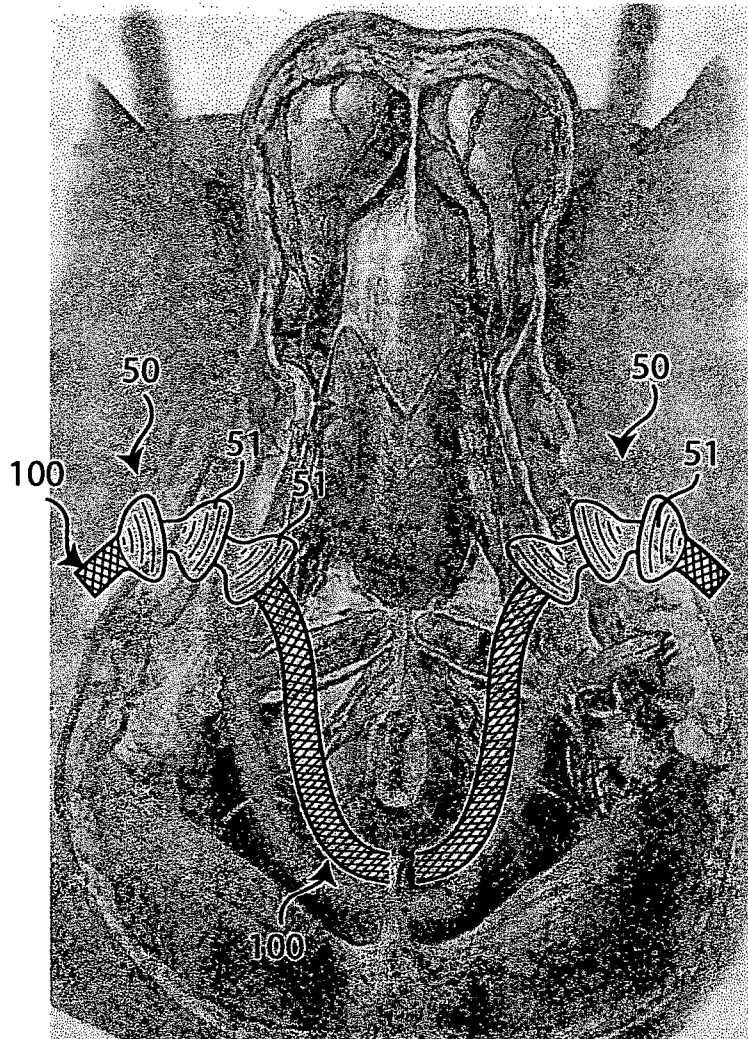
1/6



**Fig. 1a**

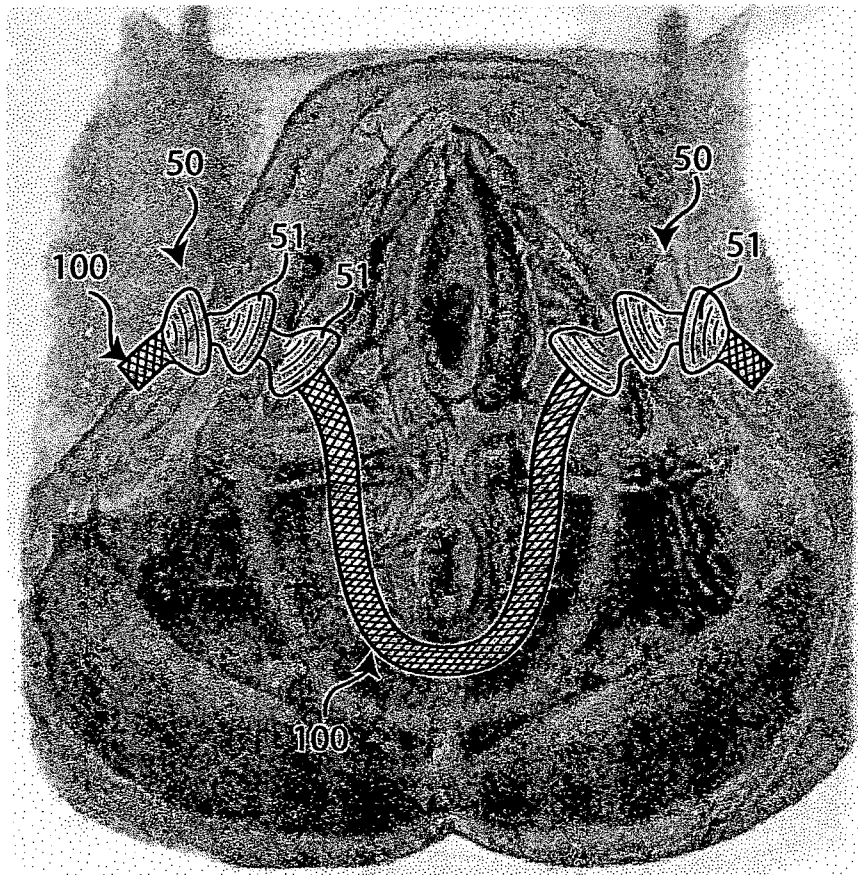


**Fig. 1b**



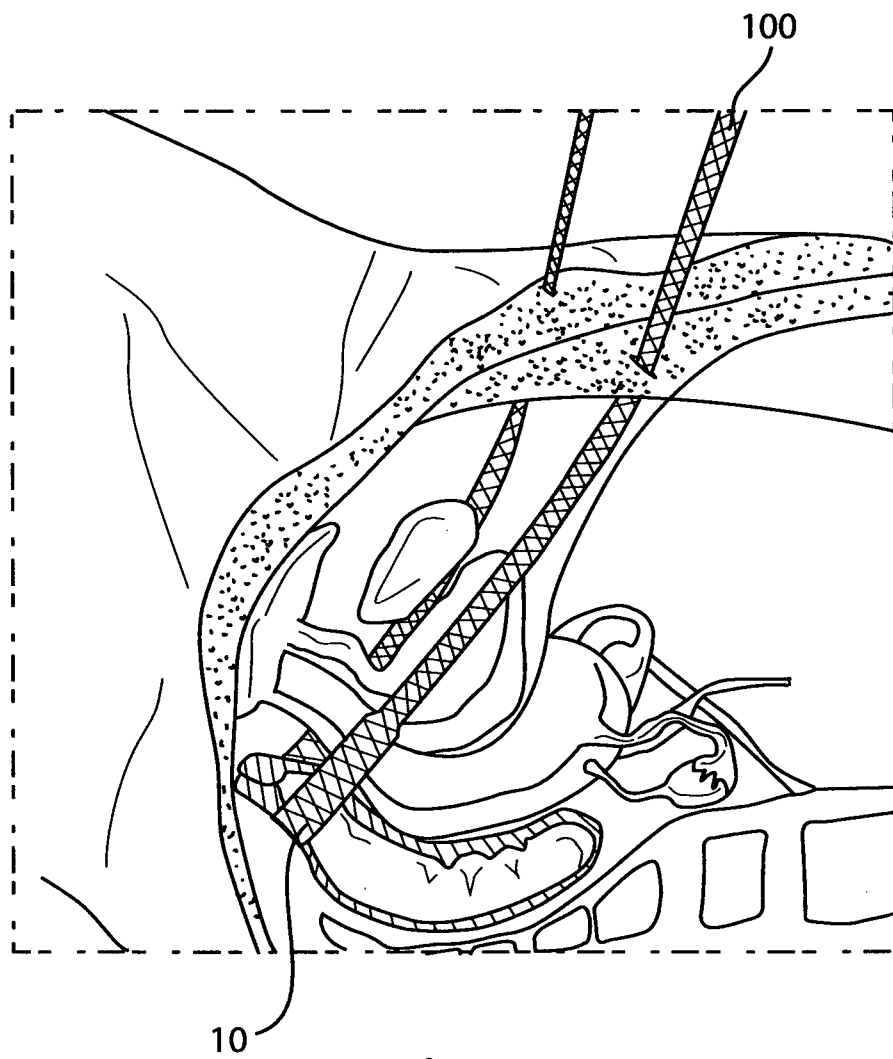
**Fig. 2a**

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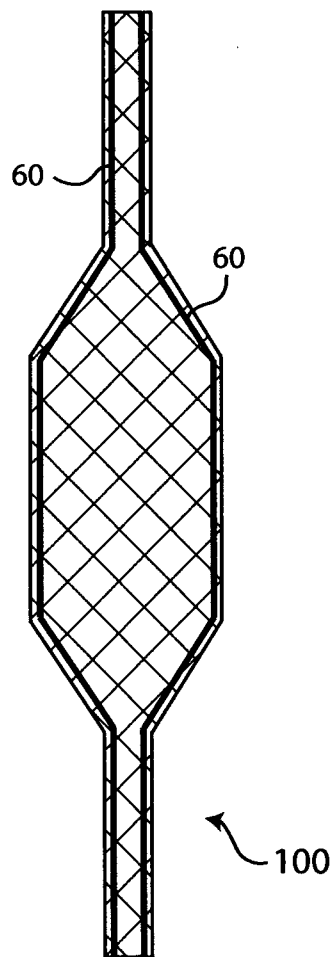
**Fig. 2b**

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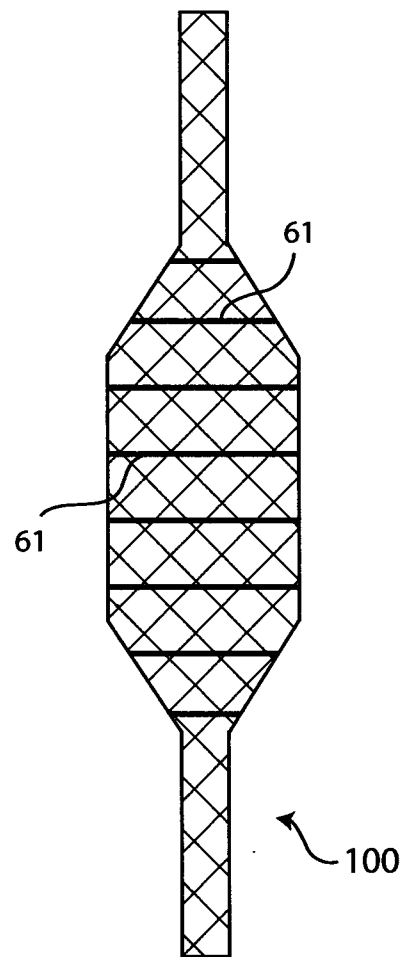


**Fig. 3**

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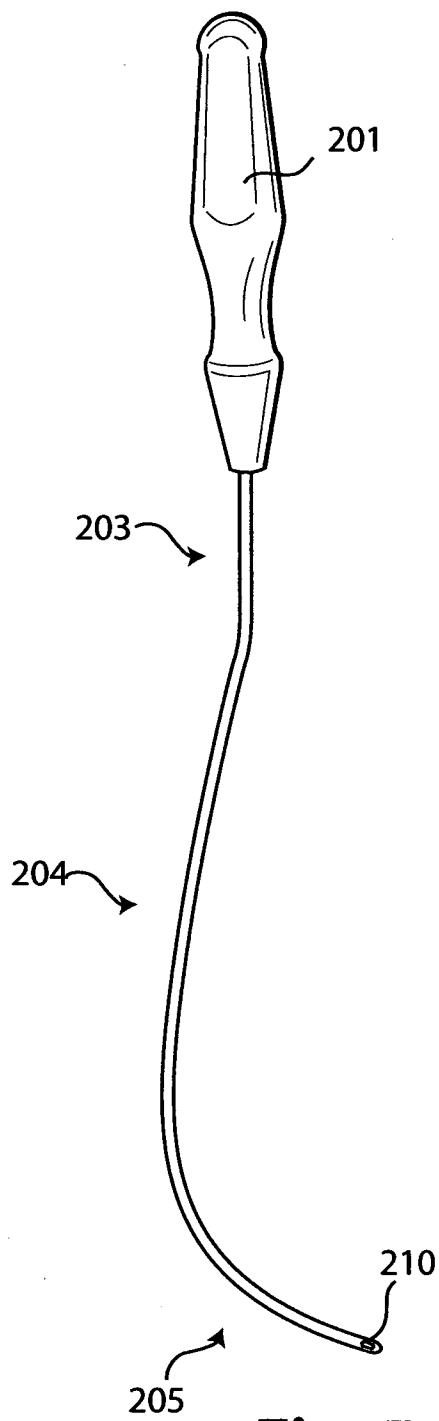


**Fig. 4a**

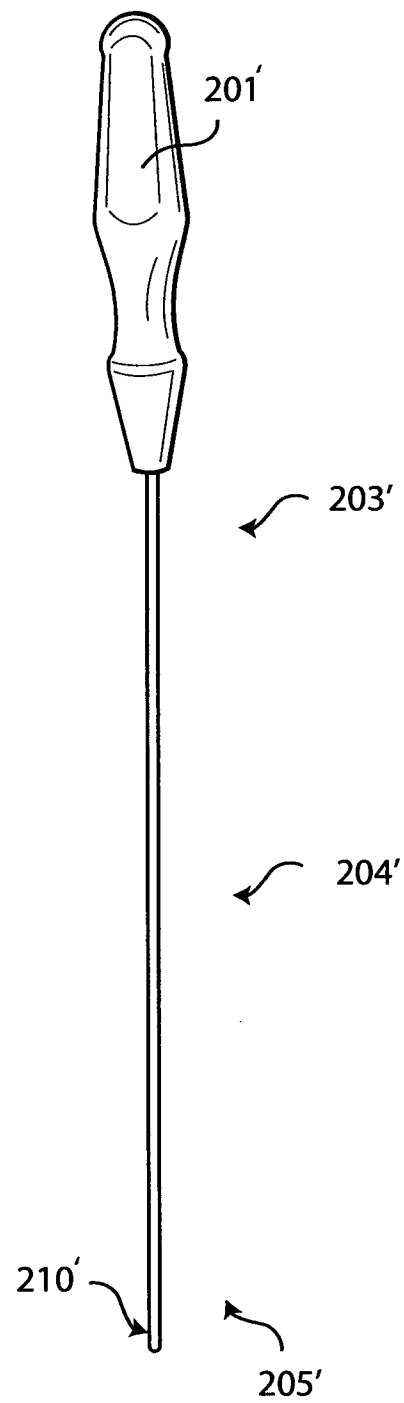


**Fig. 4b**

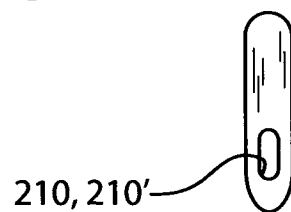
6/6



**Fig. 5a**



**Fig. 5b**



**Fig. 6**

## INTERNATIONAL SEARCH REPORT

International application No

PCT/IT2007/000560

## A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F2/00

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)

A61F

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 practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages                                                                                                                                                            | Relevant to claim No.             |
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Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

4 December 2007

Date of mailing of the international search report

13/12/2007

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## INTERNATIONAL SEARCH REPORT

International application No

PCT/IT2007/000560

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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Information on patent family members

International application No

PCT/IT2007/000560

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