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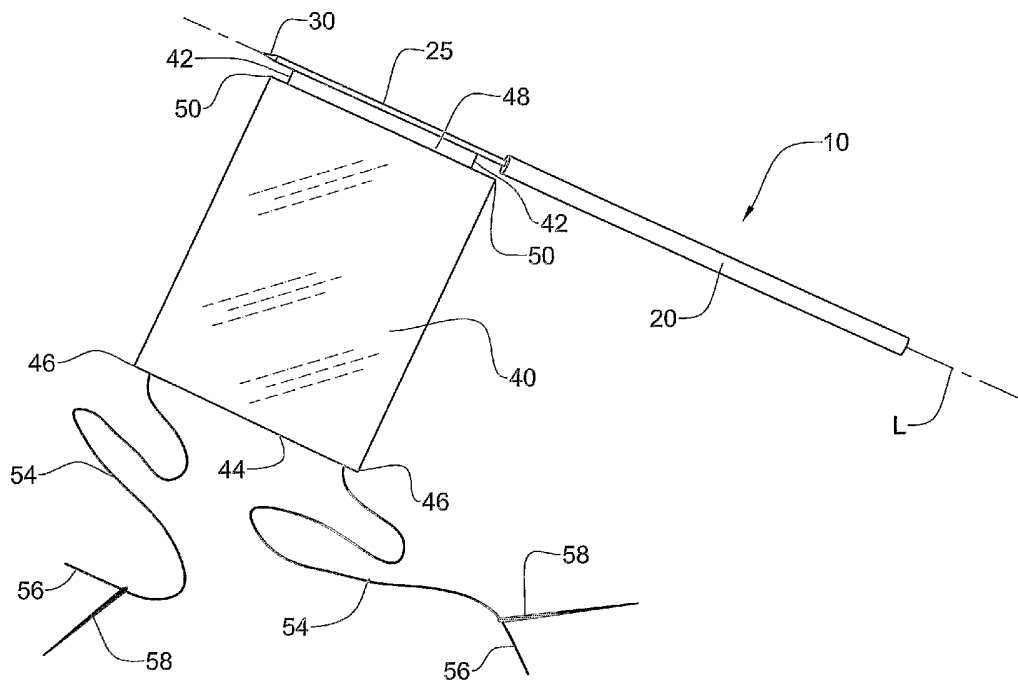
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(54) Title: DEVICE FOR DEPLOYING AND PLACING A SURGICAL PROSTHESIS MESH



(57) Abstract: A method and an apparatus for deployment and placement of a mesh-sheet through a cannula utilized in laparoscopic procedures, the apparatus comprising a deploying rod formed with a handle portion and a coaxial roller portion, where the mesh-sheet is wound around the roller portion and comprises a leading edge and a rear edge with at least one surgical thread secured to the leading edge of the mesh-sheet, and a free end of the surgical thread provided with a fixing arrangement.

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INTERNATIONAL SEARCH REPORT WIPO PCT

(PCT Article 18 and Rules 43 and 44)

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Applicant ELDAR, Samuel		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

The international search was carried out on the basis of a translation of the international application furnished this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. **Certain claims were found unsearchable** (See Box II).

3. **Unity of invention is lacking** (see Box III).

4. With regard to the **title**,

the text is approved as submitted by the applicant.

the text has been established by this Authority to read as follows:

DEVICE FOR DEPLOYING AND PLACING A SURGICAL PROSTHESIS MESH

5. With regard to the **abstract**,

the text is approved as submitted by the applicant.

the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regards to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 1

as suggested by the applicant.

as selected by this Authority, because the applicant failed to suggest a figure.

as selected by this Authority, because this figure better characterizes the invention.

b. none of the figures is to be published with the abstract.

DEVICE FOR DEPLOYING AND PLACING A SURGICAL PROSTHESIS MESH

FIELD OF THE INVENTION

The present invention relates to a tool and method for the deployment and placement of a mesh-sheet in the abdominal cavity or the inguinal space, covering a hernial defect of a patient during a hernia repair in a laparoscopic procedure. The term *hernia* as used herein the specification and claims denotes any type of hernia e.g. abdominal hernia (incisional, umbilical, epigastric or Spigelian), inguinal hernia (inguinal or femoral).

BACKGROUND OF THE INVENTION

Hernias are abnormal protrusions of an organ (or organs) through a defect or natural opening in a covering membrane, muscle or bone. Most hernias protrude in the inguinal region as inguinal (direct or indirect) or femoral hernias and in the anterior abdominal wall region, as incisional, umbilical, epigastric or Spigelian hernias.

Hernia repair typically requires surgery, which generally entails an incision in the hernia zone ranging up to about 25 centimeters in length. Several layers of the inguinal region or of the abdominal wall are generally separated to reach and expose the herniated portions. A small defective gap may be closed by sutures, and in cases of a larger defective gap it is required to apply a mesh-sheet over the gap. In some cases a mesh-sheet may be used for reinforcing a primary sutured defect in the abdominal wall. Such a procedure is completed by fixing the mesh-sheet by sutures at peripheral edges thereof to the abdominal wall, over the defective zone.

- 2 -

Traditionally, hernia repairs involve major invasive surgical procedures, which often cause excessive trauma to tissue layers and to the patient and necessitate long postoperative recuperation periods. Even more so, such procedures are typically carried out under full anesthesia, which at times and for certain
5 patients, may be a problematic issue. In addition, numerous complications, related directly or indirectly to the surgery may often result, including bleeding, infection, testicular atrophy, organ damage, nerve damage, blood vessel damage, etc. Further, cutting through the various layers of tissues to obtain access to the herniated area may cause additional trauma to the patient.

10 To avoid many of the above-mentioned problems, laparoscopic and endoscopic surgical procedures have become relatively popular and have provided additional incentive to develop such procedures further. In laparoscopic procedures, surgery is performed in the interior of the abdomen or in the inguinal space through a small incision where endoscopic tubes may then be inserted through narrow
15 entrance incisions formed in the skin and adjoining tissue.

In laparoscopic and endoscopic procedures, several tubes, often referred to as *cannulas* or *trocars*, are used for monitoring the procedure by insertion of optical equipment therethrough, connected to visualizing means, as known in the art.

Laparoscopic and endoscopic procedures generally require inflation of the
20 surgical region i.e. the abdominal or inguinal space, typically by introducing pressurized gas such as CO₂ through one of the cannulas. Accordingly, any openings through which instrumentation is inserted into the body must be sufficiently sealed to retain gas pressure.

Additionally, laparoscopic and endoscopic procedures often require the
25 surgeon to act on organs, tissues and/or vessels remote from the incisions. Thus, instruments used in such procedures are typically long and narrow while being functionally controllable from a proximal end of the instrument.

Performing such an operation requires that the surgeon be skilled and trained, as such procedures involve relatively complex actions executed through the

- 3 -

narrow cannulas, with no direct eye contact between the surgeon and the operated tissues.

As aforementioned, in hernia repair it is common to apply a prosthetic mesh-sheet to cover the opening in the defected organ. In a laparoscopic procedure, this is done by pushing the mesh-sheet, rolled or folded or squeezed, through a cannula into the abdominal or inguinal space of the patient, using laparoscopic forceps. The mesh-sheet is then unfolded and placed at the desired location by other laparoscopic instruments.

Several patents refer to special techniques in the field of placement of a prosthesis mesh-sheet for hernia repair in laparoscopic procedures.

US 5,464,403 discloses a tool for the placement of a flexible sheet in laparoscopic procedures. The tool includes an elongate tubular assembly and an elongate tubular member having a bore. A rod is disposed in the bore and terminates short of the distal extremity of the elongate tubular assembly. A rotatable member is secured to the proximal extremity of the rod. A handle is secured to the proximal extremity of the elongate tubular assembly and receives the rotatable member. The tubular assembly has a slot extending longitudinally which permits access to the annular chamber and the extremity of the rod. The distal extremity of the rod engages one edge of the sheet, hence as the rod is rotated in one direction, the sheet of mesh unwound from the rod and into the patient.

US 5,957,939 discloses a medical device for deploying surgical fabric such as mesh-sheet within a body cavity of a patient. The device includes a deploying member and a clamping member supported at the distal end of the deploying member for holding the fabric in rolled and unrolled configurations. The clamping member is engageable with a portion of a piece of surgical fabric and rotatable with respect to the deploying member so that the fabric in the unrolled configuration can be wrapped around the clamping member to the rolled configuration. The device further includes a self-unwinding member at the distal end of the deploying member, the self-unwinding member being effective in automatically unwinding the fabric from the rolled configuration to the unrolled configuration.

- 4 -

The above mentioned patents refer to means for deploying a mesh sheet but no reference is made to placing the mesh-sheet in its position within the abdominal cavity.

Other patents referring to techniques for deploying a prosthetic mesh-sheet during a laparoscopic procedure are, for example, US 5,147,374, US 5,176,692, US 5,263,969, US 5,304,187, US 5,405,360, US 6,156,045.

An object of the present invention is to provide an apparatus and a method for deployment and placement of a mesh-sheet in a laparoscopic procedure where reduced skills and training are required to perform such a procedure, and wherein trauma to the patient is minimized, recovery time is significantly shortened as well as the time required to complete the laparoscopic procedure.

The proposed apparatus and the method utilizing same are suitable for abdominal hernias that may include incisional, umbilical, Spigelian and epigastric hernias, and with some modifications may be suitable for treating inguinal and femoral hernias.

SUMMARY OF THE INVENTION

For sake of convenience, reference is made hereinafter to abdominal hernia repairs of any of the aforementioned types namely incisional, umbilical, Spigelian and epigastric hernias, though it is appreciated that the invention is applicable in a variety of similar operations, such as, for example inguinal hernias, etc (direct and indirect) and femoral hernias.

The present invention is directed to an apparatus for deployment and placing a mesh-sheet in a laparoscopic procedure, the apparatus comprising a rod formed with a handle portion and a coaxial roller portion, said roller portion having the mesh-sheet wound there-around. According to one particular application the roller portion has a distal end provided with a tissue-anchoring stud. According to still a particular embodiment, the roller portion is rotatably attached to the handle portion.

The apparatus is fitted for insertion into the abdominal cavity or inguinal space of a patient through a cannula and accordingly, its overall diameter is sized

– 5 –

depending on the particulars (size and thickness) of the mesh used and the specific cannula used in conjunction therewith.

The mesh-sheet according to the present invention comprises a leading edge and a rear edge. At least one surgical thread is secured to the leading edge of the mesh-sheet, where according to one specific application a free end of the surgical thread is provided with a surgical needle. The one or more surgical threads are useful in extraction, positioning (orientation) and securing the mesh-sheet in site.

According to one particular embodiment, the mesh-sheet has a rectangular shape having two essentially straight edges with a first pair of corners defining the leading edge and a second pair of corners defining the rear edge. Each of two surgical threads is secured to the mesh-sheet at one of the first pair of corners.

The rear edge of the mesh-sheet is detachably attached to the roller portion of the apparatus according to the invention, e.g. with surgical threads or by any other means such as adhesive material, and the mesh-sheet is wound around the roller portion before use.

A process of deploying a mesh-sheet using the apparatus according to the present invention comprises the step of insertion of the roller portion of the rod with the mesh-sheet wound there-around into the space through a cannula. The tissue-anchoring stud at the distal end of the roller portion is anchored to the tissues, e.g. by stabbing, to thereby facilitate easy unrolling of the mesh-sheet and for positioning of the rear edge of the mesh-sheet.

The mesh-sheet is placed within the abdominal cavity or inguinal space by pulling the surgical threads of the leading edge towards a pre-determined position within the cavity/space to thereby cover the hernial defect. This is achieved by suitable forceps used for manipulating the needles. The needles provided at the ends of the surgical threads are then used for stitching to the appropriate tissues of the patient, possibly by piercing the tissues of the patient from the abdominal cavity to the outside of the patient. During the stage of pulling the leading edge of the mesh-sheet by the surgical threads, the rod remains stationary and the roller rotates freely

- 6 -

to enable smooth and easy deployment and positioning of the mesh-sheet over the hernial defect.

According to another particular embodiment of the invention, the roller portion of the rod is fixed with respect to the handle portion, where the diameter of the roller portion is small enough to enable a free rotation of the rod within the cannula. Thus when the mesh-sheet is unwound from the rod, the free rotation of the rod facilitates its unwinding.

To conclude the hernia repair, the corners of the mesh-sheet are stitched to the body of the patient, or otherwise attached, e.g. by stapling, etc. and the surgical threads are cut and discarded. The mesh-sheet is then detached from the roller portion of the rod whereby the rod may be removed.

The same apparatus may be utilized also for repair of inguinal or femoral hernias. The method is similar with the obvious required differences resulting in the different anatomical structure. It is however advantageous to provide the free ends of the at least one surgical thread, secured to the leading edge of the mesh-sheet, with a bone anchor.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to better understand the invention and to see how it may be carried out in practice, an embodiment will now be described, by way of a non-limiting example only, with reference to the accompanying drawings, in which:

Fig. 1 shows an apparatus according to an embodiment of the present invention, in an unfolded state;

Fig. 2 shows the apparatus of Fig. 1 with a mesh-sheet partially wound over a rod;

Fig. 3 shows the apparatus ready to be inserted through a cannula;

Fig. 4 is a schematic representation illustrating the abdomen of a patient with a hernia, with several cannulas fitted thereto, as a prior step to carrying out a hernia repair procedure, using an apparatus according to the present invention;

- 7 -

Fig. 5 illustrates deploying a mesh-sheet in a hernia repair operation, using an apparatus according to the present invention;

Fig. 6 illustrates another phase of a hernia repair procedure using the apparatus of the present invention; and

5 **Fig. 7** illustrates a last phase of a hernia repair procedure using the apparatus of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring first to Fig. 1, an apparatus generally designated **10** is illustrated, in the form of a rod comprising a handle portion **20**, and a roller portion **25** 10 coaxially and rotatably connected thereto; the apparatus having a longitudinal axis **L** extending through the rod **20**. According to one particular embodiment, the handle portion **20** and the roller portion **25** are integral and fixedly attached to one another, whilst according to a modification thereof, the roller portion **25** is rotatably attached to the handle portion **20**.

15 A distal end of the roller portion **25** is formed with a pointed end **30**, useful as an anchoring arrangement as will become apparent hereinafter.

A rectangular mesh-sheet **40** made of a bio-compatible material and suited for its purpose, as known *per se*, is detachably attached to the roller portion **25** by two threads **42**. A free or leading edge **44** of the mesh-sheet **40** is defined between 20 two first corners **46**, and a rear edge **48** is defined between two second corners **50**. The leading edge **44** has secured thereto two surgical threads **54** adjacent the two first corners **46**. A free end **56** of each of the two surgical threads **54** is provided with a needle **58**.

The apparatus **10** may be a disposable device made of an inexpensive 25 material, or it may be intended for multiple use where it is made of a material suitable for sterilization thereof and where a fresh mesh-sheet **40** may be attached to the roller portion thereof. Furthermore, the roller portion **25** may be integral with or rotationally fixed to the handle portion **20** (where it is possible to wind and unwind the mesh-sheet), or the roller portion may be rotatable with respect to the handle

- 8 -

portion, in which case, if desirable, an arrangement may be provided for fixing the roller portion to the handle portion.

Fig. 2 shows the apparatus **10** with the mesh-sheet **40** partially wound around the roller portion **25**.

5 Fig. 3 shows the apparatus **10** with the mesh-sheet **40** fully wound around the roller portion **25** with the threads **54** folded over the rolled mesh-sheet and the needles **58** adjacent the mesh-sheet (practically, positioned parallel the edges of the rolled mesh-sheet aligned with the longitudinal axis **L**). In this state, the apparatus is ready to be used in a laparoscopic procedure.

10 With further attention to the remaining figures, it is to be appreciated that whilst reference is made to abdominal hernia (incisional, umbilical, epigastric or Spigelian), the same apparatus and method may be applied for repairing other types of hernia, e.g. inguinal hernia (indirect and direct) as well as femoral hernia, *mutatis mutandis*.

15 Referring now to Fig. 4 of the drawings, an abdomen **60** of a patient is schematically shown with a hernia identified at **62**. In order to perform the hernia repair in a laparoscopic procedure a small localized incision **64** is made in the abdominal wall, through which a first cannula **70** is inserted. A second cannula **72** is inserted through another small, localized incision **66** and is used for introducing
20 pressurized gas for insufflating the abdominal cavity to facilitate the operation. A third cannula **74** is inserted through another small localized incision **68** and is used for introducing optical equipment (not shown) to the abdominal cavity for monitoring the surgery. The locations of the two small localized incisions **66** and **68**, as illustrated in Fig. 4, are merely exemplary and they may be located in a
25 variety of locations, at the surgeon's choice.

Cannulas **72** and **74** are not essential components of the apparatus **10** referred to by the present invention and will thus not be discussed or shown in further detail.

Turning now to Fig. 5, there is illustrated the use of the apparatus **10**
30 according to the present invention in a hernia repair during a laparoscopic

- 9 -

procedure. The apparatus **10** is inserted through the first cannula **70**. The pointed end **30** of the roller portion **25** is stabbed into the flesh of the abdomen at a location designated **80**, giving rise to a stabilized and firm rolling axis extending between that point and a second anchoring point **82** provided by holding the apparatus **10** at the handle portion **20**, extending outside of the cannula **70**. The two needles **58** are then grasped by laparoscopic forceps (not shown) introduced through one of the other cannulas **72** and **74** and directed towards anchoring points **84** and **86**. Whilst pulling the needles **58** the mesh-sheet **40** is unwound from the roller portion **25**. Once the mesh-sheet **40** is deployed and positioned at a pre-determined position over the hernia **62** (Fig. 6), it may be secured in position for example by piercing the abdominal wall at anchoring points **84** and **86** and then tightening and tying the threads **54**. Alternatively, the threads **54** may be tensioned and stitched to the internal wall portions of the abdomen without piercing the abdomen wall.

It is apparent that while pulling the surgical threads **54** by the needles **56**, the apparatus **10** freely rotates within the cannula **70**, to facilitate unwinding of the mesh-sheet **40**.

After initially positioning and fixing the mesh-sheet **40** by stitching, it is then secured by further stitching to the abdominal wall at several locations **90** by a laparoscopic stitching tool (not shown) whereby the mesh-sheet is thus affixed in place. At a further stage, the second corners **50** of the mesh-sheet **40** are detached from the roller portion **25** of the apparatus **10** by detaching/cutting the threads **54**.

At a final stage (Fig. 7), after affixing the mesh-sheet **40** by the stitches **90**, the apparatus **10** is retracted through the cannula **70**, the cannula **70** is then withdrawn through incision **68** which is then stitched.

A person versed in the art can appreciate that the same apparatus is useful also for repair of inguinal or femoral hernia. In such procedures (not illustrated), an apparatus similar to that previously described is introduced through a trocar (cannula) placed either laterally above the anterior superior iliac spine, or medially, above the pubis. The apparatus is introduced such that the roller portion **25** extends above and parallel to the anterior pelvic bone. After manipulating the hernial sac,

- 10 -

the leading edge 44 of the mesh-sheet 40 is pulled to thereby unroll the sheet in front of the lower anterior abdominal wall. When the leading edge 44 of the mesh-sheet 40 reaches the pubic bone the mesh-sheet is positioned over (in front) of the hernial defect.

5 The leading edge 44 is then affixed by attaching the threads 54 to the pelvic bone. This may be carried out, for example, by several anchors fixable to the bone (e.g. in the form of studs, etc.), whereby a thread extends through a hooked portion of the anchor. To prevent unintentional detaching of the thread from such a hooked portion, the thread may be provided with a bulge which will not pass through the
10 hooked portion.

 The rear edge 48 of the mesh-sheet 40 may then be detached from the roller portion of the rod, as described hereinabove in connection with the previous embodiment. The rear edge 48 of the mesh-sheet 40 is then anchored to the upper anterior abdomen wall, whereby it effectively extends over the hernial defect, and
15 then the rod may be removed from site.

 It is noted that the leading edge 44 of the mesh-sheet 40 may be brought down to the vicinity of the pelvic rim in several ways. For example, it may be pulled down along the anterior abdominal wall with the aid of a laparoscopic instrument introduced through one of the trocars. Alternatively, as mentioned
20 hereinabove, anchor members may be anchored to the medial pelvis lower rim, where it is expected that the medial free edge of the mesh-sheet 40 be attached, and then pulling a thread through a ring/hook portion of the anchor and pulling the thread whereby the mesh-sheet is thus pulled over to meet caudally the pelvic rim. By reaching that point, the medial corner of the free edge of the mesh-sheet is
25 anchored to the medial pelvic rim, adjacent the symphysis pubis.

 Whilst some embodiments have been shown and described, it is to be understood that it is not intended thereby to limit the disclosure, but rather it is intended to cover all modifications and arrangements falling within the spirit and the scope of the invention, as defined in the appended claims, *mutatis mutandis*.

CLAIMS:

1. An apparatus for deployment and placement of a mesh-sheet through a cannula utilized in laparoscopic procedures; the apparatus comprising a deploying rod formed with a handle portion and a coaxial roller portion, where said mesh-sheet is wound around the roller portion and comprises a leading edge and a rear edge with at least one surgical thread secured to the leading edge of the mesh-sheet, with a free end of the surgical thread provided with a fixing arrangement.
2. The apparatus according to claim 1, wherein the fixing arrangement is a surgical needle.
3. The apparatus according to claim 1, wherein the roller portion is fixedly attached to the handle portion.
4. The apparatus according to claim 1, wherein the roller portion is rotatably attached to the handle portion.
5. The apparatus according to claim 4, wherein the roller portion may be rotationally fixed with respect to the handle portion.
6. The apparatus according to claim 1, wherein the deploying rod is made of a disposable material.
7. The apparatus according to claim 1, wherein the deploying rod is made of a reusable material suitable for sterilization and where a fresh mesh-sheet may be attached thereto.
8. The apparatus according to claim 1, wherein the leading edge of the mesh-sheet comprises two or more surgical threads.
9. The apparatus according to claim 1, wherein the deploying rod is sized to freely rotate within the cannula when the mesh-sheet is wound on the deploying rod.
10. The apparatus according to claim 1, wherein a distal end of the roller portion is provided with a tissue-anchoring stud.
11. The apparatus according to claim 1, wherein the mesh-sheet is deployed from the roller portion of the deploying rod by pulling the at least one surgical thread.

- 12 -

12. The apparatus according to claim 2, wherein the mesh-sheet is positioned within the abdominal cavity by pulling the surgical threads to a pre-determined location within the abdominal cavity and piercing abdominal tissues by the respective at least one needle.
- 5 13. The apparatus according to claim 1, wherein the deploying rod has a distal end provided with a tissue anchoring stud for anchoring a fore end of the roller portion to tissue.
14. The apparatus according to claim 8, wherein the mesh-sheet has a rectangular shape having a first pair of corners defining the leading edge and a
10 second pair of corners defining the rear edge and wherein each of said two surgical threads is secured to the mesh-sheet at one of said first pair of corners.
15. The apparatus according to claim 1, wherein the fixing arrangement is a bone anchor.
16. The apparatus according to claim 15, wherein the thread is slidable within a
15 hook portion of the bone anchor.
17. A method for hernial repair, comprising the following steps:
- (a) Obtaining an apparatus comprising a deploying rod formed with a handle portion and a coaxial roller portion, where a mesh-sheet is wound around the roller portion and comprises a leading edge and a
20 rear edge with at least one surgical thread secured to the leading edge of the mesh-sheet, with a free end of the surgical thread provided with a fixing arrangement;
- (b) Introducing said deploying rod with the mesh-sheet into the hernial cavity through a guiding trocar;
- 25 (c) Deploying the mesh-sheet from the roller portion of the deploying rod by pulling the at least one surgical thread by laparoscopic forceps;
- (d) Positioning the mesh-sheet to a location over the hernial defect;
- (e) Affixing the leading edge of the mesh-sheet to tissue layers;
- (f) Detaching the rear edge of the mesh-sheet from the roller portion of
30 the deploying rod; and

– 13 –

(g) Affixing the rear edge and other locations of the mesh-sheet to tissue layers;

18. The method according to claim 17, wherein the deploying rod is removed at any time after step (e).
- 5 19. The method according to claim 17, wherein a fore end of the deploying rod is formed with an anchoring stab and wherein after step (b) the anchoring stab is stabbed into tissue layer.
20. The method according to claim 17, wherein the fixing arrangement is a surgical needle.
- 10 21. The method according to claim 20, wherein step (e), is carried out by piercing the abdominal wall tissues and then pulling and tensioning the surgical threads outside the body.
22. The method according to claim 20, wherein corners of the mesh-sheet are stitched to the body of the patient and the surgical threads are cut and discarded.
- 15 23. The method according to claim 20, wherein corners of the mesh-sheet are stitched to the body of the patient and the surgical threads are cut and discarded.
24. The method according to claim 17, for repairing abdominal hernia defects.
25. The method according to claim 17, wherein the fixing arrangement is a bone anchor.
- 20 26. A method according to claim 17, for repairing inguinal or femoral hernia defects.

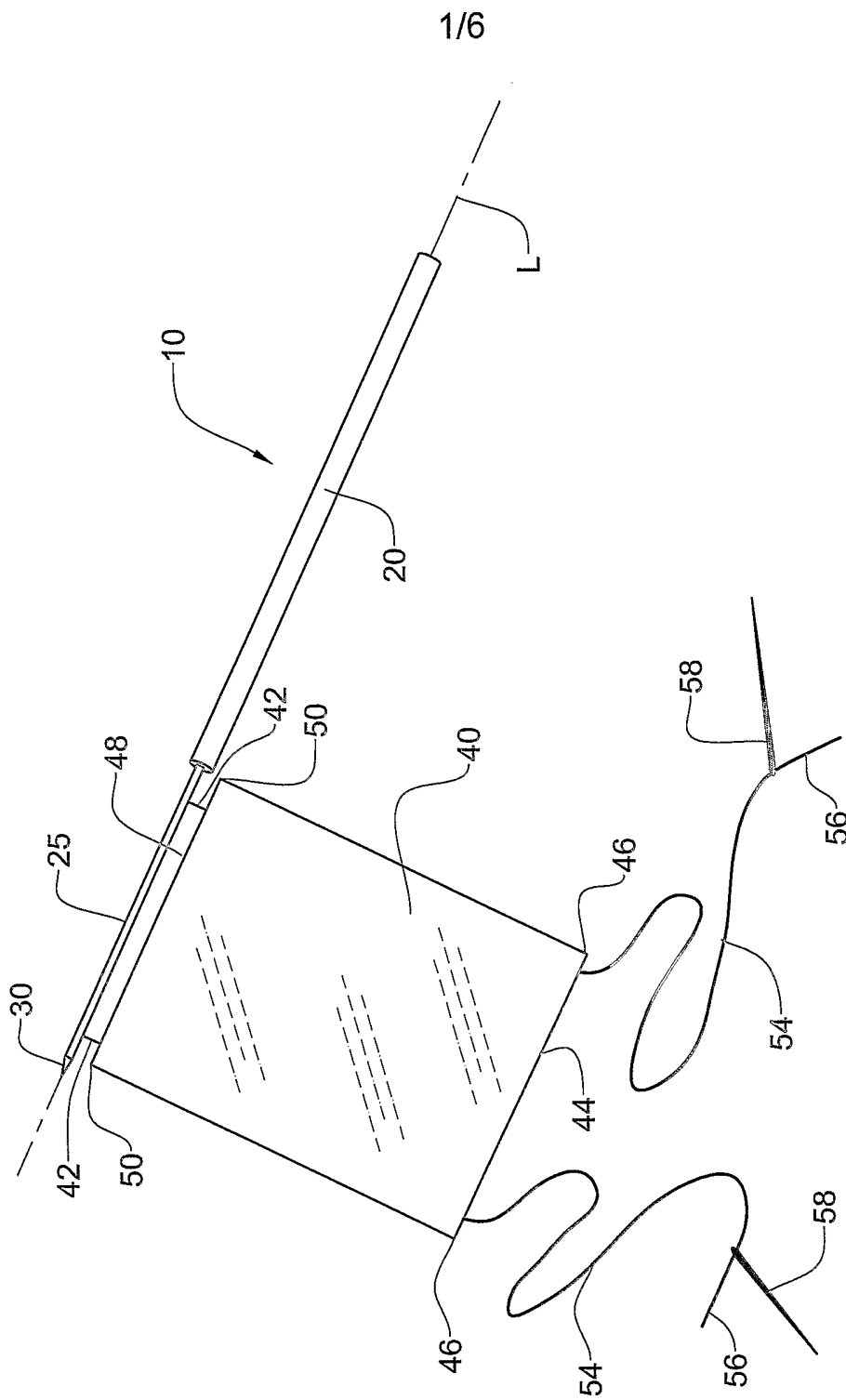


FIG. 1

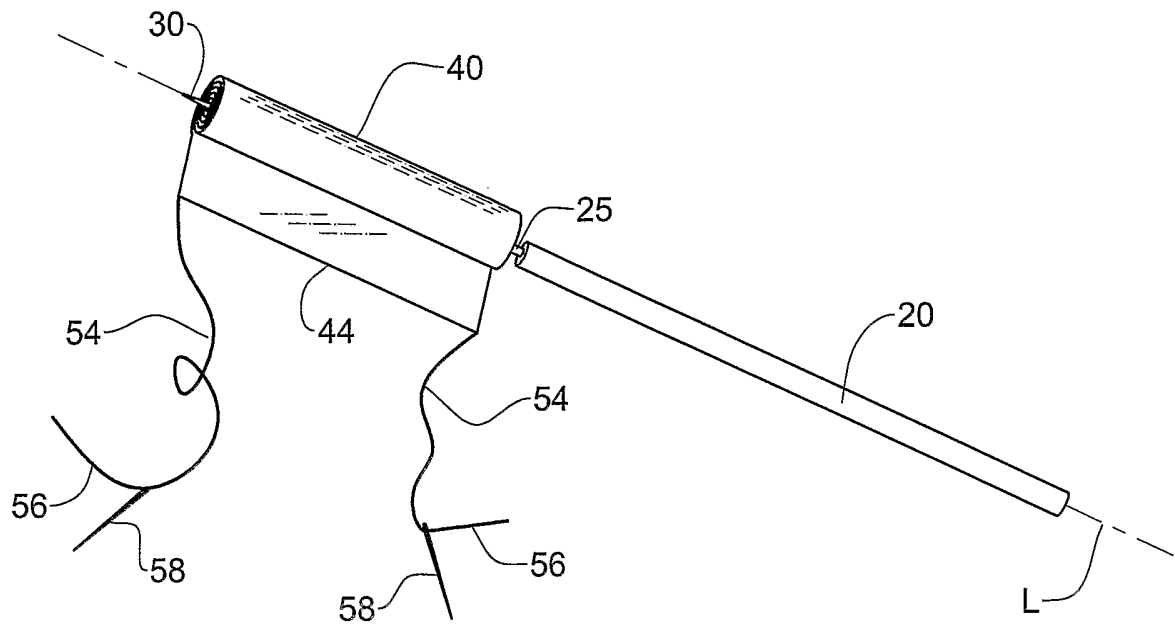


FIG. 2

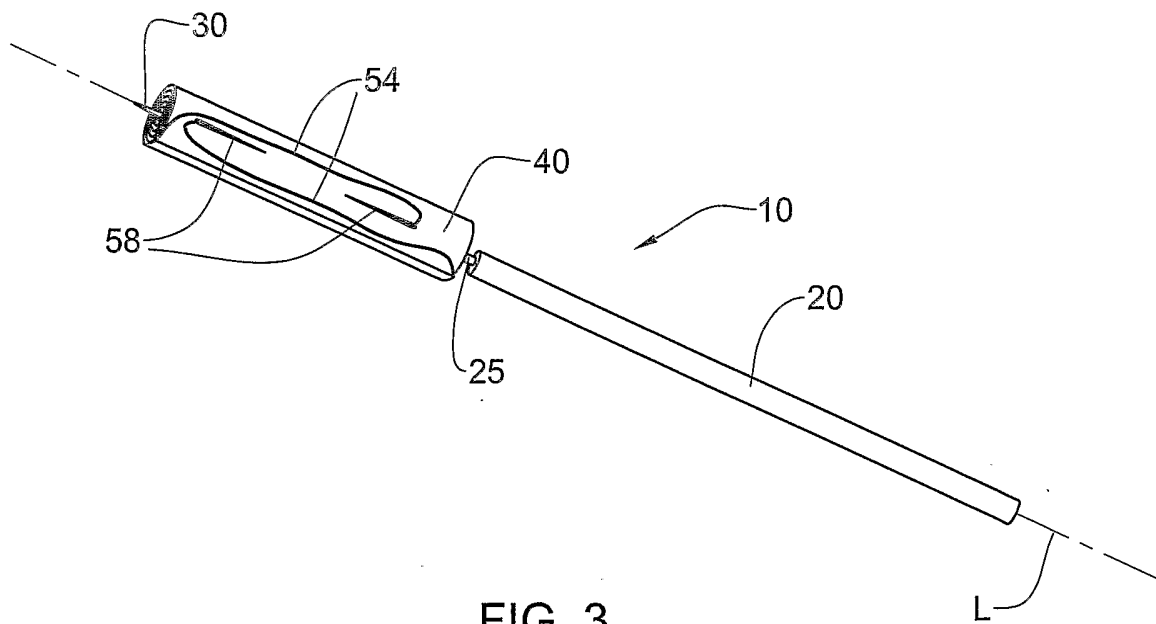


FIG. 3

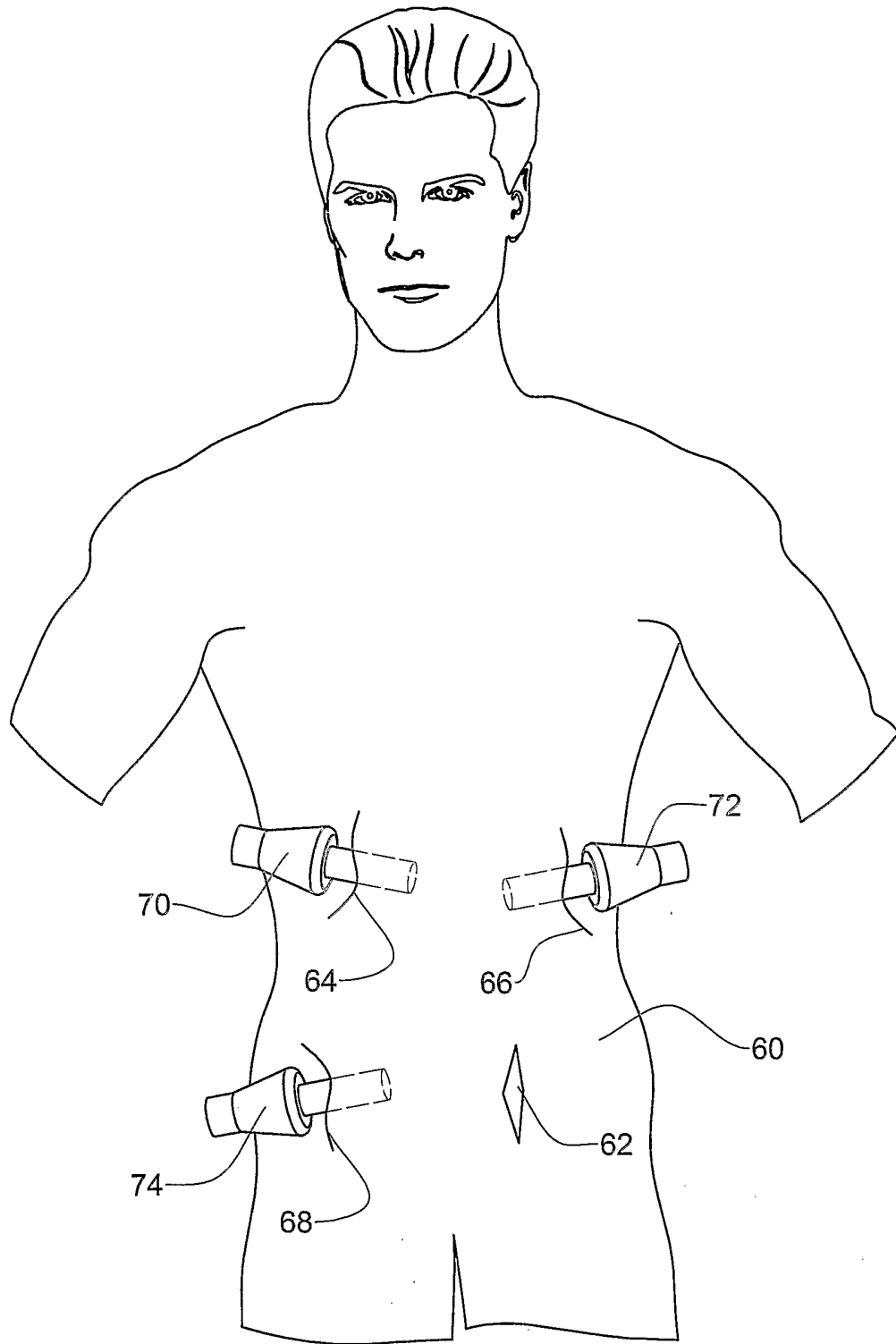


FIG. 4

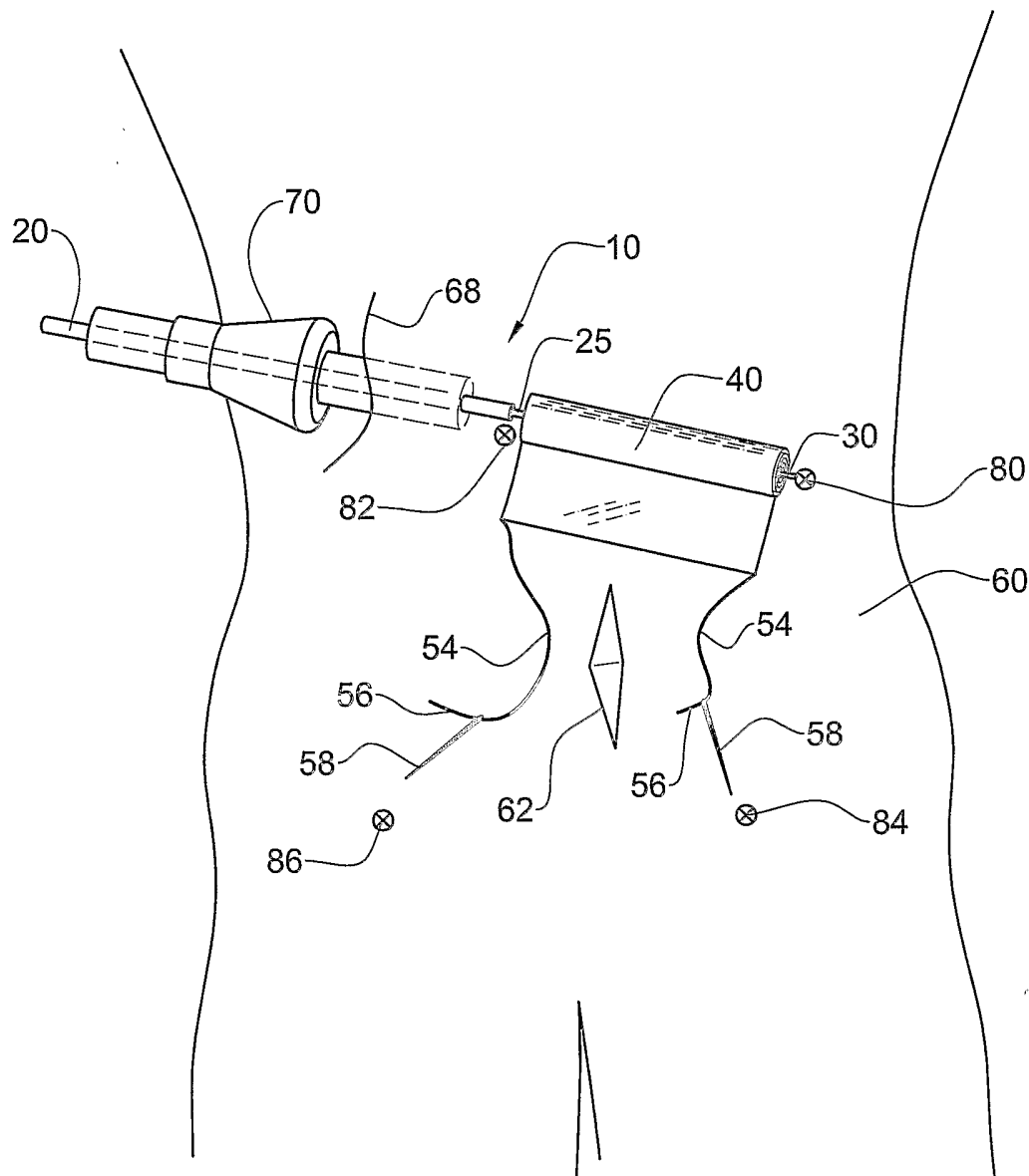


FIG. 5

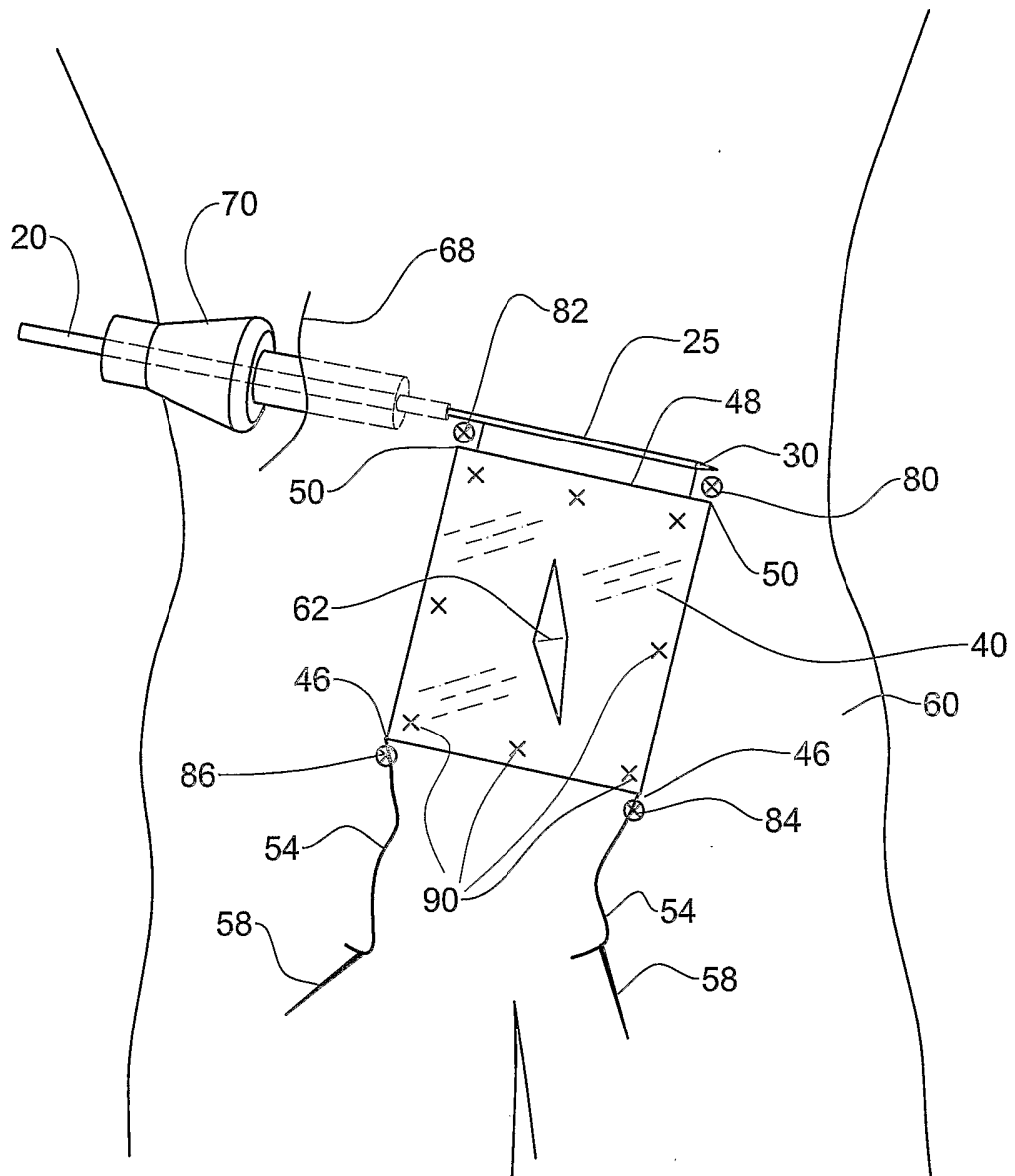


FIG. 6

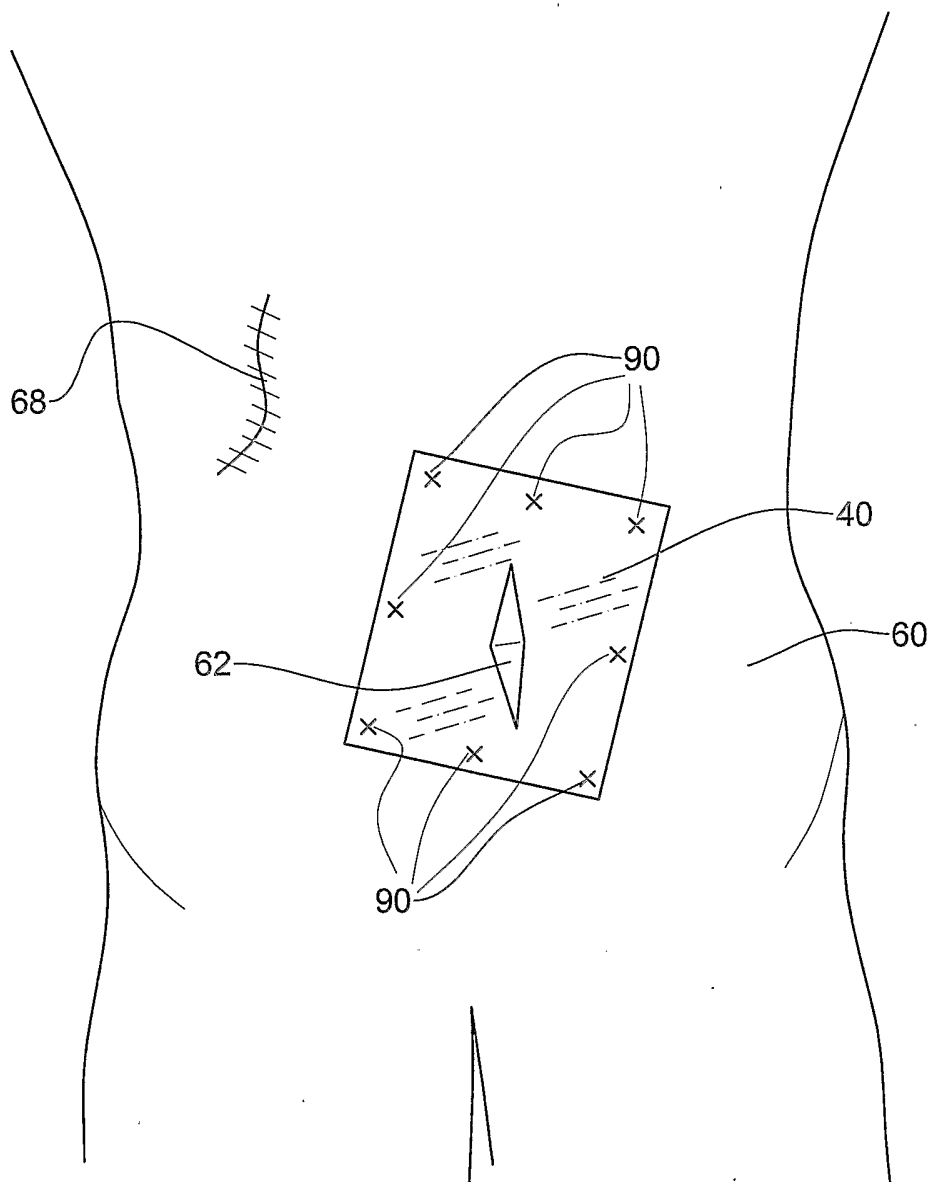


FIG. 7

INTERNATIONAL SEARCH REPORT

International Application No
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A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61F2/00 A61B17/00				
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) IPC 7 A61F A61B				
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.		
X	US 5 304 187 A (GREEN DAVID T ET AL) 19 April 1994 (1994-04-19) cited in the application column 4, line 14 - line 41; figures	1,3-5,9, 10		
A	---	13		
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-/--				
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex.				
° Special categories of cited documents :				
<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none; vertical-align: top;"> *A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed </td> <td style="width: 50%; border: none; vertical-align: top;"> *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. *&* document member of the same patent family </td> </tr> </table>			*A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. *&* document member of the same patent family
A document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. *&* document member of the same patent family			
Date of the actual completion of the international search		Date of mailing of the international search report		
24 June 2004		01/07/2004		
Name and mailing address of the ISA		Authorized officer		
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Neumann, E		

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IL2004/000212

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 010 447 A (KARDJIAN PAUL M) 4 January 2000 (2000-01-04) figures ---	1,8,11, 14
A	WO 95/30374 A (ORIGIN MEDSYSTEMS INC) 16 November 1995 (1995-11-16) page 6, line 39 -page 7, line 30; figure 6 -----	1,8,13, 14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2004/000212

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 17-26
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IL2004/000212

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