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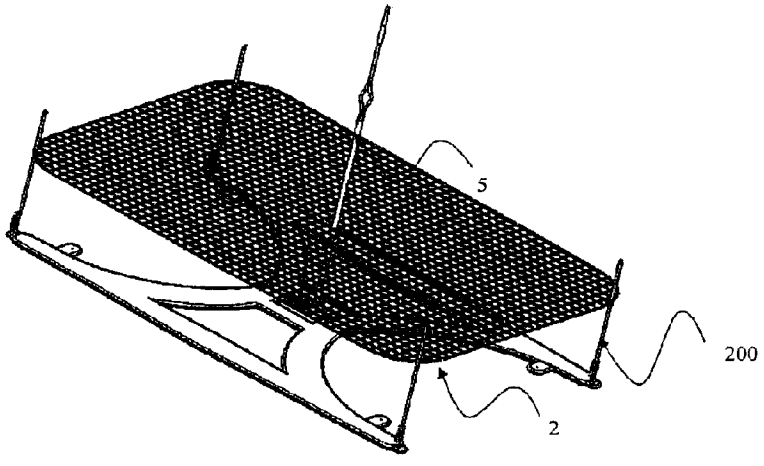
(54) Titre : MOYENS DE FIXATION ENTRE UNE MAILLE ET DES MOYENS DE DEPLOIEMENT D'UNE MAILLE, UTILES NOTAMMENT POUR LES CHIRURGIES DE REPARATION DES HERNIES ET PROCEDES ASSOCIES

(54) Title: FIXATING MEANS BETWEEN A MESH AND MESH DEPLOYMENT MEANS ESPECIALLY USEFUL FOR HERNIA REPAIR SURGERIES AND METHODS THEREOF



(57) Abrégé/Abstract:
The present invention provides a fixating means adapted for use in hernia repair surgeries in attaching a mesh and mesh deployment means; said fixating means are attached to said mesh deployment means; said fixating means comprising: (a) a first portion coupled to said deployment means; and, (b) a second portion, comprising a coil having a predetermined retracted shape; said coil is reconfigurable from a plurality of unretracted positions to a plurality of retracted positions and from said plurality of retracted positions to said plurality of unretracted positions; wherein said attachment between said deployment means and said mesh is obtained by reconfiguration of said coil from at least one of said unretracted positions to at least one of said retracted positions.

ABSTRACT

The present invention provides a fixating means adapted for use in hernia repair surgeries in attaching a mesh and mesh deployment means; said fixating means are attached to said mesh deployment means; said fixating means comprising: (a) a first portion coupled to said deployment means; and, (b) a second portion, comprising a coil having a predetermined retracted shape; said coil is reconfigurable from a plurality of unretracted positions to a plurality of retracted positions and from said plurality of retracted positions to said plurality of unretracted positions; wherein said attachment between said deployment means and said mesh is obtained by reconfiguration of said coil from at least one of said unretracted positions to at least one of said retracted positions.

FIXATING MEANS BETWEEN A MESH AND MESH DEPLOYMENT MEANS ESPECIALLY USEFUL FOR HERNIA REPAIR SURGERIES AND METHODS THEREOF

This is a divisional Canadian Patent Application Serial No. 2,925,611 filed on March 30, 2016, which is a divisional of Canadian National Phase Patent Application Serial No. 2,702,882 filed on October 22, 2008.

FIELD OF THE INVENTION

This invention generally relates to fixating means between a hernia repair mesh and a mesh deployment means used to deploy the mesh, especially useful for hernia repair surgery.

BACKGROUND

[01] This invention generally relates to an inflatable balloon and/or other mesh deployment means, especially useful for hernia repair surgery.

Modern surgical techniques are intended to be minimally invasive. Endoscopic surgery is a prime example of this minimally invasive approach and has led to the development of various instruments that may be inserted through a small incision to operate internally. Minimally invasive procedures are also commonly employed in the treatment of hernia (inguinal, femoral, hiatal, ventral, incisional and umbilical hernias).

Hernia is a common medical condition in which an organ protrudes through an opening in its surrounding tissue (especially in the abdominal region). The hernia is sometimes treated in a tension free repair, such as implementation of meshes/patches. In carrying out laparoscopic ventral or incisional or umbilical or inguinal hernia procedures, the surgeon usually rolls the patch/mesh and then inserts it into a trocar sleeve or its opening and delivers it into the abdominal or pre-peritoneal cavity. A laparoscopic forceps is then used to unfurl the mesh/patch and place it posterior to the hernia defect completely covering it with a sufficient overlap. The mesh/patch may then be held in place by stapling or suturing it to underlying tissue.

One of the major problems of the above procedure is the unrolling or spreading and the positioning or deploying of the mesh inside the abdominal or the pre-peritoneal cavity. The step of unrolling the mesh, directing the right side of the mesh and its orientation, positioning

and fixating the mesh and positioning it in the right place and orienting it to the right direction, usually adds significantly to the time required for carrying out the procedure.

US patent no. 5,824,082 ('082)relates to a prosthetic hernia repair patch that can be rolled into a tube for laparoscopic delivery through a trocar and which deploys to a generally planar form when ejected from the trocar into the abdominal cavity. The deployment of the prosthetic is done by embedding a wire frame made of shape memory alloys into the prosthetic. When the prosthetic is inserted into the body it is heated thus, activated - i.e. it springs into its functional, predetermined configuration and deploys the patch. However, embedding a wire frame in a prosthetic is complicated.

Another approach to the problem of folds in a deployed mesh was to attach it to an inflatable balloon which, after inflation, expands and spreads the mesh. Such a device was disclosed in PCT publication no. WO08/065653. It was found that the fixation of the mesh to the inflatable balloon is of utmost importance, since a method of connecting and disconnecting should be stand specific standards. It should not only allow a rapid fixation, but also, if necessary, rapid disconnection. The user should be able to perform the fixation and the disconnection not only outside the body, but also in a narrow abdominal cavity, during an open and even a laparoscopic procedure. Despite the required detachment abilities, the fixation should be strong as long as it is required, so that the mesh, deployed under laparoscopic measures, won't detach or fold in the abdominal cavity. The fixation should not harm the inflatable balloon or the mesh, and should allow the fixation of different sizes of meshes to different sizes of balloons, so as not to limit the options.

SUMMARY OF THE INVENTION

[02] Some embodiments of the present invention provide a hernia kit useful in minimal invasive and/or open surgery, comprising:

a. a mesh;

b. at least one deployment means, adapted to deploy said mesh within the abdominal cavity and/or pre-peritoneal and/or hollow body organs and/or natural and/or artificial orifices and/or spaces and/or post operative spaces; and,

c. fixating means coupled to said deployment means, adapted to attach said deployment means to said mesh; said fixating means are characterized by at least two portions:

i. a first portion coupled to said deployment means; and,

ii. a second portion, comprising a coil having a predetermined retracted shape; said coil is reconfigurable from a plurality of unretracted positions to a plurality of retracted positions and from said plurality of retracted positions to said plurality of unretracted positions;

wherein said attachment between said deployment means and said mesh is obtained by reconfiguration of said coil from at least one of said unretracted positions to at least one of said retracted positions.

Some embodiments of the present invention provide the hernia kit as defined above, wherein said deployment means is an inflatable balloon.

Some embodiments of the present invention provide the hernia kit as defined above, wherein said fixating means additionally comprising means reversibly coupled to said second portion, adapted to thread said second portion through said mesh.

Some embodiments of the present invention provide the hernia kit as defined above, wherein said fixating means additionally comprising a third portion having at least one sharpened element, adapted to fully penetrate said mesh.

Some embodiments of the present invention provide the hernia kit as defined above, wherein said fixating means are coupled to said deployment means by means selected from a group consisting of glue, Velcro, mechanical connections selected from a group consisting of a disc or a knot, welding means, threading means or any combination thereof.

Some embodiments of the present invention provide the hernia kit as defined above, wherein said unretracted position is at least partially linear configuration.

Some embodiments of the present invention provide the hernia kit as defined above, wherein said coil is made of materials selected from a group consisting of nylon, shape memory materials, Thermoplastic materials, Polyurethane, EAP, biodegradable materials or any combination thereof.

Some embodiments of the present invention provide the hernia kit as defined above, wherein said deployment means is made of materials selected from a group consisting of nylon, shape memory materials, Thermoplastic materials, Polyurethane, EAP, biodegradable materials, stainless steel, other metals, plastic or any combination thereof.

Some embodiments of the present invention provide the hernia kit as defined above, wherein said coil is a coaxial structure, comprising at least partially a helical and/or spiral shape, such that said structure can be unretracted to a more linear shape and retracted back to at least partially a helical and/or spiral shape.

Some embodiments of the present invention provide the hernia kit as defined above, wherein said coil is a coaxial structure, comprising an outer cannula with a longitudinal slit and an inner thread, such that said cannula collapses into a helical configuration after said inner thread is pulled out.

Some embodiments of the present invention provide the hernia kit as defined above, wherein said coil is reconfigurable from a retracted position to an unretracted position by means selected from a group consisting of mechanically pulling or pushing said coil, applying electrical current on said coil, thermoregulating said coil, applying magnetic field.

Some embodiments of the present invention provide the hernia kit as defined above, wherein said coil is spontaneously reconfigurable from a retracted position to an unretracted position.

Some embodiments of the present invention provide the hernia kit as defined above, wherein said coil has at least one coiling radius.

Some embodiments of the present invention provide the hernia kit as defined above, wherein said sharpened element is selected from a group consisting of a stylet or a needle.

Some embodiments of the present invention provide the hernia kit as defined above, wherein said deployment means additionally comprises at least one appendage to which said first portion of said fixating means is coupled.

Some embodiments of the present invention provide the hernia kit as defined above, wherein said first portion of said fixating means is coupled to various locations on said deployment means, thus accommodating a variety of mesh sizes.

Some embodiments of the present invention provide the hernia kit as defined above, wherein said deployment means is in communication with inflating means adapted to inflate said deployment means.

Some embodiments of the present invention provide the hernia kit as defined above, wherein the shape of said deployment means is selected from a group comprising a polygonal shape, a curved shape, a symmetrical, a non-symmetrical shape, a linear shape, continuous, non-continuous, a concave shape, a irregular shape, a square-like shape, a rectangular shape, an oval shape, a U-like shape, an H-like shape, a grid-like shape, a flat structure, a 3D structure and a rake-like shape or any combination thereof.

Some embodiments of the present invention to provide the hernia kit as defined above, wherein said deployment means additionally comprises centering means adapted to adjust the center of said deployment means and said mesh to the center of said hernia.

Some embodiments of the present invention provide the hernia kit as defined above, wherein said deployment means additionally comprises means adapted to ensure the right side of said mesh is directed to said hernia.

Some embodiments of the present invention provide the hernia kit as defined above, wherein said deployment means additionally comprises means adapted to ensure the right direction of said mesh in the abdominal cavity.

Some embodiments of the present invention provide the hernia kit as defined above, wherein said centering means additionally comprises means adapted to thread said centering means through said mesh.

Some embodiments of the present invention provide the hernia kit as defined above, wherein said deployment means additionally comprises at least one clip adapted to grab sutures.

Some embodiments of the present invention provide the hernia kit as defined above, wherein said centering means additionally comprises means adapted to enable the grasp of said centering means with a surgical tool.

Some embodiments of the present invention provide a method for attaching a mesh to deployment means, comprising steps selected inter alia from:

a. obtaining a hernia kit comprising:

i. a mesh;

ii. at least one deployment means, adapted to deploy said mesh with in the abdominal cavity and/or pre-peritoneal and/or hollow body organs and/or natural and/or artificial orifices and/or spaces and/or post operative spaces; and,

iii. fixating means coupled to said deployment means, adapted to attach said deployment means to said mesh;

said fixating means are characterized by:

I. a proximal portion coupled to said deployment means;

II. a middle portion, comprising a coil having a predetermined retracted shape; said coil is reconfigurable from a plurality of unretracted positions to a plurality of retracted positions and from said plurality of retracted positions to said plurality of unretracted positions; and,

III. a distal portion comprising at least one sharpened element, adapted to fully penetrate said mesh;

b. threading said sharpened element through said mesh;

c. reconfiguring said coil from said retracted position to an unretracted position; thereby at least partially passing said coil through said mesh; and,

d. reconfiguring said coil from said unretracted position to said retracted position thereby attaching said mesh to said deployment means.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of selecting said deployment means from a group consisting of inflatable balloon.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of cutting said distal portion of said fixating means, thereby removing said sharpened element.

Some embodiments of the present invention provide the method as defined above, additionally comprising steps of (a) adjusting said mesh attached to said deployment means; and, (b) inserting said adjusted deployment means attached to said mesh into the abdominal cavity and/or pre-peritoneal and/or hollow body organs and/or natural and/or artificial orifices and/or spaces and/or post operative spaces.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of spreading and/or deploying said mesh.

Some embodiments of the present invention provide the method as defined above, wherein said step of spreading and/or deploying said mesh additionally comprising a step of inflating at least a portion of said deployment means or actuating at least a part of the deployment means.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of coupling said fixating means to said deployment means by means selected from a group consisting of glue, Velcro, mechanical connections selected from a group consisting of a disc or a knot, welding means, threading or any combination thereof.

Some embodiments of the present invention provide the method as defined above, wherein said step (c) of reconfiguring said coil from said retracted position to an unretracted position additionally comprises a step of mechanically pulling said coil.

Some embodiments of the present invention provide the method as defined above, wherein said step (d) of reconfiguring said coil unretracted position to said retracted position additionally comprises a step of releasing said mechanical stress.

Some embodiments of the present invention provide the method as defined above, wherein said step (c) or said step (d) of reconfiguring said coil is performed by means selected from a group consisting of application of electrical current on said coil, thermoregulating said coil, application of magnetic field on said coil.

Some embodiments of the present invention provide the method as defined above, wherein said step (d) of reconfiguring said coil unretracted position to said retracted position is performed spontaneously.

Some embodiments of the present invention provide the method as defined above, wherein said step of step (c) of reconfiguring said coil from said retracted position to an unretracted position additionally comprises a step of transforming said coil to a more linear configuration.

Some embodiments of the present invention provide the method as defined above, wherein said step (d) of reconfiguring said coil unretracted position to said retracted position additionally comprises a step of transforming said coil to at least partially a helical and/or spiral configuration.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of selecting said coil to have more than one coiling radius.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of selecting said sharpened element from a group consisting of a stylet or a needle.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of coupling said proximal portion of said fixating means to appendages on said deployment means.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of coupling said proximal portion of said fixating means to various locations on said deployment means, thus accommodating a variety of mesh sizes.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of extracting said deployment means from said abdominal cavity and/or pre-peritoneal and/or hollow body organs and/or natural and/or artificial orifices and/or spaces and/or post operative spaces.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of deflating or minimizing said deployment means.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of continuing inflating or preserving the shape of said deployment means according to a predetermined medical need.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of fitting the center of said deployment means to the center of said hernia.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of threading centering means through said mesh.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of ensuring the right side of said mesh is directed to said hernia.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of ensuring the right direction of said mesh in the abdominal cavity.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of selecting the shape of said deployment means from a group comprising a polygonal shape, a curved shape, a symmetrical, a non-symmetrical shape, a linear shape, continuous, non-continuous, a concave shape, a irregular shape, a square-like shape, a rectangular shape, an oval shape, a U-like shape, an H-like shape, a grid-like shape, a flat structure, a 3D structure and a rake-like shape or any combination thereof.

Some embodiments of the present invention provide a method for attaching a mesh to deployment means, comprising steps selected inter alia from:

a. obtaining a hernia kit comprising:

i. a mesh;

ii. at least one deployment means, adapted to deploy said mesh within the abdominal cavity and/or pre-peritoneal and/or hollow body organs and/or natural and/or artificial orifices and/or spaces and/or post operative spaces; and,

iii. fixating means coupled to said deployment means, adapted to attach said deployment means to said mesh;

said fixating means are characterized by at least two portions:

I. a first portion coupled to said deployment means;

II. a second portion, comprising a coil having a predetermined retracted shape; said coil is reconfigurable from a plurality of unretracted positions to a plurality of retracted positions and from said plurality of retracted positions to said plurality of unretracted positions;

b. obtaining attaching means adapted to thread said second portion through said mesh;

c. reversibly coupling said attaching means to said second portion;

d. threading said second portion through said mesh via said attaching means;

e. reconfiguring said coil from said retracted position to an unretracted position; thereby at least partially passing said coil through said mesh; and,

f. reconfiguring said coil from said unretracted position to said retracted position thereby attaching said mesh to said deployment means.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of selecting said deployment means from a group consisting of inflatable balloon.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of uncoupling said attaching means from said second portion.

Some embodiments of the present invention provide the method as defined above, additionally comprising steps of (a) adjusting said mesh attached to said deployment means; and, (b) inserting said adjusted deployment means attached to said mesh into the abdominal cavity and/or pre-peritoneal and/or hollow body organs and/or natural and/or artificial orifices and/or spaces and/or post operative spaces.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of spreading and/or deploying said mesh.

Some embodiments of the present invention provide the method as defined above, wherein said step of spreading and/or deploying said mesh additionally comprising step of inflating or actuating said deployment means.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of coupling said fixating means to said deployment means by means selected from a group consisting of glue, Velcro, mechanical connections selected from a group consisting of a disc or a knot, welding means, threading or any combination thereof.

Some embodiments of the present invention provide the method as defined above, wherein said step (e) of reconfiguring said coil from said retracted position to an unretracted position additionally comprises a step of mechanically pulling said coil.

Some embodiments of the present invention provide the method as defined above, wherein said step (f) of reconfiguring said coil unretracted position to said retracted position additionally comprises a step of releasing said mechanical stress.

Some embodiments of the present invention provide the method as defined above, wherein said step (e) or said step (f) of reconfiguring said coil is performed by means selected from a group consisting of application of electrical current on said coil, thermoregulating said coil, application of magnetic field on said coil.

Some embodiments of the present invention provide the method as defined above, wherein said step (f) of reconfiguring said coil unretracted position to said retracted position is performed spontaneously.

Some embodiments of the present invention provide the method as defined above, wherein said step (e) of reconfiguring said coil from said retracted position to an unretracted position additionally comprises a step of transforming said coil to a more linear configuration.

Some embodiments of the present invention provide the method as defined above, wherein said step (f) of reconfiguring said coil unretracted position to said retracted position additionally comprises a step of transforming said coil to at least partially a helical and/or spiral configuration.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of selecting said coil to have more than one coiling radius.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of selecting said attaching means from sharpened element selected from a group consisting of a stylet or a needle.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of coupling said first portion of said fixating means to appendages on said deployment means.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of coupling said first portion of said fixating means to various locations on said deployment means, thus accommodating a variety of mesh sizes.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of extracting said deployment means from said hernia.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of deflating or minimizing said deployment means.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of continuing inflating or preserving the shape of said deployment means according to a predetermined medical need.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of fitting the center of said deployment means to the center of said hernia.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of threading centering means through said mesh.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of ensuring the right side of said mesh is directed to said hernia.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of ensuring the right direction of said mesh in the abdominal cavity.

Some embodiments of the present invention provide the method as defined above, additionally comprising a step of selecting the shape of said deployment means from a group comprising a polygonal shape, a curved shape, a symmetrical, a non-symmetrical shape, a linear shape, continuous, non-continuous, a concave shape, a irregular shape, a square-like shape, a rectangular shape, an oval shape, a U-like shape, an H-like shape, a grid-like shape, a flat structure, a 3D structure and a rake-like shape or any combination thereof.

Some embodiments of the present invention provide a fixating means adapted for use in hernia repair surgeries in attaching a mesh and mesh deployment means; said fixating means are attached to said mesh deployment means; said fixating means comprising:

a. a first portion coupled to said deployment means; and,

b. a second portion, comprising a coil having a predetermined retracted shape; said coil is reconfigurable from a plurality of unretracted positions to a plurality of retracted positions and from said plurality of retracted positions to said plurality of unretracted positions;

wherein said attachment between said deployment means and said mesh is obtained by reconfiguration of said coil from at least one of said unretracted positions to at least one of said retracted positions.

Some embodiments of the present invention provide the fixating means as defined above, wherein said deployment means is an inflatable balloon.

Some embodiments of the present invention provide the fixating means as defined above, wherein said fixating means additionally comprises means reversibly coupled to said second portion, adapted to thread said second portion through said mesh.

Some embodiments of the present invention provide the fixating means as defined above, wherein said fixating means additionally comprise a third portion having at least one sharpened element, adapted to fully penetrate said mesh.

Some embodiments of the present invention provide the fixating means as defined above, wherein said retracted position is at least partially helical and/or spiral configuration.

Some embodiments of the present invention provide the fixating means as defined above, wherein said fixating means are coupled to said deployment means by means selected from a group consisting of glue, Velcro, mechanical connections selected from a group consisting of a disc or a knot, welding means, threading means or any combination thereof.

Some embodiments of the present invention provide the fixating means as defined above, wherein said unretracted position is at least partially linear configuration.

Some embodiments of the present invention provide the fixating means as defined above, wherein said coil is made of materials selected from a group consisting of nylon, shape memory materials, Thermoplastic materials, Polyurethane, EAP, biodegradable materials or any combination thereof.

Some embodiments of the present invention provide the fixating means as defined above, wherein said deployment means is made of materials selected from a group consisting of nylon, shape memory materials, Thermoplastic materials, Polyurethane, EAP, biodegradable materials, stainless steel, other metals, plastic or any combination thereof.

Some embodiments of the present invention provide the fixating means as defined above, wherein said coil is a coaxial structure, comprising an outer cannula with a longitudinal slit and an inner thread, such that said cannula collapses into a helical configuration after said inner thread is pulled out.

Some embodiments of the present invention provide the fixating means as defined above, wherein said coil is reconfigurable from a retracted position to an unretracted position by

means selected from a group consisting of mechanically pulling or pushing said coil, applying electrical current on said coil, thermoregulating said coil, applying magnetic field.

Some embodiments of the present invention provide the fixating means as defined above, wherein said coil is spontaneously reconfigurable from a retracted position to an unretracted position.

Some embodiments of the present invention provide the fixating means as defined above, wherein said coil has at least one coiling radius.

Some embodiments of the present invention provide the fixating means as defined above, wherein said sharpened element is selected from a group consisting of a stylet or a needle.

Some embodiments of the present invention provide the fixating means as defined above, wherein said deployment means additionally comprise at least one appendage to which said first portion of said fixating means is coupled.

Some embodiments of the present invention provide the fixating means as defined above, wherein said first portion of said fixating means is coupled to various locations on said deployment means, thus accommodating a variety of mesh sizes.

Some embodiments of the present invention provide the fixating means as defined above, wherein said deployment means is in communication with inflating means adapted to inflate said deployment means.

Some embodiments of the present invention provide the fixating means as defined above, wherein the shape of said deployment means is selected from a group comprising a polygonal shape, a curved shape, a symmetrical, a non-symmetrical shape, a linear shape, continuous, non-continuous, a concave shape, a irregular shape, a square-like shape, a rectangular shape, an oval shape, a U-like shape, an H-like shape, a grid-like shape, a flat structure, a 3D structure and a rake-like shape or any combination thereof.

Some embodiments of the present invention provide the fixating means as defined above, wherein said deployment means additionally comprise centering means adapted to adjust the center of said deployment means and said mesh to the center of said hernia.

Some embodiments of the present invention provide the fixating means as defined above, wherein said deployment means additionally comprise means adapted to ensure the right side of said mesh is directed to said hernia.

Some embodiments of the present invention provide the fixating means as defined above, wherein said deployment means additionally comprise means adapted to ensure the right direction of said mesh in the abdominal cavity.

Some embodiments of the present invention provide the fixating means as defined above, wherein said centering means additionally comprise means adapted to thread said centering means through said mesh.

Some embodiments of the present invention provide the fixating means as defined above, wherein said deployment means additionally comprise at least one clip adapted to grab sutures.

Some embodiments of the present invention provide the fixating means as defined above, wherein said centering means additionally comprise means adapted to enable the grasp of said centering means with a surgical tool.

According to an aspect of the present invention, there is provided a hernia repair system, comprising: a deployment device adapted to deploy a hernia repair patch within a body of a patient, wherein the deployment device has a reduced configuration for delivering the hernia repair patch to a placement site within the patient and an expanded configuration for deploying the hernia repair patch; and a fixating component extending from said deployment device, said fixating component having an unretracted configuration adapted for at least one of attaching or detaching the hernia repair patch to said deployment device and a retracted configuration adapted to retain the hernia repair patch to said deployment device, wherein said fixating component is adapted to pass through the hernia repair patch in the unretracted

configuration and to remain passed through the hernia repair patch in the retracted configuration to attach the hernia repair patch to said deployment device.

According to another aspect of the present invention, there is provided a method of attaching a hernia repair patch to a deployment device, the method comprising acts of: configuring a fixating component, having a retracted configuration and an unretracted configuration, to the unretracted configuration, the fixating component extending from a deployment device; and associating the unretracted fixating component with a hernia repair patch, wherein associating the unretracted fixating component with the hernia repair patch includes passing the unretracted fixating component through the hernia repair patch.

According to another aspect of the present invention, there is provided a hernia repair system, comprising: a deployment device adapted to deploy a hernia repair patch within a body of a patient, wherein the deployment device has a reduced configuration for delivering the hernia repair patch to a placement site within the patient and an expanded configuration for deploying the hernia repair patch; a fixating component extending from the deployment device, the fixating component having an unretracted configuration adapted for at least one of attaching or detaching the hernia repair patch to the deployment device and a retracted configuration adapted to maintain attachment between the hernia repair patch and the deployment device; and a centering component extending from the deployment device adapted to position the deployment device relative to a hernia, the centering component adapted for insertion through the hernia repair patch.

According to another aspect of the present invention, there is provided a hernia repair system, comprising: a deployment device adapted to deploy a hernia repair patch within a body of a patient, wherein the deployment device has a reduced configuration for delivering the hernia repair patch to a placement site within the patient and an expanded configuration for deploying the hernia repair patch; and a fixating component extending from the deployment device, the fixating component having an unretracted configuration adapted for at least one of attaching or detaching the hernia repair patch to the deployment device and a retracted configuration adapted to maintain attachment between the hernia repair patch and the

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deployment device, the fixating component including a sharp end adapted for insertion through the hernia repair patch.

According to another aspect of the present invention, there is provided a device for delivering a soft tissue repair prosthetic, comprising: a deployment device adapted to deploy a hernia repair patch within a body of a patient, wherein the deployment device has a reduced configuration for delivering the hernia repair patch to a placement site within the patient and an expanded configuration for deploying the hernia repair patch, the deployment device comprising a first outer expandable segment, a second outer expandable segment and an intermediate expandable segment extending between the first outer expandable segment and the second outer expandable segment, wherein a first through-hole opening is at least partially defined by the first outer expandable segment, and a second through-hole opening is at least partially defined by the second outer expandable segment, the first and second through-hole openings being separate and distinct from one another and being different sizes, and wherein the first outer expandable segment, the second outer expandable segment and the intermediate expandable segment are arranged such that, when the deployment device is fully expanded, a line can intersect the first, second and outer expandable segments simultaneously.

BRIEF DESCRIPTION OF THE DRAWINGS

Figs. 1A-1C schematically illustrate one embodiment of deployment means and mesh for treating abdominal hernia.

[03] **Figs. 2A-2C** schematically illustrates appendages of the deployment means and the preferred embodiment of a fixating means.

[04] **Figs. 3A-3F** schematically represent a method of fixating the mesh to the deployment means using the preferred embodiment of a fixating means.

[05] **Figs. 4A- 4B** schematically represent the adjustment of the preferred embodiment of a fixating means to different size of a mesh.

[06] **Figs. 5A- 5L** schematically represent other embodiments of the coil part of the fixating means.

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Figs. 6A, 6B and 6C are a schematic drawing of the deployment means (e.g., the inflatable balloon) having a flat structure.

Figs. 6D, 6E and 6F are a schematic drawing of the deployment means (e.g., the inflatable balloon) having a 3D structure.

Figs. 6G and 6H are a schematic drawing of the deployment means (e.g., the inflatable balloon) with an incomplete structure.

Figure 7 schematically represents one embodiment of an inflatable balloon as a deployment means inside the abdominal cavity.

Figs. 8A-8B schematically represent the inflatable balloon as the deployment means comprising several independent parts.

[07] **Figs. 9A-9B** discloses a method for using the preferred embodiment of the fixating means.

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[08] **Figs. 10-11** illustrate another embodiment of the present invention.

[09] **Figs. 12A-12B** schematically represent another patch/mesh deployment means.

[10] **Figs. 13A-13C** schematically represent an example of a rigid patch/mesh deployment means.

DETAIL DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The term **"coil"** refers hereinafter to any flexible and elastic object (e.g., any wire or spring) that can store mechanical energy. Said coil has a predetermined retracted spatial shape and is adapted to restore said shape when mechanical loads, electrical forces, magnetic forces or any combination thereof loads are applied on said coil. Furthermore said coil is adapted to alter its spatial shape to an unretracted spatial shape when force (e.g., mechanical, magnetic, electrical, or any combination of forces thereof) is applied on it. Furthermore said coil is adapted to alter its spatial shape back to a retracted spatial shape when said force (e.g., mechanical, magnetic, electrical, or any combination of forces thereof) is applied on it again and/or removed. In a preferred embodiment said object comprises a long and narrow thread, twine; wire, cord; filament, fiber, floss or filum.

The term **"balloon"** refers hereinafter to any flexible bag which can inflates or expands. The balloon can be made from materials such as rubber, latex, silicone, polyurethane, chloroprene or a nylon fabric or any thermoelastomeric materials or any combination of materials thereof. The balloon can be made of biocompatible materials, self-dissolving materials or shape memory materials.

The term **"deployment means"** refers hereinafter to any device adapted to spread and/or position meshes in any body cavity. The mesh deployment means can be made of any rigid, stiff or flexible materials. It can be made of stainless steel, other metals, plastic, biocompatible materials, electroactive polymers, biodegradable materials, shape memory materials, nylon, thermoelastic or thermoplastic materials, or any combination of materials thereof. In a specific embodiment of the present invention, the deployment means are an inflatable balloon.

The term **"side of the mesh"** refers hereinafter to two sides of the mesh, one which faces the abdominal wall and the other faces the bowels.

The term **"orientation or direction of the mesh"** refers hereinafter to orientation of the mesh within the abdominal cavity, i.e., the ability to rotate the mesh within the abdominal cavity. Usually the mesh is not symmetric in shape (i.e., rectangular or i.e., ellipse) - therefore it has different directions. By rotating the mesh within the abdominal cavity - one can decide what direction is turned where.

The term **"Hernia"** refers hereinafter to hernia in the abdominal cavity or in pre-peritoneal. Moreover the term hernia may be regarded as umbilical hernia, hiatal hernia, ventral hernia, post-operative hernia, epigastric hernia, spiegelian hernia, inguinal hernia and femoral hernia, generally any abdominal wall related hernia.

Yet more, it may be regarded in the most general interpretation as hernia in any hollow body organs and/or said natural and/or said artificial orifices and/or said spaces and/or said post-operative spaces.

[11] The terms **"mesh"** and/or "patch" refer hereinafter in a non-limiting manner to a flexible plane member of desired contour, selected in a non-limiting manner from biocompatible compositions selected from polymeric compositions; glassware; titanium containing, stainless steel, nitinol (Nickel Titanium alloys), and/or other metalware; composite materials; cardboard, natural fiber, silicone, rubber or rubber-like compositions or any mixture thereof.

The term **"minimally invasive surgery"** refers hereinafter to a procedure that is carried out by entering the body through the skin or through a body cavity or anatomical opening, but with the smallest damage possible.

The term **"trocar"** refers hereinafter to a surgical instrument passed through the body or abdominal wall, used to allow easy exchange of endoscopic instruments during endoscopic or other minimally invasive surgery.

The term "**Biocompatible materials**" refers hereinafter to materials that have the ability to perform with an appropriate host response in a specific application. Biocompatible materials have the quality of not having toxic or injurious effects on biological systems.

The term "**adjusting**" refers hereinafter to rolling, bending, twisting, folding and winding of the mesh, thus preparing and enabling the insertion of said mesh into the body.

The term "**biodegradable materials**" refers hereinafter to materials that are degraded by the body's enzymatic and/or hydrolytic pathways through a reaction against "foreign" material. Some urologists may prefer self-dissolving materials in catheter simply because then they don't have to go necessarily through the procedure of removing them afterwards. Examples of self-dissolving polymers are Polydioxanone (PDO), Polycaprolactone (PCL), Polylactic acid (PLA), Polyglycolic acid (PGA), Adipic acid, PEG and glutamic acid.

The term "**shape memory materials**" refers hereinafter to materials which can "remember" their original geometry. After a sample of shape memory materials has been deformed from its original geometry, it regains its original geometry by itself during heating (one-way effect) or, at higher ambient temperatures, simply during unloading (pseudo-elasticity or superelasticity). The thermally induced shape-memory effect has been described for different material classes: polymers, such as polyurethanes, poly(styrene-block-butadiene), Polydioxanone and polynorbornene, metallic alloys, such as copper-zinc-aluminium-nickel, copper-aluminium-nickel, and nickel-titanium (NiTi) alloys.

The term "**Electroactive Polymers or EAPs**" refers hereinafter to polymers whose shape is modified when a voltage is applied to them. EAP can have several configurations, but are generally divided in two principal classes:

1. Dielectric EPAs, in which actuation is caused by electrostatic forces between two electrodes which squeeze the polymer. This kind of EAP is characterized by a large actuation voltage (several thousand volts). Examples are electrostrictive polymers and dielectric elastomers.

2. Ionic EAPs, in which actuation is caused by the displacement of ions inside the polymer. Only a few volts are needed for actuation. Examples of ionic EAPs are conductive polymers, ionic polymer-metal composites (IPMCs), and responsive gels.

Some embodiments of the present invention provide a hernia kit useful in minimal invasive and/or open surgery. The hernia kit comprises:

a. a mesh **(2)**;

b. at least one deployment means **(3)**, adapted to deploy said mesh within the abdominal cavity and/or pre-peritoneal and/or hollow body organs and/or natural and/or artificial orifices and/or spaces and/or post-operative spaces; and,

c. fixating means **(200)** coupled to said deployment means **(3)**, adapted to attach said deployment means **(3)** to said mesh **(2)**; said fixating means are characterized by at least two portions:

i. a first (proximal) portion **(200a)** coupled to said inflatable deployment means **(3)**;

ii. a second (middle) portion **(200b)**, comprising a coil **(252)** having a predetermined retracted shape; said coil is reconfigurable from a plurality of unretracted positions to a plurality of retracted positions and from said plurality of retracted positions to said plurality of unretracted positions;

wherein said attachment between said deployment means **(3)** and said mesh **(2)** is obtained by reconfiguration of said coil **(252)** from at least one of said unretracted positions to at least one of said retracted positions.

The attachment is obtained by bringing into physical contact and holding together said mesh and said mesh deployment means.

It should be emphasized that according to a preferred embodiment of the present invention, said deployment means **(3)** is an inflatable balloon. However, some embodiments of the present invention could be suitable to any deployment system.

Some embodiments of the present invention provide the hernia kit as defined above, wherein said fixating means additionally comprises attaching means reversibly coupled to said second portion, adapted to thread said second portion **(200b)** through said mesh **(2)**.

It should be emphasized that said attaching means could be any means that can insert the coil through the mesh.

According to one embodiment of the present invention the fixating means additionally comprises a third (distal) portion **(200c)** comprising at least one sharpened element **(256)**, adapted to fully penetrate said mesh **(2)**.

As discussed earlier, one of the time consuming procedures or obstacle is the attachment of the mesh (and/or the patch) to the deployment means.

Some embodiments of the present invention provide means for said attachment by threading attachment means that are connected to the deployment means, into or through the mesh.

It should be emphasized that the following disclosure describes an inflatable balloon as the deployment means. However, any other mesh/patch deployment means can be used as well.

Reference is now made to **figures 1a** and **1b** which schematically display in a non-limiting manner one embodiment of a mesh deployment means (e.g., inflatable balloon) **(3)** and the mesh **(2)** in the hernia kit. The figures illustrate the inflatable balloon **(3)** that serves as the deployment means according to one embodiment of the present invention with **(fig. 1b)** and without **(fig. 1a)** a mesh **(2)**. The fixating means **(200)** are illustrated in the following figures.

The deployment means **(3)** can be made of materials selected from a group comprising of biocompatible materials, Nylon, self-dissolving materials, Thermoplastic Polyurethane, EAP and shape memory materials and any combination of materials thereof.

According to an embodiment, the deployment means (3) can be shaped to include a first and second expandable outer segments (1000a, 1000b) connected by way of an intermediate expandable segment (1001) extending between the first and second expandable outer segments. This arrangement of the deployment means can form at least a first and second through-hole opening (1002a, 1002b), delimited by the expandable outer segments and the intermediate expandable segment (as demonstrated in figure 1a). The deployment means can also have third and fourth through-hole openings. These through-hole openings can be separate and distinct from one another and can have different sizes. The inflatable segments of the deployment means can be arranged such that a line can intersect all expandable segments simultaneously when the deployment means is fully expanded.

The first and second outer expandable segments (1000a, 1000b) of deployment means (3) can be arranged such that the two outer expandable segments are connected directly to one another, directly to the intermediate expandable segment (1001), and connected to one another and to the intermediate expandable segment at two spaced apart locations. Alternatively, the first and second expandable outer segments can also be arranged such that the outer segments form a V-shape, providing that the segments have substantially V-shaped portions. The first outer expandable segment can also have an outwardly curving portion.

The shape of the deployment means **(3)** can be an eccentric shape, a concentric shape, an "H"/modified "H", shape a polygonal shape, a curved shape, a symmetrical shape, a non-symmetrical shape, a linear shape, a branching shape, a continuous shape, a non-continuous shape, a concave shape, a irregular shape, a square-like shape, a U-like shape, a grid-like shape, a substantially elliptical shape, and a rake-like shape or any combination thereof. The length of the deployment means (3) can be greater than its width.

If a balloon is used as the deployment means **(3)** - thus it can be inflated by air, CO2, saline etc. in order to inflate the balloon, inflating means are coupled to the balloon (not shown in the figures).

If the deployment means is not a balloon, its shape can be modified and/or at least one of its parts can be actuated to allow the spreading and/or deploying of the mesh.

The deployment means (e.g., the inflating balloon) **(3)** may also comprise a centering means **(5)**, for ensuring that the center of said deployment means (e.g., inflatable balloon) and thus the center of the mesh will be aligned with the center of said hernia.

Furthermore, said centering means enables movement of said deployment means (e.g., the balloon) and thus the mesh into the desired position inside the abdominal cavity. The distal part of the centering means may be attached to grasping means (e.g., a needle or a closed loop) **(9)** enabling said movement of said deployment means (e.g., inflatable balloon) and the mesh. Said means **(9)** enables the grasp of said centering means **(5)** via a surgical tool.

Reference is now made to **figure 1c** illustrating a closer view of another possible embodiment of said centering means **(5)**. According to said embodiment, the centering means **(5)** comprises grasping means **(9)** which is a closed loop coupled to a needle/sharp element **(11)**. Needle **(11)** is provided to enable with the penetration of said centering means **(5)** through the mesh.

It should be emphasized that according to a preferred embodiment of the present invention, if the deployment means are an inflatable balloon thus the centering means **(5)** are also the inflating means adapted to inflate or deflate the inflatable balloon **(3)**. Reference is now made to **figure 2a**, schematically representing a preferred embodiment of the fixating (attachment)

means **(200)** which are adapted to attach the mesh to the deployment means (e.g., the inflating balloon). **Figure 2a** also represents the appendages **(4)** of the deployment means (e.g., the inflatable balloon) **(3)**.

[12] The distal portion **(200c)** of the fixating means **(200)** comprises a stylet **(256)** or any other sharp object (e.g., needle), which can puncture the deployment means' (e.g., the inflating balloon's) appendage **(4)** and the mesh.

[13] According to another embodiment, the deployment means (e.g., the inflating balloon) will have appendages having at least one aperture through which the stylet **(256)** passes. Thus, the stylet **(256)** only has to puncture the mesh.

[14] The proximal portion **(200a)** of the fixating means **(200)** is coupled to the deployment means (e.g., the inflatable balloon) **(3)**. The coupling of the proximal portion and the deployment means (e.g., the inflatable balloon) could be obtained by glue, Velcro, mechanical connections (such as for example a disc or for example a knot), or by welding or threading of the proximal portion **(200a)** to the appendages **(4)** or to any other part of the deployment means, or any combination thereof.

[15] The middle portion **(200b)** of the fixating means **(200)** is a suture cord or an injected material or a pre-formed material which comprises, according to one embodiment, two sections.

[16] The first section **(252)** serves as a self retracting coil (e.g., helical), which can be actively pulled into a more elongated and less retracted configuration (said part will refer hereinafter as the helical part or the coil **(252)**).

[17] The second section **(254)** is a relatively linear part of the fixating means **(200)** which connects the helical part to the sharpened part. It should be emphasized that this second section can be removed after the sharpened end is inserted through the mesh.

[18] According to another embodiment, the middle portion **(200b)** of the fixating means **(200)** is a suture cord or an injected or a pre-formed material which comprises only the first section **(252)** - i.e., the self retracting coil.

Figure 2a also represents the appendages **(4)** of the deployment means (e.g., the inflatable balloon) **(3)**. The appendages **(4)** can be made of the same material as the inflatable balloon **(3)**, being a direct extension of the inflatable balloon **(3)**. It can also be made of another material coupled or attached to the deployment means (e.g., the inflatable balloon) **(3)**.

It should be emphasized that the deployment means (e.g., the inflatable balloon) **(3)** may have a different number of appendages **(4)**; it could be for example 4 (as demonstrated in **figure 2b**) or for example 8 (as demonstrated in **figure 2c**).

According to one embodiment of the present invention, the fixating means **(200)** can be made of any flexible or rigid materials. According to another embodiment the fixating means **(200)** can be made of nylon, biodegradable material, EAP, shape memory materials, Thermoplastic Polyurethane or any combination thereof.

[19] Reference is now made to **figures 3a-3e**, schematically representing a method of fixating the mesh **(2)** to the deployment means (e.g., the inflatable balloon) **(3)** using the preferred embodiment of a fixating means shown in figure **(2)**.

[20] At the initial configuration, the fixating means **(200)** are attached to the deployment means (e.g., the inflatable balloon) **(3)** at diverse locations (denoted as numerical reference **(31)**), chosen to optimize the covering of the deployment means (e.g., the inflatable balloon) **(3)** by the mesh **(2)** (**figure 3a**).

[21] Next, the stylet **(256)** of each fixating means **(200)** is pulled through the mesh at the appropriate locations.

[22] It should be pointed out that if the fixating means **(200)** are not connected to the deployment means (e.g., the balloon), then the stylet **(256)** is threaded through the appendages **(4)** or through insertion holes **(250)** in the appendages **(4)** and then into the mesh **(2)**.

[23] It should be noted that if centering means **(5)** exists, it can also be pulled through the mesh (**figure 3b**).

[24] Next, the retracted part (i.e., coil **(252)**) of fixating means **(200)** is pulled into a less retracted configuration (**figure 3c**) and passes through the mesh. In other words, the configuration of the coil **(252)** is altered from a retracted position (e.g., helical shape) into an unretracted position (e.g., at least partially linear shape).

[25] As it is released (i.e., the mechanical stress is released), it resumes its retractable position, pushing and driving the mesh against the deployment means (e.g., the inflatable balloon) **(3)** (**figures 3d and 3e**). In other words, the configuration of the coil **(252)** is retracted from said unretracted position (e.g., at least partially linear shape) into a retracted position (e.g., helical shape).

[26] Other retraction options may be either due to intrinsic elastic or magnetic properties of the coil **(252)** of fixating means **(200)**, or by an external stimulation, such as applying electric current (in case of EAP), applying heat (in case of a shape memory material), applying mechanical means or any other means of actuating a helical configuration.

[27] According to another embodiment of the present invention, the coil **(252)** is a coaxial structure, comprising at least partially a helical and/or spiral structure that can unretract to a more linear structure, and retract back to at least partially, helical and/or spiral structure.

[28] According to another embodiment of the present invention, the coil **(252)** is a coaxial structure, comprising an outer cannula with a longitudinal slit and an inner thread. The retraction of said coil is performed by pulling out the inner thread thus the cannula collapses into a helical configuration.

[29] It should be emphasized that the attachment between the mesh and the deployment means (e.g., the inflatable balloon) is most preferably done as preparation prior to the abdominal insertion, but it could also be used during a laparoscopic operation.

[30] The linear part **(254)** of the fixating means **(200)** and/or the stylet **(256)** then may be cut away (**figure 3f**), and the mesh is fixated to the deployment means (e.g., the inflatable balloon) **(3)**.

[31] The flexible part of fixating means **(254)** can alternatively be ablated by an electrical current, when the stimulation for coil retraction is an electrical current.

[32] Alternatively only the stylet **(256)** may be cut away.

[33] **Figures 4a to 4b** schematically represent the adjustment of the preferred embodiment of a fixating means to different size of a mesh. The appendages **(4)** and the fixating means **(200)** can be located at various locations (**figure 4a**), thus enabling the use of a mesh smaller than the deployment means (e.g., the inflatable balloon) **(3)** size (**figure 4b**).

[34] **Figures 5a to 5b** schematically represent other embodiments of the helical part **(252)** of the fixating means **(200)**, which can have a varying radius of coiling (**figure 5a**) and varying number of rotations (**figure 5b**).

[35] **Reference is now made to figures 5c-5f**, which show another preferred embodiment of the fixating (attachment) means **(200)**. According to that embodiment all parts of the fixating means **(252, 254** and **256)** lie in the same plane.

[36] **Figure 5c** illustrates the fixating (attachment) means **(200)** having anchoring means **(201)**. Said anchoring means can be encapsulated within the appendages **(4)** or trapped below the appendages **(4)**.

[37] **Figure 5d** illustrate the fixating (attachment) means **(200)** displayed in **figure 5c** encapsulated within the appendages **(4)**.

[38] **Figure 5e** illustrates another embodiment of the fixating (attachment) means **(200)** having a different shape for the anchoring means **(201)**.

[39] **Figure 5f** illustrates the fixating (attachment) means **(200)** displayed in **figure 5e** encapsulated within the appendages **(4)**.

[40] **Figure 5g** illustrates another embodiment of the fixating (attachment) means **(200)** having a different shape for the anchoring means **(201)**.

[41] **Figure 5h** illustrate the fixating (attachment) means **(200)** displayed in **figure 5g** encapsulated within the appendages **(4)**.

[42] **Figure 5i** illustrates another embodiment of the fixating (attachment) means **(200)** having a different shape for the anchoring means **(201)**.

[43] **Figures 5j-5k** illustrate the different anchoring means **(201)** displayed in **figure 5i** trapped below the appendages **(4)**.

[44] **Figure 5l** illustrates the different anchoring means **(201)** displayed in **figure 5i** encapsulated within the appendages **(4)**.

[45] It should be emphasized that the anchoring of the anchoring means can be reinforced with glue, welding, magnetic forces or any combination thereof.

[46] The following figures are examples of different inflating balloons used as deployment means:

The inflatable balloon **(3)** may have a flat structure as displayed in **figures 6a**, **6b** and **6c**, or a 3D structure as displayed in **figures 6d**, **6e** and **6f**.

Figure 6d and **6f** illustrate a 3D structure of the balloon which additionally comprises at least two arcs 10. The inflated balloon 3 is fixed in place by creating pressure on the mesh/patch towards the abdominal wall.

The inflatable balloon **(3)** may not have a complete closed shape as can be seen in **figures 6g** and **6h**. The parts of the balloon may be connected to each other with glue, wire, scotch, etc.

As described above, if an inflating balloon is used as deployment means, the balloon will be coupled to an inflating means adapted to inflate said balloon.

When the deployment means (e.g., the inflatable balloon) is used in hernia repair surgeries it can additionally comprise means (such as bulge, lines, signs and symbols) for adjusting the center of said deployment means (e.g., the inflatable balloon) to the center of said hernia. Moreover the deployment means (e.g., the inflatable balloon) may additionally comprise

means (such as bulge, lines, signs and symbols,) adapted to ensure that the right side of the mesh (or patch) is directed to the abdominal or the pre-peritoneal cavity. Moreover the deployment means (e.g., the inflatable balloon) may additionally comprise means (such as bulge, lines, signs and symbols,) adapted to ensure the right direction of the mesh in the abdominal cavity.

Reference is now made to **figure 7** which schematically represents one embodiment of an inflatable balloon **(3)** used as deployment means and the mesh **(2)** inside the abdominal cavity 10.

It should be emphasized that the inflatable balloon might be composed of several parts. Each of said part will be coupled to an inflating means. Reference is now made to **figures 8a, 8b** which schematically display an inflatable balloon having several independent parts 20 and several inflating tubes 21 (which will be coupled to the inflating means). In the same manner, other deployment means may comprise of several independent parts and several independent connectors and other mechanical parts enabling the deployment of meshes/patches.

According to another embodiment of the present invention the deployment means (e.g., inflatable balloon) additionally comprises means adapted to adjust the center of said deployment means (e.g., the inflatable balloon) to the center of said hernia.

According to another embodiment of the present invention the deployment means (e.g., the inflatable balloon) additionally comprises means **(11)** adapted to thread said centering means through the mesh and/or through the abdominal wall **(9)** (as can be seen in **figure 1c**).

According to another embodiment of the present invention the deployment means (e.g., the inflatable balloon) additionally comprises means adapted to ensure the right side of said mesh is directed to the hernia.

According to another embodiment of the present invention the deployment means (e.g., the inflatable balloon) additionally comprises means adapted to ensure the right direction of the mesh in the abdominal cavity.

[47] **Figure 9a** illustrates in a flowchart for a method **(700)** for attaching a mesh to deployment means according to the preferred embodiment of the fixating means. The method comprises steps of obtaining (step **702**) a hernia kit comprising:

i. a mesh **(2)**;

ii. at least one deployment means **(3)**, adapted to deploy said mesh within the abdominal cavity and/or pre-peritoneal and/or hollow body organs and/or natural and/or artificial orifices and/or spaces and/or post-operative spaces; and,

iii. fixating means **(200)** coupled to said deployment means **(3)** adapted to attach said deployment means **(3)** to said mesh **(2)**; said fixating means are characterized by:

a. a first (proximal) portion **(200a)** coupled to said deployment means **(3)**;

b. a second (middle) portion **(200b)**, comprising a coil **(252)** having a predetermined retracted shape; said coil is reconfigurable from a plurality of unretracted positions to a plurality of retracted positions and from said plurality of retracted positions to said plurality of unretracted positions; and,

c. a third (distal) portion **(200c)** comprising at least one sharpened element **(256)**, adapted to fully penetrate said mesh **(2)**;

[48] The next step is to thread the sharpened element (i.e., stylet **256**) through the mesh **(2)** (step **703**).

[49] Then, the stylet **(256)** is pulled through the mesh **(2)** (step **704**) thus, reconfiguring the coil **(252)** from a retracted (e.g., helical) configuration into at least partially linear configuration.

[50] Next (step **705**), re-actuating the coil **(252)** of the fixating means **(200)** thus, reconfiguring said coil **(252)** from unretracted position (linear shape) into its retracted configuration (e.g., helical configuration).

[51] Then (step **706**) the sharpened element (i.e., stylet **256**) is detached.

[52] It should be emphasized that it is optional to detach the linear part **(254)** of fixating means **(200)** from the coil **(252)**.

[53] Once the sharpened element is removed, the mesh (which is attached to the deployment means) is adjusted and inserted into the abdominal cavity and/or pre-peritoneal and/or hollow body organs and/or natural and/or artificial orifices and/or spaces and/or post-operative spaces.

[54] According to one embodiment of the present invention, the deployment means are an inflated balloon **(3)**. However, it should be emphasized that the above mentioned method can be employed on any deployment means and it should not be restricted to an inflatable balloon.

[55] According to another embodiment of the present invention, the method as described above additionally comprises a step of uncoupling said attaching means from said second portion **(200b)**.

[56] According to another embodiment of the present invention, the retracted shape of the coil **(252)** is at least partially helical and/or spiral.

[57] According to another embodiment of the present invention, the method as described above additionally comprises a step of adjusting said mesh attached to said deployment means and inserting said adjusted deployment means attached to said mesh into the abdominal cavity and/or pre-peritoneal and/or hollow body organs and/or natural and/or artificial orifices and/or spaces and/or post-operative spaces.

[58] According to another embodiment of the present invention, the method additionally comprises a step of inflating at least a portion of said inflatable balloon or actuating at least one part of other deployment means; thereby spreading and/or deploying said mesh.

According to another embodiment of the present invention, the method additionally comprises a step of coupling said fixating means **(200)** to said deployment means (e.g., the inflatable balloon) **(3)** by means selected from a group consisting of glue, Velcro, mechanical

connections (such as for example a disc or for example a knot), welding of the proximal portion **(200a)** to the appendages **(4)**, threading said fixating means through the appendages **(4)** or through holes in the appendages **(4)** or through any other part of the deployment means or any combination thereof.

According to another embodiment of the present invention, the step of reconfiguring said coil from said retracted position to an unretracted position additionally comprises a step of mechanically pulling said coil.

According to another embodiment of the present invention, the step of reconfiguring said coil from said unretracted position to said retracted position additionally comprises a step of releasing said mechanical stress.

According to another embodiment of the present invention, the step of reconfiguring said coil is performed by means selected from a group consisting of application of electrical current on said coil, thermoregulating said coil, application of magnetic field on said coil or any combination of means thereof.

According to another embodiment of the present invention, the step of reconfiguring said coil from said unretracted position to said retracted position is performed spontaneously.

According to another embodiment of the present invention, the method additionally comprises a step of selecting said coil to have more than one coiling radius.

According to another embodiment of the present invention, the method additionally comprises a step of selecting said sharpened element from a group consisting of a stylet or a needle.

According to another embodiment of the present invention, the method additionally comprises a step of coupling said proximal portion of said fixating means **(200)** to appendages **(4)** or to any other part on the deployment means (e.g., the inflatable balloon) **(3)**.

According to another embodiment of the present invention, the method additionally comprises a step of coupling said proximal portion **(200a)** of said fixating means **(200)** to various

locations on said deployment means (e.g., the inflatable balloon) **(3)**, thus accommodating a variety of mesh sizes.

[59] According to another embodiment of the present invention, the method additionally comprises a step of extracting said deployment means (e.g., the inflatable balloon) **(3)** from within the abdominal cavity and/or pre-peritoneal and/or hollow body organs and/or natural and/or artificial orifices and/or spaces and/or post-operative spaces (i.e., hernia).

According to another embodiment of the present invention, the method additionally comprises a step of deflating said inflatable balloon, or minimizing the relevant segments/parts of any other deployment means.

According to another embodiment of the present invention, the method additionally comprises a step of continuing inflating said inflatable balloon according to a predetermined medical need, or preserving the needed size of other deployment means.

According to another embodiment of the present invention, the method additionally comprises a step of fitting the center of said deployment means (e.g., the inflatable balloon) to the center of said hernia or any desired position in the abdominal cavity and/or said pre-peritoneal and/or said hollow body organs and/or said natural and/or said artificial orifices and/or said spaces and/or said post-operative spaces.

According to another embodiment of the present invention, the method additionally comprises a step of threading centering means **(5)** through said mesh.

According to another embodiment of the present invention, the method additionally comprises a step of ensuring that the right side and the right direction of said mesh is directed to said hernia, or to abdominal cavity and/or said pre-peritoneal and/or said hollow body organs and/or said natural and/or said artificial orifices and/or said spaces and/or said post-operative spaces.

[60] According to another embodiment of the present invention, the method additionally comprises a step of selecting the shape of said deployment means (or specifically

the inflatable balloon) from a group comprising a polygonal shape, a curved shape, a symmetrical shape, a non-symmetrical shape, a linear shape, continuous, non-continuous, a concave shape, a irregular shape, a square-like shape, a rectangular shape, an oval shape, a U-like shape, an H-like shape, a grid-like shape, a flat structure, a 3D structure and a rake-like shape or any combination thereof.

[61] It should be further emphasized that different deployment means can be used. Although the above disclosure is related to a specific deployment means (i.e., an inflated balloon), the fixating means 200 can be utilized with any deployment means available.

[62] **Figure 9b** illustrates in a flowchart for a method **(700)** for attaching a mesh to deployment means according to a preferred embodiment of the fixating means. The method comprises steps of obtaining (step **702**) a hernia kit comprising:

i. a mesh **(2)**;

ii. at least one deployment means **(3)**, adapted to deploy said mesh within the abdominal cavity and/or pre-peritoneal and/or hollow body organs and/or natural and/or artificial orifices and/or spaces and/or post-operative spaces; and,

iii. fixating means **(200)** coupled to said deployment means **(3)**, adapted to attach said deployment means **(3)** to said mesh **(2)**; said fixating means are characterized by at least two portions:

a. a first (proximal) portion **(200a)** firmly coupled to said deployment means **(3)**;

b. a second (middle) portion **(200b)**, comprising a coil **(252)** having a predetermined retracted shape; said coil is reconfigurable from a plurality of unretracted positions to a plurality of retracted positions and from said plurality of retracted positions to said plurality of unretracted positions.

[63] The next step (step **703**) is to obtain attaching means adapted to thread said second portion **(200b)** through said mesh **(2)**.

[64] Next, (step **704**) the attaching means are reversibly coupled to said second portion **(200b)**.

[65] Then (step **705**), the second portion **(200b)** is thread through said mesh **(2)** via said attaching means.

[66] Next (step **706**), the coil **(252)** is reconfigurable from retracted (e.g., helical) configuration into at least partially linear configuration.

[67] Next (step **707**), re-actuating the coil **(252)** of the fixating means **(200)** thus, reconfiguring said coil **(252)** from unretracted position (linear shape) into its retracted configuration (e.g., helical configuration).

[68] Then, (step **708**) the attaching means can be uncoupled from said second portions.

[69] It should be emphasized that it is optional to detach also the linear part **(254)** of fixating means **(200)** from the coil **(252)**.

[70] Once the attaching means are removed, the mesh (which is attached to the deployment means (e.g., an inflatable balloon)) is adjusted and inserted into the abdominal cavity and/or pre-peritoneal and/or hollow body organs and/or natural and/or artificial orifices and/or spaces and/or post-operative spaces.

[71] According to one embodiment of the present invention, the deployment means are an inflatable balloon. However, it should be emphasized that the above mentioned method can be employed on any deployment means and it should not be restricted to an inflatable balloon.

[72] According to another embodiment of the present invention, the retracted shape of the coil **(252)** is at least partially helical and/or spiral.

According to another embodiment of the present invention, the method additionally comprises a step of inflating at least a portion of said inflatable balloon or actuating only part of the other deployment means; thereby spreading and/or deploying said mesh.

[73] According to another embodiment of the present invention, the method as described above additionally comprises a step of adjusting said mesh attached to said deployment means (e.g., the inflatable balloon) and inserting said adjusted deployment means attached to said mesh into the abdominal cavity and/or pre-peritoneal and/or hollow body organs and/or natural and/or artificial orifices and/or spaces and/or post-operative spaces.

According to another embodiment of the present invention, the method additionally comprises a step of coupling said fixating means **(200)** to said deployment means (e.g., the inflatable balloon) **(3)** by means selected from a group consisting of glue, Velcro, mechanical connections selected from a group consisting of a disc or a knot, welding proximal portion **(200a)** to the appendages **(4)**, threading said fixating means through the appendages **(4)** or through holes in the appendages **(4)** or through any other part of the deployment means or any combination thereof.

According to another embodiment of the present invention, said step (e) of reconfiguring said coil from said retracted position to an unretracted position additionally comprises a step of mechanically pulling said coil.

According to another embodiment of the present invention, said step (f) of reconfiguring said coil unretracted position to said retracted position additionally comprises a step of releasing said mechanical stress.

According to another embodiment of the present invention, said step (e) or said step (f) of reconfiguring said coil is performed by means selected from a group consisting of application of electrical current on said coil, thermoregulating said coil, application of magnetic field on said coil.

According to another embodiment of the present invention, said step (f) of reconfiguring said coil unretracted position to said retracted position is performed spontaneously.

According to another embodiment of the present invention, the method additionally comprises a step of selecting said coil to have more than one coiling radius.

According to another embodiment of the present invention, the method additionally comprises a step of selecting said attaching means from sharpened element selected from a group consisting of a stylet or a needle.

According to another embodiment of the present invention, the method additionally comprises a step of coupling said first portion of said fixating means **(200)** to appendages on said deployment means (e.g., the inflatable balloon) **(3)**.

According to another embodiment of the present invention, the method additionally comprises a step of coupling said first portion **(200a)** of said fixating means **(200)** to various locations on said deployment means (e.g., the inflatable balloon) **(3)**, thus accommodating a variety of mesh sizes.

According to another embodiment of the present invention, the method additionally comprises a step of extracting said deployment means (e.g., the inflatable balloon) from said hernia.

According to another embodiment of the present invention, the method additionally comprises a step of deflating said inflatable balloon, or minimizing the relevant segments/parts of any other deployment means.

According to another embodiment of the present invention, the method additionally comprises a step of continuing inflating said inflatable balloon or preserving the needed size of other deployment means, according to a predetermined medical need.

According to another embodiment of the present invention, the method additionally comprises a step of fitting the center of said inflatable balloon or other deployment means, to the center of said hernia or any desired position in said abdominal cavity and/or said pre-peritoneal and/or said hollow body organs and/or said natural and/or said artificial orifices and/or said spaces and/or said post-operative spaces.

According to another embodiment of the present invention, the method additionally comprises a step of threading centering means (**5**) through said mesh.

According to another embodiment of the present invention, the method additionally comprises a step of ensuring the right side of said mesh is directed to said hernia or to abdominal cavity and/or said pre-peritoneal and/or said hollow body organs and/or said natural and/or said artificial orifices and/or said spaces and/or said post-operative spaces.

According to another embodiment of the present invention, the method additionally comprises a step of selecting the shape of said deployment means (or specifically the inflatable balloon) from a group comprising a polygonal shape, a curved shape, a symmetrical, a non-symmetrical shape, a linear shape, continuous, non-continuous, a concave shape, a irregular shape, a square-like shape, a rectangular shape, an oval shape, a U-like shape, an H-like shape, a grid-like shape, a flat structure, a 3D structure and a rake-like shape or any combination thereof.

Reference is now made to **figures 10a** and **10b** illustrating another embodiment of the hernia kit. According to said embodiment the deployment means (e.g., the inflatable balloon) additionally comprises at least one clip/slit (**10**) adapted to grab a suture.

Figure 10b illustrates a balloon (**3**) as the deployment means, a mesh (**2**), a clip/slit (**10**) and a suture (**20**) running through said mesh and grabbed in said clip. Thus, creating an attachment between said balloon and said mesh.

[74] **Figure 11** illustrates a mesh (**2**) coupled to the deployment means (and specifically an inflatable balloon) via said sutures (**20**).

[75] As described above, it should be emphasized that the present invention can be used in any deployment means and is not limited to an inflatable balloon.

[76] **Figures 12a and 12b** illustrate, in a non-limiting manner, another deployment means which is described in US application no. US2001/0053919 and in PCT application no. WO95/30374 respectfully. The attachment means (**200**) as described in the present

invention can be used, for example, in the deployment means described and claimed in US application no. US2001/0053919 and in PCT application no. WO95/30374.

[77] **Figures 13a** to **figure 13c** illustrate another deployment means, wherein said deployment means is rigid.

[78] **Figure 13a** illustrates the mesh deployment means in which the mesh is adjusted.

[79] **Figure 13b** illustrates the mesh deployment means in which the mesh is partially spread.

[80] **Figure 13c** illustrates the mesh deployment means in which the mesh is fully spread. **Figure 13c** also illustrates the use of the fixating means 200 to attach the mesh and the mesh deployment means.

[81] As described above, the fixating means 200 can be used in all kinds of deployment means, including the deployment means illustrated in **figure 13**.

[82] In the foregoing description, embodiments of the invention, including preferred embodiments, have been presented for the purpose of illustration and description. They are not intended to be exhaustive or to limit the invention to the precise form disclosed. Obvious modifications or variations are possible in light of the above teachings. The embodiments were chosen and described to provide the best illustration of the principals of the invention and its practical application, and to enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such modifications and variations are within the scope of the invention as determined by the appended claims when interpreted in accordance with the breadth they are fairly, legally, and equitably entitled.

CLAIMS:

1. A hernia repair system, comprising:

a deployment device adapted to deploy a hernia repair patch within a body of a patient, wherein the deployment device has a reduced configuration for delivering the hernia repair patch to a placement site within the patient and an expanded configuration for deploying the hernia repair patch;

a fixating component extending from the deployment device, the fixating component having an unretracted configuration adapted for at least one of attaching or detaching the hernia repair patch to the deployment device and a retracted configuration adapted to maintain attachment between the hernia repair patch and the deployment device; and

a centering component extending from the deployment device adapted to position the deployment device relative to a hernia, the centering component adapted for insertion through the hernia repair patch.

2. The hernia repair system of claim 1, wherein the fixating component includes a sharp end adapted for insertion through the hernia repair patch.

3. The hernia repair system of claim 1 or 2, wherein the fixating component is substantially coil-shaped in the retracted configuration.

4. The hernia repair system of claim 3, wherein the fixating component has a substantially linear shape in the unretracted configuration.

5. The hernia repair system of any one of claims 1 to 4, wherein the fixating component is reconfigurable from the retracted configuration to the unretracted configuration upon either mechanical pulling or pushing, application of an electrical current, application of heat, or application of a magnetic field.

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6. The hernia repair system of any one of claims 1 to 4, wherein the fixating component is automatically reconfigurable from the unretracted configuration to the retracted configuration.

7. The hernia repair system of any one of claims 1 to 6, wherein the fixating component has a greater length in the unretracted configuration than in the retracted configuration.

8. The hernia repair system of any one of claims 1 to 7, wherein the deployment device includes an appendage and the fixating component extends from the appendage.

9. The hernia repair system of claim 8, wherein the appendage is thinner than adjacent portions of the deployment device.

10. The hernia repair system of any one of claims 1 to 9, wherein the deployment device is flexible.

11. The hernia repair system of any one of claims 1 to 9, wherein the fixating component extends in a direction perpendicular to a plane of the deployment device in the expanded configuration.

12. The hernia repair system of any one of claims 1 to 9, wherein the fixating component extends in a direction parallel to a plane of the deployment device in the expanded configuration.

13. The hernia repair system of any one of claims 1 to 9, further comprising a plurality of fixating components extending from the deployment device, each fixating component including a sharp end adapted to pass through the hernia repair patch in an unretracted configuration and to remain passed through the hernia repair patch in a retracted configuration to attach the hernia repair patch to the deployment device.

14. The hernia repair system of any one of claims 1 to 13, wherein the centering component is adapted to be threaded through the hernia repair patch.

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15. The hernia repair system of any one of claims 1 to 14, wherein the centering component is adapted to be grasped by a surgical tool.

16. The hernia repair system of any one of claims 1 to 15, wherein the centering component is adapted to adjust the center of the deployment device with the center of the hernia repair patch.

17. A hernia repair kit comprising the hernia repair system of any one of claims 1 to 9, and a hernia repair patch, the hernia repair patch being configured to enable the fixating component extending from the deployment device to pass through the hernia repair patch when the fixating component is in an unretracted configuration so that the fixating component remains passed through the hernia repair patch in the retracted configuration and attaches said hernia repair patch to the deployment device.

18. A hernia repair system, comprising:

a deployment device adapted to deploy a hernia repair patch within a body of a patient, wherein the deployment device has a reduced configuration for delivering the hernia repair patch to a placement site within the patient and an expanded configuration for deploying the hernia repair patch; and

a fixating component extending from the deployment device, the fixating component having an unretracted configuration adapted for at least one of attaching or detaching the hernia repair patch to the deployment device and a retracted configuration adapted to maintain attachment between the hernia repair patch and the deployment device, the fixating component including a sharp end adapted for insertion through the hernia repair patch.

19. The hernia repair system of claim 18, further comprising a centering component extending from the deployment device adapted to position the deployment device relative to a hernia.

20. The hernia repair system of claim 19, wherein the centering component is adapted for insertion through a hernia repair patch.

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21. The hernia repair system any one of claims 18 to 20, wherein the fixating component is substantially coil-shaped in the retracted configuration.

22. The hernia repair system of claim 21, wherein the fixating component has a substantially linear shape in the unretracted configuration.

23. The hernia repair system of any one of claims 18 to 22, wherein the fixating component is reconfigurable from the retracted configuration to the unretracted configuration upon either mechanical pulling or pushing, application of an electrical current, application of heat, or application of a magnetic field.

24. The hernia repair system of claim 18, wherein the fixating component is automatically reconfigurable from the unretracted configuration to the retracted configuration.

25. The hernia repair system of any one of claims 18 to 24, wherein the fixating component has a greater length in the unretracted configuration than in the retracted configuration.

26. The hernia repair system of any one of claims 18 to 25, wherein the deployment device includes an appendage and the fixating component extends from the appendage.

27. The hernia repair system of claim 26, wherein the appendage is thinner than adjacent portions of the deployment device.

28. The hernia repair system of any one of claims 18 to 27, wherein the deployment device is flexible.

29. The hernia repair system of any one of claims 18 to 28, wherein the fixating component extends in a direction perpendicular to a plane of the deployment device in the expanded configuration.

30. The hernia repair system of claim 18, wherein the fixating component extends in a direction parallel to a plane of the deployment device in the expanded configuration.

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31. The hernia repair system of any one of claims 18 to 30, further comprising a plurality of fixating components extending from the deployment device, each fixating component including a sharp end adapted to pass through the hernia repair patch in an unretracted configuration and to remain passed through the hernia repair patch in a retracted configuration to attach the hernia repair patch to the deployment device.

32. A hernia repair kit comprising the hernia repair system of any one of claims 18 to 31 and a hernia repair patch, the hernia repair patch being configured to enable the fixating component extending from the deployment device to pass through the hernia repair patch when the fixating component is in an unretracted configuration so that the fixating component remains passed through the hernia repair patch in the retracted configuration and maintains attachment between said hernia repair patch and the deployment device.

33. A device for delivering a soft tissue repair prosthetic, comprising:

a deployment device adapted to deploy a hernia repair patch within a body of a patient, wherein the deployment device has a reduced configuration for delivering the hernia repair patch to a placement site within the patient and an expanded configuration for deploying the hernia repair patch, the deployment device comprising a first outer expandable segment, a second outer expandable segment and an intermediate expandable segment extending between the first outer expandable segment and the second outer expandable segment,

wherein a first through-hole opening is at least partially defined by the first outer expandable segment, and a second through-hole opening is at least partially defined by the second outer expandable segment, the first and second through-hole openings being separate and distinct from one another and being different sizes, and

wherein the first outer expandable segment, the second outer expandable segment and the intermediate expandable segment are arranged such that, when the deployment device is fully expanded, a line can intersect the first, second and outer expandable segments simultaneously.

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34. The device of claim 33, wherein the deployment device comprises a balloon and the first outer expandable segment and the second outer expandable segment comprise inflatable segments.

35. The device of claim 33, wherein the deployment device further comprises a third through-hole opening and a fourth through-hole opening.

36. The device of claim 33, wherein the first outer expandable segment includes an outwardly curving portion.

37. The device of claim 33, wherein a length of the deployment device is greater than a width of the deployment device.

38. The device of claim 33, wherein the deployment device has an asymmetric shape.

39. The device of claim 33, wherein the deployment device is substantially elliptically shaped.

40. The device of claim 33, wherein the first outer expandable segment is connected directly to the second outer expandable segment.

41. The device of claim 33, wherein the first and second outer expandable segments are connected directly to the intermediate expandable segment.

42. The device of claim 33, wherein the first and second outer expandable segments are connected together at two spaced apart locations and are connected to the intermediate expandable segment at the two spaced apart locations.

43. The device of claim 33, further comprising first and second expandable end segments that form a V-shape, wherein the first and second expandable end segments include substantially V-shaped portions.

44. The device of claim 33, further comprising a soft tissue repair prosthetic removably connected with the deployment device.

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45. The device of claim 44, wherein the soft tissue repair prosthetic is formed from a mesh fabric.

46. The device of claim 33, further comprising a plurality of attachment components configured to removably connect the soft tissue repair prosthetic with the deployment device.

47. The device of claim 33, further comprising an inflation tube, wherein the inflation tube is attached to the intermediate expandable segment.

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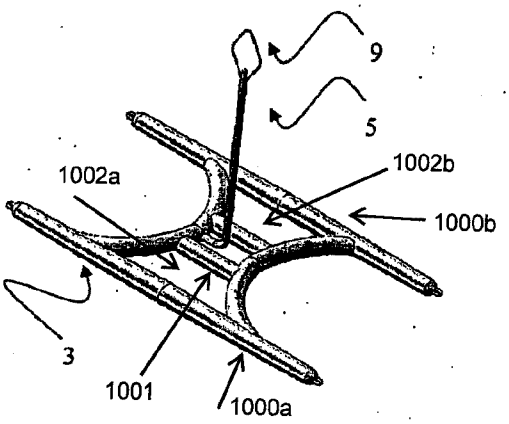


Figure 1A

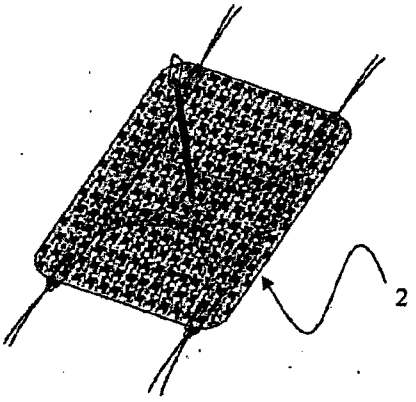


Figure 1B

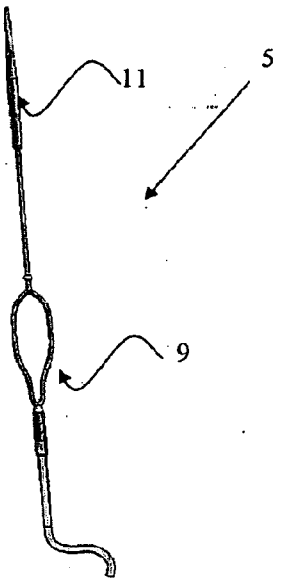


Figure 1C

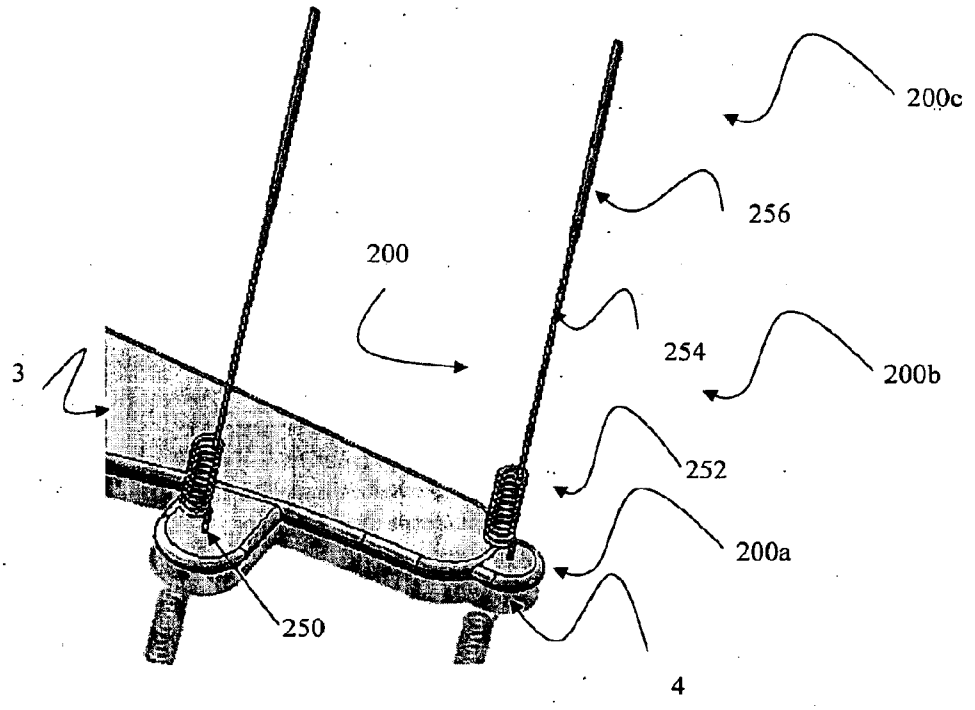


Figure 2A

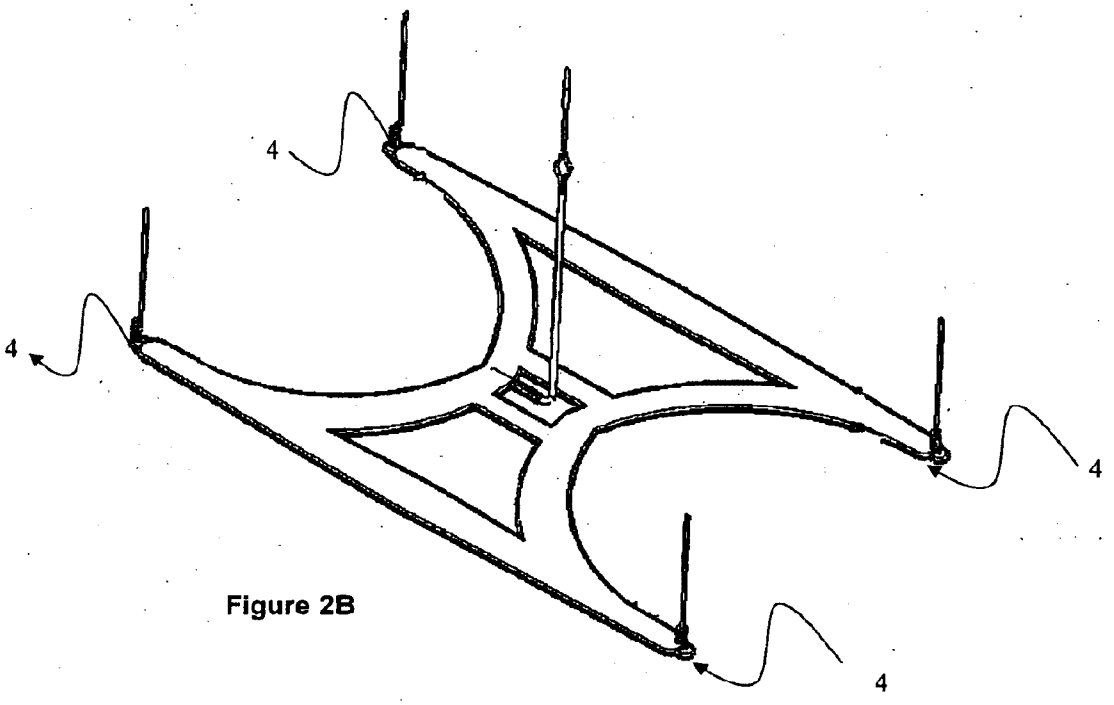


Figure 2B

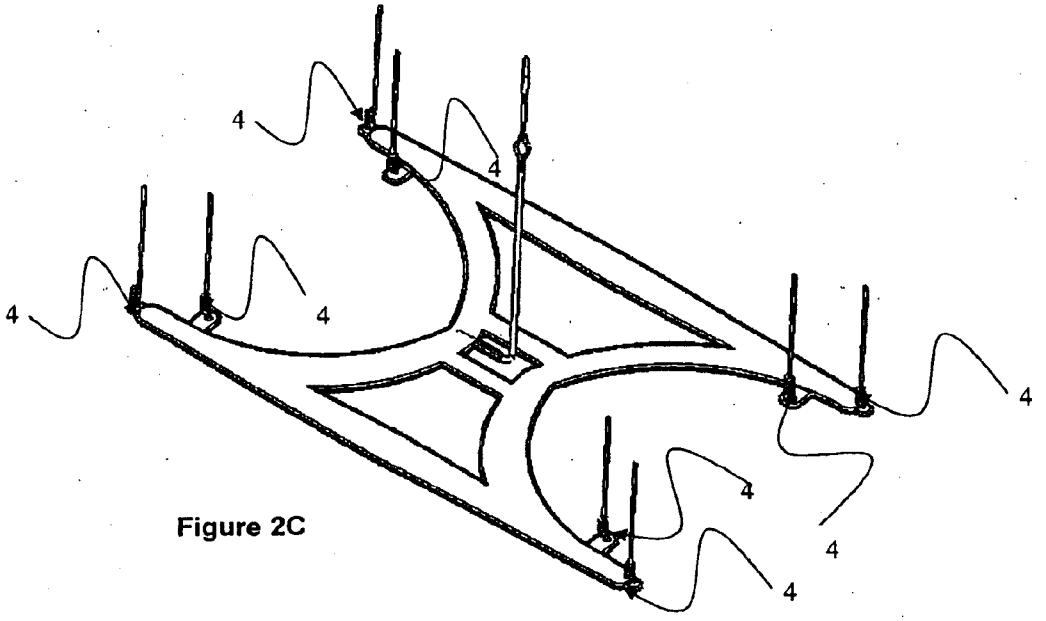


Figure 2C

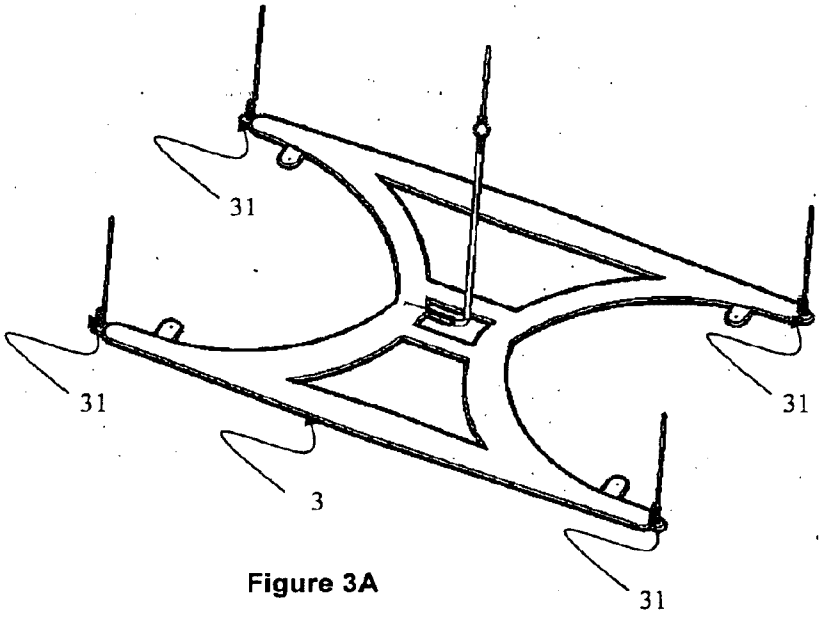


Figure 3A

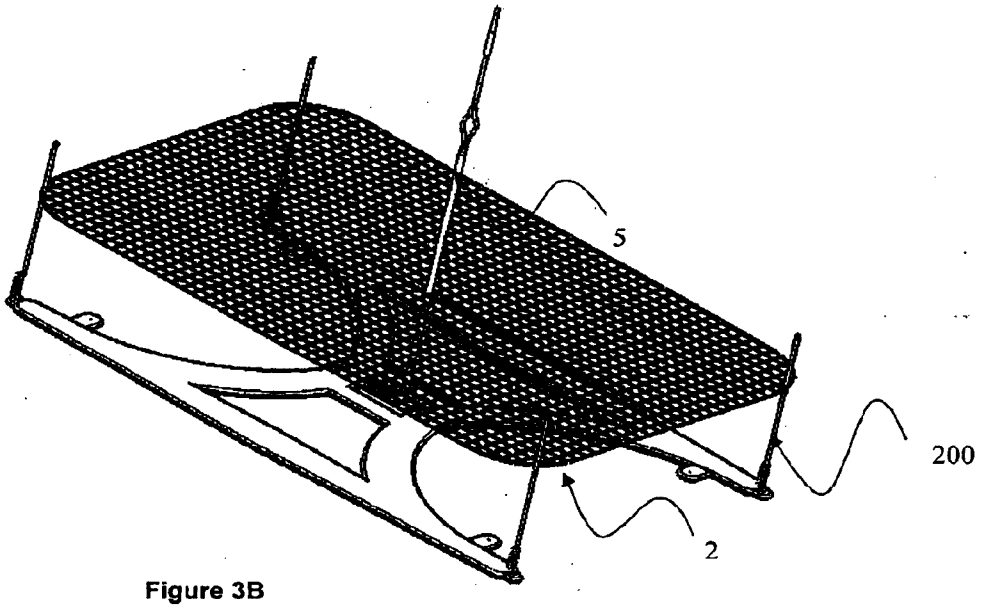


Figure 3B

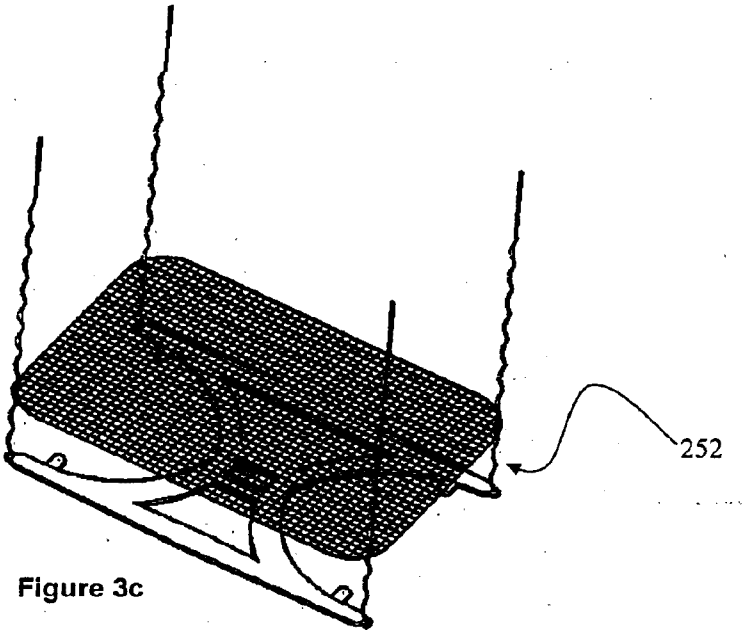


Figure 3c

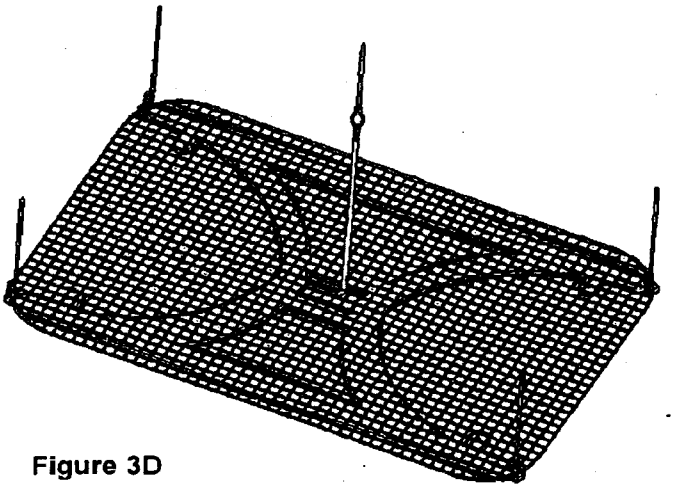


Figure 3D

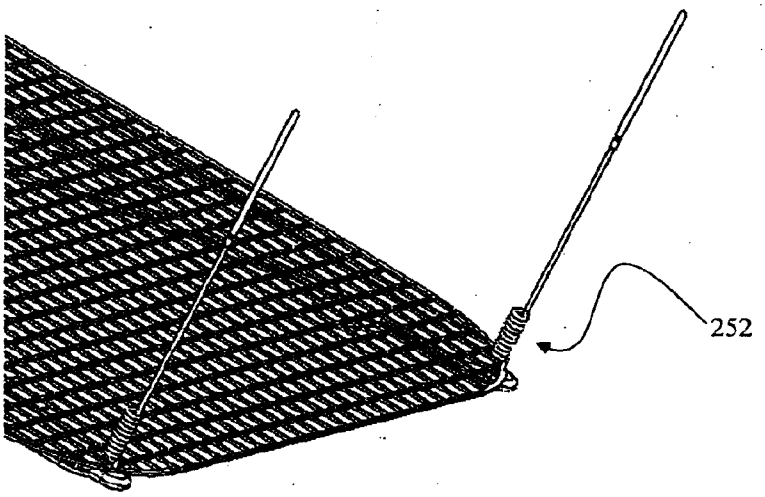


Figure 3E

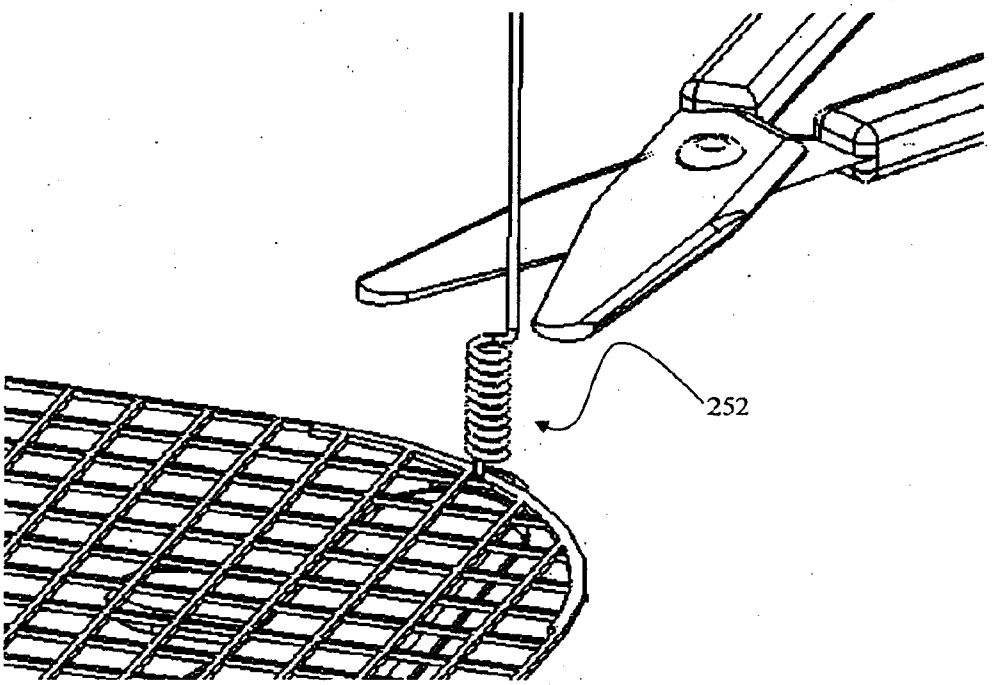


Figure 3F

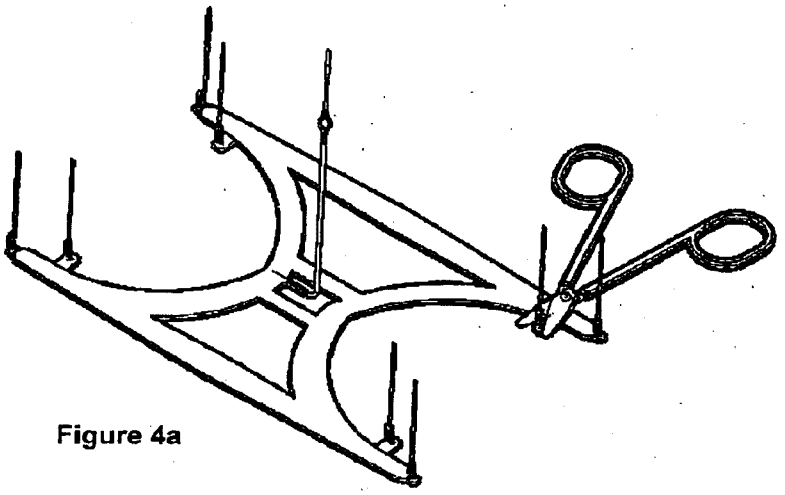


Figure 4a

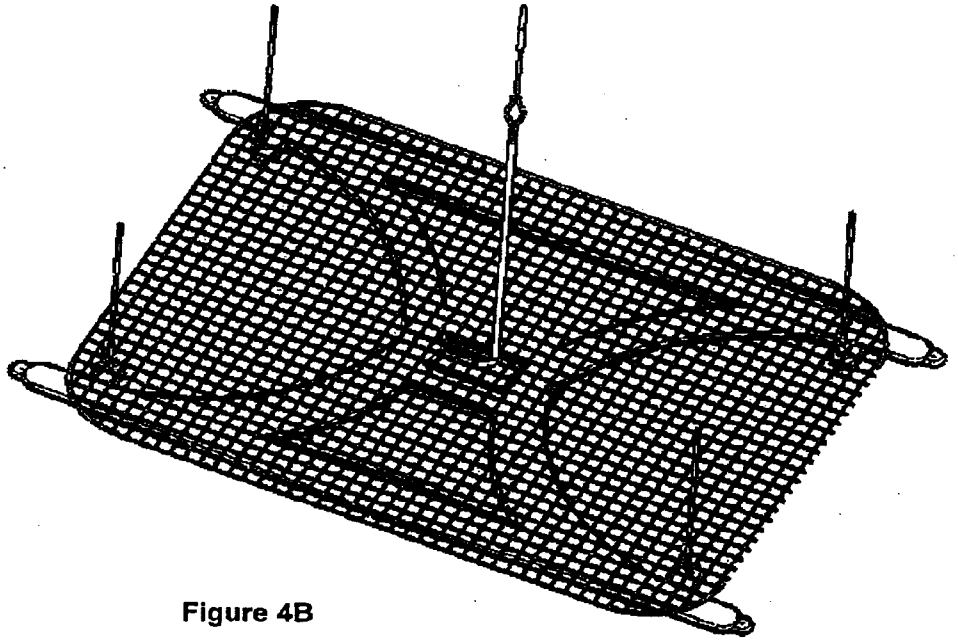


Figure 4B

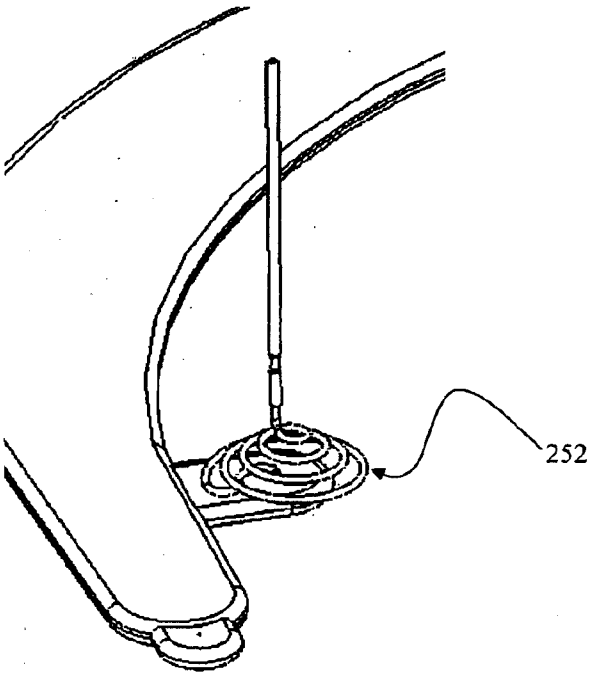


Figure 5A

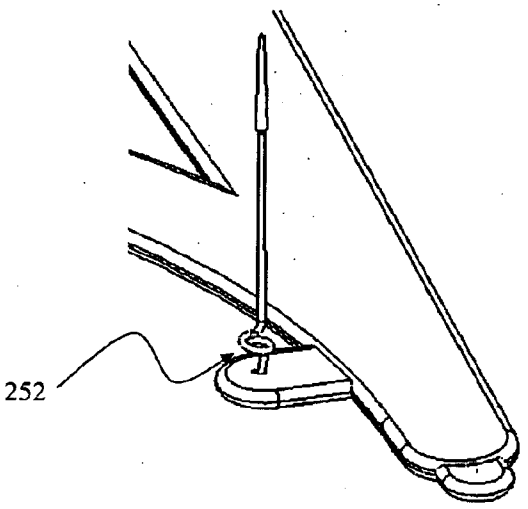


Figure 5B

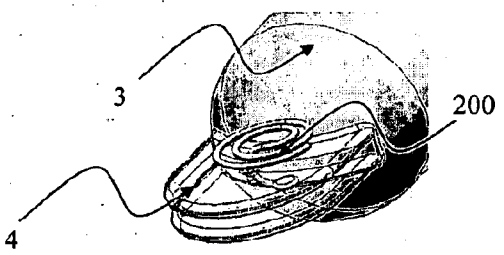


Figure 5D

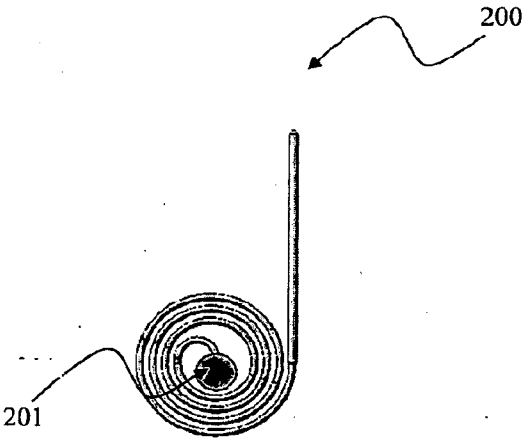


Figure 5C

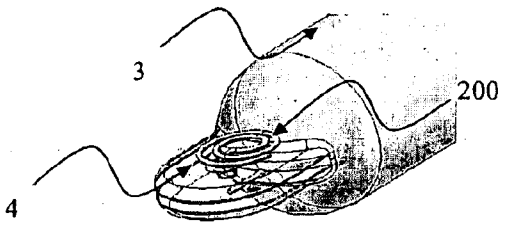


Figure 5F

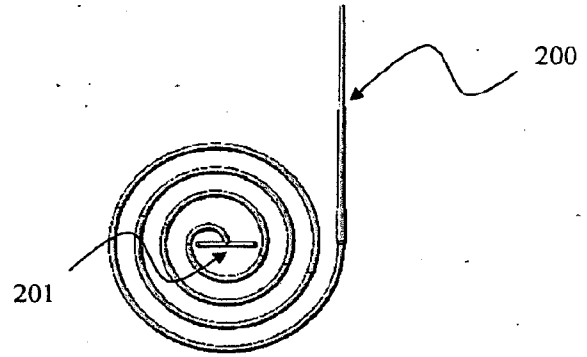


Figure 5E

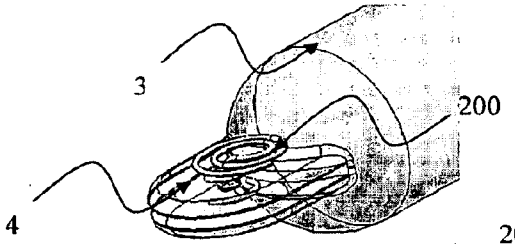


Figure 5H

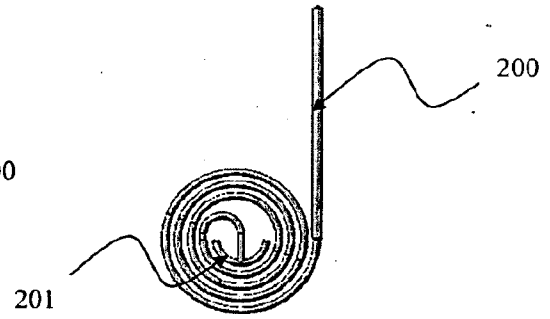


Figure 5G

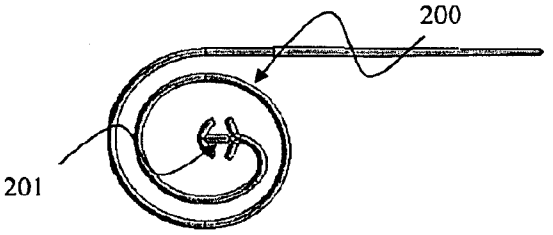


Figure 5I

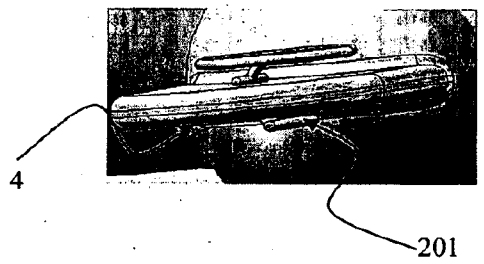


Figure 5K

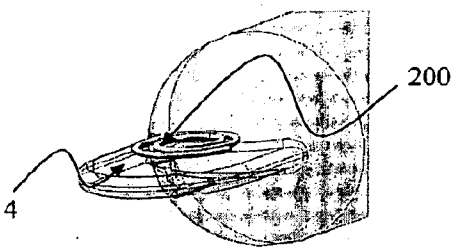


Figure 5J

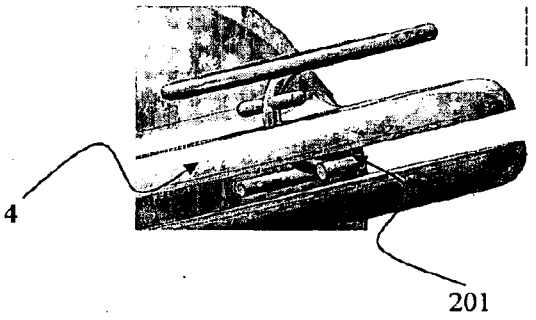


Figure 5L

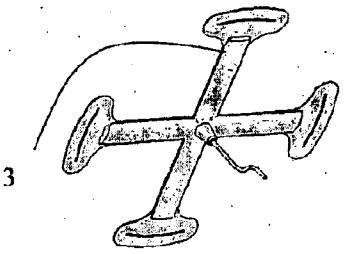


Figure 6A

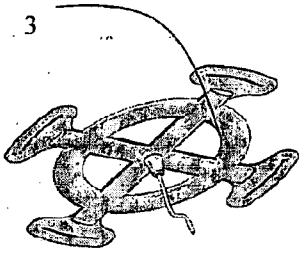


Figure 6B

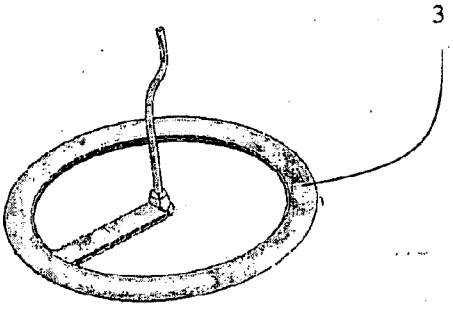


Figure 6C

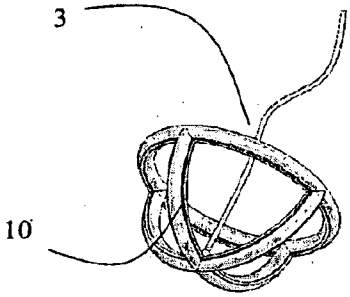


Figure 6D

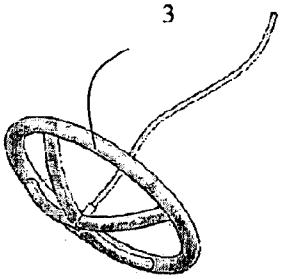


Figure 6E

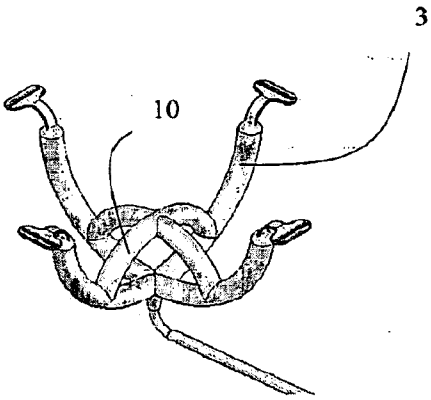


Figure 6F

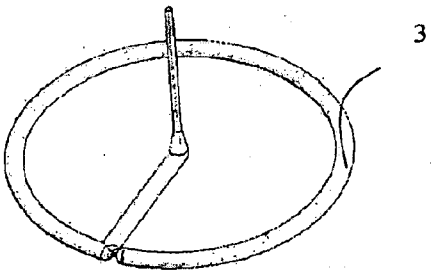


Figure 6G

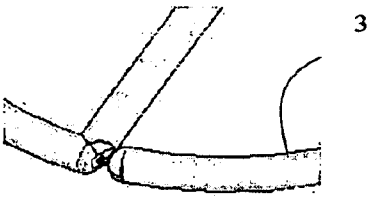


Figure 6H

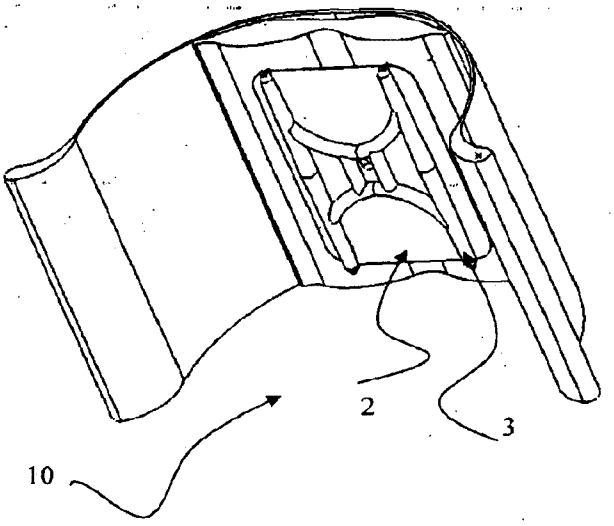


Figure 7

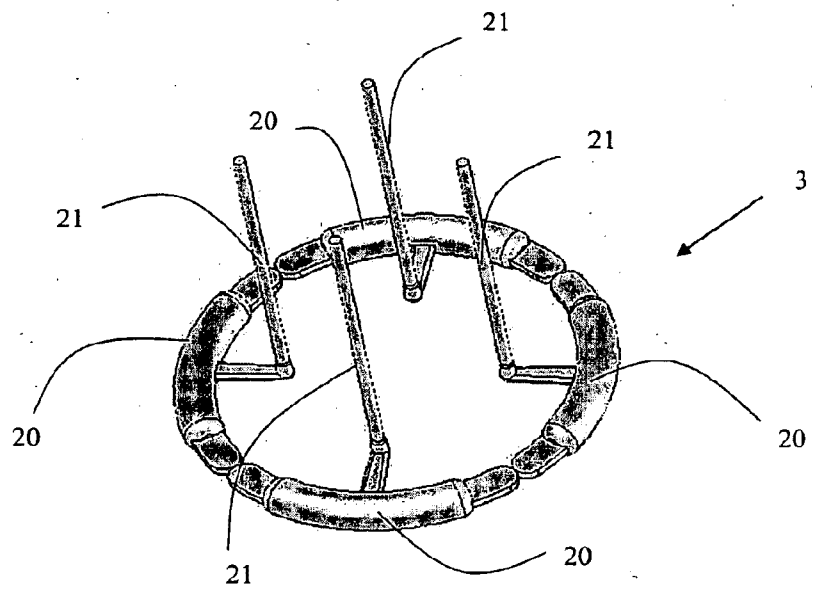


Figure 8A

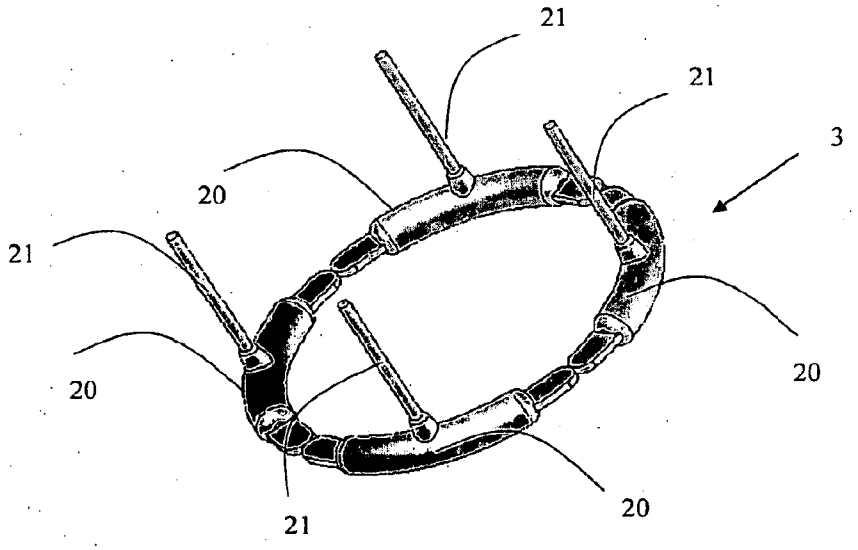


Figure 8B

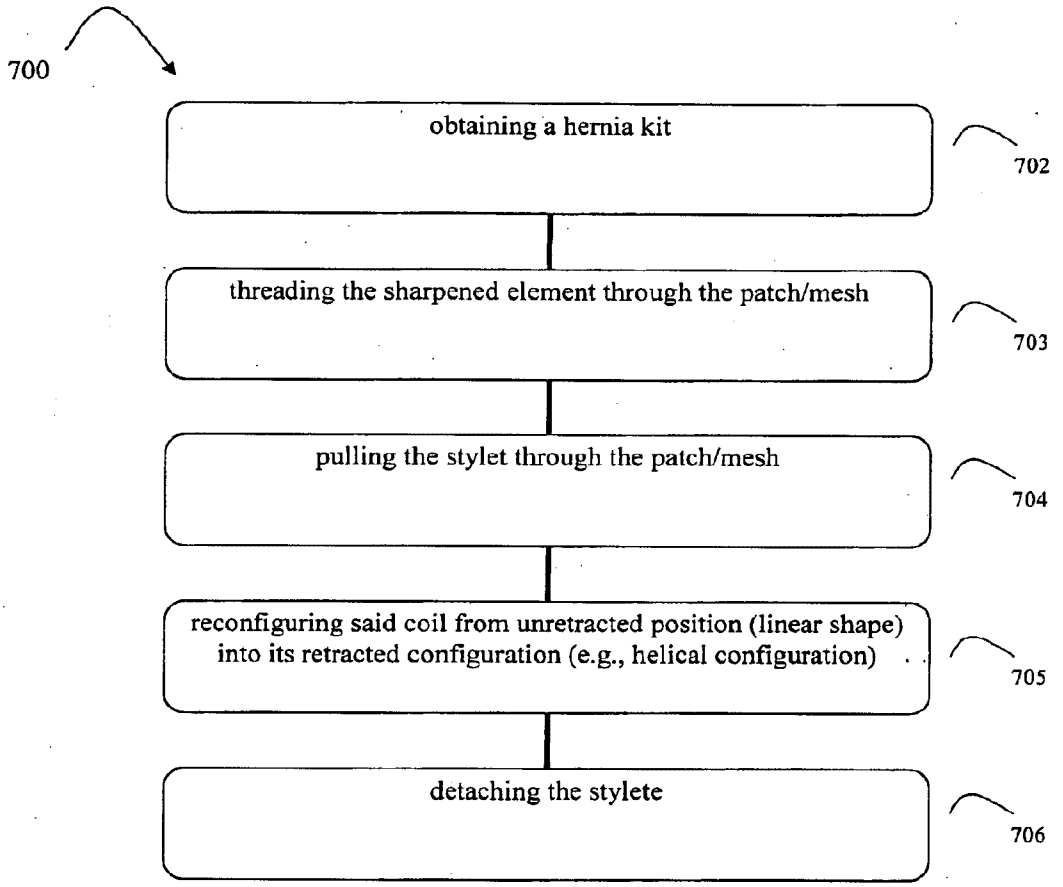

700
obtaining a hernia kit
702
threading the sharpened element through the patch/mesh
703
pulling the stylet through the patch/mesh
704
reconfiguring said coil from unretracted position (linear shape) into its retracted configuration (e.g., helical configuration)
705
detaching the stylete
706

Figure 9A

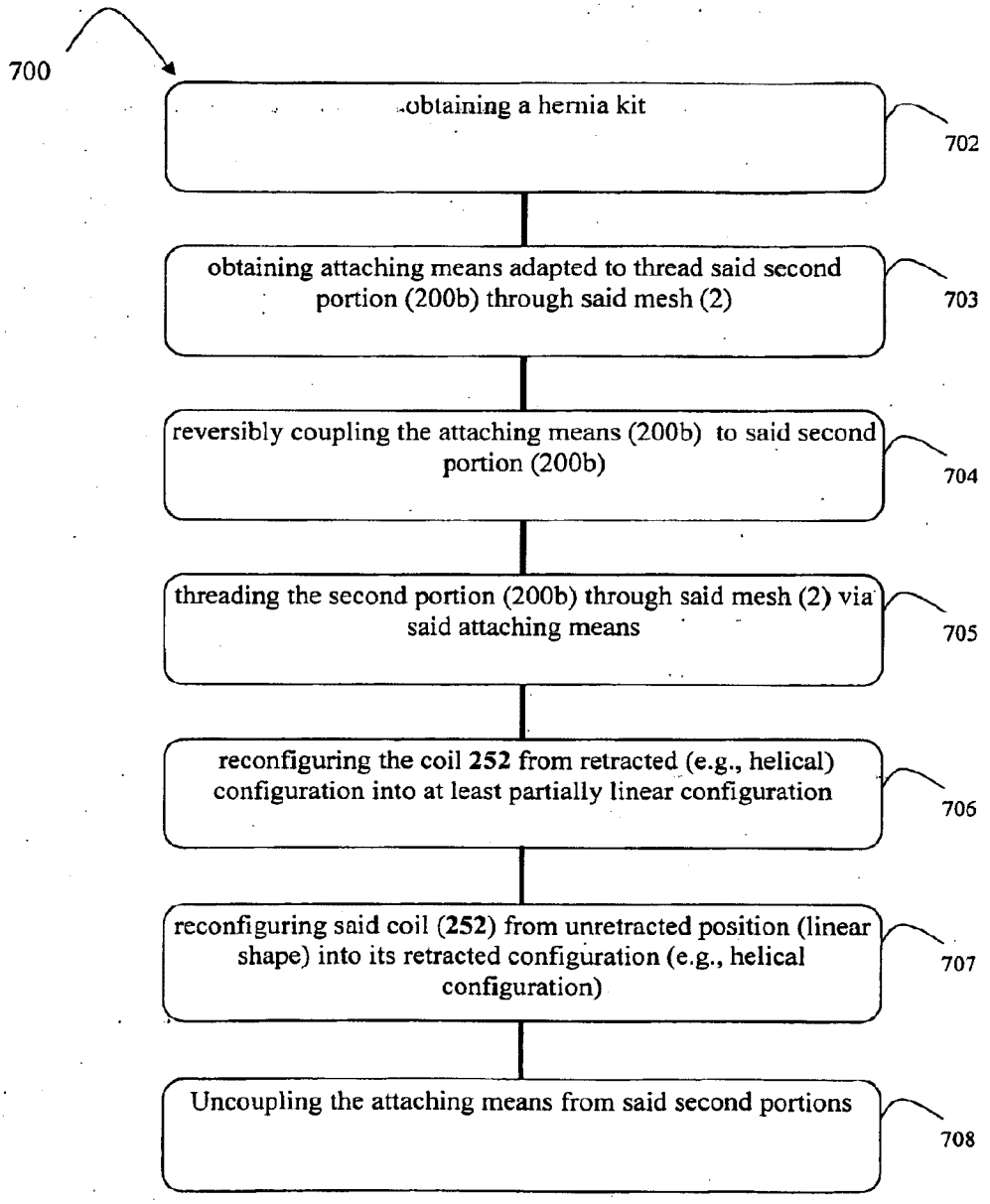

700
obtaining a hernia kit
702
obtaining attaching means adapted to thread said second portion (200b) through said mesh (2)
703
reversibly coupling the attaching means (200b) to said second portion (200b)
704
threading the second portion (200b) through said mesh (2) via said attaching means
705
reconfiguring the coil 252 from retracted (e.g., helical) configuration into at least partially linear configuration
706
reconfiguring said coil (252) from unretracted position (linear shape) into its retracted configuration (e.g., helical configuration)
707
Uncoupling the attaching means from said second portions
708

Figure 9B

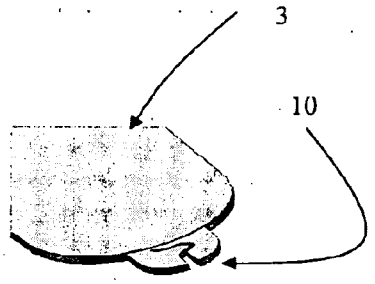


Figure 10A

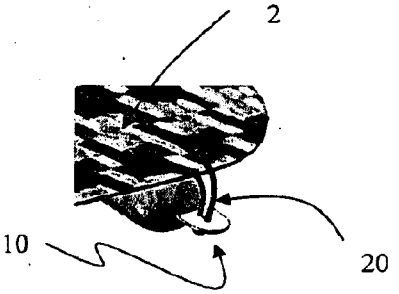


Figure 10B

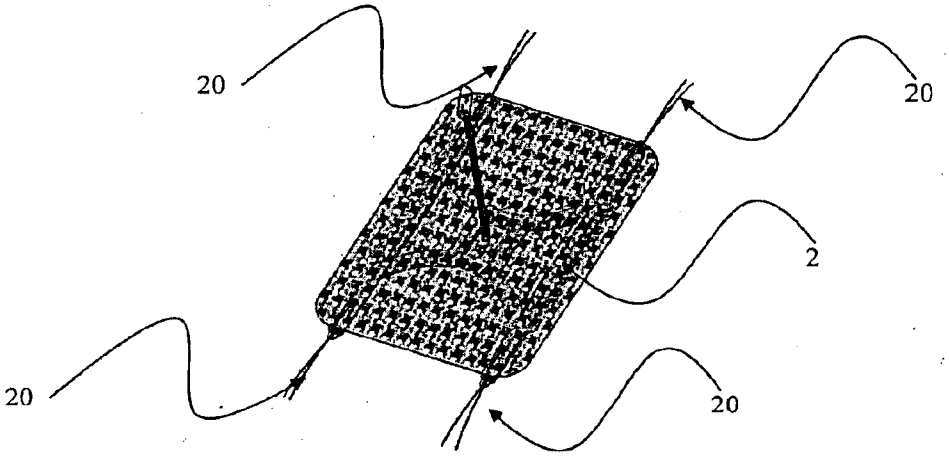


Figure 11

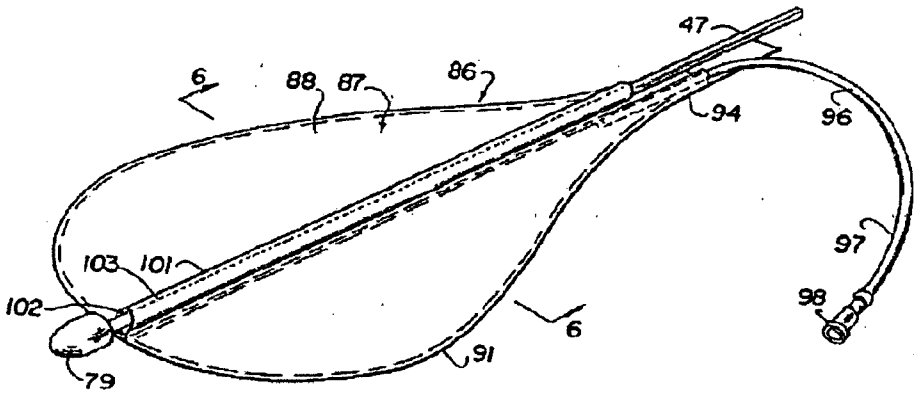


Figure 12A

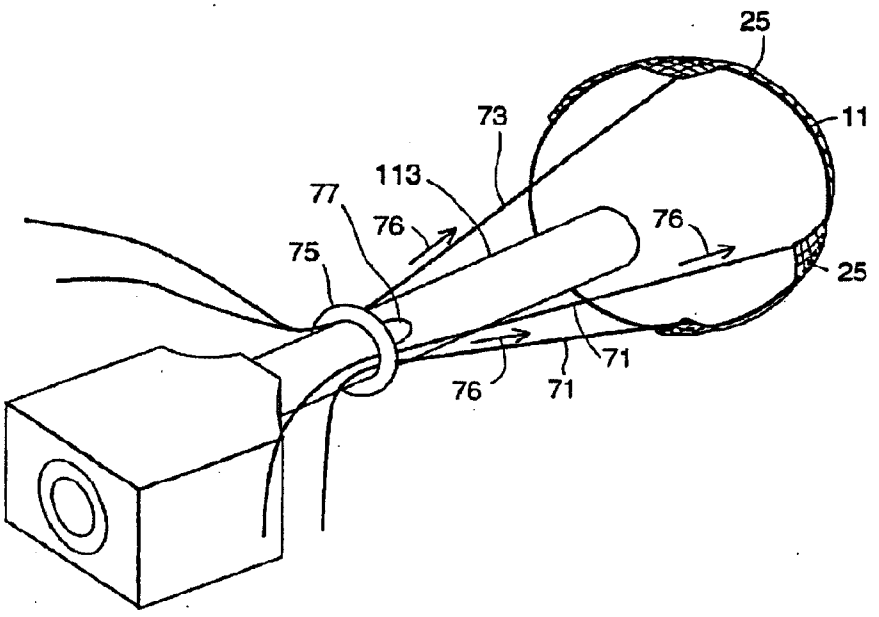


Figure 12B

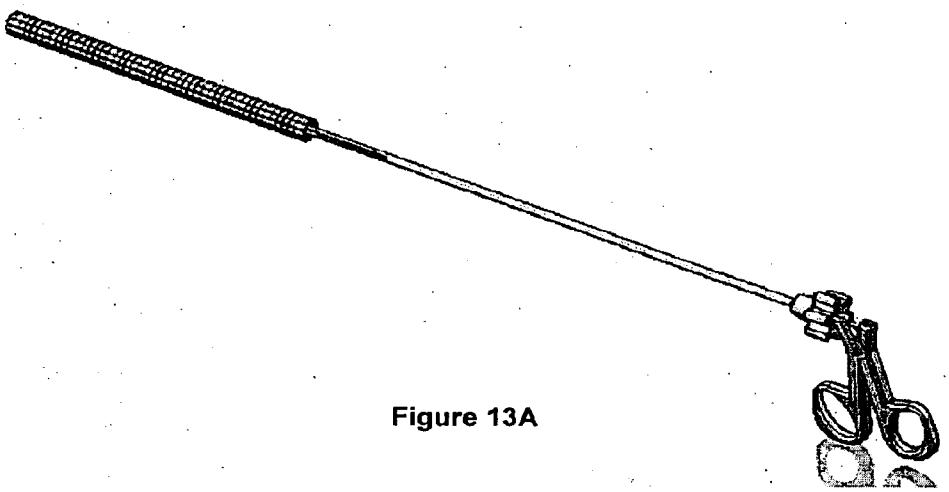


Figure 13A

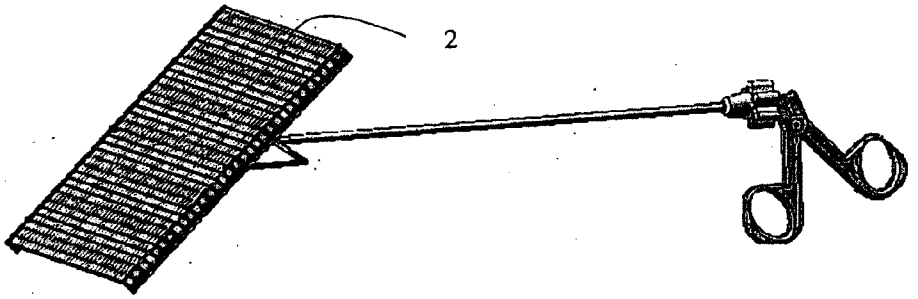


Figure 13B

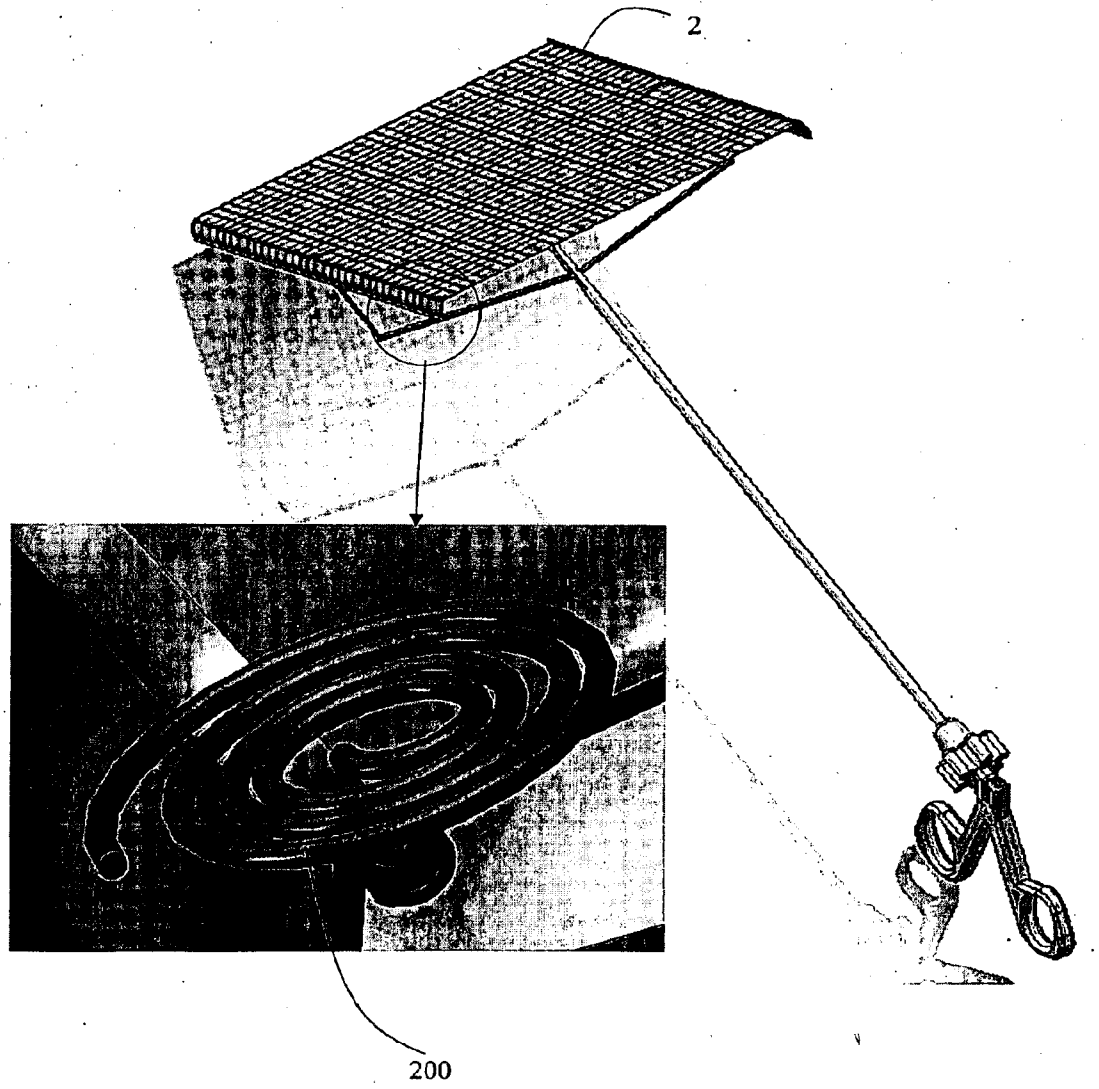
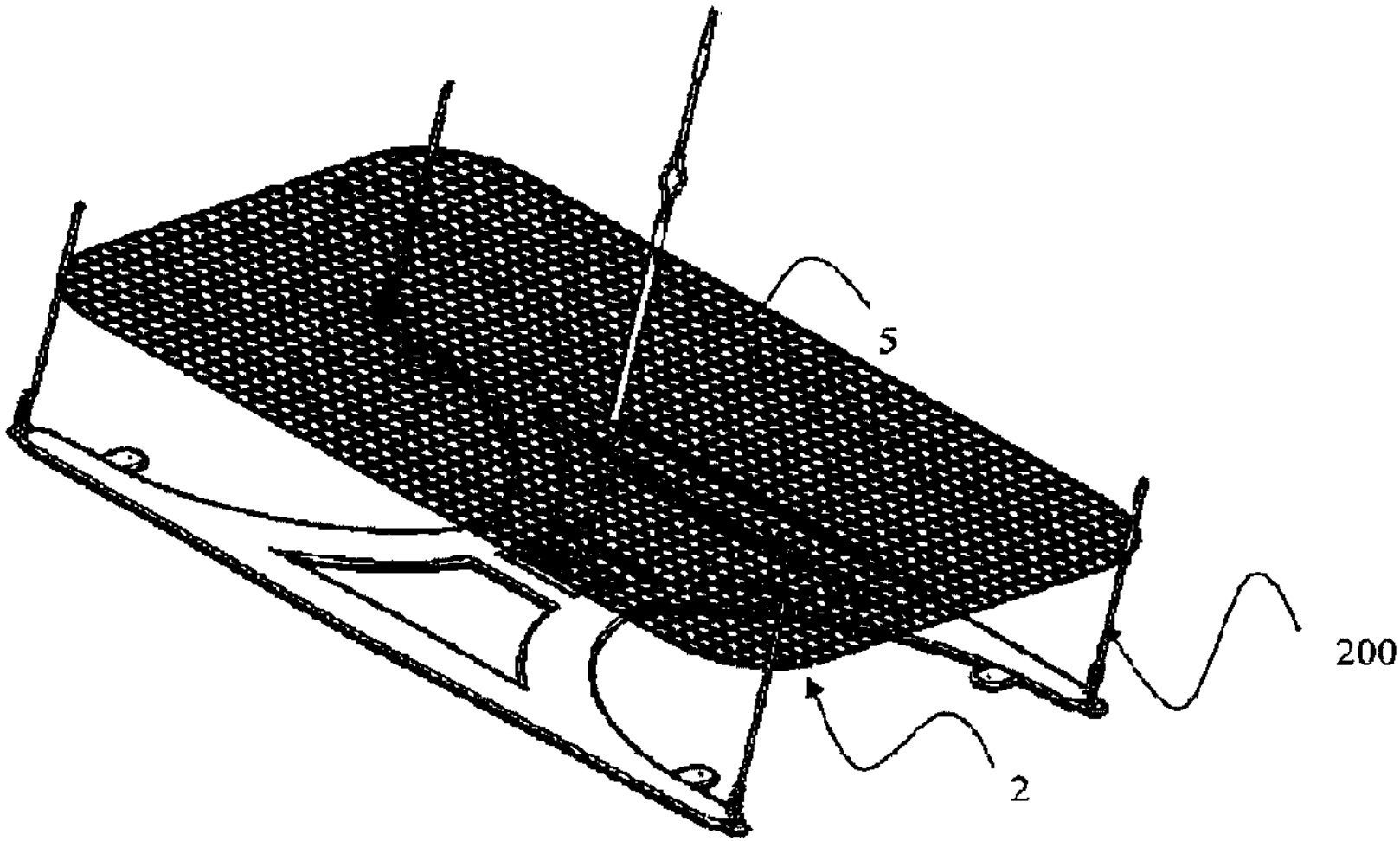


Figure 13C


5
200
2