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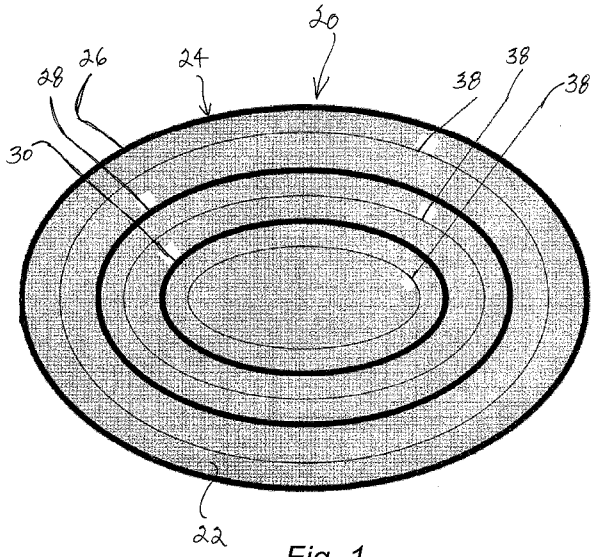

Fig. 1

(57) Abstract: An implantable prosthesis is provided for repairing an anatomical defect, such as a tissue or muscle wall defect. The prosthesis is trimmable to any of one or more predefined configurations. The prosthesis may include one or more predefined or preformed trim regions that define different configurations suitable for particular anatomical regions having different shapes and/or sizes. In the event that the initial prosthesis configuration is undesirable for the particular anatomical region or repair procedure, a surgeon may reconfigure the prosthesis by selectively trimming the prosthesis along a desired trim region to achieve the desired prosthesis configuration suitable for the particular repair. Each trim region may be constructed to provide a finished edge for the selected prosthesis configuration when the repair fabric is trimmed along the trim region. Each trim region may be formed by heat sealing a portion of the prosthesis.

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TRIMMABLE IMPLANTABLE PROSTHESIS

FIELD OF INVENTION

The present invention relates to an implantable prosthesis and, more particularly, to a prosthesis for soft tissue or muscle wall defects.

BACKGROUND

Various prosthetic materials are used to repair and/or reinforce anatomical defects, such as tissue and muscle wall hernias. For example, ventral and inguinal hernias are commonly repaired using a sheet of biocompatible fabric, such as a knitted polypropylene mesh (BARD MESH). Tissue integration with the fabric, such as by tissue ingrowth into the fabric, eventually completes the repair.

A prosthesis or prosthetic material may be pre-shaped with a particular configuration for repairing or reinforcing a defect in a particular anatomical region. Alternatively, a prosthesis or prosthetic material may be shaped by a surgeon during a repair procedure to accommodate or fit the anatomical region of the defect.

A prosthesis or prosthetic material may be provided with a finished edge, such as a selvage edge or sealed edge, that may provide one or more desired characteristics. For example, a finished edge may reduce the roughness of the edge, reduce potential fraying of the edge, and/or reduce adhesions to the edge. For some situations, trimming a prosthesis to fit a particular anatomical region may be undesirable. For example, it may require the removal of the finished edge. Therefore, a medical facility may carry a large inventory of prostheses having different sizes and/or shapes to reduce, if not eliminate, the need for a surgeon to trim a prosthesis when repairing and/or reinforcing defects in particular anatomical regions.

SUMMARY OF INVENTION

The present invention relates to an implantable prosthesis for repairing an anatomical defect, such as a tissue or muscle wall defect.

In one embodiment, the implantable prosthesis comprises a repair fabric adapted to repair the tissue or muscle wall defect. The repair fabric includes an outer periphery with a first finished edge and at least one predefined trim region located inward from the outer periphery. The outer periphery defines a first configuration of the repair fabric. The repair fabric is trimmable along the

at least one trim region to reconfigure the repair fabric to a second configuration. The at least one trim region is adapted to provide a second finished edge for the second configuration of the repair fabric.

In another embodiment, the implantable prosthesis comprises a repair fabric adapted to repair the tissue or muscle wall defect. The repair fabric includes a plurality of predefined trim regions that define a plurality of configurations that are different from each other. The repair fabric is selectively trimmable along any of the trim regions to reconfigure the repair fabric into one of the configurations defined by a corresponding trim region. Each trim region is adapted to provide a finished edge for the configuration of the repair fabric defined by the trim region.

In a further embodiment, the implantable prosthesis comprises a repair fabric adapted to repair the tissue or muscle wall defect, and at least first and second reinforcing members. The repair fabric includes at least first and second predefined trim regions that define first and second configurations for the repair fabric. The repair fabric is trimmable along the first and second trim regions to shape the repair fabric into the first and second configurations. Each trim region is adapted to provide a finished edge for the corresponding configuration of the repair fabric defined by the trim region. The first reinforcing member is located between the first and second trim regions, and the second reinforcing member is located inward of the second trim region.

In another embodiment, a method is provided of repairing a tissue or muscle wall defect. The method comprises an act of providing implantable prosthesis including a repair fabric adapted to repair the tissue or muscle wall defect. The repair fabric includes an outer periphery with a first finished edge and at least one preformed trim region located inward from the outer periphery. The outer periphery defines a first configuration of the repair fabric. The method also comprises an act of reconfiguring the prosthesis to a second configuration by trimming the repair fabric along the at least one trim region to remove an outer portion of the repair fabric. The at least one trim region forms a second finished edge for the second configuration.

BRIEF DESCRIPTION OF DRAWINGS

Various embodiments of the invention will now be described, by way of example, with reference to the accompanying drawings, in which:

FIG. 1 is a top plan view of an implantable prosthesis according to one illustrative embodiment of the present invention;

FIG. 2 is a bottom plan view of the prosthesis of FIG. 1;

FIG. 3 is a cross-sectional view of the outer margin of the prosthesis taken along section line 3-3 of FIG. 2;

FIG. 4 is a top plan view of an implantable prosthesis according to another illustrative embodiment of the present invention; and

FIG. 5 is a cross-sectional view of the prosthesis taken along section line 5-5 of FIG. 4.

DETAILED DESCRIPTION OF INVENTION

An implantable prosthesis is provided for repairing an anatomical defect, such as a tissue or muscle wall defect. The prosthesis may be adapted to promote tissue or muscle ingrowth into the prosthesis and subsequently strengthen the area of the defect.

The prosthesis is trimmable to any of one or more predefined configurations. In this manner, the prosthesis may advantageously replace several prostheses of different sizes and/or shapes. The prosthesis may include one or more predefined or preformed trim regions that define different configurations suitable for particular anatomical regions having different shapes and/or sizes. In the event that the initial prosthesis configuration is undesirable for the particular anatomical region or repair procedure, a surgeon may reconfigure the prosthesis by selectively trimming the prosthesis along a desired trim region to achieve the desired prosthesis configuration suitable for the particular repair.

The prosthesis includes an outer periphery that may define a first configuration for the prosthesis. The outer periphery may include a finished edge, such as a selvage edge or sealed edge, that may reduce the roughness of the edge, reduce potential fraying of the edge, enhance suture retention, and/or reduce tissue adhesion to the edge. Each trim region may be constructed to provide a finished edge for the selected prosthesis configuration when the repair fabric is trimmed along the trim region.

Each trim region may be spaced inward from the outer periphery of the prosthesis so that at least a portion of the outer periphery may be removed to reconfigure the prosthesis. For a prosthesis with multiple trim regions, the trim regions may be arranged with an inner trim region and at least one outer trim region that surrounds the inner trim region. Such an arrangement may be desired to provide a prosthesis that is trimmable to different sizes and/or shapes.

Each trim region may be formed by sealing a portion of the prosthesis. In one embodiment, each trim region may be formed by heat sealing the material of the prosthesis. For example, a portion of the prosthesis may be melted and resolidified to form the trim region. However, other suitable methods may be used to seal the prosthesis to form the trim regions as would be apparent to one of skill in the art.

The prosthesis may be configured to minimize the incidence of postoperative adhesions between a portion of the prosthesis and surrounding tissue or organs. In one embodiment, the prosthesis may include an adhesion resistant barrier that minimizes or eliminates the incidence of postoperative adhesions to one or more selected portions of the prosthesis. However, an adhesion resistant barrier is not required for each embodiment of the invention.

The prosthesis may be configured to strike a balance between being sufficiently rigid to aid in manipulation and deployment in the area of desired coverage and sufficiently flexible to be acceptable to both the surgeon and the patient. In one embodiment, the prosthesis may include one or more reinforcing members that contribute to the stability of the prosthesis, allowing it to remain in a desired shape. Such stability may facilitate deployment and placement of the prosthesis by making it easy to handle. However, a reinforcing member is not required for each embodiment of the invention.

Embodiments of the prosthesis may be particularly suited for the repair of various soft tissue or muscle wall defects, including, but not limited to, inguinal and ventral hernias, chest or abdominal wall reconstruction or large defects, such as those that may occur in obese patients. The prosthesis may include one or more features, each independently or in combination, contributing to such attributes.

FIG. 1 illustrates one embodiment of an implantable prosthesis for repairing soft tissue and wall defects, such as ventral and inguinal hernias, and/or for chest wall reconstruction. The prosthesis 20 includes a repair fabric 22 having a first configuration that may have a particular shape and/or size suitable for one or more repair applications. The repair fabric includes an outer periphery 24 that may be provided with a finished edge 26 to reduce the roughness of the outer periphery, reduce potential fraying of the edge and/or reduce tissue adhesion to the edge.

The prosthesis 20 may be relatively flat and sufficiently pliable to allow a surgeon to manipulate the shape of the implant to conform to the anatomical site of interest and to be sutured, stapled or otherwise attached thereto. The shape and size of the prosthesis, and of the respective

repair fabric 22, may vary according to the surgical application as would be apparent to one of skill in the art. In this regard, it is contemplated that the prosthesis may be preshaped or shaped by the surgeon during the surgical procedure.

The prosthesis may include one or more trim regions that are preformed on the repair fabric 22 and provide additional predefined configurations for the prosthesis that may be desired by a surgeon. The trim regions may define configurations having different sizes and/or shapes relative to the first configuration. Each trim region may also provide a finished edge for the selected prosthesis configuration when the repair fabric is trimmed along the trim region. In this manner, the reconfigured prosthesis will maintain a finished edge along its outer periphery to reduce the roughness of the outer periphery, reduce potential fraying of the edge, enhance suture retention, and/or reduce tissue adhesion to the edge when the repair fabric is trimmed along a trim region.

In the illustrative embodiment shown in FIG. 1, the prosthesis 20 includes a first trim region 28 spaced inwardly from the outer periphery 24 and a second trim region 30 spaced inwardly from the first trim region 28. As shown, each trim region 28, 30 may be shaped similar to the outer periphery 24 so that trimming the prosthesis along one of the trim regions results in a reconfigured prosthesis having a second configuration with a shape similar to, but smaller than, the first configuration. The trim regions 28, 30 also be arranged in a concentric manner, as shown, although such an arrangement is not required for each embodiment of the prosthesis.

Although the prosthesis is illustrated as having two trim regions 28, 30, it is to be appreciated that the prosthesis may be provided with any number of preformed trim regions as would be apparent to one of skill in the art. For example, the prosthesis may include one trim region or more than two trim regions. It is also to be understood that the trim regions may be configured with shapes that are different from the outer periphery and/or each other.

The repair fabric 22 may include one or more layers of biocompatible material suitable for soft tissue repair. In one embodiment, the repair fabric 22 includes at least one layer of tissue infiltratable material. The repair fabric 22 may be formed of a biologically compatible, flexible material that includes a plurality of interstices or openings which allow sufficient tissue ingrowth to secure the prosthesis to host tissue after implantation. In one embodiment, the repair fabric includes a layer of mesh material that is conducive to tissue ingrowth.

The finished edge 26 along the outer periphery 24 and the trim regions 28, 30 may be formed by altering the repair fabric. These features may be formed by sealing regions of the fabric

22 corresponding to the finished edge and trim regions. In one embodiment, the finished edge 26 and the trim regions 28, 30 may be formed by heat sealing portions of the repair fabric. However, it is to be understood that other processes may be employed for sealing regions of the fabric as would be apparent to one of skill in the art. For example, the fabric 22 may be sealed using ultrasonic, induction, vibration, infrared/laser welding and the like, adhesive sealing or chemical sealing. Other contemplated processes may include impregnating or otherwise occluding interstices or openings of the repair fabric along the outer margin and desired trim regions with a biocompatible material, such as silicone, polyethylene, polypropylene, urethane and the like.

In one illustrative embodiment, the finished edge 26 and the trim regions 28, 30 may be formed by melting one or more rings of a mesh fabric 22 in one or more desired configurations for the prosthesis. This may be accomplished by placing a sheet of the mesh fabric in a fixture and heat sealing desired regions of the layer using a heated die configured with the desired shape of the finished edge and the trim regions of the prosthesis. The melted rings may be formed by applying heat to the fabric at a temperature range of approximately 320° F to 400° F for a period of approximately 3 to 5 seconds.

The repair fabric 22 may be configured to have any suitable shape that is conducive to facilitating the repair of a particular defect. In the illustrative embodiment shown in FIG. 1, the initial prosthesis configuration and the trim region configurations have a generally elliptical or oval shape. Examples of other shapes include, but are not limited to, circular, square and rectangular shapes. It is also to be understood that the trim regions may have different configurations relative to the finished edge and each other.

In one embodiment, the repair fabric 22 is formed of a sheet of knitted polypropylene monofilament mesh fabric such as BARD MESH available from C.R. Bard, Inc. When implanted, the polypropylene mesh promotes rapid tissue or muscle ingrowth into and around the mesh structure. Alternatively, other surgical materials which are suitable for tissue or muscle reinforcement and defect correction may be utilized including SOFT TISSUE PATCH (microporous ePTFE – available from W.L. Gore & Associates, Inc.); SURGIPRO (available from US Surgical, Inc.); TRELEX (available from Meadox Medical); PROLENE and MERSILENE (available from Ethicon, Inc.); and other mesh materials (e.g., available from Atrium Medical Corporation). Absorbable materials, including polyglactin (VICRYL -- available from Ethicon, Inc.) and polyglycolic acid (DEXON -- available from US Surgical, Inc.), may be suitable for

applications involving temporary correction of tissue or muscle defects. Collagen materials such as COOK SURGISIS, available from Cook Biomedical, Inc. may also be used. It also is contemplated that the mesh fabric may be formed from multifilament yarns and that any suitable method, such as knitting, weaving, braiding, molding and the like, may be employed to form the prosthetic mesh material.

In an exemplary embodiment, the prosthesis 20 includes an approximately .027 inch thick sheet 22 of BARD MESH knitted from polypropylene monofilament with a diameter of approximately 0.006 inches. The width of the heat seal forming the finished edge and trim regions may have a width of approximately 5-15 mm.

As indicated above, the prosthesis 20 may have a generally elliptical or oval shape that may be configured to have any desired size. In one embodiment, the prosthesis, as measured generally along the major and minor axes of the ellipse or oval, may have an untrimmed size of approximately 14 inches by 10 inches. A first trimmed configuration of the prosthesis, resulting from being trimmed along the first or outer trim region 28, may have a size of approximately 10 inches by 8 inches. A second trimmed configuration of the prosthesis, resulting from being trimmed along the second or inner trim region 30, may have a size of approximately 8 inches by 6 inches. It should be understood, however, that the materials and dimensions described are merely exemplary and that any suitable sizes and shapes may be employed for the prosthesis.

For certain procedures, such as in the correction of ventral hernias or in the reconstruction of chest or abdominal walls, the repair fabric may come into contact with tissue, muscle or organs, which is not intended to grow into the prosthesis. Such contact could potentially lead to undesirable postoperative adhesions between the repair fabric and the surrounding tissue, muscle or organs. To minimize or eliminate the incidence of postoperative adhesions to selected portions of the prosthesis, if desired, the prosthesis may include a tissue, muscle or organ adhesion resistant barrier layer overlying at least a portion, and preferably all, of one side of the repair fabric 22.

In one illustrative embodiment shown in FIG. 2, a barrier layer 32 is attached to one side of the repair fabric. The prosthesis 20 is to be positioned in a patient such that the barrier layer 32 faces the region of potential undesired adhesion, such as the abdominal viscera (e.g., intestines) or the thoracic viscera (e.g., heart or lungs). The barrier layer 32 may be formed of a material and/or with a structure that does not substantially stimulate and in fact resists tissue, muscle or organ ingrowth and adhesion formation when implanted, thereby limiting or completely eliminating the

incidence of undesired postoperative adhesions between the repair fabric and adjacent tissue, muscle or organs.

As illustrated in FIGS. 2-3, the barrier layer 32 may cover the entire surface of a first side 34 of the repair fabric 22. This particular configuration allows tissue ingrowth to a second side 36 of the repair fabric while inhibiting adhesions to tissue and organs located opposite the anatomical defect site. It is to be appreciated, however, that the barrier layer 32 may be configured to cover only selected portions of the first side of the fabric 22 to enhance tissue ingrowth from both sides of the fabric in those portions free of the barrier layer.

In some instances, it may be desirable to employ a finished edge and trim regions that are also adhesion resistant to adjacent tissue and organs. In one illustrative embodiment, the repair fabric 22 may be altered so as to substantially eliminate tissue infiltratable interstices or openings along its outer margin and the desired trim regions, thereby creating a finished edge and trim regions which inhibit tissue ingrowth to those regions of the fabric.

As indicated above, a margin along the outer periphery 24 and inner regions of the repair fabric 22 may be melted to seal the fabric material and form the finished edge 26 and the trim regions 28, 30 that act as an outer peripheral barrier for the selected configuration. The barrier layer 32 may be configured, such as with submicronal sized pores, so that a portion of the melted fabric material becomes fused to the barrier layer 32. In this arrangement, the finished edge 26 and the trim regions 28, 30 may act to increase the stiffness of the outer margin and inner areas of the barrier layer, such that the outer edge or trimmed edge of the barrier layer may become more resistant to being inadvertently folded back. Additionally, the outer margin of the barrier layer may tend to soften and thereby reduce the brittleness of the peripheral barrier.

As shown in FIG. 3, the finished edge 26 may be configured to decrease in thickness in an outward direction toward the outer periphery of the prosthesis. In one embodiment, the finished edge 26 has a tapered shape resulting in a low profile edge relative to the rest of the prosthesis that may enhance the adhesion resistance of the finished edge. The tapered shape may also provide the prosthesis with a relatively flexible, adhesion resistant outer margin. It is to be understood, however, that any suitable shape may be employed for the finished edge and trim regions as would be apparent to one of skill in the art. For example, the finished edge and trim regions may be formed with a stepped configuration, with a non-uniform taper, or with a constant thickness.

In one embodiment, the barrier layer 32, if employed, may be formed from a sheet of expanded polytetrafluoroethylene (ePTFE) having fibril lengths--also referred to as pore size or internodal distance--that will not permit significant tissue ingrowth. In one embodiment, the fibril lengths of the ePTFE are less than 5 microns. In another embodiment, the fibril lengths of the ePTFE are less than 1 micron and in still another embodiment, the fibril lengths are less than 0.5 microns. Examples of other suitable materials for forming the barrier layer 36 include FLUORO-TEX Pericardial and Peritoneum Surgical Membrane and FLUORO-TEX Dura Substitute available from C. R. Bard, and PRECLUDE Pericardial Membrane, PRECLUDE Peritoneal Membrane and PRECLUDE Dura Substitute membrane available from W. L. Gore & Associates, Inc.

A representative and non-limiting sampling of other suitable micro to non-porous materials includes silicone elastomer, such as SILASTIC Rx Medical Grade Sheeting (Platinum Cured) distributed by Dow Corning Corporation, and microporous polypropylene sheeting (available from Celgard, Inc.) and film. Autogenous, heterogenous and xenogeneic tissue also are contemplated including, for example, pericardium and small intestine submucosa. Absorbable materials, such as SEPRAFILM available from Genzyme Corporation and oxidized, regenerated cellulose (Intercede (TC7)) may be employed for some applications. It is to be appreciated that other suitable biocompatible adhesion resistant materials also may be used.

In the illustrative embodiment described above, the repair fabric 22 and the barrier layer 32 may be integrally connected with one or more connecting stitches 38. As shown in FIGS. 1-2, multiple series of stitches 38 may be formed in a concentric pattern that follows the shape of the outer periphery 24 and trim regions 28, 30. Stitching may allow total tissue infiltration to the fabric while providing a strong connection between the fabric 22 and the barrier layer 32. The concentric pattern also maintains composite integrity by preventing the barrier 32 and underlying fabric 22 from separating should the prosthesis be trimmed by the surgeon to match a particular size and shape of the repair site. Any suitable pattern, however, may be employed so as to minimize separation of the fabric and the barrier layer.

Where stitches are employed to attach the repair fabric 22 to the barrier layer 32, to further minimize adhesions, the stitches may be formed from a non-porous, adhesion resistant material. In one embodiment, the stitches 38 are formed with a polytetrafluoroethylene (PTFE) monofilament. PTFE stitches may provide a softer, more flexible prosthesis that is easier to manipulate as compared to a prosthesis using other stitch materials, such as polypropylene monofilament. PTFE

monofilament also facilitates the manufacturing process due to the low friction characteristics of the material. Additionally, PTFE stitches may tend to be more adhesion resistant than other materials. Nevertheless, it should be understood that any suitable material, such as polypropylene monofilament, may be employed for the stitches.

The barrier layer 32 may be stitched to the repair fabric 22 by positioning the barrier material on the fabric to face the sewing needle so that the locking portion of each stitch is formed on the fabric side of the composite rather than on the barrier side to reduce the incidence of localized adhesions with tissue and organs. The stitches may be formed using a #10 ball-tipped needle to reduce the potential incidence of tissue ingrowth through the stitch holes. The sheets of fabric and barrier material may be held by a frame during the sewing procedure on a computer controlled table that has been programmed with the desired stitch pattern.

Any other suitable fastening technique and material may be employed to attach the barrier layer 32 to the repair fabric 22. For example, the barrier layer 32 may be bonded to the fabric 22 using an adhesive dispensed in a desired pattern, such as a spiral pattern, a serpentine pattern or a grid-like pattern of dots or beads, that maintains a sufficient quantity of open or non-impregnated interstices for tissue infiltration. Alternatively, the barrier layer 32 may be laminated or heat fused to the fabric 22 by a combination of heat and pressure. This lamination technique may be enhanced by a second layer of fabric such as is described in U.S. Patent No. 6,120,539 which is also assigned to C.R. Bard, Inc., the assignee of the present application, and is incorporated herein by reference. The barrier may also be insert molded to the fabric using any suitable molding process.

In one embodiment, the barrier layer, if desired, may be formed of an approximately .006 to .008 inch thick sheet of ePTFE attached to the mesh using approximately 3mm to 4mm long stitches formed of a 0.008 inch to 0.012 inch diameter PTFE monofilament. It should be understood, however, that these dimensions are merely exemplary and that any suitable sizes and shapes may be employed for the prosthesis.

Although one embodiment described above may include a barrier layer, the present invention is not limited in this respect. Thus, other embodiments may or may not include the adhesion resistant barrier layer and/or an adhesion resistant finished edge and trim regions.

In some instances, such as (but not limited to) the correction of relatively large defects, it may be desirable to employ a prosthesis that is sufficiently rigid so that it can be easily and effectively manipulated and positioned in the desired area yet sufficiently flexible so that the

prosthesis is adequately tolerated by both the physician implanting the prosthesis and the patient receiving the prosthesis. The prosthesis should conform to the shape of the area being covered and should be sufficiently rigid such that the edges do not excessively curl. To balance the stiffness and flexibility, the prosthesis 20 may include one or more reinforcing members, which may also be referred to as support or stiffening members.

In one illustrative embodiment shown in FIG. 4, the prosthesis 20 may include a first support or reinforcing member 40, a separate second support or reinforcing member 42 inwardly spaced from the first reinforcing member 40 and a separate third support or reinforcing member 44 inwardly spaced from the second reinforcing member 42. The support or reinforcing members may be coupled to the repair fabric 22 in any suitable manner, as will be described in more detail below.

The reinforcing members contribute to the stability of the prosthesis, allowing it to remain in a desired shape. For example, the reinforcing members aid in allowing the prosthesis to remain substantially planar. This stability facilitates deployment and placement of the prosthesis by making it easy to handle. Also, the stability minimizes the tendency of the prosthesis to sag, fold, bend or otherwise become dislocated. The reinforcing members may be resilient so that they can be collapsed or deformed from an expanded configuration to facilitate delivery of the prosthesis to a surgical site and then return to their expanded configuration to facilitate handling and support of the prosthesis at the surgical site. Difficulty in handling or dislocation or bending could require additional operative procedures and/or additional anchoring during implantation. During implantation of the prosthesis, sutures may be passed around one or more of the reinforcing members to maintain the prosthesis in generally the desired configuration and location.

In one embodiment, each reinforcing member 40, 42, 44 is substantially continuous and surrounds a portion of the prosthesis to reinforce at least that portion. In the illustrative embodiment, each reinforcing member is spaced inwardly of one of the finished edge and the trim regions. However, it should be appreciated that the present invention is not limited in this respect, as each reinforcing member may be disposed at the respective finished edge and trim region.

As shown, the first reinforcing member 40 is located inwardly of the finished edge 26 and may be employed to reinforce the outer area of the prosthesis. The second reinforcing member 42 is disposed inwardly of the first trim region 28 and may be employed to reinforce a middle area of the prosthesis. The third reinforcing member 44 is disposed inwardly of the second trim region 30 and may be employed to reinforce an inner area of the prosthesis.

In one embodiment, each support or reinforcing member 51 may be formed of a resorbable material. The resorbable reinforcing members facilitate initial handling and deployment of the prosthesis. Thereafter, each reinforcing member will gradually degrade until it is completely resorbed by the body. Such an arrangement may be advantageous in that each reinforcing member is eventually resorbed by the body after it is no longer needed to facilitate the handling and deployment of the prosthesis.

In one embodiment, the reinforcing members are formed from a polydioxonane (PDO) monofilament having a diameter of approximately 0.038 inches. However, it is contemplated that the reinforcing members may be formed of any biocompatible, resorbable or non-resorbable material, such as PET, including monofilaments, multifilaments or molded shapes, provided suitable stiffness and handling properties are maintained. It should be appreciated that the reinforcing members (or the individual filaments or bands collectively forming the reinforcing member) may have any suitable cross-sectional size and shape, such as circular, square, rectangular, triangular, elliptical, etc.

In one illustrative embodiment, the prosthesis employs reinforcing members 40, 42, 44 that are configured in the shape of a ring. However, the reinforcing members may be configured in any pattern, such as a spiral pattern, a square pattern, an elliptical pattern, a circular pattern or the like. In one embodiment as shown, the reinforcing members include a continuous, uninterrupted ring. The ring may be formed by joining the end portions of a length of material, such as a monofilament. However, it should be appreciated that the reinforcing member may be formed of one or more discrete, discontinuous segments, arranged in any configuration that may impart suitable stiffness and handling to the prosthesis.

In the embodiment shown, the reinforcing members are arranged in a concentric pattern. However, it should be appreciated that the invention is not limited in this respect as other suitable arrangements may be employed.

The reinforcing members may be positioned on the prosthesis such that at least one of the members will generally align with the edges of the defect when the prosthesis is implanted. In this manner, during implantation, sutures may be passed around or near the reinforcing member, and used to provisionally attach corresponding area of the prosthesis to the tissue or muscle near the edges of the defect. Also, sutures may be passed around or near one or more of other reinforcing

members that have not been removed from the prosthesis so that other areas of the prosthesis may also be provisionally attached to the tissue or muscle.

The reinforcing members 40, 42, 44 may be supported on the prosthesis in any suitable manner as the present invention is not limited in this respect. In one embodiment illustrated in FIG. 5, the reinforcing members may be sandwiched between two layers of material, which may include either two tissue ingrowth layers 22a, 22b or a tissue ingrowth layer 22 and a barrier layer 32, and may or may not be physically attached thereto. The reinforcing members may be tightly or loosely held within channels 46 formed by the attachment of the layers at attachment lines 48, such as stitch lines.

A single stitch line 48 formed by sewing threads typically is stitched at least along the outside or inside edge of each reinforcing member to keep them from moving with respect to the layers. Because of the rigidity of the reinforcing members, one stitch line placed along only one side of each reinforcing member may be sufficient to hold each reinforcing member in place. However, it may be desirable to employ two stitch lines 48, one on each side of a reinforcing member, to hold each reinforcing member in place by forming the channels 46 in which they reside. The stitches may extend through both layers 22a, 22b of material, although it may be desirable to avoid penetrating through a barrier layer 32, if it is present. Another advantage is that the reinforcing members, if stitched or bonded to one or more layers, may hold the layers together in a manner to prevent billowing of the layers with respect to each other.

Alternatively, the reinforcing members 40, 42, 44 may overlie or underlie the ingrowth layer 22 and may be attached, regardless of location, with stitches or a bonding agent, or fused by ultrasonic, induction, vibration, infrared/laser welding and the like. Alternatively, the reinforcing members may be woven through at least one of the ingrowth layers 22a, 22b or integrally formed with the ingrowth layer as the layer is being fabricated. In instances where a barrier layer 32 is employed, it may be desirable to avoid positioning the reinforcing members under the barrier layer or protrude therethrough, as doing so may result in undesirable adhesions forming on the reinforcing members.

Although the reinforcing members 40, 42, 44 are described as being formed of a monofilament, other suitable constructions may be employed. For example, the reinforcing members may be molded elements that are subsequently attached to the prosthesis or molded onto the prosthesis. An example includes the ring shown in U.S. Patent No. 5,695,525 which is

incorporated herein by reference. If desired, the finished edge and trim regions may be formed in a manner that also act as reinforcing members for the prosthesis. In another example, the reinforcing members may be formed of multiple stitches passing through one or more layers, such as, for example, an embroidered section. Alternatively, the reinforcing members may be formed by altering the weave pattern in the zone of desired reinforcement. In this manner, the area of the repair fabric where tissue ingrowth is desired is formed with a relatively loose or open weave whereas the area or zone of reinforcement is formed with a relatively tight weave to provide the desired rigidity. Other suitable methods or mechanisms to form the reinforcing members may be employed, as the present invention is not limited in this respect.

To aid in positioning and/or provisionally attaching the prosthesis, the prosthesis may include at least one pocket. In this manner, a surgeon may use the pocket to position the prosthesis in the desired area. Thereafter, the surgeon may suture or staple one of the layers of material to the surrounding ingrowth tissue, muscle or peritoneum layer. As such, the prosthesis may be provisionally held in place at least until sufficient tissue or muscle ingrowth occurs.

In one embodiment illustrated in FIGS. 4-5, the first and second layers 22a, 22b are attached in a manner to form one or more pockets 50 therebetween. However, it should be appreciated that the invention is not limited in this respect and that a pocket need not be employed or that other suitable pockets formed in other suitable manners may be employed. For example, a pocket may be formed from an additional layer of material or portion thereof attached to the first layer 22a.

To gain access to the interior of the pocket, the prosthesis may include at least one opening to the pocket 50. In one embodiment, the opening may include an elongated cut or slit 52 formed in the first layer 22a. However, it is to be appreciated that the prosthesis may include any suitable opening that allows access to the pocket as would be apparent to one of skill in the art.

To position the prosthesis, the surgeon may insert one or more fingers (or a suitable surgical instrument) into the pocket and manipulate the prosthesis into place. In one embodiment, the pocket 50 is sized to accept several fingers of the surgeon's hand, although other suitably sized pockets may be employed, as the present invention is not limited in this respect. Further, the pocket 50 may be formed of multiple pockets with multiple openings so that one or more fingers may be inserted into individual finger sections. For example, a pocket may be provided between the finished edge 26 and the outer trim region 28, and/or between each trim region 28, 30, if desired.

As one of skill in the art would appreciate, an opening may be provided to gain access to each pocket.

It should be understood that the foregoing description of various embodiments of the invention are intended merely to be illustrative thereof and that other embodiments, modifications, and equivalents of the invention are within the scope of the invention recited in the claims appended hereto. Further, the prosthesis described above includes various features that may be employed singularly or in any suitable combination.

What is claimed is:

CLAIMS

1. An implantable prosthesis for repairing a tissue or muscle wall defect, the implantable prosthesis comprising:

a repair fabric adapted to repair the tissue or muscle wall defect, the repair fabric including an outer periphery with a first finished edge and at least one predefined trim region located inward from the outer periphery, the outer periphery defining a first configuration of the repair fabric, the repair fabric being trimmable along the at least one trim region to reconfigure the repair fabric to a second configuration, the at least one trim region adapted to provide a second finished edge for the second configuration of the repair fabric.

2. The implantable prosthesis according to claim 1, wherein the first finished edge and the at least one trim region are formed by sealing portions of the repair fabric.

3. The implantable prosthesis according to claim 2, wherein the portions of the repair fabric are heat sealed.

4. The implantable prosthesis according to claim 3, wherein the portions of the repair fabric are melted and resolidified to form the first finished edge and the at least one trim region.

5. The implantable prosthesis according to any of claims 1 to 4, wherein the at least one trim region includes a plurality of trim regions of different sizes.

6. The implantable prosthesis according to claim 5, wherein the plurality of trim regions are arranged in a concentric pattern.

7. The implantable prosthesis according to any of claims 1 to 6, further comprising at least one reinforcing member supported on the repair fabric.

8. The implantable prosthesis according to claim 7, wherein the at least one reinforcing member is located between the first finished edge and the at least one trim region.

9. The implantable prosthesis according to claim 7, wherein the at least one reinforcing member includes a first reinforcing member located outward of the trim region and a second reinforcing member located inward of the trim region.

10. The implantable prosthesis according to any of claims 1 to 9, wherein the repair fabric includes at least one layer of mesh fabric that is susceptible to the formation of adhesions with tissue and organs.

11. The implantable prosthesis according to claim 10, wherein the layer of mesh fabric includes a plurality of interstices that are constructed and arranged to allow tissue ingrowth.

12. The implantable prosthesis according to any of claims 10 to 11, further comprising an adhesion resistant barrier layer adapted to inhibit tissue ingrowth, the barrier layer covering at least a portion of the layer of mesh fabric.

13. The implantable prosthesis according to claim 12, wherein the first finished edge and the at least one trim region are adapted to inhibit tissue ingrowth.

14. An implantable prosthesis for repairing a tissue or muscle wall defect, the implantable prosthesis comprising:

a repair fabric adapted to repair the tissue or muscle wall defect, the repair fabric including a plurality of predefined trim regions that define a plurality of configurations that are different from each other, the repair fabric being selectively trimmable along any of the trim regions to reconfigure the repair fabric into one of the configurations defined by a corresponding trim region, each trim region adapted to provide a finished edge for the configuration of the repair fabric defined by the trim region.

15. The implantable prosthesis according to claim 14, the plurality of trim regions are formed by sealing portions of the repair fabric.

16. The implantable prosthesis according to claim 15, wherein the portions of the repair fabric are heat sealed.

17. The implantable prosthesis according to claim 16, wherein the portions of the repair fabric are melted and resolidified to form the plurality of trim regions.

18. The implantable prosthesis according to any of claims 14 to 17, further comprising a plurality of reinforcing members supported on the repair fabric.

19. The implantable prosthesis according to claim 18, wherein each reinforcing member is located inward of a corresponding trim region.

20. The implantable prosthesis according to claim 19, wherein the plurality of trim regions and the plurality of reinforcing members are arranged in a concentric pattern.

21. The implantable prosthesis according to any of claims 14 to 20, wherein the repair fabric includes at least one layer of mesh fabric that is susceptible to tissue ingrowth.

22. The implantable prosthesis according to claim 21, further comprising an adhesion resistant barrier layer that inhibits tissue ingrowth, the barrier layer covering at least a portion of the layer of mesh fabric.

23. The implantable prosthesis according to claim 22, wherein each of the plurality of trim regions is adapted to inhibit tissue ingrowth.

24. An implantable prosthesis for repairing a tissue or muscle wall defect, the implantable prosthesis comprising:

a repair fabric adapted to repair the tissue or muscle wall defect, the repair fabric including at least first and second predefined trim regions that define first and second configurations for the repair fabric, the repair fabric being trimmable along the first and second trim regions to shape the

repair fabric into the first and second configurations, each trim region adapted to provide a finished edge for the corresponding configuration of the repair fabric defined by the trim region; and

at least first and second reinforcing members, the first reinforcing member being located between the first and second trim regions, the second reinforcing member being located inward of the second trim region.

25. The implantable prosthesis according to claim 24, wherein the first and second trim regions are formed by sealing portions of the repair fabric.

26. The implantable prosthesis according to claim 25, wherein the portions of the repair fabric are heat sealed.

27. The implantable prosthesis according to claim 26, wherein the portions of the repair fabric are melted and resolidified to form the first and second trim regions.

28. The implantable prosthesis according to any of claims 24 to 27, wherein the first and second trim regions and the first and second reinforcing members are arranged in a concentric pattern.

29. The implantable prosthesis according to claim 28, wherein each of the first and second trim regions surrounds a portion of the repair fabric.

30. The implantable prosthesis according to claim 29, wherein each the first and second reinforcing members includes a ring of material.

31. The implantable prosthesis according to any of claims 24 to 30, wherein the repair fabric includes first and second layers of material, the first and second reinforcing members being located between the first and second layers of material.

32. The implantable prosthesis according to claim 31, wherein at least one of the first and second layers of material includes a mesh fabric that is susceptible to tissue ingrowth.

33. The implantable prosthesis according to claim 32, wherein one of the first and second layers of material includes an adhesion resistant barrier layer that inhibits tissue ingrowth, the barrier layer covering at least a portion of the mesh fabric.

34. A method of repairing a tissue or muscle wall defect, the method comprising acts of :

(a) providing implantable prosthesis including a repair fabric adapted to repair the tissue or muscle wall defect, the repair fabric including an outer periphery with a first finished edge and at least one preformed trim region located inward from the outer periphery, the outer periphery defining a first configuration of the repair fabric; and

(b) reconfiguring the prosthesis to a second configuration by trimming the repair fabric along the at least one trim region to remove an outer portion of the repair fabric, the at least one trim region forming a second finished edge for the second configuration.

35. The method according to claim 34, wherein act (b) includes removing the first finished edge.

36. The method according to any of claims 34 to 35, wherein the implantable prosthesis includes at least first and second reinforcing members supported on the repair fabric, the at least one trim being located between the first and second reinforcing members, and wherein act (b) includes removing the first reinforcing member from the prosthesis.

37. The method according to any of claims 34 to 36, wherein the at least one trim region includes a plurality of trim regions arranged in a concentric pattern, at least one of the plurality of trim regions being located in the outer portion, and wherein act (b) includes removing the at least one of the plurality of trim regions from the prosthesis.

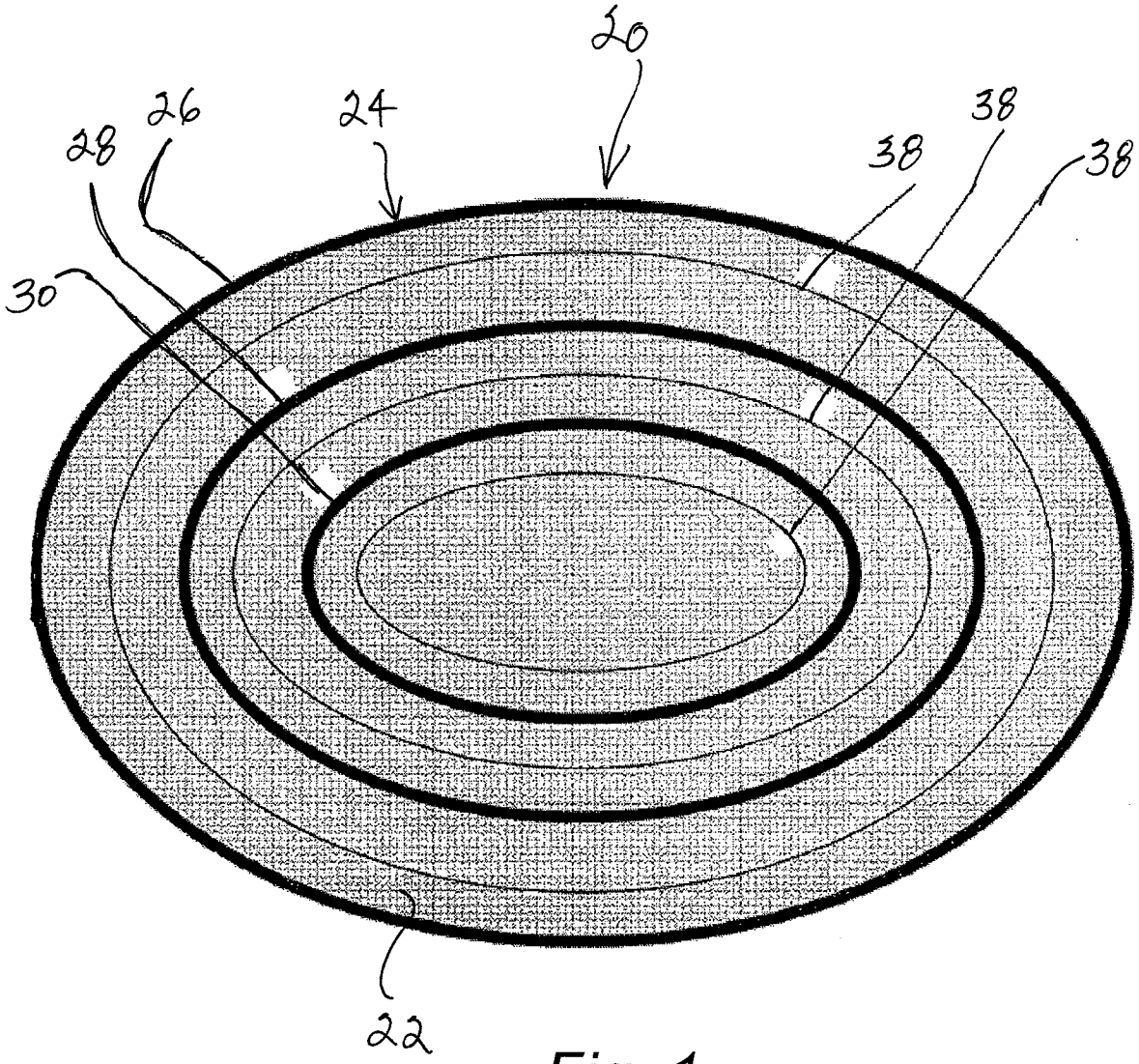

Fig. 1

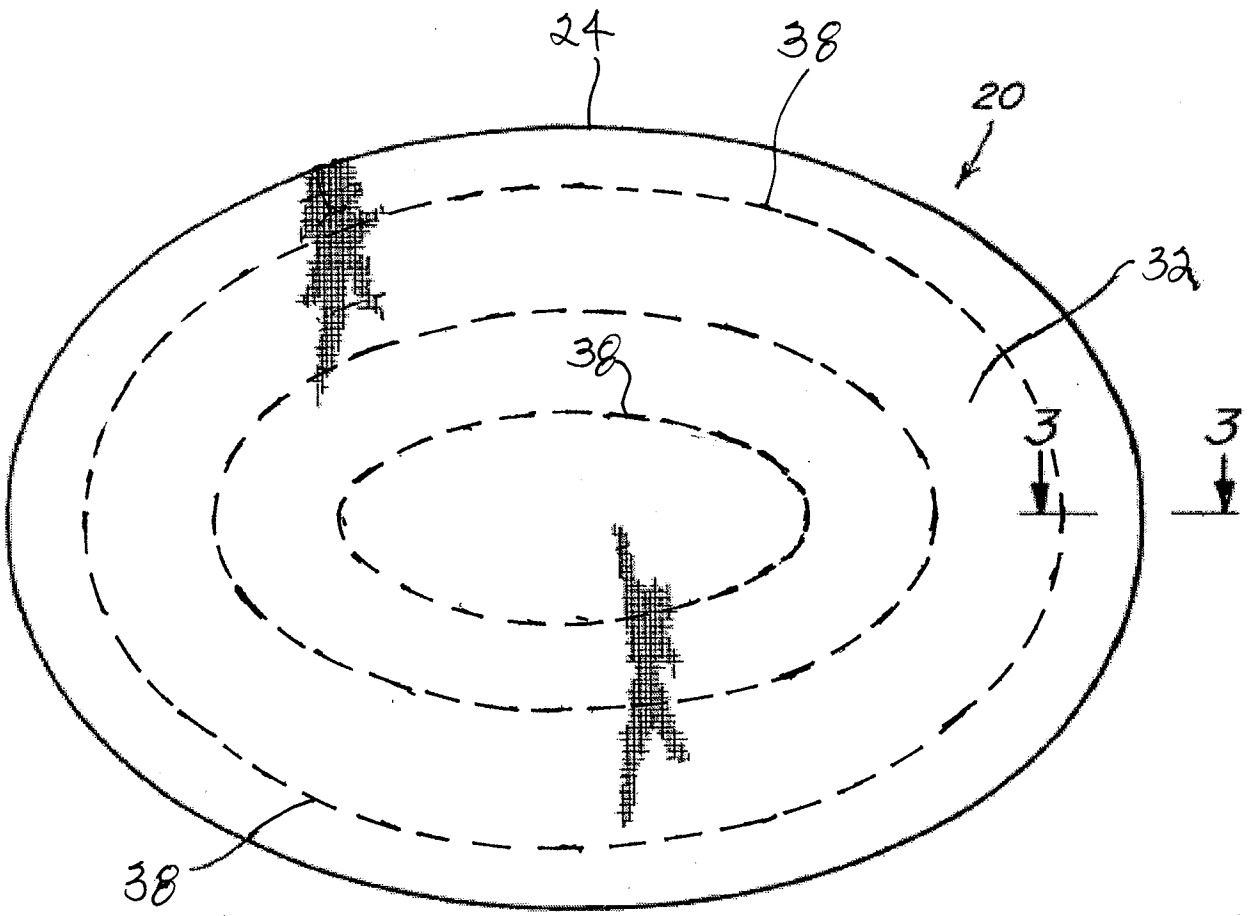

Fig. 2

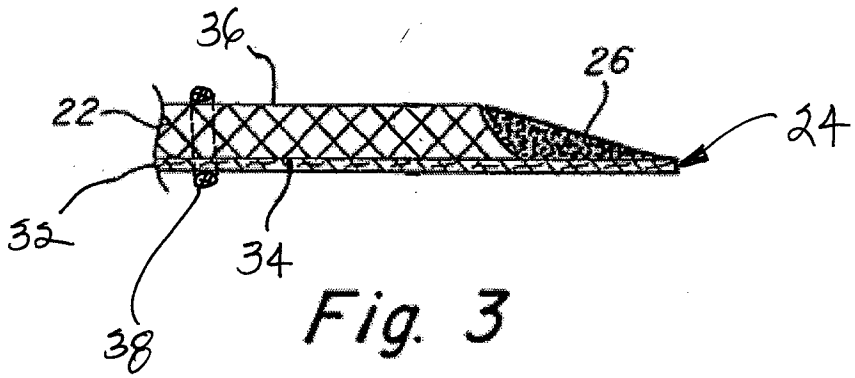

Fig. 3

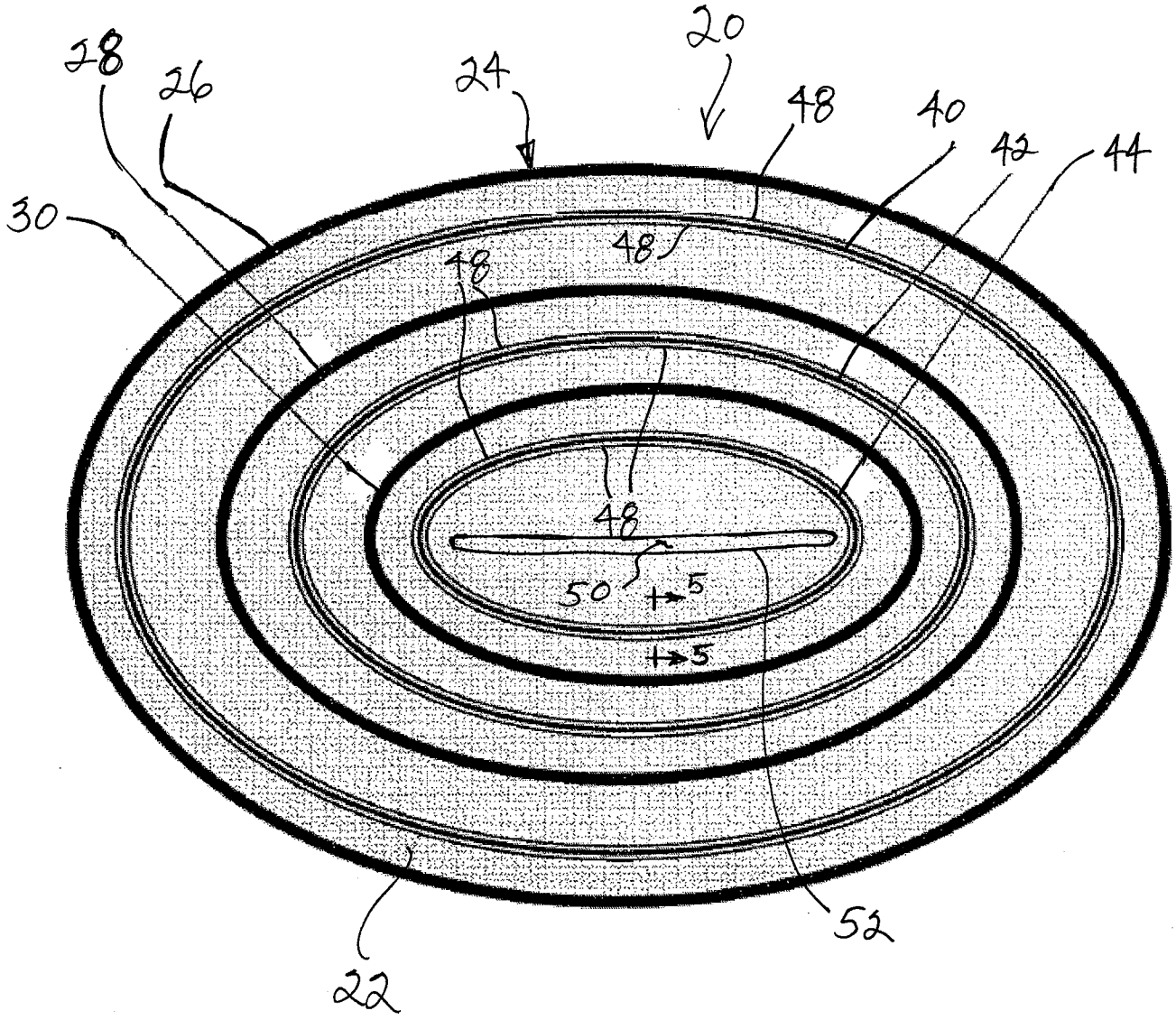

Fig. 4

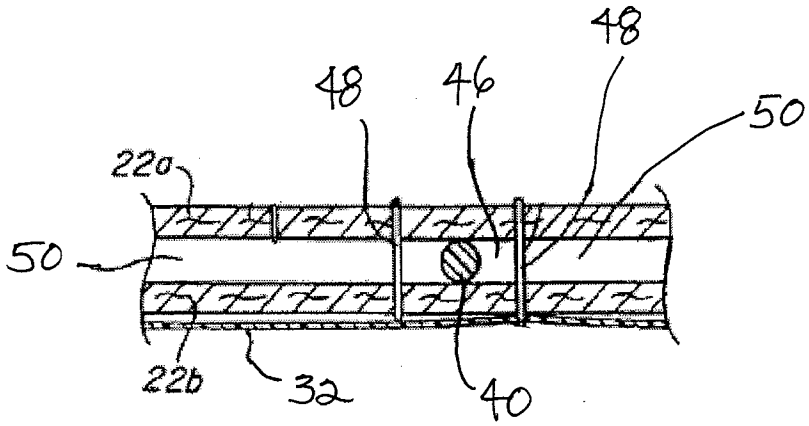

Fig. 5

INTERNATIONAL SEARCH REPORT

2011/052339 17.01.2012

International application No.
PCT/US 11/52339

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/00 (2011.01)
USPC - 606/151
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
USPC: 606/151

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 600/37----see search terms below----

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PUBWEST (US Pre-Grant Pub Full-Text, US Patents Full-Text, EPO Abstracts, JPO Abstracts); Google Patents (All); PubMed (All)----search terms: prosthesis, implant, mesh, trimmable, hernia, cut, patch, concentric, finished edge, multi edge, multi size, trim region, etc.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2005/0288691 A1 (LEIBOFF) 29 December 2005 (29.12.2005) see entire document, particularly FIG. 3C; para [0001], [0018], [0028] and [0032].	1-6, 14-20, 24-30, 34-36
Y	US 6,790,213 B2 (CHEROK ET AL.) 14 September 2004 (14.09.2004) see entire document, particularly FIGS. 1 and 3-6; col 9, ln 15 to col 11, ln 57.	1-6, 14-20, 24-30, 34-36
A	US 6,736,823 B2 (DAROIS ET AL.) 18 May 2004 (18.05.2004) see entire document.	1-6, 14-20, 24-30, 34-36
A	US 2009/0306688 A1 (PATEL ET AL.) 10 December 2009 (10.12.2009) see entire document.	1-6, 14-20, 24-30, 34-36
A	US 2003/0212461 A1 (VADURRO ET AL.) 13 November 2003 (13.11.2003) see entire document.	1-6, 14-20, 24-30, 34-36
A	US 2002/0042658 A1 (TYAGI) 11 April 2002 (11.04.2002) see entire document.	1-6, 14-20, 24-30, 34-36

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 January 2012 (02.01.2012)	17 JAN 2012
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 7-13, 21-23, 31-33 and 37
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.