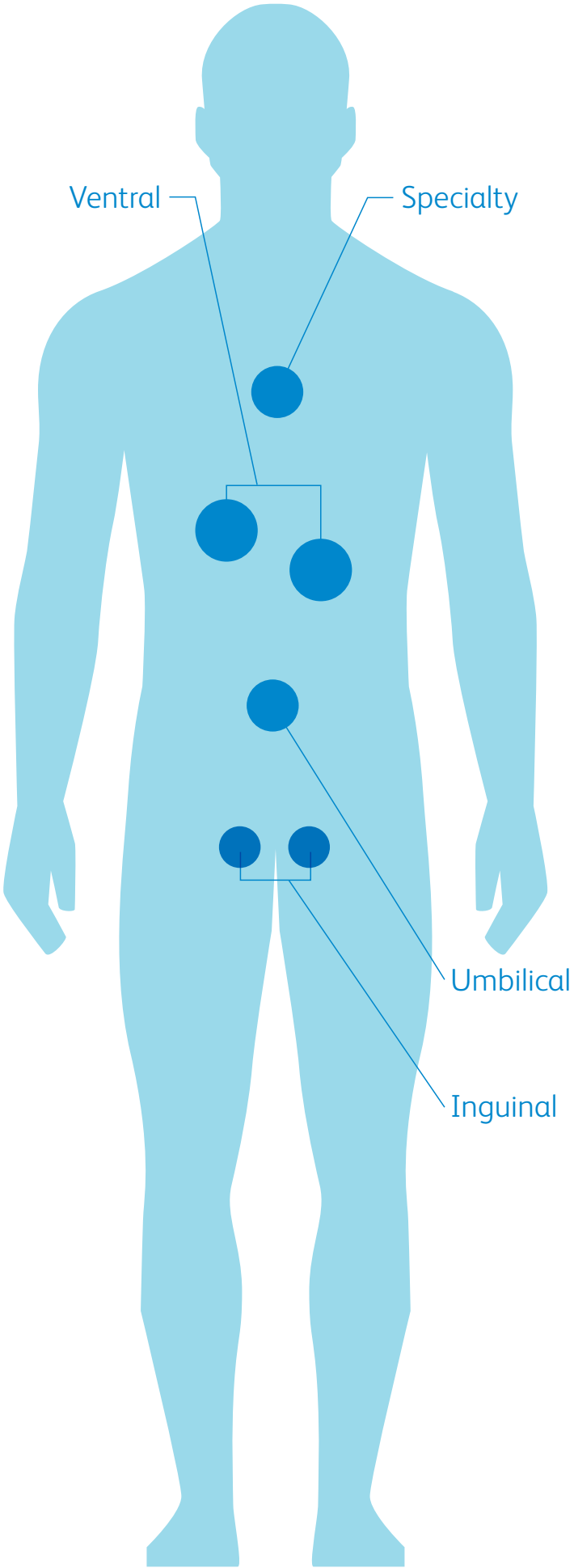
BD Surgical Product Catalogue

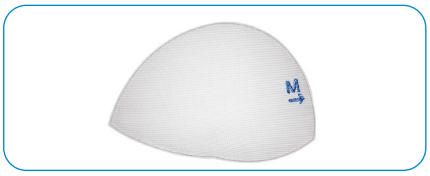
Ventral, umbilical, inguinal, biological implants and mesh fixation

Now more than ever, your hospital must run as efficiently as possible and still provide the best patient care. Since hernia repair is one of the most common surgical procedures in the country, hernia repair product standardisation, ongoing training and patient education will help you achieve these goals. That's where we come in. BD gives you a comprehensive range of hernia repair products and services that let you operate at peak efficiency while ensuring optimal patient care.

BD

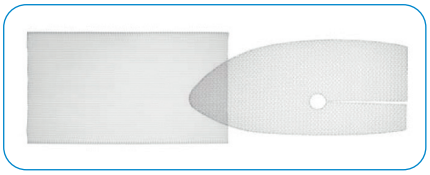

Ventral
Specialty
Umbilical
Inguinal

Inguinal

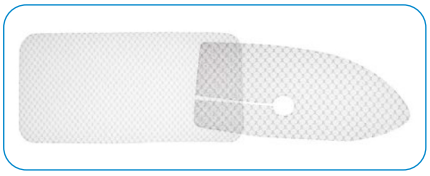


3DMax™ Mesh
Unique three-dimensional polypropylene mesh for laparoscopic inguinal hernia repair.

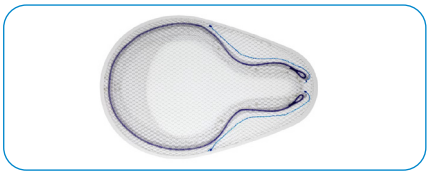
3DMax™ Light Mesh
Lighter-weight version of the popular 3DMax™ Mesh, featuring a large pore knit design.



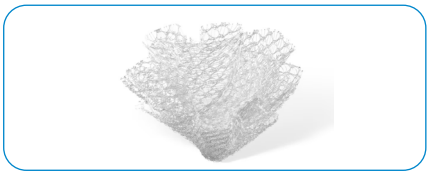
Bard® Mesh Flats and Pre-shaped
Monofilament polypropylene mesh for use in ventral or inguinal hernia repair.



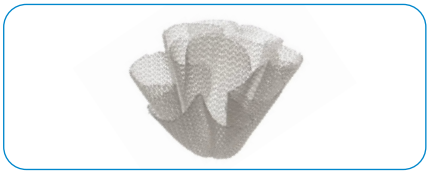
Bard® Soft Mesh
Large pore monofilament polypropylene mesh that has a soft, compliant knit structure.



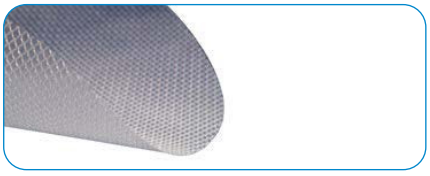
Onflex® Mesh
Self-expanding lightweight mesh for open preperitoneal inguinal hernia repair with SorbaFlex™ Memory Technology.



Perfix™ Light Plug
Lighter-weight version of the proven PerFix™ Plug, for use when a reduced amount of material is indicated.

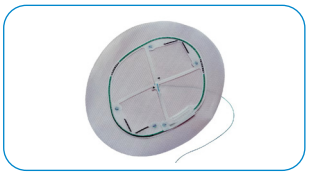


Perfix™ Plug
Plug and patch designed for use in a tension-free open inguinal hernia repair technique

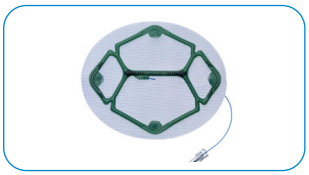


Adhesix™ Self-Adhering Reinforcement Implant
Unique lightweight polypropylene mesh with gel coating in polyvinyl-pyrrolidone (PVP) and polyethylene-glycol (PEG) that provides an atraumatic repair in laparoscopic and open inguinal procedures.

Ventral

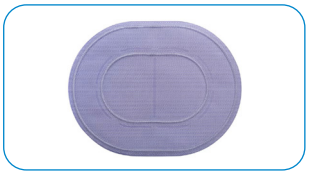


Ventralight™ ST Mesh with Echo 2™ Positioning System Mesh
The Echo 2™ Positioning System is a deployment and positioning device that comes attached to Ventralight™ ST Mesh. It facilitates mesh positioning and centring over the hernia defect, for a consistent, reproducible technique

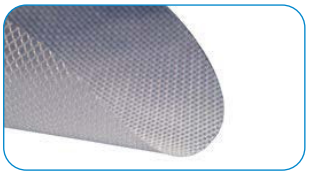


Ventralight™ ST Mesh with Echo PS™ Positioning System
Ventralight™ ST Mesh with a pre-attached low-profile balloon to help facilitate deployment, placement and positioning in laparoscopic ventral hernia repair.

Ventralight™ ST Mesh
Uncoated medium weight monofilament polypropylene mesh on the anterior side with an absorbable hydrogel barrier based on Sepra® Technology on the posterior for laparoscopic ventral hernia repair.



Ventrio™ ST Hernia Patch
Uncoated monofilament polypropylene mesh with SorbaFlex™ Memory Technology and an absorbable barrier based on Sepra® Technology.

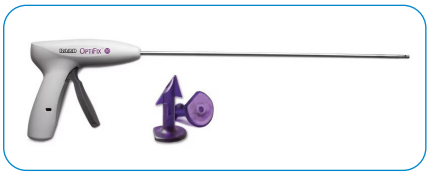


Adhesix™ Self-Adhering Reinforcement Implant
Unique lightweight polypropylene mesh with gel coating in polyvinyl-pyrrolidone (PVP) and polyethylene-glycol (PEG) that provides an atraumatic repair in laparoscopic and open inguinal procedures.

Umbilical

Ventralex™ ST Hernia Patch
A clinically proven umbilical hernia repair solution designed for ventral, incisional, umbilical and epigastric hernia repair, with an absorbable barrier featuring Sepra® technology.

Fixation

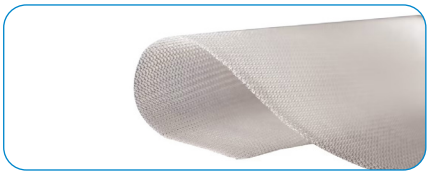


OptiFix™ Absorbable Fixation System
Absorbable PDLLA fasteners available in both a 15 and 30 count configuration delivered via a disposable 5mm stored energy delivery system.

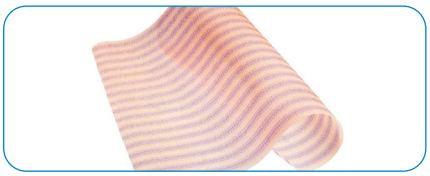
SorbaFix™ Absorbable Fixation System
Absorbable PDLLA fasteners available in both a 15 and 30 count configuration delivered via a disposable 5 mm delivery system.

CapSure™ Permanent Fixation System
Permanent 316L stainless steel helical coil fasteners with a smooth cap available in both a 15 and 30 count configuration via a disposable 5mm delivery system.

Complex abdominal wall



Phasix™ Mesh
Composed of material derived from a fermentation process, Poly-4-hydroxybutyrate (P4HB), Phasix™ Mesh provides critical strength during the initial healing phase.



Phasix™ ST Mesh
A fully bioresorbable Poly-4-hydroxybutyrate (P4HB) scaffold featuring proven Sepra® technology barrier to adhesions.

Ordering information – inguinal

3DMax™ Mesh

Unique three-dimensional polypropylene mesh for laparoscopic inguinal hernia repair.

Product item ID	Packaging (SKU)	Dimensions
0115310	1/cs.	Medium, Left 3DMax™ Mesh, 8.5 cm x 13.7 cm
0115311	1/cs.	Large, Left 3DMax™ Mesh, 10.8 cm x 16.0 cm
0115312	1/cs.	Extra-Large, Left 3DMax™ Mesh, 12.4 cm x 17.3 cm
0115320	1/cs.	Medium, Right 3DMax™ Mesh, 8.5 cm x 13.7 cm
0115321	1/cs.	Large, Right 3DMax™ Mesh, 10.8 cm x 16.0 cm
0115322	1/cs.	Extra-Large, Right 3DMax™ Mesh, 12.4 cm x 17.3 cm

3DMax™ Light Mesh

Lighter-weight version of the popular 3DMax™ Mesh, featuring a large pore knit design.

Product item ID	Packaging (SKU)	Dimensions
0117310	1/cs.	Left, Medium 3DMax™ Light Mesh, 7.9 cm x 13.4 cm
0117311	1/cs.	Left, Large 3DMax™ Light Mesh, 10.3 cm x 15.7 cm
0117312	1/cs.	Left, Extra-Large 3DMax™ Light Mesh, 12.2 cm x 17.0 cm
0117320	1/cs.	Right, Medium 3DMax™ Light Mesh, 7.9 cm x 13.4 cm
0117321	1/cs.	Right, Large 3DMax™ Light Mesh, 10.3 cm x 15.7 cm
0117322	1/cs.	Right, Extra-Large 3DMax™ Light Mesh, 12.2 cm x 17.0 cm

Bard® Mesh

Monofilament polypropylene mesh for use in ventral or inguinal hernia repair.

Product item ID	Packaging (SKU)	Dimensions
0112640G	3/cs.	2.5 cm x 10 cm
0112650G	3/cs.	5 cm x 10 cm
0112660G	1/cs.	25 cm x 35.5 cm
0112670G	2/cs.	5 cm x 30.5 cm
0112680G	3/cs.	7.5 cm x 15 cm
0112720G	3/cs.	15 cm x 15 cm

Bard® Soft Mesh

Large pore monofilament polypropylene mesh that has a soft, compliant knit structure.

Product item ID	Packaging (SKU)	Dimensions
0117008	3/cs.	5 cm x 10 cm
0117009	3/cs.	7.5 cm x 15 cm
0117010	3/cs.	10 cm x 15 cm
0117011	3/cs.	15 cm x 15 cm
0117016	1/cs.	30.5 cm x 30.5 cm

Bard® Mesh Pre-shaped

Product item ID	Packaging (SKU)	Dimensions
0112700	3/cs.	Pre-shaped, 4.5 cm x 10 cm
0112710	3/cs.	Pre-shaped with Keyhole, 4.5 cm x 10 cm
0113700	3/cs.	Large Pre-shaped, 6 cm x 13.7 cm
0113710	3/cs.	Large Pre-shaped with Keyhole, 6 cm x 13.7 cm

Bard® Soft Mesh Pre-shaped

Product item ID	Packaging (SKU)	Dimensions
0117012	3/cs.	Pre-shaped, 4.5 cm x 10 cm
0117013	3/cs.	Pre-shaped with Keyhole, 4.5 cm x 10 cm
0117014	3/cs.	Large Pre-shaped, 6 cm x 13.7 cm
0117015	3/cs.	Large Pre-shaped with Keyhole, 6 cm x 13.7 cm

PerFix™ Plug

Plug and patch designed for use in a tension-free open inguinal hernia repair technique.

Product item ID	Packaging (SKU)	Dimensions
0112750	2/cs.	Small PerFix™ Plug, 2.5 cm x 3.4 cm
0112760	2/cs.	Medium PerFix™ Plug, 3.3 cm x 3.9 cm
0112770	2/cs.	Large PerFix™ Plug, 4.1 cm x 4.8 cm
0112780	2/cs.	Extra Large PerFix™ Plug, 4.1 cm x 5.0 cm
0112950	6/cs.	Small PerFix™ Plug, 2.5 cm x 3.4 cm
0112960	6/cs.	Medium PerFix™ Plug, 3.3 cm x 3.9 cm
0112970	6/cs.	Large PerFix™ Plug, 4.1 cm x 4.8 cm
0112980	6/cs.	Extra Large PerFix™ Plug, 4.1 cm x 5.0 cm

PerFix™ Light Plug

Lighter-weight version of the proven PerFix™ Plug, for use when a reduced amount of material is indicated.

Product item ID	Packaging (SKU)	Dimensions
0117050	1/cs.	Small PerFix™ Light Plug, 2.5 cm x 3.4 cm
0117060	1/cs.	Medium PerFix™ Light Plug, 3.3 cm x 3.9 cm
0117070	1/cs.	Large PerFix™ Light Plug, 4.1 cm x 4.8 cm
0117080	1/cs.	Extra Large PerFix™ Light Plug, 3.8 cm x 5.0 cm
0117150	6/cs.	Small PerFix™ Light Plug, 2.5 cm x 3.4 cm
0117160	6/cs.	Medium PerFix™ Light Plug, 3.3 cm x 3.9 cm
0117170	6/cs.	Large PerFix™ Light Plug, 4.1 cm x 4.8 cm
0117180	6/cs.	Extra Large PerFix™ Light Plug, 3.8 cm x 5.0 cm

OnFlex™ Mesh

Self-expanding lightweight mesh for open preperitoneal inguinal hernia repair with SorbaFlex™ memory technology.

Product item ID	Packaging (SKU)	Dimensions
0115410	1/cs.	Medium with pocket 8.6 cm x 14.2 cm
0115411	1/cs.	Large with pocket 10.2 cm x 15.7 cm

Adhesix™ Implant Laproscopic Inguinal

Unique lightweight polypropylene mesh with gel coating in polyvinyl-pyrrolidone (PVP) and polyethylene-glycol (PEG) that provides an atraumatic repair in laparoscopic and open inguinal procedures.

Product item ID	Packaging (SKU)	Dimensions
0114310	1/cs.	10 cm x 15 cm
0114320	1/cs.	12 cm x 15 cm

Adhesix™ Implant Lichtenstein

Unique lightweight polypropylene mesh with gel coating in polyvinyl-pyrrolidone (PVP) and polyethylene-glycol (PEG) that provides an atraumatic repair in laparoscopic and open inguinal procedures.

Product item ID	Packaging (SKU)	Dimensions
0119310	1/cs.	4 cm x 10 cm
0119330	1/cs.	6 cm x 13.5 cm
0119350-R	1/cs.	7.5 cm x 15.5 cm
0119320-L	1/cs.	7.5 cm x 15.5 cm
0119340	1/cs.	8.5 cm x 12.5 cm

Ordering information – ventral

Ventralight™ ST Mesh with Echo PS™ Positioning System

Ventralight™ ST Mesh with a pre-attached low-profile balloon to help facilitate deployment, placement and positioning in laparoscopic ventral hernia repair.

Product item ID	Packaging (SKU)	Dimensions
5955450G	1/cs.	11.4 cm, circle
5955460G	1/cs.	10.2 cm x 15.2 cm, ellipse
5955600G	1/cs.	15.2 cm, circle
5955680G	1/cs.	15.2 cm x 20.3 cm, ellipse
5955610G	1/cs.	15.2 cm x 25.4 cm, oval
5955790G	1/cs.	17.8 cm x 22.9 cm, ellipse
5955800G	1/cs.	20.3 cm, circle
5955810G	1/cs.	20.3 cm x 25.4 cm, ellipse
5955113G	1/cs.	25.4 cm x 33 cm, ellipse
5955124G	1/cs.	30.5 cm x 35.6 cm, rectangle

Ventralight™ ST Mesh with Echo 2™ Positioning System

Ventralight™ ST Mesh with a pre-attached balloon to help facilitate deployment, placement and positioning in laparoscopic ventral hernia repair.

Product item ID	Packaging (SKU)	Dimensions
5990011G	1/cs.	11 cm, circle
5990015G	1/cs.	15 cm, circle
5990020G	1/cs.	20 cm, circle
5991015G	1/cs.	10 cm x 15 cm, ellipse
5991520G	1/cs.	15 cm x 20 cm, ellipse
5991525G	1/cs.	15 cm x 25 cm, oval
5991823G	1/cs.	18 cm x 23 cm, ellipse
5992025G	1/cs.	20 cm x 25 cm, ellipse
5992533G	1/cs.	25 cm x 33 cm, ellipse
5993035G	1/cs.	30 cm x 35 cm, ellipse

Ventrio™ ST Hernia Patch

Uncoated monofilament polypropylene mesh with SorbaFlex™ memory technology and an absorbable barrier based on Sepra® technology.

Product item ID	Packaging (SKU)	Dimensions
5950030G	1/cs.	8.0 cm x 12.0 cm, small oval
5950040G	1/cs.	11.0 cm x 14.0 cm, medium oval
5950050G	1/cs.	13.8 cm x 17.8 cm, large oval
5950010G	1/cs.	7.6 cm diameter, small circle
5950020G	1/cs.	11.4 cm diameter, large circle
5950070G	1/cs.	19.6 cm x 24.6 cm Extra large oval
5950080G	1/cs.	22.1 cm x 27.1 cm, extra large oval
5950090G	1/cs.	27.4 cm x 34.9 cm, extra large oval
5950060G	1/cs.	15.5 cm x 25.7 cm, midline

Ventralight™ ST Mesh

Uncoated medium weight monofilament polypropylene mesh on the anterior side with an absorbable hydrogel barrier based on Sepra® technology on the posterior side for laparoscopic ventral hernia repair.

Product item ID	Packaging (SKU)	Dimensions
5954450G	1/cs.	11.4 cm, circle
5954460G	1/cs.	10.2 cm x 15.2 cm, ellipse
5954600G	1/cs.	15.2 cm, circle
5954680G	1/cs.	15.2 cm x 20.3 cm, ellipse
5954610G	1/cs.	15.2 cm x 25.4 cm, oval
5954790G	1/cs.	17.8 cm x 22.9 cm, ellipse
5954800G	1/cs.	20.3 cm, circle
5954810G	1/cs.	20.3cm x 25.4 cm, ellipse
5954113G	1/cs.	25.4 cm x 33 cm, ellipse
5954124G	1/cs.	30.5 cm x 35.6 cm, rectangle

Adhesix™ Implant Open Ventral

Unique lightweight polypropylene mesh with gel coating in polyvinyl-pyrrolidone (PVP) and polyethylene-glycol (PEG) that provides an atraumatic repair in laparoscopic and open ventral procedures.

Product item ID	Packaging (SKU)	Dimensions
0113310	1/cs.	15 x 20 cm
0113420	1/cs.	20 x 25 cm
0113530	1/cs.	30 x 30 cm

Ordering information – umbilical

Ventralex™ ST Hernia Patch

A clinically proven umbilical hernia repair solution designed for ventral, incisional, umbilical and epigastric hernia repair as well as trocar site closure, with an absorbable barrier featuring Sepra® technology.

Product item ID	Packaging (SKU)	Dimensions
5950007G	1/cs.	4.3 cm diameter, small circle with strap
5950008G	1/cs.	6.4 cm diameter, medium circle with strap
5950009G	1/cs.	8.0 cm diameter, large circle with strap

Ordering information – fixation

SorbaFix™ Absorbable Fixation System

Absorbable PDLLA fasteners delivered via a disposable 5 mm applier.

Product item ID	Packaging (SKU)	Dimensions
0113115	5/cs.	15 fasteners
0113116	5/cs.	30 fasteners

CapSure™ Permanent Fixation System

Permanent 316L stainless steel helical coil fasteners with a smooth cap delivered via a disposable 5 mm delivery system.

Product item ID	Packaging (SKU)	Dimensions
0113215G	5/cs.	15 fasteners
0113230G	5/cs.	30 fasteners

OptiFix™ Absorbable Fixation System

Absorbable PDLLA fasteners delivered via a disposable 5 mm delivery system.

Product item ID	Packaging (SKU)	Dimensions
0113126	5/cs.	30 absorbable fasteners
0113127	5/cs.	15 absorbable fasteners

Ordering information – complex abdominal wall

Phasix™ Mesh

Clinically proven Poly-4-hydroxybutyrate (P4HB) bioresorbable mesh for abdominal wall repair.

Product item ID	Packaging (SKU)	Dimensions
1190100G	1/cs.	7.6 cm round
1190200G	1/cs.	10.2 cm x 15.2 cm, rectangle
1190820G	1/cs.	8 cm x 20 cm, rectangle
1190300G	1/cs.	15.2 cm x 20.3 cm, rectangle
1191530G	1/cs.	15 cm x 30 cm, rectangle
1190400G	1/cs.	20.3 cm x 25.4 cm, rectangle
1192040G	1/cs.	20 cm x 40 cm, rectangle
1190500G	1/cs.	25.4 cm x 30.5 cm, rectangle
1193045G	1/cs.	30 cm x 45 cm, rectangle
1195050G	1/cs.	50 cm x 50 cm, square

Phasix™ ST Mesh

Poly-4-hydroxybutyrate (P4HB) bioresorbable mesh with resorbable hydrogel barrier for abdominal wall and hiatal hernia repair.

Product item ID	Packaging (SKU)	Dimensions
1200008G	1/cs.	8 cm, round
1200011G	1/cs.	11 cm, round
1200015G	1/cs.	15 cm, round
1200710G	1/cs.	7 cm x 10 cm, rectangle
1201010G	1/cs.	10 cm x 10 cm, square
1201015G	1/cs.	10 cm x 15 cm, rectangle
1201020G	1/cs.	10 cm x 20 cm, rectangle
1201325G	1/cs.	13 cm x 25 cm, rectangle
1201520G	1/cs.	15 cm x 20 cm, rectangle
1202530G	1/cs.	25 cm x 30 cm, rectangle
1203035G	1/cs.	30 cm x 35 cm, rectangle

IFU information

3DMax™ Mesh

Indications

Bard® 3DMax™ mesh is indicated to reinforce soft tissue where weakness exists, e.g., for repair of hernia and chest wall defects.

Contraindications

Literature reports that there may be a possibility for adhesion formation when Bard® 3DMax™ mesh is placed in direct contact with the bowel or viscera. Do not use Bard® 3DMax™ mesh in infants and children, whereby future growth will be compromised by use of such material.

Adverse Reactions

Possible complications include seromas, adhesions, hematomas, inflamma¬tion, extrusion, fistula formation and recurrence of the hernia or soft tissue defect.

Adhesix™ Self-Adhering Reinforcement Implant

Indications

Parietal repair and reinforcement of inguinal, umbilical, Linea alba, and ventral hernias.

Uses

These meshes can be used in laparoscopic surgery or traditional surgery. The Adhesix™ P8 device is designed for extraperitoneal implantation. Adhesix™ mesh is biocompatible with a resorbable adhesive hydrogel. The mesh promotes a reactional fibrosis which takes over from the reinforcing system six months after implantation. The meshes are coated with an adhesive hydrogel. Some of the advantages of these meshes are that they can easily be cut to fit various dimensions, are very flexible, and facilitate quick and optimum tissue integration and colonisation.

Contraindications

Do not implant in the following cases: allergy to one of the components; septic environment; anticoagulant treatment; pregnant woman; growing child (<18 years).

Adverse Side Effects

As with all implantable medical devices, this implant may produce adverse side effects such as: Recurrence; Infection; Discomfort.

Specific Recommendations for the Lichtenstein Surgical Technique

The adhesive side of the implant (smooth side) must be placed on the fascia. The implant should first be slid onto the pubis, then the arms wrap around the spermatic cord.

Specific Recommendations for Preperitoneal Implantation for Ventral Hernias

Adhesix™ is for preperitoneal placement. It is recommended that the adhesive hydrogel side be implanted deeply. The size of the implant must be fitted to the size of the defect. It is recommended to place an abdominal binder around the patient's abdomen for several days following surgery in order to reinforce the abdominal wall.

Echo 2™ Positioning System

Indications

The Echo 2™ Positioning System is intended to facilitate the delivery and positioning of the soft tissue prosthesis during laparoscopic hernia repairphragmatic, scrotal, umbilical and incisional hernia repair.

Echo 2™ Positioning System with Ventralight™ ST Mesh

Indications

The Echo™ PS positioning system is intended to be used to facilitate the delivery of soft tissue prostheses during laparoscopic hernia repair. Ventralight™ ST Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for repair of hernias.

Contraindications

Literature reports that there may be a possibility for adhesion formation when the polypropylene is placed in direct contact with the bowl or viscera. Do not use in infants or children, whereby future growth will be compromised by use of such mesh material. Do not use for the reconstruction of cardiovascular defects.

Adverse Reactions

Possible complications may include, but are not limited to, seroma, adhesions, haematoma, pain, infection, inflammation, extrusion, erosion, migration, fistula formation and recurrence of the hernia or soft tissue defect.

Fixation

Indications

The OptiFix™ and SorbaFix™ Absorbable Fixation CapSure™ Permanent Fixation systems are indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures. The OptiFix™ Open Absorbable Fixation System is indicated for the fixation of surgical mesh to tissues during open surgical procedures, such as hernia repair.

Contraindications

Contraindications associated with laparoscopic and open surgical procedures relative to mesh fixation apply including but not limited to: fixation of vascular or neural structures, fixation of bone and cartilage; and for the OptiFix™, OptiFix™ Open Absorbable Fixation Systems and the SorbaFix™ Absorbable Fixation System only: situations with insufficient in-growth of tissue into the mesh over time, which could result in inadequate fixation once the fastener is resorbed. Carefully inspect the area in the vicinity of the tissue being fastened to avoid inadvertent penetration of underlying structures such as nerves, vessels, viscera or bone. Use of the OptiFix™ Absorbable Fixation System, the OptiFix™ Open Absorbable Fixation System, the SorbaFix™ Absorbable Fixation System or the CapSure™ Permanent Fixation System in the close vicinity of such underlying structures is contraindicated. For reference, the length of the OptiFix™ and OptiFix™ Open fastener is 6.1mm, the fastener head is another 0.6mm (total 6.7mm); the length of the SorbaFix™ fastener is 6.0mm, the fastener head is another 0.7mm (total 6.7 mm); the length of the CapSure™ fastener is 3.2 mm, the fastener head is another 1 mm (total 4.2 mm).

Adverse Reactions

Adverse reactions and potential complications associated with fixation devices such as the OptiFix™, OptiFix™ Open and SorbaFix™ Absorbable Fixation System and the CapSure™ Permanent Fixation System may include, but are not limited to the following: haemorrhage; pain, oedema and erythema at wound site; allergic reaction to Poly (D,L)-lactide (OptiFix™, OptiFix™ Open and SorbaFix™ Absorbable Fixation System) or known sensitivities to PEEK and metals contained in 316L stainless steel, including chromium, nickel, copper, and iron (CapSure™ Permanent Fixation System); septicaemia/infection; hernia recurrence/wound dehiscence.

Onflex™ Mesh

Indications

The OnFlex™ Mesh is indicated for use in the reinforcement of soft tissue where weakness exists, such as in the repair of inguinal hernias.

Contraindications

Do not use this mesh in infants, children, or pregnant women, whereby future growth may be compromised by the use of such mesh material. The use of this mesh has not been studied in breastfeeding or pregnant women. Literature reports there may be a possibility for adhesion formation when the polypropylene is placed in contact with the bowel or viscera.

Adverse Reactions

Possible complications may include, but are not limited to, seroma, adhesion, hematoma, pain, infection, inflammation, extrusion, erosion, migration, fistula formation, allergic reaction, and recurrence of the hernia or soft tissue defect. The mesh must be removed immediately if the SorbaFlex™ PDO monofilament is cut or damaged during insertion of fixation. If the SorbaFlex™ PDO monofilament is cut or damaged, additional complications may include, but are not limited to, bowel or skin perforation and infection.

OptiFix™

Indications

The OptiFix™ Absorbable Fixation System is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

Contraindications

This device is not intended for use except as indicated. Do not use this device where hemostasis cannot be verified visually after application. Contraindications associated with open and laparoscopic surgical procedures relative to mesh fixation apply, including but not limited to, fixation of vascular or neural structures, fixation of bone and cartilage, situations with insufficient ingrowth of tissue into the mesh over time, which could result in inadequate fixation once the fastener is absorbed. Carefully inspect the area in the vicinity of the tissue being fastened to avoid inadvertent penetration of underlying structures such as nerves, vessels, viscera, or bone. Use of the OptiFix™ Absorbable Fixation System in the close vicinity of such underlying structures is contraindicated. For reference, the length of the fastener below the fastener head is 6.1 mm; the fastener head is another 0.6 mm (total 6.7 mm). This device should not be used in tissues that have a direct anatomic relationship to major vascular structures. This would include the deployment of fasteners in the diaphragm in the vicinity of the pericardium, aorta, or inferior vena cava during diaphragmatic hernia repair.

Adverse Reactions

Adverse reactions and potential complications associated with fixation devices such as the OptiFix™ Absorbable Fixation System may include, but are not limited to the following: hemorrhage; pain, edema and erythema at wound site; allergic reaction to Poly(D, L)-lactide; infection/septicemia; hernia recurrence/wound dehiscence.

Phasix™ ST Mesh

Indications

Phasix™ ST Mesh is indicated for use in the reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, such as for the repair of hernias, including hiatal hernias.

Contraindications

Because Phasix™ ST Mesh is fully resorbable, it should not be used in repairs where permanent wound or organ support from the mesh is required.

Adverse Reactions

In preclinical testing, Phasix™ ST Mesh elicited a minimal tissue reaction characteristic of foreign body response to a substance. The tissue reaction resolved as the mesh was resorbed. Possible complications may include, but are not limited to, seroma, adhesion, haematoma, pain, infection, inflammation, allergic reaction, haemorrhage, extrusion, erosion, migration, fistula formation and recurrence of the hernia or soft tissue defect. Possible complications in hiatal hernia repair may include oesophageal erosion and dysphagia related to crural fibrosis.

SorbaFix™

Indications

The SorbaFix™ Absorbable Fixation System is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during laparoscopic surgical procedures, such as hernia repair.

Contraindications

This device is not intended for use except as indicated. Do not use this device where hemostasis cannot be verified visually after application. Contraindications associated with laparoscopic surgical procedures relative to mesh fixation apply, including but not limited to, fixation of vascular or neural structures, fixation of bone and cartilage, situations with insufficient in-growth of tissue into the mesh over time, which could result in inadequate fixation once the fastener is resorbed. Carefully inspect the area in the vicinity of the tissue being fastened to avoid inadvertent penetration of underlying structures such as nerves, vessels, viscera, or bone. Use of the SorbaFix™ Absorbable Fixation System in the close vicinity of such underlying structures is contraindicated. For reference, the length of the fastener is 6.0 mm, the fastener head is another 0.7 mm (total 6.7 mm).

Adverse Reactions

Adverse reactions and potential complications associated with fixation devices such as the SorbaFix™ Absorbable Fixation System may include, but are not limited to the following: hemorrhage; pain, edema, and erythema at wound site; allergic reaction to Poly (D, L)-lactide; septicemia/infection; hernia recurrence/wound dehiscence.

Synthetic mesh

Indications

Mesh intended for use in the reconstruction of soft tissue deficiencies such as hernia.

Contraindications

Literature reports that there may be a ossibility for adhesion formation when the polypropylene or macroporous side is placed in direct contact with the bowel or viscera. Use of this device is contraindicated for infants, children, or pregnant women, whereby future growth will be compromised by use of such mesh material. Do not use for the reconstruction of cardiovascular defects (Composix™ L/P, Ventralex™, Ventralex™ ST, Ventrio™, Ventrio™ ST, Ventralight™ ST, Sepramesh™ IP) or between joint surfaces and passive membranes such as the dura pericardium or peritoneum.

Adverse Reactions

Possible complications may include, but are not limited to, seroma, adhesions, haematoma, pain, infection, inflammation, extrusion, erosion, migration, fistula formation and recurrence of the hernia or soft tissue defect.

Please consult package insert for more detailed safety information and instructions for use.

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