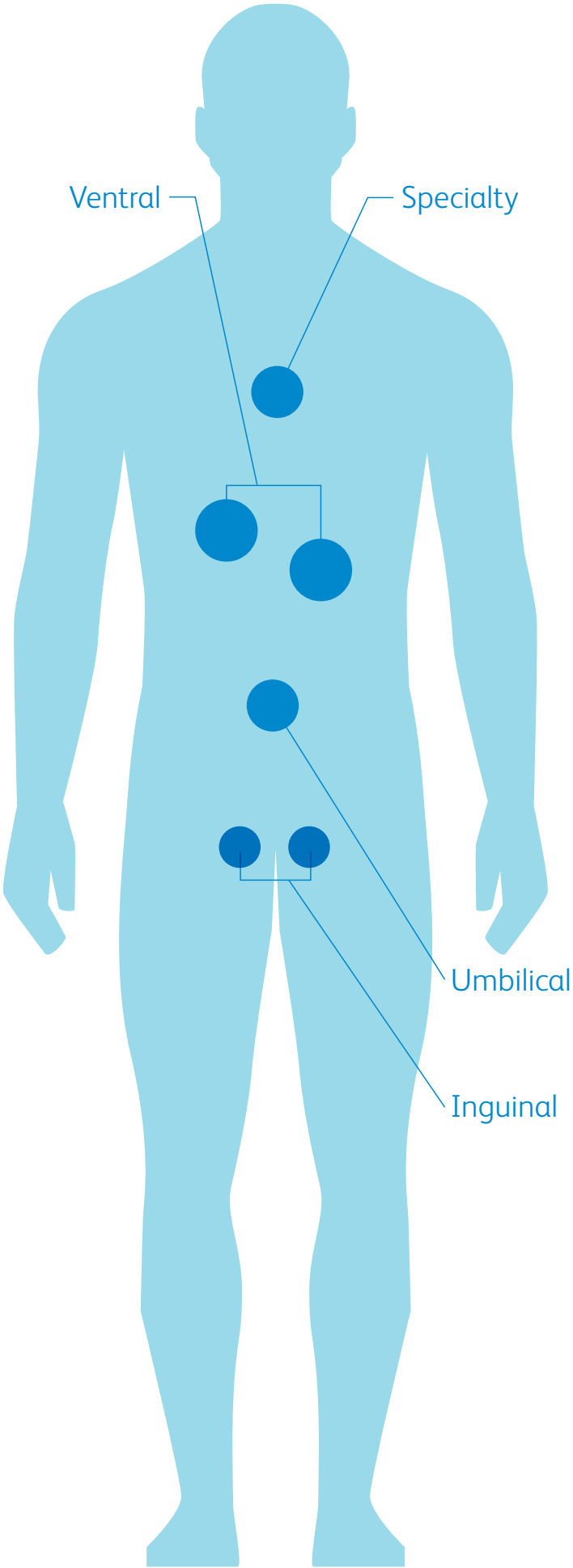
BD Surgical Product Catalogue

Ventral, umbilical, inguinal, bioresorbable implants and mesh fixation

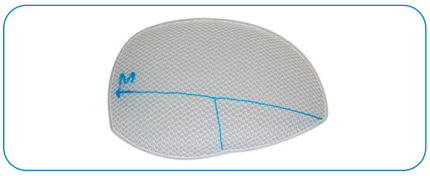
Now more than ever, your hospital must run as efficiently as possible and still provide the best patient care. Since hernia repair is one of the most common surgical procedures in the country, hernia repair product standardisation, ongoing training and patient education will help you achieve these goals. 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

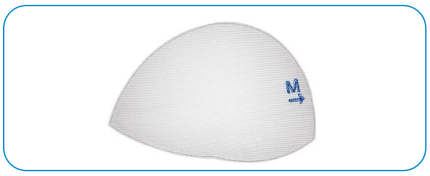
Scan the QR code to explore BD products and discover our professional education programmes



Inguinal

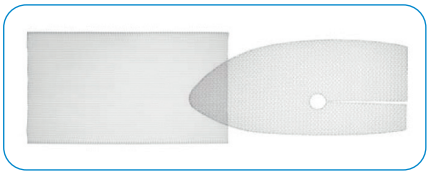


3DMax™ MID Anatomical Mesh
Medium weight, open pore monofilament mesh for laparoscopic inguinal hernia repair.

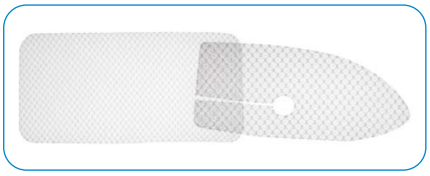


BD® 3DMax™ Mesh
Unique three-dimensional polypropylene mesh for laparoscopic inguinal hernia repair.

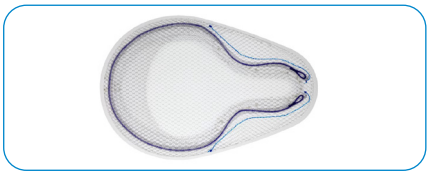
3DMax™ Light Mesh
Lighter-weight version of the popular 3DMax™ Mesh, featuring a large pore knit design.



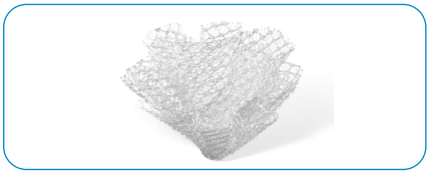
Bard® Mesh Flats and Bard® Mesh Pre-shaped
Monofilament polypropylene mesh for use in ventral or inguinal hernia repair.



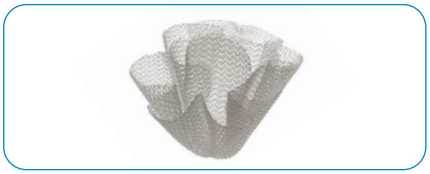
Bard® Soft Mesh and Bard® Soft Mesh Pre-shaped
Large pore monofilament polypropylene mesh that has a soft, compliant knit structure.



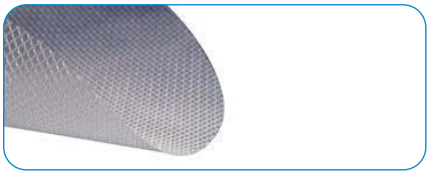
Onflex™ Mesh
Self-expanding lightweight mesh for open preperitoneal inguinal hernia repair with SorbaFlex™ Memory Technology.



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

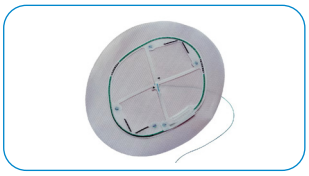


Perfix™ Plug
Plug and patch designed for use in a tension-free open inguinal hernia repair technique

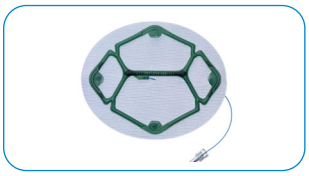


Mesh Adhesix™ – Adhesive Parietal Reinforcement Implant
Unique lightweight polypropylene mesh with gel coating in polyvinyl-pyrrolidone (PVP) and polyethylene-glycol (PEG) that provides an atraumatic repair in laparoscopic and open inguinal procedures.

Ventral

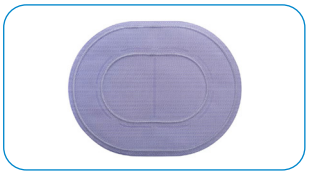


Ventralight™ ST Mesh with Echo 2™ Positioning System
The Echo 2™ Positioning System is a deployment and positioning device that comes attached to Ventralight™ ST Mesh. It facilitates mesh positioning and centring over the hernia defect, for a consistent, reproducible technique

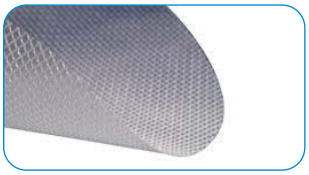


Ventralight™ ST Mesh with Echo PS™ Positioning System
Ventralight™ ST Mesh with a pre-attached low-profile balloon to help facilitate deployment, placement and positioning in laparoscopic ventral hernia repair.

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.

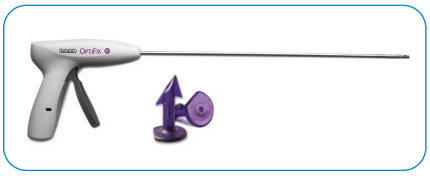


Mesh Adhesix™ – Adhesive Parietal Reinforcement Implant
Unique lightweight polypropylene mesh with gel coating in polyvinyl-pyrrolidone (PVP) and polyethylene-glycol (PEG) that provides an atraumatic extraperitoneal ventral hernia repair.

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

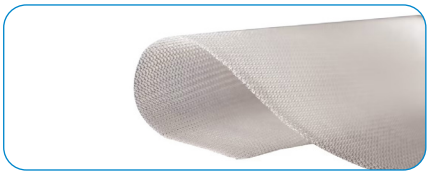


OptiFix™ Absorbable Fixation System
Absorbable PDLLA fasteners available in both a 15 and 30 count configuration delivered via a disposable 5mm stored energy delivery system.

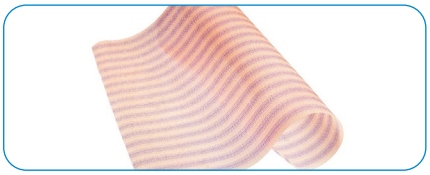
SorbaFix™ Absorbable Fixation System
Absorbable PDLLA fasteners available in both a 15 and 30 count configuration delivered via a disposable 5 mm delivery system.

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.

Bioresorbable mesh



Phasix™ Mesh
Composed of material derived from a fermentation process, Poly-4-hydroxybutyrate (P4HB), Phasix™ Mesh provides critical strength during the initial healing phase, for ventral hernia and other abdominal fascial defect procedures including prophylactic use.



Phasix™ ST Mesh
A fully bioresorbable Poly-4-hydroxybutyrate (P4HB) scaffold featuring proven Sepra® technology barrier to adhesions, for ventral and hiatal hernia repair procedures.

Ordering information – inguinal

3DMax™ MID Anatomical Mesh

Medium weight, open pore monofilament mesh for laparoscopic inguinal hernia repair.

Product item ID	Packaging (SKU)	Dimensions
0116310	1/cs.	Medium, Left, 8.0 cm x 14.0 cm
0116311	1/cs.	Large, Left, 10.0 cm x 16.0 cm
0116312	1/cs.	Extra-Large, Left, 12.0 cm x 17.0 cm
0116320	1/cs.	Medium, Right, 8.0 cm x 14.0 cm
0116321	1/cs.	Large, Right, 10.0 cm x 16.0 cm
0116322	1/cs.	Extra-Large, Right, 12.0 cm x 17.0 cm

3DMax™ Mesh

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

Product item ID	Packaging (SKU)	Dimensions
0115310	1/cs.	Medium, Left, 8.5 cm x 13.7 cm
0115311	1/cs.	Large, Left, 10.8 cm x 16.0 cm
0115312	1/cs.	Extra-Large, Left, 12.4 cm x 17.3 cm
0115320	1/cs.	Medium, Right, 8.5 cm x 13.7 cm
0115321	1/cs.	Large, Right, 10.8 cm x 16.0 cm
0115322	1/cs.	Extra-Large, Right, 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.	Medium, Left, 7.9 cm x 13.4 cm
0117311	1/cs.	Large, Left, 10.3 cm x 15.7 cm
0117312	1/cs.	Extra-Large, Left, 12.2 cm x 17.0 cm
0117320	1/cs.	Medium, Right, 7.9 cm x 13.4 cm
0117321	1/cs.	Large, Right, 10.3 cm x 15.7 cm
0117322	1/cs.	Extra-Large, Right, 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 10.0 cm
0112650G	3/cs.	5.0 cm x 10.0 cm
0112660G	1/cs.	25.0 cm x 35.5 cm
0112670G	2/cs.	5.0 cm x 30.5 cm
0112680G	3/cs.	7.5 cm x 15.0 cm
0112720G	3/cs.	15.0 cm x 15.0 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.	5.0 cm x 10.0 cm
0117009	3/cs.	7.5 cm x 15.0 cm
0117010	3/cs.	10.0 cm x 15.0 cm
0117011	3/cs.	15.0 cm x 15.0 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 10.0 cm
0112710	3/cs.	Pre-shaped with Keyhole, 4.5 cm x 10.0 cm
0113700	3/cs.	Large Pre-shaped, 6.0 cm x 13.7 cm
0113710	3/cs.	Large Pre-shaped with Keyhole, 6.0 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 10.0 cm
0117013	3/cs.	Pre-shaped with Keyhole, 4.5 cm x 10.0 cm
0117014	3/cs.	Large Pre-shaped, 6.0 cm x 13.7 cm
0117015	3/cs.	Large Pre-shaped with Keyhole, 6.0 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, 2.5 cm x 3.4 cm
0112760	2/cs.	Medium, 3.3 cm x 3.9 cm
0112770	2/cs.	Large, 4.1 cm x 4.8 cm
0112780	2/cs.	Extra-Large, 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, 2.5 cm x 3.4 cm
0117060	1/cs.	Medium, 3.3 cm x 3.9 cm
0117070	1/cs.	Large, 4.1 cm x 4.8 cm
0117080	1/cs.	Extra-Large, 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

Mesh Adhesix™ – Adhesive Parietal Reinforcement Implant – Laparoscopy

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.	10.0 cm x 15.0 cm
0114320	1/cs.	12.0 cm x 15.0 cm

Mesh Adhesix™ – Adhesive Parietal Reinforcement 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.	4.0 cm x 10.0 cm
0119330	1/cs.	6.0 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.	Circle, 11.4 cm diameter
5955460G	1/cs.	Ellipse, 10.2 cm x 15.2 cm
5955600G	1/cs.	Circle, 15.2 cm diameter
5955680G	1/cs.	Ellipse, 15.2 cm x 20.3 cm
5955610G	1/cs.	Oval, 15.2 cm x 25.4 cm
5955790G	1/cs.	Ellipse, 17.8 cm x 22.9 cm
5955800G	1/cs.	Circle, 20.3 cm diameter
5955810G	1/cs.	Ellipse, 20.3 cm x 25.4 cm
5955113G	1/cs.	Ellipse, 25.4 cm x 33.0 cm
5955124G	1/cs.	Rectangle, 30.5 cm x 35.6 cm

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.	Circle, 11.4 cm diameter
5990015G	1/cs.	Circle, 15.0 cm diameter
5990020G	1/cs.	Circle, 20.0 cm circle diameter
5991015G	1/cs.	Ellipse, 10.0 cm x 15.0 cm
5991520G	1/cs.	Ellipse, 15.0 cm x 20.0 cm
5991525G	1/cs.	Oval, 15.0 cm x 25.0 cm
5991823G	1/cs.	Ellipse, 18.0 cm x 23.0 cm
5992025G	1/cs.	Ellipse, 20.0 cm x 25.0 cm
5992533G	1/cs.	Ellipse, 25.0 cm x 33.0 cm

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.	Small Oval, 8.0 cm x 12.0 cm
5950040G	1/cs.	Medium Oval, 11.0 cm x 14.0 cm
5950050G	1/cs.	Large Oval, 13.8 cm x 17.8 cm
5950010G	1/cs.	Small Circle, 7.6 cm diameter
5950020G	1/cs.	Large Circle, 11.4 cm diameter
5950070G	1/cs.	Extra-Large Oval, 19.6 cm x 24.6 cm
5950080G	1/cs.	Extra-Large Oval, 22.1 cm x 27.1 cm
5950090G	1/cs.	Extra-Large Oval, 27.4 cm x 34.9 cm
5950060G	1/cs.	Midline, 15.5 cm x 25.7 cm

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.	Circle, 11.4 cm diameter
5954460G	1/cs.	Ellipse, 10.2 cm x 15.2 cm
5954600G	1/cs.	Circle, 15.2 cm diameter
5954680G	1/cs.	Ellipse, 15.2 cm x 20.3 cm
5954610G	1/cs.	Oval, 15.2 cm x 25.4 cm
5954790G	1/cs.	Ellipse, 17.8 cm x 22.9 cm
5954800G	1/cs.	Circle, 20.3 cm diameter
5954810G	1/cs.	Ellipse, 20.3cm x 25.4 cm
5954113G	1/cs.	Ellipse, 25.4 cm x 33.0 cm
5954124G	1/cs.	Rectangle, 30.5 cm x 35.6 cm

Mesh Adhesix™ – Adhesive Parietal Reinforcement Implant – Open Ventral

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

Product item ID	Packaging (SKU)	Dimensions
0113310	1/cs.	15.0 cm x 20.0 cm
0113420	1/cs.	20.0 cm x 25.0 cm
0113530	1/cs.	30.0 cm x 30.0 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.	Small Circle with Strap, 4.3 cm diameter
5950008G	1/cs.	Medium Circle with Strap, 6.4 cm diameter
5950009G	1/cs.	Large Circle with Strap, 8.0 cm diameter

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 absorbable fasteners
0113116	5/cs.	30 absorbable 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 permanent fasteners
0113230G	5/cs.	30 permanent 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 – bioresorbable mesh

Phasix™ Mesh

Clinically proven Poly-4-hydroxybutyrate (P4HB) bioresorbable mesh for ventral hernia and other abdominal fascial defect procedures including prophylactic use.

Product item ID	Packaging (SKU)	Dimensions
1190100G	1/cs.	Round, 7.6 cm diameter
1190616G	1/cs.	Rectangle, 6.0 cm x 16.0 cm
1190820G	1/cs.	Rectangle, 8.0 cm x 20.0 cm
1190830G	1/cs.	Rectangle, 8.0 cm x 30.0 cm
1191040G	1/cs.	Rectangle, 10.0 cm x 40.0 cm
1190845G	1/cs.	Rectangle, 8.0 cm x 45.0 cm
1190200G	1/cs.	Rectangle, 10.2 cm x 15.2 cm
1190300G	1/cs.	Rectangle, 15.2 cm x 20.3 cm
1190400G	1/cs.	Rectangle, 20.3 cm x 25.4 cm
1190500G	1/cs.	Rectangle, 25.4 cm x 30.5 cm
1191025G	1/cs.	Rectangle, 10.0 cm x 25.0 cm
1191525G	1/cs.	Rectangle, 15.0 cm x 25.0 cm
1191530G	1/cs.	Rectangle, 15.0 cm x 30.0 cm
1192030G	1/cs.	Rectangle, 20.0 cm x 30.0 cm
1192040G	1/cs.	Rectangle, 20.0 cm x 40.0 cm
1193045G	1/cs.	Rectangle, 30.0 cm x 45.0 cm
1195050G	1/cs.	Square, 50.0 cm x 50.0 cm

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.	Round, 8.0 cm diameter
1200011G	1/cs.	Round, 11.0 cm diameter
1200015G	1/cs.	Round, 15.0 cm diameter
1200710G	1/cs.	Rectangle, 7.0 cm x 10.0 cm
1201010G	1/cs.	Square, 10.0 cm x 10.0 cm
1201015G	1/cs.	Rectangle, 10.0 cm x 15.0 cm
1201020G	1/cs.	Rectangle, 10.0 cm x 20.0 cm
1201325G	1/cs.	Rectangle, 13.0 cm x 25.0 cm
1201520G	1/cs.	Rectangle, 15.0 cm x 20.0 cm
1202025G	1/cs.	Rectangle, 20.0 cm x 25.0 cm
1202530G	1/cs.	Rectangle, 25.0 cm x 30.0 cm
1203035G	1/cs.	Rectangle, 30.0 cm x 35.0 cm

IFU information

3DMax™ MID Anatomical Mesh

Indications

The 3DMax™ MID Anatomical Mesh is indicated for use in the reinforcement of soft tissue where weakness exists in the repair of inguinal hernias.

Contraindications

1. Do not use this mesh in infants, children or pregnant or breastfeeding women, whereby future growth may be compromised by use of such mesh material. 2. Literature reports that there may be a possibility for adhesion formation when polypropylene mesh is placed in direct contact with the bowel or viscera.

Warnings

1. The use of any permanent mesh or patch in a contaminated or infected wound could lead to fistula formation and/or extrusion of the mesh. 2. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require removal of the mesh. 3. If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with bodily fluids, discard mesh with care to prevent risk of transmission of viral infections. 4. To prevent recurrences when repairing hernias, the mesh should be sized with appropriate overlap for the size and location of the defect, taking into consideration any additional clinical factors applicable to the patient. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue. 5. This mesh is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 6. This mesh has been designed for single use only. Reuse, reprocessing, resterilisation or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the mesh and may lead to mesh failure which may result in injury to the patient. Reuse, reprocessing, resterilisation or repackaging may also create a risk of contamination of the mesh and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the mesh may lead to injury, illness or death of the patient or end user. 7. To avoid injury, careful attention is required if fixating the mesh in the presence of nerves, vessels or the spermatic cord. Fastener penetration into underlying tissue containing nerves or blood vessels may result in the need for medical/surgical intervention, cause serious injury or permanent impairment to a body structure. 8. This device is not for the use of repair of pelvic organ prolapse. 9. This device is not for the use of treatment of stress urinary incontinence.

Precautions

1. Please read all instructions prior to use. 2. Only physicians qualified in appropriate surgical techniques should use this mesh. 3. Do not cut or reshape the 3DMax™ MID Anatomical Mesh as this may affect its effectiveness. 4. Use an appropriately sized trocar to allow mesh to slide down the trocar with minimal force.

Adverse Reactions

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

Instructions for use

It is recommended to use 8 mm or larger internal diameter trocar* to introduce 3DMax™ MID Anatomical Mesh. *If the trocar has a proximal cap, removing it can help facilitate insertion of the device. Insertion forces may vary depending on rolled device size and graspers/trocar used.

3DMax™ Mesh

Indications

Bard® 3DMax™ Mesh is indicated for use in the reinforcement of soft tissue where weakness exists, in the repair of inguinal hernias.

Contraindications

1. Do not use this mesh in infants, children, or pregnant women, whereby future growth may be compromised by use of such materials. 2. The use of this mesh has not been studied in pregnant or breastfeeding women. 3. Literature reports that there may be a possibility for adhesion formation when polypropylene is placed in direct contact with the bowel or viscera.

Warnings

1. The use of any synthetic mesh or patch in a contaminated or infected wound can lead to fistula formation and/or extrusion of the mesh. 2. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require removal of the mesh. 3. If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard with care to prevent risk of transmission of viral infections. 4. To prevent recurrences when repairing hernias, the mesh should be sized with appropriate overlap for the size and location of the defect, taking into consideration any additional clinical factors applicable to the patient. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue. 5. The mesh is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 6. This mesh had been designed for single use only. Reuse, reprocessing, resterilisation, or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the mesh and may lead to mesh failure which may result in injury to the patient. Reuse, reprocessing, resterilisation, or repackaging may also create a risk of contamination of the mesh and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the mesh may lead to injury, illness or death of the patient or end user. 7. To avoid injury, careful attention is required if fixating the mesh in the presence of nerves, vessels, or the spermatic cord. Fastener penetration into underlying tissue containing nerves or blood vessels may result in the need for medical/surgical intervention, cause serious injury or permanent impairment to a body structure.

Precautions

1. Please read all instructions prior to use. 2. Only physicians qualified in appropriate surgical techniques should use this mesh. 3. Do not cut or reshape the Bard® 3DMax™ Mesh as this may affect its effectiveness. 4. It is recommended to use a 10 mm internal diameter trocar to introduce a medium Bard® 3DMax™ Mesh, and an 11 mm internal diameter trocar to introduce a large Bard® 3DMax™ Mesh. The size of the extra-large Bard® 3DMax™ Mesh may inhibit deployment through a trocar. Use an appropriately sized trocar to allow mesh to slide down the trocar with minimal force. If mesh will not easily deploy down the trocar, remove trocar and insert mesh through incision. Reinsert trocar. 5. If fixation is used, Bard® permanent or absorbable fixation devices or nonabsorbable monofilament sutures are recommended to properly secure the device. If other fixation devices are used, they must be indicated for use in hernia repair. 6. If fixation is used, care should be taken to ensure that the mesh is adequately fixated to the abdominal wall. If necessary, additional fasteners and/or sutures should be used.

Adverse Reactions

Possible complications may include, but are not limited to, seroma, adhesions, haematomas, pain, infection, inflammation, extrusion, erosion, migration, fistula formation, allergic reaction, and recurrence of the hernia or soft tissue defect. Please consult product package insert for more detailed safety information and instructions for use.

3DMax™ Light Mesh

Indications

The 3DMax™ Light Mesh is indicated for use in the reinforcement of soft tissue where weakness exists, in the repair of inguinal hernias.

Contraindications

1. Do not use this mesh in infants, children, or pregnant women, whereby future growth may be compromised by use of such materials. 2. The use of this mesh has not been studied in pregnant or breastfeeding women. 3. Literature reports that there may be a possibility for adhesion formation when polypropylene is placed in direct contact with the bowel or viscera.

Warnings

1. The use of any synthetic mesh or patch in a contaminated or infected wound can lead to fistula formation and/or extrusion of the mesh. 2. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require removal of the mesh. 3. If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard with care to prevent risk of transmission of viral infections. 4. To prevent recurrences when repairing hernias, the mesh should be sized with appropriate overlap for the size and location of the defect, taking into consideration any additional clinical factors applicable to the patient. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue. 5. The mesh is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 6. This mesh had been designed for single use only. Reuse, reprocessing, resterilisation, or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the mesh and may lead to mesh failure which may result in injury to the patient. Reuse, reprocessing, resterilisation, or repackaging may also create a risk of contamination of the mesh and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the mesh may lead to injury, illness or death of the patient or end user. 7. To avoid injury, careful attention is required if fixating the mesh in the presence of nerves, vessels, or the spermatic cord. Fastener penetration into underlying tissue containing nerves or blood vessels may result in the need for medical/surgical intervention, cause serious injury or permanent impairment to a body structure. 8. This device is not for the use of repair of pelvic organ prolapse. 9. This device is not for the use of treatment of stress urinary incontinence.

Precautions

1. Please read all instructions prior to use. 2. Only physicians qualified in appropriate surgical techniques should use this mesh. 3. Do not cut or reshape the 3DMax™ Light Mesh as this may affect its effectiveness. 4. Use an appropriately sized trocar to allow mesh to slide down the trocar with minimal force. 5. If fixation is used, Bard® permanent or absorbable fixation devices or nonabsorbable monofilament sutures are recommended to properly secure the device. If other fixation devices are used, they must be indicated for use in hernia repair. 6. If fixation is used, care should be taken to ensure that the mesh is adequately fixated to the abdominal wall. If necessary, additional fasteners and/or sutures should be used.

Adverse Reactions

Possible complications may include, but are not limited to, seroma, adhesions, haematomas, pain, infection, inflammation, extrusion, erosion, migration, fistula formation, allergic reaction and recurrence of the hernia or soft tissue defect. Please consult product package insert for more detailed safety information and instructions for use.

Mesh Adhesix™ – Adhesive Parietal Reinforcement Implant

Indications

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

Uses

Adhesix™ meshes can be used in laparoscopic surgery or in open surgery and are designed for extraperitoneal implantation. Adhesix™ meshes are coated with a resorbable adhesive hydrogel and are biocompatible. These devices promote reactional fibrosis. They can be easily cut to fit any hernia size. Adhesix™ meshes are also very flexible and allow good tissue ingrowth as well as rapid and optimum tissue colonisation.

Contraindications

Do not implant in the following cases: • Allergy to one of the components • Infected site • Anticoagulant therapy • Pregnant woman • Growing child (<18 years).

Adverse Side Effects

As with any implantable medical device, Adhesix™ Mesh may induce adverse side effects such as: • Recurrence • Inflammation • Adhesions • Pain • Infection • Allergic reaction • Seroma •Cutaneous dehiscence • Cutaneous necrosis • Migration • Discomfort • Extrusion • Haematomas • Fistula formation • Erosion • Foreign Body Reaction • Obstruction • Lymphocele •Deformation of the mesh and irritation of nearby organs.

Precautions for Use

The device must be implanted only by a qualified surgeon with knowledge of anatomy and visceral surgery, proper expertise of the device, its intended use and the surgical technique. Adhesix™ meshes are delivered sterile; verify the integrity of the packaging (do not use if the labels and/or blister packs/ peeled pouches are damaged). Do not use if the device is damaged or has expired.

General Recommendations

Keep the mesh dry (away from any type of liquids) until placement in the abdomen during surgery. The adhesive hydrogel does not affect haemostasis: the area of dissection and the fascia on which the Adhesix™ implant is placed must be clean and dry. If necessary, use a surgical gauze to ensure the surgical field is dry. The adhesive hydrogel is activated by heat and moisture. Once the implant is in place, it must not be repositioned by the surgeon.

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™ Mesh is indicated for preperitoneal placement. It is recommended that the adhesive hydrogel side should be implanted deeply. The size of the implant must fit the size of the defect. It is recommended to place an abdominal strap around the patient's abdomen for several days following surgery in order to reinforce the abdominal wall. IMPORTANT: DO NOT REUSE - DO NOT RESTERILISE As stipulated on the product's label, Adhesix™ Mesh is a single-use device. Under no circumstances should it be reused and/or resterilised (potential risks include, but are not limited to: loss of product sterility, risk of infection, loss of product efficacy, and recurrence).

Specific Recommendations for Laparoscopy

Following standard dissection, the Adhesix™ Mesh and its protective film are rolled horizontally. The protective film is rolled towards the inner side of the mesh. Both the mesh and the protective film must be inserted in a 12 mm trocar. The implant is unrolled from top to bottom or from bottom to top. It must completely cover the weakened area. The nonadhesive side of the implant (rough side) must be placed on the fascia. The protective film must be removed.

Storage Precautions

Store in a dry place, away from light, and in its original packaging.

Ventralight™ ST Mesh with Echo PS™ Positioning System

Indications

Ventralight™ ST Mesh is indicated for use in the reconstruction of soft tissue deficiencies, in the repair of ventral, incisional, and umbilical hernias. The Echo PS™ Positioning System is intended to be used to facilitate the delivery of the Ventralight™ ST Mesh during laparoscopic hernia repair.

Contraindications

1. Do not use this mesh in infants, children, or pregnant women, whereby future growth may be compromised by the use of such mesh materials. 2. The use of this mesh has not been studied in breastfeeding or pregnant women. 3. Do not use this mesh for the reconstruction of cardiovascular defects. 4. Literature reports there is a possibility for adhesion formation when the polypropylene is placed in direct contact with the bowel or viscera.

Warnings

1. The use of any permanent mesh in a contaminated or infected wound could lead to infection, fistula formation, and/or extrusion of the mesh. 2. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require removal of the mesh. 3. If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard with care to prevent risk of transmission of

viral infections. 4. To prevent recurrences when repairing hernias, the mesh should be sized with appropriate overlap for the size and location of the defect, taking into consideration any additional clinical factors applicable to the patient. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue. 5. This device is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use 6. This device has been designed for single use only. Reuse, resterilisation, reprocessing and/or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient. Reuse, reprocessing, resterilisation, or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient or end user. 7. The mesh should be used once the exterior foil pouch has been opened. Do not store for later use. Unused portions of the mesh should be discarded. 8. Ensure proper orientation; the coated side of the mesh should be oriented against the bowel or sensitive organs. Do not place the polypropylene side against the bowel. There may be a possibility for adhesion formation when the polypropylene side is placed in direct contact with the bowel or viscera (reference Surface Orientation section). 9. Do not apply sharp, heat emitting, or ultrasonic tools (such as scissors, needles, tackers, diathermic tools, etc.) to the Echo PS™ Positioning System. 10. The Echo PS™ Positioning System should not be used with any other hernia mesh aside from those with which it comes pre-attached/packaged. 11. Ventralight™ ST Mesh is the only permanent implant component of the device. The inflation adapter and syringe are to be kept external to the patient and discarded after use. The Echo PS™ Positioning System (including the balloon, all connectors, and inflation tube) must be removed from the patient and appropriately discarded. It is not part of the permanent implant. 12. Discard Introducer Tool and all components of the Echo PS™ Positioning System (including the inflation adapter and syringe) after use. This product may be a potential biohazard. Handle and dispose in accordance with accepted medical practice and applicable local, state, and federal laws and regulations. 13. This mesh is not for the use of repair of pelvic organ prolapse via transvaginal approach. 14. This mesh is not for the use of treatment of stress urinary incontinence.

Precautions

1. Please read all instructions prior to use. 2. Only physicians qualified in the appropriate surgical techniques should use this device. 3. The safety and effectiveness of Ventralight™ ST Mesh with Echo PS™ Positioning System has not been evaluated in clinical studies for the presence of malignancies in the abdominopelvic cavity. 4. Visualisation must be maintained throughout the course of the entire procedure. Additionally, laparoscopic removal of the Echo PS™ Positioning System must be performed under sufficient visualisation of the entire device and surrounding anatomy to ensure proper removal. 5. Do not trim the mesh. This will affect the interface between the mesh and positioning system.

Adverse Reactions

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

Ventralight™ ST Mesh with Echo 2™ Positioning System

Indications

Ventralight™ ST Mesh is indicated for use in the reconstruction of soft tissue deficiencies in the repair of ventral, incisional, and umbilical hernias. The Echo 2™ Positioning System is intended to facilitate the delivery and positioning of the Ventralight™ ST Mesh during laparoscopic hernia repair.

Contraindications

1. Do not use this mesh in infants, children, or pregnant women, whereby future growth may be compromised by the use of such mesh materials. 2. The use of this mesh has not been studied in breastfeeding or pregnant women. 3. Do not use this mesh for the reconstruction of cardiovascular defects. 4. Literature reports there is a possibility for adhesion formation when the polypropylene is placed in direct contact with the bowel or viscera.

Warnings

1. The use of any permanent mesh or patch in a contaminated or infected wound can lead to fistula formation and/or extrusion of the mesh. 2. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require removal of the mesh. 3. If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard with care to prevent risk of transmission of viral infections. 4. To prevent recurrences when repairing hernias, the mesh should be sized with appropriate overlap for the size and location of the defect, taking into consideration any additional clinical factors applicable to the patient. Careful attention to mesh fixation, placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue. 5. This device is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 6. This device is designed for single use only. Reuse, resterilisation, reprocessing and/or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient. Reuse, reprocessing, resterilisation, or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient or end user. 7. This mesh should be used once the exterior foil pouch has been opened. Do not store for later use. Unused portions of the mesh should be discarded. 8. Ensure proper orientation; the coated side of the mesh should be oriented against the bowel or sensitive organs. Do not place the polypropylene side against the bowel. There may be a possibility for adhesion formation when the polypropylene side is placed in direct contact with the bowel or viscera (see "Surface Orientation"). 9. Do not apply sharp, pointed, cautery devices, or ultrasonic tools (such as scissors, needles, tackers, diathermic tools, etc.) to the Echo 2™ Positioning System frame. 10. This device contains superelastic nitinol wire; do not cut and avoid direct contact/coupling with active surgical electrodes. 11. Ventralight™ ST Mesh is the only permanent implant component of the device. The Echo 2™ Positioning System (which includes deployment frame, center hoisting suture and all connectors) must be removed from the patient and appropriately discarded. It is not part of the permanent implant. 12. The Echo 2™ Positioning System should not be used with any other hernia mesh aside from those with which it comes pre-attached/packaged. 13. Discard the Echo 2™ Positioning System (including the frame, center hoisting suture, all connectors and Mesh Introducer) after use. These may be a potential biohazard. Handle and dispose in accordance with accepted medical practice and applicable local, state and federal laws and regulations. 14. This mesh is not for the use of repair of pelvic organ prolapse via transvaginal approach. 15. This mesh is not for the use of treatment of stress urinary incontinence.

Precautions

1. Please read all instructions prior to use. 2. Only physicians qualified and trained in the appropriate surgical techniques should use this device. 3. The safety and effectiveness of the device has not been evaluated in clinical studies for the presence of malignancies in the abdominopelvic cavity. 4. Visualisation must be maintained throughout the course of the entire procedure. Additionally, laparoscopic removal of the Echo 2™ Positioning System must be performed under sufficient visualisation of the entire device and surrounding anatomy to ensure proper removal. 5. Do not trim the mesh. This will affect the interface between the mesh and the positioning system.

Adverse Reactions

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

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

1. Use of this device is contraindicated for infants, children, or pregnant women, whereby future growth will be compromised by use of such mesh material.2. Literature reports that there is a possibility for adhesion formation when polypropylene is placed in direct contact with the bowel or viscera.

Warnings

1. The use of any synthetic mesh or patch in a contaminated or infected wound can lead to fistula formation and/or extrusion of the mesh and is not recommended. 2. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. Unresolved infection may require removal of the mesh.3. If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard mesh with care to prevent risk of transmission of viral infections.4. To prevent recurrences when repairing hernias, the mesh should be large enough to provide sufficient overlap beyond the margins of the defect. If fixation is used, careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue.5. To avoid injury, careful attention is required if fixating the mesh in the presence of nerves, vessels, or spermatic cord structures. 6. The mesh is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 7. This device is for single use only. Do not resterilise or reuse any portion of the Onflex™ Mesh. 8. Do not cut or reshape the Onflex™ Mesh, except at the opening in the interrupted SorbaFlex™ PDO monofilament, to accommodate the spermatic cord and outside the blue limit line in the lateral portion of the mesh, as this could affect its effectiveness. Care should be taken not to cut or nick the SorbaFlex™ PDO monofilament

Precautions

Please read all instructions prior to use. 2. Only physicians qualified in the appropriate surgical techniques should use this prosthesis. 3. Care should be taken not to cut or nick the SorbaFlex™ PDO monofilament. 4. If fixation is used, care should be taken to ensure that the mesh is adequately fixated. If necessary, additional fasteners and/or sutures should be used.

Adverse Reactions

Possible complications may include, but are not limited to, seroma, adhesion, haematoma, pain, infection, inflammation, extrusion, erosion, migration, fistula formation and recurrence of the hernia or soft tissue defect. If the SorbaFlex™ PDO monofilament is cut or damaged, additional complications may include, but are not limited to, bowel or skin perforation and infection.

Bard® Soft Mesh

Indications

Bard® Soft Mesh is indicated for the repair of ventral, incisional, and inguinal hernias.

Contraindications

1. Do not use Bard® Soft Mesh in infants, children, or pregnant women, whereby future growth may be compromised by use of such mesh material. 2. The use of this mesh has not been studied in breastfeeding or pregnant women. 3. Do not use this mesh for the reconstruction of cardiovascular defects. 4. Literature reports that there may be a possibility for adhesion formation when the polypropylene mesh is placed in direct contact with the bowel or viscera.

Warnings

1. The use of any synthetic mesh or patch in a contaminated or infected wound could lead to fistula formation and/or extrusion of the mesh. 2. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require removal of the mesh. .3. If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard with care to prevent risk of transmission of viral infections. 4. To prevent recurrences when repairing hernias, the mesh should be sized with appropriate overlap for the size and location of the defect, taking into consideration any additional clinical factors applicable to the patient. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue. 5. The mesh is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 6. This mesh has been designed for single use only. Reuse, reprocessing, resterilisation or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the mesh and may lead to mesh failure which may result in injury to the patient. Reuse, reprocessing, resterilisation or repackaging may also create a risk of contamination of the mesh and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the mesh may lead to injury, illness, or death of the patient end user. 7. To avoid injury, careful attention is required if fixating the mesh in the presence of nerves, vessels or the spermatic cord. Fastener penetration into underlying tissue containing nerves or blood vessels may result in the need for medical/surgical intervention, cause serious injury or permanent impairment to a body structure. 8. This mesh is not for the use of repair of pelvic organ prolapse. 9. This mesh is not for the use of treatment of stress urinary incontinence.

Precautions

1. Please read all instructions prior to use. 2. Only physicians qualified in the appropriate surgical techniques should use this mesh.

Adverse Reactions

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

Bard® Soft Mesh Pre-shaped

Indications

Bard® Soft Mesh Pre-shaped is indicated for the repair of inguinal hernia defects.

Contraindications

1. Do not use Bard® Soft Mesh Pre-shaped in infants, children, or pregnant women, whereby future growth may be compromised by use of such mesh material. 2. The use of this mesh has not been studied in breastfeeding or pregnant women. 3. Literature reports that there may be a possibility for adhesion formation when the polypropylene is placed in direct contact with the bowel or viscera.

Warnings

1. The use of any synthetic mesh or patch in a contaminated or infected wound could lead to fistula formation and/or extrusion of the mesh. 2. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require removal of the mesh. 3. If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard with care to prevent risk of transmission of viral infections. 4. To prevent recurrences when repairing hernias, the mesh should be sized with appropriate overlap for the size and location of the defect, taking into consideration any additional clinical factors applicable to the patient. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue. 5. The mesh is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 6. This mesh has been designed for single use only. Reuse, reprocessing, resterilisation or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the mesh and may lead to mesh failure which may result in injury to the patient. Reuse, reprocessing, resterilisation or repackaging may also create a risk of contamination of the mesh and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the mesh may lead to injury, illness, or death of the patient or end user.7. To avoid injury, careful attention is required if fixating the mesh in the presence of nerves, vessels or the spermatic cord. Fastener penetration into underlying tissue containing nerves or blood vessels may result in the need for medical/surgical intervention, cause serious injury or permanent impairment to a body structure. 8. This mesh is not for the use of repair of pelvic organ prolapse. 9. This mesh is not for the use of treatment of stress urinary incontinence.

Precautions

1. Please read all instructions prior to use. 2. Only physicians qualified in the appropriate surgical techniques should use this mesh.

Adverse Reactions

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

Bard® Mesh Pre-shaped

Indications

Bard® Pre-shaped mesh is indicated for the repair of inguinal hernia defects.

Contraindications

1. Do not use Bard® Pre-shaped mesh in infants or children,

whereby future growth will be compromised by use of such mesh material. 2. Literature reports there may be a possibility for adhesion formation when Bard® mesh is placed in direct contact with the bowel or viscera.
Warnings
1. This device must be sterile before use. Please inspect the packaging to be sure it is intact and undamaged. 2. This device is for single use only. Do not resterilise or reuse any portion of Bard® Mesh Pre-shaped. 3. Careful attention to Bard® Pre-shaped mesh handling, fixation, and suture technique is most important in the presence of known or suspected wound contamination or infection. 4. The use of any permanent mesh or patch in a contaminated or infected wound can lead to fistula formation and/or extrusion of the prosthesis. 5. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require removal of the device. 6. To prevent recurrences when repairing inguinal hernias, the mesh should be large enough to extend beyond the pubic tubercle and should fit securely around the spermatic cord at the internal ring. Many surgeons cut a keyhole in the mesh to allow for easier placement around the cord. 7. Reuse, reprocessing, resterilisation or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient. Reuse, reprocessing, resterilisation or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient or end user. 8. If unused prosthesis has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard with care to prevent risk of transmission of infection.
Precautions
1. Please read all instructions prior to use. 2. Only physicians qualified in the appropriate surgical techniques should use this prosthesis. 3. Intact Bard® Pre-shaped mesh exhibits high burst and tensile strength. However, when custom tailoring, in special circumstances where excessive force is placed on the mesh, the following guidelines may be helpful: • When cutting a notch in the mesh, a V-shape with a radiused point will withstand more force than a V-shape which comes to a sharp point. 4. Davol™ permanent or absorbable fixation devices or nonabsorbable monofilament sutures are recommended to properly secure the prosthesis. If absorbable fixation devices are used, they must be indicated for use in hernia repair. 5. Care should be taken to ensure that the mesh is adequately fixated to the uncompromised tissue of the inguinal floor. If necessary, additional fasteners and/or sutures should be used.
Adverse Reactions
Possible complications include seroma, adhesions, haematoma, inflammation, extrusion, fistula formation and recurrence of the hernia or soft tissue defect.

Bard® Mesh
Indications
Bard® Mesh is indicated for the repair of ventral, incisional, umbilical, and inguinal hernias.
Contraindications
1. Do not use this mesh in infants, children, or pregnant women, whereby future growth may be compromised by use of such mesh material. 2. The use of this mesh has not been studied in breastfeeding or pregnant women. 3. Do not use this mesh for the reconstruction of cardiovascular defects. 4. Literature reports there may be a possibility for adhesion formation when the polypropylene is placed in direct contact with the bowel or viscera.
Warnings
1. The use of any permanent mesh or patch in a contaminated or infected wound could lead to fistula formation and/or extrusion of the mesh. 2. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require removal of the mesh. 3. If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard with care to prevent risk of transmission of viral infections. 4. To prevent recurrences when repairing hernias, the mesh should be sized with appropriate overlap for the size and location of the defect, taking into consideration any additional clinical factors applicable to the patient. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue. 5. The mesh is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 6. This mesh has been designed for single use only. Reuse, reprocessing, resterilisation or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the mesh and may lead to mesh failure which may result in injury to the patient. Reuse, reprocessing, resterilisation or repackaging may also create a risk of contamination of the mesh and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the mesh may lead to injury, illness or death of the patient or end user. 7. To avoid injury, careful attention is required if fixating the mesh in the presence of nerves, vessels or the spermatic cord. Fastener penetration into underlying tissue containing nerves or blood vessels may result in the need for medical/surgical intervention, cause serious injury or permanent impairment to a body structure. 8. This mesh is not for the use of repair of pelvic organ prolapse via transvaginal approach. 9. This mesh is not for the use of treatment of stress urinary incontinence.
Precautions
1. Please read all instructions prior to use. 2. Only physicians qualified in the appropriate surgical techniques should use this mesh. 3. Intact Bard® Mesh exhibits high burst and tensile strength. However, when custom tailoring, in special circumstances where excessive force is placed on the mesh, the following guidelines may be helpful: • When cutting a notch in the mesh, a V-shape with a radiused point will withstand more force than a V-shape which comes to a sharp point. • For best results, it is recommended that the mesh be cut perpendicular to the selvage edge. • The inherent tensile strength of Bard® Mesh is strongest in the direction perpendicular to the selvage edges. Doubling the mesh may also increase the strength of the repair. Note: The selvage edges are recognised as the parallel, finished edges with a smooth appearance and slightly raised contour.
Adverse Reactions
Possible complications may include, but are not limited to, seroma, adhesions, haematomas, pain, infection, inflammation, extrusion, erosion, migration fistula formation, allergic reaction and recurrence of the hernia or soft tissue defect.

Ventralex™ ST Hernia Patch
Indications
The Ventralex™ ST Hernia Patch is indicated for use in the reinforcement of soft tissue, where weakness exists, in procedures involving the repair of ventral, incisional, and umbilical hernias.
Contraindications
1. Do not use this mesh in infants, children, or pregnant women, whereby future growth may be compromised by the use of such mesh materials. 2. The use of this mesh has not been studied in breastfeeding or pregnant women. 3. Do not use this mesh for the reconstruction of cardiovascular defects. 4. Literature reports that there may be a possibility for adhesion formation when the polypropylene is placed in contact with the bowel or viscera.
Warnings
1. The use of any permanent mesh or patch in a contaminated or infected wound could lead to fistula formation and/or extrusion of the mesh. 2. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require the removal of the mesh. 3. If the unused mesh has been in contact with instruments or supplies used on a patient or contaminated with bodily fluids, discard with care to prevent the risk of transmission of viral infections. 4. To prevent recurrences when repairing hernias, the mesh should be sized with appropriate overlap for the size and location of the defect, taking into consideration any additional clinical factors applicable to the patient. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue. 5. This mesh is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 6. This mesh has been designed for single use only. Reuse, resterilisation, reprocessing and/ or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the mesh and may lead to mesh failure which may result in injury to the patient. Reuse, reprocessing, resterilisation, or repackaging may also create a risk of contamination of the mesh and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient or end user. 7. This mesh should be used once the exterior foil pouch has been opened. Do not store for later use. Unused portions of the mesh should be discarded. 8. Ensure proper orientation; the bioresorbable coated side of the mesh should be oriented against the bowel or sensitive organs. Do not place the polypropylene side against the bowel. There may be a possibility for adhesion formation when the mesh is placed in direct contact with the bowel or viscera. 9. Do not cut or reshape any portion of the Ventralex™ ST Hernia Patch, except for the polypropylene positioning strap, as this could impact its effectiveness. Care should be taken not to cut or nick the SorbaFlex™ PDO monofilament. If the SorbaFlex™ PDO monofilament is cut or damaged during insertion or fixation, additional complications may include but are not limited to, bowel or skin perforation and infection. 10. Follow proper folding techniques for all patches as described in these Instructions for Use as other folding techniques may potentially compromise the SorbaFlex™ PDO monofilament. 11. To ensure a strong repair, the mesh should be secured with tacks or sutures through the polypropylene mesh straps or positioning pocket. 12. Excess positioning strap material above the fixation line must be cut off and discarded to eliminate excess material from remaining in the body. 13. When used to repair deficiencies caused by trocars, the mesh should be used under endoscopic guidance or direct visualisation. 14. This mesh is not for the use of repair of pelvic organ prolapse via transvaginal approach. 15. This mesh is not for the use of treatment of stress urinary incontinence.
Precautions
1. Please read all instructions prior to use. 2. Only physicians qualified in the appropriate surgical techniques should use this mesh. 3. Care should be taken not to cut or nick the SorbaFlex™ PDO monofilament during fixation. 4. The safety and effectiveness of Ventralex™ ST Hernia Patch has not been evaluated in clinical studies in the presence of malignancies in the abdominopelvic cavity.
Adverse Reactions
Possible complications may include, but are not limited to, seroma, adhesions, haematomas, pain, infection, inflammation, extrusion, erosion, migration, fistula formation, allergic reaction, and recurrence of the hernia or soft tissue defect. If the SorbaFlex™ PDO monofilament is cut or damaged during insertion or fixation, additional complications may include bowel or skin perforation and infection.

Ventralight™ ST
Indications
Ventralight™ ST Mesh is indicated for use in the reconstruction of soft tissue deficiencies in the repair of ventral, incisional, and umbilical hernias.
Contraindications
1. Do not use this mesh in infants, children, or pregnant women, whereby future growth may be compromised by the use of such mesh materials. 2. The use of this mesh has not been studied in breastfeeding or pregnant women. 3. Do not use this mesh for the reconstruction of cardiovascular defects. 4. Literature reports there may be a possibility for adhesion formation when the polypropylene is placed in contact with the bowel or viscera.
Warnings
1. The use of any permanent mesh or patch in a contaminated or infected wound could lead to fistula formation and/or extrusion of the mesh. 2. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require removal of the mesh. 3. If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard with care to prevent risk of transmission of viral infections. 4. To prevent recurrences when repairing hernias, the mesh should be sized with appropriate overlap for the size and location of the defect, taking into consideration any additional clinical factors applicable to the patient. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue. 5. This mesh is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 6. This mesh has been designed for single use only. Reuse, resterilisation, reprocessing and/or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the mesh and may lead to mesh failure which may result in injury to the patient. Reuse, reprocessing, resterilisation, or repackaging may also create a risk of contamination of the mesh and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the mesh may lead to injury, illness, or death of the patient or end user. 7. This mesh should be used once the exterior foil pouch has been opened. Do not store for later use. Unused portions of the mesh should be discarded. 8. Ensure proper orientation; the coated side of the mesh should be oriented against the bowel or sensitive organs. Do not place the polypropylene side against the bowel. There may be a possibility for adhesion formation when the polypropylene side is placed in direct contact with the bowel or viscera. (Reference Surface Orientation section.) 9. This mesh is not for the use of repair of pelvic organ prolapse via transvaginal approach. 10. This mesh is not for the use of treatment of stress urinary incontinence.
Precautions
1. Please read all instructions prior to use. 2. Only physicians qualified in the appropriate surgical techniques should use this mesh. 3. The safety and effectiveness of Ventralight™ ST Mesh has not been evaluated in clinical studies in the presence of malignancies in the abdominopelvic cavity.
Adverse Reactions
Possible complications may include, but are not limited to, seroma, adhesions, haematomas, pain, infection, inflammation, extrusion, erosion, migration, fistula formation, allergic reaction, and recurrence of the hernia or soft tissue defect.

Phasix™ Mesh
Indications
Phasix™ Mesh is indicated to reinforce soft tissue where weakness exists, in patients undergoing abdominal, plastic, and reconstructive surgery in ventral hernia repair and other abdominal fascial defect procedures including prophylactic use to reinforce surgical incisions.
Contraindications
Because Phasix™ Mesh is fully resorbable, it should not be used in repairs where permanent wound or organ support from the mesh is required.
Warnings
1. Phasix™ Mesh must not be put in direct contact with the bowel or viscera. 2. The use of any mesh or patch in a contaminated or infected wound can lead to fistula formation and/or extrusion of the mesh. 3. Mesh manufacture involves exposure to tetracycline hydrochloride and kanamycin sulfate. The safety and product use for patients with hypersensitivities to these antibiotics is unknown. The use of this mesh in susceptible patients with known allergies to tetracycline hydrochloride or kanamycin sulfate should be avoided. 4. The safety and effectiveness of Phasix™ Mesh in the following applications has not been evaluated or established: a. Pregnant or breastfeeding women. b. Paediatric use. c. Neural and cardiovascular tissue. 5. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require the removal of the mesh. 6. To prevent recurrences when repairing hernias or to prevent occurrences when reinforcing surgical incisions prophylactically, the mesh should be sized with appropriate overlap for the size and location of the defect or surgical incision, taking into consideration any additional clinical factors applicable to the patient. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue. 7. The mesh is supplied sterile. Prior to use, carefully examine package and product to verify neither is damaged and that all seals are intact. Do not use if the foil pouch or package is damaged or open, or if the center of the temperature indicator on the foil pouch is black. 8. This mesh has been designed for single use only. Reuse, reprocessing, resterilisation, or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the mesh and may lead to mesh failure which may result in injury to the patient. Reuse, reprocessing, resterilisation, or repackaging may also create a risk of contamination of the mesh and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the mesh may lead to injury, illness, or death of the patient or end user. 9. If unused Phasix™ Mesh has been in contact with instruments or supplies used on a patient or contaminated with

body fluids, handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations to prevent risk of transmission of viral infections. 10. This mesh is not for the use of repair of pelvic organ prolapse via transvaginal approach. 11. This mesh is not for the use of treatment of stress urinary incontinence. 12. Phasix™ Mesh has not been studied for use in breast reconstructive surgeries.

Precautions

1. Please read all instructions prior to use. 2. Only physicians qualified in the appropriate surgical techniques should use this mesh. Users should be familiar with mesh strength and size requirements. Improper selection, placement, positioning, and fixation of the mesh can cause subsequent undesirable results. 3. Clinical data in accordance with EU MDR has not been established for laparoscopic/robotic procedures. 4. The safety and effectiveness of Phasix™ Mesh in the proximity of existing or excised cancer has not been established.

Adverse Reactions

In preclinical testing, Phasix™ 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 infection, seroma, pain, mesh migration, wound dehiscence, haemorrhage, adhesions, haematoma, inflammation, allergic reaction, extrusion, erosion, fistula formation and recurrence of the hernia or soft tissue defect.

Phasix™ ST Mesh

Indications

Phasix™ ST Mesh is indicated for use in the reinforcement of abdominal soft tissue, where weakness exists, in ventral and hiatal hernia repair procedures.

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.

Warnings

1. Mesh manufacture involves exposure to tetracycline hydrochloride and kanamycin sulfate. The safety and product use for patients with hypersensitivities to these antibiotics is unknown. Use of this mesh in patients with known allergies to tetracycline hydrochloride or kanamycin sulfate should be avoided. 2. Ensure proper orientation; the coated side of the mesh should be oriented against the bowel or sensitive organs. Do not place the uncoated mesh side against the bowel. There is a risk for adhesion formation or erosions when the uncoated mesh side is placed in direct contact with the bowel or viscera. (Reference Surface Orientation section.) 3. The safety and effectiveness of Phasix™ ST Mesh in bridging repairs has not been evaluated or established. 4. The safety and effectiveness of Phasix™ ST Mesh in laparoscopic/robotic ventral hernia repair procedures has not been evaluated or established. 5. The use of any mesh or patch in a contaminated or infected wound could lead to fistula formation and/or extrusion of the mesh and it is not recommended. 6. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require the removal of the mesh. 7. To prevent recurrences when repairing hernias, mesh should be sized with appropriate overlap for the size and location of the defect, taking into consideration any additional clinical factors applicable to the patient. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue. 8. For hiatal hernia repair, the use of Phasix™ ST Mesh circumferentially around the esophagus is not recommended. 9. For hiatal hernia repair, the use of Phasix™ ST Mesh to bridge the hiatus is not recommended. 10. The safety and effectiveness of Phasix™ ST Mesh in the following applications has not been evaluated or established: a. Pregnant or breastfeeding women b. Paediatric use 11. Product should be used once exterior foil pouch has been opened. Do not store for later use. 12. Unused portions of the mesh should be discarded. If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard mesh with care to prevent risk of transmission of viral and other infections. 13. This mesh is designed for single use only. Reuse, resterilisation, reprocessing and/or repackaging of any portion of the Phasix™ ST Mesh may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the mesh and may lead to mesh failure which may result in injury to the patient. Reuse, reprocessing, resterilisation, or repackaging may also create a risk of contamination of the mesh and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the mesh may lead to injury, illness, or death of the patient or end user. 14. This mesh is supplied sterile. Prior to use, carefully examine package and product to verify neither is damaged and that all seals are intact. Do not use if the foil pouch or package is damaged or open, or if the center of the temperature indicator on the foil pouch is black. 15. This mesh is not for the use of repair of pelvic organ prolapse via transvaginal approach. 16. This mesh is not for the use of treatment of stress urinary incontinence. 17. This mesh is not for use of repair of neural and cardiovascular tissue. 18. Phasix™ ST Mesh has not been studied for use in breast reconstructive surgeries.

Precautions

1. Please read all instructions prior to use. 2. Only physicians qualified in the appropriate surgical techniques should use this mesh. Users should be familiar with strength and mesh size requirements. Improper selection, placement, positioning and fixation of the mesh can cause subsequent undesirable results. 3. The safety and effectiveness of the mesh has not been evaluated in the presence of malignancies in the abdominopelvic cavity. 4. The safety and effectiveness of Phasix™ ST Mesh in the proximity of existing or excised cancer has not been established.

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 esophageal erosion and dysphagia related to crural fibrosis.

CapSure™ Permanent Fixation System

Indications

The CapSure™ Permanent Fixation System is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during laparoscopic surgical procedures in ventral and inguinal hernia repair.

Contraindications

1. This device is not intended for use except as indicated. 2. Do not use this device where haemostasis cannot be verified visually after application. 3. Contraindications associated with laparoscopic surgical procedures relative to mesh fixation apply, including but not limited to: fixation of vascular or neural structures and in ischaemic or necrotic tissue. 4. Carefully inspect the area in the vicinity of the tissue being fastened to avoid inadvertent penetration of underlying structures such as bone, nerves, vessels, and viscera. Use of the CapSure™ Permanent Fixation System in the close vicinity of such underlying structures is contraindicated. For reference, the length of the fastener below the fastener head is 3.2 mm, the fastener head is another 1 mm (total 4.2 mm). 5. This device should not be used in tissues that have a direct anatomic relationship to major vascular or nerve structures. This includes the deployment of tacks in the diaphragm in the vicinity of the pericardium, aorta, or inferior vena cava during diaphragmatic hernia repair.

Warnings

1. The CapSure™ Permanent Fixation System is intended for Single Use Only - DO NOT RESTERILISE. Reuse, reprocessing, resterilisation or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient. Reuse, reprocessing, resterilisation or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient or end user. 2. Do not use beyond the expiration date on the package. 3. This product is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 4. Verify mechanical and electrical compatibility of devices from different manufacturers prior to using them together in a procedure. 5. Prosthetics should be evaluated for compatibility prior to use. 6. Users should be familiar with surgical procedures and techniques involving permanent materials before employing CapSure™ Permanent Fixation System fasteners for wound closure, as the risk of wound dehiscence may vary with the site of application and the material used. 7. As with any implant material, the presence of bacterial contamination may enhance bacterial infectivity. Accepted surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds. After use, the CapSure™ Permanent Fixation System may be a potential biohazard. Handle and dispose of in accordance with any local and federal laws regarding medical waste.

Precautions

1. Please read all instructions before using the CapSure™ Permanent Fixation System. 2. Only persons having adequate medical training and familiarity with surgical techniques should perform surgical procedures. Consult the medical literature relative to technique, complications and hazards prior to any surgical procedure. 3. The CapSure™ Permanent Fixation System can be used with most 5 mm trocars. Ensure compatibility by inserting the device into the trocar prior to introduction into the patient. The CapSure™ Permanent Fixation System should enter and exit the trocar easily without excessive force. The use of too much force could damage the instrument. 4. Adequate counter pressure should be applied on the target area. Avoid placing hand or finger directly over the area where fastener is being deployed to prevent injury. 5. Use caution when applying the CapSure™ fastener over or in proximity to underlying bone, vessels, nerves, or viscera. The intended fixation site should be assessed to ensure that while the tissue is compressed the total distance from the surface of the tissue to any underlying structures is greater than the length of the CapSure™ fastener. 6. Care should be taken not to use excessive counter pressure as this may damage the tissue, the material being fixated, and/or the device. 7. If the device locks and cannot be separated from a fastener that has been deployed into mesh and/or tissue, rotate the device counterclockwise to free the fastener from the tissue and/or to free the device. If the fastener does not deploy properly, remove the device from the patient and test the device in gauze to ensure proper fastener deployment, otherwise discard the device appropriately and use a new CapSure™ Permanent Fixation System. Once proper fastener deployment is confirmed, the device may be reinserted into the patient. 8. The safety and effectiveness of CapSure™ Permanent Fixation System have not been evaluated or established in pregnant or breast feeding women. 9. This device contains the following substance(s) defined as CMR 1B in a concentration above 0.1% weight by weight: Cobalt; CAS No. 7440-48-4; EC No. 231-158-0. Current scientific evidence supports that medical devices manufactured from stainless-steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects. For more information, please consult the ECHA website: https://echa.europa.eu/home.

Adverse Reactions

Adverse reactions and potential complications associated with fixation devices such as the CapSure™ Permanent Fixation System may include, but are not limited to the following: haemorrhage, pain, edema and erythema at wound site; septicemia/infection; hernia recurrence/wound dehiscence, erosion and allergic response in patients with known sensitivities to PEEK and metals contained in 316L stainless steel, including chromium, nickel, copper, and iron.

OptiFix™ Absorbable Fixation System

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

1. This device is not intended for use except as indicated. 2. Do not use this device where haemostasis cannot be verified visually after application. 3. 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 • Situations with insufficient ingrowth of tissue into the mesh over time, which could result in inadequate fixation once the fastener is absorbed. 4. 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). 5. 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.

Warnings

1. The OptiFix™ Absorbable Fixation System is intended for Single Use Only – DO NOT RESTERILISE. Reuse, reprocessing, resterilisation or repackaging may compromise the structural integrity and/ or essential material and design characteristics that are critical to the overall performance of the device and may leadto device failure which may result in injury to the patient. Reuse, reprocessing, resterilisation or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient or end user. 2. Do not use beyond the expiration date on the package. 3. Prior to use, carefully examine package and product to verify neither is damaged and that all seals are intact. Do not use if the foil pouch or package is damaged or open, or if the center of the temperature indicator on the foil pouch is black. 4. As with any implant material the presence of bacterial contamination may enhance bacterial infectivity. Accepted surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds. 5. Users should be familiar with surgical procedures and techniques involving synthetic absorbable materials before employing OptiFix™ Absorbable Fixation System fasteners for wound closure, as the risk of wound dehiscence may vary with the site of application and the material used. 6. The device may not fixate through prosthetics derived from biologic material such as xenografts and allografts. Prosthetic should be evaluated for compatibility prior to use. After use, the OptiFix™ Absorbable Fixation System may be a potential biohazard. Handle and dispose of in accordance with any local and federal laws regarding medical waste.

Precautions

1. Please read all instructions before using the OptiFix™ Absorbable Fixation System. 2. Only persons having adequate medical training and familiarity with surgical techniques should perform surgical procedures. Consult the medical literature relative to technique, complications and hazards prior to any surgical procedure. 3. The OptiFix™ Absorbable Fixation System can be used with most 5 mm trocars. Ensure compatibility by inserting the device into the trocar prior to introduction into the patient. The OptiFix™ Absorbable Fixation System should enter and exit the trocar easily without excessive force. The use of too much force could damage the instrument. 4. Counterpressure should be applied on the target area. Avoid placing hand/finger directly over the area where fastener is being deployed to prevent injury. 5. Use caution when deploying the OptiFix™ fastener over or in proximity to underlying bone, vessels, nerves, or viscera. The intended fixation site should be assessed to ensure that while the tissue is compressed the total distance from the surface of the tissue to any underlying structures is greater than the length of the OptiFix™ fastener. 6. Insertion of fasteners is possible into some collagenous structures such as ligaments and tendons, but is NOT possible directly into bone or cartilage. This may damage the device and result in compromised fixation strength. 7. Care should be taken not to use excessive counterpressure as this may damage the distal tip of the device as well as the mesh and/or tissue. 8. If the device locks and cannot be separated from a fastener that has been deployed into mesh and/or tissue, place a grasper adjacent to the deployed fastener and pull to free the device. If needed, you may use laparoscopic scissors to cut below the fastener head. The remaining portion of the fastener stem left in the mesh can be removed with graspers. The device should then be discarded and a new device should be used. 9. If the fastener does not deploy properly, remove the device from the patient and test the device in gauze to ensure proper fastener deployment. Once proper fastener deployment is confirmed, the device may be reinserted into the patient.

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: haemorrhage;

pain, edema and erythema at wound site; allergic reaction to Poly(D, L)-lactide; infection/septicemia; hernia recurrence/wound dehiscence.

SorbaFix™ Absorbable Fixation System

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

1. This device is not intended for use except as indicated. 2. Do not use this device where haemostasis cannot be verified visually after application. 3. 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. 4. 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).

Warnings

1. The SorbaFix™ Absorbable Fixation System is intended for Single Use Only – DO NOT RESTERILISE. Reuse, reprocessing, resterilisation, or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient. Reuse, reprocessing, resterilisation, or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient or end user. This product is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 2. Do not use beyond the expiration date on the package. 3. Do not use if the center of the temperature indicator is black. 4. As with any implant material the presence of bacterial contamination may enhance bacterial infectivity. Accepted surgical practices must be followed with respect to drainage and closure of infected or contaminated wounds. 5. Users should be familiar with surgical procedures and techniques involving synthetic absorbable materials before employing SorbaFix™ Absorbable Fixation System fasteners for wound closure, as the risk of wound dehiscence may vary with the site of application and the material used. 6. The device may not fixate through prosthetics derived from biologic material such as xenografts and allografts. Prosthetics should be evaluated for compatibility prior to use. 7. To prevent patient injury from the piloting tip, stay clear of vessels, nerves, bowel, and viscera when entering the surgical site, manipulating tissue, and fixating mesh. After use, the SorbaFix™ Absorbable Fixation System may be a potential biohazard. This device has a piloting tip, which should be considered a sharp even when the device is not actuated. Handle and dispose of in accordance with any local and federal laws regarding medical waste and sharps disposal requirements to prevent sharps injuries.

Precautions

1. Please read all instructions before using the SorbaFix™ Absorbable Fixation System. 2. Only persons having adequate medical training and familiarity with surgical techniques should perform surgical procedures. Consult the medical literature relative to technique, complications, and hazard prior to any surgical procedure. 3. The SorbaFix™ Absorbable Fixation System can be used with most 5 mm trocars. Ensure compatibility by inserting the device into the trocar prior to introduction into the patient. The SorbaFix™ Absorbable Fixation System should enter and exit the trocar easily without excessive force. The use of too much force could damage the instrument. 4. Counter pressure should be applied on the target area. Avoid placing hand/finger directly over the area where the fastener is being deployed to prevent injury. 5. Insertion of fasteners into some collagenous structures such as ligaments and tendons is possible but is NOT possible directly into bone or cartilage. This may damage the device. 6. Avoid excessive trigger force as this may damage the device. 7. If the device locks, remove the device from the patient and lightly tap the trigger forward toward the tip to release. 8. If the device locks and cannot be separated from a fastener that has been deployed into tissue, you may rotate the device counterclockwise to free the device. The locked device should then be discarded, and a new device should be used. 9. If the fastener does not deploy properly, remove the device from the patient and test the device in air to ensure proper fastener deployment. Once proper fastener deployment is confirmed, the device may be reinserted into the patient. 10. The safety and effectiveness of SorbaFix™ Absorbable Fixation System have not been evaluated or established in pregnant or breast feeding women. 11. This device contains the following substance(s) defined as CMR 1B in a concentration above 0.1% weight by weight: Cobalt; CAS No. 7440-48-4; EC No. 231-158-0. Current scientific evidence supports that medical devices manufactured from stainless-steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects. For more information, please consult the ECHA website: https://echa.europa.eu/home

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: haemorrhage; pain, edema, and erythema at wound site; allergic reaction to Poly (D, L)-lactide; septicemia/infection; hernia recurrence/wound dehiscence.

PerFix™ Plug

Indications

The PerFix™ plug is indicated for use in the reinforcement of soft tissue where weakness exists, in the repair of inguinal and femoral hernias.

Contraindications

1. Do not use the PerFix™ plug in infants, children, or pregnant women whereby future growth may be compromised by use of such mesh material. 2. The use of this mesh has not been studied in breastfeeding or pregnant women. 3. Literature reports that there may be a possibility for adhesion formation when polypropylene mesh is placed in direct contact with the bowel or viscera.

Warnings

1. The use of any permanent mesh or patch in a contaminated or infected wound could lead to fistula formation and/or extrusion of the mesh. 2. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require removal of the device. 3. If the unused mesh has been in contact with instruments or supplies used on a patient or contaminated with bodily fluids, discard with care to prevent risk of transmission of viral infections. 4. To prevent recurrences when repairing hernias, the mesh should be sized with appropriate overlap for the size and location of the defect, taking into consideration any additional clinical factors applicable to the patient. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue.5. This device is for single use only. Do not resterilise or reuse any portion of the PerFix™ plug. Reuse, reprocessing, resterilisation or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient. Reuse, reprocessing, resterilisation or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient or end user. 6. To avoid injury, careful attention is required if fixating the mesh in the presence of nerves, vessels or the spermatic cord. Fastener penetration into underlying tissue containing nerves or blood vessels may result in the need for medical/surgical intervention, cause serious injury or permanent impairment to a body structure. 7. This device is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 8. This device is not for the use of repair of pelvic organ prolapse. 9. This device is not for the use of treatment of stress urinary incontinence.

Precautions

1. Care should be taken to ensure that the mesh is adequately fixated to uncompromised tissue. If necessary, additional fasteners and/or sutures should be used. 2. Monofilament sutures are recommended to properly secure the mesh. 3. Only physicians qualified in the appropriate surgical techniques should use this mesh. 4. Please read all instructions prior to use. Adverse reactions Possible complications include, but are not limited to, seroma, adhesions, haematoma, pain, infection, inflammation, extrusion,erosion, mesh migration, fistula formation, allergic reaction and recurrence of the hernia or soft tissue defect.

PerFix™ Light Plug

Indications

The Perfix™ light plug is indicated for reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair of inguinal hernia defects.

Contraindications

1. Do not use this mesh in infants, children or pregnant women, whereby future growth may be compromised by use of such mesh material. 2. The use of this mesh has not been studied in breastfeeding or pregnant women. 3. Literature reports that there may be a possibility for adhesion formation when polypropylene mesh is placed in direct contact with the bowel or viscera.

Warnings

1. The use of any synthetic mesh or patch in a contaminated or infected wound could lead to fistula formation and/or extrusion of the mesh. 2. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require removal of the mesh. 3. If the unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard with care to prevent risk of transmission of viral infections. 4. To prevent recurrences when repairing hernias, the mesh should be sized with appropriate overlap for the size and location of the defect, taking into consideration any additional clinical factors applicable to the patient. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue. 5. This mesh is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 6. This mesh has been designed for single use only. Reuse, reprocessing, resterilisation or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the mesh and may lead to mesh failure which may result in injury to the patient. Reuse, reprocessing, resterilisation or repackaging may also create a risk of contamination of the mesh and/or cause patient infection or cross infection including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the mesh may lead to injury, illness or death of the patient or end user. 7. To avoid injury, careful attention is required if fixating the mesh in the presence of nerves, vessels or the spermatic cord. Fastener penetration into underlying tissue containing nerves or blood vessels may result in the need for medical/surgical intervention, cause serious injury or permanent impairment to a body structure. 8. This device is not for the use of repair of pelvic organ prolapse. 9. This device is not for the use of treatment of stress urinary incontinence. 10. The safety and effectiveness of PerFix™ Light Plug in laparoscopic inguinal hernia repair procedures have not been evaluated or established. Precautions 1. Please read all instructions prior to use. 2. Only physicians qualified in the appropriate surgical techniques should use this mesh. 3. Care should be taken to ensure that the mesh is adequately fixated to the uncompromised tissue of the inguinal floor. If necessary, additional fasteners and/or sutures should be used. 4. Monofilament sutures are recommended to properly secure the mesh. 5. When two or more plugs are used for large direct or pantaloon hernias, they should be joined together with sutures where the plugs abut. Adverse reactions Possible complications include, but are not limited to, seroma, adhesions, haematomas, pain, infection, inflammation, extrusion, erosion, mesh migration, fistula formation, allergic reaction and recurrence of the hernia or soft tissue defect.

Ventrio™ ST Hernia Patch

Indications

The Ventrio™ ST Hernia Patch is indicated for use in the reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair of ventral, incisional, and umbilical hernias.

Contraindications

1. Do not use this mesh in infants, children, or pregnant women, whereby future growth may be compromised by the use of such mesh materials. 2. The use of this mesh has not been studied in breastfeeding or pregnant women. 3. Do not use this mesh for the reconstruction of cardiovascular defects. 4. Literature reports that there may be a possibility for adhesion formation when the polypropylene is placed in contact with the bowel or viscera.

Warnings

1. The use of any permanent mesh or patch in a contaminated or infected wound could lead to fistula formation and/or extrusion of the mesh. 2. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require the removal of the mesh. 3. If the unused mesh has been in contact with instruments or supplies used on a patient or contaminated with bodily fluids, discard with care to prevent risk of transmission of viral infections. 4. To prevent recurrences when repairing hernias, the mesh should be sized with appropriate overlap for the size and location of the defect, taking into consideration any additional clinical factors applicable to the patient. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue. 5. This mesh is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 6. This mesh has been designed for single use only. Reuse, resterilisation reprocessing and/or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the mesh and may lead to mesh failure which may result in injury to the patient. Reuse, reprocessing, resterilisation, or repackaging may also create a risk of contamination of the mesh and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the mesh may lead to injury, illness, or death of the patient or end user. 7. This mesh should be used once the exterior foil pouch has been opened. Do not store for later use. Unused portions of the mesh should be discarded. 8. Ensure proper orientation; the bioresorbable coated side of the mesh should be oriented against the bowel or sensitive organs. Do not place the polypropylene side against the bowel. There may be a possibility for adhesion formation when the mesh is placed in direct contact with the bowel or viscera. 9. Do not cut or reshape the Ventrio™ ST Hernia Patch, as this could impact its effectiveness. Care should be taken not to cut or nick the SorbaFlex™ PDO monofilament during insertion or 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. 10. Follow proper folding techniques for all patches as described in these Instructions for Use as other folding techniques may compromise the SorbaFlex™ PDO monofilament. 11. To ensure a strong repair, the mesh should be secured with tacks or sutures through the polypropylene mesh structure or full mesh. Suturing or tacking on the edge of the mesh alone is not recommended. 12. This mesh is not for the use of repair of pelvic organ prolapse via transvaginal approach. 13. This mesh is not for the use of treatment of stress urinary incontinence.

Precautions

1. Please read all instructions prior to use. 2. Only physicians qualified in the appropriate surgical techniques should use this mesh. 3. Care should be taken not to cut or nick the SorbaFlex™ PDO monofilament during fixation. 4. The safety and effectiveness of Ventrio™ ST Hernia Patch has not been evaluated in clinical studies in the presence of malignancies in the abdominopelvic cavity.

Adverse Reactions.

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

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

Not all products, services, claims or features of products may be available or valid in your local area. Please check with your local BD Representative.

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