

BARD® Fixation Systems

SORBAFIX™ Absorbable Fixation System

Catalog Number	Quantity	
0113116	30 Absorbable Fasteners	<input type="checkbox"/>
0113115	15 Absorbable Fasteners	<input type="checkbox"/>

- Please add the SORBAFIX™ Absorbable Fixation System to my preference card.
- I would like to have the SORBAFIX™ Absorbable Fixation System in stock.
- I would like to trial the SORBAFIX™ Absorbable Fixation System.

PERMAFIX™ Permanent Fixation System

Catalog Number	Quantity	
0113120	30 Permanent Fasteners	<input type="checkbox"/>
0113119	15 Permanent Fasteners	<input type="checkbox"/>

- Please add the PERMAFIX™ Permanent Fixation System to my preference card.
- I would like to have the PERMAFIX™ Permanent Fixation System in stock.
- I would like to trial the PERMAFIX™ Permanent Fixation System.

Surgeon's Signature _____

Purchase Order Number _____

Date _____ Quantity _____

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Medical Services & Support 1.800.562.0027

Please consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions and instructions for use.

References:

¹ Twardowski ZJ et al "Intraabdominal Pressures during Natural Activities in Patients Treated with Continuous Ambulatory Peritoneal Dialysis" Nephron 44:129-135 1986. Cobb WS et al. "The Argument for Lightweight Polypropylene Mesh in Hernia Repair" Surgical Innovation. Vol 12 (1). 63-69, 2005.

² Data generated from a preclinical study using the SORBAFIX™ Absorbable Fixation System and from a cadaver study using the PERMAFIX™ Permanent Fixation System. Data on file. **Results may not correlate to performance in humans.**

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BARD
DAVOL INC.



PERMAFIX®
Permanent
Fixation System

SORBAFIX™
Absorbable
Fixation System

Technique Guide

Laparoscopic Inguinal,
Open and Laparoscopic Ventral Hernia Repair

BARD
DAVOL INC.

TECHNOLOGY
TECHNIQUE
TRAINING
TRUST

The opinions and techniques presented herein are for informational purposes only and the decision of which technique to use in a particular surgical application should be made by the surgeon based on the individual facts and circumstances of the patient and previous surgical experience.



**SORBAFIX™ ABSORBABLE FIXATION SYSTEM
PERMAFIX™ PERMANENT FIXATION SYSTEM**

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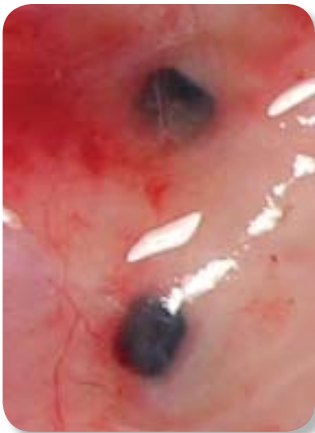
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Introduction

BARD has redefined fixation. The SORBAFIX™ Absorbable and PERMAFIX™ Permanent Fixation Systems are unique from their design and, to their delivery systems.

They are indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

SORBAFIX™ Absorbable and PERMAFIX™ Permanent Fixation Systems are preloaded with either 15- or 30-fasteners that are deployed via a 5 mm, low-profile delivery system.



This image is from a preclinical study using the SORBAFIX™ Absorbable Fixation System.

At 4 weeks post implantation, SorbaFix™ fasteners show rapid reperitonealization and incorporation into the tissue.

Data on file. Results may not correlate to performance in humans. Note the smooth head of the fastener with no exposed points.

Benefits of the BARD® Fixation Systems

STRONG

- Repair strength approximately 7x greater than maximum Intraabdominal Pressure (IAP).^{1,2}
- Threaded, hollow core allows for tissue ingrowth through interior of fastener.

CONSISTENT

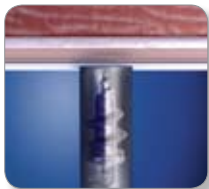
- The consistent diameter of the threads from head to tip and fastener length are designed to maximize tissue engagement.
- Obturator with piloting tip accurately pilots fastener through mesh and tissue.

RELIABLE

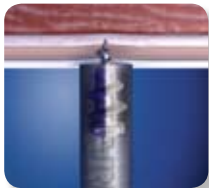
- Atraumatic blunt tip fastener with smooth head and no exposed points.
- Innovative mechanical design enables a durable delivery system.
- **SORBAFIX™**: Absorption of the poly (D, L) – lactide (PLA) fasteners is nearly complete at approximately 12 months post implantation, leaving less foreign material behind.²
- **PERMAFIX™**: Molded polymer based material similar to other implant devices. Non-radio opaque material.

SORBAFIX™ and PERMAFIX™ Fastener Deployment Technology

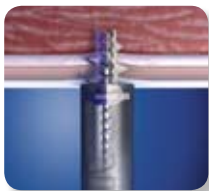
The SORBAFIX™ Absorbable and PERMAFIX™ Permanent Fixation Systems have a 5 mm, low-profile delivery system that offers smooth, efficient deployment. Keeping track of the preloaded 15- or 30- fastener configurations is now easy with a new fastener gauge.



Shaft tip is applied to tissue or prosthetic mesh with adequate pressure.



Piloting tip creates engagement space.



Fastener is driven into tissue. Design prevents piloting tip from extending beyond the fastener.



Fastener releases from tip.

FASTENER GAUGE INFORMATION



The device includes a fastener gauge located on the back of the handpiece. The gauge will move right to left as the fasteners are deployed and indicates approximate level of fasteners remaining in the device.

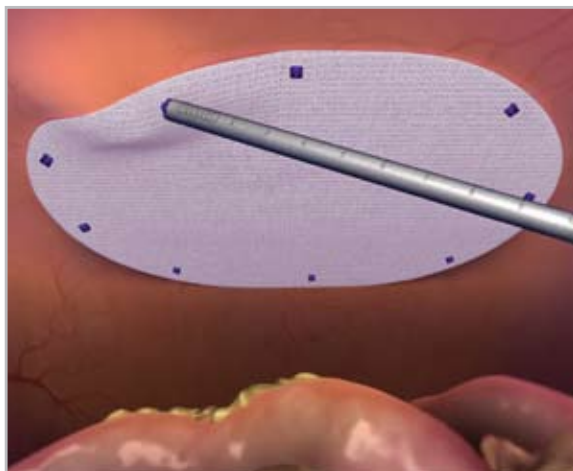


15 count fastener gauge ■ starts at midpoint and moves towards left as fasteners deplete.



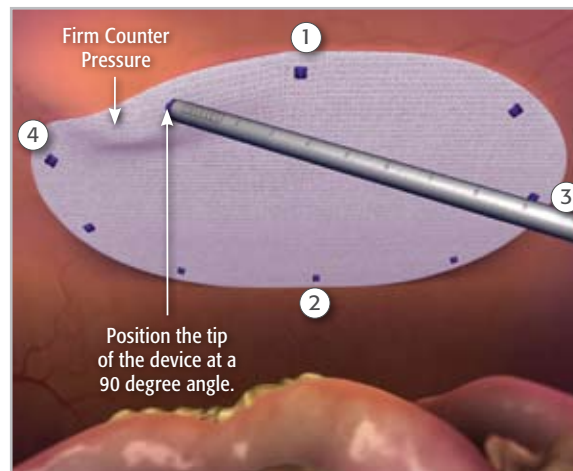
30 count fastener gauge ■ starts on the right and moves towards left as fasteners deplete.

LAPAROSCOPIC VENTRAL HERNIA REPAIR USING VENTRALIGHT™ ST MESH.



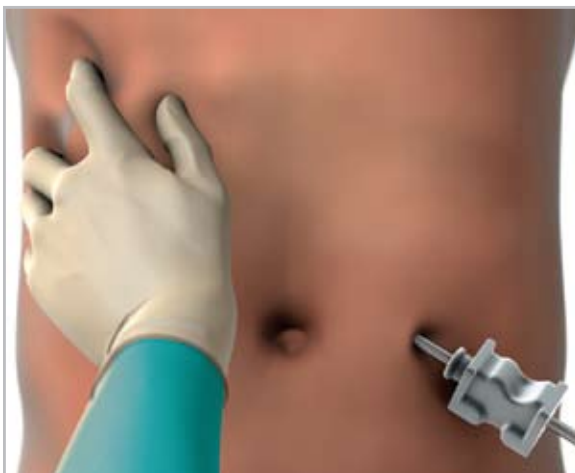
1

The trocar in which you are inserting the fixation device should be in the quadrant of the body 180 degrees away from the area where the mesh is being attached. Bring the prosthesis (mesh) or tissue into position. Place the tip of the SORBAFIX™/PERMAFIX™ Fixation System at the desired location on the mesh or tissue. Prior to fixating reduce the pneumoperitoneum appropriately to achieve optimal depth penetration and better abdominal wall compliance and apply adequate pressure. Compress the hand piece trigger in a single complete, uninterrupted stroke to drive a fastener through the mesh into the tissue. Keep consistent pressure on the tip of the device through the entire stroke. Release the trigger allowing it to return completely to its resting position.



2

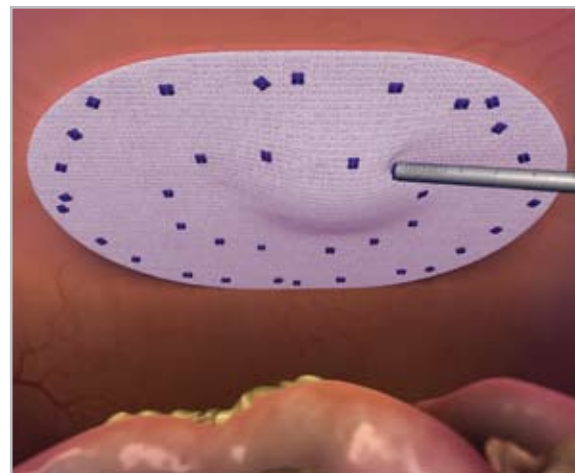
The fasteners should be placed around the edge of the patch to set the location (①-④). Then, fixate the VENTRALIGHT™ ST Mesh or other hernia mesh into place around the perimeter of the mesh.



3

Firm counter pressure should be applied on the skin of the abdominal wall. Use counter pressure to allow the abdominal wall to be pushed down perpendicular to the fixation device thus securing the mesh to the abdominal wall.

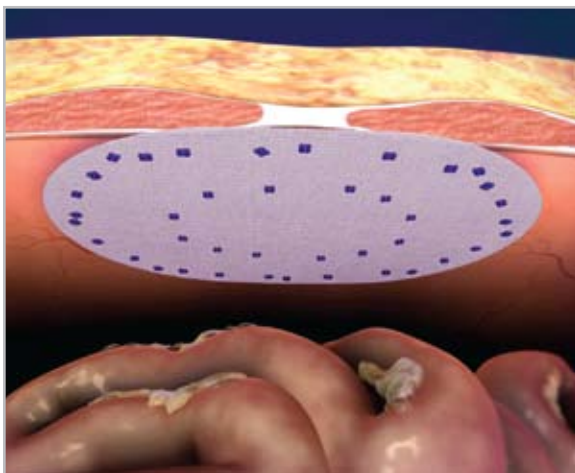
Avoid placing hand/finger directly over the area where the fastener is being deployed to prevent potential injury.



4

Several fasteners are placed around the margins of the defect to hold the mesh to the abdominal wall. Fasteners should be placed 1-2 cm apart.

For mesh selection, reference the mesh instructions for use.

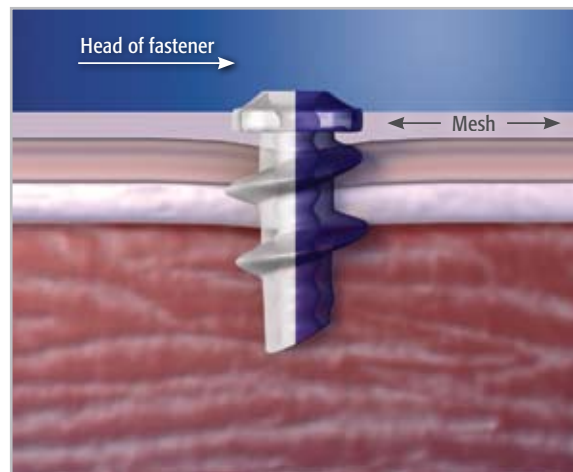


The number of fasteners presented here is for informational purposes only and the decision of fastener numbers to use in a particular surgical application should be made by the surgeon based on the individual facts and circumstances of the patient and previous surgical experience.

5

Release pneumoperitoneum. Once the VENTRALIGHT™ ST Mesh or other hernia mesh is secured, gently pull on the edge of the mesh with a grasper. This shows that the patch is secure, and when adequately secured in this technique, pulling on the patch will actually move the entire abdominal wall. This can be visualized from inside and outside of the abdomen. Care should be taken to ensure that the patch is adequately fixated to the abdominal wall. If necessary additional fasteners and/or sutures should be used.

Desufflating the abdomen with the mesh under view shows that the mesh does not roll or curl and remains flat to the abdominal wall, thus completing the hernia repair.

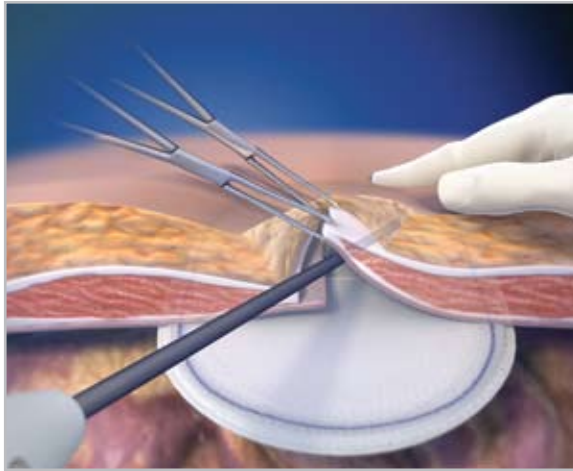


This illustration shows both a PERMAFIX™ and SORBAFIX™ fastener.

6

The fasteners should be placed entirely into the tissue and the head of the fastener should be firm against the mesh or tissue in order to achieve the best fixation performance. If the fastener head is not flush in mesh or tissue, use a grasper to fully seat the fastener by turning the grasper clockwise. If the fastener still does not fully seat, use a grasper to remove the fastener by turning the grasper counterclockwise and place another fastener in the same area.

OPEN VENTRAL HERNIA REPAIR USING THE VENTRIO™ HERNIA PATCH OR COMPOSIX™ KUGEL™ PATCH

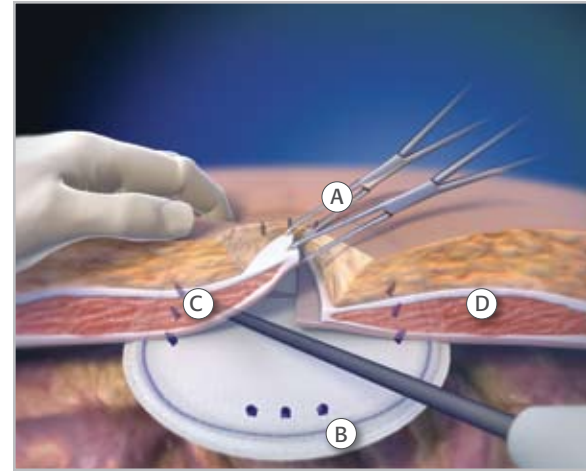


1

The patch should be fixated in a way that:

- Keeps the patch flat and from buckling around the edges.
- Allows for a minimal tension repair.

If the margins of the defect are to be reapproximated, it is important to ensure that the patch lies completely flat in the intraabdominal space. To accomplish this, the defect should be pretensioned prior to fixation. Pretensioning can be accomplished by grasping one side of the defect at a time with two pairs of Allis clamps.

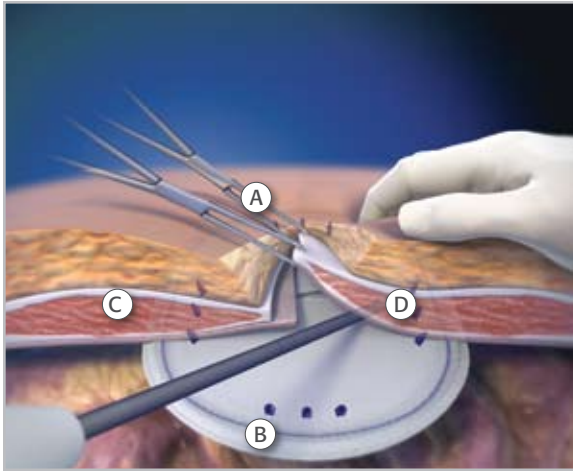


2

Initially fixate the patch in positions (A) and then (B), to ensure the patch is centered. Then, while pretensioning each side of the defect, fixate positions (C) and then (D). Place three fasteners approximately 1 cm apart in each of these four locations.

Then, while pretensioning each side of the defect, fixate the remaining perimeter of the patch, placing additional fasteners approximately 1 cm apart.

(See next page for more fixation instructions)

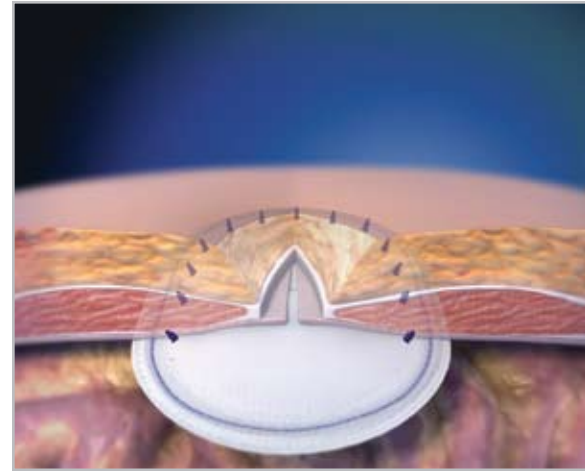


3

To fixate:

- Place the fixation device through the incision and into the outer positioning pocket (in between the two layers of mesh).
- Make sure that the tip of the device is as far lateral in the positioning pocket as possible, then back the tip up 1-2 mm and tilt it upward toward the abdominal wall and away from the SORBAFLEX™ or POSIFLEX™ Memory Technology.

(Continued on next page)



4

- Ensure optimal contact between the fixation device tip and the underlying mesh and tissue is achieved by palpating the abdominal wall with your hand. Ideally, the abdominal wall should be cupped around the tip of the device, forming a 90° angle.
- Lift the edge of the incision enough to visualize that bowel has not slipped between the abdominal wall and the edge of the mesh.
- Using a low opposition force, activate the fixation device, placing fasteners approximately 1 cm apart.
- Care should be taken to ensure that the patch is adequately fixated to the abdominal wall. If necessary additional fasteners and/or sutures should be used.

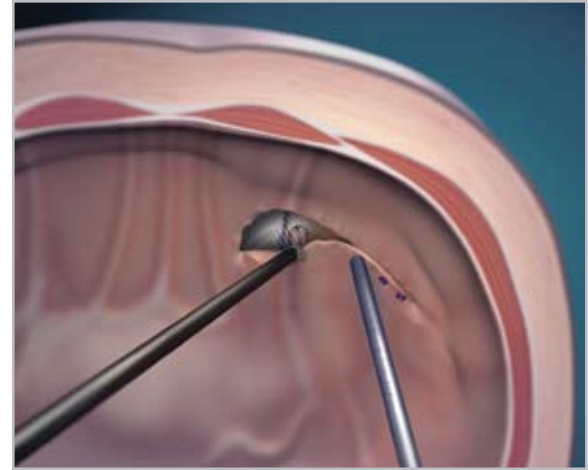
LAPAROSCOPIC INGUINAL HERNIA REPAIR USING BARD® SOFT MESH



1

In laparoscopic inguinal hernia repair procedures, SORBAFIX™/PERMAFIX™ fasteners may be used to fixate mesh, such as BARD® Soft Mesh. Fasteners may be deployed in soft tissue as well as the medial aspect of Cooper's Ligament, but must not be deployed directly into the bone.

To prevent patient injury, stay clear of vessels, nerves, bowel and viscera when entering the surgical site, manipulating tissue and fixating mesh.



2

The SORBAFIX™/PERMAFIX™ Fixation System may also be used for the reapproximation of soft tissue in a TAPP repair. Use counter pressure to allow the abdominal wall to be pushed down perpendicular to the fixation device.

Using a grasper reapproximate the peritoneum, do not overlap or stretch the peritoneum. Fixate from lateral to medial in a uniform motion.

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 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 hemostasis 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 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 RESTERILIZE. Reuse, reprocessing, resterilization 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, resterilization 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. If package is damaged or open, do not use product. Check package for damage prior to use.
3. Do not use beyond the expiration date on the package.
4. Do not use if the temperature indicator is black.
5. 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.
6. 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.

7. 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.
8. 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 hazards 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 fastener is being deployed to prevent injury.
5. 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.
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 counter clockwise 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.

Adverse Reactions:

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

Instructions For Use:

1. Take the SORBAFIX™ Absorbable Fixation System out of the sterile package using sterile technique.
2. Bring the prosthesis (mesh) or tissue into position. For tissue approximation, be sure that adequate overlap of tissue exists.
3. For laparoscopic ventral hernia repair it is recommended to reduce the pneumoperitoneum appropriately for better abdominal wall compliance and optimal fastener depth penetration.
4. Place the tip of the SORBAFIX™ Absorbable Fixation System at the desired location perpendicular to the mesh or tissue and apply adequate pressure. Different types of mesh may require different amounts of counterpressure. Adjust angle and counterpressure appropriately.
5. Compress handpiece trigger in a single, complete and uninterrupted stroke to drive an absorbable fastener through the mesh into the tissue. Keep consistent pressure on the tip of the device through the entire stroke. Release the trigger allowing it to return completely to its resting position. Repeat this procedure until all required fasteners are deployed.
6. The device should be considered a sharp during handling and disposal. To minimize exposure of sharp or unintended fastener delivery, do not actuate the trigger during removal from the trocar.
7. The fasteners should be placed entirely in tissue and the head of the fastener should be firm against the mesh or tissue in order to achieve the best fixation performance. If the fastener head is not

flush in mesh or tissue, use a grasper to fully seat the fastener by turning the grasper clockwise. If the fastener still does not fully seat, use a grasper to remove the fastener by turning the grasper counter clockwise and place another fastener in the same area.

8. After successful deployment of all required fasteners, handle and dispose of in accordance with any local and federal laws regarding medical waste and sharps disposal requirements to prevent sharps injury.

Storage:

Store the SORBAFIX™ Absorbable Fixation System in a dry environment at a temperature less than 40°C (104°F). It is for single use only. Do not use if the package is damaged or open, or if the temperature indicator is black.

IFU Part # PK3795295 106R

PERMAFIX™ PERMANENT FIXATION SYSTEM

Indications:

The PERMAFIX™ 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 hemostasis 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
4. This device should not be used in patients with a known allergy or hypersensitivity to acetal polymers.
5. 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 PERMAFIX™ 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 PERMAFIX™ Fixation System is intended for Single Use Only – DO NOT RESTERILIZE. Reuse, reprocessing, resterilization 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, resterilization 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. If package is damaged or open, do not use product. Check package for damage prior to use.
3. Do not use beyond the expiration date on the package.
4. As with any implant the presence of bacterial contamination may enhance bacterial infection. Accepted surgical practice must be followed with respect to prevention of infection and drainage and closure of infected or contaminated wounds.
5. Users should be familiar with surgical procedures and techniques involving permanent fixation before employing PERMAFIX™ 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 from naturally derived material such as xenografts and allografts. Prosthetic 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 PERMAFIX™ 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 PERMAFIX™ 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 PERMAFIX™ 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 PERMAFIX™ 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 fastener is being deployed to prevent injury.

5. Insertion of fasteners is possible into some collagenous structures such as ligaments and tendons, but the fasteners are not intended for use in bone or cartilage as 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 counter clockwise 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.

Adverse Reactions:

Adverse reactions and potential complications associated with fixation devices such as the PERMAFIX™ Fixation System may include, but are not limited to the following: hemorrhage, pain, edema, and erythema at wound site; septicemia/infection; allergic reaction to acetal; hernia recurrence/wound dehiscence.

Instructions For Use:

1. Take the PERMAFIX™ Fixation System out of the sterile package using sterile technique.
2. Bring the prosthesis (mesh) or tissue into position. For tissue approximation, be sure that adequate overlap of tissue exists.
3. For laparoscopic ventral hernia repair it is recommended to reduce the pneumoperitoneum appropriately for better abdominal wall compliance and optimal fastener depth penetration.
4. Place the tip of the PERMAFIX™ Fixation System at the desired location perpendicular to the mesh or tissue and apply adequate pressure. Different types of mesh may require different amounts of counterpressure. Adjust angle and counterpressure appropriately.
5. Compress handpiece trigger in a single, complete and uninterrupted stroke to drive a permanent fastener through the mesh into the tissue. Keep consistent pressure on the tip of the device through the entire stroke. Release the trigger allowing it to return completely to its resting position. Repeat this procedure until all required fasteners are deployed.
6. The device should be considered a sharp during handling and disposal. To minimize exposure of sharp or unintended fastener delivery, do not actuate the trigger during removal from the trocar.

7. The fasteners should be placed entirely in tissue and the head of the fastener should be firm against the mesh or tissue in order to achieve the best fixation performance. If the fastener head is not flush in mesh or tissue, use a grasper to fully seat the fastener by turning the grasper clockwise. If the fastener still does not fully seat, use a grasper to remove the fastener by turning the grasper counter clockwise and place another fastener in the same area.
8. After successful deployment of all required fasteners, handle and dispose of in accordance with any local and federal laws regarding medical waste and sharps disposal requirements to prevent sharps injury.

Storage:

Store the PERMAFIX™ Fixation System at room temperature. Avoid prolonged exposure to elevated temperatures. It is for single use only. Do not use if the package is damaged or open.

IFU Part # PK3796520 107R