OPTIFIX™ OPEN

Absorbable Fixation System

Instructions for Use

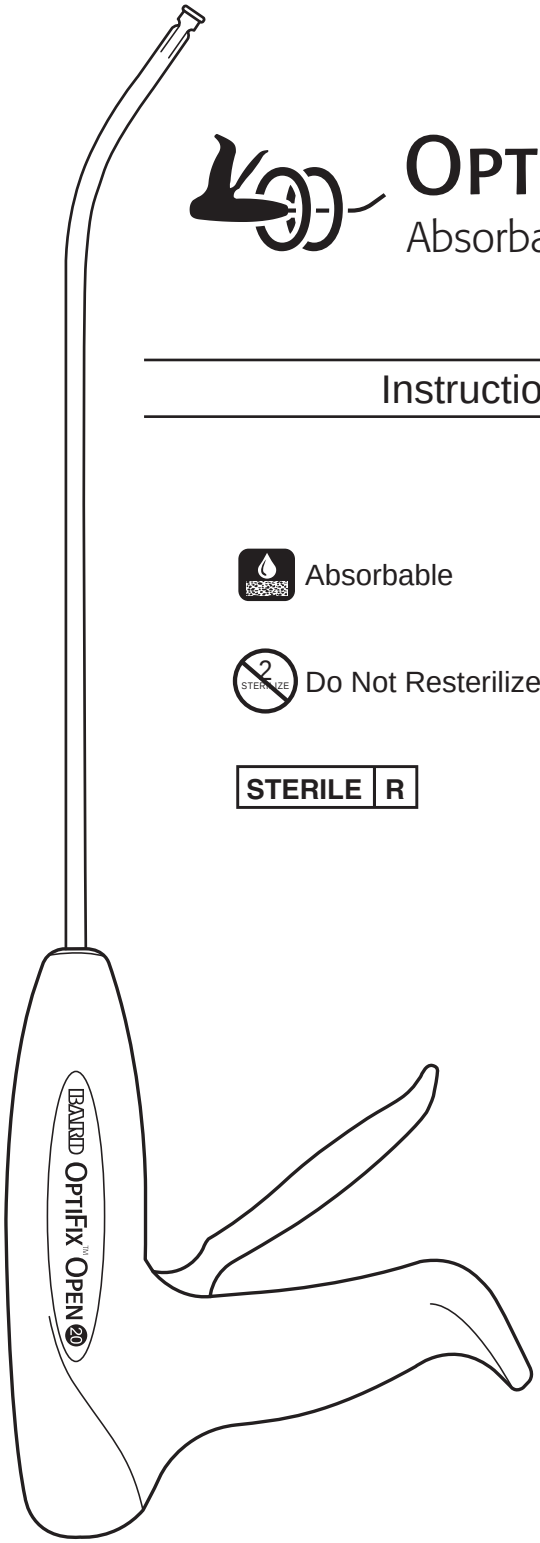
Absorbable

Single Use

Do Not Resterilize

℞ Only

STERILE R



BARD

DAVOL INC.

OPTIFIX™ OPEN
Absorbable Fixation System

PRODUCT DESCRIPTION

The OPTIFIX™ OPEN Absorbable Fixation System is a sterile single use device that delivers 20 synthetic absorbable fasteners via a curved shaft. The shaft of the OPTIFIX™ OPEN Absorbable Fixation System is 27cm in length. The fasteners are 6.7mm in length, are manufactured from Poly(D, L)-lactide and are dyed with D & C Violet No. 2. The fixation instrument shafts have an outer diameter of 5 mm and may be used in open procedures.

Absorption profile of Poly(D, L)-lactide: Simple chemical hydrolysis of the hydrolytically unstable backbone is the prevailing mechanism for the polymer's degradation. This occurs in two phases. In the first phase, water penetrates the bulk of the device, preferentially attacking the chemical bonds in the amorphous phase and converting long polymer chains into shorter water-soluble fragments. Because this occurs in the amorphous phase initially, there is a reduction in molecular weight without a loss in physical properties, since the device matrix is still held together by the crystalline structure. The reduction in molecular weight is soon followed by a reduction in physical properties (bulk erosion), as water begins to fragment the device. In the second phase, enzymatic attack and metabolism of the fragments occurs resulting in a rapid loss of polymer mass. In-vitro studies indicate that the fastener retains 100% of its original strength at 60 days. Absorption of the fastener is nearly complete after 360 days.

INDICATIONS

The OPTIFIX™ OPEN Absorbable Fixation System is indicated for the fixation of surgical mesh to tissues during open surgical procedures, such as hernia repair.

CONTRAINDICATIONS

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 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™ OPEN 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™ OPEN 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. **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™ OPEN 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™ Open 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™ Open 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. Counterpressure should be applied on the target area. Avoid placing hand/finger directly over the area where fastener is being deployed to prevent injury.
4. Use caution when applying the OptiFix™ Open 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™ Open fastener.
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 and result in compromised fixation strength.
6. 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.
7. 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.
8. 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™ Open Absorbable Fixation System may include, but are not limited to the following: hemorrhage, pain, edema and erythema at wound site, allergic reaction to Poly(D, L)-lactide, infection/septicemia, hernia recurrence/wound dehiscence.

INSTRUCTIONS FOR USE

1. Take the OptiFix™ Open Absorbable Fixation System out of the sterile package using sterile technique.
2. Bring the prosthesis (mesh) or tissue into position.
3. Place the tip of the OptiFix™ Open Absorbable Fixation System at the desired location perpendicular to the mesh or tissue and apply adequate counterpressure. Different types of mesh may require different amounts of counterpressure. Adjust angle and counterpressure appropriately.
4. Counterpressure should be applied to ensure the fastener is fully deployed. Compress handpiece actuation lever in a single, complete and uninterrupted stroke to drive an absorbable fastener through the mesh into the tissue. Keep consistent pressure on the distal tip of the device through the entire stroke. Release the actuation lever allowing it to return completely to its resting position. After each deployment, each fastener should be visually assessed for proper placement against the mesh or tissue. Repeat this procedure until all required fasteners are deployed.
5. 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, laparoscopic scissors can be used to cut the fastener head off and a grasper can be used to remove the head of the fastener. Place another fastener in the same vicinity.
6. After successful deployment of all required fasteners, handle and dispose of in accordance with any local and federal laws regarding medical waste.

STORAGE

Store the OptiFix™ Open Absorbable Fixation System in a dry environment at room temperature. Avoid prolonged exposure to elevated temperatures. It is for single use only. 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.

	Do not use if the center of the temperature indicator is black
R_x Only	U.S. Federal law restricts this device to sale by or on the order of a physician.
	Do not use if package is damaged
	Absorbable
	Patent Pending
	Do Not Resterilize
	Contents
	27cm x 5mm Cannula 20 Absorbable Fasteners
OPEN	Open

Manufacturer:
Davol Inc.
Subsidiary of C. R. Bard, Inc.
100 Crossings Boulevard
Warwick, RI 02886 USA
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Medical Services & Support
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