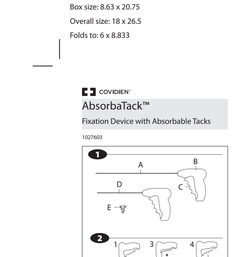
Box size: 8.63 x 20.75
Overall size: 18 x 26.5
Folds to: 6 x 8.833

COVIDIEN™
AbsorbaTack™
Fixation Device with Absorbable Tacks
1027603



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BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.
IMPORTANT
This booklet is prepared in accordance with Covidien's standard specifications and requirements.
This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of this device may lead to failure and subsequent patient injury. Reprocessing and/or sterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or sterilize this device.
DESCRIPTION
AbsorbaTack™ is a 5 mm device in a sterile, single use device for fixation of prosthetic material, such as mesh, to soft tissue. The mesh is contoured out of absorbable synthetic polymer copolymer derived from lactic and glycolic acid and is dyed with D&C Violet No. 2. The device is offered with 5, 10 or 20 absorbable tacks.
INDICATIONS
The device is intended for fixation of prosthetic material to soft tissue in various minimally invasive and open surgical procedures such as hernia repair.
CONTRAINDICATIONS
1. The device is not intended for use when prosthetic material fixation is contraindicated.
2. Do not use AbsorbaTack™ fixation devices in patients who are allergic to hypoallergenic polyglycolic acid or polylactic acid.
3. The device should not be used in tissue that have a direct anatomic relationship to major vascular structures. This would include the deployment of tacks in the diaphragm or the vicinity of the pericardium and/or anterior vena cava during diaphragmatic hernia repair.
4. Do not use in patients in neonatal ilium.
WARNINGS
The tack is made of the common copolymer polyglycolide-co-L-lactide (PGLA). This copolymer degrades and is absorbed by hydrolysis to glycolic acid and lactic acid which are then metabolized by the body.
The absorption profile of polyglycolide-co-L-lactide (PGLA) is the first two weeks after implantation, the copolymer retains approximately 50% of its original strength. After approximately 4 to 5 months, following the significant breakdown the copolymer absorption is essentially completed (up to one year).
WARNING AND PRECAUTIONS
1. Provisions for endoscopic and laparoscopic fixation surgery should be performed only by qualified physicians familiar with these techniques.
2. Where instruments and accessories from different manufacturers are employed together to a procedure, verify compatibility prior to installation of the procedure and ensure that any electrical insulation or electrical integrity is not impaired.
3. Do not use the device if the sterile barrier has been breached or if the product is damaged. Return any damaged or opened product to your sales representative.
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