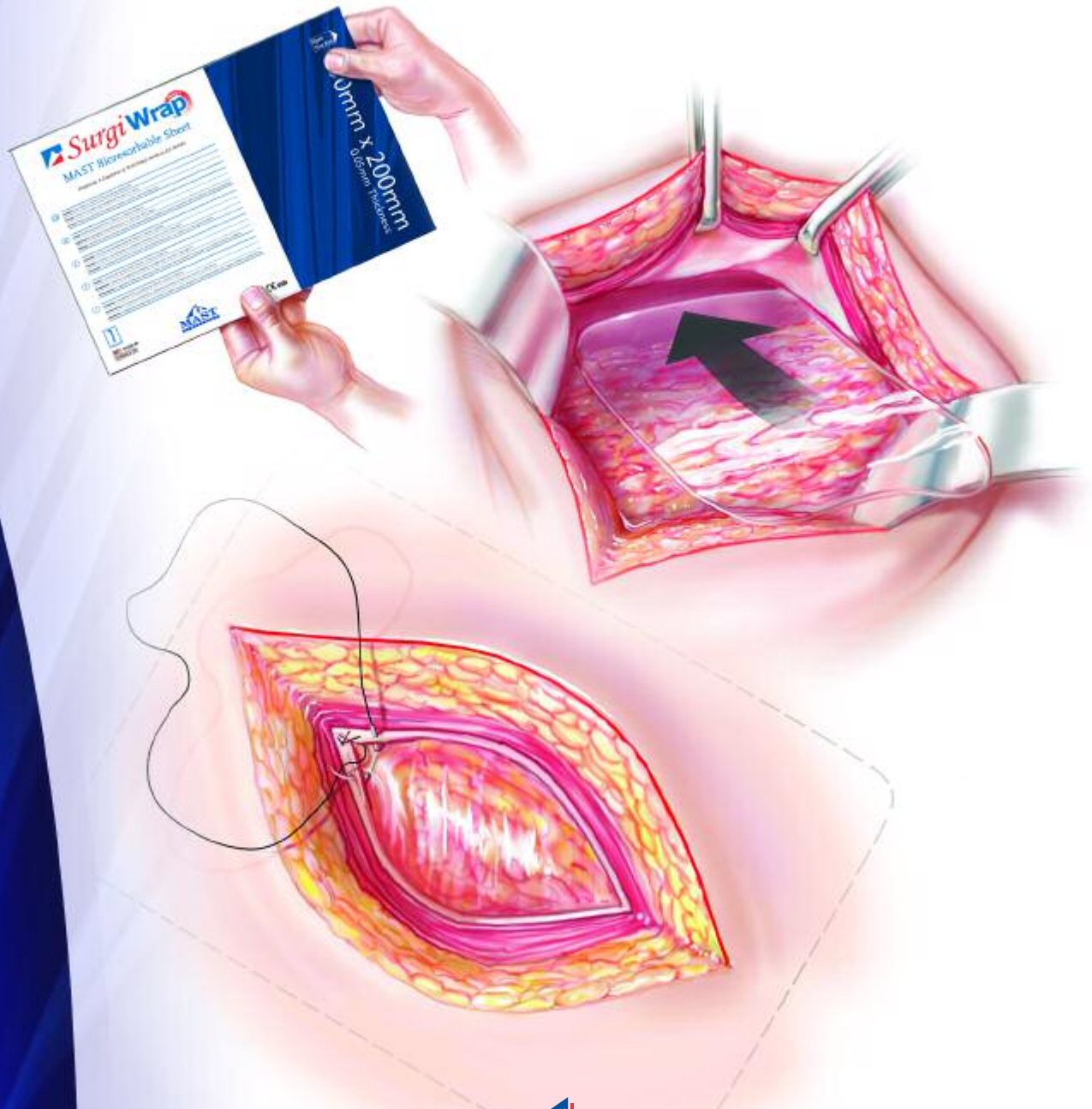




MAST Bioresorbable Sheet

General Abdominal Closure Surgical Technique

Clinical text authored by Gregory Imler, M.D.



SURGIWRAP® MAST BIORESORBABLE SHEET

General Abdominal Closure Surgical Technique

Indications: SurgiWrap MAST Bioresorbable Sheet is to be used wherever temporary wound support is required, to reinforce soft tissue where weakness exists, or for the repair of fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The resorbable protective sheet minimizes tissue attachment to the device in case of direct contact with the viscera.

Material Description: SurgiWrap MAST Bioresorbable Sheet is made from PLA (Polylactide), an amorphous bioresorbable copolymer of 70:30 Poly(L-lactide-co-D,L-lactide). The SurgiWrap MAST Bioresorbable Sheet is transparent and offers an ultra-thin profile with significant mechanical strength to allow for intraoperative placement and repositioning without obscuring surgical visualization.

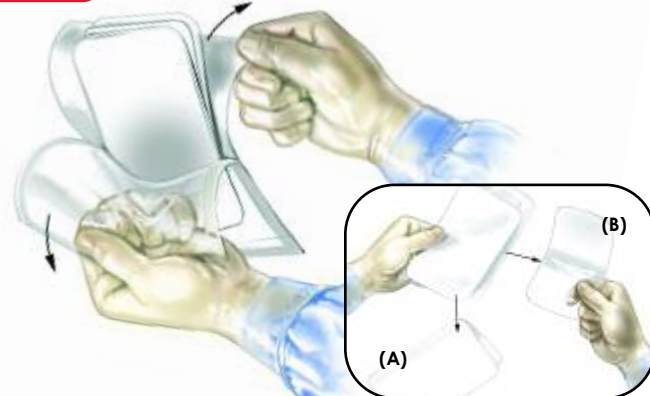
STEP 1



Product Packaging:

SurgiWrap MAST Bioresorbable Sheet is delivered sterile in a multi-layered package. The outer layer of the package consists of a protective envelope that provides detailed warnings, precautions, and storage and handling instructions. Within the envelope, a foil pouch provides the first sterile barrier, and contains the Instructions For Use and a Tyvek® pouch. The SurgiWrap MAST Bioresorbable Sheet is contained within the Tyvek pouch held loosely within a folded Tyvek sleeve. SurgiWrap MAST Bioresorbable Sheet should be stored at a controlled room temperature of 59–86°F (15–30°C), and should not be exposed to temperatures above 120°F (49°C). A temperature indicator, on the protective envelope, will turn black if the package has been exposed to temperatures above 120°F (49°C). The product is sterilized by electron beam irradiation, and should only be used if the sterilization indicator, provided on the protective envelope and foil pouch, is red. This is a single-use item and can not be re-sterilized.

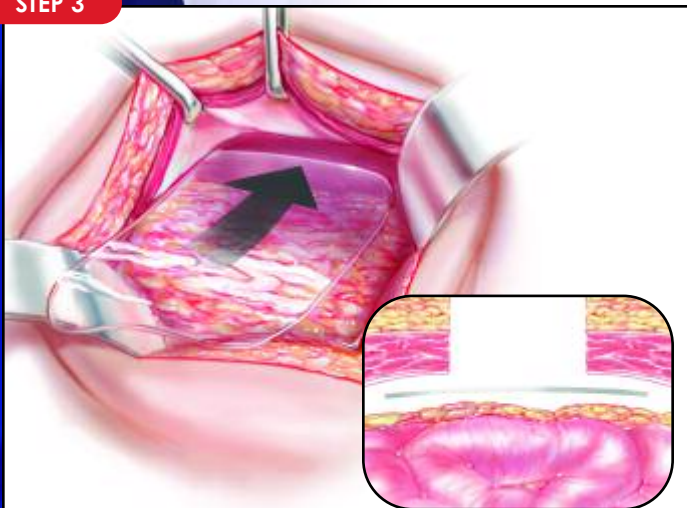
STEP 2



Implant Delivery:

To introduce the SurgiWrap MAST Bioresorbable Sheet into the sterile field, the foil pouch should be opened by a nonsterile operator to expose the sterile Tyvek pouch inside. The sterile Tyvek pouch should then be received by a sterile operator and opened within the sterile field. The SurgiWrap MAST Bioresorbable Sheet is located within this Tyvek pouch, between a folded sleeve of white Tyvek material. Please note the difference between the folded sleeve of white Tyvek material (A) and the clear bioresorbable sheet implant (B). Once the SurgiWrap MAST Bioresorbable Sheet is removed and handed to the clinician, the rest of the packaging should be discarded immediately. The transparent sheet should appear to have a smooth or moderately wavy texture.

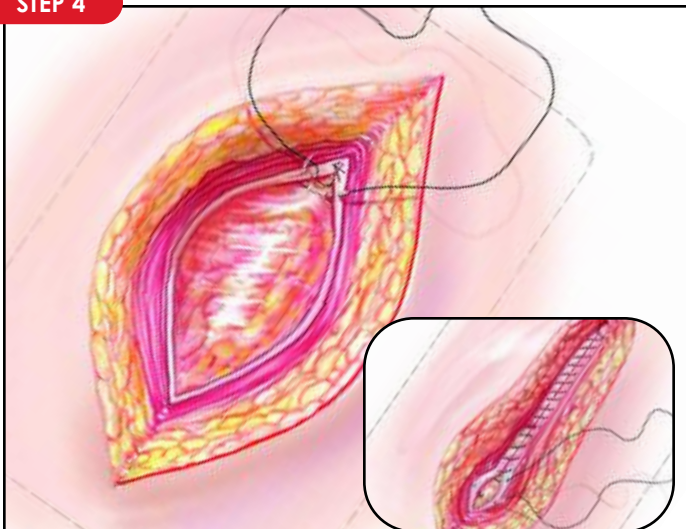
STEP 3



Intraoperative Placement:

Before fascial closure begins, sterile scissors can be used to customize the sheet to any desired shape or configuration. The SurgiWrap MAST Bioresorbable Sheet is placed between the omentum (or underlying abdominal contents) and peritoneum. The edges of the SurgiWrap MAST Bioresorbable Sheet should extend beyond both ends of the wound. SurgiWrap MAST Bioresorbable Sheet can be easily repositioned intraoperatively.

STEP 4



Fascial Closure:

To prevent postoperative migration of the sheet, it is recommended that the sheet be held in place with sutures. During the fascial closure, loop one of the first and one of the last sutures of either an interrupted or continuous series through the sheet. The SurgiWrap MAST Bioresorbable Sheet is transparent, and allows direct surgical visualization of underlying abdominal contents for simplified suture placement.

This surgical technique was developed by Gregory Imler, MD, Chairman Division of General Surgery, Sharp Rees-Stealy Medical Group, San Diego, CA. MAST Biosurgery, as the manufacturer of this device, does not practice medicine and does not recommend surgical procedures for patients. The surgeon who performs any implant procedure is responsible for determining and utilizing the appropriate surgical technique. Furthermore, it is the responsibility of the operating surgeon to review product information and labeling limitations, as described in the package insert.



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