

– Instructions for Use –  
**SurgiWrap™ MAST Bioresorbable Sheet**

**DESCRIPTION**

The SurgiWrap™ MAST Bioresorbable Sheet is a biodegradable surgical mesh for trauma and reconstructive surgical procedures involving soft tissues. SurgiWrap™ MAST Bioresorbable Sheet is available in various sizes and thicknesses for use in maintaining the relative position of healing tissues. The implants maintain the stability of soft tissues during the healing period and minimize the attachment of tissue to the device. The SurgiWrap™ material is subsequently reabsorbed by the body once the soft tissues have healed. In this manner, it is possible to avoid a second surgical procedure that may otherwise be necessary to remove permanent implants. The implants are not intended for use where permanent implants are required.

**MATERIAL**

The SurgiWrap™ MAST Bioresorbable Sheet is made from the amorphous biodegradable copolymer 70:30 poly (L-lactide-co, DL-lactide). This copolymer degrades and resorbs *in vivo* by hydrolysis and is metabolized by the body into CO<sub>2</sub> and H<sub>2</sub>O.

**INDICATIONS**

The SurgiWrap™ MAST Bioresorbable Sheet is to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, gynecological or gastroenterological anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. This includes, but is not limited to the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor and sacral colposuspension. The resorbable Protective Film minimizes tissue attachment to the device in case of direct contact with the viscera. The device is indicated for open and laparoscopic procedures. Laparoscopic procedures are limited to sizes from 0.02mm – 0.2mm in thickness.

**CONTRAINDICATIONS**

The following are contraindications for use of SurgiWrap™ MAST Bioresorbable Sheet:

- Where permanent implants are needed.
- Active infection.
- Patient conditions including blood supply limitations, or latent infection.

**STERILITY**

• SurgiWrap™ MAST Bioresorbable Sheet is sterilized by electron beam irradiation.

**STORAGE AND HANDLING**

- DO NOT STORE AT TEMPERATURES ABOVE 120°F (49°C).
- Use only if sterilization indicator square is **RED**.
- Store at controlled room temperature 59–86°F (15–30°C).
- Do not use if temperature indicator is **BLACK**.

**WARNINGS**

- DO NOT USE in procedures where permanent implants are needed. These biodegradable devices provide temporary fixation and are not intended to replace normal healthy tissue.
- Discard and DO NOT USE previously opened or damaged devices, and use only devices that are packaged in unopened and undamaged containers. **FOR SINGLE USE ONLY.**
- **DO NOT USE if there is loss of sterility of the device.**

- **DO NOT RESTERILIZE.**
- **DO NOT USE AFTER THE EXPIRATION DATE!**

### **PRECAUTIONS**

- Improper selection, placement, positioning, and fixation of the devices can cause subsequent undesirable result. The surgeon is to be familiar with the devices and the surgical procedure prior to performing surgery.
- The device can break or be damaged due to excessive activity or trauma. This could lead to failure of the device which could require additional surgery and device removal.
- The SurgiWrap™ MAST Bioresorbable Sheet can be cut with sterile scissors.

### **POSSIBLE ADVERSE EFFECTS**

- Infection can lead to treatment failure.
- Neurovascular injuries can occur due to surgical trauma.
- Bending, fracture, loosening, rubbing, and migration of the fixation devices can occur as a result of excessive activity, trauma or load bearing.
- While rare, implantation of foreign materials can result in an inflammatory response or allergic reaction.
- Hematoma.
- Suture pull out.

### **SUTURING**

- When suturing the SurgiWrap™ MAST Bioresorbable Sheet, suture the prosthetic material to the natural tissue by using the appropriate number of sutures uniformly spaced.
- Choose an appropriate size suture and needle for the defect to be reconstructed.
- Choose an appropriate size suture and needle for the prosthetic implant being utilized.
- Use minimal tension when pulling on suture line and placing knots.
- To avoid mechanical damage and suture hole elongation, smoothly pierce the SurgiWrap™ MAST Bioresorbable Sheet and follow the curve of the needle through the material. If the needle falls out of the needle hole following membrane puncture, care must be taken to pass the suture back through this original needle hole.
- Suture pull through strength can be increased through a buttressing technique of folding over the edges of the thin SurgiWrap™ sheet, creating a double layer of SurgiWrap™ sheet of which to suture through.

**CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.**



Do Not Reuse



Use By Expiration Date

LOT

Lot Number

STERILE R

Sterilized Using Irradiation



Attention, See Instructions for Use



Keep Package Dry



Avoid Extreme Heat



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