

– Instructions for Use –
OrthoWrap™ MAST Bioresorbable Sheet

DESCRIPTION

The OrthoWrap™ MAST Bioresorbable Sheet is a biodegradable surgical mesh for trauma and reconstructive surgical procedures involving tendons. OrthoWrap™ 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 are subsequently reabsorbed by the body. 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 OrthoWrap™ 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 CO₂ and H₂O.

INDICATIONS

The OrthoWrap™ MAST Bioresorbable Sheet is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue. The resorbable Protective Film minimizes tissue attachment to the device in case of direct contact with the tissues. The OrthoWrap™ MAST Bioresorbable Sheet is also indicated for reinforcement of soft tissues repaired by suture or suture anchors, during tendon repair surgery, including reinforcement of the rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. OrthoWrap™ is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair of the rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. Sutures used to repair the tear and sutures or bone anchors used to attach the tissue to the bone provide biomechanical strength for the tendon repair. The OrthoWrap™ MAST Bioresorbable Sheet reinforces soft tissue and provides a remodelable scaffold that is replaced by the patients own soft tissue. The device is indicated for open and laparoscopic/endoscopic procedures. Laparoscopic/endoscopic procedures are limited to sizes from 0.02mm-0.2mm thickness.

CONTRAINDICATIONS

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

- Where permanent implants are needed.
- Active infection.

STERILITY

- OrthoWrap™ 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 OrthoWrap™ 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 OrthoWrap™ MAST Bioresorbable Sheet, suture the prosthetic material to the natural tissue or to itself by using the appropriate number of sutures.
- 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 OrthoWrap™ 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.

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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