

XCM BIOLOGIC[®] Tissue Matrix

DESCRIPTION

XCM BIOLOGIC[®] Tissue Matrix is a resorbable surgical mesh intended to reinforce soft tissue where weakness exists. The device is derived from porcine skin and is supplied sterile in double layer packages. The product is packaged hydrated in sterile saline.

INDICATIONS

XCM BIOLOGIC[®] Tissue Matrix is indicated for use in general surgical procedures for the reinforcement and repair of soft tissue where weakness exists including, but not limited to; defects of the thoracic wall, suture line reinforcement, muscle flap reinforcement, hernia repair, soft tissue recon-structive procedures including plastic and reconstructive surgical applications, and for reinforcement of soft tissues which are repaired by suture or suture anchors.

CONTRAINDICATIONS

This device is derived from a porcine source and should not be used for patients with known sensitivity to porcine material. The device is contraindicated for patients known to be undergoing desensitization injections to meat products, as these injections can contain porcine collagen. The device is contraindicated for use in any patient in whom soft tissue implants are contraindicated, including:

- Blood supply limitations
- Pathologic soft-tissue conditions that would prevent secure fixation

The device is contraindicated in uses that require rolling, folding, or layering, and which may create a space impermeable to fluid, cells, and blood vessels. Such uses may result in excessive inflammation, drainage, extrusion, or infection. Folding of the product edges (1cm or less) to increase suture retention strength has not resulted in any reported problems in similar products, and is appropriate when indicated.

The device is contraindicated for patients with severe allergies manifested by a history of anaphylaxis, history of multiple severe allergies, or known allergies against porcine collagen.

WARNINGS

Use of this product in applications other than those intended for implantation to reinforce soft tissue where weakness exists has the potential for serious complications.

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

POTENTIAL COMPLICATIONS

The following complications are possible with the use of surgical mesh materials. If any of these conditions occur, the device may need to be removed at the surgeon's discretion.

- Infection
- Acute or Chronic inflammation (Initial application of surgical graft materials may be associated with transient, mild, localized inflammation.)
- Adhesion
- Seroma or hematoma formation
- Fistula formation
- Allergic reaction
- Product extrusion
- Recurrence of tissue defect
- Dehiscence
- Pain (persistent)
- Evisceration
- Tissue Necrosis

PRECAUTIONS

- Do not use this product without reading and understanding the complete instructions enclosed herein.
- Do not resterilize. Discard all open and unused portions of XCM BIOLOGIC[®] Tissue Matrix.
- Device is sterile if the package is unopened and undamaged. Device has a double sterile barrier. Do not use if either the inner or outer package seal is broken. Do not use if the outer package is not present.
- XCM BIOLOGIC[®] Tissue Matrix should be fully hydrated and moist upon opening the package. If the product is dry, do not use.
- Discard device if mishandling has caused possible damage or contamination, or if the device is past its expiration date.
- Ensure that device is hydrated prior to cutting, suturing, stapling, or loading the device laparoscopically.
- Aseptic technique must be adhered to throughout the procedure.
- Single patient use only. Do not reuse, reprocess, or resterilize any remaining, not implanted portion of this device. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury or illness.

STERILIZATION

This device has been sterilized by radiation, using a validated process to ensure a SAL of 10⁻⁶.

STORAGE

This device should be stored in a clean, dry location at room temperature. Do not expose the product to temperatures greater than 95°F (35°C).

INSTRUCTIONS FOR USE

Note: Always handle XCM BIOLOGIC[®] Tissue Matrix using aseptic technique.

Required Materials:

- Sterile forceps
 - Sterile scissors
1. Prepare the graft site using standard surgical techniques.
 2. Using aseptic technique, remove the XCM BIOLOGIC[®] Tissue Matrix inner packaging from its outer pouch, and place the inner packaging in the sterile field. Open the package using the tear strip on the inner package. If scissors are used, use caution to ensure that the device is not damaged.
 3. XCM BIOLOGIC[®] Tissue Matrix can be used directly out of the package with no additional hydration. Keep the product hydrated until ready for use; package should not be opened until ready to use.
 4. Using aseptic technique, trim the XCM BIOLOGIC[®] Tissue Matrix to fit the implant site with sterile scissors, providing allowance for overlap.
 5. Using aseptic technique, transfer the XCM BIOLOGIC[®] Tissue Matrix to the graft site and suture or staple into place, avoiding excess tension. Place the device in maximum contact with well-vascularized tissue to optimize healing response.
 6. Complete the standard surgical procedure.
 7. Discard any unused portions of the XCM BIOLOGIC[®] Tissue Matrix.



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