Organogenesis

PuraForce™

Tendon Reinforcement Matrix

DESCRIPTION

PuraForce™ tendon reinforcement matrix is a resorbable collagen based material intended for implantation to reinforce soft tissue. The device is supplied sterile in double layer peel-open packages. The device is packaged hydrated and is ready to use.

Manufactured By:
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350-001-1

APPLICATIONS/INTENDED USE

PuraForce™ tendon reinforcement matrix is intended for reinforcement of soft tissues repaired by sutures or suture anchors, during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps or other tendons.

PuraForce™ tendon reinforcement matrix 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. PuraForce™ tendon reinforcement matrix reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue.

The device is intended for single patient use only.

CONTRAINDICATIONS

This device is derived from a porcine source and should not be used for patients with known sensitivity to porcine material.

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The device is contraindicated for use in any patient in whom soft tissue implants are contraindicated including:

- Active or latent infection
- Blood supply limitations
- Pathologic soft-tissue conditions that would prevent secure fixation

The device is contraindicated for use in any patient with mental or neurologic conditions who is unwilling or incapable of following postoperative care instructions.

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 (1 cm or less) to increase suture retention strength has not resulted in any reported problems and is appropriate when indicated.

WARNING

Use of this device in applications other than those intended for implantation to reinforce soft tissue where weakness exists has the potential for serious complications. The patient is to be made aware of the possible adverse effects as listed.

PRECAUTIONS

- Do not use this device without reading and understanding the complete instructions enclosed herein.
- **Do not resterilize.** Discard all open and unused portions of PuraForce™ tendon reinforcement matrix.
- Device is sterile if the package is unopened and undamaged. Do not use if the package seal is broken.
- Do not reuse after opening.
- 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 suturing or stapling.
- Aseptic technique must be adhered to throughout the procedure.
- Single patient use only.

POTENTIAL COMPLICATIONS

The following complications are possible with the use of surgical graft 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.)
- Allergic reaction
- Tissue erosion
- Product extrusion

INSTRUCTIONS FOR USE

Note: Always handle PuraForce™ tendon reinforcement matrix using aseptic technique.

Required Materials:

- Sterile forceps
- Sterile scissors or sharp blade

1. Prepare the graft site using standard surgical techniques.
2. Using aseptic technique, remove PuraForce™ tendon reinforcement matrix inner tray from its outer pouch, and place the tray in the sterile field.
3. Remove the lid from the inner tray. Keep device submerged in the tray until ready to implant. PuraForce™ tendon reinforcement matrix does not require rehydration if used within 5-10 minutes following opening of the inner tray. If the device becomes dehydrated after opening, rehydrate by submerging the material in the tray with room temperature sterile normal saline or sterile lactated Ringer's solution.
4. Aseptically remove the PuraForce™ tendon reinforcement matrix from tray with sterile forceps. Using aseptic technique, trim the PuraForce™ to fit the implant site, providing a small allowance for overlap.

INSTRUCTIONS FOR USE CONTINUED

5. Using aseptic technique, transfer the PuraForce™ tendon reinforcement matrix to the graft site and suture or staple into place, avoiding excess tension.
6. Complete the standard surgical procedure.
7. Discard any unused portions of PuraForce™ tendon reinforcement matrix.

STORAGE

This device should be stored in a clean, dry location at room temperature. Do not expose the device to temperatures greater than 120°F (49°C) and less than -4°F (-20°C).

STERILIZATION

This device has been sterilized using a minimum dose 25 kGy Gamma Radiation. Do not resterilize. Do not use after expiration date.

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

SYMBOLS USED ON LABELING

STERILE R	**Sterilized using irradiation**
	Use by date
LOT	**Batch Code**
	Consult instructions for use

Revision Date May 2020