ROTIUM®

INDICATIONS

Rotium® is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

PRODUCT DESCRIPTION

Rotium is composed of two types of polymer fibers: Poly(lactide-co-caprolactone) (PLCL) and Polyglycolic acid (PGA). It is designed to function as a non-constricting, protective layer between the tendon and surrounding tissues. Rotium is conformable and designed for easy placement between the tendon and surrounding tissue and may be secured in place using standard fixation techniques. Rotium is provided sterile, non-pyrogenic, for single-use only, in a variety of sizes, ranging from 20mm x 20mm to 70mm x 25mm. Rotium is designed for stand-alone use. At the discretion of the surgeon, Rotium may be hydrated with sterile isotonic solution

Rotium is provided in the following sizes:

Reference #	Size
FG-0007	2cm x 2cm
FG-0325	3cm x 2.5cm
FG-0043	4cm x 3cm
FG-0525	5cm x 2.5cm
FG-0630	6cm x 3cm
FG-0725	7cm x 2.5cm

CONTRAINDICATIONS

Rotium is not designed, marketed, or intended for use except as described in the indications for use and is contraindicated in the following situations:

- Rotium is not indicated to replace damaged tendons or to reinforce the strength of any tendon repair.
- Rotium is not indicated for use in the presence of foreign body sensitivity. If material sensitivity is suspected, testing should be completed prior to device implantation.

WARNINGS

- Contents are sterile unless package is opened or damaged. Do not re-sterilize. For single-use only. Discard any open, unused product. Do not use after the expiration date.
- Inspect each package prior to use, and do not use if the product sterilization barrier or its packaging is compromised.

PRECAUTIONS

- Rotium should not be applied until bleeding and infection are controlled.

POTENTIAL ADVERSE REACTIONS

- Infection is an inherent risk with any surgical procedure.
- Allergic reaction to device materials.

INSTRUCTIONS

- Follow standard procedures for treatment of the injured tendon.
- Determine the tendon width and length in centimeters, and select an appropriate size of Rotium to provide protective coverage of the tendon repair. Rotium can be trimmed to fit the surgical site.

INSTRUCTIONS (cont.)

- For applications in open or mini-open repair:
  - Apply Rotium to the tendon.
  - Any appropriate surgical instrument (forceps, grasper) may be used to assist in passing Rotium under the tendon, if it is being placed as a wrap.
- For applications in arthroscopic repair (2x2cm, 3x2.5cm, and 4x3cm sizes ONLY):
  - Advance the Rotium through the cannula using a suture grasper. Sutures may be placed through the device to secure it in place before or after the advancement through the cannula, depending on the preferred surgical technique.
  - Apply Rotium to the repair site.
- Secure Rotium in place. A suturing pattern(s) appropriate for the tendon repair may be used. Examples include a simple suture or a whip stitch.
- Close the incision using standard technique.
- Application of Rotium does not modify the post-operative treatment. The surgeon must determine motion and strength requirements according to standard practice.

HOW SUPPLIED

Rotium is supplied sterile for single-use. The device has been sterilized using gamma irradiation. It is supplied as a stand-alone implant. Rotium is packaged in a duel sterile barrier pouch configuration. Contents of the package are sterile and non-pyrogenic unless the package is damaged or opened. Rotium does not contain natural rubber latex.

STORAGE, HANDLING, AND DISPOSAL

Rotium must be stored in its original packaging, preferably in a cool and dry place (30°C max). After use, the device is a potential biohazard since it may be contaminated with blood or other body fluids, bone, or tissue. Handle and dispose of product in accordance with accepted medical practice and with applicable local, state, and national laws and regulations.

PATIENT COUNSELING INFORMATION

The patient is to be made aware and warned of general surgical risks and possible adverse effects as listed in advance. Accepted practices in postoperative care are important.

CUSTOMER SUPPORT

For product complaints and potential adverse events, please contact your local Sales Representative or Customer Support.

Rx CAUTION

Federal law restricts this device to sale by or on the order of a physician.

SYMBOLS

Lot Number

Reference Number


Manufacturer Information


Date of Manufacture


Maximum Storage Temperature

Caution: US Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.


Do Not Re-sterilize


Single Use Only


Do Not Use if Package is Damaged or Crushed


Use By Date

Sterilized via irradiation


Refer to Instructions for Use Before Use