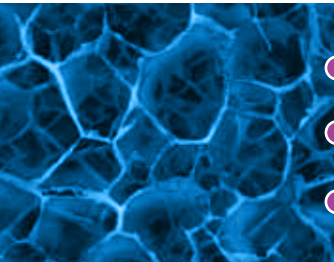


Inforce™

REINFORCEMENT MATRIX



TENDON REPAIR SOLUTIONS



SURGICAL TECHNIQUE

COLLAGEN
SOFT
TISSUE



Tendon repair solutions

What is the Inforce™ Reinforcement Matrix?

The Inforce Reinforcement Matrix is a naturally derived type I collagen matrix bioengineered with FortaFlex® Technology to provide biocompatibility and biomechanical strength during the healing phase of a repaired tendon. Through FortaFlex® Technology, eight layers of cross-linked porcine-derived collagen create a thin, pure durable matrix that provides a resorbable scaffold that is replaced by the patient's own soft tissue.

Product Benefits

- **Safe –**
Biocompatible and low antigenicity. High pure collagen content and negligible amount of DNA existing from derived source¹
- **Supports Healing –**
Allows cell infiltration and provides a resorbable scaffold that is replaced by the patient's own soft tissue
- **Controlled Remodeling –**
Cross-linking modifies the structure of the collagen matrix to control the rate of in-situ remodeling to match the clinical application²
- **Minimal Implant Bulk –**
Low profile matrix minimizes volume of repair while providing adequate reinforcement
- **Ready-to-use –**
Delivered hydrated in sterile sealed packaging with no special handling or additional preparation required
- **Convenient –**
Implant can be trimmed to desired size to accommodate a wide variety of procedures

1. Commercial Extracellular Matrix Scaffolds for Rotator Cuff Tendon Repair. Biomechanical, Biochemical, and Cellular Properties. Kathleen A. Derwin, Andrew R. Baker, Rebecca K. Spragg, Diane R. Leigh and Joseph P. Iannotti. J. Bone Joint Surg. Am. 88:2665-2672, 2006.

2. Effects of Carbodiimide Crosslinking Conditions on the Physical Properties of Laminated Intestinal Submucosa. Kristen Billiar, Jim Murray, Damien Laude, Ginger Abraham, Nathaniel Bachrach. J Biomed Mater Res 56: 101-108, 2001



Indications

The Inforce Reinforcement Matrix is intended to be used for implantation to reinforce the soft tissues that are repaired by suture or suture anchors, during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps or other tendons.

The Inforce 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. Inforce 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 use.

Contraindications

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

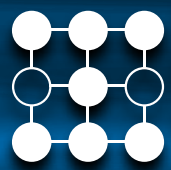
The device is contraindicated for use in any patient in whom soft tissue implants are contraindicated including:

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

See package insert for complete product information.



inforce™

Reinforcement Matrix

Achilles Tendon Surgical Technique

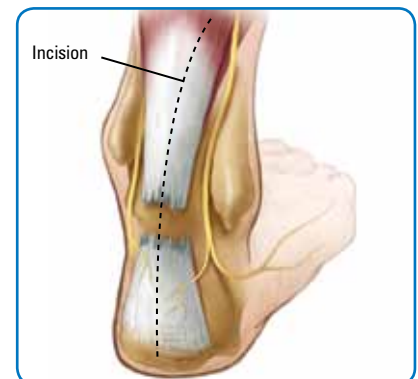


As the manufacturer of this device, Integra does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate techniques in each patient.

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

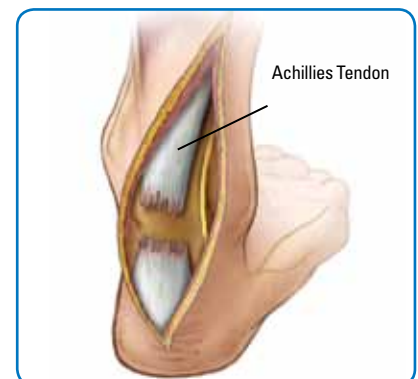
Step 1 • Surgical Approach

The rupture is localized by physical examination or musculoskeletal intraoperative ultrasound and the skin is marked so that dissection can be minimized. Appropriate anesthesia is administered in the supine position and a thigh-high tourniquet is applied. The patient is then placed into the prone position. The appropriate incision is made and meticulous dissection is carried down to the paratenon (crural fascia).



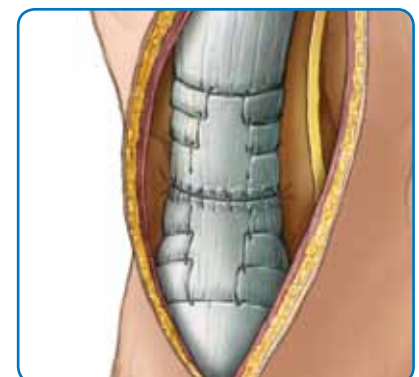
Step 2 • Paratenon Incision

The sural nerve is identified if desired, mobilized and protected. The paratenon (crural fascia) is incised longitudinally, tagged for latter approximation and retracted. Care is taken to treat the resultant tissue flaps.



Step 3 • Suture Repair

The Achilles tendon rupture is explored and the tendon ends are mobilized and freed from adhesions. The proximal muscle bellies are massaged and the foot is plantar flexed to deliver the tendon ends to anatomic apposition. The proximal and distal stump ends are secured with the suture and stitch of individual preference.



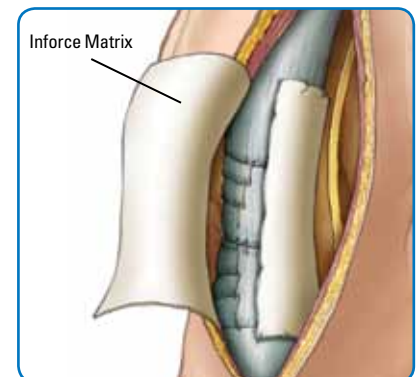
Bioengineered with **FortaFlex® Technology**

Step 4 • Wrap and Secure Matrix

The Inforce matrix is tagged and placed circumferentially around the tendon. The end suture tags are used to facilitate graft and tendon mobilization.

Once the matrix is placed in the desired position, it is tubularized with a running locking stitch (a non-absorbable 0 or 2-0 suture may be used). The excess matrix is trimmed, taking care not to overlap the matrix by more than 1cm. The suture line is rotated away from the injured soft tissue so that a smooth surface is most superficial, thereby decreasing the chance for pressure damage to the overlying tissues and skin. The matrix material is then sutured to the proximal and distal portions of the tendon.

A number of sutures are placed through the midpoint of the tendon matrix in orthogonal planes to decrease the chance of matrix delamination from the tendon during the healing process. The surgeon may choose to double the collagen reinforcement by folding the Inforce edges (1cm or less). This may reduce suture cut through and increase pull out strength.



Step 5 • Closure

The repair is tested by the surgeon, taking into account an intraoperative comparison with the contralateral limb. The paratenon (crural fascia) is reapproximated carefully with a 3-0 monofilament suture or similar suture. A meticulous closure is performed in layers. A sterile dressing is applied with the foot in plantar flexion.



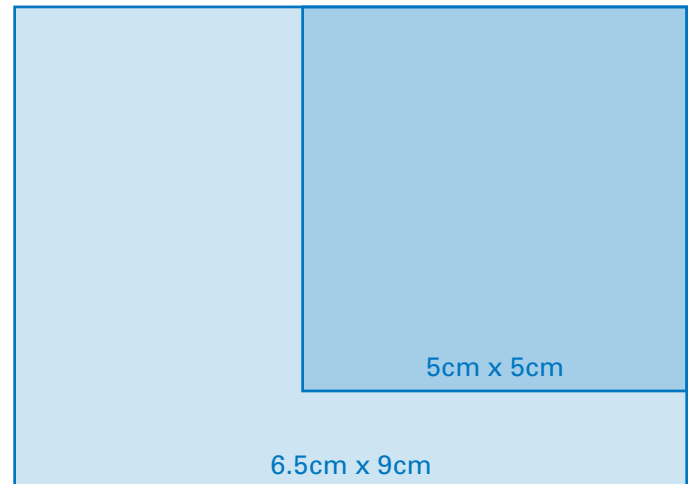
Inforce™

REINFORCEMENT MATRIX

ORDERING INFORMATION

| Reference | Size |
|-----------|-----------------------------|
| INF20659 | 6.5cm x 9cm (2.5in x 3.5in) |
| INF20505 | 5cm x 5cm (2in x 2in) |

Product Sizes Shown To Scale



 **INTEGRA™**
Extremity Reconstruction

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