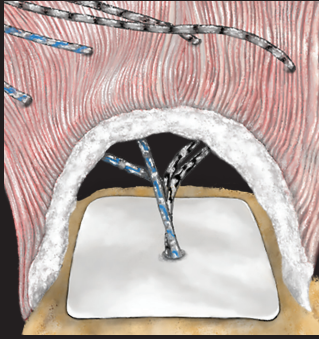




**ROTIUM™**

*Engineered to Regenerate & Restore*



ROTIUM™ An interpositional, bioresorbable wick engineered to promote native biology, and regenerate & restore torn rotator cuff tendons to their pre-injury state.

## The Science of ROTIUM™

### COVERAGE

- **Size mimics supraspinatus insertion footprint** — supraspinatus is the most frequently injured rotator cuff tendon

### OPTIMIZED TISSUE REGENERATION & HEALING

- **Fiber size and pore volume** facilitate native cell behavior and the body's natural healing process
- **Polymer degradants** are weak organic acids with known healing properties, including ECM deposition, recruitment of cells, stimulation of neoangiogenesis, and acceleration of tissue repair and regeneration
- **Native enthesis tissue architecture** is regenerated, including **Sharpey's fibers** that strengthen the tendon-bone attachment
- **Restores** joint to its pre-injured state

### ECM BIOMIMETIC

- **3D bioinductive scaffold**, engineered to mimic the physical structure of the native extracellular matrix (ECM)
- **Fiber size** promotes cell adhesion and migration
- **Pore volume** (85% porous) promotes cell infiltration and proliferation
- **Wicking action** holds biologically active cells and growth factors at the repair site

### NON-IMMUNOGENIC & BIORESORBABLE

- Comprises **biodegradable & bioresorbable polymers**, PGA and PLCL, widely used in medical devices, including biodegradable suture systems
- Fully **bioresorbed within** 3-6 months
- Contains **NO allogeneic or xenogeneic components**
- **Biomedical safety profiles** of PGA and PLCL are well-established

## Surgical & Clinical Advantages

### VERSATILITY

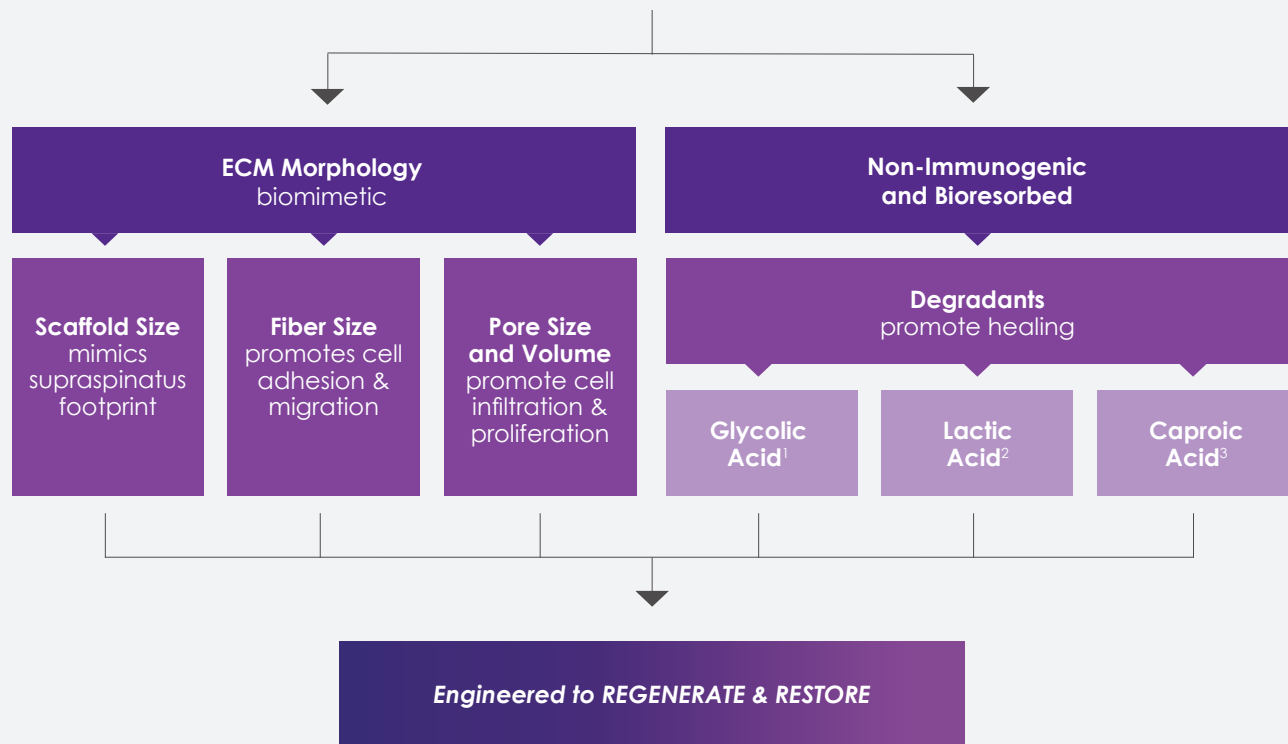
- **Anchor Agnostic**  
FDA-indicated for use with over 40 anchors
- **Technique Independent**  
Applicable with any technique
- **No special instrumentation** required
- Compatible with any anchor placement configuration
- Apply arthroscopically or in open procedure

### SIGNIFICANT FOOTPRINT COVERAGE

- **9x greater surface area** than competing interpositional implant (400 mm<sup>2</sup>)
- **Optimally covers supraspinatus footprint** (368 mm<sup>2</sup>)

### IMPROVED CLINICAL & FINANCIAL OUTCOMES

- **Engineered to reduce retear rate** via regeneration of native enthesis tissue architecture
- **Benefits patients, providers, & insurers**



## ROTIUM™ is engineered to:

- Support **cell adhesion, infiltration and proliferation**
- Provide **vital biology** via
  - wicking action (repository for cells and growth factors)
  - morphology (porous structure of bioinductive fibers)
  - actions of degradants
- Support the **natural phases of healing**
  - hemostasis/inflammation
  - proliferation
  - maturation/remodeling
- Enable **M1-M2 macrophage immunomodulation** which
  - harnesses inflammation
  - promotes proliferation
- Promote **angiogenesis**
  - neovascularization is vital to healing
- Facilitate and accelerate regeneration of **native tissue architecture**
- Restore **enthesis** (tendon-bone interface) to its pre-injured state

## ROTIUM™ is designed to reduce pH at the repair site.

Known wound healing properties of acidic pH:

- Restores **protease/protease-inhibitor balance** (MMP/TIMP)
- Increases **tissue oxygenation** via Bohr-effect
- Promotes **angiogenesis**
- Reduces **toxicity** of bacterial enzymes/metabolites
- Increases **resorption** of defective collagen
- Increases **macrophage & fibroblast** activity

MMP/TIMP – matrix metalloproteinase/  
tissue-inhibitor of metalloproteinase  
VEGF – vascular endothelial growth factor  
ECM – extracellular matrix

## Degradants

### <sup>1</sup>Glycolic Acid

- Anti-microbial properties
- Anti-inflammatory properties
- Increases fibroblast proliferation and production of collagen & hyaluronic acid

### <sup>2</sup>Lactic Acid

- Anti-microbial properties
- Provides major fuel source
- Stimulates VEGF and collagen gene expression
- Recruits endothelial progenitor cells
- Promotes reparative angiogenesis
- Stimulates reperfusion of ischemic wounds
- Activates collagen factors
- Promotes ECM deposition
- Accelerates healing

### <sup>3</sup>Caproic Acid

- Anti-microbial properties
- Anti-inflammatory properties

# ROTIUM™ Acute Repair

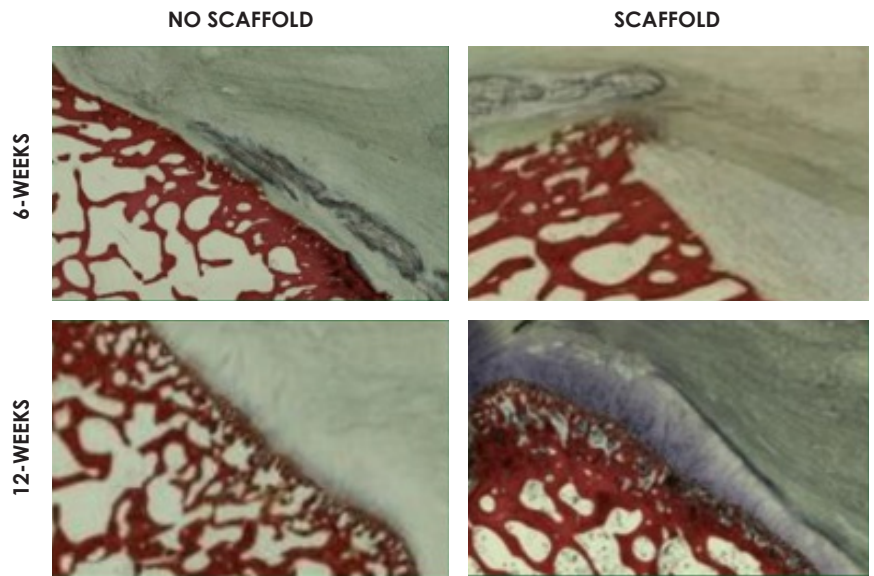
Sheep Study<sup>20</sup>

## 12-WEEK POINT

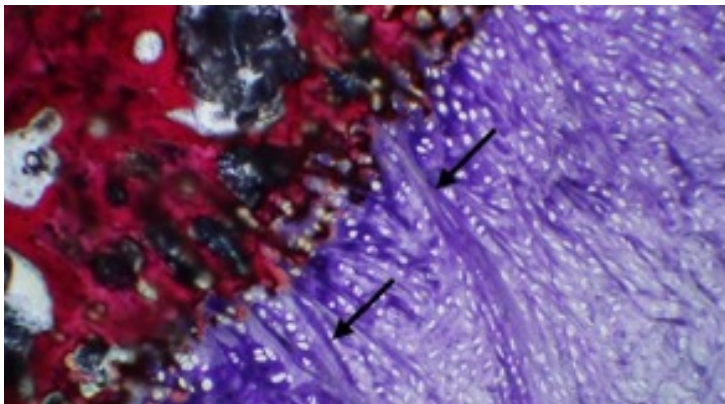
The Scaffold-treated group displayed an insertion of the fibrous tendon with the humeral footprint that was beginning to be organized in a manner consistent with “native” direct/fibrocartilaginous insertion of the ovine infraspinatus tendon.

Prominent perforating collagen fibers, comparable to “**Sharpey’s fibers**”, were present, extending through a region of calcified fibrocartilage, and attaching to the humeral footprint.

There were no surgical complications in any of the 40 sheep, including delayed wound healing or infection.



Representative images highlighting the fibrocartilaginous zone of attachment at the tendon-bone interface for both study arms at both time points. [Manuscript submitted for publication]<sup>20</sup>



## REGENERATION OF SHARPEY'S-LIKE FIBERS

Image demonstrates the formation of collagen fibers, comparable to Sharpey's fibers, along the fibrocartilaginous zone of attachment at the tendon-bone interface (black arrows). When present, these fibers were characterized as broad, distinctive, bundles of dense collagen which originated from the tendon fibrous connective tissue, extended through fibrocartilage or hyaline-like cartilage, and attached to the underlying humeral bone along the tendon-bone interface region of interest. (Nanofiber scaffold treatment, 12 weeks, 10x magnification). [Manuscript submitted for publication]<sup>20</sup>

**“ROTIUM enables the regeneration of the bone-to-tendon interface (Sharpey’s fibers) which PRP, stem cells and dermal allografts have never been able to do.”**

ANTHONY A. ROMEO, MD





*“Fixation methods to repair a torn rotator cuff are no longer the problem with failure resulting from a lack of biology. ROTIUM stimulates and enhances native biological activity at the repair site, is quick & easy to apply, and significantly improves the biological integrity of my repairs.”*

BRIAN L. BADMAN, MD

## ROTIUM™ Retrospective Case Series

Arthroscopic rotator cuff repair augmented with ROTIUM<sup>40</sup>

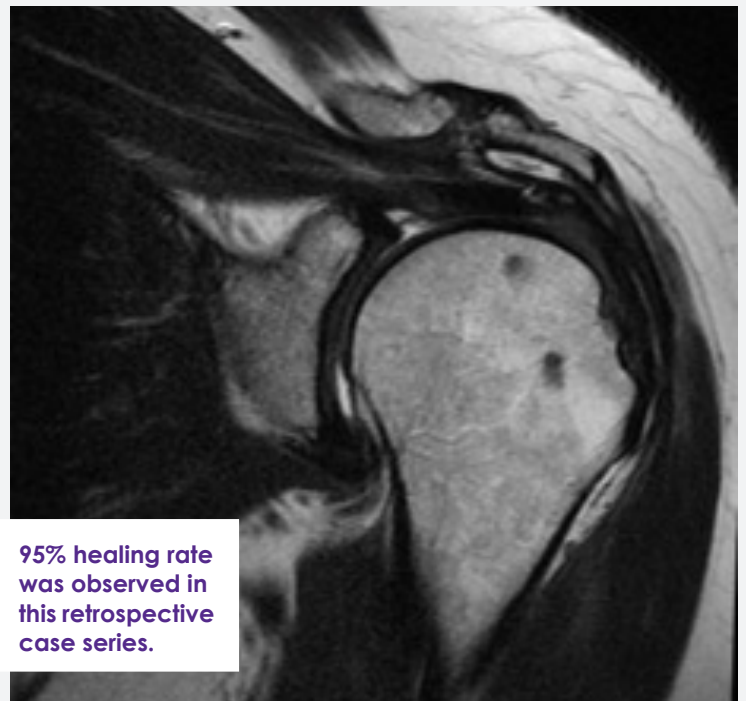
**Twenty patients underwent arthroscopic rotator cuff repair augmented with ROTIUM** secured as an inlay between the tendon and underlying bone.

- **Average Age:** 61 years
- **Average BMI:** 31
- **Cofield Classification of Tear Size (% of patients):**
  - 15% Small (< 1 cm)
  - 70% Medium (1-3 cm)
  - 10% Large (3-5 cm)
  - 5% Massive (>5 cm)
- **Tendons Torn (% of patients):**
  - 100% Supraspinatus
  - 20% Infrapinatus (concomitant)

MRI was obtained for all patients at a minimum of 6 months following surgery to evaluate the integrity of rotator cuff repair (avg. 10.5 months; range 6.5 – 16.7 months).

**19/20 patients showed complete healing of the repaired tendon with intact anchors and tendon footprint.**

- The single failure identified was a trans-tendon medial failure of the supraspinatus tendon, and not a failure at the tendon bone interface.
- The patient's initial tear was classified as chronic & **large (3-5cm).**
- Despite the radiographic finding, the patient reported significant improvement in both ASES and SST scores at 1-year follow-up.

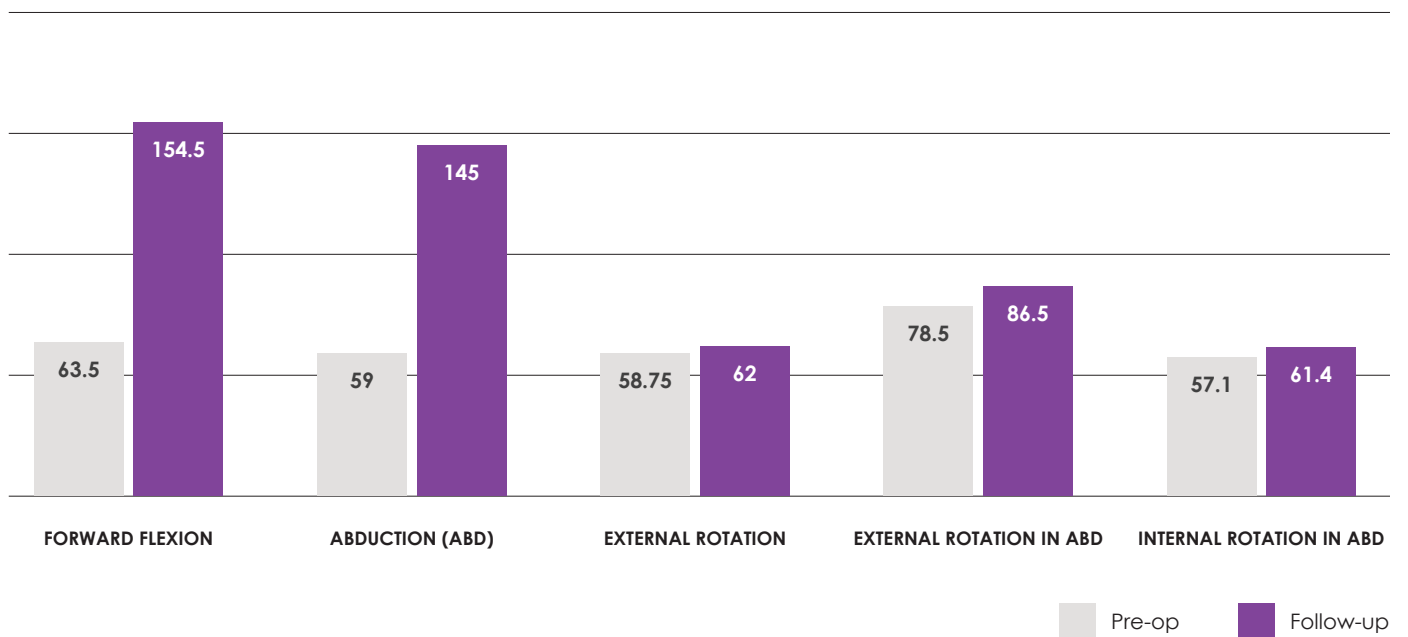


### ROTATOR CUFF TENDON(S) TORN & TEAR SIZE

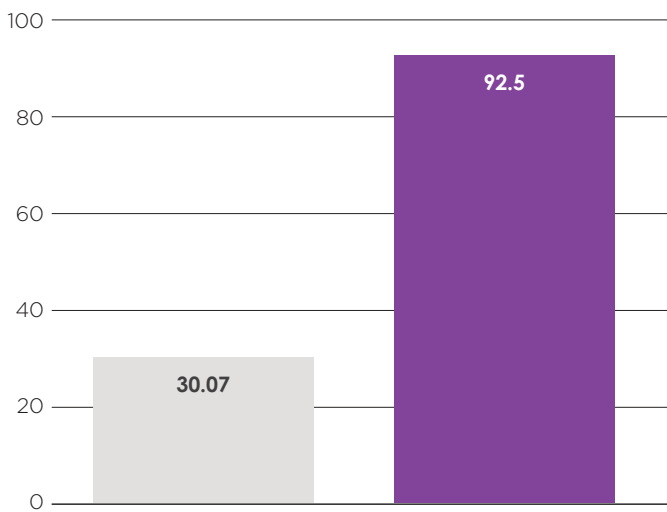
Tendon Torn	# of Patients	Tear Size	# of Patients
Supraspinatus	20	Small (<1cm)	3
Infrapinatus	4	Medium (1-3cm)	14
Subscapularis	0	Large (3-5cm)	2
Teres Minor	0	Massive (>5cm)	1

## ROTIUM™ Retrospective Case Series

ACTIVE SHOULDER RANGE OF MOTION (DEGREES)  
AT PRE-OPERATIVE VERSUS POST-OPERATIVE VISIT\*

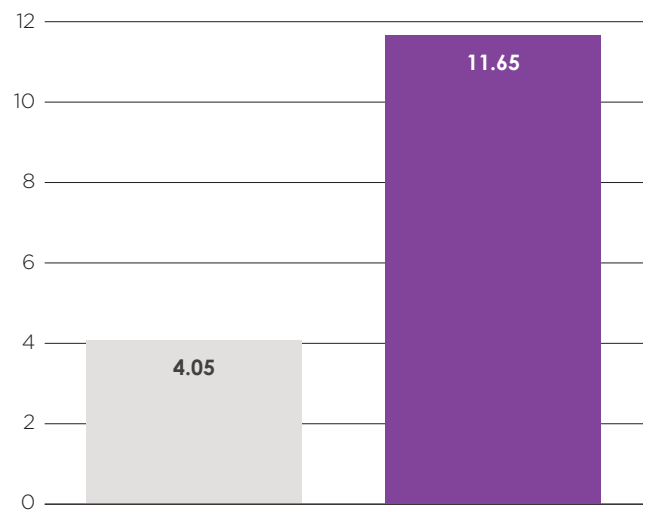


### PRE-OPERATIVE AND POST-OPERATIVE ASES SCORES\*



Pre-op Latest Post-op Follow-up

### PRE-OPERATIVE AND POST-OPERATIVE SST SCORES\*



Pre-op Latest Post-op Follow-up

\*Manuscript submitted for publication

 ROTIUM™