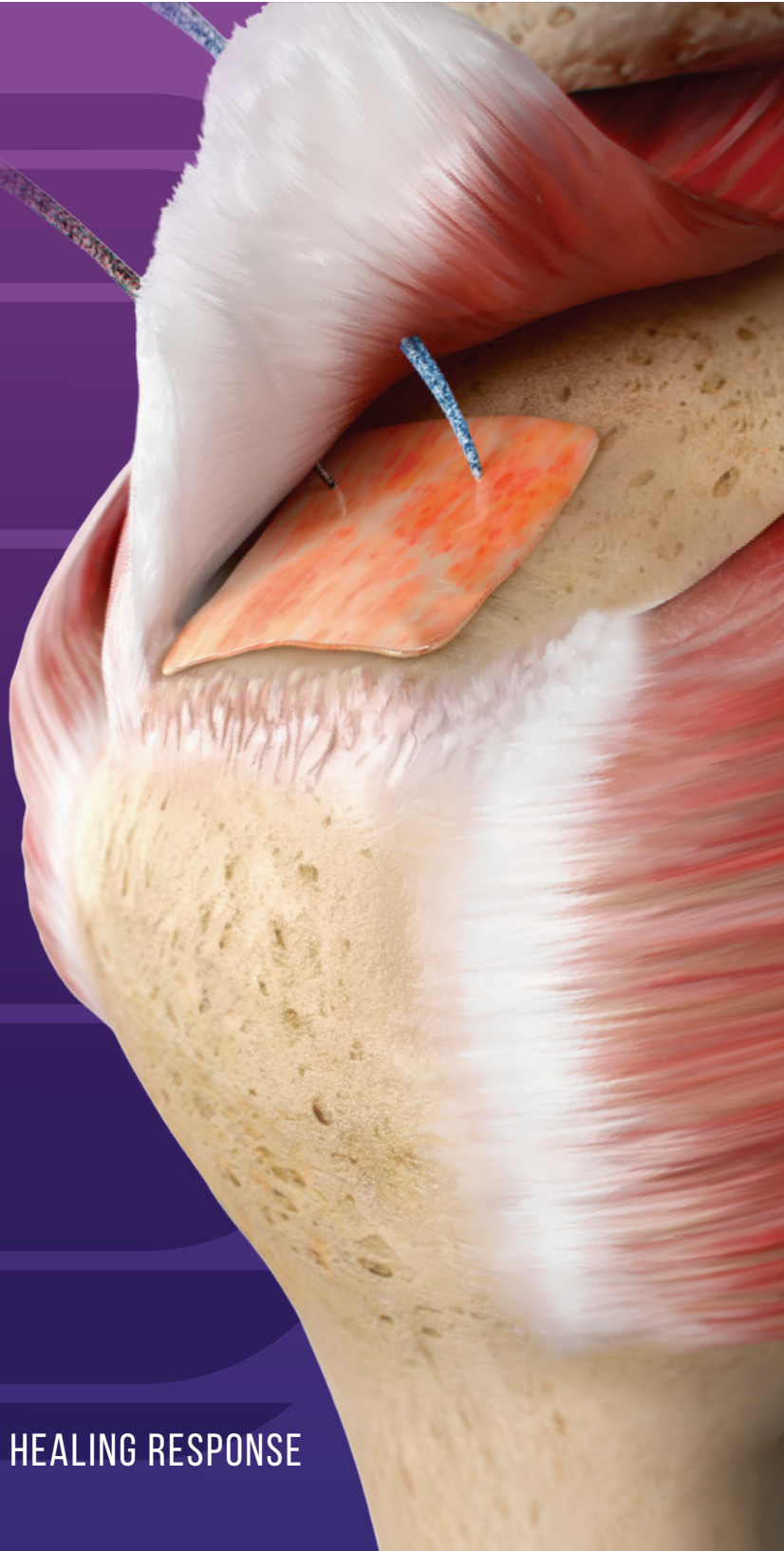




ELECTROSPUN SYNTHETIC SCAFFOLDS FOR ROTATOR CUFF REPAIR: TENDON-BONE INTERFACE



AUTOBIOLOGIC™ SCAFFOLDS: POWERING THE HEALING RESPONSE



THE BIOLOGIC CHALLENGE

Scar tissue formation without a healthy enthesis may increase the chance of biologic failure and lead to inferior healing or inconsistent functional outcomes. Rotator cuff repairs continue to experience average retear rates of approximately 35%.²

REDEFINING THE MICROENVIRONMENT

ROTIUM® is a bioresorbable wick placed at the tendon–bone interface designed to:

- Kickstart and optimize the biologic healing environment
- Promote native tissue remodeling and integration
- Deliver consistent, long-term healing outcomes in rotator cuff repairs

DESIGNED AS A SCAFFOLD

100% Synthetic Composition

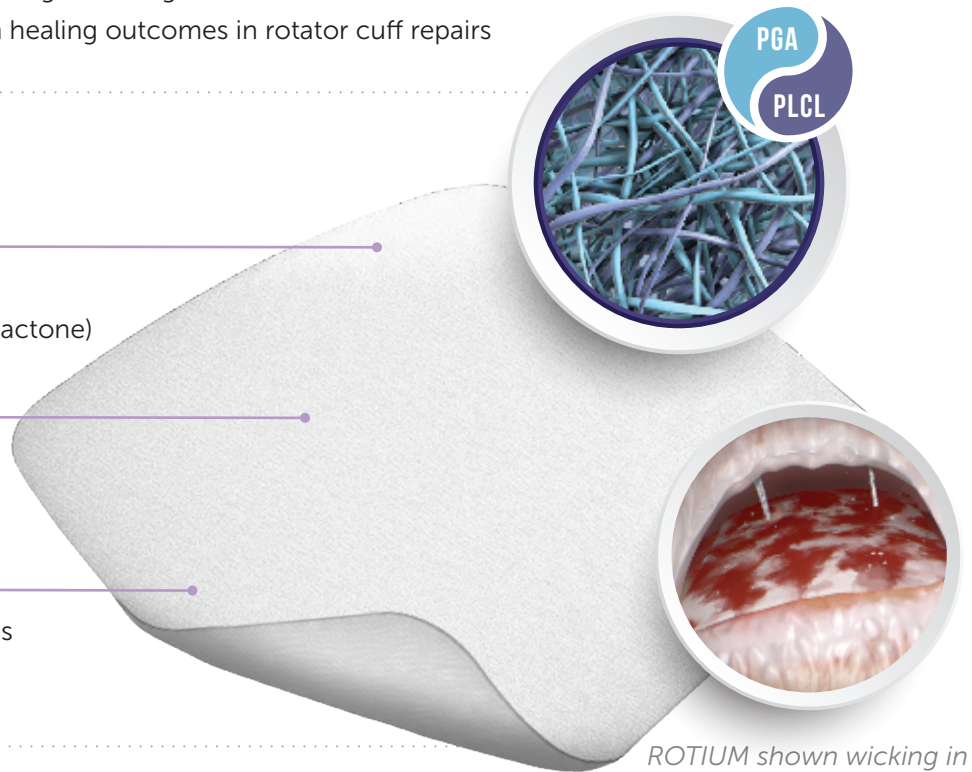
- **PGA:** Polyglycolic acid
- **PLCL:** Poly(lactide-co-caprolactone)

Electrospun Matrix Design

- Mimics native ECM
- 85% porous structure

Biphasic Resorption Profile

- Fully resorbed in 3 - 4 months
- Thickness: 0.85mm



ROTIUM shown wicking in a rotator cuff repair at the enthesis

A SOLUTION FOR TENDON-BONE HEALING



Smart Economics & Simplified Technique

- No disposables or additional fixation required
- Compatible with commercially-available anchor systems



Robust Handling Characteristics

- Easy to deploy
- Accommodates suture & trimming



Interpostional Wick

- Holds active biology at repair site (up to ~500% its weight)
- Kickstarts a pro-healing environment & promotes cellular proliferation



Biologic Microenvironment

- Biphasic resorption of PGA & PLCL encourages cellular integration
- Bioactive degradants known to facilitate tissue remodeling

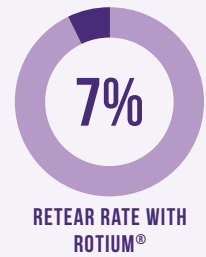
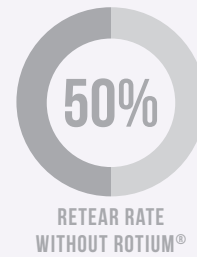
IMPROVED CLINICAL OUTCOMES

Retrospective Study (OJSM)⁴

- 33 Patients
- Small - Large Tear Sizes
- 91% Success Rate

Prospective Study (JOEJ)²

- 30 Patients - Randomized
- Small - Large Tear Sizes
- 93% Success Rate



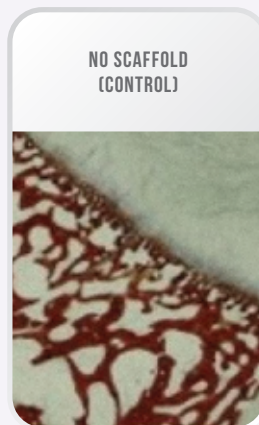
IMPROVED HEALING

Sheep CSU Study (JSES, 2022)³

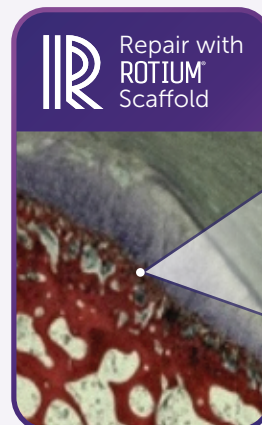
- Formation of Sharpey's-like fibers at the tendon-bone interface
- Development of a remodeled enthesis with similar characteristics to native tissue



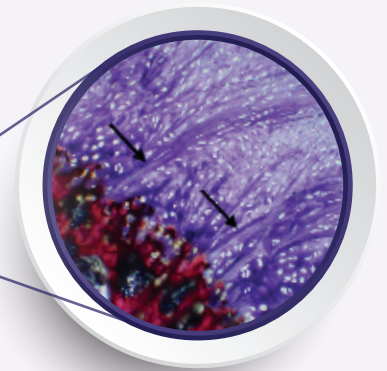
Winner of the 2023
Neviaser Award for
Basic Science
(ASES & JSES)



NO SCAFFOLD
(CONTROL)



Repair with
ROTIUM®
Scaffold

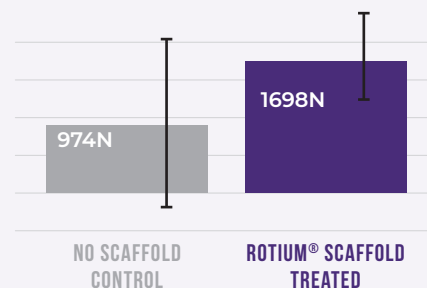


*Healing with scar tissue vs. healthy
bone-tendon integration*

IMPROVED STRENGTH

Safe and Effective

- Increased strength with consistent repair outcomes
- Synthetic polymers have demonstrated excellent biocompatibility without adverse effects



74%
INCREASE

MEDIAN ULTIMATE
BREAKING
STRENGTH (N)
AT 12 WEEKS³

VITAL ROLE OF BIOACTIVE DEGRADANTS

Biphasic resorption of PGA and PLCL releases bioactive degradants that modulate the local environment, fuel cellular activity, and promote tendon healing & tissue remodeling:

Glycolic Acid^{6, 7, 9}

- Modulates inflammation
- Promotes fibroblast proliferation & collagen expression

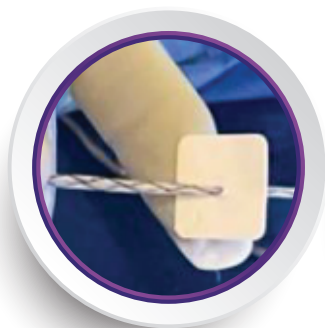
Lactic Acid^{8, 10}

- Stimulates VEGF expression & enhances cellular migration
- Promotes angiogenesis & ECM deposition

Caproic Acid⁷

- Addresses microbial contaminants
- Modulates inflammation

SIMPLIFIED TECHNIQUE



1 Pass suture through scaffold



2 Taco & push through cannula



3 Position on the repair footprint



4 Complete repair with cuff over **ROTIUM®**

ORDERING INFORMATION

PART #	DESCRIPTION	QTY
FG-0007	ROTIUM® Bioresorbable Wick Implant (2cm x 2cm)	1
FG-0043	ROTIUM® Bioresorbable Wick Implant (4cm x 3cm)	1

FDA 510(k) Clearance: **ROTIUM®** is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

No special storage requirements. Recommended storage in original packaging, preferably in a cool and dry place.

CONTACT YOUR ATREON REPRESENTATIVE FOR MORE INFORMATION OR VISIT

atreonortho.com/contact-us/



Legal Manufacturer: Nanofiber Solutions
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View U.S. patent information at <https://nanofibersolutions.com/technology>

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◇ All claims supported by data on file.

* Please refer to the IFU for a complete list of compatible anchors.

§ References available upon request



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