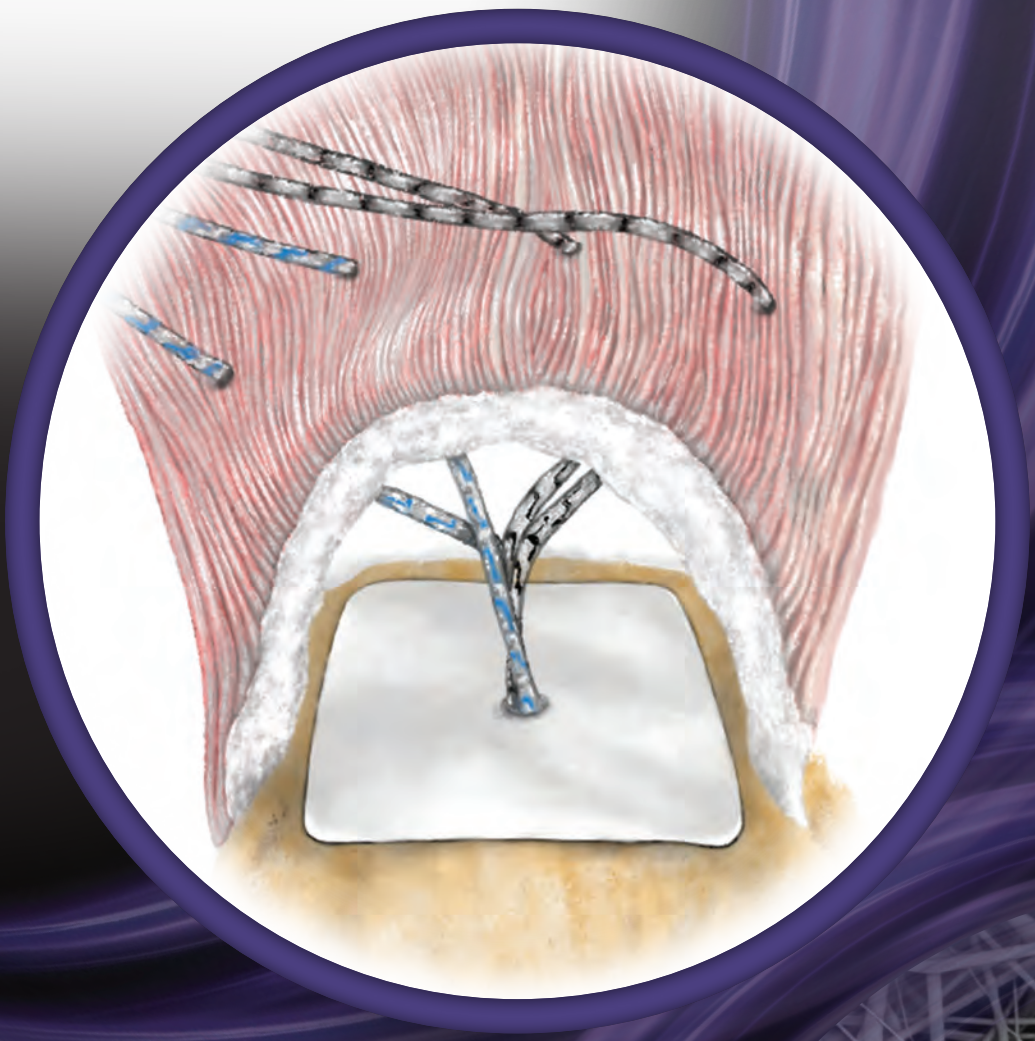
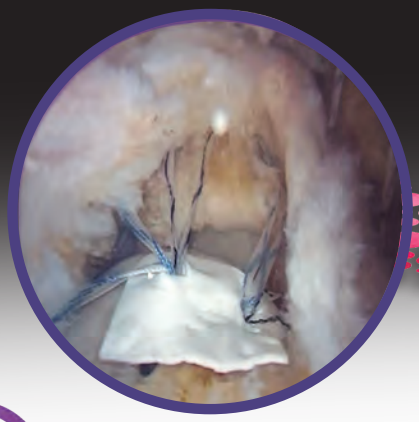
ROTIUM®
Bioresorbable Wick

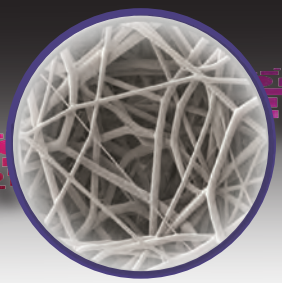
Advancing the Journey of Tendon-to -Bone Healing



ATREON
ORTHOPEDICS

Where Innovation Meets Healing™





ROTIUM®

Right Environment
Harness autologous biology

A bioresorbable wick placed at the tendon-bone interface designed to address the biologic environment for better support of the healing cascade, remodeling of healthy tissue and improvement in long-term outcomes after rotator cuff repair.

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.

35% average retear rate

A BREAKTHROUGH HEALING SOLUTION

Interpositional Wick
- Mimics extracellular matrix (ECM) & holds active biology at the repair site
- Kickstarts a pro-healing environment

Synthetic & Bioresorbable
- Biphasic absorption encourages cellular integration & proliferation
- Degradants known to facilitate healthy tissue remodeling

Smart Economics & Simplified Technique
- Priced for use on every repair
- Easily incorporated into current RTC surgeries without disposables

Reproducible Clinical Success
- Promotes the natural healing process
- Delivers consistent long-term results & restoration of function

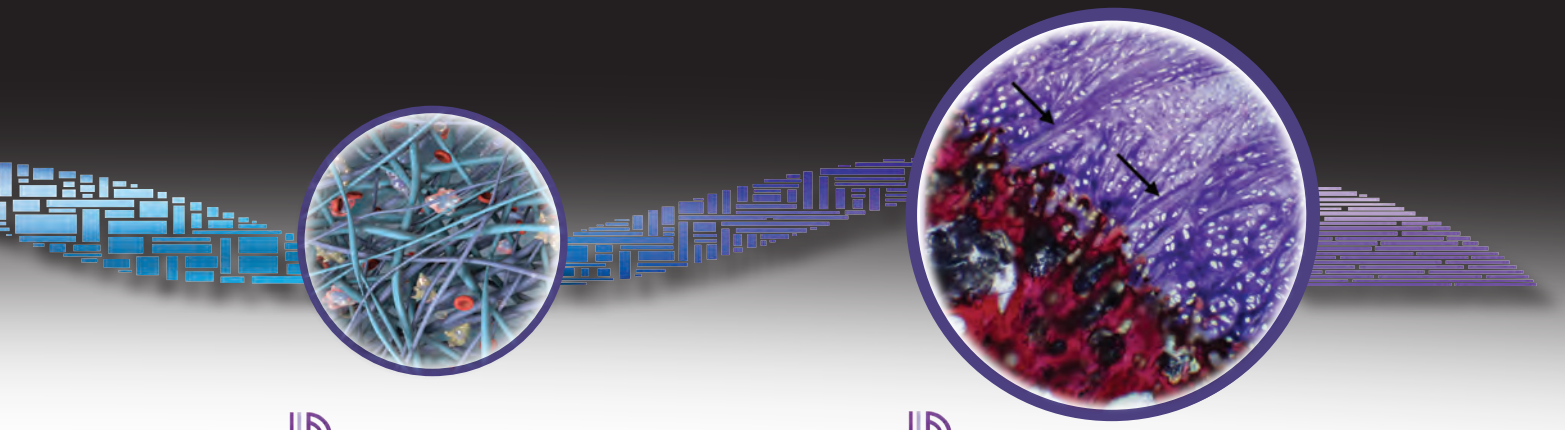
DESIGNED AS A SCAFFOLD

100% Synthetic
PGA – Poly-Glycolic Acid
PLCL – Poly-Lactide co-caprolactone

Absorbable
3-4 months

85% Porous
microfiber matrix

Footprint Coverage
20x20 mm
40x30 mm
0.6 mm thickness



Right Biology
Improve tendon healing

Right Regeneration
Remodel a healthy enthesis

THE POWER OF A HEALTHY INTERFACE

Improved Outcomes

Retrospective Study (OJSM)[4]
- 33 Patients
- Small - Large Tear Sizes
- 91% Success Rate

Prospective Study IRB (JOEI)[2]
- 30 Patients - Randomized
- Small - Large Tear Sizes
- 93% Success Rate

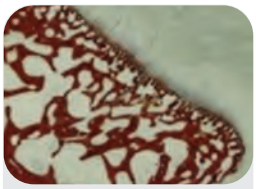
50% RETEAR RATE WITHOUT ROTIUM®

7% RETEAR RATE WITH ROTIUM®

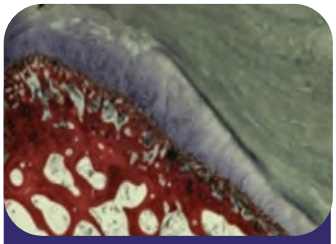
Improved Healing

Sheep CSU Study (JSES)[3]
- Development of Sharpey's like fibers at the tendon-bone interface (vs. the control group)
- Remodeled enthesis with characteristics similar in thickness & organization to native tendon

Healing with Healthy Bone-Tendon Integration vs. Scar Tissue



REPAIR WITHOUT ROTIUM®



REPAIR WITH ROTIUM®

Improved Consistency and Safety

- Increased strength with reproducible repair outcomes
- Synthetic polymers have demonstrated excellent biocompatibility & no reported adverse effects

MEDIAN Ultimate Breaking Strength (N) at 12 Weeks[3]

CONFIDENCE IN SYNTHETICS

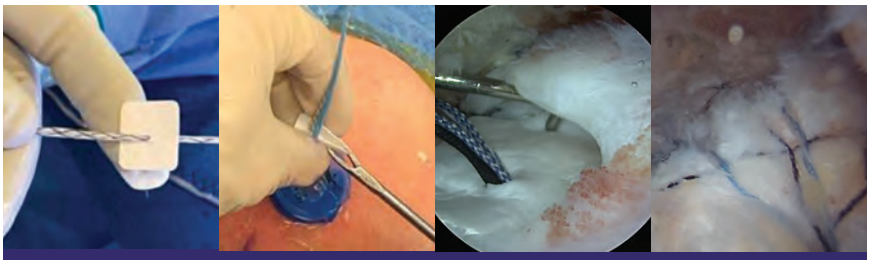
ROTIUM aims to solve the ROOT CAUSE of tendon failures and is designed for widespread case use for all tear sizes by addressing the weak link in tendon-bone healing. Degradative polymer contributions:

Glycolic Acid[6,7,9]
- Anti-Inflammatory properties
- Increases fibroblast proliferation & production of collagen & HA

Lactic Acid[5,8,10]
- Stimulates VEGF & collagen gene expression
- Modulates inflammation & accelerates cellular migration
- Promotes ECM deposition & reparative angiogenesis

Caproic Acid[7]
- Anti-microbial properties
- Anti-inflammatory properties

VERSATILE & 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®

Contact your Atreon Representative for the detailed ROTIUM Surgical Technique Guide. A manuscript of this surgical procedure can also be found in the Techniques in Arthroscopy Techniques Journal[1]

> **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***

> **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***

Part Number	Description	Qty.	Unit of Measure
FG-0007	ROTIUM® Bioresorbable Wick Implant - 2cm x 2cm	1	Each
FG-0043	ROTIUM® Bioresorbable Wick Implant - 4cm x 3cm	1	Each

INDICATIONS:

The ROTIUM® Bioresorbable Wick is intended to be used in conjunction with suture anchors for the reattachment of tendon to bone in rotator cuff repairs. Please refer to the instructions for use for a complete list of indications, contraindications, warning and precautions.

WARNING:

Please also refer to the package insert(s) or other labeling associated with the devices identified in this brochure for additional information.

CAUTION:

Rx Only

ATREON ORTHOPEDICS

Legal Manufacturer: Nanofiber Solutions
Distributed by: Atreon Orthopedics 5164 Blazer Pkwy.
Dublin, OH 43017 USA
614-429-1471
www.atreonortho.com

[1] Beleckas, C. M., Bishai, S.K., & Badman, B. L. (2021). Rotator Cuff Repair Augmented with Interpositional Nanofiber Scaffold. *Arthroscopy Techniques*. https://doi.org/10.1016/j.eats.2022.08.061

[2] Beleckas, C. M., Minetos, P., & Badman, B. L. (2023). Short-term radiographic and clinical outcomes of arthroscopic rotator cuff repair with and without augmentation with an interpositional nanofiber scaffold. *Journal of Orthopaedic Experience & Innovation*. https://doi.org/10.60118/001c.84269

[3] Romeo, A., Easley, J., Regan, D., Hackett, E., Johnson, J., Johnson, J., Puttlitz, C., & McGilvray, K. (2022). Rotator cuff repair using a bioresorbable nanofiber interposition scaffold: A biomechanical and histologic analysis in sheep. *Journal of Shoulder and Elbow Surgery, 31*(2), 402–412. https://doi.org/10.1016/j.jse.2021.07.018

[4] Seetharam A, Abad J, Baessler A, Badman BL. Use of a Nanofiber Resorbable Scaffold During Rotator Cuff Repair: Surgical Technique and Results After Repair of Small- to Medium-Sized Tears. Orthop J Sports Med. 2022 May 13;10(5):23259671221094848. doi: 10.1177/23259671221094848. PMID: 35601733; PMCID: PMC9118444.

[5] Beckert, S., et al., *Lactate stimulates endothelial cell migration.* Wound Repair Regen, 2006. 14(3): p. 321-4.

[6] Green, B.A., R.J. Yu, and E.J. Van Scott, *Clinical and cosmeceutical uses of hydroxyacids.* Clin Dermatol, 2009. 27(5): p. 495-501.

[7] Huang, C.B., et al., *Short- and medium-chain fatty acids exhibit antimicrobial activity for oral microorganisms.* Arch Oral Biol, 2011. 56(7): p. 650-4.

[8] Sun, S., et al., Lactic Acid: *No Longer an Inert and End-Product of Glycolysis.* Physiology (Bethesda), 2017. 32(6): p. 453-463.

[9] Tang, S.C. and J.H. Yang, *Dual Effects of Alpha-Hydroxy Acids on the Skin.* Molecules, 2018. 23(4).

[10] Zhang, D., et al., (2020). Endothelial Lactate Controls Muscle Regeneration from Ischemia by Inducing M2-like Macrophage Polarization. Cell Metab. 31. 1136-1153 e7

◊ All claims supported by data on file § References available upon request

View U.S. patent information at https://nanofibersolutions.com/technology/