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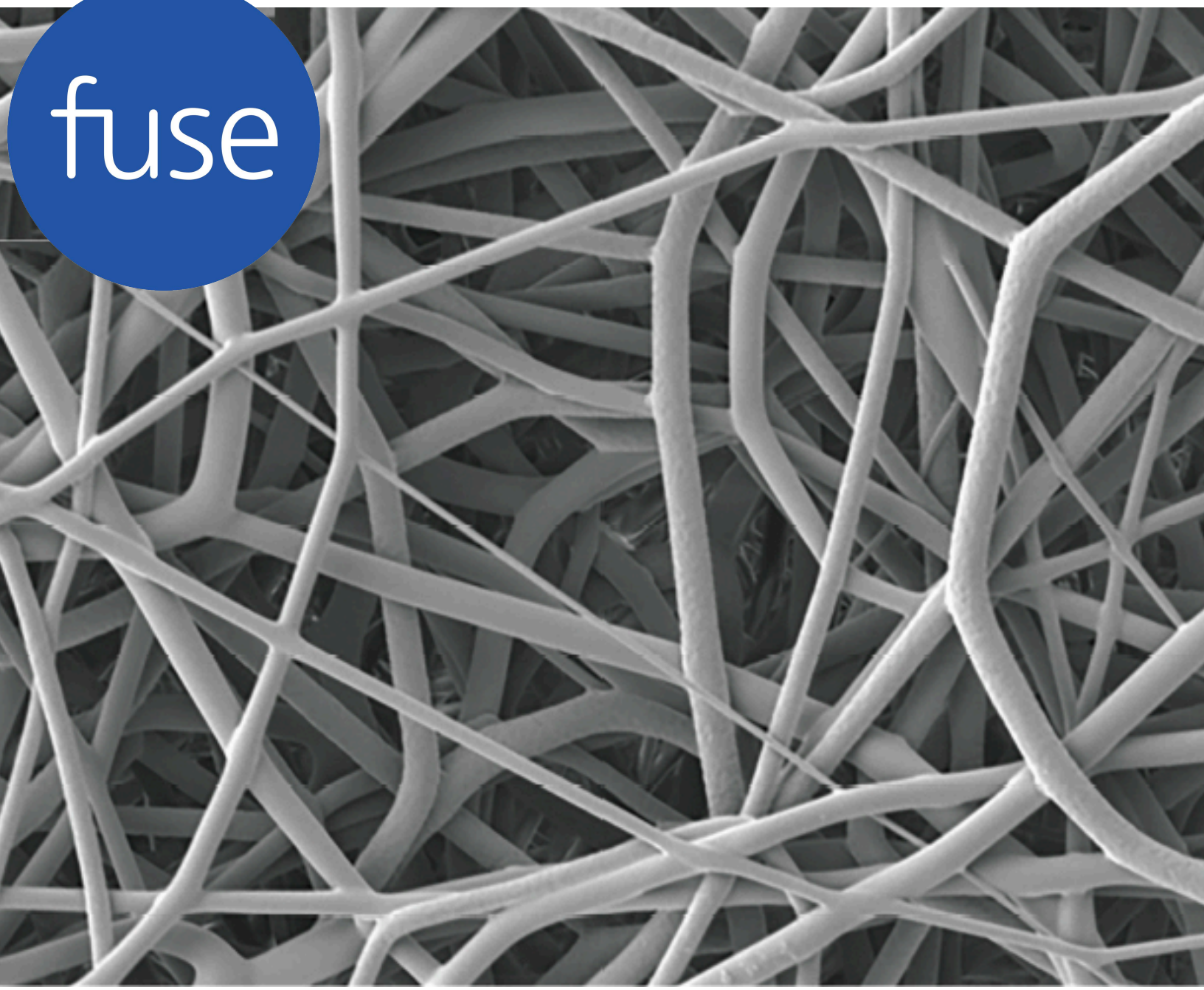


The Rotium™ Bioresorbable Scaffold Wick

for Rotator Cuff Repair

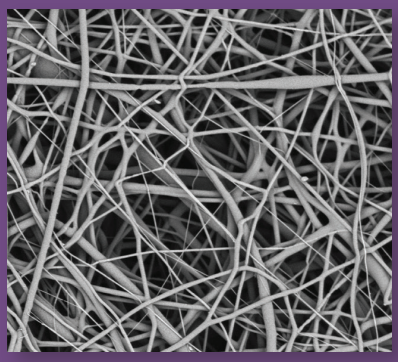
ANIMAL STUDIES

ROTIUM™

ROTIUM™ SEM IMAGES

Fibers act as a scaffold that support cellular ingrowth and proliferation. The Rotium™ Wick supports and encourages the regeneration of healthy tendon and Sharpey fibers.

SEM image of native tendon ECM

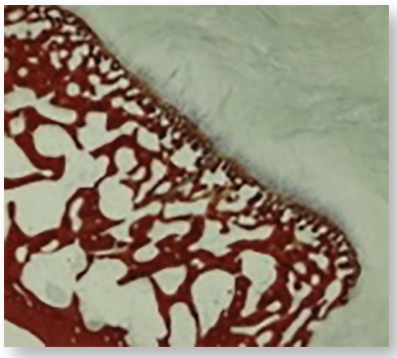


SEM image of Rotium™ Wick

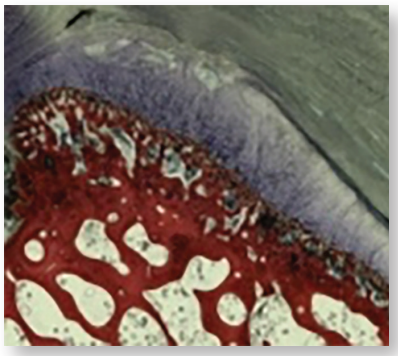
ROTIUM™ ACUTE REPAIR

12-Week Histology

Collagen fibers, similar to Sharpey, extend through calcified fibrocartilage and attach to remnant scaffold, humeral head.



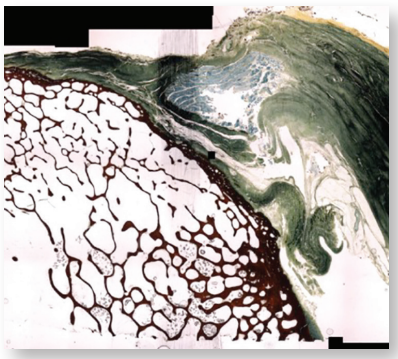
Control anchor only rotator cuff repair



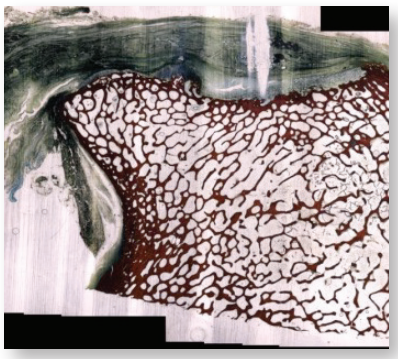
Rotium™ Wick rotator cuff repair

ROTIUM™ CHRONIC REPAIR

12-Week Histology



Sharp transection with anchor only repair



Sharp transection with Rotium™ Wick repair

Mechanical Data

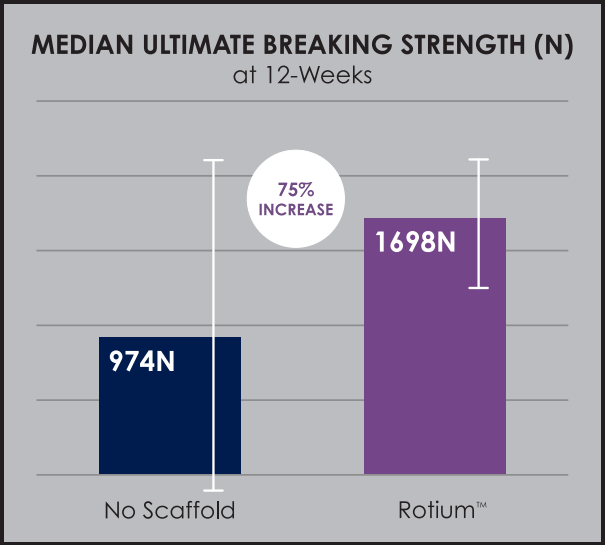
ROTIUM™ ACUTE REPAIR MODEL:
Ultimate Strength at Failure Data

Acute Repair Sheep Model at Colorado State University

CONTROL:
Repaired with four Arthrex 4.75 Swivel Lock suture anchors in a Speed Bridge configuration

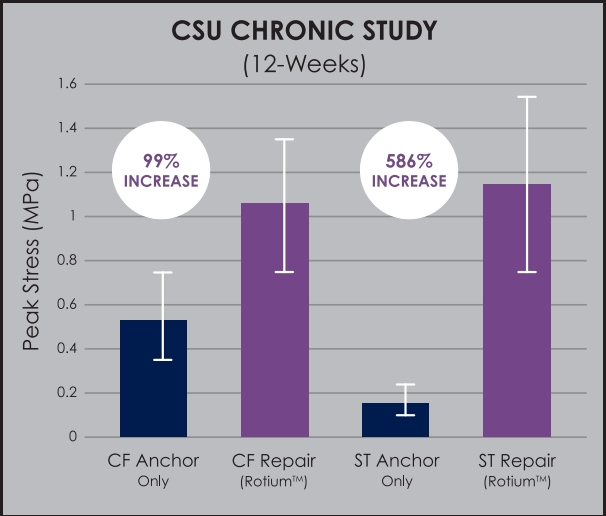
EXPERIMENTAL GROUP:
Control repair method, plus the Rotium™ as an inlay between the bone and tendon

RESULTS:
At 12 weeks, the tendon/bone was tested to determine the ultimate strength at failure. The Rotium™ Wick provided **increased strength** with more **consistent results**



ROTIUM™ CHRONIC REPAIR MODEL:
Peak Stress at 8% Strain Data

Chronic Repair Sheep Model at Colorado State University



Two different methods of chronic injury:
- combed fenestration (CF)
- sharp transection (ST)

CONTROL:
Repaired with four Arthrex 4.75 Swivel Lock suture anchors in a Speed Bridge configuration

EXPERIMENTAL GROUP:
Control repair method, plus the Rotium™ as an inlay between the bone and tendon. Tested to determine peak stress at 8% strain

References

1. Curtis AS, et al. The insertional footprint of the rotator cuff: an anatomic study. Arthroscopy. 2006 Jun:22(6):609.e 1.
2. Colvin, AC., et al., National trends in rotator cuff repair. J Bone Joint Surg Am, 2012. 94(3): p. 227-33.
3. Wu, et al. " Intraoperative Determinants of Rotator Cuff Repair Integrity: An Analysis of 500 Consecutive Repairs". The American Journal of Sports Medicine, 2012.
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5. Thangarajah, T., et al., Augmentation of Rotator Cuff Repair With Soft Tissue Scaffolds. Orthopaedic Journal of Sports Medicine, 2015. 3(6).
6. Aurora, A, et al., The biomechanical role of scaffolds in augmented rotator cuff tendon repairs. Journal of Shoulder and Elbow Surgery, 2012.21 (8): p. 1064-1071.
7. Apostolakos, J., et al., The en thesis: a review of the tendon-to-bone insertion. Muse/es, ligaments and tendons journal, 2014. 4(3): p. 333-342.
8. Agudelo-Garcia, P.A., et al., Glioma Cell Migration on Three-dimensional Nanofiber Scaffolds Is Regulated by Substrate Topography and Abolished by Inhibition of STAT3 Signaling. Neoplasia, 2011. 13(9): p. 831-U96.
9. Fukunishi, T., et al., Role of Bone Marrow Mononuclear Cell Seeding for Nano fiber Vascular Grafts. Tissue Engineering Part A. 2017.
10. Fukunishi, T., et al., Preclinical study of patient-specific cell-free nano fiber tissue-engineered vascular grafts using 3-dimensional printing in a sheep model. The Journal of Thoracic and Cardiovascular Surgery.
11. Clark, J.M., Harryman, D. T., "Tendons, Ligaments, and Capsule of the Rotator Cuff", The Journal of Bone and Joint Surgery, 1992.
12. Provenzano, P.P. et al., Collagen fibril morphology and organization: Implications for force transmission in ligament and tendon, Matrix Biology 25 (2006) 71 - 84.
13. Regan, D. Johnson, J. In-Vivo Characterization of Nanofiber Solutions Suture Anchor Technology. Final Report. 2018. Animal Studies: Data on file.

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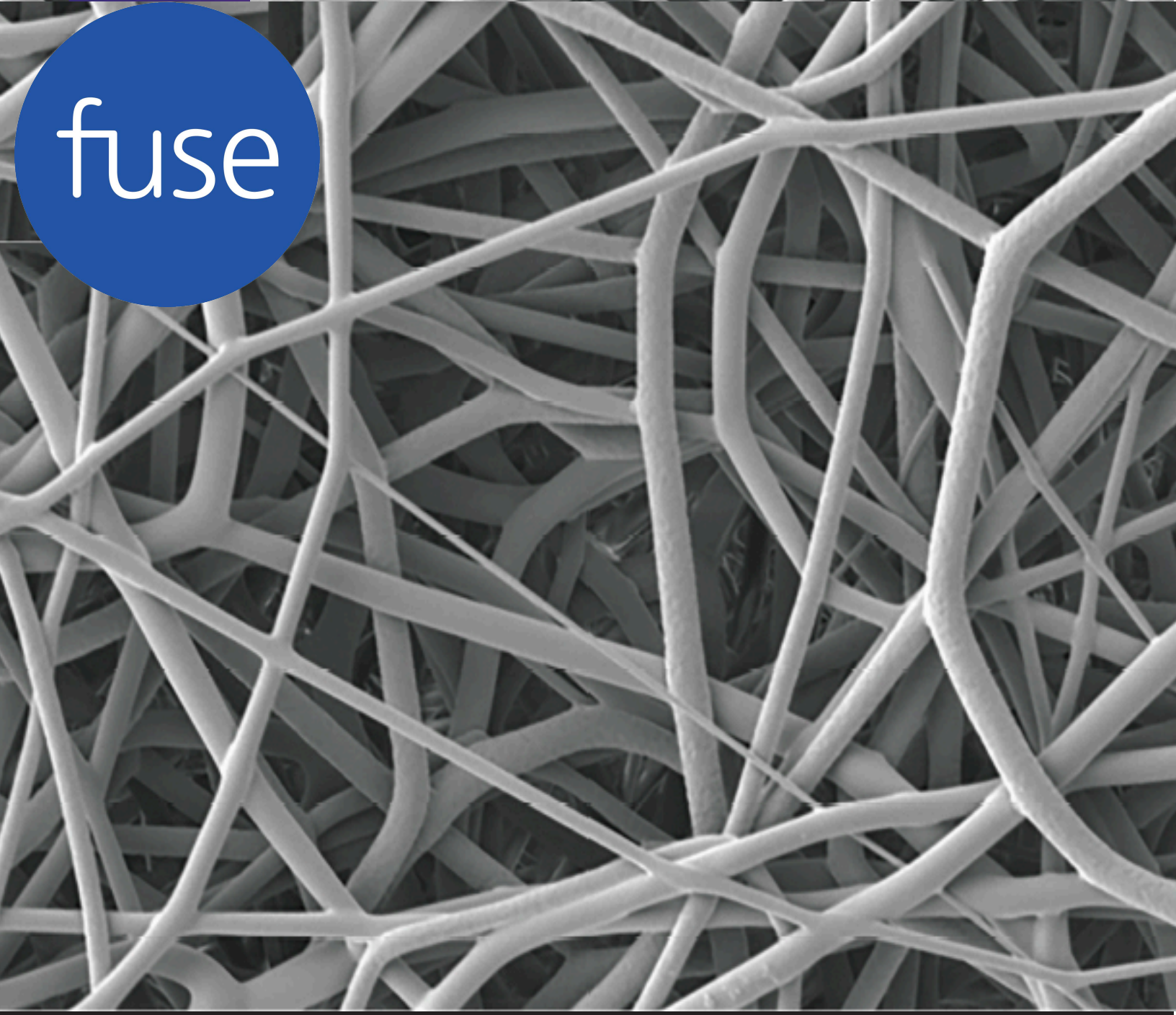


The Rotium™ Bioresorbable Scaffold Wick

for Rotator Cuff Repair

ROTIUM™

Product Composition

VERSATILITY

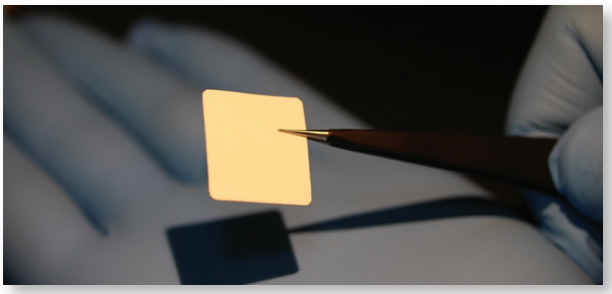
- Rotium™ is FDA indicated to be used in conjunction with over 40 commonly used anchors. Similar products on the market only have one suture anchor product configuration.
- Ease of use allows for incorporation into existing repair techniques without adding time.
- No change is required in placement configuration for existing anchors or procedures Furthermore, no special instrumentation is required.
- Can be used in open or arthroscopic procedures.

COVERAGE

- The Rotium™ Wick provides over **9 times** the surface area coverage than a comparable product, with a surface area of 400 sq. mm.
- Rotium™ provides optimum coverage of the supraspinatus footprint of 368sq. mm.

AFFORDABILITY

- Rotium™ benefits patients, surgeons, and insurers by providing a lower overall cost per procedure than comparable products while offering greater benefits, such as increased wick retention and strength. Currently, alternative scaffold products cost significantly more than Rotium™ per procedure.



PRODUCT STRUCTURE

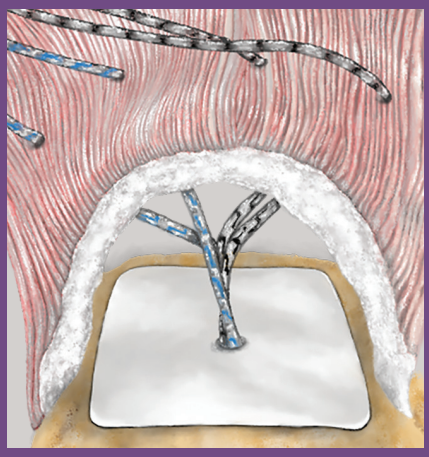
Fibers Designed to Mimic Physical Structure of Extracellular Matrix

- Rotium™ is composed of two types of polymer fibers: PLCL and PGA, with the intent to mimic the extracellular matrix of the rotator cuff tendon.
- Rotium™ is approximately 85% porous to promote rapid cellular infiltration.

VERSATILE POSITIONING

Bioresorbable Scaffold Wick

- Arthroscopically deployed between bone and tendon.
- Scaffold is placed at the bone-tendon interface.
- Anchor sutures are passed through the Rotium™ device.



The Rotium™ Bioresorbable Wick is comprised of biodegradable polymer fibers that replicate the structure of the native extracellular matrix and are designed to completely resorb after 3-4 months. The fibers are designed to act as a scaffold that supports cellular ingrowth and facilitates healthy tissue regrowth, such as Sharpey fibers. Traditional rotator cuff repair results in high levels of scar tissue at the bone-tendon interface, resulting in weaker connection of the tendon to the bone. The Rotium™ Wick is engineered to support and encourage the regeneration of healthy tendon at the bone-tendon interface.

**Claims as supported by animal studies and are not necessarily predictive of human results.*

References

1. Curtis AS, et al. The insertional footprint of the rotator cuff: an anatomic study. Arthroscopy. 2006 Jun:22(6):609.e 1.
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