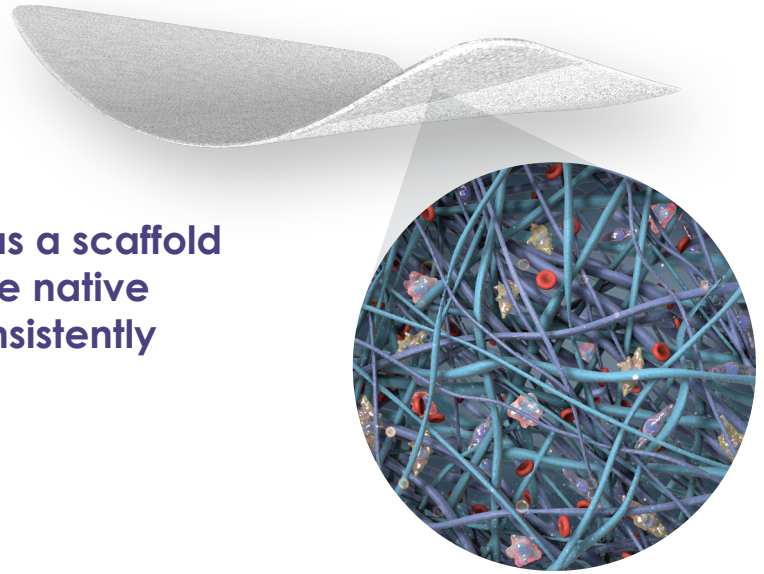


ROTIVM[®] BIORESORBABLE WICK FOR ROTATOR CUFF REPAIR

SURGICAL TECHNIQUE



An interpositional wick designed as a scaffold to improve healing and regenerate native tissue architecture, resulting in consistently strong tendon-bone integration.*

One Size

2cm X 2cm and 0.6mm thick

Material

Bioresorbable Polyglycolic Acid (PGA) & Poly(lactide-co-caprolactone) (PLCL) synthetic fibers

Architecture

Non-woven, 85% porous, soft & flexible microfibers

Interpositional Placement

At interface, between the tendon and bone (repair site)

Indications

Any rotator cuff (RTC) tears, full thickness or high-grade partial, where tendon to bone healing is needed

Value

No extra disposables required

TECHNIQUE VERSATILITY

Rotium's simplified insertion technique means it can be easily incorporated into your current RTC surgical procedure without adding noticeable surgical time.

**Single row
technique**

**Double row
technique**

**Any size
full thickness tear**

**Suture anchor
of choice**

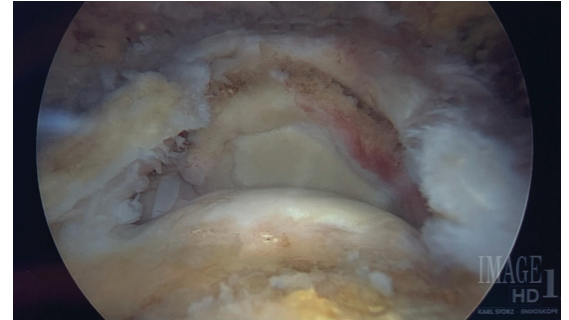
(Approved for use with over
150 popular suture anchors)

DETERMINE RTC REPAIR PLAN

1

Assess tear to determine repair plan and anchor configuration. Rotium does not require a change to your preferred technique.

- Single row or double row repair
- One or two medial row suture anchors

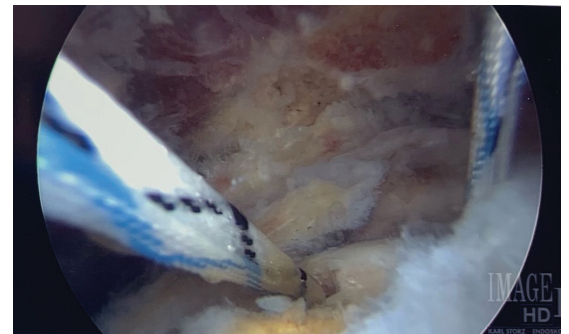


DEPLOY MEDIAL ROW SUTURE ANCHOR(S)

2

When using **TWO medial row suture anchors, deploy the posterior anchor first and retrieve sutures through posterior accessory portal.**

- It is recommended to place the posterior anchor first for ease of suture management.



3

Deploy the anterior suture anchor and leave sutures outside of accessory portal.

- This portal should be positioned and used to bring Rotium into the subacromial space

SUTURE HOLE PLACEMENT PREPARATION

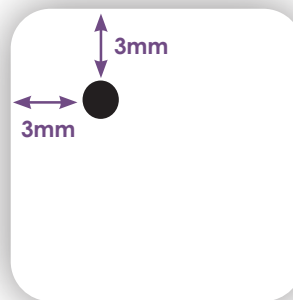
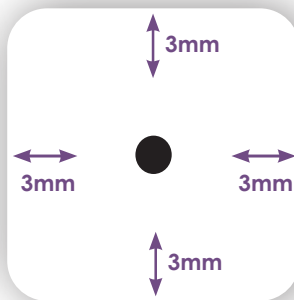
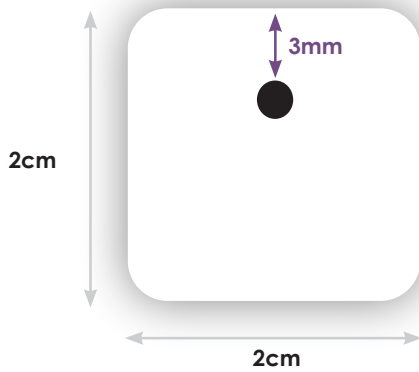
Rotium's versatility gives you the choice to secure the scaffold using suture from either **ONE** or **TWO** suture anchors and through various locations on the scaffold.

Note: When considering suture hole placement be sure to maintain no less than a **3mm border** from the scaffold edges to reduce risk of scaffold tear or suture pull through.

Pass all suture limbs from one anchor through one hole.

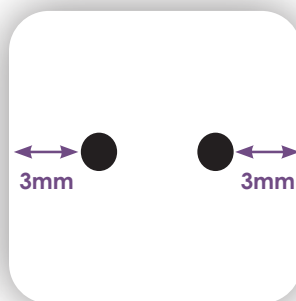
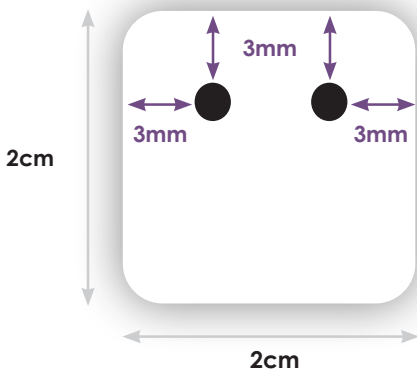
ONE ANCHOR

Suture Hole Placement Options



TWO ANCHOR

Suture Hole Placement Options



PASS SUTURES THROUGH ROTIUM – TWO ANCHOR TECHNIQUE

4

Pass the sutures from the anterior suture anchor through the Rotium wick.

- A pilot hole can be created with a sharp blade or surgical scissors.
 - or –
- Suture can be passed directly through Rotium using various tools such as
 - Straight Keith Needle
 - Suture Passer
 - Bird Beak Suture Passer
 - Various sharp instruments



5

Retrieve the posterior anchor sutures through the same portal as the anterior anchor sutures and pass through the Rotium wick.

- When passing suture through two holes, position them as far apart as possible while maintaining the 3mm minimum distance from edge of scaffold. This will help prevent bunching of the scaffold and suture tear-through when deploying Rotium at the repair site.

Note: There is no need to measure the distance between suture anchors to determine suture hole placement.

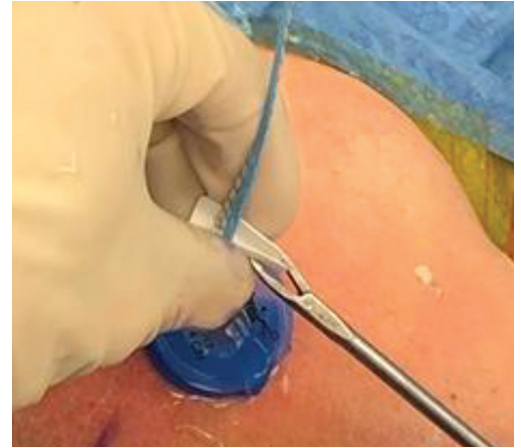
Note: If the prepared tuberosity exceeds the size of the Rotium scaffold (2x2 cm) it is recommended to use a second device to obtain full coverage.



PASS ROTIVUM INTO SUBACROMIAL SPACE

6

Fold Rotivum wick in half, forming a “taco” shape. Grasp the folded scaffold using a grasping tool (Kingfisher) making sure not to clamp the sutures.



7

While maintaining tension on the sutures, push the scaffold through the cannula/portal and into the joint space.

- No need to position Rotivum exactly on the tuberosity at this point. Place the scaffold into the subacromial space, release and retract grasping tool.

Note: Use a 6mm or larger size cannula. The technique can be done without a cannula if the skin incision is widened enough for the graft to be inserted.



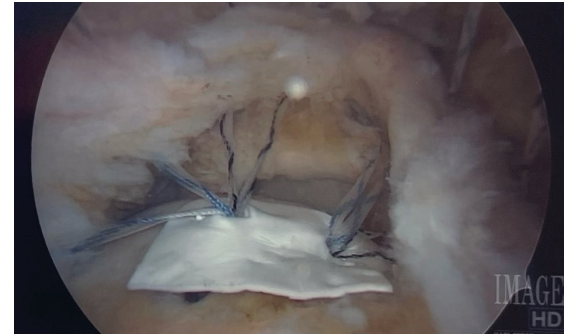
DEPLOY ROTIUM AT THE REPAIR SITE

8

Retrieve the posterior sutures through the posterior portal and the anterior suture limbs through the anterior portal.

- Rotium will slide down the rest of the way and sit flush against the bone. You may use a probe to gently manipulate further if needed.

Note: It is preferred to have the scaffold lay flat but repair is not compromised if there is a dog ear or folded section of the scaffold.

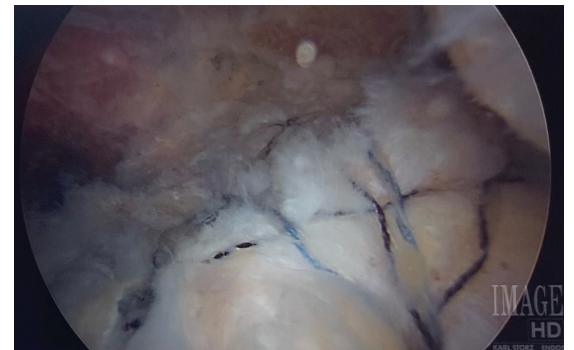


9

Pass sutures through cuff using preferred technique and suture passing tools. Complete rotator cuff repair.

- Rotium will not affect suture passing or placement of lateral row anchors

Note: The completed repair will have the cuff positioned on top of Rotium. It is safe to have parts of the scaffold sticking out from underneath the cuff.



ORDERING INFORMATION & PRODUCT CODES

Part Number	Description	Qty.	Unit of Measure
FG-0007	Rotium® Bioresorbable Wick Implant -2cm x 2cm	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.



Legal Manufacturer: Nanofiber Solutions
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*Romeo A, Easley J, Regan D, et al. **Rotator Cuff Repair Using a Bioresorbable Nanofiber Interposition Scaffold:** A Biomechanical and Histological Analysis in Sheep. *J Shoulder and Elbow Surg.* 2021 DOI: <https://doi.org/10.1016/j.jse.2021.07.081> (Funded by Nanofiber Solutions, LLC)