Comprehensive Product Offerings for Your Rotator Cuff Repair

Pioneering Rotator Cuff Repair Solutions

Customizable Construct Options | Minimal Anatomic Disruption | Efficient and Reliable Repairs

ULTRATAPE™ Suture
HEALICOIL® REGENESORB Suture Anchor
HEALICOIL PK Suture Anchor
Q-FIX™ All-Suture Anchor
FOOTPRINT™ ULTRA PK Knotless Suture Anchor
MULTIFIX™ S Knotless Suture Anchor
FIRSTPASS™ ST Suture Passer
When You Demand Performance for Your Rotator Cuff Repair

Our wide array of innovative shoulder repair solutions gives surgeons a comprehensive product offering for rotator cuff repairs. From a steady starting position to a precisely controlled single or double row anchor fixation solution, we have what it takes to overcome your specific challenges.

Customizable construct options

- Provided by choice of implant, suture type and configuration based on each patient’s tear pattern and tissue and bone quality

Minimal anatomic disruption

- Achieved through open architecture, small, all-suture options, and next generation biocomposite material

Efficient, reliable repair

- Accomplished with implants and suture passers designed to reduce repair steps, including suture shuttling and bone hole preparation

Insertion of a second HEALCOIL™ PK Suture Anchor into the medial aspect of the greater tuberosity.

Completed construct from a double row repair of a massive rotator cuff tear using HEALCOIL PK Suture Anchors loaded with ULTRATAPE™ and FOOTPRINT™ ULTRA PK Knotless Suture Anchors.
**Suture Solutions**

**ULTRATAPE®**

**Suture**

**Ultra Contact. Less Material. Make More of Your Rotator Cuff Repair**

Increased tendon-to-bone contact can mean an improved repair.¹,²

- 75% more contact than #2 suture
- 60% more contact than FiberTape TM³ (demonstrated in pre-clinical testing).

A smaller amount of material can be advantageous when passed through compromised tissue.

- 58% less material than FiberTape
- More evenly distributed pressure³
- Fewer peak pressure points³

More repair options and expanding techniques.

- Use for knotless or knotted repairs
- Available pre-loaded on HEALICOIL® Suture Anchors

**Significantly More Contact Area**

Contact area on pressure sensitive film for ULTRATAPE compared to two controls, measured in inches squared, with confidence intervals.

<table>
<thead>
<tr>
<th>Material</th>
<th>Contact Area</th>
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<tbody>
<tr>
<td>ULTRATAPE</td>
<td>21</td>
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<tr>
<td>ULTRABRAID #2 Suture</td>
<td>12</td>
</tr>
<tr>
<td>FiberTape TM³</td>
<td>13</td>
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</tbody>
</table>

ULTRATAPE: Cross section showing smooth braid

Arthrex® FiberTape™: Cross section showing solid inner core

ULTRATAPE used in a rotator cuff repair
REGENESORB material
An advanced biocomposite absorbed and completely replaced by bone within 24 months in pre-clinical studies.
REGENESORB biocomposite material contains PLGA and dual osteoconductive components, β-TCP and calcium sulfate.

Gross anatomy and histology images of a 9x10 mm REGENESORB interference screw evaluated in a direct-in-bone sheep model. Images clearly demonstrate absorption and complete replacement by bone within 24 months.

Suture and Fixation Solutions

HEALICOIL® REGENESORB
Suture Anchor

HEALICOIL PK
Suture Anchor

A Unique Combination of Innovative Design and Materials

Open-architecture design
The HEALICOIL Suture Anchor has a distinctive open-architecture that differs from solid-core implants by eliminating the material between the anchor threads. The open design allows blood and bone marrow from surrounding cancellous bone to enter the implant.

Bone ingrowth
The unique HEALICOIL open-architecture allows for new bone to fill the fenestrations between the threads and into the central channel by 12 weeks post-implantation, as demonstrated in a pre-clinical ovine study.

Micro-CT images at 12 weeks of a 5.5 mm HEALICOIL PK Suture Anchor show a web of bone beginning to fill the center of the implant. Histology at the same point in time clearly demonstrates bone growing across the implant’s open architecture.
Less material
The unique open-architecture design of the HEALICOIL® Anchor reduces the amount of implanted material in the shoulder compared to traditional, solid-core anchors, permitting easier revision when necessary.5

Durable design
Even with its reduced volume of material, the HEALICOIL REGENESORB Suture Anchor meets the demanding biomechanical specifications of the most advanced surgical implants, providing the benefits of an absorbable implant with fixation strength comparable to non-absorbable PEEK implants.7

And when compared to competitive biocomposite suture anchors, its superior biomechanical performance includes stronger fixation security in poor-quality bone, and greater torsional strength – essential when inserting the anchor into harder bone densities.8

Superior pullout strength
The extended, fully-threaded HEALICOIL anchor design provides more threaded engagement than leading competitive biocomposite anchors, delivering greater pullout strength in poor-quality, osteoporotic bone.9

Minimal size
In biomechanical testing, the 4.75 mm HEALICOIL REGENESORB Suture Anchor demonstrated higher pullout strength than the larger, 5.5 mm competitive anchors.10

Sustained fixation
The initial strength of the HEALICOIL REGENESORB Suture Anchor is designed to hold fixation over time throughout the healing period in poor quality bone,11 withstanding typical shoulder loading forces and supporting the range of motion necessary for physical therapy and rehabilitation.

Snapshot of REGENESORB material at 18 months12

18-month histology snapshot of 2.3 mm REGENESORB instability anchor evaluated in a direct-in-bone sheep model (viewed under partially polarized light).
Next Generation All-Suture Anchor Technology

The 2.8 mm Q-FIX Anchor’s fixation performance and small footprint makes it a great option for rotator cuff repairs. With performance similar to traditional corkscrew anchors more than twice its size, the 2.8 mm Q-FIX anchor is ideal for medial row fixation where space is limited.

**Consistent deployment**

Q-FIX Anchors provide consistent deployment due to the radially expanding implant design and delivery system that acts like a knot pusher.

**Strong performance**

The Q-FIX Anchor delivery system, with automated suture pull to a target of 140 newtons, ensures full deployment of the implant within the bone hole.\(^{13}\)

**Streamlined technique**

Implant deployment with a turn of the dial through the drill guide streamlines implant placement.
To insert, tap the FOOTPRINT ULTRA PK Knotless Suture Anchor preloaded with ULTRATAPE™ into the prepared pilot hole.

After tensioning the sutures, rotate the inserter knob clockwise to advance the inner-locking plug and securely trap the sutures within the anchor eyelet.
Multiple Fixation Options Ideal for Multi-Suture Constructs

The MULTIFIX System is a family of knotless, all-PEEK, pound-in implants. The system provides multiple fixation options as well as a streamlined technique ideal in multi-suture constructs, allowing surgeons to meet the needs of a diverse patient population.

Multiple fixation options

The MULTIFIX System allows the surgeon to create various biomechanically stable constructs with two bone lock options.

Streamlined technique

- Pound-in technique (bone hole may be required)
- Suture lock with the turn of a dial
- Hand tension sutures for tactile feedback

Ideal in multi-suture constructs

- Accommodates 2-4 suture strands to allow multiple construct configurations

1. Insert PEEK tip into bone
2. Tension sutures
3. Turn dial to lock sutures

Customizable construct options
Suture Passing Solutions

**FIRSTPASS® ST**
Suture Passer

**The Always Ready Solution for a Variety of Repair Needs**

The FIRSTPASS ST Suture Passer is a single-use suture passer pre-loaded with a needle and sterile packed allowing for immediate out-of-the-box use.

**Pre-loaded and sterile packed for single case use**

- Eliminates the time and inconvenience associated with sterilizing a reusable suture passer
- Needle loading and unloading are no longer required
- No capital cost or instrument maintenance needed

**Round, pre-curved nitinol needle**

- Provides added strength and reliability
- Suture is carried in a recess on the needle, which helps maintain suture integrity

**Deep bite**

- Allows for tissue manipulation and suture passage through cuff tissue, up to 10 mm in thickness and 18 mm in bite depth

**Ability to pass MAGNUMWIRE®, ULTRABRAID® and ULTRATAPE® sutures**

- The surgeon is not limited by suture type and can make product decisions based on the repair needs.

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**Surgical technique**

**Load suture** Place the suture firmly into the suture slot on the bottom jaw of the instrument. The free tail should be short, about 2-3 cm (approximately an inch).

**Grasp tissue** Close the jaw and insert the working end of the suture passer into the surgical field, open the jaw and position around the target tissue and squeeze the lever to the tissue clamping position (first stop).

**Pass and retrieve suture** Deploy the needle through the tissue by using the index finger to depress the trigger, and continue to squeeze the lever as far as is required to engage a 2 mm diameter loop of suture. The suture will remain engaged in the self-capture (22-4038). Allow the lever to open fully in order to retract the needle and unclamp the tissue.

**Remove captured suture** Manually grasp the suture. Pull down and proximal (toward the handle) to disengage the suture from the self-capture.
Successful Procedures are Accomplished with Skilled Hands and Dependable Instruments

Designed specifically for rotator cuff procedures, the TRUEPASS Suture Passer offers surgeons the reliability and performance synonymous with our legendary line of hand instrumentation. Simple, one-handed operation and precise control over jaw positioning can help your procedures run smoothly, and simultaneous suture passing and retrieval makes the suture passing step technically easier.

**Reliable**
Reliably pass and retrieve #2 ULTRABRAID° Suture or ULTRATAPE, in one easy motion\(^1\)

**Simple**
Simple to load, operate and manage sutures

**Innovative**
Innovative design allows for tissue manipulation and suture passage through cuff tissue, up to 10 mm in thickness

**Ergonomic**
Ergonomically designed for one-handed operation and optimal maneuverability

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Self-capture door facilitates simultaneous suture passing and retrieval

Front loading slot enables quick and easy loading of suture

Polymer-coated needle aids smooth passage through tissue, protecting the needle and helping to prevent breakage
References


4. Validation 15001193 and in WRP TE024-94. Note: Animal data is not necessarily indicative of human clinical outcomes. These results have not been demonstrated in humans having a variety of bone quality based on specific disease states such as osteoporosis. The effect of formation of new bone on pullout strength was not shown.

5. In vivo animal testing has demonstrated that REGENESORB material is bioabsorbable and is replaced by bone. Implants (9x10 mm) were implanted in ovine cancellous bone and compared to an empty defect (9x10 mm) at 6, 12, 18, and 24 months (n=6). Micro-CT analysis demonstrated that by 24 months, bone in-growth into this material (289.5 mm3) was significantly greater (p<0.05) than bone in-growth into an empty defect (170.2 mm3) and reaches a bone volume not statistically different from intact bone (188.2 mm3). Results of in vivo simulation have not been shown to quantitatively predict clinical performance. Data on file at Smith & Nephew in report 15000897.

6. See note 4 above.

7. Data on file at Smith & Nephew in reports 15001873 and 15002036.


9. See note 8 above.

10. See note 8 above.


12. In vivo animal testing has demonstrated that the composite material is bioabsorbable and is replaced by bone. Results of in vivo simulation have not been shown to quantitatively predict clinical performance. Data on file at S&N in report 15001194.

13. P/N 45189 Rev F, Section 4.3 and P/N 49190-01, Section 3.5.


# Ordering Information

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<tr>
<th>ULTRATAPE® Suture</th>
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<tr>
<td>72203896</td>
<td>ULTRATAPE Suture (Blue, 6 per box)</td>
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<tr>
<td>72203897</td>
<td>ULTRATAPE Suture (Cobraid Blue, 6 per box)</td>
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**ULTRATAPE Suture Passing**

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<tr>
<td>72204385</td>
<td>ARTHRO-PIERCER® ULTRATAPE, 35° up</td>
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**HEALICOIL® PK Suture Anchor Pre-loaded with ULTRATAPE Suture**

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<td>HEALICOIL PK 4.5 mm Suture Anchor with one ULTRATAPE Suture (Cobraid Blue)</td>
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<td>HEALICOIL PK 5.5 mm Suture Anchor with one ULTRATAPE Suture (Blue) and one #2 ULTRABRAID® Suture</td>
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**HEALICOIL PK Accessory Devices**

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<tr>
<td>72202621</td>
<td>3.8 mm Tapered Awl, disposable</td>
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<tr>
<td>72201915</td>
<td>3.8 mm Tapered Awl, reusable</td>
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<tr>
<td>72202633</td>
<td>4.5 mm HEALICOIL/TWINFIX® ULTRA Threaded Dilator, reusable</td>
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<td>72203634</td>
<td>5.5 mm HEALICOIL/TWINFIX ULTRA Threaded Dilator, reusable</td>
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**HEALICOIL REGENESORB Suture Anchor Pre-loaded with ULTRABRAID Suture**

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**HEALICOIL REGENESORB Accessory Devices**

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<td>HEALICOIL REGENESORB 4.75 mm Threaded Dilator, disposable</td>
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<td>72203952</td>
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**Q-FIX® All-Suture Anchor**

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<tr>
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<td>Q-FIX 2.8 mm All Suture Anchor</td>
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<td>25-2810</td>
<td>Q-FIX 2.8 mm All Suture Anchor Disposable Kit – Drill, Drill Guide, and Obturator</td>
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<td>25-2820</td>
<td>Q-FIX 2.8 mm All Suture Anchor Bone Punch, reusable</td>
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<td>25-2812</td>
<td>Q-FIX 2.8 mm PATHFINDER®, reusable</td>
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**FOOTPRINT® ULTRA Knotless Suture Anchor**

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<td>FOOTPRINT Ultra PK 5.5 mm</td>
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<td>72201915</td>
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**MULTIFIX® S Knotless Suture Anchors**

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<td>OM-9220</td>
<td>Tapered Punch</td>
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<td>OM-9615</td>
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**FIRSTPASS® ST Suture Passer**

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<td>FIRSTPASS ST Suture Passer, Standard</td>
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**TRUEPASS® Suture Passer**

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<td>72203792</td>
<td>TRUEPASS Suture Passer, Standard</td>
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<tr>
<td>72203793</td>
<td>TRUEPASS Disposable Needles (5 per box)</td>
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Supporting healthcare professionals for over 150 years.

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