Comprehensive Product Offerings for Your Rotator Cuff Repair

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
ULTRA
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
Increased tendon-to-bone contact can mean an improved repair.\(^1,2\)

- **75%** more contact than #2 suture\(^3\)
- **60%** more contact than FiberTape\(^\text{TM}\)\(^3\)
  (demonstrated in pre-clinical testing).

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

- **58%** less material than FiberTape\(^3\)
- More evenly distributed pressure\(^3\)
- Fewer peak pressure points\(^3\)

More repair options and expanding techniques.

- Use for knotless or knotted repairs
- Available pre-loaded on HEALICOIL\(^\circ\) Suture Anchors

ULTRATAPE: Cross section showing smooth braid

Arthrex\(^\text{®}\) FiberTape\(^\text{TM}\): Cross section showing solid inner core

ULTRATAPE used in a rotator cuff repair
A Unique Combination of Innovative Design and Materials

Greater healing potential though 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, vented design is intended to allow blood and bone marrow from surrounding cancellous bone to enter the implant. A recent study in 70 subjects reported that vented suture anchors provided greater healing potential than solid, non-vented anchors at six weeks post-surgery, as measured by rotator cuff thickness.4

HEALICOIL PK Suture Anchor: Bone-fill at 12 weeks in a pre-clinical ovine study.

Greater bone ingrowth compared to Arthrex Corkscrew® FT Suture Anchor

At 18 months, μCT imaging showed HEALICOIL REGENESORB Suture Anchor had a significantly greater bone ingrowth compared to the Arthrex Corkscrew® FT Suture Anchor (54.5% ± 14.1 vs. 29.8% ± 8.8, respectively; p<0.001) in a pre-clinical ovine study.5
**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.6

**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

**Greater 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.8

**Minimal size**

In biomechanical testing, the 4.75mm HEALICOIL REGENESORB Suture Anchor demonstrated higher pullout strength than the larger, 5.5mm competitive anchors.8

**Sustained fixation strength for healing**

The initial strength of the HEALICOIL REGENESORB Suture Anchor is designed to hold fixation over time throughout the healing period in poor quality bone,9 withstanding typical shoulder loading forces and supporting the range of motion necessary for physical therapy and rehabilitation.

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**Anchor pullout testing**

Note: Testing conducted in 5pcf bone block. 5pcf bone density is equivalent to the worst-case, poorest-quality decorticated humeral bone. (pcf = pounds per cubic feet).
REGENESORB Material

An advanced biocomposite absorbed and completely replaced by bone within 24 months in pre-clinical studies.\(^\text{10}\)

Developed by Smith & Nephew’s Advanced Healing Technologies group, REGENESORB biocomposite material contains PLGA and dual osteoconductive components, β-TCP and calcium sulfate.

6 months 12 months 18 months 24 months

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 mos.

Snapshot of REGENESORB material at 18 months\(^\text{11}\)

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

Faster absorption

Histomorphometry showed a faster absorption of HEALICOIL REGENESORB, with 70% absorption at 18 months compared with 57% for the PLLA/β-TCP-based Arthrex BioComposite Corkscrew FT (p<0.001).\(^\text{12}\)

New bone ingrowth into areas of absorbed HEALICOIL REGENESORB Suture Anchor at 18 months.\(^\text{13}\)
Next Generation All-Suture Anchor Technology

The 2.8mm 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 2.8mm 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.
MULTIFIX° S ULTRA
Knotless Suture Anchor

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 up to four #2 sutures or four ULTRATAPE Sutures.

1. Load sutures using double snare
2. Insert PEEK tip into bone
3. Turn dial to lock sutures

Customizable construct options
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.

### 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 2-3cm (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 2mm 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.
TRUEPASS°
Suture Passer

Designed Specifically for
Rotator Cuff Procedures

Reliable
Reliably pass and retrieve #2 ULTRABRAID° Suture or ULTRATAPE, in one easy motion

Simple
Simple to load, operate and manage sutures

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

Ergonomic
Ergonomically designed for one-handed operation and optimal maneuverability

References
6. Validation 15001193. 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.
7. Data on file at Smith & Nephew in reports 15001873 and 15002036.
10. 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.
11. 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.
### ULTRATAPE Suture*

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<tr>
<th>Reference #</th>
<th>Description</th>
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<tbody>
<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 Instrumentation*

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<th>Reference #</th>
<th>Description</th>
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<tr>
<td>72204385</td>
<td>ARTHRO-PIERCE* ULTRATAPE, 35° up</td>
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### HEALICOIL* PK Suture Anchor* Pre-loaded with ULTRATAPE Suture*

<table>
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<th>Reference #</th>
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<tbody>
<tr>
<td>72203981</td>
<td>HEALICOIL PK 4.5mm Suture Anchor with one ULTRATAPE Suture (Blue)</td>
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<tr>
<td>72203982</td>
<td>HEALICOIL PK 4.5mm Suture Anchor with one ULTRATAPE Suture (Cobraid Blue)</td>
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<tr>
<td>72203983</td>
<td>HEALICOIL PK 5.5mm Suture Anchor with one ULTRATAPE Suture (Blue) and one #2 ULTRABRAID* Suture</td>
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<tr>
<td>72203984</td>
<td>HEALICOIL PK 5.5mm Suture Anchor with one ULTRATAPE Suture (Cobraid Blue) and one #2 ULTRABRAID Suture</td>
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### Q-FIX* All-Suture Anchor**

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<th>Reference #</th>
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<tbody>
<tr>
<td>25-2800</td>
<td>Q-FIX 2.8mm All Suture Anchor</td>
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<tr>
<td>25-2810</td>
<td>Q-FIX 2.8mm All Suture Anchor Disposable Kit – Drill, Drill Guide, and Obturator</td>
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<tr>
<td>25-2820</td>
<td>Q-FIX 2.8mm All Suture Anchor Bone Punch, reusable</td>
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<tr>
<td>25-2812</td>
<td>Q-FIX 2.8mm PATHFINDER®, reusable</td>
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### HEALICOIL REGENESORB Suture Anchor* Pre-loaded with ULTRATAPE Suture*

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<tbody>
<tr>
<td>72203704</td>
<td>HEALICOIL REGENESORB 4.75mm Suture Anchor with two #2 ULTRABRAID* sutures (Blue, Cobraid Blue)</td>
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<tr>
<td>72203706</td>
<td>HEALICOIL REGENESORB 5.5mm Suture Anchor with two #2 ULTRABRAID sutures (Blue, Cobraid Blue)</td>
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<tr>
<td>72203707</td>
<td>HEALICOIL REGENESORB 5.5mm Suture Anchor with three #2 ULTRABRAID sutures (Blue, Cobraid Blue, Cobraid Black)</td>
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### HEALICOIL REGENESORB Accessory Devices*

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<th>Reference #</th>
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<tr>
<td>72203709</td>
<td>HEALICOIL REGENESORB 4.75mm Threaded Dilator, reusable</td>
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<tr>
<td>72203710</td>
<td>HEALICOIL REGENESORB 5.5mm Threaded Dilator, reusable</td>
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<td>72203951</td>
<td>HEALICOIL REGENESORB 4.75mm Threaded Dilator, disposable</td>
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<tr>
<td>72203952</td>
<td>HEALICOIL REGENESORB 5.5mm Threaded Dilator, disposable</td>
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### MULTIFIX* S ULTRA Knotless Suture Anchors**

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<tr>
<td>72290001</td>
<td>MULTIFIX S ULTRA 5.5mm Knotless Suture Anchor</td>
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<tr>
<td>72290002</td>
<td>MULTIFIX S ULTRA 6.5mm Knotless Suture Anchor</td>
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<tr>
<td>OM-9420</td>
<td>3.4mm Bone Punch</td>
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<tr>
<td>OM-9220</td>
<td>Tapered Punch</td>
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<tr>
<td>OM-9615</td>
<td>SPEEDSCREW*/MULTIFIX S ULTRA Insertion Guide and Obturator Set: Insertion Guide with Obturator</td>
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### FIRSTPASS* ST Suture Passer**

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<th>Reference #</th>
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<tr>
<td>22-4038</td>
<td>FIRSTPASS ST Suture Passer, Self-Capture</td>
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<td>22-4039</td>
<td>FIRSTPASS ST Suture Passer, Standard</td>
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### TRUEPASS* Suture Passer*

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<tr>
<td>72203791</td>
<td>TRUEPASS Suture Passer, Self-Capture</td>
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<tr>
<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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To learn more about Smith and Nephew's rotator cuff solutions, go to [www.smith-nephew.com](http://www.smith-nephew.com) or call your sales representative at +1 800 343 5717.