Open-architecture. Now open to even greater possibilities.

Available in our advanced REGENESORB biocomposite material, offering exceptional bone ingrowth and fast absorption.

smith&nephew

HEALICOIL◇ REGENESORB
Suture Anchor

HEALICOIL PK
Suture Anchor

Supporting healthcare professionals

Open to more possibilities through a unique combination of innovative design and materials – PEEK or REGENESORB

Greater healing potential through open-architecture design

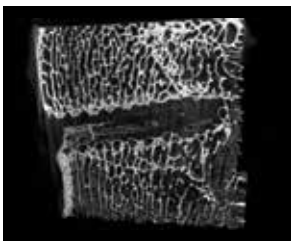
The HEALICOIL Suture Anchor has a distinctive open architecture that differs from solid-core implants by eliminating the material between the anchor threads.

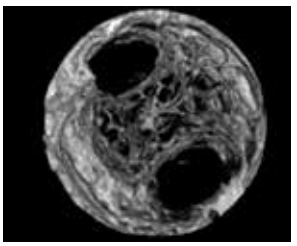
The open, vented design is intended to allow blood and bone marrow from surrounding cancellous bone to enter the implant. A recent study in 70 subjects reported that vented suture anchors provided greater healing potential than solid, non-vented anchors at six weeks post-surgery, as measured by rotator cuff thickness.[1]

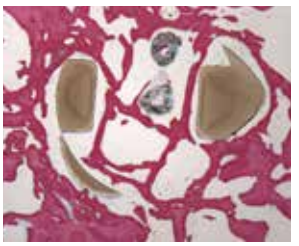
Designed to facilitate bone ingrowth

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.[2]

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





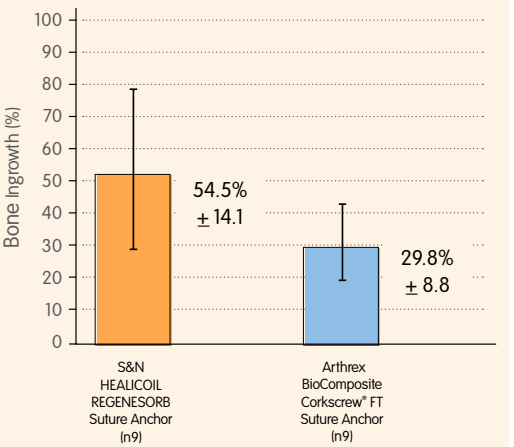


Micro-CT images at 12 weeks of a 5.5mm HEALICOIL PK Suture Anchor show a web of bone beginning to fill the center of the implant. Histology at the same point in time clearly demonstrates bone growing across the implant's open architecture.

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 versus 29.8% ± 8.8, respectively; p<0.001) in a pre-clinical ovine study.[3]

Percentage of bone ingrowth at 18 mos.[3]



Designed for durability

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.[4]

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.[5]

Greater pullout strength in poor-quality bone

The extended, fully-threaded HEALICOIL REGENESORB anchor design provides more threaded engagement than leading competitive biocomposite anchors, delivering greater pullout strength in poor-quality, osteoporotic bone.[5]

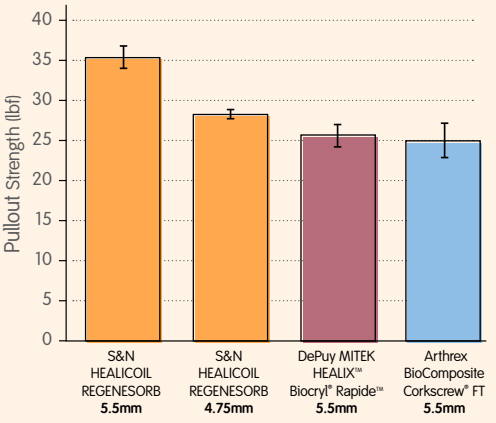
Sustained fixation strength for healing

The initial strength of the HEALICOIL REGENESORB Suture Anchor is designed to hold fixation over time throughout the healing period in poor quality bone,[6] withstanding typical shoulder loading forces and supporting the range of motion necessary for physical therapy and rehabilitation.

Minimal size, maximal strength

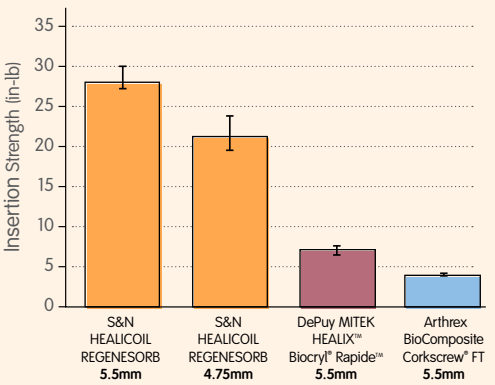
In biomechanical testing, the 4.75mm HEALICOIL REGENESORB Suture Anchor demonstrated higher pullout strength and significantly higher torsional strength than the larger, 5.5mm competitive anchors shown in the accompanying graphs.[5]

Anchor pullout testing[9]



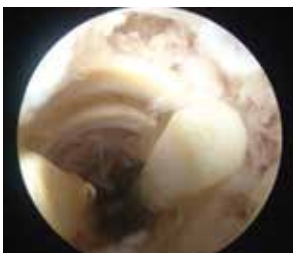
Note: Testing conducted in 5pcf bone block; 5pcf bone density is equivalent to the worst-case, poorest-quality decorticated humeral bone. (pcf = pounds per cubic feet).

Anchor insertion testing (torque-to-failure)[9]



Note: Testing conducted in 30pcf bone block; 30pcf bone density is equivalent to hard bone density – e.g. young, male athlete. (pcf = pounds per cubic feet).

Greater torsional strength for insertion into bone



The HEALICOIL® inserter engages 100% the anchor's length, minimizing stress and providing predictable insertion into hard bone by distributing torque along the entire length of the anchor.

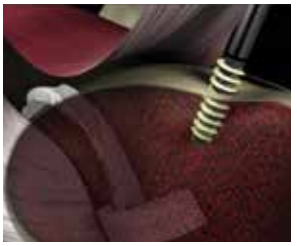


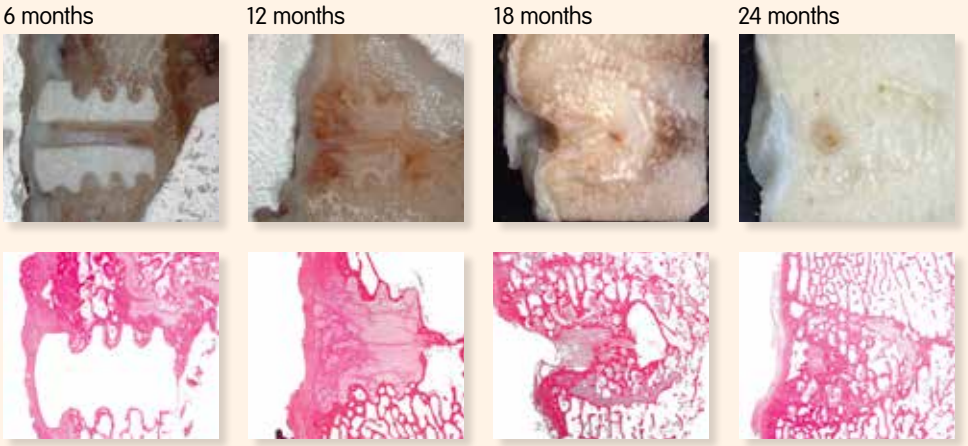
Illustration of HEALICOIL PK Suture Anchor being inserted into humeral head for rotator cuff repair.

The unique open-architecture design reduces the amount of implanted material compared to traditional, solid-core anchors, permitting easier revision when necessary.[2]

REGENESORB Material

An advanced biocomposite absorbed and completely replaced by bone within 24 months in pre-clinical studies.[7]

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

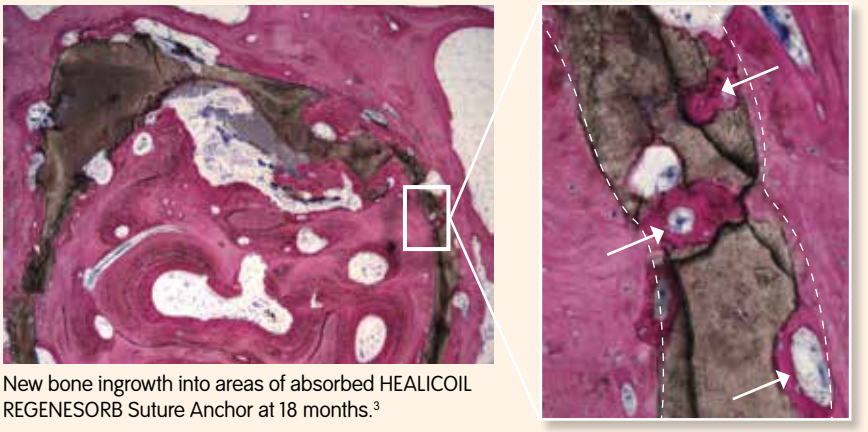


Gross anatomy and histology images of a 9x10 mm REGENESORB interference screw evaluated in a direct-in-bone sheep model. Images clearly demonstrate absorption and complete replacement by bone within 24 mos.

Snapshot of REGENESORB material at 18 months

Faster absorption

Histomorphometry showed a faster absorption of HEALICOIL REGENESORB, with 70% absorption at 18 months compared with 57% for the PLLA/ß-TCP-based Arthrex BioComposite Corkscrew FT ($p<0.001$).[3]

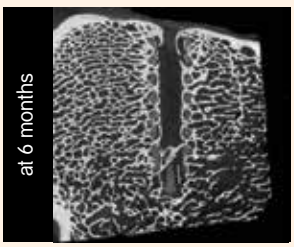


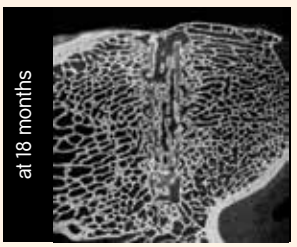
New bone ingrowth into areas of absorbed HEALICOIL REGENESORB Suture Anchor at 18 months.[3]

New bone ingrowth indicated by arrows.

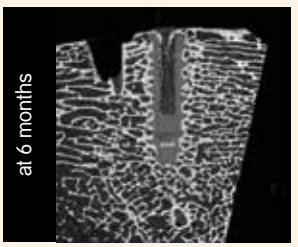
Sanderson's Rapid Bone stain at 25X magnification.

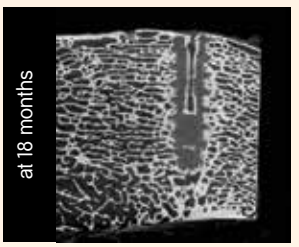
HEALICOIL REGENESORB





Arthrex Biocomposite Corkscrew® FT





Comparisons of absorption, measured via µCT, at 6 and 18 months.[3]

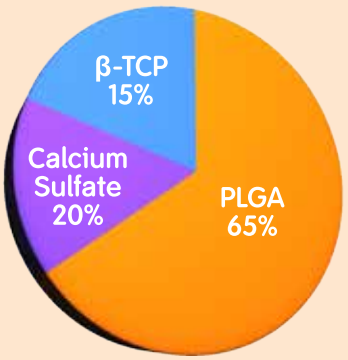
Unique formulation of proven materials

REGENESORB biocomposite material is a unique formulation of PLGA, β-TCP, and calcium sulfate – each of which has been proven safe and biocompatible over decades of clinical use. The safety of REGENESORB material has been confirmed through several pre-clinical studies.[8]

Calcium sulfate: the material difference

Most biocomposite materials rely solely on the osteoconductive properties of β-TCP, which provides sustained bone formation over 18 months[9] and acts primarily as a scaffold for enhancing new bone formation.[10] But REGENESORB material includes a second osteoconductive material, calcium sulfate, which has been shown to work in the early stages (4-12 weeks) of bone healing[9] and is associated with increased levels of local growth factors.[11]

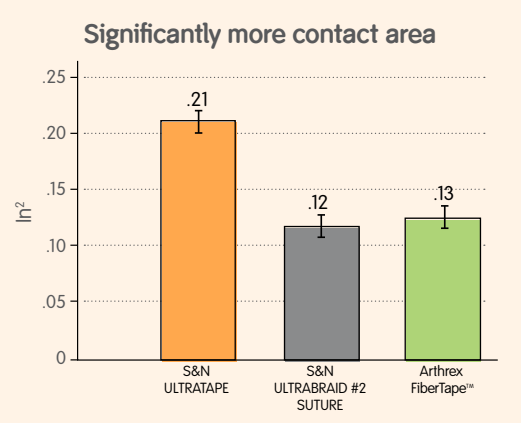
So REGENESORB material contains two osteoconductive components – β-TCP and calcium sulfate – which have been individually shown to act during a different stage in the bone healing process and through different mechanisms of action – physical and biochemical.



A proprietary blend of three proven components

PLGA Poly-L-lactic co-glycolic acid	**β-TCP** Beta tricalcium phosphate	**Calcium Sulfate**
• Long history of clinical use[12] • Degrades faster than PLLA[13] • Comprised of natural products – lactic acid and glycolic acid	• Longer-term (18 months) absorption profile for **sustained bone formation**[9] • Osteoconductive (**physical**) – Scaffold to allow for bone ingrowth[10]	• Shorter-term (4-12 weeks) absorption profile for enhanced **early bone formation**[9] and **calcium release**[14] • Osteoconductive (**biochemical**) – Increased levels of local growth factors[11]
Polymer	Bioactive Calcium Materials	

Ultra Contact. Less Material. Make more of your rotator cuff repair.



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

Increased tendon-to-bone contact can mean an improved repair.[15, 16]

- 75% more contact than #2 suture[17]
- 60% more contact than FiberTape™[17] (demonstrated in pre-clinical testing).
- More evenly distributed[17]
- Fewer peak pressure points[17]

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

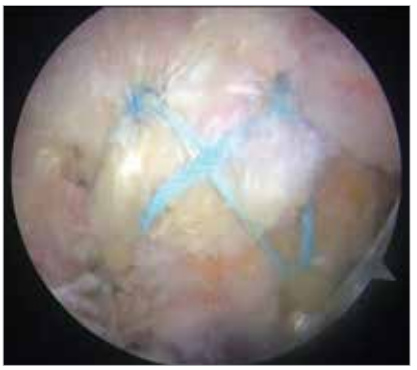
- 58% less material than FiberTape[17]

ULTRATAPE: Cross section showing smooth, flat braid pattern

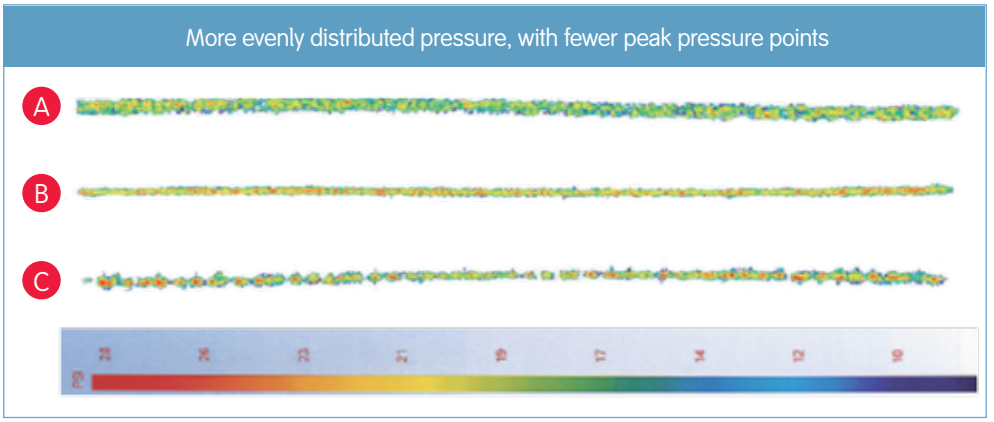
Arthrex® FiberTape™: Cross section showing solid inner core

More repair options and expanding techniques.

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



ULTRATAPE used in a rotator cuff repair



ULTRATAPE (A), ULTRABRAID #2 Suture (B) and FiberTape™ (C) suture pressure scale results, with red representing peak pressure in pounds per square inch (PSI).

The information contained in this document is based on pre-clinical testing, which is not necessarily indicative of human clinical outcomes.

References

1. Clark TR, Guerrero EM, Song A, O'Brien MJ, Savoie FH (2016) Do Vented Suture Anchors Make a Difference in Rotator Cuff Healing. Ann Sports Med Res 3(3): 1068.
2. 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.
3. Data on file at Smith and Nephew, report NCS248.
4. Data on file at Smith & Nephew in reports 15001873 and 15002036.
5. Report Number 15002036 HEALICOIL Suture Anchor competitive testing. Data on file. August 2013.
6. Data on file at Smith and Nephew in report 15001609.
7. 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 (170.2mm3) 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.
8. Data on file at Smith & Nephew in reports 15000897, 15001194, 15000921, 15000919.
9. Costantino and Friedman (1994) Otolaryngol Clin North Am. 1994 Oct;27(5).
10. Ogose et al. (2006) Biomaterials Vol. 27(8).
11. Walsh et al. (2003) Clin. Orthop. Rel. Res. Vol 406, Allison Et al (2011) US Oncology and Hematology Vol 7(1).
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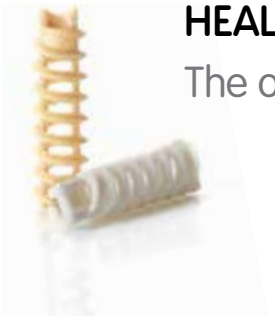
13. Chih-Chu Chang, Section IV:44, "Biodegradable Polymeric Biomaterials" in The Biomedical Engineering Handbook. Bronzino JD Ed. CRC Press.
14. Pietrzak and Ronk (2000) J Craniofacial Surg. Vol 11(4).
15. Bisson LJ, Manohar LM. A biomechanical comparison of the pullout strength of No. 2 FiberWire suture and 2-mm FiberWire tape in bovine rotator cuff tendons. Arthroscopy 2010; 26(11):1463-1468.
16. Park MC, ElAttrache NS, Tibone JE, Ahmad CS, Jun BJ, Lee TQ. Part I: Footprint contact characteristics for a transosseous-equivalent rotator cuff repair technique compared with a double-row repair technique. J Shoulder Elbow.
17. Data on File at Smith & Nephew, report 15001847, 2013.



HEALICOIL° REGENESORB and HEALICOIL PK Suture Anchors

The open-architecture anchors filled with possibilities

Ordering Information

ULTRATAPE° Suture*

Reference #	Description
72203896	ULTRATAPE Suture (Blue, 6 per box)
72203897	ULTRATAPE Suture (Cobraid Blue, 6 per box)

ULTRATAPE Suture Passing Instrumentation*

Reference #	Description
72204385	ARTHRO-PIERCE° ULTRATAPE, 35° up

HEALICOIL° PK Suture Anchor* Pre-loaded with ULTRATAPE Suture*

Reference #	Description
72203981	HEALICOIL PK 4.5mm Suture Anchor with one ULTRATAPE Suture (Blue)
72203982	HEALICOIL PK 4.5mm Suture Anchor with one ULTRATAPE Suture (Cobraid Blue)
72203983	HEALICOIL PK 5.5mm Suture Anchor with one ULTRATAPE Suture (Blue) and one #2 ULTRABRAID° Suture
72203984	HEALICOIL PK 5.5mm Suture Anchor with one ULTRATAPE Suture (Cobraid Blue) and one #2 ULTRABRAID Suture

HEALICOIL PK Suture Anchor* Pre-loaded with ULTRABRAID Suture*

Reference #	Description
72203378	HEALICOIL PK 4.5mm Suture Anchor with two #2 ULTRABRAID Sutures (Blue, Cobraid Blue)
72203379	HEALICOIL PK 5.5mm Suture Anchor with two #2 ULTRABRAID Sutures (Blue, Cobraid Blue)
72203380	HEALICOIL PK 5.5mm Suture Anchor with three #2 ULTRABRAID Sutures (Blue, Cobraid Blue, Cobraid-Black)

HEALICOIL PK Accessory Devices*

Reference #	Description
72202621	3.8mm Tapered Awl, disposable
72201915	3.8mm Tapered Awl, reusable
72202633	4.5mm HEALICOIL/TWINFIX° ULTRA Threaded Dilator, reusable
72203634	5.5mm HEALICOIL/TWINFIX ULTRA Threaded Dilator, reusable

HEALICOIL REGENESORB Suture Anchor* Pre-loaded with ULTRATAPE*

Reference #	Description
72203705	HEALICOIL REGENESORB 4.75mm Suture Anchor with one ULTRATAPE Suture (Blue) and one #2 ULTRABRAID Suture
72203697	HEALICOIL REGENESORB 4.75mm Suture Anchor with one ULTRATAPE Suture (Cobraid Blue) and one #2 ULTRABRAID Suture
72203708	HEALICOIL REGENESORB 5.5mm Suture Anchor with one ULTRATAPE Suture (Blue) and one #2 ULTRABRAID Suture
72203801	HEALICOIL REGENESORB 5.5mm Suture Anchor with one ULTRATAPE (Cobraid Blue) and one #2 ULTRABRAID Suture

HEALICOIL REGENESORB Suture Anchor* Pre-loaded with ULTRABRAID Suture*

Reference #	Description
72203704	HEALICOIL REGENESORB 4.75mm Suture Anchor with two #2 ULTRABRAID° sutures (Blue, Cobraid Blue)
72203706	HEALICOIL REGENESORB 5.5mm Suture Anchor with two #2 ULTRABRAID sutures (Blue, Cobraid Blue)
72203707	HEALICOIL REGENESORB 5.5mm Suture Anchor with three #2 ULTRABRAID sutures (Blue, Cobraid Blue, Cobraid Black)

HEALICOIL REGENESORB Accessory Devices*

Reference #	Description
72203709	HEALICOIL REGENESORB 4.75mm Threaded Dilator, reusable
72203710	HEALICOIL REGENESORB 5.5mm Threaded Dilator, reusable
72203951	HEALICOIL REGENESORB 4.75mm Threaded Dilator, disposable
72203952	HEALICOIL REGENESORB 5.5mm Threaded Dilator, disposable

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