Part of **ADVANCED HEALING SOLUTIONS** Biological Portfolio

Redefining biological healing

Open architecture anchor facilitates healing[1, 2]

Smith+Nephew

HEALICOIL◊
Suture Anchor Family

HEALICOIL® Suture Anchor

Potential biologic healing advantage[1]

- Open architecture anchor facilitates healing by allowing access of bone marrow and associated stem cells to the repair site.[2]
- Proven to improve tendon healing following rotator cuff repair.[1]

Significant increase in rotator cuff thickness vs competitor[1]

Mean rotator cuff thickness at six weeks was significantly greater compared to Healix Advance™ Suture Anchor. (See data below)

Open architecture design

Unique open architecture is designed to reduce the amount of implanted material in the shoulder compared to traditional, solid-core anchors.

Open architecture design facilitated greater bone ingrowth than non-open architecture designed anchors.[2]

Increasing bone density around the anchor may contribute to higher pullout strength and offer the potential for reduced failure.[2]

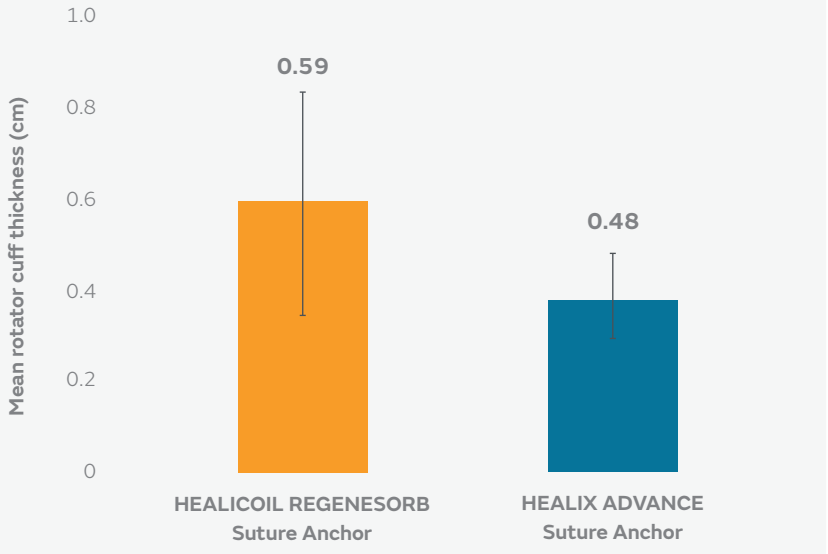


Figure X. Mean (±SD) rotator cuff tendon thickness six weeks post-operatively[5]

> *The real advantage of the [HEALICOIL] open architecture is that the stem cells from the bone marrow can reach the bone-tendon interface to promote healing where it is most needed.*

Jan Vonhoegen, MD
Specialist for Orthopaedics and Trauma Surgery

HEALICOIL◊ KNOTLESS Suture Anchor

Least amount of suture displacement during cyclic loading vs competitors[4]

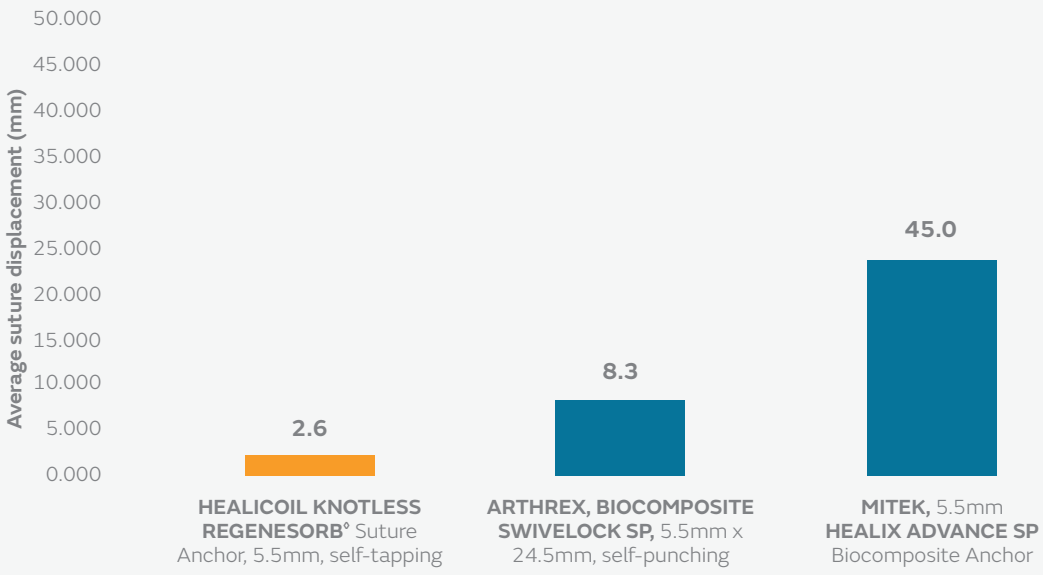
69%

less suture displacement than Arthrex BioComposite SwiveLock™ 5.5mm Self-Punching (SP) after cyclic loading for 500 cycles*

94%

less suture displacement than Healix Advance™ 5.5mm SP Biocomposite Anchor after cyclic loading for 500 cycles**

AVERAGE SUTURE DISPLACEMENT AFTER POSTOPERATIVE CYCLIC LOADING (MM)



** As demonstrated in benchtop testing p = 0.002*

*** As demonstrated in benchtop testing p < 0.001; All Healix Advance 5.5mm SP Biocomposite Anchors failed to complete the cyclic loading due to suture slipping within the anchor construct under the maximum cyclic load of 45 N*

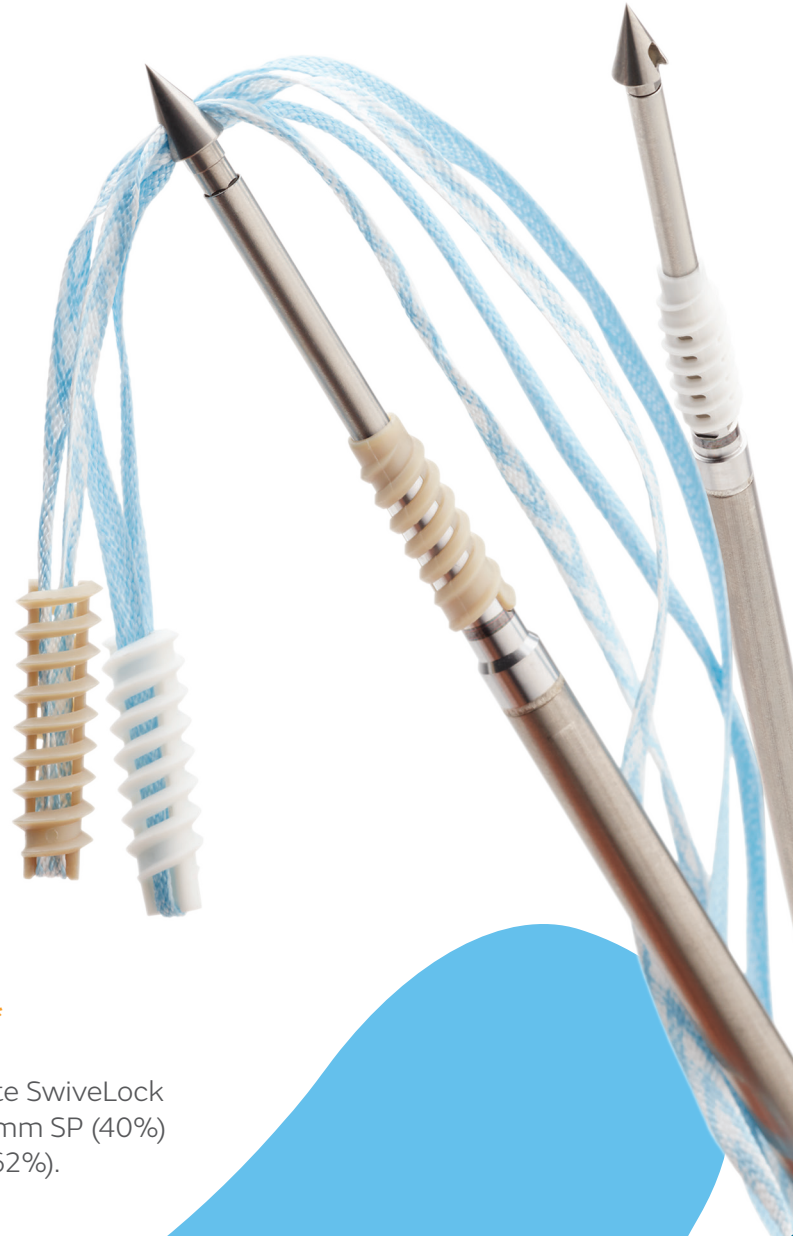
The HEALICOIL anchor leads to more robust healing of that tendon to the bone.

Ian Lo, MD FRCS(C) Assistant Professor
University of Calgary

HEALICOIL◊ KNOTLESS
Suture Anchor

✚ Proven internal locking mechanism[5]

By descending a plug in the distal implant, the suture is securely locked in place providing an **additional point of fixation.**†



✚ Most open architecture design vs competitors[7†]

- **Three times** more open than Arthrex BioComposite SwiveLock™ 4.75mm SP
- **Four times** more open than Arthrex BioComposite SwiveLock 5.5mm SP
- May **facilitate healing** by allowing access of bone marrow and associated stem cells to the repair site[1, 2]
- Shown to facilitate **better bone ingrowth** than solid anchors[2, 6]

✚ Least amount of foreign material vs competitors[7†*]

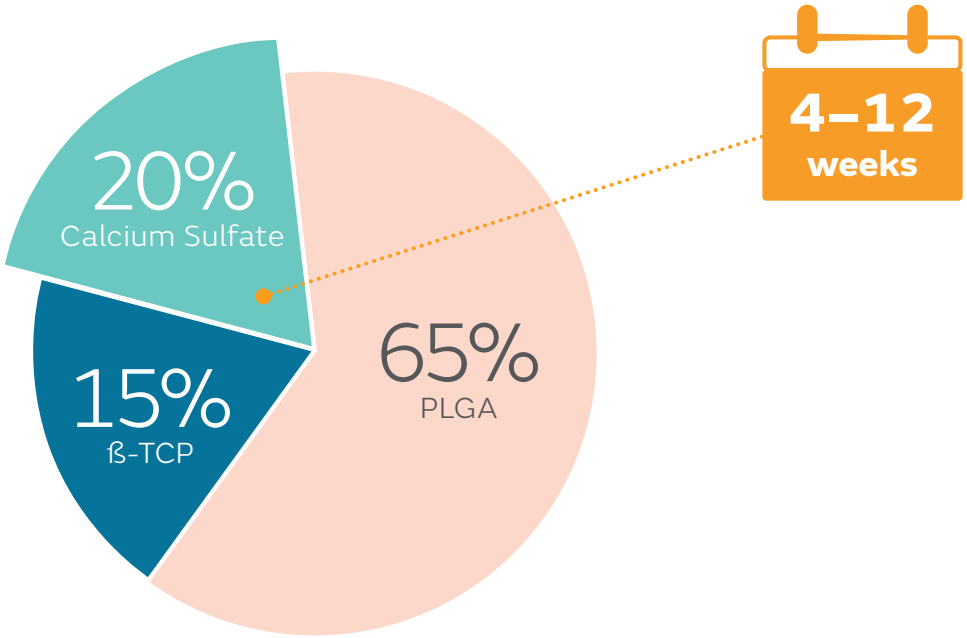
Less material volume compared to Arthrex BioComposite SwiveLock 4.75mm SP (20%), Arthrex BioComposite SwiveLock 5.5mm SP (40%) and Healix Advance™ 5.5mm SP BioComposite Anchor (62%).

†As demonstrated in benchtop testing

*Compared to Arthrex BioComposite SwiveLock 5.5mm SP and Healix Advance 5.5mm SP Biocomposite Anchor

REGENESORB◊ Material

Designed to provide a jump start in bone healing and formation

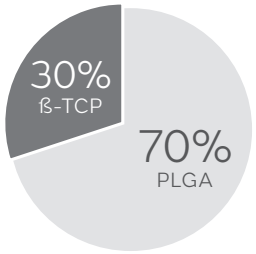


Calcium Sulfate: Works in early healing stages at 4–12 weeks[3, 8, 9]

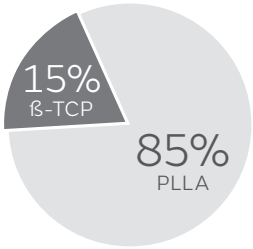
ß-TCP: Sustained bone formation for up to 2 years[10, 11]

PLGA: Comprised of natural products — lactic acid and glycolic acid[12, 13]

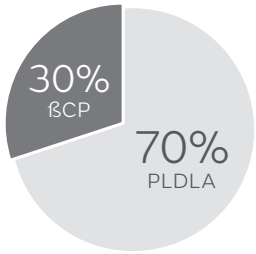
Most biocomposite materials rely solely on the osteoconductive properties of ß-TCP. REGENESORB◊ material contains two osteoconductive components — ß-TCP and calcium sulfate — which act during different stages in the bone healing process and through different mechanisms of action, physical and biochemical. REGENESORB Material is unique in this regard. No other biocomposite material can claim this.[8,16,17]



Mitek Biocryl™[14]



Arthrex BioComposite™ Anchor[15]



Arthrex BioComposite Screw[15]

*The **REGENESORB◊** material has three different components. In the ultrasound study that we did, you can actually see the bone growing across the coils of that vented anchor — and that's related to the extra components, providing biologic stimulation.*

Felix H. "Buddy" Savoie III, MD
Chairman of Orthopaedic Surgery;
Chief of Sports Medicine
Tulane University School of Medicine
New Orleans, LA

Ordering information

HEALICOIL◊ KNOTLESS Suture Anchors	
Reference	Description
72205135	HEALICOIL KNOTLESS REGENESORB◊ Suture Anchor, 5.5mm
72205136	HEALICOIL KNOTLESS REGENESORB Suture Anchor, 5.5mm, self-tapping
72205137	HEALICOIL KNOTLESS PK Suture Anchor, 5.0mm
72205138	HEALICOIL KNOTLESS PK Suture Anchor, 5.0mm, self-tapping
HEALICOIL KNOTLESS Suture Anchor Hole Prep	
72203952	HEALICOIL REGENESORB Fully Threaded Dilator, 5.5mm, disposable
72203710	HEALICOIL REGENESORB Fully Threaded Dilator, 5.5mm, reusable
72205308	HEALICOIL KNOTLESS Spade Drill, 4.75mm, disposable
72202621*	Tapered Awl, 3.8mm, disposable
72201915*	Tapered Awl, 3.8mm, reusable
HEALICOIL REGENESORB◊ Suture Anchors Pre-loaded with MINITAPE◊ Suture	
72205385	HEALICOIL REGENESORB Suture Anchor, 4.75mm, with two MINITAPE Sutures: blue, cobraid-white
72205386	HEALICOIL REGENESORB Suture Anchor, 4.75mm, with three MINITAPE Sutures: blue, cobraid-white, cobraid-blue
72205387	HEALICOIL REGENESORB Suture Anchor, 5.5mm, with two MINITAPE Sutures: blue, cobraid-white
72205388	HEALICOIL REGENESORB Suture Anchor, 5.5mm, with three MINITAPE Sutures: blue, cobraid-white, cobraid-blue

HEALICOIL REGENESORB Suture Anchors Pre-loaded with ULTRATAPE◊ Suture	
Reference	Description
72203705	HEALICOIL REGENESORB Suture Anchor, 4.75mm, with one ULTRATAPE Suture, blue, and one ULTRABRAID◊ #2 Suture, cobraid-black
72203697	HEALICOIL REGENESORB Suture Anchor, 4.75mm, with one ULTRATAPE Suture, cobraid-blue, and one ULTRABRAID #2 Suture, blue
72203708	HEALICOIL REGENESORB Suture Anchor, 5.5mm, with one ULTRATAPE Suture, blue, and one ULTRABRAID #2 Suture, cobraid-black
72203801	HEALICOIL REGENESORB Suture Anchor, 5.5mm, with one ULTRATAPE Suture, cobraid-blue, and one ULTRABRAID #2 Suture, blue
HEALICOIL REGENESORB Suture Anchors Pre-loaded with ULTRABRAID Suture	
72203704	HEALICOIL REGENESORB Suture Anchor, 4.75mm, with two ULTRABRAID #2 Sutures: blue, cobraid-blue
72203706	HEALICOIL REGENESORB Suture Anchor, 5.5mm, with two ULTRABRAID #2 Sutures: blue, cobraid-blue
72203707	HEALICOIL REGENESORB Suture Anchor, 5.5mm, with three ULTRABRAID #2 Sutures: blue, cobraid-blue, cobraid-black
HEALICOIL REGENESORB Accessory Devices	
72203951	HEALICOIL REGENESORB Dilator, 4.75mm, fully threaded, disposable
72203952	HEALICOIL REGENESORB Dilator, 5.5mm, fully threaded, disposable
72203709	HEALICOIL REGENESORB Dilator, 4.75mm, fully threaded, reusable
72203710	HEALICOIL REGENESORB Dilator, 5.5mm, fully threaded, reusable
72203482	HEALICOIL Spade Tip Drill, 3.5mm, disposable
72203483	HEALICOIL Spade Tip Drill, 4.5mm, disposable

Ordering information (cont.)

HEALICOIL® PK Suture Anchors Pre-loaded with MINITAPE® Suture	
Reference	Description
72205381	HEALICOIL PK Suture Anchor, 4.5mm, with two MINITAPE Sutures: blue, cobraid-white
72205382	HEALICOIL PK Suture Anchor, 5.5mm, with two MINITAPE Sutures: blue, cobraid-white
72205383	HEALICOIL PK Suture Anchor, 5.5mm, with three MINITAPE Sutures: blue, cobraid-white, cobraid-blue

HEALICOIL PK Suture Anchors Pre-loaded with ULTRATAPE® Suture	
Reference	Description
72203981	HEALICOIL PK Suture Anchor, 4.5mm, with one ULTRATAPE Suture, blue
72203982	HEALICOIL PK Suture Anchor, 4.5mm, with one ULTRATAPE Suture, cobraid-blue
72203983	HEALICOIL PK Suture Anchor, 5.5mm, with one ULTRATAPE Suture, blue, and one ULTRABRAID® #2 Suture, cobraid-black
72203984	HEALICOIL PK Suture Anchor, 5.5mm, with one ULTRATAPE Suture, cobraid-blue, and one ULTRABRAID #2 Suture, blue

Ordering information (cont.)

HEALICOIL® PK Suture Anchors Pre-loaded with ULTRABRAID® Suture	
Reference	Description
72203378	HEALICOIL PK Suture Anchor, 4.5mm, with two ULTRABRAID #2 Sutures: blue, cobraid-blue
72203379	HEALICOIL PK Suture Anchor, 5.5mm, with two ULTRABRAID #2 Sutures: blue, cobraid-blue
72203380	HEALICOIL PK Suture Anchor, 5.5mm, with three ULTRABRAID #2 Sutures: blue, cobraid-blue, cobraid-black
HEALICOIL PK Accessory Devices	
72202621	Tapered Awl, 3.8mm, disposable
72201915	Tapered Awl, 3.8mm, reusable
72202633	HEALICOIL/TWINFIX® Awl-Dilator, 4.5mm, reusable
72202634	HEALICOIL/TWINFIX Awl-Dilator, 5.5mm, reusable
72203482	HEALICOIL Spade Tip Drill, 3.5mm, disposable
72203483	HEALICOIL Spade Tip Drill, 4.5mm, disposable

FIRSTPASS® ST Suture Passer	
Reference	Description
22-4038	FIRSTPASS ST Suture Passer, self-capture
22-4039	FIRSTPASS ST Suture Passer, standard
MINITAPE® Suture	
72205129	MINITAPE, cobraid-white, 6 per box
72205128	MINITAPE, cobraid-white, 6 per box
72205127	MINITAPE, blue, 6 per box
ULTRATAPE® Suture	
72203896	ULTRATAPE Suture, blue, 6 per box
72203897	ULTRATAPE Suture, cobraid-blue, 6 per box
ULTRABRAID Suture	
72200886	ULTRABRAID Suture, #2, white, 10 per box
72200887	ULTRABRAID Suture, #2, cobraid blue, 10 per box
72202965	ULTRABRAID Suture, #2, blue, 10 per box

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References

1. Clark TR, Guerrero EM, Song A, O'Brien MJ, Savoie FH. Do Vented Suture Anchors Make a Difference in Rotator Cuff Healing. *Ann Sports Med Res.* 2016, 3(3): 1068.**2.** Chahla J, Liu JN, Manderle B, et al. Bony ingrowth of coil-type open-architecture anchors compared with screw-type PEEK anchors for the medial row in rotator cuff repair: a randomized controlled trial. *Arthroscopy.* 2019 Dec 3. [Epub ahead of print]. **3.** Calori GM, Mazza E, Colombo M, Ripamonti C. The use of bone-graft substitutes in large bone defects: Any specific needs? *Injury.* 2011;42(2):S56-S63. **4.** Data on file at Smith+Nephew, internal report no. 15009719, 2020 **5.** Data on file at Smith+Nephew, internal report no. 15009718, 2020 **6.** Kim JH, Kim YS, Park I, Lee HJ, Han SY, Jung S, SHin SJ. A Comparison of Open-Construct PEEK Suture Anchor and Non-Vented Biocomposite Suture Anchor in Arthroscopic Rotator Cuff Repair: A Prospective Randomized Clinical Trial. *Arthroscopy.* 2020, 36 (2): 389-396. **7.** Data on file at Smith+Nephew, internal report no. 15009720, 2020 **8.** Walsh WR, Morberg P, Yu Y, Response of a Calcium Sulfate Bone Graft Substitute in a Confined Cancellous Defect, *Clin. Orthop. Rel. Res.* 2003 Jan;(406):228-36. **9.** Constantino, Friedman. Synthetic Bone Graft Substitutes Otolaryngol *Clin North Am.* 1994 27(5):1037-1074. **10.** Arai E, Nakashima H, Tsukushi S, et al. Regenerating the fibula with beta-tricalcium phosphate minimizes morbidity after fibula resection. *Clin Orthop Relat Res.* 2005(431):233-237. **11.** Gaasbeek RD, Toonen HG, van Heerwaarden RJ, Buma P. Mechanism of bone incorporation of beta-TCP bone substitute in open wedge tibial osteotomy in patients. *Biomaterials.* 2005;26(33):6713-6719. **12.** Chu C-C. Section IV:44, Biodegradable Polymeric Biomaterials: An Updated Overview. In: The Biomedical Engineering Handbook: Bronzino JD Ed. *CRC Press.*; 1995. **13.** Park K, Skidmore S, Hadar J, et al. Injectable, long-acting PLGA formulations: Analyzing PLGA and understanding microparticle formation. *J Control Release.* 2019;304:125-134. **14.** Milewski MD, et al. Bone replacement of fast-absorbing biocomposite anchors in arthroscopic shoulder labral repairs, *The American Journal of Sports Medicine*, 2012. **15.** Arthrex Inc. BioComposite SutureTak, BioComposite Corkscrew FT and BioComposite PushLock: An In Vitro Degradation Study, 2009. **16.** Allison DC, Lindberg AW, Mirzayan R, Samimi B, Menendez LR. A Comparison of Mineral Bone Graft Substitutes for Bone Defects. *US Oncology and Hematolog.* 2011. **17.** Ogose A, Kondo N, Umezu H, et al. Histological assessment in grafts of highly purified beta-tricalcium phosphate (OSferions) in human bones. *Biomaterials.* 2006;27(8):1542-1549.