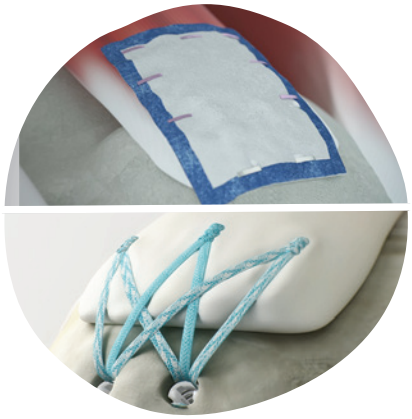
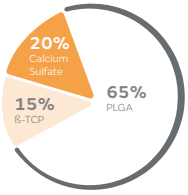
Advanced healing solutions



Redefining healing potential for rotator cuff repair

Smith+Nephew

REGENETEN◊
Bioinductive Implant



REGENESORB◊
Material

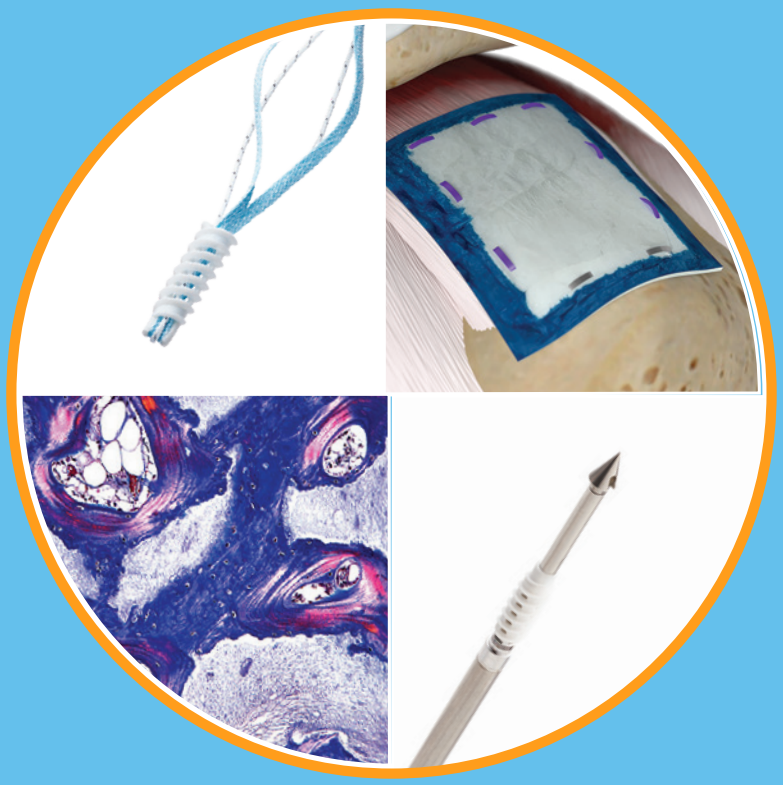
HEALICOIL◊ REGENESORB
Suture Anchor

HEALICOIL KNOTLESS
Suture Anchor

Powered by evidence.

HEALICOIL◊
REGENESORB◊
Suture Anchor

REGENESORB
Material



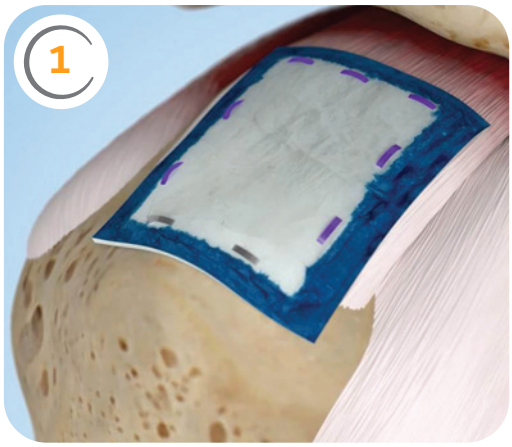
REGENETEN◊
Bioinductive Implant

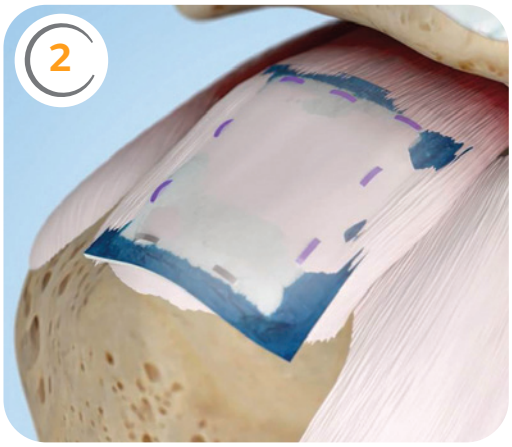
HEALICOIL
KNOTLESS
Suture Anchor

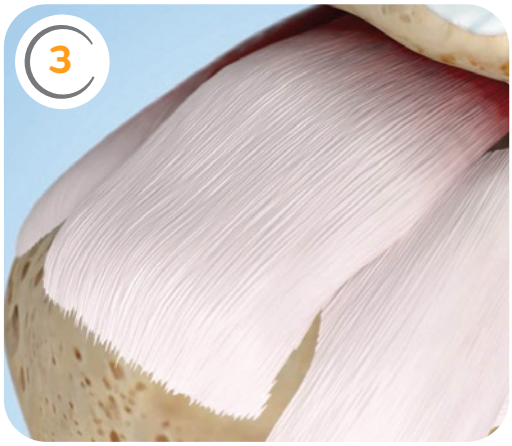
REGENETEN◊ Bioinductive Implant

Changing the course of rotator cuff disease

The REGENETEN Bioinductive Implant stimulates the body's natural healing response to support new tendon-like tissue growth and disrupt disease progression.[1-5] Derived from highly purified bovine Achilles tendon, it creates an environment that is conducive to healing.[1-3]







What it is ✚ how it works

- Proprietary, highly porous implant design facilitates the formation of new tendon-like tissue.[1, 2]
- New tissue reduces the peak strain at the site of the tear.[6]
- Gradually absorbs within 6 months and leaves a layer of new tendon-like tissue to biologically augment the existing tendon.[3, 7]*

"[REGENETEN is the] first regenerative pathway to stimulate angiogenesis and be restorative, not reparative. If you believe in biology, this is a big step."

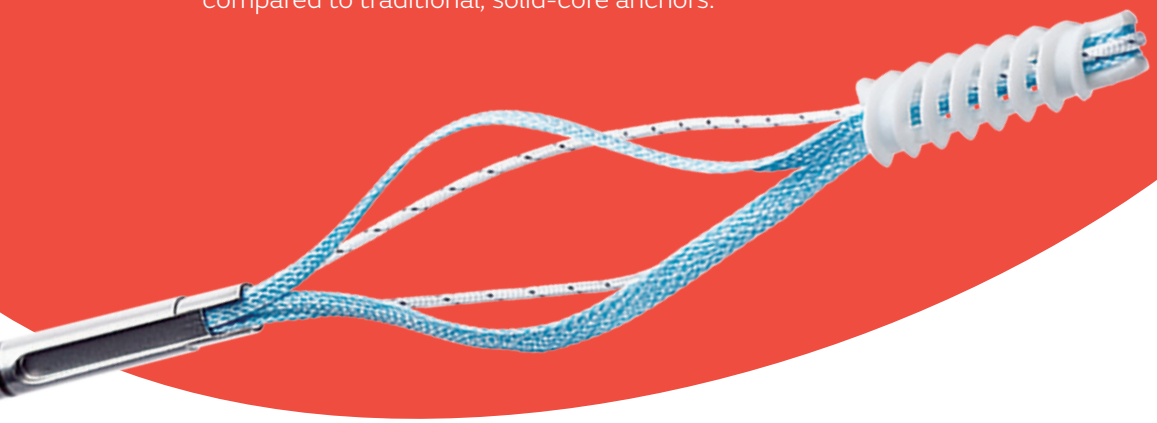
Felix H. "Buddy" Savoie III, MD
Chairman of Orthopaedic Surgery;
Chief of Sports Medicine
Tulane University School of Medicine
New Orleans, LA

* On human biopsy (n=1) and *in-vivo* sampling

HEALICOIL Suture Anchor

Open-architecture.
Now open to even greater possibilities.

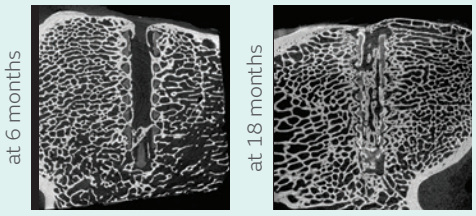
The proprietary open-architecture design of HEALICOIL anchors reduces the amount of implanted material in the shoulder compared to traditional, solid-core anchors.



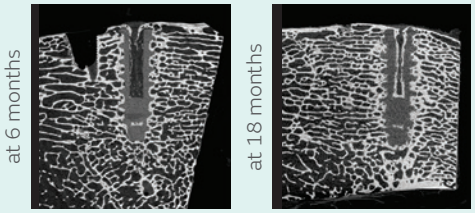
- **May facilitate greater increase in rotator cuff thickness vs competitor[8]**
- **May provide a biologic healing advantage[8]**

Faster, more complete bone infill than Arthrex's Biocomposite material.[9]

HEALICOIL◊ REGENESORB◊



Arthrex Biocomposite Corkscrew® FT



Comparisons of bone infill, measured via µCT, at 6 and 18 months.[9]

"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[10]

69%

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

94%

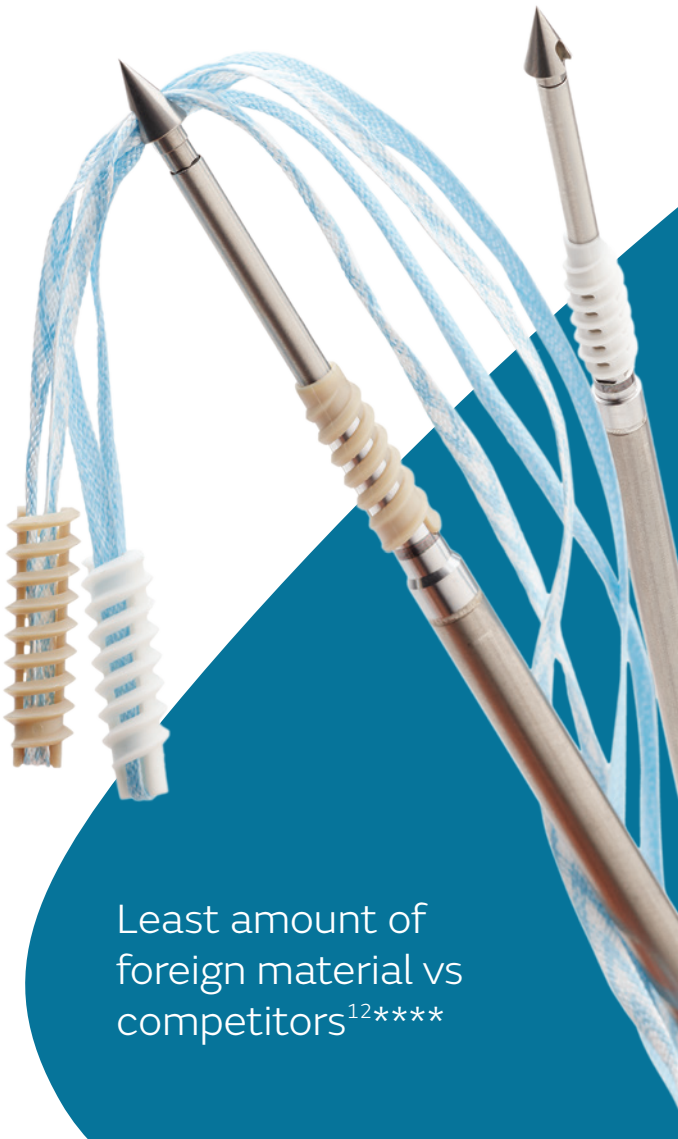
less suture displacement than Healix Advance™ 5.5mm SP Biocomposite Anchor after cyclic loading for 500 cycles**

Proven internal locking mechanism[11]

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[12]*****

- Three times more open than Arthrex BioComposite SwiveLock® 4.75mm SP[12]
- Four times more open than Arthrex BioComposite SwiveLock® 5.5mm SP[12]
- May facilitate healing by allowing access of bone marrow and associated stem cells to the repair site[8, 13]
- Shown to facilitate better bone ingrowth than solid anchors[13, 14]



Least amount of foreign material vs competitors[12]*****

* As demonstrated in benchtop testing; p = 0.002

** As demonstrated in benchtop testing; p < 0.001; All Healix Advance 5.5 mm 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

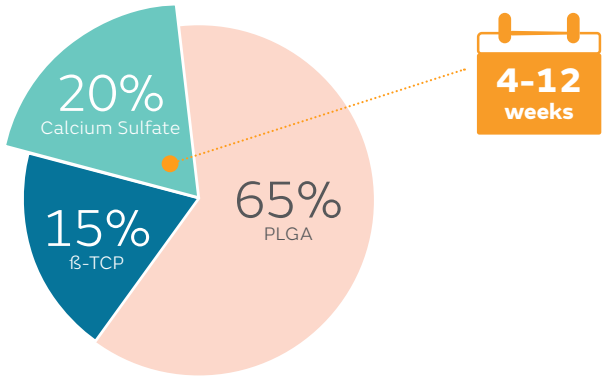
*** As demonstrated in benchtop testing

**** Compared to Arthrex, BioComposite SwiveLock 4.75mm SP, 5.5mm SP and Healix Advance 5.5 mm SP Biocomposite Anchor

REGENESORB◊ Material

A unique formulation of proven materials.

Full absorption and bone replacement in 24 months.[15-17]*
REGENESORB material is designed to provide a jump start in bone healing and formation.



Calcium sulfate makes the difference in REGENESORB

- **Calcium Sulfate:** Works in early healing stages at 4-12 weeks[18-20]
- **ß-TCP:** Sustained bone formation for up to 2 years[21, 22]
- **PLGA:** Comprised of natural products – lactic acid and glycolic acid[23, 24]

Absorbtion and bone replacement
The timeline of implant

REGENESORB material is designed to remain mechanically stable for a minimum of six months** before being absorbed and replaced by bone within 24 months.[15-17, 25, 26]*

* Demonstrated clinically and *in vivo*
** As demonstrated *in vivo*

"The difference for me with REGENESORB is its base is PLGA, which has different resorption characteristics and tends to resorb. On MRI follow-ups of patients, we noticed the material is actually changing to bone, and much earlier too – usually in less than two years – it's a major advantage."

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

Ordering information

REGENETEN® Implants	
Reference #	Description
4565	Medium Bioinductive Implant with Arthroscopic Delivery (1)
4566	Large Bioinductive Implant with Arthroscopic Delivery (1)

REGENETEN Anchors	
Reference #	Description
4403	Bone Anchors (3) with Advanced Delivery System
2504-1	Tendon Anchors (8)

REGENETEN Accessory Devices	
Reference #	Description
4173-1	Tendon Marker (2)
2503-S	Bone Anchor (1)

HEALICOIL® REGENESORB® Suture Anchors Pre-loaded with ULTRATAPE and ULTRABRAID®	
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
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

HEALICOIL PK Suture Anchor Pre-loaded with ULTRATAPE and ULTRABRAID	
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
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

Ordering information (cont.)

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	
Reference #	Description
72201915	Tapered Awl, 3.8mm, reusable
72202621	Tapered Awl, 3.8mm, disposable
72205308	HEALICOIL Knotless Spade Drill, 4.75mm, reusable
72203710	5.5mm Reusable Threaded Dilator
72203952	5.5mm Disposable Threaded Dilator

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

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For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product's applicable Instructions for Use (IFU) prior to use.

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1. Bokor DJ, Sonnabend D, Deady L et al. Evidence of healing of partial-thickness rotator cuff tears following arthroscopic augmentation with a collagen implant: a 2-year MRI follow-up. *MLTJ.* 2016;6(1):16-25. **2.** Schlegel TF, Abrams JS, Bushnell BD, Brock JL, Ho CP. Radiologic and clinical evaluation of a bioabsorbable collagen implant to treat partial-thickness tears: a prospective multicenter study. *J Shoulder Elbow Surg.* 2018;27(2):242-251. **3.** Van Kampen C, Arnockzky S, Parks P et al. Tissue-engineered augmentation of a rotator cuff tendon using a reconstituted collagen scaffold: A histological evaluation in sheep. *MLTJ.* 2013;3:229-235. **4.** Bokor DJ, Sonnabend DH, Deady L, et al. Healing of partial-thickness rotator cuff tears following arthroscopic augmentation with a highly porous collagen implant: a 5-year clinical and MRI follow-up. *Muscles, Ligaments Tendons J.* 2019;9(3):338-347. **5.** McElvany MD, McGoldrick E, Gee AO, Neradilek MB, Matsen FA, 3rd. Rotator cuff repair: published evidence on factors associated with repair integrity and clinical outcome. *Am J Sports Med.* 2015;43(2):491-500. **6.** Material and Structural Testing Core, Mayo Clinic 2019. Proof-of-concept Finite Element Modelling of Effect of Tissue Induction on Rotator Cuff Tears. Internal Report. EO/SPM/REGENTEN/001/V1. **7.** Arnoczky SP, Bishai SK, Schofield B, et al. Histologic Evaluation of Biopsy Specimens Obtained After Rotator Cuff Repair Augmented With a Highly Porous Collagen Implant. *Arthroscopy.* 2017;33(2):278-283. **8.** 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. **9.** Data on file at Smith & Nephew, study NCS248 (18-month interim report), 2014. **10.** Smith+Nephew 2020. HEALICOIL KNOTLESS claims testing, less suture displacement after postoperative cyclic loading 15009719 A. **11.** Smith+Nephew 2020. HEALICOIL KNOTLESS claims testing, proven internal locking plug mechanism 15009718 A. **12.** Smith+Nephew 2020. HEALICOIL KNOTLESS claims testing, less foreign material than competitor 15009720 A. **13.** 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.* 2020;36(4):952-961 **14.** 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 Clincial Trial. *Arthroscopy.* 2020, 36 (2): 389-396. **15.** Vonhoegen J, John D, Hägermann C. Osteoconductive resorption characteristics of a novel biocomposite suture anchor material in rotator cuff repair. *Orthop Traumatol Surg Res.* 2019;14(1):12. **16.** Smith+Nephew 2010. Micro-CT and histological evaluation of specimens from resorbable screw study (RS-II / OM1-08) 24-month post-implantation. Internal Report WRP-TE045-700-08. **17.** Smith+Nephew 2016. HEALICOIL REGENESORB Suture Anchor – a study to assess implant replacement by bone over a 2 year period. NCS248. **18.** Constantino, Friedman. Synthetic Bone Graft Subsitutes. *Otolaryngol Clin North Am.* 1994 27(5):1037-1074. **19.** Walsh WR, Morberg P, Yu Y, et al. Response of a calcium sulfate bone graft substitute in a confined cancellous defect. *Clin Orthop Relat Res.* 2003(406):228-236. **20.** 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. **21.** 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. **22.** 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. **23.** 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. **24.** Chu C-C. Section IV:44, Biodegradable Polymeric Biomaterials: An Updated Overview. In: The Biomedical Engineering Handbook. Bronzino JD Ed. CRC Press.; 1995. **25.** Smith+Nephew 2019 Verification, Microraptor Knotless Real Time Degredation. Revision B. Internal Report 15007134. **26.** Smith and Nephew 2019. Verification, Microraptor Knotless Accelerated Degredation. Internal Report 15007045.