

REGENESORB

ADVANCED BIOCOMPOSITE MATERIAL



It's all about
the material

REGENESORB material is absorbed
and replaced by bone in 24 months¹

 **smith&nephew**

Supporting healthcare
professionals for over 150 years

“ The difference for me with REGENESORB material is, first of all, its base is PLGA, which has different resorption characteristics and tends to resorb. Second, we also know the additives of TCP and calcium sulfate allow for induction of bone. When we have done MRI follow-ups of patients, we notice that the material actually is changing to bone, and it changes to bone much earlier, as well – usually in less than two years – and we believe that to be a **major advantage**. ”

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



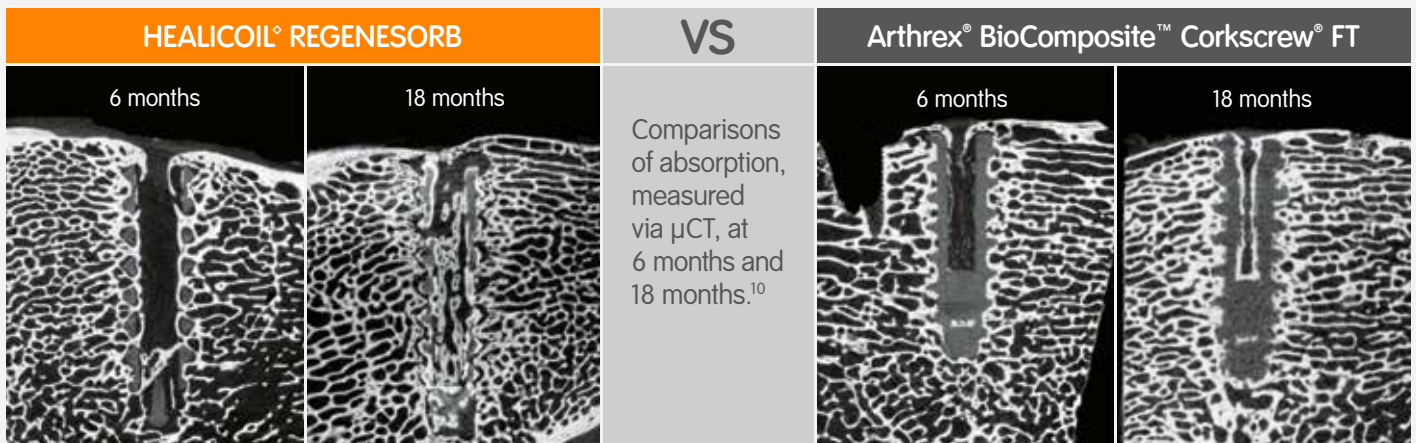


No other biocomposite can do this

Full absorption and bone replacement in **24 months**¹

Ongoing efforts to further improve suture anchors include modifying their design and composition, thereby enhancing biological healing, bone formation, and repair strength in order to facilitate improved clinical outcomes.² With this in mind, **REGENESORB** material provides a jump start in bone healing and formation.

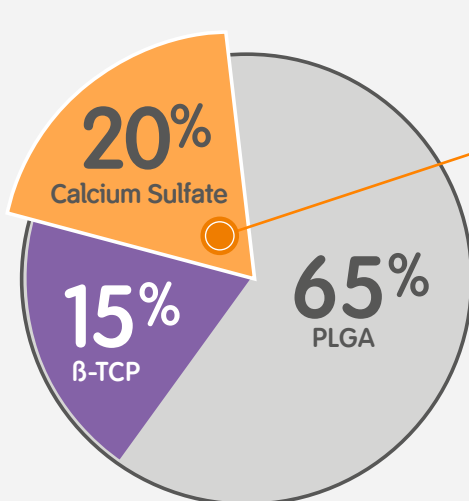
Faster, more complete absorption than Arthrex's biocomposite material



REGENESORB material: a unique formulation of proven materials

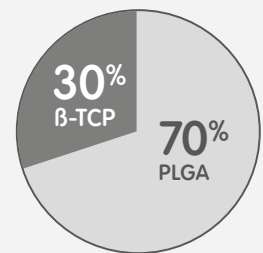
REGENESORB material uses a novel poly (PLGA) based biocomposite material that contains β -tricalcium phosphate (β -TCP) and calcium sulfate, both previously demonstrated to be osteoconductive.³⁻⁶

Calcium sulfate makes the difference in REGENESORB

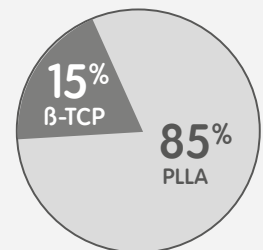


- Calcium Sulfate:** Works in early healing stages at 4-12 weeks⁵
- β -TCP:** Sustained bone formation over 18 months⁵
- PLGA:** Comprised of natural products – lactic acid and glycolic acid

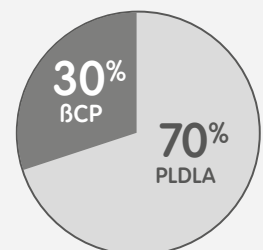
Most biocomposite materials rely solely on the osteoconductive properties of β -TCP, which provides sustained bone formation over 18 months⁵ and acts primarily as a scaffold for enhancing new bone formation.⁷ REGENESORB material includes a second osteoconductive material, calcium sulfate, which has been shown to work in the early stages (4-12 weeks) of bone healing⁵ and is associated with increased levels of local growth factors.⁸ REGENESORB material contains two osteoconductive components – β -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.**



Mitek Biocryl™



Arthrex® BioComposite™ Anchor

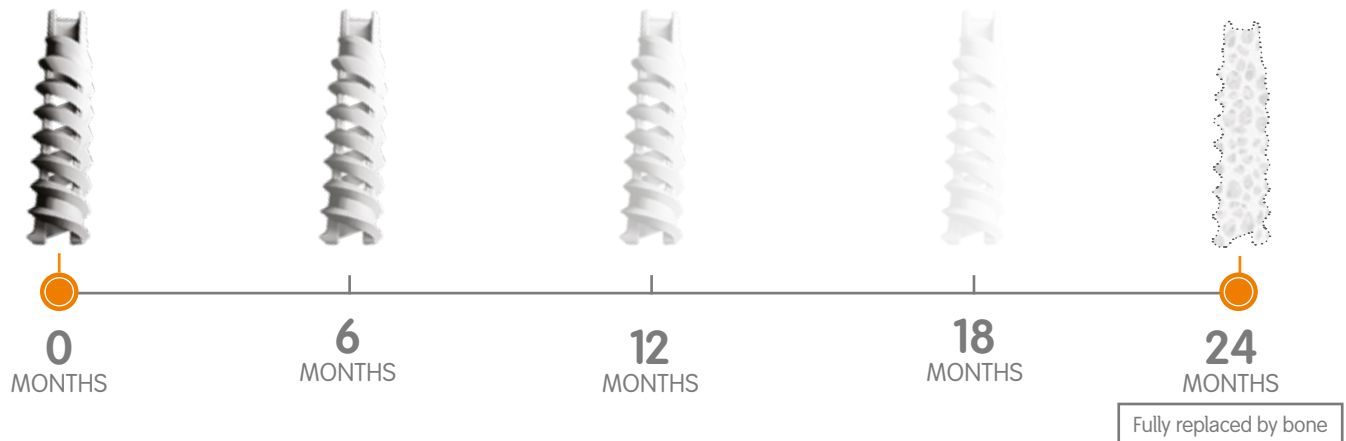


Arthrex® BioComposite™ Screw

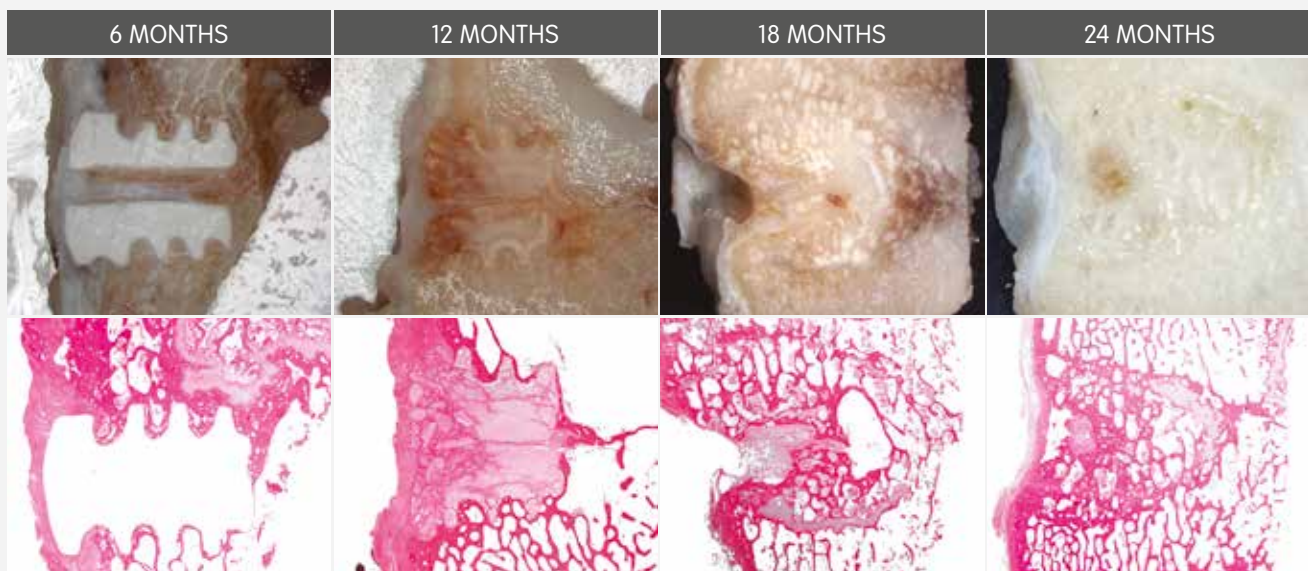
Absorption and bone replacement

The timeline of implant

Smith & Nephew REGENESORB material is designed to remain mechanically stable for a minimum of six months before being absorbed and replaced by bone within 24 months.*



Absorption profile of solid REGENESORB implant in a preclinical model

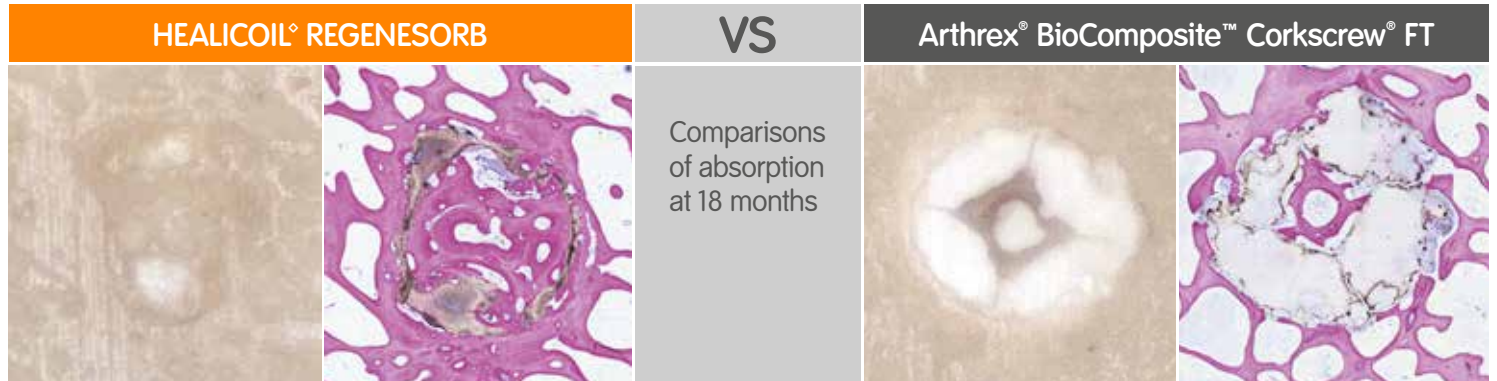


Gross anatomy and histology images of a 9x10mm implant of REGENESORB material evaluated in a direct-in-bone sheep model. Images clearly demonstrate absorption and complete replacement by bone in 24 months. Please note this implant was designed for this preclinical study and is not an exact replica of a BIOSURE® REGENESORB Interference Screw.

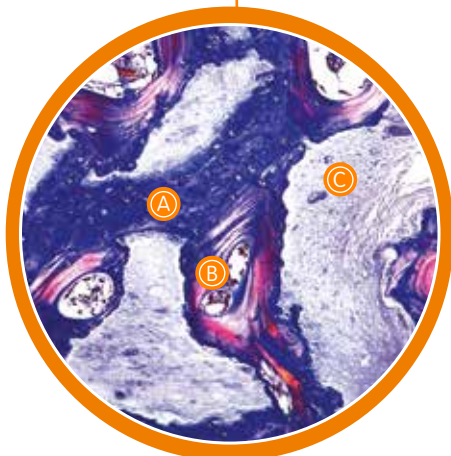
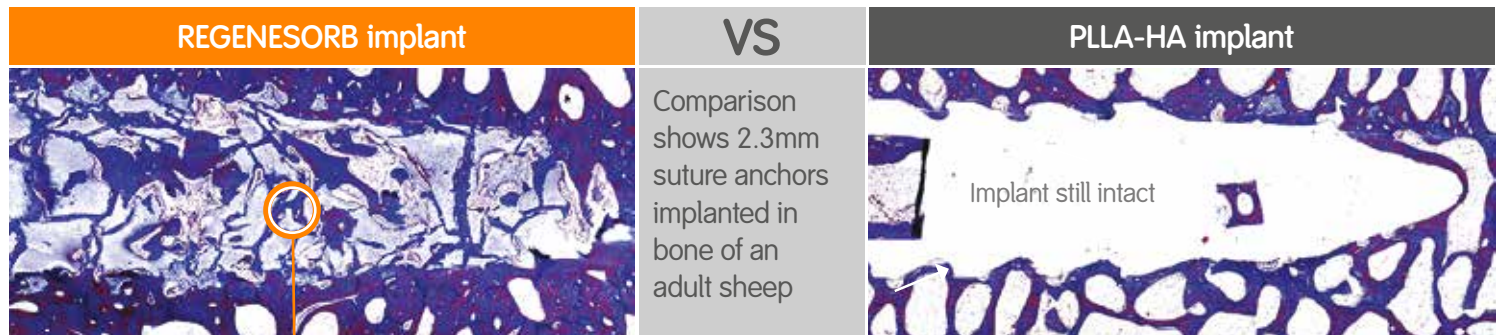
REGENESORB material is absorbed and replaced by bone faster than other biocomposites

REGENESORB material vs. PLLA/ β -TCP at 18 months*

Histology and histomorphometry also demonstrated faster material absorption of the HEALICOIL REGENESORB anchor compared with the Arthrex PLLA/ β -TCP-based solid body anchor implant, with **70% absorption at 18 months** compared with 57% for the PLLA/ β -TCP-based Arthrex BioComposite Corkscrew FT ($p < 0.001$).¹⁰



REGENESORB material vs. PLLA-HA at 18 months*



- Ⓐ Osteoblasts forming new bone
- Ⓑ More mature bone in the form of organized collagen sheets (lamellar bone)
- Ⓒ REGENESORB fragment being absorbed and replaced by bone

“REGENESORB material has three different components (PLGA β -TCP and Calcium Sulfate), and I think they speed up biologic healing.”

Felix H. “Buddy” Savoie III, MD
Chairman of Orthopaedic Surgery; Chief of Sports
Medicine, Tulane University School of Medicine

Ordering information

Reference #	Description
BIOSURE® REGENESORB Interference Screw	
72204389	BIOSURE REGENESORB Interference Screw 5mm x 20mm*
72204390	BIOSURE REGENESORB Interference Screw 5mm x 25mm*
72204391	BIOSURE REGENESORB Interference Screw 6mm x 20mm
72204392	BIOSURE REGENESORB Interference Screw 6mm x 25mm
72204393	BIOSURE REGENESORB Interference Screw 6mm x 25mm Reverse Thread
72204394	BIOSURE REGENESORB Interference Screw 7mm x 20mm
72204395	BIOSURE REGENESORB Interference Screw 7mm x 25mm
72204396	BIOSURE REGENESORB Interference Screw 7mm x 25mm Reverse Thread
72204397	BIOSURE REGENESORB Interference Screw 7mm x 30mm
72204398	BIOSURE REGENESORB Interference Screw 8mm x 20mm
72204399	BIOSURE REGENESORB Interference Screw 8mm x 25mm
72204400	BIOSURE REGENESORB Interference Screw 8mm x 25mm Reverse Thread
72204401	BIOSURE REGENESORB Interference Screw 8mm x 30mm
72204402	BIOSURE REGENESORB Interference Screw 8mm x 35mm
72204403	BIOSURE REGENESORB Interference Screw 9mm x 20mm
72204404	BIOSURE REGENESORB Interference Screw 9mm x 25mm
72204405	BIOSURE REGENESORB Interference Screw 9mm x 30mm
72204406	BIOSURE REGENESORB Interference Screw 9mm x 35mm
72204407	BIOSURE REGENESORB Interference Screw 10mm x 20mm
72204408	BIOSURE REGENESORB Interference Screw 10mm x 25mm
72204409	BIOSURE REGENESORB Interference Screw 10mm x 30mm
72204410	BIOSURE REGENESORB Interference Screw 10mm x 35mm
72204411	BIOSURE REGENESORB Interference Screw 11mm x 25mm
72204412	BIOSURE REGENESORB Interference Screw 11mm x 30mm
72204413	BIOSURE REGENESORB Interference Screw 11mm x 35mm
72204414	BIOSURE REGENESORB Interference Screw 12mm x 35mm

*BIOSURE REGENESORB Interference Screws with 5mm diameter require use with 5mm BIOSURE Driver.

Reference #	Description
HEALICOIL® REGENESORB Suture Anchor** Pre-loaded with ULTRATAPE**	
72203705	HEALICOIL REGENESORB 4.75mm Suture Anchor with one ULTRATAPE Suture (Blue) and one
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

Reference #	Description
HEALICOIL REGENESORB Suture Anchor** Pre-loaded with 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)

Reference #	Description
HEALICOIL REGENESORB Accessory Devices**	
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

Reference #	Description
MICRORAPTOR® REGENESORB Suture Anchor	
72204983	MICRORAPTOR REGENESORB Suture Anchor with one ULTRABRAID (#1) Suture (blue)
72204984	MICRORAPTOR REGENESORB Suture Anchor with one ULTRABRAID (#1) Suture (blue cobraid)

**Manufactured by: ArthroCare Corporation
7000 West William Cannon Drive Austin, TX 78735 USA

Sports Medicine
Smith & Nephew, Inc.
150 Minuteman Road
Andover, MA 01810

www.smith-nephew.com
T +978 749 1000
US Customer Service:
+1 800 343 5717

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10. 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.
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