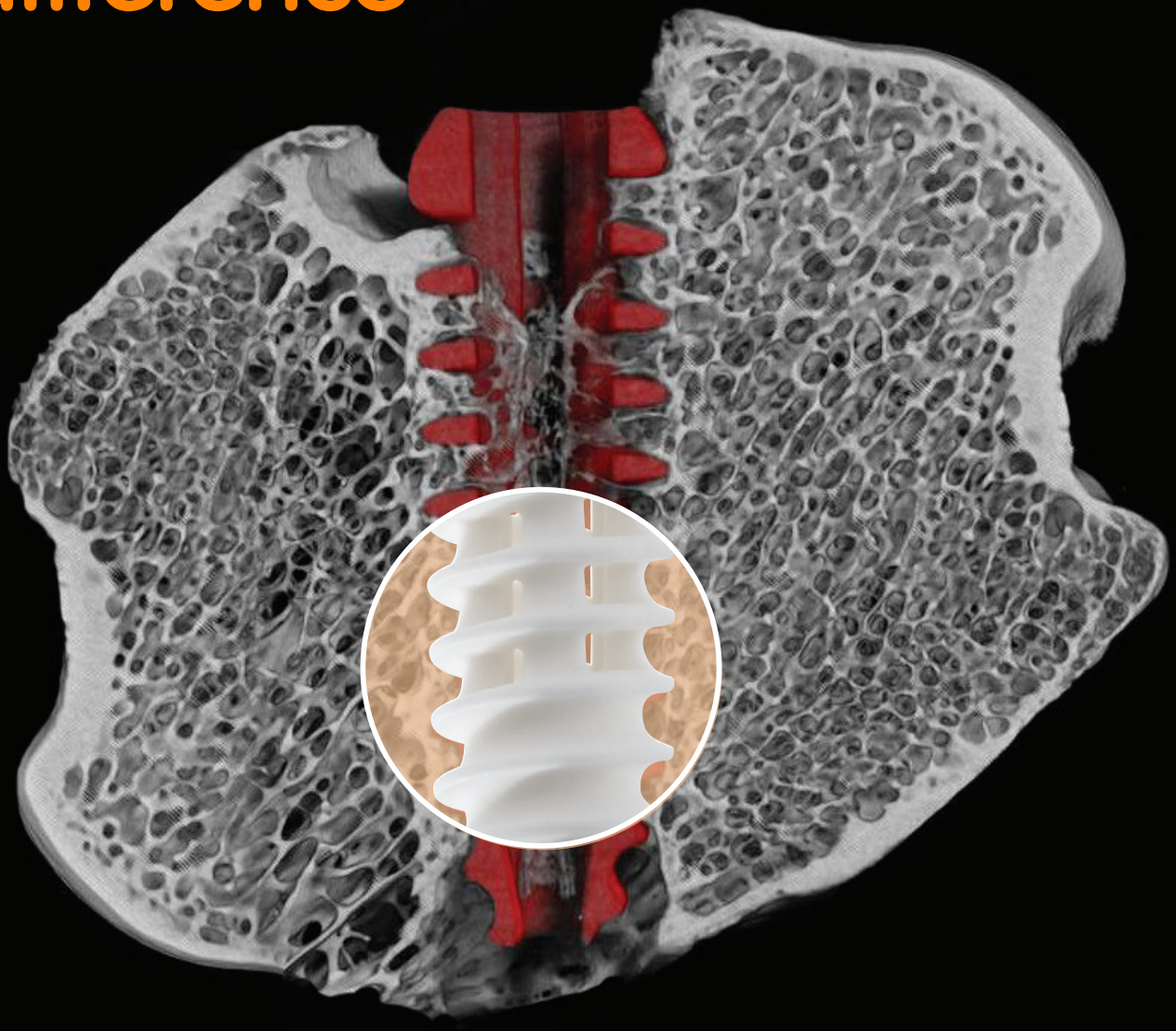
Made to make a difference



The difference is bone ingrowth

Smith+Nephew

BIOSURE® REGENESORB

Interference Screw

Supporting healthcare professionals

Not all interference screws are created equal

Bone ingrowth
Open architecture to allow for bone to grow through the screw and attach to the graft[1]

Reliable performance
Strength expected from a solid absorbable interference screw[2]

Advanced material
REGENESORB Material is replaced by bone within 24 months in preclinical studies[3]

BIOSURE◇ REGENESORB

Interference Screw

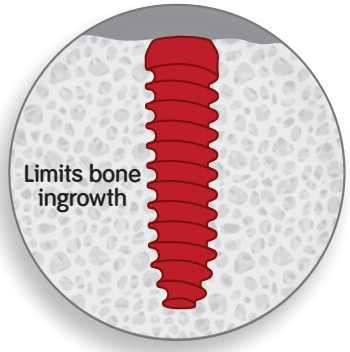
The unique BIOSURE REGENESORB Screw is the first interference screw made out of an advanced biocomposite material with an open-architecture design to allow for bone ingrowth, while also providing the kind of performance expected with a solid absorbable interference screw.[2]

The difference is bone ingrowth

1 Open architecture allows bone ingrowth...

Solid interference screw

Conventional solid interference screws limit bone ingrowth to the head and tip of the screw

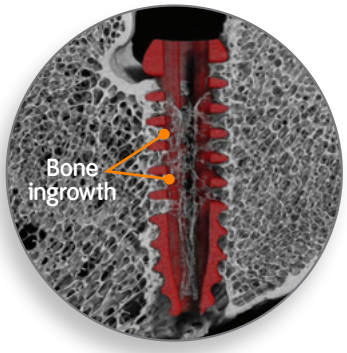


Renderings are for illustrative purposes

VS

BIOSURE REGENESORB Interference Screw

Open-architecture design allows bone ingrowth across the interference screw[1]

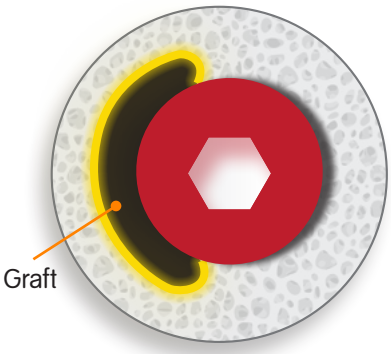


Micro-CT scan at 12 weeks post-implantation, in an ovine ACL reconstruction study[1]

Approximately **50% bone volume is restored** by new bone within center cannulation at 12 weeks as demonstrated by pre-clinical studies.[1]

2 Which leads to circumferential graft-to-bone integration...

Solid interference screw



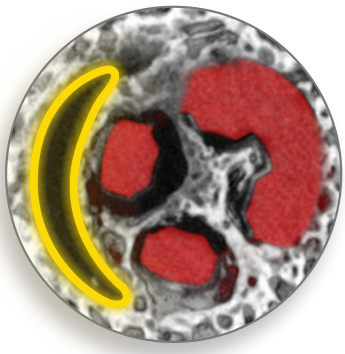
Renderings are for illustrative purposes

Limited graft-to-bone integration

A solid screw only allows integration on the side contacting the tunnel wall

VS

BIOSURE REGENESORB Interference Screw



Transverse micro-CT scan at 12 weeks post-implantation, in an ovine ACL reconstruction study[4]

Circumfrential graft-to-bone integration

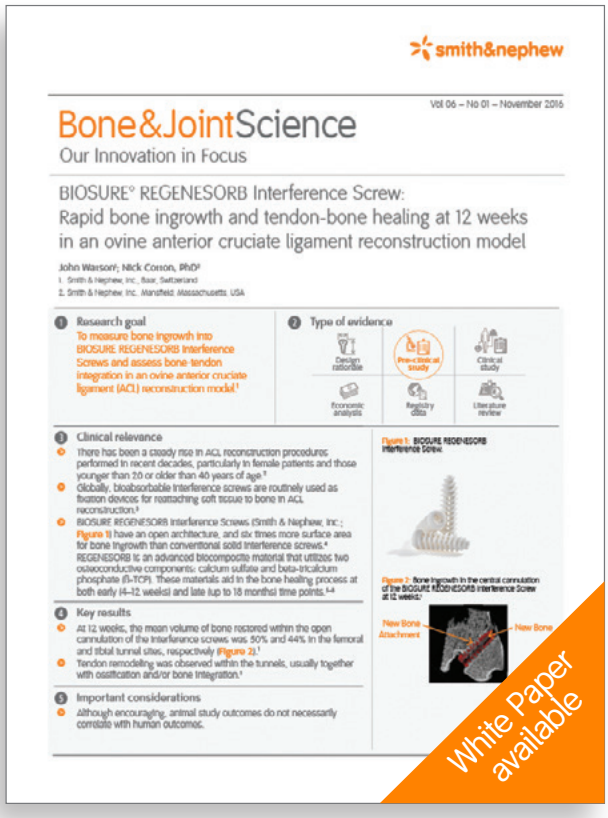
Proven integration by bone on all sides of the graft, as demonstrated by a pre-clinical study

New bone is integrated into the graft in areas not previously accessed by solid conventional interference screws, resulting in **circumfrential graft-to-bone integration**, as demonstrated by a pre-clinical study.[4]

3

And impacts the healing process.

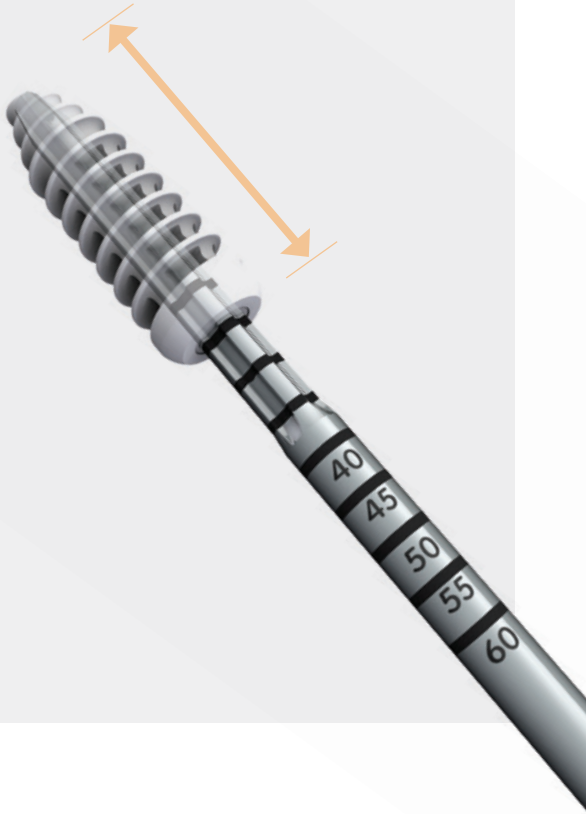
Integration between bone and graft plays a role in the remodeling and healing process, as suggested by several studies.[5-8]



RELIABLE PERFORMANCE THAT'S EXPECTED FROM A SOLID SCREW

The open-architecture design provides the benefits of bone ingrowth without compromising strength or reliability.
The BIOSURE® REGENESORB Interference Screw exhibits the fixation strength of a solid absorbable interference screw without statistical difference throughout the healing period in a simulated degradation environment.[9]

The full length of the BIOSURE REGENESORB Interference Screw is supported by the BIOSURE Driver.
Torsional stress is transferred off the screw and onto the driver, resulting in superior performance during insertion.[10,11]

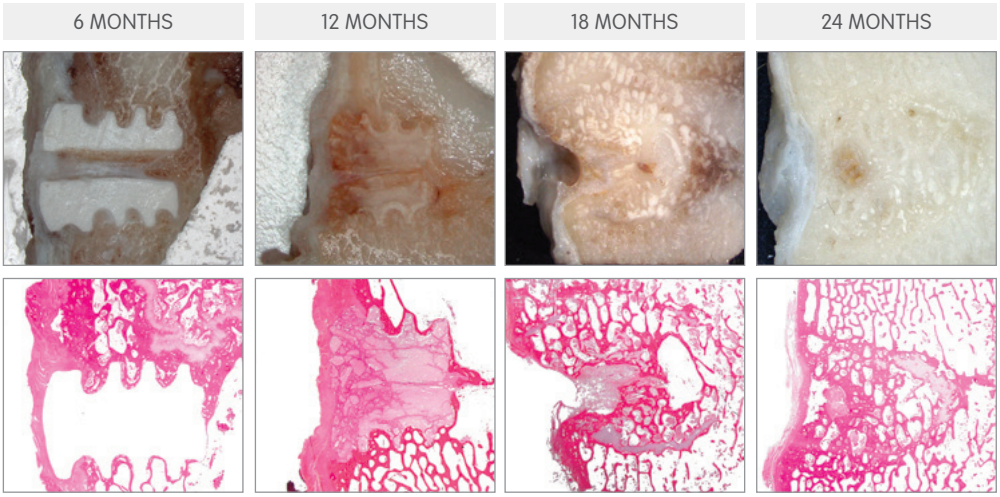


Advanced biocomposite material

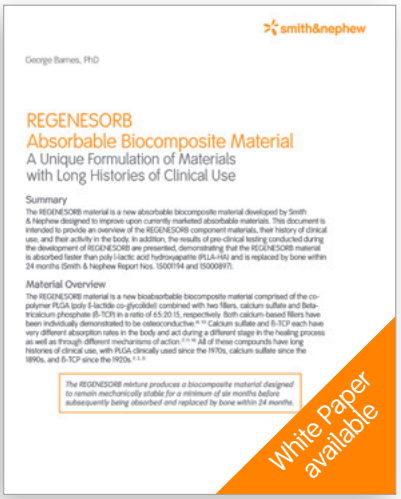
REGENESORB Material is replaced by bone within 24 months

The REGENESORB Material mixture is designed to remain mechanically stable for a minimum of six months before subsequently being absorbed and replaced by bone within 24 months.[12]

Long-term absorption profile of solid REGENESORB Implant in a preclinical model

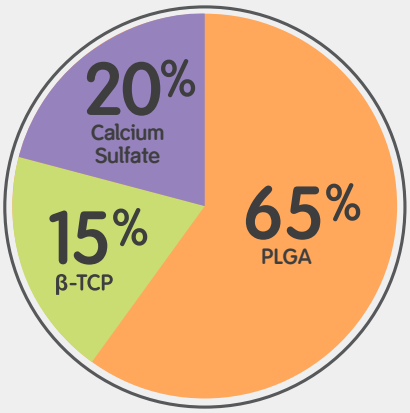


Gross anatomy and histology images of a 9x10mm implant of REGENESORB Material evaluated in a direct-in-bone sheep model. Images clearly demonstrate absorption and complete replacement by bone in 24 months. Please note this implant was designed for this preclinical study and is not an exact replica of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



The science behind REGENESORB Material

REGENESORB Material is a unique formula of osteoconductive component materials, each proven safe and biocompatible with over decades of clinical use.[13,14]



Calcium Sulfate
Works in early healing stages at **4–12** weeks[15]

β-TCP
Sustained bone formation over **18 months**[15]

PLGA
Comprised of natural products – lactic acid and glycolic acid

Unlike competitive materials, REGENESORB Material includes a second osteo-conductive material, calcium sulfate.

- Works in early stages (4–12 weeks) of bone healing[15]
- Associated with increased levels of local growth factors[16]

References

1. As demonstrated by micro-CT analysis and quantifications of bone ingrowth within cannulation of implanted screw in femoral tunnel compared to undisturbed bone in a preclinical ovine ACLR study (49.5%, stdev 12.5%). Data on File at Smith & Nephew, report NCS250. Results of in vivo simulation have not been shown to quantitatively predict clinical performance.
2. Compared to BIOSURE HA Interference Screws. Data on file at Smith & Nephew, reports 15004843, 15002832, 15002353, 15002699.
3. In vivo animal testing has demonstrated that REGENESORB Material is bioabsorbable and is replaced by bone. Implants (9x10mm) were implanted in ovine cancellous bone and compared to an empty defect (9x10mm) at 6, 12, 18 and 24 months (n=6). Micro-CT analysis demonstrated that by 24 months, bone ingrowth into this material (289.5mm3) was significantly greater ($p<0.05$) than bone ingrowth into an empty defect (170.2mm3) and reaches a bone volume not statistically different from intact bone (188.2mm3). Results of in vivo simulation have not been shown to quantitatively predict human clinical performance. Data on file at Smith & Nephew, report 15000897.
4. Data on file at Smith & Nephew, report NCS250.
5. Kuang GM, Yau WP, Lu WW et al. Osteointegration of soft tissue grafts within the bone tunnels in anterior cruciate ligament reconstruction can be enhanced. Knee Surg Sports Traumatol Arthrosc. 2010 Aug;18(8):1038-51. doi: 10.1007/s00167-009-0910-1. Epub 2009 Sep 25.
6. The Anterior Cruciate Ligament: Reconstruction and Basic Science. Chadwick C. Prodromos, editor. Philadelphia: Saunders; 2008. ISBN: 978-1-4160-3834-4.
7. Current Concepts in ACL Reconstruction. Freddie H. Fu and Stephen B. Cohen, editors. SLACK Incorporated NJ, USA. ISBN: 978-1556428135.
8. Anterior Cruciate Ligament Reconstruction: A Practical Surgical Guide. Siebold, Rainer, Dejour, David, Zaffagnini, Stefano, editors. Springer Science & Business, 2014 ISBN 978-3-642-45349-6.
9. Compared to BIOSURE HA Interference Screws in biomechanical studies. Results between BIOSURE REGENESORB and BIOSURE HA were not statistically significant. Data on file at Smith & Nephew, reports 15004843, 15002832, 15002353, 15002699.
10. Data on file at Smith & Nephew, report 15004843 and 15005418.
11. Compared to 7x23mm Arthrex BioComposite and 7x23mm Mitek Milagro ($p<.05$). Data on file at Smith & Nephew, report 15005418.
12. In vivo animal testing has demonstrated that REGENESORB Material is bioabsorbable and is replaced by bone. Implants (9x10mm) were implanted in ovine cancellous bone and compared to an empty defect (9x10mm) at 6, 12, 18 and 24 months (n=6). Micro-CT analysis demonstrated that by 24 months, bone ingrowth into this material (289.5mm3) was significantly greater ($p<0.05$) than bone ingrowth into an empty defect (170.2mm3) and reached a bone volume not statistically different from intact bone (188.2mm3). Results of in vivo simulation have not been shown to quantitatively predict clinical performance. Data on file at Smith & Nephew, report 15000897.
13. Smith & Nephew White Paper 10601161 REGENESORB: Absorbable Biocomposite Material.
14. Data on file at Smith & Nephew, reports 15000897, 15001194, 15000921, 15000919, NCS250.
15. Costantino and Friedman. Synthetic Bone Graft Substitutes (1994) Otolaryngol Clin North Am. 1994 Oct;27(5).
16. Walsh et al, (2003) Clin. Orthop. Rel. Res. Vol 406, Allison Et al (2011) US Oncology and Hematology Vol 7(1).

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
Instruments	
7211138	Guide Wire, 1.2mm x 12" sterile (5 per box)
72201201	Guide Wire, 1.2mm x 18" sterile (5 per box)
72201887	BIOSURE Driver
72204647	BIOSURE Driver, 5mm*
72201888	BIOSURE Ratchet Driver (requires 7207707)
7207707	Ratcheting Handle with Hudson Adapter

Reference #	Description
72201941	BIOSURE TAP System - includes 1 each of:
72201889	6mm BIOSURE Tap
72201890	7mm BIOSURE Tap
72201891	8mm BIOSURE Tap
72201892	9mm BIOSURE Tap
72201893	10mm BIOSURE Tap
72201887	BIOSURE Driver
72201938	BIOSURE Tap Tray

Reference #	Description
72201942	BIOSURE EASY TAP System - includes 1 each of:
72201190	6mm BIOSURE EASY Tap
72201191	7mm BIOSURE EASY Tap
72201192	8mm BIOSURE EASY Tap
72201193	9mm BIOSURE EASY Tap
72201194	10mm BIOSURE EASY Tap
72201888	BIOSURE Ratchet Driver
7207707	Ratcheting Handle with Hudson Adapter
72201939	BIOSURE EASY Tap Tray

For more information
contact your local sales representative

BIOSURE REGENESORB Interference Screw

BIOSURE Driver

BIOSURE TAP System