Open-architecture. Now open to even greater possibilities.

All the advantages of the HEALICOIL PK design, now available in our advanced REGENESORB biocomposite material.
The HEALICOIL™ Suture Anchor Family
Open to more possibilities through a unique combination of innovative design and materials – PEEK or REGENESORB Material

The open-architecture HEALICOIL Suture Anchor and the inherent advantages of its design are now available in our new REGENESORB biocomposite material.

Unique, 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 design allows blood and bone marrow from surrounding cancellous bone to enter the implant.

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.¹

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

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

The information contained in this document is based on pre-clinical testing, which is not necessarily indicative of human clinical outcomes.
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.³

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.⁴

Superior 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

Minimal size, maximal strength In biomechanical testing, the 4.75 mm HEALICOIL REGENESORB Suture Anchor demonstrated higher pullout strength than the larger, 5.5 mm competitive anchors shown in the accompanying graph.⁶

![Anchor Pullout Testing](image)

**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).

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 bone⁷, withstanding typical shoulder loading forces and supporting the range of motion necessary for physical therapy and rehabilitation.
Superior 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.

Effective thread purchase is clearly seen in this bird's-eye view of the HEALICOIL PK Suture Anchor (cadaveric study, post-insertion).

Minimal size, maximal strength In biomechanical testing, both the 5.5 mm and 4.75 mm HEALICOIL REGENESORB Suture Anchor demonstrated significantly higher torsional strength than the 5.5 mm competitive anchors.8

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).

Illustration of HEALICOIL PK Suture Anchor being inserted into humeral head for rotator cuff repair.
REGENESORB Material
An advanced biocomposite absorbed and completely replaced by bone within 24 months in pre-clinical studies⁹.

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 months.

Snapshot of REGENESORB material at 18 months¹⁰

18-month histology snapshot of 2.3 mm REGENESORB instability anchor evaluated in a direct-in-bone sheep model (viewed under partially polarized light).
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.11

Calcium sulfate: the material difference

Most biocomposite materials rely solely on the osteoconductive properties of β-TCP, which provides sustained bone formation over 18 months12 and acts primarily as a scaffold for enhancing new bone formation.13 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 healing14 and is associated with increased levels of local growth factors.15

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

<table>
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<th>Polymer</th>
<th>Bioactive Calcium Materials</th>
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| PLGA Poly-L-lactic co-glycolic acid | • Long history of clinical use*
| | • Degrades faster than PLLA17
| | • Comprised of natural products – lactic acid and glycolic acid
| β-TCP Beta tricalcium phosphate | • Longer-term (18 months) absorption profile for sustained bone formation*
| | • Osteoconductive (physical) – Scaffold to allow for bone ingrowth19
| Calcium Sulfate | • Shorter-term (4-12 weeks) absorption profile for enhanced early bone formation18 and calcium release21
| | • Osteoconductive (biochemical) – Increased levels of local growth factors22

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*Literature references omitted for brevity.
References

1. 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.

2. See note 1 above.

3. Data on file at Smith & Nephew in reports 15001873 and 15002036.


5. See note 4 above.

6. See note 4 above.


8. See note 4 above.

9. 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.

10. In vivo animal testing has demonstrated that the composite material is bioabsorbable and is replaced by bone. Results of in vivo simulation have not been shown to quantitatively predict clinical performance. Data on file at S&N in report # 15001194.

11. Data on file at Smith & Nephew in reports 15000897, 15001194, 15000921, 15000919.


14. See note 12 above.


18. See note 12 above.

19. See note 13 above.

20. See note 12 above.


22. See note 15 above.

23. See note 9 above.
HEALICOIL® REGENESORB and HEALICOIL PK Suture Anchors

The open-architecture anchors filled with possibilities

Ordering Information

HEALICOIL REGENESORB Suture Anchor

The HEALICOIL REGENESORB Suture Anchor is made from REGENESORB Material, a new biocomposite material that is bioabsorbable and completely replaced by bone within 24 months in pre-clinical studies.23

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

Accessory Devices

72203709 | HEALICOIL REGENESORB 4.75 mm Fully Threaded Dilator, Reusable
72203710 | HEALICOIL REGENESORB 5.5 mm Fully Threaded Dilator, Reusable
72203951 | HEALICOIL REGENESORB 4.75 mm Fully Threaded Dilator, Disposable
72203952 | HEALICOIL REGENESORB 5.5 mm Fully Threaded Dilator, Disposable
72203482 | 3.5 mm HEALICOIL Spade Tip Drill for use with the 4.5/4.75 mm HEALICOIL Suture Anchor
72203483 | 4.5 mm HEALICOIL Spade Tip Drill for use with the 5.5 mm HEALICOIL Suture Anchor

HEALICOIL PK Suture Anchor

The HEALICOIL PK Suture Anchor is made from PEEK-OPTIMA® Polymer from Invibio® material for proven biocompatibility, strength, and radiolucency.

**Reference #** | **Description**
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72203378 | 4.5 mm HEALICOIL PK Suture Anchor with two ULTRABRAID® (#2) Sutures (blue, blue-Cobraid), sterile
72203379 | 5.5 mm HEALICOIL PK Suture Anchor with two ULTRABRAID (#2) Sutures (blue, blue-Cobraid), sterile
72203380 | 5.5 mm HEALICOIL PK Suture Anchor with three ULTRABRAID (#2) Sutures (blue, blue-Cobraid, Cobraid-black), sterile

Accessory Devices

72202621 | 3.8 mm Tapered Awl, disposable
72201915 | 3.8 mm Tapered Awl, reusable
72202633 | 4.5 mm HEALICOIL/TWINFIX® ULTRA Threaded Dilator, reusable
72202634 | 5.5 mm HEALICOIL/TWINFIX ULTRA Threaded Dilator, reusable
72203482 | 3.5 mm HEALICOIL Spade Tip Drill for use with the 4.5/4.75 mm HEALICOIL Suture Anchor
72203483 | 4.5 mm HEALICOIL Spade Tip Drill for use with the 5.5 mm HEALICOIL Suture Anchor

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