TheraCell

TheraFuze DBF® FIBER ANCHOR™

FIBER ANCHOR™

FIBER ANCHORS AVAILABLE TO FIT A BROAD RANGE OF SCREW SIZES

TheraFuze DBF®

THE CLINICAL NEED

- Loosening of screws is a common complication reported in musculoskeletal surgery [1,2].
- Screw loosening results in a loss of construct stability and ineffective spine fusion leading to poor clinical outcomes[3,4,5].
- Rates of screw loosening as high as 62% have been observed in osteoporotic vertebra [6].
- Screw loosening following revision surgery in patients with poor bone quality is particularly prevalent [6,7,8].

THERAFUZE DBF® FIBER ANCHOR™ SOLUTION

Based on guidance and input from leading surgeons to address an unmet need;

- Tapered shape to ease insertion into prepared sites.
- Screw centering design.
- Proximal flare resists downward migration during insertion.
- The cortex is a critical region for repair to resist the toggling action that loads a pedicle screw.
- Fiber Anchors™ improve initial screw fixation and deliver osteoconductive graft material with osteoinductive potential.

SURGICAL TECHNIQUE

- Fiber Anchor™ interfaces with existing surgical techniques.
- The surgeon selects the required screw size.
- An awl is used to produce a cavity that matches the anchor for that screw size.
- The Fiber Anchor™ is then placed in the cavity either by hand or using the screw or a probe.

THERAFUZE DBF® PRE-CLINICAL EFFICACY STUDIES

A series of studies conducted at the Surgical and Orthopaedic Research Laboratories at UNSW confirmed the excellent performance of TheraFuze DBF® Fibers;

- Osteoinductivity of the TheraFuze DBF® Fibers was confirmed following the ASTM method for in vivo osteoinductive potential.
- In-vitro studies examining cell attachment and biocompatibility demonstrate that TheraFuze DBF® Fiber exposed to osteoblast-like cell lines supported migration and attachment of the cells onto and into the fibers.
- Excellent bone remodeling properties of the TheraFuze DBF® Fibers were demonstrated in two preclinical animal models: A Rabbit Distal Femoral Condyle Model and a Rabbit Posterolateral Fusion (PLF) Model.

For more details of the above studies see TheraCell Brochure TCM-100 and www.theracellinc.com.

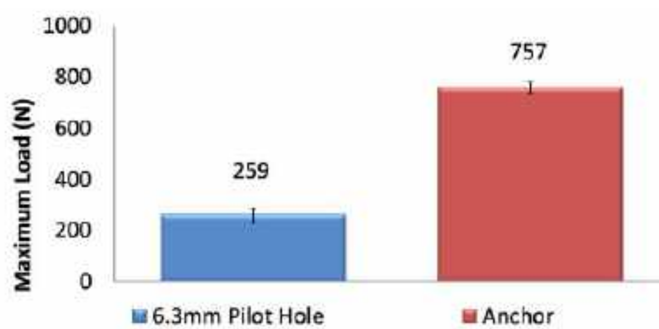
SCREW FIXATION CAPABILITY

Pull out strength was tested in (1) an Osteoporotic Model and (2) a Revision Model. Pull-out testing was performed using Sawbones Foam (1522-09; 10 pfc), a bone analog specified in ASTM standards for screw pull-out testing.

- Screw pull-out at 20mm/min. N=5 per group.

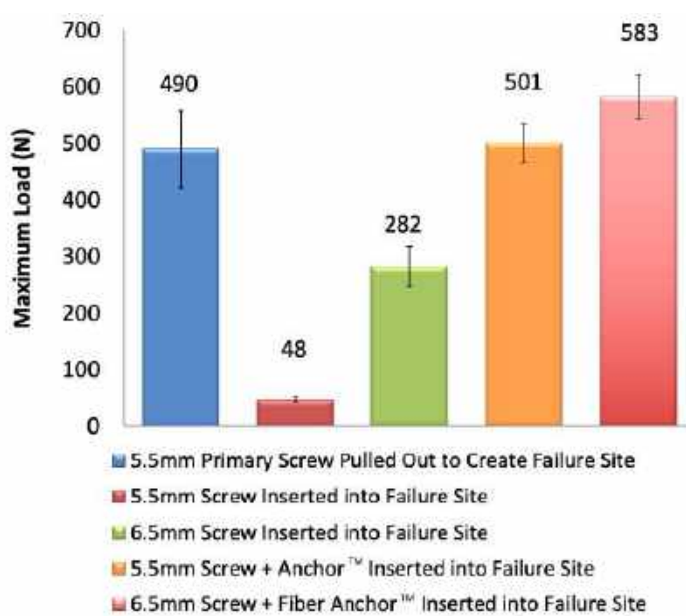
Osteoporotic Model

- A 6.3mm control hole was made in the Sawbones Foam.
- Pull out force for a 7.5mm screw in the 6.3mm hole was compared with pull out force for a Fiber Anchor™+ 7.5mm screw inserted in the same size hole.
- The Fiber Anchor™ improved fixation 2.9x.



Revision Model

- 5.5mm screw inserted in 10pcf Sawbones foam and pulled out to simulate screw failure[10]. The resulting hole simulated the revision site. Then several experimental groups were compared as shown in the graphs below.
- Use of the Fiber Anchor™ restored the fixation strength of the original screw size that was further enhanced when a larger screw was used.



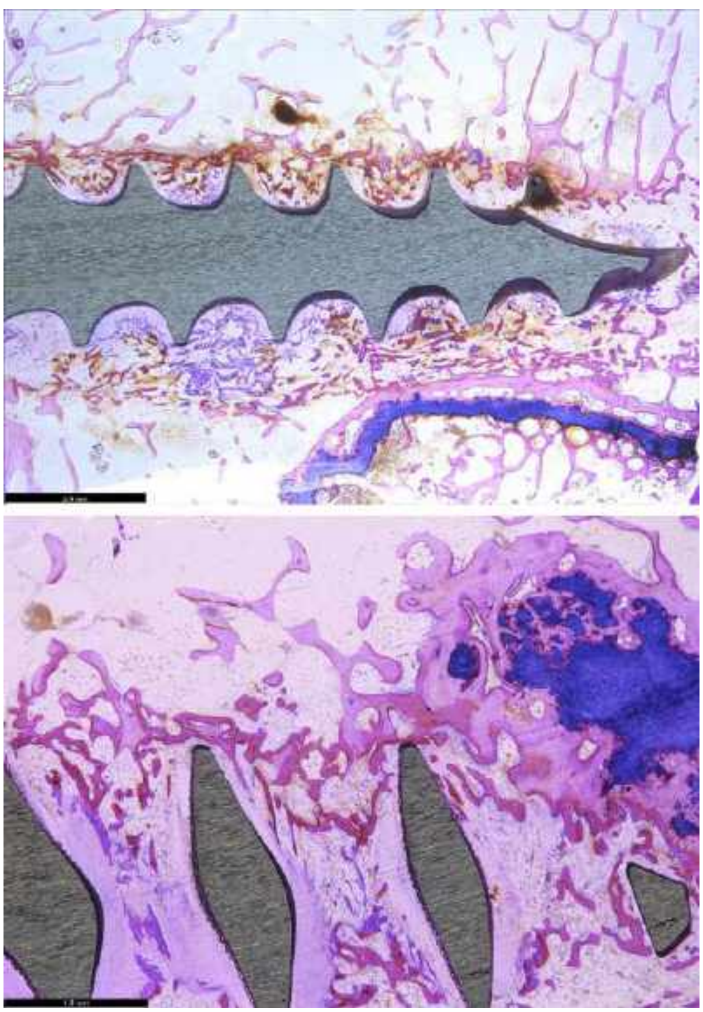
FIBER ANCHOR™ SHEEP STUDY

- Ovine DBF Fiber Anchor™ implants were evaluated in the metaphysis of the proximal tibia and distal femur of sheep using an established model for investigation of the implant-bone interface.
- Fiber Anchors were inserted into 6.0mm diameter cancelous defects and then 5.5mm pedicle screws were inserted into the Fiber Anchor

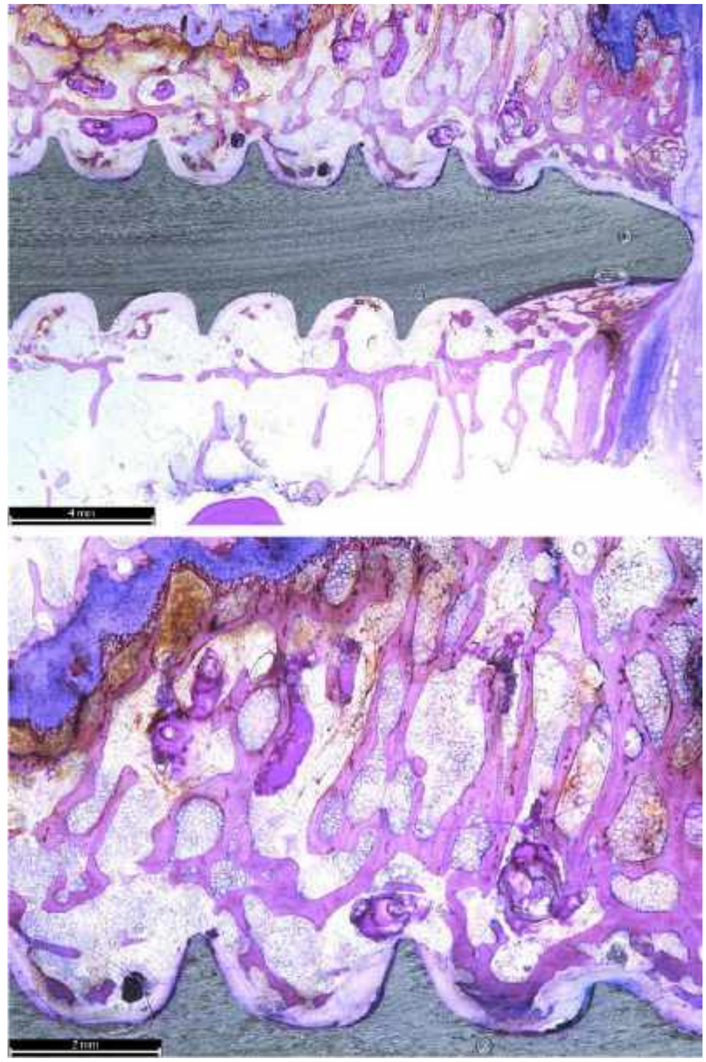
A radiograph of the inserted screw is shown above.

HISTOLOGY

- Samples were processed for histology and analyzed at 4 and 12 week time points.
- New bone formation was confirmed at 4 weeks (below).



- Bone remodeling progressed forming new woven bone in apposition to the screw and the edge of the defect at 12 weeks as shown below.



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Fiber Matrix Sleeve for Screw Augmentation. Osteoconductive Demineralized Bone Fibers with Osteoinductive Potential.

1 ANCHOR
Fits 5.5 / 6.0 mm screw
ORDER: TC-FA-5560

1 ANCHOR
Fits 6.5 / 7.0 mm screw
ORDER: TC-FA-6570

1 ANCHOR
Fits 7.5 / 8.0 mm screw
ORDER: TC-FA-7580

1 ANCHOR
Fits 8.5 / 9.0 mm screw
ORDER: TC-FA-8590

What is it?	A demineralized bone fiber implant to augment screw fixation.
What is it made of?	Demineralized bone fibers molded into a proprietary tapered shape with depression at top for screw insertion. 100% cortical bone, with no excipients. Produced in compliance with HCT/P regulations under Title 21 Code of Federal Regulations (CFR) Part 1271.
How can it be used?	The Fiber Anchor™ can be inserted into a cavity formed in bone prior to insertion of a screw for increased fixation in compromised bone or into the cavity left by a screw for revision surgery.
How does it work?	Enhances immediate fixation strength of screws in compromised bone or revisions. Osteoconductive with osteoinductive potential to stimulate bone formation for long term fixation.
What sizes are available?	Anchor to fit 5.5 / 6.0 mm screw Anchor to fit 6.5 / 7.0 mm screw Anchor to fit 7.5 / 8.0 mm screw Anchor to fit 8.5 / 9.0 mm screw
Patents	The implants and/or techniques associated with this product may be covered by one or more of the United States Patents: US 9,572,912 US 9,486,557 AUS 2014253753 Other patents pending

TO ORDER OR FOR MORE INFORMATION PLEASE CONTACT US AT - 630-953-9594

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