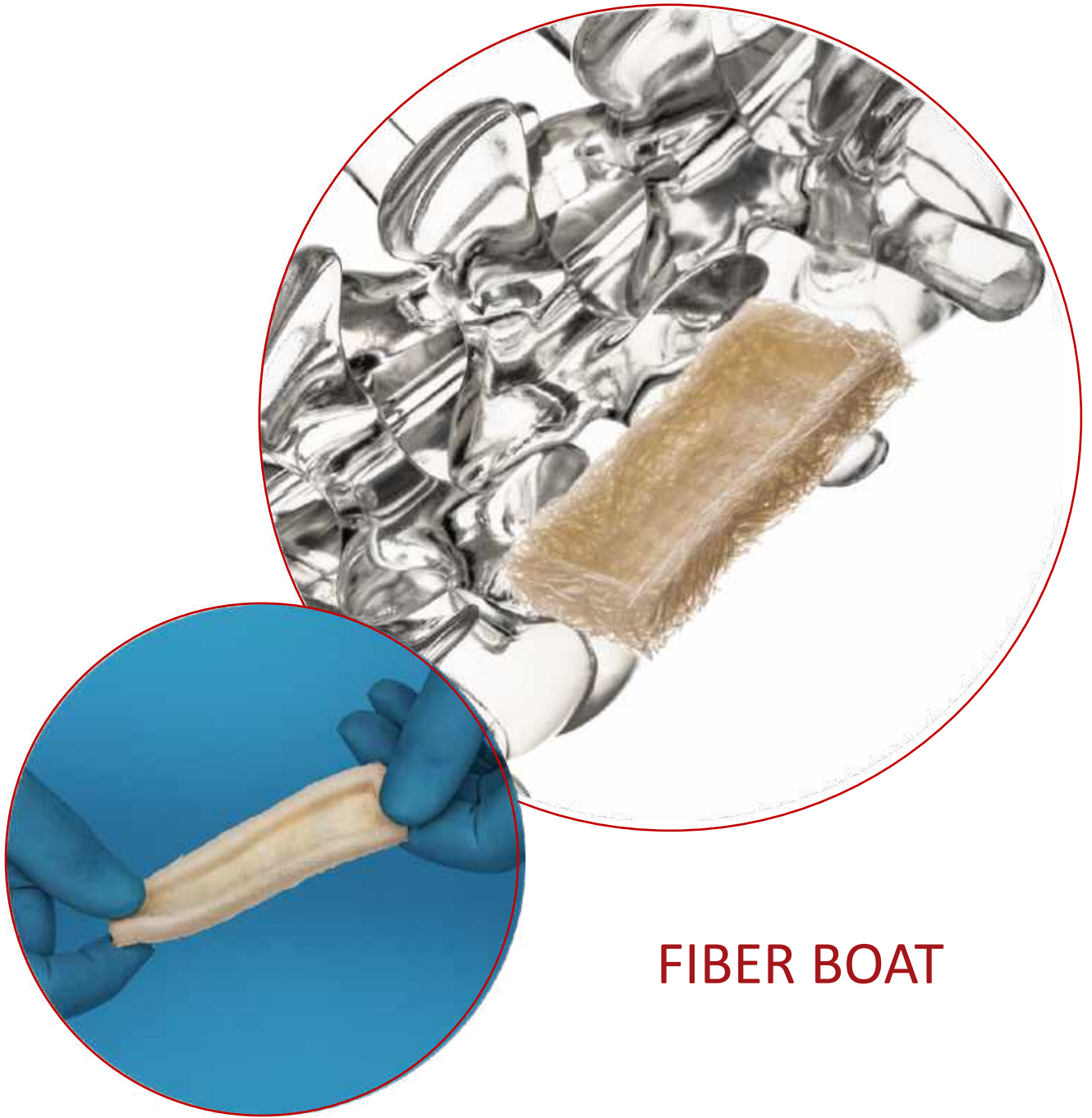


TheraCell



TheraFuze DBF®

FIBER BOAT™



FIBER BOAT

SM: 1-level • LG: 2-level • XL: 3-level

TheraFuze DBF®

THE CLINICAL NEED

- Morselized autograft and allograft can migrate away from the surgical site.
- Many of the currently available boats are too tall to fit easily into the posterolateral gutters.

THERACELL'S THERAFUZE DBF FIBER BOAT SOLUTION

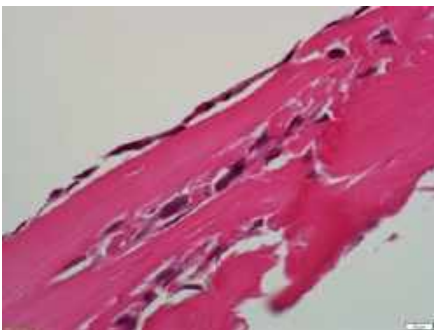
- Low-profile boats for posterolateral fusion with FormLok™ technology.
- FormLok™ technology allows the boat to maintain form and integrity when wet.
- The depression in the boat can be filled with autograft or additional allograft.
- Readily absorbs blood, BMA, or other fluids.

SURGICAL TECHNIQUE

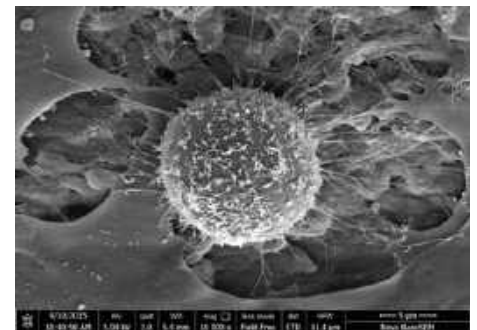
- Hydrate the Fiber Boat to provide flexibility.
- Fill the Fiber Boat with morselized autograft or other graft material.
 - Osteogenic potential is enhanced with autograft and BMA.
- Place the Fiber Boat into the defect ensuring that it completely spans and fills the site.

**PRECLINICAL EFFICACY**

TheraFuze DBF Fibers have been tested for osteoinductivity following the ASTM method for in vivo osteoinductive potential. TheraCell, in collaboration with the Surgical and Orthopaedic Research Laboratories at UNSW, have also examined cell attachment and biocompatibility properties of the unique nanotopography of the TheraFuze DBF Fibers.

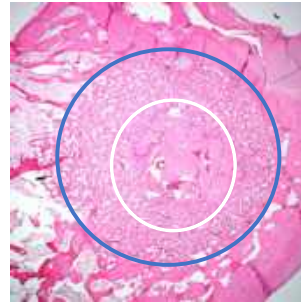
**Cell Attachment and Biocompatibility**

In an in-vitro study TheraFuze DBF Fiber was exposed to MG63 cells (an immortalized osteoblast-like cell line). After 3 days, the cells have migrated into the TheraFuze DBF Fibers, have attached and are migrating on and within the fibers (left). A scanning electron microscope image shows MG63 cells adhering to the surface of the TheraFuze DBF Fibers (right).

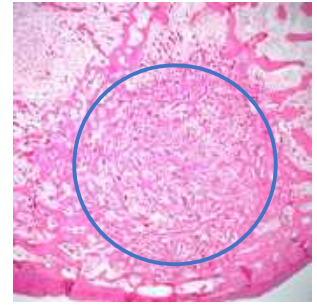


OSTEOGENIC POTENTIAL**Rabbit Distal Femoral Condyle Model**

The histology of a critical size defect (6mm diameter) at 2 weeks post-implant is shown in the first image to the right. The perimeter of the original defect is indicated by the blue circle. New woven bone formation that initiates at the margins of the defect has progressed through much of the defect, with residual DBF still seen at the center (within the white circle). The defect area is filled with new woven bone within four weeks (second image to the right).



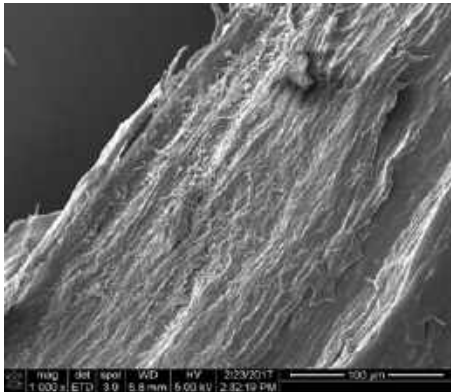
2 WEEKS



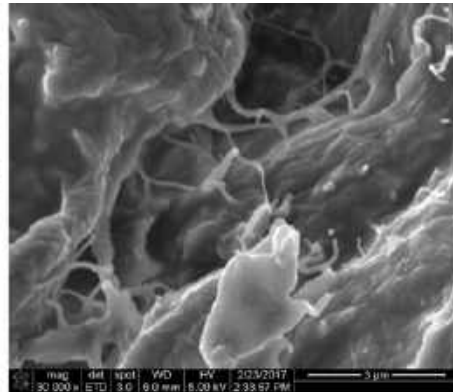
4 WEEKS

NANOTOPOGRAPHY

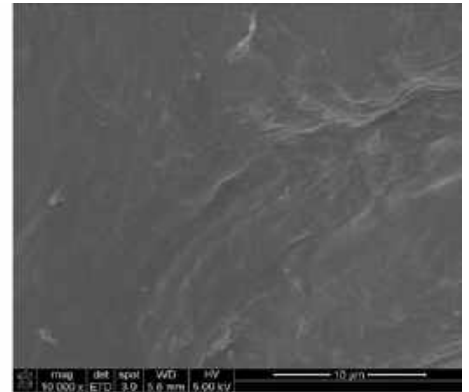
The topography of an implant's surface can influence cellular response. The surfaces of different demineralized allograft products are not the same and are dependent on processing techniques. The methods used to manufacture the TheraFuze DBF fibers are designed to maintain the collagen structure of bone and preserve osteoinductive proteins. This is achieved using patented processing technologies in which the mineral component of bone is removed prior to cleaving of the bone along the axis of the collagen orientation. These gentle procedures provide a surface topography that is not seen in conventional demineralized bone matrix products. The nanotopography of TheraFuze DBF Fibers is shown in the first two scanning electron micrograph images below. In contrast, the image on the right is of a conventional DBM particle and demonstrates the smoothed surface topography that results from acid treatment of the bone particles.



TheraFuze DBF Fiber (1,000x)



TheraFuze DBF Fiber (30,000x)



DBM Powder Particle (10,000x)

BONE TEXTILE[™] AND FORMLOK[™] TECHNOLOGY

The size and uniformity of our elongated TheraFuze DBF fibers form the basis of our Bone Textile platform. Utilizing specific and patent-protected processes, our Bone Textile platform provides 'controlled geometry' tissue engineered fibers. These fibers undergo additional non-woven process steps to produce novel 2D and 3D procedure-specific implants of various shapes for improved ease of use and to address common surgical needs.

It is important in some applications that the hydrated implant retain its shape and integrity to allow adequate time for manipulation and implantation by the surgeon. TheraCell's proprietary FormLok Technology imparts a degree of mechanical integrity to these product forms so that the implant shape and strength are maintained even when the fibers are wet. Products with FormLok Technology can be easily manipulated following rehydration. They can be bent, folded, even sutured without losing their original form. Additionally, the fiber entanglement that is maintained with the FormLok Technology provides ample porosity, which is necessary for cellular infiltration, bone healing and remodeling.

Demineralized Bone Fiber Form with FormLok[™] Technology for Posterolateral Fusion



ONE LEVEL BOAT
ORDER: P/N TC-FB-SM



TWO LEVEL BOAT
ORDER: P/N TC-FB-LG



THREE LEVEL BOAT
ORDER: P/N TC-FB-XL

What is it?	Demineralized bone fibers molded into a low-profile boat shape with FormLok technology.
What is it made of?	100% cortical bone, 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 lyophilized boat may be rehydrated with saline or the patient's blood or bone marrow. The depression in the Fiber Boat can be loaded with autograft and placed in the posterolateral gutters for one, two or three level fusions.
How does it work?	Osteoconductive with osteoinductive potential to stimulate long term bone formation. TheraCell's proprietary FormLok technology provides strength to the hydrated boat to allow it to be manipulated and placed in the intended surgical site.
What sizes are available?	SM: One level (5cm x 2.5cm) LG: Two level (10cm x 2.5cm) XL: Three level (15cm x 2.5cm)

TO ORDER OR FOR MORE INFORMATION PLEASE CONTACT US AT **1-630-953-9594**

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Other patents pending.

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