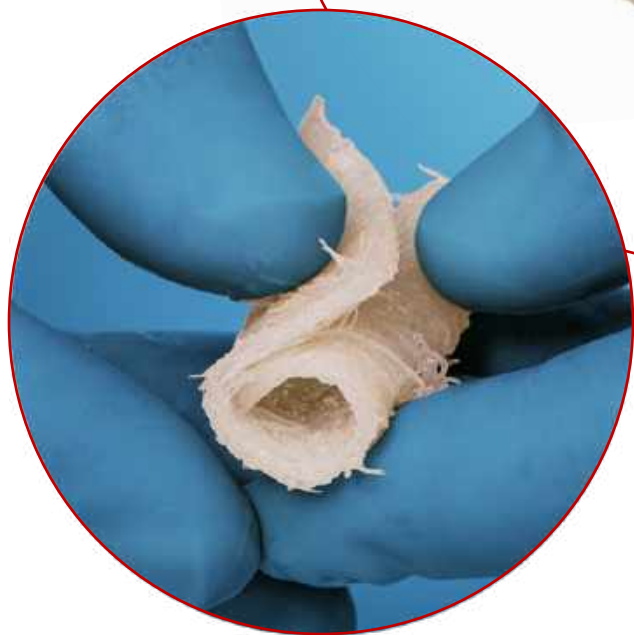


TheraCell



TheraFuze DBF[®]

FIBER WRAP[™]



FIBER WRAP

10cm x 11cm, 10cm x 5.5cm, 5cm x 5.5cm • 1mm thickness

TheraFuze DBF[®]

THE CLINICAL NEED

- Morselized autograft and allograft can migrate away from the surgical site.
- Many of the currently available delivery methods do not adequately contain added graft material.
- No options exist that are fully contained and 100% biologic in composition.

THERACELL'S THERAFUZE DBF FIBER WRAP SOLUTION

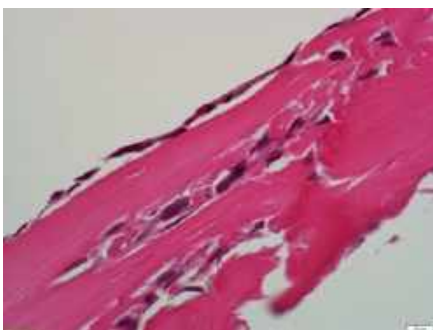
- Self-contained delivery mechanism that resists graft migration.
- FormLok[™] technology allows the wrap to maintain form and integrity when wet.
- Can be rolled up with autograft or additional allograft.
- Readily absorbs blood, BMA, or other fluids.

SURGICAL TECHNIQUE

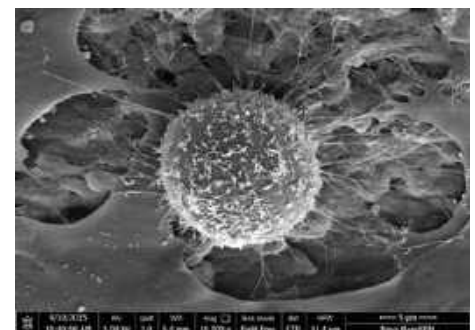
- Hydrate the Fiber Wrap to provide flexibility.
- Fill the Fiber Wrap with morselized autograft or other graft material.
 - Osteogenic potential is enhanced with autograft and BMA.
- Roll the Fiber Wrap to contain the added graft material.
- Place the Fiber Wrap into the defect ensuring that it completely 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.

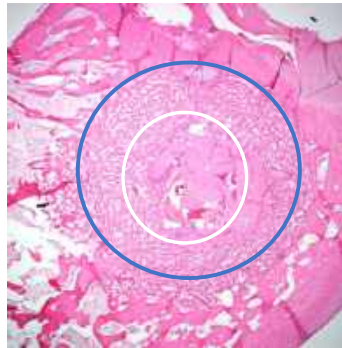
**Cell Attachment and Biocompatibility**

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).

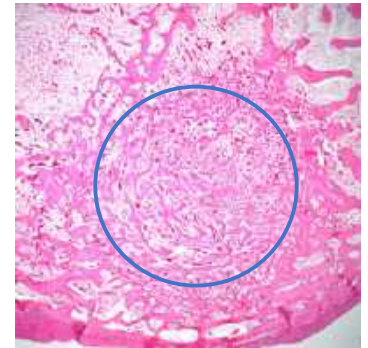


OSTEOGENIC POTENTIAL**Rabbit Distal Femoral Condyle Model**

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

POSTEROLATERAL FUSION MODEL

TheraFuze DBF fibers alone and TheraFuze DBF fibers combined with autograft were implanted at separate levels in a rabbit PLF study. The radiographs shown below demonstrate significant new bone formation with TheraFuze DBF fibers when used alone and when used as an autograft extender. An extensive and integrated network of new bone formation is evident at both levels in these 12 week results, which suggests remodeling and fusion at the implant sites.

**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 Sheet with FormLok[™] Technology for Graft Containment



10 cm X 11 cm X 1 mm
ORDER: P/N TC-FW-101101



10 cm X 5.5 cm X 1 mm
ORDER: P/N TC-FW-105501



5 cm X 5.5 cm X 1 mm
ORDER: P/N TC-FW-055501

What is it?	Demineralized bone fibers molded into a 1mm thick sheet 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 sheet may be rehydrated with saline or the patient's blood or bone marrow creating a flexible sheet that can be manipulated at the surgeon's discretion. For example: <ul style="list-style-type: none"> • As a versatile lower profile alternative to boats for PLF procedures. • Rolled up with autograft to make a "cigar" that can be laid in the posterolateral gutters for PLF. • Periosteum replacement in trauma applications to contain bone fragments / graft. • TJR (acetabular reconstruction). • As a bone bandage.
How does it work?	Osteoconductive with osteoinductive potential to stimulate long term bone formation. TheraCell's proprietary FormLok technology provides strength to the hydrated wrap to allow it to be manipulated and packed with additional graft materials.
What sizes are available?	10 cm x 11 cm x 1 mm 10 cm x 5.5 cm x 1 mm 5 cm x 5.5 cm x 1 mm

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

TheraCell, Inc.
14930 VENTURA BLVD., SUITE #325
SHERMAN OAKS, CA 91403

1-630-953-9594

www.theracellinc.com

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Other patents pending.

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