

TheraCell



TheraFuze DBF[®]

FIBER BAG[™]



FIBER BAG
THE BAG THAT IS A GRAFT[™]

5 cm Length, 10 cm Length • 12 mm Lumen

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 BAG SOLUTION

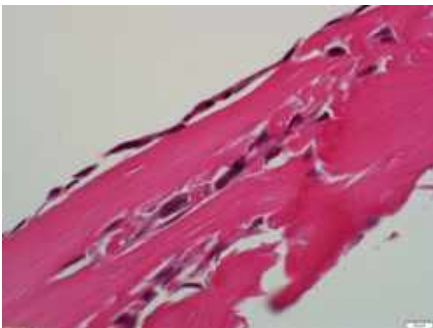
- The Bag That is a Graft – comprised of 100% demineralized cortical fibers.
- A new alternative to the traditional boat and plastic bag options.
- Self-contained delivery mechanism that resists graft migration.
- More efficient autograft management.
 - Can be easily packed with up to 5 cc (SM) or 10 cc (LG) of autograft or additional allograft.
 - Can be filled and then placed in the site to reduce manipulation within the graft site.
- Excellent porosity allows for communication with the decorticated site, cellular infiltration and vascular ingrowth.
- Readily absorbs blood, BMA, or other fluids.
- The solution to graft migration is to put it "In the Bag".

SURGICAL TECHNIQUE

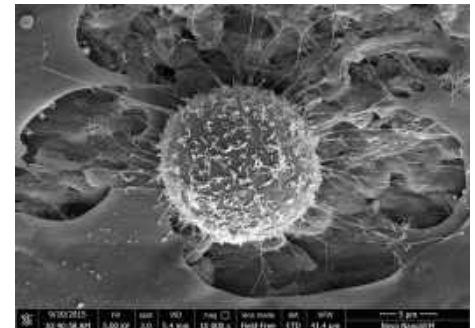
- Prepare the site by removing soft tissue and decorticating to bleeding bone.
- Prior to hydrating, fill the Fiber Bag with morselized autograft or other graft material.
 - Osteogenic potential is enhanced with autograft and BMA.
- Optionally hydrate the Fiber Bag prior to implantation or allow it to absorb fluids after implant.
- Place the Fiber Bag into the defect ensuring that it completely spans and fills the site.
 - Once hydrated, the Fiber Bag is malleable and easily conformable to the defect.

**CELL ATTACHMENT AND BIOCOMPATIBILITY**

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).



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.

**THE BAG THAT IS A GRAFT**

Small Fiber Bag is made of 6cc of TheraFuze DBF Fiber

Large Fiber Bag is made of 11cc of TheraFuze DBF Fiber

Demineralized Bone Fiber Bag for Graft Containment
Osteoconductive Demineralized Bone Fibers with Osteoinductive Potential



1-level – 5 cm length
ORDER: P/N TC-FBG-SM



2-level – 10 cm length
ORDER: P/N TC-FBG-LG

What is it?	A demineralized bone fiber implant for graft containment.
What is it made of?	Demineralized bone fibers molded into a proprietary cylindrical shape with one end open for loading of additional graft material. 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 Fiber Bag can be packed with autograft or additional allograft material and placed in the posterolateral gutters or a bone void or cavity. The hydrated Fiber Bag can be sutured for closure.
How does it work?	Osteoconductive with osteoinductive potential to stimulate long term bone formation. TheraCell's proprietary FormLok technology provides strength to the hydrated bag to allow it to be manipulated and packed with additional graft materials.
What sizes are available?	1-level: 5 cm (L) x 15 mm (OD) 2-level: 10 cm (L) x 15 mm (OD)

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

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US 9,572,912, US 9,486,557, US 10,639,157, US 10,987,224
Other patents pending.

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