EnFix™

DEMINERALIZED BONE FIBER IMPLANT FOR ENTHESIS REPAIR

EnFix RC™

EnFix TAC™

IT'S ALL ABOUT THE ENTHESIS™

TETROUS™

EnFix™

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Enthesis Failure Syndrome

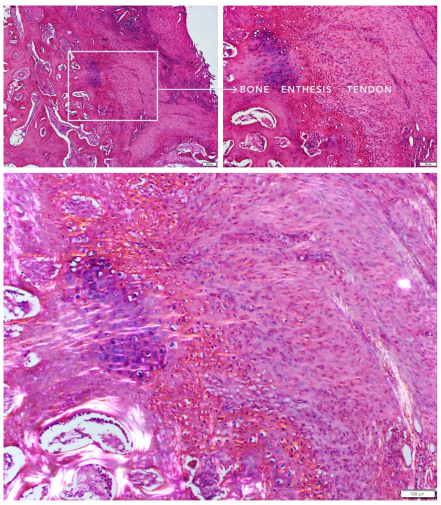
Lack of healing at the tendon bone interface is a common mode of failure in rotator cuff repair.

Rotator Cuff Repair

In the United States alone, nearly 500,000 rotator cuff repairs are performed annually and 20% to 70% of these repairs fail structurally. Inadequate tendon-to-bone ingrowth results in incomplete healing, gap formation and a higher risk of re-tear. Tendon reattachment is a crucial clinical need, especially in larger tears because failure rates increase linearly with tear size.

Most augmentation products have been designed as "overlays" to reinforce the tendon. EnFix RC and EnFix TAC change the paradigm by enhancing healing at the enthesis where failure often occurs. This enhanced biologic repair at the interface from the bone to the tendon is a significant advance. EnFix implants are produced using demineralized bone fiber (DBF) to provide optimal biologic performance while also easily integrating into current surgical techniques.

The images below demonstrate reformation of the enthesis at 12 weeks following treatment with EnFix RC in a pre-clinical sheep study.



H&E histology at 12 weeks under normal light (top left and right) for DBF treated enthesis revealed an active interface with some residual DBF and enthesis reformation. Polarized light (bottom) confirmed Sharpey's fibers in the DBF treated groups that were not present in the controls.

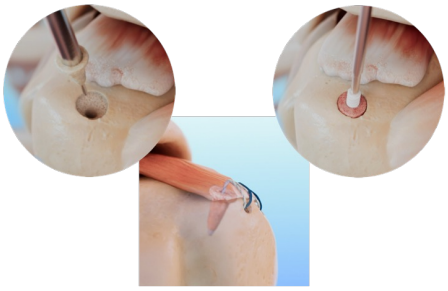
Surgical Technique

Preparing the Implant Site

- The EnFix products interface easily with existing surgical techniques
- Prepare implant site as usual
- Use an awl to make the insertion site

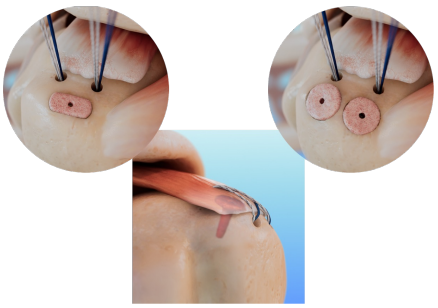
EnFix RC Surgical Technique

- Hydrate the implant in saline for 1 – 5 minutes
- Place device on introducer and insert the hydrated graft fully so the top of the device is flush with, or on the cortical surface
- Tap device to receive a suture anchor using suture anchor's tap
- Insert suture anchor
- Insert additional devices / suture anchors as required
- Complete repair in usual manner



EnFix TAC Surgical Technique

- Place device on introducer and insert the non-hydrated graft fully so the top of the device is flush with, or on the cortical surface
- Insert additional devices as required
- Complete repair in usual manner



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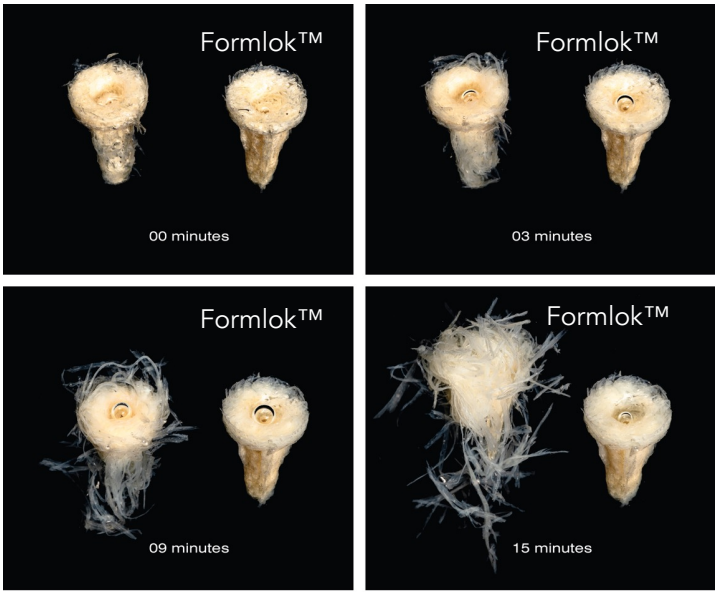
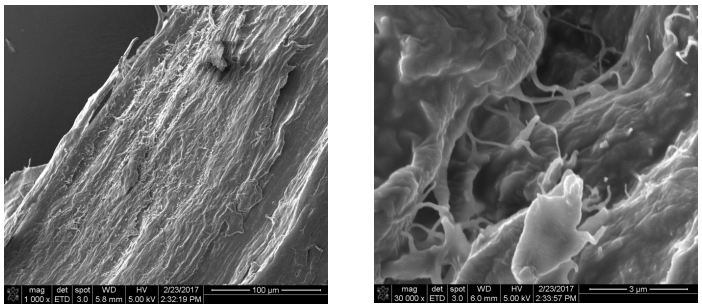
FormLok™ Technology

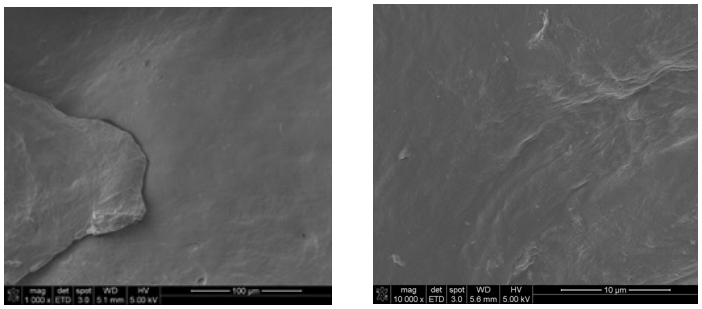
The EnFix family of implants uses DBF with FormLok to provide optimal biologic performance while also making it easy for the surgeon to use with no disruption to current surgical technique. The implants are 100% cortical bone and there are no excipients, so they conform with the regulations for minimally manipulated tissue. The DBF is molded into a "top hat" shape such that the shaft of the device sits in the awl hole used for suture anchor insertion and the top surface sits at the interface between bone and tendon. This allows cells and other factors to wick up from the subchondral bone to the top surface of the device that sits at the enthesis. The FormLok process imparts shape retention to the device, even when immersed in liquid, as is often required for use in arthroscopic surgery.

The figure below shows timelapse images of the devices with and without FormLok treatment. The immersed sample on the left rapidly loses its shape, while the FormLok treated device on the right is still stable, retaining its shape at 15 minutes, and beyond.





Tetrous DBF fibers at low and high magnification



Conventional DBM at the same magnifications

Nanotopography

Topography of a surface can influence cellular response. The process to manufacture the DBF fibers is designed to conserve the collagen structure of bone while preserving the inductive proteins (the BMPs). This is achieved by the proprietary process that demineralizes the bone and then makes the fibers by cleaving the bone along the axis of collagen orientation along the surfaces of the collagen fibrils. This gentle process provides a nanotopography that is not seen in conventional bone matrix products that are acid treated to demineralize the bone after particle or fiber formation.

The DBF fiber nanotopography of the Tetrous fibers is shown in the top images above. In contrast, the lower images shown above are of a conventional DBM particle where it can be seen that the acid treatment smooths the surface destroying its beneficial topography.

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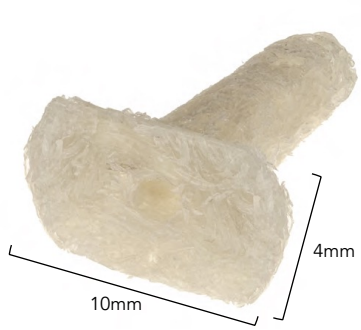
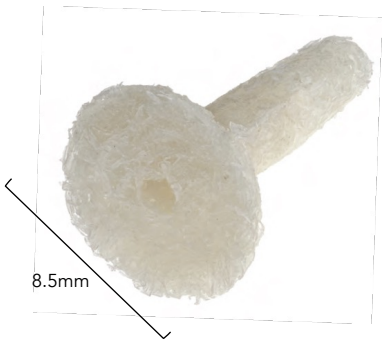
EnFix RC

Part Number	Size/Description
TET-RC-4515	For use with suture anchors 4.5mm to 5.5mm
TET-RC-5515	For use with suture anchors larger than 5.5mm



EnFix TAC-T

Part Number	Size/Description
TET-TAC-T	4mm x 10mm



EnFix TAC-O

Part Number	Size/Description
TET-TAC-O	8.5mm diameter

For use with all-suture anchor or independent of an anchor

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US 9,486,557, US 9,572,912, US 11,660,373, US 11,759,548
Other patents pending.
For more information, see www.tetrous.com/patents.

The Tetrous DBF technology and other processes are licensed exclusively from TheraCell, Inc., an ISTO Biologics company.

Part Number	Description	Size
MO-AWL-0650-A	Standard Awl	4.5mm/5.5mm
MO-AWL-0650-C	Cutting Awl	4.5mm
MO-AWL-0650-B	Cutting Awl	5.5mm
MO-PRB-0651-A	Introducer	
MO-TRA-0670	Instrument Tray	4 Instruments

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