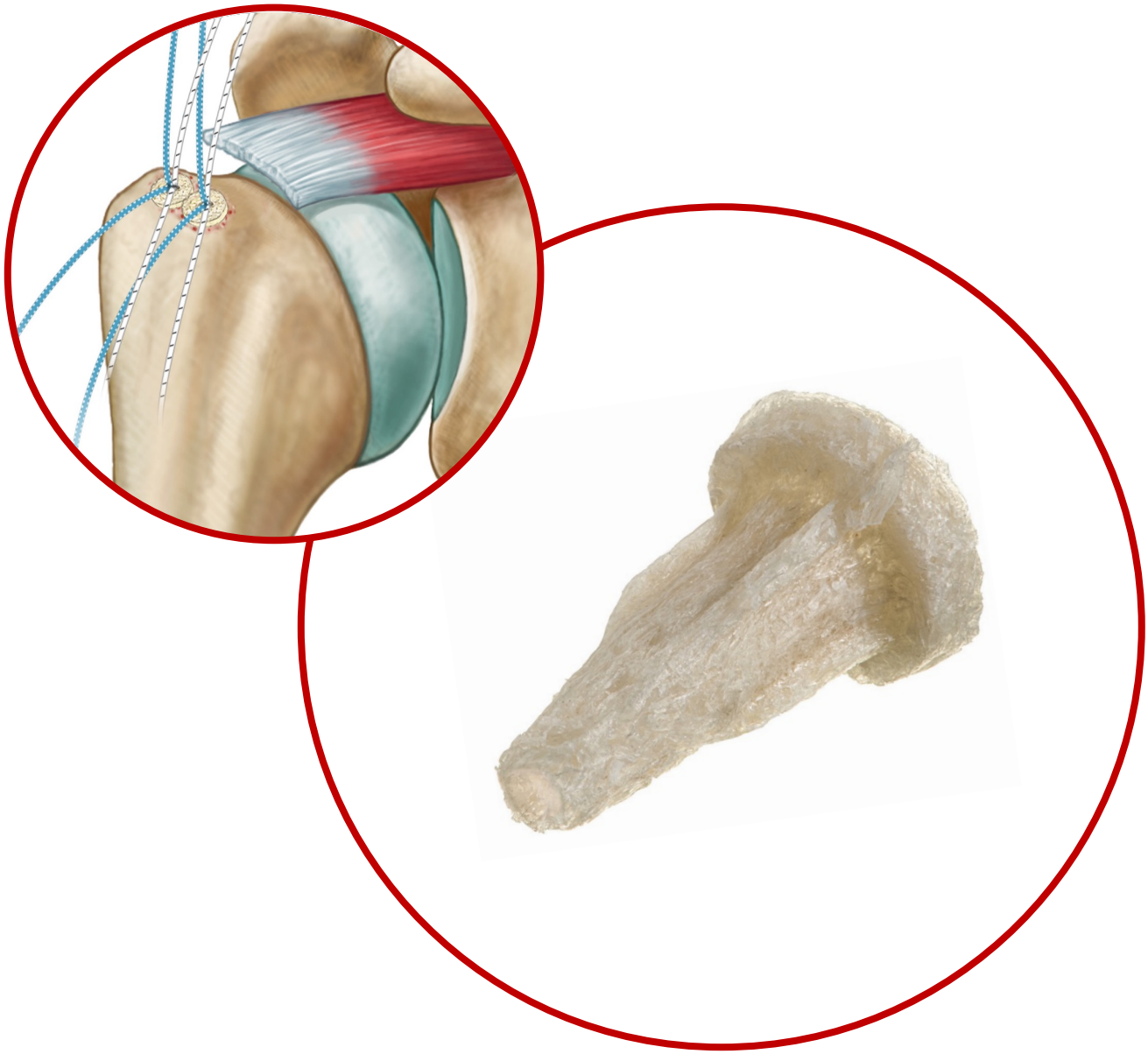
EnFix RC™

DEMINERALIZED BONE FIBER IMPLANT FOR ENTHESIS REPAIR



TETROUS™

P5011 Rev. 01

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Enthesis Failure Syndrome

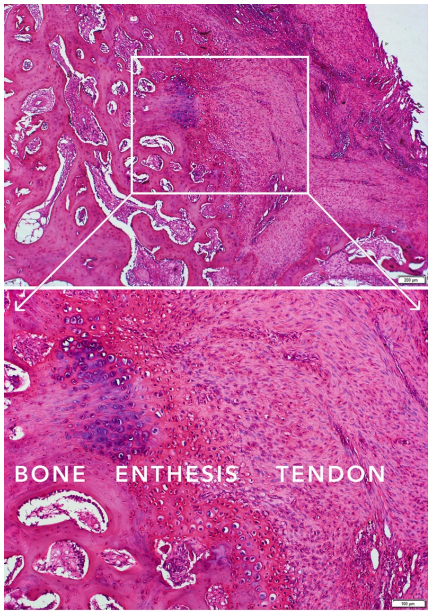
Lack of healing at the tendon bone interface is a common mode of failure in rotator cuff repair.

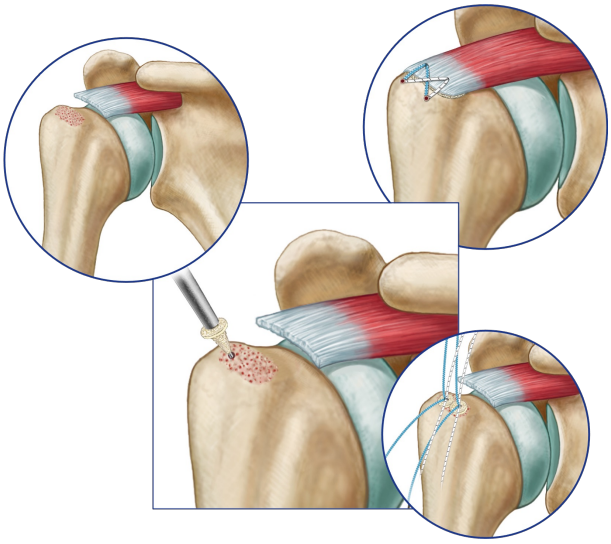
Rotator Cuff Repair

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 changes 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 RC is 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.





Surgical Technique

- EnFix RC interfaces easily with existing surgical techniques
- Prepare implant site as usual
- Use an awl to make the insertion site
- Place device on introducer and insert into the cavity produced by the awl
- 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

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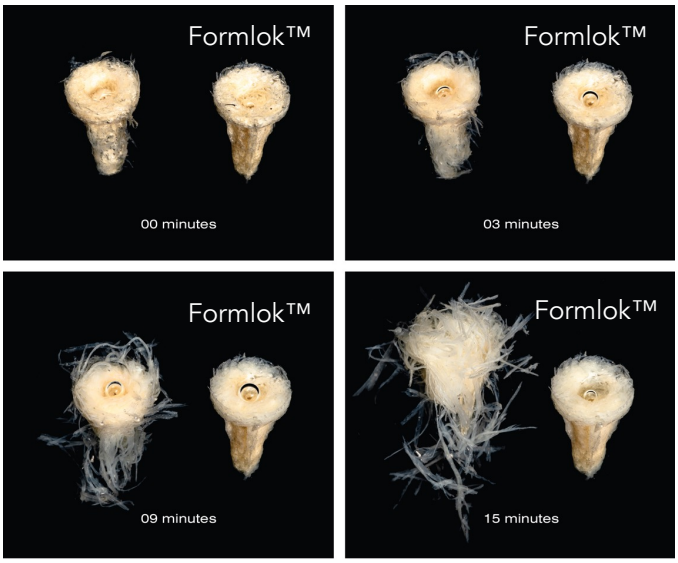
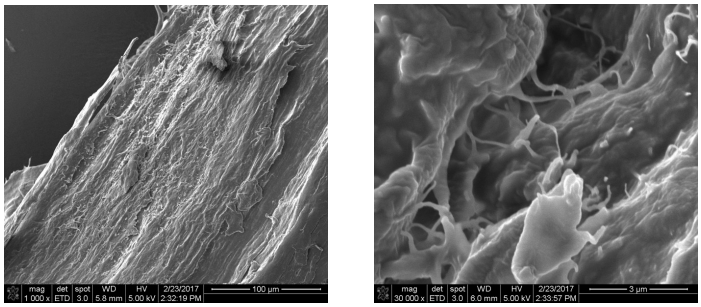
FormLok™ Technology

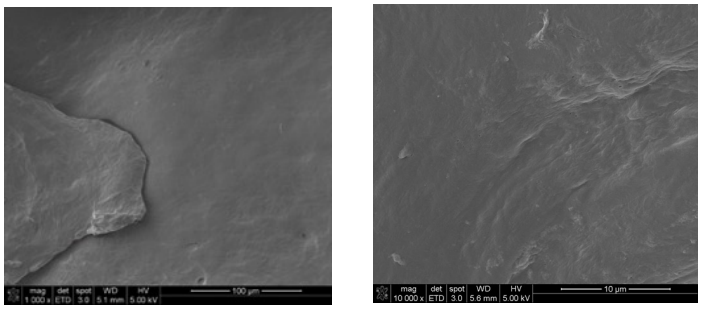
The EnFix RC implant uses DBF with FormLok to provide optimal biologic performance while also making it easy for the surgeon to use with no disruption to current surgical technique. There are two sizes of implant, one for use with suture anchors 4.5mm diameter and greater and one for suture anchors 5.5mm diameter and greater. The implant is 100% cortical bone and there are no excipients, so it conforms 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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Part Number	Description	Size
TET-RC-45	Enthesis Repair Implant	4.5mm
TET-RC-55	Enthesis Repair Implant	5.5mm

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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