

EnFix[®]

DEMINERALIZED BONE FIBER IMPLANT FOR ENTESIS REPAIR

SHOULDER

BONE TO TENDON AUGMENT FOR ENTESIS REPAIR



Rotator Cuff Repair
Biceps Tenodesis
Subscapularis Repair
Total Shoulder Arthroplasty

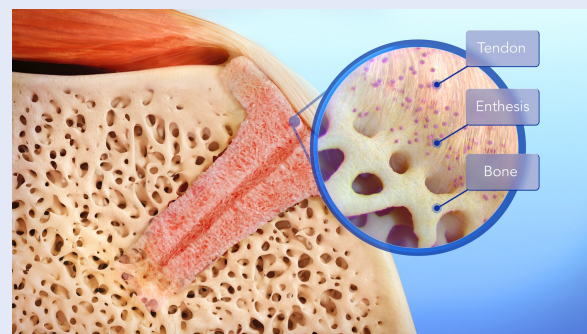


TETROUS[®]

IT'S NOT JUST ABOUT FIXATION. IT'S ABOUT RESTORING THE ENTHESES.

"This is the first thing that truly fixes the biology,
not just the mechanics."

- Kevin Setter, MD



THE CLINICAL CHALLENGE

The Repair is Only as Strong as the Interface

The native enthesis transitions gradually from tendon to fibrocartilage to bone. After repair, that architecture may be replaced by mechanically inferior scar tissue – leaving the bone-tendon interface as a persistent point of failure.

500K

ROTATOR CUFF SURGERIES
performed annually in the U.S.¹

20-94%

REPAIR FAILURE RATE
reported in the literature²

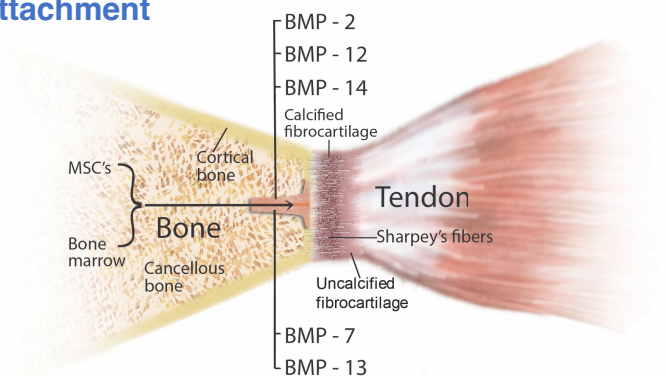
\$430M+

ESTIMATED U.S. COST
of failed repair in 2022³

A DIFFERENT BIOLOGIC STRATEGY

Support Reformation of a Functional Bone-to-Tendon Attachment

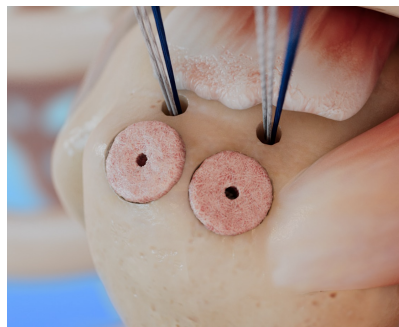
- ❑ **Endochondral Ossification:** EnFix is 100% demineralized bone fiber, which naturally contains BMPs and signaling molecules that promote organized tissue regeneration at the enthesis, rather than scar tissue.
- ❑ **Intraosseous Implantation:** EnFix is implanted within the bone at the bone-tendon interface, where healing begins.
- ❑ **Access to Bone Marrow:** The proprietary cannulated peg design facilitates migration of blood and marrow elements directly through the implant to the repair site.



ENFIX TAC®

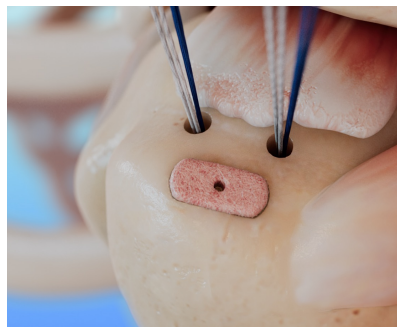
Independent Interpositional Placement

- ❑ **Placed in the Footprint:** EnFix TAC is implanted independent of the suture anchor, within the prepared footprint.
- ❑ **Flexibility of Footprint Coverage:** Select desired geometry based on tear size, anatomy and available footprint.



TAC-O

8.5 mm diameter, 13 mm peg



TAC-T

4 x 10 mm. 13 mm peg

Also Available – EnFix RC®

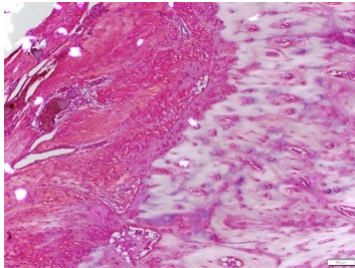


- ❑ Designed for use with threaded anchors from 4.5 – 6.5 mm.
- ❑ Implanted in the awl hole and secured with an anchor.
- ❑ Increases suture anchor fixation strength.⁴

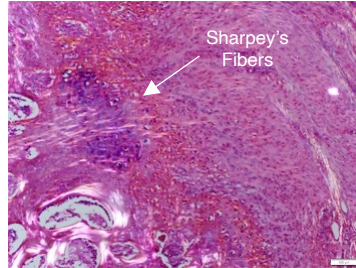
PRECLINICAL SUPPORT

Outcome: Biologic Enthesis Reformation

Histological evaluation at 12 weeks in a sheep model.⁴



Control



EnFix DBF

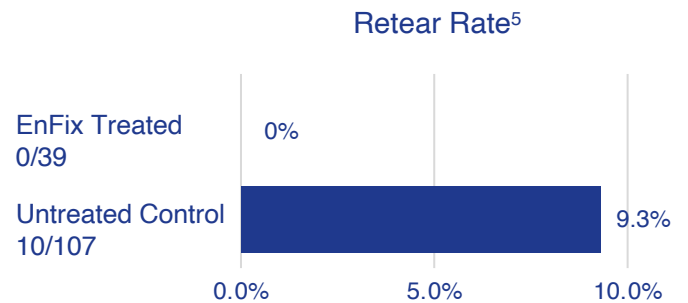
Control lacks evidence of healing at the bone-tendon interface, generating only scar tissue.

Sharpey's fibers are evident in the EnFix treated sample, indicating enthesis reformation.

CONSISTENT LONG-TERM CLINICAL OUTCOMES

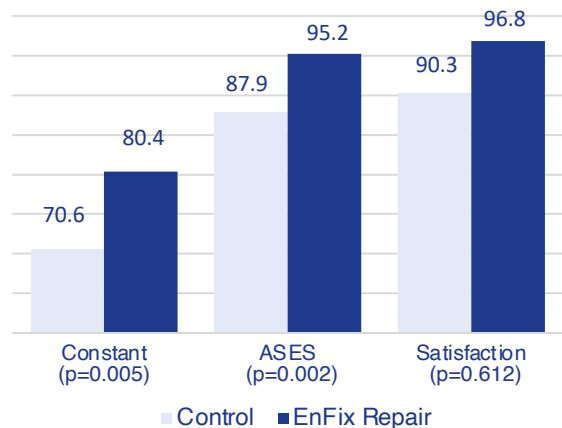
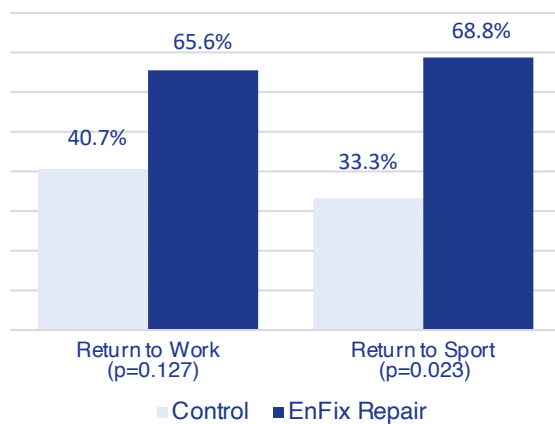
Reduced Retear Rates

- 146 Patients
- Exclusion Criteria
 - Isolated subscapularis tear
 - Partial or full thickness tear smaller than 1 cm
 - Full thickness tear larger than 3 cm
- Retears assessed by MRI at 6 and 12 weeks
- Repair integrity assessed by MRI at 12 months



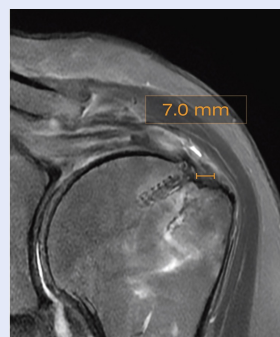
Patients Return to Activity Faster

- 31 Patients in each group
- Complete return to work/sport at 6 months
- Patient Reported Outcomes (PROMs) at 6 months - All statistically significantly better⁵

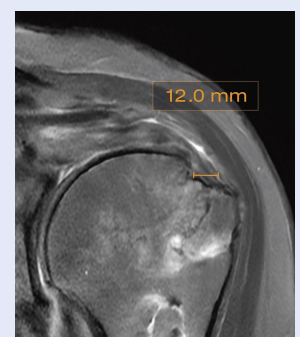


Clear Bone-to-Tendon Integration

- High quality coverage of the greater tuberosity footprint
- Similar in morphology to a native enthesis
- No evidence of edema, cystic change or adverse tissue reaction



3 month Post-Op



6 month Post-Op

IT'S ALL ABOUT THE ENTHESESIS®

100% DEMINERALIZED CORTICAL BONE FIBERS



EnFix TAC®-O



EnFix TAC®-T



EnFix RC®

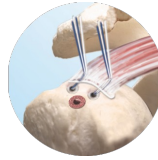
Cannulated for easy implantation
Intraosseous implantation
Accesses marrow space to wick up cells and blood components

SIMPLE, REPRODUCIBLE TECHNIQUE

EnFix TAC-O Repair



1. Make insertion hole
below medial row



2. Insert EnFix graft



3. Prepare lateral row



4. Complete repair

For more detailed information, please reference Instructions for Use (IFU), Surgical Technique Guides (STG) and White Paper.

PRODUCT PORTFOLIO

Part Number	Description	Size
TET-TAC-T	EnFix TAC-T	4mm x 10mm surface
TET-TAC-O	EnFix TAC-O	8.5mm surface (diameter)
TET-TAC-O-2	EnFix TAC-O 2 Pack	8.5mm surface (diameter), 2 per package
TET-RC-4515	EnFix RC	For use with 4.5mm – 5.5mm anchors
TET-RC-5515	EnFix RC	For use with 5.5mm or larger anchors

REFERENCES

¹ iData 2018

² Anthony Ratcliffe et al., "Scaffolds for Tendon and Ligament Repair and Regeneration," *Annals of Biomedical Engineering* 43, no. 3 (2015): 819–31, <https://doi.org/10.1007/s10439-015-1263-1>.

³ Bradley L. Young et al., "Healthcare Costs of Failed Rotator Cuff Repairs," *JSES Reviews, Reports, and Techniques* 3, no. 3 (2023): 318–23, <https://doi.org/10.1016/j.xrrt.2023.03.008>.

⁴ Andrew Carter et al., "Rotator Cuff Healing Using Demineralised Bone Fibers in Ovine Infraspinatus Tendon Models", AOSSM 2023, Poster 105.

⁵ Tetrus, Inc., data on file

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Other patents pending.

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