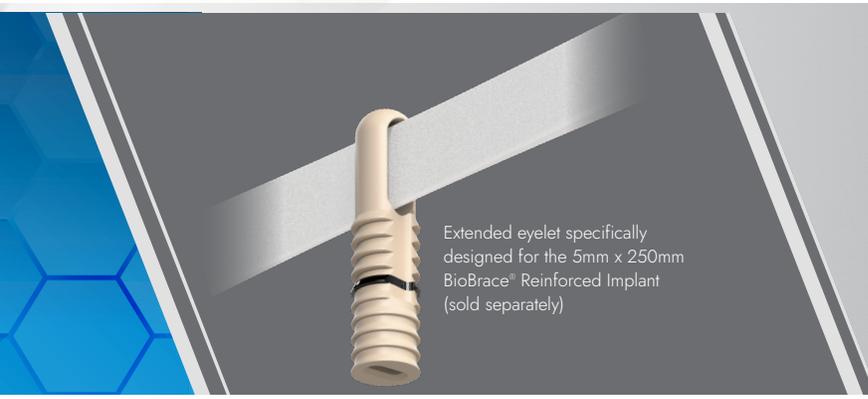




Hercules[®] XE

Extended Eyelet Knotless Anchor
for BioBrace[®]



Extended eyelet specifically designed for the 5mm x 250mm BioBrace[®] Reinforced Implant (sold separately)

SURGICAL TECHNIQUE



Hercules® XE

Extended Eyelet Knotless Anchor for BioBrace®

Product Information

Product Description

The Hercules® XE Knotless Anchor System provides a radiolucent PEEK implant for use in a range of soft tissue fixation applications. The extended eyelet (XE) allows for use with BioBrace® 5 x 250mm, which is a biocomposite soft tissue scaffold intended for use in a range of surgical procedures to reinforce soft tissue where weakness exists.

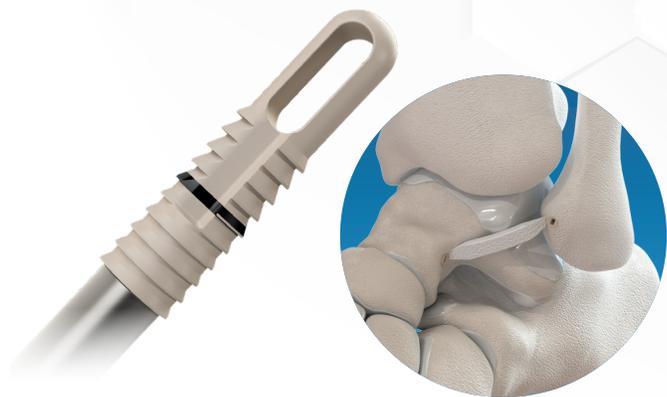
The BioBrace® Reinforced Implant is sold separately.

Important: BioBrace® is not intended to be a standalone construct, but an augment to other tissue/ligament repair procedures.

Indications

The Hercules® Knotless XE Anchors with BioBrace® are intended for use in the following applications for:

- **Shoulder:** Rotator Cuff, Bankart and SLAP lesion repair, Biceps tenodesis, Acromio-Clavicular separation and Deltoid Repair, Capsular shift and Capsulolabral reconstruction
- **Foot and Ankle:** Lateral and medial ankle instability, Achilles tendon and Metatarsal ligament repair, Hallux Valgus and Midfoot reconstruction
- **Knee:** Medial collateral and Lateral collateral ligament repair, Patellar tendon, and Posterior oblique ligament repair
- **Hand/Wrist:** Scapholunate ligament, Radial collateral ligament and Ulnar collateral ligament reconstruction
- **Elbow:** Biceps tendon reattachment, Tennis elbow repair, Ulnar and Radial collateral ligament reconstruction.



Contraindications

General contraindications for the use of these implants for joint reconstruction include:

- Significant bone demineralization
- Inadequate neurovascular status
- Poor blood supply, which may impair the healing process
- Inadequate skin or musculotendinous system
- Physiologically or psychologically unsuitable patient
- Surgical procedures other than those indicated
- Possibility for conservative treatment
- Bone, musculature, tendons, or adjacent soft tissue compromised by disease, infection, or prior implantation, which cannot provide adequate support or fixation for the prosthesis.
- Known allergies
- Diabetes
- Active infection to materials
- Patients with high level of activity
- Pathological conditions of the soft tissue which would compromise secure fixation

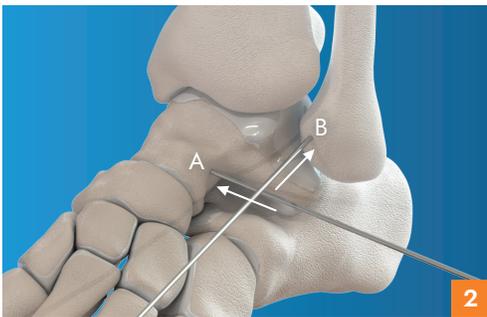
Hercules[®] XE Extended Eyelet Knotless Anchor for BioBrace[®]

Surgical Technique | ATFL Repair



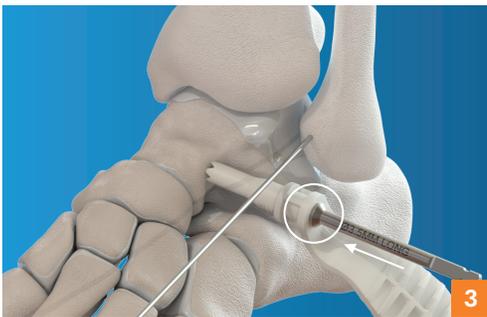
Site Preparation

Expose and prepare the site following standard procedures (**Figure 1**), using available equipment and instrumentation, per surgeon discretion and expertise. Implantation of the Hercules[®] XE Knotless Anchors with BioBrace[®] should be performed as an augment to tissue/ligament repair procedures. Identify good quality bone for effective Anchor placement and determine appropriate Anchor size and corresponding Instrument Kit for the indicated area.



Insert Guide Wires

Insert the first Guide Wire (Ø.062mm x 9" length) perpendicular to the bone surface into the talus (**A**) at the insertion point of the anterior talofibular ligament (ATFL). Then insert the second Guide Wire into the fibula (**B**) at the origin of the ATFL (**Figure 2**).



Create Pilot Holes

Starting with the talus, place the Cannulated Drill and Drill Guide over the Guide Wire (**Figure 3**). Advance the Drill until the drill stop reaches the Guide, then remove the Drill and Guide Wire.

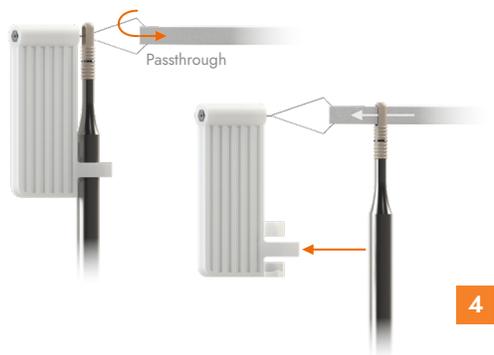
Repeat for the fibula.

Note: The Guide Wires may be left in the site for reference until ready to insert the Anchors, so that the pilot holes are not mislocated.

Where softer bone quality is present, the Drill contained in the Hercules[®] 4.5mm Fully Threaded Anchor Instrument Kit (A02 S0004) can be used as the primary drill for the 3.5mm Hercules[®] XE Knotless Anchor.

Hercules[®] XE Extended Eyelet Knotless Anchor for BioBrace[®]

Surgical Technique | ATFL Repair

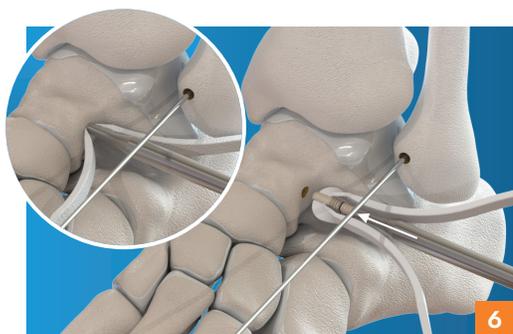


Thread BioBrace[®] into the Anchor

Using the Suture Threader attached to the Driver assembly, pass the BioBrace[®] Reinforced Implant through the extended eyelet of the Hercules[®] Knotless XE Anchor and pull the Suture Threader through the eyelet until one end of BioBrace[®] is made available opposite the point of entry (**Figure 4**).

Alternative Method:

If needed, cut the end(s) of BioBrace[®] to a shallow taper. With the Anchor loaded onto the driver, thread the tapered end of BioBrace[®] manually through the eyelet of the Anchor and grab with fingertips or forceps on the opposite side of the eyelet and pull through (**Figure 5**).



Talus Anchor Insertion

Ensure that only a portion of the BioBrace[®] material is pulled through the eyelet of the initial Anchor for the Talus, allowing the majority of the material to remain available for placement in the fibula. Using the Driver assembly, insert the Knotless Anchor into the talus through the prepared hole and advance the Anchor with a mallet until fully seated and flush to the bone surface. Pull the Driver away from the Anchor to disengage (**Figure 6**).

Note: *Do not apply clockwise quarter turn for use with BioBrace[®].*

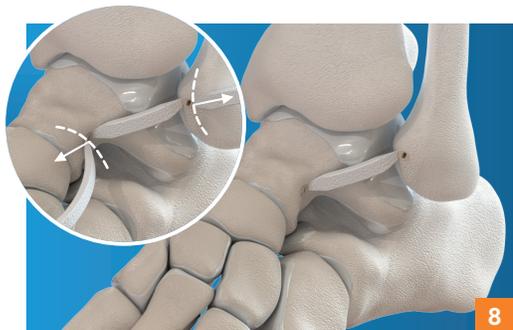


Fibula Anchor Insertion

Using the longer, loose tail, thread a second Anchor with the BioBrace[®] and manually tension the BioBrace[®], via surgeon-preferred method, prior to final seating of the second Anchor (**Figure 7**). Trim away any excess BioBrace[®] (**Figure 8**).

Close the Site

Close the site via surgeon-preferred method.



Hercules® XE

Extended Eyelet Knotless Anchor for BioBrace®

Hercules® XE Knotless Anchor *Implant Kits*



DESCRIPTION

Hercules® XE Knotless Anchor, 3.5mm - Sterile
Hercules® XE Knotless Anchor, 4.5mm - Sterile
Hercules® Knotless Anchor, 5.5mm - Sterile

CATALOG NO.

A40 SP135
A40 SP145
A40 SP055

Hercules® XE Knotless Anchor *Instrument Kits*



DESCRIPTION

Hercules® XE Knotless Instrument Kit, Size 3.5mm
Hercules® XE Knotless Instrument Kit, Size 4.5mm, 4.7mm Drill
Hercules® Fully Threaded Anchor Instrument Kit, 4.5mm - Sterile
Hercules® Knotless Anchor Instrument Kit, 5.5mm - Sterile

CATALOG NO.

A04 S0135
A04 S0147
A02 S0004
A04 S0055

Guide Wire Kit



DESCRIPTION

Guide Wires (2), S. Trocar, Smooth, .062" x 9", Sterile, Single-Use

CATALOG NO.

PO6 S2301



5mm x 250mm



23mm x 30mm



40mm x 60mm

BioBrace® FA Reinforced Implants (Sold Separately)

DESCRIPTION

BioBrace® FA 5mm x 250mm
BioBrace® FA 23mm x 30mm
BioBrace® FA 40mm x 60mm

CATALOG NO.

BB5X250-FA
BB23X30-FA
BB40X60-FA



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