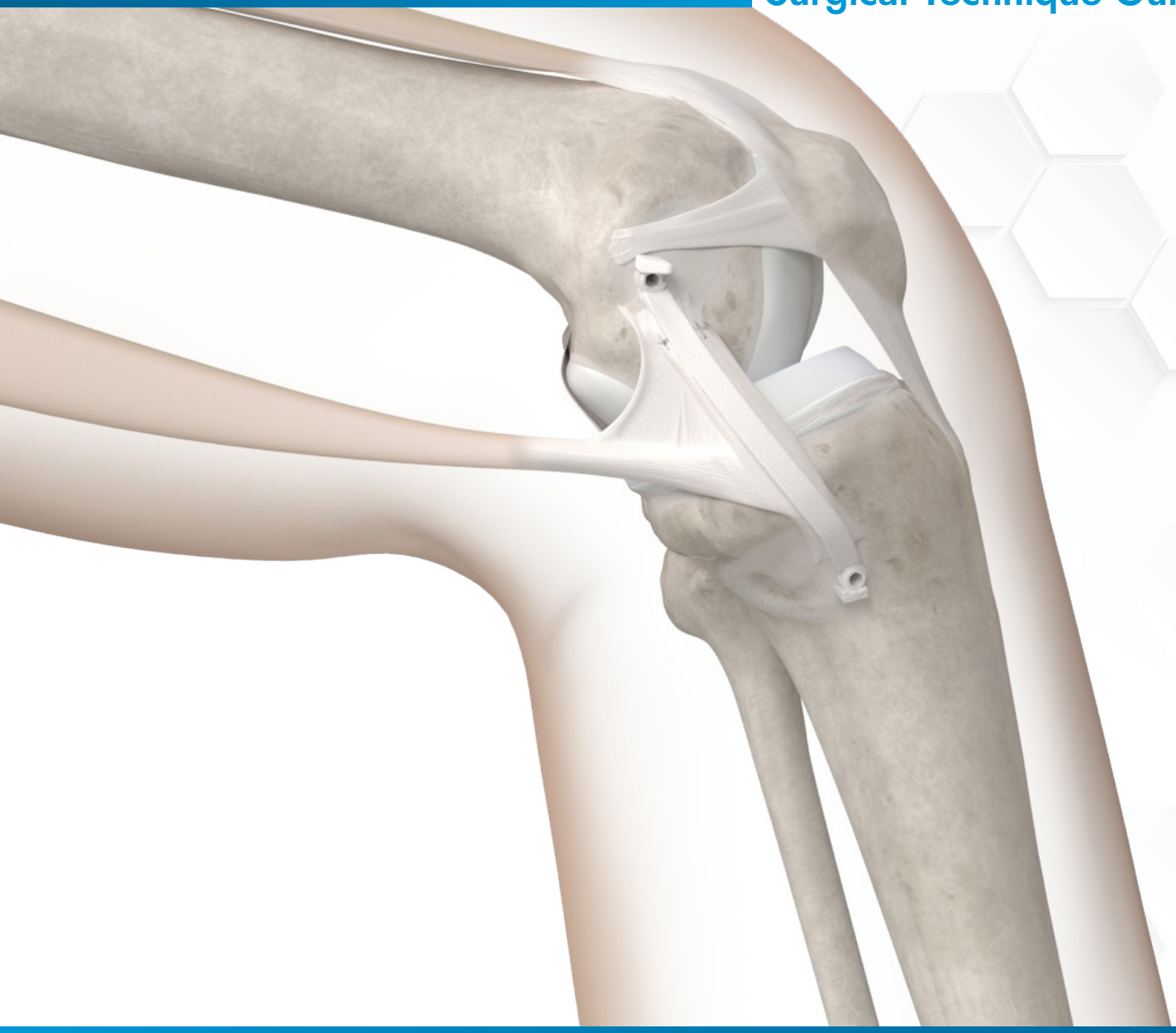
ConMed

MCL Repair Augmentation Using

BioBrace® Extra-Articular Ligament Augmentation Kit

Surgical Technique Guide



Technique Preface

The BioBrace® Reinforced Bioinductive Implant is a novel reinforced bioinductive implant[1]. It consists of a highly porous collagen matrix reinforced with resorbable PLLA microfilaments used to reinforce tendon and ligament repairs and improve healing[1].

The BioBrace® Extra-Articular Ligament Augmentation Kit is intended to reattach soft tissue to bone and reinforce soft tissue where weakness exists in extra-articular knee ligament surgical procedures. The kit offers advanced products to streamline a strong repair, kitted sterile and ready to go.

The following outlines a simple and efficient technique to repair and augment a medial collateral ligament (MCL) using the BioBrace® Extra-Articular Ligament Augmentation Kit.

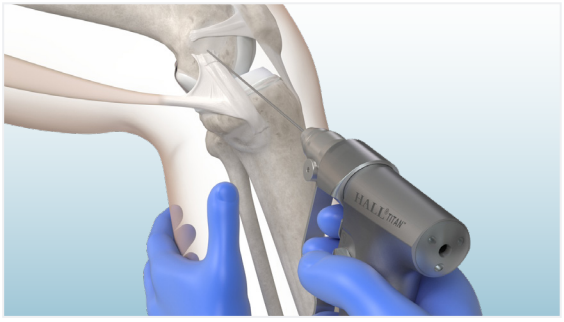
Procedural Recommendations

- The BioBrace® implant does not need to be hydrated prior to use. However, it can hold up to 5cc of fluid if surgeon prefers.
- Prepare a separate, free needle to execute the soft-tissue repair.
- The included instrumentation is sized specifically for interference fixation of the BioBrace® implant with the 4.75mm Argo Knotless® GENESYS™ Anchor.

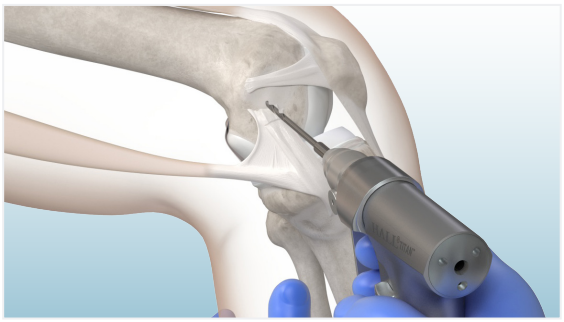
MCL Repair and Augmentation Using the **BioBrace® Extra-Articular Ligament Augmentation Kit**

Prior to completing augmentation with the BioBrace® implant, the MCL tear should be repaired. This can be done with the stay suture within the Argo Knotless® GENESYS™ Anchor. These steps will detail a percutaneous repair/augmentation for a femoral-based MCL tear; however the same technique can be applied to all insertional tears. Additionally, an open or mini-open approach can also be used if preferred.

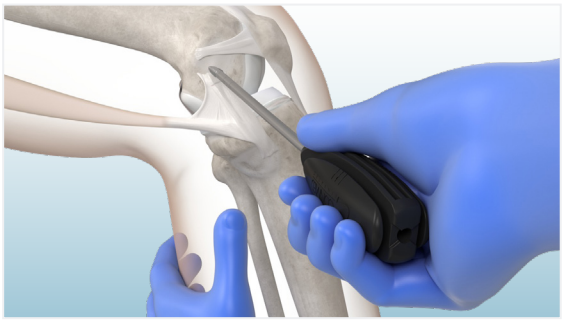
To begin, identify landmarks on the medial condyle and posteromedial crest of the tibia with the knee in neutral position. Make a small incision at the femoral superficial MCL attachment site, and another at the tibial superficial MCL attachment site.



Insert the 2.4mm High Strength Guide Pin at the femoral fixation site.

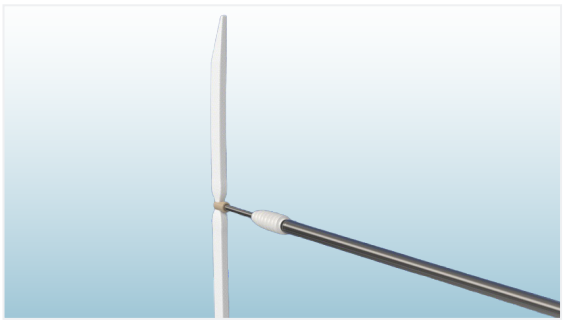


Drill the cannulated 5.0mm Constant Diameter Reamer over the guide pin to a depth of 25mm.

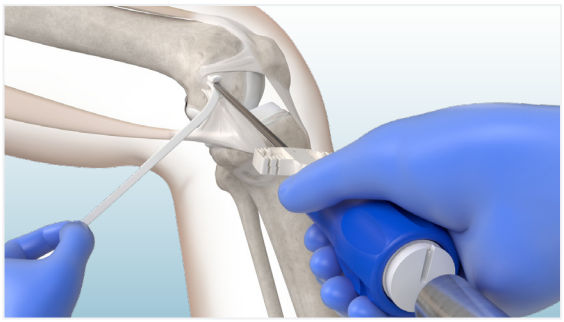


Tap the drill site using the hard bone tap until flush with bone. Ensure the pilot hole is clean to avoid any impedance to the implant.

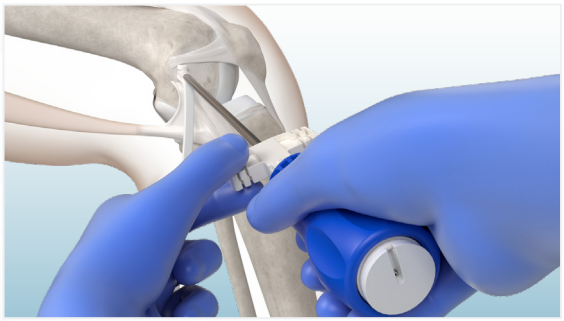
Pass one tapered end of the 5x250mm BioBrace® implant through the eyelet of an Argo Knotless® GENESYS™ Anchor, ensuring at least 35mm of the implant is pulled through the eyelet.



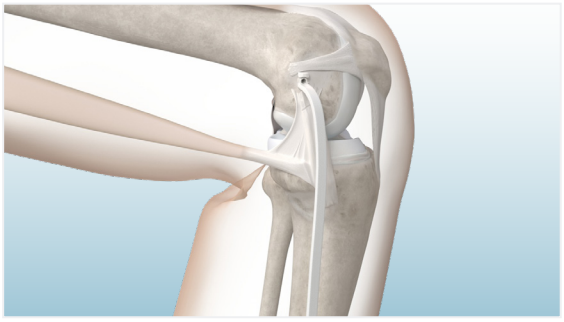
Tip: The BioBrace® implant comes pre-tapered and can be manually further angled/feathered to facilitate easier threading through the anchor eyelet. The nitinol anchor threader can also be used to pass the tip of the BioBrace® implant through the eyelet.



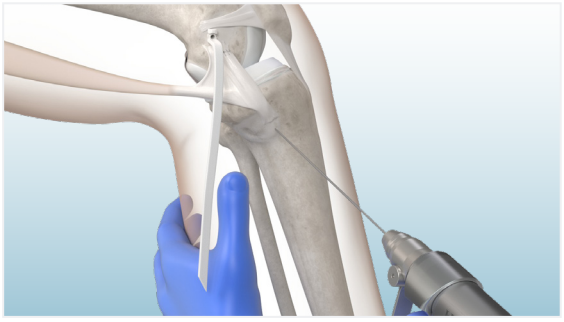
Insert the anchor tip with the BioBrace® implant into the femoral pilot hole, and mallet the device until the laser line on the center shaft is below the bone surface- be sure to avoid lateral loading.



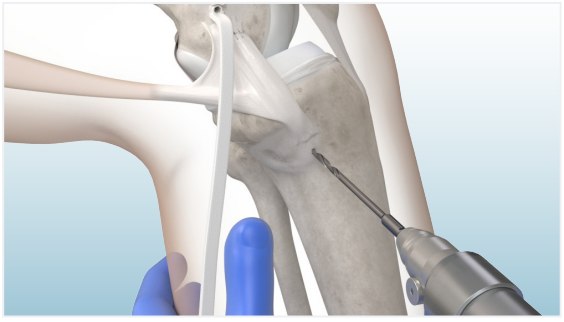
While holding the suture cleat, rotate the handle to insert the threaded anchor until the proximal laser line behind the screw is flush with the bone surface.



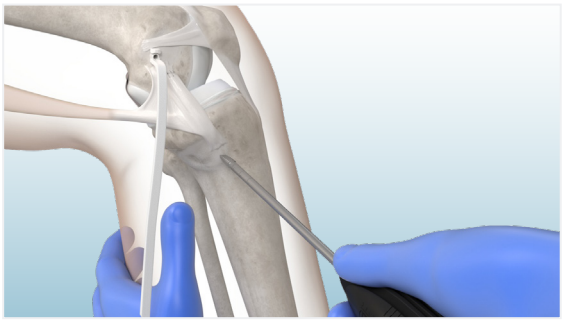
The #2 suture preloaded in the anchor can then be used to repair the MCL tear with a free needle. You can now turn your attention to the tibia for socket preparation.



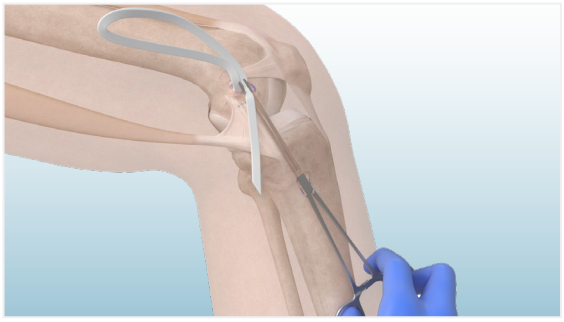
At the tibial site, drill the second 2.4mm High Strength Guide Pin into bone.



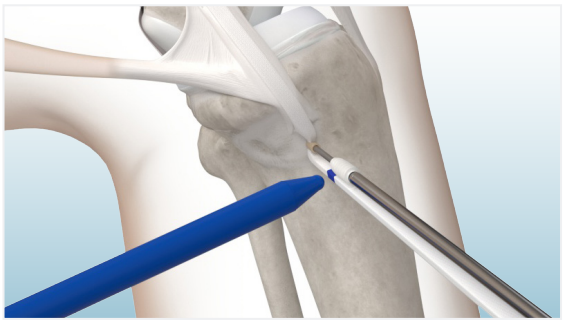
Use the cannulated 5.0mm Constant Diameter Reamer to drill over the guide pin to a depth of 25mm.



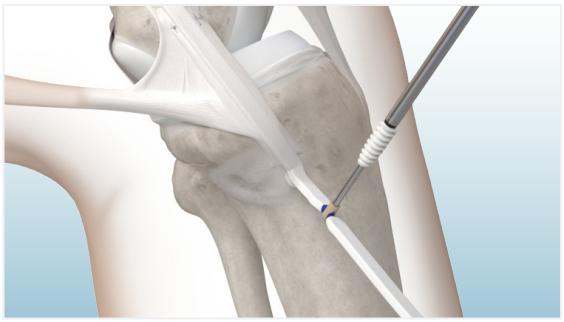
Tap the drilled tibial socket until the hard bone tap is flush with bone.



Shuttle the BioBrace® implant from the proximal incision to the distal incision using tonsil forceps through the soft-tissue route. Pass the free end of theBioBrace® implant through the eyelet of the second anchor.



Place the knee in 30 degrees of flexion with varus stress while inserting the tip of the second anchor into the tibial pilot hole. Appropriately tension the BioBrace® implant equal to the underlying tissue by marking the depth of the laser line and placing the eyelet at that point.



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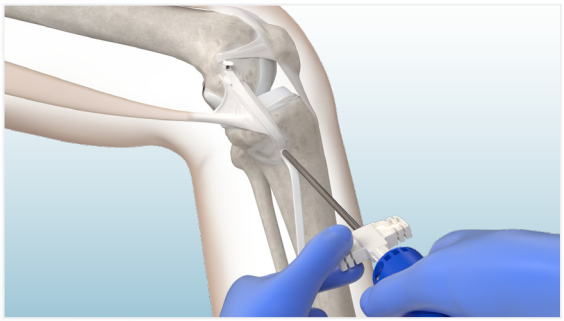
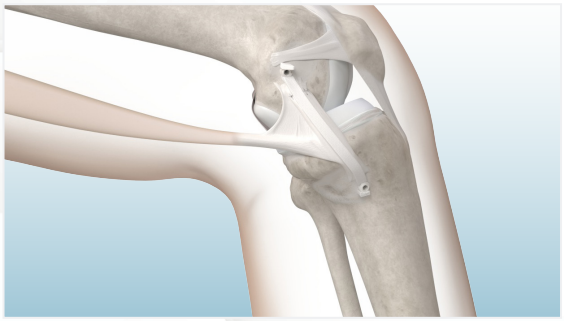


Tip: Place the eyelet with BioBrace® implant over the pilot hole. Using the excess BioBrace® implant length, mark the distance from the eyelet to the laser line on the Argo GENESYS™ anchor driver. Migrate the eyelet to the new mark, and push the anchor into the site. If satisfied with tension, deploy the anchor.



All sutures can then be cut and excess the BioBrace® implant trimmed before closing the incisions according to surgical preference.

BioBrace® Extra-Articular Ligament Augmentation Kit

Ordering Information

Description	Catalog Number
BioBrace® Extra-Articular Ligament Augmentation Kit	BBXA
– BioBrace® Reinforced Implant 5mmx250mm	
– Constant Diameter Reamer (5.0mm x 178.0mm, cannulated)	
– High Strength Guide Pins (9.0" x 2.4mm) X2	
– 5.5mm Argo Knotless® GENESYS™ Tap	
– Tap4.75mm Argo Knotless® GENESYS™ Anchors with #2 Hi-Fi Suture X2	

Resources: [1]K252946 – 510(k) Clearance Letter - BioBrace® Extra-Articular Ligament Augmentation Kit

Strengthened Augmentation. Enhanced Healing.

BioBrace®
Extra-Articular

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