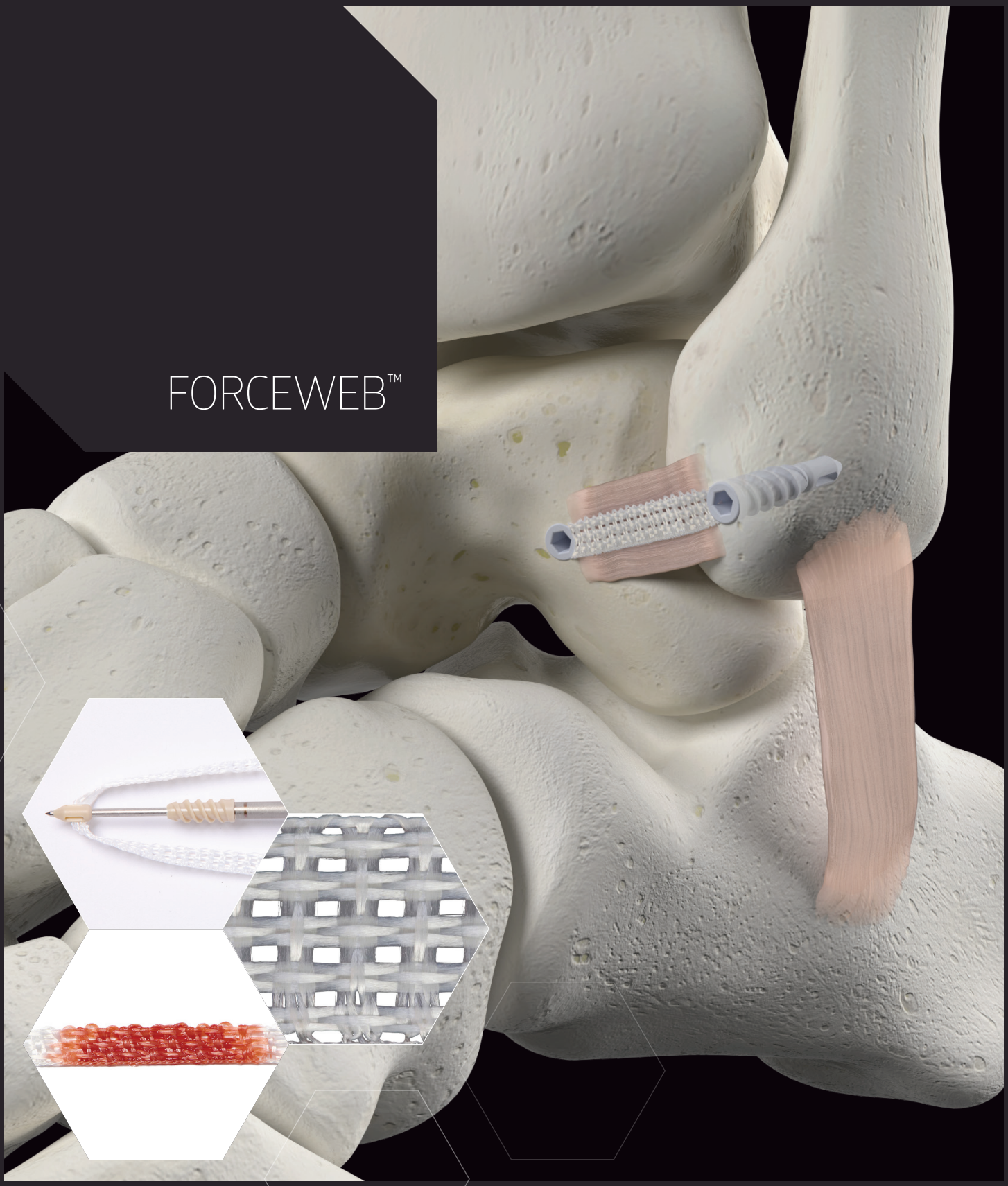
UNITE®
FOOT & ANKLE

Synthetic Ligament Augmentation Implant

Product Overview and Surgical Technique



Discover the next generation
in tendon and ligament repair, reinforcement, and augmentation of reconstructions.

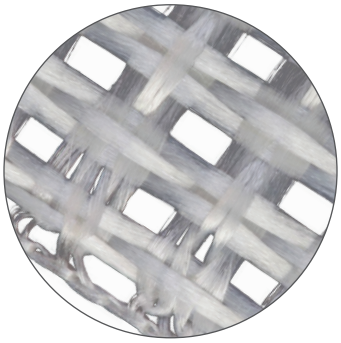
FORCEWEB™

SYNTHETIC LIGAMENT AUGMENTATION

Intelligently designed

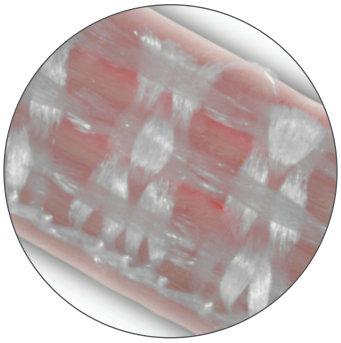
LOW PROFILE
Broad and flat design to reduce bulk

SYNTHETIC MATERIAL
Constructed from synthetic non-resorbable fibers (Polyethylene Terephthalate)



OPEN WEAVE STRUCTURE
Macroporous woven architecture allows for wicking of biological fluids

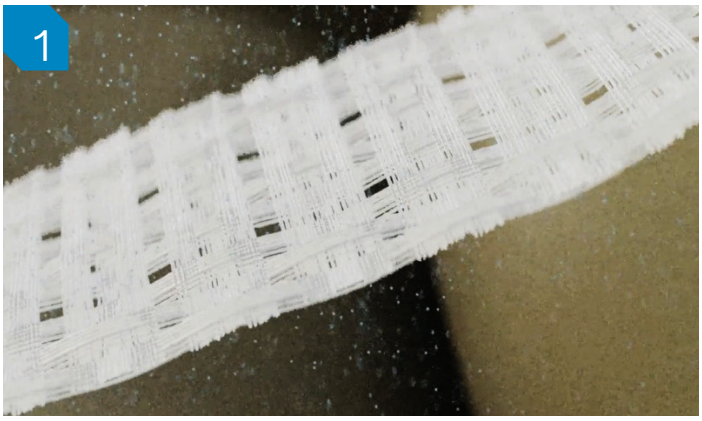
POROUS SCAFFOLD
Multifilament structure and large pores allow for tissue ingrowth for load-sharing



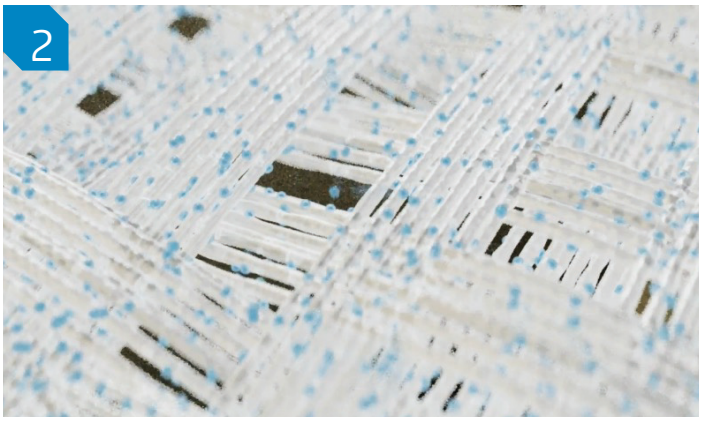
Compatible with DEXLOCK® Knotless Anchors*

*Data on file and available upon request

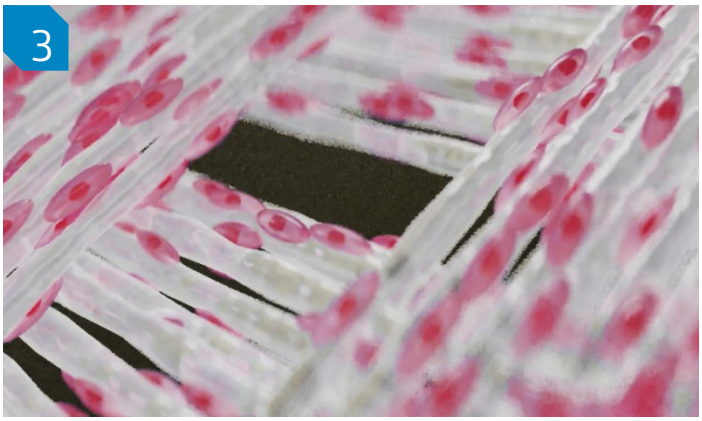
How it works



The tissue ingrowth cascades begins immediately upon implantation, as the increased surface area from the microfilaments making up the woven construct readily wicks biological fluids.

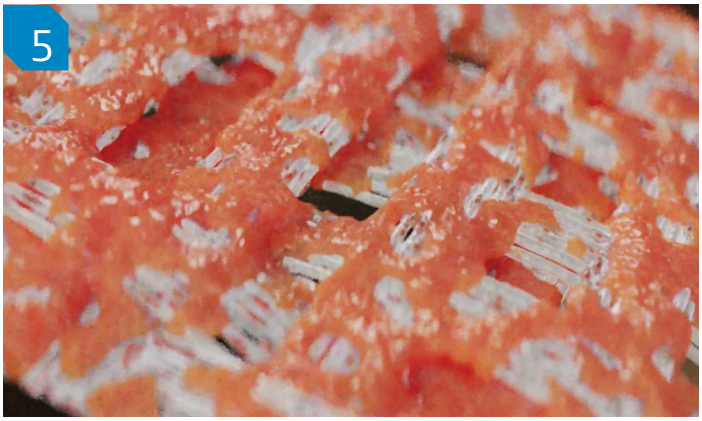


Precursor connective tissue cells and signaling molecules swarm the FORCEWEB implant, attaching to the microfilaments. Signaling molecules help potentiate cellular migration and proliferation.[1]

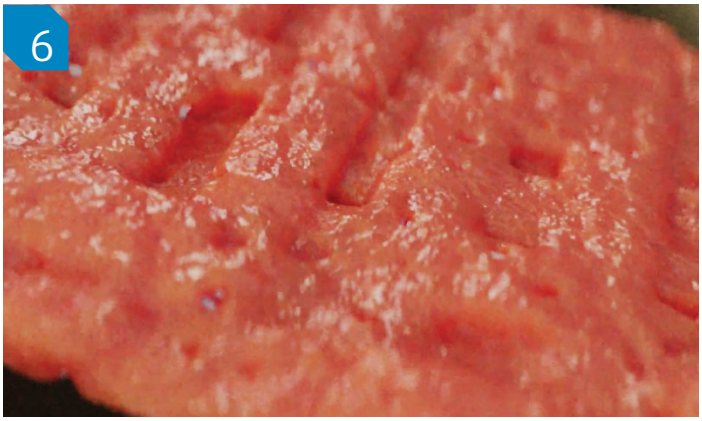


The attached cells experience stretching and relaxing as FORCEWEB undergoes cyclic tensile loading. This mechanical stimulus causes the cells to elongate and form an extracellular matrix in a spindle shape, a characteristic feature of connective tissue cells.[2]

Cellular proliferation and differentiation continues along the filaments, and cellular formation eventually expands to fill the porous space in the woven structure.



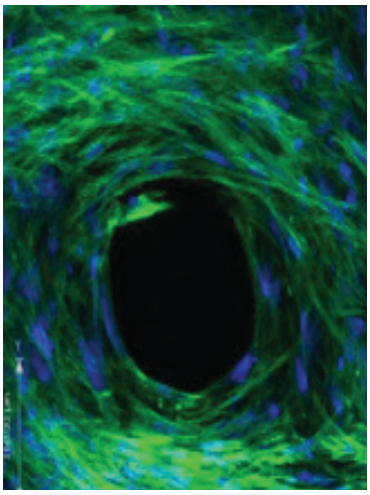
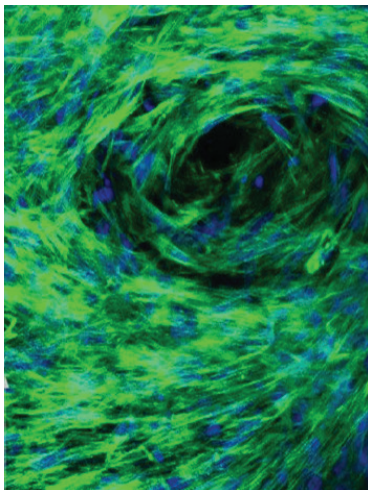
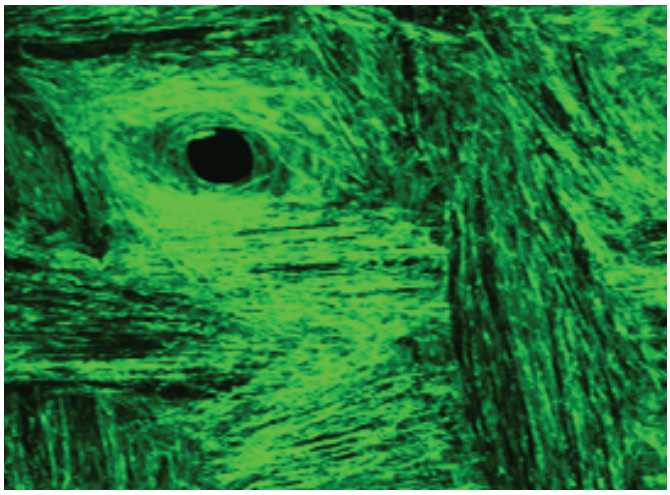
The pores and filaments throughout this woven implant are strategically sized to allow for this continued cellular attachment and tissue remodeling.[3,4,5]



With repeated cyclic tensile loading, the macroporous woven structure supports the continued tissue remodeling and angiogenesis. Mature connective tissue and collagen proteins fully incorporate through and around the implant.[6]

BUILT FOR BIOLOGY

Increased surface area from microfilaments encourages cellular adherence and tissue ingrowth throughout the open-weave construct

Confocal microscopy images of implanted FORCEWEB with nuclei shown in blue and cytoskeleton in green. Imaging confirms fibroblast adherence and differentiation throughout the implant.[5]

Maturation process continues over 5 years, resulting in tissue over the artificial ligament that is well-functioning with the presence of longitudinally oriented collagen fiber bundles with spindleshaped fibroblasts, sufficient neo-vascularisation and elastic fibers.[5]

Closest synthetic augmentation alternative to native ATFL compared to similar co-polymer alternatives*

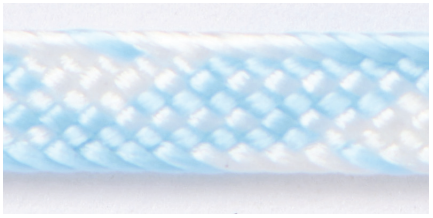
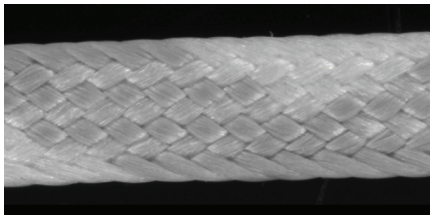
- Supplemental strength without bulk
- Predictable stretch closely mirrors native ATFL ligament
- Broad, low-profile, open weave structure provides load sharing across augmentation

	Arthrex® 2mm FiberTape®	MedlineUNITE® FORCEWEB	Native ATFL[7]	ConMed® BioBrace®	Stryker® FlexBand®
Average Peak Tensile Force (N)	369N	233.5N	154N	132.5N	138N
Displacement (mm)	3mm	4.5mm	5mm	9mm	58mm

*Data on file and available upon request

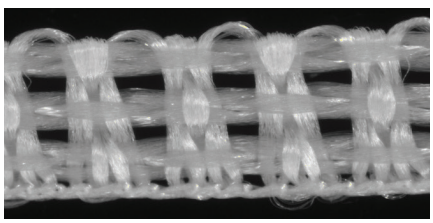
Suture tape

- Rigid, tightly braided suture
- No space for tissue ingrowth
- Classified as a suture/suture tape

FORCEWEB

- Open, woven construct
- Encourages tissue ingrowth
- Classified as a co-polymer surgical mesh

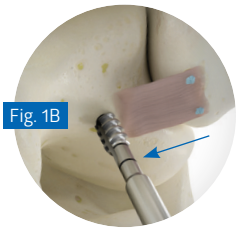
SURGICAL TECHNIQUE

ATFL Augmentation

FORCEWEB™ and DEXLOCK® Knotless Anchors

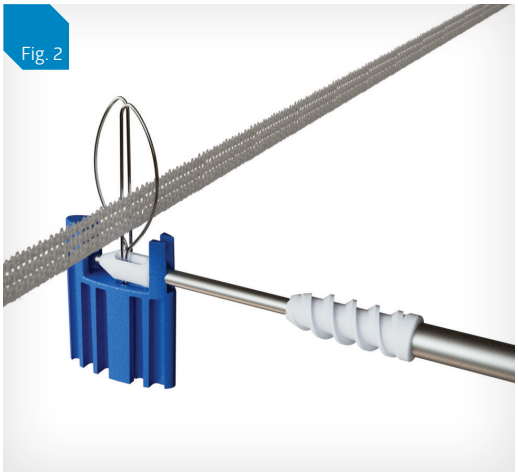
Step 1 | Talus Bone Tunnel Preparation

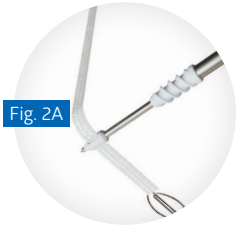
Utilizing the Ø3.6mm drill and the "Twist-In" side of the suture anchor drill guide, drill at a 45° angle into the body of the talus until the shoulder stop (Fig. 1A). If cannulated technique is desired for positioning and placement of the talar anchor, the Ø2.0mm guidepin and Ø3.6mm cannulated drill from the Ø5.5mm Cannulated Screw System may be used. Take care to avoid drilling into the articular cartilage of the talus. Tap until the proximal laser line is flush with the cortex (Fig. 1B). The AO/QC Ø4.5mm tap may be used carefully on power or by hand depending on surgeon preference.



Step 2 | Load FORCEWEB

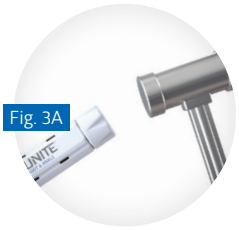
Load approximately 1 inch of the FORCEWEB implant through one of the preloaded whip wire loops (Fig. 2). Using counterpressure, pull the whip wire through the anchor eyelet until the FORCEWEB is passed. Pull the implant fully through the eyelet until the length is evenly distributed on both sides of the anchor (Fig. 2A). Wrap the implant tails around anchor cleats on the anchor handle (Fig. 2B).





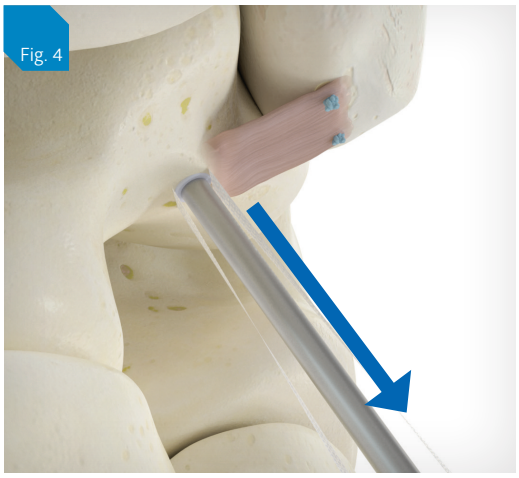
Step 3 | Anchor Insertion

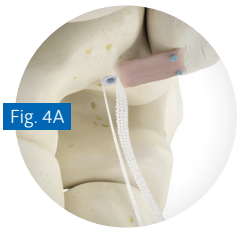
Insert the anchor eyelet into the prepared hole under the same drill angulation. Insert the eyelet until the threaded anchor body contacts the bone. A mallet may be used for initial advancement (Fig. 3A). Unlock the anchor by rotating the inserter knob clockwise until a tactile click is felt (Fig. 3B). Advance the anchor by rotating the handle clockwise while holding the distal collar of the inserter (cone-shaped part of the handle with cleats) to avoid twisting the implant.



Step 3 | Anchor Insertion (cont.)

Rotate the handle clockwise to advance the anchor into the bone. Continue advancing until the laser line on the shaft is flush with the cortex. Un-cleat the FORCEWEB tails and release the anchor by pulling the handle straight backwards (Fig. 4).





Step 4 | Fibula Bone Tunnel Preparation

Prior to preparing the fibula bone tunnel, confirm the anchor trajectory and resulting drill length visually and/or fluoroscopically (Fig. 5). Note: The total anchor length is 20mm (including the eyelet).

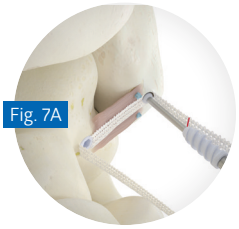
Drill and tap the fibula utilizing the same technique and instrumentation as the talus from Step 1.

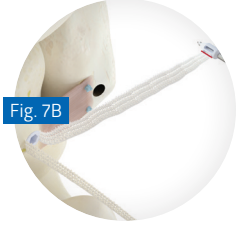
Step 5 | Set Tensioning

Load roughly 1 inch of the FORCEWEB through the eyelet of the anchor in the same manner as the previous anchor (Fig. 6).

Note: It is recommended to pass only one FORCEWEB tail through one of the eyelet slits. Optionally, the remaining tail from the fibula anchor may be used to bring down to the calcaneus if CFL augmentation is desired.

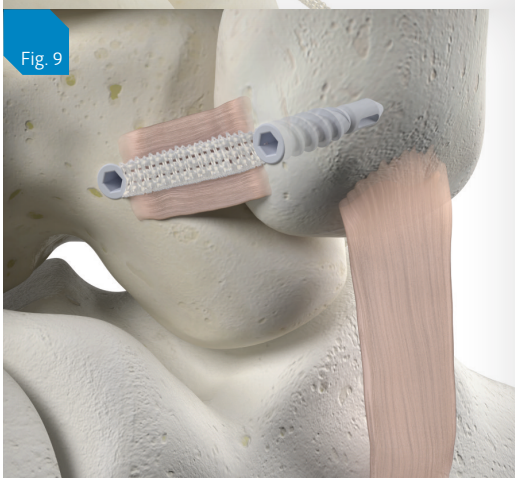
With the foot in a neutral inversion/eversion position and slight plantarflexion (10 - 15°), insert the anchor eyelet into the fibular bone tunnel (Fig. 7). Set the desired final tension by removing all slack from the FORCEWEB tail and make a mark where the tail first meets the distal tip of the anchor body (Fig. 7A). Remove the eyelet from the bone tunnel and reposition the eyelet over the marked portion of the FORCEWEB (Fig. 7B).

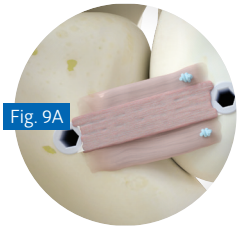




Step 6 | Anchor Insertion

Advance the anchor eyelet until the anchor body is touching the bone (Fig. 8). A mallet may be used to aid with initial insertion (Fig. 8A). Twist the handle knob clockwise until a tactile click is felt (Fig. 8B), then advance the anchor into the bone until the laser mark on the shaft is flush with the bone. Pull the handle straight backwards to disengage the inserter and deploy the anchor. Trim the remaining FORCEWEB tails from the talus and fibula (Fig. 9).

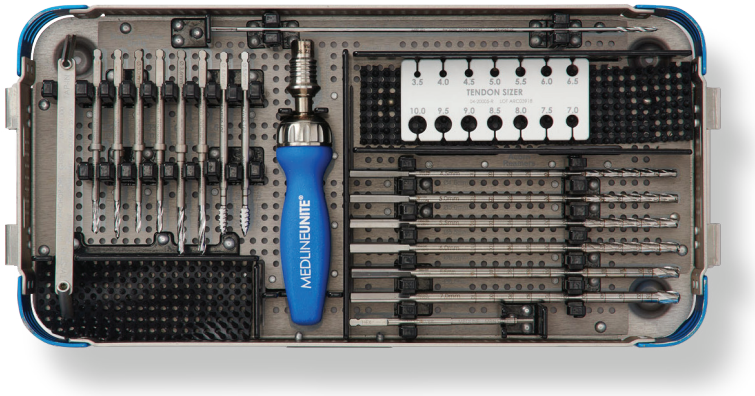




Ordering Information

FORCEWEB™ Implant and DEXLOCK® Knotless Anchors

Item No.	Description	Qty.
MWEB5040	FORCEWEB™, 5 x 500mm	1
MRPK4520	DEXLOCK® Knotless Anchor, Ø4.5mm x 20mm	2
MRN11036	Ø3.6mm Anchor Drill	1
MRN31045	Ø4.5mm Anchor Tap	1
MRN41000	Suture Anchor Drill Guide	1
MSN90001	AO/QC Handle	1



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