EXPERT

Joint Fixation System

Surgical Implantation Technique

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SURGICAL IMPLANTATION TECHNIQUE
EXPERT – JOINT FIXATION SYSTEM

GENERAL INFORMATION

- Single-use product, do not reuse, even if it is in perfect condition;
- Sterile supplied product by EO;
- Prohibited reprocessing.

INDICATIONS FOR USE

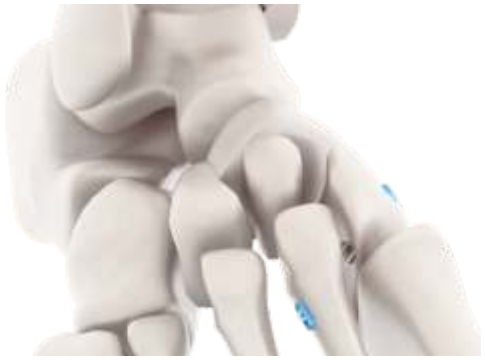
The EXPERT – Joint Fixation System is intended as an adjunct in fracture repair involving metaphyseal and periarticular bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and nails, with fracture braces and casting.

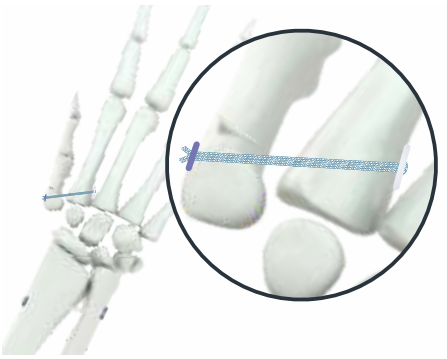
The Mini EXPERT, EXPERT Knotless and EXPERT Knotless Dual are intended to provide fixation during the healing process following:

Mini EXPERT

When used for fixation of bone-to-bone, the Mini EXPERT is intended as fixation posts, distribution bridges, or for distributing suture tension over areas of ligament or tendon repair, such as:

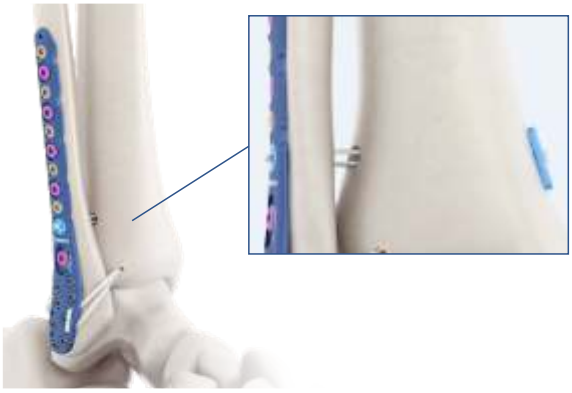
- Syndesmotic trauma, such as fixation of dorsal distal radioulnar ligament (DRUL) disruptions;
- Tarsometatarsal (TMT) injury, such as fixation of foot soft tissue separations due to a Lisfranc injury (Midfoot Reconstruction); and
- Carpal Metacarpal (CMC) joint arthroplasty as an adjunct in the healing process of the reconstruction of the ligament at the base of the thumb metacarpal by providing stabilization between the base of the first and second metacarpal when the trapezium has been excised due to osteoarthritis.





EXPERT Knotless and EXPERT Knotless Dual

- Syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.



CONTRAINDICATIONS

The patients, who present some clinical condition described below, should not be subject to the procedure with the use of the product. The contraindications include those listed below, but are not limited to:

- Active infection or history of recent infection of bone tissue or of soft parts locations;
- Osteometabolic diseases that cause weakness or reduction of bone mass;
- Insufficient bone mass or of poor quality;
- Inadequate vascularization in the implant placement local that could compromise the adequate blood supply in the place of deployment;
- Allergy and/or sensitivity to metals (pure titanium and titanium aluminum alloy-Vanadium)
- Patients without conditions to follow the medical advice and the health team at any time of their treatment.
- It should not be used in surgical procedures other than those specified.

PURPOSE OR INTENDED USE OF THE PRODUCT

The success of the treatment is directly related to the appropriate surgical technique applied by the surgeon and the correct choice of implants, following their characteristics: model, shape, type, dimensions, etc.
The size and anatomy of the bone structures are the main factors in the definition of the implants to be used.
The recommendations in the Table below should be followed:

Model	Bone Structure
Mini EXPERT	Foot, Hand and Wrist
EXPERT Knotless EXPERT Knotless Dual	Ankle

SIDE EFFECTS OR UNDESIRABLE SIDE EFFECTS

Pain, discomfort and abnormal sensations due to the presence of the implant;
Infections, both deep and superficial;
Allergies and other reactions with implanted materials.

NOTE 1: A second surgery may be needed to repair the secondary effects
NOTE 2: Smokers with metabolic disorders have greater difficulties in achieving the bone consolidation, consequently there is a greater chance to occur deformation, rupture or loosening of the implants and does not reach the bone and suffer more progressive degeneracy.

MRI SAFETY INFORMATION

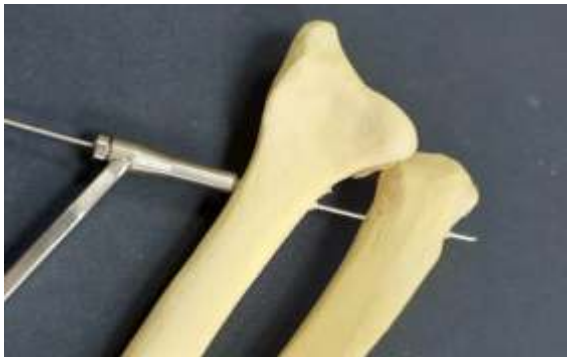
The EXPERT – Joint Fixation System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of EXPERT – Joint Fixation System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury."

INDICATION OF TRAINING

Only properly trained, empowered in procedures of orthopedic surgery may use the product.
Note 1: The surgeon should be aware of all recommendations described in the product "Use Instructions" and other information on the label.

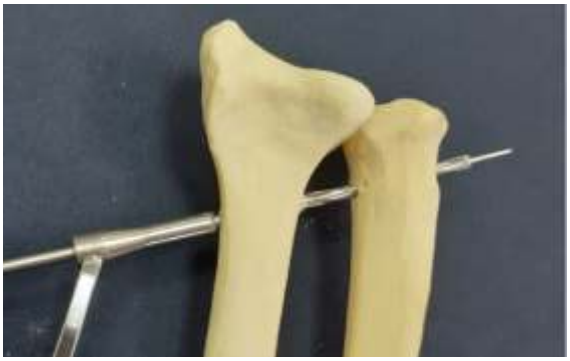
SURGICAL TECHNIQUE

SYNDESMOTIC TRAUMA (dorsal distal radioulnar ligament disruptions - DRUL)



Step 1:

Position de guide on the lateral cortex of the distal radius and apply a guidewire towards the medial cortex of the ulna. The position of the guidewire must be checked on radioscopy.

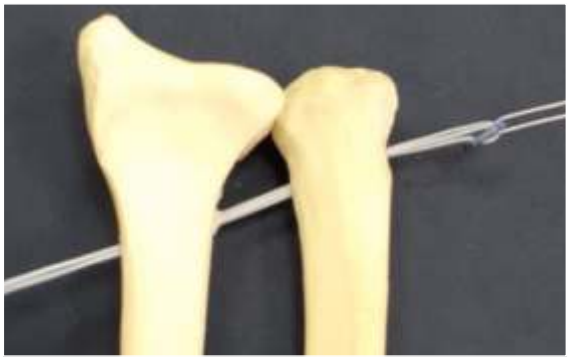


Step 2:

Using the guidewire, drill the tunnels in the radius and ulna with the 2.7 mm cannulated drill.

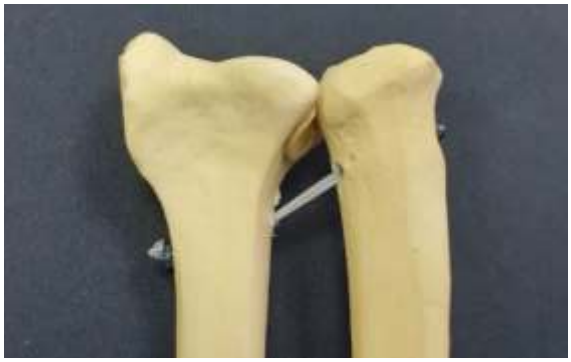
Step 3:

Use the Guidewire Ø1.6 mm that is assembled on the rectangular plate to transport in through the bone perforation, from the lateral cortex of the radius to the medial cortex of the ulna.



Step 4:

Perform a tipping maneuver of the rectangular plate on the medial face of the ulna, and then pull the surgical sutures of the circular plate, bringing it closer to the radius cortex.



Step 5:

Apply at least four knots on the side of the Mini Expert, cut the remaining surgical sutures and discard them.

Check in radioscopy again the positioning of the Mini Expert´s metal plates, and perform maneuvers to confirm the stability of the distal raioulnar joint.

Time for healing the ligament treated: The complete healing occurs in 6 to 8 weeks.

Post-operative recommendations: Early immobilization kept fot at least 3 to 4 weeks. After this period an assisted physiotherapy with care grip strenght.

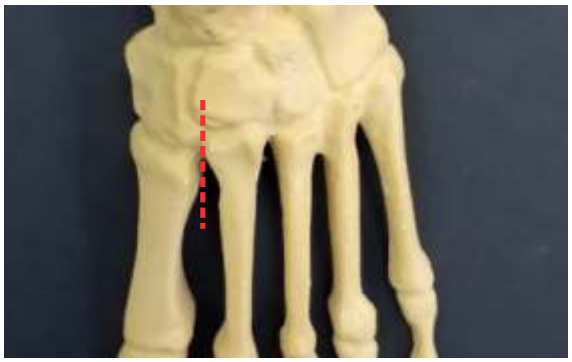
SURGICAL TECHNIQUE

TARSOMETATARSAL INJURY - LISFRANC (TMT)

Introduction

The stability of the 2nd metatarsal articulation with de 2nd cuneiform is maintained by booth soft tissue and bone structures. The Lisfranc ligament extends from the 1st cuneiform to the base of the 2nd metatarsal, helping to maintain the anatomic orientation of the 2nd metatarsal with the adjacent 1st metatarsal, 1st cuneiform, 2nd cuneiform, the 3rd metatarsal as well as the 3rd cuneiform. Stability is further imparted by the ´´keystone´´ fitting of the 2nd metatarsal between the 1st and 2nd cuneiforms.

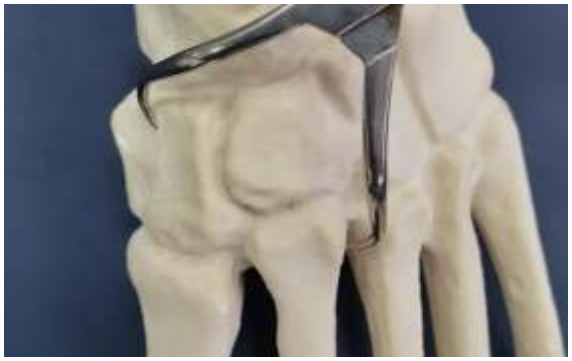
An isolated rupture of the Lisfranc ligaments leads to dorsal and/or lateral subluxation and displacement of the base of the 2nd metatarsal.



Step 1:

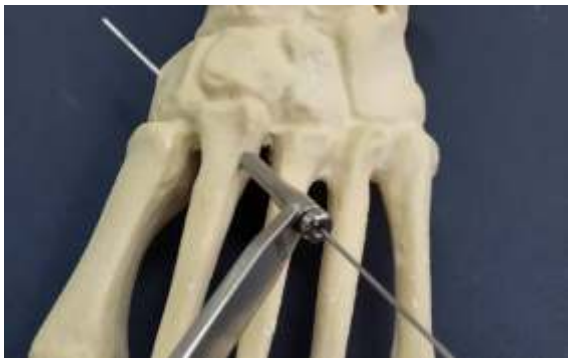
A longitudinal dorsal incision is centered in an area extending from the lateral border of the 1st metatarsal and 1st cuneiform to a line over the dorsal aspect of the 2nd metatarsal.

The exact position within this zone is determined by the location of other associated fractures and injuries and the specific location of the dorsalis pedis artery.



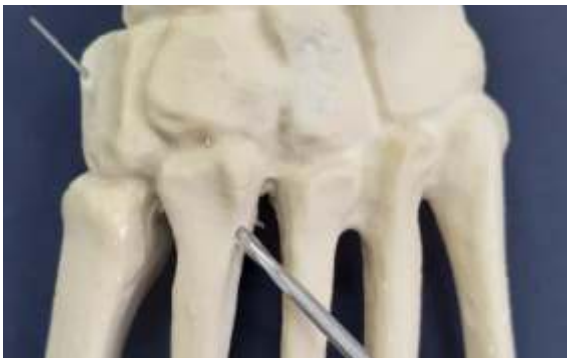
Step 2:

The incision is continued through the dorsal retinaculum. Beware of the possible injury ti the distal branch of deep peroneal nerve and the dorsalis pedis artery. After the subperiosteal dissection, the 2nd metatarsal-cuneiform joint and the space between the base of the 2nd metatarsal and the 1st metatarsal are cleared of any soft tissues that might restrict anatomic reduction. Bone reduction forceps may now be utilized to secure the reduction.



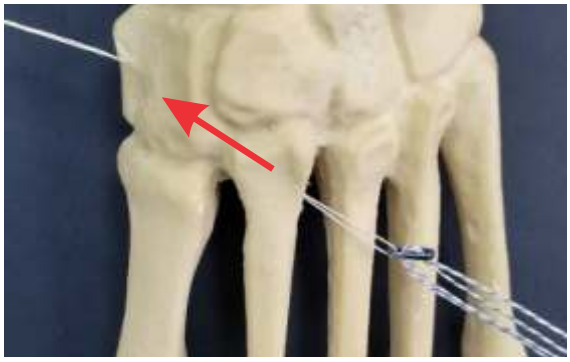
Step 3:

The insertion of the 1.0 mm Guidewire from the lateral aspect of the base of the 2nd metatarsal toward the 1st cuneiform exits over the medial aspect of the foot. Exposure of the base of the 2nd metatarsal may be facilited by using a Hohmann retractor around the lateral face of the 2nd metatarsal. NOTE: If the lateral approach is not possible due the anatomic contraints at the lateral base of the 2nd metatarsal, the surgeon may perform the procedure from a medial to lateral direction.



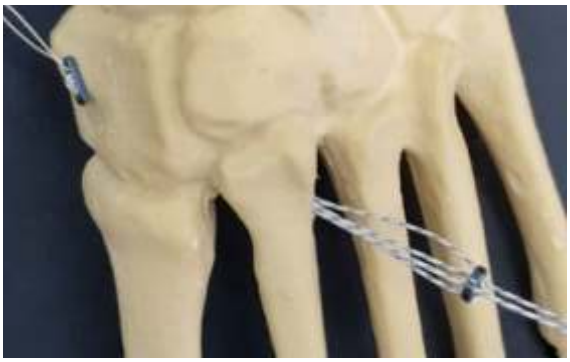
Step 4:

The bone tunnel for passage of the Mini Expert is created by overdrilling the Cannulated Drill Bit Ø2.7 mm it is important to maintain the stability of the reduction during this portion of the procedure.



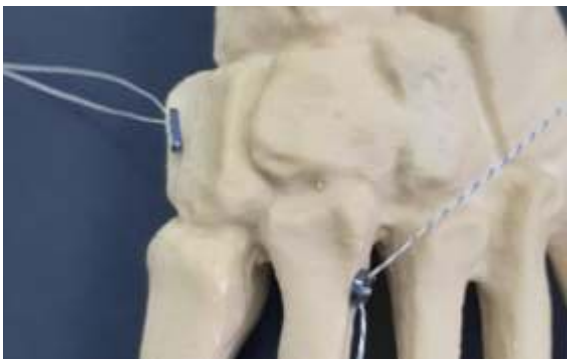
Step 5:

The leading Guidewire Ø1.6 mm connected to the Rectangular Plate is passed in a lateral to medial direction through the bone tunnel.



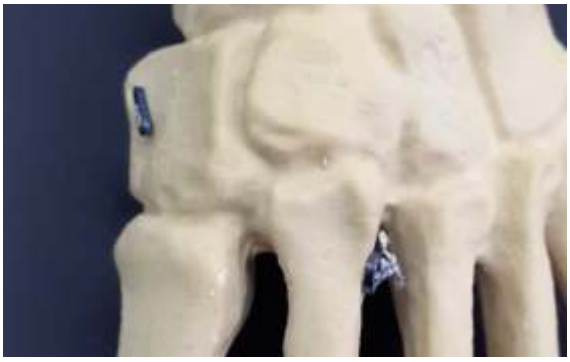
Step 6:

After exiting the medial aspect of the 1st cuneiform, the rectangular plate is turned 90° to engage the medial cortex. Confirm that there is no soft tissue interposed between the rectangular plate and the cortex of the 1st cuneiform.



Step 7:

The lateral Round Plate is tightened to the cortex of the 2nd metatarsal by simultaneously pulling (sometimes with an alternating differential pull) on the two lateral surgical sutures. To prevent any possible shearing, the angle between the surgical sutures should be no more than 20°.



Step 8:

Apply at least four knots on the side of the Mini Expert, cut the remaining surgical sutures and discard them.

Check in radioscopy again the positioning of the Mini Expert´s metal plates to confirm the adequancy of the reduction.

Time for healing the ligament treated: The complete healing occurs in 6 to 8 weeks.

Post-operative recommendations: Boot and crutches are discontinued typically 3 weeks after surgery if it is tolerate by the patient. Rehabilitation begins after 3 weeks with progressive return to daily life activities. The stitches are relieved after 2 weeks.

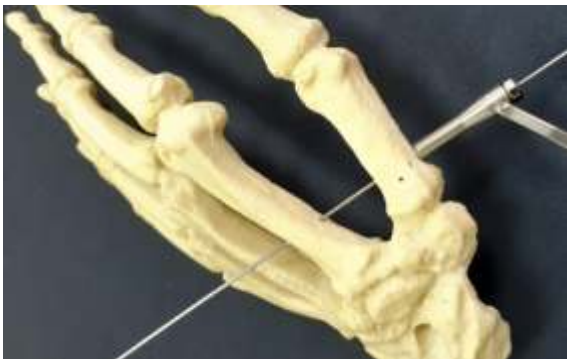
SURGICAL TECHNIQUE

CARPAL METACARPAL INJURY (CMC) JOINT ARTHROPLASTY

Step 1:

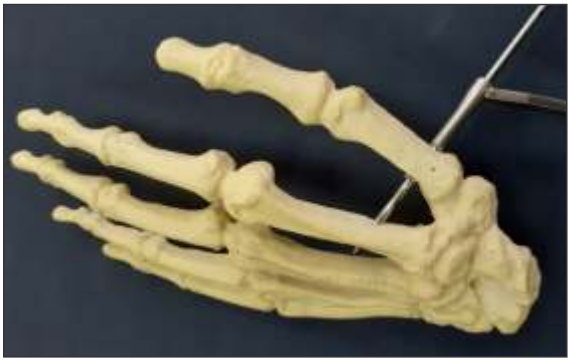
Make 1 cm incision over the dorsal ulnar methaphysis of the proximal 2nd metacarpal. Retract the extensor tendons and use blunt dissection to expose the dorsal ulnar cortex of the 2nd metacarpal.

Make other 1 cm incision over the lateral methaphysis of the 1st metacarpal.



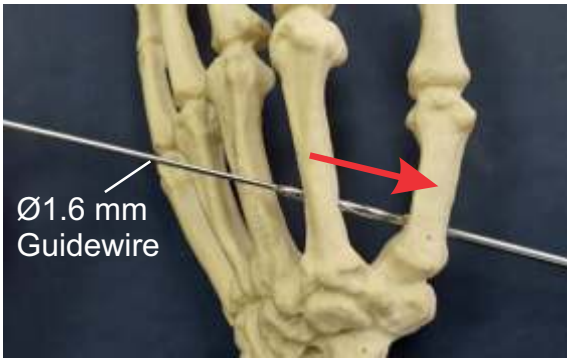
Step 2:

The insertion of the 1.0 mm Guidewire from the lateral aspect of the base of the 1st metacarpal toward the dorsal ulnar cortex of the 2ns metacarpal. NOTE: The surgeon may perform the procedure from a medial to lateral direction.



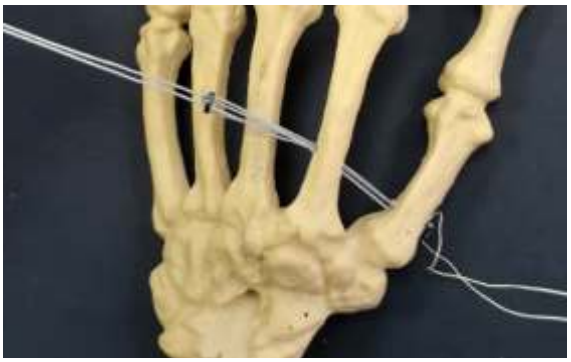
Step 3:

Position the supplied 2.7 mm Cannulated Drill Bit over the Guidewire and drill radial to ulnar, exiting the medial cortex of the 2nd metacarpal. Remove the guidewire, but do not remove the drill bit.



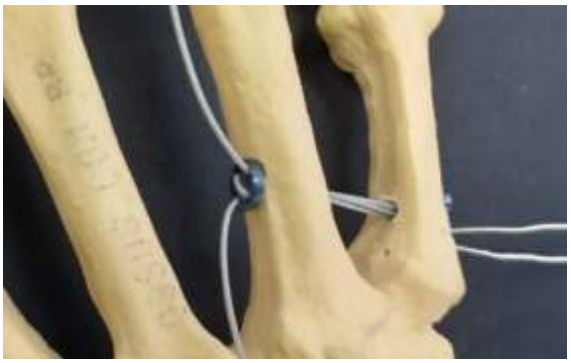
Step 4:

Insert the Ø1.6 mm Guidewire of implant assembly into the ulnar end of the cannulated tip of the drill bit and advanced into the bone tunnels. Withdraw the drill bit from 1st metacarpal cortex.



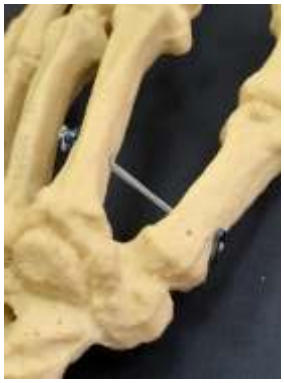
Step 5:

Genly pull the Guidewire implant assembly after exiting the lateral cortex of the 1st metacarpal and the rectangular plate is turned 90° using USP 2-0 white surgical suture, to engage the lateral cortex.



Step 6:

Reduce the 1st metacarpal subluxation to the desired position in relation to the 2nd metacarpal and have assistant hold reduction. Gradually begin tensioning both USP 2 surgical sutures until the round plate is seated firmly against the 2nd metacarpal cortex and does not impinge the extensor tendons.



Step 7:

Under tension, secure 4 surgeons knots over the 2nd metacarpal round plate. Trim the excedent medial and lateral sutures and dispose it.

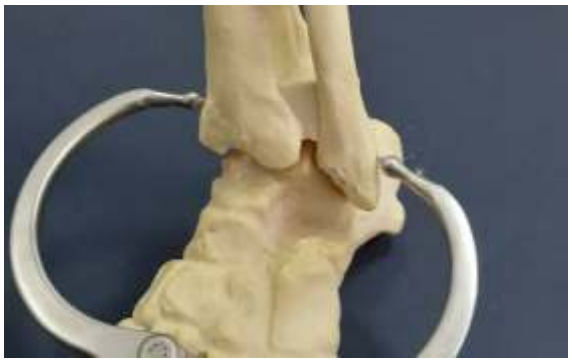
Check in radioscopy again the positioning of the Mini Expert´s metal plates, and close the surgical sites.

Time for healing the ligament treated: The complete healing occurs in 180 days.

Post-operative recommendations: Remove the dressing, splint, and sutures at 1 week to 10 days post-op. Fabricate a thumb spica splint holding the thumb in a slightly abducted position. Discontinue splint at 4 weeks and begin controlled thumb motion and gentle strengthening exercises.

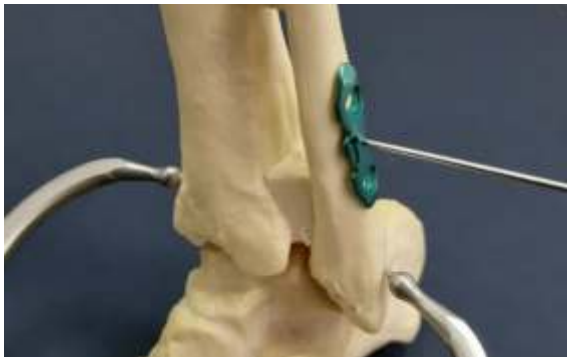
SURGICAL TECHNIQUE

SYNDESMOSIS REDUCTION



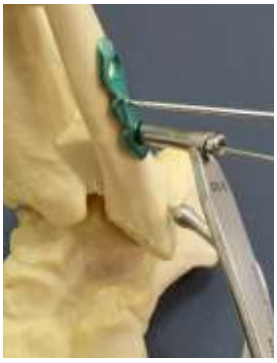
Step 1:

Reduce the syndesmosis anatomically with the Syndesmosis Plier. Reduction may be confirmed using fluoroscipy, direct visualization during open reduction, or arthroscopy, based upon surgeon preference and severity of injury.



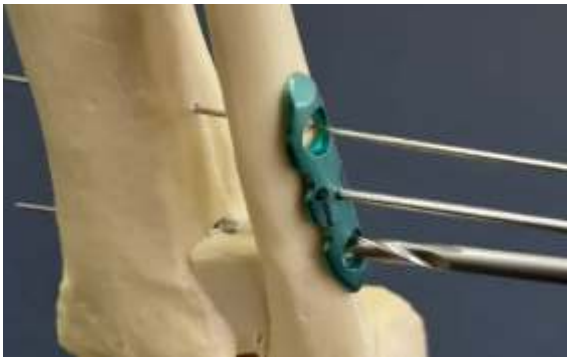
Step 2:

Apply the Support Plate to the lateral fibula, the distal hole should be centered 2 cm proximal to the tibial plafond. insert 1.6 mm guidewire throgh the center hole of the plate for temporary fixation.



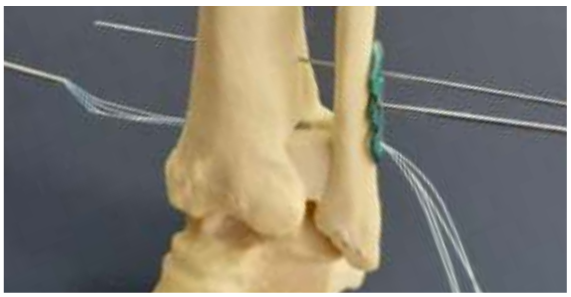
Step 3:

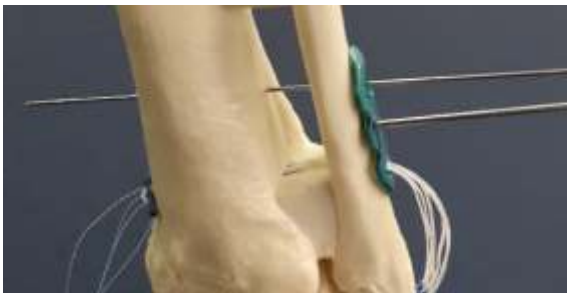
Insert the first 1.0 guidewire through the distal hole, parallel to the tibial plafond, in the transmalleolar plane (directed 30 degrees anterior to the coronal plane). Insert second guidewire , divergente from the first in the coronal plane (usually directed posteriorly), still parallel to tibial plafond. NOTE: the use of a guidewires and cannulated drill bit is recommended, alowing confirmation of accurate guidewires positioning prior drilling; but if the surgeon prefers non-cannulated drill, a solid drill bit is also provided.



Step 4:

Drill with the Ø3.8 Cannulated Drill Bit over the distal guidewire through all four cortices and remove the distal guidewire.





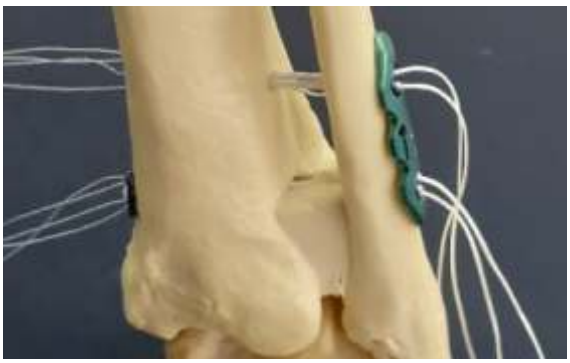
Step 5:

Insert the first Expert Knotless through the distal hole of Support Plate by pushing the Ø1.6 Guidewire assembled to the rectangular plate from fibular to tibial tunnels.

The White Surgical Suture USP 2-0 pull-through suture advances the leading Rectangular Plate, until it just exits the medial tibial cortex. Slight upward tension should be placed on the white pull-through suture, while placing downward tension on the White and Blue Surgical Suture USP 2-0. This maneuver effectively “flips” the button from horizontal to vertical. With lateral traction on the round button, the Rectangular Plate should seat flat along the medial cortex of the tibia. Confirm placement using fluoroscopy.

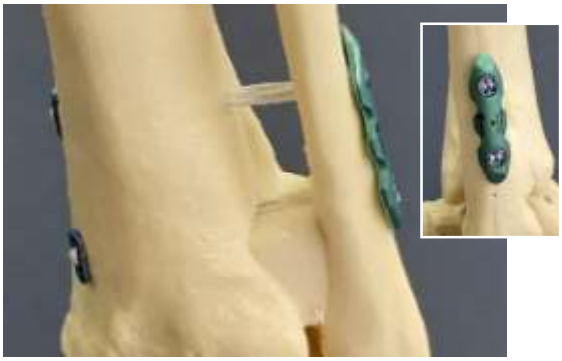
Step 6:

A blunt hemostat is inserted under the lateral round plate. With alternating short draws, pull the white strands on the lateral side of the ankle straight back toward the surgeon one at a time. The Round Plate will be drawn towards the fibula. Remove the hemostat before final tightening. The lateral plate will sit flush in the Support Plate. The Rectangular Plate will sit on the medial cortex of the tibia and should be checked fluoroscopically. Some surgeons will choose to tension the sutures with the ankle in dorsiflexion.



Step 7:

Repeat the steps 4, 5 and 6 in the proximal hole of the Support Plate to implant the second Expert Knotless.



Step 8:

Cut the remaining surgical sutures and discard them.

Perform maneuvers to confirm the stability of the syndemosis.

Check in radioscopy again the positioning of the Expert Knotless Dual components.

NOTE: The Expert Knotless can be used individually or in pairs, without the Support Plate, using the same steps of implantation technique; removing the placement and temporary fixation of the Support Plate steps.

Time for healing the ligament treated: The complete healing occurs in 8 to 12 weeks.

Post-operative recommendations: Following wound closure, immobilize the ankle in neutral dorsiflexion using a short leg, postoperative splint. Depending on fixation stability and severity of syndesmosis disruption, partial weight-bearing may be permitted in a cast or walker boot, between two to six weeks based upon surgeon preference. Full weight-bearing is typically allowed at six weeks, transitioning to a functional brace as tolerated. Postoperative management is patient and surgeon dependent.

It is recommended immobilization with cast or splint until complete healing of all structures treated, for 8 up to 12 weeks. After this period, it is recommended controlled load on the ligament with assisted physiotherapy.

INSTRUMENTS USED FOR EXPERT IMPLANTATION

EXPERT	DRILL GUIDE	GUIDEWIRE CANNULA	GUIDEWIRE	DRILL BIT
Mini EXPERT– Joint Fixation (C: 311-2000)	Double Drill Guide Ø3.8/Ø2.7 mm (C:310-01-10)	Cannula for Guidewire Ø1.0 mm / Drill Bit Ø2.7 mm (C: 310-01-11)	Guidewire Ø1.0 x 250.0 mm (C: 310-01-07)	Cannulated Drill Bit Ø2.7/1.2 x 180.0 mm (C: 310-01-06)
EXPERT Knotless – Joint Fixation Knotless (C: 312-2000)		Cannula for Guidewire Ø1.0mm/Drill Bit Ø3.8 mm (C: 310-01-05)		Cannulated Drill Bit Ø3.8/1.2 x 180.0 mm (C: 310-01-08) or Drill Bit Ø3.8 x 180 mm (C: 310-01-08-S)
EXPERT Knotless Dual - Joint Fixation Knotless Dual (C: 314-2000)				

EXPERT COMPONENTS

The Mini EXPERT and EXPERT Knotless products are supplied sterile, already assembled as a joint fixation, both the implantable components (round plate, rectangular plate and fixation suture), as the components used during the surgery, but that are not implanted in the patient (wires and guidewire).

EXPERT Knotless Dual is also supplied sterile, containing two articulation fasteners assembled (as the EXPERT Knotless) and more a Syndesmosis Support Plate, and all the components are coupled in the surgical procedure.

The components for each product are:

	Mini EXPERT – Joint Fixation (C: 311-2000)	**EXPERT Knotless – Joint Fixation Knotless (C: 312-2000)**	**EXPERT Knotless Dual - Joint Fixation Knotless Dual (C: 314-2000)**
Implantable			
Round Plate	Mini Round Plate Ø5.5 mm (C: 311-01-02) 1 un.	Round Plate Ø6.5 mm (C: 312-01-02) 1 un.	Round Plate Ø6.5 mm (C: 312-01-02) 2 un.
Rectangular Plate	Mini Rectangular Plate 2.6 x 8.0 mm (C: 311-01-03) 1 un.	Rectangular Plate 3.3 x 13.0 mm (C: 312-01-03) 1 un.	Rectangular Plate 3.5 x 10.0 mm (C: 310-01-03) 2 un.
Fixation Suture	Blue and White Surgical Suture USP 2 965.0 mm (C: 9915093) 1 un.	White Suture USP 5 UHMWPE (965.0mm) (C: MLHA-5XC) 1 un.	White Suture USP 5 UHMWPE (965.0mm) (C: MLHA-5XC) 2 un.
Plate	-	-	Support Plate for Tibial Syndesmosis (C: 314-05) 1 un.
Non - implantable			
Surgical Sutures	White Surgical Suture USP 2-0 305.0 mm (C: 9915092) 1 un.	White Surgical Suture USP 2-0 305.0mm (C: 9915092) 1 un.	White Surgical Suture USP 2-0 305.0 mm (C: 9915092) 2 un.
	-	White and Blue Surgical Suture USP 2-0 410.0 mm (C: 9915093) 1 un.	White and Blue Surgical Suture USP 2-0 410.0 mm (C: 9915093) 2 un.
Guidewire	Guidewire Ø1.6 mm (C: 310-01-01) 1 un.	Guidewire Ø1.6 mm (C: 310-01-01) 1 un.	Guidewire Ø1.6 mm (C: 310-01-01) 2 un.

WARNING REGARDING THE PRODUCT CONDITION WHICH RESTRICT THE USE

The product should not present any visual abnormality in its surface, as risks, failures, dirt or other.
The implantable components that exhibit abnormalities in their surface should be destroyed and disposed of according to the procedure of "Destruction and disposal".

CAUTION ASSOCIATED IN CASE OF FALL OF SOME COMPONENT

In case of fall of any component or suffer any kind of damage, it should be destroyed and disposed of according to the Procedure of Disposal.

DEVICE REMOVAL

If it is necessary to remove the implant, make a small incision over each plate (round and rectangular), cut the surgical suture with a surgical scissors or scalpel, and all the components must be removed using surgical tweezers. It is not possible to adjust or reimplant the Expert removed. The surgeon must implant a new device.

CUSTOMER COMPLAINT

If the medical product presents a risk specific unpredictable, being outside of its specifications or being generated any dissatisfaction, notify directly the GMReis Customer Service (SAC). The product should be sent cleaned and packed in plastic bag, properly identified and with the description of non-compliance to the following address: G. M. dos Reis Indústria e Comércio Ltda - Pierre Simon de Laplace Avenue, no. 600 Lote 3 - Quadra F – Quarteirão 9677 - TECHNOPARK – CEP: 13069-320 – Campinas – SP – BRAZIL or directly notify at Telephone Number:(0xx19)3765-9900/ E-mail: sac@gmreis.com.br.

USER WARNING

The Surgical Technique is available in format that is not printed, through the electronic address of the manufacturer: http://www.gmreis.com.br/produtos/IFU,. and can be checked in the search field by trade name, described on the label of the product packaging. The Instructions for Use and Surgical Technique provided will always be in accordance with the current latest version. If there is interest from the user, the documents may be available in printed format, without additional cost. Ask free by e-mail: sac@gmreis.com.br.

IMPLANT LIST

Part Number	Description
311-2000	MINI EXPERT – JOINT FIXATION
312-2000	EXPERT KNOTLESS – JOINT FIXATION KNOTLESS
314-2000	EXPERT KNOTLESS DUAL – JOINT FIXATION KNOTLESS DUAL

INSTRUMENTAL LIST

Part Number	Description
310-01-05	Guidewire Ø1mm – Drill Bit Ø3.8mm
310-01-11	Guidewire Ø1mm – Drill Bit Ø2.7mm
310-01-07	Guidewire Ø 1.0 x 250.0 mm
310-16-100	Guidewire Ø 1.6 x 80.0 mm
311-01-06	Cannulated Drill Bit Ø 2.7 / 1.2 mm x 180.0 mm
310-01-08	Cannulated Drill Bit Ø 3.8 / 1.2 mm x 180.0 mm
310-01-08-S	Drill Bit Ø 3.8 x 180.0 mm
310-01-10	Double Drill Guide Ø2.7mm/Ø3.8mm
311-16	Nitinol Wire Suture with Loop Ø 0.7 x 203 mm
314-100	Syndesmosis Plier
310-25-280	EXPERT Protector Tube