



ANKLE ARTHRODESIS USING THE TRUELOK RING FIXATION SYSTEM

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INTRODUCTION

Background on the Ilizarov Technique

In 1951, Professor Gavril Ilizarov of Kurgan, Siberia developed a new external fixation apparatus and technique to lengthen long bones and correct bone deformities. The technique revolutionized the management of many previously unsolvable reconstructive problems.

In essence, the apparatus consists of rings or arches centered on the patient's limb and secured to the bone by crossed, tensioned wires or half pins. The rings or arches are connected externally to provide stable bone fixation. These external connecting elements are either threaded or telescopic rods, which allow the surgeon to adjust the relative position of rings to each other. The ring positions are then manipulated in minute increments to affect the correction of the deformity, lengthening, or bone segment transportation as required by the surgeon.

ADVANTAGES OF THE TRUELOK SYSTEM

Simple

- TrueLok offers pre-assembled functional components which are easy to connect and operate for both patient and surgeon
- TrueLok Hinges and Angular Distractors preserve fixator alignment when temporarily detached
- Slotted Plates make it easier to connect different External Supports (Rings, Threaded Rods and Foot Plates)

Stable

- The anti-rotation feature on Connection Elements helps prevent undesired movement
- TrueLok's unique Wire and Half-Pin Fixation Elements provide efficient bone segment stabilization
- The patented metal-plastic interface is stable both during and between adjustments

Versatile

- The TrueLok system is modular, allowing customizable frame constructs to treat a variety of orthopedic conditions
- TrueLok Universal Hinges offer self-alignment flexibility
- By providing full control of each individual bone segment, TrueLok ensures overall limb stability while affording precise positioning of bone segments.



COMPONENTS REQUIRED

ANKLE ARTHRODESIS - RECOMMENDED COMPONENTS

Component	Part Number	Quantity
Full Ring	(Size dependent)	2
Foot Plate	(Size dependent)	2
Foot Plate Extension	(Size dependent)	2
Half Ring	(Size dependent)	1
60mm Threaded Rod	55-11720	4
85mm Threaded Rod	55-10530	1
115mm Threaded Rod	55-10060	6
10mm Nut	50-1008	60
12mm Bolt	54-1050	4
16mm Bolt	54-1010	2
Universal Wire Fixation Bolt	54-1152	20
Bayonet Wire	54-1216	3
Stopper Wire	54-1215	7
Rubber Stopper	54-1133	20
2 Hole Post	54-11610	1
40mm Plate	55-11671	1

OPTIONAL COMPONENTS FOR ADDITIONAL STABILITY

Component	Part Number	Quantity
115mm Threaded Rod	55-10060	2
10mm Nut	50-1008	8
12mm Bolt	54-1050	2
40mm Plate	55-11671	2
Foot Plate (Single or Double Row)	(Size dependent)	1

ADDITIONAL COMPONENTS (AS NEEDED)

Component	Part Number
Spacing Washer(s)	(Size dependent)
Post(s)	(Size dependent)
5mm Quick Connect Half Pin	54-11240
Universal Half Pin Fixation Bolt 4mm - 6mm	54-11530
TL 8mm Half Pin Bolt	54-11540

NOTE: Quick Adjust Struts may be used instead of rods for acute correction of residual deformity prior to compression.

Quick Adjust Struts (Material out of the tray)

Part Number	Description
50-10170	Short
50-10180	Medium
50-10190	Long



CLEANING, STERILIZATION AND MAINTENANCE

For information on Cleaning, Disinfection, Sterilisation and Maintenance please refer to PQ ISP.

INDICATIONS FOR TRUELOK

The TrueLok system is intended for limb lengthening by metaphyseal or epiphyseal distractions, fixation of open and closed fractures, treatment of non-union or pseudoarthrosis of long bones and correction of bony or soft tissue defects or deformities.

Within this intended use the following indications are included:

- Primary ankle arthrodesis:**
- Compromised bone quality
 - Complex ankle pathology
 - Soft tissue compromise

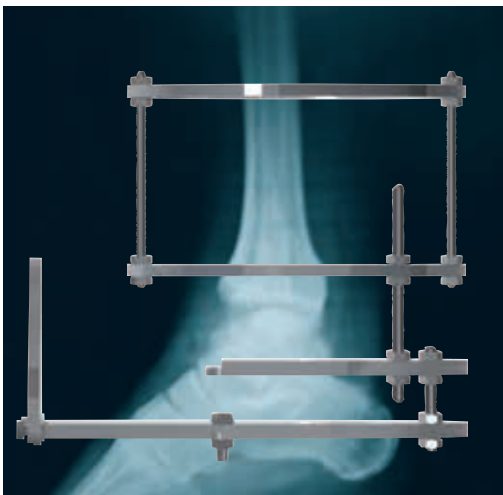
Revision ankle arthrodesis
Pantalar arthrodesis

PRE-OPERATIVE PLANNING

The TrueLok system offers the surgeon great flexibility in pin, ring, and wire positioning. The surgeon should modify the following technique to optimize the TrueLok system to the individual anatomy, pathology and clinical peculiarities presented by the patient at the time of surgery.

Select the proper ring diameter for the patient using the TrueLok ring sizing templates. To allow for normal post-operative swelling, it is advisable to provide appropriate space between the inner diameter of the TrueLok ring and the patient's skin. In general 3cm (~ two finger breadths) of anterior clearance and 5cm (~ three finger breadths) of posterior clearance affords ample room for the expected soft-tissue swelling.

A lateral x-ray and clinical examination may be used to determine the probable placement of the rings during pre-operative planning.



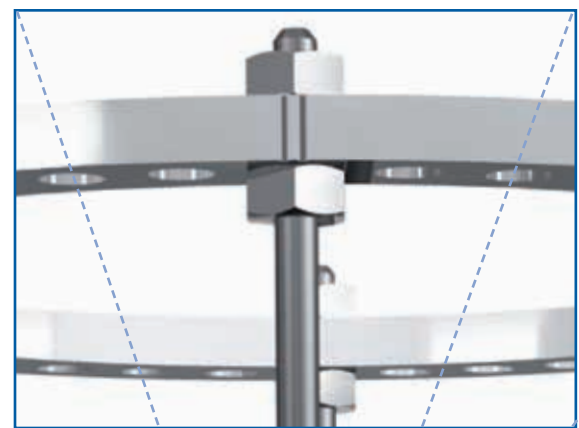
The proximal ring may be positioned a hand breadth and a half from the tibial tubercle or slightly distal to the distal extent of the medial Gastrocnemius muscle belly. To maximize stability, the distal tibial ring should be approximately 1cm proximal to the tibio-talar joint. The Talar Ring should equatorially bisect the dome of the talus. The Foot Support Assembly should be parallel to the plantar aspect of the foot, optimally allowing the placement of a 1.8mm wire above and below the foot plate for fixation into the posterior aspect of the calcaneus. Estimate the length of threaded rod needed to connect the Tibial Ring Block, Talar Ring and Foot Support Assembly. Allow enough threaded rod length between the distal tibial ring and the Talar Ring to compress the tibio-talar joint to achieve arthrodesis.

PRE-ASSEMBLE FRAME

The TrueLok frame may be applied pre-assembled in full, partially pre-assembled, or may be constructed at the time of surgery according to surgeon preference. A pre-assembled frame can save surgical time, minimize intraoperative frustration and markedly lower a patient's anesthetic exposure.

TrueLok rings, half rings, 5/8 rings and foot plates have two sets of quadrant markings. The double line is considered the Anterior/Posterior (A/P) reference line.

The single line is the Medial/Lateral (M/L) reference line.



1. Assemble the Tibial Ring Block

Create a ring block by inserting the proper length threaded rod through the A/P reference holes in two rings. Adjust the space between the two rings according to your pre-operative planning measurements. Secure the ring block with 10mm nuts on either side of the ring.

2. Prepare the Foot Support Assembly

The Foot Support Assembly consists of a foot plate, two foot plate extensions and a half ring. Connect the foot plate extensions to the foot plate with 16mm bolts and nuts. Hand-tighten the nuts. Insert 12mm bolts through the connection holes in half rings and into the tapped hole on the foot plate extensions. Firmly tighten these bolts. Push the foot plate and the extension assembly firmly together to eliminate any gap at the connection hole, then firmly tighten all nuts and bolts.



3. Attach the Foot Support Assembly to the Talar Ring

Connect the Foot Support Assembly to the Talar Ring using threaded rods in the 5th hole on either side of the A/P reference line.



4. Connect the Tibial Ring Block to the Talar Ring

Connect the Tibial Ring Block to the Talar Ring by placing two threaded rods into the fourth holes medially and laterally from the posterior AP reference line on the Talar Ring.



5. Inspect the Pre-Assembled TrueLok Ankle Arthrodesis Frame

Your pre-assembled TrueLok Ankle Arthrodesis Frame is now ready to be sterilized. Confirm the overall geometry of the TrueLok system is as desired and recheck the appropriate tightening of all nuts.





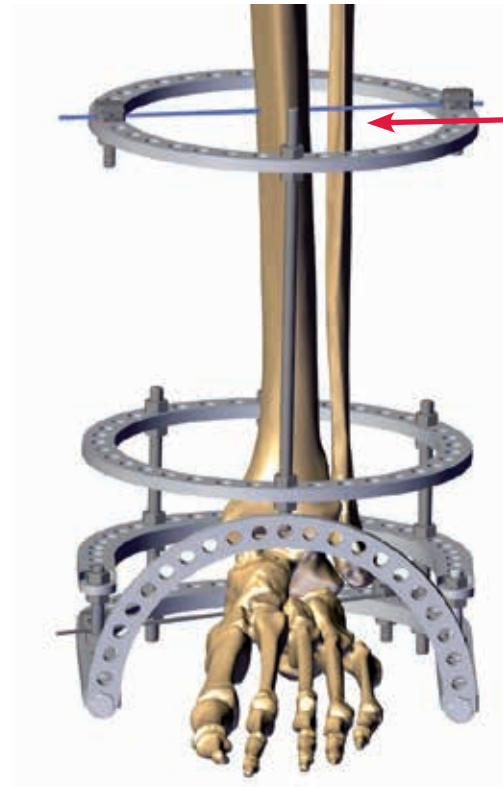
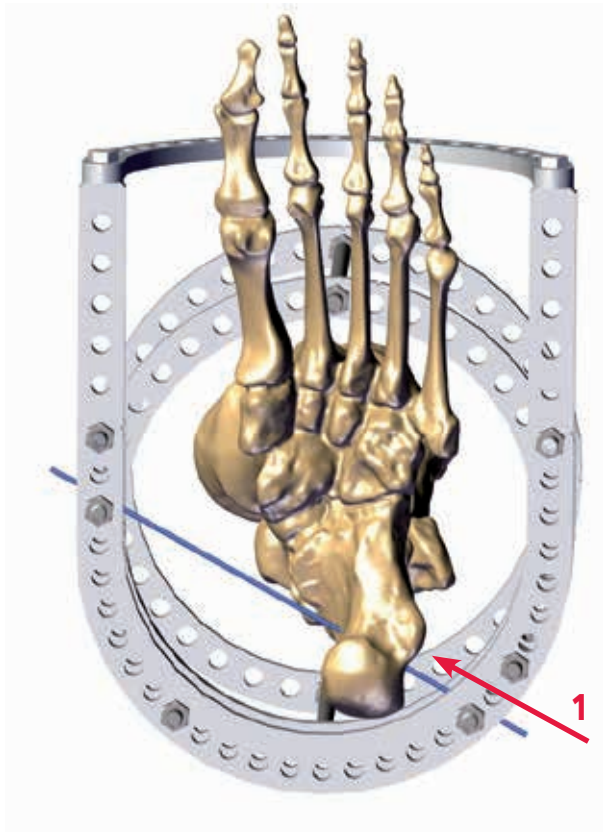
PATIENT POSITIONING

The TrueLok System has been designed to allow easy application from a variety of positions including the supine, prone, arthroscopic leg holder and lateral positions. Optimal patient position is as dictated by the individual clinical situation and surgeon preference. In many cases, a supine position may allow optimal joint preparation, limb alignment and TrueLok frame application.

APPLICATION OF THE TRUELOK ANKLE ARTHRODESIS FRAME

Slide the pre-assembled frame onto the patient. Verify adequate space between the skin and the inner surface of the ring to allow expected soft tissue swelling. Verify rod lengths, ring and foot plate positions to allow proper fixation of the foot, talus and tibia.

The Talar Ring and Tibial Ring Block should be positioned to allow easy pin and wire capture of the talus and tibia. Ring position may be confirmed under fluoroscopy. A skin marker may be useful to mark bony and soft tissue landmarks.



Wires and pins may be placed as per surgeon preference, taking into account the patient's anatomy and co-existing soft tissue and bony pathology. In most cases the limb is provisionally positioned with towel bumps in the TrueLok frame and progressively suspended in the frame by increasing numbers of wires and half pins. What follows is one of many techniques which may be used to successfully affix the TrueLok Ankle Arthrodesis Frame to the limb. A thorough knowledge of limb cross-sectional anatomy is critical for the proper placement of wires and half pins (Hoppenfeld, 2003).

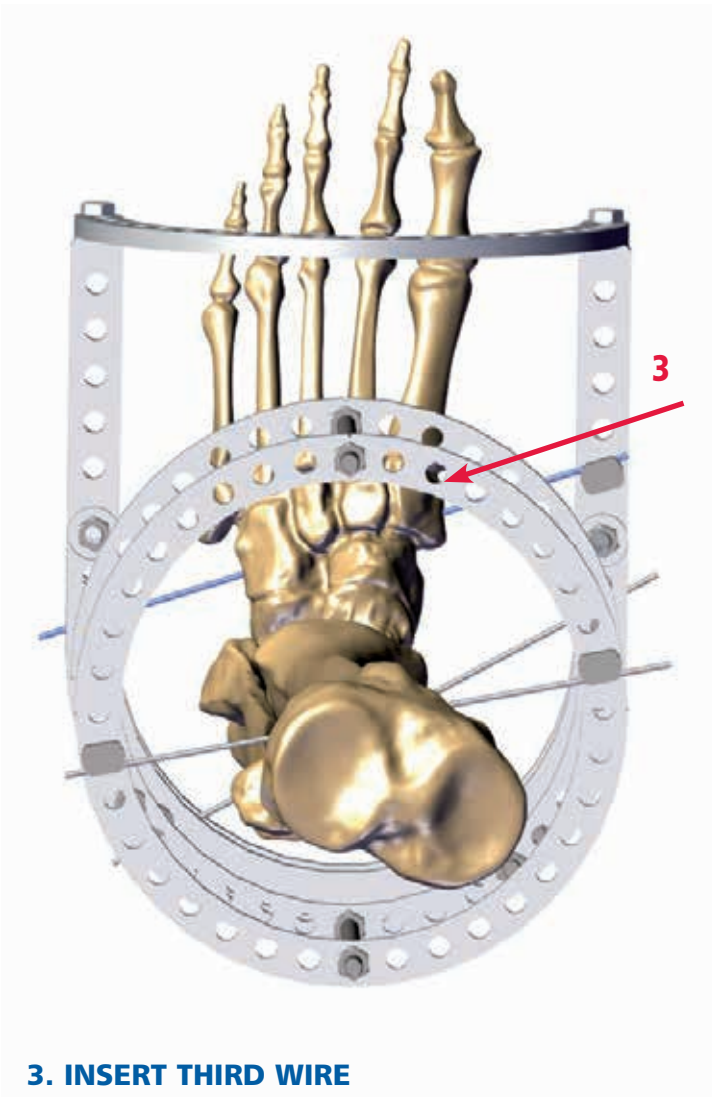
1. INSERT FIRST WIRE

Insert a transverse stopper wire (1) from the lateral side of the calcaneal. Be cautious to avoid the structures close to the sinus tarsi.

Verify proper alignment of the foot within the Foot Support Assembly and alignment of the tibia within the tibial ring block. Tighten the wire fixation bolt on the stopper side and tension the wire to 100kg.

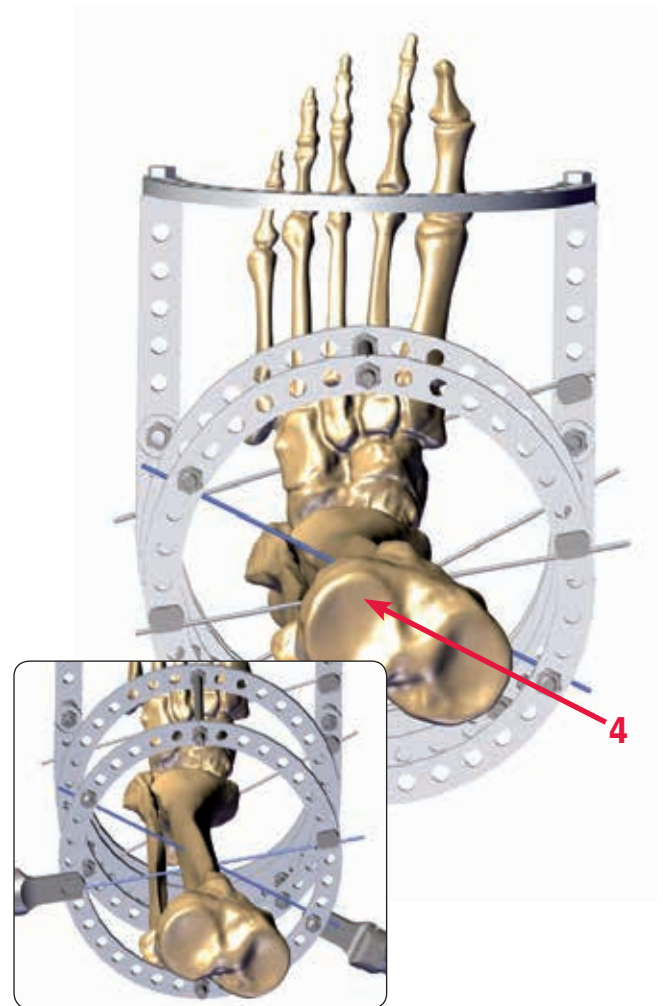
2. INSERT SECOND WIRE

Insert a transverse smooth wire (2) from the lateral side of the tibia. Secure the lateral wire fixation bolt and tension the wire to 130kg. Re-verify that the frame is parallel to the mechanical axis of the tibia in both A/P and lateral views.



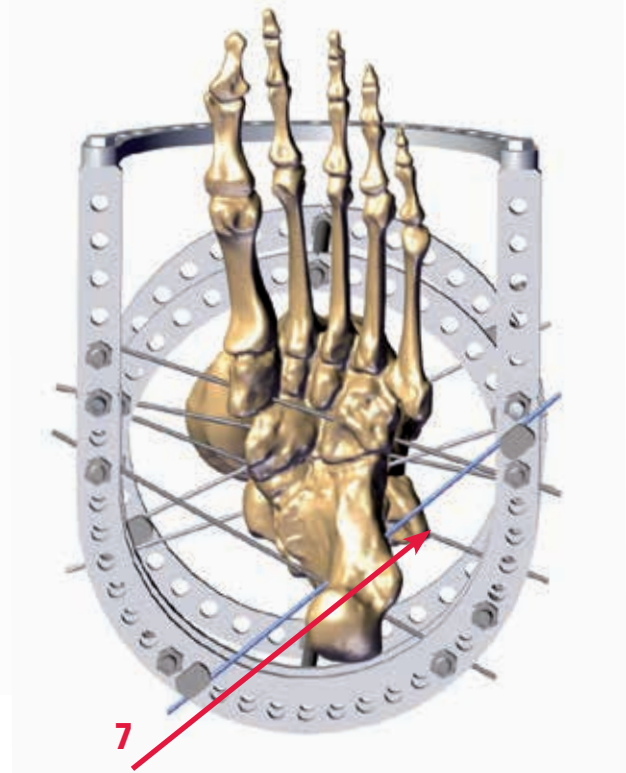
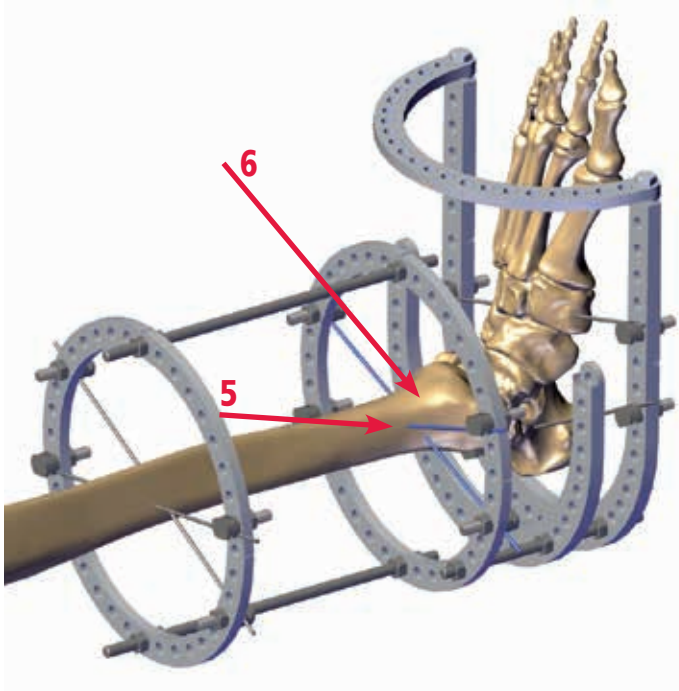
3. INSERT THIRD WIRE

Insert a stopper wire (3) through the midfoot. Tension this wire to 100kg and then cut the wire ends flush with the frame avoiding sharp edges. Alternatively, to avoid causing injury the ends of wires should be protected with special covers or bent at the ends as soon as they are tensioned.



4. INSERT FOURTH WIRE

Insert a medial face wire (4) at the proximal tibial ring level to complete stabilization of the proximal tibia. Loosen the first wire and then simultaneously tension both wires on the proximal ring to 130kg. Cut all wire ends flush with the ring avoiding sharp edges. Alternatively, to avoid causing injury the ends of wires should be protected with special covers or bent at the ends as soon as they are tensioned.

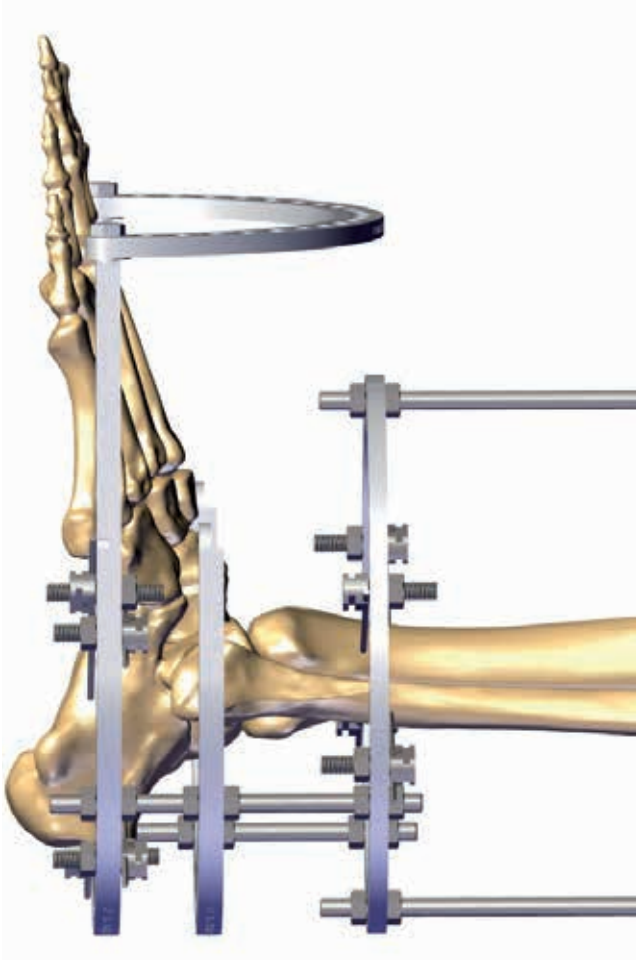


5. INSERT DISTAL TIBIAL WIRES

At the distal tibial ring level, insert a stopper wire (5) through the fibula and tibia to stabilize the distal tibia. Insert a smooth wire (6) at the appropriate crossing angle to complete stabilization of the distal tibia. Add threaded rods near the M/L reference lines to stabilize the ring block. Simultaneously tension the wires to 130kg and then cut the wire ends flush with the ring avoiding sharp edges. Alternatively, to avoid causing injury the ends of wires should be protected with special covers or bent at the ends as soon as they are tensioned.

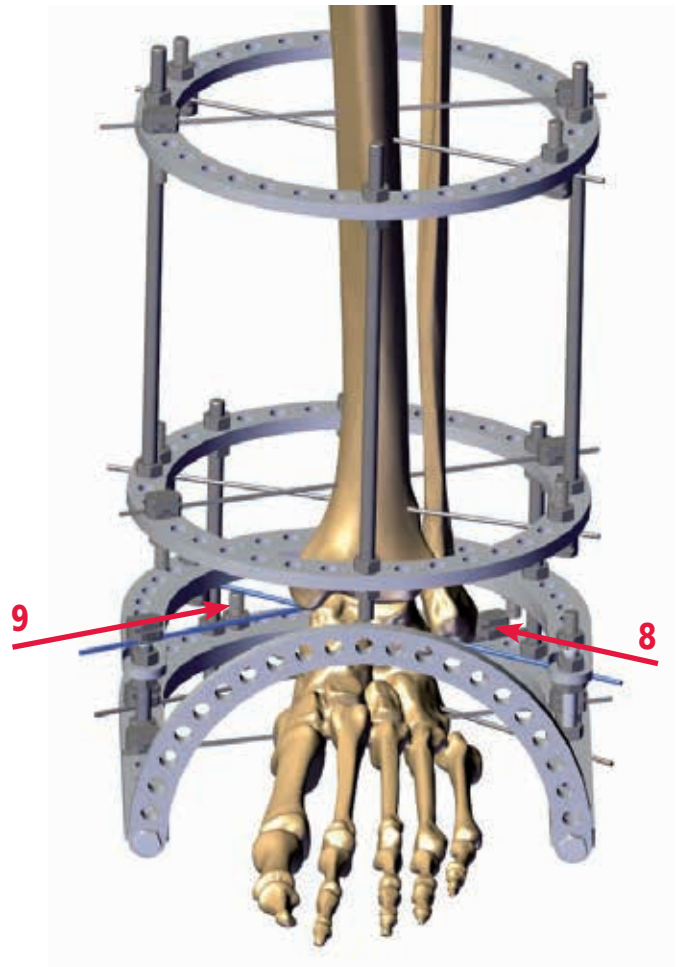
6. INSERT SECOND CALCANEAL WIRE

Insert a stopper wire (7) at approximately 60° to 70° to the first wire. Release tension on the first wire and then simultaneously tension both calcaneal wires to 100kg. Cut all wire ends flush with the ring avoiding sharp edges. Alternatively, to avoid causing injury the ends of wires should be protected with special covers or bent at the ends as soon as they are tensioned.



7. PROXIMAL FOOT PLATE ADJUSTMENT

Adjust the level of the proximal foot plate as necessary to ensure it bisects the dome of the talus.

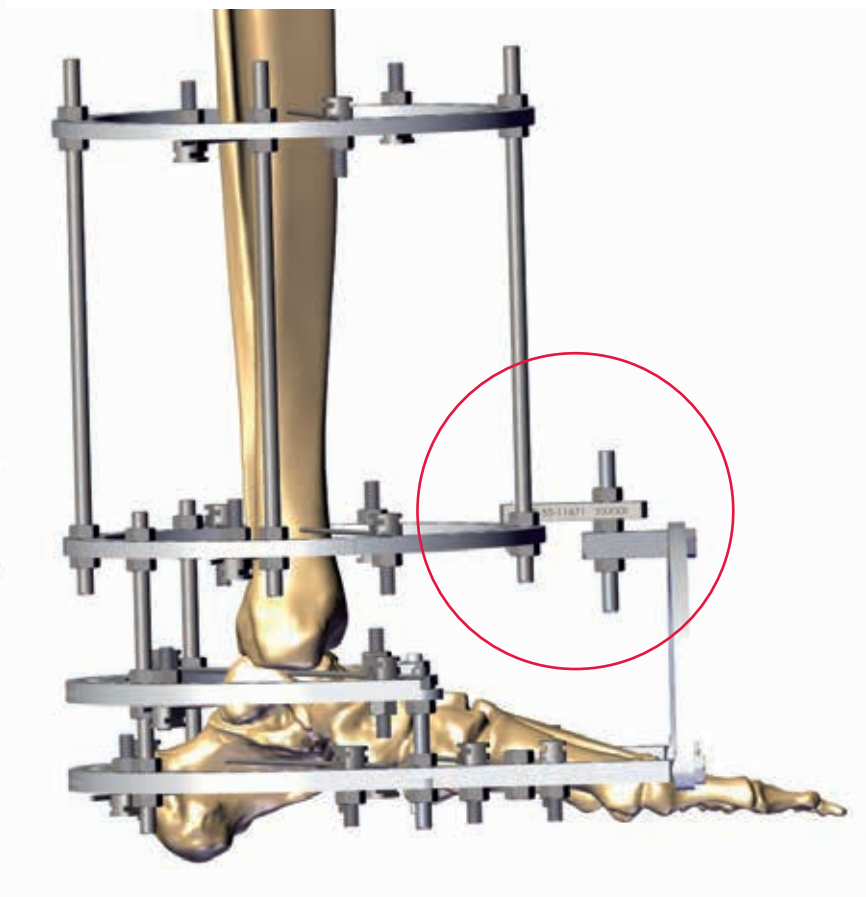
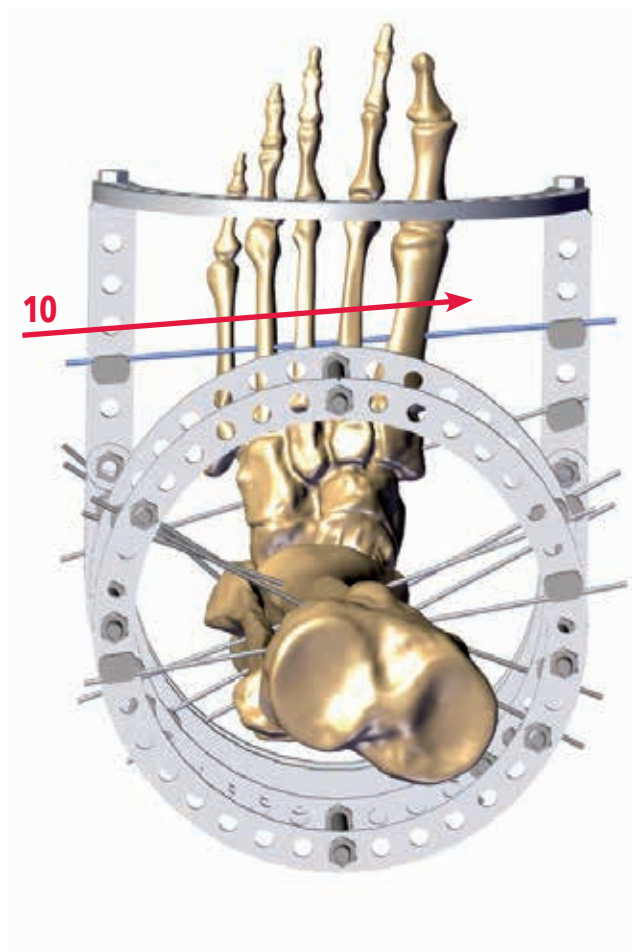


8. INSERT WIRES THROUGH TALUS

Insert the first stopper wire (8) from lateral-posterior to medial-anterior. Insert a second stopper wire (9) from medial-posterior to lateral-anterior. The crossing angle of these wires will be between 30° and 45°.

Confirm proper placement of the talar wires. Place threaded rods near the M/L reference lines to connect the anterior portion of the Talar Ring to the Foot Support Assembly

Simultaneously tension these wires to 100kg, then cut the wire ends flush with the ring avoiding sharp edges. Alternatively, to avoid causing injury the ends of wires should be protected with special covers or bent at the ends as soon as they are tensioned.

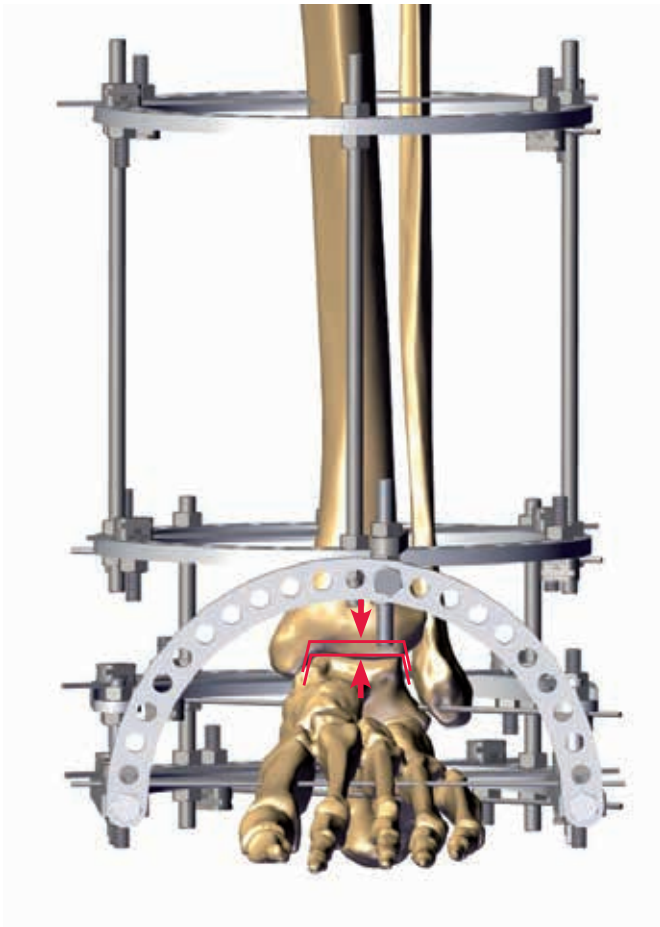


9. METATARSAL WIRE

Insert a stopper wire (10) through the metatarsals, starting at the base of the 5th and exiting through the base of the 1st. This wire may be needed in heavier or osteopenic patients where additional stability is desired. Tension this wire to approximately 70-80kg, then cut the wire ends flush with the ring avoiding sharp edges. Alternatively, to avoid causing injury the ends of wires should be protected with special covers or bent at the ends as soon as they are tensioned.

10. CONNECT FOOT SUPPORT ASSEMBLY

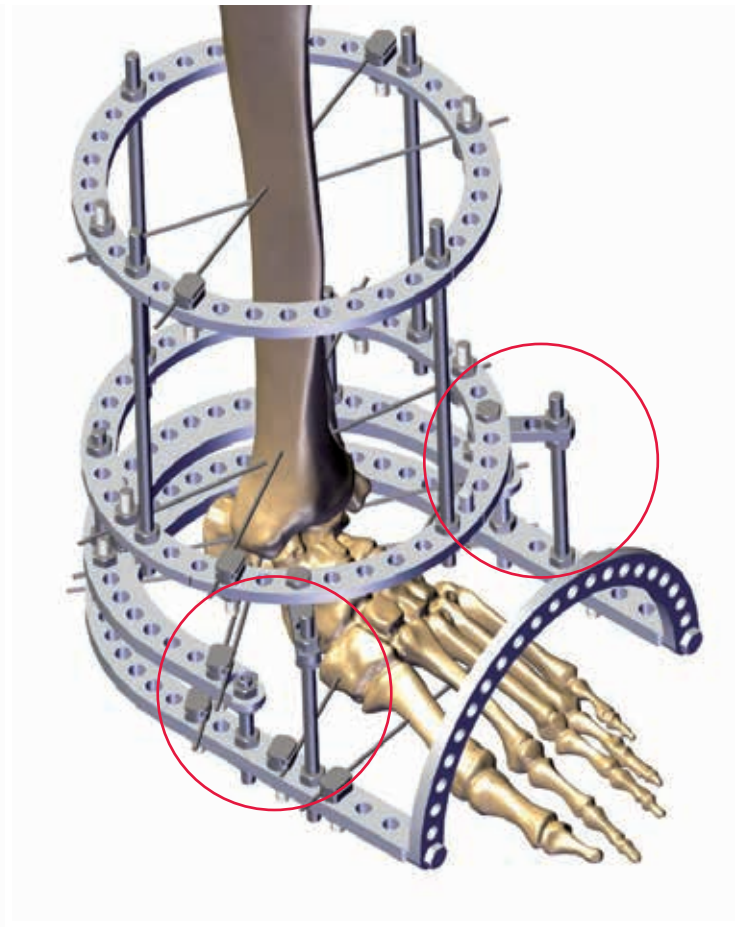
Connect the anterior portion of the Foot Support Assembly to the distal ring of the Tibial Ring Block using an appropriate length plate, threaded rod and post.



11. APPLY COMPRESSION ACROSS THE TIBIO-TALAR JOINT

Loosen the nuts distal to the distal tibial ring. Compress the tibio-talar joint. Once the desired compression is achieved tighten all nuts securely.

Verify adequate compression across the tibio-talar joint by fluoroscopy or direct visualization. The TrueLok wires may bow slightly under applied compression load.



12. OPTIONAL SUPPORT

Additional stability may be desirable for heavier patients or when additional compression is needed across the tibio-talar joint. In such cases the surgeon may choose to use plates and threaded rods to connect the foot plate extension portions of the foot support assembly directly to the distal ring of the Tibial Ring Block.

CLOSURE AND DRESSING

Ensure all nuts, bolts and frame connection points are tight. Closure is as routine. A sterile compression dressing is applied.

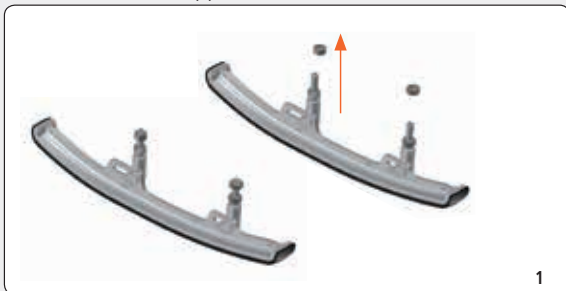
POST-OPERATIVE CARE

Post-operative care is tailored to the surgeon's preference and clinical situation. In many cases, patients may be allowed to weight bear as tolerated immediately. Pin site care is as per surgeon preference. The frame is typically removed once radiographic and clinical signs of union have been achieved.

TrueLok ROCKERRAIL

- A. The TrueLok RockerRail is compatible with TrueLok and TL-HEX Foot Plates
- B. Patient should be warned about hazard related to slippage
- C. For important medical information and maintenance consult Instructions for Use PQ TLK, PQ TLH
- D. Steam sterilization not allowed

TrueLok RockerRail Application



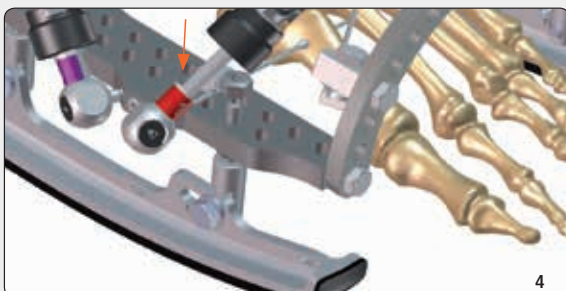
1. Remove the outer locking nut from the fixation rods on the rails



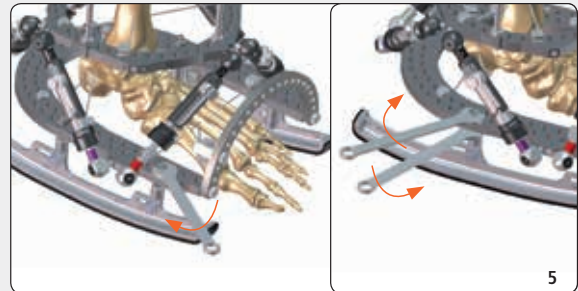
2. Loosen the adjustable sliding fixation



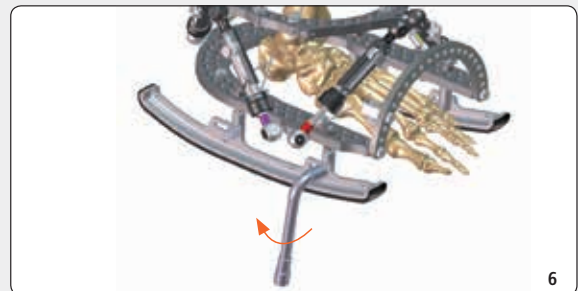
3. Place the TrueLok RockerRail with the FRONT marking anteriorly onto the Foot Plate by inserting its fixation rods into the appropriate holes



4. Place locking nuts back onto the fixation rods of the rails

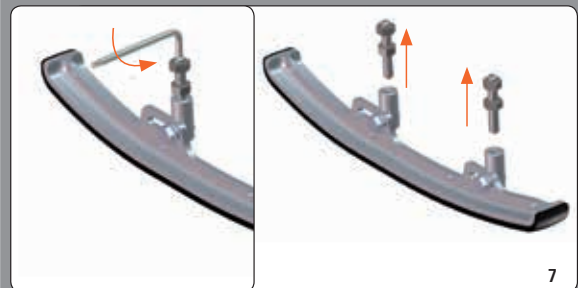


5. Use two 10mm wrenches to lock the rails onto the Foot Plate firmly

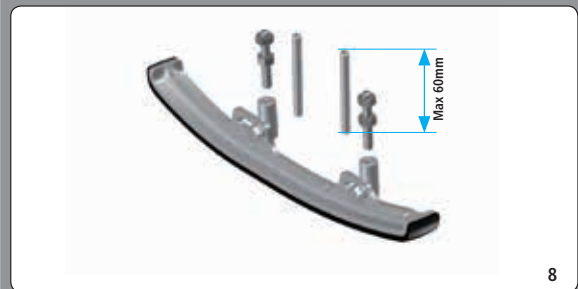


6. The rails should be adjusted as needed for ideal placement. Lock the adjustable sliding fixation

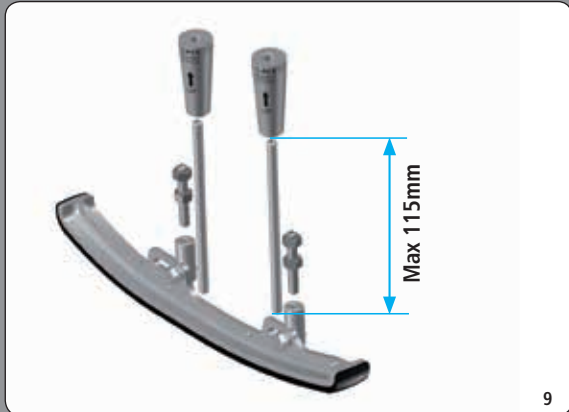
TrueLok RockerRail Height Adjustment



7. In the case of needing longer threaded rods, please remove the provided rods with the 1/8" Allen wrench



8. Exchange the rods with the threaded rods of the desired length



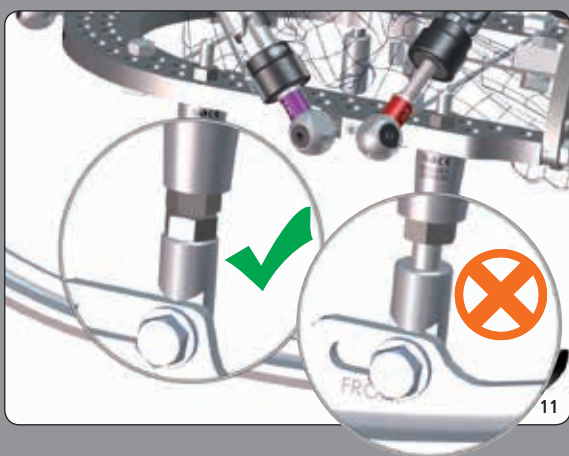
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9. If threaded rods longer than 60mm are necessary, strengthen the construct with the Rocker Rail Extension Kits. Do not use threaded rods longer than 115mm. In case a greater extension is needed, consider adding an additional footplate



10

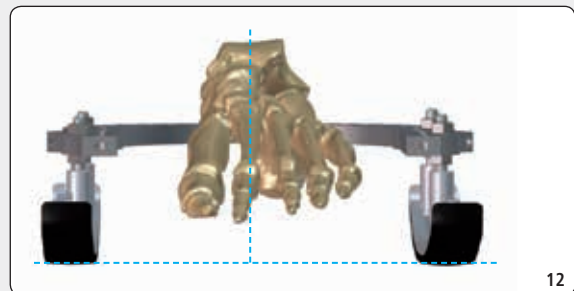
10. The larger side of the Extender must be in direct contact with the footplate



11

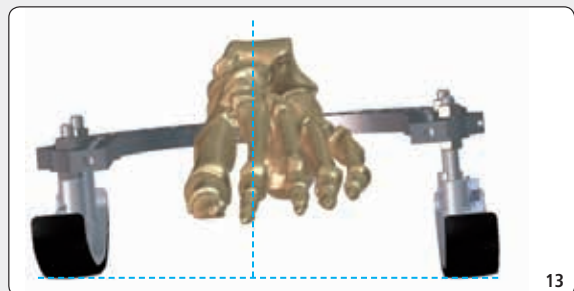
11. To adjust the distance between Footplate and Rocker Rail insert nuts and/or extended nuts between the Extender and the Rocker Rail. Do not allow any portion of bare rod.

TrueLok RockerRail Final Check (Warnings & Precautions)



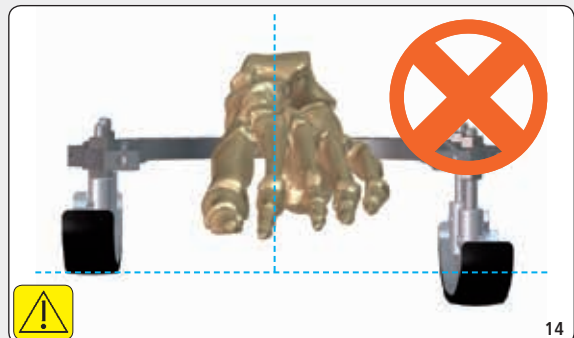
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12. Make sure that the two rails are placed onto the Foot Plate to provide a balanced platform to the foot, keeping it in a neutral position



13

13. The rails can be placed unevenly relative to each other but, they should keep the foot in a neutral position



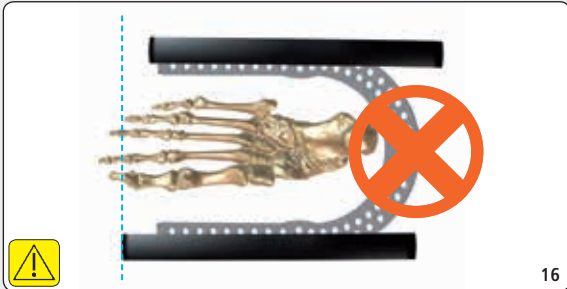
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14. The rails should never be placed in a way to pronate or supinate the foot in static position



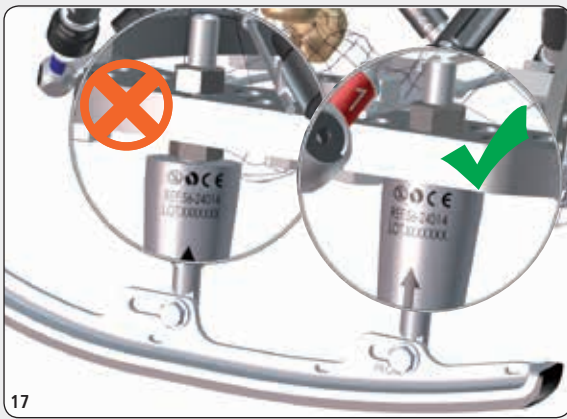
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15. The front and the rear of the rails should always be in line with each other



16

16. The rails should never be placed offset to each other



17

17. Do not put nuts between the Footplate and the Extender




18. Use maximum one Extension Tube per threaded rod.

56-24000



56-24014

INSTRUMENT

Part#	Description	Qty.
52-1020	TL-HEX Driver 90°	1
		
54-1154	Wrench, Combo - 10mm	2
		
54-2226	Tubular Wrench	1
		

If your leaflet does not include the text in your language, please refer to the electronic instructions.

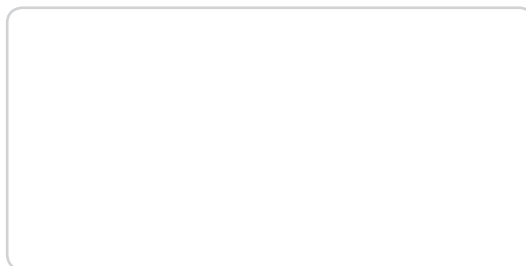
Electronic Instructions for use available at the website
<http://fu.orthofix.it>

Electronic Instructions for use - Minimum requirements for consultation:

- Internet connection (56 kbps)
- Device capable to visualize PDF (ISO/IEC 32000-1) files
- Disk space: 50Mbytes

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Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience. Please refer to the TrueLok Instructions for Use (PQ TLK) supplied with the product for specific information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.