TrueLok™ Elevate

Transverse Bone Transport System
Surgical Technique

ORTHOFIX®

Table Of Contents

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please kindly refer to the product IFU PQTLE, PQTLK and PQEVO, to the Orthofix implantable devices and related instrument IFU PQSCR, and to the reusable medical devices IFU PQRMD that contain instructions for use of the product.

INTRODUCTION

General Description
The TrueLok™ Elevate (TL Elevate) Transverse Bone Transport System consists of a device that is connected to the bone by means of half pins. It can be used as a standalone device (Fig. 1) or it can also be used in combination with circular external fixator (one or two rings) to create hybrid frames (Fig. 2).

The circular fixators used with TL Elevate can be the TrueLok™, the TL-HEX™ TrueLok Hexapod System and the TrueLok™ EVO.

To distract the bone segment, the knob of the device shall be pulled and rotated counterclockwise (following the direction of rotation indicated by the arrow marked on the knob).

Every quarter of a turn the knob returns pushed in contact with the bar. To activate it again, the knob shall be pulled and rotated as previously described. During each turn (counterclockwise) the number of dots (from 1 to 4) aligned with the Orthofix logo will increase.

Contrarily, to compress the bone segment, the knob of the device shall be pulled and rotated clockwise.

Every quarter of a turn, the device moves the bone segment of 0.25mm from the previous position.

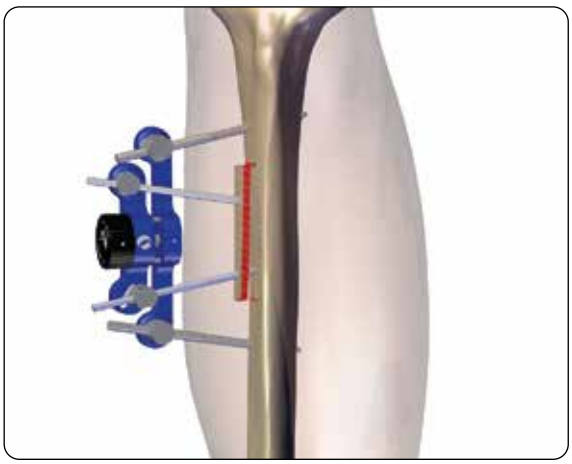


Fig. 1 TL Elevate - Stand Alone

Fig. 2 TL Elevate - Hybrid Frame

Fig. 3 TL Elevate - Hybrid Frame

MRI (Magnetic Resonance Imaging) Safety Information

The TL Elevate external fixator is MR unsafe "MR".
Keep away from MRI examination room.

Instrumentations, since they do not enter in an MR environment, have not been evaluated for safety in the MR environment. They have not been tested for heating or unwanted movement in the MR environment. The safety of instrumentations in the MR environment is unknown. Performing an MR exam on a person who has these medical devices may result in injury or device malfunction.

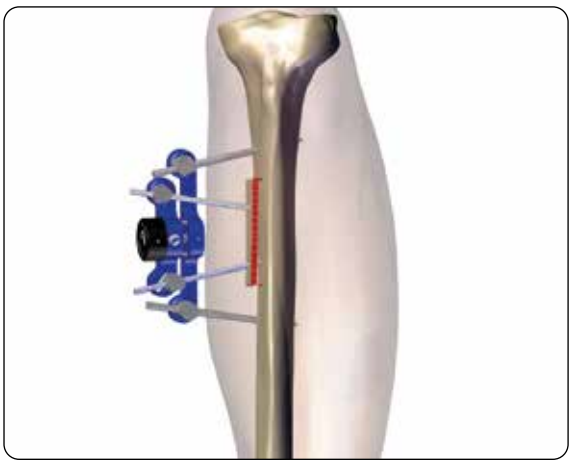


Fig. 4 TL Elevate Proximal Tibia application

Fig. 5 TL Elevate Mid-shaft Tibia application

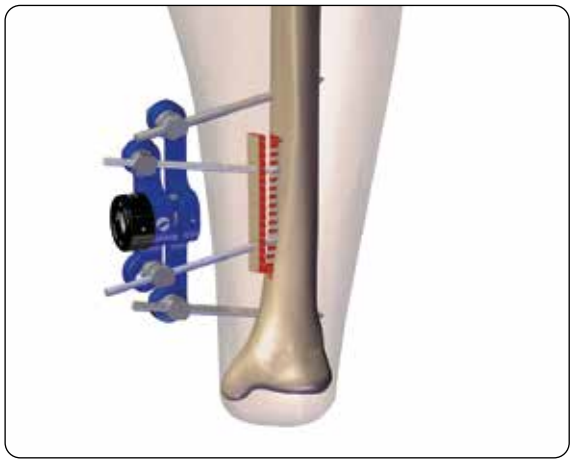


Fig. 6 TL Elevate Distal Tibia application

SYSTEM OVERVIEW

Features and Benefits

- Simple: The TL Elevate offers functional components that are easy to connect, align and operate
- Stable: The connection element avoids undesired rotation and component loosening during treatment
- Dedicated sterile packaging, ready to use
- Template for bone osteotomy included in the packaging allowing the surgeon to have a precise reference for bone cutting
- One mechanism to activate the device

Description of Product Components

The TL Elevate transverse bone transport is a device that is connected to the bone by means of half pins. TL Elevate is made up of the following components:

External Fixator

TL Elevate consists of a static and dynamic bar interconnected by a central bolt and three guide pins allowing movement of the dynamic bar.

- **Two Bars**
  One dynamic bar has two slots accepting two TL half pin fixation bolts and two half pins that connect to a transport bone segment and a static bar with two slots accepting two TL half pin fixation bolts and two half pins that connect to the bone. The dynamic bar has a maximum travel of 14mm and moves by rotating the knob in either a clockwise or counter-clockwise direction, depending on whether the device is distracting or compressing.

- **Knob**
  A spring-loaded knob that allows movement of the dynamic bar up to 14mm by pulling and turning in either a clockwise or counterclockwise direction followed by an audible locking of the knob with a “click”.

- **TL Half Pin Fixation Bolts**
  Four TL Half Pin Fixation bolts attach to the static (2pcs) and dynamic (2pcs) bars and accept half pins and are tightened by spherical nuts (3pcs) and a flat nut (1pc) (Fig. 8 and 9).

Template

A template with two threaded holes that accept threaded guide tubes (2pcs) that then accept wire inserts (2pcs) and drill inserts (2pcs) (Fig. 10). The template includes a 2.0mm central hole that accepts a central stabilization wire and two anterior slots that allow template to slide out after insertion of transport segment half pins and removal of threaded guide tubes.

Guide Tubes

Two, hexagonal threaded guide tubes (Fig. 11) that are pre-threaded into template at a 20° angle that accept wire inserts (2pcs) and drill inserts (2pcs) (Fig. 11).

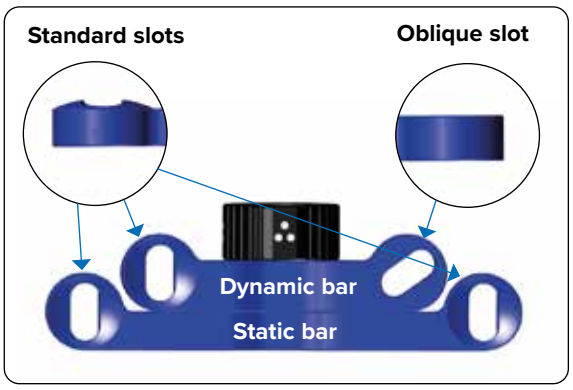


Fig. 7

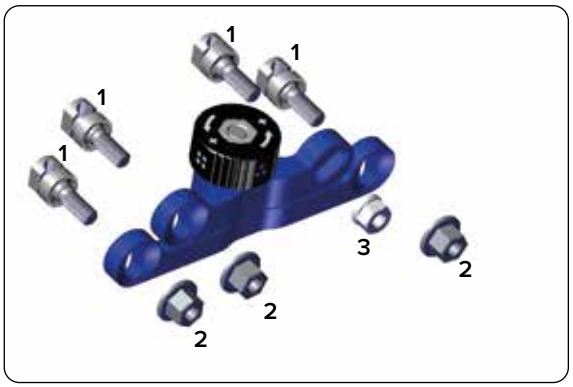


Fig. 8

Ref.		Description
1		TL HALF PIN FIXATION BOLT
2		TL SPHERICAL NUT
3		TRUELOK EVO NUT WITH WASHER

Fig. 9

Fig. 10

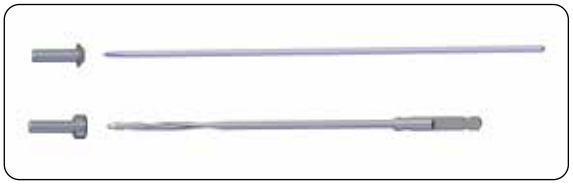


Fig. 11

TrueLok Elevate Drill Positioning guide:
The TL Elevate Drill Positioning Guide is a new tool specifically designed for TrueLok Elevate, whose three terminals serve to: A) unscrew the hexagonal pin guides, (B) guide the drilling at the template's corners (with the dedicated 'X' end), and C) guide the drilling template along the long sides of the cutting guide ('I' end).

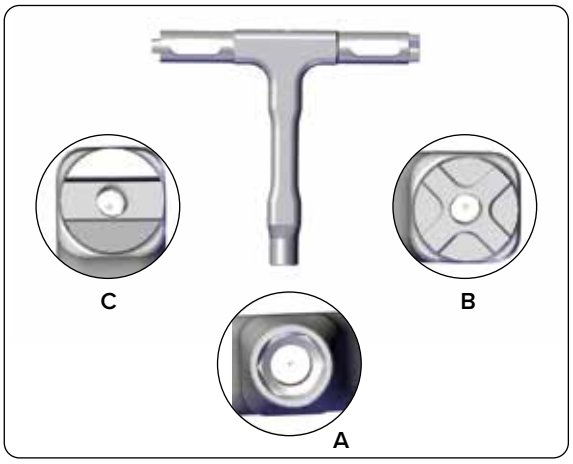


Fig. 12

Transport Segment Half Pins L120mm D4mm, Thread L18mm D4mm:
New monocortical half pins specifically developed to ensure optimal purchase on the corticotomy (Fig. 13).

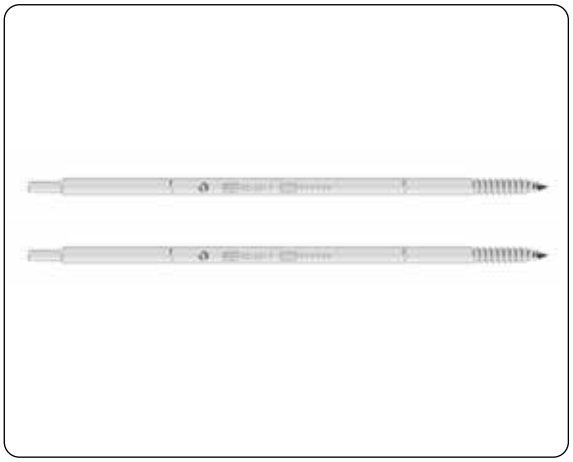


Fig. 13

TrueLok Straight tube wrench (Fig. 14).

Fig. 14

OPERATIVE TECHNIQUE

Surgical Steps

1. Template Positioning & Marking of Incisions
Using standard instrumentation, place template on the skin, paying attention that the template is oriented with slots directing anteriorly (Fig. 15).

PRECAUTION: Pay attention that the template is positioned at least 40mm from the joint to allow the positioning of bicortical half pins in the static bar.

Plane of template during x-ray should be parallel to x-ray.

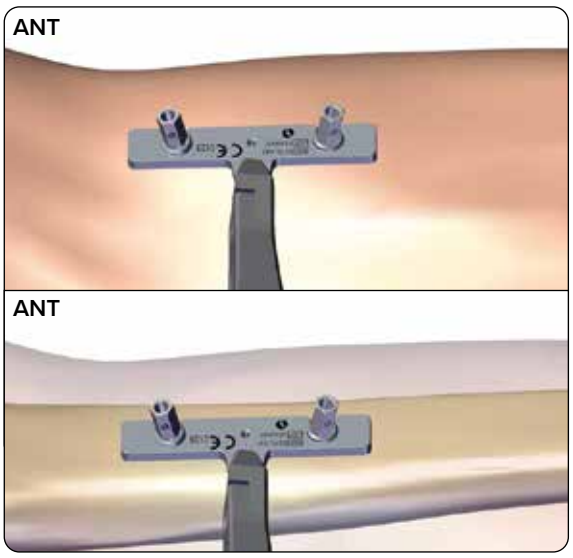


Fig. 15

Under fluoroscopy, confirm the position of the template at desired level (at least 40mm from joint line) and orientation (between two cortices and parallel to x-ray source) (Fig. 16).

WARNING: The template must be positioned within the medullary canal during fluoroscopy check.

PRECAUTION: Utilizing fluoroscopy, ensure that the template is positioned within the medullary canal in order to assure an unicortical transport segment.

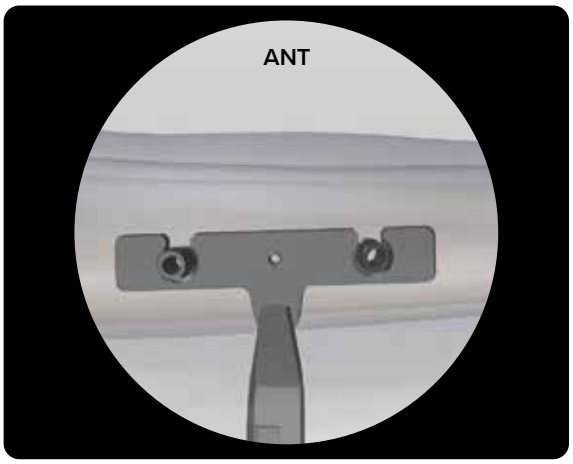


Fig. 16

Place a 1.8mm bi-cortical central stabilization wire through the central hole of the template (Fig. 17 and Fig. 18).

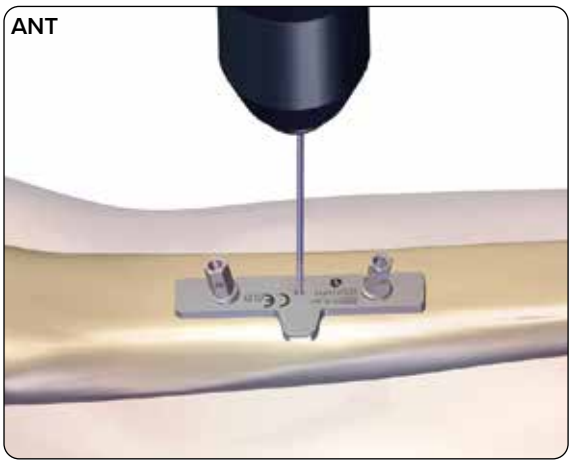


Fig. 17

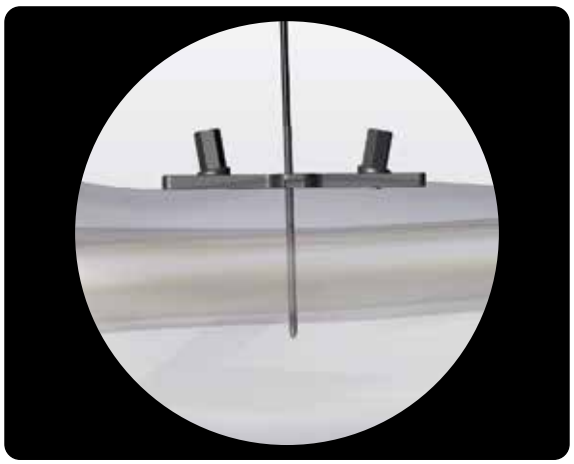


Fig. 18

Mark around the perimeter of the template the location of two incisions for two guide tubes, and the incision to approach the osteotomy site on the skin (Fig. 19).

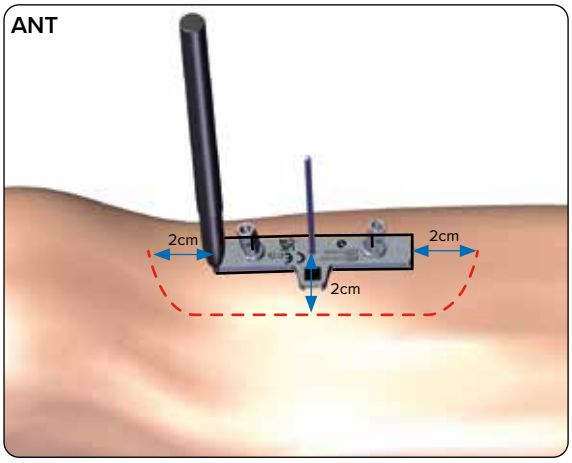


Fig. 19

To mark the location of the guide tube incisions, mark the slots on the anterior side of the template, then rotate the template on the central stabilization wire and draw a mark to indicate the incision location of both guide tubes (Fig. 20).

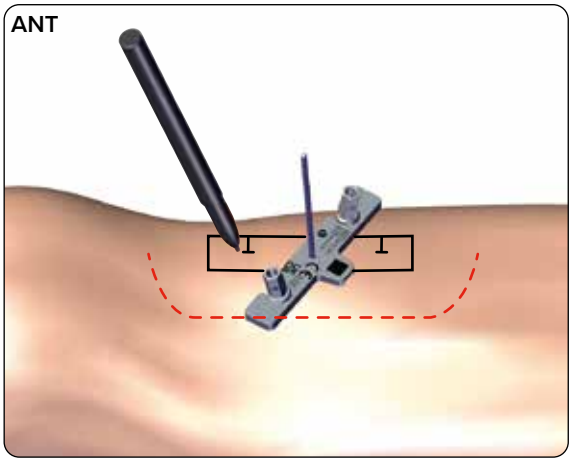


Fig. 20

Cut the central stabilization wire, leaving approximately 5mm from the template in order to remove the wire easily (Fig. 21).

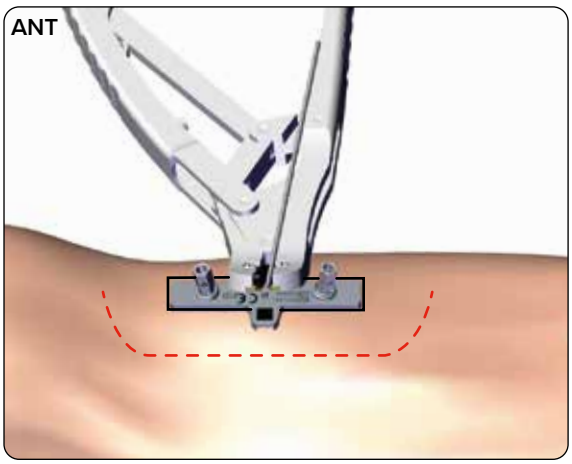


Fig. 21

Remove the template by lifting it off of the central stabilization wire (Fig. 22).

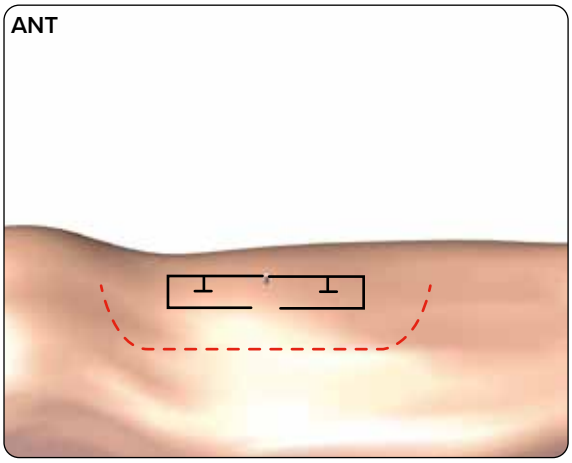


Fig. 22

2. Corticotomy Site Preparation
Make two previously marked longitudinal, full-thickness incisions for the guide tubes, each least 10mm long (Fig. 23).

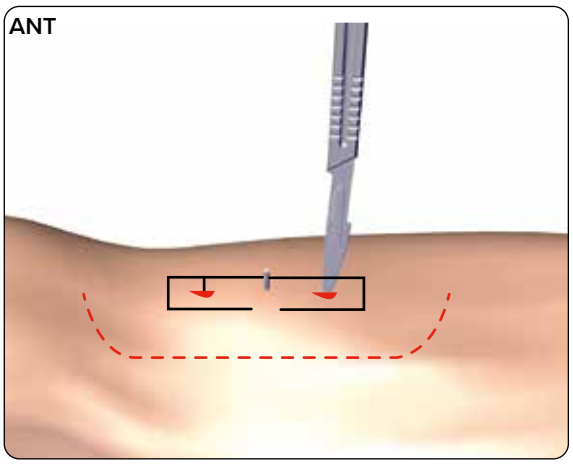


Fig. 23

Make an approximately 180mm long, full-thickness arched incision along the posterior aspect of the template outline to approach the corticotomy site (Fig. 24).

The shape of the incision can be modified (e.g. anterior to template) per surgeon preference.

Flip the created skin flap anteriorly and secure with 2-3 sutures to provide desired approach to osteotomy site.

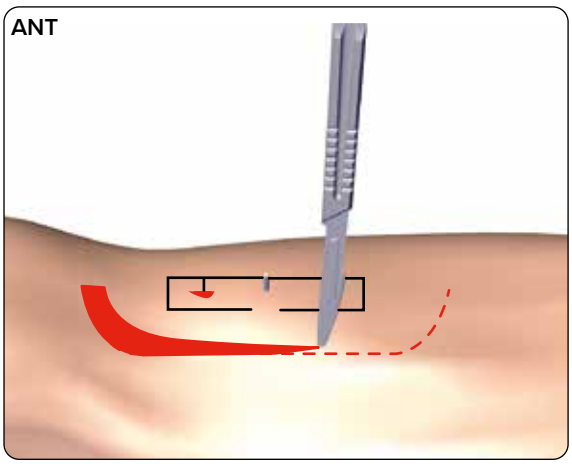


Fig. 24

Make sure the created opening allows enough space for the subsequent repositioning of the template, predrilling and partial cutting of the corticotomy. (Fig. 25).

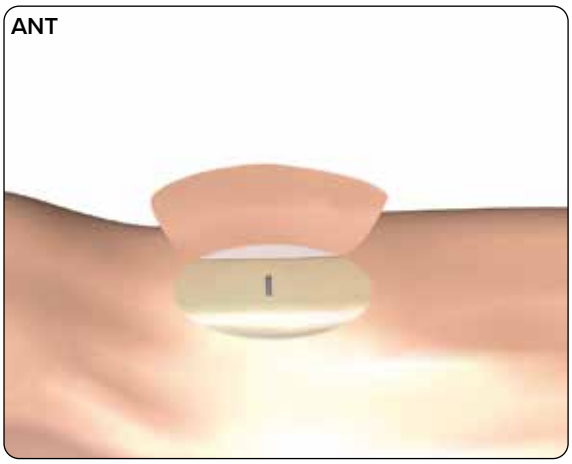


Fig. 25

Reposition template by placing central hole of the template back onto the previously inserted central guide wire.

Under fluoroscopy, reconfirm the orientation of the template (Fig. 26) and place two wire inserts into the guide tubes on the template.

PRECAUTION: Utilizing fluoroscopy, ensure that the template is positioned within the medullary canal in order to assure a unicortical transport segment.

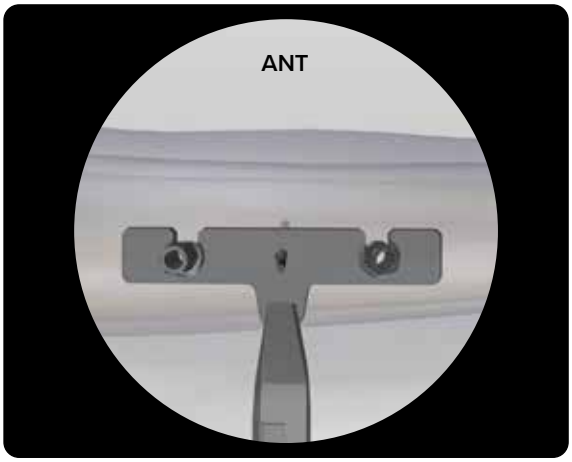


Fig. 26

Insert the first bi-cortical oblique stabilization wire through the wire insert and guide tube of the template (Fig. 27).

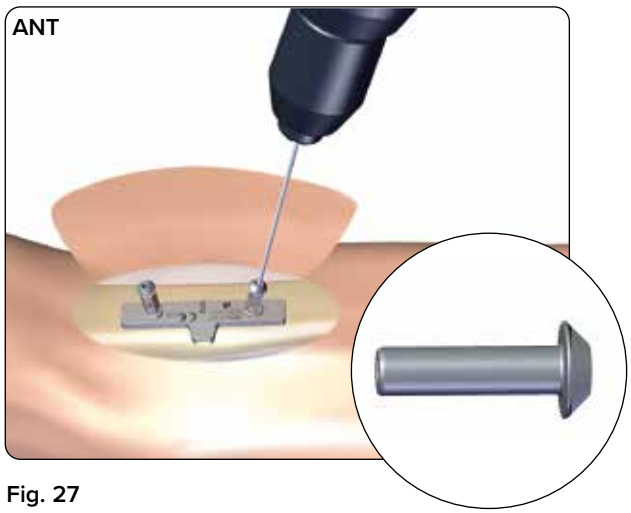


Fig. 27

Insert second bi-cortical oblique stabilization wire through the wire insert and guide tubes of the template (Fig. 28 and Fig. 29).

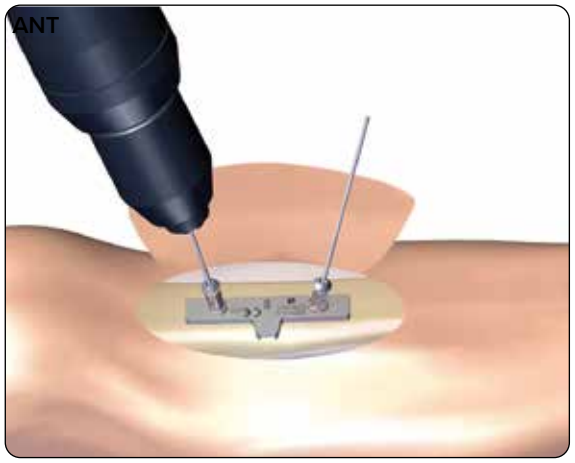


Fig. 28

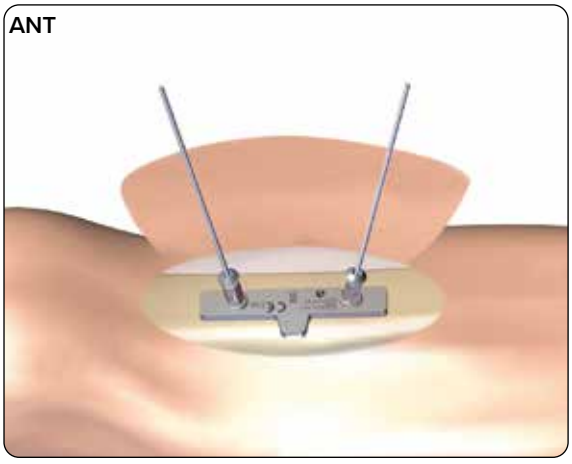


Fig. 29

Cut both oblique stabilization wires flush with the tops of the wire inserts (Fig. 30).

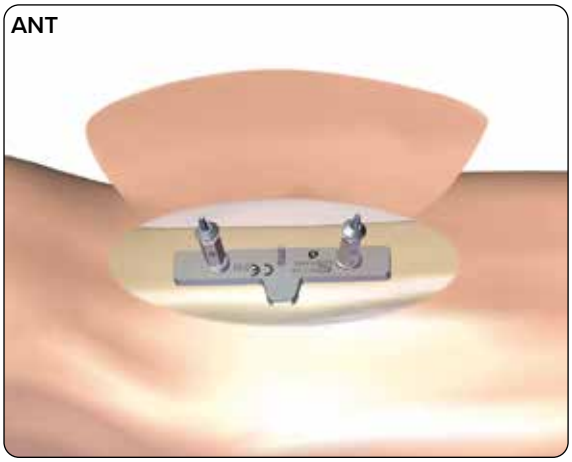


Fig. 30

3. Partial Transport Segment Corticotomy

Using the 2.7mm drill bit and drill positioning guide, drill holes around te perimeter of the template to outline the transport segment. Be sure to use the appropriate side of the drill positioning guide when drilling corner and side holes. Use the cross end of the drill positioning guide to drill the corners first (Fig. 31 and Fig. 32), followed by using the flat end of the drill positioning guide to drill on the sides of the template (Fig. 33 and Fig. 34).

Use appropriate end of the drill guide when drilling corner and side holes.

PRECAUTION: When drilling angulate the drill guide slightly (approximately 3-4°) to form a trapezoidal shape of the transport segment to prevent its impingement.

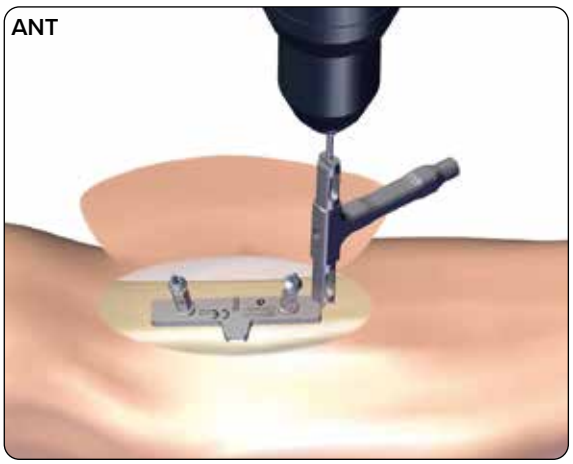


Fig. 31

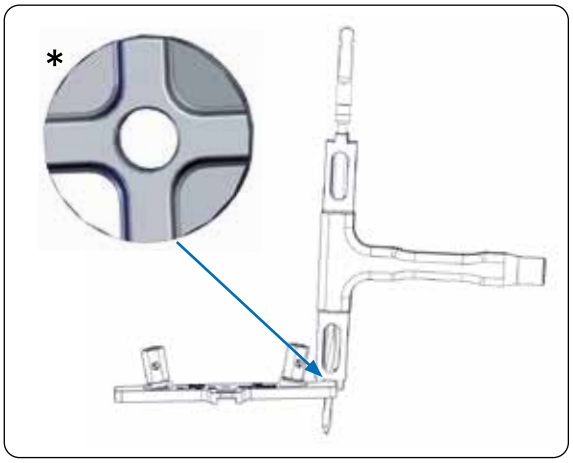


Fig. 32 - * Zoom of “cross” end of TrueLok Elevate drill positioning guide

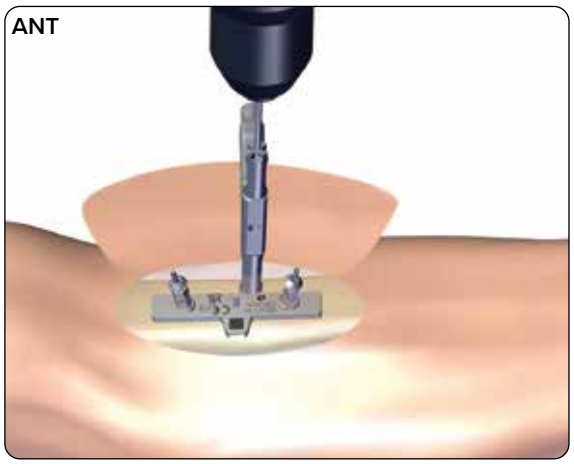


Fig. 33

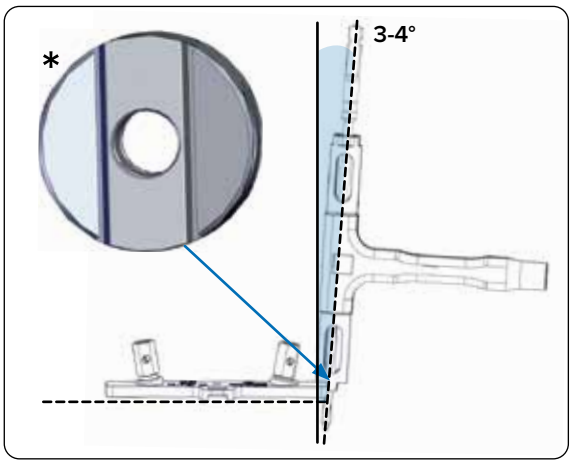


Fig. 34 - * Zoom of “flat” end of TrueLok Elevate drill positioning guide

Using either a narrow osteotome or an oscillating saw, perform corticotomy of proximal, distal, and anterior sides through predrilled holes leaving posterior side intact (Fig. 35 and Fig. 36).

It is recommended to start the cuts on the posterior sides of the corticotomy, but go no more that half the saw blade width on either side.

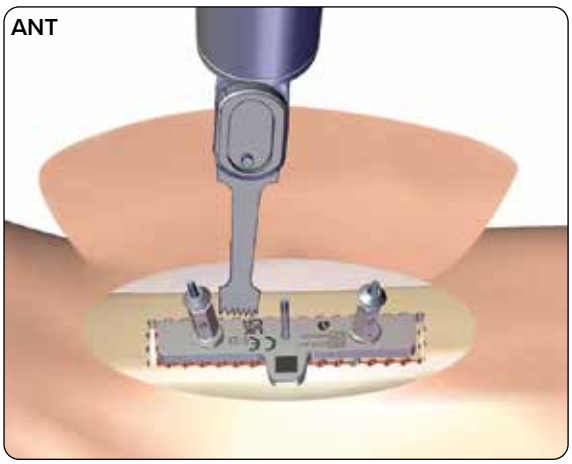


Fig. 35

WARNING: During partial corticotomy, do not cut all the sides of the transport segment, leaving a majority of the posterior side intact.

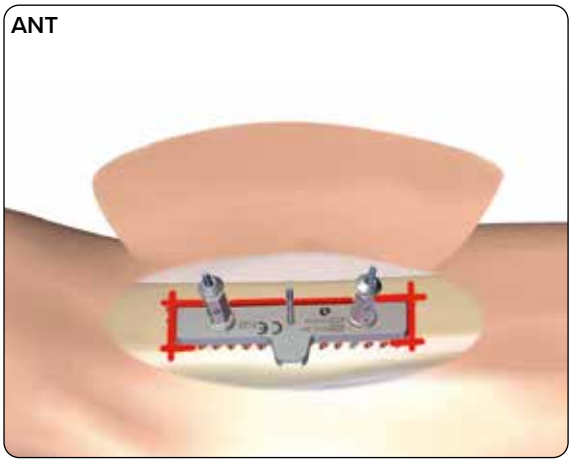


Fig. 36

4. Insertion of the Transport Segment Half Pins
Reposition the skin flap over the template ensuring that the guide tubes and central wire protrude through the skin (Fig. 37).

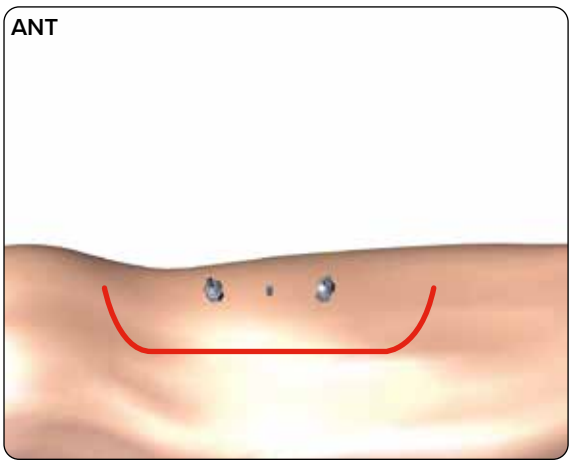


Fig. 37

Check if the guide tubes are tightened to the template and remove the first wire insert and corresponding bi-cortical oblique stabilization wire from the guide tube (Fig. 38).

PRECAUTION: Before half pins insertion, do not remove simultaneously all the wires that stabilize the template, but only one at a time.

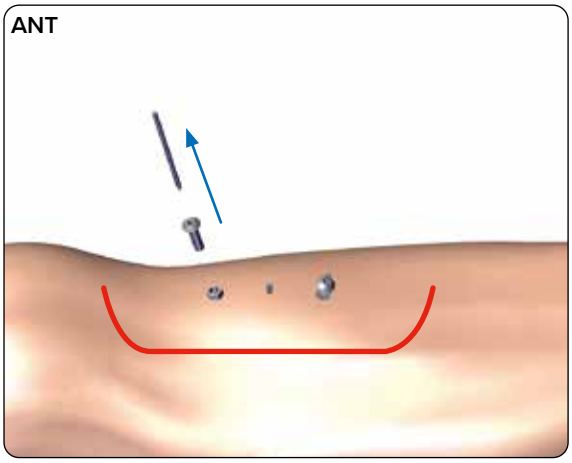


Fig. 38

Place the first drill bit insert into the guide tube (Fig. 39).

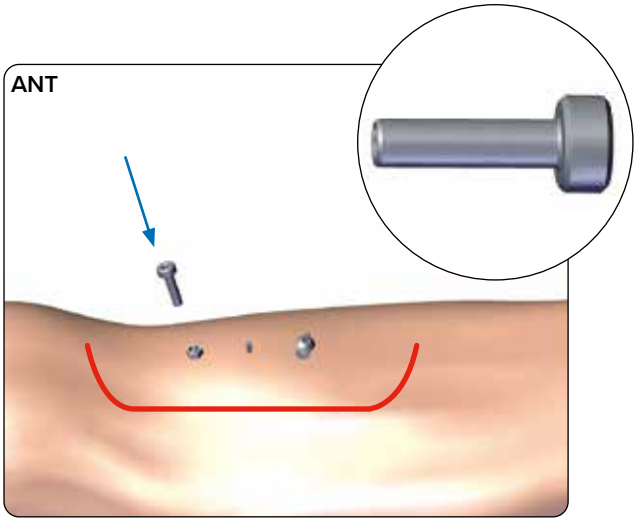


Fig. 39

Predrill monocortical hole for the first transport segment half pin using 2.7mm drill bit (Fig. 40).

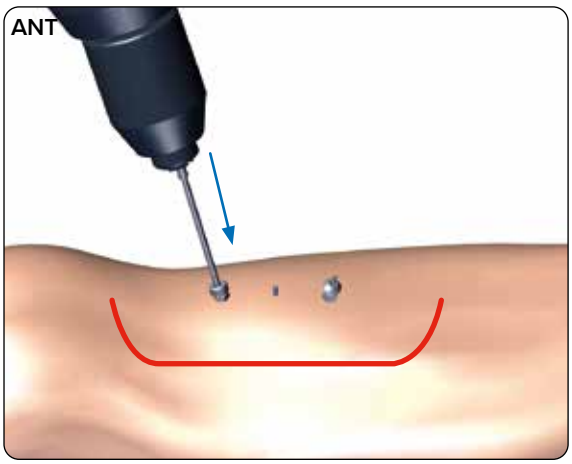


Fig. 40

Remove drill bit insert from the guide tube (Fig. 41).

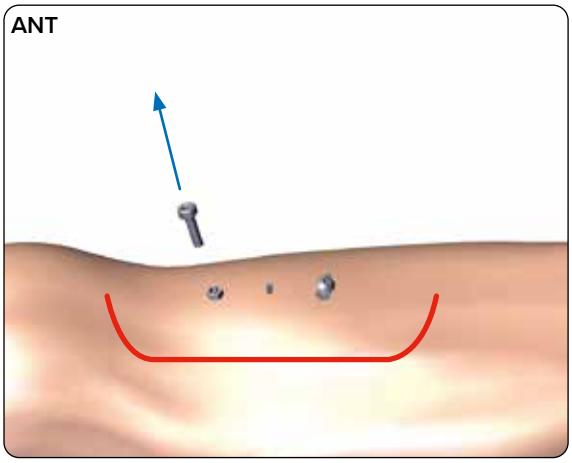


Fig. 41

Using M210 T-Wrench, manually insert the first transport segment half pin until the groove on the transport segment half pin is flush with the pin guide (Fig. 42).

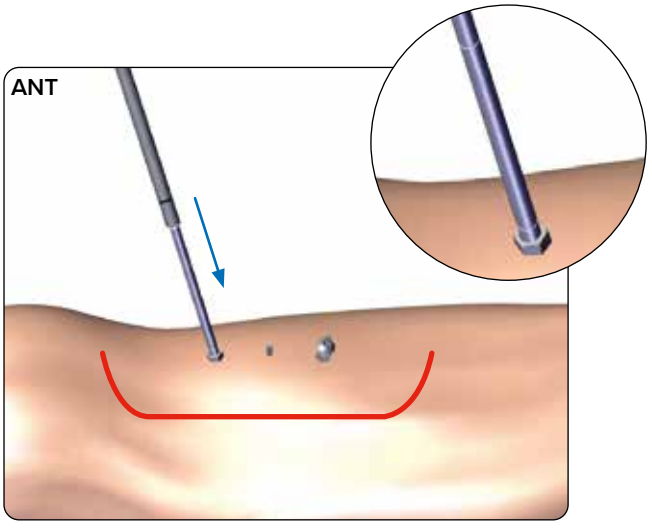


Fig. 42

Under fluoroscopy, verify the correct insertion depth of the transport segment half pin.

Take care to only achieve unicortical purchase with the transport segment half pins until the groove is flush to the pin guide (Fig. 43).

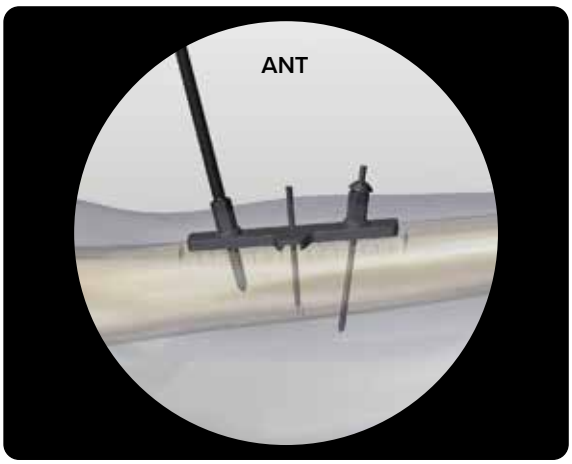


Fig. 43

Repeat the same steps for insertion of the second transport segment half pin (Fig. 44, 45 and 46).

PRECAUTION: Check with fluoroscopy the correct insertion of the half pins through the cortex.

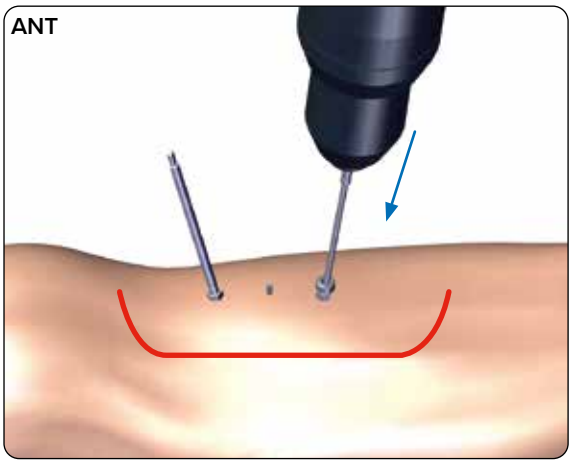


Fig. 44

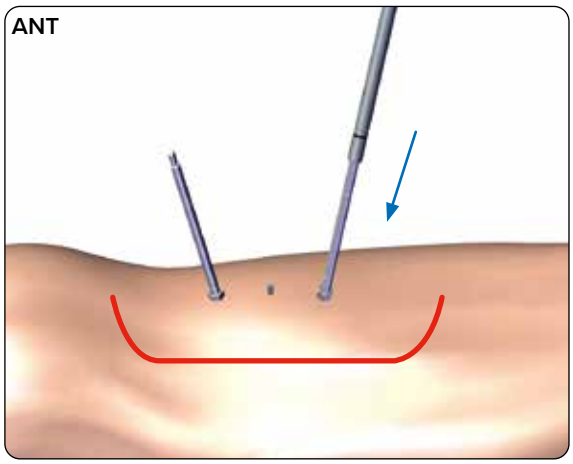


Fig. 45

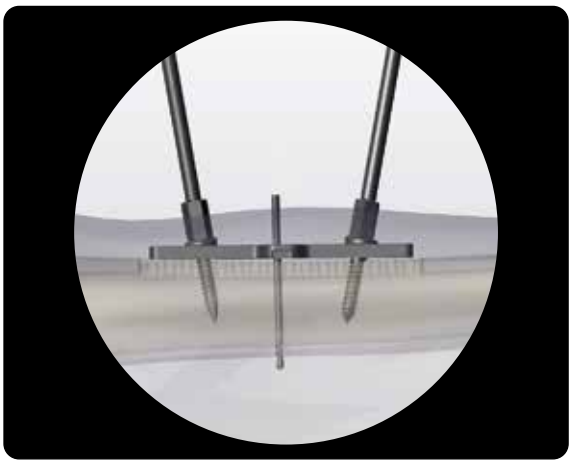


Fig. 46

Remove guide tubes using cannulated hexagonal drill positioning guide (Fig. 47 and Fig. 48).

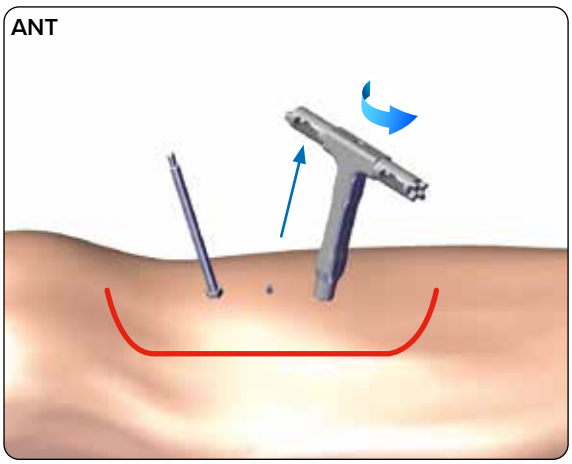


Fig. 47

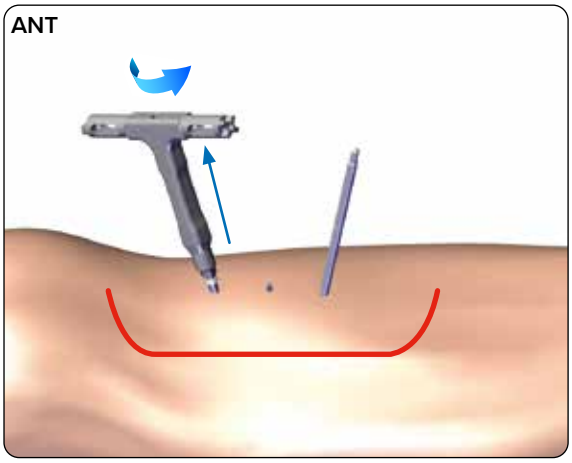


Fig. 48

Remove the central stabilization wire and slide template out, leaving both transport segment half pins (Fig. 49 and Fig. 50).

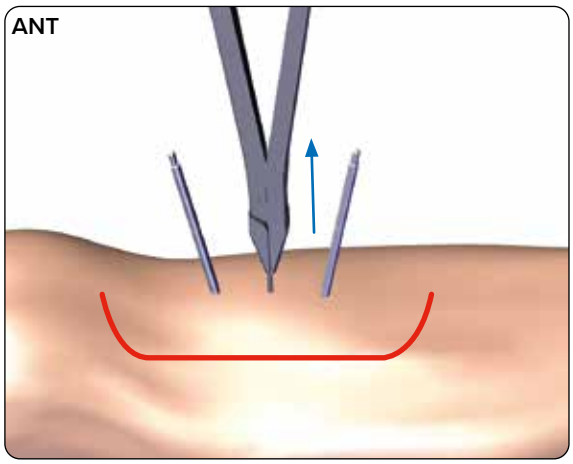


Fig. 49

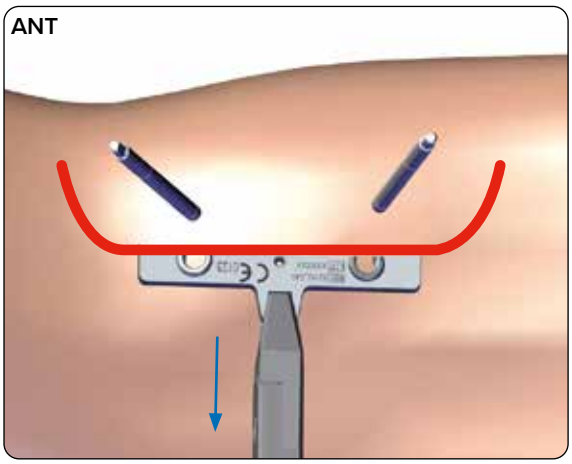


Fig. 50

5. TL Elevate External Fixator Positioning
Remove the universal half pin fixation bolt from the oblique slot on the dynamic bar of the TL Elevate device and slide it over the associated transport segment half pin as in Fig. 51, in order to have the concave portion of the device facing the incision. Slide the remaining half pin fixation bolt over the other half pin followed by attachment of the previously removed bolt back to the oblique slot of the dynamic bar and place the retained washer nut on the shaft of the bolt.

Position the TL Elevate device parallel to tibial crest

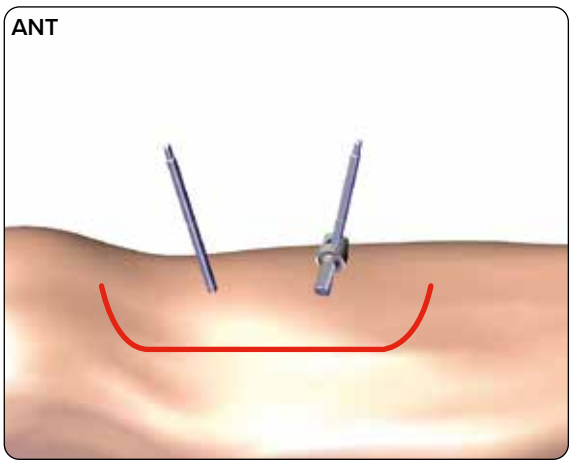


Fig. 51

and approximately 40mm away from skin followed by provisional tightening of both nuts on the 4mm transport segment half pin. This can also be achieved by placing the universal half pin bolt under the distal groove on transport segment half pins. Position the device so that the concave portion of the device is facing the incision in order to have room to complete the transport segment corticotomy (Fig. 52, Fig. 53 and Fig. 54).

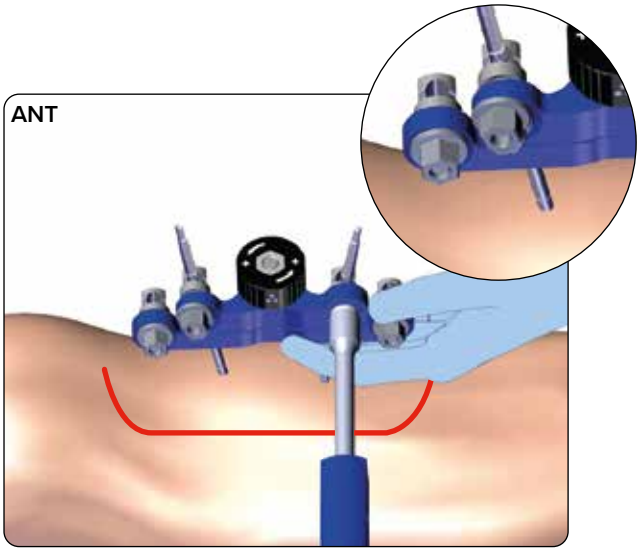


Fig. 52

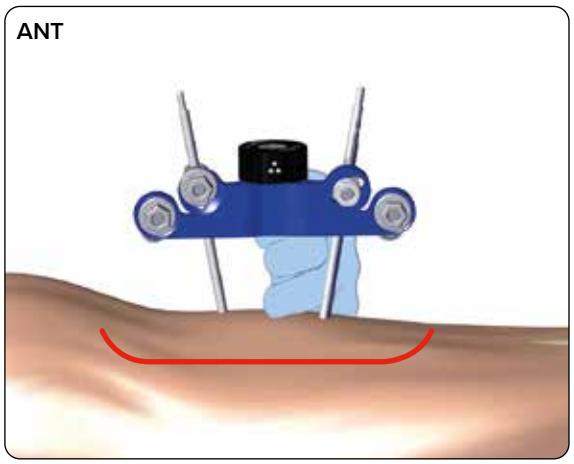


Fig. 53

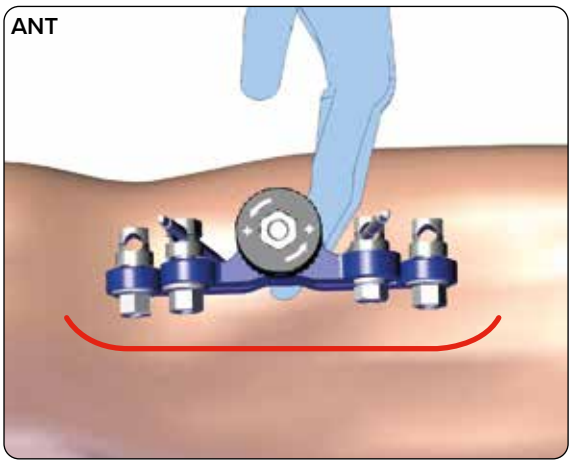


Fig. 54

Mark the level of transport segment half pins cutting (approximately 10mm above half pin fixation bolts) with marker (Fig. 55).

PRECAUTION: Before marking, to avoid instability of half pins inserted in the bone segment, perform provisional tightening of both nuts of the external fixator.

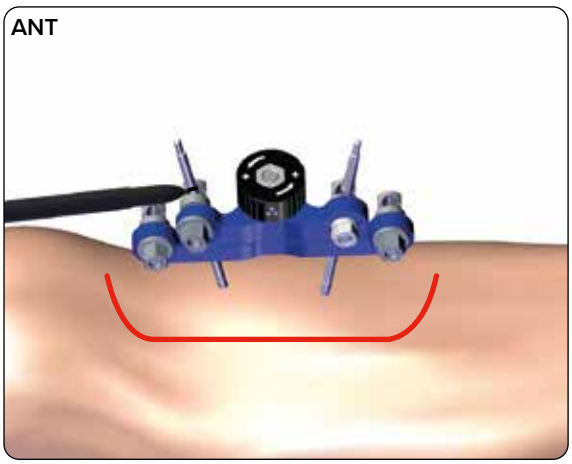


Fig. 55

Loosen nuts on both half pin fixation bolts on the dynamic bar to allow TL Elevate device to slide down to skin (Fig. 56 and Fig. 57).

PRECAUTION: During and after loosening of the nuts on transport segment half pin fixation bolts, pay attention not to push down the external fixator to avoid half pin instability.

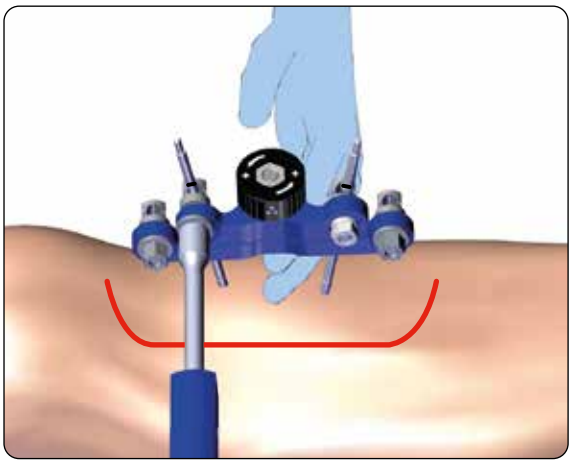


Fig. 56

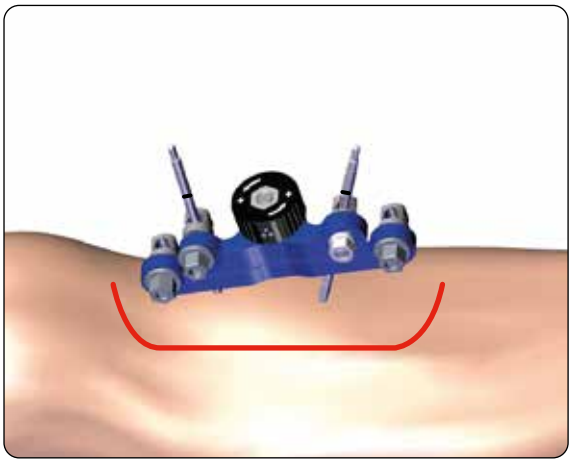


Fig. 57

Cut the transport segment half pins to the previously marked level, followed by repositioning of the TL Elevate device and provisionally retightening of both nuts on the dynamic bar (Fig. 58, Fig. 59 and Fig. 60).

Use caution when cutting half pins to avoid torque when cutting to reduce the risk of fracturing transport segment.

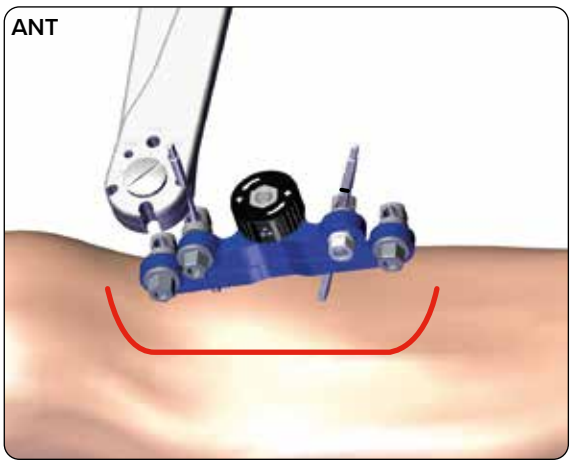


Fig. 58

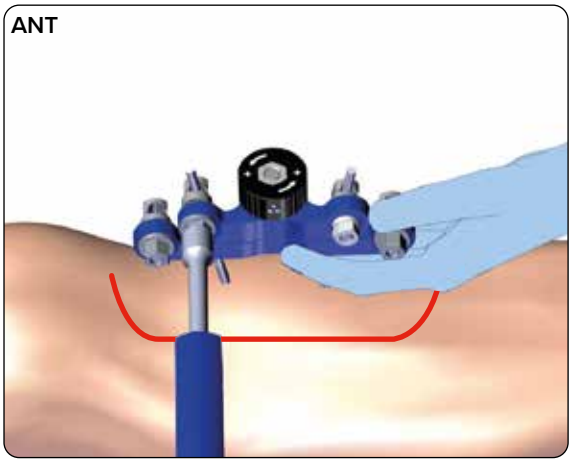


Fig. 59

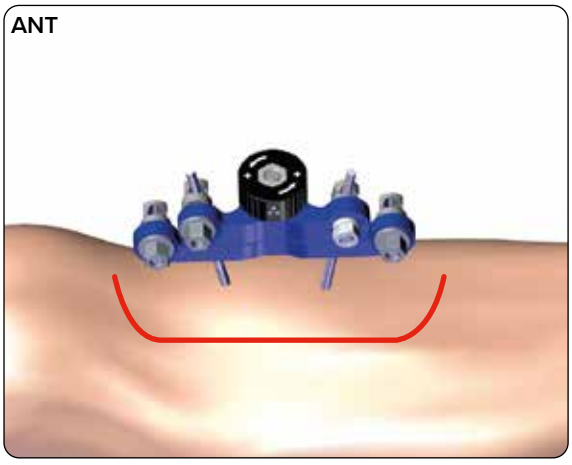


Fig. 60

6. TL Elevate Device Stabilization
Using half pin fixation bolts on the static bar as a guide, insert two bi-cortical 5mm or 6mm half pins and tighten both nuts. Pay attention the half pin fixation bolt to be attached to the body of fixator (Fig. 61 and Fig. 62).

If pre-drilling is desired, please use the appropriate drill guides for the half pins being used. Drill guides for the TL 5mm half pins are included in the sterilizable instrument tray."

PRECAUTION: Check with fluoroscopy the correct insertion of the half pins in the second cortex.

PRECAUTION: During the insertion of bi-cortical half pins, pay attention that the universal half pin fixation bolts are in contact with the external fixator. You can help holding the bolts attached to the fixator.

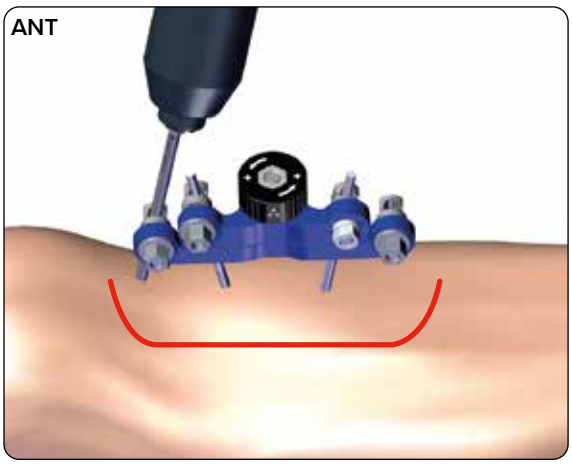


Fig. 61

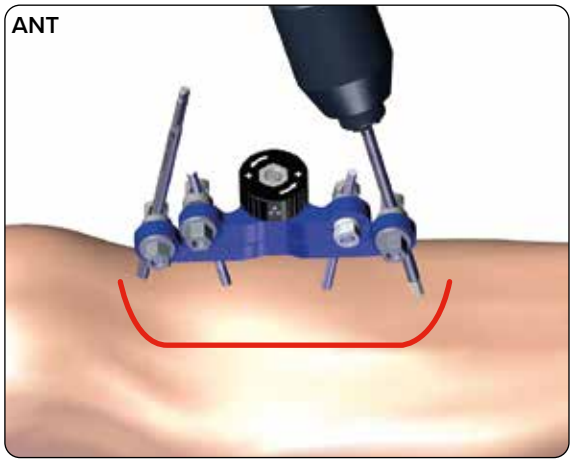


Fig. 62

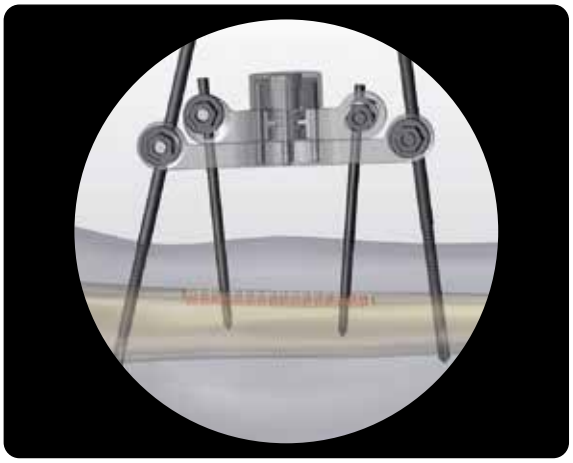


Fig. 63

7. Completion of the Transport Segment Corticotomy
Untighten nuts on transport segment half pin fixation bolts and complete the transport segment corticotomy on posterior side with a narrow osteotome or an oscillating saw (Fig. 64). Use osteotome to confirm corticotomy completeion at each corner.

PRECAUTION: Ensure to untighten the nuts on the transport segment half pins of the external fixator before completing the corticotomy.

Tighten both nuts on the half pin fixation bolts on dynamic bar. Under fluoroscopy, confirm completion of transport segment corticotomy by acute transverse distraction approximately 5mm followed by return of the transport segment to original position of the dynamic bar.

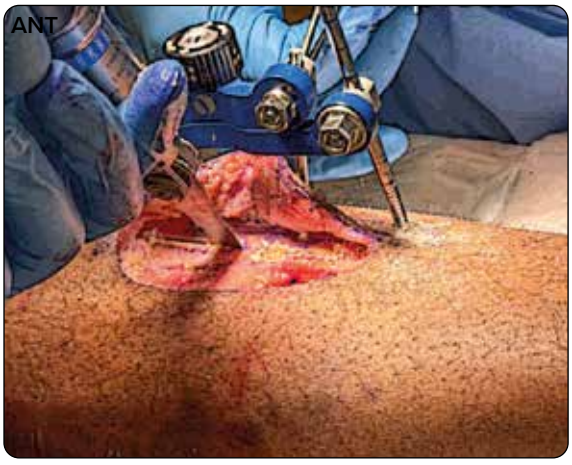


Fig. 64

PRECAUTION: Before concluding the surgical operation, check that the nuts of the external fixator are securely tightened.

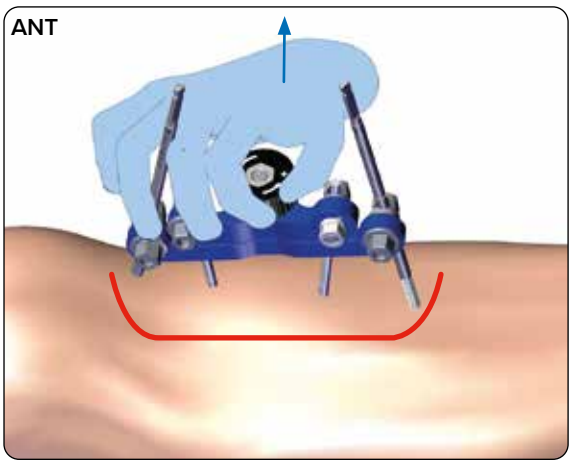


Fig. 65

If during the final check the transport segment does not align correctly with the docking site, loosen the nuts, adjust the fixator body position, and then securely tighten all nuts to achieve proper alignment (Fig. 66-68).

PRECAUTION: Before concluding the surgical operation, check that the transverse bone transport occurs correctly.

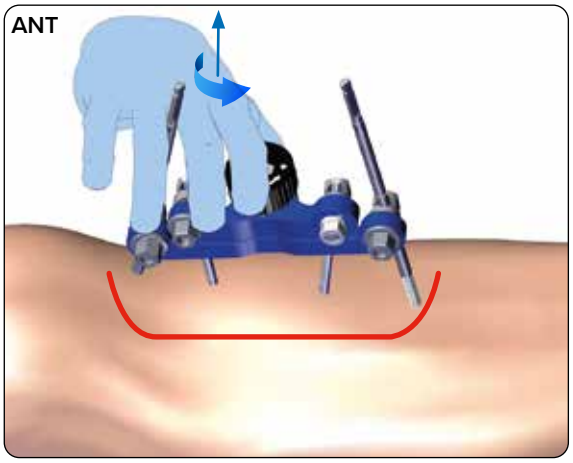


Fig. 66

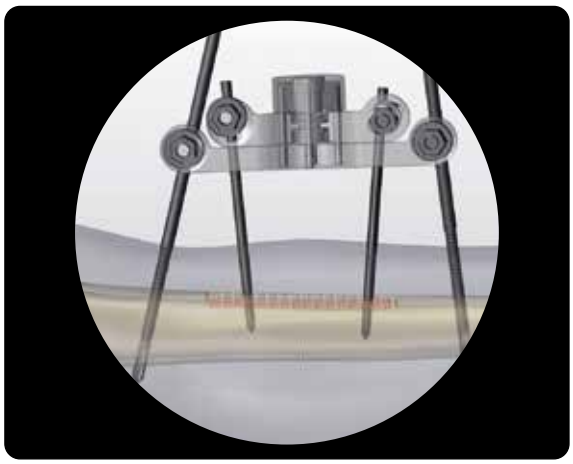


Fig. 67

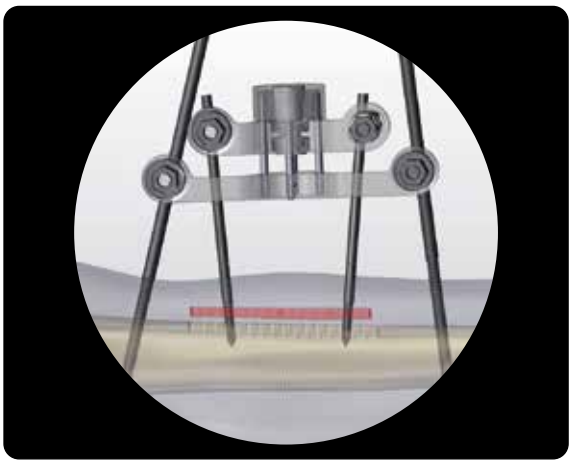


Fig. 68

Cut both bi-cortical tibial half pins at the level of (Fig. 69).

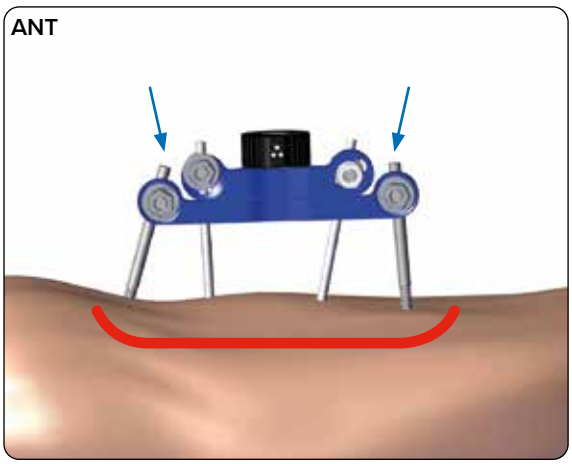


Fig. 69

Skin Closure
Close skin incision. Using 10mm wrench and tubular wrench, perform final tightening of all four nuts on the TL Elevate device (Fig. 70-71).

PRECAUTION: Before concluding the surgical operation, check that the nuts of the external fixator are securely tightened.

PRECAUTION: The bone segment must be checked periodically during treatment, making any necessary adjustments to the fixation.

PRECAUTION: The surgeon shall instruct the patient/caregiver about the correct adjustment to be performed during the treatment.

PRECAUTION: The surgeon must evaluate the integrity of the construct at follow-up visits.

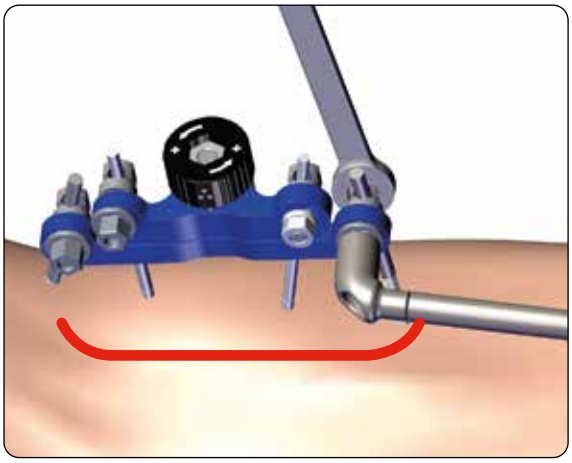


Fig. 70

7. Suggested Post Op Protocol for Distraction and Compression
It is suggested to allow a 5-7 day latencey period after application of the TL Elevate device. The TL Elevate device can be distracted up to 14mm. The rate of distraction is at the discretion of the surgeon and can be based on several things (i.e. skin quality, pain tolerance, etc). Rate of distraction can be .25mm, .50mm, .75mm or 1mm per day. After distraction is achieved (up to 14mm), it is suggested to allow a 2-3 day rest period, followed by compression of the transport segment at a rate of up to 1mm per day. Again, this should be at the surgeon's discretion.

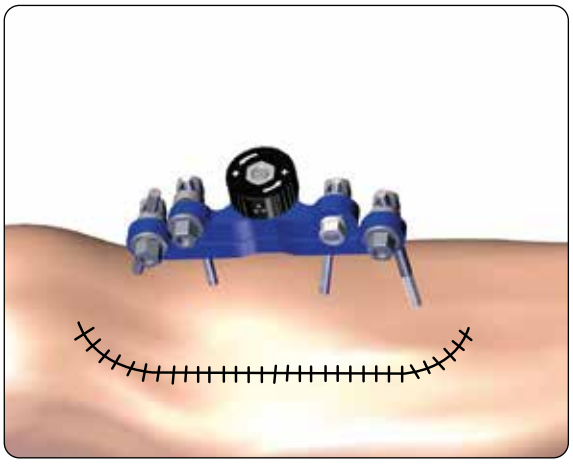


Fig. 71

IMPLANT REMOVAL

Untighten all half pin bolts using the appropriate wrenches (54-1154 or 54-2226). Remove the TL Elevate device from the half pins and remove the half pins with the universal T-Wrench (91150 for 6mm shaft, 93175 for 4mm shaft) or a power drill.

Part #	Description
91150 or 93175	Universal "T" Wrench
54-1154	TL Wrench 10mm
54-2226	TL 90 degree tubular wrench

CLEANING AND STERILIZATION

CLEANING

General Considerations

In these instructions Orthofix provides two methods of cleaning: a manual method and an automated method. Wherever applicable, the cleaning phase should start immediately after the pre-cleaning phase to avoid soil drying. The automated cleaning process is more reproducible and therefore more reliable, and the staff is less exposed to the contaminated devices and to cleaning agents used. Staff shall follow the safety precautions to comply with the procedure of the healthcare facility using protective equipment. In particular, staff should take note of the instructions provided by the cleaning agent manufacturer for correct handling and use of the product. Observe all instructions provided by the detergent's manufacturer regarding the immersion time of the device in the cleaning agent/ disinfectant and its concentration. The quality of the water used for diluting cleaning agents and for rinsing medical devices should be carefully considered.

Manual Cleaning

1. Wear protective equipment following safety precautions to comply with the procedure of the healthcare facility.
2. Ensure that the cleaning receptacle is clean and dry, no visible foreign material can be present.
3. Fill the receptacle with sufficient cleaning solution. Orthofix recommends the use of a slightly alkaline enzymatic cleaning solution.
4. Carefully immerse the component in the solution in order to displace trapped air; it is important to ensure that the cleaning solution reached all surfaces, including holes or cannulations.
5. Thoroughly scrub the device in the cleaning solution with a soft brush until all visible soiling is removed. Use a soft bristeled nylon brush to remove residuals from lumens, rough or complex surfaces using a twisting motion.
6. Rinse cannulations at least three times with cleaning solution using a syringe. Never use metal brushes or steel wool.
7. Remove the device from the cleaning solution.
8. Brush the single components in running tap water.
9. Put single components in ultrasonic device with degassed cleaning solution. Orthofix recommends the use of a detergent solution based on a detergent containing <5% anionic surfactants, non-ionic. Surfactants and enzymes, prepared using deionized water. Orthofix recommends on the basis of the validation performed to use an ultrasound frequency of 35kHz, power 300Weff, time 15 minutes. The use of other solutions and parameters shall be validated by the used and the concentration shall be in compliance with the detergent's manufacturer technical datasheet.
10. Rinse the components in purified sterile water until all traces of cleaning solution are removed.
11. Rinse the cannulations, rough or complex surfaces at least three times with purified sterile water. When cannulations are present it is possible to use a syringe to facilitate this step.
12. Remove item from rinse water and drain.
13. If, after completion of the cleaning steps, some encrusted soil remained on the device and had to be removed with the brush, the cleaning step must be repeated as described above.
14. Carefully hand-dry using a clean, lint-free cloth.

Manual Disinfection

1. Ensure that the cleaning receptacle is clean and dry, no visible foreign material can to be present.
2. Fill the receptacle with sufficient disinfectant solution. Orthofix recommends the use of a 6% hydrogen peroxide solution for 30 minutes prepared using water for injection.
3. Carefully immerse the component in the solution in order to displace trapped air; it is important to ensure that the disinfectant solution reached all surfaces, including holes or cannulations.
4. Rinse cannulations, rough or complex surfaces at least three time with disinfectant solution. Use a syringe filled with disinfectant solution to rinse cannulations.
5. Remove the items from the solution and drain.
6. Soak in water for injection (WFI) to remove traces of disinfectant solution.
7. Rinse the cannulations at least three times with a syringe (filled with WFI).
8. Remove item from rinse water and drain.
9. Repeat the rinsing procedure as described above.
10. Carefully hand-dry using a clean, lint-free cloth.
11. Visually inspect and repeat manual cleaning and disinfection if necessary.

Automatic Cleaning and Disinfection Using Washer-disinfector

1. Perform a pre-cleaning if necessary due to the contamination of the device. Take special care when the items to be cleaned contain or have:
   a. Cannulations
   b. Long blind holes
   c. Mating surfaces
   d. Threaded components
   e. Rough surfaces
2. Use a Washer-disinfector in compliance with EN ISO 15883 that is properly installed, qualified and regularly subjected to maintenance and testing.
3. Ensure that the cleaning receptacle is clean and dry, no visible foreign material can be present.
4. Ensure that the washer-disinfector and all services are operational.
5. Load the medical devices into the washer-disinfector. Place heavier devices in the bottom of the baskets. Products must be disassembled before placing them in the baskets according to the specific instructions provided by Orthofix. Wherever possible, all parts of disassembled devices should be kept together in one container.
6. Connect cannulations to the rinsing ports of the washer-disinfector. If no direct connection is possible, locate the cannulations directly on injector jets or in injector sleeves of the injector basket. Orient instruments into the automated washer's carriers as recommended by the washer manufacturer.
7. Avoid contact between devices because movement during washing could cause damageto devices and the washing action could be compromised.
8. Arrange medical devices in order to locate the cannulations in vertical position and blind holes incline downwards to promote the leakage of any material.
9. Use approved thermal disinfection program. When using alkaline solutions, a neutralizer must be added. Orthofix recommends that cycle steps are at least as follows:
   a. Pre-cleaning for 4 min.
   b. Cleaning with the appropriate solution. Orthofix recommends the use of the detergent solution based on a detergent containing <5% anionic surfactants, non-ionic surfactants and enzymes, prepared using deionazied water for 10 min at 55°C.
   c. Neutralization with basic neutralizing agent solution. Orthofix recommends the use of a detergent solution based on citric acid, concentration 0,1% for 6 min.
   d. Final rinsing with deionised water for 3 min.
   e. Thermal disinfection at least 90°C or 194°F (max 95°C or 203°F) for 5 minutes or until A0=30000 is reached, The water used for thermal disinfection must be purified.
   f. Drying at 110°C for 40 minutes. When the instrument has a cannulation, an injector should be used to dry the internal part. The suitability of other solutions, concentration, time and temperature shall be checked and validated by the user following the detergent's manufacturer technical datasheet.
10. Select and start a cycle according to the recommendations of the washer manufacturer.
11. On completion on the cycle, ensure that all stages and parameters have been achieved.
12. Wearing protective equipment unload the washer disinfector when it complete the cycle.
13. If necessary, drain off excess water and dry by using clean, linf.free cloth.
14. Visually inspect each device for remaining soil and dryness. If soil remains repeat the cleaning process as described above.

MAINTENANCE, INSPECTION AND FUNCTIONAL TESTING

The following guidelines shall be applied to all Orthofix instruments that are labeled for multiple use. All functional checks and inspections described below also cover the interfaces with other instruments or components.

The failure modes below may be caused by end of life of the product, improper use or improper maintenance. Orthofix does not typically specify the maximum number of uses for re-useable medical devices.

The useful life of these devices depends on many factors including the method and duration of each use, and the handling between uses. Careful inspection and functional test of the device before use is the best method of determining the end of the serviceable life for the medical device. For sterile devices the end of life has been defined, verified and specified with an expiration date.

The following general instructions apply to all Orthofix products:

- All instruments and product components must be visually inspected under good light for cleanliness. If some areas are not clearly visible, use a 3% hydrogen peroxide solution to detect the presence of organic residuals. If blood is present, bubbling will be observed. After the inspection, the device shall be rinsed and drained as the instruction given above.
- If visual inspection evidences that the device was not properly cleaned, repeat the cleaning and disinfection steps or discard the device.
- All instruments and product components must be visually inspected for any signs of deterioration that may cause failure during use (such as cracks or damage to surfaces) and functions tested before being sterilized. If a component or instrument is believed to be faulty, damaged or suspect, it must NOT BE USED.
- Products that show excessive fadind of marked product code, UDI and lot, thus preventing clear identification and traceability, must NOT BE USED.
- Cutting instruments must be checked for sharpness.
- When instruments form part of an assembly, check assembly with matching components.
- Lubricate hinges and moving parts with an oil that does not interfere with steam sterilization as per manufacturer's instructions before sterilization.

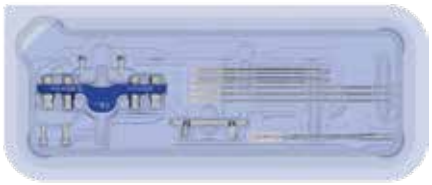
Do not use silicone based lubricant or mineral oil. Orthofix recommends the use of a highly purified white oil composed by paraffinum liquidum of food and pharmaceutical grade.

As a general preventive action Orthofix recommends following the instructions in the operative technique to avoid damage related to incorrect use. Specific instructions may be available for some product codes. These instructions are linked to the product code and are available in a dedicated Orthofix website. Moreover, it is important to follow the cleaning procedure suggested by Orthofix to avoid damages related to incorrect handling.

SALES CONFIGURATION

TL-Elevate is available in a sterile kit including the items below:

99-50-2513 TRUELOK ELEVATE SET STERILE		
Part Number	**Description**	**Q.ty**
1-1355001	Drill Bit D.2,7mm L.127mm TIN	1
50-25071	Drill Insert	2
50-25070	Wire Insert	2
50-2505	TrueLok Elevate External Fixator	1
50-2506	TrueLok Elevate Template	1
50-2511	Half Pin L120mm D4.0mm Thread D4.0xL18mm	2
50-2508	K-Wire L180mm D1.8mm	3



The instruments below are not included in the sterile kit and are necessary to implant TL-Elevate

50-2590C TRUELOK ELEVATE INSTRUMENT TRAY COMPLETE		
Part Number	**Description**	**Q.ty**
M210	T-Wrench For Bone Screws	1
50-2510	TL Straight Tube Wrench	1
54-1154	TL, Wrench, Combo, 10mm	1
93162	T-Wrench Hexagon 5-5 QC	1
54-2226	TL, 90 Degree Tubular Wrench	1
50-2509	TrueLok Elevate Drill Positioning Guide	1
W1003	Wire Cutter	1
54-2227	Needle Nose Pliers, Stainless Steel	1
50-2515	Drill Guide D3.2mm L60mm	1
11138	Drill Guide D4.8mm L60mm	1

Refer to the Orthofix catalog for compatible bi-cortical 5-6mm bone screws options.

TrueLok™ Elevate

Transverse Bone Transport System

Please refer to the **Instructions For Use** supplied with the product for specific information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.

Electronic Instructions For Use available at the website http://ifu.orthofix.it

Electronic Instructions For Use - Minimum requirements for consultation:
- Internet connection (56 Kbit/s)
- Device capable to visualize PDF (ISO/IEC 32000-1) files
- Disk space: 50 Mbytes

Free paper copy can be requested from customer service (delivery within 7 days):
tel +39 045 6719301, fax +39 045 6719370,
e-mail: customerservice@orthofix.it

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. 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.

Manufactured by:
ORTHOFIX Srl
Via Delle Nazioni 9, 37012 Bussolengo
(Verona), Italy
Telephone: +39 045 6719000
Fax: +39 045 6719380
www.orthofix.com

Rx Only

CE 0123

Distributed by: