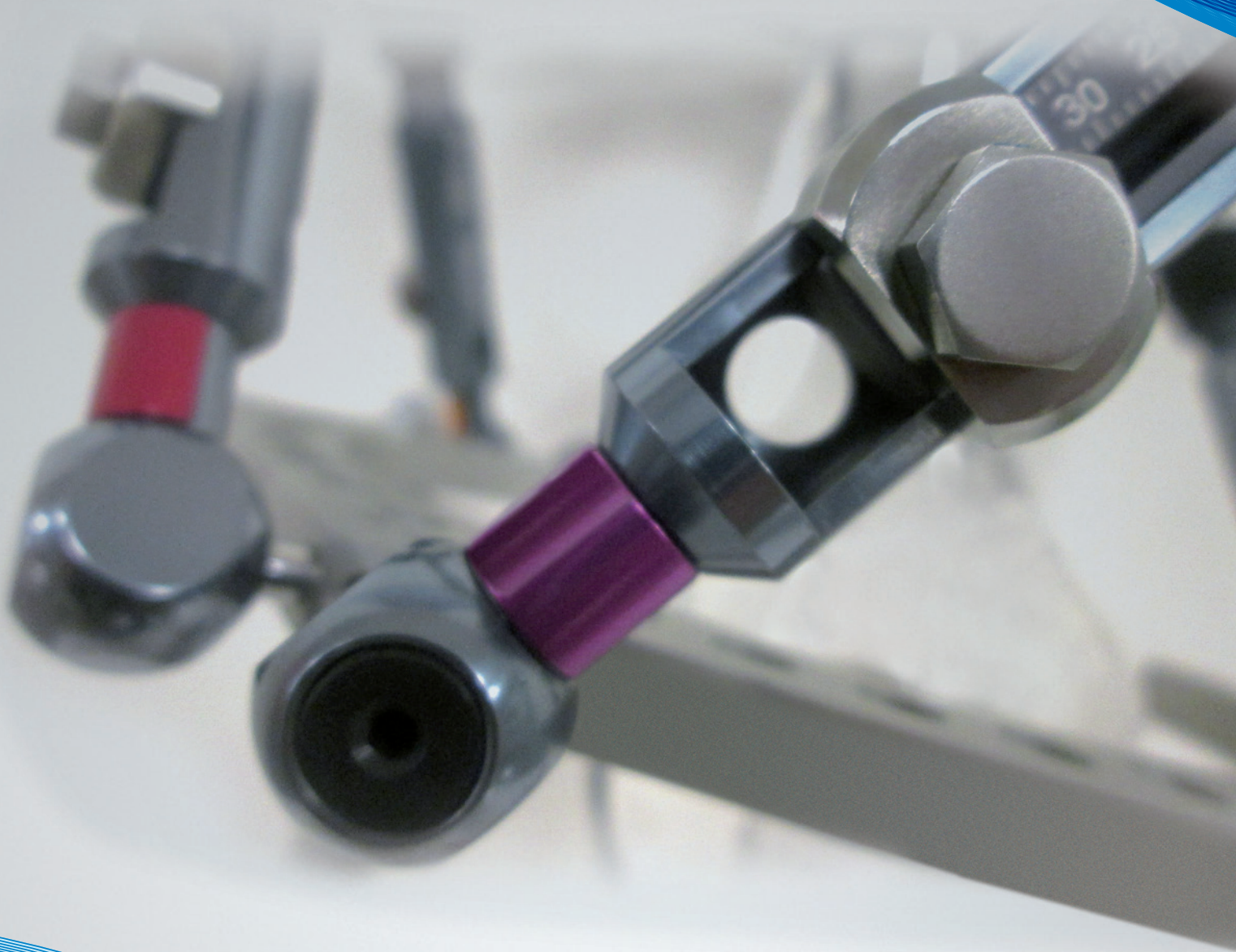


GENERAL PRINCIPLES

TL-HEX™

TrueLok Hexapod System

**General Principles
of Frame Assembly
for the TL-HEX™
TrueLok Hexapod System**



TL-HEX™

TrueLok Hexapod System

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Appropriate 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 kindly refer to the product IFU PQTLK, 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.

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INTRODUCTION

In 1951, Professor Gavril Ilizarov of Kurgan, Russia introduced a new external fixation apparatus and technique for fracture reduction, limb lengthening and deformity correction. The technique revolutionized the management of many previously unsolvable reconstructive problems. The Ilizarov apparatus experienced many modifications over the last fifty years. One of those modifications is TrueLok Ring Fixation System, developed at Texas Scottish Rite Hospital for Children (TSRHC) in Dallas, Texas. Although significantly improved when compared to the original Ilizarov apparatus, TrueLok system preserves most of the original principles and methodology of Professor Ilizarov.

The TL-HEX™ is a hexapod-based system designed at TSRHC as a three-dimensional bone segment reposition module to augment the previously developed TrueLok frame. In essence, the system consists of circular and semi-circular external supports secured to the bones by wires and half pins that are interconnected by six struts. This allows multi-planar adjustment of the external supports. Ring positions are adjusted either rapidly or gradually in precise increments to perform bone segment repositioning in three-dimensional space.

All components of the TL-HEX system are compatible with the TrueLok™ system; therefore external supports from both systems can be connected to each other when building fixation blocks. All the basic components from the TrueLok system (wire and half pin fixation bolts, posts, threaded rods, plates as well as other assembly components and instrumentation) should be utilized with the TL-HEX system. As with any other hexapod-type external fixators, for successful application of the TL-HEX system, an associated software is available (see TL-HEX Software User Guide).

TL-HEX EXTERNAL SUPPORTS

TL-HEX external supports are 9.5mm thick and made of anodized high-strength aircraft grade aluminum. They are offered in variety of sizes to allow custom constructs to suit the particular clinical situation. TL-HEX full rings and 5/8 rings have similar design features and match the hole pattern of TrueLok external supports. Full rings can also be obtained by attaching a 3/8 ring to a 5/8 ring using 2 bolts and nuts (Fig. 1).

All TL-HEX external supports are light, strong and stable. They have two sets of quadrant markings (double-line and single-line) to simplify alignment and frame assembly.

Full Rings

TL-HEX full rings are available in 10 sizes with internal diameters of 100mm, 120mm, 140mm, 160mm, 180mm, 200mm, 220mm, 240mm, 280mm and 300mm. Each full ring has six angulated tabs to accommodate up to 12 struts. Each tab has 2 mounting holes on the sides to accept the struts and a single retained locking screw to secure the struts in place (Fig. 2).

Two opposing tabs on each full ring are marked with a double line indicating the anterior and posterior tabs. The exact orientation of the anterior tab is very important (see TL-HEX Frame Assembly) and is referenced in the Software User Guide. In addition, each full ring has 2 single-line marks oriented 90° relative to anterior and posterior tabs to simplify external support alignment and frame assembly (Fig. 1).

5/8 and 3/8 Rings

5/8 and 3/8 rings are also offered in 10 sizes with internal diameters of 100mm, 120mm, 140mm, 160mm, 180mm, 200mm, 220mm, 240mm, 280mm and 300mm. Each 5/8 ring has five tabs (Fig. 1). Similar to full ring tabs, each tab has 2 mounting holes on the sides to accommodate the struts and a single retained locking screw to secure the struts in place (Fig. 2).

The central tab on each 5/8 ring is marked with a double line to facilitate its orientation. The exact orientation of this tab is important (see TL-HEX Frame Assembly) and is referenced in the Software User Guide. In addition, each 5/8 ring has 2 single-line marks oriented 90° relative to the central tab to simplify external support alignment and frame assembly (Fig. 1).

Double Row Foot Plate

The double row foot plate has a wide base, two rows of fixation holes, and two long side mounting areas for additional elements. The wide and long fixation mounting areas provide greater versatility for wire fixation and connection element attachment. The ends are tapped to accept standard 6mm threaded elements such as threaded rods or bolts. The double row foot plate is available in six sizes, ranging from 120mm to 220mm.

Fig. 1

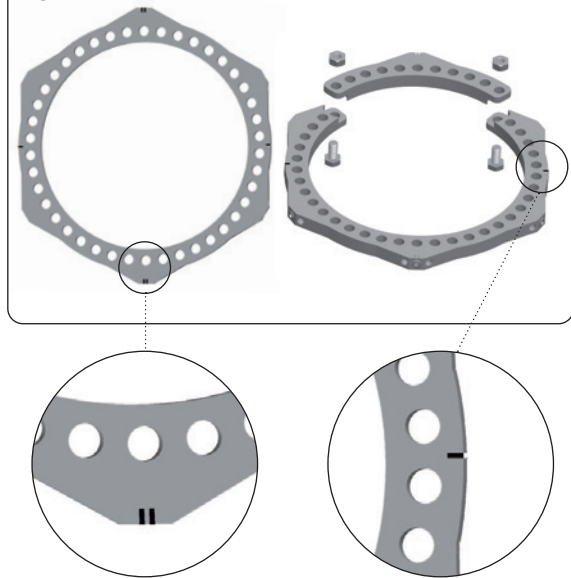


Fig. 2

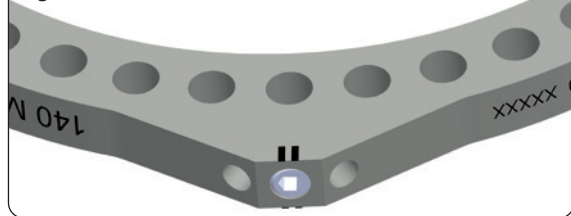


Fig. 3A

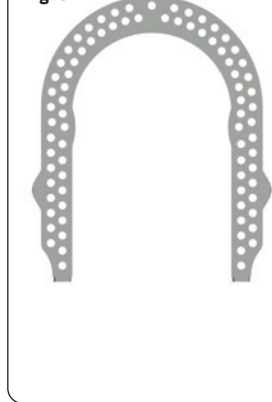
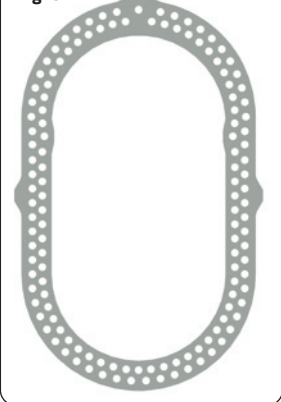


Fig. 3B



It has two sets of quadrant markings, matching the markings found on full rings of the same diameter. Each foot plate has three tabs (Fig. 3). Similar to full ring tabs, each tab has 2 mounting holes on the sides to accommodate the struts and a single retained locking screw to secure the struts in place.



WARNING: The locking screws on the rings and the strut locking bolt are retained and should never be removed for any reason. Rings and struts must be cleaned and sterilized in the assembled state with the locking screws in the ring and strut locking bolt only untightened.

TL-HEX STRUTS

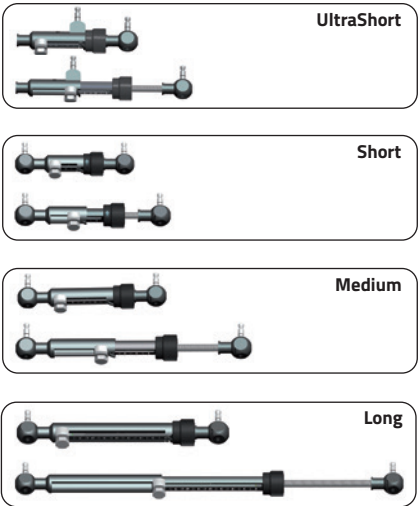
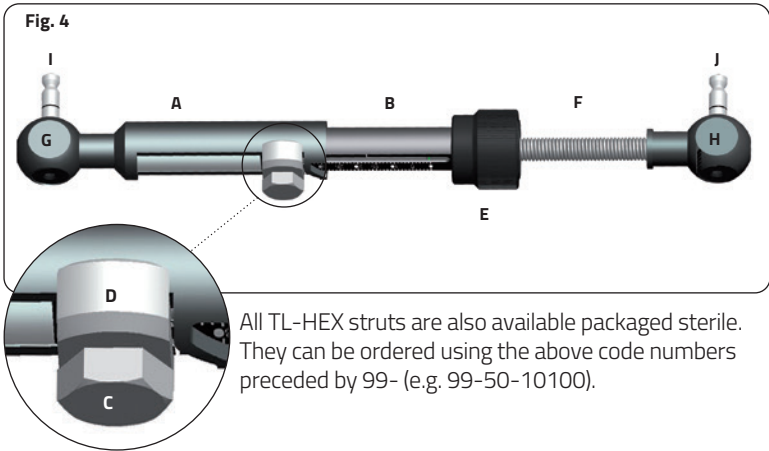
TL-HEX struts (Fig. 4) consist of two telescoping aluminum tubes, an outer tube (A) and an inner tube (B), which can be locked together at various lengths using the side locking bolt (C) and clamp washer (D).

Warning: The locking screws on the rings and the strut locking bolt are retained and should never be removed for any reason. Rings and struts must be cleaned and sterilized in the assembled state with the locking screws in the ring and strut locking bolt only untightened.

TL-HEX struts are available in four sizes (ultrashort, short, medium, long), providing adjustment range from 45mm to a maximum extension to 318mm (Table 1).

Table 1. Minimum and maximum lengths of TL-HEX struts

Part Number	Description	Minimum Length	Maximum Length
50-10100	UltraShort	45mm	101mm
50-10200	Short	92mm	122mm
50-10300	Medium	114mm	184mm
50-10400	Long	158mm	318mm



The inner tube is attached to a spring-loaded, black knurled adjustment knob (E). The adjustment knob mates with the threaded rod (F) in a manner such that the rod translates relative to the inner tube when the knob is rotated. This will provide gradual changes of overall strut length in 0.5-mm increments. A reference arrow with (+) sign located on the base of the adjustment knob (Fig. 5) indicates the direction of turning to perform strut elongation (distraction).

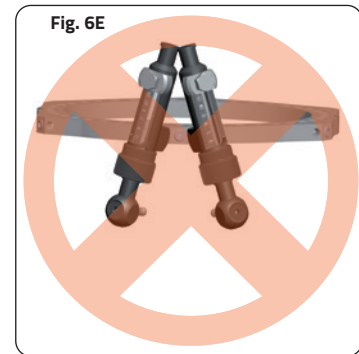
Each strut has two special joints (G) and (H) (Fig. 4), one at the base of the outer tube (tube end joint) and the other at the end of the threaded rod (rod end joint). Each joint has a mounting stud (I) and (J) (Fig. 4), which can be inserted into the mounting holes on the ring tabs and held in place by the locking screw (Figs. 6A, 6B).



When using ultrashort struts, attach them to the ring as described in Figs. 6C-D. Do not insert both central studs into the same tab (Fig. 6E) since this might cause interference between the two struts during assembly and correction maneuvers.

Avoid horizontal placement of the struts. This can lead to software errors.

In some cases (e.g., equinus deformity correction using ultra short struts), there can be interference during the strut tightening when using the configuration shown in Fig. 6D. To avoid this inconvenience, tighten first the set screw in the tab with the most difficult access leaving the other end free. Then connect the free end to the proper tab and tighten the set screw at the opposing ring tab.

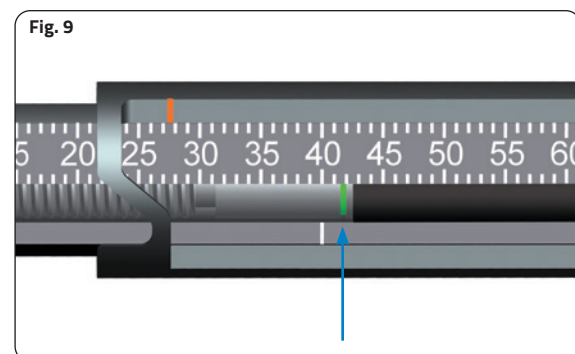
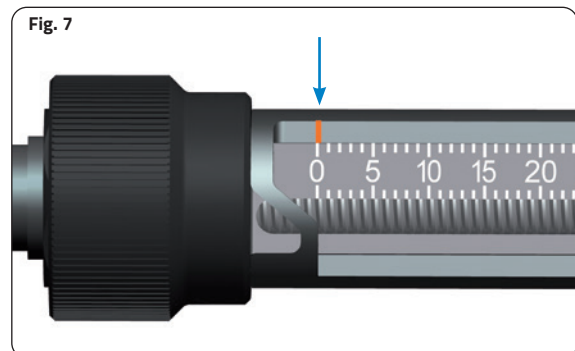


The rapid adjustment of the strut length is achieved by untightening the side locking bolt, sliding the inner tube relative to the outer tube to the desired length and re-tightening the locking bolt. Rapid adjustment is indicated by the inner tube scale in 1-mm increments relative to the orange-line mark on the outer tube (Fig. 7).

Gradual adjustment is achieved by pulling and rotating the adjustment knob resulting in a noticeable detent (click) every 0.5mm of adjustment (Fig. 8).

Gradual adjustment is indicated by the same scale relative to the green-line mark on the end of the threaded rod (Fig. 9).

The struts are shipped with the outer tube locked to the inner tube at the zero rapid adjustment position. The threaded rod for gradual adjustment is set in the middle of the scale. This allows the surgeon to rapidly adjust the struts to the desired length followed by gradual compression or distraction.



There are two types of removable aluminum strut clips: number clips to indicate the strut number and direction clips to indicate the direction of gradual adjustment. The clips are snapped onto the struts and remain in place throughout the treatment.

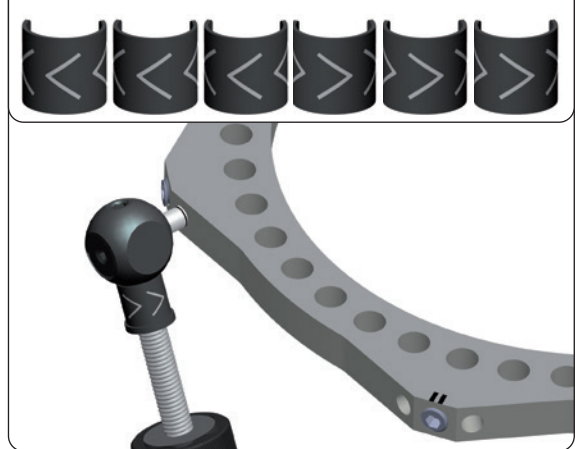
The number clips are numbered from 1 to 6 and color coded as red (1), orange (2), yellow (3), green (4), blue (5), and purple (6). They are usually attached to the groove at the tube end joint (Fig. 10).

Fig. 10



The direction clips are universal for all struts. They have an arrow indicating in which direction the adjustment knob should be turned to achieve the desired gradual adjustment. They are usually attached to the groove in the rod end joint of the strut (Fig. 11). The direction clip should be attached after surgery according to the prescription.

Fig. 11



STERILIZATION TRAYS

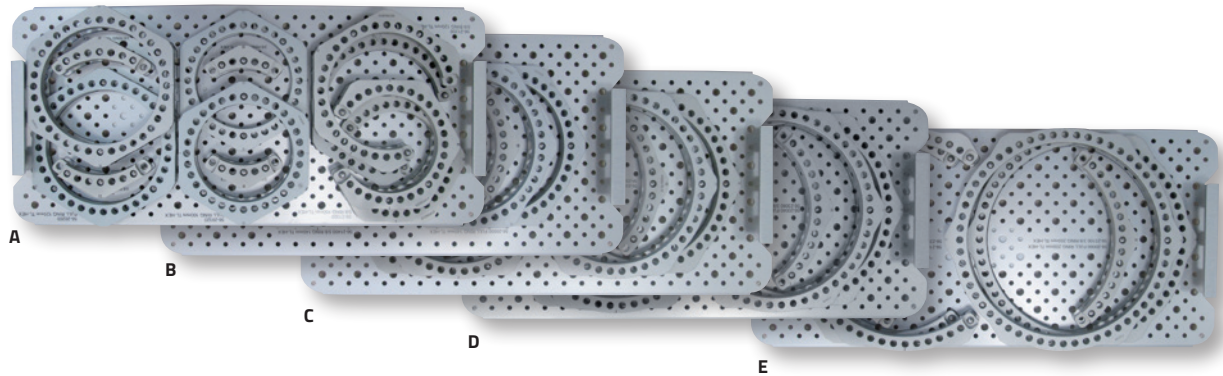
There are two TL-HEX sterilization trays: the rings tray and the struts tray.

Rings Tray

Ring sizes from 100mm to 200mm are accommodated by the rings sterilization tray. The rings tray includes 5 removable inserts (Figs. 12A-E), four of which (Figs. 12B-E) can hold 2 full rings, 2 5/8 rings and 2 3/8 rings of sizes greater than 120mm, while the top insert (Fig. 12A) can hold 2 full rings, 2 5/8 rings and 2 3/8 rings of 100mm and 120mm sizes.

Ring sizes from 220mm to 300mm come sterile packaged (280mm and 300mm are supplied upon request).

Fig. 12



Combination of any three layers can be combined to form a full rings tray.

Struts Tray

The struts tray contains four sets of struts (6 of each): ultrashort, short, medium, and long (Fig. 13). The tray includes an ancillary clip caddy, which can hold up to 18 number clips (3 of each number) and 18 direction clips (Fig. 14). The torque wrench is also included in this tray.

Fig. 13

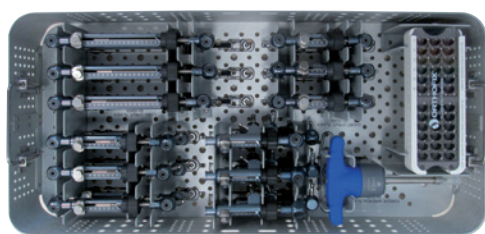


Fig. 14

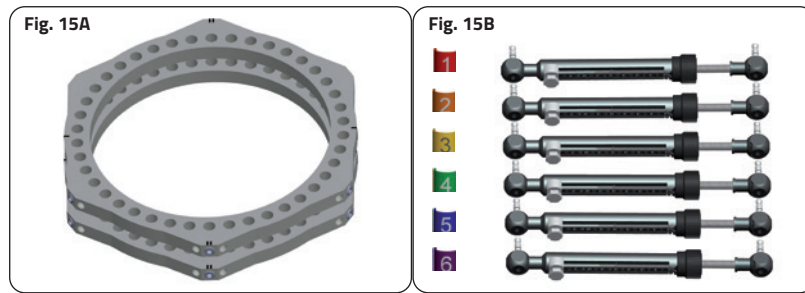


TL-HEX Trauma

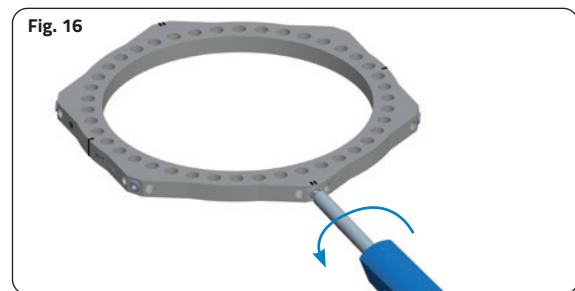
All the instrumentation, fixation elements, rapid struts and rings necessary to perform at least two surgeries with the TL-HEX trauma set will be available in a specific sterilization tray.

TL-HEX FRAME ASSEMBLY

Select two rings, six struts and six number clips (Fig. 15A, 15B).



Confirm that the stud locking screws are backed out to the stops (Fig. 16).



Snap the number clips into the groove at the tube end joint (Fig. 17).

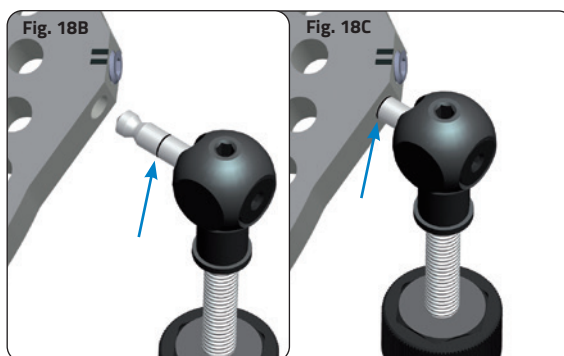


Position the proximal ring with the double-line marked tab facing the surgeon. Insert the mounting stud of strut #1 into the left mounting hole of the anterior tab (which becomes the ring orientation tab) of the ring (Fig. 18A).



Confirm that the stud depth insertion line is fully hidden in the mounting hole (Fig. 18B, 18C).

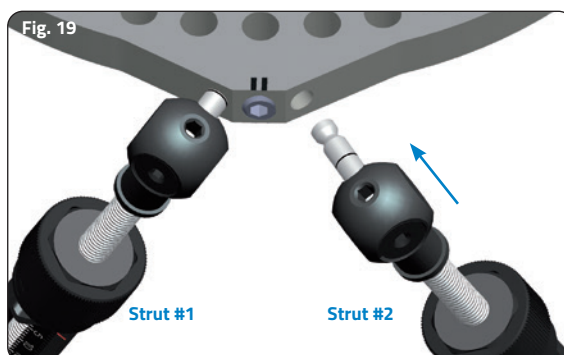
If the strut stud does not fully seat in the mounting hole, back out the locking screw to the stop and repeat strut mounting.



While holding strut #1 in place, insert the mounting stud of strut #2 into the right mounting hole of the same tab (Fig. 19).



PRECAUTION: Be sure that both adjustment knobs on the struts are pointing in the same (preferably proximal) direction.



Using the 1/8" HEX Driver, partially tighten the stud locking screw to hold the struts in place (Fig. 20).



WARNING: Do not overtighten the stud locking screw in the ring and the strut locking bolt as this causes stripping of their threads. Final locking of the set screw of the TL-HEX rings is performed with torque driver 54-2236, which must be turned in a clockwise direction only. The torque wrench is pre-set at a specific value and a click indicates that the correct torque has been applied. Any attempt to unlock any screw using the torque wrench will damage its gearing.

Moving to the right of the ring orientation tab, skip one tab and insert struts #3 and #4 following the same procedure. Continue moving to the right, skip one more tab and insert struts #5 and #6 (Fig. 21). Confirm that all struts are sequentially positioned counterclockwise around the proximal ring.

Align the ring orientation tab of the distal ring with the ring orientation tab of the proximal ring (Fig. 22). Insert the opposite end mounting studs of struts #2 and #3 into the mounting holes of the next tab to the right relative to anterior tab. Secure the struts in place as previously instructed.

Fig. 20

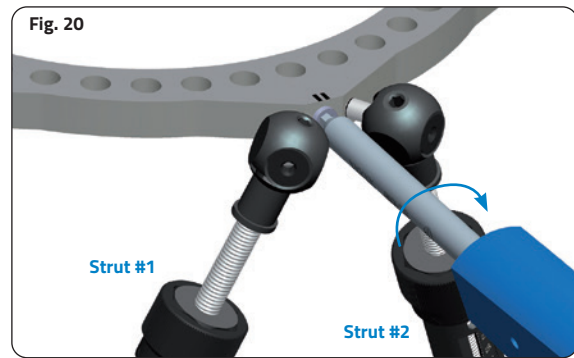


Fig. 21

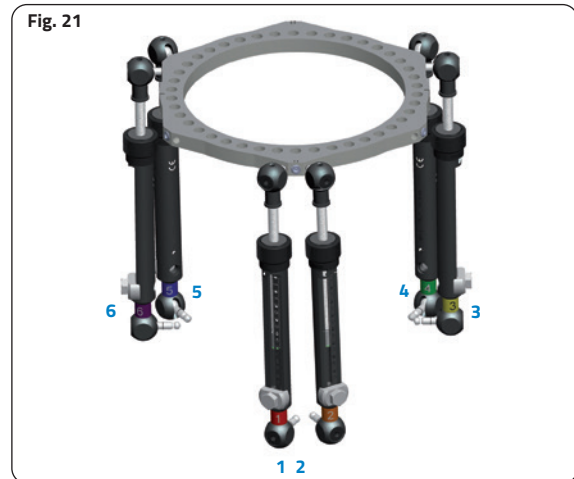
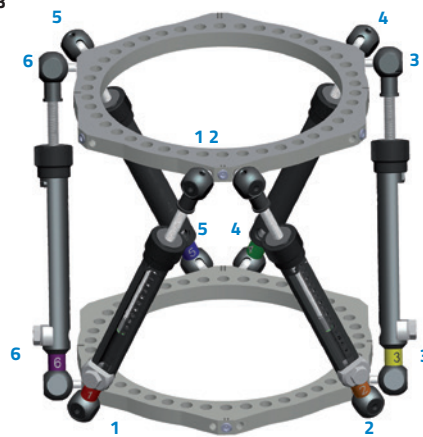


Fig. 22



Moving to the right, skip one tab and insert struts #4 and #5 following the same procedure. Continue moving to the right, skip one more tab and insert struts #6 and #1 (Fig. 23). Confirm that all struts are sequentially positioned counterclockwise around the distal ring.

Fig. 23



The rapid adjustment of the strut length is achieved by untightening the locking bolt, sliding the inner tube relative to the outer tube to the desired length and re-tightening the locking bolt (Fig. 24).



WARNING: Do not overtighten the stud locking screw in the ring and the strut locking bolt as this causes stripping of their threads. Final locking of the set screw of the TL-HEX rings is performed with torque driver 54-2236, which must be turned in a clockwise direction only. The torque wrench is pre-set at a specific value and a click indicates that the correct torque has been applied. Any attempt to unlock any screw using the torque wrench will damage its gearing.

The gradual adjustment is achieved by pulling and rotating the adjustment knob (Fig. 25).

Fig. 24

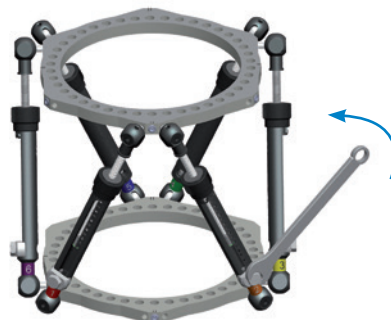
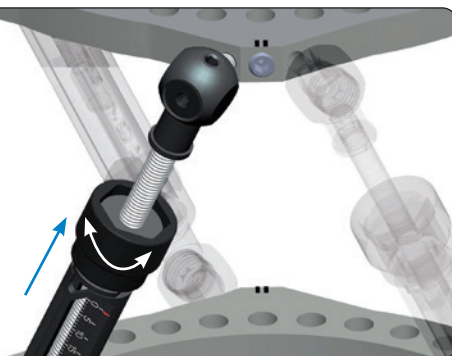


Fig. 25

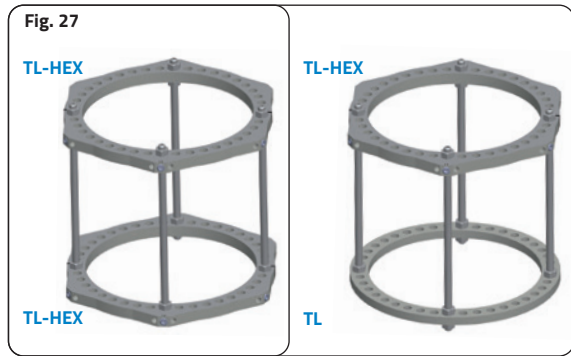


To expedite the gradual adjustment, the rod end joint can be temporarily disconnected from the tab and rotated manually or rapidly using the TrueLok power adapter (Fig. 26).

Fig. 26



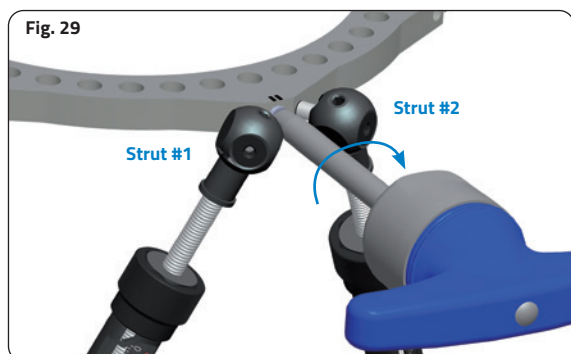
When additional stability is required, a second external support can be added to the proximal or distal rings. Since components of the TL-HEX are compatible with the TrueLok™ system, external supports from both systems can be connected to each other when building fixation blocks (Fig. 27).



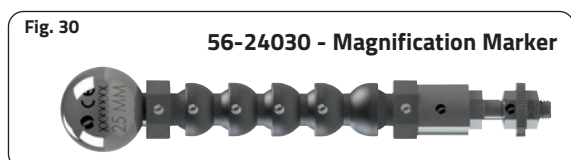
The preassembled TL-HEX frame (Fig. 28) is now ready to be attached to the limb as defined by Ilizarov principles. All basic components from the TrueLok system (wire and half pin fixation bolts, posts, threaded rods, plates as well as other assembly components and instrumentation) are required to perform the surgery with the TL-HEX (see General Principles: Limb Lengthening and Deformity Correction with TrueLok Ring Fixation System).

In some cases, TL-HEX external supports (fixation blocks) are mounted to the limb first. TL-HEX struts are then applied in the proper sequence as described above. Surgeon should place external supports as orthogonal to bone axis as possible to minimize measurement errors and reduce the number of residual corrections. However, perfect orthogonal orientation of the TL-HEX external supports relative to the bone axis is not required. Deviation of ring alignment will be taken into consideration by the software (see TL-HEX Software User Guide).

At the end of the surgery, firmly tighten all the set screws using the dedicated torque wrench (Fig. 29).



The TL-HEX Magnification Marker (Fig. 30) is a device specifically developed to calibrate the magnification of the X-Ray (both in Anterior/Posterior and Medial/Lateral view). The ball size is 1 inch (= 2.54 cm) and must be positioned as close as possible to the bone, using the flexible structure of the system that can be oriented in any plane.

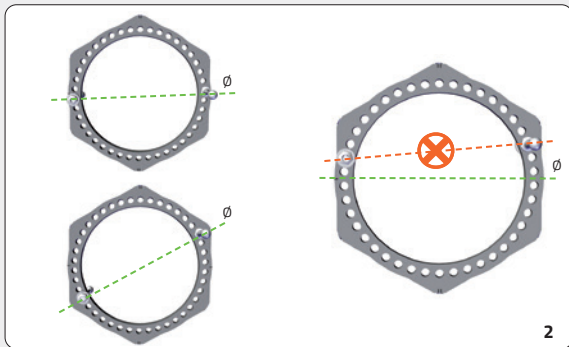
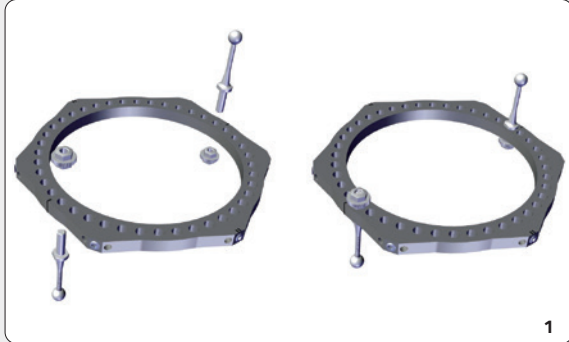
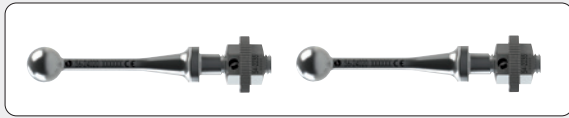


The Centering Pin Kit (Fig. 31) is used to locate the center of the reference support element (either ring or foot plate), which is one of the measurements required in the software.



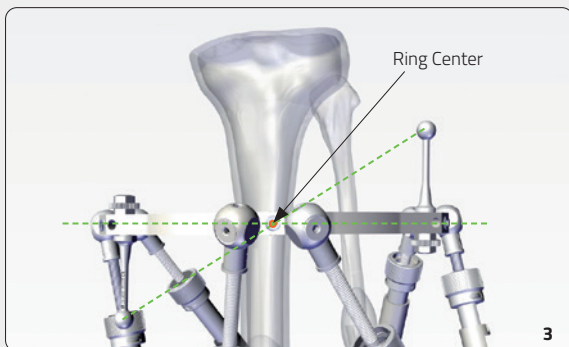
CENTERING PIN KIT

56-24020

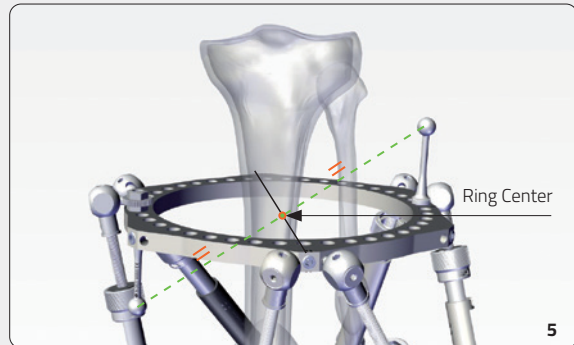
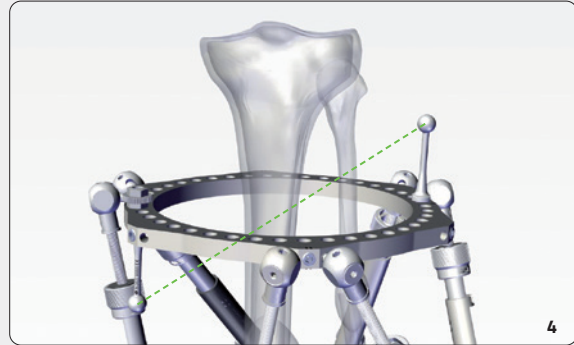


Fix the two pins on any of the holes on the Reference Support, paying attention to the following rules:

- the chosen holes must be facing each other on opposing sides of the support
- the pins must be mounted in opposite directions (one facing up and one facing down on the ring). (Fig. 1-2)



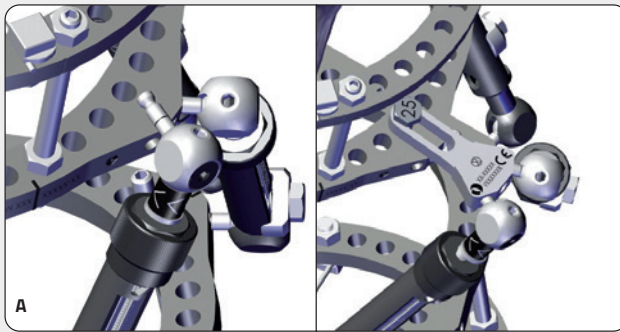
When the x-ray is taken perfectly orthogonal the Reference Ring/Support appears as a line. The center of the ring is defined by the point of intersection between the bisector line of the ring and the line connecting the two spheres of the pins. (Fig. 3)



When the x-ray is not taken orthogonal to the Reference Ring/Support and it appears tilted, you must find the midpoint of the line connecting the two spheres of the pins. This is the center of the Reference Support. Once the bone axis is defined, the anterior/posterior translation as well as the medial/lateral is represented by the distance between this center and the axis of the bone. (Fig. 4-5)

Remember that the Mounting Parameters always describe the position of the center of the Reference Support in relation to the bone and NOT vice versa, for example in Fig. 3 you should enter the AP View Reference Ring Translation as Lateral since the center is put laterally in relation to the bone.

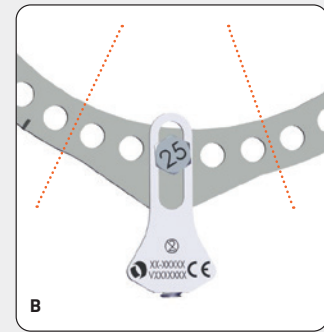
TL-HEX EMERGENCY TAB KIT



A. INDICATIONS FOR USE

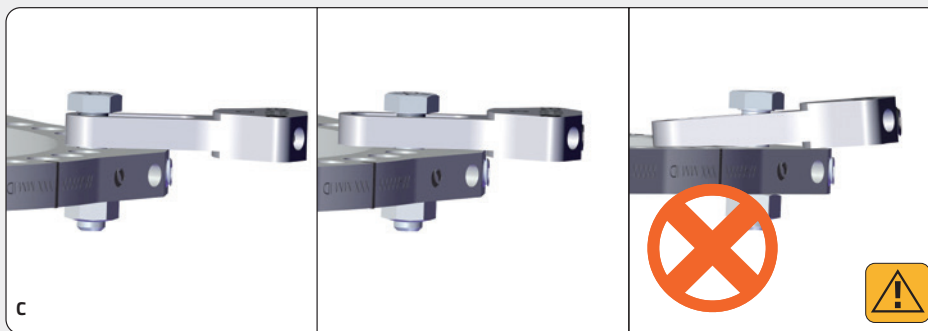
The TL-HEX Emergency Tab Kit (TL-HEX ETK) is used exclusively in combination with the TL-HEX system. The device can be used to relocate two adjacent struts' extremities in case of temporary struts and ring impingement or temporary strut out of range.

NOTE ABOUT THE USE WITH THE TL-HEX SOFTWARE: the TL-HEX ETK has not been developed to be used with the TL-HEX software. However, a software calculation based on the original strut's position can be used provisionally as best approximation of the treatment when using TL-HEX ETK. The device cannot be used to convert a standard circular frame into a hexapod (software assisted) frame.




B. APPLICATION RANGE - RING HOLES

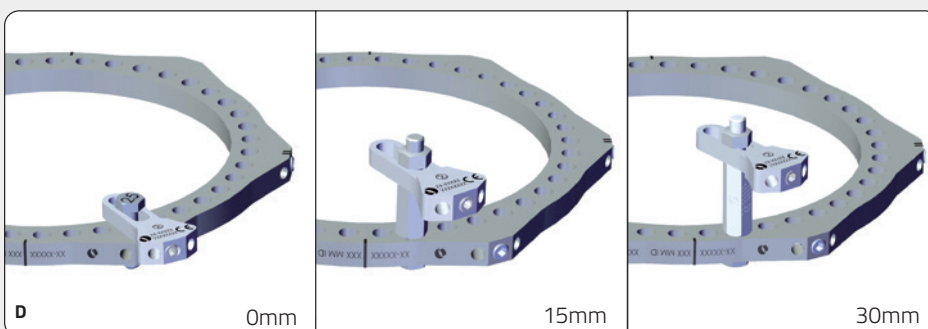
The TL-HEX ETK should be connected a maximum two holes away from the initial Tab.



C. APPLICATION RANGE - SLOT

The TL-HEX ETK must be connected to the ring using the specific slot.

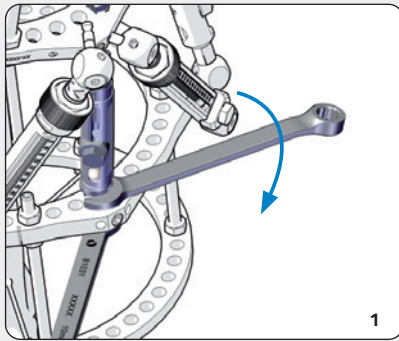
 when connecting the TL-HEX ETK to the ring, ensure that their surfaces are on an even plane.



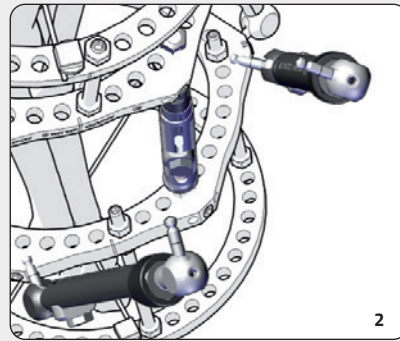
D. APPLICATION RANGE - HEIGHT

The TL-HEX ETK can be connected through a standoff hex (54-11650, 54-11660) no higher than 30mm.

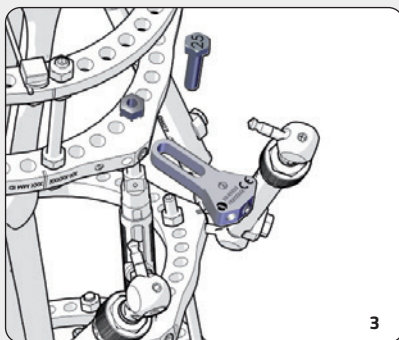
E. ASSEMBLY & REMOVAL



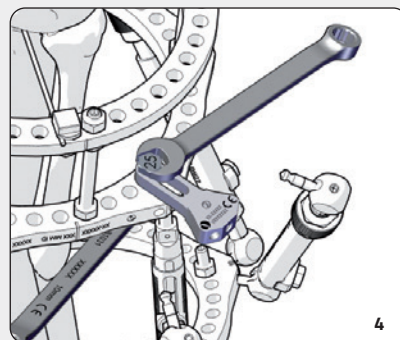
1. Before disconnecting the TL-HEX struts, insert a quick adjust strut to firmly stabilize the rings



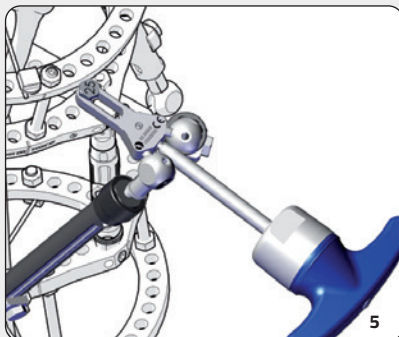
2. Disconnect the strut ends from the TL-HEX ring tab



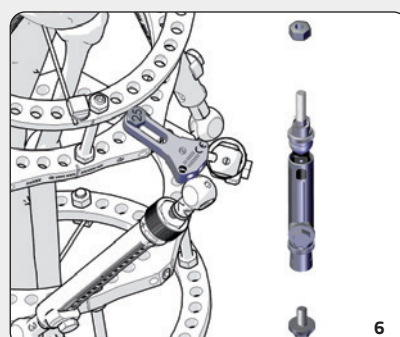
3. Connect the TL-HEX ETK



4. Firmly tighten the TL-HEX ETK using two 10mm wrenches



5. Connect the struts to the TL-HEX ETK and tighten the retention set screw using the TL-HEX Torque Wrench



6. Disconnect the quick adjust strutwrenches
7. Remove the TL-HEX ETK with the TL-HEX Driver as soon as the struts can be connected again into the initial TL-HEX ring tab

56-24040



INSTRUMENTS

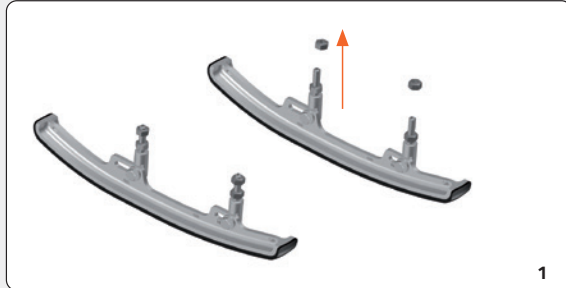
Part#	Description	Qty.	Part#	Description	Qty.
50-10190	Quick Adjust Strut - Long	1	54-2236	Torque Wrench, TL-HEX	1
54-1154	Wrench, Combo - 10mm	2	52-1018	TL-HEX Driver - Straight, 1/8"	1

The TL-HEX Emergency Tab Kit is also available packaged sterile. It can be ordered using the above code numbers preceded by 99- (e.g. 99-56-24040)

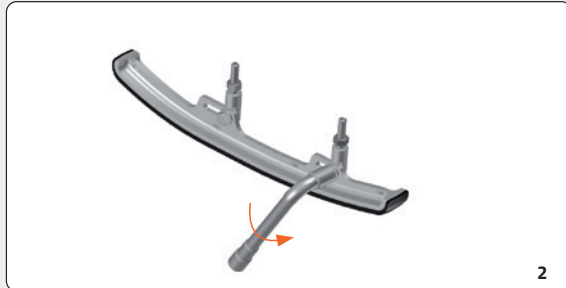
TRUELOK™ ROCKERRAIL

- 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 PQTLK
- D. Steam sterilization not allowed
- E. Remove the caps from both RockerRail ends before application

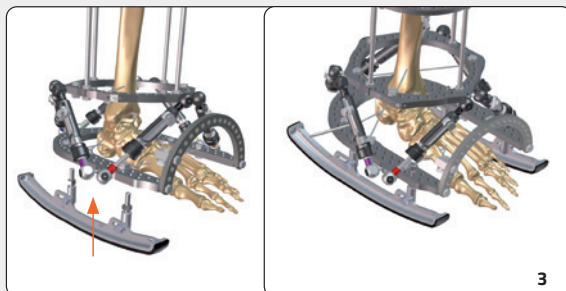
TrueLok RockerRail Application



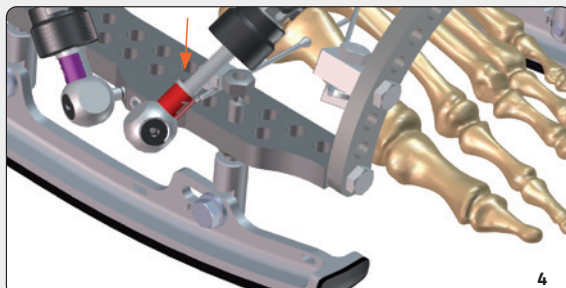
1. Remove the outer locking nut from the fixation rods on the rails



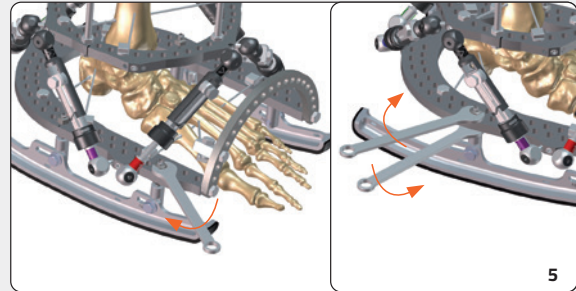
2. Loosen the adjustable sliding fixation



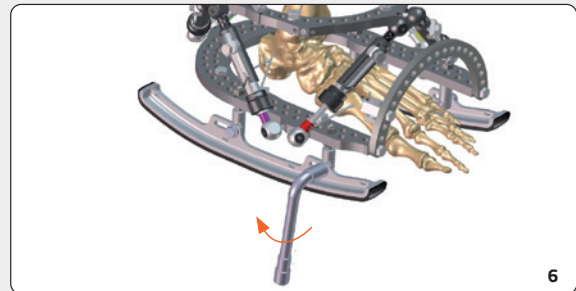
3. Place the TrueLok RockerRail with the FRONT marking anteriorly onto the Foot Plate by inserting its fixation rods into the appropriate holes



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

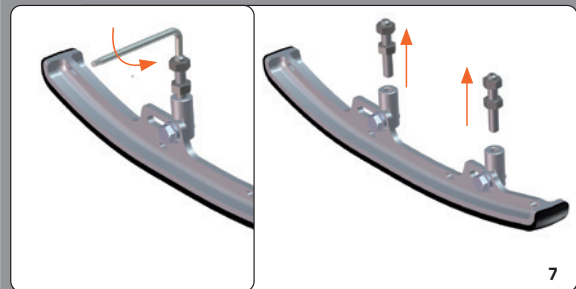


5. Use two 10mm wrenches to lock the rails onto the Foot Plate firmly

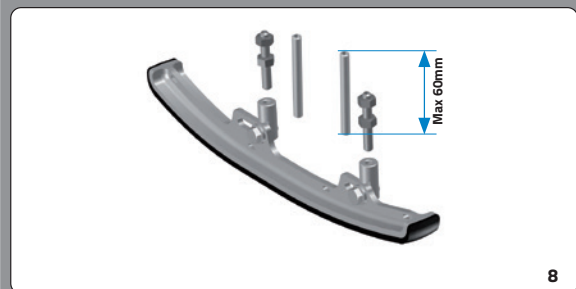


6. The rails should be adjusted as needed for ideal placement. Lock the adjustable sliding fixation

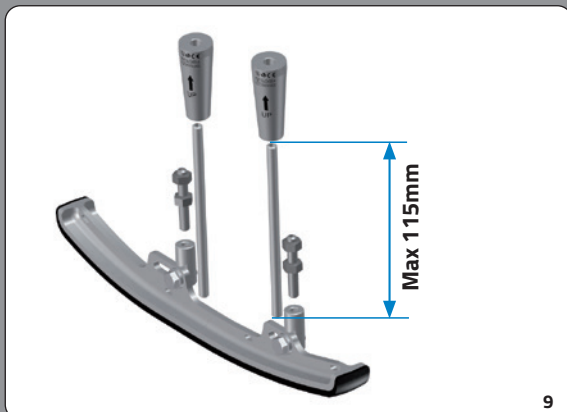
TrueLok RockerRail Height Adjustment



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

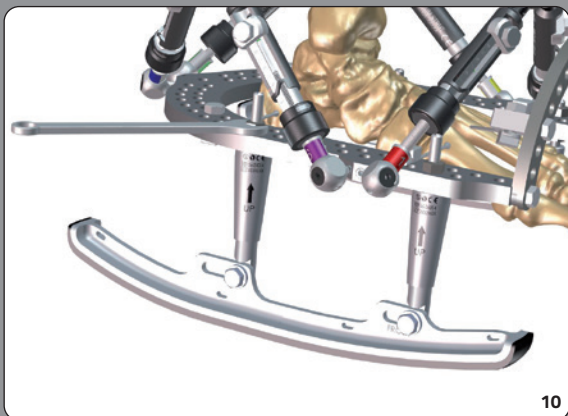


8. Exchange the rods with the threaded rods of the desired length



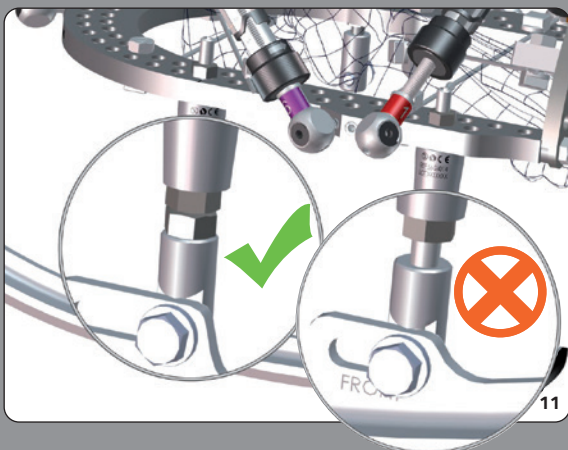
9

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



10

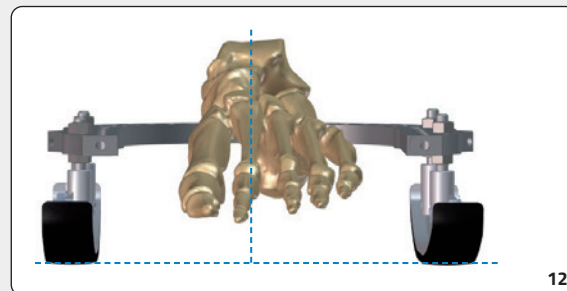
10. The larger side of the Extender must be in direct contact with the footplate



11

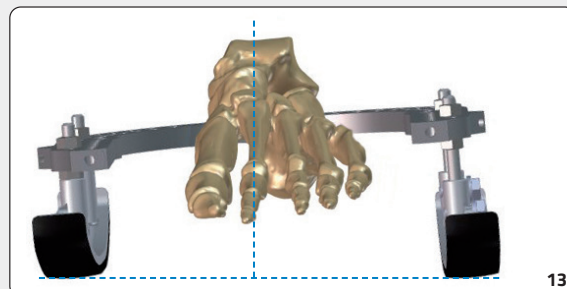
11. To adjust the distance between Footplate and RockerRail insert nuts and/or extended nuts between the Extender and the RockerRail. Do not allow any portion of bare rod.

TrueLok RockerRail Final Check (Warnings & Precautions)



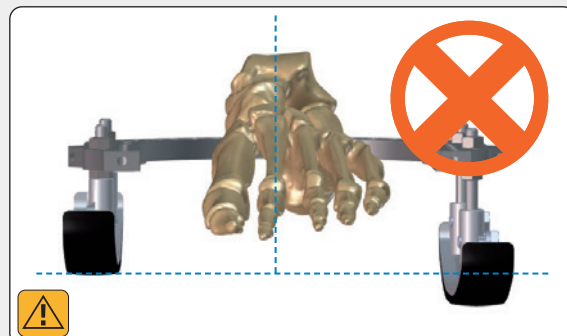
12

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

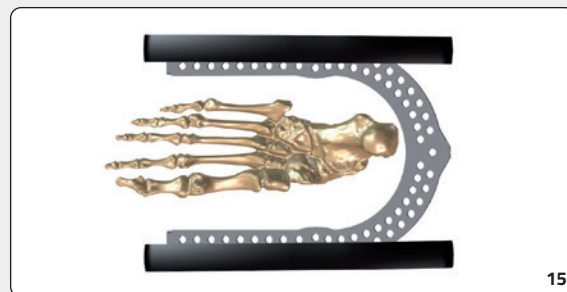


13

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

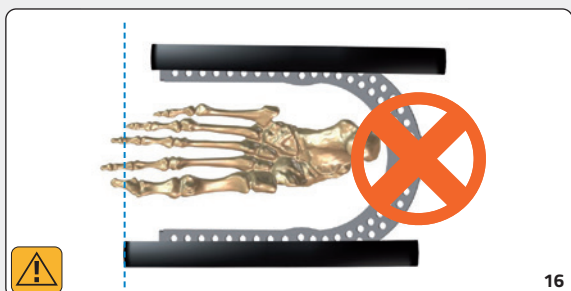


14. The rails should never be placed in a way to pronate or supinate the foot in static position



15

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



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



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

18. Use maximum one Extension Tube per threaded rod

56-24000



56-24014

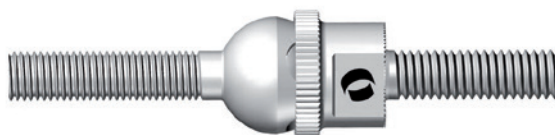
INSTRUMENT

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

Spherical Joint

99-50-2310M (sterile, pack of 2)

The Spherical Joint is a versatile component that allows the surgeon to connect the dynamization module and external frame elements at virtually any angle up to 45°. The Spherical Joint can be locked in any position by tightening a standard nut and an external support against the joint housing.



TL DYNAMIZATION MODULE

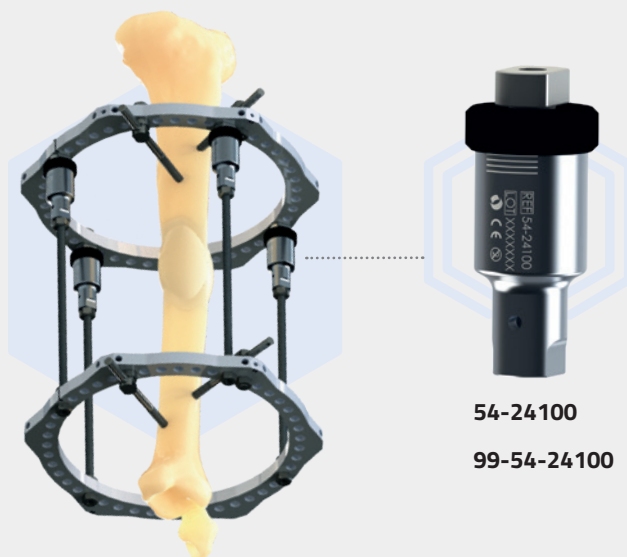
54-24100, 99-54-24100 (sterile)

Controlled Axial Dynamization

The TrueLok Dynamization Module can be used to dynamize an existing frame towards the end of treatment or at any stage where dynamization of the fracture callus or regenerate is required.

- Controlled micromotion amplitude up to 3mm
- No effect on ring separation distance no matter which micromotion setting from 0 to 3mm
- Compatible with all TrueLok and TL-HEX components
- Can be used with non-parallel ring orientation

For best results, the Dynamization Module must be orientated parallel to the bone anatomical axis.



WARNING: Do not use in applications that bridge an articulation.

PRECAUTION: The direction of dynamization is along the axis of the dynamization modules: hence, carefully define their orientation based on the intended direction of dynamization.

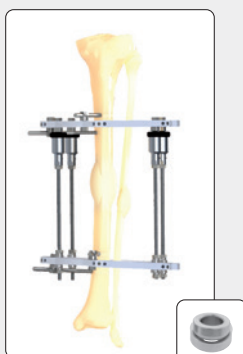
PRECAUTION: In order to dynamize correctly, the four dynamization modules must be placed on the same ring.

PRECAUTION: All the dynamizers must be fixed as parallel as possible to the bone axis.

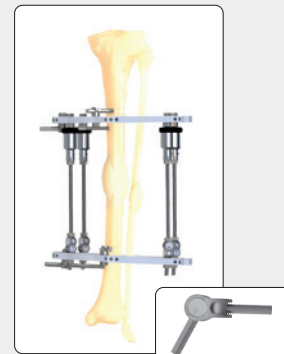
PRECAUTION: The same level of dynamization must be set on all dynamization modules (code 55-24100 or 99-54-24100) using the reference lines.



DIRECT CONNECT WITH THREADED RODS



NON-PARALLEL WITH CONICAL WASHERS



NON-PARALLEL WITH UNIVERSAL HINGES

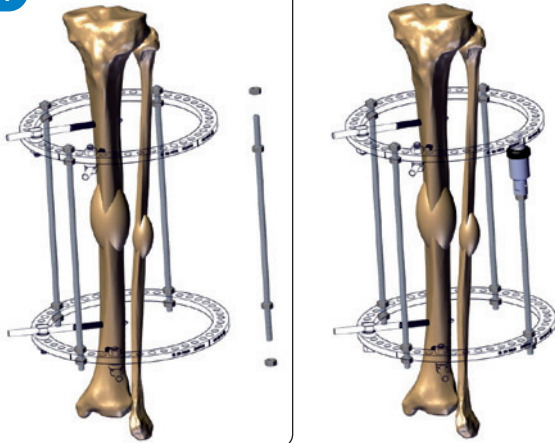
The amplitude of micromotion (dynamization) is achieved by turning the black knob. When the stroke is set to 0mm (Fig. A), the Dynamization Module produces no micromotion and, therefore, no dynamization is achieved. When the stroke is set to 3mm (Fig. B), up to 3mm of axial compression during dynamization can be achieved depending on patient body-weight loading.

N.B. The ring separation distance remains the same between Fig. A and Fig. B

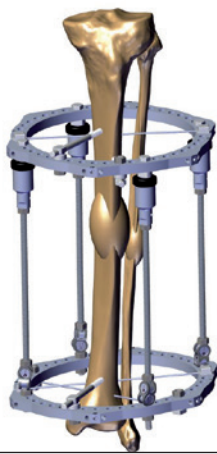


Part #	Description	Notes
54-24100	TL Dynamization Module	Out of the tray
99-54-24100	TL Dynamization Module, Sterile	Out of the tray

1



2



Instruments

Qty

Part#

54-1154



2

52-1018



1

RADIOLUCENT DYNAMIZERS

99-50-2300M (sterile)

Controlled Axial Dynamization

The Radiolucent Dynamizers are a sterile single-use component that can be used to dynamize an existing frame towards the end of treatment or at any stage where dynamization of the fracture callus or regenerate is required.

- It can be assembled through connection elements
- Controlled micromotion amplitude by 3mm
- Compatible with all TrueLok and TL-HEX components
- Axial movement cannot be changed during treatment
- Can be used with non-parallel ring orientation using spherical joint or hinges



WARNING: Do not use in applications that bridge an articulation.



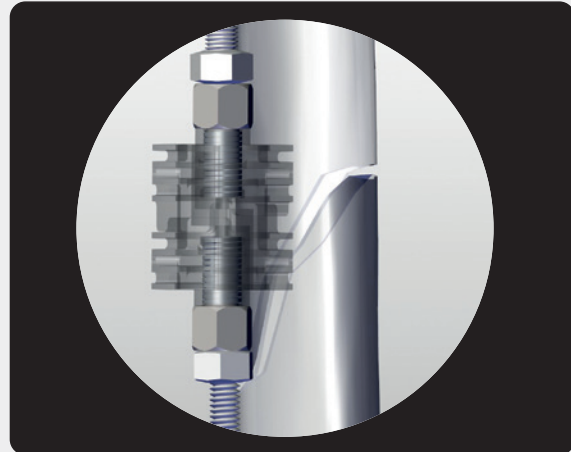
PRECAUTION:

1. In order to dynamize correctly, the four radiolucent dynamizers must be placed on the same ring.
2. The direction of dynamization is along the axis of the radiolucent dynamizers: hence, carefully define their orientation based on the intended direction of dynamization.



PRECAUTION:

All the dynamizers must be fixed as parallel as possible to the bone axis.

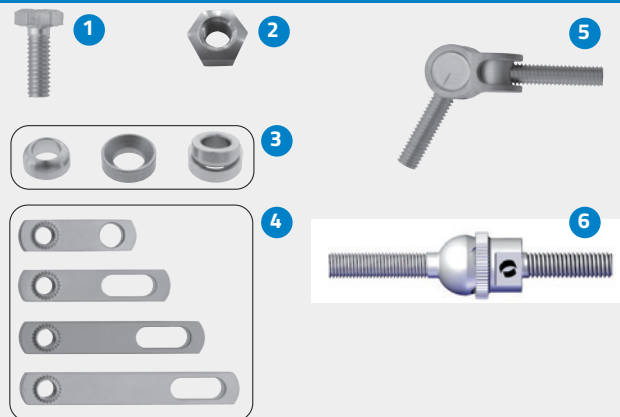


Radiolucent Dynamizer

CONNECTION ELEMENTS

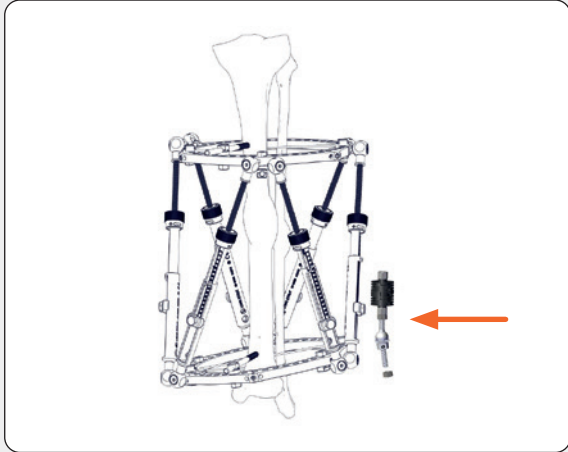
Part #	Description
54-1050 54-1050M 54-1010 54-1010M 54-1018	1 BOLTS
54-1008 54-1008M	2 NUTS
54-1150 54-1150M	3 CONICAL WASHER
55-10340 55-11670 55-11671 55-11680	4 PLATES
55-1176	5 UNIVERSAL HINGE
99-50-2310M	6 SPHERICAL JOINT

CONNECTION ELEMENTS



Instruments

Part #		Qty
54-1154		2
52-1018		1



In the case of a TL Hex frame, insert all dynamizer structures and remove one connector at a time.



The final dynamization position set up. The image show the use of connections elements including Spherical Joint and a plate since the rings are not parallel.

BASIC TL-HEX FRAME CONSTRUCTS

Presented below are some examples of the basic TL-HEX frame assemblies for reduction and stabilization of midshaft tibial fracture, correction of midshaft tibial malunion associated with complex deformity, correction of proximal tibial Blount's deformity, correction of distal femoral valgus deformity and correction of foot and ankle deformities.

Midshaft Tibial Fracture

Option 1 - TL-HEX Trauma Frame

Indications for the TL-HEX trauma frame include temporary stabilization of closed and open fractures and situations when a majority of fracture reduction can be achieved rapidly.

TL-HEX rings can be applied in any desired position using the most preferred combination. It is also possible to use two 5/8 rings with the opening on the same side, allowing the surgeons to keep the traction on the patient limb. The basic principles of aligning a ring on the limb perpendicular to its long axis remain strongly recommended. Either wires or half pins (or a combination of both) can be used to secure the ring to the limb depending on surgeon preferences and space availability. The insertion technique for wires and half pins is the same as for a standard circular frame (see TL-1001-OPT). Two rapid adjust struts engaged on the ring and partially tightened are suggested for the first stage (Figs. 32A, 32B).

Once all the necessary half pins and wires have been inserted at the discretion of the surgeon based upon training, knowledge of anatomic safe zones and surgical preference, a manual reduction of the fracture can be performed releasing the locking bolt and two locking nuts on the struts. After achieving a satisfactory reduction, all the nuts and bolts must be tightened (Figs. 33A, 33B) and a third rapid adjust strut added for definitive stabilization (Figs. 33C). A fourth strut can be added at surgeon's discretion.

A final micrometric adjustment and compression can be achieved by turning the plastic bushing of the struts by the desired amount (Fig. 34).

Fig. 32A



Fig. 32B



Fig. 33A

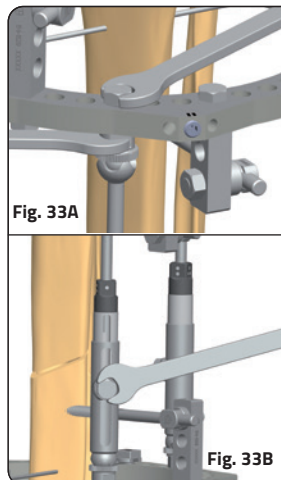


Fig. 33B

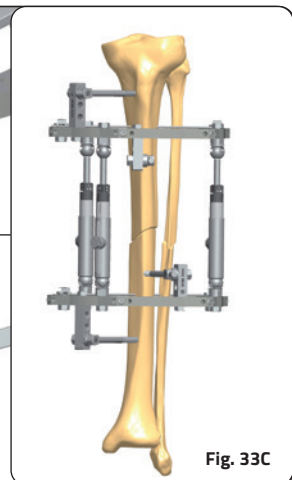


Fig. 33C

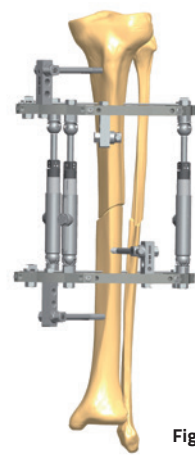
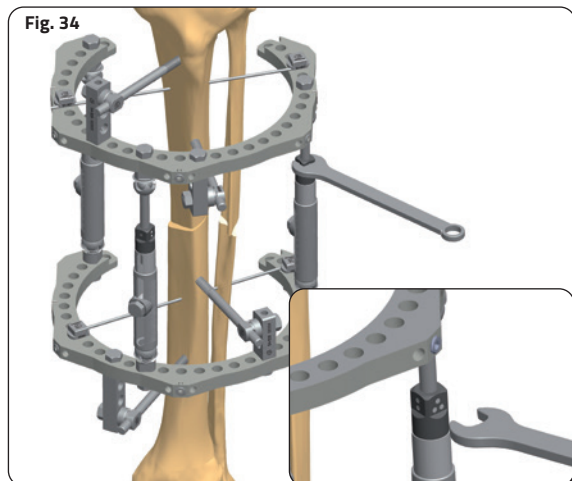
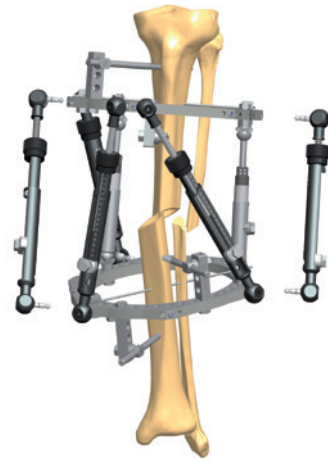


Fig. 34



In cases requiring gradual three - dimensional precise reductions, TL-HEX struts can be added to the rings, transforming the TL-HEX trauma frame into software guided TL-HEX standard frame. The unique TL-HEX strut connection to the ring allows the rapid adjust struts to stay in place while connecting the TL-HEX struts (Fig. 35). This procedure can be performed by the surgeon outside the operating theatre.

Fig. 35



In case of two 5/8 rings with the opening on the same side, a 3/8 ring must be added to one of the rings to allow for transition to the TL-HEX standard frame (Fig. 36). Due to the unique feature of the TL-HEX 5/8 and 3/8 rings, this step can be done at any desired moment if bone fixation has been performed with half pins. In case of wires, the 3/8 ring can be attached only before they are tensioned.

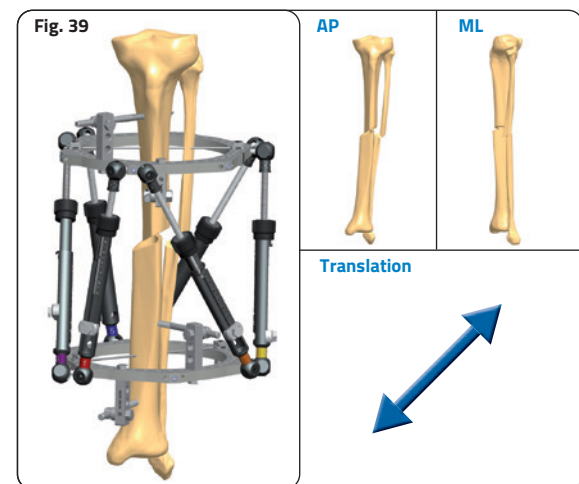
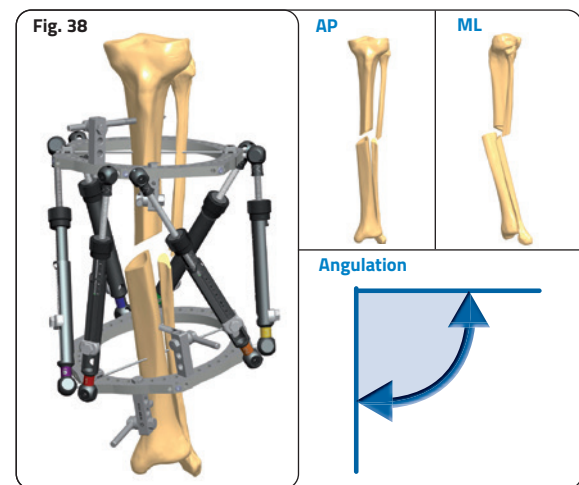
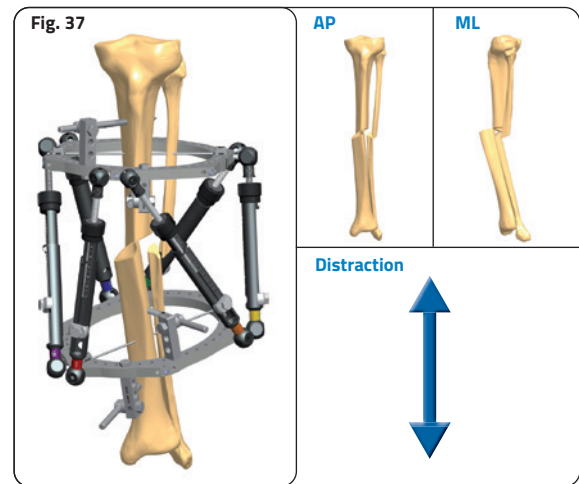
Fig. 36



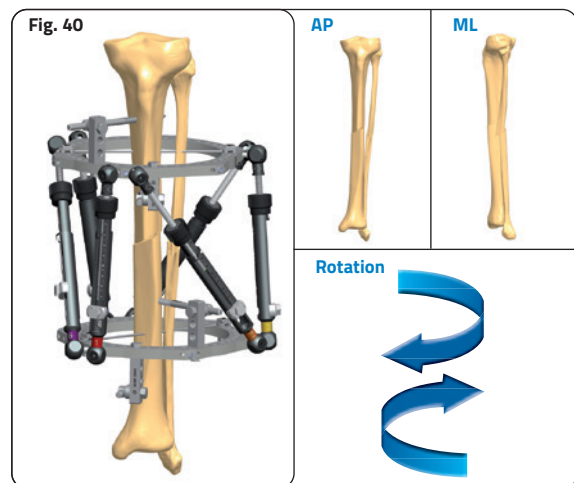
Option 2 - TL-HEX Standard Frame

The TL-HEX frame for reduction of a midshaft tibial fracture with displacement (shortening, angulation, horizontal translation and rotation) consists of the proximal and distal TL-HEX full rings interconnected by six TL-HEX struts. Each ring is secured to the proximal and distal tibial fragments by one wire and two half-pins.

For rapid fracture reduction, the side locking bolts are released on all struts to allow for rapid strut adjustments. Longitudinal traction to eliminate axial translation and bring the tibia up to length is performed first (Fig. 37), followed by angular deformity correction (Fig. 38) and reduction of the horizontal translation (Fig. 39).



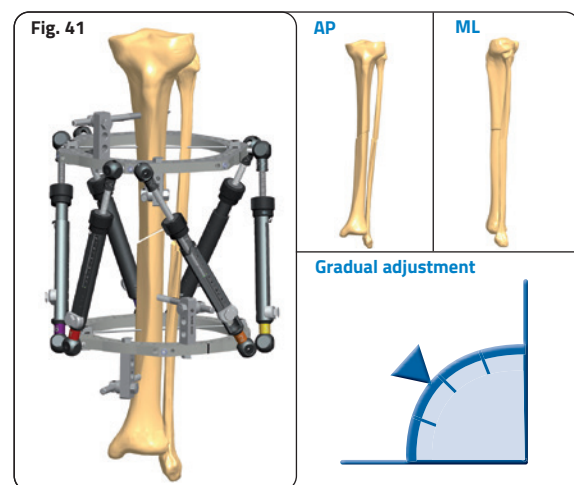
Finally, rotational deformity correction is performed (Fig. 40) and side locking bolts are re-tightened to lock the length on all struts.



For gradual, precise, three - dimensional fracture reduction, the associated software should be used (see TL-HEX Software User Guide).

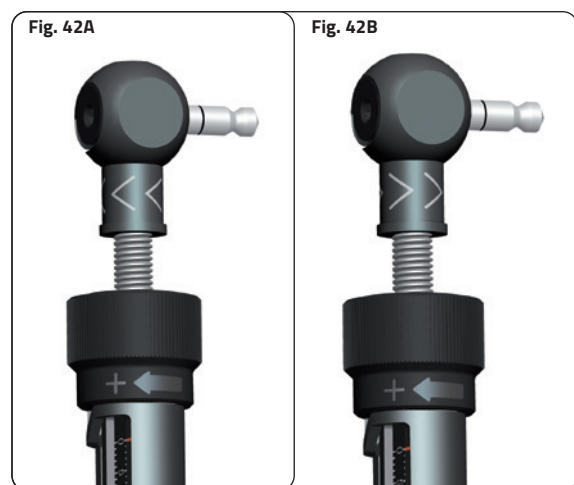
If necessary, incremental compression can be performed using gradual adjustment of the struts (Fig. 41).

After the frame is mounted to the limb, AP and ML radiographs are taken with the reference ring positioned perpendicular to the x-ray cassette (see Software User Guide). Deformity and frame mounting parameters are then obtained from the radiographs and entered into the software. The software generates a prescription, for surgeon review and approval, that indicates the turning direction and amount which each strut should be adjusted per day.



The direction clips are then applied to the rod end joints according to the prescription. Surgeons may apply the clips adopting one of the following techniques:

1. If strut elongation is required (positive numbers in the prescription), the arrow on the clip should point in the same direction as the reference arrow on the adjustment knob (Fig. 42). If strut shortening is required (negative numbers in the prescription), the clip should be applied with the arrow pointing in the opposite direction of the arrow on the adjustment knob.
2. Clips should always point toward the plus sign on the knob. When the direction on the prescription changes (minus) the patient must be advised to simply turn the knob into the opposite direction. Clip repositioning is not required.



TL-HEX Frame Construct

The TL-HEX system can be used for the treatment of several pathologies, as shown below. For further explanation, recommended surgical techniques and suggestions, please visit www.tlhex.com, Instructions for Use – Tutorials.



POST-OPERATIVE MANAGEMENT OF THE TL-HEX SYSTEM

Gradual Deformity Correction

The correction of limb deformity is performed by gradual strut adjustment according to prescription. Each full turn of the adjustment knob produces 1mm of strut length increase/decrease. The amount of gradual strut adjustment is monitored by a noticeable detent (click) every half turn of the adjustment knob (0.5mm) or using the position of the green-line mark at the end of the threaded rod relative to the scale at the inner tube of the strut. The direction of strut length change (increase or decrease) depends on the type of deformity corrected and is outlined in Table 2.

The patient/caregiver must be instructed by the physician to:

- Make the adjustments or get help in making the adjustments as needed
- Identify on the prescription when to return for a strut change and for follow up visits
- Report if adjustment schedule cannot be met
- Report any adverse or unexpected effects (strut breakage or disengagement, component damage, clip dislodgement, lost prescription)

Table 2. Direction of strut length adjustment depending on the deformity type

Deformity Type	Left Limb		Right Limb	
	Strut Length Increased	Strut Length Decreased	Strut Length Increased	Strut Length Decreased
Shortening	1, 2, 3, 4, 5, 6		1, 2, 3, 4, 5, 6	
Medial Translation	2, 5	1, 4	1, 4	2, 5
Lateral Translation	1, 4	2, 5	2, 5	1, 4
Anterior Translation	1, 2, 4, 5	3, 6	1, 2, 4, 5	3, 6
Posterior Translation	3, 6	1, 2, 4, 5	3, 6	1, 2, 4, 5
Varus	6 (1, 5)	3 (2, 4)	3 (2, 4)	6 (1, 5)
Valgus	3 (2, 4)	6 (1, 5)	6 (1, 5)	3 (2, 4)
Procurvatum	4, 5	1, 2	4, 5	1, 2
Recurvatum	1, 2	4, 5	1, 2	4, 5
Internal Rotation	2, 4, 6	1, 3, 5	1, 3, 5	2, 4, 6
External Rotation	1, 3, 5	2, 4, 6	2, 4, 6	1, 3, 5

In extreme cases of external/internal rotation, these directions may change during the correction to the opposite of what is indicated in Table 2.

Strut Readjustment and Exchange

Strut readjustment and exchange are utilized to increase the gradual adjustment range (distraction or compression). For either strut readjustment or exchange, external supports must be stabilized using a temporary “brace” (e.g. TrueLok Rapid Adjust Struts) (Figs. 43A, 43B).

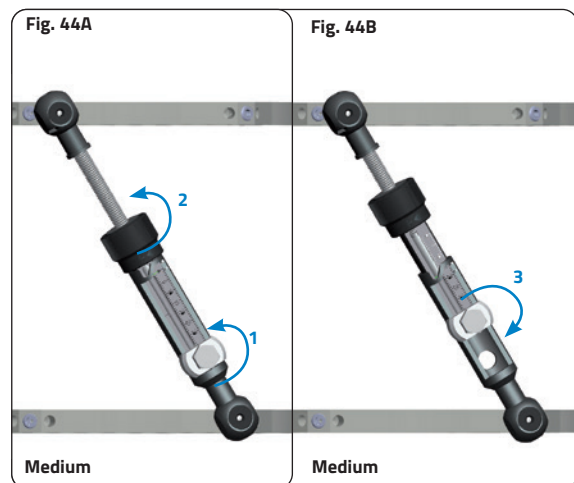
Fig. 43A



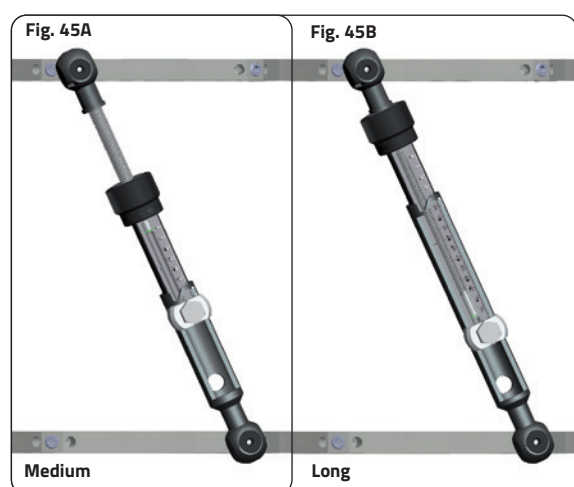
Fig. 43B



For strut readjustment, untighten the side locking bolt (1) and turn the adjustment knob (2) until the gradual and rapid adjustment indicators align with the new prescribed values on the scale (Figs. 44A, 44B). Retighten the side locking bolt (3) and remove the temporary brace.



For strut exchanges (Figs. 45A, 45B), loosen the side locking bolt on the strut, untighten the stud locking screws on the appropriate proximal and distal tabs and remove the strut. Prepare the new strut according to prescription, insert the mounting studs into appropriate mounting holes and retighten the stud locking screws confirming that the stud depth insertion line is fully hidden in the mounting hole. Replace the number and direction clips to the new strut and remove the temporary ring stabilizing brace.



GENERAL PRINCIPLES OF SOFTWARE USAGE

Please refer to TL-HEX Software User Guide. Registration page can be accessed through www.tlhex.com.

SUGGESTED READING

G.A. Ilizarov. *Transosseous Osteosynthesis. Theoretical and Clinical Aspects of the Regeneration and Growth of Tissue*. 800 pages, Springer-Verlag, New York-Berlin-Heidelberg, 1992

S.R. Rozbruch, S. Ilizarova. *Limb Lengthening and Reconstruction Surgery*. 695 pages, Informa Healthcare, New York, 2007

D. Paley. *Principles of Deformity Correction*. 806 pages, Springer-Verlag, New York-Berlin-Heidelberg, 2002

TrueLok FOOT ALIGNMENT SUPPORT - US only
99-56-24200 sterile, pack of 3

Attach a half-pin bolt to the foot plate, slide the foot alignment support in the half-pin bolt and secure it by hand-tightening the bolt. Attach two additional foot alignment supports to the foot plate and if needed to the other rings as described above.

The Foot Alignment Support should be inserted through a pin fixation bolt. Manually tighten the bolt or the spin bolt to fix the Foot Alignment Support in the desired position. Finally, the bolt of the spin bolt should be firmly secured with a wrench.

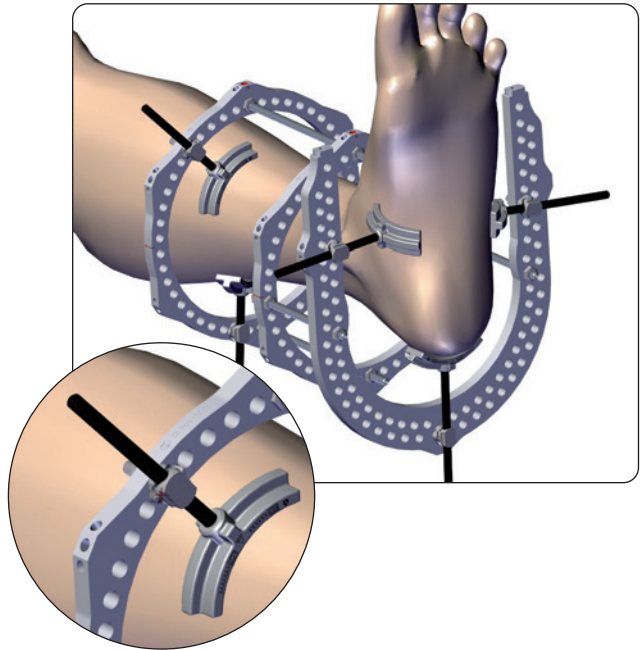
At the end of the surgery, remove the Leg Support.



PRECAUTION: Ensure that the TL Foot Alignment Support that interfaces with the patient's skin is free from burrs or sharp edges.



PRECAUTION: Ensure that three TL Foot Alignment Supports are attached to one TL ring in order to achieve correct limb placement. The position of each Support shall be evaluated based on patient's case.



TL-HEX COMPONENTS

Full Rings

Part Number	Description	Q.ty
56-20320	Full ring, 100mm TL-HEX	1
56-20200	Full ring, 120mm TL-HEX	1
56-20000	Full Ring, 140mm, TL-HEX	1
56-20020	Full Ring, 160mm, TL-HEX	1
56-20040	Full Ring, 180mm, TL-HEX	1
56-20060	Full Ring, 200mm, TL-HEX	1
99-56-20080	Full Ring, 220mm, TL-HEX (Sterile)	1
99-56-20220	Full Ring, 240mm, TL-HEX (Sterile)	1
99-56-20240	Full Ring, 280mm, TL-HEX (Sterile)	1
99-56-20340	Full Ring, 300mm, TL-HEX (Sterile)	1

5/8 Rings

Part Number	Description	Q.ty
56-21320	5/8 Modular Ring 100mm TL-HEX	1
56-21200	5/8 Modular Ring 120mm TL-HEX	1
56-21400	5/8 Modular Ring 140mm TL-HEX	1
56-21420	5/8 Modular Ring 160mm TL-HEX	1
56-21440	5/8 Modular Ring 180mm TL-HEX	1
56-21460	5/8 Modular Ring 200mm TL-HEX	1
99-56-21480	5/8 Modular Ring 220mm TL-HEX (Sterile)	1
99-56-21220	5/8 Modular Ring 240mm TL-HEX (Sterile)	1
99-56-21240	5/8 Modular Ring 280mm TL-HEX (Sterile)	1
99-56-21340	5/8 Modular Ring 300mm TL-HEX (Sterile)	1

3/8 Rings

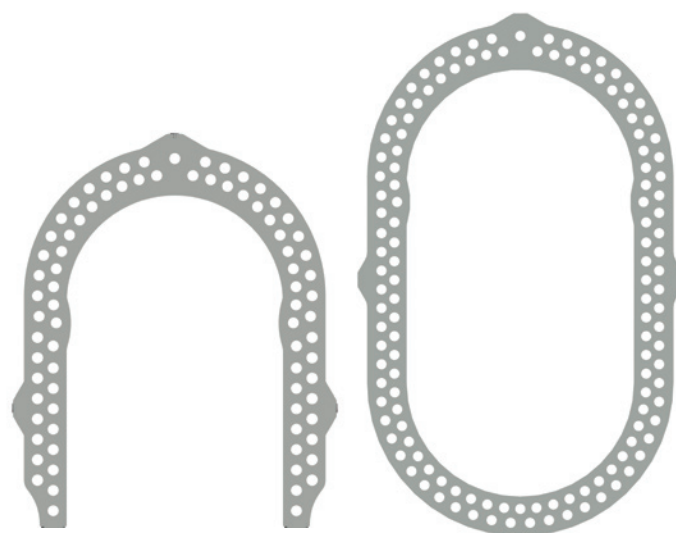
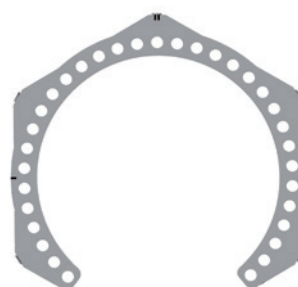
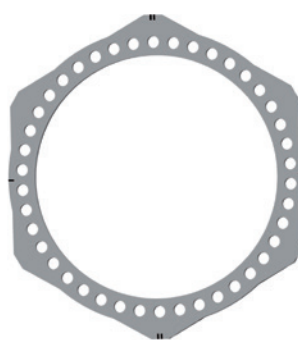
Part Number	Description	Q.ty
56-23000	3/8 Ring 100mm TL-HEX	1
56-23020	3/8 Ring 120mm TL-HEX	1
56-23040	3/8 Ring 140mm TL-HEX	1
56-23060	3/8 Ring 160mm TL-HEX	1
56-23080	3/8 Ring 180mm TL-HEX	1
56-23100	3/8 Ring 200mm TL-HEX	1
99-56-23120	3/8 Ring 220mm TL-HEX (Sterile)	1
99-56-23140	3/8 Ring 240mm TL-HEX (Sterile)	1
99-56-23160	3/8 Ring 280mm TL-HEX (Sterile)	1
99-56-23180	3/8 Ring 300mm TL-HEX (Sterile)	1

Foot Plates

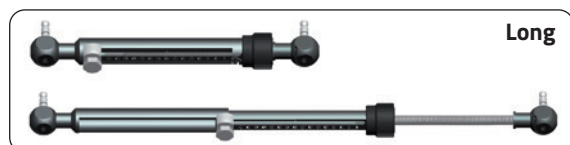
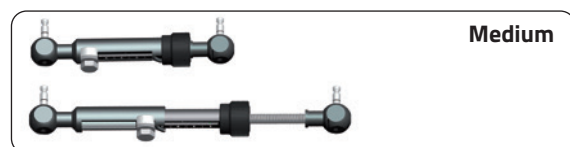
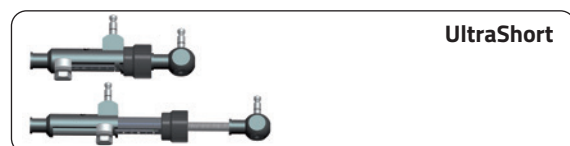
Part Number	Description	Q.ty
99-56-22000	Double Row Foot Plate TL-HEX, 120mm (Sterile)	1
99-56-22020	Double Row Foot Plate TL-HEX, 140mm (Sterile)	1
99-56-22040	Double Row Foot Plate TL-HEX, 160mm (Sterile)	1
99-56-22060	Double Row Foot Plate TL-HEX, 180mm (Sterile)	1
99-56-22080	Double Row Foot Plate TL-HEX, 200mm (Sterile)	1
99-56-22100	Double Row Foot Plate TL-HEX, 220mm (Sterile)	1
99-56-22440	Full Double Row Footplate, 160mm, TL-HEX (Sterile)	1
99-56-22450	Full Double Row Footplate, 180mm, TL-HEX (Sterile)	1

K-Wires

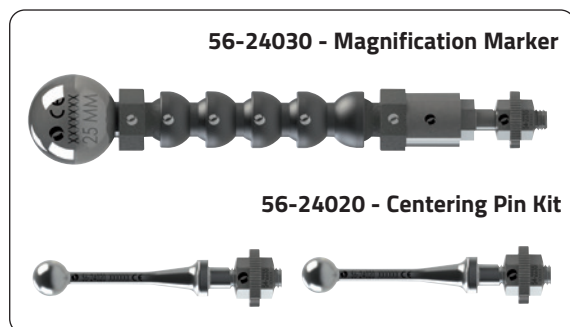
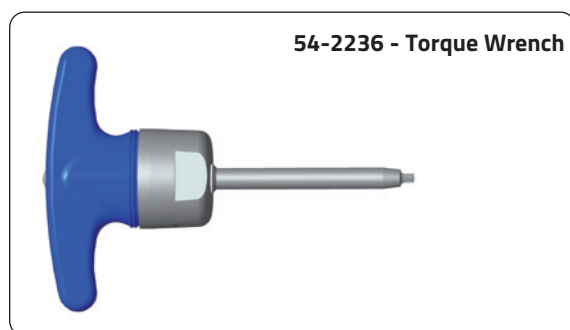
Part Number	Description	Q.ty
99-54-1750	K-Wire, 550mm, with Olive (Sterile)	1
99-54-1650	K-Wire, 450mm, no Olive (Sterile)	1



Struts	
Part Number	Length
50-10100	UltraShort Strut TL-HEX - 45mm-101mm
50-10200	Short Strut TL-HEX - 92mm-122mm
50-10300	Medium Strut TL-HEX - 114mm-184mm
50-10400	Long Strut TL-HEX - 158mm-318mm



56-24014 - TrueLok System Rocker Rail Extension Kit



Number Clips	
Part Number	Description
50-10215	Strut Number Clip Kit, TL-HEX (6 pcs)
	Consisting of:
	Strut Number Clip, #1, TL-HEX
	Strut Number Clip, #2, TL-HEX
	Strut Number Clip, #3, TL-HEX
	Strut Number Clip, #4, TL-HEX
	Strut Number Clip, #5, TL-HEX
	Strut Number Clip, #6, TL-HEX

The Strut Number Clip Kit is also available packaged sterile. It can be ordered using the above code numbers preceded by 99- (e.g. 99-50-10215).



Struts	
Part Number	Description
50-10214	Strut Direction Clip Kit, TL-HEX (6 pcs)



The Strut Direction Clip Kit is also available packaged sterile. It can be ordered using the above code numbers preceded by 99- (e.g. 99-50-10214).

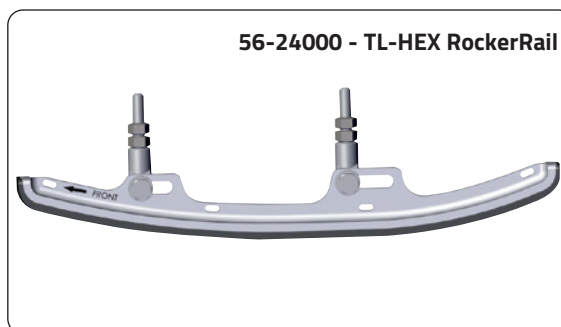
TL-HEX Strut Exchange Kit cod. 50-10500

Part Number	Description	Q.ty
50-10180	TL Plus Medium Quick Adjust Strut	1
50-10190	TL Plus Long Quick Adjust Strut	1
52-10210	TL+ AO 1/8" HEX Power Driver Attachment	1
52-1018	TL - 1/8" HEX Driver	1
54-1154	TL - Wrench, Combo, 10mm	1
54-2226	TL - 90 Degree Tubular Wrench	1
50-13020	TL+ Extended Nut M6 X 1	2
50-10214	Strut Direction Clip Kit, TL-HEX (6 pcs)	1

56-24040 - TL-HEX Emergency Tab Kit



The TL-HEX Emergency Tab Kit is also available packaged sterile. It can be ordered using the above code numbers preceded by 99- (e.g. 99-56-24040).



Rings Tray

The rings tray includes 5 removable inserts. Four inserts can hold 2 full rings, 2 5/8 rings and 2 3/8 rings of sizes greater than 120mm, while the top insert can hold 2 full rings, 2 5/8 rings and 2 3/8 rings of 100mm and 120mm sizes.

Rings Tray cod. 30110088 (empty)

Part Number	Description	Q.ty
56-20320	Full ring, 100mm TL-HEX	2
56-20200	Full ring, 120mm TL-HEX	2
56-20000	Full Ring, 140mm, TL-HEX	2
56-20020	Full Ring, 160mm, TL-HEX	2
56-20040	Full Ring, 180mm, TL-HEX	2
56-20060	Full Ring, 200mm, TL-HEX	2
56-21320	5/8 Ring 100mm TL-HEX	2
56-21200	5/8 Ring 120mm TL-HEX	2
56-21400	5/8 Ring 140mm TL-HEX	2
56-21420	5/8 Ring 160mm TL-HEX	2
56-21440	5/8 Ring 180mm TL-HEX	2
56-21460	5/8 Ring 200mm TL-HEX	2
56-23000	3/8 Ring 100mm TL-HEX	2
56-23020	3/8 Ring 120mm TL-HEX	2
56-23040	3/8 Ring 140mm TL-HEX	2
56-23060	3/8 Ring 160mm TL-HEX	2
56-23080	3/8 Ring 180mm TL-HEX	2
56-23100	3/8 Ring 200mm TL-HEX	2

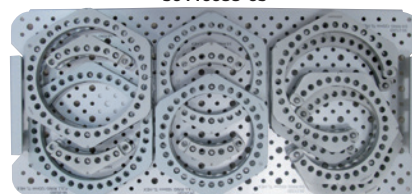
Material out of the tray

All the sterile components are supplied out of the tray (see pag.23)

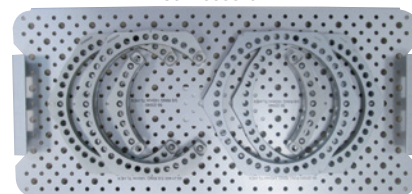
The TL-HEX rings tray accommodates all five layers as shown.

All Rings are also available packaged sterile. They can be ordered using the above code numbers preceded by 99- (e.g. 99-56-20320).

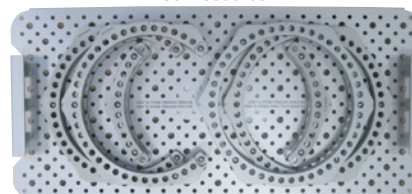
30110088-05



30110088-04



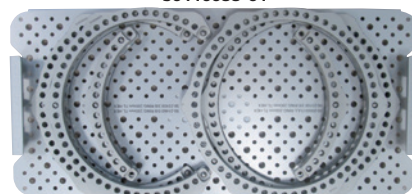
30110088-03



30110088-02



30110088-01

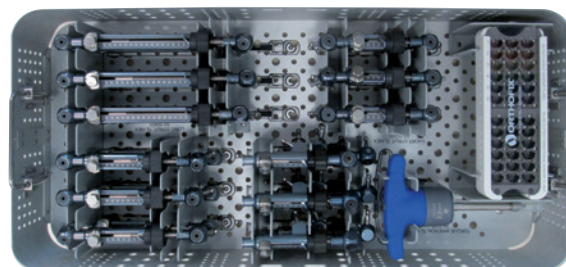


Struts Tray cod. 30110087 (empty)

Part Number	Description	Q.ty
can accommodate:		
50-10214	Strut Direction Clip Kit, TL-HEX 3	3 Kits*
50-10215	Strut Number Clip Kit, TL-HEX 3	3 Kits**
54-2236	Torque Wrench	1
50-10100	UltraShort Strut, TL-HEX - 45mm-101mm	6
50-10200	Short Strut, TL-HEX - 92mm-122mm	6
50-10300	Medium Strut, TL-HEX - 114mm-184mm	6
50-10400	Long Strut, TL-HEX - 158mm-318mm	6

* 18 Strut Direction Clips

** 3 of each Strut Number Clip

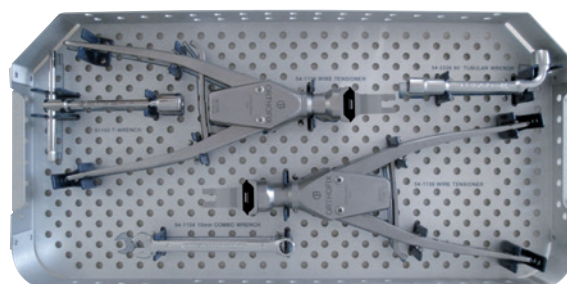
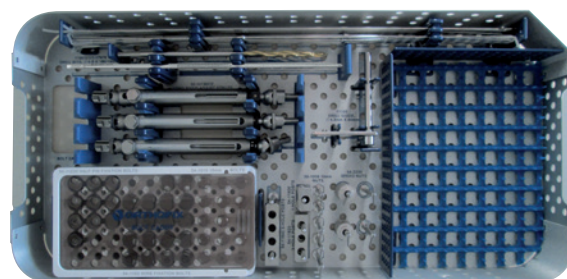
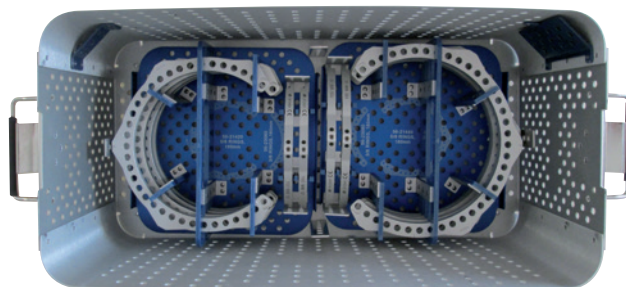


Trauma Tray, TL-HEX

The TL-HEX trauma tray is available* to accommodate all the instruments and implantable material necessary for the surgery, so it is ideal for emergency applications when saving time is a priority.

Trauma Tray, TL-HEX, code 30110129 (empty)

Part Number	Description	Q.ty
30110129C	Trauma Tray, TL-HEX, complete	1
56-23060	3/8 Ring, 160mm, TL-HEX	2
56-21420	Modular 5/8 Ring, 160mm, TL-HEX	4
56-23080	3/8 Ring, 180mm, TL-HEX 2	2
56-21440	Modular 5/8 Ring, 180mm, TL-HEX	4
50-10190	True Lok Plus Long Quick Adjust Strut	6
92050	Transfixing Pin, Thread L 50mm Shaft Ø 4mm, Thread Ø 5mm	1
54-1215	TL, Wire, W/Stopper, 1.8mm x 400mm	6
54-1216	TL, Wire, Bayonet, 1.8mm x 400mm	2
54-11600	TL+ One Hole Post	3
54-11620	TL+ Three Hole Post	3
54-11640	TL+ Five Hole Post	3
54-11540	TL 8mm Half Pin Bolt	15
OPTIONAL	TL+ Universal Half Pin Fixation Bolt	15
54-11530	4mm - 6mm	
54-1152	TL, Bolt, Wire Fixation, Universal	20
54-1010	TL, Bolt, 16mm	15
50-1008	TL, Nut, Stainless Steel, 10mm	30
54-2235	M6 X 1 HEX, Speednut, TrueLok System	12
17976	Short Graduated Drill Bit 4.8X180mm	1
or		
1100101	Drill Bit, 4.8mm x 180mm Tin Coated - Quick Connect	1
11.105	Drill Guide Ø 4.8mm Length 80mm	1
91150	Universal T-Wrench	1
54-2226	TL, 90 Degree Tubular Wrench	1
54-1154	TL, Wrench, Combo, 10mm	1
54-1139	TL PLUS Wire Tensioner With Tip	2



Material out of the tray (Sterile)

Part Number	Description
99-56-22040	Double Row Footplate, 160mm, TL-HEX
99-56-22060	Double Row Footplate, 180mm, TL-HEX
99-911530**	XCaliber Bone Screw L150/30mm Thread Ø 6.0-5.6mm
99-911540**	XCaliber Bone Screw L150/40mm Thread Ø 6.0-5.6mm
99-911550**	XCaliber Bone Screw L150/50mm Thread Ø 6.0-5.6mm
99-54-1650	K-Wire, 450mm, No Olive TL-HEX Sterile
99-54-1750	K-Wire, 550mm, Olive TL-HEX Sterile

* Please contact Orthofix for availability

** HA half pins also available

TL-HEX™ System is compatible with Standard bone screws, Titanium bone screws, Standard coated bone screws, Self-drilling coated bone screws, self-drilling bone screws, Transfixing Pins and Implantable wires.

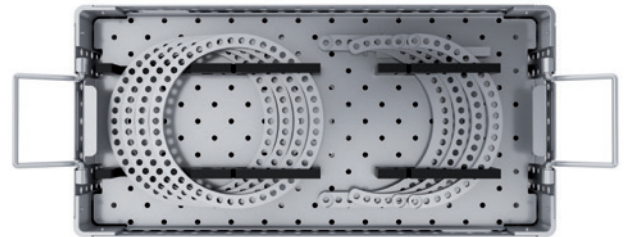
TRUELOK COMPONENTS

Ring Tray, TrueLok, Empty - 450500

A combination of any three layers can be combined to form a full rings tray.

450500-01 - LAYER 80-100 Can accommodate		
Part Number	Description	Quantity
56-10840	TL Plus Full Ring 80mm	4
56-11570	TL Plus Half Ring 80mm	2
56-12580	TL Plus Five Eighths Ring 100mm	1
56-10860	TL Plus Full Ring 100mm	4
56-11580	TL Plus Half Ring 100mm	2
56-13580	TL+ Footplate 100mm	1
450500-02 - LAYER 120 Can accommodate		
Part Number	Description	Quantity
56-10890	TL Plus Full Ring 120mm	4
56-11590	TL Plus Half Ring 120mm	2
56-12590	TL Plus Five Eighths Ring 120mm	1
56-13590	TL Plus Footplate 120mm	1
450500-03 - LAYER 130 Can accommodate		
Part Number	Description	Quantity
56-10900	TL Plus Full Ring 130mm	4
56-11600	TL Plus Half Ring 130mm	2
56-12600	TL Plus Five Eighths Ring 130mm	1
56-13600	TL+ Footplate 130mm	1
450500-04 - LAYER 140 Can accommodate		
Part Number	Description	Quantity
56-10910	TL Plus Full Ring, 140mm	4
56-11610	TL Plus Half Ring 140mm	2
56-12610	TL Plus Five Eighths Ring 140mm	1
56-13610	TL+ Footplate 140mm	1
450500-05 - LAYER 150 Can accommodate		
Part Number	Description	Quantity
56-12620	TL Plus Five Eighths Ring 150mm	1
56-13620	TL Plus Footplate 150mm	1
56-10920	TL Plus Full Ring, 150mm	4
56-11620	TL Plus Half Ring 150mm	2
450500-06 - LAYER 160 Can accommodate		
Part Number	Description	Quantity
56-10930	TL Plus Full Ring 160mm	4
56-11630	TL Plus Half Ring 160mm	2
56-12630	TL Plus Five Eighths Ring 160mm	1
56-13630	TL+ Footplate 160mm	1
450500-07 - LAYER 170 Can accommodate		
Part Number	Description	Quantity
56-10940	TL Plus Full Ring, 170mm	4
56-11640	TL Plus Half Ring 170mm	2
56-12640	TL Plus Five Eighths Ring 170mm	1
56-13640	TL+ Footplate 170mm	1

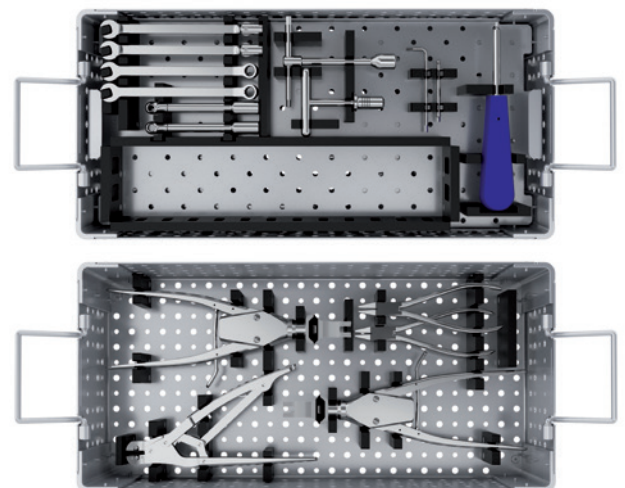
450500-08 - LAYER 180 Can accommodate		
Part Number	Description	Quantity
56-10950	TL Plus Full Ring 180mm	4
56-11650	TL Plus Half Ring 180mm	2
56-12650	TL Plus Five Eighths Ring 180mm	1
56-13650	TL+ Footplate 180mm	1
450500-09 - LAYER 200 Can accommodate		
Part Number	Description	Quantity
56-10960	TL Plus Full Ring, 200mm	4
56-11660	TL Plus Half Ring 200mm	2
56-12660	TL Plus Five Eighths Ring 200mm	1
56-13660	TL+ Footplate 200mm	1



450500C

Instrument Tray, TrueLok, 450501 Can accommodate

Part Number	Description	Quantity
W1003	Wire Cutter	1
54-1139	TL Plus Wire Tensioner with Tip	2
54-2227	Needle Nose Pliers, Stainless Steel	2
52-1018	TL, 1/8' Hex Driver	1
52-1020	TL, Hex Driver, 90-Degree, 1/8"	1
54-1154	TL,Wrench, Combo, 10mm	2
54-1155	TL,Wrench, Hinged Combo, 10mm	2
54-2226	TL, 90 Degree Tubular Wrench	2
91150	Universal T-Wrench	1
52-10210	TL+ AO 1/8' Hex Power Driver Attachment	1
54-2229	T-Wrench With AO Connection	1

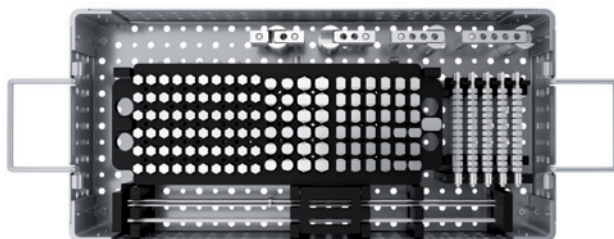


450501

Fixation Elements Tray, TrueLok, 450503

Can accommodate

Part Number	Description	Quantity
50-1008	TL, Nut, Stainless Steel, 10mm	120
50-13010	TL+ Metal Distraction / Compression Nut	16
50-13020	TL+ Extended Nut M6 X 1	10
54-1010	TL, Bolt, 16mm	24
54-1018	TL, Bolt, 20mm	12
54-1050	TL, Bolt, 12mm	24
54-1064	TL Washer, Slotted	8
54-1133	Stopper, Red Rubber, Wire	27
54-1136	Stopper, Gray Rubber, Half Pin	9
54-11530	TL+ Universal Half Pin Fixation Bolt 4mm - 6mm	12
54-11600	TL+ One Hole Post	4
54-11610	TL+ Two Hole Post	4
54-11620	TL+ Three Hole Post	4
54-11630	TL+ Four Hole Post	2
54-11640	TL+ Five Hole Post	2
54-1215	TL, Wire, W/Stopper, 1.8mm x 400mm	12
54-1216	TL, Wire, Bayonet, 1.8mm x 400mm	12
54-1134	TL, Applicator Rubber Stopper	2
54-1142	Stainless Steel Washer, 2mm Thick	12
54-1150	TL, Washer, Conical Pair	16
54-1152	TL, Bolt, Wire Fixation, Universal	24
54-1151	TL, Short Bolt, Wire Fixation, Universal	12
54-2235	M6 X 1 Hex, Speednut, Truelok System	16
54-11540	TL 8mm Half Pin Bolt	12

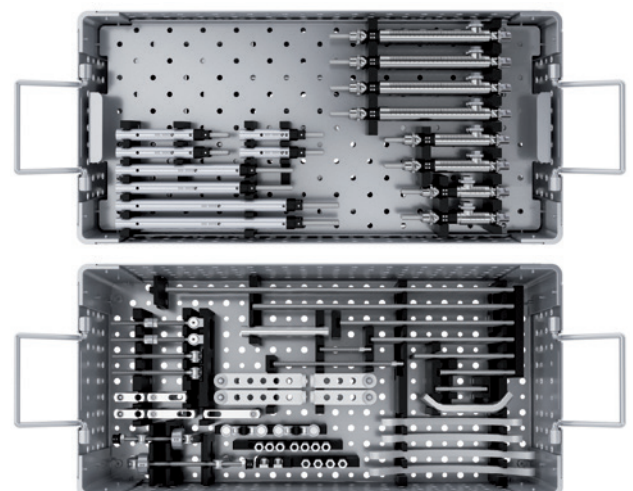


450503

Hinges and Distractors Tray, TrueLok, 450504

Can accommodate

Part Number	Description	Quantity
51-10300	TL+ Threaded Hinge Rod, 60mm	4
51-10430	TL+ Cannulated Inline Hinge Assembly	2
51-10440	TL+ Outboard Hinge Assembly	2
51-10460	TL+ Angular Distractor Assembly, 100mm	1
51-10470	TL+ Angular Distractor Assembly, 150mm	1
51-10550	TL+ Threaded Hinge Rod 150mm	4
55-10060	115mm Threaded Rod	8
55-10070	165mm Threaded Rod	8
55-10340	TL Plus 20mm Plate	8
55-10530	85mm Threaded Rod	8
55-10.99	TL, Oblique Support	4
55-11670	TL+ 30mm Plate	4
55-11671	TL+ 40mm Plate	4
55-11680	TL+ 50mm Plate	4
55-11720	60mm Threaded Rod	8
54-11650	TL+ Hex Standoff	4
54-11660	TL Plus Hex Standoff 30mm	8
55-1176	TL, Hinge, Universal	4
55-11730	TL+ Threaded Hex End Rod 200mm	4
55-11740	TL+ Threaded Hex End Rod 300mm	4
55-11750	TL+ Threaded Hex End Rod 400mm	4
51-10220	TL+, 100mm Telescopic Hinge Extender	2
56-14580	TL+ Foot Plate Extension 3 Hole	4
56-14590	TL+ Foot Plate Extension 5 Hole	4
55-10760	TL Plus 90mm Arch	2
55-10800	TL Plus 120mm Arch	2
51-10462	Bracket Assembly, Swivel Stud, Angular Distractor, Truelok	2
50-10140	TL+ Telescopic Linear Distractor 100mm	4
50-10150	TL+ Telescopic Linear Distractor 150mm	4
50-10160	TL+ Telescopic Linear Distractor 200mm	4
50-11010	TL+ Telescopic Linear Distractor 70Mm	4
50-10170	TrueLok Plus Short Quick Adjust Strut	4
50-10180	TrueLok Plus Medium Quick Adjust Strut	4
50-10190	TrueLok Plus Long Quick Adjust Strut	8



450504

Components available also in sterile packaging

Part Number	Description
99-50-10100	ULTRA SHORT STRUT TL-HEX - 45MM-101MM STERILE
99-50-10200	SHORT STRUT TL-HEX - 92MM-122MM STERILE
99-50-10300	MEDIUM STRUT TL-HEX - 114MM-184MM STERILE
99-50-10400	LONG STRUT TL-HEX - 158MM-318MM STERILE
99-50-10170	TRUE LOK PLUS SHORT QUICK ADJUST STRUT STERILE
99-50-10180	TRUE LOK PLUS MEDIUM QUICK ADJUST STRUT STERILE
99-50-10190	TRUE LOK PLUS LONG QUICK ADJUST STRUT STERILE
99-56-20000	FULL RING, 140MM, TL-HEX STERILE
99-56-20020	FULL RING, 160MM, TL-HEX STERILE
99-56-20040	FULL RING, 180MM, TL-HEX STERILE
99-56-20060	FULL RING, 200MM, TL-HEX STERILE
99-56-20200	FULL RING, 120MM, TL-HEX STERILE
99-56-20320	FULL RING, 100MM, TL-HEX STERILE
99-56-21200	MODULAR 5/8 RING, 120MM, TL-HEX STERILE
99-56-21320	MODULAR 5/8 RING, 100MM, TL-HEX STERILE
99-56-21400	MODULAR 5/8 RING, 140MM, TL-HEX STERILE
99-56-21420	MODULAR 5/8 RING, 160MM, TL-HEX STERILE
99-56-21440	MODULAR 5/8 RING, 180MM, TL-HEX STERILE
99-56-21460	MODULAR 5/8 RING, 200MM, TL-HEX STERILE
99-56-23000	3/8 RING, 100MM, TL-HEX STERILE
99-56-23020	3/8 RING, 120MM, TL-HEX STERILE
99-56-23040	3/8 RING, 140MM, TL-HEX STERILE
99-56-23060	3/8 RING, 160MM, TL-HEX STERILE
99-56-23080	3/8 RING, 180MM, TL-HEX STERILE
99-56-23100	3/8 RING, 200MM, TL-HEX STERILE
99-56-24040	TL HEX EMERGENCY TAB KIT STERILE
99-54-11230	TL+ HALF PIN QUICK CONNECT 4MM X 180MM STERILE
99-54-11240	TL+ HALF PIN QUICK CONNECT 5MM X 180MM STERILE
99-54-11250	TL+ HALF PIN QUICK CONNECT 6MM X 180MM STERILE
99-50-10215	STRUT NUMBER CLIP KIT, TL-HEX (6 PCS) STERILE
99-50-10214	STRUT DIRECTION CLIP KIT, TL-HEX (6 PCS) STERILE
99-50-10140	TL+ TELESCOPIC LINEAR DISTRATOR 100MM STERILE
99-50-10150	TL+ TELESCOPIC LINEAR DISTRATOR 150MM STERILE
99-50-10160	TL+ TELESCOPIC LINEAR DISTRATOR 200MM STERILE
99-50-11010	TL+ TELESCOPIC LINEAR DISTRATOR 70MM STERILE
99-54-1215	TL, Wire, W/Stopper, 1.8mm x 400mm Sterile
99-54-1216	TL, Wire, Bayonet, 1.8mm x 400mm Sterile

Please refer to the "Instructions for Use" supplied with the product for specific information on indications for use, contraindications, warnings, precautions, possible adverse events, MRI (Magnetic Resonance Imaging) safety information 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.



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