

LRS Advanced

Limb Reconstruction System™



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Operative Technique Contributing Surgeons:

M. Oleksak, MD M. De Peppo, MD

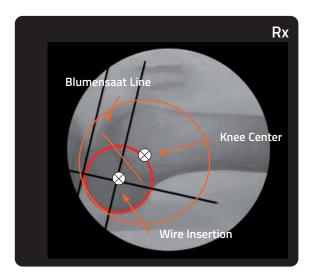
INTRODUCTION

The rotation center of the knee joint appears to change relative to the position of knee flexion. The femoral condyle in sagittal section is composed of the arcs of two circular facets, a small posterior arc (flexion facet), and a larger anterior arc (extension facet). The knee moves from an extended position along the larger anterior arc of the femoral condyle towards a smaller posterior arc of the flexion facet when flexion occurs.

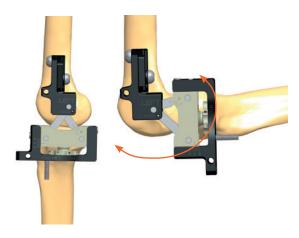
Hence the rotational axis seems to be situated between the centers of the respective arcs of rotation, and migrates from a position above Blumensaat Line towards a spot below this line with flexion of the knee joint.

The Knee Hinge aims to mimic the cruciate function of the knee and its moving rotational axis in the sagittal plane. The main purpose of the hinge is to permit anatomical rotation of the knee joint between a monolateral femoral external fixator (LRS) and a circular tibial device (SRF/Truelok).

Please kindly refer to the product IFU PQREC, 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.



Knee Motion

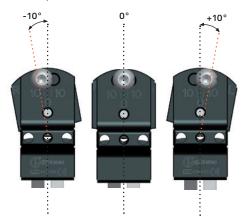


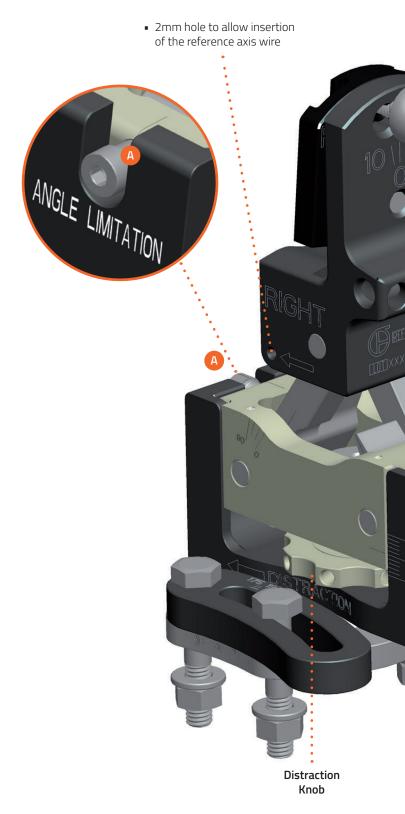
- The hinge mechanism permits a similar range of knee motion to that of the Anterior and Posterior Cruciate Ligaments, from 0° to 90° in the sagittal plane
- Facility for limiting range of motion (locking screw A)
- Passive R.O.M. possible with additional use of compression-distraction unit.



Femoral alignment of the rotation axis:

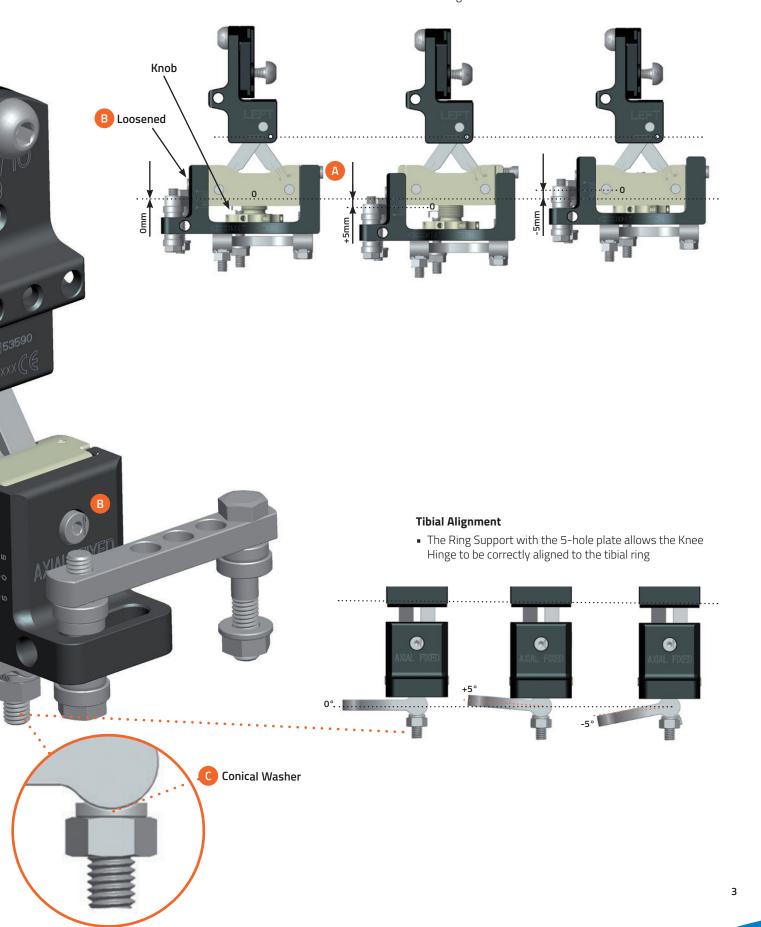
- Radiolucent central body
- The proximal part of the Knee Hinge is able to swivel
- ±10° in the frontal plane to allow for positioning of the rail parallel to the femoral anatomical axis





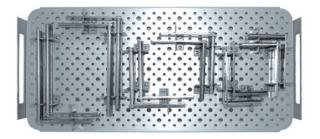
Knee Distraction

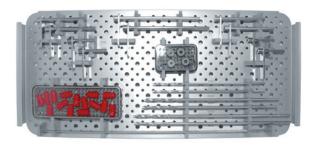
• ±5mm tibial axial distraction-compression is possible from the tibial side by turning the distraction knob with locking screw B loosened



EQUIPMENT REQUIRED

| E200E - | ADVIDE In about a start Book English | |
|----------------|--|-----|
| | ADV LRS Instruments Steri-Box Empty | |
| can accomr | | Ohu |
| | Component Description | Qty |
| Upper tra | | 10 |
| | Screw Guide, L 100mm | 10 |
| 11103 11124 | Screw Guide, L 100mm | |
| 11124 | Screw Guide, L 160mm | 10 |
| Central tra | ay | |
| 11104 | Drill Guide, Ø 4.8mm, L 40mm | 2 |
| 11105 | Drill Guide, Ø 4.8mm, L 80mm | 2 |
| 11106 | Drill Guide, Ø 3.2mm, L 40mm | 2 |
| 11116 | Drill Guide, Ø 3.2mm, L 80mm | 2 |
| 11125 | Drill Guide, Ø 4.8mm, L 140mm | 2 |
| 80122 | X-Wire without olive Ø 2mm, L 400mm | 5 |
| 1100201 | Drill Bit, Ø 4.8mm, L 240mm | 2 |
| 1100301 | Drill Bit, Ø 3.2mm, L 200mm | 2 |
| 1100701 | Drill Bit, Ø 4.8mm, L 280mm | 2 |
| 10200 | Sterilizable Screw Covers (pack of 20) | 1 |
| 11005 | Drill Bit Stop Unit, Ø 4.8mm | 2 |
| 11006 | Drill Bit Stop Unit, Ø 3.2mm | 2 |
| Lower tra | v | |
| Lower tra | Allen Wrench 3mm | 2 |
| 10012 | Allen Wrench 6mm | 2 |
| 10017 | Torque Wrench 6mm | 1 |
| 91150 | Universal T-Wrench | 2 |
| 11004 | Tapered Trocar | 1 |
| 30025 | Torque Wrench 5mm (31000 Series) | 1 |
| 1101101 | Cannulated Drill Bit Ø 3.2mm, L 200mm | 2 |
| 1101201 | Cannulated Drill Bit Ø 4.8mm, L 280mm | 2 |
| 11144 | Ruland Pilot Wire Guide Ø 2mm, L 75mm | 2 |
| 11145 | Ruland Pilot Wire Guide Ø 2mm, L 115mm | 2 |
| 30017 | Allen Wrench 5mm | 2 |
| 36017 | Allen Wrench 4mm | 2 |
| 11111 | Hammer | 1 |
| Compose | nts out of the tray | |
| 53592 | ADV Knee Hinge Replacement Kit | 1 |
| 54-1150 | TrueLok conical washer couple | 1 |
| 55-1171 | TrueLok plate 5-hole | 1 |
| 55 | dezon place o Hole | |







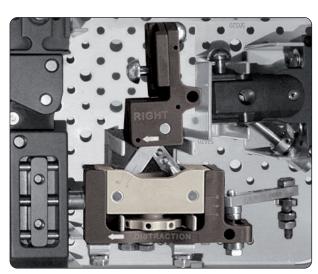
53990 - ADV LRS Components Steri-Box Empty A can accommodate: Part # Component Description Quality Upper tray

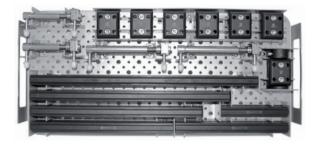
| Part # | Component Description | | | | |
|------------|--|---|--|--|--|
| Upper tray | | | | | |
| 53530 | ADV Straight Clamp | 6 | | | |
| 53560R | ADV Radiolucent LRS rail 400mm or ADV LRS | 1 | | | |
| or 53560 | rail 400mm | ' | | | |
| 53555R | ADV Radiolucent LRS rail 350mm or ADV LRS | 1 | | | |
| or 53555 | rail 350mm | | | | |
| 53550R | ADV Radiolucent LRS rail 300mm or ADV LRS | 1 | | | |
| or 53550 | rail 300mm | | | | |
| 53549R | ADV Radiolucent LRS rail 250mm or ADV LRS | 1 | | | |
| or 53549 | rail 250mm | ' | | | |
| 53545R | ADV Radiolucent LRS rail 200mm or ADV LRS | 1 | | | |
| or 53545 | rail 200mm | ' | | | |
| 53544R | ADV Radiolucent LRS rail 120mm or ADV LRS | 1 | | | |
| or 53544 | rail 120mm | ' | | | |
| 50008 | Compression Distraction Clicker-extends to 4cm | 2 | | | |
| 50009 | Compression Distraction Clicker-extends to 8cm | 2 | | | |
| 53580 | ADV Inclination Clamp | 1 | | | |
| | | | | | |

| Lower tray | | | | | |
|------------|--|---|--|--|--|
| 53115 | ADV Micrometric Swivelling Clamp | 1 | | | |
| 53111 | ADV Translation Clamp | 1 | | | |
| 53585 | ADV Micrometric Translation-Angulation Clamp | 1 | | | |
| 53520 | ADV Metaphyseal Clamp | 1 | | | |
| 53031 | ADV T Garches Clamp | 1 | | | |
| 53004 | ADV Garches CD Unit Standard extends 5,5cm | 1 | | | |
| 53005 | ADV Garches CD Unit Long extends 10cm | 1 | | | |
| 53034 | ADV TrueLok™ kit for Ring Connectio | 1 | | | |
| 53581 | ADV Multiplanar Clamp | 1 | | | |
| 53570 | ADV Ring Hinge | 1 | | | |
| 53536 | ADV Dyna-Ring | 2 | | | |
| 53590 | ADV Knee Hinge | 1 | | | |

LRS Advanced Limb Reconstruction 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, Implantable wires.

To be positioned in the steri-box, the Knee Hinge must be assembled as shown below.

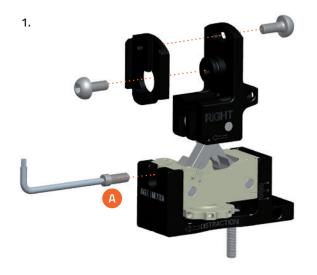






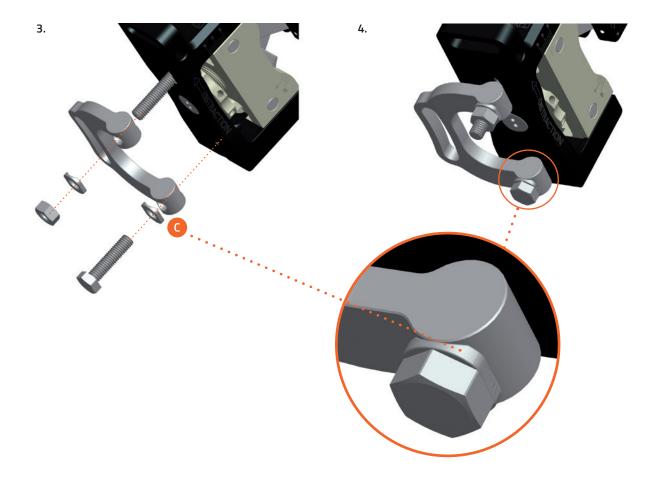
KNEE HINGE ASSEMBLY

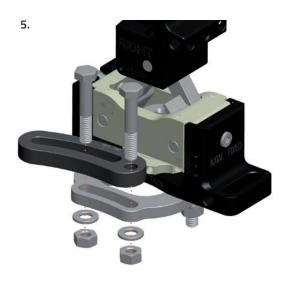
In case the Knee Hinge has been dismantled, please attend to the following instructions for reassembly.

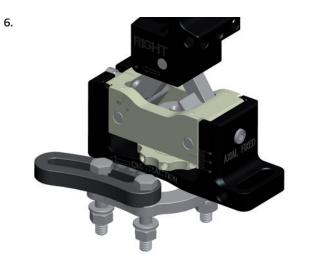


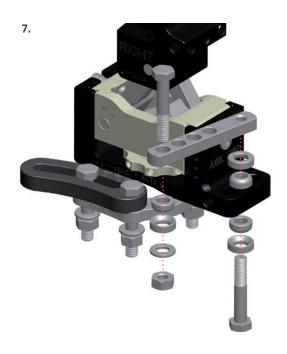


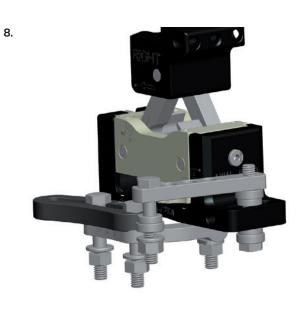








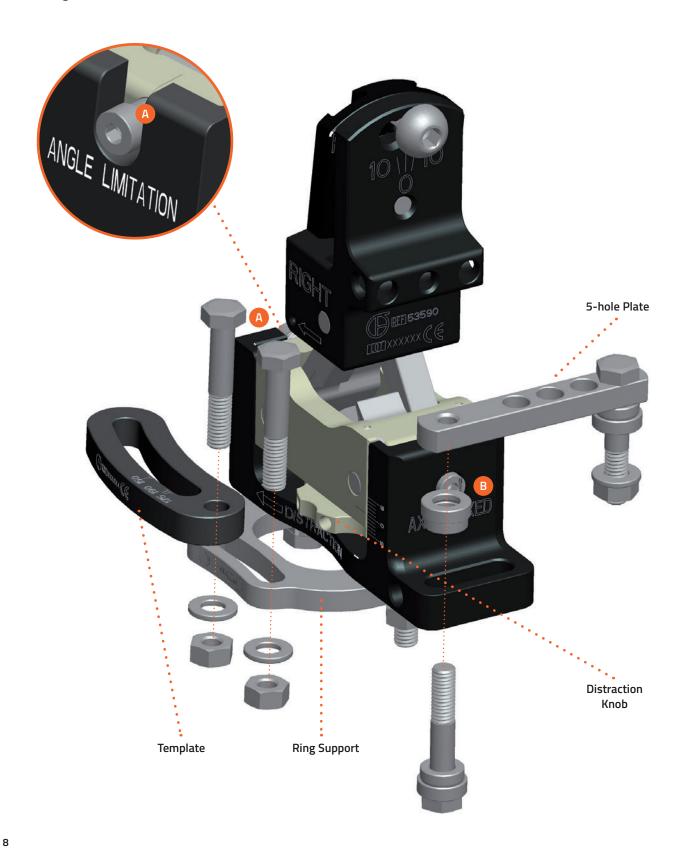




TRAUMA

1. Knee Hinge Preparation

Remove the template, the 5-hole plate with locking screws and washers. Before applying the Knee Hinge to the ring, ensure that locking screw A is loosened (free hinge movement).

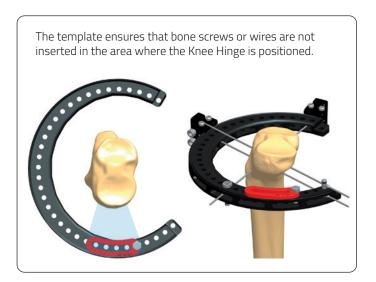


2. Template Positioning

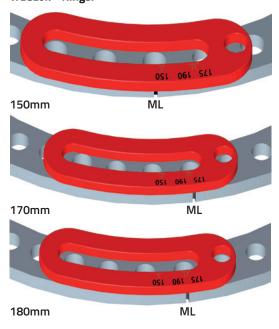
The template is designed to be used with 150, 175 (170mm TrueLok™ Ring), 190mm diameter rings. The markings on the template help the surgeon to position it correctly onto the ring:

■ TrueLok™ Ring: Align the template marking corresponding to the ring diameter used with the ring Medial Line (ML).

 Sheffield Ring: When locking the template, use the 3rd hole of a 150mm diameter ring or the 4th hole of a 175 or 190mm diameter ring.



TrueLok™ Rings:



Sheffield Rings:



Ring 150mm, hole 3



Ring 175mm, hole 4



Ring 190mm, hole 4

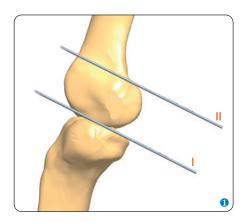
In the pictures, the red color of the template is only for demonstration purposes. The actual component is grey, as all the other metal components.

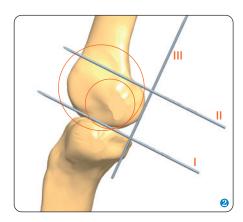
3. Reference Wire Placement

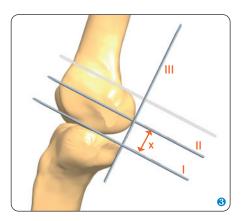
- Place a K-wire (I) on the skin at the level of the knee joint and parallel to the tibial plateau.

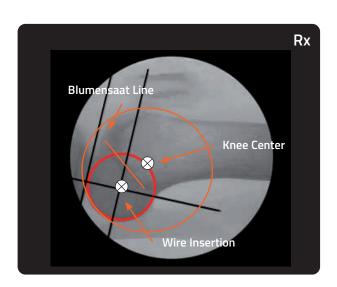
 Place a second (II) wire parallel to the first (I), at the level of the proximal end of the condyles.
- ② A third (III) wire is placed at right angles, at the level of the posterior part of the femoral condyles.
- Move the proximal parallel wire (II) down to the center of the condyles.
 Measure the distance "X" between the parallel wires.
- Move the posterior wire (III) anteriorly of a distance equal to "X".

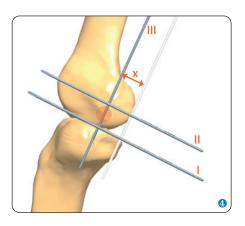
The point where wires two (II) and three (III) meet will be the reference axis of the Knee Hinge (Rx image).



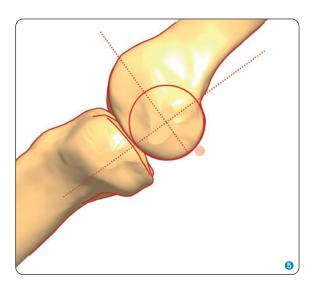




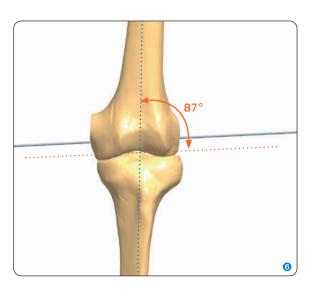




Insert a K-wire in the center of the flexion arc.



The wire needs to be parallel to the knee joint (87° to the mechanical axis).



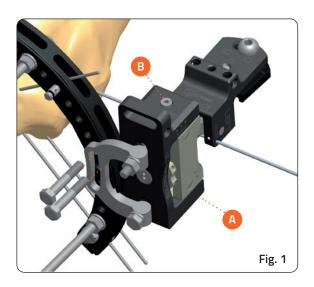
4. Sheffield Ring

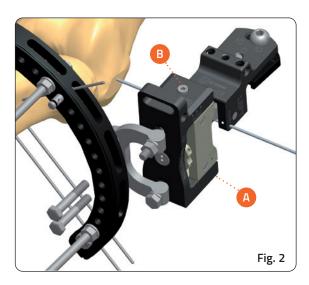
4a. Apply the Sheffield Ring Fixator

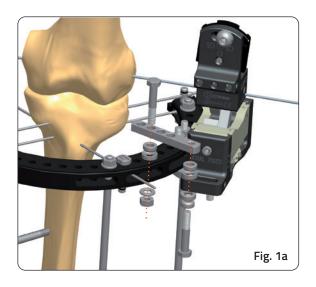
4b. Knee Hinge Positioning

- Remove the template before applying the Knee Hinge.
- Depending upon which leg is treated (L or R), the corresponding mark should face the surgeon.
- Apply the Knee Hinge over the reference axis wire, making sure that locking screw A and locking screw B are loosened. If necessary, turn the distraction knob in order to adjust the distance between the ring support and the ring.
- The ring support can be attached above or below the proximal ring.











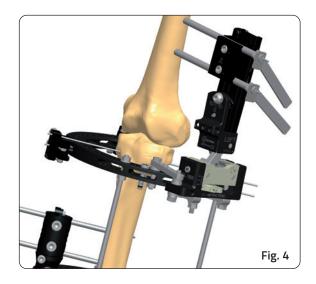
4c. Insertion of Femoral Screws

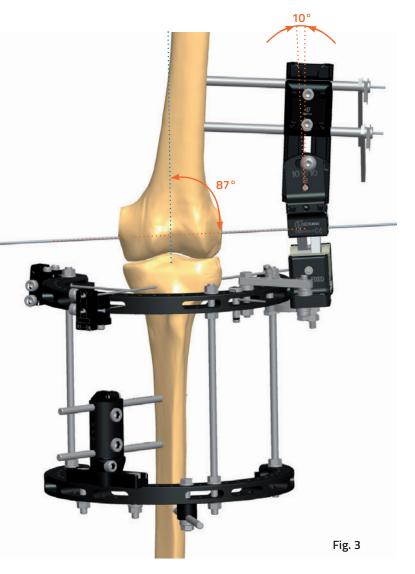
- Insert the rail with a straight clamp on the hinge.
 Position the straight clamp 15-20mm from the hinge.
- Ensure that the rail is in line with the anatomical axis of the femur. If necessary, swivel the proximal part of the hinge in the frontal plane to allow perpendicular placement of bone screws (see page 2).
- Insert 2 wire guides into the screw guides positioned in the screw seats 1 and 5 of the straight clamp.
 Insert the wires (Fig. 3).
- Remove the reference wire (Fig. 4).

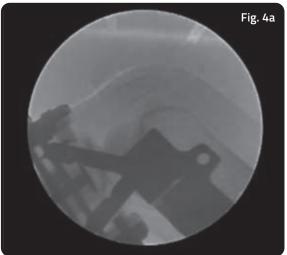


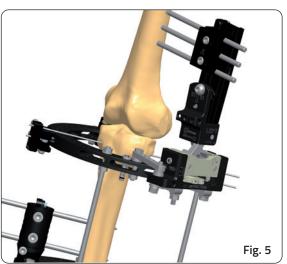
PRECAUTION: Before stabilising the femur with bone screws, check under image intensification that flexion-extension of the knee is not impeded. This will confirm correct positioning of the hinge. If necessary, replace the K-wire correctly in the Reference Axis. (see page 10)

• Remove the wires and wire guides. Insert the screws after drilling with 4.8mm drill guide and drill bit (Fig. 5).









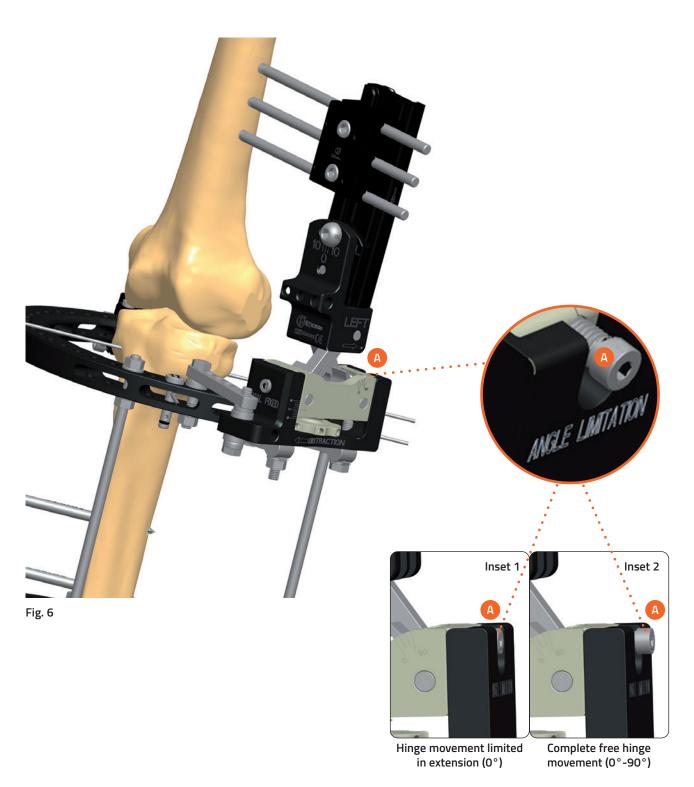
4d. R.O.M. Check

If necessary, distract the knee joint by turning the distraction knoh

Knee flexion can be limited by tightening the locking screw A.



PRECAUTION: Once all bone screws have been inserted, check again the R.O.M. and if not complete, tighten the posterior locking screw to limit the hinge movement to the R.O.M.



5. TrueLok™ Ring

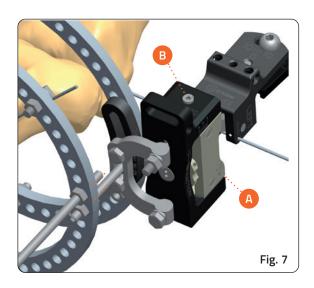
5a. Apply the TrueLok™ Fixator

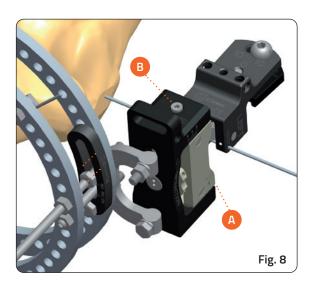
5b. Knee Hinge Positioning

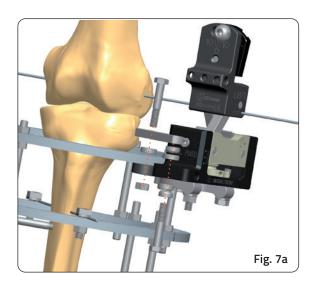
The distraction knob can be used to adjust the distance between the Knee Hinge and the Truelok Ring.

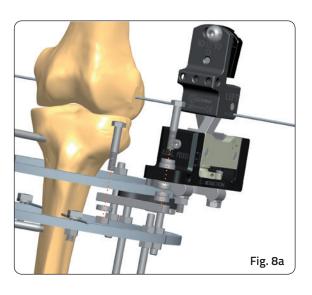
The template needs to be used to apply the hinge on the TrueLok Ring.



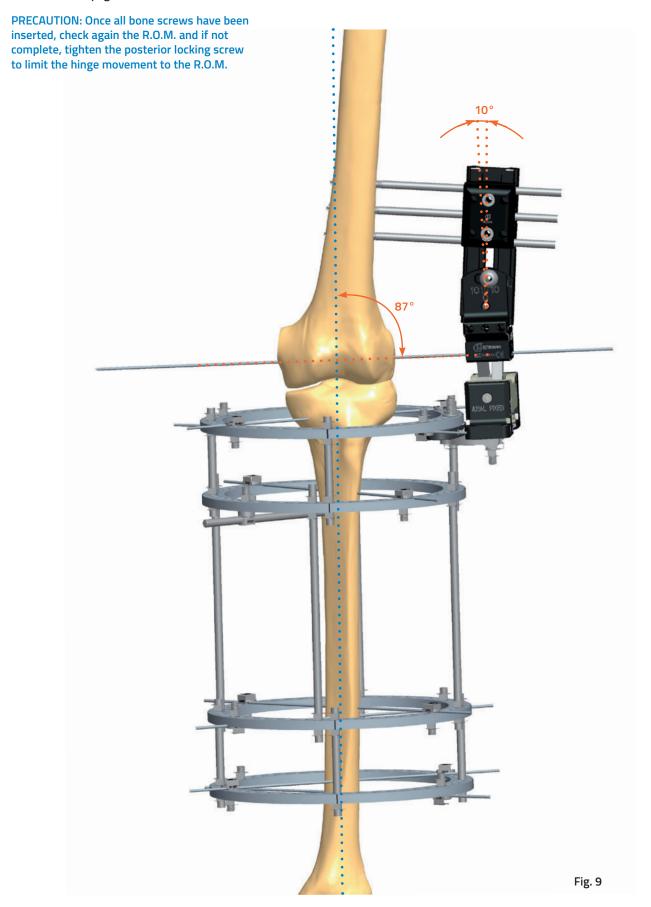








- For insertion of Femoral Screws (see page 13).
- Check the R.O.M. (see page 14).



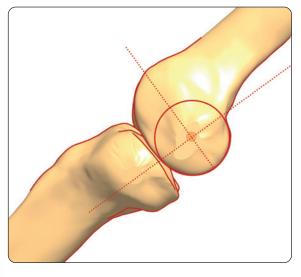
KNEE DISLOCATION

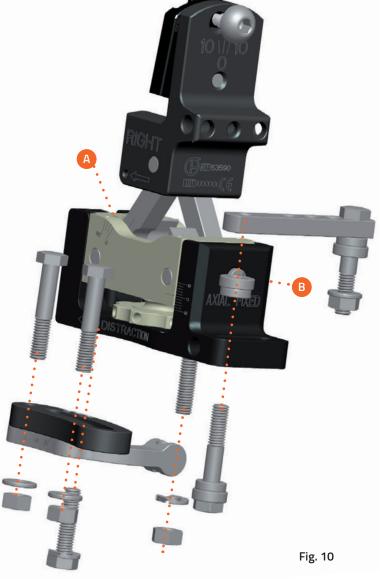
- Disassemble the Knee Hinge completely (Fig. 10).
- Insert the reference axis wire (see page 10) and apply the Knee Hinge over it, making sure that locking screw A and locking screw B are loosened. Depending upon which leg is treated (L or R), the corresponding mark should face the surgeon

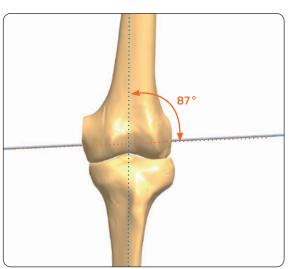
Sheffield Ring System

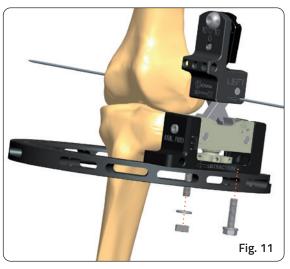
• Attach the Knee Hinge directly to the ring, without using the ring support or 5-hole plate (Fig. 11).

Use flat washers with the bolt and nut.









- Insert the rail with a straight clamp on the hinge.
 Position the straight clamp 15-20mm from the hinge.
- Ensure that the rail is in line with the anatomical axis of the femur. If necessary, swivel the proximal part of the hinge in the frontal plane (see page 2).
- Insert 2 wire guides into the screw guides positioned in the screw seats 1 and 5 of the straight clamp.
 Insert the wires.
- Attach a Sheffield Clamp to the ring on the medial aspect of the tibia.
- Insert 2 wire guides into the screw guides positioned in the screw seats 2 and 5 of the Sheffield Clamp (Fig. 12). Insert the wires.
- Remove the reference wire (Fig. 13).

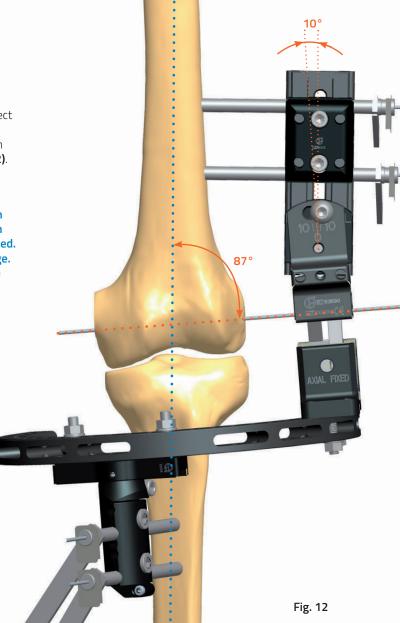


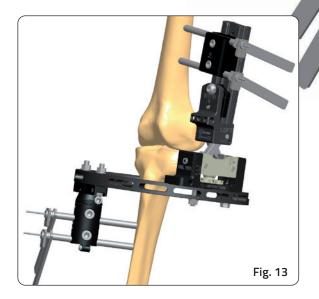
PRECAUTION: Before stabilising the femur with bone screws, check under image intensification that flexion-extension of the knee is not impeded. This will confirm correct positioning of the hinge. If necessary, replace the K-wire correctly in the Reference Axis.

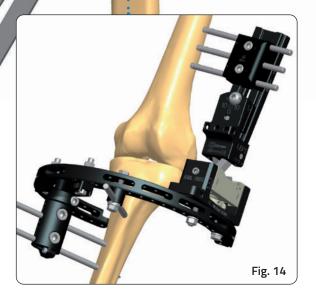
- Remove the wires and wire guides.
 Insert the screws after drilling with 4.8mm drill guide and drill bit (Fig. 14).
- Check the R.O.M. (see page 14).



PRECAUTION: Once all bone screws have been inserted, check again the R.O.M. and if not complete, tighten the posterior locking screw to limit the hinge movement to the R.O.M.

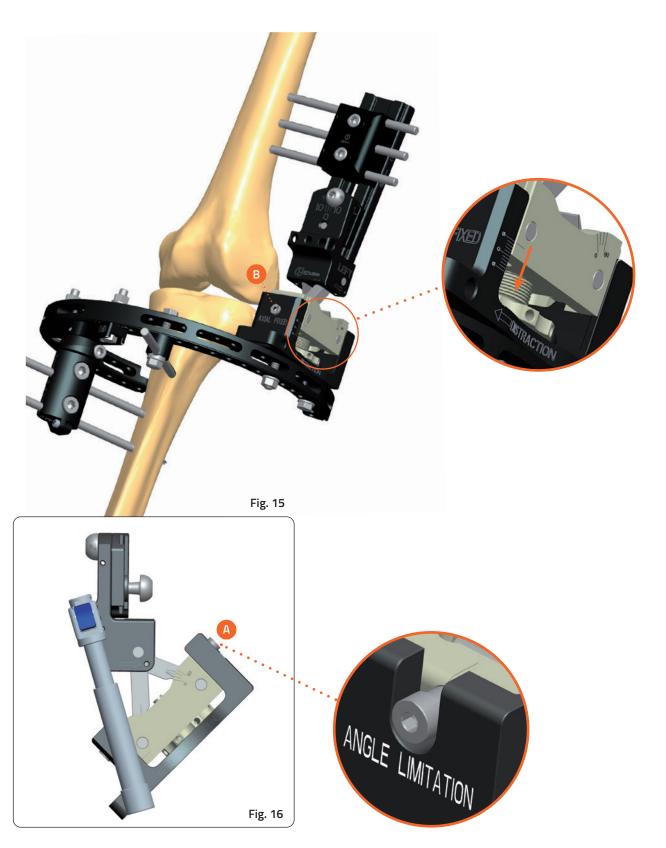






Distraction of the knee joint is possible by turning the distraction knob. Tighten locking screw B.

The range of motion of the knee can be increased by using the compression-distraction unit (see Fig. 16).



TrueLok™ System

- Attach the Knee Hinge directly to the ring using ADV TrueLok™ Kit for ring connection (53034), without the ring support or 5-hole plate.
- Insert the rail with a straight clamp on the hinge.
 Position the straight clamp 15-20mm from the hinge.
- If necessary, rotate the proximal part of the hinge in the sagittal plane (see page 2).
- Insert 2 wire guides into the screw guides positioned in the screw seats 1 and 5 of the straight clamp.
 Insert the wires.
- Attach a post to the distal ring and, using half pin fixation bolts, secure two wire guides. Insert two wires into the wire guides.
- Remove the reference wire (Fig. 17).

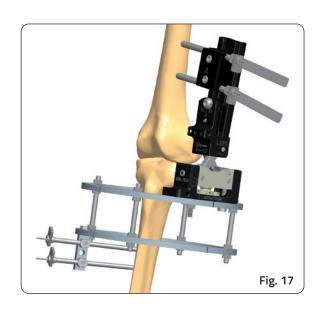


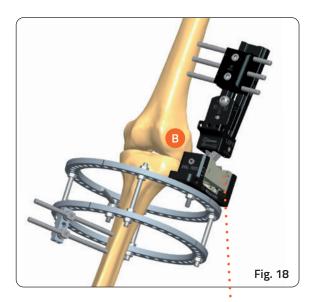
PRECAUTION: Before stabilising the femur with bone screws, check under image intensification that flexion-extension of the knee is not impeded. This will confirm correct positioning of the hinge. If necessary, replace the K-wire correctly in the Reference Axis.

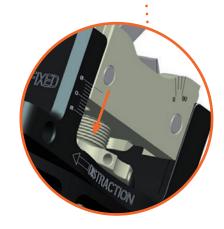
- Remove the wires and wire guides. Insert the screws after drilling with 4.8mm drill guide and drill bit (Fig. 18).
- Check the R.O.M. (see page 14).



PRECAUTION: Once all bone screws have been inserted, check again the R.O.M. and if not complete, tighten the posterior locking screw to limit the hinge movement to the R.O.M.







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.



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



