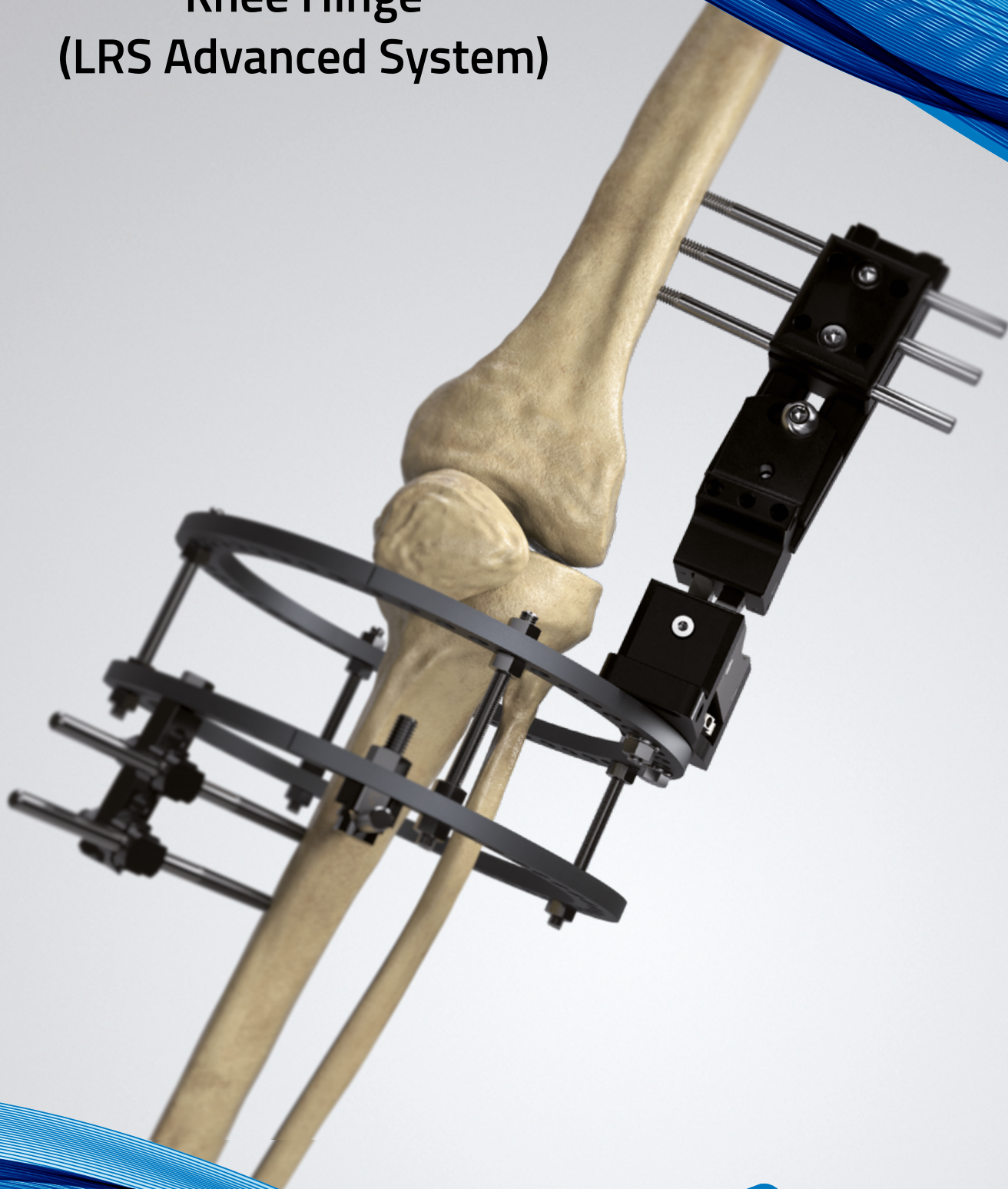


OPERATIVE TECHNIQUE

LRS Advanced[™]

Limb Reconstruction System

Knee Hinge (LRS Advanced System)



LRS Advanced™

Limb Reconstruction System

Table of Contents

1	Introduction	
4	Equipment required	
6	Knee hinge assembly	
8	Trauma	
17	Knee dislocation	

Operative Technique Contributing Surgeons:

M. Oleksak, MD
M. De Peppo, MD

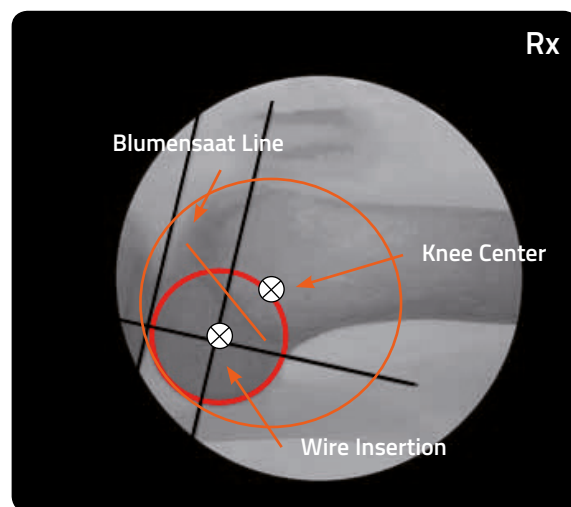
INTRODUCTION

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.

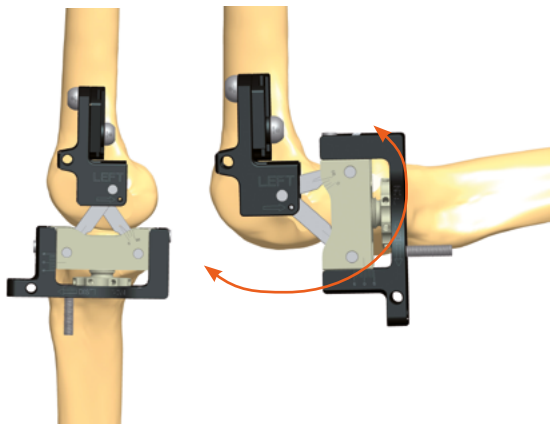
Hence the rotational axis seems to be situated between the centers of the respective arcs of rotation, and migrates from a position above Blumensaat Line towards a spot below this line with flexion of the knee joint.

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).

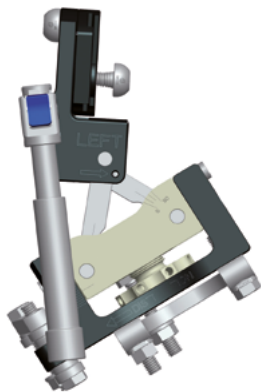
Please kindly refer to the product IFU PQREC, to the Orthofix implantable devices and related instrument IFU PQSCR, and to the reusable medical devices IFU PQRMD that contain instructions for use of the product.



Knee Motion

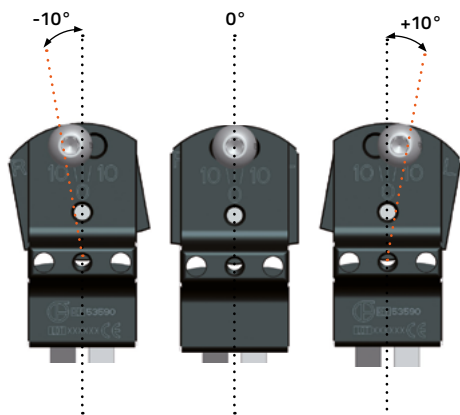


- The hinge mechanism permits a similar range of knee motion to that of the Anterior and Posterior Cruciate Ligaments, from 0° to 90° in the sagittal plane
- Facility for limiting range of motion (locking screw A)
- Passive R.O.M. possible with additional use of compression-distraction unit.

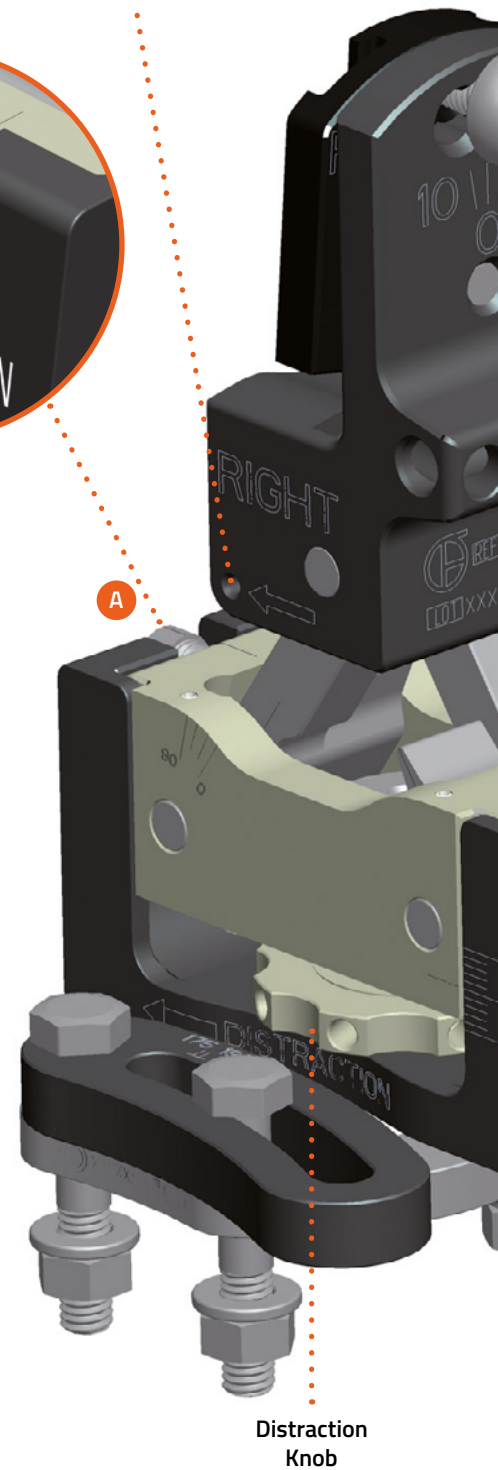
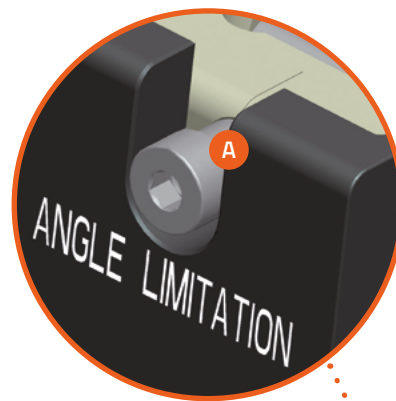


Femoral alignment of the rotation axis:

- Radiolucent central body
- The proximal part of the Knee Hinge is able to swivel
- $\pm 10^\circ$ in the frontal plane to allow for positioning of the rail parallel to the femoral anatomical axis

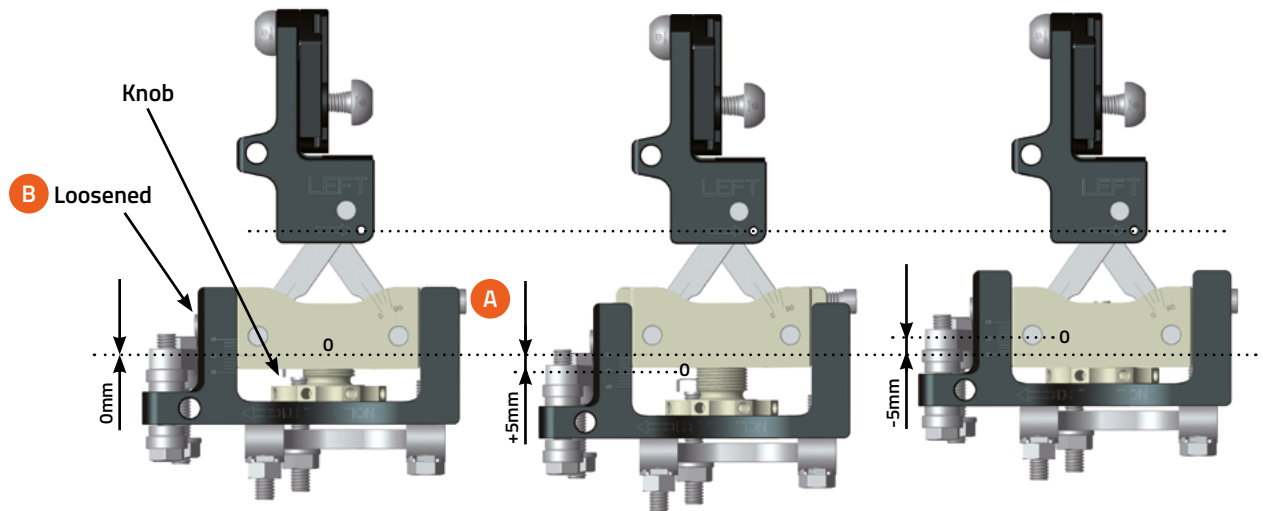


- 2mm hole to allow insertion of the reference axis wire



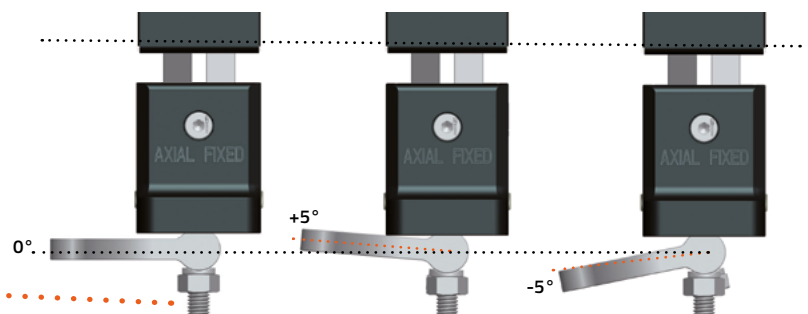
Knee Distraction

- $\pm 5\text{mm}$ tibial axial distraction-compression is possible from the tibial side by turning the distraction knob with locking screw B loosened

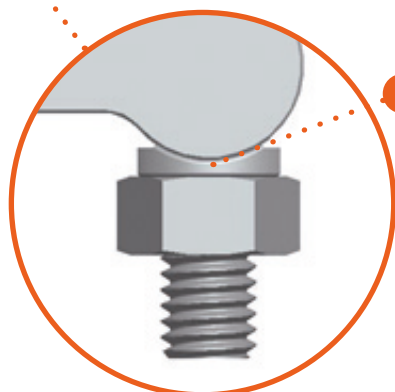


Tibial Alignment

- The Ring Support with the 5-hole plate allows the Knee Hinge to be correctly aligned to the tibial ring



C Conical Washer

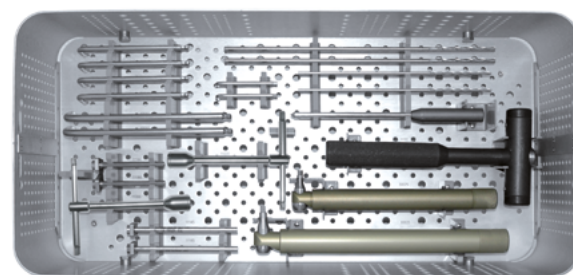
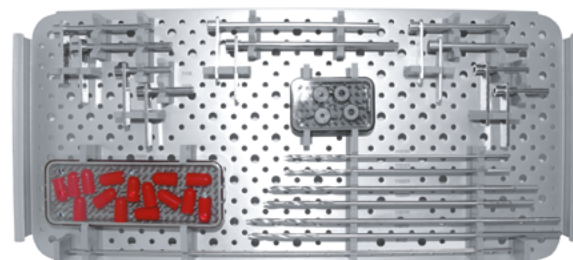
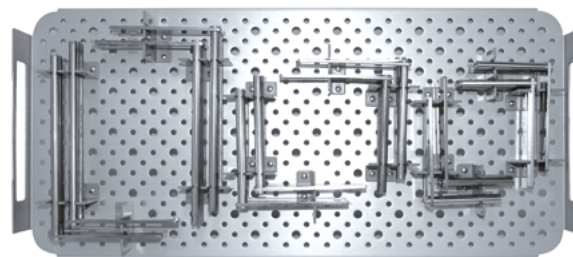


EQUIPMENT REQUIRED

53995 - ADV LRS Instruments Steri-Box Empty

can accommodate:

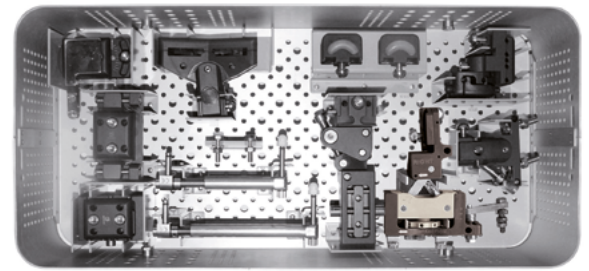
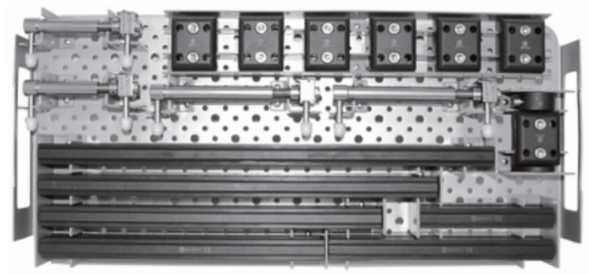
Part #	Component Description	Qty
Upper tray		
11102	Screw Guide, L 60mm	10
11103	Screw Guide, L 100mm	10
11124	Screw Guide, L 160mm	10
Central tray		
11104	Drill Guide, Ø 4.8mm, L 40mm	2
11105	Drill Guide, Ø 4.8mm, L 80mm	2
11106	Drill Guide, Ø 3.2mm, L 40mm	2
11116	Drill Guide, Ø 3.2mm, L 80mm	2
11125	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 tray		
10012	Allen Wrench 3mm	2
10017	Allen Wrench 6mm	2
10025	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
Components 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



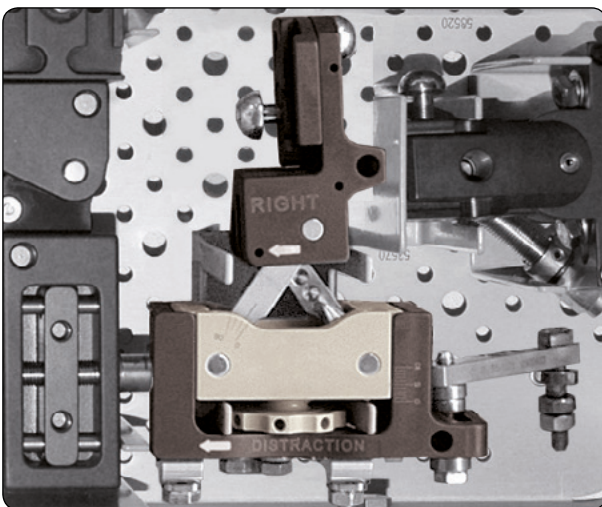
53990 - ADV LRS Components Steri-Box Empty A

can accommodate:

Part #	Component Description	Qty
Upper tray		
53530	ADV Straight Clamp	6
53560R or 53560	ADV Radiolucent LRS rail 400mm or ADV LRS rail 400mm	1
53555R or 53555	ADV Radiolucent LRS rail 350mm or ADV LRS rail 350mm	1
53550R or 53550	ADV Radiolucent LRS rail 300mm or ADV LRS rail 300mm	1
53549R or 53549	ADV Radiolucent LRS rail 250mm or ADV LRS rail 250mm	1
53545R or 53545	ADV Radiolucent LRS rail 200mm or ADV LRS rail 200mm	1
53544R or 53544	ADV Radiolucent LRS rail 120mm or ADV LRS rail 120mm	1
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

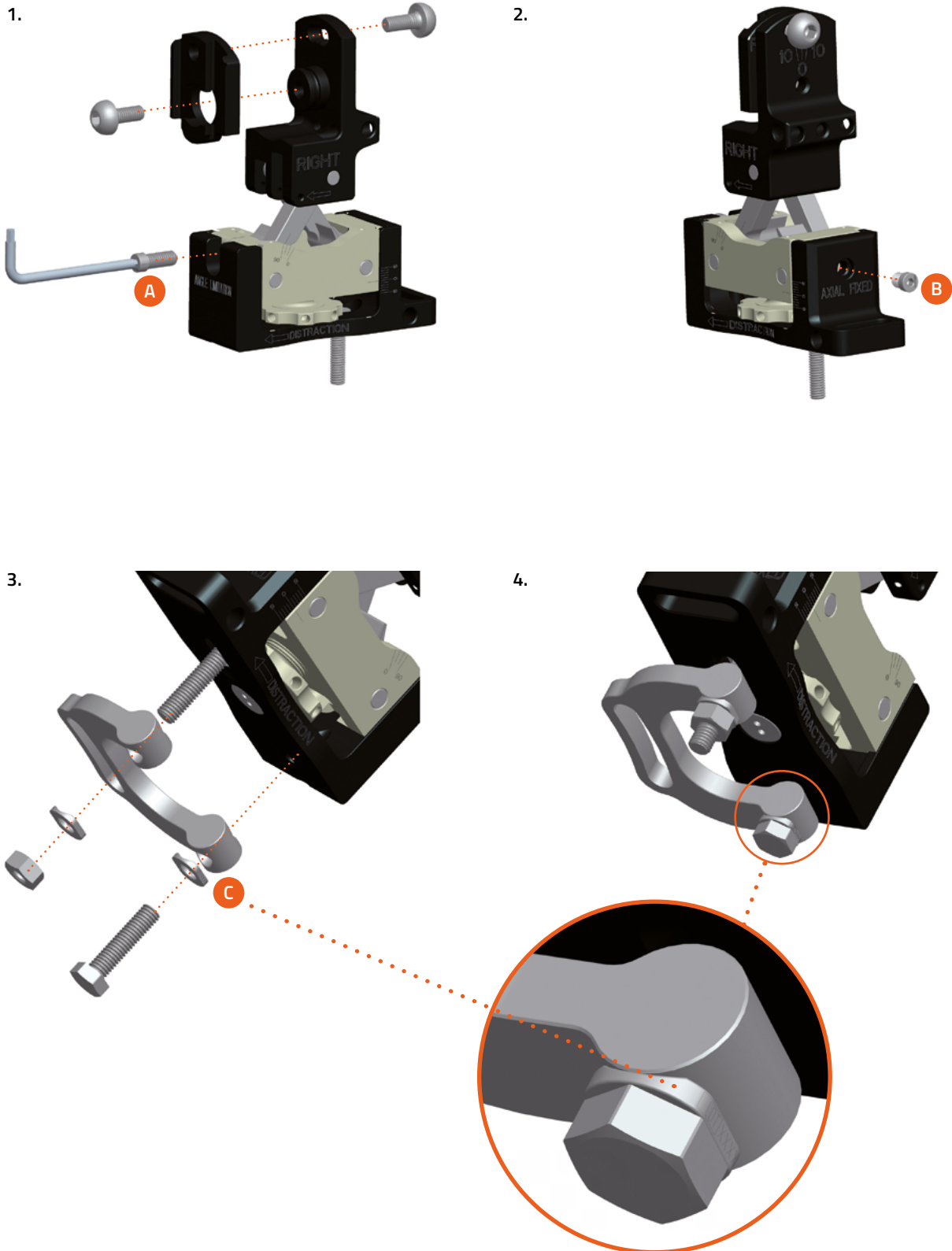


To be positioned in the steri-box, the Knee Hinge must be assembled as shown below.

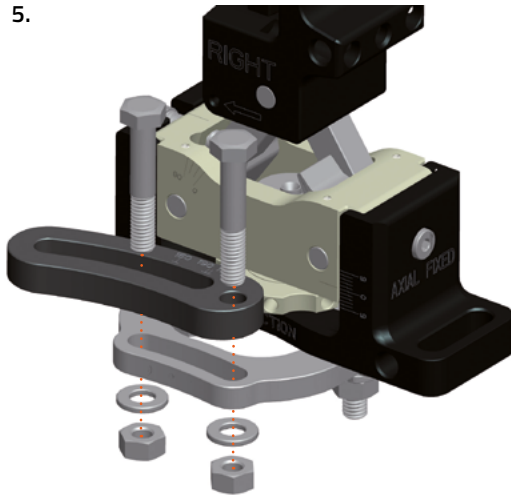


KNEE HINGE ASSEMBLY

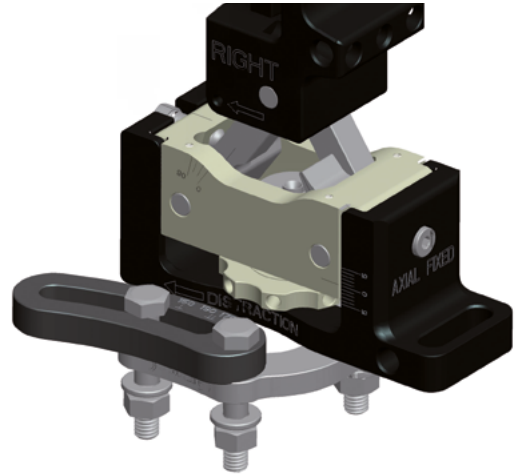
In case the Knee Hinge has been dismantled, please attend to the following instructions for reassembly.



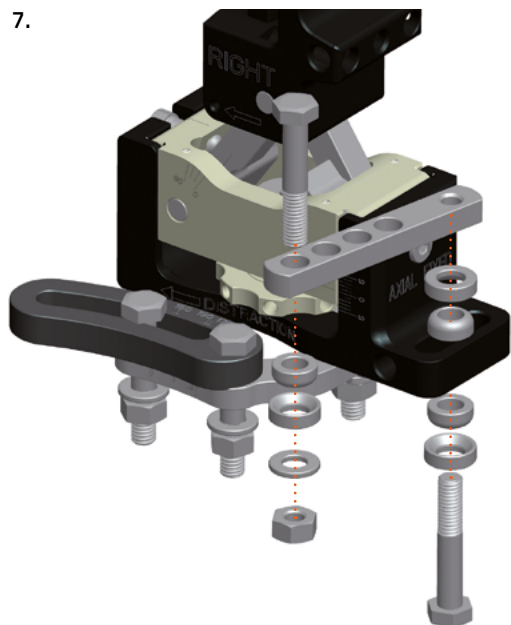
5.



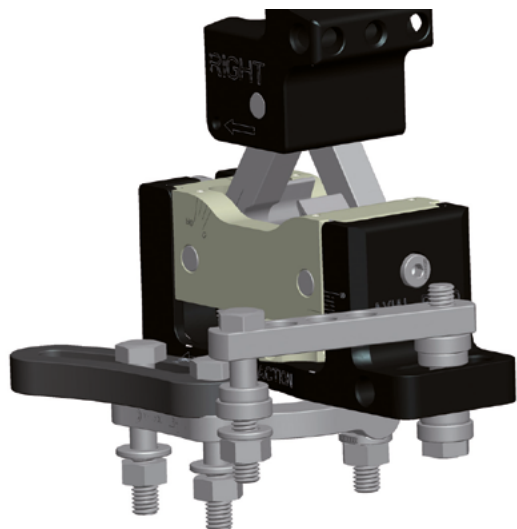
6.



7.



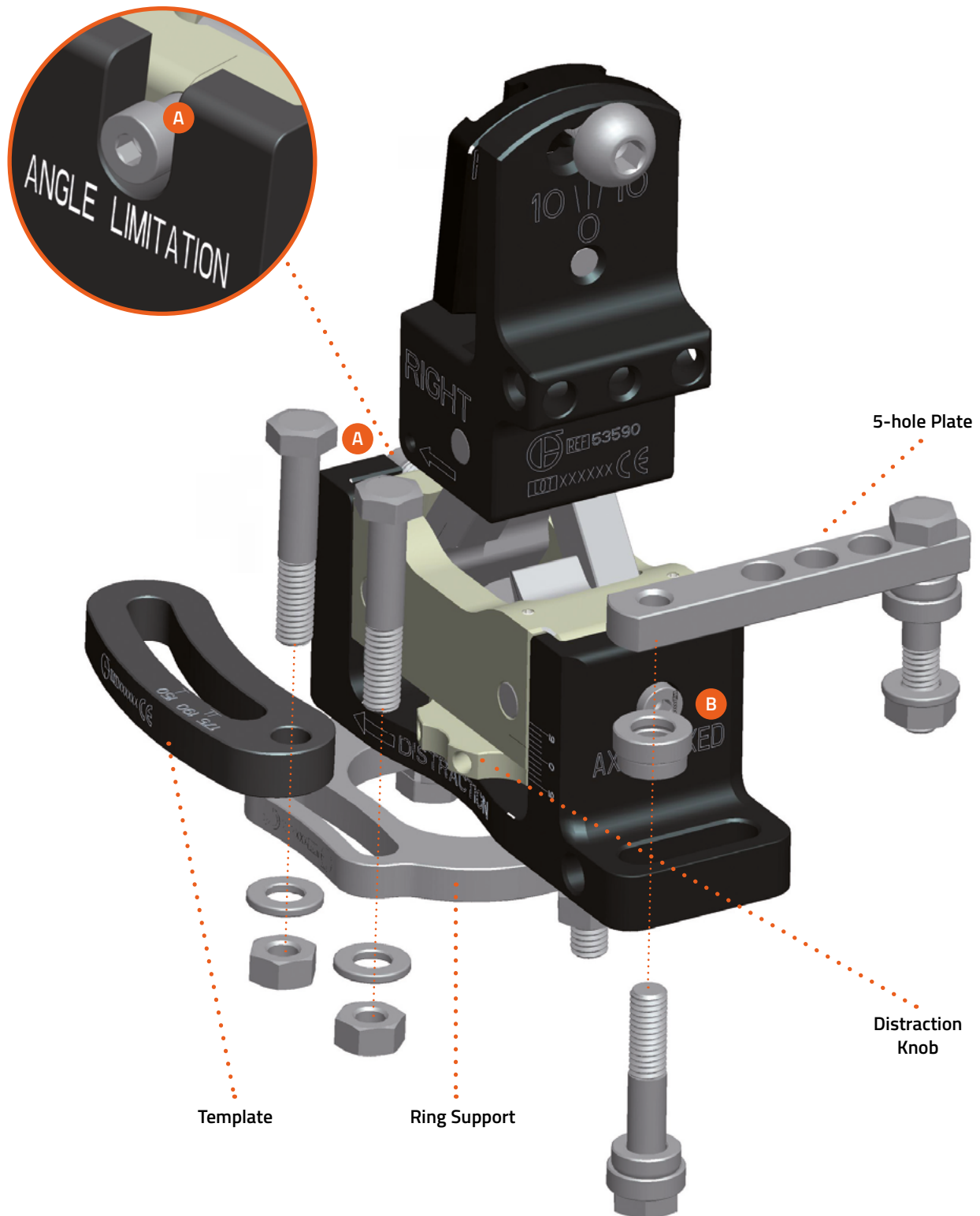
8.



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).

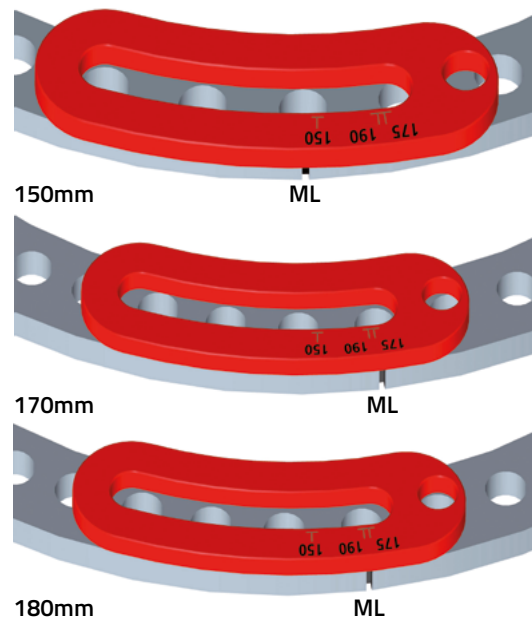


2. Template Positioning

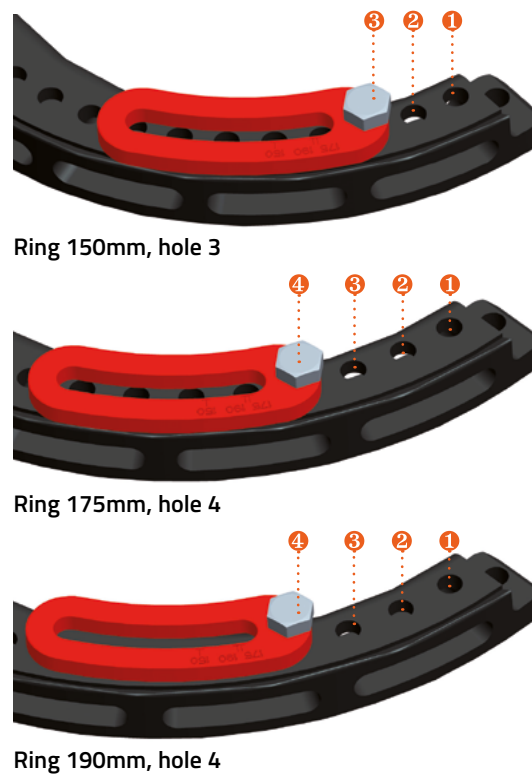
The template is designed to be used with 150, 175 (170mm TrueLok™ Ring), 190mm diameter rings. The markings on the template help the surgeon to position it correctly onto the ring:

- 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.

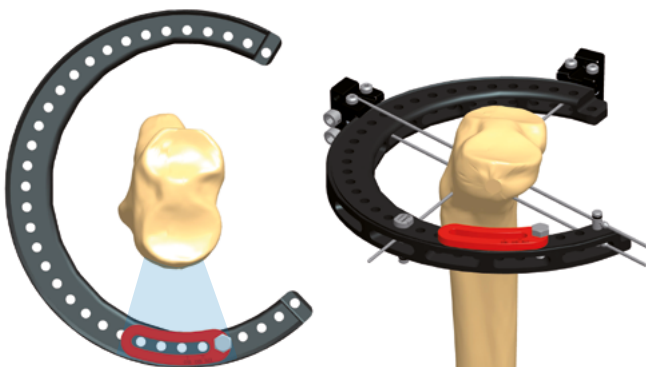
TrueLok™ Rings:



Sheffield Rings:



The template ensures that bone screws or wires are not inserted in the area where the Knee Hinge is positioned.

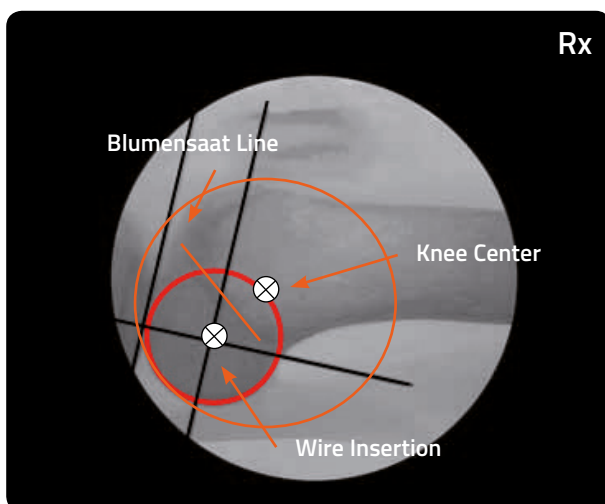
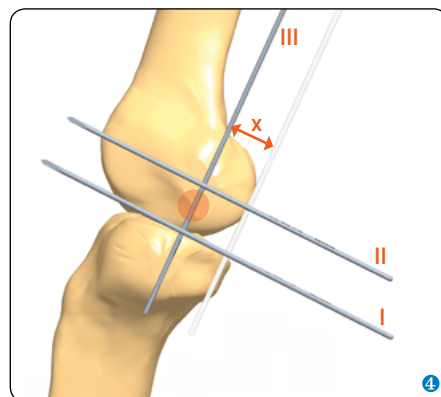
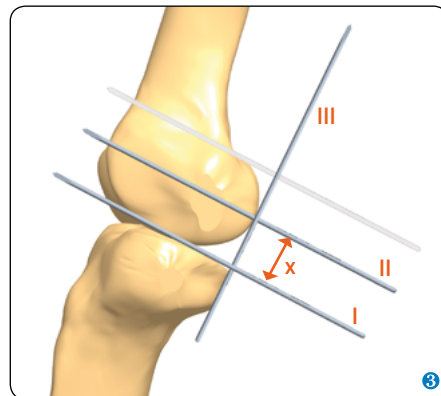
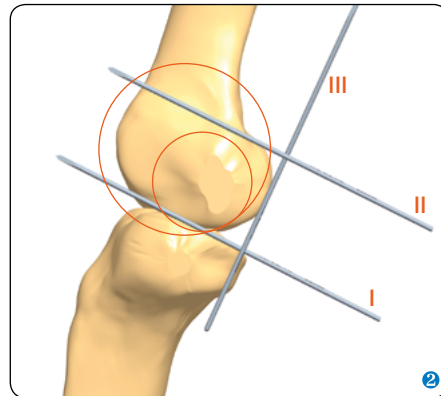
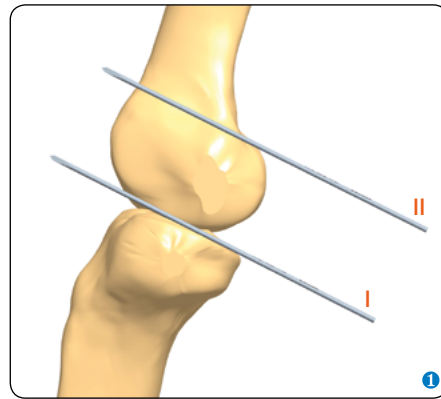


In the pictures, the red color of the template is only for demonstration purposes. The actual component is grey, as all the other metal components.

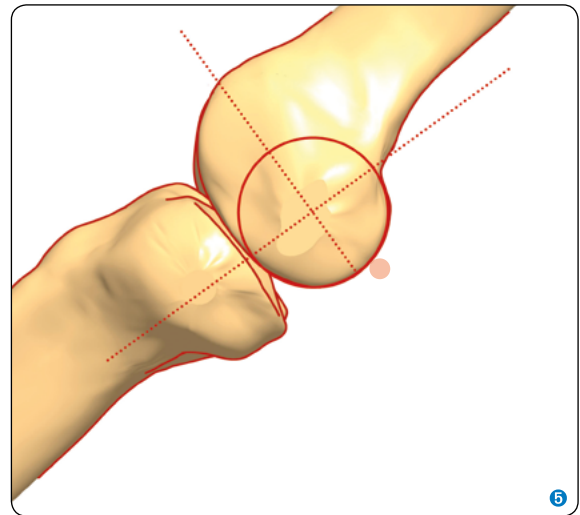
3. Reference Wire Placement

- ❶ 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.
- ❷ A third (III) wire is placed at right angles, at the level of the posterior part of the femoral condyles.
- ❸ Move the proximal parallel wire (II) down to the center of the condyles. Measure the distance "X" between the parallel wires.
- ❹ Move the posterior wire (III) anteriorly of a distance equal to "X".

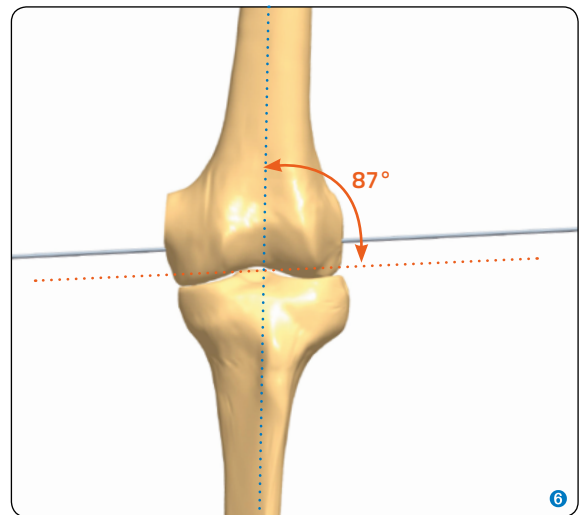
The point where wires two (II) and three (III) meet will be the reference axis of the Knee Hinge (Rx image).



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



- 6 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.

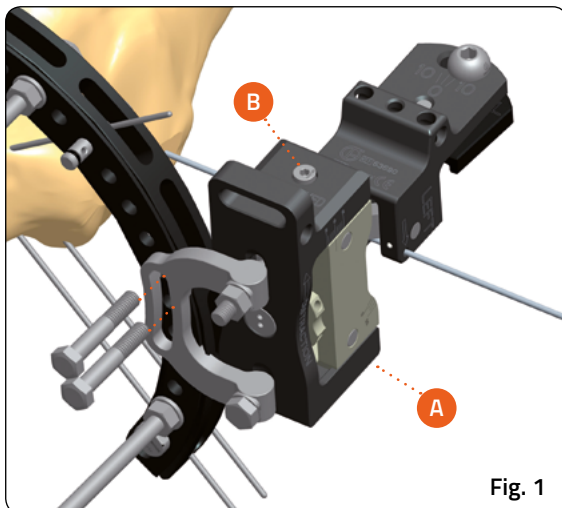
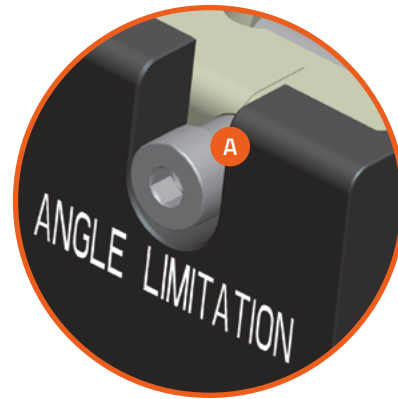


Fig. 1

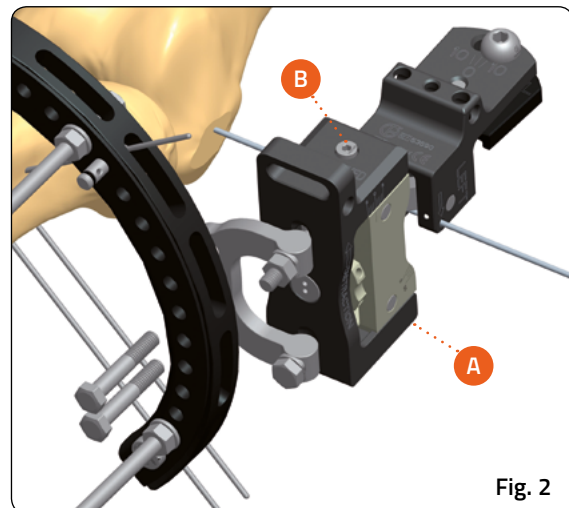


Fig. 2

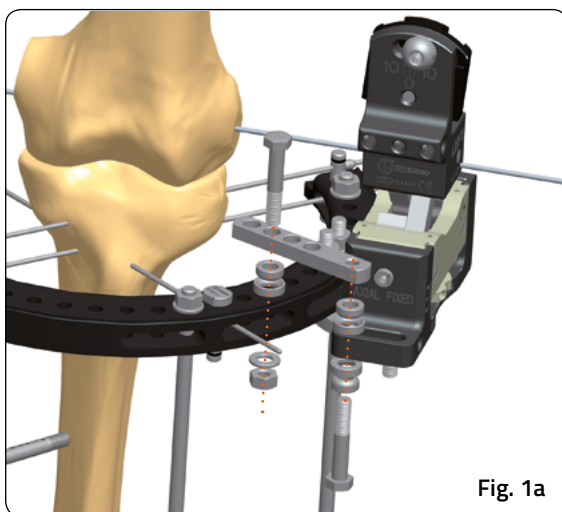


Fig. 1a

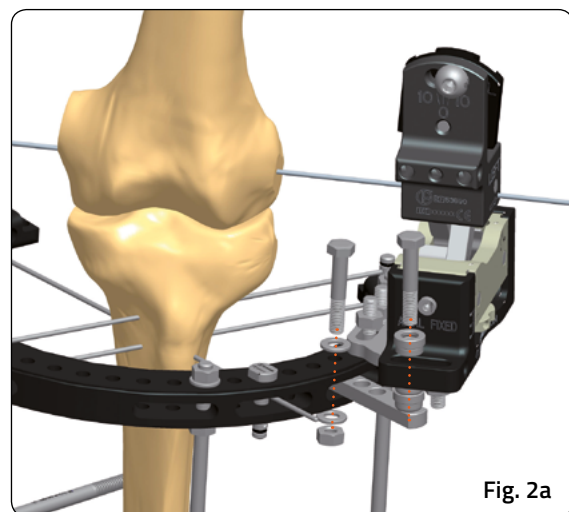


Fig. 2a

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).

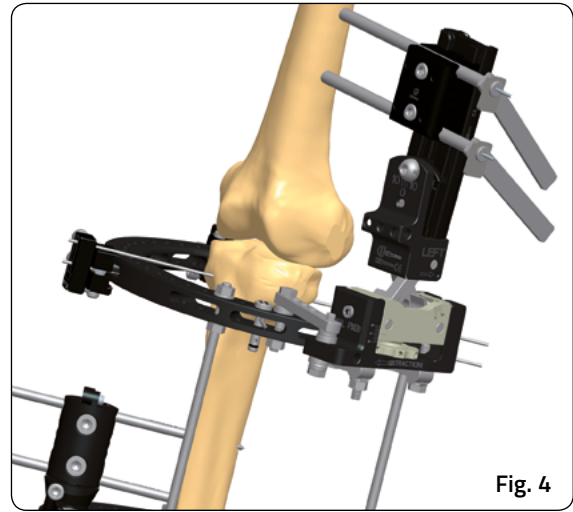


Fig. 4

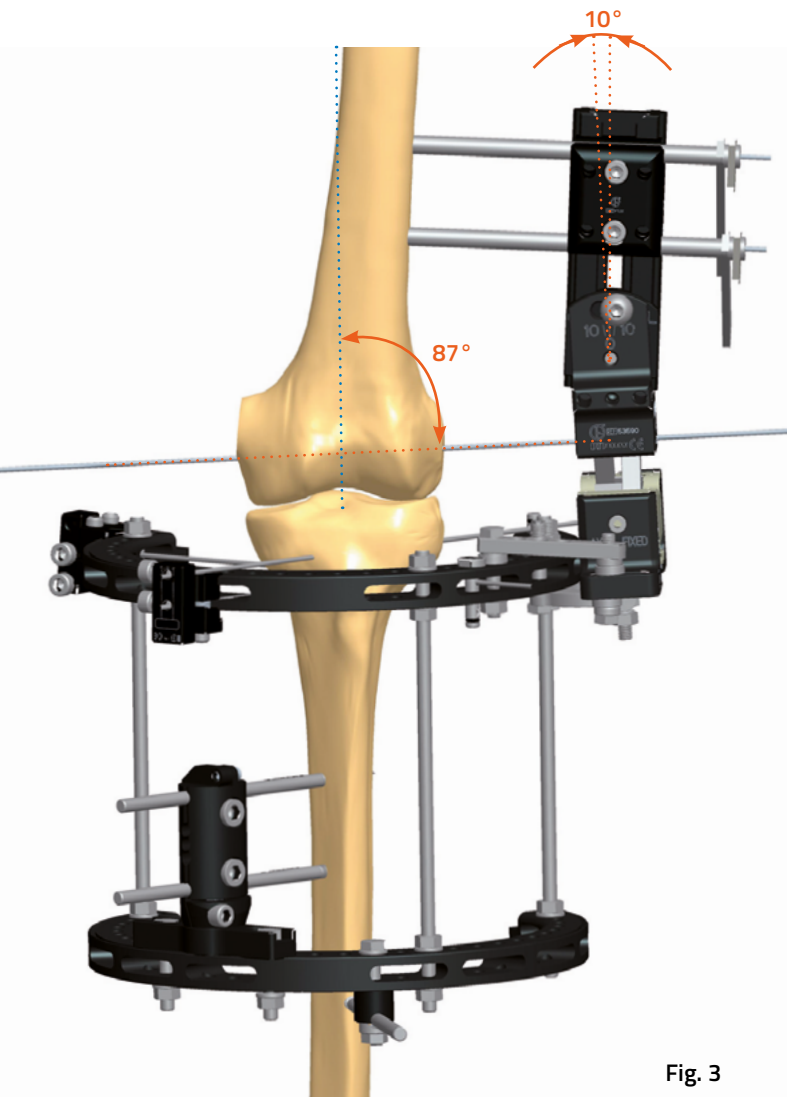


Fig. 3

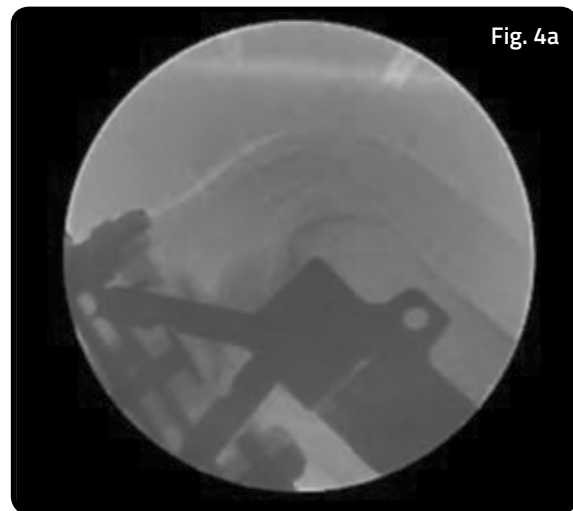


Fig. 4a

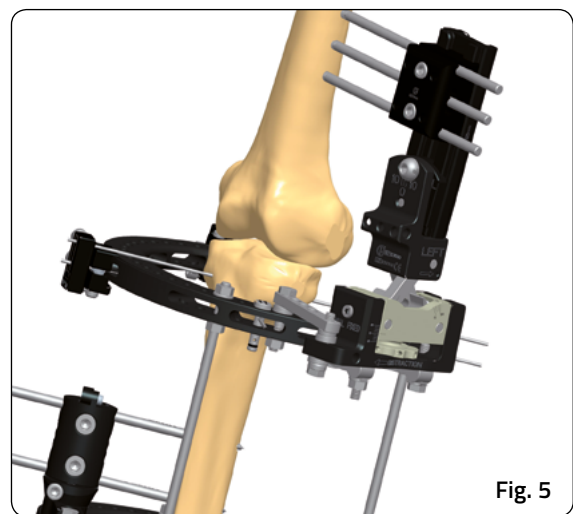


Fig. 5

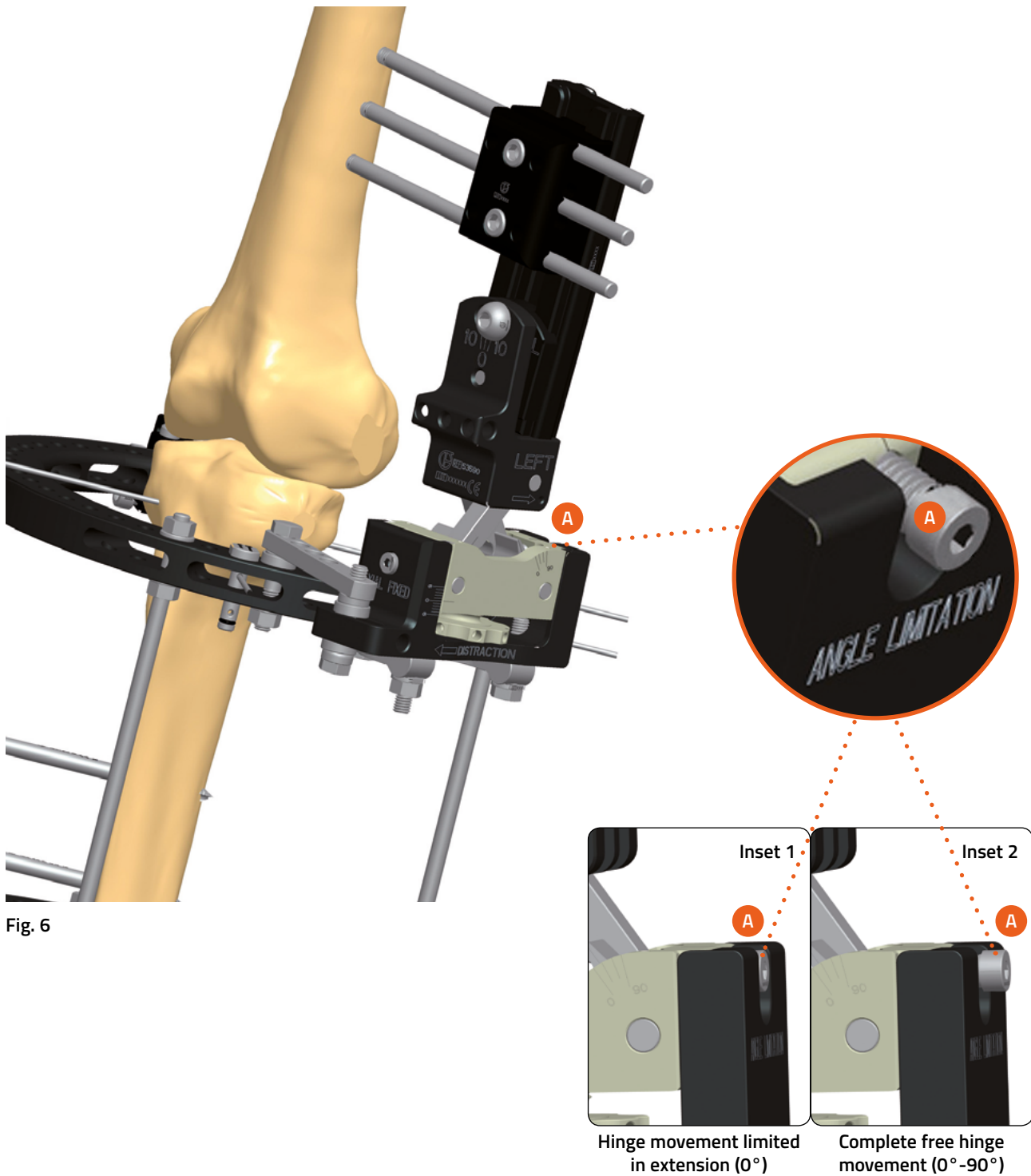
4d. R.O.M. Check

If necessary, distract the knee joint by turning the distraction knob.

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.

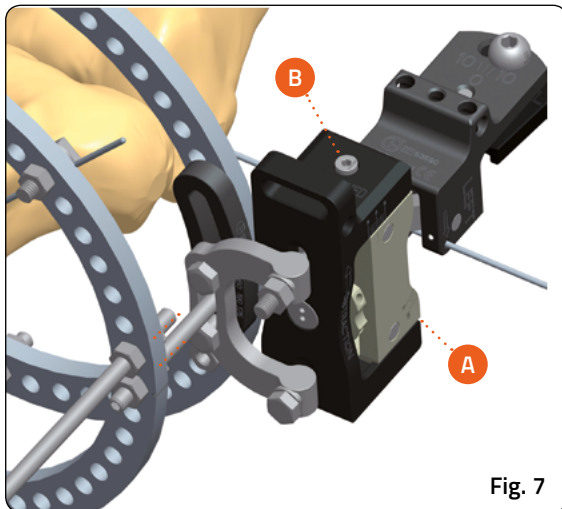
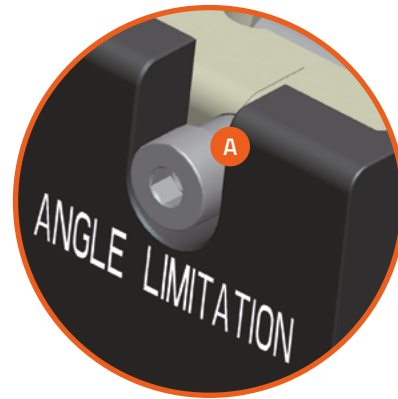


Fig. 7

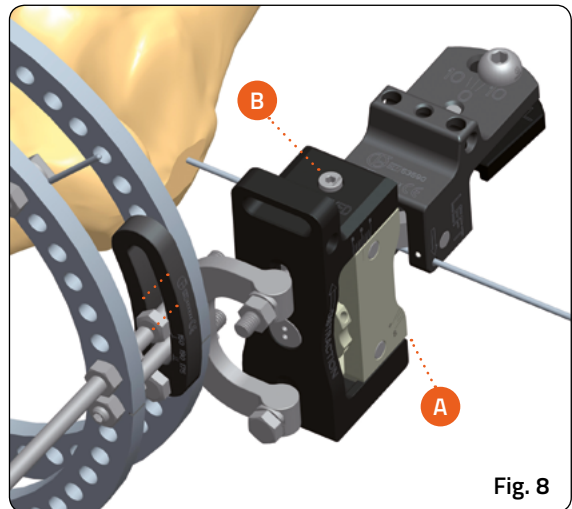


Fig. 8

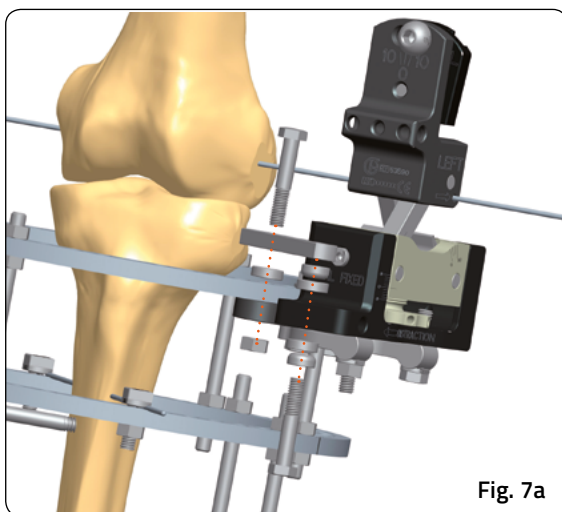


Fig. 7a

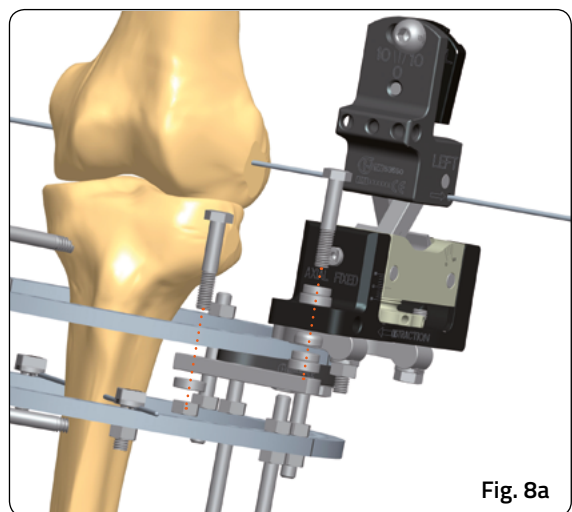


Fig. 8a

- For insertion of Femoral Screws (see page 13).
- 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.

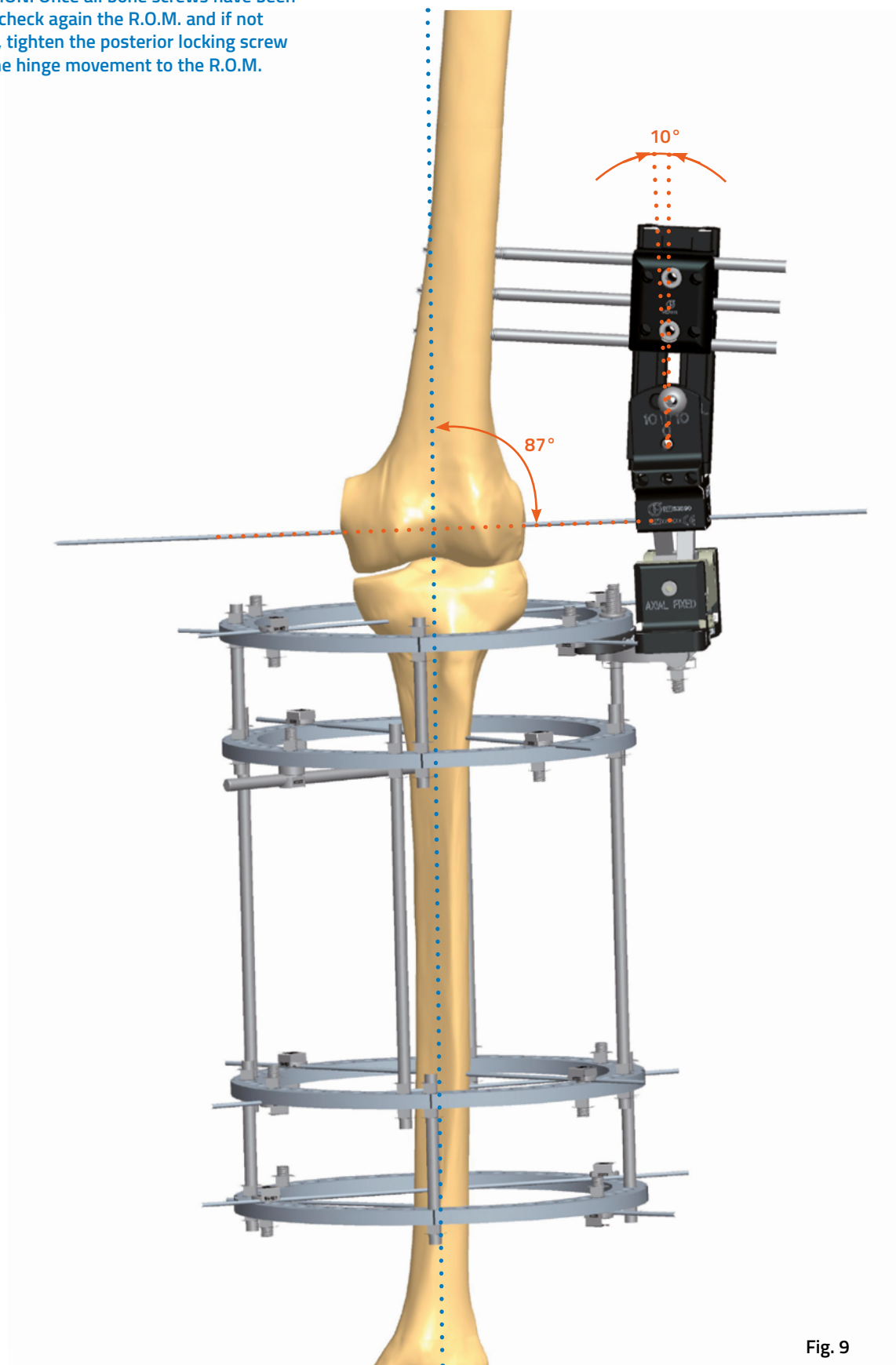


Fig. 9

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.

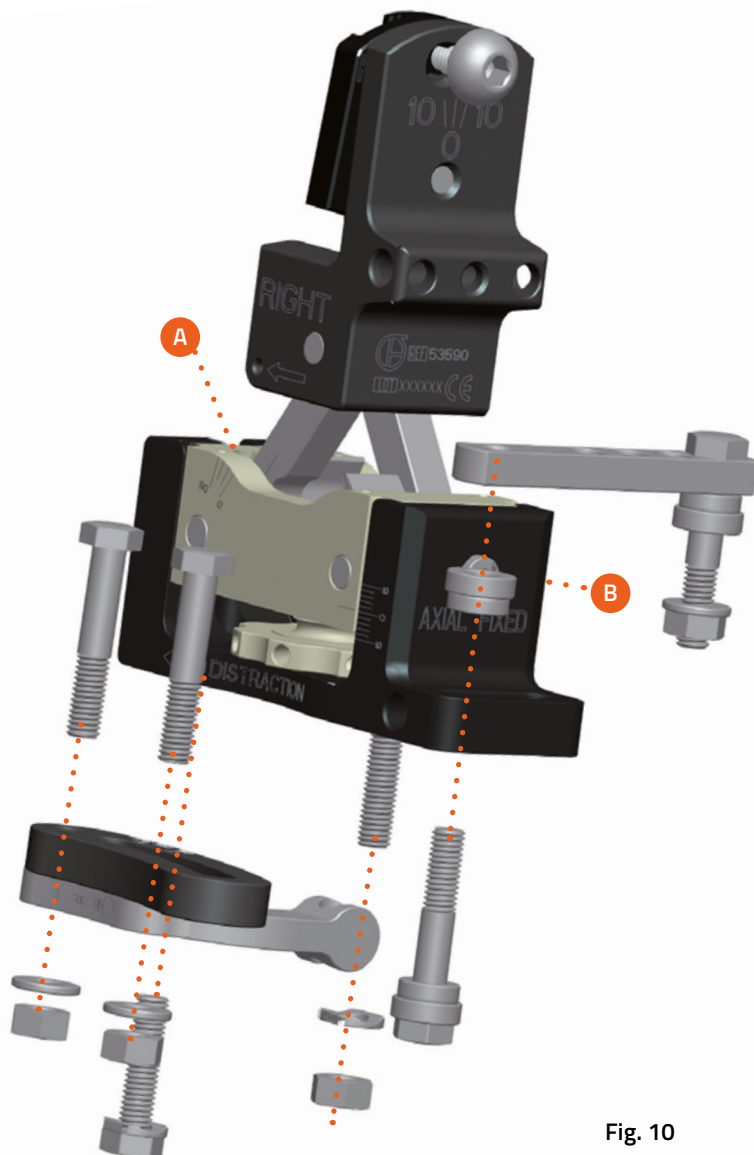
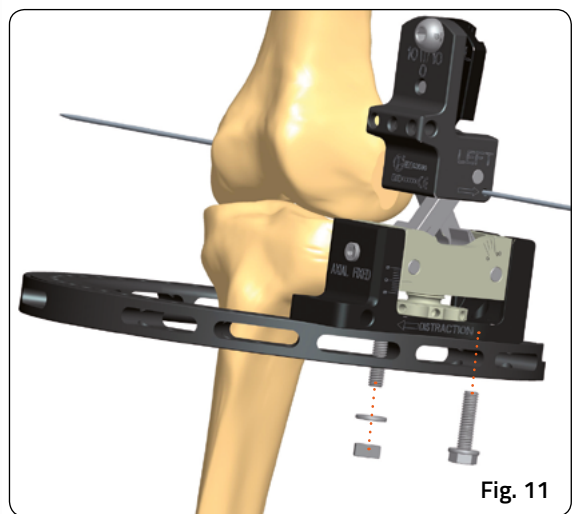
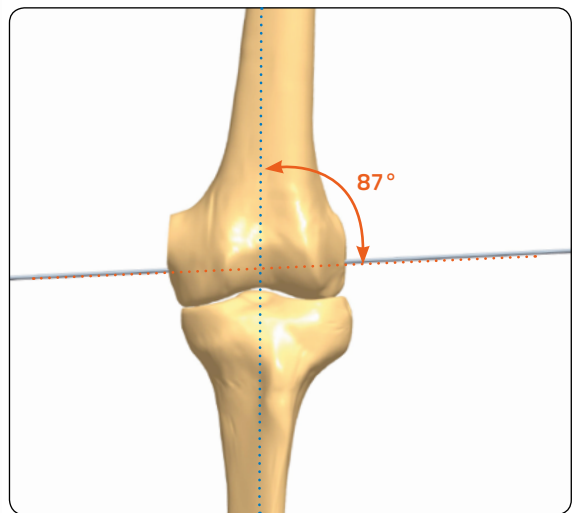
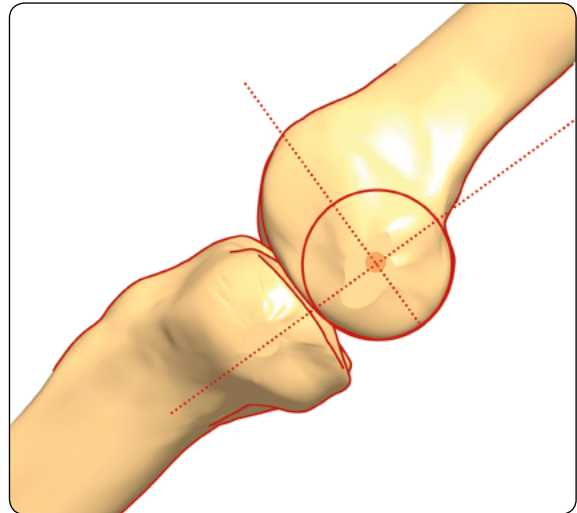


Fig. 10

Fig. 11

- 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.

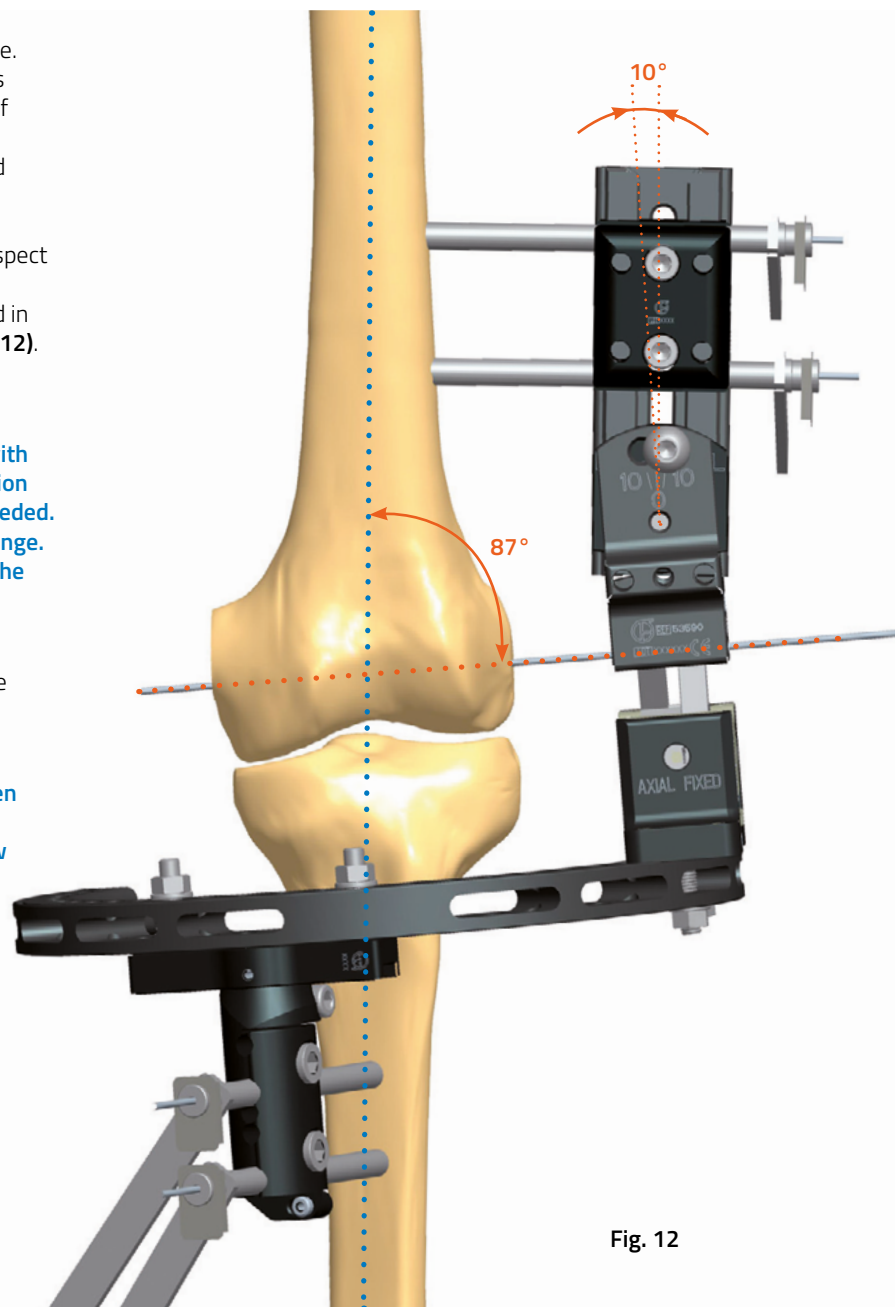


Fig. 12

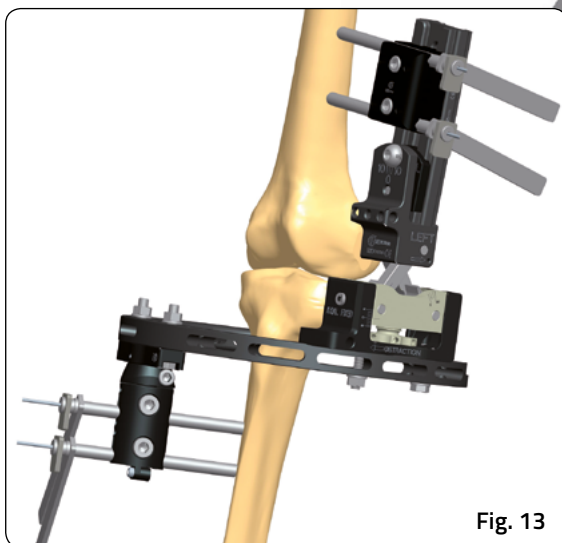


Fig. 13

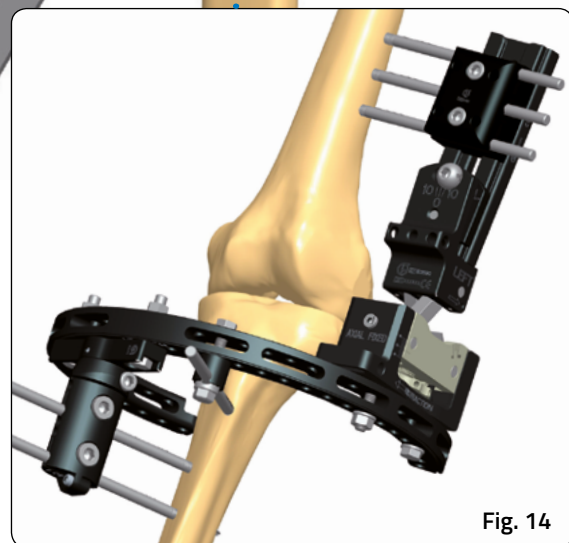
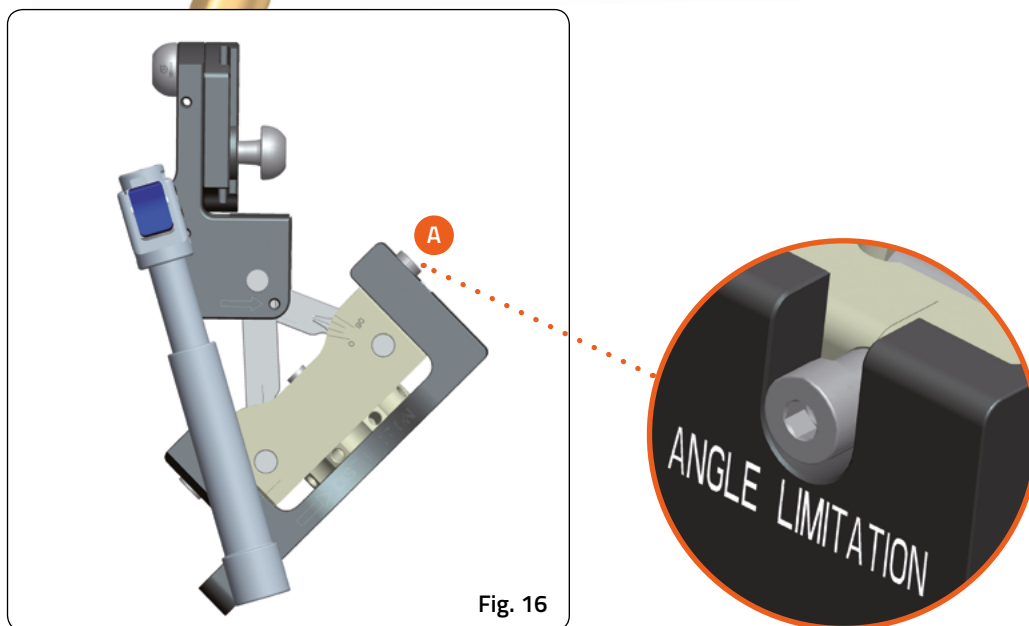
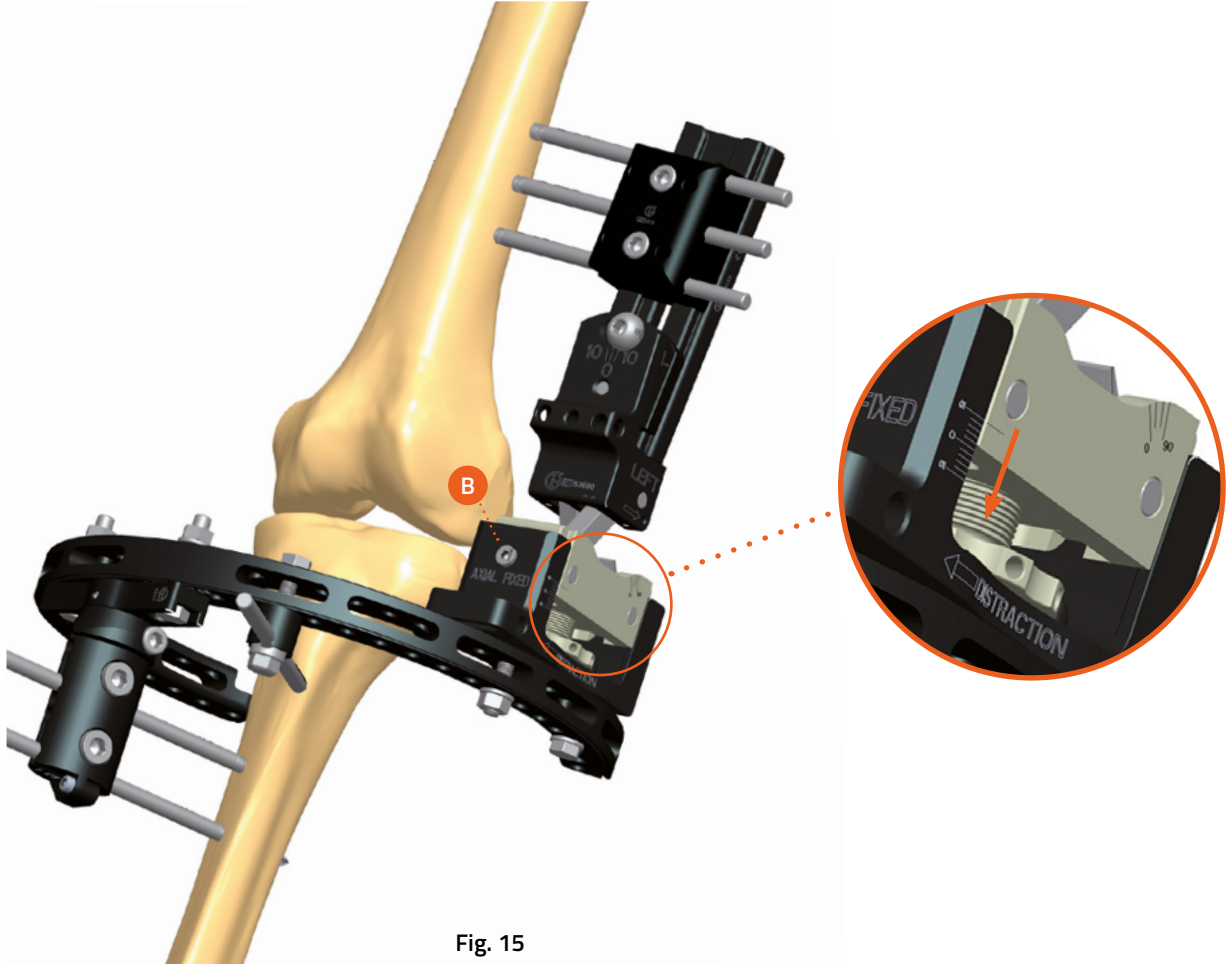


Fig. 14

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.

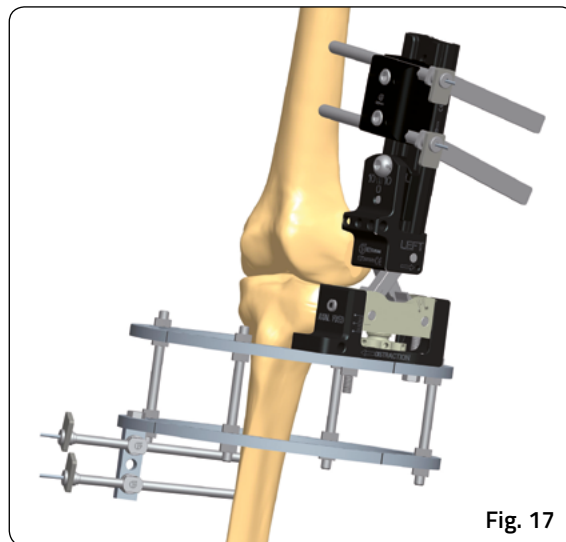


Fig. 17

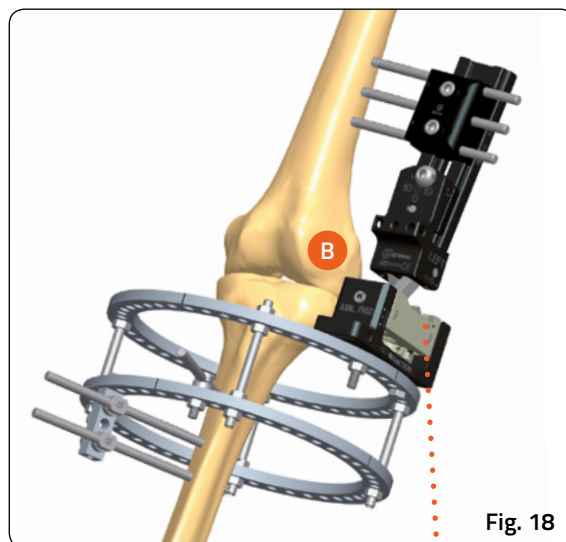
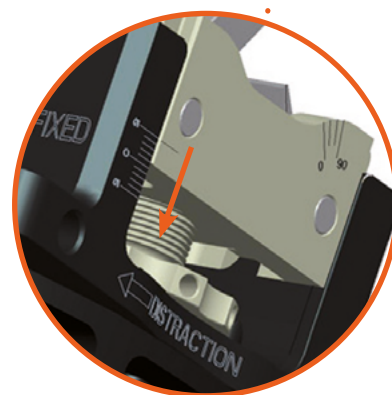


Fig. 18



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

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

Electronic Instructions for use - Minimum requirements for consultation:

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

Free paper copy can be requested from customer service (delivery within 7 days):

tel: +39 045 6719301, fax: +39 045 6719370

e-mail: customerservice@orthofix.it

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience.



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

Rx Only

CE 0123

Distributed by:

