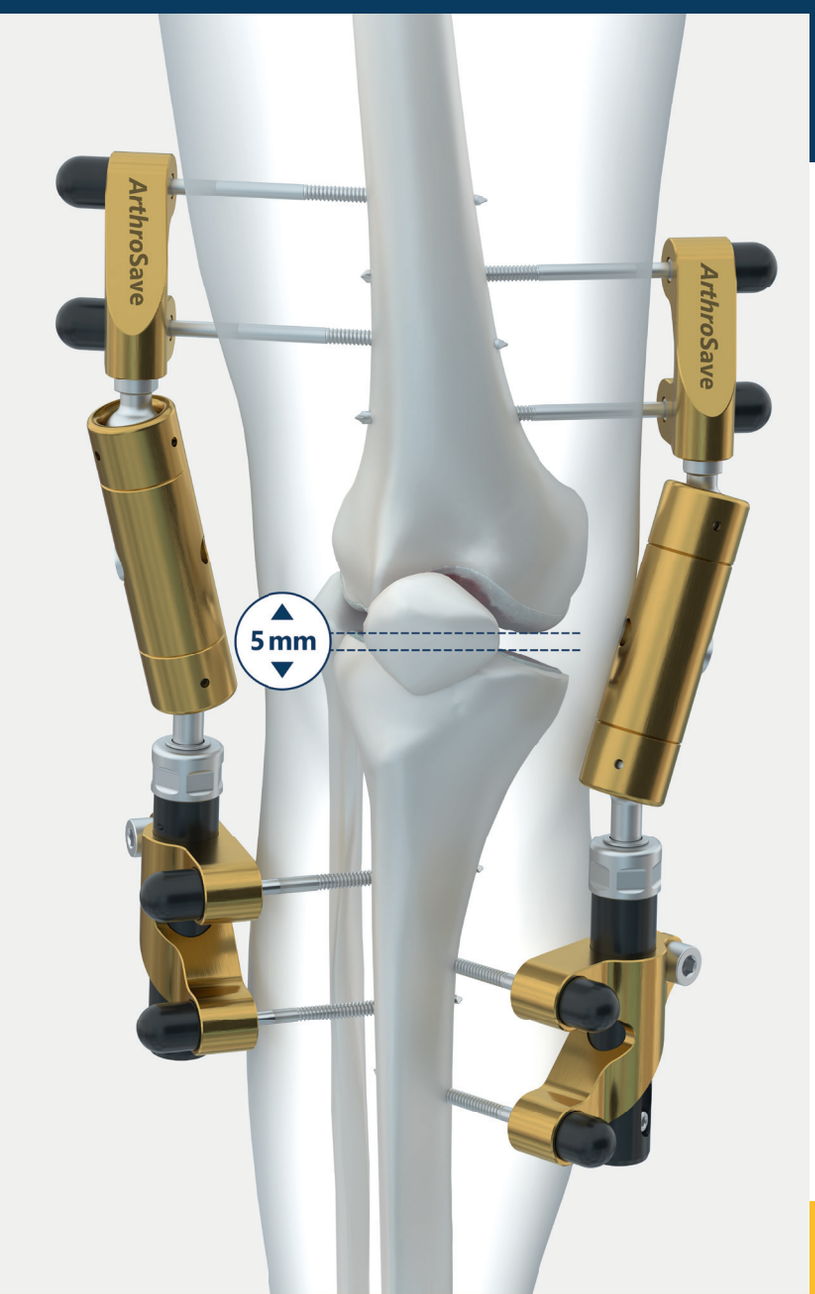
Surgical technique

ArthroSave's KneeReviver



This protocol provides recommended procedures as a guidance. One must consider the particular needs of each patient and make appropriate adjustments when and as required for each individual patient.

ArthroSave
joint reviving medical treatment

Please report mistakes or options for improvements at info@arthrosave.com

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1. Introduction

The *Arthro*Save KneeReviver is a knee joint distraction device, intended for use in surgical treatment of a persisting painful knee osteoarthritis resistant to conservative treatment. The *Arthro*Save KneeReviver is designed to distract the osteoarthritic knee joint, which results in clinically relevant pain relief, improved functioning, delaying the need for a knee prosthesis and which also may result in tissue repair. The distraction of the joint is achieved by fixation of an external frame to the femur and tibia, and extension of the fixational elements. The frame extension can unload the painful osteoarthritic knee joint by creating an extra joint space width of 5 mm (+ max 2 mm) for 6 weeks (+ max 5 days) with maintenance of the natural intra articular fluid pressure changes during loading and unloading of the joint (resulting from an axial displacement of max 3 mm). These joint fluid pressure changes are considered vital for joint homeostasis. Patients are encouraged to walk full weight bearing as tolerated, with aids (e.g., crutches) if needed, to load and unload the joint axially, but without overloading (pain determines the amount of weight bearing) the joint or device.

A separate manual for care of the device and pin tracts during the distraction period, for patients and nurses is provided (Patient information, Patient instructions and Care protocol)

In all case, the severity of pain determines the amount of (partial) weight bearing of the distracted joint (using crutches).

CONTACT SURGEON
In case of any doubt about the condition of the knee, device, and/or pin tracts, and in case of unanticipated severe pain, the patient must always inform the treating orthopaedic surgeon.

2. Indications for use

- Significant persistent primarily femoral-tibial pain resistant to previous adequate conservative treatment
- Radiological signs of primarily femoral-tibial cartilage loss (joint space narrowing); Kellgren & Lawrence grade 2-4
- Indication for a hemi- or total knee arthroplasty or femoral/tibial osteotomy

3. Contra indications

- Age > 65 years
- Pain predominant due to patellofemoral osteoarthritis
- History of a septic arthritis of the knee
- Severe malalignment (varus or valgus > 10 degrees)
- Bone abnormalities, such as severe osteopenia or osteoporosis which may hamper proper pin fixation
- Psychological inabilities to cope with the external fixator
- Unable to personally provide adequate pin tract wound care
- Lack of a social network for support during the treatment period
- Non-cooperative patients
- Presence of artificial implants or expected need within 6 months
- Kneeflexion contracture of more than 15 degrees
- Vascular and/or soft-tissue abnormalities
- BMI >35 kg/m2 or weight >120 kg
- Increased risk for thrombosis or pulmonary embolism (e.g., in familiar history)

4. Warnings and precautions

POTENTIAL ADVERSE EFFECTS

Potential adverse effects are:

General surgical / procedure-related

- Wound related complications
- General infection / pin tract infections [1]
- Osteomyelitis
- Cardiovascular related complications (e.g., bleeding, deep venous thrombosis (DVT [2,3])
- Pulmonary related complications (e.g. pulmonary embolus[2, 3])
- Neurological complications (e.g. peroneal nerve injury)
- Compartment syndrome
- Need for reoperation / revision

Device-related

- Device failure (e.g., distractor failure, pin breakage)
- ROM limitations (e.g. joint stiffness)

NON STERILE

The *Arthro*Save KneeReviver and KneeReviverToolbox are offered being not sterile and must therefore be cleaned and sterilized prior to use. Disinfection and sterilization specifications can be found in the IFU.

USE HALF-PIN GUIDING SLEEVE

The half-pins should always be inserted through the half-pin sleeves under x-ray control to minimize risk of direct damage to soft tissues and neurovascular structures.

EXPERIENCED SURGEON

In case of lacking experience with the drilling of half-pins into the femoral and /or tibial bone and placement of external fixators, the orthopaedic surgeon is advised to attend at least two KneeReviver procedures to be performed by an experienced colleague before doing such procedure independently.

In all cases, at least two procedures should be supported by an *Arthro*Save competent product specialist - experienced with this knee distraction procedure - prior to performing the procedure independently, to avoid unnecessary complications.

[1] The patient should check the pinholes daily. At the first signs of an infection the use of antibiotics is recommended. See separate manuals: Patient information, Patient instructions and Care protocol.

[2] The use of anticoagulant during the entire distraction period (+1 week) is a prerequisite to minimize the risk on deep venous thrombosis and pulmonary embolism. See separate manuals: Patient instructions and Care protocol.

[3] Physical activity (regularly tightening of the muscles of the upper leg by actively lifting the leg without using the hands, while flexing the foot) during distraction is strongly recommended to minimize the risk on deep venous thrombosis and pulmonary embolism. See separate manuals: Patient information and Care protocol.

5. Composition of sterile sets

Before starting surgery, check the composition of the trays and if parts are missing (or not functional) take a completely new tray and return the tray with missing or non-functional parts.

Please refer to the IFU for a full overview of the set compositions.

6. Composition of additional sets

General orthopaedic surgical set is needed, not provided by *Arthro*Save and is at least including:

- Surgical knife handles, with knife blades number 11 and 15
- Pair of blunt scissors
- Half-pin drill (electric or pneumatic) enabling drilling of the half-pins
- Suture material
- Electrocautery

Additional sterile prerequisites not provided by *Arthro*Save:

- K-wires
- Skin marker
- C-arm and radio translucent operating table

Unsterile materials not provided by *Arthro*Save:

- Pin cutter

Unsterile removal tools:

- Spanner (m10) for removal of distractor
- Allen key (#6) for removal of distractor

Unsterile patient materials to be kept by patient:

- 10 half-pin protective pin-caps, see Figure 1 Patient half-pin protective pin-capsFigure 1
- Distraction spanner, see Figure 2

Figure 1 Patient half-pin protective pin-caps

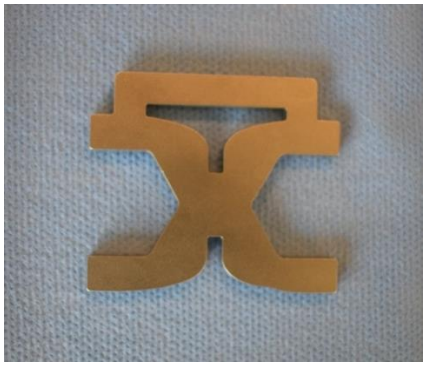


Figure 2 Patient distraction spanner

7. Assembly of *Arthro*Save's KneeReviver

Start with the assembly of the distractors:

- Assemble the Tibial block left (AS3) to the black distraction tube of the Distractor left (AS1). The screw-threaded openings with recess are directed towards the surgeon and the Tibial block is positioned above the Distractor. See Figure 3.
- Assemble the Tibial block right (AS4) to the black distraction tube Distractor right (AS2). The screw-threaded openings with recess are directed towards the surgeon and the Tibial block is positioned above the Distractor. See Figure 3.

Note: Check if the assembly has been done correctly. Figure 4 shows the incorrect assemblies.

Figure 3 Assembly of the KneeReviver

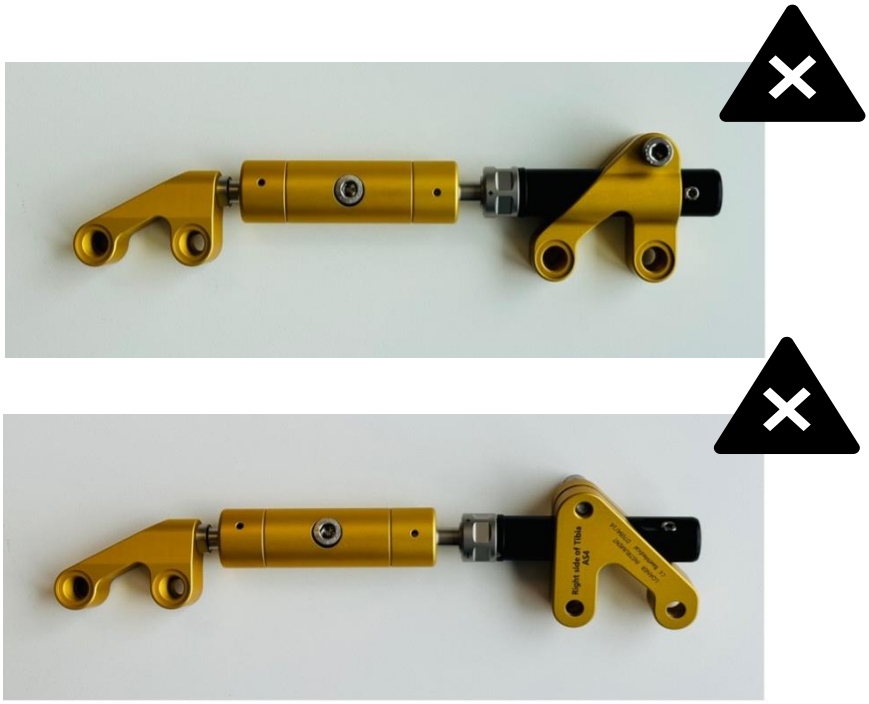


Figure 4 Incorrect assembly of the KneeReviver

Checks

The metallic hex thumb screw should be into the zero position; no screw-thread should be visible above the hex thumb screw as depicted in Figure 5.

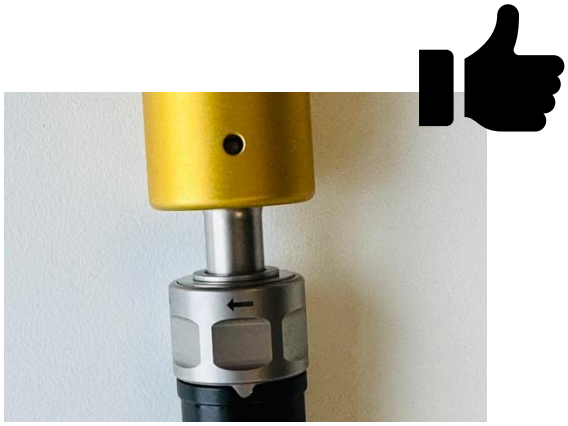


Figure 5 Correct position of the metallic hex thumb screw

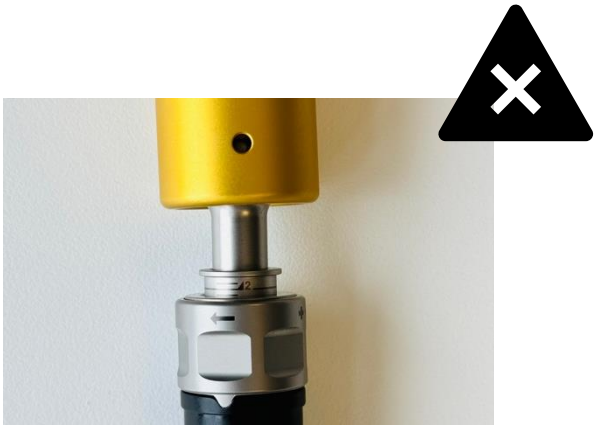


Figure 6 Incorrect position of the metallic hex thumb screw

The 10 Half-pin locking bolts (AS8) should have collets in place, see Figure 7. Note: the locking bolt consists of a push bolt and a collet.

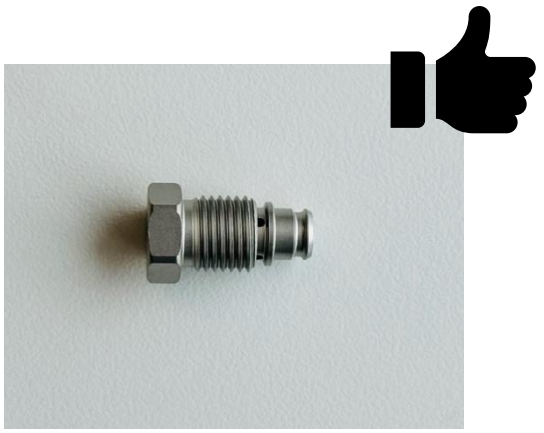


Figure 7 Correct assembly of the Half-pin locking bolts

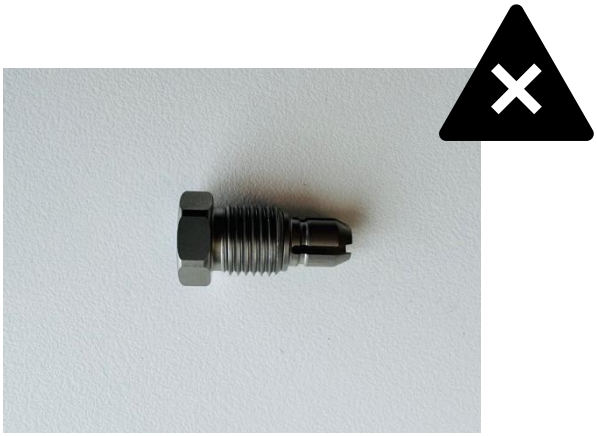


Figure 8 Incorrect assembly of the Half-pin locking bolt

Note: Do not detach collets from the bolts. Only in case this occurs (see Figure 8 then re-assemble according to Figure 7).

8. Patient preparation

MARK THE SURGICAL SIDE
Mark the correct knee before patient transfer to the operating room.

- Place the patient in the supine decubitus position on a radiolucent operating table.
- The affected limb must be placed into a neutral position permitting free access to lateral and medial side.
- Be sure the limb and knee remain in a neutral position (no rotation or flexion)
- Rotate the C-arm to ensure optimal anterior-posterior (AP) and lateral visualization of the entire femur and tibia.
- Note the amount of flexion in the hip joint and, if any, extension deficit of the affected knee joint.
- By using a K-wire or otherwise, and the C-arm, indicate and mark the joint space of the knee joint (Blue line in Figure 9).
- Indicate in the same way the preferred site of the medial distal femoral Half-pin just proximal to the distal femoral metaphysis with a skin-marker (Line 1 in Figure 9).

LOCATION PIN INSERTION
Avoid pin insertion distal of the superior pole of the patella, as being too closely to the synovial tissue of the joint to prevent penetration of the joint capsule (with chance of septic arthritis), damage to the neurovascular structures, and damage to the area for future arthroplasty.

- Draw the lines parallel to the joint space.
- The similar procedure should be done on the lateral proximal tibial Half-Pin. The proper location is just below the tibial tuberosity (Line 8 Figure 9).
- Standard procedures for skin disinfection and sterile draping should be applied.

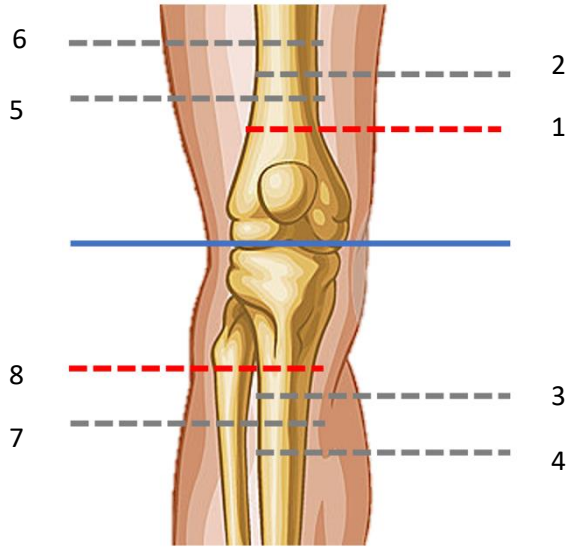


Figure 9 Knee markings; parallel to the joint space outside the synovial cavity

9. Summary of surgical procedure

The Half-pins are placed in the sequence starting with number 1 at the medial femur distal position and ending with number 8 at the lateral tibia proximal position.

Place the femur Half-pins parallel to the knee joint line in an approximately 10 degrees dorsomedial - ventrolateral direction, which is 10 degrees tilt/angulation to the frontal plane.

Place the tibial Half-pins parallel to the knee joint space, and if possible perpendicular to tibial bone axis and the antero-medial tibial face, which is approximately 35 degrees to the frontal plane.

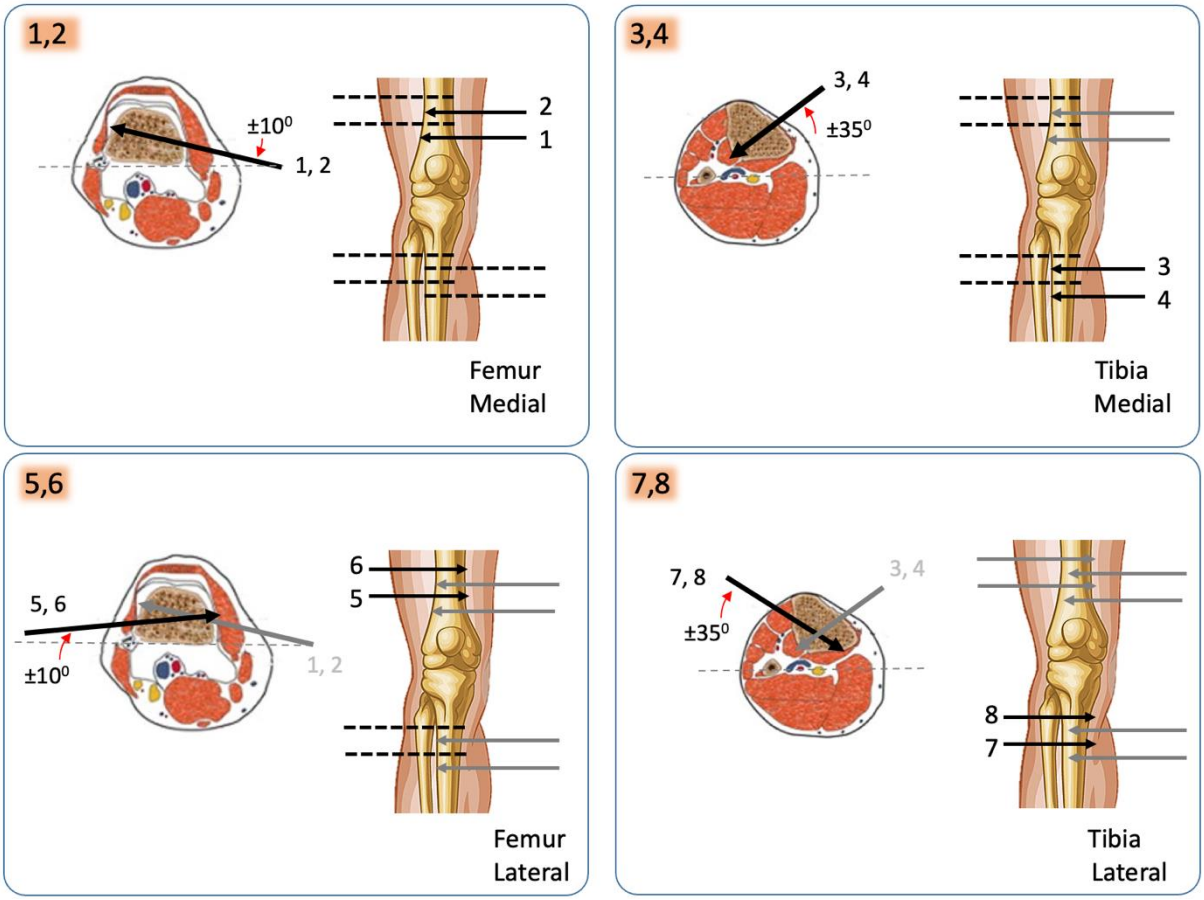


Figure 10 Summary in view

This figure can also be found at the last page Figure 53 ‘Summary in view’.

Each half-pin should be drilled at a sufficient depth through the second cortex, which can be confirmed on fluoroscopy. This means that most half-pins should be drilled with at least a full thread through the second cortex, as depicted in the figure below. An overview of all half-pins and their preferred drill depth is provided in the table below, including some remarks for specific half-pins given that these are drilled close to critical structures.

Pin	Location	Angle	Drill depth	Remarks
1	Femur, medial, distal	10°	Through second cortex	
2	Femur, medial, proximal	10°	Full thread through second cortex	
3	Tibia, medial, proximal	35°	Through second cortex	

4	Tibia, medial, distal	35°	Through second cortex	Careful with critical structures (nerves and veins)
5	Femur, lateral, distal	10°	Full thread through second cortex	
6	Femur, lateral, proximal	10°	Full thread through second cortex	
7	Tibia, lateral, distal	35°	Full thread through second cortex	
8	Tibia, lateral, proximal	35°	Through second cortex	

Table 1: drill depth per half-pin

Note: full thread as depicted below:

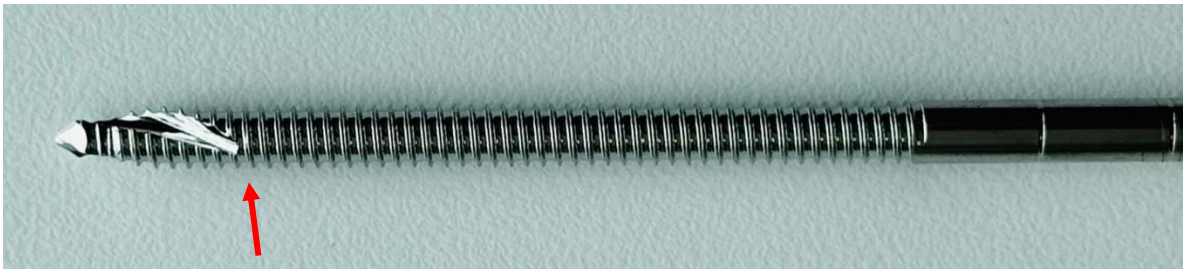


Figure 11: Full thread of drill pin (red arrow points to the first full thread)

10. Positioning of the medial distractor

- Hold the Distractor along the limb to assess proper positioning. It can be helpful to temporarily tighten the Tibial block to the Distractor with the Hexagonal bit.

POSITIONING OF THE DISTRACTOR
Check that the Distractor can be placed parallel to the leg (tibia and femur) in a straight as possible position. Prevent flexion of the ball and socket joints of the distractor as much as possible. Check if the black distraction tube has been placed parallel to the tibia.

- Check the position of the distractor

CORRECT SIDE OF THE DISTRACTOR
For use on the right knee joint: the 'left distractor' should be placed medially to the femoral bone. For use on the left knee joint the 'right distractor' should be placed medially.

- The black distraction tube is directed parallel to the tibia.
- The screw-threaded openings with recess are directed towards the surgeon and the Tibial block is positioned above the Distractor. See Figure 3.
- Check the proper site and direction of half-pin insertion by using the C-arm.
- In case of bulky soft tissues, insertion of a K-wire may be helpful in localizing the femoral bone by penetrating the skin and soft tissues.

For the placement of Half-pins in general:

- Make an incision parallel to the leg long enough to avoid tension of the skin margins after half-pin placement. Approach the bone by blunt dissection with a scissor.
- Pay attention to meticulous hemostasis because of the extended vascularization of that area (beware of the greater saphenous vein).

- The Distractor can be put aside as the first Half-pin is drilled into the distal femur, medial at the junction of the metaphysis-diaphysis without using the distractor as a guidance, see arrow 1 in Figure 12.

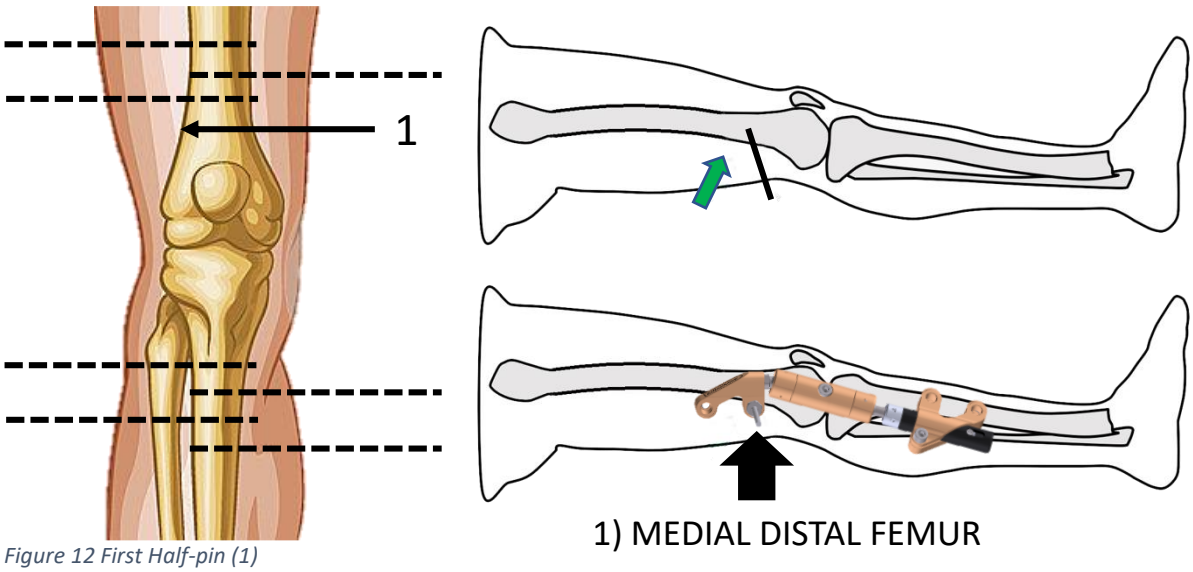


Figure 12 First Half-pin (1)

11. Drilling of medial distal femoral half-pin (1)

DEPTH HALF-PIN
The half-pin must be drilled through both cortices with slight protrusion of the pointed tip only through the second cortex of the bone. Take care that during removal of the half-pins the half-pins are not drilled deeper, this may cause injury.

For advice on drill depth of each pin, please refer to table 1.

HALF-PIN
Pay attention that the correct half-pin is used. There is a self-drilling half-pin available and a non-self-drilling half-pin available.

BONE DAMAGE
To avoid damage to the bone during drilling the drilling should be performed at low RPM and with little force. Furthermore, pay attention that the half-pin follows the pre-drilled hole to avoid bone damage.

Insertion of the Half-pin can be done either by a Self-drilling half-pin or by a Half-pin.
For the Self-drilling half-pin the KneeReviver Toolbox is needed and for the Half-pin the KneeReviver pre-drilling Toolbox is needed.

In case of using the Self-drilling half-pin:

- Put the Trocar (AS5) into the Half-pin guiding sleeve (AS6) and insert both into the incision to locate the dorsal, ventral and the medial part of the femoral bone shaft. See Figure 13.
- Keep the Half-pin guiding sleeve firmly against the bone shaft, parallel to the knee joint line in an approximately 10 degrees dorsomedial - ventrolateral direction (10 degrees tilt/angulation to the frontal plane) to minimize interference of the second half-pin with the quadriceps muscles. See 'Summary in view' at the last page Figure 53.
- Replace the Trocar by a Self-drilling half-pin mounted to the drill. See Figure 14.
- Check the appropriate position and direction of the Half-pin guiding sleeve with the aid of the fluoroscopy image intensifier using the C-arm ensuring that the Half-pin is parallel to the joint line.
- Drill this Self-drilling half-pin through both cortices of the femoral bone under simultaneous fluoroscopy viewing ensuring that the half-pin is parallel to the joint line. About 2 mm of thread should protrude beyond the second cortex. See Figure 15.
- Remove the Half-pin guiding sleeve. See Figure 16.

Figure 13 Put the Trocar in Half-pin guiding sleeve

Figure 14 Replace the Trocar by a Self-drilling half-pin

Figure 15 Drill the Self-drilling half-pin

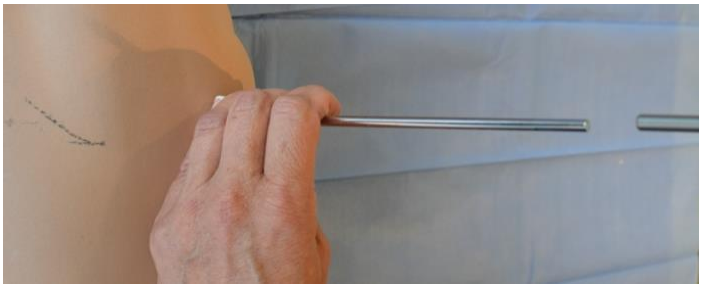


Figure 16 Remove the Half-pin guiding sleeve

In case of using the Half-pin:

- Put the Trocar (AS5) into the Half-pin guiding sleeve (AS6) and insert both into the incision to locate the dorsal, ventral and the medial part of the femoral bone shaft. See Figure 17.
- Keep the Half-pin guiding sleeve firmly against the bone shaft, parallel to the knee joint line in an approximately 10 degrees dorsomedial - ventrolateral direction (10 degrees tilt/angulation to the frontal plane) to minimize interference of the second half-pin with the quadriceps muscles. See 'Summary in view' at the last page Figure 53.
- Replace the Trocar by the Drill guiding sleeve (AS18). See Figure 18.

- If necessary, you can use the Ø3.5 mm Trocar (AS17) to identify the right position on the bone before drilling. See Figure 19.
- Insert the 3.5.mm Drill bit into the Drill guiding sleeve. See Figure 20.

Figure 17 Put 5mm Trocar in Half-pin guiding sleeve

Figure 18 Replace Trocar by the Drill guiding sleeve

Figure 19 Use 3.5mm Trocar

Figure 20 Insert the Drill bit

- Drill parallel to the joint line through both cortices of the femoral bone by simultaneous fluoroscopy control.
- Remove the Drill bit and the Drill guiding sleeve and insert the correct Half-pin by hand under fluoroscopy control. See Figure 21.
- Turn the Half-pin with the T-handle keyless chuck (AS19) in the drill shaft. About 2 mm of thread should protrude beyond the second cortex.
- Remove the Half-pin guiding sleeve. See Figure 22.

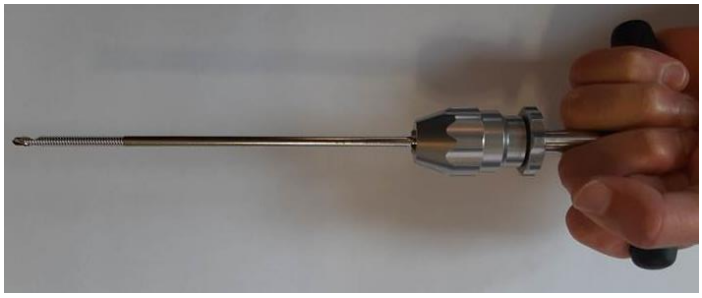


Figure 21 Insert the Half-pin with the T-Handle keyless chuck

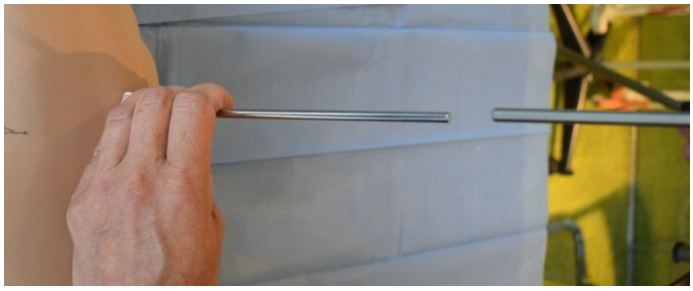


Figure 22 Remove the Half-pin guiding sleeve

For both the Self-drilling half-pin and the Half-pin:

- Check in the appropriate planes with fluoroscopy the final positioning of the Half-pin, being parallel to the joint line check depth with slight protrusion (of the pointed tip only) through the second cortex.
- When the Half-pin is positioned, place the distal opening of the distractor over the half-pin with the screw treaded openings with recess towards the surgeon.
- Place one of the Half-pin locking bolts (AS8) over the Half-pin (see Figure 23) and fix the Distractor temporarily onto the Half-pin, using the Hexagonal box spanner bit on the Torque limiter; you feel/hear a light click. See Figure 24. Do not tight it completely but allow active movement of the Distractor over the Half-pin.

Figure 23 Place Half-pin locking bolt over the Half-pin

Figure 24 Place Half-pin locking bolt over the Half-pin and tighten with the Torque limiter

12. Drilling of remaining medial half-pins (2, 3, 4)

Procedure for both the Half-pin and the Self-drilling half-pin:

- Place the medial pins in the following order: 2. proximal femur / 3. proximal tibia / 4. distal tibia

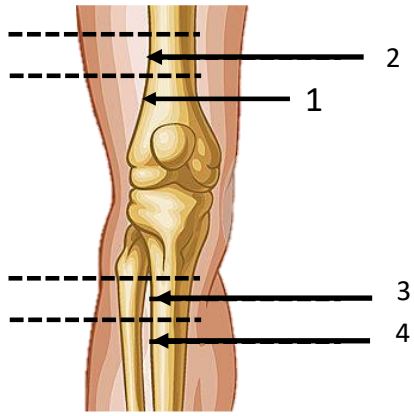


Figure 25 Sequence of Half-pin placement

- Now use the Distractor as a guidance to drill the Half-pins.
- Screw the sleeve guiding bolt (AS7) into the opening of the distractor. See Figure 26.
- Insert a Half-pin guiding sleeve (AS6) with Trocar (AS5) into the distractor through the next Sleeve guiding bolt. See Figure 27.

Figure 26 Screw the Sleeve guiding bolt

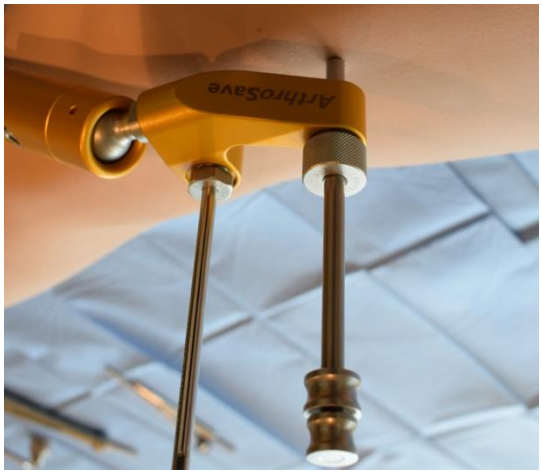


Figure 27 Insert Half-pin guiding sleeve with Trocar

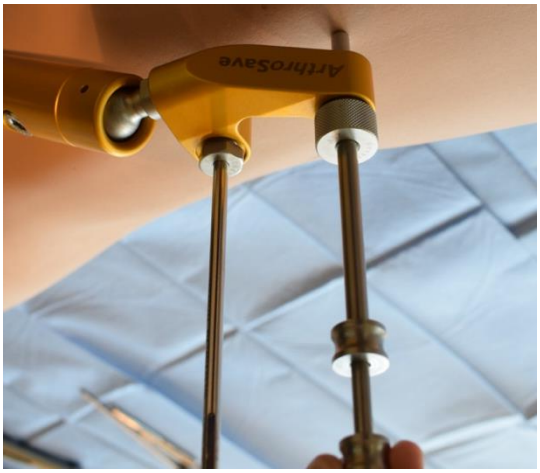


Figure 28 Remove the Trocar

- Make a second skin incision and approach the bone by blunt dissection.
- Direct the Half-pin guiding sleeve with Trocar to the middle of the bone shaft.

- Remove the Trocar. See Figure 28.

In case of using the Self-drilling half-pin repeat the steps as described from Figure 15 onwards:

- Drill the Self-drilling half-pin into the bone. Drill parallel to the last Half-Pin through both cortices of the femoral bone by simultaneous fluoroscopy control. About 2 mm of thread should protrude beyond the second cortex. See Figure 29.
- About 2 mm of thread should protrude beyond the second cortex.
- Unscrew the Sleeve guiding bolt and remove both this bolt with the Half-pin guiding sleeve. See Figure 30.

Figure 29 Drill the Self-drilling half-pin into the bone

Figure 30 Unscrew the Sleeve guiding bolt and remove it with the Half-pin guiding sleeve

In case of using the Half-pin repeat the steps as described from Figure 18 onwards:

- Replace the Trocar by the Drill guiding sleeve (AS18). See Figure 31.
- If necessary, you can use the Ø3.5 mm Trocar (AS17) to identify the right position on the bone before drilling. See Figure 32.

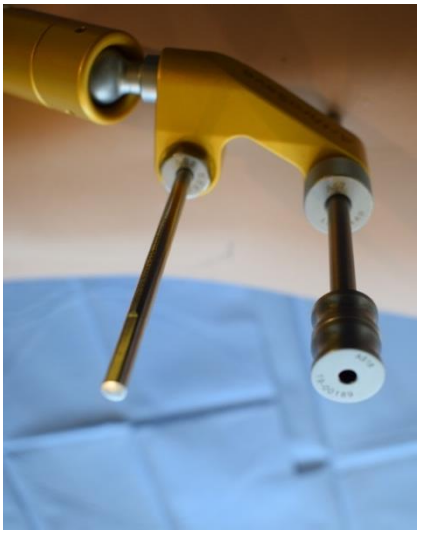


Figure 31 Replace the 5 mm Trocar by Drill guiding sleeve

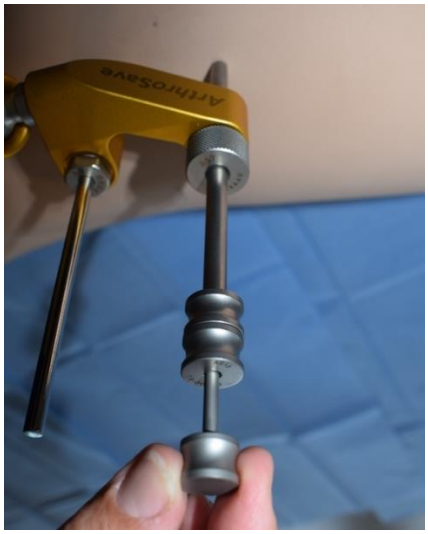


Figure 32 Use 3.5 mm Trocar

- Insert the 3.5.mm Drill bit into the drill guiding sleeve. See Figure 33.
- Drill parallel to the joint line through both cortices of the femoral bone by simultaneous fluoroscopy control.
- Remove the Drill bit and the Drill guiding sleeve and insert the correct Half-pin by hand under fluoroscopy control. About 2 mm of thread should protrude beyond the second cortex. See Figure 34.
- Unscrew the Sleeve guiding bolt and remove both this bolt with the Half-pin guiding sleeve. See Figure 35.

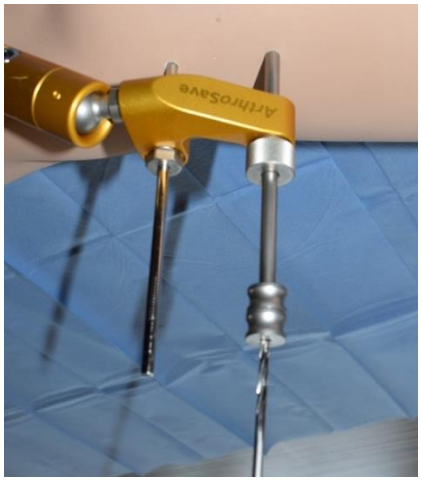


Figure 33 Drill a hole with a Drill bit

Figure 34 Insert Half-pin

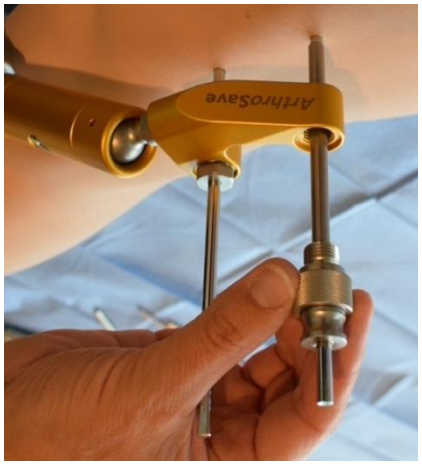


Figure 35 Unscrew the Sleeve guiding bolt and remove it with the Half-pin guiding sleeve

For both the Self-drilling half-pin and Half-pin from Figure 30 and Figure 35 onwards:

- Use fluoroscopy to ensure depth and proper position of the pin in the AP and lateral direction and check whether the Half-pins are parallel.
- Place a Half-pin locking bolt (AS8) over the Half-pin. See Figure 36.

Figure 36 Place Half-pin locking bolt

- Adjust the Distractor moving it over the Half-pins leaving at least a distance of 15 mm from the skin to allow proper pin site care.

⚠

SKIN CARE
Insufficient care of the skin around the half-pins may cause infection. Leave at least a distance of 15 mm between the skin and the pin fixation element to allow proper pin site care.

- Fix the Half-pin locking bolt of the Half-pin provisionally with the Torque limiter (feel/hear the click). Prevent passive movement but allow active movement.

Specific for the medial proximal femoral Half-pin (2):

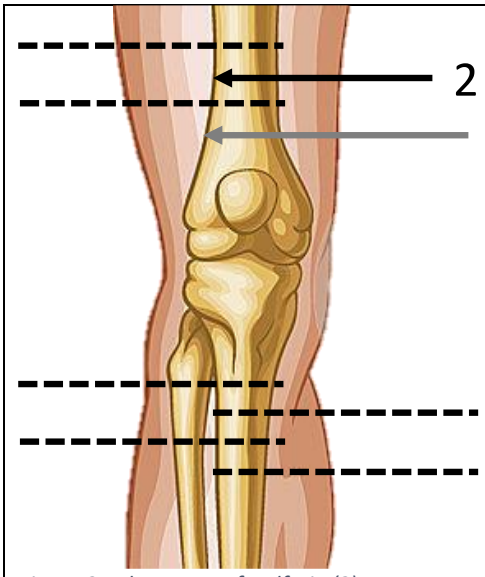
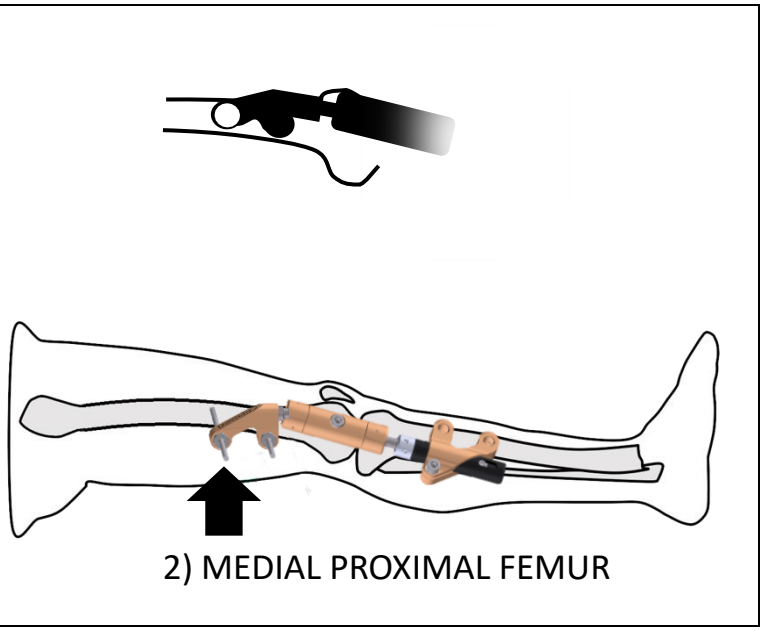


Figure 37 Placement of Half-pin (2)



- Note that the proximal pin position may be more anteriorly than the distal pin due to the antecurvation of the femoral bone.
- The same direction as Half-pin (1) of approximately 10 degrees, is used for the insertion of the next Half-pin (2). See 'Summary in view' at the last page Figure 53.

Specific for the medial proximal tibial Half-pin (3):

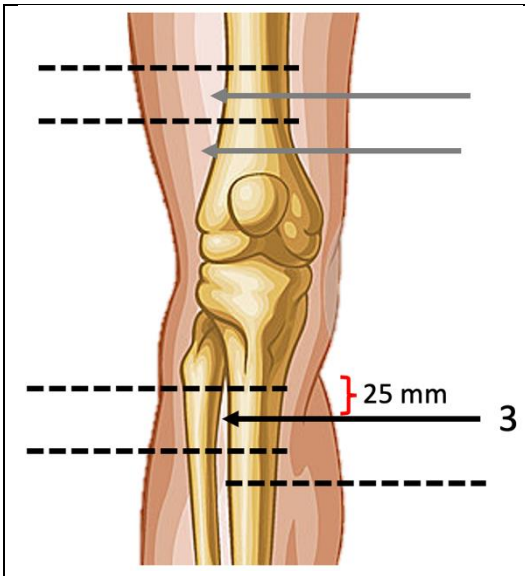
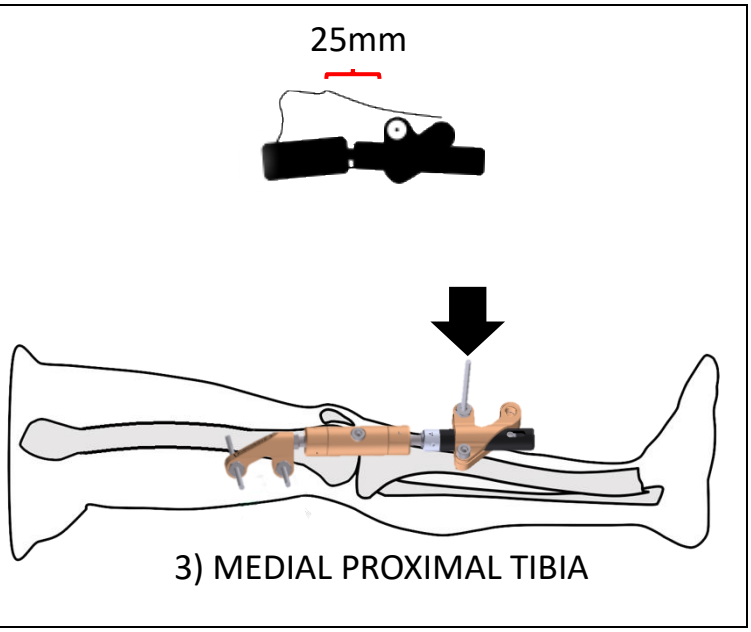


Figure 38 Placement of Half-pin (3)



- Make sure the Tibial block and the black distractor tube of the distractor body are freely moving.
- If motion between these parts of the distractor is limited, use the hexagonal-bit (AS10) on the Torque limiter (AS9) to untighten:
    - the Allen-bolt on the Tibia block by using the Hexagonal-bit (AS10) on the Torque limiter (AS9). See Figure 39.
    - the Allen-bolt in the middle of the yellow tube. See Figure 40.

Figure 39 Untighten the Tibial block

Figure 40 Untighten the yellow tube

- To obtain the optimal position for the Tibial block shorten or elongate the distractor by moving the Tibial block over the black distraction tube. See Figure 41.
- Note that the screw-threaded openings with recess are directed towards the surgeon and the Tibial block is positioned above the Distractor. See Figure 3.
- Be sure that a part of the black distraction tube will always protrude from the distal end of the tibial block. See Figure 41.

Figure 41 Protrusion of the black distraction tube

- Check frequently the position of the entire Distractor if being parallel to the leg axis.
- Check if the chosen position of the proximal tibial Half-pin (3) will allow a proper positioning of the next distal Half-pin (4) as well into the tibial bone.
- Ensure once again that the distraction thumb wheel (metallic) is in the ‘zero’ position. See Figure 5.
- The location of this medial proximal tibial Half-pin (3) is chosen at **least 25 mm distally to the tibial tuberosity** in order to allow a proper insertion of the lateral most proximal Half-pin (8). See Figure 38.
- Place the tibial Half-pin (3) parallel to the knee joint space, and if possible perpendicular to tibial bone axis and the antero-medial tibial face, which is approximately 35 degrees to the frontal plane. See ‘Summary in view’ at the last page Figure 53.
- Pay attention to a meticulous hemostasis.

- Follow procedures as under Chapter 12. If preferred, after placement of the first Half-pin through the Half-pin guiding sleeve and Sleeve guiding bolt, the second Half-pin may be placed by using the second Guiding bolt and Half-pin guiding sleeve. After placement of both Half-pins, both Half-pin guiding sleeves and both Sleeve guiding bolts can be removed and Locking bolts can be placed.
- Check frequently the position of the entire Distractor to be parallel to the leg axis.

Specific for the medial distal tibial Half-pin (4):

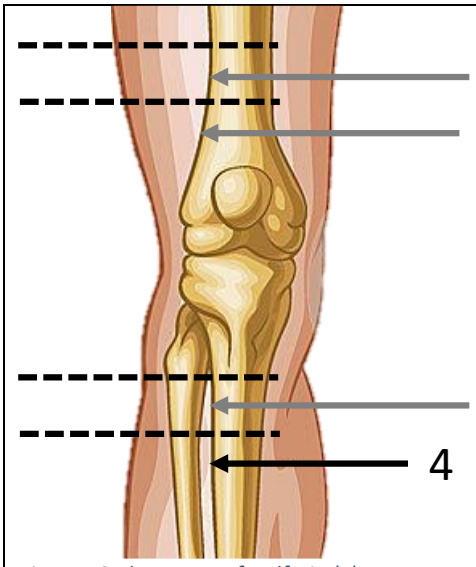
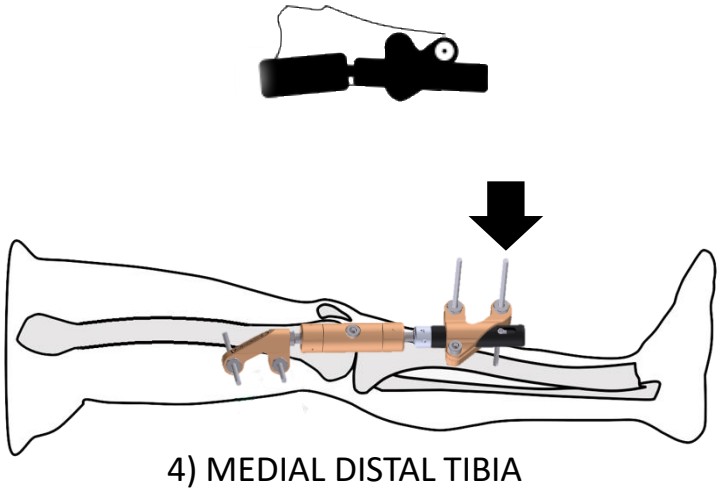


Figure 42 Placement of Half-pin (4)



- The same direction as for the proximal Half-pin (3) of approximately 35 degrees is used for drilling of the distal Half-pin (4). See 'Summary in view' at the last page Figure 53.

13. Drilling of lateral distal femoral half-pin (5)

- Hold the Distractor along the lateral side of the limb to assess proper (mirrored) positioning of the Distractor and half-pin insertions.
- Be sure the Tibial block and the black distraction tube are freely moving and provisionally fix them in the preferred length and position. See Figure 39 and Figure 40.
- Take away the Distractor; the first lateral pin can be placed without guidance by the Distractor.

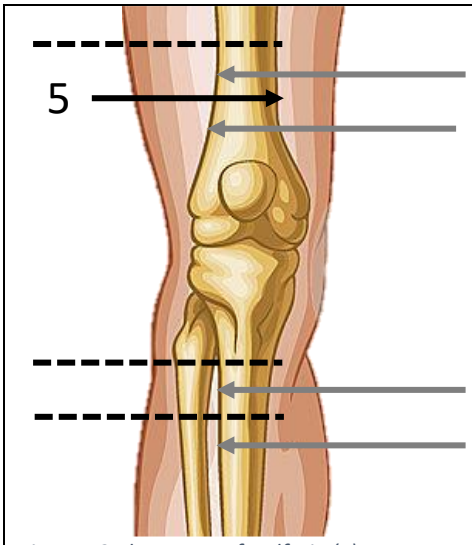
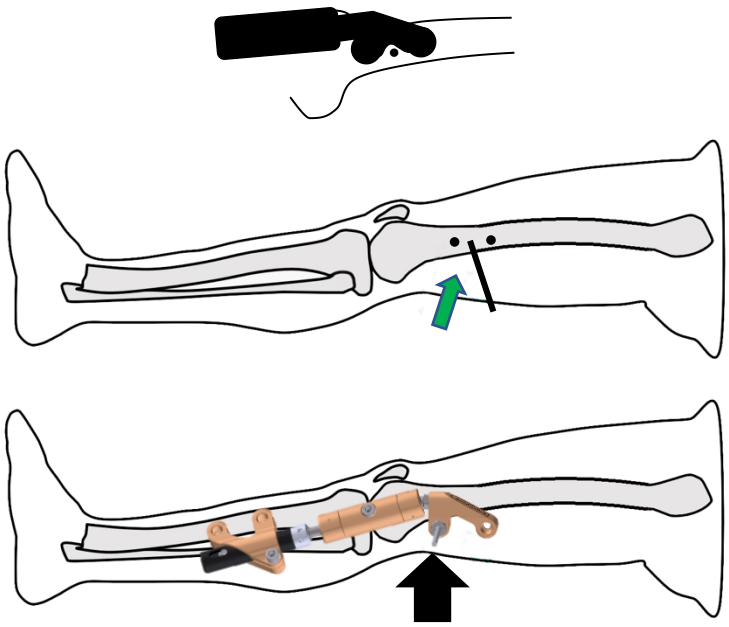


Figure 43 Placement of Half-pin (5)



- The optimal position of the first lateral Half-pin is in-between the ends of both medial half-pins and parallel to them.
- In case of bulky soft tissue, a K-wire may be used again to localize the femoral bone by penetrating skin and soft tissues.
- Both lateral femoral Half-pins should be placed parallel to the medial femoral Half-pins.
- Make an incision through the skin and continue by adequate blunt dissection of the fascia lata and muscles with scissors to the femoral bone. The fascia lata must be adequately split longitudinally to prevent tethering of the pin.
- Make sure the skin incisions are adequate to prevent tension of the skin around the Half-pins.
- Pay attention to a meticulous hemostasis.
- Insert a Half-pin guiding sleeve with Trocar through the incision and follow the same procedures as in Chapter 12.
- Keep the Half-pin guiding sleeve firmly against the bone shaft, parallel to the knee joint line in an approximately 10 degrees dorsomedial - ventrolateral direction (10 degrees tilt/angulation to the frontal plane) to minimize interference with the quadriceps muscles knowing that you have to place two femoral pins; Half-pin (5) and Half-pin (6). See 'Summary in view' at the last page Figure 53.
- When the distal Half-pin is positioned, place the distal opening of the Distractor over the Half-pin with the screw treaded openings with recess towards the surgeon.

- Fix the Locking bolt of the pin provisionally (feel/hear the click) by using the Torque limiter allowing active but not passive movement of the Distractor over the Half-pin.

14. Drilling of remaining lateral half-pins (6, 7, 8)

Procedure for both the Half-pin and the Self-drilling half-pin.

Place the pins in the following order:

- Place the lateral pins in the following order: 6. Proximal femur / 7. Distal tibia / 8. Proximal tibia.

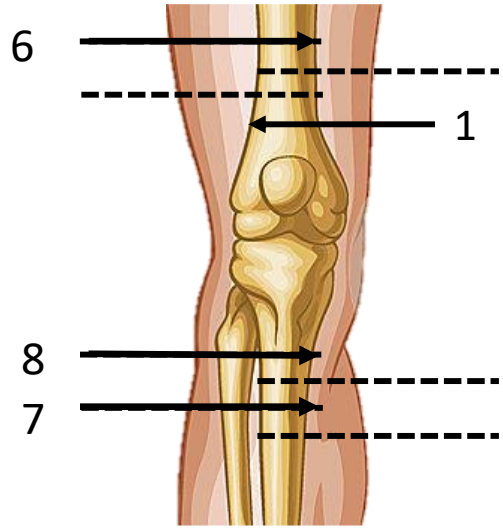


Figure 44 Sequence of Half-pin placement

Specific for the lateral proximal femoral Half-pin (6):

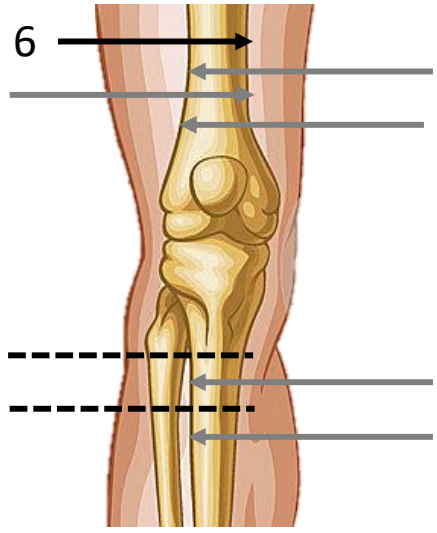
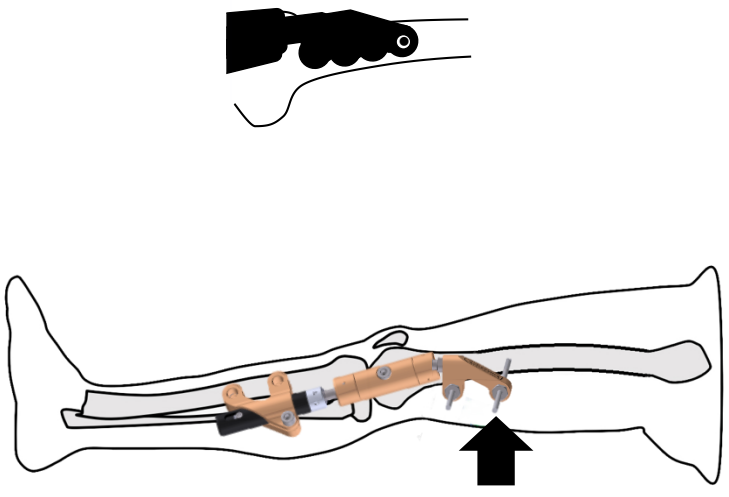


Figure 45 Placement of Half-pin (6)



6) LATERAL PROXIMAL FEMUR

- Now use the Distractor as a guidance to drill the Half-pins.
- Use the same procedures as described in Chapter 12.

- Both femoral Half-pins (5 and 6) will be drilled into the same direction of approximately 10 degrees to the frontal plane. See 'Summary in view' at the last page Figure 53.

Specific for the lateral distal tibial Half-pin (7):

- Check the position of the entire Distractor to be parallel to the leg axis.
- To obtain the optimal position for the Tibial block shorten or elongate the Distractor by moving the Tibial block over the black distraction tube. See Figure 41.
- The screw-threaded openings with recess are directed towards the surgeon and the Tibial block is positioned above the Distractor. See Figure 3.
- Ensure once again that the distraction thumb wheel (metallic) is in the 'zero' position. See Figure 5.

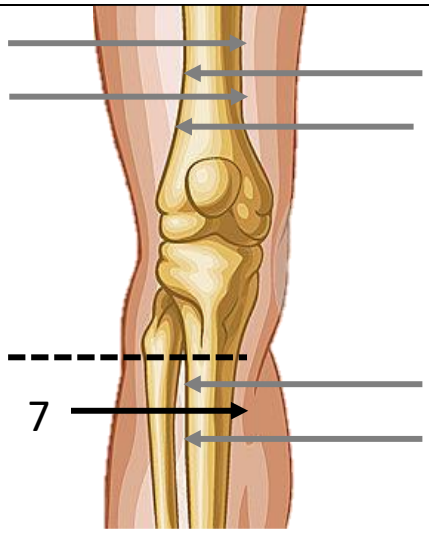
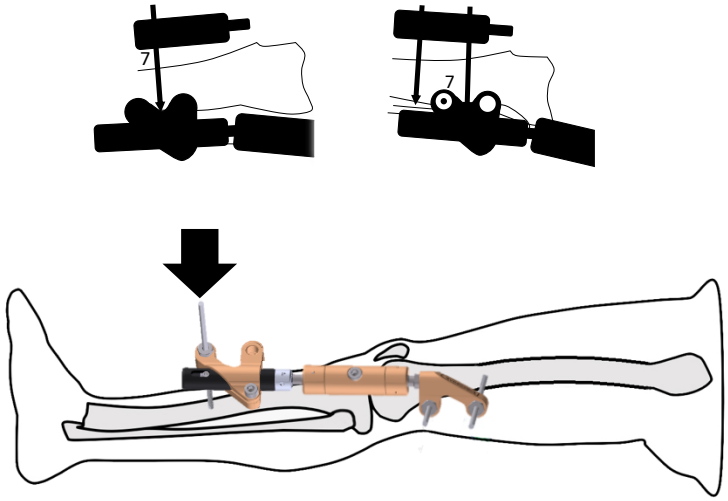


Figure 46 Placement of Half-pin (7)



- Note that at first the lateral tibia distal Half-pin (7) should be placed.
- The location of the lateral tibia distal Half-pin (7) is in-between the two medial tibial Half-pins (3) and (4).
- Place the Half-pin parallel to the two medial tibial Half-pins (3) and (4), and if possible perpendicular to tibial bone axis and parallel to the antero-medial tibial face, which is approximately 35 degrees to the frontal plane in a ventro- medial to a dorso- lateral direction. See 'Summary in view' at the last page Figure 53.
- Check by fluoroscopy the proper Half-pin position being parallel to and in-between the two medial tibial Half-pins (3) and (4) with slight protrusion (of the pointed tip only) through the second cortex of the tibial bone.

Specific for the lateral proximal tibial Half-pin (8):

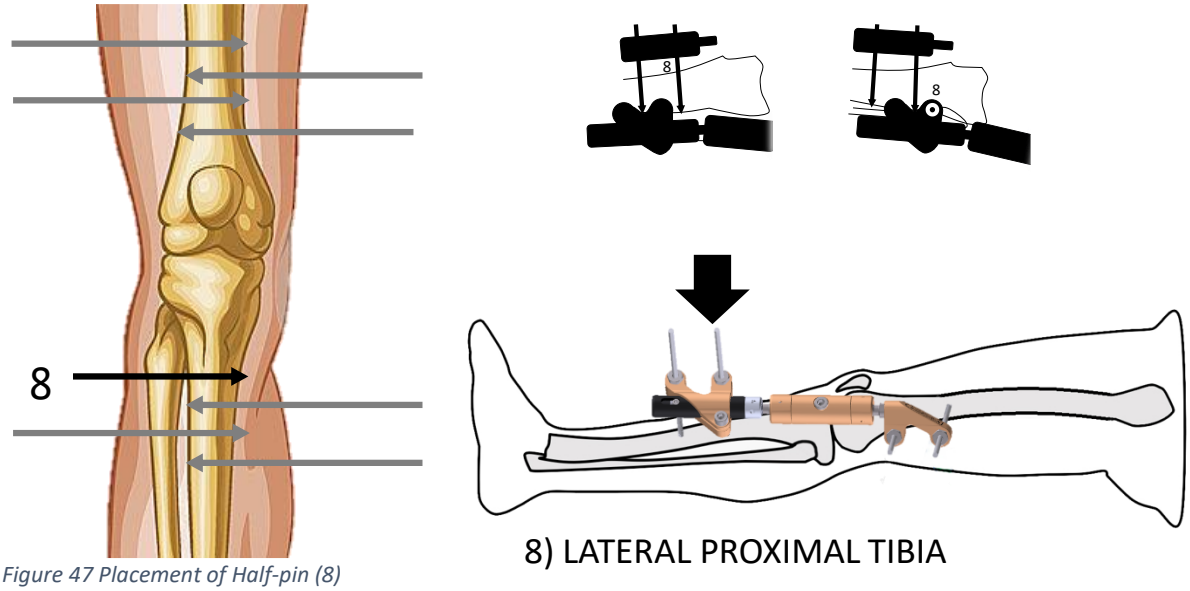


Figure 47 Placement of Half-pin (8)

- Both tibial Half-pins 7 and 8 will be drilled into the same direction of approximately 35 degrees See 'Summary in view' at the last page Figure 53.

15. Finalizing the procedure

- Move the Tibial block and the Distractor over the Half-pins to a distance of at least 15 mm from the skin.
- Note that the Half-pin locking bolts should not be tightened on the pin's screw thread.

HALF-PIN LOCKING BOLTS
Before fixing the Half-pin locking bolts tight, check the proper position of the Half-pin locking bolts. The Half-pin locking bolts should be levelled with the yellow fixation element.

Incorrect positioning of the collects or insufficient locking of the Locking bolts may result in loosening of a Half-pin which subsequently may lead to overloading of the other Half-pin and thus may cause breakage of a Half-pin.

Fix all 8 Half-pin locking bolts in subsequent order tight using the Hexagonal box spanner bit on the Torque limiter with maximal torque indicated by clicking of the Torque limiter.

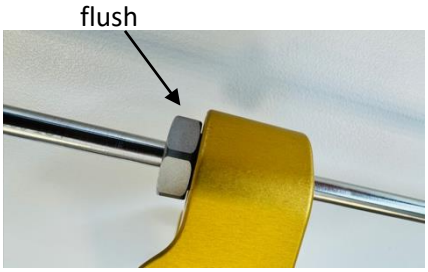


Figure 48 Proper position of Half-pin locking bolt

CORRECTION OF LEG POSITION
If needed, correct a varus/valgus position towards a more neutral position by manual adjustment of the KneeReviver to prevent any compression of cartilage tissue.

- Fix both Tibial blocks to the black distraction tubes with the Allen-bolts and fix the bolt and socket joints subsequently at the yellow tube at both sides of the leg by using the Hexagonal bit on the Torque limiter using maximal torque indicated by clicking of the Torque limiter (in total 4 Allen-bolts).

STABILIZE KNEEREVIVER
Take care to stabilize the KneeReviver firmly with one hand to prevent unnecessary stress on the Half-pins during fixation of the Tibial block to the black distraction tubes and fixation of the yellow tube.

- Check for skin- or fascial tethering at the end of the procedure and perform skin or fascial releases if necessary.

Perform distraction:
- Use the metallic thumb wheel to perform distraction. By rotating the metallic thumb wheel the distraction will be applied. To apply distraction first lift the V-notch from its fixed position and then turn the wheel 180 degrees. See Figure 49.

- By every turn of 180 degrees the knee joint will be distracted with 0.5mm. After every 180 degrees of turning the thumb wheel the wheel needs to be lifted before the next rotation is possible.
- Perform a distraction at both sides of +2 mm (use the Distraction key AS12 if needed).

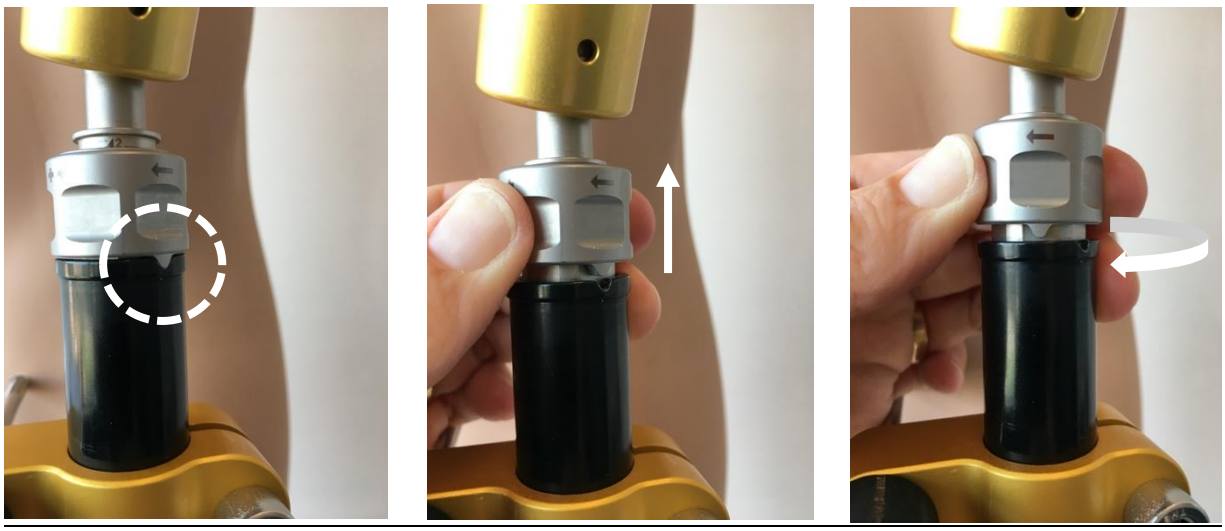


Figure 49 Perform distraction

DISTRACTION
Use the metallic thumb wheel to perform a distraction at both sides of the knee of +2 mm. Over distraction can lead to pain.

- Check the widening of the joint space by fluoroscopy. Distraction may result into an asymmetrical widening due to an asymmetrical resistance to distraction. Asymmetry in distraction may require adjustment of the Distractor at one of both sides to make widening of the knee joint as symmetrical as possible.
- All 8 half-pin insertion sites are covered with a small sterile gauze dressing (5x5).

- Place the Distance bush (AS13) over the Half-pins. See Figure 50.

Figure 50 Place Distance bush and cut the Half-pin

- Cut the Half-pin to a length of 15 mm protruding the distractor. See Figure 51. Repeat the later for the rest of the Half-pins.

Figure 51 Cut the Half-pin

- All 8 Half-pins locking bolts with Half-pins are capped with the plastic half-pin protective pin-caps. They fit very tight and slight hammering may be needed. See Figure 52.
- Provide the patient with the two spare pin caps and the disposable distraction spanner.

Figure 52 Place plastic pin-caps over the cutted Half-pin

Important:

- Patients should check on a daily basis the distraction distance at both sides of the knee. The distance may vary between patients and between left and right side. However, in case the distraction distance deviates from the distraction distance defined by you as orthopaedic surgeon, patients should be instructed to adjust the distance by themselves. In case of any doubt about the proper distance they should be instructed to contact you.

16. Instructions for removal after 6 weeks of treatment

Removal of the KneeReviver

- Remove the Distractor after six to seven weeks.
- Removal of the Distractor can be performed in day-care surgery.
- Type of Anaesthesia at choice.

Steps in the procedure

- Remove the protection caps from the eight half-pin ends on the Distractor.
- Remove the gauzes from the skin surrounding each Half-Pin.
- Take off the distraction tension between the femoral and tibial Half-pins by turning the metallic hex thumbscrew into an opposite direction for 2 mm.
- Unlock the Allen bolt on the tibial block around the black distraction tube by using an Allen key (size 6).
- Unlock the Allen bolt in the yellow tube between the two pin fixation elements.
- Unlock all eight half-pin locking bolts with a Hexagonal box spanner (size M10).
- Remove the Half-pins by using a (electric or pneumatic) drill.
- Remove both Distractors.
- The pin tract wounds can be debrided if needed using regular sterile instruments (curette, knife, etc).

REMOVAL DISTRACTOR OVER HALF-PINS
In case of difficulties in removing the distractor over the half-pins due to damage to the pin, remove first the half-pin by using a (electric or pneumatic) drill.
Note: first remove the gauzes from the skin surrounding the half-pins.

Mobilization

- The knee joint might be stiffened considerably by fibrous adhesions at the former pin sites due to the six-seven weeks immobilization.
- Mobilize the knee joint under anaesthesia by repeated gentle flexion and extension movements until an adequate range of motion (conform pre-distraction) has been achieved.

Wound care

- Pin tracts will heal spontaneously within days. If necessary, antibiotics can be continued in case of persisting pin tract infection.
- Cover the former pin tract wounds with gauze dressings.
- Apply a pressure bandage for 24-48 hrs.

Advise for patients

- Patients may remove gauze dressings after 24-48 hrs and do not need to cover them anymore if wounds have been healed.
- The use of anticoagulants needs to be continued for at least one extra week. Consider extended treatment if needed based on familiar background or reduced mobility.

Patients' mobilization

- Walking with crutches is encouraged post-operatively, when immediate full weight bearing is not yet possible (although allowed). Flexion and extension exercise of the knee joint including intensive quadriceps muscles exercises should start directly postoperatively in order to promote restoration of muscle power and joint movement. Supervision by the physiotherapist is on patient's demand.

Summary in view

Visualisation of the sequence of Half-pin placement and the direction of the Half-pin placement

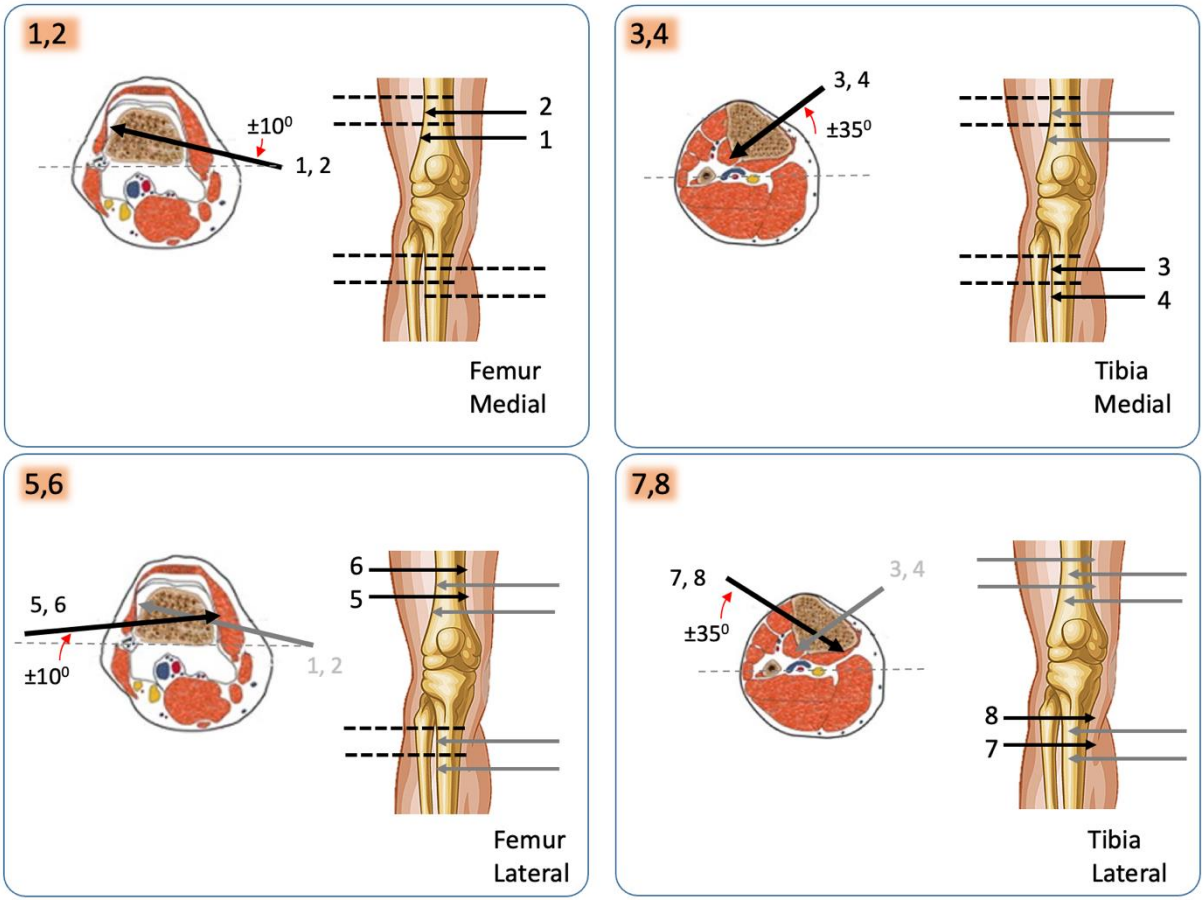


Figure 53 Summary in view

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