

Monolateral External Fixation System for Trauma and Orthopaedics

Segment Transport MEFiSTO

Surgical Technique

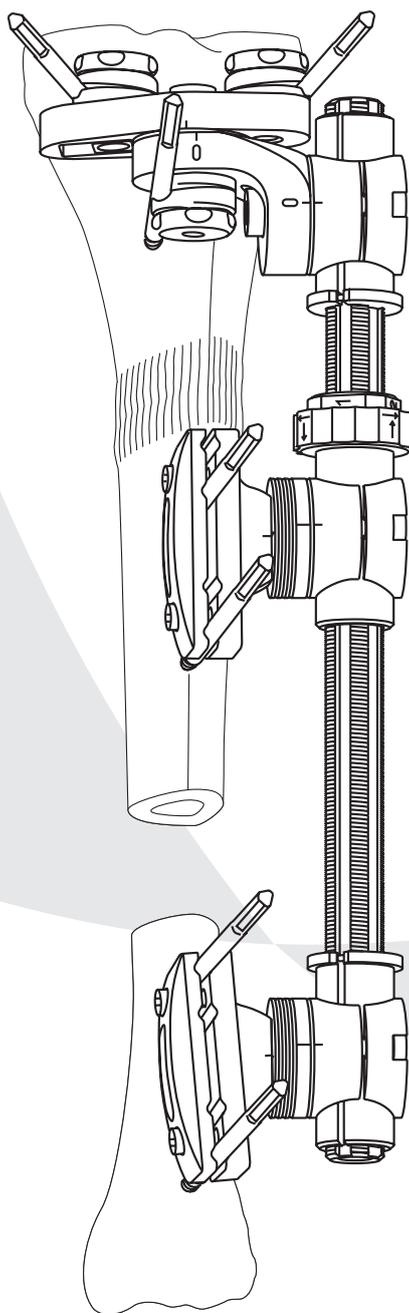


 Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

<http://emea.depuyshes.com/hcp/reprocessing-care-maintenance>

For general information about reprocessing, care and maintenance of DePuy Synthes reusable devices, instrument trays and cases, as well as processing of DePuy Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:

<http://emea.depuyshes.com/hcp/reprocessing-care-maintenance>

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This surgical technique for MEFiSTO segment transport is a supplement to the standard surgical technique for MEFiSTO.

Indications, Contraindications and Warning

Indications

Tibial and femoral segment transport in:

- post-traumatic defects with or without deformity
- necrosis
- infections
- pseudarthroses
- tumours

Contraindications

No specific contraindications.

Warning: The treating physician should make patient specific clinical judgment and decision to use External Fixation System in patients with the following conditions:

- Patients who for social and physical reasons are not suitable for an external fixator.
- Agitation
- Patients in whom screws cannot be inserted due to a bone or soft tissue disease.

System Description

Splined shaft

The assembly is based on a threaded splined shaft, available in three lengths: 300 mm, 350 mm, and 400 mm.

Sleeve for segment transport

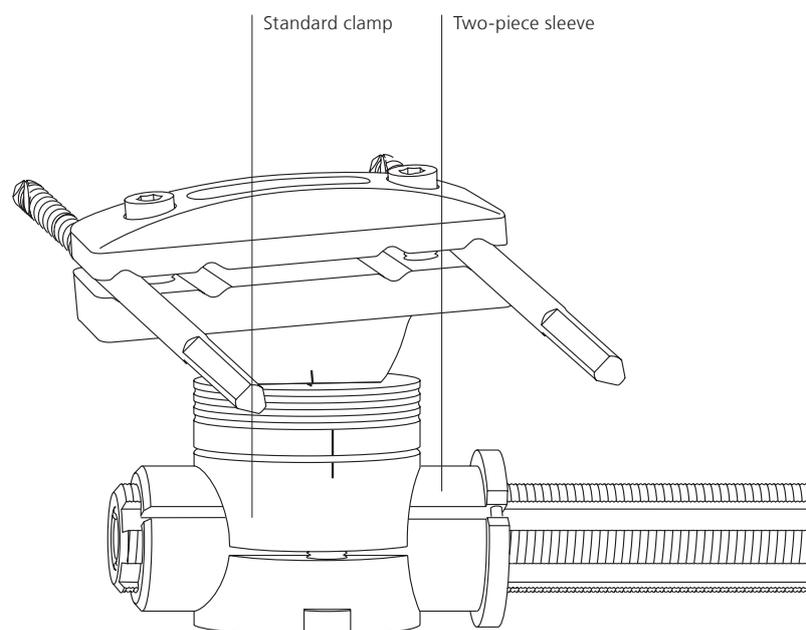
The sleeve for segment transport is used for transporting the bone segment. The sleeve can be moved up and down the thread and is fitted with a stepped mechanism in 0.25 mm increments.

T-clamp for segment transport

The assembled T-clamp for segment transport holds three Schanz screws by means of three vice plates, allowing placement of the screws in the proximal fragment of the tibia or the distal fragment of the femur. The three vice plates can rotate, allowing the Schanz screws to be inserted at different angles. Additionally, one of the upper vice plates is horizontally adjustable, providing various options for the placement of the Schanz screws. (see page 6 for assembly of the T-clamp for segment transport)

Standard clamp

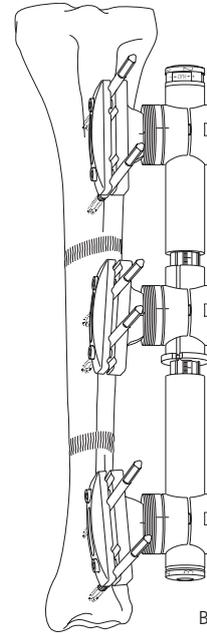
The wide swivel range of the standard clamps in all planes allows existing axial deformities to be corrected intraoperatively.



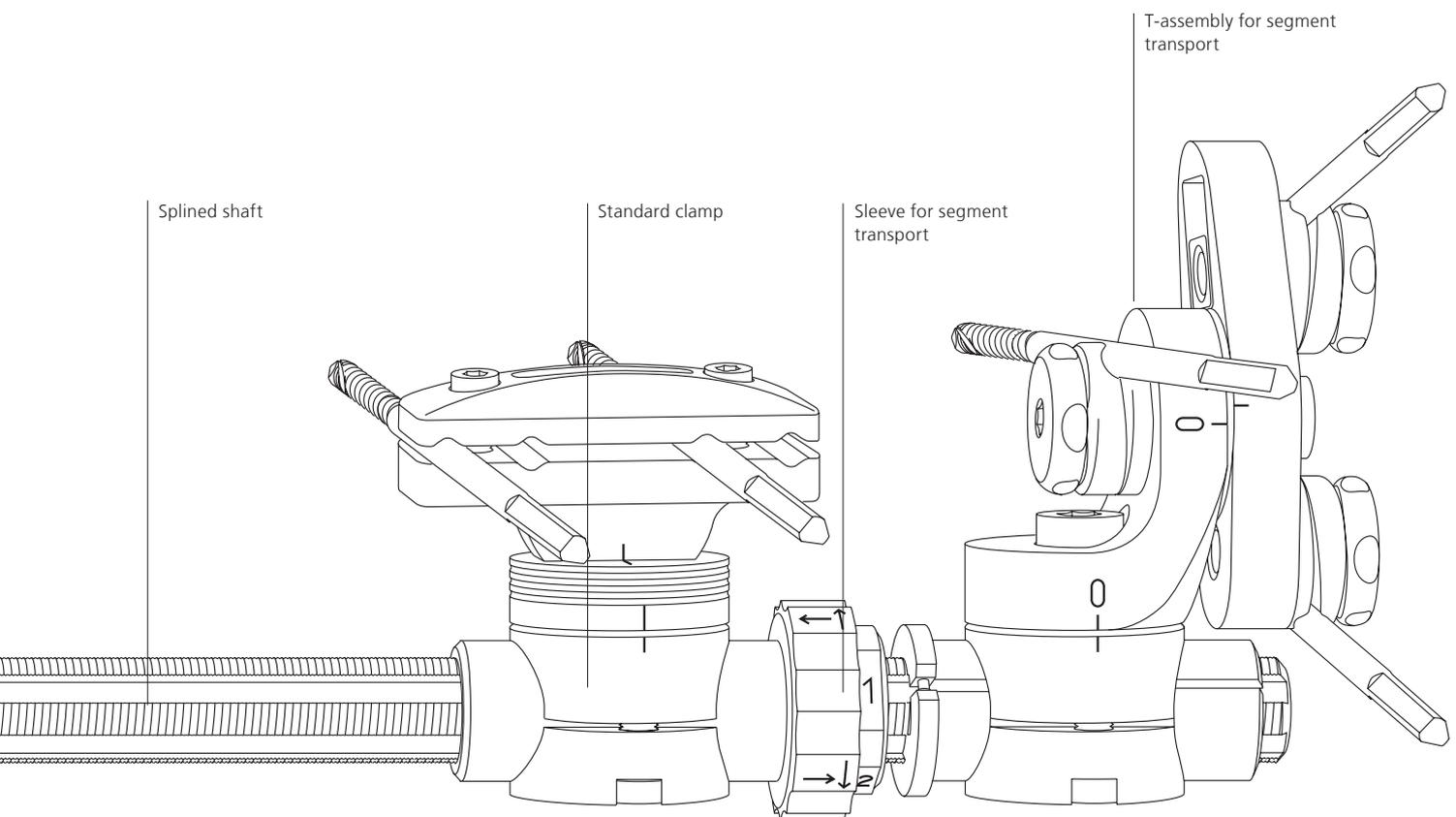
Two-piece sleeve

The standard clamps, single pin clamps and/or the assembled T-clamp for segment transport are mounted freely on the splined shaft by means of clamping two-piece sleeves. Other than the sleeve for segment transport, the two-piece sleeves are open, allowing adaptation to the anatomical situation and, if necessary, subsequent fixation.

The two-piece sleeves can also be used for bifocal bone lengthening, in which case they are attached in the middle of the threadless splined shaft of the central body. During bifocal bone lengthening, the outer, long sleeves of the central body are transported. This variant of the segment transport technique requires meticulous planning and a certain understanding of its function on the part of the patient.

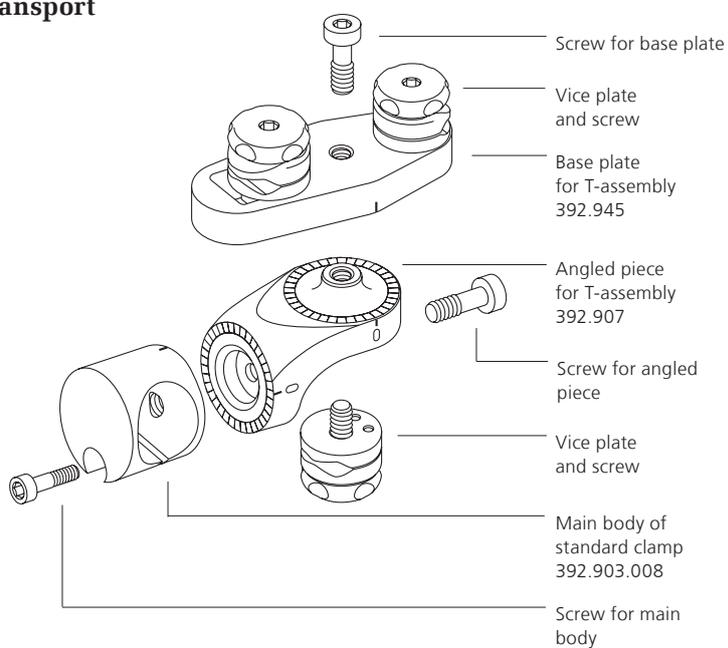


Bifocal bone lengthening

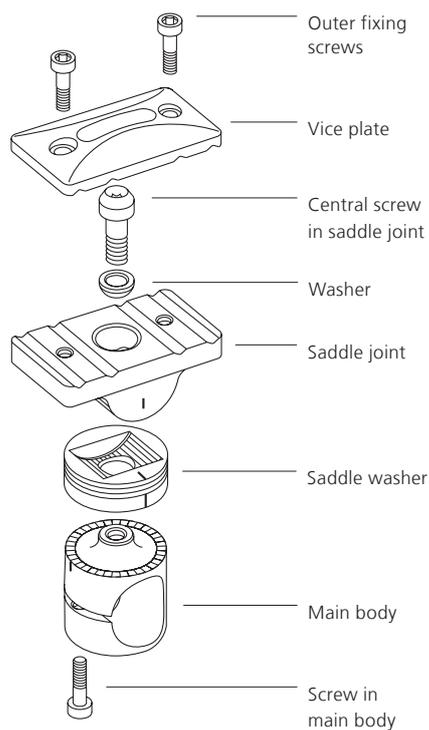


Clamp Assembly

Assembly of the T-clamp for segment transport



Assembly of the standard clamp



Preoperative Planning

Obtain AP and lateral radiographic overviews, if necessary backed up by CT or ultrasound scans of the relevant bone. An x-ray calibrator can be helpful in determining the defect and the transport length.

The radiographs provide information for the following, vital preoperative preparations:

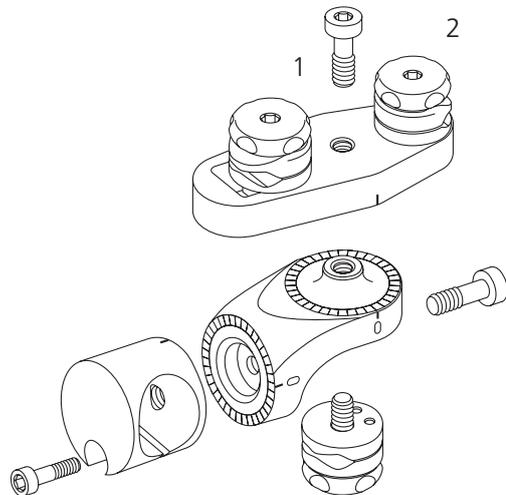
- Selection of the splined shaft (length: 300, 350 or 400 mm)
- Determination of the transport distance/length of the defect
- Determination of the position of the Schanz screws
- Determination of the incision site for the corticotomy

1. Assemble T-clamp for segment transport

The use of the T-clamp is recommended since the three anchoring points enhance fixation in the proximal tibial and distal femoral fragments.

- Screw the Angled Piece for T-Assembly (392.907) onto the Main Body of Standard Clamp (392.903.008).
- Screw the Base Plate for T-Assembly (392.945) with two mounted vice plates (1 and 2) onto the angled piece for T-assembly.

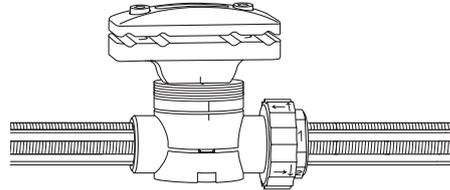
Do not assemble the third vice plate at this point. Otherwise, it will not be possible to tighten the screw of the angled piece for T-assembly. Only mount the vice plate onto the angled piece immediately before insertion of the third Schanz screw (see step 5 on page 11).



2. Prepare remaining components

- Slide the transport sleeve onto the splined shaft and turn the knurled nut until the sleeve is grasped by the thread of the splined shaft. Continue turning until the sleeve is positioned in the first third of the splined shaft, bearing in mind that the corticotomy/osteotomy is normally performed at the distal or proximal ends, but rarely in the centre of the shaft.
- Attach a Standard Clamp (392.903) to the transport sleeve.
- Prepare a second standard clamp, the assembled T-clamp for segment transport and the two-piece sleeves.
- Determine the diameter for the Schanz screws. Diameters of 5.0 mm and 6.0 mm, respectively, are recommended for the tibia and femur.

Note: If the assembly is to be connected to a hybrid ring fixator, a Central-Body-to-Ring Clamp (392.913) can be attached to the two-piece sleeves or the transport sleeve.



Surgical and Assembly Technique

This surgical technique is shown based on the example of a segment transport on a tibia with a distal defect. In the proximal fragment, the T-assembly for segment transport is used for fixation.

Note: For a detailed handling description of the Schanz screws, refer to the Surgical Technique Schanz Screws and Steinmann Pins (DSEM/TRM/0516/0677).

1. Insert distal Schanz screws and mount standard clamp

Precaution: Select the appropriate Schanz screw for the patient's bony anatomy.

Mark the optimal position of the Schanz screws on the skin. Anteromedial siting of the screws is recommended. The tendon of the anterior tibial muscle must be preserved, and intact during this procedure. The positioning and alignment of the screws can be determined using Kirschner wires and radiographs. Schanz screws need not be inserted exactly parallel with the longitudinal bone axis.

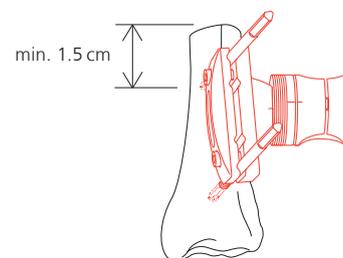
- ①

Insert the two distal Schanz screws through Drill Sleeves (393.840) and the Parallel Drill Sleeve Holder (392.915), or directly through drill sleeves and the standard clamp, ensuring, if possible, that the proximal screw is at least 1.5 cm from the defective bone area.

Remove the drill sleeve and mount the prepared standard clamp onto the Schanz screws.

Precautions:

- The tip of the self-tapping Schanz screw should be embedded in the far cortex to effectively resist cantilever forces and to provide sufficient stability.
- Only when bones are osteoporotic, the SELDRILL™ Schanz screw has to be screwed a bit further into the distant cortical bone, and it may even slightly penetrate through it since this can increase anchoring stability.



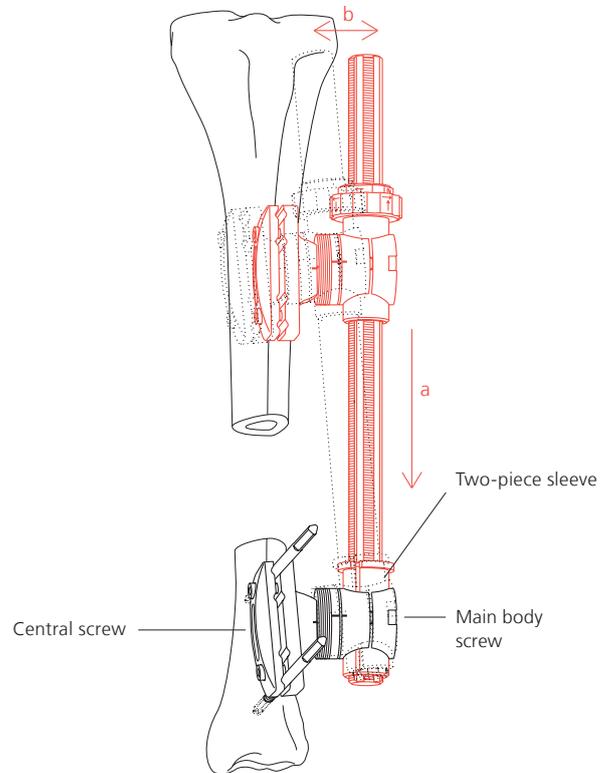
2. Mount the preassembly on the standard clamp

Attach a two-piece sleeve to the distal end of the splined shaft. Push the sleeve/preassembly through the main body of the standard clamp (a) and tighten the main body screw. Align the transport device in the frontal and sagittal planes parallel with the longitudinal bone axis (b) and check the AP and lateral alignments under the image intensifier. Tighten the central screw in the saddle joint of the standard clamp to fix the alignment of the splined shaft.



Precautions:

- Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin.
- Handle devices with care and dispose worn bone cutting instruments in an approved sharps container.



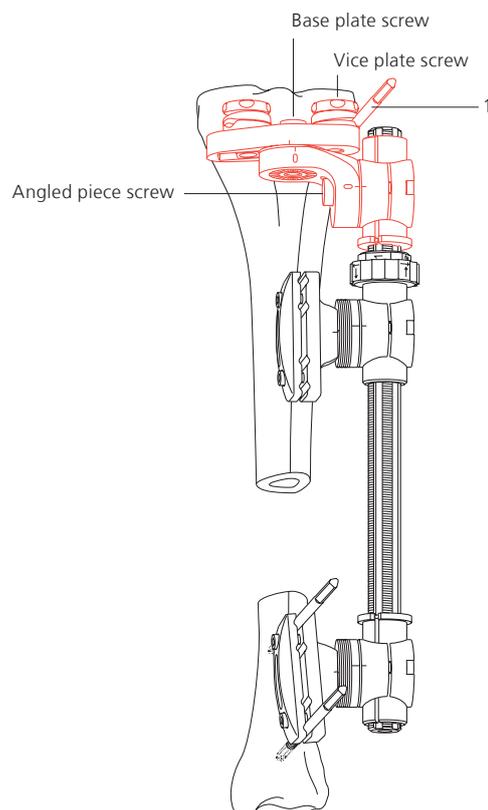
3. Insert first Schanz screw in the proximal fragment

Mount a two-piece sleeve on the proximal end of the splined shaft. Slide the assembled T-clamp for segment transport over the sleeve and align according to the situation. Do not tighten the screw in the base plate nor the screw in the angled piece for the time being to allow full exploitation of the rotation options of the angled piece.

Insert Schanz screw (1) through a drill sleeve into the upper, non-adjustable vice plate. Select the insertion site and angle according to the anatomical situation and check against the radiograph. If possible, insert the Schanz screw parallel with, and 1 cm away from the tibial plateau. Remove the drill sleeve.

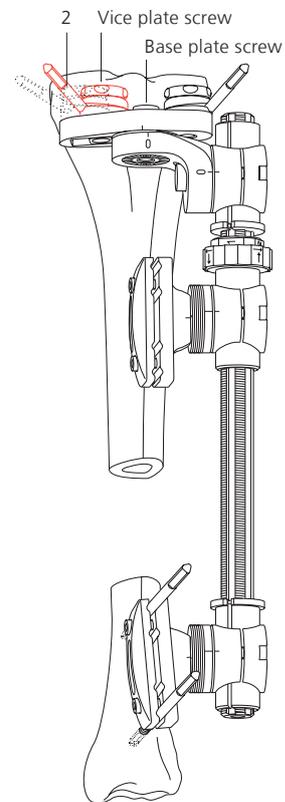


Position the whole transport device as close to the bone as possible, taking into account the soft tissue situation, and tighten the vice plate screw. Allow enough space to guarantee the regular care of the insertion sites of the Schanz screws.



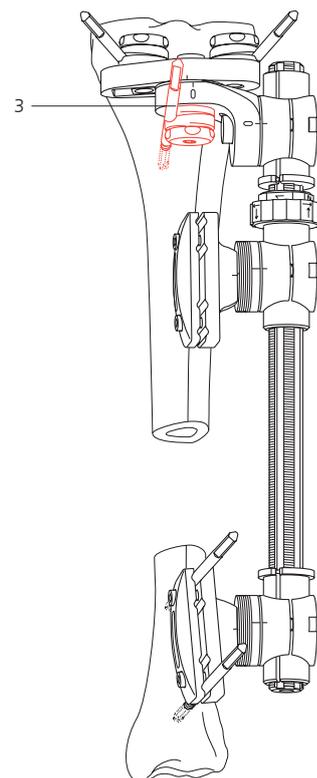
4. Insert second Schanz screw in the proximal fragment

Insert Schanz screw (2) as described through the adjustable vice plate into the bone. The adjustable vice plate facilitates enhanced adaptation of the screw to the anatomical situation. Tighten the screws of the vice plate and the base plate, if possible using the hexagonal Screwdriver with Torque Indication (392.920).



5. Insert third Schanz screw in the proximal fragment

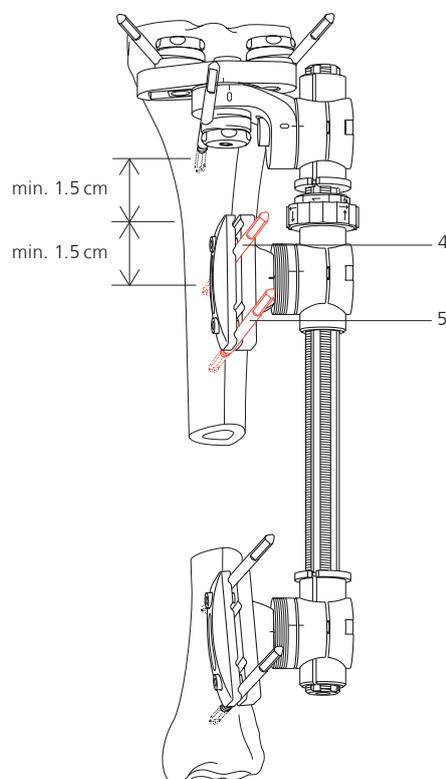
Mount the lower vice plate on the angled piece for T-assembly. Insert Schanz screw (3) through the drill sleeve and vice plate into the bone. Remove the drill sleeve and tighten the vice plate screw, if necessary using the long, angled Hexagonal Wrench (392.919).



6. Insert two Schanz screws in the transport segment

Determine the position of the Schanz screw (4) in the bone segment to be transported. This should be located at least 1.5 cm from the planned corticotomy site. Insert the Schanz screws (4) and (5) through the drill sleeve and standard clamp into the bone. Remove the drill sleeve and tighten the vice plate fixing screws.

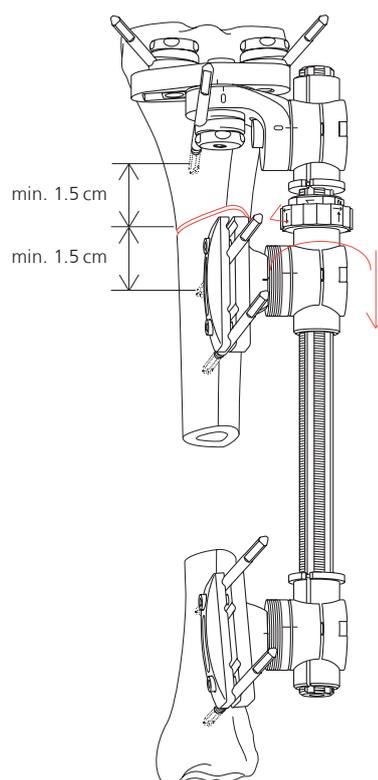
Check to ensure that all clamp screws are tightened.



7. Perform corticotomy and check the gap

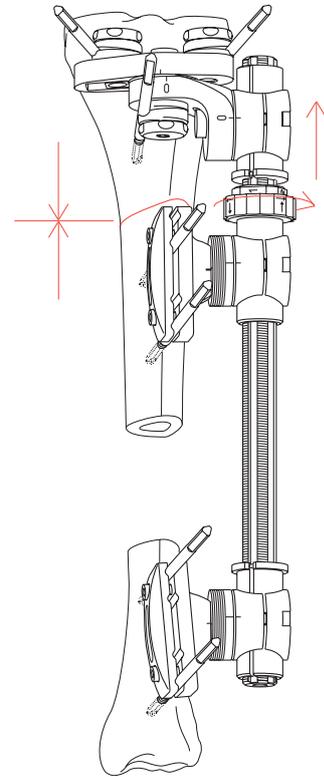
Perform the corticotomy/osteotomy. Use small flat chisels and/or small drills to avoid bone cracks. The gap between the section line and the Schanz screws should be at least 1.5 cm, if possible, to avoid the development of bone cracks and splinters during corticotomy/osteotomy.

Turn the knurled nut on the transport sleeve – if necessary using the Hexagonal Wrench (392.924) – in the desired direction of transport (distally on the illustration), to confirm that the corticotomy is complete. The corticotomy gap must be clearly visible under the image intensifier. Turn back the knurled nut/transport sleeve.



8. Compress corticotomy

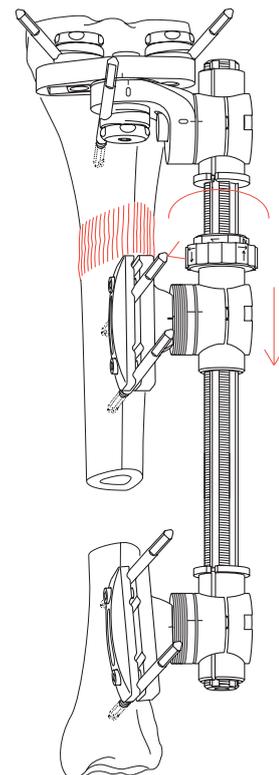
Before segment transport can begin, slight compression must be generated at the corticotomy site for 7 to 10 days.



9. Start segment transport

Segment transport can begin after the compression period. Normally the segment is moved at a rate of 1 mm per day, corresponding to one complete rotation of the knurled nut on the transport sleeve. The transport sleeve is fitted with a stepped mechanism, with perceptible 0.25 mm increments and numbering from 1 to 4, to facilitate handling of the device by the surgeon and/or patient.

- ⓘ Check callus formation on radiographs after 2 to 3 weeks and then at regular intervals of about two weeks.



10. Dock transported segment and consolidate

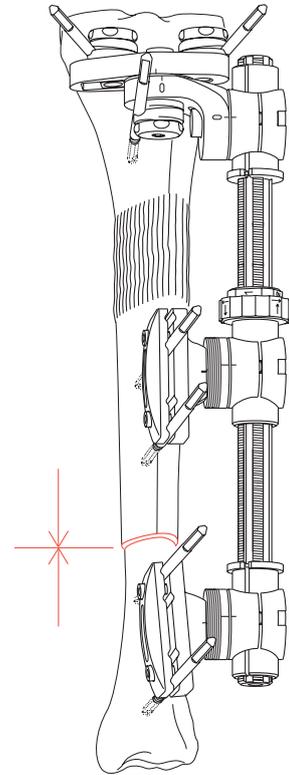
Before the segment is docked to the distal portion of the tibia, a slight compression, freshening up the distal docking site and/or bone grafting can be performed to support optimal growth.

- Monitor consolidation by regular radiographs. Particular attention must be paid to the care of the soft tissues.

A standard value for the consolidation period – from docking of the segment to removal of the transport device – would be approx. 1.5 to 2 times the transport period.

Precautions:

- **Implant sites should be meticulously cared to avoid pin-tract infection. Schanz screws may be surrounded with antiseptic coated foam sponges in an effort to avoid infection. An implant-site care procedure should be reviewed with the patient.**
- **To minimize the risk of pin track infection, the following points should be observed:**
 - a. **Placement of Schanz screws taking anatomy into consideration (ligaments, nerves, arteries).**
 - b. **Slow insertion and/or cooling, particularly in dense, hard bone to avoid heat necrosis.**
 - c. **Release of skin tension at soft tissue entry point of implant.**

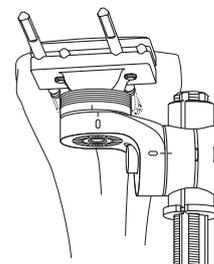


Alternative Assembly Techniques

Using a standard clamp in the proximal segment instead of the T-clamp for segment transport

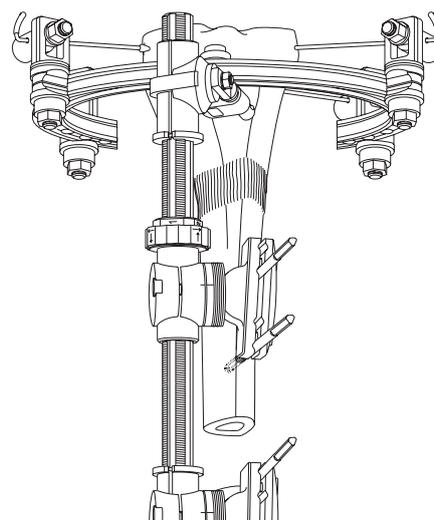
In the proximal segment, two Schanz screws can be inserted through a third Standard Clamp (392.903) instead of three Schanz screws and the assembled T-clamp for segment transport (392.945, 392.907, 392.903.008).

If the two Schanz screws are to be inserted parallel with the tibial plateau, the third standard clamp can be converted into a T-clamp by adding the Angled Piece for T-Assembly (392.907). In contrast with the special T-clamp for segment transport, in this case the Schanz screws must be inserted parallel with each other.



Connecting the transport device to a hybrid ring fixator

If segments in the proximal or distal tibia are to be secured with wires (hybrid ring fixator), the transport device can easily be connected to the hybrid ring using the Central-Body-to-Ring Clamp (392.913) and the Ring-to-Rod Clamp (393.436).



Mounting the transport device on the Schanz screws of an existing external fixator

In cases where the segment transport is to be performed on a bone where an external fixation device is already in use, the Schanz screws in place should be used wherever possible. The screws to be used are selected at the pre-operative planning stage.

The adjustable vice plate of the base plate for T-assembly allows the transport device to be moved as close to the bone as possible, following removal of the existing external fixator, via Schanz screws inserted at a particular angle during the primary procedure.

Single pin clamps may also prove useful in this situation.

Components

Splined Shaft, threaded

Length: 300 mm (392.941)

Length: 350 mm (392.942)

Length: 400 mm (392.943)



Sleeve for Segment Transport (392.926)



Standard clamp (392.903)



Sleeve, two piece

Length: 50 mm (392.927)

Length: 80 mm (392.928)



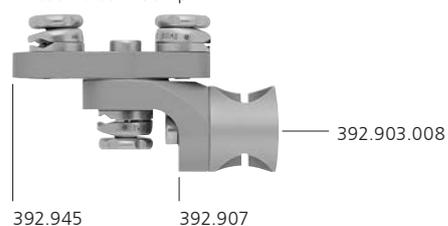
Base Plate for T-Assembly (392.945)



Angled Piece for T-Assembly (392.907)



Assembled T-clamp



Main Body of Standard Clamp (392.903.008)



End Cap for Splined Shaft, threaded (392.944)



Vice Plate and Locking Screw
(392.905.001 and 392.905.003)



Wrench for Sleeve for Segment Transport and Angulator
(392.924)



MRI Information

The “MEFiSTO” is MR unsafe. Do not use this device in any MR environment. This device is known to pose hazards in all MR environments.

