



**stryker**

# AxSOS<sup>®</sup>

## Monoaxial Locking Plate System

### Operative Technique

- Proximal Lateral Tibia
- Targeting instrumentation



# Tibia Fractures

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This publication sets forth detailed recommended procedures for using Stryker devices and instruments.

It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

A workshop training is recommended prior to first surgery.

All non-sterile devices must be cleaned and sterilized before use.

Follow the instructions provided in our reprocessing guide (OT-RG-1).

Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly / disassembly instructions.

Please remember that the compatibility of different product systems have not been tested unless specified otherwise in the product labeling.

See package insert (V15011 and V15013) for a complete list of potential adverse effects, contraindications, warnings and precautions. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

**Warning:**

**Fixation Screws: Stryker Osteosynthesis bone screws are not approved or intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.**

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# Indications, Precautions & Contraindications

## Indications

The indication for use of this internal fixation device includes metaphyseal extra- and intra-articular fractures of the proximal Tibia.

## Precautions

AxSOS has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of AxSOS in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

## Contraindications

The physician's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

- Any active or suspected latent infection or marked local inflammation in or about the affected area
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site
- Bone stock compromised by disease, infection or prior implantation that can not provide adequate support and/or fixation of the devices
- Material sensitivity, documented or suspected
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself
- Patients having inadequate tissue coverage over the operative site
- Implant utilization that would interfere with anatomical structures or physiological performance
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care
- Other medical or surgical conditions which would preclude the potential benefit of surgery

Detailed information is included in the instructions for use being attached to every implant.

See package insert for a complete list of potential adverse effects and contraindications. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

### Caution:

**Bone Screws are not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.**

# Operative Technique

## General Guidelines

### Patient Positioning:

Supine with option to flex the knee. Visualization of the proximal tibia using Fluoroscopy in both the lateral and AP views is necessary.

### Surgical Approach:

Lateral Parapatellar.  
Lateral curved (hockey stick) or straight.

### Reduction

Anatomical reduction of the fracture should be performed either by direct visualization with the help of percutaneous clamps, or alternatively by using a bridging external fixator to aid with indirect reduction.

Fracture reduction of the articular surface should be confirmed by direct vision, or fluoroscopy. Use K-Wires as necessary to temporarily secure the reduction. Typically, K-Wires set parallel to the joint axis will not only act to hold and support the reduction, but also help to visualize / identify the joint.

Care must be taken that these K-Wires do not interfere with the required plate and screw positions. Also, consideration must be taken when positioning independent Lag Screws prior to plate placement to ensure that they do not interfere with the planned plate location or Locking Screw trajectories.

If any large bony defects are present they should be filled by either bone graft or bone substitute material.

### Bending

In most cases the pre-contoured plate will fit without the need for further bending.

Plate contouring will affect the ability to use the Targeting Device for percutaneous screw placement. Thus, plate contouring is not recommended.

If for any reason the plate needs intra-operative contouring, it is recommended to perform shaft fixation using the conventional screw insertion technique without the use of the Targeting Device.



# Operative Technique

## General Guidelines

### Screw Measurement

There are four options to obtain the proper Screw length as illustrated below. The Screw Scale (REF 703587) should always be used with the assembled Tissue Protection Sleeve and the Drill Guides.

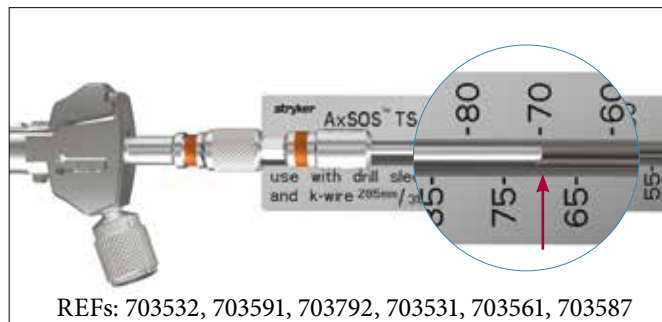
### Correct Screw Selection

Select a screw approximately 2–3mm shorter than the measured length to avoid screw penetrations through the opposite cortex in metaphyseal fixation. Add 2–3mm to measured length for optimal bi-cortical shaft fixation.

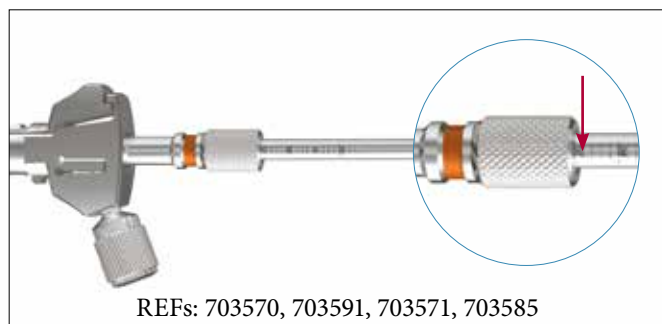
### Soft-Tissue Re-attachment

Special undercuts on the reverse side of the plate correlating to the two proximal K-Wire holes allow simple passing of sutures for meniscus re-attachment after final plate fixation.

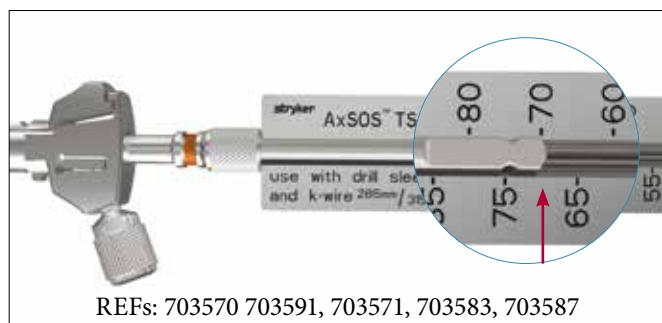
### Measurement Options



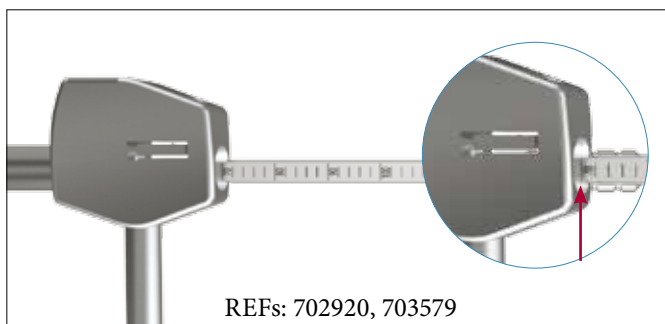
### Measure off K-Wire



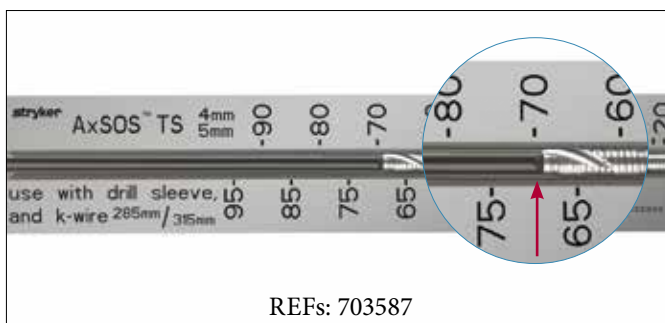
### Measure off Drill Calibration



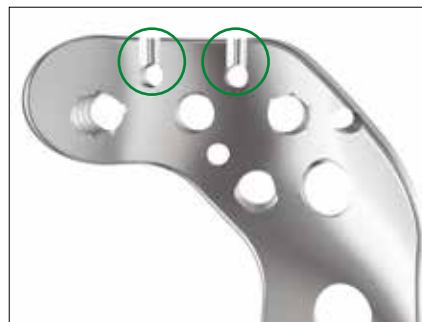
### Measure off Drill end



### Measure off Measure Gauge



### Screw Length Control



# Operative Technique

## Step 1 – Pre-Operative Planning

Use of the X-Ray Template (REF 981081) in association with fluoroscopy can assist in the selection of an appropriately sized implant (Fig. 1).

### Note:

**If additional Locking Screws are chosen for the plate shaft, pre-operative insertion of Locking Inserts is recommended.**

A Ø4.0mm Locking Insert (REF 370002) is attached to the Locking Insert Insertor (REF 702762) and placed into the chosen hole(s) in the shaft portion of the plate (Fig. 2).

Ensure that the Locking Insert is properly placed. The inserter should then be removed (Fig. 2A).

### Note:

**Do not place Locking Inserts with the threaded Drill Sleeve.**

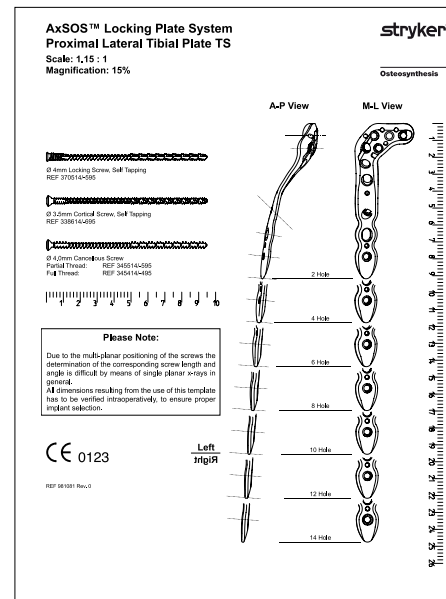


Fig. 1



Fig. 2



Fig. 2A

### Locking Insert Extraction

Should removal of a Locking Insert be required for any reason, then the following procedure should be used.

Thread the central portion (A) of the Locking Insert Extractor (REF 702767) into the Locking Insert that you wish to remove until it is fully seated (Fig. 2B).

Then turn the outer sleeve / collet (B) clockwise until it pulls the Locking Insert out of the plate (Fig. 2C). The Locking Insert must then be discarded, as it should not be reused.

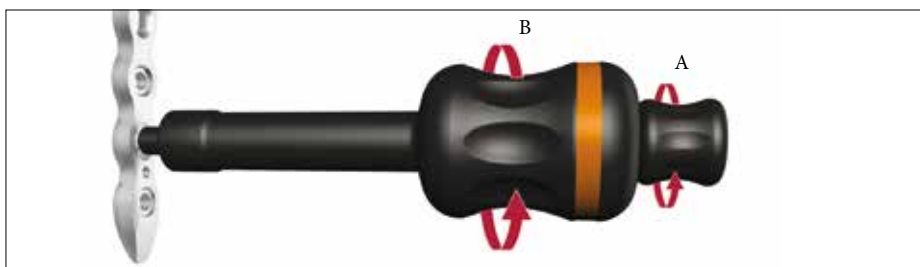


Fig. 2B



Fig. 2C

# Operative Technique

## Step 2 – Plate Insertion Handle Assembly

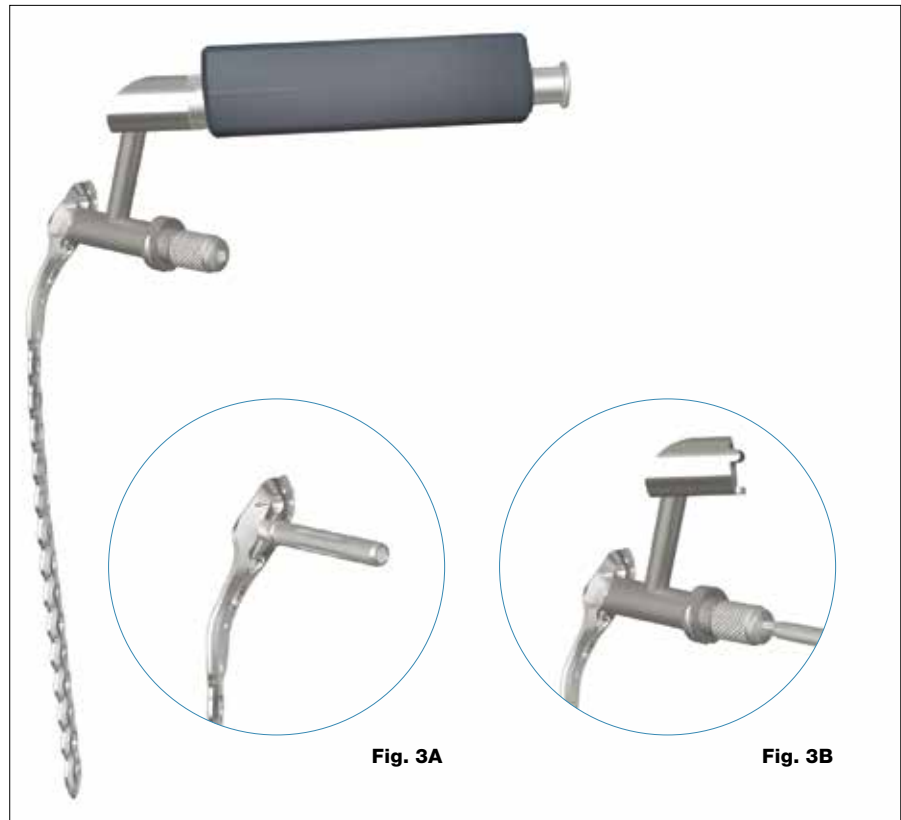
Screw the Connecting Pin (REF 702974) to the plate using the hex Screwdriver Ø2.5/4.3mm (REF 703592) (Fig. 3A).

Connect the Adaptor Nut (REF 702977) to the Plate Adaptor (REF 703562/703563) and slide the Plate Adaptor over the Connecting Pin. Once aligned, and the teeth engage in the corresponding grooves in the plate, secure the Plate Adaptor by tightening the Adaptor Nut with the same hex Screwdriver (Fig. 3B).

It is recommended to provisionally apply the corresponding Targeting Arm to check for proper alignment of the Targeting Device and plate. Insert a Drill through the assembled Tissue Protection Sleeve and Drill Sleeve (REF 703585, 703570 and 703571) into the relevant threaded plate hole prior to plate application.

The Targeting Arm can now be removed again.

The Plate Insertion Handle (REF 702978) can now be attached to help facilitate plate positioning and sliding of longer plates sub-muscularly (Fig. 3).



**Fig. 3**



# Operative Technique

## Step 3 – Submuscular Plate Application

When implanting longer plates, a minimally invasive technique can be used.

The Soft Tissue Elevator (REF 702782) is designed to create a pathway for the implant (Fig. 4).

The implant has a special rounded and tapered end, which further allows for smooth insertion under the soft tissue.



Fig. 4

After the skin incision is performed and anatomical reduction is achieved, the plate is applied so that the lateral tibial plateau is supported, with the proximal end of the plate approximately 5–10mm below the articular surface (Fig. 5).

Essentially, ensuring that the most proximal Locking Screws are directly supporting the joint surface.

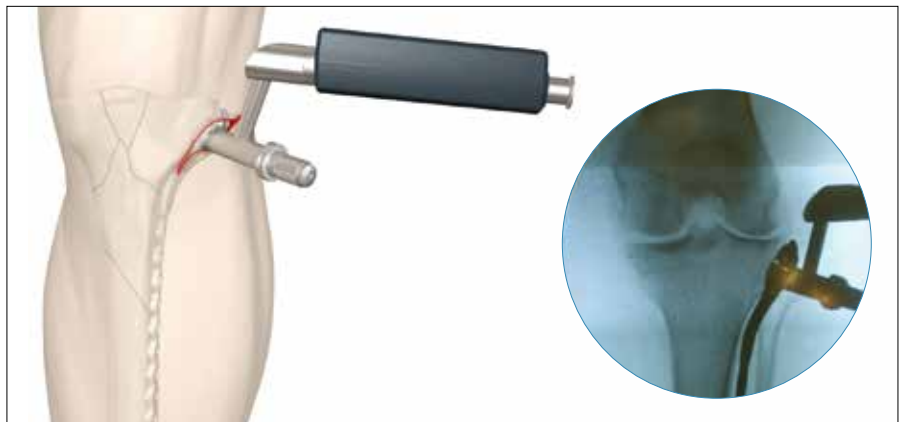


Fig. 5

In addition, Plate End Markers (REF 703568) may be inserted into the appropriate holes of the Targeting Arm to assist in locating the plate end and holes with Locking Inserts during the entire procedure (Fig. 6).

### Note:

**A slightly extended distal shaft incision is recommended to visualize the superficial peroneal nerve.**



Fig. 6

In certain cases this nerve crosses the tibia in the proximity of the distal part of a 12 – 14 hole plate.

# Operative Technique

## Step 4 – Primary Plate Fixation

A K-Wire Ø2.0 x 285mm (REF 703583) can now be inserted through the cannulation of the Adaptor Nut and the Plate Adaptor to help secure the plate to the bone (Fig. 7). Also, other independently placed K-Wires can help to support depressed articular surface fragments. Insertion of a K-Wire should be checked by fluoroscopy to avoid penetration into the articulating surface.

To remove the insertion handle, press the metal button at the top of the Handle.

At this point, alignment of the plate to the shaft of the tibia should be checked by fluoroscopy in both the AP and lateral planes, both proximally and distally.

Attach the correct Aiming Block (REF 703564 / 703565) to the Plate Adaptor. Ensure that the Aiming Block is properly seated on the Adaptor shaft and secured with the Aiming Block Screw.

Using the Tissue Protection Sleeve (REF 703578) together with the Drill Sleeve (REF 703571) and the Trocar (REF 703577), a Drill Sleeve can be inserted into the most posterior hole of the metaphyseal portion of the plate.

Ensure that the Drill Sleeve is properly seated in the thread of the plate hole.

Remove the Trocar, replace it with the K-Wire Sleeve (REF 703575) and then insert a Ø2.0 x 285mm K-Wire (REF 703583).

The above step shows the position of a posterior screw and its relation to the joint surface. Also, this will confirm that the screw will not be placed intraarticularly or too posterior exiting the cortex into the popliteal space (Fig. 8).

Using fluoroscopy, the K-Wire position can be checked until the optimal position is achieved, and the plate is positioned correctly.

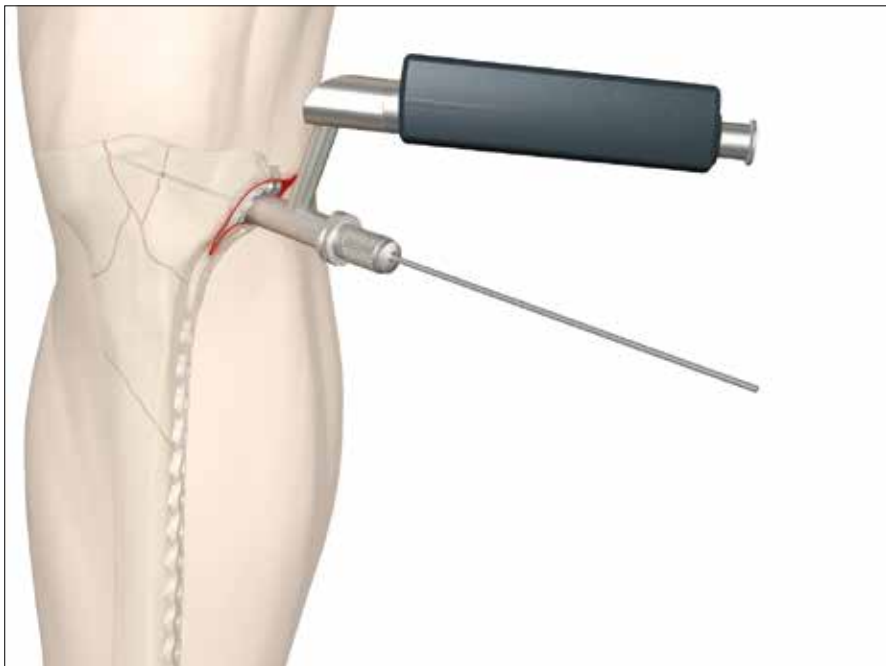


Fig. 7



Fig. 8

# Operative Technique

Correct distal placement should be re-confirmed using fluoroscopy to make sure the plate shaft is properly aligned over the lateral surface of the tibial shaft. If the proximal and axial alignment of the plate is not achieved, then the K-Wires should be removed and the plate should be re-adjusted. The aforesaid procedure should be repeated until both the posterior K-Wire and the plate are in the desired position.

Do not remove K-Wires as a loss of plate position could result.

The distal end of the plate must now be secured using the most distal hole of the shaft.

Attach the Targeting Arm (REF 703566 / 703567) to the Plate Adaptor.

Mark the skin at the most distal hole using the Tissue Protection Sleeve (REF 703570) and make a small incision.

Insert the Trocar with sharp tip (REF 703576) into the Tissue Protection Sleeve (REF 703570) and manipulate the assembly through the Targeting Arm and the stab incision until the tip of the Trocar is in contact with the plate.

Push the Tissue Protection Sleeve further into the hole until the locking notches of the Tissue Protection Sleeve fully engage in the corresponding groove in the Targeting Arm (for details see step 6 shaft fixation). Ensure that the sleeve fixation screw is orientated posteriorly as displayed on the Targeting Arm.

Essentially, this will securely lock the Tissue Protection Sleeve in the Targeting Arm.

Remove the Trocar and replace it with a Drill Sleeve (REF 703571) and Trocar Ø3.1mm (REF 703577) and continue to manipulate the assembly into the plate hole. Ensure that the Drill Sleeve is fully engaged in the thread of the plate hole to create a stable construct between the Targeting Arm and the plate, providing sufficient stability for accurate screw targeting.

Secure the Drill Sleeve by tightening the Sleeve Fixation Screw.

A Ø2.0 x 285mm K-Wire (REF 703583) can now be inserted using the K-Wire Sleeve (REF 703575) (Fig. 9).

Alternatively, the Ø3.1mm Calibrated Drill (REF 703585) can be inserted bi-cortically. Additionally, it is recommended to leave the Drill Bit in place for primary plate stabilization.



Fig. 9

# Operative Technique

If desired, the plate can be pushed to the bone by using the Frame Fixator (REF 703573) instead of the drill or K-Wire. To do so, remove the outer sleeve of the fixator. The self-drilling, self-tapping tip of the Frame Fixator pin should be inserted bi-cortically through the Drill Sleeve (REF 703571).

To confirm bi-cortical purchase use fluoroscopy.

When inserting the pin by power, make sure to use a low-speed to avoid significant temperature increase which can lead to bone necrosis.

**Note:**

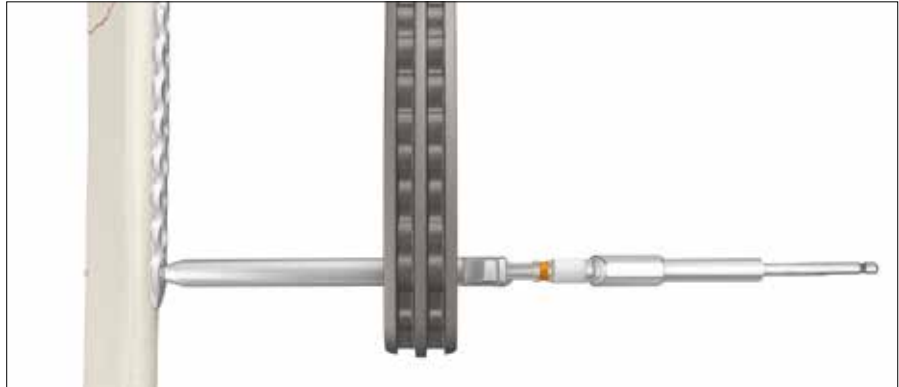
**A locking screw and locking insert should not be used in the hole where the temporary plate holder is used.**

Re-attach the outer sleeve over the threaded part of the pin and turn the sleeve until the plate is in the desired position (Fig. 10).

**Note:**

**Using plates with 10 holes or longer, it is recommended to insert additional Tissue Protection / Drill Sleeve assemblies in further threaded holes in the mid way position of the plate shaft. Essentially, this will provide additional rigidity to the frame and will help to compensate plate deformity that might occur using a standard cortical screw to push the plate against the bone (Fig. 11).**

The Frame Fixator can also be used for indirect fracture reduction anywhere along the tibial shaft using the “Pull Reduction Method”.



**Fig. 10**



**Fig. 11**

# Operative Technique

## Step 5 – Metaphyseal Plate Fixation

Locking Screws cannot act as lag screws. Should an interfragmentary compression effect be required in metaphyseal fragments, then a Ø3.5mm standard cortex screw or Ø4.0mm cancellous screw must first be placed in one of the unthreaded metaphyseal plate holes inferior to the Plate Adapter prior to the placement of any Locking Screws. The sleeve assembly and the K-Wire in the posterior metaphysal hole should be removed.

Disconnect and remove the Aiming Block.

Freehand placement of this screw(s) can now be performed using the free-hand Tissue Protection Sleeve Ø2.5mm (REF 702920) together with the Drill Sleeve (REF 703572). Using the Calibrated Drill Ø2.5mm (REF 703586), drill the core hole to the appropriate depth (Fig. 12).

The Screw length can directly be read off the Calibrated Drill or using the Screw Scale (REF 703587) as described under the Measurement Options on page 6. Over-drill the first cortex using the drill Ø3.5mm (REF 703590) through the Tissue Protection Sleeve. A fully threaded cortical screw can then be inserted through the Tissue Protection Sleeve.

If inserting a Ø4.0mm cancellous screw, the near cortex should be pre-tapped using the Tap (REF 703589).

Care must be taken, that these screws do not interfere with the Locking Screw trajectories.

### Note:

**The distal holes of plates longer than 14 holes cannot be approached with the targeting arm.**



Fig. 12

# Operative Technique

Locking Fixation of the metaphyseal portion of the plate can now begin. Re-attach and tighten the Aiming Block to the Plate and insert the Tissue Protection Sleeve and the Drill Sleeve into the most posterior metaphyseal locking screw hole again.

Drill the core hole for the Locking Screw using a Ø3.1mm drill (REF 703585).

Using fluoroscopy, check the correct depth of the drill. The screw length can be checked with a direct read off the calibration of the drill, or any other measurement option as described on page 6 can be used.

The drill and the Drill Sleeve should now be removed and the correct length Ø4.0mm Locking Screw is inserted using the screwdriver T15 (REF 703594) (Fig. 13).

Final seating position of the screw occurs when the groove around the shaft of the Screwdriver is approaching the end of the Tissue Protection Sleeve (Fig. 13A).

Locking Screws should initially be inserted manually to ensure proper alignment.

## Note:

- **Ensure that the screwdriver tip is fully seated in the screw head, but do not apply axial force during final tightening**
- **If the Locking Screw thread does not immediately engage the plate thread, reverse the screw a few turns and re-insert the screw once it is properly aligned**

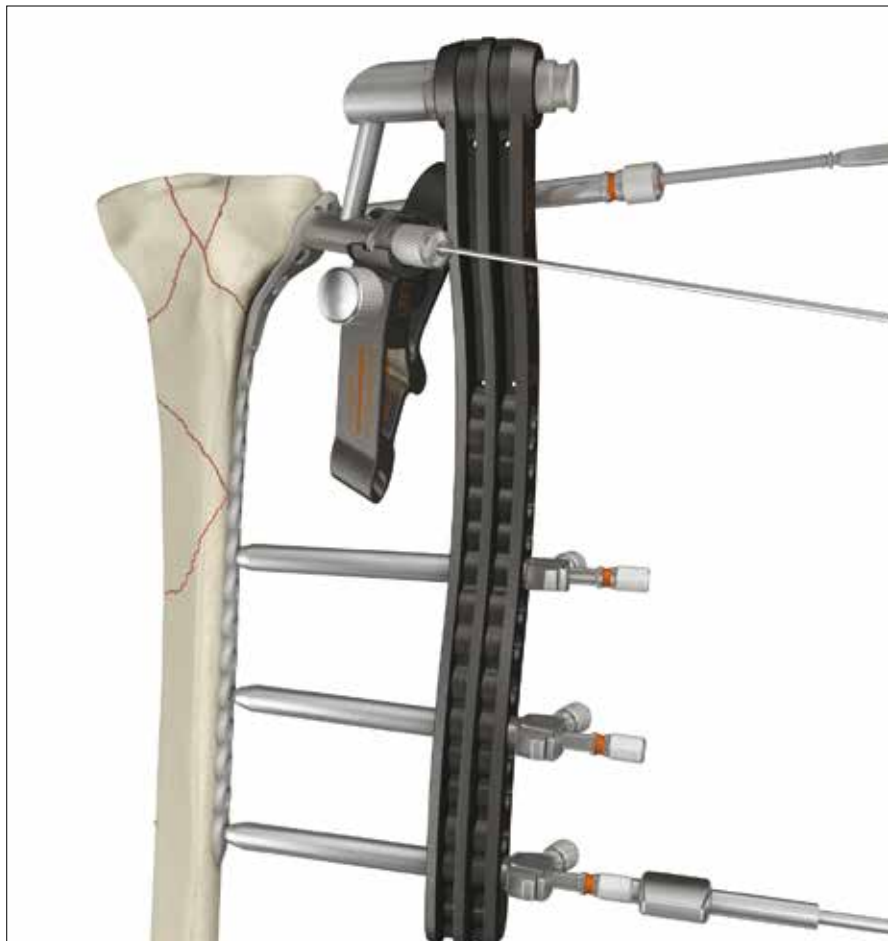


Fig. 13



Fig. 13A



# Operative Technique

Final tightening of Locking Screws should always be performed manually using the Torque Limiting Attachment (REF 702750) together with the Screwdriver Bit T15 (REF 703595) and the T-Handle (REF 702427) (Fig. 14).

The Torque Limiter helps prevent overtightening of Locking Screws, and also ensures that these screws are tightened to a torque of 4.0Nm. The device will click when the torque reaches 4.0Nm.

**Note:**

**The Torque Limiters require routine maintenance. Refer to the Instructions for Maintenance of Torque Limiters (V15020).**

If inserting Locking Screws under power, make sure to use a low speed drill setting to avoid damage to the screw / plate interface and potential heat necrosis.

Perform final tightening by hand, as described above.

Remove the K-Wire in the plate adaptor before inserting subsequent metaphyseal screws to avoid interference with the drill / screws.

The two remaining superior Locking Screws supporting the articular surface are inserted following the same technique with or without the use of K-Wires.

To ensure maximum stability, it is recommended that all locking holes are filled with a Locking Screw of the appropriate length.

However, it is recommended to place the lower Rafter Screw and the Kick-Stand screw after completion of the shaft fixation.



**Fig. 14**

# Operative Technique

## Step 6 – Shaft Fixation

### a) Standard Screws

**Standard cortical screws in the shaft must be placed prior to any Locking Screws.**

Mark the chosen standard shaft hole using the Tissue Protection Sleeve and make a small incision. Insert the Tissue Protection Sleeve (REF 703570) together with the Trocar with sharp tip (REF 703576) until the tip is in contact with the plate (Fig. 15).

Push the Tissue Protection Sleeve further until you hear a click, confirming that the sleeve has snapped into position (Fig. 16).

Remove the Trocar and replace it with the Drill Sleeve (REF 703572). Insert the Trocar Ø2.5mm (REF 703584) and manipulate the assembly into the plate hole. Lock the Drill Sleeve and remove the Trocar (Fig. 17).

The Calibrated Drill Ø2.5mm (REF 703586) is then used to drill the core hole for the Ø3.5mm cortical screw (Fig. 18).

Drill through both cortices for bi-cortical screw fixation. If lagging is desired, remove the drill guide after drilling the core hole, and over-drill the first cortex using the drill Ø3.5mm (REF 703590).

The screw length can be determined with a direct read off the calibration of the drill, or any other measurement option as described on page 6 can be used. Remove the Drill Sleeve. The appropriate size self-tapping cortical screw is inserted using the hex Screwdriver (REF 703592) or the Screwdriver Bit (REF 703593) should power insertion be desired (Fig. 19).

In hard cortical bone, it is recommended to use the Tap Ø3.5mm (REF 703588) before screw insertion. Repeat the same procedure for other chosen unthreaded shaft holes.



Fig. 15

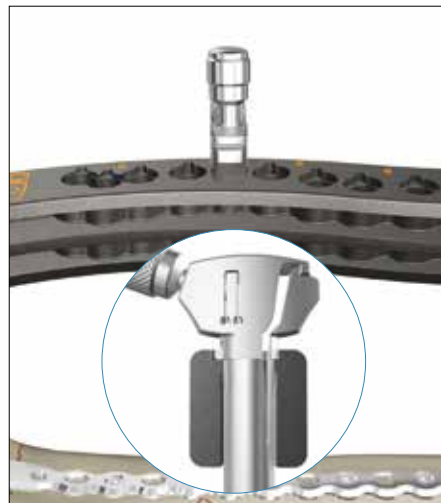


Fig. 16



Fig. 17



Fig. 18



Fig. 19



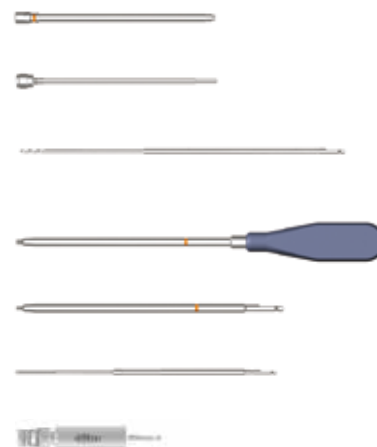
# Operative Technique

## b) Locking Screws

Ø4.0mm Locking Screws can be placed in the threaded shaft holes or holes with pre-placed Locking Inserts.

For the placement of these screws, follow the same procedure detailed in step a) Standard Screws. For Locking Screws use appropriate instrumentation listed:

- Drill Sleeve Ø3.1mm (REF 703571)
- Trocar Ø3.1mm (REF 703577)
- Calibrated Drill Ø3.1mm (REF 703585)
- Screwdriver T15 (REF 703594)
- Screwdriver Bit T15 (REF 703595)
- Tap Locking (REF 703574)
- 4Nm Torque Limiter (REF 702750)



Remove the Targeting Arm.

## Step 7 – Lower Rafter and Kick-Stand Screw Placement

Re-attach the Aiming Block and insert the necessary Sleeves to insert a Ø4.0mm Locking Screw in the remaining metaphyseal locking hole (See Step 5 for insertion guidelines).

The oblique "Kick-Stand" Locking Screw provides strong triangular fixation to the medial metaphyseal fragments. It is recommended to insert the Kick Stand Screw after completion of the shaft fixation.

It is advised to place this screw with the assistance of fluoroscopy to prevent joint penetration and impingement with other metaphyseal screws (Fig. 20).

Remove all Targeting Attachments. Final plate and screw positions are shown in figures 21–23.



Fig. 20



Fig. 21



Fig. 22

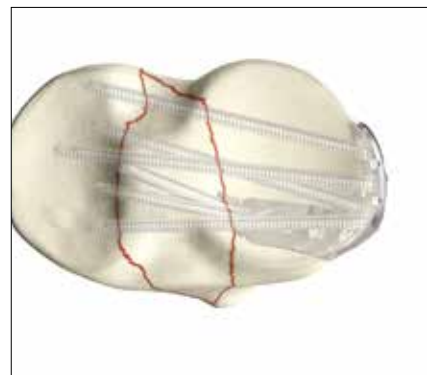


Fig. 23

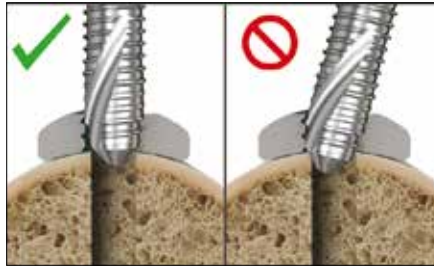
# Additional Tips

1. Always use the threaded Drill Sleeve when drilling for Locking Screws (threaded plate hole or Locking Insert).



Free hand drilling will lead to a misalignment of the Screw and therefore result in screw jamming during insertion. It is essential, to drill the core hole in the correct trajectory to facilitate accurate insertion of the Locking Screws.

2. Always start inserting the screw manually to ensure proper alignment in the plate thread and the core hole. It is recommended to start inserting the screw using “the three finger technique” on the Teardrop handle. Avoid any angulations or excessive force on the screwdriver, as this could cross-thread the screw.



If the Locking Screw thread does not immediately engage the plate thread, reverse the screw a few turns and re-insert the screw once it is properly aligned.

If power insertion is selected after manual start (see above), use low speed only, do not apply axial pressure, and never “push” the screw through the plate!

Allow the single, continuous threaded screw design to engage the plate and cut the thread in the bone on its own, as designed.

Stop power insertion approximately 1cm before engaging the screw head in the plate.



Power can negatively affect Screw insertion, if used improperly, damaging the screw/plate interface (screw jamming). This can lead to screw heads breaking or being stripped. Again, if the Locking Screw does not advance, reverse the screw a few turns, and realign it before you start re-insertion.

4. It is advisable to **tap hard** (dense) **cortical bone** before inserting a Locking Screw. Use Ø4.0mm Tap (REF 70272).



The spherical tip of the Tap precisely aligns the instrument in the predrilled core hole during thread cutting. This will facilitate subsequent screw placement.

5. Do not use power for final insertion of Locking Screws. It is imperative to engage the screw head into the plate using the Torque Limiting Attachment. Ensure that the screwdriver tip is fully seated in the screw head, but do not apply axial force during final tightening. If the screw stops short of final position, back up a few turns and advance the screw again (with torque limiter on).





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