stryker

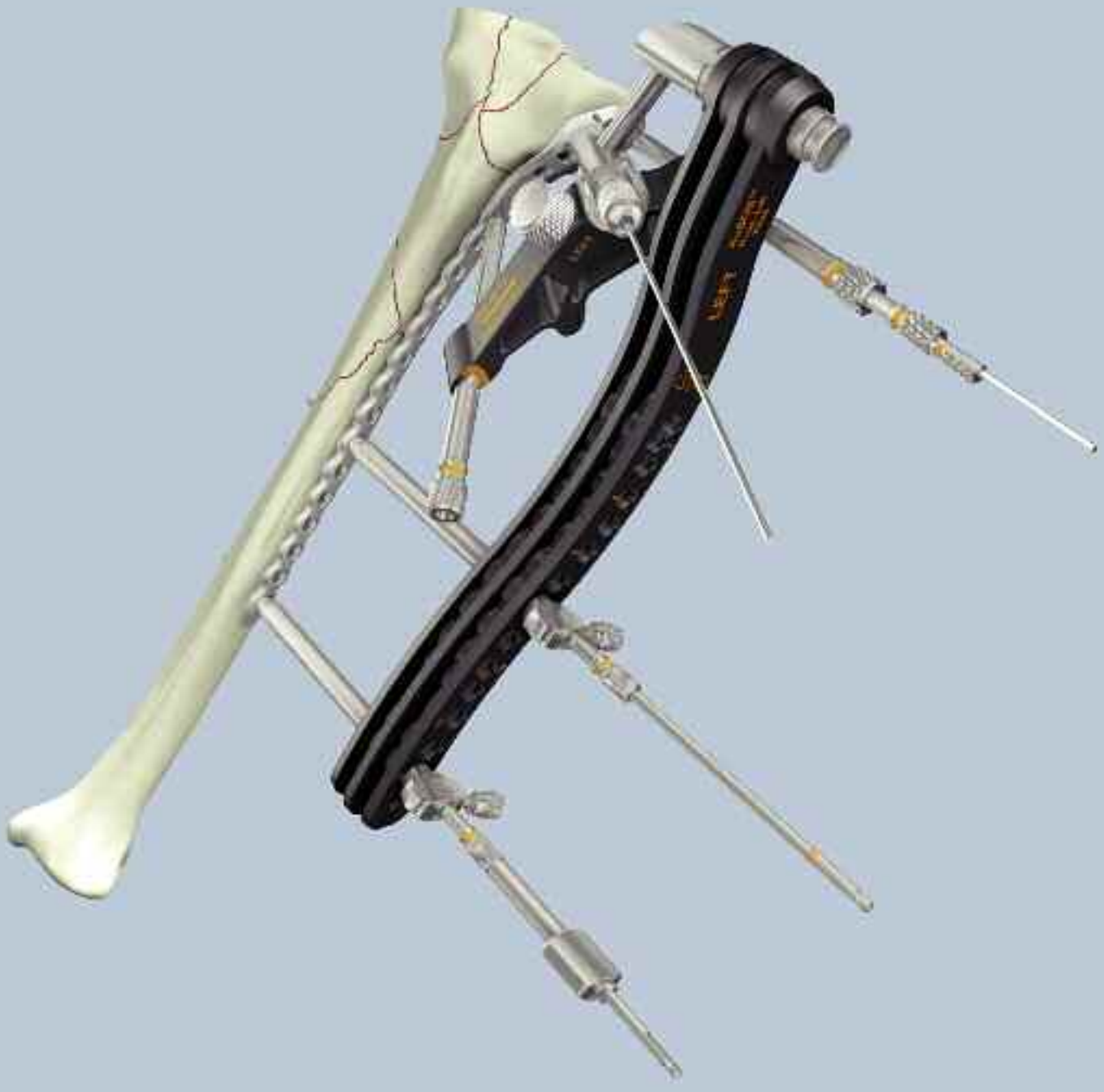
Osteosynthesis

AxSOS

Targeting System

Operative Technique

• Proximal Lateral Tibia



Introduction

The AxSOS Locking Plate System is designed to treat periarticular or intra-articular fractures of the Proximal Humerus, Distal Femur, Proximal Tibia and the Distal Tibia. The system design is based on clinical input from an international panel of experienced surgeons, data from literature, and both practical and biomechanical testing.

The anatomical shape, the fixed screw trajectory, and high surface quality take into account the current demands of clinical physicians for appropriate fixation, high fatigue strength, and minimal soft tissue damage. This Operative Technique contains a simple step-by-step procedure for the implantation of the Proximal Lateral Tibial Plate using the specially designed Targeting Device.

Features & Benefits

System

- The proximal Lateral Tibial Plate is designed with divergent fixed-angled screw trajectories in the metaphyseal region providing improved biomechanical stability. This helps prevent loss of reduction.

Instruments

- Simple technique, easy instrumentation with sufficient components.
- Designed for MIPO (Minimally Invasive Plate Osteosynthesis) technique using state of the art instrumentation.

Range

- Longer plates cover a wider range of fractures.

Unthreaded Free-Holes

- Freehand placement of screws.
- Lag Screw possibility.

5 Monoaxial Holes (metaphyseal)

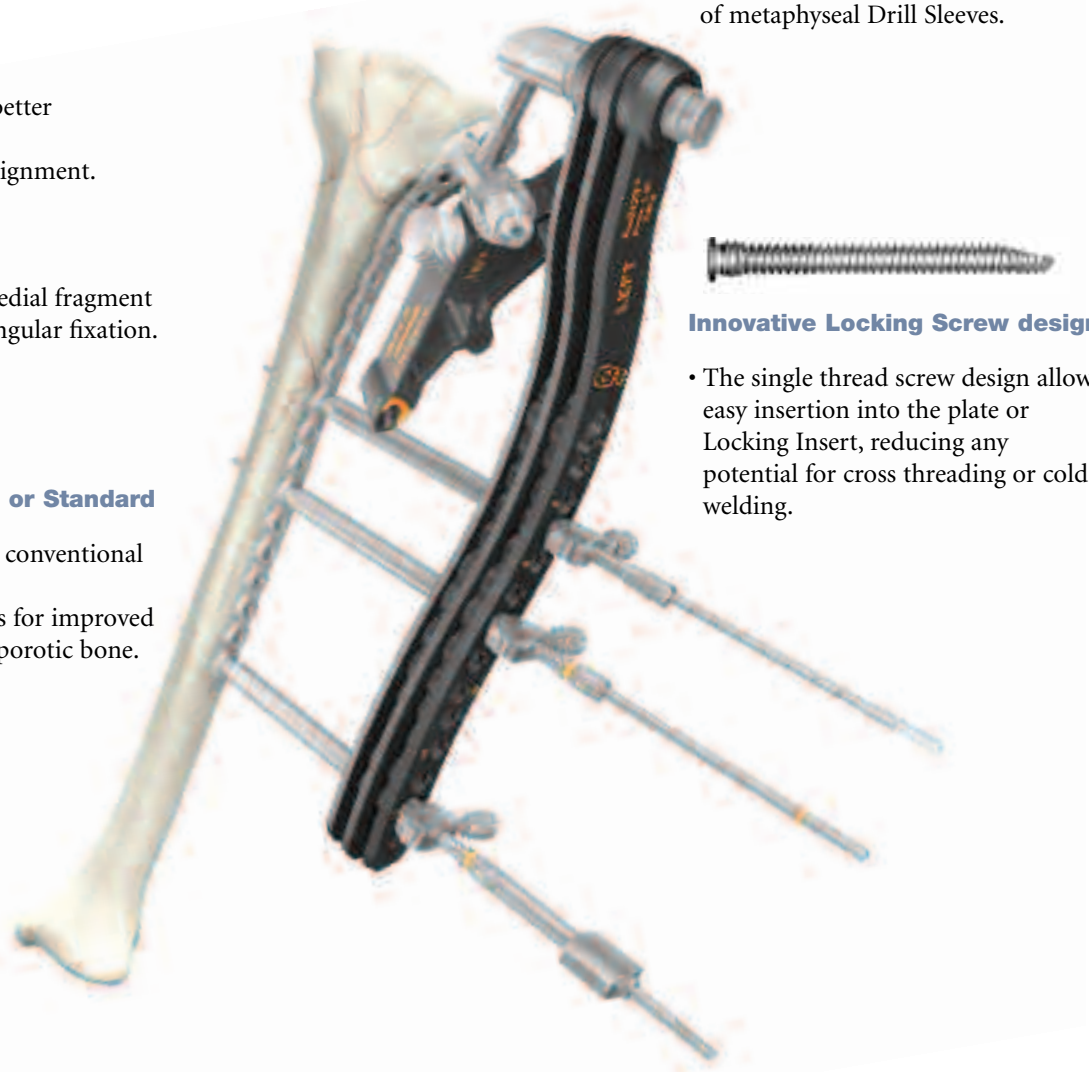
- Allow axially stable screw placement, bringing rigidity to the construct.

Aiming Block

- Radiolucent for optimized view of periarticular region during fluoroscopy control.
- Facilitates precise placement of metaphyseal Drill Sleeves.

Anatomically contoured

- No bending required.
- May reduce OR time.
- Facilitates/allows for better soft tissue coverage.
- Helps confirm axial alignment.



Kick-Stand Screw

- Aimed at posterior/medial fragment to provide strong triangular fixation.

Shaft Holes Locking or Standard

- Neutral fixation using conventional 3.5/4.0mm screws.
- Accept Locking Inserts for improved shaft fixation in osteoporotic bone.

Innovative Locking Screw design

- The single thread screw design allows easy insertion into the plate or Locking Insert, reducing any potential for cross threading or cold welding.

Rounded & Tapered Plate End

- Helps facilitate sliding of plates sub-muscularly.

Frame Fixator

- Creates a stable construct between the Targeting Arm and plate for exact screw targeting.

Targeting Arm

- Precise fit between targeting holes and sleeves for accurate screw placement.
- Radiolucent for unobstructed fluoroscopy control.
- Optimized view of periarticular region during fluoroscopy control.

Relative Indications & Contraindications

Relative Indication

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

Relative Contraindications

The physician's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment. The following contraindications may be of a relative or absolute nature, and must be taken into account by the attending surgeon:

- 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 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.

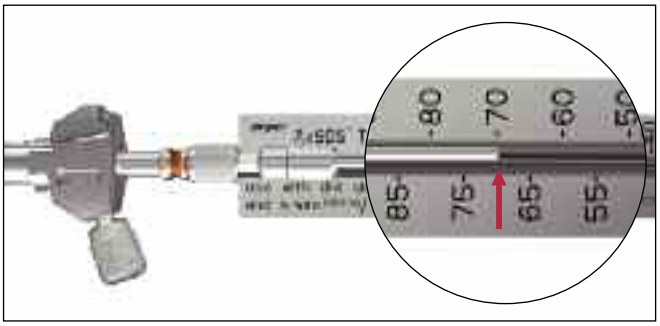
Correct Screw Selection

For metaphyseal fixation, select a screw approximately 2-3mm shorter than the measured length to avoid screw penetrations through the opposite cortex.

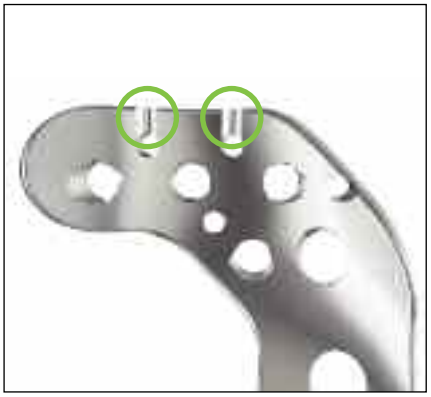
Add 2-3mm to measured length for optimal bi-cortical shaft fixation.

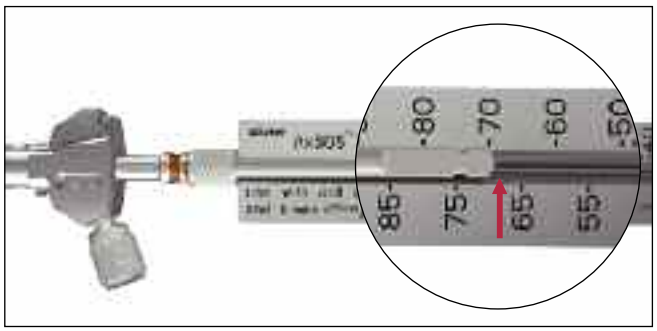
Soft-Tissue Re-attachment

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.

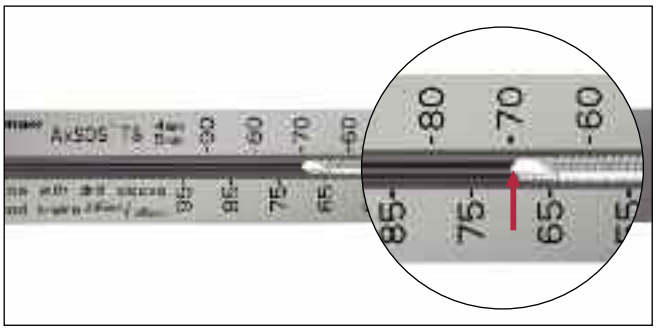


Measure off K-Wire

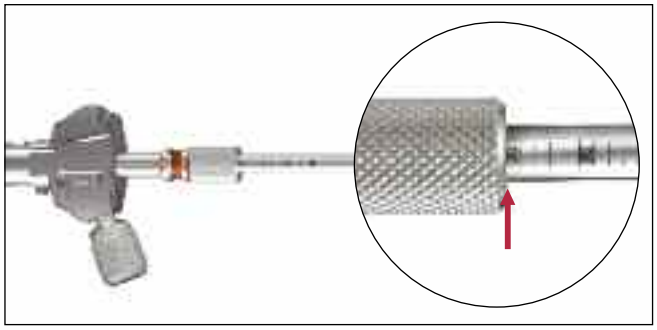




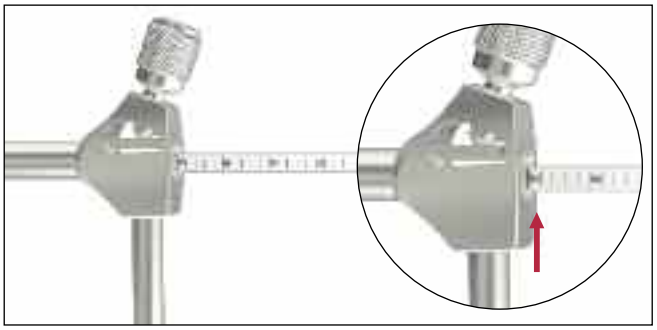
Measure off Drill



Screw Length Control



Read off Calibration



Measure off Measure Gauge

Operative Technique

Step 1 – Pre Operative Planning

Use of the X-Ray Template (REF 981091 REV.1) in association with fluoroscopy can assist in the selection of an appropriately sized implant (Fig. 1).

It is essential to insert a Locking Insert in the last shaft hole of the plate for a later distal fixation of the Targeting Arm ('close the box', details see page 11 Primary Plate Fixation).

If more Locking Screws are chosen for the plate shaft, pre-operative insertion of these Locking Inserts is also recommended.
A 4.0mm Locking Insert (REF 370002) is attached to the Locking Insert Inserter (REF 702762) and placed into the chosen hole(s) in the shaft portion of the plate (Fig. 2).

It is recommended to perform insertion on the back table with the inserter being transverse to the plate in both planes. Proper insertion is confirmed by a "click".

Once the Locking Insert is placed, remove the inserter. (Fig. 2A).

Do not place Locking Inserts with the threaded Drill Sleeve.

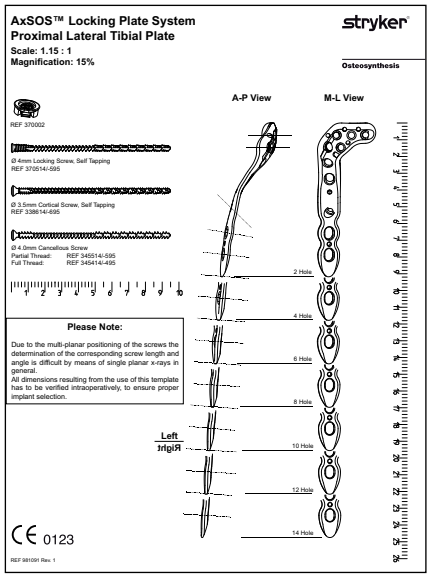


Fig. 1

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).
Discard the Locking Insert.

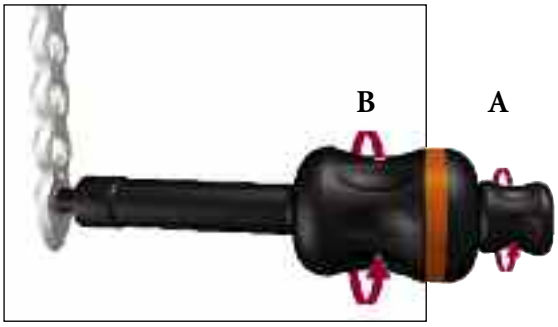


Fig. 2B

Fig. 2C

Operative Technique

Optional – Intra-Operative Locking Insert Application

If desired, a Locking Insert can be applied in a standard hole(s) in the shaft of the plate intra-operatively by using the Locking Insert Forceps (REF 702968), Centering Pin (REF 703621), Adaptor for Centering Pin (REF 702675) and Guide for Centering Pin (REF 703622).

Use the holes and markings on the Targeting Arm as a guide to locate the respective hole in the plate.

A small stab incision can then be made and the soft tissue separated using the Tissue Protection Sleeve (REF 703570) and the Trocar with sharp tip (REF 703576) to allow access to the selected plate hole.

Push the Tissue Protection Sleeve in the Targeting Arm until you hear a click, confirming that the Sleeve is locked into position. (Fig. A)

Insert the Guide for Centering Pin (REF 703622) until the tip is correctly seated in the plate hole. The two flat surfaces should be aligned with the plate shaft axis. It is important to use the guide as this centers the Guide pin precisely in the plate hole for correct placement of the Locking Insert.

The selfdrilling Centering Pin (REF 703621) is then inserted bi-cortically with the Adaptor (REF 702675) by power. (Fig. B)

Remove the Adaptor, the Soft Tissue Protection Sleeve and the Guide for Centering Pin. Next, place a Locking Insert (REF 370002) on the end of the Forceps (REF 702968) (Fig. C) and slide the instrument over the Centering Pin down into the plate hole.
The handle of the instrument should be perpendicular to the plate shaft axis in its final position.

Once the Locking insert is correctly seated in the plate hole (ensure that no soft tissues are trapped between Locking Insert and plate), apply the Locking Insert by triggering the Forceps handle.

Push the button on the Forceps to remove the Instrument. (Fig. D)
After insertion, remove the Centering Pin.

Fig. A

Fig. B

Fig. C

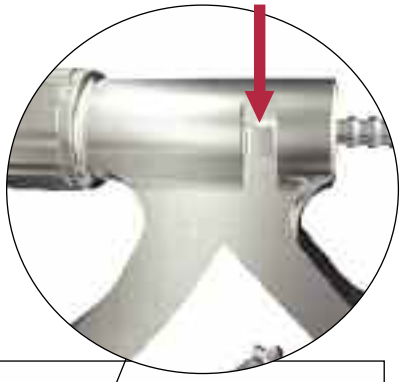


Fig. D

Operative Technique

Step 2 – Plate Preparation

Screw the Connecting Pin (REF 702974) to the plate using the hex Screwdriver 2.5/4.3mm (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. After correct engagement of the alignment teeth 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 the correct alignment of the Targeting Device and plate. Insert a Drill through the assembled Tissue Protection Sleeve and Drill Sleeve (REF's 703585, 703570 and 703571) into the Locking Insert in the most distal shaft 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).

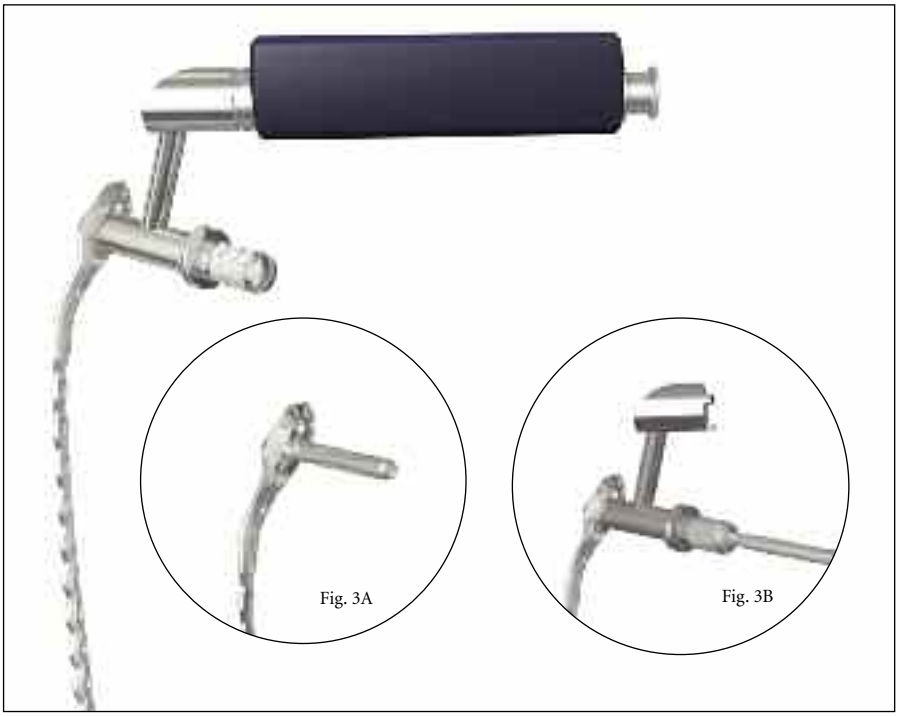


Fig. 3

Fig. 4

Step 3 – Submuscular Plate Application

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

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

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

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

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

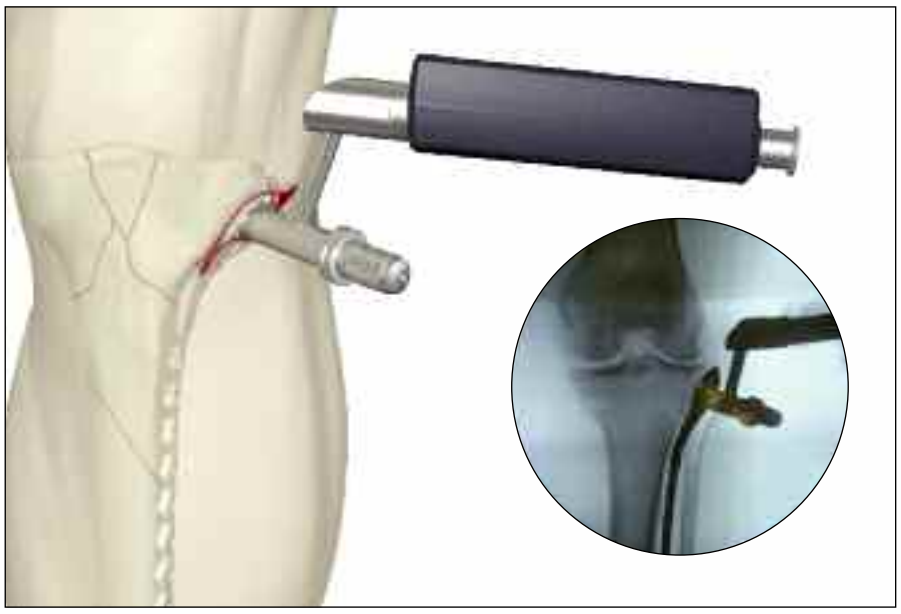


Fig. 5

Operative Technique

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

Note: A slightly extended distal shaft incision is recommended to visualize the superficial peroneal nerve.
In certain cases this nerve crosses the tibia in the proximity of the distal part of a 12 -14 hole plate.

Fig. 6

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). This, in addition to other independently placed K-Wires can help to support depressed articular surface fragments. Insertion of this K-Wire should be checked by fluoroscopy to avoid penetration into the articulating surface.

Remove the Handle for Insertion by pressing 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), the Drill Sleeve can be inserted into the most posterior hole of the metaphyseal plate part.

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 insert a 2.0 x 285mm K-Wire (REF 703583).

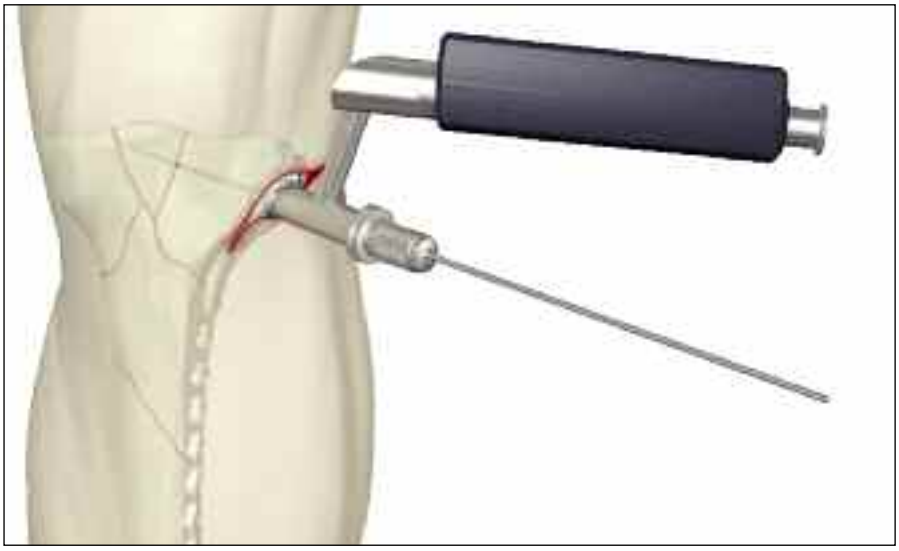


Fig. 7

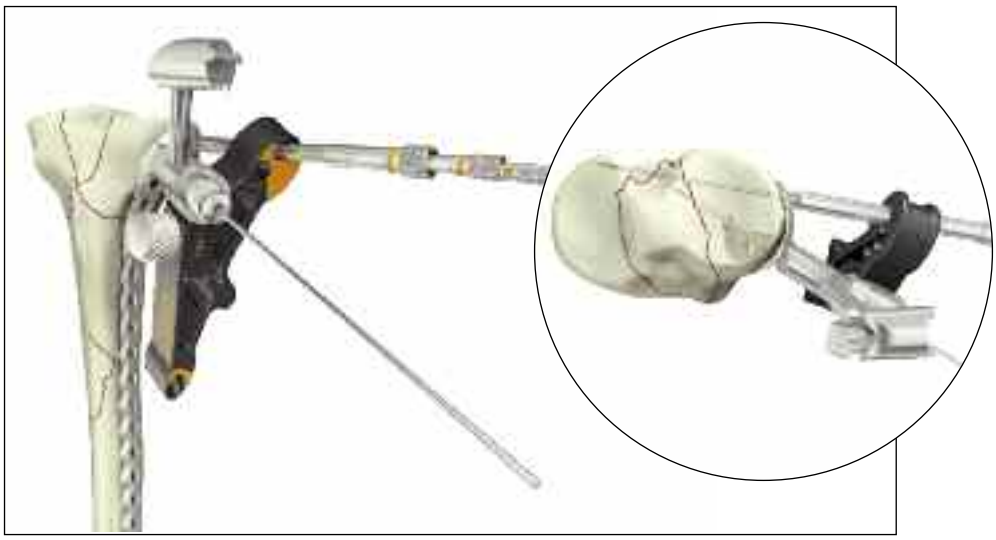


Fig. 8

The above step shows the position of a posterior screw, and its relation to the joint surface. Also, this will confirm that the screw is not intra-articularly placed, or too posterior exiting the cortex into the pupliteal space.

Using fluoroscopy, the position of this K-Wire can be checked until the optimal position (tip aiming at posterior medial plateau) is achieved and the plate is correctly positioned.

Operative Technique

Also correct distal placement should be re-confirmed with fluoroscopy at this point 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 cannot be achieved, the K-Wires should be removed, the plate re-adjusted and the above procedure repeated until both the posterior K-Wire and the plate are in the desired position.

Do not remove any K-Wires, as this could result in a loss of plate position.

The distal end of the plate must now be secured using the most distal hole of the shaft, with the pre-inserted Locking Insert.

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

Mark the skin above the most distal hole of the plate using the Tissue Protection Sleeve (REF 703570) with inserted Sleeve Fixation screw (REF 703591) 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 until the locking notches fully engage in the corresponding groove in the Targeting Arm (details see step 6 shaft fixation). Ensure that the sleeve fixation screw is orientated posteriorly as displayed on the Targeting Arm. This will securely lock the Tissue Protection Sleeve in the Targeting Arm.

Remove the sharp Trocar and replace it with a Drill Sleeve (REF 703571) and Trocar ø3.1mm (REF 703577) and manipulate the assembly into the thread of the Locking Insert. Ensure that the Drill Sleeve is fully engaged in the thread to create a stable construct between the Targeting Arm and the plate, providing sufficient stability for accurate drill/screw targeting.

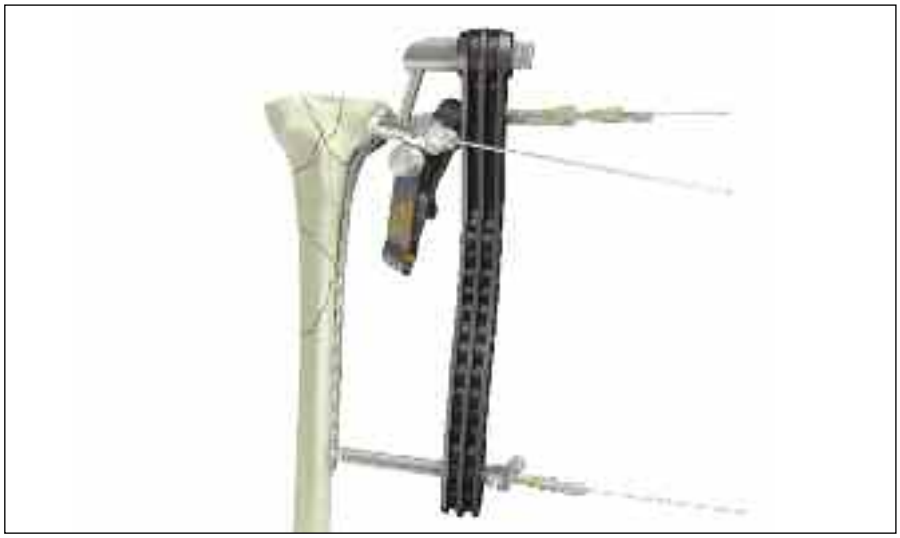


Fig. 9

Fig. 10

Secure the Drill Sleeve by tightening the Sleeve Fixation Screw. A 2.0x285mm K-Wire (REF 703583) can now be inserted using the K-Wire Sleeve (REF 703575) (Fig. 9).

Alternatively, the 3.1mm Calibrated Drill (REF 703585) can be inserted bi-cortically. Leave the Drill Bit in place for primary plate stabilization.

If desired, the plate can be pushed to the bone by using the Frame Fixator (REF 703573) instead of the drill or K-Wire. 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).

Use fluoroscopy to confirm bi-cortical purchase when necessary.
When inserting the pin by power, make sure to use a low-speed to avoid significant temperature increase which can lead to bone necrosis.
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).

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

Using plates with 8 holes or longer, it is recommended to insert an additional Tissue Protection/Drill Sleeve assembly in a pre-inserted Locking Insert placed in a more central position (holes 4 – 6). Do not lock the Drill Sleeve!
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).

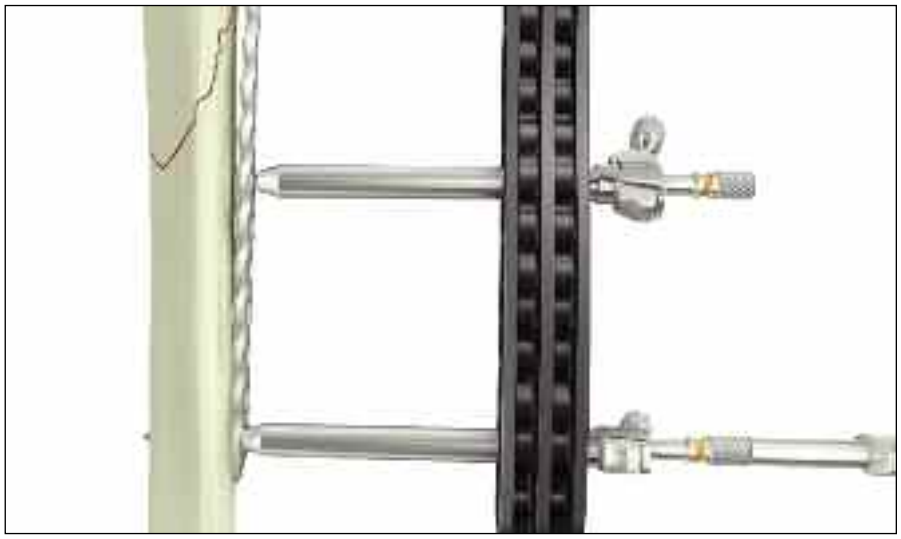


Fig. 11

Step 5 – Metaphyseal Fixation

Locking Screws cannot act as lag screws. Should an interfragmentary compression effect be required in metaphyseal fragments, a 3.5mm standard cortex screw or 4.0mm 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. Remove the sleeve assembly and the K-Wire in the posterior metaphyseal hole.
Disconnect and remove the Aiming Block.
Freehand placement of this screw(s) can now be performed using the free-hand Tissue Protection Sleeve (REF 702920) together with the Drill Sleeve ø2.5mm (REF 703572).
Use the Calibrated Drill ø2.5mm (REF 703586) and drill the core hole to the appropriate depth (Fig. 12).

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 using a fully threaded cortical screw.
A 3.5mm cortical screw can then be inserted through the Tissue Protection Sleeve. If inserting a 4.0mm cancellous screw, the near cortex should be pre-tapped using the Tap (REF 703589).
Care must always be taken, that these screws do not interfere with the Locking Screw trajectories.

Operative Technique

Locking Fixation of the metaphyseal portion of the plate can now be started. Re-attach and tighten the Aiming Block to the Plate Adaptor 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 3.1mm 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 can now be removed and the correct length 4.0mm Locking Screw is inserted using the screwdriver T15 (REF 703594). (Fig. 13)

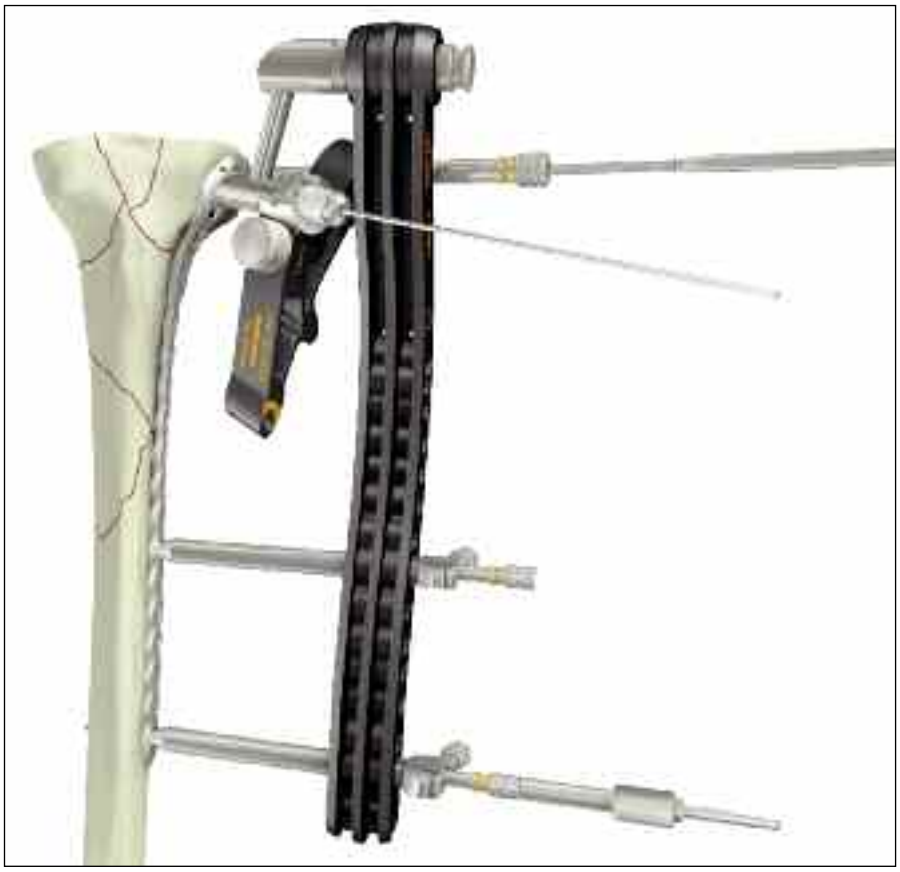


Fig. 13

The screw is near its final seating position when the groove around the shaft of the Screwdriver is approaching the end of the Tissue Protection Sleeve (Fig. 14).

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

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. 14

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. 15).

This helps prevent over-tightening 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 4Nm.

Note: The Torque Limiters require routine maintainance. Refer to the Instructions for Maintainance of Torque Limiters (V15020).

If inserting Locking Screws under power using the Screwdriver Bit (REF 703595), make sure to use a low speed drill setting to avoid damage to the screw/plate interface.
Perform initial insertion and final tightening by hand, as described before.

The remaining proximal Locking Screws are inserted following the same technique with or without the use of K-Wires.
Remove the K-Wire in the plate adaptor before inserting subsequent metaphyseal screws to avoid interference with the drill/screws.

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

It is recommended however to place the Kick-Stand screw after completion of the shaft fixation.

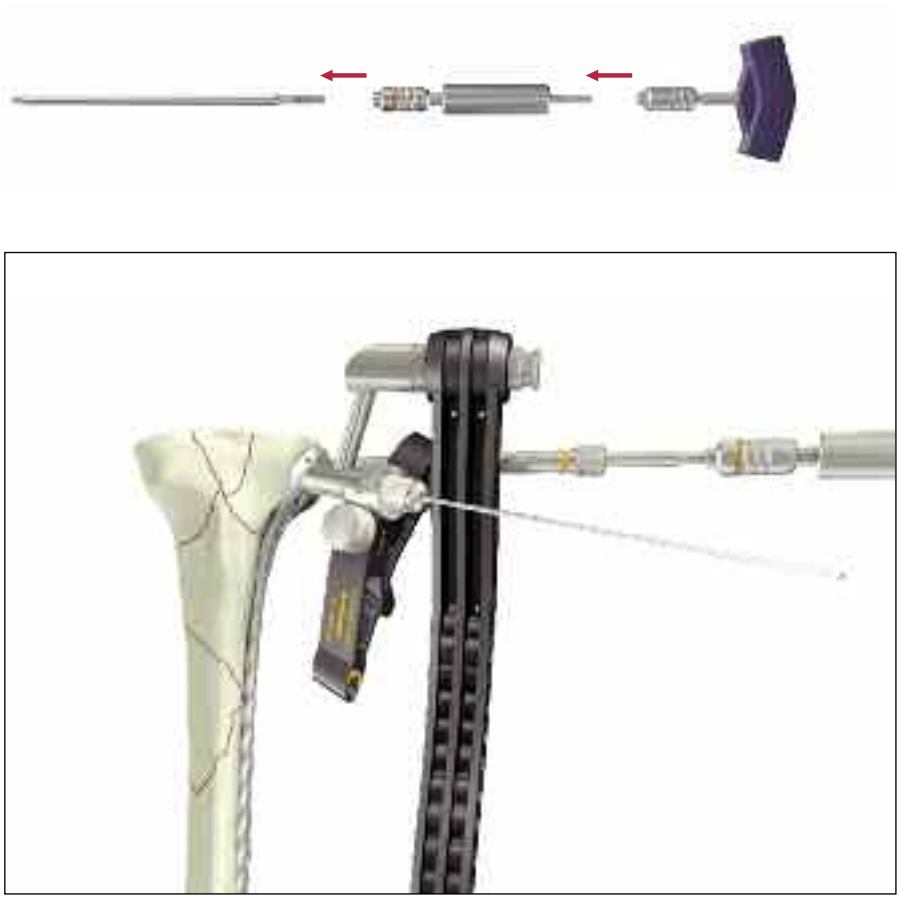


Fig. 15

Step 6 – Shaft Fixation

a) Standard Screws

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

Mark the skin above the chosen standard shaft hole using the Tissue Protection Sleeve (REF 703570) and make a small incision.
Insert the Tissue Protection Sleeve together with the Trocar with sharp tip (REF 703576) through the incision until the tip is in contact with the plate (Fig. 16).

Push the Tissue Protection Sleeve further until you hear a click, confirming that the sleeve has snapped into position (Fig. 17).

Remove the Trocar and replace it with the Drill Sleeve (REF 703572) and the Trocar ø2.5mm (REF 703584) and manipulate the assembly into the plate hole. Lock the Drill Sleeve and remove the Trocar (Fig. 18).

The Calibrated Drill ø2.5mm (REF 703586) is then used to drill the core hole for the 3.5mm cortical screw (Fig. 19).

Drill through both cortices for bi-cortical screw fixation.
If the screw is set in a lag function, remove the drill guide after core hole drilling 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) for power insertion (Fig. 20).

In hard cortical bone, it is advised to use the Tap ø3.5mm (REF 703588) before screw insertion. Repeat the same procedure for other chosen unlocked shaft holes.

Fig. 16

Fig. 17

Fig. 18

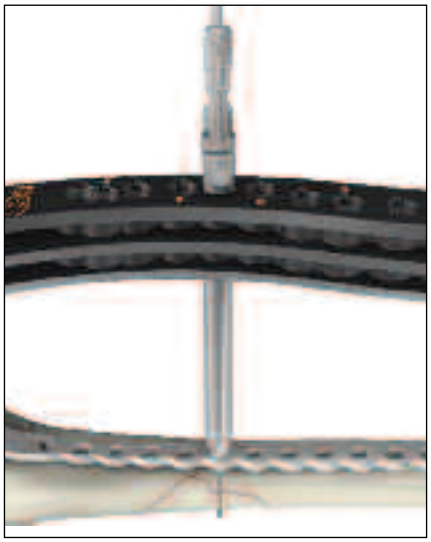


Fig. 19

Fig. 20

b) Locking Screws

4.0mm Locking Screws can be placed in holes with pre-placed Locking Inserts. For the placement of these screws, follow the same procedure detailed in step a) Standard Screws. However use the appropriate instruments for Locking Screws i.e.

- 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)

The Targeting Arm can now be removed.

Operative Technique

Step 7 – Kick-Stand Screw Placement

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

Re-attach the Aiming Block and insert the necessary Sleeves to insert a 4.0mm Locking Screw as described before (Fig. 21).

It is advised to place this screw with the assistance of fluoroscopy to prevent joint penetration and impingement with other metaphyseal Screws (See Step 5 for insertion guidelines).

All targeting attachments can now be removed.

Final plate and screw positions are shown in figures 22–24.

Fig. 21

Fig. 22

Fig. 23

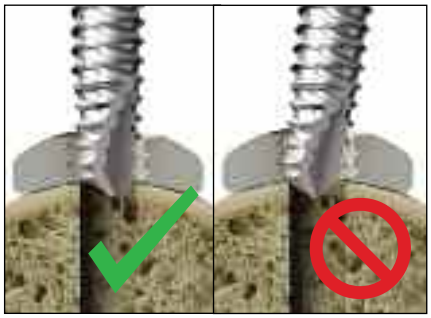
Fig. 24

Tips & Tricks

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.

3. 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.

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).

Tips & Tricks

6. It is advisable to follow these operative steps to perform final distal shaft fixation using Locked Screws in long plates.

Insert and provisionally secure the plate with a proximal K-wire through the cannulation of the plate adaptor as described in Step 4 of the Op-Technique.

Attach the Targeting Arm and fix the plate to the bone using the Frame Fixator in the most distal shaft hole with a Locking Insert. **Do not tighten the Frame Fixator.**

Insert an additional Tissue Protection Sleeve/Drill Sleeve assembly in a pre-inserted Locking Insert somewhere in middle of the plate shaft.
Do not lock the Drill Sleeve.

A nonlocking screw is inserted proximally and the Frame Fixator is tensioned distally to approximate the plate to the bone.

The metaphyseal Locking Screws can now be inserted.

Shaft fixation using **Standard cortical Screws** must now be performed prior to any Locking Screws.

Insertion of Locking Screws should then start in the proximal part of the shaft.

After final tightening of the last shaft Locking Screw using the Screwdriver Bit T15 and the Torque Limiter, leave the Screw Driver Bit in the Screw head (see picture).

Disconnect the Torque Limiter and the T-Handle and **lock the Screw Driver Bit in the Soft Tissue Protection Sleeve.**

Remove the Frame Fixator in the shaft end hole and **pre-drill the core hole** using the Drill ø3.1mm.

Insert the Locking Screw in the preset Locking Insert and remove all remaining instruments.

Ordering Information - Targeting Instruments

	REF	Description
	902845	Metal Tray Prox. Lat.Tibia Targeting Instruments with lid
	702974	Connecting Pin - Prox. Lat. Tibia
	703562	Plate Adapter - Prox. Lat. Tibia, left
	703563	Plate Adapter - Prox. Lat. Tibia, right
	702977	Adapter Nut - Prox. Lat. Tibia
	703564	Aiming Block - Prox. Lat. Tibia, left
	703565	Aiming Block - Prox. Lat. Tibia, right
	703597	Aiming Block Screw
	703566	Targeting Arm - Prox. Lat. Tibia, left
	703567	Targeting Arm - Prox. Lat. Tibia, right
	703568	Plate End Marker

Ordering Information - 4.0mm Instruments

	REF	Description
	902846	Metal Tray Instruments with lid
	703592	Screwdriver HEX 2.5/4.3mm
	703593	Screwdriver Bit HEX 2.5/4.3mm, small AO
	703594	Screwdriver T15
	703595	Screwdriver Bit T15, small AO
	703585	Calibrated Drill Bit ø3.1x285mm, small AO
	703586	Calibrated Drill Bit ø2.5x285mm, small AO
	703587	Screw Scale
	703573	Frame Fixator
	703570	Tissue Protection Sleeve, centric
	703591	Sleeve Fixation Screw
	703578	Tissue Protection Sleeve, Aiming Block
	703571	Drill Sleeve ø3.1mm
	703572	Drill Sleeve ø2.5mm
	703575	K-Wire Sleeve
	703577	Trocar ø3.1mm
	703584	Trocar ø2.5mm
	703576	Trocar sharp Tip
	703574	Tap 4.0mm Locking
	703583	K-Wire with Drill Tip ø2.0x285mm
	703579	Screw Measure Gauge
	703590	Drill ø3.5mm, small AO
	702978	Plate Insertion Handle
	702920	Tissue Protection Sleeve, free hand
	702750	4Nm Torque Limiter

Ordering Information - 4.0mm Instruments

	REF	Description
	702762	Locking Insert Inserter
	702767	Locking Insert Extractor
	702782	Soft Tissue Elevator
	702427	Small T-Handle, AO Coupling
		Other Instruments
	702755	Torque Tester with Adapters
	702755-2	T8/T15 Adapter
	702968	Locking Insert Forceps
	703621	Centering Pin
	702675	Adaptor for Centering Pin
	703622	Guide for Centering Pin
	703580	Screwdriver Hex 2.5mm, self retaining
	703581	Screwdriver T15, self retaining
	703588	Tap 3.5mm, cortical
	703589	Tap 4.0mm, cancellous

Ordering Information - Implants

PROXIMAL LATERAL TIBIA

Locking Screws Ø4.0mm
Standard Screws Ø3.5, 4.0mm

Stainless Steel REF		Plate Length	Shaft Holes	Locking Holes	Locking Holes
Left	Right	mm		Metaphyseal	Shaft
438302	438322	95	2	5	1
438304	438324	121	4	5	2
438306	438326	147	6	5	3
438308	438328	173	8	5	4
438310	438330	199	10	5	5
438312	438332	225	12	5	6
438314	438334	251	14	5	7

4.0MM LOCKING INSERT

Stainless Steel REF	System mm
370002	4.0

Note: For Sterile Implants, add 'S' to REF

Ordering Information - Implants

4.0MM LOCKING SCREW, SELF TAPPING
T15 DRIVE

Stainless Steel REF	Screw Length mm
370514	14
370516	16
370518	18
370520	20
370522	22
370524	24
370526	26
370528	28
370530	30
370532	32
370534	34
370536	36
370538	38
370540	40
370542	42
370544	44
370546	46
370548	48
370550	50
370555	55
370560	60
370565	65
370570	70
370575	75
370580	80
370585	85
370590	90
370595	95

4.0MM CANCELLOUS SCREW, PARTIAL THREAD
2.5MM HEX DRIVE

Stainless Steel REF	Screw Length mm
345514	14
345516	16
345518	18
345520	20
345522	22
345524	24
345526	26
345528	28
345530	30
345532	32
345534	34
345536	36
345538	38
345540	40
345545	45
345550	50
345555	55
345560	60
345565	65
345570	70
345575	75
345580	80
345585	85
345590	90
345595	95

3.5MM CORTICAL SCREW, SELF TAPPING
2.5MM HEX DRIVE

Stainless Steel REF	Screw Length mm
338614	14
338616	16
338618	18
338620	20
338622	22
338624	24
338626	26
338628	28
338630	30
338632	32
338634	34
338636	36
338638	38
338640	40
338642	42
338644	44
338646	46
338648	48
338650	50
338655	55
338660	60
338665	65
338670	70
338675	75
338680	80
338685	85
338690	90
338695	95

4.0MM CANCELLOUS SCREW, FULL THREAD
2.5MM HEX DRIVE

Stainless Steel REF	Screw Length mm
345414	14
345416	16
345418	18
345420	20
345422	22
345424	24
345426	26
345428	28
345430	30
345432	32
345434	34
345436	36
345438	38
345440	40
345445	45
345450	50
345455	55
345460	60
345465	65
345470	70
345475	75
345480	80
345485	85
345490	90
345495	95

Note: For Sterile Implants, add 'S' to REF

Additional Information

HydroSet Injectable HA

Indications

HydroSet is a self-setting calcium phosphate cement indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, craniofacial, spine, and pelvis). These defects may be surgically created or osseous defects created from traumatic injury to the bone. HydroSet is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure.

HydroSet cured in situ provides an open void/gap filler than can augment provisional hardware (e.g K-Wires, Plates, Screws) to help support bone fragments during the surgical procedure. The cured cement acts only as a temporary support media and is not intended to provide structural support during the healing process.

Tibia Plateau Void Filling

Note: Screw fixation must be provided by bone

Scanning Electron Microscope image of HydroSet™ material crystalline microstructure at 15000x magnification

HydroSet is an injectable, sculptable and fast-setting bone substitute. HydroSet is a calcium phosphate cement that converts to hydroxyapatite, the principle mineral component of bone. The crystalline structure and porosity of HydroSet makes it an effective osteoconductive and osteointegrative material, with excellent biocompatibility and mechanical properties[1]. HydroSet was specifically formulated to set in a wet field environment and exhibits outstanding wet-field characteristics.[2] The chemical reaction that occurs as HydroSet hardens does not release heat that could be potentially damaging to the surrounding tissue. Once set, HydroSet can be drilled and tapped to augment provisional hardware placement during the surgical procedure. After implantation, the HydroSet is remodelled over time at a rate that is dependent on the size of the defect and the average age and general health of the patient.

CE 1275

Advantages

Injectable or Manual Implantation

HydroSet can be easily implanted via simple injection or manual application techniques for a variety of applications.

Fast Setting

HydroSet has been specifically designed to set quickly once implanted under normal physiological conditions, potentially minimizing procedure time.

Isothermic

HydroSet does not release any heat as it sets, preventing potential thermal injury.

Excellent Wet-Field Characteristics

HydroSet is chemically formulated to set in a wet field environment eliminating the need to meticulously dry the operative site prior to implantation.[2]

Osteoconductive

The composition of hydroxyapitite closely match that of bone mineral thus imparting osteoconductive properties.[3]

Augmentation of Provisional Hardware during surgical procedure

HydroSet can be drilled and tapped to accommodate the placement of provisional hardware.

References
1. Chow, L, Takagi, L. A Natural Bone Cement – A Laboratory Novelty Led to the Development of Revolutionary New Biomaterials. J. Res. Natl. Stand. Technolo. 106, 1029-1033 (2001).
2. 1808.E703. Wet field set penetration (Data on file at Stryker)
3. Dickson, K.F., et al. The Use of BoneSource Hydroxyapatite Cement for Traumatic Metaphyseal Bone Void Filling. J Trauma 2002; 53:1103-1108.

Ordering Information

Ref	Description
397003	3cc HydroSet
397005	5cc HydroSet
397010	10cc HydroSet
397015	15cc HydroSet

Note: For more detailed information refer to Literature No. 90-07900

Notes

Notes

Notes

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Stryker Trauma AG
Bohnackerweg 1
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www.osteosynthesis.stryker.com

Literature Number: **982341**
LOT **A2308**

US Patents pending