AxSOS 3° Titanium
Monoaxial Locking Plate System

Operative Technique

- Distal Lateral Femur
- Universal Holes
- Targeting Instrumentation
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 (L24002000). 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.
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Indications

The AxSOS 3 Titanium Locking Plate System is intended for long bone fracture fixation. Indications include:
- Diaphyseal, metaphyseal, epiphyseal, extra- and intra-articular fractures
- Non-unions and malunions
- Normal and osteopenic bone
- Osteotomies

Precautions

Stryker Systems have not been evaluated for safety and compatibility in Magnetic Resonance (MR) environment and have not been tested for heating or migration in the MR environment, unless specified otherwise on the product labels and/or respective operative technique.

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 cannot 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.
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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.

Intended Use

The AxSOS 3 Titanium Locking Plate System is intended for long bone fracture fixation.
Operative Technique – General Guidelines

Patient Positioning:
Supine with option to flex the knee up to 60° over a leg support. Visualization of the distal femur under fluoroscopy in both the lateral and AP views is necessary.

Surgical Approach:
Standard lateral, modified lateral or lateral parapatellar approach.

Reduction
Anatomical reduction of the fracture should be performed either by direct visualization with the help of percutaneous clamps, or alternatively a bridging external fixator to aid with indirect reduction to correct the length, rotation, recurvatum and varus-valgus.
Fracture reduction of the articular surface should be confirmed by direct visualization, or fluoroscopy.
Use K-Wires and/or lag screws 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. Consideration must also 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 and is therefore not recommended. However, should additional bending of the plate be required (generally at the junction from the metaphysis to the shaft) the Table Plate Bender (REF 702900) should be used.
If for any reason the plate needs intraoperative contouring, it is recommended to perform shaft fixation using the conventional screw insertion technique without the use of the Targeting Device.

Note:
When using a sub-muscular technique, please refer to the relevant section on page 9.
Operative Technique – General Guidelines

Screw Measurement

Correct Screw Selection

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.

Select a screw approximately 2-3mm shorter than the measured length to avoid screw penetrations through the medial cortex in metaphyseal fixation.

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

Measurement Options

Measure off K-Wire

Measure off Calibration

Measure off Drill End

Screw Length Control
Operative Technique

Step 1 – Pre-Operative Planning

Use of the X-Ray Template (REF 981204) in association with X-Rays can assist in the selection of an appropriately sized implant (Fig. 1).

Fig. 1
Operative Technique

Step 2 – Plate Insertion Handle Assembly

Thread the Connection Pin (REF 703521) to the plate using the hex Screwdriver 3.5mm / 4.3mm (REF 703537) (Fig. 3A).

Connect the Adaptor Nut (REF 702977) to the Plate Adaptor (REF 703523 left / 703522 right) and slide the Plate Adaptor over the Connecting Pin with the connecting part for the Targeting Arm pointing to the anterior curvature of the plate. 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 temporarily apply the corresponding Targeting Arm to check the correct alignment of the Targeting Device and plate.

Insert a Drill (REF 703541) through the assembled Tissue Protection Sleeve and Drill Sleeve (REFs 703532, 703792) 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).
Operative Technique

Step 3 – Submuscular Plate Application

**Patient Position**

Place the patient in the supine position on a radiolucent table to allow visualization from knee to hip. One may need a small bump under the ipsilateral hip to correct the proximal leg external rotation. Use the leg elevator to provide leg support and knee flexion to allow fluoroscopy of the femur in both the AP and lateral views. Prep and drape the leg circumferentially extending proximal to the hip to allow proximal extension of the surgical incision if needed. A sterile tourniquet may be useful if treating a distal femur fracture.

**Surgical Approach**

Surgeon may use an anterolateral or lateral parapatellar approach, depending on the fracture pattern. (Surgical Exposures in Orthopaedics The Anatomic Approach, 4th ed., Hoppendfield et al.) Lateral / Anterolateral surgical approach is commonly used for OTA A, B, and “simple” C (C-1/C-2) fracture patterns. The skin incision starts at Gerdy’s tubercle and extends proximally to a direct lateral incision. The iliotibial band is incised in the same pattern. The joint capsule is then incised if intra-articular reduction needs to be performed or confirmed.

Lateral para-patellar surgical approach is used for OTA C fractures with significant intra-articular disruption. The skin incision starts just lateral to the tibial tuberosity and extends proximally on the lateral border of the patella. The incision can then traverse to a lateral position. A capsulotomy is performed at the lateral border of the patella and the patella mobilized medially to allow joint visualization.

The Soft Tissue Elevator (REF 702782) has been designed to create a pathway for the plate (Fig. 4). The plate has a special rounded and tapered end, which further allows for smooth insertion under the soft tissue.

After the appropriate surgical exposure, based on fracture pattern, is complete (lateral/anterolateral/lateral parapatellar as described above) obtain fracture reduction.

Fracture reduction, once obtained, can be held provisionally with K-Wires and/or reduction forceps. External fixation may also be utilized to help with axial, angular, and rotational control across the fracture. Confirm anatomic reduction of the articular surface via direct visualization, palpation, and/or fluoroscopy. (Skeletal Trauma, 2nd ed., Master Techniques in Orthopaedic Surgery: Fractures). Position the plate on the lateral surface of the femur by using the insertion handle to slide the plate proximally in a sub-muscular fashion. As you insert the plate, use the plate to feel the femur to confirm a direct lateral position, not anterior or posterior to the femoral shaft. Avoid plate insertion through the muscle to avoid intramuscular vessel disruption.

Avoid periosteal disruption while inserting the plate to help preserve bone blood supply. Prior to any screw fixation, confirm that the plate placement is correct. Confirm that the capsule edges and iliotibial band are not trapped under the plate, as these layers will need to be available for layered wound closure. Confirm that the plate is sub-muscular, not intra-muscular. The proper position is achieved when the distal and anterior margin of the plate is approx. 5-10mm from the articular surface (Fig. 5). This helps to ensure that the most distal locking screws are directly supporting the joint surface.

In addition, it is recommended to insert Plate End Markers (REF 703530) into the appropriate holes of the Targeting Arm before plate application. This will assist in locating the plate end and holes designated for locked fixation during the entire procedure (Fig. 6).
Operative Technique

Step 4 – Primary Plate Fixation

A K-Wire Ø2.0mm x 315mm (REF 703561) 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).

Precise alignment of the K-Wire can be achieved by using a K-Wire Sleeve (REF 703531) through the cannulation of the Plate Adaptor. For increased provisional plate fixation, it is also recommended to insert a K-Wire in one of the distal plate K-Wire holes.

This, in addition to other independently placed K-Wires can help to support articular surface fragments.

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 femur should be checked by fluoroscopy both on the A/P and lateral projections.

Attach the correct Aiming Block (REF 703527 left / 703526 right) to the Plate Adaptor (Fig. 8A). Ensure that the Aiming Block is properly seated on the Adaptor shaft by a 90° rotation on the Plate Adaptor and secured with the Aiming Block Screw (REF 703597) (Fig. 8B).

Using the Aiming Block Tissue Protection Sleeve (REF 703533) together with the Drill Sleeve (REF 703792) and the Trocar (REF 703524), the Drill Sleeve can now be inserted into either one of the two distal universal holes 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 703531) and insert a Ø2.0mm x 315mm K-Wire (REF 703561) (Fig. 8).

This wire should be parallel to the joint line to assure proper alignment of the distal femur. The K-Wire indicates the position of a later placed screw that shows its relation to the joint surface and also confirms the screw will not be placed intra-articularly.
Operative Technique

Correct proximal plate placement should also be re-confirmed at this point to make sure the plate shaft is properly aligned over the lateral surface of the femoral shaft. If the distal 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 distal K-Wires and the plate are in the desired position.

Do not remove K-Wires as a loss of plate position could result. The proximal end of the plate must now be secured using the most proximal hole of the shaft.

Attach the correct targeting arm to the plate adaptor. The Right targeting arm (REF 703528) is used for the right leg and the Left targeting arm (REF 703529) is used for the left leg.

Mark the skin at the most proximal shaft hole using the Tissue Protection Sleeve (REF 703532) and make a small incision. Insert the Trocar with sharp tip (REF 703525) into the Tissue Protection Sleeve (REF 703532) and manipulate the assembly through the Targeting Arm and the stab incision until the tip of the Trocar is in contact with the plate.

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. Remove the Trocar.

A Ø2.0mm x 315mm K-Wire (REF 703561) can now be inserted using the K-Wire Sleeve (REF 703531) (Fig. 9).

Alternatively, the Ø4.3mm Calibrated Drill (REF 703541) can be inserted bi-cortically. Leave the Drill Bit in place for primary proximal plate stabilization (Fig. 9).
Operative Technique

If desired, the plate can be pushed to the bone by using the Frame Fixator (REF 703545) instead of the drill or K-Wire.

Remove the flat butterfly-nut of the fixator. The self-drilling, self-tapping tip of the Frame Fixator pin should be inserted bi-cortically through the Drill Sleeve (REF 703792) (Fig. 10).

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.

Unlock the Drill Sleeve by loosening the Sleeve Fixation Screw, and re-attach the flat butterfly-nut over the threaded part of the pin and turn the nut until the plate is in the desired position on the bone. (Fig. 11).

Note:
When using plates with 10 holes or longer, it is recommended to insert one or two additional Tissue Protection / Drill Sleeve (REF 703532 / REF 703792) assemblies in holes in the middle positions of the plate shaft.

This will help to compensate for plate deformity that might occur using standard cortical screws to push the plate against the bone. (Do not use the Sleeve Fixation Screw (REF 703591) to fix the locking drill sleeve to the tissue protection sleeve.) This will allow the sleeve and the plate to contour to the bone without compromising the accuracy of the locking screws (Fig. 12).
Step 5 – Metaphyseal Plate Fixation

Locking screws cannot act as lag screws. Should an interfragmentary compression effect be required for metaphyseal fragments, a partially threaded Ø6.0mm cancellous screw must first be placed in any of the metaphyseal plate holes prior to the placement of any locking screws.

Freehand placement of this screw(s) can be performed using the Freehand Tissue Protection Sleeve (REF 703546) together with the Drill Sleeve Ø3.2mm (REF 703535) (Fig. 13).

It is recommended to use the most posterior metaphyseal hole (second screw row) by placing the Freehand Tissue Protection Sleeve in the recess (see arrow) at the posterior aspect of the Aiming Block (Fig. 13A). This screw trajectory helps to avoid interference with any of the later inserted Screws in the metaphysis.

Use the Calibrated Drill Ø3.2mm (REF 703542) and drill the core hole to the appropriate depth.

It is recommended to drill under fluoroscopy control to avoid interference with preset K-Wires. Manipulate the K-Wires as necessary.

The screw length may be directly read off the Calibrated Drill or using the Screw Scale (REF 703587) as described under Measurement Options on page 6.

Over-drill the first cortex using the Cortical Opener Ø4.5mm (REF 703543) through the Tissue Protection Sleeve.

The screw can then be inserted through the Tissue Protection Sleeve using the screwdriver T20 (REF 703539) or screwdriver bit T20 (REF 703540).

Additional non-locked screws can be inserted in any metaphyseal holes using the same technique through the guiding holes in the Aiming Block.

When using the Aiming Block (REF 703527 Left/703526 Right) the Tissue Protection Sleeve (REF 703533), the Drill Sleeve (REF 703535) and the Calibrated Drill Ø3.2mm (REF 703542) should be used.

Ø4.5mm cortical screws can be used alternatively.

Care must be taken that these screws do not interfere with the given locking screw trajectories. The usage of the aiming block will aid in preventing screw collision.
Locking Fixation of the metaphyseal portion of the plate can now be started in the remaining plate holes. Remove the preset K-Wire and K-Wire Sleeve in the posterior plate hole.

Using the calibrated Drill Bit Ø4.3mm (REF 703541) together with the Soft Tissue Protection Sleeve (REF 703533) and the Drill Sleeve (REF 703792) drill the core hole for the locking screw.

Stop drilling once the drill tip touches the medial cortex to ensure that the screw tip will not protrude.

It is recommended to use multiple fluoroscopic views which may be necessary to ensure proper location and depth of the drill.

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.

The drill and the drill sleeve should now be removed and the correct length of the Ø5.0mm locking screw is inserted using the screwdriver T20 (REF 703539), or screwdriver bit T20 (REF 703540) (Fig. 14).

The screw is near its final seating position when the blue marking around the shaft of the Screwdriver approaches the end of the Tissue Protection Sleeve (Fig. 14A). 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 inserting locking screws under power, make sure to use a low speed drill setting to avoid damage to the screw / plate interface and bone necrosis
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Final tightening of Locking Screws should always be performed manually using the Torque Limiter (REF 702750) together with the Screwdriver Bit T20 (REF 703540) and the T-Handle (REF 702430) (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 the appropriate tightening torque (4.0Nm).

**Note:**
The Torque Limiters require routine maintenance. Refer to the Instructions For Use of Torque Limiters (REF V15020).

The remaining metaphyseal locking screws are inserted following the same technique.

To ensure maximum stability, it is recommended that all six metaphyseal Universal holes are filled with locking screws of the appropriate length (Fig 16).

The targeter attachment hole accepts only non-locking screws.

**Note:**
In the extreme event of broken or stripped screws, the Stryker implant extraction set (Literature number LIES-OT) includes a variety of removal instruments.
Step 6 – Shaft Fixation

a) Standard Screws

Standard non-locked cortical screws in the shaft must be placed prior to any locking screws.

Mark the chosen shaft hole using the Tissue Protection Sleeve and make a small incision. Insert the Tissue Protection Sleeve (REF 703532) together with the Trocar with sharp tip (REF 703525) until the tip is in contact with the plate (Fig. 17).

Push the Tissue Protection Sleeve further until you hear a click, confirming that the sleeve has snapped into position (Fig. 18). Remove the Trocar with sharp tip and replace it with the Drill Sleeve (REF 703535). Insert the Trocar Ø3.2mm (REF 703536) and manipulate the assembly into the plate hole. Lock the Drill Sleeve with the Sleeve Fixation Screw (REF 703591) and remove the Trocar (Fig. 19).

The Calibrated Drill Ø3.2mm (REF 703542) is then used to drill the core hole for the Ø4.5mm cortical screw (Fig. 20).

Drill through both cortices for bi-cortical screw fixation. The screw length can be determined with a direct read off the calibration of the core drill, or any other measurement option as described on page 6.

If the screw is set in a lag function, remove the Drill Sleeve after core hole drilling and over-drill the first cortex using the Cortical Opener Ø4.5mm (REF 703543).

The appropriate size of the cortical screw is inserted using the T20 Screwdriver (REF 703539) or the Screwdriver Bit (REF 703540) for power insertion (Fig. 21).

In hard cortical bone, it is advised to use the Cortical Tap Ø4.5mm (REF 703551) before screw insertion. Repeat the same procedure for other chosen non-locked shaft holes.
Operative Technique

b) Locking Screws

Ø5.0mm locking screws can be placed in any shaft hole except the oval hole and the most proximal metaphyseal hole at the junction from the metaphysis to the shaft part. For the placement of these screws, follow the same procedure detailed in step 6a) above with the appropriate instrumentation for locking screws, outlined as follows:

- Drill Sleeve Ø4.3mm (REF 703792)
- Trocar Ø4.3mm (REF 703524)
- Calibrated Drill Ø4.3mm (REF 703541)
- Screwdriver T20 (REF 703539)
- Screwdriver Bit T20 (REF 703540)
- Tap Ø5mm Locking (REF 703554)
- 4.0Nm Torque Limiter, AO Fitting (REF 702750)

Note:
If an uncommonly thick cortex is identified during preoperative planning, pre-tap both cortices using the Tap for Locking Screws (REF 703554) before screw insertion. If power tapping is selected, use low speed only and do not apply axial pressure on the power tool.

Final plate and screw positions are shown in Figures 22-24.

Fig. 22

Fig. 23

Fig. 24
Additional Tips

1. Always use the threaded Drill Sleeve when drilling for Locking Screws.

Free hand drilling will lead to a misalignment of the screw and therefore may result in screw jamming during final insertion. It is essential to drill the core hole in the correct trajectory to facilitate accurate insertion of the locking screws.

2. It is recommended that screw insertion be performed using the Soft Tissue Protection Sleeve to ensure proper screw alignment in the core hole.

Freehand screw placement may result to a misalignment of the threads in the screw/plate interface during final insertion resulting in screw jamming.

3. If power insertion is selected use low speed only, do not apply axial pressure, and never push the screw through the plate!

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

Power can negatively affect final screw insertion, and if used improperly, can damage the screw/plate interface (screw jamming). This can lead to screw head breaking or stripping or may result in damaging or breakage of the screw driver blade.

4. It is advisable to tap hard (dense) cortical bone before inserting a Locking Screw.

Use Ø5.0mm Tap (REF 703554).

The spherical tip of the Tap precisely aligns the instrument in the pre-drilled 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 Limiter. 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).

Freehand drilling will lead to a misalignment of the screw and therefore may result in screw jamming during final insertion. It is essential to drill the core hole in the correct trajectory to facilitate accurate insertion of the locking screws.

Freehand screw placement may result to a misalignment of the threads in the screw/plate interface during final insertion resulting in screw jamming.

Power can negatively affect final screw insertion, and if used improperly, can damage the screw/plate interface (screw jamming). This can lead to screw head breaking or stripping or may result in damaging or breakage of the screw driver blade.

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