AxSOS 3® Titanium
Monoaxial Locking Plate System

Operative Technique
• Distal Lateral Femur
• Universal Holes
• ORIF 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 performing your 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 (Instruction for Use) V15011, V15020 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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Introduction

The AxSOS 3 Titanium Locking Plate System is intended for long bone fracture fixation.

The AxSOS 3 Titanium design concept draws upon the broad clinical expertise of an international panel of surgeons who assisted with the development, testing and validation of the AxSOS system.

The system allows for the use of locking and non-locking screws in the metaphysis and the shaft. This hybrid fixation concept allows the surgeon to stabilize any fracture by use of the lag screw technique through the plate, or locking screws to allow for adequate stability in comminuted, unstable metaphyseal fractures.

This operative technique contains a simple step-by-step procedure for the implantation of the Distal Lateral Femur Plate using the ORIF instrumentation.
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
- Periprosthetic fractures of the femur and proximal tibia

Precautions

Stryker systems have not been evaluated for safety and compatibility in MR environment and have not been tested for heating or migration in the MR environment, unless specified otherwise in the product labeling.

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

Intended Use

The AxSOS 3 Titanium Locking Plate System is intended for long bone fracture fixation.

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

See instructions for use 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.
Operative Technique

Step 1 – Pre–Operative Planning

Use of the X-Ray Template (REF 981204) or E-Template in association with fluoroscopy can assist in the selection of an appropriately sized implant.

Note:
For conventional templates the scale is 1:1.15 which usually matches with analogous X-Rays. If digital X-Ray images are used correct magnification has to be verified prior to use.
Operative Technique – Patient Preparation

Step 2 – Patient Preparation

**Patient Positioning:**
Supine with option to flex the knee up to 60° over a leg support. Visualisation 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 then be checked by fluoroscopy or direct visualisation. 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.

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 screw trajectories.

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

**Note:**
Distal Femur Plates of the Axsos 3 Titanium system can be inserted in a minimally invasive technique with targeting instrumentation. Please refer to the specific Targeting Operative Technique available from your Stryker Representative.
Step 3 – Aiming Block/Plate Insertion Handle Assembly

In order to help facilitate drill sleeve insertion as well as plate handle attachment to the plate, the aiming block may be used.

Attach the appropriate Aiming Block (Right REF 705067/Left REF 705068) to the plate by hand. If desired, the Handle for Plate Insertion (REF 702778) can now be attached to help facilitate plate positioning and sliding of longer plates sub-muscularly (Fig. 1).
Operative Technique

Step 4 – Plate Application

After the appropriate surgical exposure, based on fracture pattern, is complete (lateral/anterolateral/lateral para-patellar as described above) obtain fracture reduction. Fracture reduction, once obtained, can be held provisionally with K-Wires 2.0 x 150mm (REF 390192) or K-Wires 2.0 x 234mm (REF 705002) 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, 2nd ed.)

Bending

In most cases, anatomically pre-contoured plates will fit without the need for further bending. However, should additional bending of the plate be required the Table Plate Bender (REF 702900) should be used.

Note:

Bending of the plate in the region of the universal holes may affect the ability to correctly seat the locking screws into the plate and is therefore not permitted. Do not over-bend the plate or bend back and forth as this may weaken the plate.

Plate Positioning

Position the plate on the lateral surface of the femur by using the Handle for Plate Insertion (REF 702778) 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 intra-muscular vessel disruption. Avoid periosteal disruption while inserting the plate to help preserve bone blood supply.

Prior to any screw fixation, confirm that 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 plate is in the proper position when the distal and anterior margin of the plate is approximately 5-10mm from the articular surface (Fig. 2, 3).

Depending on the position and angulation of the image intensifier relative to the plate vs. the bone the correct placement of the plate can vary on the picture on the screen. It is recommended to check with a true medial-lateral on plate for the 5-10mm approximate distance from the joint surface (Fig. 2, 3, 4).

This helps to ensure that the most distal locking screws are directly supporting the joint surface.

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In most cases, anatomically pre-contoured plates will fit without the need for further bending. However, should additional bending of the plate be required the Table Plate Bender (REF 702900) should be used.

Note:

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Plate Positioning

Position the plate on the lateral surface of the femur by using the Handle for Plate Insertion (REF 702778) 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 intra-muscular vessel disruption. Avoid periosteal disruption while inserting the plate to help preserve bone blood supply.

Prior to any screw fixation, confirm that 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 plate is in the proper position when the distal and anterior margin of the plate is approximately 5-10mm from the articular surface (Fig. 2, 3).

Depending on the position and angulation of the image intensifier relative to the plate vs. the bone the correct placement of the plate can vary on the picture on the screen. It is recommended to check with a true medial-lateral on plate for the 5-10mm approximate distance from the joint surface (Fig. 2, 3, 4).

This helps to ensure that the most distal locking screws are directly supporting the joint surface.

Bending

In most cases, anatomically pre-contoured plates will fit without the need for further bending. However, should additional bending of the plate be required the Table Plate Bender (REF 702900) should be used.

Note:

Bending of the plate in the region of the universal holes may affect the ability to correctly seat the locking screws into the plate and is therefore not permitted. Do not over-bend the plate or bend back and forth as this may weaken the plate.

Plate Positioning

Position the plate on the lateral surface of the femur by using the Handle for Plate Insertion (REF 702778) 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 intra-muscular vessel disruption. Avoid periosteal disruption while inserting the plate to help preserve bone blood supply.

Prior to any screw fixation, confirm that 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 plate is in the proper position when the distal and anterior margin of the plate is approximately 5-10mm from the articular surface (Fig. 2, 3).

Depending on the position and angulation of the image intensifier relative to the plate vs. the bone the correct placement of the plate can vary on the picture on the screen. It is recommended to check with a true medial-lateral on plate for the 5-10mm approximate distance from the joint surface (Fig. 2, 3, 4).

This helps to ensure that the most distal locking screws are directly supporting the joint surface.

Bending

In most cases, anatomically pre-contoured plates will fit without the need for further bending. However, should additional bending of the plate be required the Table Plate Bender (REF 702900) should be used.

Note:

Bending of the plate in the region of the universal holes may affect the ability to correctly seat the locking screws into the plate and is therefore not permitted. Do not over-bend the plate or bend back and forth as this may weaken the plate.

Plate Positioning

Position the plate on the lateral surface of the femur by using the Handle for Plate Insertion (REF 702778) 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 intra-muscular vessel disruption. Avoid periosteal disruption while inserting the plate to help preserve bone blood supply.

Prior to any screw fixation, confirm that 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 plate is in the proper position when the distal and anterior margin of the plate is approximately 5-10mm from the articular surface (Fig. 2, 3).

Depending on the position and angulation of the image intensifier relative to the plate vs. the bone the correct placement of the plate can vary on the picture on the screen. It is recommended to check with a true medial-lateral on plate for the 5-10mm approximate distance from the joint surface (Fig. 2, 3, 4).

This helps to ensure that the most distal locking screws are directly supporting the joint surface.
Step 5 – Primary Plate Fixation – Distal

The K-Wire holes in the metaphyseal part of the plate allow for temporary plate fixation to the articular block (Fig. 5).

Using the K-Wire Sleeve (REF 705041) in conjunction with the Drill Sleeve (REF 705076 or REF 705042), a 2.0 x 234mm K-Wire (REF 705002) can now be inserted into one of the distal locking screw holes (Fig. 6). This step shows the position of the locking screw in relation to the joint and the intercondylar notch, and confirms the screw will not be placed intra-articularly.

This wire should be parallel to the joint line to assure proper alignment of the distal femur. Using fluoroscopy, the position of this K-Wire can be checked to ensure correct plate positioning. Correct proximal 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 (Fig. 7).

If the distal and axial alignment of the plate cannot be achieved, the K-Wire should be removed, the plate readjusted, and the above procedure repeated until both the K-Wire and the plate are in the desired position.

Additional 2.0 x 234mm K-Wires (REF 705002) can be inserted in the K-Wire holes around the universal holes to further help secure the plate to the bone and also support depressed areas in fragments of the articular surface.

Do not remove the drill sleeve and K-Wire sleeve at this point as it will cause a loss of the plate position or reduction.

Remove the Handle for Plate Insertion (REF 702778) by pushing the metal lever on top of the handle sideward.
Operative Technique

Step 6 – Primary Plate Fixation – Proximal

The proximal end of the plate can now be secured. This can be achieved through one of four methods:

- A K-Wire inserted in a K-Wire hole
- A 4.5mm cortex screw using the standard technique
- A K-Wire can be inserted in a universal hole through the K-Wire/Drill Sleeve assembly
- The Temporary Plate Fixator (REF 705019) in a universal hole

In addition to providing temporary fixation, the Temporary Plate Fixator pushes the plate to the bone. Also, it has a self-drilling, self-tapping tip for quick insertion into cortical bone (Fig. 8).

In order to protect surrounding soft tissues during pin insertion, the Temporary Plate Fixator Sleeve must be pre-assembled onto the Temporary Plate Fixator Pin with the self-drilling tip of the pin being flush with the tip of the Sleeve as shown on Figure 8.

The insertion of the Temporary Plate Fixator Pin must be done through the Sleeve to prevent tissue damage, especially when used in a MIPO approach.

To help prevent thermal necrosis during the drilling stage, it is recommended that the Temporary Plate Fixator Pin is inserted by hand.

Once the device is inserted through the far cortex, the threaded outer sleeve is turned clockwise until the plate is in contact with the bone (Fig.11).

Replacing the Temporary Plate Fixator with locking or non-locking screws for definitive fixation is not recommended as proper alignment of the Temporary Plate Fixator pin may not be guaranteed.

If placing a screw should be required for final fixation, pre-drilling the hole using the appropriate drill guide as described by the following cortex, cancellous, and locking screw fixation guidelines is required.
Operative Technique

Step 7 – Cortex Screw Fixation

Take the Drill Guide for Non-Locking Screws (REF 705036) together with the Ø3.2mm Drill Bit (REF 705032) and drill through both cortices for bi-cortical screw fixation (Fig. 12).

The correct screw length can be determined by using the Blue Depth Gauge (REF 705014) or by reading off of the drill. See page 13 for details.

To set the screw in a lag function, over-drill the first cortex using the Cortical Opener Ø4.5mm (REF 700354) and the Ø4.5mm corresponding end of the Double Drill Guide (REF 705037). Then insert the opposite Ø3.2mm end of the double drill guide into the predrilled hole. Drill through the second cortex using the Ø3.2mm Drill Bit (REF 705032).

The appropriate cortex screw is inserted using the T20 Screwdriver (REF 705021) or the Screwdriver Bit (REF 705020).

In hard cortical bone, it is advised to use the Cortical Tap Ø4.5mm (REF 702806) before screw insertion.

Step 8 – Cancellous Screw Fixation

Take the Drill Guide for Non-Locking Screws (REF 705036) together with the Ø3.2mm Drill Bit (REF 705032) and drill through both cortices in case bi-cortical screw fixation is performed.

To set the partially threaded cancellous screw in a lag function, over-drill the first cortex using the Cortical Opener Ø4.5mm (REF 705006) and the Ø4.5mm corresponding end of the Double Drill Guide (REF 705037). Then insert the opposite Ø3.2mm end of the double drill guide into the predrilled hole. Drill through the second cortex using the Ø3.2mm Drill Bit (REF 705032). The appropriate cancellous screw is inserted using the T20 Screwdriver (REF 705021) or the Screwdriver Bit (REF 705020) for power insertion.

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<tr>
<th>REF</th>
<th>Description</th>
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<tr>
<td>705036</td>
<td>Drill Guide for Non-Locking Screws Ø3.2mm</td>
</tr>
<tr>
<td>705037</td>
<td>Double Drill Guide Ø4.5/3.2mm</td>
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Operative Technique

Correct Screw Selection

Appropriate screw length selection is important for the stability of the fixation. Measurements follow the principle of "what you read is what you get". This means that the measured value in millimeters on the Blue Depth Gauge or the Drill Bit is the exact value of the screw to be selected. In case a self-tapping screw is intended to be positioned bi-cortically make sure the tip is slightly sticking out on the far cortex (1-3mm) in order to allow for good cortical purchase.

Step 9 – Locking Screw Fixation

Always lag before you lock. The plate fixation should always begin with non-locking screws prior to the placement of any locking screws. Use the Drill Sleeve (REF 705042 Short, REF 705076 Medium) together with a 4.3mm Drill Bit (REF 705043 Short, REF 705078 Medium) to pre-drill the core hole for subsequent locking screw placement. Medium size sleeves and drill bits show 2 blue color lines, short sleeves and drill bits show 1 line. Blue color represents the color code for the 5.0mm Locking System.

All instruments with a blue color ring are to be used for preparation of monoaxial locking screw placement. The locking screw length can then be measured using one of the two options illustrated below (Fig. 13, 14).

Note:
When using the “read off drill bit calibration” measurement option, always make sure to use the drill and sleeve with the corresponding number of color rings (Fig. 14).

Measurement Options

Conventional direct measurement.

Read off the drill bit with scale.

Fig. 13

Fig. 14
Operative Technique

The appropriately sized locking screw is then inserted using either the Screwdriver T20 (REF 705021) (Fig. 15) or the Screwdriver Bit T20 (REF 705020) with a selected handle (Teardrop Handle Small (REF 702429) or the T-Handle (REF 702430)). If inserting locking screws under power, make sure to use a low speed drill setting to avoid potential thermal necrosis.

Always perform final tightening by hand using the torque limiter (REF 702750) in combination with a Screwdriver Bit T20 (REF 705020) and T-Handle (REF 702430) (Fig. 16, 17). This helps to prevent over-tightening of locking screws, and also ensures that these screws are tightened to a torque of 4Nm. The device will click when the torque reaches 4Nm. Ensure that the screwdriver tip is fully seated in the screw head, and do not angulate the screwdriver. In the extreme event of broken or stripped screws, the Stryker Implant Extraction Set (Literature number LIES-OT) includes a variety of broken screw removal instruments.

The torque limiters require routine maintenance. Refer to the instructions for maintenance of torque limiters (V15020).
Step 10 – Metaphyseal Fixation

Locking screws cannot act as lag screws. Should an interfragmentary compression effect be required in cases of intracondylar splits, non-locking screws must be placed prior to the placement of any locking screws.

Consideration must be taken when positioning non-locking screws to ensure that they do not interfere with the given locking screw trajectories (Fig. 19, 20). Those trajectories may be visualized using K-Wires (REF 705002) inserted through a K-Wire Locking Drill Sleeve assembly (REF 705041 in REF 705042) (Fig. 19).

Note:
The targeter attachment hole (A) and the metaphyseal non-locking hole (B) do not allow locking screw fixation. They accept non-locking screws only (Fig. 18).
Operative Technique

Step 11 – Shaft Fixation

The universal shaft holes of the AxSOS 3 Titanium distal femoral plates have been designed to accept either 4.5mm cortex, 6.0mm cancellous or 5.0mm locking screws (Fig. 21). Detailed instructions are described in the cortex, cancellous, and locking screw fixation sections.

Note:
If a combination of non-locking and locking screws are used in the shaft, the plate fixation should begin with non-locking screws prior to the placement of any locking screws. Always lag before you lock.

Final plate and screw positions are shown in Figures 22-23.
Additional Tips

1. **Always use the threaded drill sleeve when drilling for locking screws.**

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

2. **It is best to insert the screw manually** to ensure proper alignment in the core hole which aligns the screws so it locks properly after being fully advanced. It is recommended to start inserting the screw using “the three finger technique” on the teardrop handle.

   Locking screws should be aligned perpendicular to the plate/hole. If the locking screw head does not immediately engage the plate thread, reverse the screw and re-insert it once it is properly aligned.

3. **Use low speed only and do not apply axial pressure if power screw insertion is selected.** 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.

4. **It is advisable to tap hard (dense) cortical bone before inserting a locking screw.** Use 5.0mm Tap (REF 702773).

   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 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 positioning, back up and advance the screw again (with torque limiter on).
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