stryker®

Trauma & Extremities

AxSOS 3® Titanium
Locking Plate System

Humerus Fractures

Operative Technique

- Proximal Lateral Humerus
- 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 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 Instructions for Use (90-03200,90-01953, 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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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 developed, tested and validated the AxSOS system.

This hybrid fixation concept is designed to allow the surgeon to stabilize fractures by use of the lag screw technique through the plate, or locking screws to allow for adequate stability to comminuted, unstable fractures.

This Operative Technique contains a step-by-step procedure for Open Reduction Internal Fixation (ORIF) implantation of the AxSOS 3 Proximal Lateral Humerus plate.

Product Details

Screw Types

4.0mm Cancellous Full Thread Screw

4.0mm Cancellous Partial Thread Screw

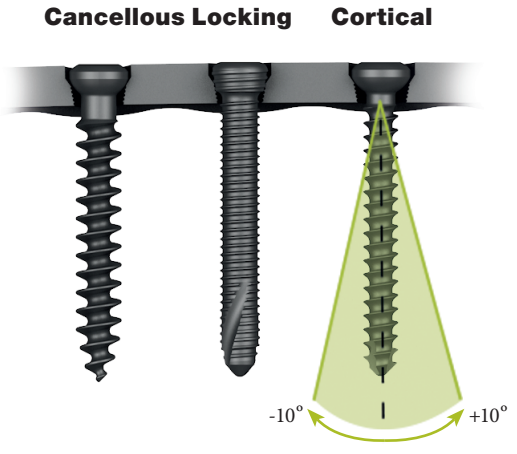
3.5mm Cortex Shaft Screw

3.5mm Cortex Screw

4.0mm Locking Screw

Screwdriver interface
T15 for all screws
(locking and non-locking)

Material
Anodized type II titanium alloy (Ti6Al4V)



The universal holes allow the use of locking and non-locking screws except for the oblong and freedom/unthreaded holes, which accept non-locking screws only.

Indications, Precautions & Contraindications

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

Intended Use

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

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.

See instruction 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

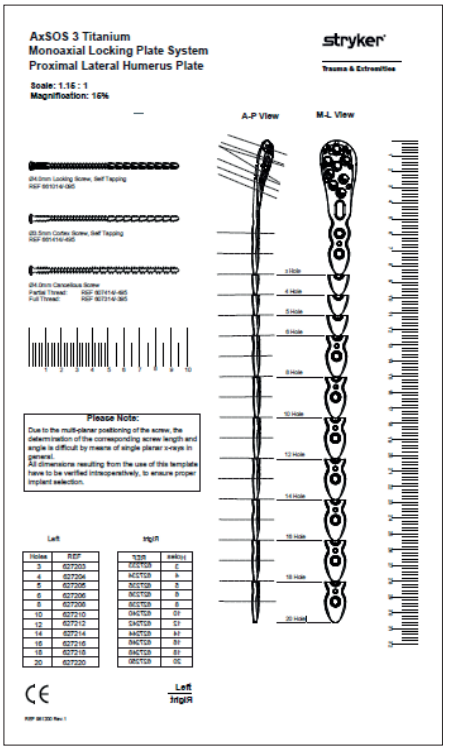
Pre-operative Planning

Use of the X-Ray Template or E-Templates can assist in the selection of an appropriately sized implant.

- REF 981200 – Proximal Lateral Humerus

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

Patient Positioning - Beach Chair positioning on a radiolucent table allowing for free movement of the shoulder joint and the affected arm

Surgical Approaches - **Deltopectoral Approach**

The deltopectoral incision is the standard approach allowing for plate fixation of proximal humerus fractures

- **Double Incision Approach***

An alternative is to perform an additional incision for better visualization of the greater tuberosity and rotator cuff

This approach offers without extensive incision length:

- **Direct deltopectoral view on the fracture site**

  On the humeral head, if desired

  On the lesser tuberosity allowing for suture placement

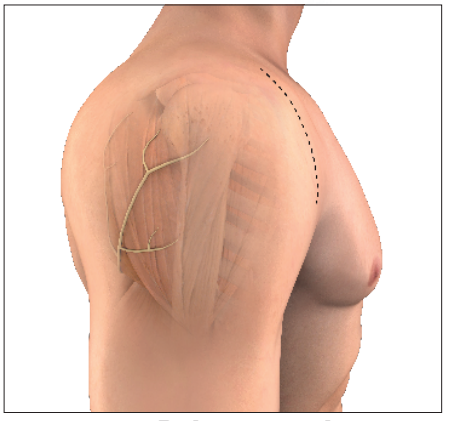
- **Direct lateral view on the greater tuberosity and the rotator cuff allowing for suture placement, simultaneous rotator cuff repair and allowing for additional Neer's acromioplasty to avoid, if necessary, subacromial impingement of the plate**

  Insertion of the plate and fixation of the humeral head screws via the lateral incision, control of the distal plate positioning and insertion of the distal screws via the deltopectoral incision.

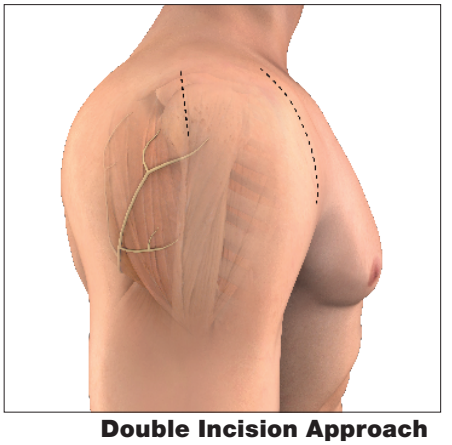
  Due to the large distance between the two incisions there is no increased risk for soft tissue necrosis.

Note:

When making the lateral incision, care must be taken not to damage the axillary nerve.



Deltopectoral Approach



Double Incision Approach

The 2 incisions are carefully marked before the procedure. A standard deltopectoral incision line is drawn first, while a longitudinal lateral incision line is placed at the posterior border of the humeral head. The 2 incisions are parallel and separated by roughly 10cm.

*Gallo RA, Zeiders GJ, Altman GT. Two-incision technique for treatment of complex proximal humerus fractures. J Orthop Trauma. 2005 Nov- Dec;19(10):734-40.

Operative Technique

Reduction

In the first step, a gross reduction of the fragments should be achieved by indirect reduction maneuvers or direct fragment reduction using elevators, retractors, or K-Wires as joysticks.

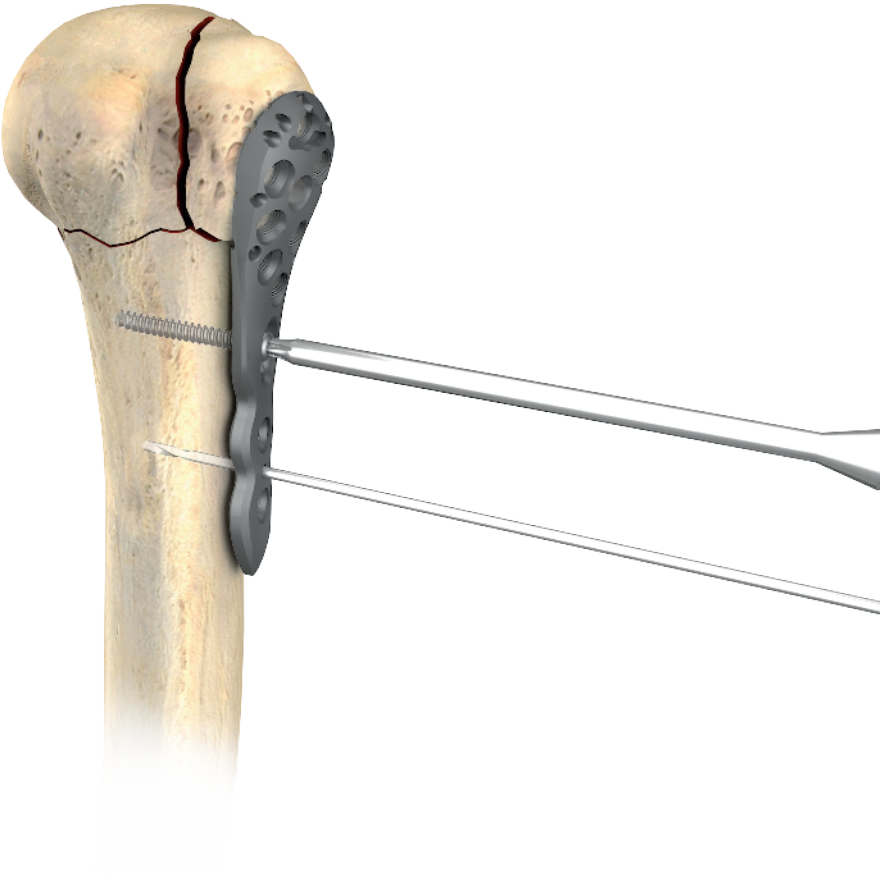
Note:

Care has to be taken to avoid additional injury of the surrounding soft tissue structures that may affect the blood supply of the bone fragments.

Initial Plate Fixation

When an almost correct reduction of the fragments is achieved and verified by fluoroscopy, the plate is positioned to the bone laterally to the intertubercular sulcus, whereby the superior rim of the plate should be placed approximately 10mm below the superior aspect of the greater tuberosity in order to minimize the risk of subacromial impingement.

For preliminary fixation of the plate, a non-locking 3.5mm cortex screw is inserted in the oblong hole and a K-Wire is inserted in the most distal K-Wire hole in the plate to align the plate with the bone axis.

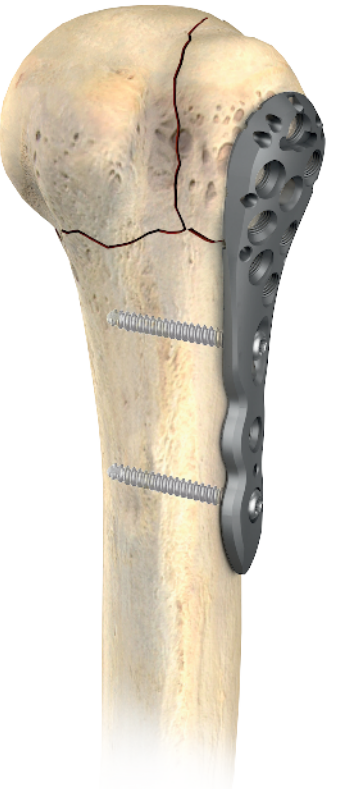


Operative Technique

With the preliminary fixed plate in position, fine reduction of the head fragment and the greater tuberosity is performed using the proximal portion of the anatomically pre-shaped plate as support. Correct fragment reduction and the plate positioning have to be verified by fluoroscopy.

If required, the plate position can be slightly adapted by removal of the distal K-Wire and shifting of the plate along the oblong hole.

After final plate positioning, the alignment of the plate to the humeral shaft is secured by insertion of a second 3.5mm cortex screw distally to the oblong hole.

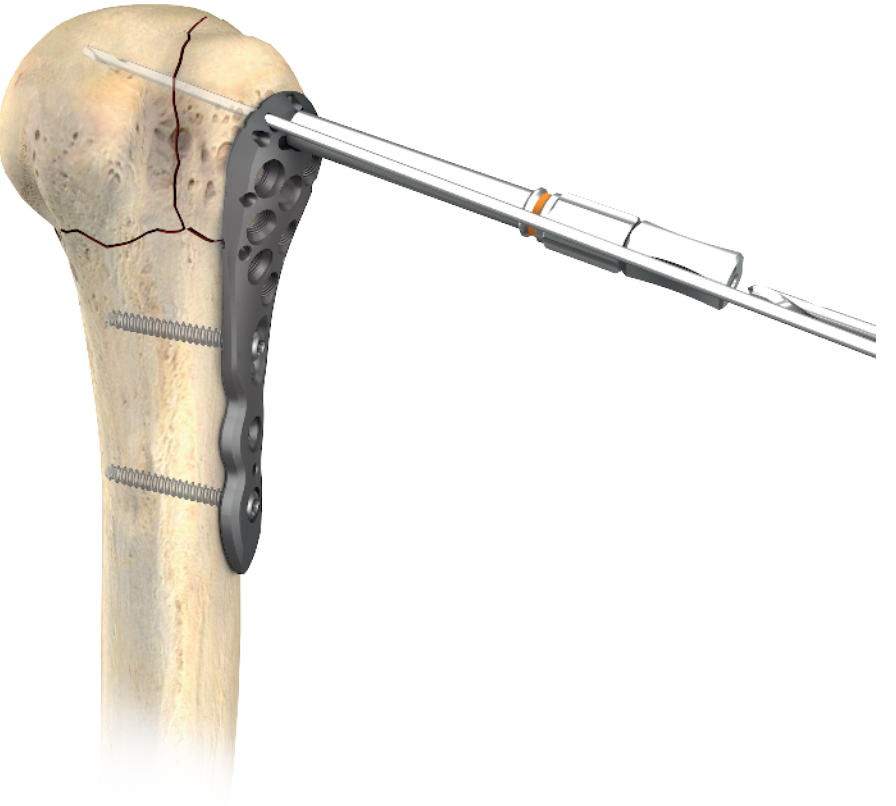


Fixation of the Humeral Head

The humeral head fragment and greater tuberosity are preliminarily fixed with at least three 2.0mm K-Wires (705002) or (390192) that are inserted either in the suture holes at the rim of the plate or via a K-Wire Sleeve (705003) attached to a Drill Sleeve (705004 or 705075) in a proximal plate hole.

When correct positioning of the head fragment and the greater tuberosity is confirmed by fluoroscopy, locking screws are successively inserted in the humeral head, whereby a minimum number of 5 locking screws is desired.

To optimize stability, it is recommended to use more screws than less in the humeral head.



Operative Technique

Insertion of non-locking screws in the humeral head is only desired in exceptional situations, whereby non-locking screws must first be placed in the plate prior to the placement of any locking screws - (following the “lag before lock” principle).

Insertion of a locking screw is started with insertion of a Drill Sleeve (705004 short or 705075 medium) in the universal holes of the proximal plate. Predrilling of the core hole is performed using a 3.1mm Drill Bit (705031 short, 705077 medium) for subsequent locking screw placement.

Note:

Orange color represents the color code for the 4.0mm Locking System. Medium size sleeves and drill bits show 2 orange color lines, short sleeves and drill bits show 1 line. Always make sure to use the drill and sleeve with the corresponding number of color rings.

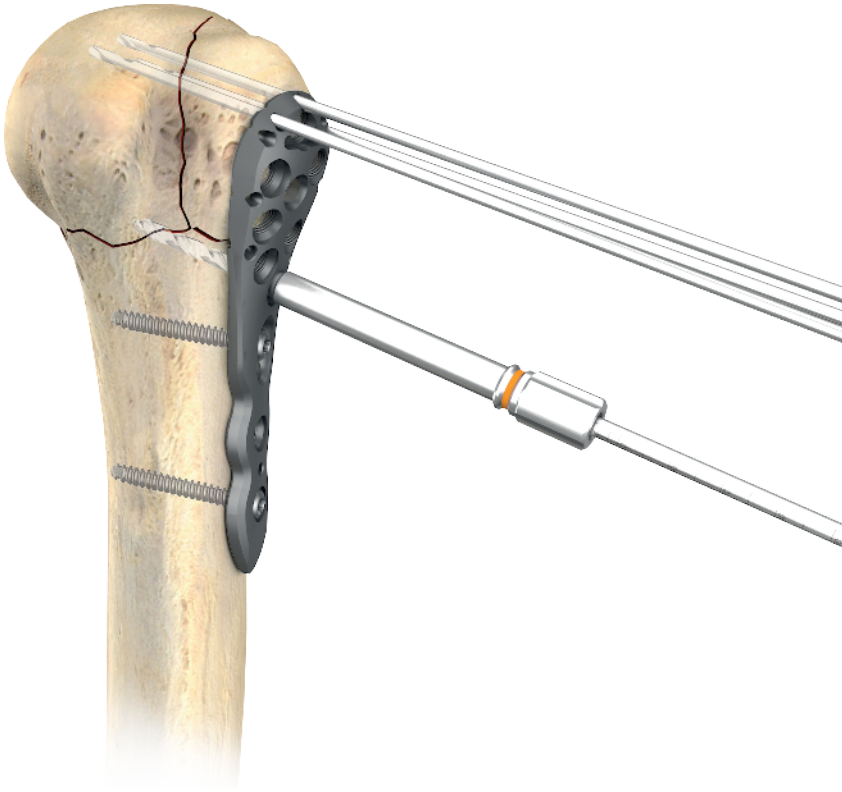
Under repetitive fluoroscopic views, the tip of the drill bit is inserted in the cancellous bone structure of the humeral head, whereby a true distance of the tip of the drill bit to the subchondral compacta of humeral head circumference of approximately 5mm is desired.

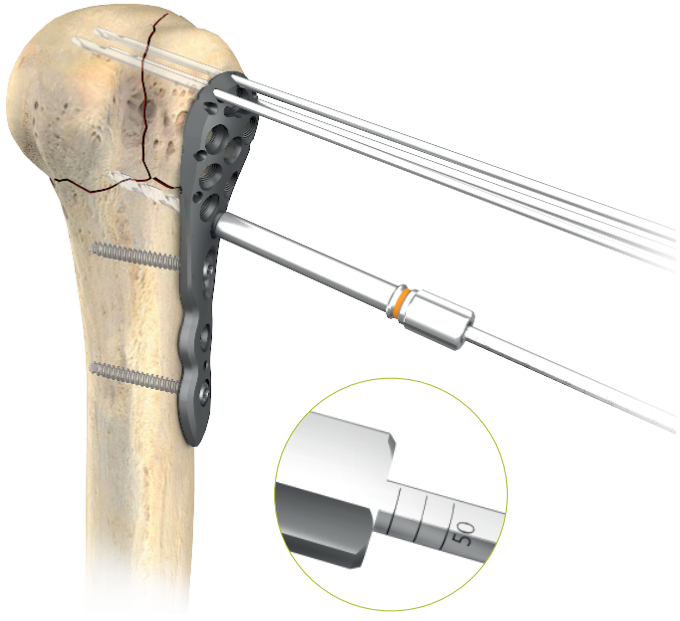
The required screw length is directly read off from the scale at the drill bit.

Note:

Correct length of the locking screws in the humeral head are essential.

- **Particularly in osteopenic bone, there is only limited substantial cancellous bone structure close to the subchondral compacta providing reliable strength for a bone screw.**
- **Too close of a distance of the screw tip to the subchondral compacta bears an increased risk of cut out in the case of postoperative bone sintering.**



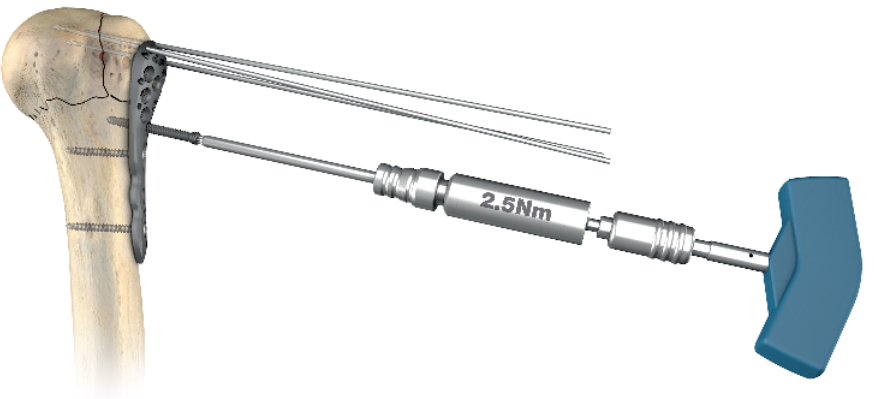


Read off drill bit with scale

Operative Technique

After removal of the Drill Sleeve, a Locking Screw in the ascertained length is inserted (preferably by hand) using the Screwdriver T15 (705016). Final tightening of the Locking Screw is always performed by hand using the 2.5Nm Torque Limiter (702760) in combination with a Screwdriver Bit T15 (705015) and the T-Handle (702427).

Performing final tightening by hand will help to prevent over-tightening of locking screws, and also ensures that these screws are tightened to a torque of 2.5Nm. The device will click when the torque reaches 2.5Nm. Ensure that the screwdriver tip is fully seated in the screw head, and do not angulate the screwdriver.



The torque limiters require routine maintenance. Refer to the instructions for maintenance of torque limiters (V15020).

Note:

Always check the correct position and length of the inserted screws by fluoroscopy.

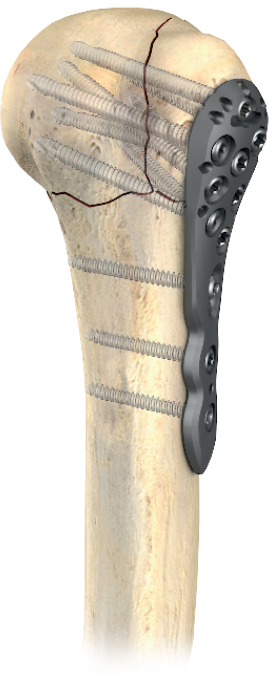
The procedure described above is repeated for all locking screws in the humeral head. When at least three locking screws are in place, the K-Wires will be gradually removed.

Final Fixation of the Shaft

A minimum of three 3.5mm cortical screws should be inserted in the humeral shaft fragment distally to the fracture zone. Cancellous screws or locking screws in the shaft portion are required only in exceptional situations.

The core holes for the 3.5mm cortical screws are performed using the Ø2.5mm Drill Bit (705025) and the Drill Guide for Non-Locking Screws (705022). Drill through both cortices for bi-cortical screw fixation.

The correct screw length can be determined by using the Orange Depth Gauge (705012) or by direct reading off of the drill scale.



Operative Technique

Additional Fixation with Sutures

Depending on the type of fracture and the bone quality, additional suture fixation may support and increase the stability (i.e. of the refixation of the greater and the lesser tuberosity).

The AxSOS 3 Proximal Lateral Humerus Plate features 8 suture holes allowing for:

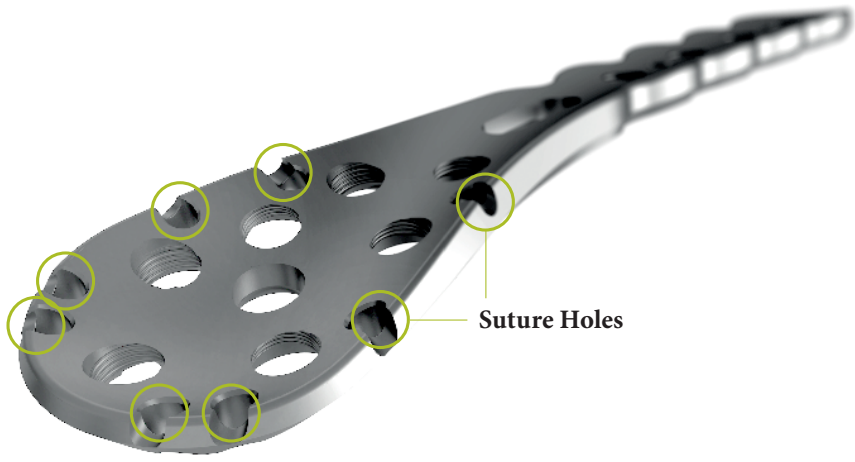
- Fixation of the subscapularis tendon
- Fixation of the supraspinatus tendon
- Fixation of the infraspinatus tendon

For suture fixation, stable nonabsorbable sutures (e.g. Stryker Force Fiber, size #2 to #5) should be used, whereby preferably U-type stitches of the respective tendon should be performed.

Note:

When a deltopectoral approach has been chosen, fixation of the supraspinatus and the infraspinatus tendon is mostly inconvenient.

The double incision approach (as described on page 8), which represents a combination of the of the deltopectoral approach and an additional short lateral delta-split incision (as it is used for "mini-open" rotator cuff repair) offers a good access to the supraspinatus and infraspinatus tendon insertion and may help to avoid proximal extension of the deltoidopectoral incision in order to reduce the surgical trauma.



Final Fluoroscopic Check

After final fixation of the plate with all screws and sutures (if applicable) a final fluoroscopic check is mandatory.

Under continuous fluoroscopy, the humerus should be rotated around its longitudinal axis and the true distance of all screw tips to the articular surface of the humeral head should be inspected to make sure that none of the screw tips has protruded into the shoulder joint.

Abduction of the arm should be checked for possible subacromial impingement that may require additional surgical measures (i.e. acromioplasty).

Implant Removal

Removal of the AxSOS 3 Proximal Lateral Humerus Plate is not required in general. The additional surgical trauma and the risks coming with additional anesthesia should be individually outweighed against the potential benefit for every patient.

In the case of implant removal, the scar of the previous incision is (partly) re-opened and the screws and the plate are successively removed.

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.

General Information

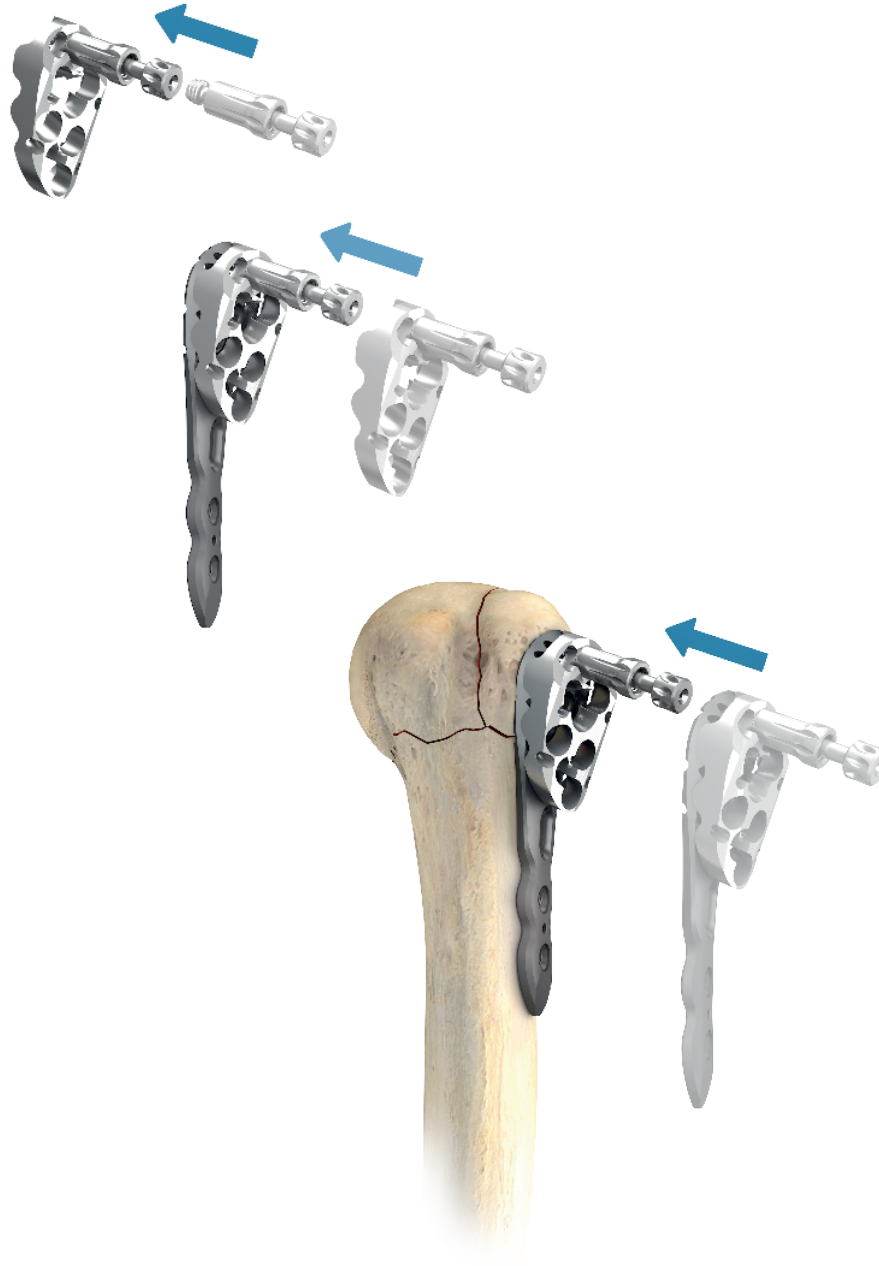
Optional Aiming Block

The AxSOS 3 system provides an optional aiming block (705069 for Right plates and 705070 for Left plates) for use with the proximal humerus plate. The aiming block is used to help guide the drill sleeves into the proximal part of the plate. This step helps ensure the proper drill trajectory.

The block is secured to the plate with the cannulated set screw for universal hole (705063). The set screw is placed in the most proximal hole of the plate. Prior to screw placement in the most proximal hole, the aiming block must be removed, and a drill sleeve must be placed directly into the hole for proper drill trajectory.

Note:

The aiming block may be used in both deltopectoral and double incision approaches described in this operative technique. However, care must be taken when using the block if inserting the plate through the deltopectoral approach not to impinge or damage the surrounding soft-tissues during reduction and fluoroscopic maneuvers.



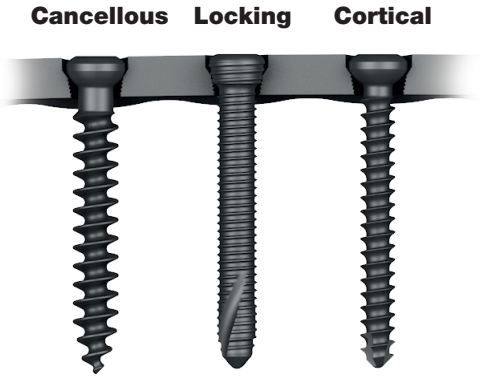
General Information

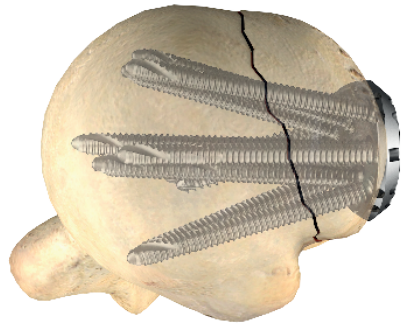
Universal Holes

The universal holes of the AxSOS 3 Proximal Lateral Humerus Plate have been designed to accept either a 3.5mm Cortex Screw, 4.0mm cancellous or 4.0mm Locking Screws.

Note:

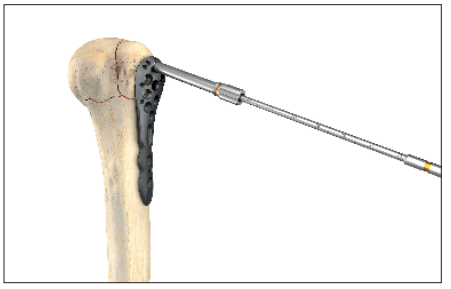
If a combination of non-locking and locking screws are used in the shaft, the plate fixation should begin with standard non-locking screws prior to the placement of any locking screws. Always lag before you lock.





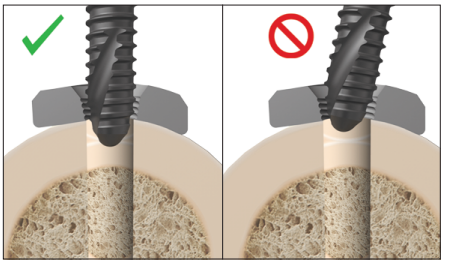
Additional Tips

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



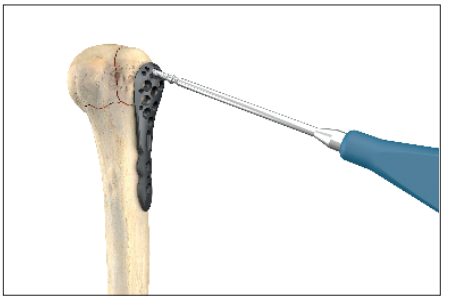
Freehand drilling may lead to a misalignment of the screw and may result in screws cross-threading during final insertion. It is essential to drill the core hole in the correct trajectory to facilitate optimal insertion of the locking screws.

2. **It is best to insert the screw manually** to ensure proper alignment in the the core hole which aligns the screw 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.



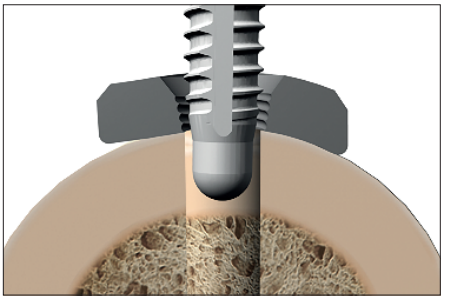
Locking screws should be aligned perpendicular to the plate/hole. If the locking screw head does not immediately engage the plate thread, reverse the screw and re-insert the screw once it is properly aligned.

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 may negatively affect final screw insertion, and if used improperly, may damage the screw/plate interface (screw jamming). This may lead to the screw head breaking or being stripped.

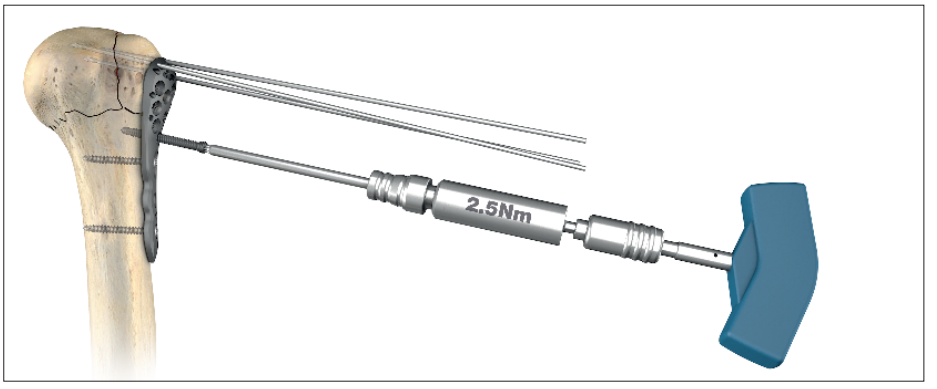
4. It is advisable to **tap hard** (dense) **cortical bone** before inserting a locking screw. Use the 4.0mm Locking Tap (702772).



The spherical tip of the tap precisely aligns the instrument in the predrilled core hole during thread cutting. This allows for 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 2.5Nm 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 2.5Nm Torque Limiter on).



Notes

Notes

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Manufactured by:

Stryker GmbH
Bohnackerweg 1
2545 Selzach
Switzerland

www.stryker.com