stryker

AxSOS 3® Titanium
Proximal Lateral Humerus Locking Plate System

Operative technique

AxSOS 3 Titanium
Proximal Lateral Humerus Locking Plate System

Contents

This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required. A workshop training is recommended prior to first surgery. All non-sterile devices must be cleaned and sterilized before use. Follow the instructions provided in our reprocessing guide (OT-RG-1).

Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly / disassembly instructions. Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.

See instruction for use V15011, V15020, V15246 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.

Introduction

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

This operative technique contains a step-by-step procedure for open reduction internal fixation (ORIF) implantation of the AxSOS 3 Titanium Proximal Lateral Humerus Plate.

Please refer to the compatibility table on page 19 showing SPS and AxSOS 3 Titanium compatibility. Please note that AxSOS 3 Titanium is made out of titanium alloy (Ti6Al4V) and is not compatible with any stainless steel plates or screws.

Product details

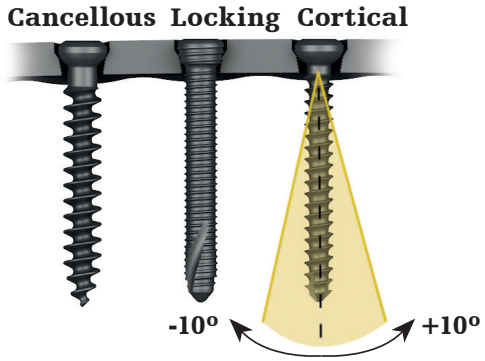
Plates used in this Operative Technique Guide:

AxSOS 3 Titanium Proximal Lateral Humerus plates

AxSOS 3 Titanium screws used with the AxSOS 3 Titanium Proximal Lateral Humerus plates:

4.0mm cancellous full thread | **4.0mm cancellous partial thread** | **3.5mm cortex shaft** | **3.5mm cortex screw** | **4.0mm locking screw**

All of the above AxSOS 3 Titanium screws have a T15 screw head interface. Please refer to the compatibility table on page 19 showing SPS and AxSOS 3 Titanium compatibility.



SPS titanium small fragment ISO screws used with the AxSOS 3 Titanium Proximal Lateral Humerus plates:

4.0mm cancellous full thread | **4.0mm cancellous partial thread** | **3.5mm cortex screw**

All of the above SPS titanium small fragment ISO screws have a Hex 2.5 screw head interface. Please refer to the compatibility table on page 19 showing SPS and AxSOS 3 Titanium compatibility.

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 and contraindications

Indications

AxSOS 3 Titanium 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

The AxSOS 3 Titanium Waisted Compression plates are also indicated for fracture fixation of:

- Periprosthetic fractures
- Diaphyseal and metaphyseal areas of long bones in pediatric patients

The 4mm waisted compression plate indications also include fixation of the scapula and the pelvis.

Precautions

MRI Safety Information

AxSOS 3 Titanium System (no periprosthetic indication)

Non-clinical testing has demonstrated the Stryker AxSOS 3 Titanium System is MR Conditional.
A patient with these devices can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5T and 3.0T
- Maximum spatial field gradient of 3000 gauss/cm (30T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the Stryker AxSOS 3 Titanium System is expected to produce a maximum temperature rise of less than 7.1°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 32mm from the Stryker AxSOS 3 Titanium System when imaged with a gradient echo pulse sequence and a 3T MRI system.

AxSOS 3 Titanium System (periprosthetic indication of the femur)

Non-clinical testing has demonstrated the Stryker AxSOS 3 Titanium System is MR conditional.
A patient with these devices can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5T and 3.0T
- Maximum spatial field gradient of 2000 gauss/cm (20T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)
- Scan time restriction: maximum 6 minutes of continuous scanning
- Only in combination with MR conditional Stryker hip implants

Under the scan conditions defined above, the Stryker AxSOS 3 Titanium System is expected to produce a maximum temperature rise of less than 8.9°C after 6 minutes of continuous scanning.
In non-clinical testing, the image artifact caused by the device extends approximately 45mm from the Stryker AxSOS 3 Titanium System when imaged with a gradient echo pulse sequence and a 3.0T MRI system.

⚠ CAUTION

The MRI safety information provided is based on testing which did not include supplementary devices. If there are supplementary devices (i.e. plates, screws, wires, prosthesis etc.) present in proximity to the System, this could result in additional MRI effects and the information provided above may not apply.

Indications, precautions and contraindications

⚠ CAUTION

The AxSOS 3 Titanium 4.0mm and 5.0mm Waisted Compression Plates should not cross the growth plates of pediatric patients.

Intended Use

AxSOS 3 Titanium 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 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 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.

NOTICE

The only plates indicated for pediatric use are the 4.0mm and 5.0mm waisted compression plates.

Pre-operative planning

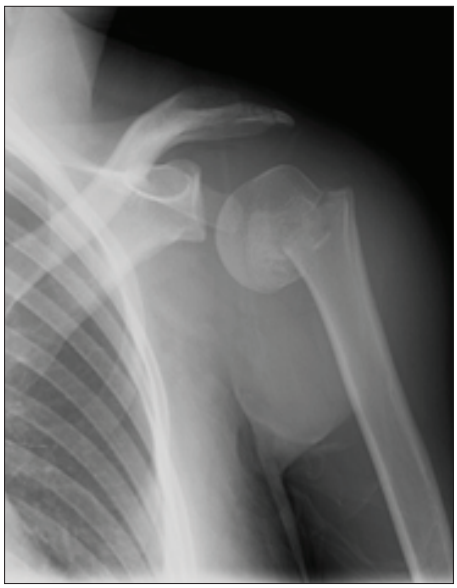
Use of the X-ray template or E-templates can assist in the selection of an appropriately sized implant.

- Ref 981200 – proximal lateral humerus

NOTICE

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 (fig. 1).



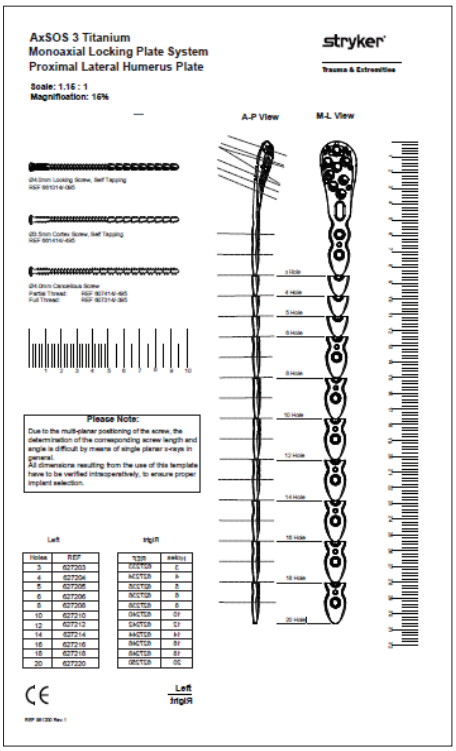


Fig. 1

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 (fig. 2).

Double incision approach*

An alternative is to perform an additional incision for better visualization of the greater tuberosity and rotator cuff (fig. 3).

This approach offers without extensive incision length:

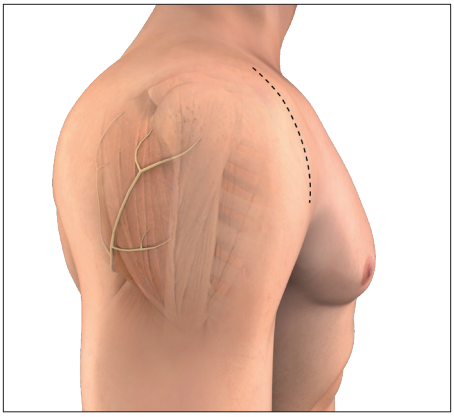


Fig. 2: Deltopectoral approach

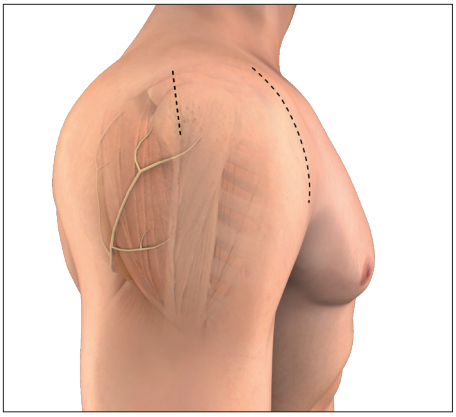


Fig. 3: Double incision approach

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.

⚠ WARNING

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

The two 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 two 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.

NOTICE

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 (fig. 4).

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.

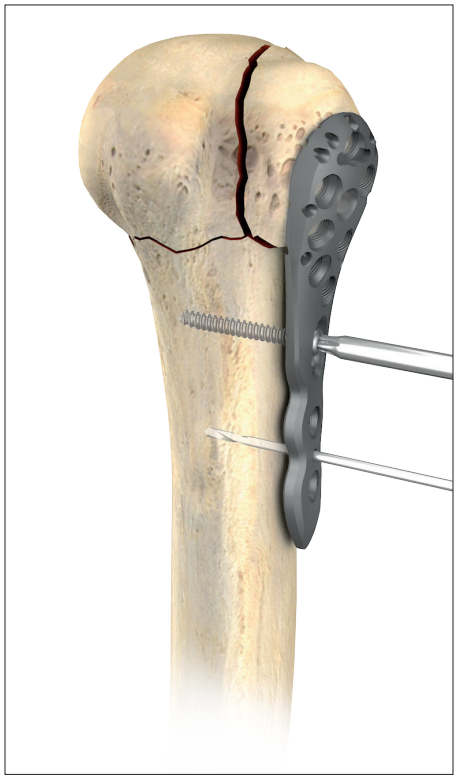


Fig. 4

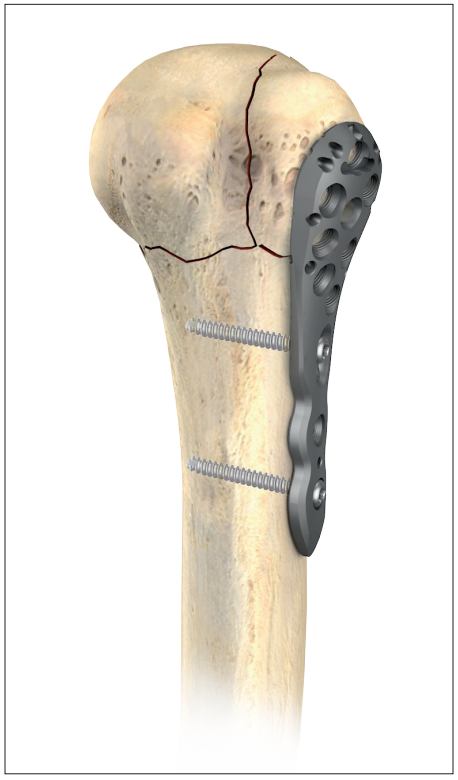


Fig. 5

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 (fig. 5).

Operative technique

Fixation of the humeral head

The humeral head fragment and greater tuberosity are preliminarily fixed with at least three Ø2.0mm K-wires (ref 705002) or (ref 390192) that are inserted either in the suture holes at the rim of the plate or via a K-wire sleeve (ref 705003) attached to a drill sleeve (ref 705004 or 705075) in a proximal plate hole (fig. 6).

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.

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 (ref 705004 short or 705075 medium) in the universal holes of the proximal plate. Pre-drilling of the core hole is performed using a 3.1mm drill bit (ref 705031 short, 705077 medium) for subsequent locking screw placement (fig. 7).

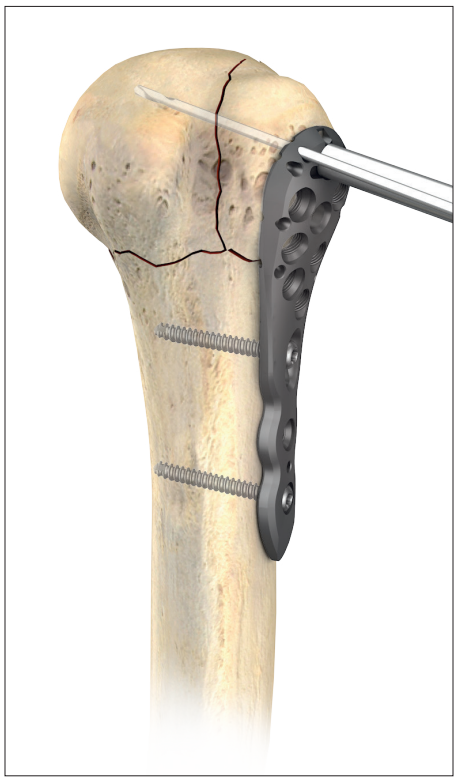


Fig. 6

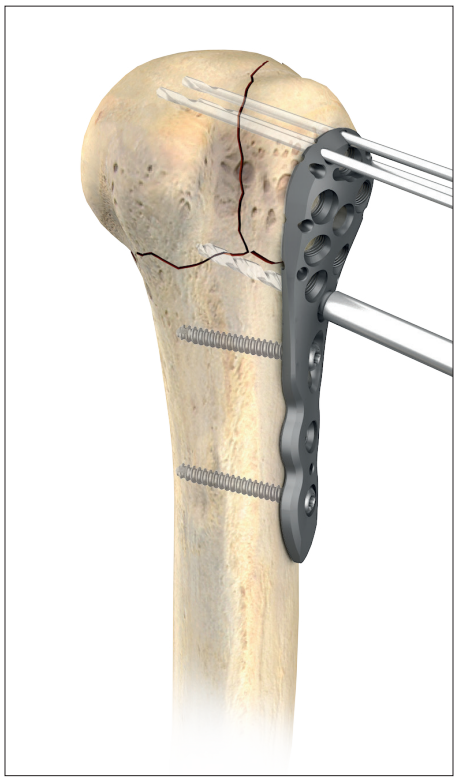


Fig. 7

NOTICE

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

Operative technique

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 (fig. 8).

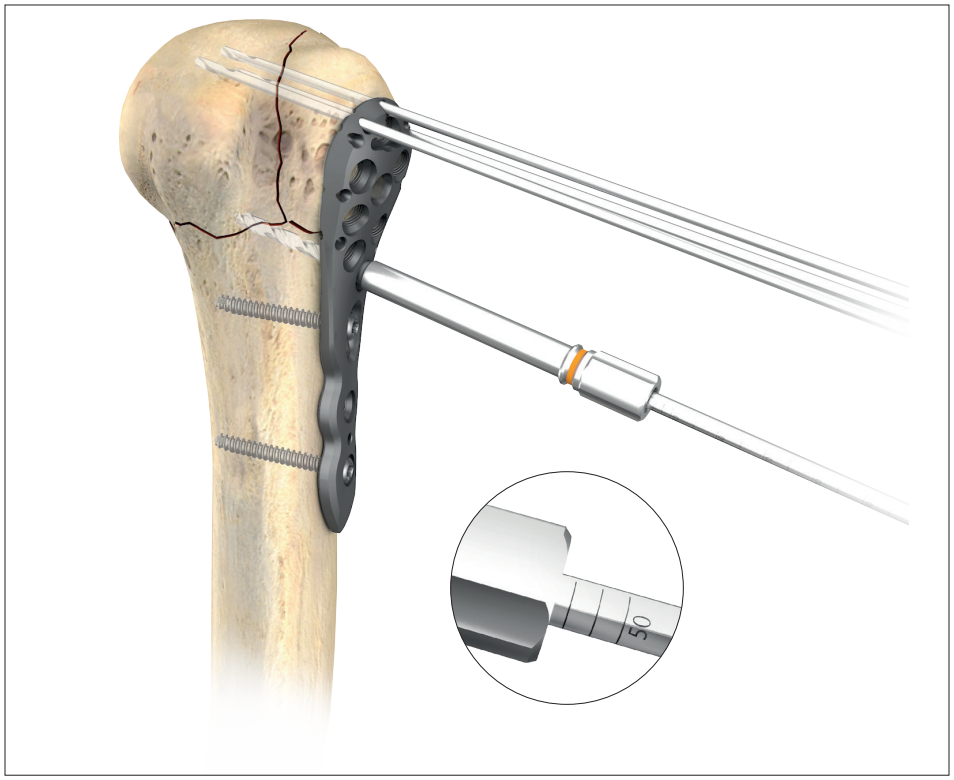
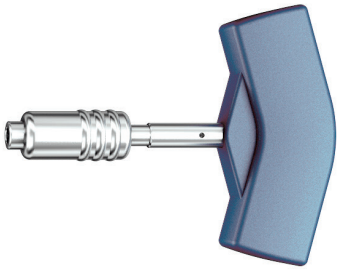


Fig. 8: Read off drill bit with scale

⚠ WARNING

Correct length of the locking screws in the humeral head is 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**

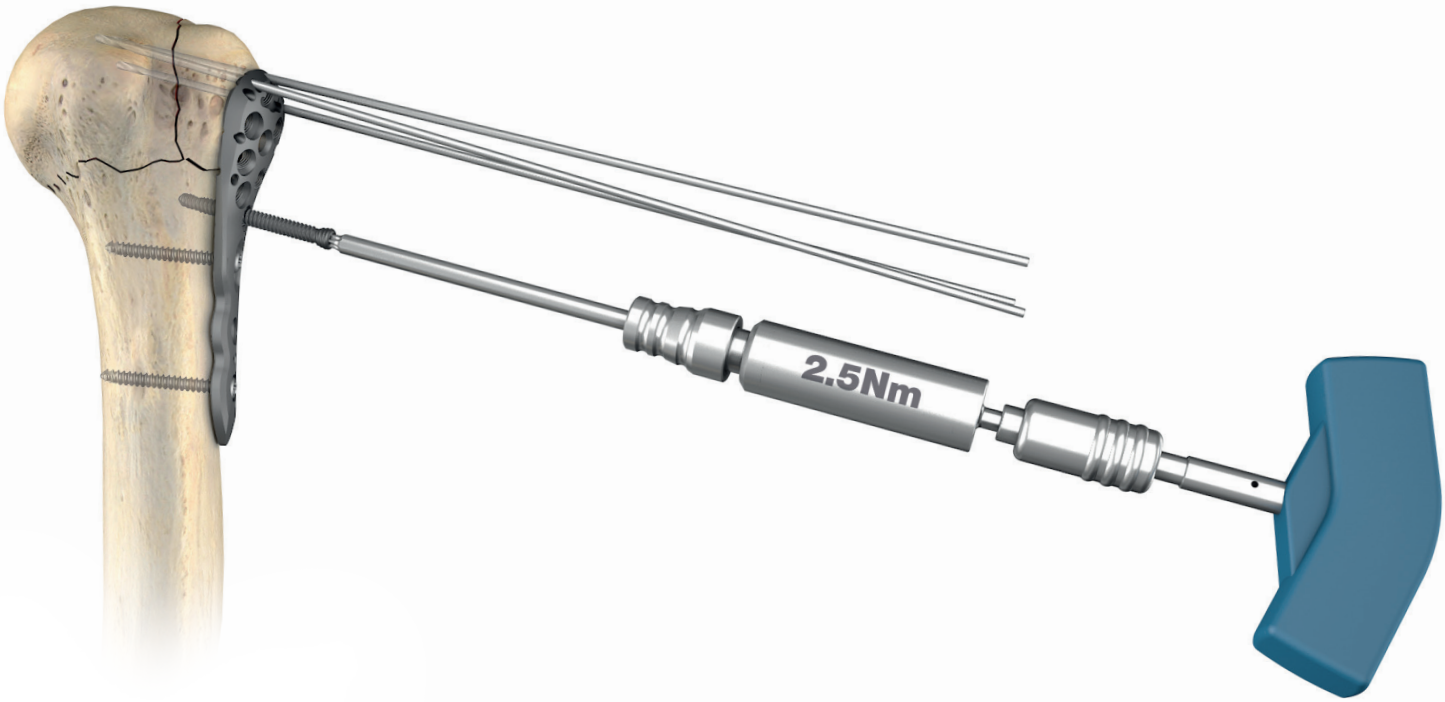


After removal of the drill sleeve, a locking screw in the ascertained length is inserted (preferably by hand) using the Screwdriver T15 (ref 705016).

⚠ CAUTION

Always perform final tightening by hand using the torque limiter (702760) in combination with a screwdriver bit T15 (ref 705015) and the T-handle (ref 702427).

Operative technique



This helps 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).

⚠ CAUTION

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 can be gradually removed.

Operative technique

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 (fig 9).

The core holes for the 3.5mm cortical screws are performed using the Ø2.5mm drill bit (ref 705025) and the drill guide for non-locking screws (ref 705022). Drill through both cortices for bi-cortical screw fixation (fig. 10).

The correct screw length can be determined by using the orange depth gauge (ref 705012) or by direct reading off of the drill scale.

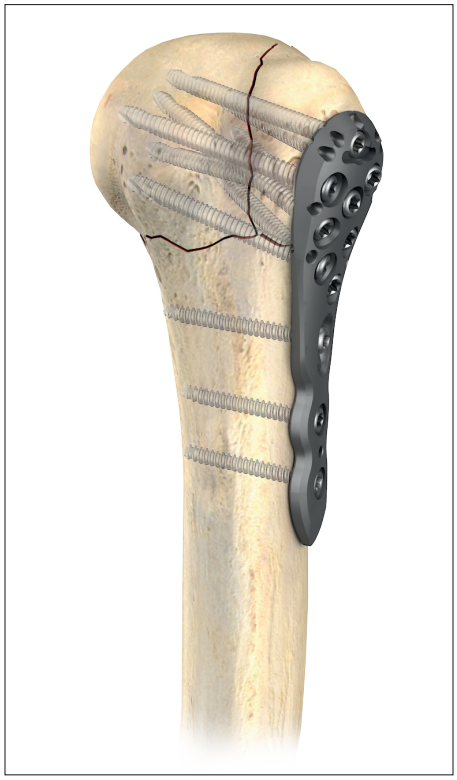


Fig. 9

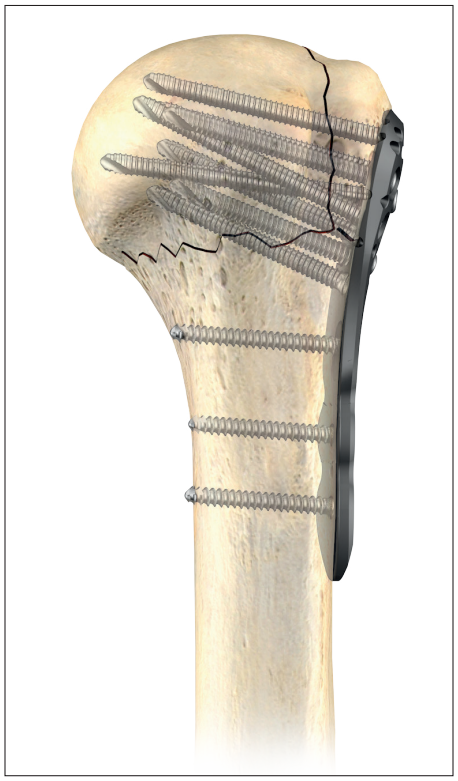


Fig. 10

Operative technique

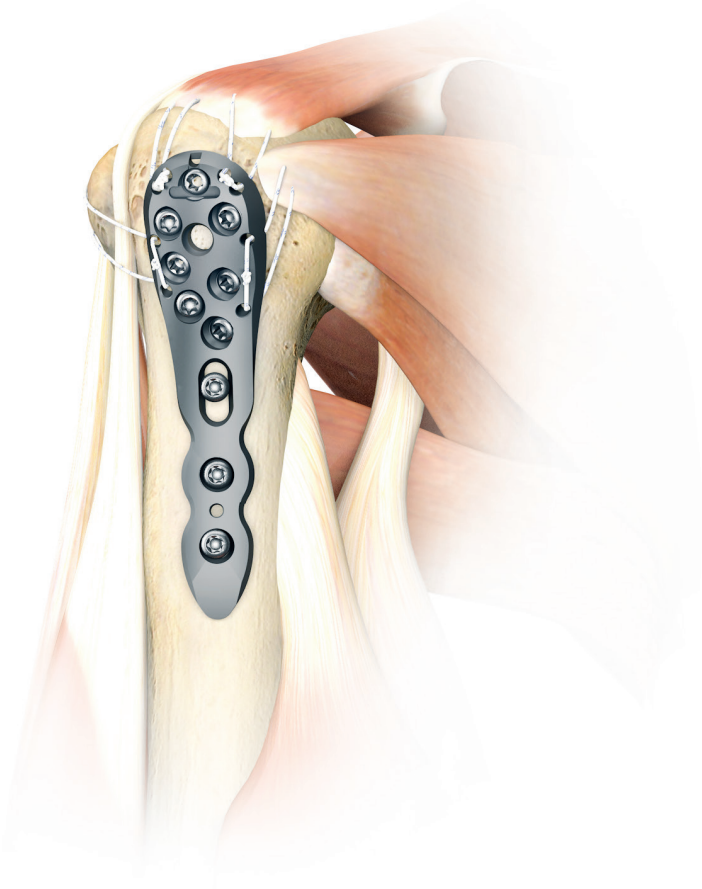
Additional fixation with sutures

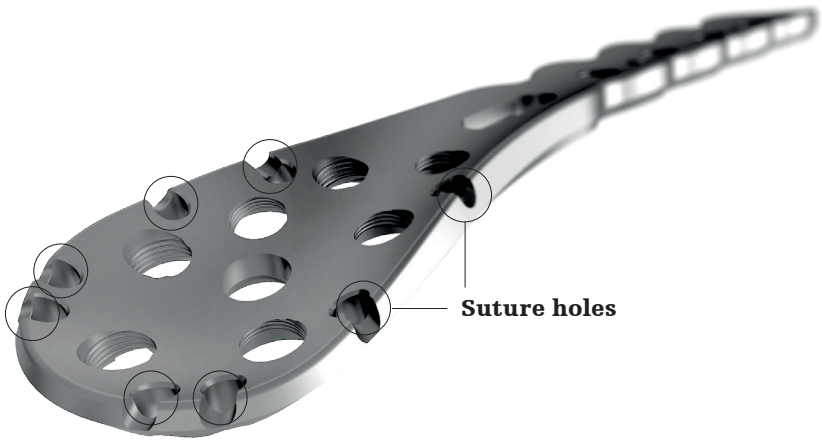
Depending on the type of fracture and the bone quality, additional suture fixation may support and increase the stability (i.e. of the refixation of the greater and the lesser tuberosity).

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 non absorbable 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.





NOTICE

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 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.

Operative technique

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 associated with additional anesthesia should be individually outweighed against the potential benefits 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.

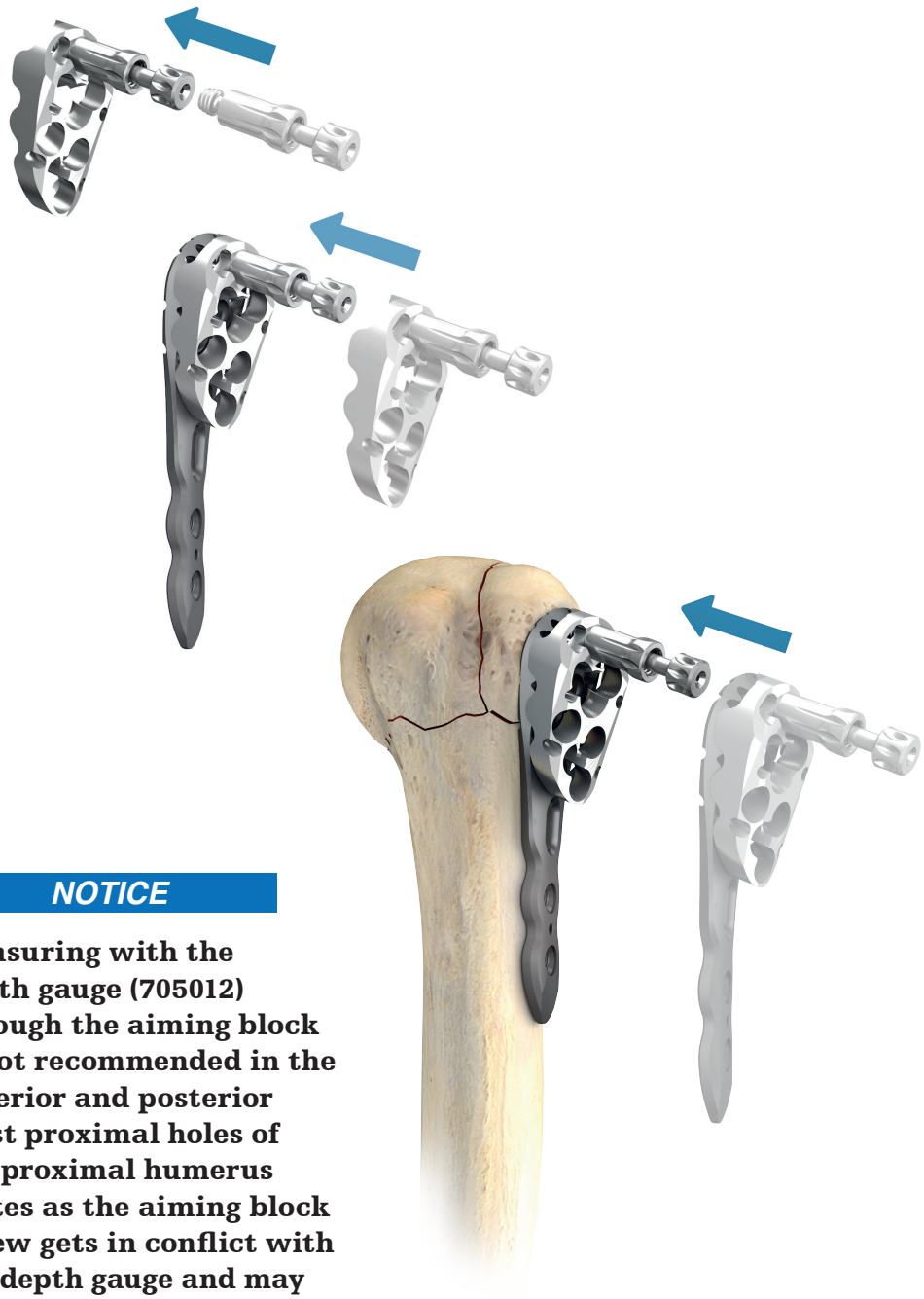
In the extreme event of broken or stripped screws, the Stryker implant extraction set (literature number LIES-OT) includes a variety of broken screw removal instruments.

General information

Optional aiming block

The AxSOS 3 System provides an optional aiming block (ref 705069 for right plates and ref 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 (ref 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.



NOTICE

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.

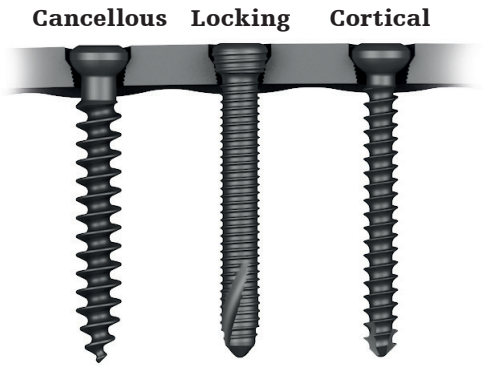
NOTICE

Measuring with the depth gauge (705012) through the aiming block is not recommended in the anterior and posterior most proximal holes of the proximal humerus plates as the aiming block screw gets in conflict with the depth gauge and may result in wrong measurement.

General information

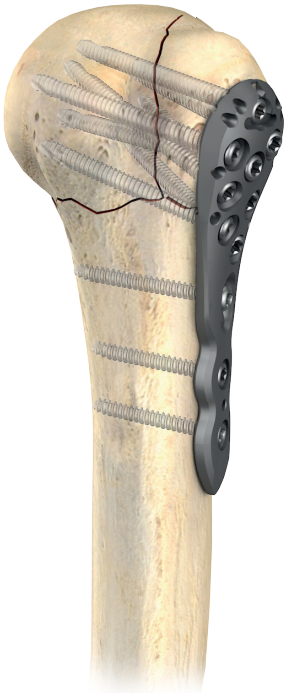
Universal holes

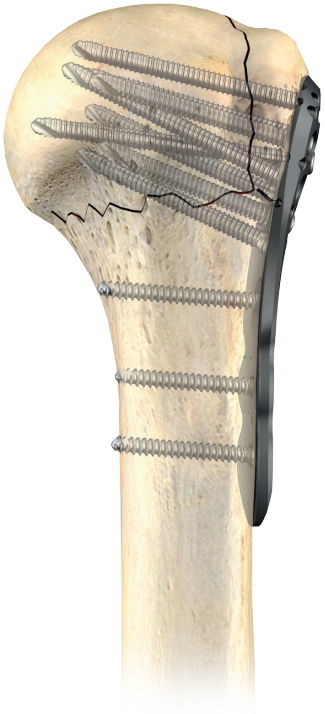
The universal holes of the AxSOS 3 Proximal Lateral Humerus Plate have been designed to accept either a 3.5mm cortex screw, 4.0mm cancellous or 4.0mm locking screws.

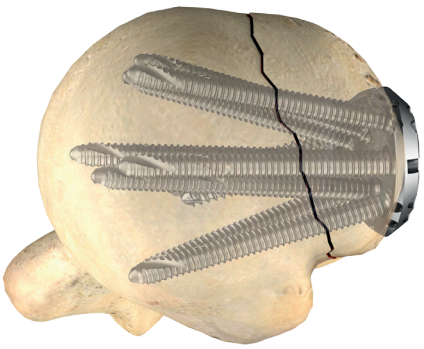


⚠ CAUTION

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.



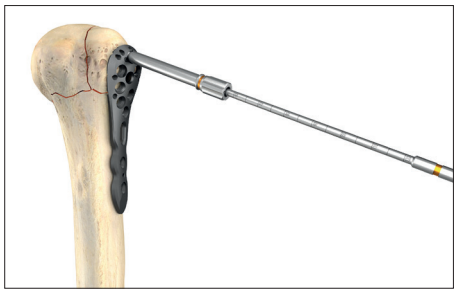




Additional tips

⚠ CAUTION

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.

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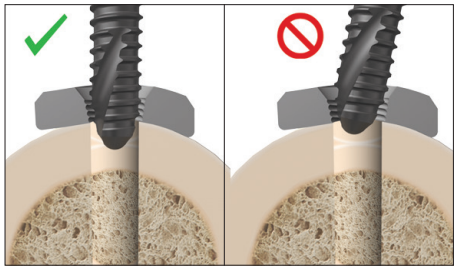
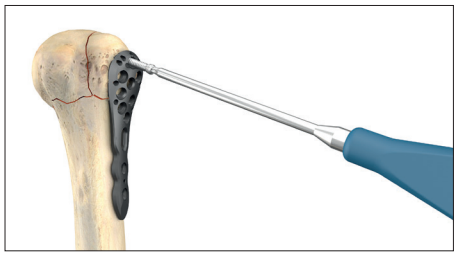
2. It is best to insert the screw manually to ensure proper alignment in the core hole which aligns the screw so it locks properly after being fully advanced. It is recommended to start inserting the screw using **"the three finger technique"** on the teardrop handle.



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.

⚠ CAUTION

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.

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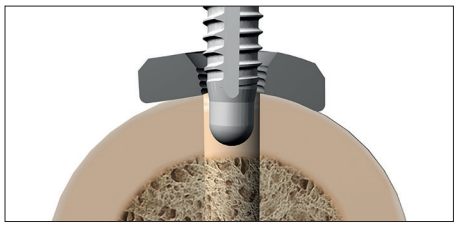
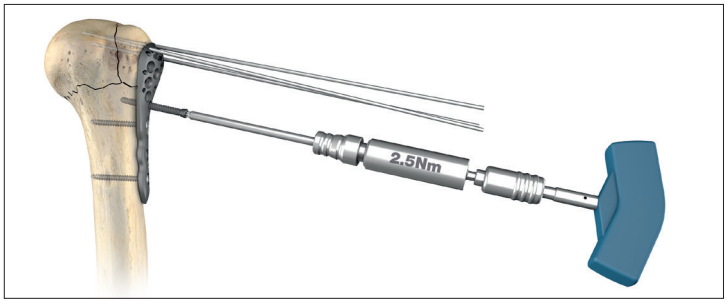
4. It is advisable to **tap hard** (dense) **cortical bone** before inserting a locking screw. Use the 4.0mm locking tap (ref 702772).



The spherical tip of the tap is designed to precisely align with the instrument in the pre-drilled core hole during thread cutting. This allows for subsequent screw placement.

⚠ CAUTION

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).



SPS Titanium – AxSOS 3 Titanium compatibility chart

The chart shows the compatibility of SPS Small and Basic Fragment Titanium screws with AxSOS 3 Titanium Plates and vice-versa.

Screws

Plates			AxSOS 3 Ti 4.0mm						AxSOS 3 Ti 5.0mm										SPS 3.5mm			SPS 4.5mm				SPS 2.7mm
			661014/-095	661410/-520	607310/-400	607410/-500	661612/-640	661004	661114/-195	661714/-850	608230/-350	608020/-150	608445/-550	661922/-975	661308/-320	661005	991088S	661002S	603010/-090	604010/-060	604210/-260	601014/-150	602030/-150	602245/-400	602420/-550	605008/-060
			4.0mm locking Ti screw	3.5mm cortex Ti screw	4.0mm cancellous Ti screw - full thread	4.0mm cancellous Ti screw - partial thread	3.5mm cortex shaft Ti screw	4.0mm blind screw	5.0mm locking screw	4.5mm cortex Ti screw	6.0mm cancellous Ti screw - TL-16	6.0mm cancellous Ti screw - full thread	6.0mm cancellous Ti screw - TL-32	4.5mm cortex shaft Ti screw	5.0mm periprosthetic locking screw	5.0mm blind screw	5.0mm variable angle extension arm*	5.0mm cable plug	SPS 3.5mm Ti cortical screw	SPS 4.0mm Ti cancellous full	SPS 4.0mm Ti cancellous partial	SPS 4.5mm Ti cortical screw	SPS 6.5mm Ti cancellous 16.0mm	SPS 6.5mm Ti cancellous 32.0mm	SPS 6.5mm Ti cancellous full thread	SPS 2.7mm Ti cortical screw
AxSOS 3 Ti 4mm	627302/-352	Proximal lateral tibia plate	X	X	X	X	X	X											X	X	X					
	627404/-452	Distal medial tibia plate	X	X	X	X	X	X											X	X	X					
	627454/-500	Distal anterolateral tibia plate	X	X	X	X	X	X											X	X	X					X
	627704/-752	Proximal medial tibia plate	X	X	X	X	X	X											X	X	X					
	627203/-250	Proximal lateral humerus plate	X	X	X	X	X	X											X	X	X					
	627502/-520	4mm compression plate	X	X	X	X	X	X											X	X	X					
AxSOS 3 Ti 5mm	627604/-650	Distal lateral femur plate							X	X	X	X	X	X	X	X	X	X				X				
	627532/-552	5mm compression plate narrow							X	X	X	X	X	X	X	X	X	X				X				
	627566/-582	5mm compression plate broad							X	X	X	X	X	X	X	X	X	X				X				
SPS Small Fragment	621423/-436	T-plate		X	X	X	X												X	X	X					
	621463/-468	Oblique T-plate		X	X	X	X												X	X	X					
	621443/-450	Cloverleaf plate		X	X	X	X												X	X	X					
	621122/-134	One third tubular plate		X	X	X	X												X	X	X					
SPS Basic Fragment	620413/-413	T-plate																				X	X	X	X	
	620454/-458	T-buttress plate																				X	X	X	X	
	620704/-706	L-buttress plate, left																				X	X	X	X	
	620754/-758	L-buttress plate, right																				X	X	X	X	

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