

Osteosynthesis

AxSOS™ Locking Plate System

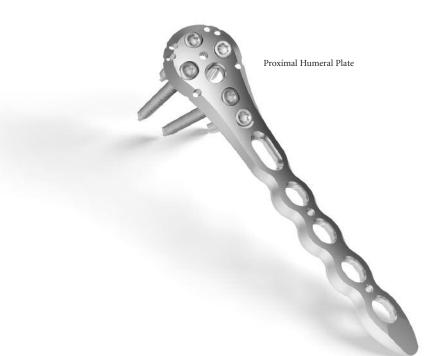
Operative Technique

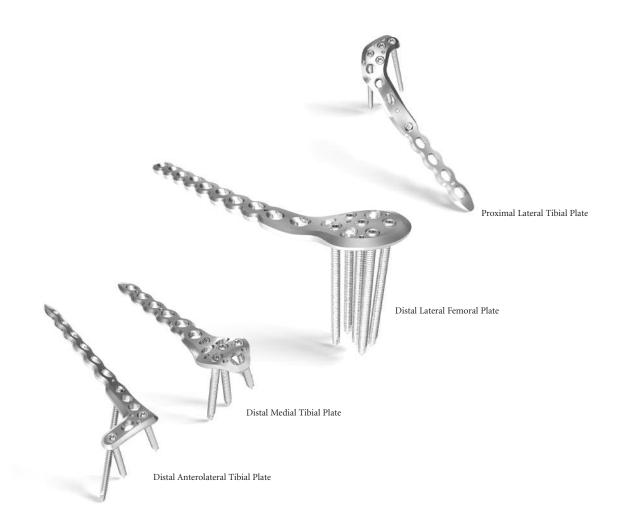


Introduction

The AxSOS[™] Locking Plate System is designed to treat periarticular or intra-articular fractures of the Proximal Humerus, Distal Femur, Proximal Tibia, and the Distal Tibia. The system design is based on clinical input from an international panel of experienced surgeons, data from literature, and both practical and biomechanical testing. The anatomical shape, the fixed screw trajectory, and high surface quality take into account the current demands of clinical physicians for appropriate fixation, high fatigue strength, and minimal soft tissue damage.

This Operative Technique contains a simple step-by-step procedure for the implantation of the Proximal Humeral Plate.





Features & Benefits

System

• The Proximal Humeral Plate is designed with divergent fixed-angled screw trajectories which provide optimal biomechanical stability. This helps prevent loss of reduction.

Instruments

• Simple technique, easy instrumentation with minimal components.

Range

• Longer plates cover a wider range of fractures.

Monoaxial Holes (5)

• Allow axially stable screw placement, bringing stability to construct.

Aiming Block

· Facilitates the placement of the Drill Sleeve.

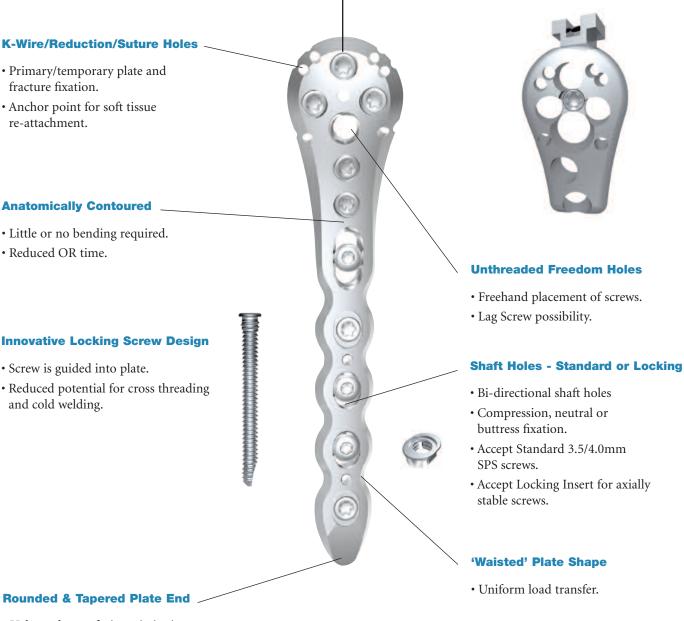
K-Wire/Reduction/Suture Holes

- Primary/temporary plate and fracture fixation.
- Anchor point for soft tissue re-attachment.

Anatomically Contoured

Innovative Locking Screw Design

- Screw is guided into plate.
- · Reduced potential for cross threading and cold welding.



• Helps reduce soft tissue irritation.

Relative Indications & Contraindications

Relative Indication

The indication for use of this internal fixation device includes fractures of the Proximal Humerus.

Relative Contraindications

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

- Any active or suspected latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, infection or prior implantation that can not provide adequate support and/or fixation of the devices.
- Material sensitivity, documented or suspected.
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.

- Patients having inadequate tissue coverage over the operative site.
- Implant utilisation that would interfere with anatomical structures or physiological performance.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

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

See package insert for a complete list of potential adverse effects and contraindications. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

Caution: Bone Screws are not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

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General Guidelines

Patient Positioning: Surgical Approach: Instrument/Screw Set: Beach Chair Deltopectoral 4.0mm

Reduction

Anatomical reduction of the fracture should be performed by direct visualisation with the help of percutaneous clamps. Fracture reduction should be confirmed by direct vision or fluoroscopy. To aid with this reduction and to provisionally hold fragments together, (humeral head and/or tuberosity) K-Wires may be used as appropriate.

The tubercles must be repositioned back to their anatomical positions either using K-Wires (tension band wiring) or screws as necessary. 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.

Bending:

In most cases, the pre-contoured plate will fit without the need for further bending. However, should additional bending of the plate be required (generally at the junction from the metaphysis to the shaft) the Bending Irons (REF 702756) should be used. Bending of the plate in the region of the metaphyseal locking holes will affect the ability to correctly seat the Locking Screws into the plate and is therefore not permitted.

Plate contouring in the shaft region should be restricted to the area between the shaft holes. Plate contouring may affect the ability to place a Locking Insert into the shaft holes adjacent to the bending point.



General Guidelines

Locking Screw Measurement

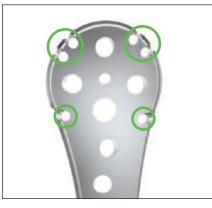
There are four options to obtain the proper Locking Screw length as illustrated below.

Measurement Options



Tissue Reattachment

Special undercuts on the reverse side of the plate correlating to the six proximal K-Wire holes allows simple passing of sutures for tissue reattachment after final plate fixation.



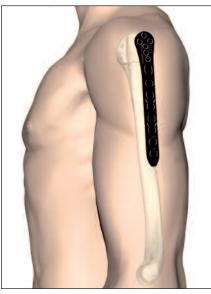


Fig. 1

Step 1 – Pre-Operative Planning

Use of the X-Ray Template (REF 981090) or Plate Trial (REF 702787) in association with fluoroscopy can help to assist in the selection of an appropriately sized implant (Fig. 1).

If the Plate Trial is more than 90mm away from the bone, e.g. with obese patients, a magnification factor of 10-15% will occur and must be compensated for. Final intraoperative verification should be made to ensure correct implant selection.

If locking screws are chosen for the plate shaft, pre-operative insertion of Locking Inserts is required. A 4.0mm Locking Insert (REF 370002) is attached to the Locking Insert Inserter (REF 702762) and placed into the chosen holes in the shaft portion of the plate (Fig. 2). Ensure that the Locking Insert is properly placed. The Inserter should then be removed (Fig. 2A).

Do not implant Locking Inserts with the Drill Sleeve.

It is important to note that if a Temporary Plate Holder is to be used primary distal plate fixation, then a Locking Insert must not be placed in the same hole as the Temporary Plate Holder (See Step 5).

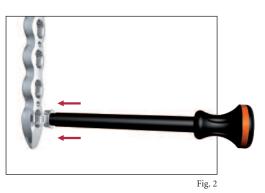




Fig. 2A

Step 2 – Aiming Block/ Plate Insertion Handle Assembly

Screw the appropriate Aiming Block (REF 702716/702717) to the plate using the Screwdriver T15 (REF 702747). If desired, the Handle for Plate Insertion (REF 702778) can now be attached to help facilitate plate positioning (Fig. 3).



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Step 3 – Plate Application

After skin incision and anatomical reduction is achieved, apply the plate. The plate should be centered against the lateral aspect of the greater tuberosity, ensuring that the plate is lateral to the biceps attachment. The superior aspect of the plate should sit approximately 10mm below the greater tuberosity (Fig. 4).

This helps to ensure that the most inferior Locking Screw is placed as inferiorly as possible within the humeral head, which minimises the chance for subacromial impingement.



Fig. 4 - AP View

Fig. 4 - Lateral View

Step 4 – Primary Plate Fixation – Proximal

A 3.5mm Cortical or 4.0mm Cancellous Screw is placed in the oblong hole in a neutral position. Using a 2.5mm Drill (REF 700355-230mm or 700347-125mm) and Double Drill Guide (REF 702418), drill a core hole to the appropriate depth.

The length is then measured using the Depth Gauge for Standard Screws (REF 702879), and 2 to 4mm is added. The appropriate screw is then inserted using a Screwdriver (REF 702841) and a Screw Holding Sleeve (REF 702732). If inserting a cancellous screw, the near cortex must be pre-tapped using the Tap (REF 702805), and the Teardrop Handle (REF 702428). If plate readjustment is required, do not fully tighten the screw (Fig. 5).

Then, a 2.0x230mm K-Wire is inserted into the most distal metaphyseal Locking Screw hole using the K-Wire Sleeve (REF 702702) in conjunction with the Drill Sleeve (REF 702707) (Fig. 6).

Keep in mind that the position of the proximal Locking Screw should be 5mm shorter than the circumference of the humeral head. Using fluoroscopy, the position of this K-Wire can be checked to ensure the correct screw and plate position. Should the axial alignment of the plate be unsuitable, the K-Wire should be removed, the plate readjusted and the above procedure repeated until both the K-Wire and plate are in the desired position.

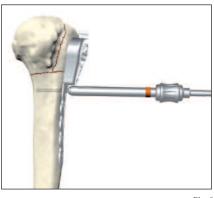
Then, make sure the screw in the oblong hole is fully tightened.

Do not remove the Drill Sleeve and K-Wire Sleeve at this point.

Remove the Handle for Insertion by pressing the metal button at the end of the Handle.

Additional K-Wires can be inserted in the K-Wire holes to further help secure the plate to the bone.

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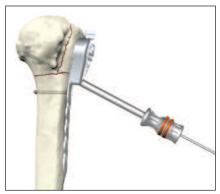


Fig. 6

Step 5 – Primary Plate Fixation – Distal

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

- A K-Wire inserted in the distal shaft K-Wire hole.
- A 3.5mm Cortical Screw using the standard technique.
- A 4.0mm Locking Screw with a Locking Insert (see Step 7 Shaft Locking).
- The Temporary Plate Holder (REF 702776).

In addition to providing temporary fixation, the Temporary Plate Holder pushes the plate to the bone. Also, it has a self drilling, self tapping tip for quick insertion into cortical bone. To help prevent thermal necrosis during the drilling stage, it is recommended that this device is inserted by hand.

Once the device has been inserted through the far cortex, the threaded outer sleeve/collet is turned clockwise until the plate is in contact with the bone (Fig. 7). The core diameter of this instrument is 2.4mm to allow a 3.5mm Cortical Screw to be subsequently inserted in the same plate hole.

Note: A Locking Insert and locking screw should not be used in the hole where the Temporary Plate Holder is used.

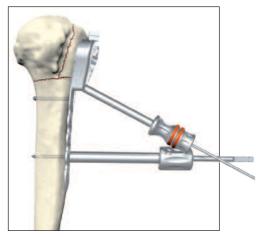






Fig. 7 – Lateral View

Step 6 – Metaphyseal Locking

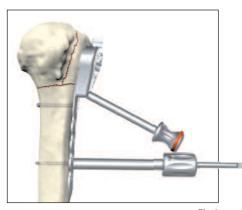
As Locking Screws cannot act as Lag Screws, should an interfragmentary compression effect be required, a 4.0mm Standard Cancellous Screw must first be placed in the unthreaded metaphyseal plate hole (Fig. 8) prior to the placement of any Locking Screws. Consideration must also be taken when positioning this screw to ensure that it does not interfere with the given Locking Screw trajectories.

The proximal Locking Screws should be 5mm shorter than the circumference of the humeral head.

Fixation of the metaphyseal portion of the plate can be started using the preset K-Wire in the distal locking hole as described in Step 4 for the measurement of the locking screw. The length of the screw can be taken by using the K-Wire side of the Drill/ K-Wire Depth Gauge (REF 702712) (See Locking Screw Measurement Guidelines on Page 7).

Remove the K-Wire and K-Wire Sleeve leaving the Drill Sleeve in Place (Fig. 9).





A 3.1mm Drill (REF 702742) is then used to drill the core hole for the Locking Screw. Using Fluoroscopy, check the correct depth of the drill, and measure the length of the screw. Avoid penetrating the far cortex of the humeral head.

The Drill Sleeve should now be removed, and the correct length 4.0mm Locking Screw is inserted using the Screwdriver T15 (REF 702753) and Screw Holding Sleeve (REF 702732).

Final tightening of Locking Screws should always be performed manually using the Torque Limiting Attachment (REF 702750) together with the Solid Screwdriver T15 (REF 702753) and T-Handle (REF 702427)(Fig. 10).

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. If inserting Locking Screws under power, make sure to use a low speed to avoid damage to the screw/plate interface, and perform final tightening by hand. The remaining proximal Locking Screws are inserted following the same technique with or without the use of a K-Wire.

To ensure maximum stability, it is recommended that all locking holes are filled with a Locking Screw of the appropriate length (Fig. 11).

The Aiming Block and any metaphyseal K-Wires should now be removed.

Step 7 – Shaft Fixation

The shaft holes of this plate have been designed to accept either 3.5mm Standard Cortical Screws or 4.0mm Locking Screws together with the corresponding Locking Inserts (Fig. 12).

If a combination of Standard and Locking Screws is used in the shaft, then the Standard Cortical Screws must be placed prior to the Locking Screws.

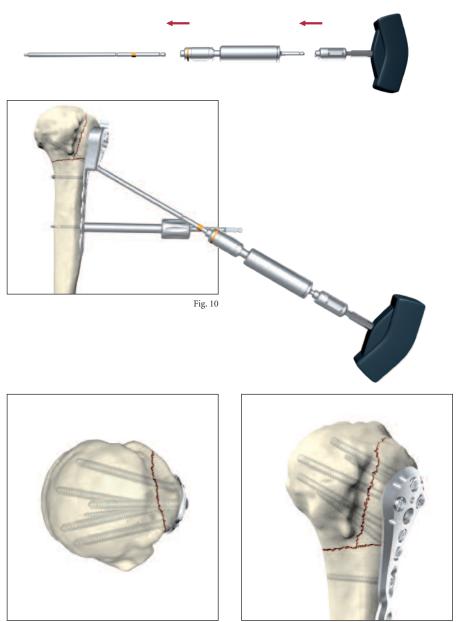


Fig. 11 - Superior View

Fig. 11 – AP View

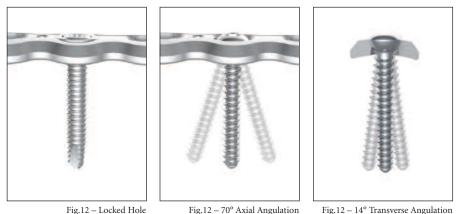


Fig.12 - Locked Hole

Fig.12 - 70° Axial Angulation

Option 1 – Standard Screws

3.5mm Standard Cortical Screws can be placed in neutral, compression or buttress positions (Fig.13) as desired using the standard technique.

These screws can also act as lag screws.

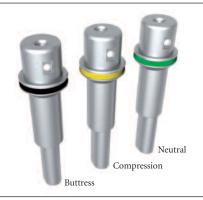




Fig. 13 – Drill Guides

Fig. 13 – Drill Sleeve Handle

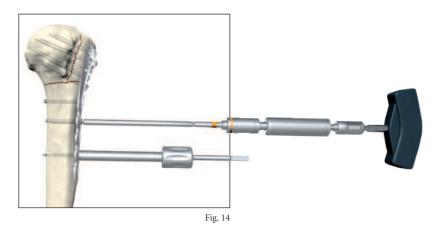
Option 2 – Locking Screws

4.0mm Locking Screws can be placed in a shaft hole provided there is a pre-placed locking insert in the hole (See Step 1).

The Drill Sleeve(REF 702707) is threaded into the Locking Insert to ensure initial fixation of the Locking Insert into the plate. This will also facilitate subsequent screw placement. A 3.1mm Drill Bit (Ref.702742) is used to drill through both cortices.

Avoid any angulation or excessive force on the drill, as this could dislodge the Locking Insert. The screw measurement is then taken. Locking Screws should initially be inserted manually to ensure proper alignment.

If the Locking Screw thread does not immediately engage the plate thread, reverse the screw a few turns and



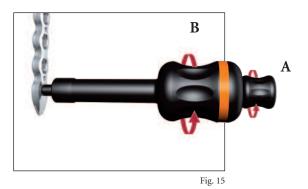
re-insert the screw once it is properly aligned.

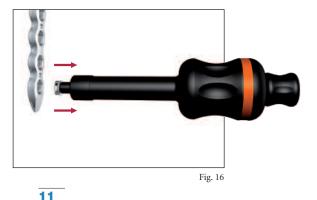
The appropriate sized Locking Screw is then inserted. Using the Solid Screwdriver T15 (REF 702753) together with the Torque Limiting Attachment (REF 702750) and T-Handle, final tightening is performed (Fig. 14). Maximum stability of the Locking Insert is achieved once the screw head is fully seated and tightened to 4.0Nm. This procedure is repeated for all holes chosen for locked shaft fixation.

All provisional plate fixation devices (K-Wires, Temporary Plate Holder, etc) can now be removed. Last, using the proximal suture holes, re-attach the rotator cuff and greater tubercle.

Locking Insert Extraction

Should removal of a Locking Insert be required for any reason, then the following procedure should be used. Thread the central portion (A) of the Locking Insert Extractor (REF 702767) into the Locking Insert that you wish to remove until it is fully seated (Fig. 15). Then turn the outer sleeve/collet (B) clockwise until it pulls the Locking Insert out of the plate (Fig. 16). The Locking Insert must then be discarded, as it cannot be reused.





Ordering Information - Implants

PROXIMAL HUMERUS

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

Stainless Steel REF		Plate Length	Shaft Holes	Locking Holes	
Left	Right	mm			
436103	436123	86	3	5	
436105	436125	112	5	5	
436108	436128	150	8	5	







Ordering Information - Implants

4.0MM LOCKING SCREW, SELF TAPPING T15 DRIVE

4.0MM CANCELLOUS SCREW, PARTIAL THREAD)
2.5MM HEX DRIVE	

Stainless Steel REF	Screw Length mm	Stainless Steel REF	Screw Length mm
370514	14	345514	14
370516	16	345516	16
370518	18	345518	18
370520	20	345520	20
370522	22	345522	22
370524	24	345524	24
370526	26	345526	26
370528	28	345528	28
370530	30	345530	30
370532	32	345532	32
370534	34	345534	34
370536	36	345536	36
370538	38	345538	38
370540	40	345540	40
370542	42	345545	45
370544	44	345550	50
370546	46	345555	55
370548	48	345560	60
370550	50	345565	65
370555	55	345570	70
370560	60	345575	75
370565	65	345580	80
370570	70	345585	85
370575	75	345590	90
370580	80	345595	95
370585	85		
370590	90		
370595	95		

3.5MM CORTICAL SCREW, SELF TAPPING 2.5MM HEX DRIVE

4.0MM CANCELLOUS SCREW, FULL THREAD 2.5MM HEX DRIVE

	Stainless Steel REF	Screw Length mm	Stainless Sto REF	eel Screw Length mm
2	338614	14	345414	14
	338616	16	345416	16
	338618	18	345418	18
	338620	20	345420	20
	338622	22	345422	22
	338624	24	345424	24
	338626	26	345426	26
	338628	28	345428	28
	338630	30	345430	30
	338632	32	345432	32
	338634	34	345434	34
	338636	36	345436	36
	338638	38	345438	38
	338640	40	345440	40
	338642	42	345445	45
	338644	44	345450	50
	338646	46	345455	55
	338648	48	345460	60
	338650	50	345465	65
	338655	55	345470	70
	338660	60	345475	75
	338665	65	345480	80
	338670	70	345485	85
	338675	75	345490	90
	338680	80	345495	95
	338685	85		
	338690	90		
	338695	95		

Ordering Information - 4.0mm Instruments

	REF	Description
	4.0mm Locking	Instruments
4000	702742	Drill Ø3.1mm x 204mm
	702772	Tap Ø4.0mm x 140mm
	702747	Screwdriver T15, L200mm
	702753	Solid Screwdriver T15, L115mm
	702732	Screw Holding Sleeve
	702702	K-Wire Sleeve
	702707	Drill Sleeve
	702884	Direct Depth Gauge for Locking Screws
	702750	Torque Limiter T15/4.0mm
	702762	Locking Insert Inserter 4.0mm
	702427	T-Handle small, AO Fitting
	38111090	K-Wire Ø2.0mm x 230mm
	702767	Locking Insert Extractor
	702778	Handle for Plate Insertion
A second se	702712	Drill/K-Wire Measure Gauge
	702776	Temporary Plate Holder
~a <u>aaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaa</u>	702776-1	Spare Shaft for Temporary Plate Holder
	702919	Soft Tissue Spreader (Optional)
	702961	Trocar (for Soft Tissue Spreader) (Optional)
	702782	Soft Tissue Elevator (Optional)
	702756	Bending Irons (x2)

Ordering Information - 4.0mm Instruments

	REF	Description	
	4.0mm Locking Instruments		
Ö	702717	Aiming Block, Proximal Humerus, Left	
Š	702716	Aiming Block, Proximal Humerus, Right	
	702716-2	Spare Set Screw for Humerus Aiming Block	
	702787	Plate Trial - Proximal Humerus (without attachment to Handle)	

SPS Standard Instruments

700347	Drill Bit Ø2.5mm x 125mm, AO
700355	Drill Bit Ø2.5mm x 230mm, AO
700353	Drill Bit Ø3.5mm x 180mm, AO
702804	Tap Ø3.5mm x 180mm, AO
702805	Tap Ø4.0mm x 180mm, AO
702418	Double Drill Guide Ø2.5/3.5mm
702822	Drill Sleeve Handle
702825	Drill Sleeve Ø2.5mm Neutral
702829	Drill Sleeve Ø2.5mm Compression
702831	Drill Sleeve Ø2.5mm Buttress
702709	Percutaneous Drill Sleeve Ø2.5mm
702957	Percutaneous Drill Sleeve Ø2.5mm Neutral
702879	Depth Gauge 0-150mm for Screws Ø3.5/4.0mm, Titanium
702849	Screwdriver Hex 2.5mm for Standard Screws L200mm
702485	Solid Screwdriver Hex 2.5mm for Standard Screws L115mm
702490	Screwdriver Holding Sleeve for Screws Ø3.5/4.0mm
702428	Tear Drop Handle, small, AO Fitting
900106	Screw Forceps
390192	K-wires 2.0mm x 150mm

390192 K-wires 2.0mm x 150mm

Other Instruments

702755 Torque	Tester with Adapters
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981090 X-Ray Template, Proximal Humerus

Cases and Trays

1

902955	Metal Base - Instruments
902929	Lid for Base - Instruments
902930	Instrument Tray 1 (Top)
902931	Instrument Tray 2 (Middle)
902948	Instrument Tray 3 (Bottom)
902932	Screw Rack
902949	Metal Base - Screw Rack
902950	Metal Lid for Base - Screw Rack
902947	Metal Base - Implants
902933	Implant Tray - Proximal Humerus
902937	Lid for Base - Proximal Humerus
902958	Locking Insert Storage Box 4.0mm

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