

Osteosynthesis

AxSOS Locking Plate System

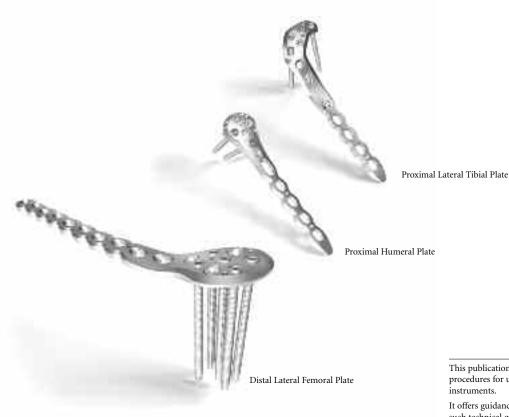
Operative Technique



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 the anterolateral and medial distal Tibial Plates.





This publication sets forth detailed recommended procedures for using Stryker Osteosynthesis 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.

Features & Benefits

System

 The anterolateral and the medial distal Tibial Plates are designed with optimised fixed-angeled screw trajectories which provide increased biomechanical stability. This helps prevent loss of reduction.

Instruments

- Simple technique, easy instrumentation with minimal components.
- Compatible with MIPO (Minimally Invasive Plate Osteosynthesis) technique using state of the art instrumentation.

Range

• Longer plates cover a wider range of fractures.

Rounded & Tapered Plate End

• Helps facilitate sliding of plates sub-muscularly.

'Waisted' plate shape 、

• Uniform load transfer.

Innovative Locking Screw design

• The single thread screw design allows easy insertion into the plate, reducing any potential for cross threading or cold welding.

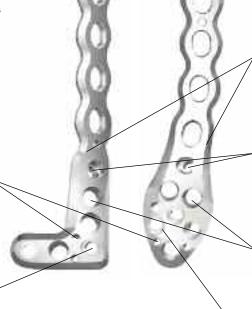


K-Wire/Reduction/Suture holes

• Primary/temporary plate and fracture fixation.

Monoaxial holes (3)

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



Shaft Holes - Standard or Locking

- Bi-directional shaft holes.
- Compression, neutral or buttress fixation.
- Accepts Standard 3.5/4.0mm SPS screws.
- Accepts Locking Insert for axially stable screws.



Anatomically contoured

- Little or no bending required.
- Reduced OR time.

Kick-Stand Screw

• Aimed at medial/lateral fragment to provide strong triangular fixation.

Unthreaded Freedom Holes

- Freehand placement of screws.
- · Lag Screw possibility.

Monoaxial holes (4)

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

Aiming Blocks

• Facilitates the placement of the Drill Sleeve.

Relative Indications & Contraindications

Relative Indications

The indication for use of these internal fixation devices includes metaphyseal extra and intra-articular fractures of the distal Tibia.

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.

General Guidelines

Patient Positioning:
Surgical Approach Lateral:
Surgical Approach Medial:

Instrument/Screw Set:

Reduction

Anatomical reduction of the fracture should be performed either by direct visualisation with the help of percutaneous clamps and/or K-Wires or alternatively a bridging external Fixator can aid indirect reduction. Fracture reduction of the articular surface should be confirmed by direct vision, or fluoroscopy. 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 visualise/identify the joint. Care must be taken that these do not interfere with the required plate and screw positions.

Consideration must also be taken when positioning independent Lag Screws prior to plate placement to ensure that they do not interfere with the planned plate location or Locking Screw trajectories.

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

Note: If a sub-muscular technique has been used please see the relevant section later in this Guide.

Supine

Between lateral Tibia and Fibula Distal oblique 1cm proximal to the medial Malleolus

4.0mm

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 will affect the ability to place a Locking Insert into the shaft holes adjacent to the bending point.





General Guidelines

Locking Screw Measurement

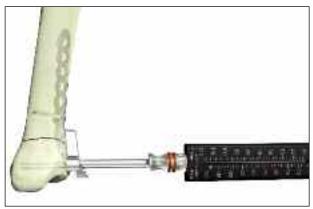
There are four options to obtain the proper Locking Screw length as illustrated below.

Correct Screw Selection

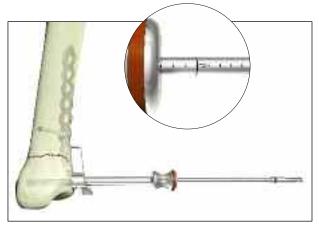
Select a screw approximatley 2-3mm shorter than the measured length to avoid screw penetrations through the opposite cortex in metaphyseal fixation.

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

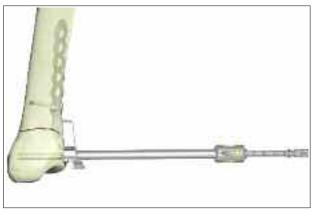
Measurement Options



Measure off K-Wire



Read off Calibration



Conventional Direct



Measure off Drill

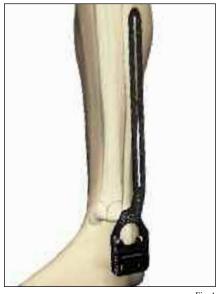


Fig. 1

Step 1 - Pre-Operative Planning

Use of the X-Ray Template (REF 981093 for lateral or 981092 for medial) or Plate Trial (REF 702797 for lateral or REF 702795 for medial respectively) in association with fluoroscopy can assist in the selection of an appropriately sized implant. (Fig. 1 and Fig. 1A).

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.

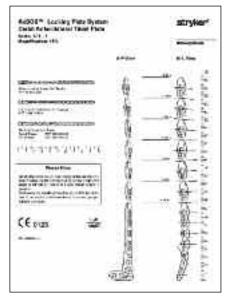


Fig. 1A

Step 2a - Pre-Operative Locking Insert Application

If Locking Screws are chosen for the plate shaft, pre-operative insertion of Locking Inserts is recommended.

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).

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. 2B).

Then turn the outer sleeve/collet (B) clockwise until it pulls the Locking Insert out of the plate (Fig. 2C). The Locking Insert must then be discarded, as it cannot be reused.

Do not place Locking Inserts with the Drill Sleeve.

It is important to note that if a Temporary Plate Holder is to be used for primary distal plate fixation, then a Locking Insert must not be placed in the same hole as the Temporary Plate Holder (See Step 6).



Fig. 2

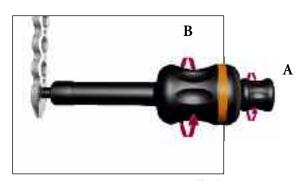


Fig. 2B



Fig. 2A

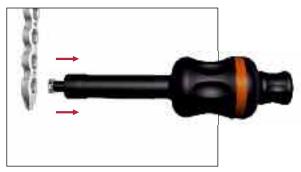


Fig. 2C

Step 2b - Intra - Operative Locking Insert Application

If desired, a Locking Insert can be applied in a compression hole in the shaft of the plate intra-operatively by using the Locking Insert Forceps (REF 702968), Centering Pin (REF 702673), Adaptor for Centering Pin (REF 702675), and Guide for Centering Pin (REF 702671).

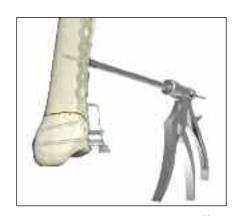
First, the Centering Pin is inserted through the chosen hole using the Adaptor and Guide (Fig. 2b). It is important to use the Guide as this centers the core hole for Locking Screw insertion after the Locking Insert is applied. After inserting the Centering Pin bi-cortically, remove the Adaptor and Guide.

Next, place a Locking Insert on the end of the Forceps and slide the instrument over the Centering Pin down to the hole (Fig. 2c).

Last, apply the Locking Insert by triggering the forceps handle. Push the button on the Forceps to remove the device (Fig. 2d). At this time, remove the Centering Pin.



Fig. 2b



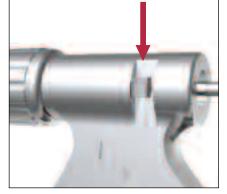


Fig. 2

Step 3 – Aiming Block/ Plate Insertion Handle Assembly

Screw the appropriate Aiming Block (REF 702723/702722 for lateral or 702725/702724 for medial respectively) 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 and sliding of longer plates sub-muscularly. (Fig 3)





Fig. 3

Step 4 - Plate Application

After skin incision and anatomical reduction is achieved, apply and manipulate the plate until optimal position in relation to the joint is achieved. (approx. 5mm above the anterior articular surface).

This helps to ensure that the most distal Locking Screws are directly supporting the joint surface. (Fig. 4)



Fig. 4 - Medial View

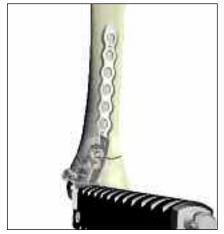


Fig. 4 – Lateral View

Step 5 – Primary Plate Fixation – Distal

The K-Wire holes in the plates allow temporary plate fixation in the metaphysis and the shaft part.

Using the K-Wire Sleeve (REF 702702) in conjunction with the Drill Sleeve (REF 702707), a 2.0x230mm K-Wire can now be inserted into one of the distal Locking Screw holes (Fig. 5). This step shows the position of the screw in relation to the joint surface and confirms the screw will not be intra articular.

Using fluoroscopy, the position of this K-Wire can be checked until the optimal position is achieved and the plate is correctly positioned.

Correct proximal placement should also be reconfirmed at this point to make sure the plate shaft is properly aligned over the lateral respectively the medial surface of the Tibial shaft (Fig. 6). Secure the position by inserting a K-Wire in the hole above the Kick-Stand Screw hole.

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

Do not remove the Drill Sleeve and K-Wire Sleeve at this point as it will cause a loss of the plate position.

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

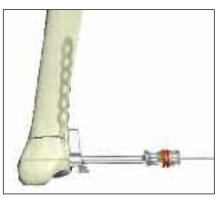


Fig. 5

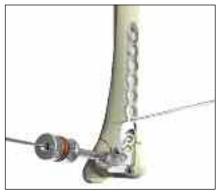
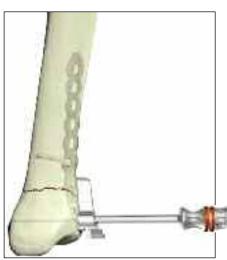


Fig. 6

Additional K-Wires can be inserted in the K-Wire holes distal to the locking holes to further help secure the plate to the bone and also support depressed areas in the articular surface.

Using a 2.5mm Drill (REF 700347-125mm or REF 700355-230mm) and Double Drill Guide (REF 702418), drill a core hole to the appropriate depth in the shaft hole above the most proximal fracture line.



The length is then measured using the Depth Gauge for Standard Screws (REF 702879) and an appropriate Self-Tapping 3.5mm Cortical Screw or a 4.0mm Cancellous Screw is then inserted using Screwdriver (REF 702841) (Fig. 7).

If inserting a cancellous screw, the near cortex must be pre-tapped using the Tap (REF 702805) and the Teardrop Handle (REF 702428).

Any K-Wires in the shaft can now be removed.

Step 6 - Primary Plate Fixation - Proximal (Optional)

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

- A K-Wire inserted in the proximal shaft K-Wire hole.
- A 3.5mm Cortical or 4.0mm Cancellous Screw using the standard technique.
- A 4.0mm Locking Screw with a Locking Insert (see Step 8 Shaft Locking).
- The Temporary Plate Holder (REF 702776).

In addition to providing temporary fixation, this device 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. 8).



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.

Step 7 - Metaphyseal Locking

Locking Screws cannot act as Lag Screws. Should an interfragmentary compression effect be required, a 4.0mm Standard Cancellous Screw or a 3.5mm Standard Cortex Screw must first be placed in the unthreaded metaphyseal plate holes (Fig. 9) prior to the placement of any Locking Screws. Measure the length of the screw using the Depth Gauge for Standard Screws (REF 702879), and pre-tap the near cortex with the Tap (REF 702805)if a Cancellous Screw is used.

Consideration must also be taken when positioning this screw to ensure that it does not interfere with the given Locking Screw trajectories. (Fig 10).





Fig. 8

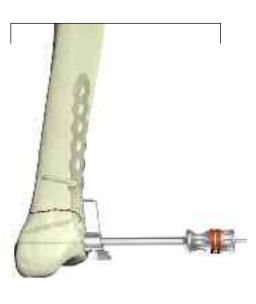


Fig. 10

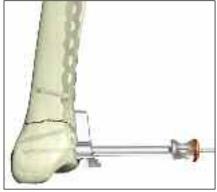


Fig. 11

Fixation of the metaphyseal portion of the plate can be started using the preset K-Wire in one of the distal locking hole as described in Step 5. 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 6).

Remove the K-Wire and K-Wire Sleeve leaving the Drill Sleeve in place. A 3.1mm Drill (REF 702742) is then used to drill the core hole for the Locking Screw (Fig. 11). Using Fluoroscopy, check the correct depth of the drill, and measure the length of the screw.

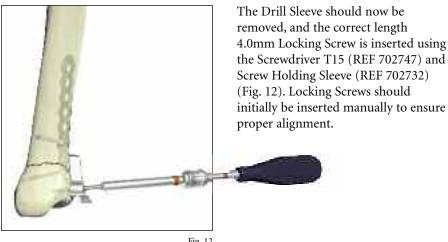
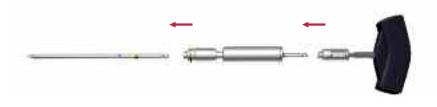


Fig. 12

If the Locking Screw thread does not engage immediately in the plate thread, reverse the screw a few turns and re-insert the screw once it is properly aligned.

Note: The Torque Limiters require routine maintenance. Refer to the Instructions for Maintenance of Torque Limiters (REF V15020)



Note: Ensure that the screwdriver tip is fully seated in the screw head, but do not apply axial force during final tightening

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).

This helps to prevent over-tightening of Locking Screws, and also ensures that these Screws are tightened to a maximum torque of 4.0Nm. The device will click when the torque reaches 4Nm (Fig. 13).

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 distal Locking Screws are inserted following the same technique with or without the use of a K-Wire.

Always use the Drill Sleeve (REF 702707) when drilling for locking holes.

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

Step 8 - 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.

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. 14)







70° Axial Angulation

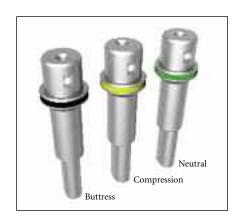


14° Transverse Angulation

Option 1 - Standard Screws

3.5mm Standard Cortical Screws can be placed in Neutral, Compression or Buttress positions as desired using the relevant Drill Guides and the standard technique.

These screws can also act as lag screws.





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 (Fig. 15).

Avoid any angulation or excessive force on the drill, as this could dislodge the Locking Insert. The screw measurement is then taken. The appropriate sized Locking Screw is then inserted using the Screwdriver T15 (REF 702753) and the Screw Holding Sleeve (REF 702732) together with the Torque Limiting Attachment (REF 702750) and the T-Handle (REF 702427).

Note: Ensure that the screwdriver tip is fully seated in the screw head, but do not apply axial force during final tightening

Maximum stability of the Locking Insert is achieved once the screw is fully seated and tightened to 4.0Nm.



Fig. 15

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.

Step 8 - Kick-Stand Screw Placement

The oblique 'Kick-Stand' Locking Screw provides strong triangular fixation to the opposite fragments. It is advised that this screw is placed with the assistance of fluoroscopy to prevent joint penetration and impingement with the distal Screws (Fig. 16).

(See Step 7 for insertion guidelines) The Aiming Block should now be removed.



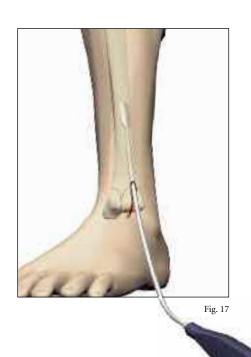
Fig. 16

Sub-Muscular Insertion Technique

When implanting longer plates, a minimally invasive technique can be used. The Soft Tissue Elevator (REF 702782) can be used to create a pathway for the implant (Fig. 17). The plate has a special rounded and tapered end, which allows a smooth insertion under the soft tissue (Fig. 18).

Additionally, the Shaft Hole Locator can be used to help locate the shaft holes. Attach the appropriate side of the Shaft Hole Locator (REF 702797 for lateral or 702795 for medial respectively) by sliding it over the top of the Handle until it seats in one of the grooves at a appropriate distance above the skin.

The slot and markings on the Hole Locator act as a guide to the respective holes in the plate. A small stab incision can then be made through the slot to locate the hole selected for screw placement (Fig. 19). The Trial can then be rotated out of the way or removed.



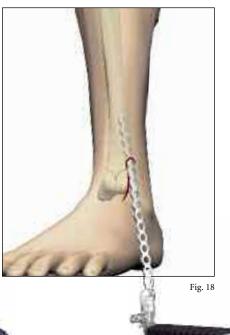




Fig. 1



Fig. 20



Fig. 21

The Standard Percutaneous Drill Sleeve (REF. 702709) or Neutral Percutaneous Drill Sleeve (REF 702957) in conjunction with the Drill Sleeve Handle (REF 702822) can be used to assist with drilling for Standard Screws. Use a 2.5mm Drill Bit (REF 700355).

With the aid of the Soft Tissue Spreader (REF 702919), the skin can be opened to form a small window (Fig. 20–21) through which either a Standard Screw or Locking Screw (provided a Locking Insert is present) can be placed. For Locking Screw insertion, use the threaded Drill Guide (REF 702707) together with the 3.1mm Drill Bit (REF 702742) to drill the core hole.

Final plate and screw positions are shown in Figures 22–27.





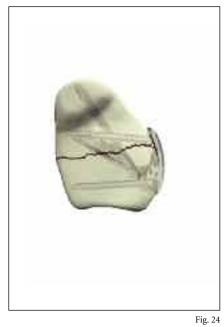


Fig. 23



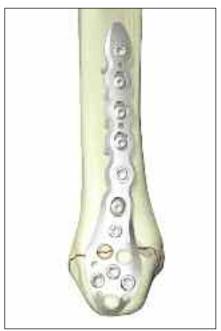
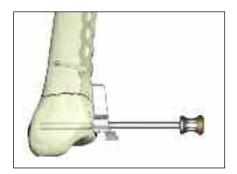




Fig. 26

Tips & Tricks

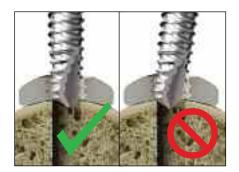
1. Always use the threaded Drill Sleeve when drilling for Locking Screws (threaded plate hole or Locking Insert).



Free hand drilling will lead to a misalignment of the Screw and therefore result in screw jamming during insertion. It is essential, to drill the core hole in the correct trajectory to facilitate accurate insertion of the Locking Screws.

2. Always start inserting the screw manually to ensure proper alignment in the plate thread and the core hole.

It is recommended to start inserting the screw using "the two finger technique" on the Teardrop handle. Avoid any angulations or excessive force on the screwdriver, as this



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.

3. If power insertion is selected after manual start (see above), use low speed only, do not apply axial pressure, and never "push" the screw through the plate!

could cross-thread the screw.

Allow the single, continuous threaded screw design to engage the plate and cut the thread in the bone on its own, as designed.

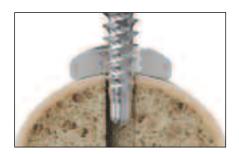
Stop power insertion approximately 1cm before engaging the screw head in the plate.



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.

Again, if the Locking Screw does not advance, reverse the screw a few turns, and realign it before you start re-insertion.

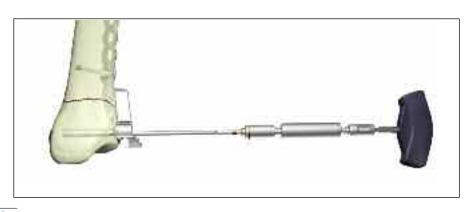
4. It is advisable to **tap hard** (dense) **cortical bone** before inserting a Locking Screw.



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 Limiting Attachment. Ensure that the screwdriver tip is fully seated in the screw head, but do not apply axial force during final tightening.

If the screw stops short of final position, back up a few turns and advance the screw again (with torque limiter on).



Ordering Information - Implants

DISTAL ANTEROLATERAL TIBIA

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



Stainle: RI		Plate Length	Shaft Holes	Locking Holes	
Left	Right	mm			
436404	436424	97	4	3	
436406	436426	123	6	3	
436408	436428	149	8	3	
436410	436430	175	10	3	
436412	436432	201	12	3	
436414	436434	227	14	3	
436416	436436	253	16	3	

DISTAL MEDIAL TIBIA

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



Stainles RE		Plate Length	Shaft Holes	Locking Holes	
Left	Right	mm			
436204	436224	94	4	4	
436206	436226	120	6	4	
436208	436228	146	8	4	
436210	436230	172	10	4	
436212	436232	198	12	4	
436214	436234	224	14	4	
436216	436236	250	16	4	

4.0MM LOCKING INSERT



Stainless Steel	System	
REF	mm	
370002	4.0	

Ordering Information - Implants

4.0MM LOCKING SCREW, SELF TAPPING T15 DRIVE



Stainless Steel REF	Screw Length mm	
370514	14	
370516	16	
370518	18	
370520	20	
370522	22	
370524	24	
370526	26	
370528	28	
370530	30	
370532	32	
370534	34	
370536	36	
370538	38	
370540	40	
370542	42	
370544	44	
370546	46	
370548	48	
370550	50	
370555	55	
370560	60	
370565	65	
370570	70	
370575	75	
370580	80	
370585	85	
370590	90	
370595	95	

4.0MM CANCELLOUS SCREW, PARTIAL THREAD 2.5MM HEX DRIVE



Stainless Steel REF	Screw Length mm	
345514	14	
345516	16	
345518	18	
345520	20	
345522	22	
345524	24	
345526	26	
345528	28	
345530	30	
345532	32	
345534	34	
345536	36	
345538	38	
345540	40	
345545	45	
345550	50	
345555	55	
345560	60	
345565	65	
345570	70	
345575	75	
345580	80	
345585	85	
345590	90	
345595	95	

3.5MM CORTICAL SCREW, SELF TAPPING 2.5MM HEX DRIVE



Stainless Steel	Screw	
REF	Length mm	
338614	14	
338616	16	
338618	18	
338620	20	
338622	22	
338624	24	
338626	26	
338628	28	
338630	30	
338632	32	
338634	34	
338636	36	
338638	38	
338640	40	
338642	42	
338644	44	
338646	46	
338648	48	
338650	50	
338655	55	
338660	60	
338665	65	
338670	70	
338675	75	
338680	80	
338685	85	
338690	90	
338695	95	

4.0MM CANCELLOUS SCREW, FULL THREAD 2.5MM HEX DRIVE



Stainless Steel REF	Screw Length mm	
345414	14	
345416	16	
345418	18	
345420	20	
345422	22	
345424	24	
345426	26	
345428	28	
345430	30	
345432	32	
345434	34	
345436	36	
345438	38	
345440	40	
345445	45	
345450	50	
345455	55	
345460	60	
345465	65	
345470	70	
345475	75	
345480	80	
345485	85	
345490	90	
345495	95	

Ordering Information - 4.0mm Instruments

	REF	Description
	4.0mm Locking	Instruments
40-0-	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
The second section	702712	Drill/K-Wire Measure Gauge
	702776	Temporary Plate Holder
*-connection 9 1)	702776-1	Spare Shaft for Temporary Plate Holder
T gamans	702919	Soft Tissue Spreader
	702961	Trocar (for Soft Tissue Spreader)
	702782	Soft Tissue Elevator
	702756	Bending Irons (x2)

Ordering Information - 4.0mm Instruments

	REF	Description
	4.0mm Locking 1	<u> </u>
	4.0IIIII LOCKIIIg	mstruments
<u>a</u>	702723	Aiming Block, Distal Anterolateral Tibia, Left
<u> </u>	702722	Aiming Block, Distal Anterolateral Tibia, Right
<i>3</i>	702725	Aiming Block, Distal Medial Tibia, Left
R	702724	Aiming Block, Distal Medial Tibia, Right
	702720-2	Spare Set Screw for Tibia Aiming Block
	702797	Plate Trial/Shaft Hole Locator - Distal Anterolateral Tibia
	702795	Plate Trial/Shaft Hole Locator - Distal Medial Tibia
	SPS Standard Ins	struments
	700347	Drill Bit Ø2.5mm x 125mm, AO
	700355	Drill Bit Ø2.5mm x 230mm, AO
	700353 702804	Drill Bit Ø3.5mm x 180mm, AO 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 702829	Drill Sleeve Ø2.5mm Neutral Drill Sleeve Ø2.5mm Compression
	702829	Drill Sleeve Ø2.5mm Buttress
	702709	Percutaneous Drill Sleeve Ø2.5mm
	702957	Percutaneous Drill Sleeve Ø2.5mm Neutral
	702879 702841	Depth Gauge 0-150mm for Screws Ø3.5/4.0 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 390192	Screw Forceps K-Wires 2.0mm x 150mm
472-7-11		
7	Other Instrumer	nts
	702968	Locking Insert Forceps
———	702671	Guide for Centering Pin
	702673	Centering Pin
	702675	Adapter for Centering Pin
	702755 981093	Torque Tester with Adapters X-Ray Template, Distal Anterolateral Tibia
	981092	X-Ray Template, Distal Medial Tibia
	Cases and Trays 902955	Metal Base - Instruments
	902935	Lid for Base - Instruments
		Instrument Tray 1 (Top)
	902931	Instrument Tray 2 (Middle)
	902963	Instrument Tray 3 (Bottom) with space for Locking Insert Forceps Instrumentation
	902932 902949	Screw Rack Metal Base - Screw Rack
	902949	Metal Lid for Base - Screw Rack
	902947	Metal Base - Implants
	902935	Implant Tray - Distal Anterolateral Tibia
	902936	Implant Tray - Distal Medial Tibia
	902939 902940	Lid for Base - Distal Lateral Tibia Lid for Base - Distal Medial Tibia
	902958	Locking Insert Storage Box 4.0mm

Locking Insert Storage Box 4.0mm

Additional Information

HydroSet Injectable HA

Indications

HydroSet is a self-setting calcium phosphate cement indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, craniofacial, spine, and pelvis). These defects may be surgically created or osseous defects created from traumatic injury to the bone. HydroSet is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure.

HydroSet cured in situ provides an open void/gap filler than can augment provisional hardware (e.g K-Wires, Plates, Screws) to help support bone fragments during the surgical procedure. The cured cement acts only as a temporary support media and is not intended to provide structural support during the healing process.



Tibia Pilon Void Filling



Note: Screw fixation must be provided by bone



Scanning Electron Microscope image of HydroSet material crystalline microstructure at 15000x magnification

HydroSet is an injectable, sculptable and fast-setting bone substitute. HydroSet is a calcium phosphate cement that converts to hydroxyapatite, the principle mineral component of bone. The crystalline structure and porosity of HydroSet makes it an effective osteoconductive and osteointegrative material, with excellent biocompatibility and mechanical properties1. HydroSet was specifically formulated to set in a wet field environment and exhibits outstanding wet-field characteristics.2 The chemical reaction that occurs as HydroSet hardens does not release heat that could be potentially damaging to the surrounding tissue. Once set, HydroSet can be drilled and tapped to augment provisional hardware placement during the surgical procedure. After implantation, the HydroSet is remodeled over time at a rate that is dependent on the size of the defect and the average age and general health of the patient.



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Advantages

Injectable or Manual Implantation

HydroSet can be easily implanted via simple injection or manual application techniques for a variety of applications.

Fast Setting

HydroSet has been specifically designed to set quickly once implanted under normal physiological conditions, potentially minimizing procedure time.

Isothermic

HydroSet does not release any heat as it sets, preventing potential thermal injury.

Excellent Wet-Field Characteristics

HydroSet is chemically formulated to set in a wet field environment eliminating the need to meticulously dry the operative site prior to implantation.²

Osteoconductive

The composition of hydroxyapitite closely match that of bone mineral thus imparting osteoconductive properties.³

Augmentation of Provisional Hardware during surgical procedure

HydroSet can be drilled and tapped to accommodate the placement of provisional hardware.

References

- Chow, L, Takagi, L. A Natural Bone Cement A Laboratory Novelty Led to the Development of Revolutionary New Biomaterials. J. Res. Natl. Stand. Technolo. 106, 1029-1033 (2001).
- 2. 1808.E703. Wet field set penetration (Data on file at Stryker)
- Dickson, K.F., et al. The Use of BoneSource Hydroxyapatite Cement for Traumatic Metaphyseal Bone Void Filling. J Trauma 2002; 53:1103-1108.

Ordering Information

Ref	Description
397003	3cc HydroSet
397005	5cc HydroSet
397010	10cc HydroSet
397015	15cc HydroSet

Note: For more detailed information refer to Literature No. 90-07900

Notes

Notes

Notes



Joint Replacements
Trauma, Extremities & Deformities
Craniomaxillofacial
Biologics
Surgical Products
Neuro & ENT
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Navigation
Endoscopy
Communications
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EMS Equipment

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Literature Number: 982279 LOT: D2608

US Patents pending

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