

Osteosynthesis

AxSOS Locking Plate System

Operative Technique

Proximal Lateral Tibia

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Introduction

The AxSOS Locking Plate System is designed to treat periarticular or intra-articular fractures of the Proximal and Distal Tibia, Proximal Humerus and Distal Femur. 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 Lateral Tibial Plate.



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 Proximal Lateral Tibial Plate is designed with divergent fixed-angled screw trajectories which provide improved biomechanical stability and better resistance to pull out. 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.

Monoaxial holes (5)

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

Range

• Longer plates cover a wider range of fractures.

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

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

Innovative Locking Screw design

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

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'Waisted' plate shape

Uniform load transfer.

Rounded & Tapered Plate End

• Helps facilitate sliding of plates sub-muscularly.



Relative Indications & Contraindications

Relative Indications

The indication for use of this internal fixation device includes metaphyseal extra and intra articular fractures of the proximal 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:

Supine with option to flex the knee. Visualisation of the proximal tibia under Fluoroscopy in both the lateral and AP views is necessary.

Lateral Parapatellar. Lateral curved (hockey stick) or straight.

Reduction

Anatomical reduction of the fracture should be performed either by direct visualisation with the help of percutaneous clamps, or alternatively a bridging external Fixator can aid with 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.

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 approximately 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







Conventional direct



Soft-Tissue Reattachment

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



Operative Steps



Fig. 1

Step 1 – Pre-Operative Planning

Use of the X-Ray Template (REF 981091) or Plate Trial (REF 702793) in association with fluoroscopy can assist in the selection of an appropriately sized implant (Fig. 1 & 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.

Note:

Do not place Locking Inserts with the threaded 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. 2A



Fig. 2C

B

Step 2b - Intra - Operative **Locking Insert Application**

If desired, a Locking Insert can be applied in a standard hole(s) 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. 3A). 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. 3B).

Last, apply the Locking Insert by triggering the forceps handle. Push the button on the Forceps to remove the device (Fig. 3C). At this time, remove the Centering Pin.



Fig. 3B







Fig. 3C

Step 3 – Aiming Block/ **Plate Insertion Handle Assembly**

Screw the appropriate Aiming Block (REF 702728/702729) 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. 4).





Step 4 – Plate Application

After skin incision is performed and anatomical reduction is achieved, apply the plate so that the lateral tibial plateau is supported, with the proximal end of the plate approximately 5mm below the articular surface (Fig. 5).

This helps to ensure that the most proximal Locking Screws are directly supporting the joint surface.





Fig. 5 - AP View

Fig. 5 - Lateral View

Step 5 – Primary Plate Fixation – Proximal

The K-Wire hole just distal to the oblong hole allows temporary plate fixation in the metaphysis (Fig. 6).

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

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 the most posterior Locking Screw hole (Fig. 7).

This step shows the position of a posterior screw and also shows its relation to the joint surface. It will also confirm the screw will not be placed intra-articularly or too posterior exiting the cortex into the pupliteal space.

Using fluoroscopy, the position of this K-Wire can be checked until the optimal position is achieved and the plate is correctly positioned. Correct distal placement should also be re-confirmed at this point to make sure the plate shaft is properly aligned over the lateral surface of the Tibial shaft (Fig. 6). If the proximal and axial alignment of the plate cannot be achieved, the K-Wires should be removed, the plate readjusted, and the above procedure repeated until both the posterior K-Wire and the plate are in the desired position. Additional K-Wires can be inserted in the K-Wire holes superior to the locking holes to further help secure the plate to the bone and also support depressed areas in the articular surface.

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

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 in the oblong hole of the plate.

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

The K-Wire below the oblong hole can now be removed.



Fig. 6







Step 6 – 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 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.



Fig. 10



Fig. 11

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. 9). The core diameter of this instrument is 2.4mm to allow a 3.5mm Cortical Screw to be subsequently inserted in the same shaft 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 Cortex Screw must first be placed in the unthreaded metaphyseal plate holes (Fig. 10) 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. 12



Fig. 9

Fixation of the metaphyseal portion of the plate can be started using the preset K-Wire in the posterior 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 8).

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.

The Drill Sleeve should now be removed, and the correct length 4.0mm Locking Screw is inserted using the Screwdriver T15 (REF 702747) and Screw Holding Sleeve (REF 702732) (Fig. 12).

Locking Screws should initially be inserted manually to ensure proper alignment.

Note:

It 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.

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. 13).

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

Note:

The Torque Limiters require routine maintainance. Refer to the Instructions for Maintainance of Torque Limiters (REF V15020).

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, as described above.

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

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.



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.

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







Locked Hole

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 Guide and the standard technique.

These screws can also act as lag screws.





Option 2 – Locking Screws

4.0mm Locking Screws can be placed in the shaft holes provided there is a pre-placed Locking Insert in the hole. (See Step 2).

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. 14).

Avoid any angulation or excessive force on the drill, as this could dislodge the Locking Insert. The screw measurement is then taken.

Step 9 – Kick-Stand Screw Placement

The oblique 'Kick-Stand' Locking Screw (Fig. 15) provides strong triangular fixation to the proximal fragments. It is advised that this screw is placed with the assistance of fluoroscopy to prevent joint penetration and impingement with the proximal Screws (See Step 7 for insertion guidelines). The Aiming Block should now be removed. The appropriate sized Locking Screw is then inserted using the Solid 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 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.



Fig. 15

Final plate and screw positions are shown in Figures 16–18.



Fig. 16

14







Fig. 18



Fig. 19



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. 19). The plate has a special rounded and

tapered end, which allows a smooth insertion under the soft tissue (Fig. 20). Additionally, the Shaft Hole Locator can be used to help locate the shaft holes. Attach the appropriate side of the Shaft Hole Locator (REF 702793) by sliding it over the top of the Handle until it seats in one of the grooves at an appropriate distance above the skin.

The slot and markings on the Shaft 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. 21). The Shaft Hole Locator can then be rotated out of the way or removed.

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. 22) 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 Sleeve (REF 702707) together with the 3.1mm Drill Bit (REF 702742) to drill the core hole.



Fig. 22

Additional Tips

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 three finger

technique" on the Teardrop handle. Avoid any angulations or excessive force on the screwdriver, as this could cross-thread the screw.

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!

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.

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



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.



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.



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

PROXIMAL LATERAL TIBIA

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

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Stainl R	ess Steel EF	Plate Length	Shaft Holes	Locking Holes
Left	Right	mm		
438302	438322	95	2	5
438304	438324	121	4	5
438306	438326	147	6	5
438308	438328	173	8	5
438310	438330	199	10	5
438312	438332	225	12	5
438314	438334	251	14	5

4.0MM LOCKING INSERT



Stainless Steel REF	System mm	
370002	4.0	

Ordering Information - Screws

4.0MM LOCKING SCREW, SELF TAPPING T15 DRIVE

4.0MM CANCELLOUS SCREW, PARTIAL THREAD 2.5MM HEX DRIVE

371514143455141437151616345516163715181834551818371520203455202037152222345522223715242434552424	
37151616345516163715181834551818371520203455202037152222345522223715242434552424	
3715181834551818371520203455202037152222345522223715242434552424	
371520203455202037152222345522223715242434552424	
371522 22 345522 22 371524 24 345524 24	
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371526 26 345526 26	
371528 28 345528 28	
371530 30 345530 30	
371532 32 345532 32	
371534 34 345534 34	
371536 36 345536 36	
371538 38 345538 38	
371540 40 345540 40	
371542 42 345545 45	
371544 44 345550 50	
371546 46 345555 55	
371548 48 345560 60	
371550 50 345565 65	
371555 55 345570 70	
371560 60 345575 75	
371565 65 345580 80	
371570 70 345585 85	
371575 75 345590 90	
371580 80 345595 95	
371585 85	
371590 90	
371595 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 Steel <u>REF</u>	Screw Length mm
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 Ins	struments
HEAR TO BE	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
F	702778	Handle for Plate Insertion
	702712	Drill/K-Wire Measure Gauge
	702776	Temporary Plate Holder
	702776-1	Spare Shaft for Temporary Plate Holder
Comments	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 In	struments
e e e e e e e e e e e e e e e e e e e	702729	Aiming Block, Proximal Tibia, Left
	702728	Aiming Block, Proximal Tibia, Right
	702720-2	Spare Set Screw for Tibia Aiming Block
	702793	Plate Trial/Shaft Hole Locator - Proximal Tibia

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
702841	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

Other Instruments





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 Plateau 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.



CE 1275

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

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