Tibia & Fibula

stryker®

AxSOS

Locking Plate System

Operative Technique

- Distal Anterolateral Tibia
- Distal Medial Tibia
- Alternating threaded shaft holes

Tibia Fractures

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.

All non-sterile devices must be cleaned and sterilized before use. Follow the instructions provided in our reprocessing guide (L24002000). Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/ disassembly instructions.

See package insert (V15011 and V15013) for a complete list of potential adverse effects, contraindications, warnings and precautions. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

Warning:

Fixation Screws:
Stryker Osteosynthesis bone screws are not approved or intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

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Introduction

The AxSOS Locking Plate System is intended for use in long bone fracture fixation. The AxSOS Locking Plate System is indicated for fixation of long bone fractures including fractures of the distal radius, the proximal humerus, the distal tibia, proximal tibia and the 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 anterolateral and medial distal Tibial plates.

Distal Medial Tibial Plate

Distal Anterolateral Tibial Plate

Proximal Lateral Tibial Plate

Proximal Humeral Plate

Distal Lateral Femoral Plate

Features & Benefits

System
The anterolateral and the medial distal tibial plates are designed with optimized fixed-angled screw trajectories in the metaphyseal part and perpendicular fixed-angled screw trajectories which provide increased biomechanical stability. This helps prevent loss of reduction.

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

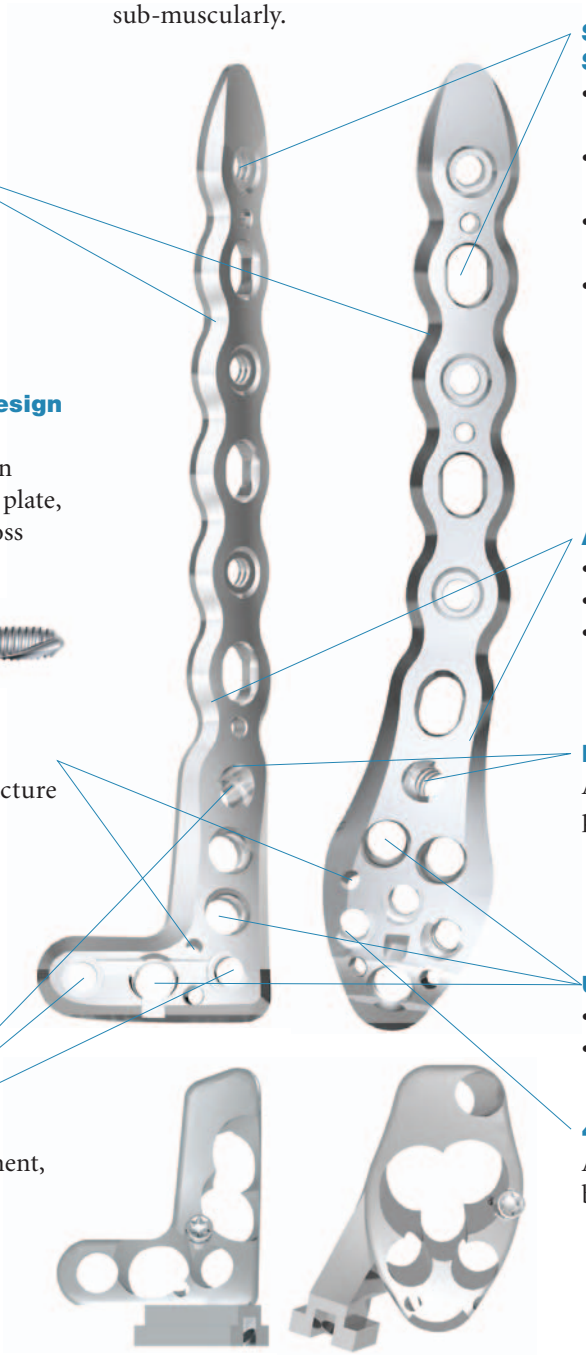
Range
Longer plates cover a wider range of fractures.

Rounded & Tapered Plate End
Helps facilitate sliding of plates sub-muscularly.

Waisted plate shape
Uniform load transfer.

Shaft Holes - Standard or Locking
- Compression, neutral or buttress fixation.
- Accept standard 3.5/4.0mm SPS screws.
- Accept locking insert for axially stable screws.
- Pre-drilled locking holes allow axially stable screw placement.

Innovative Locking Screw design
- Screw is guided into plate.
- The single thread screw design allows easy insertion into the plate, reducing any potential for cross threading or cold-welding.



Anatomically contoured
- Little or no bending required.
- May reduce OR time.
- Facilitates/allows for better soft tissue coverage

K-Wire/Reduction holes
Primary/temporary plate and fracture fixation.

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 (3)
Allow axially stable screw placement, bringing stability to construct.

4 Monoaxial holes
Allow axially stable screw placement, bringing stability to construct.

Aiming Blocks
- Facilitate the placement of the Drill Sleeve.
- Provides attachment point for Plate Insertion Handle

Indications, Precautions & Contraindications

Indications

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

Precautions

Stryker Osteosynthesis systems have not been evaluated for safety and compatibility in MR environment and have not been tested for heating or migration in the MR environment, unless specified otherwise in the product labeling or respective operative technique.

Contraindications

The physician's education, training and professional judgement must be relied upon to choose the most ap-propriate 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 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.

Operative Technique

General Guidelines

Patient Positioning: Supine

Surgical Approach Lateral: Between lateral tibia and fibula

Surgical Approach Medial: Distal oblique 1cm proximal to the medial malleolus

Instrument / Screw Set: 4.0mm

Reduction

Anatomical reduction of the fracture should be performed either by direct visualization with the help of percutaneous reduction 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 visualize/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.

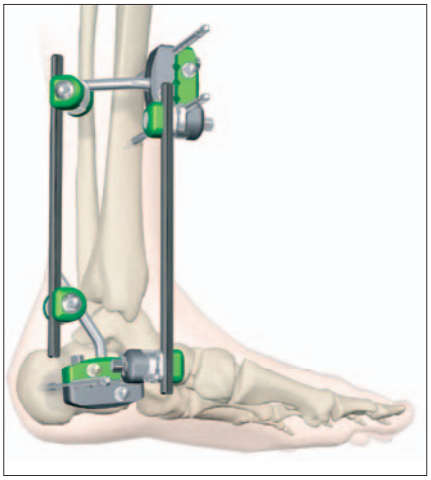
Note:

When using a sub muscular technique, please refer to the relevant section on page 18.

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 below the oblong hole is not recommended. Plate contouring will affect the ability to place a Locking Insert into the shaft holes adjacent to the bending point.



Operative Technique

General Guidelines

Locking Screw Measurement

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

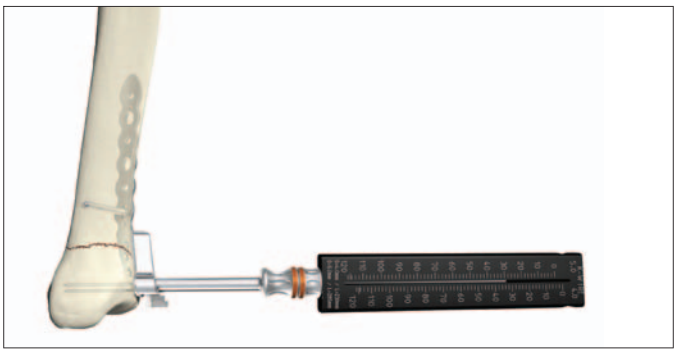
Correct Screw Selection

Note:

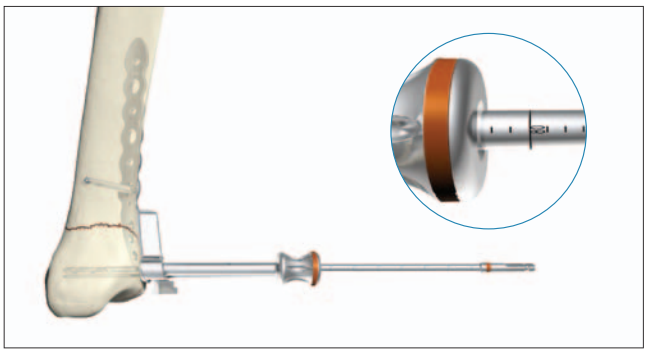
Select a screw approximately 2-3mm shorter than the measured length to avoid screw penetration through the opposite cortex in metaphyseal fixation.

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

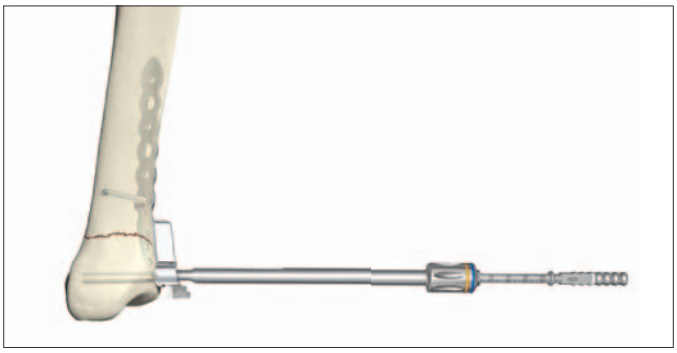
Measurement Options



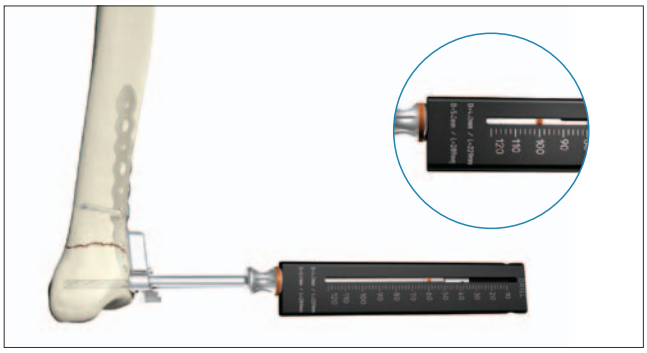
Measure off K-Wire



Read off drill bit calibration



Conventional direct measurement



Measure off the end of drill bit

Operative Technique

Step 1 – Pre-Operative Planning

Use of the X-Ray template (REF 981083 for lateral or 981082 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 - 1B).

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. 1

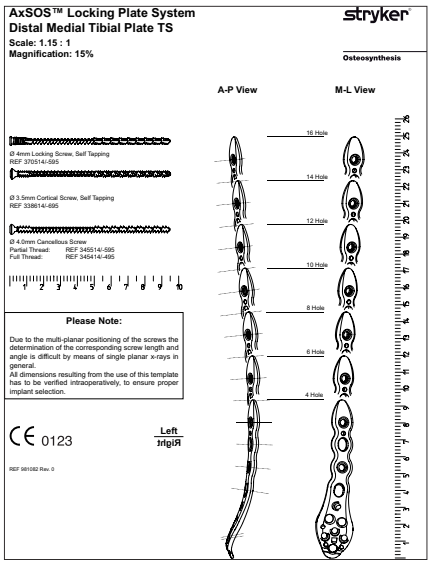


Fig. 1A

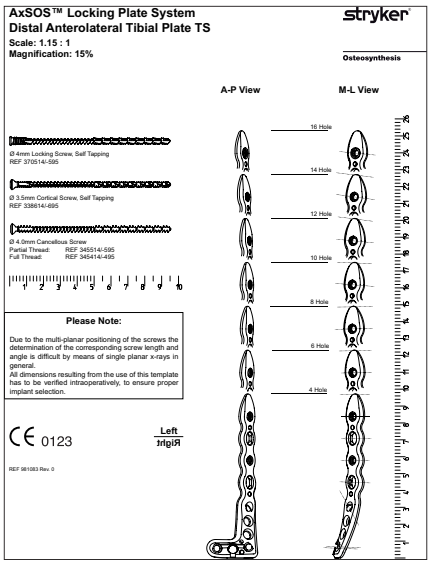


Fig. 1B

Step 2 – Pre-Operative Locking Insert Application

If additional 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).

Note:

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 proximal plate fixation, then a Locking Insert must not be placed in the same hole as the Temporary Plate Holder (See Step 6).

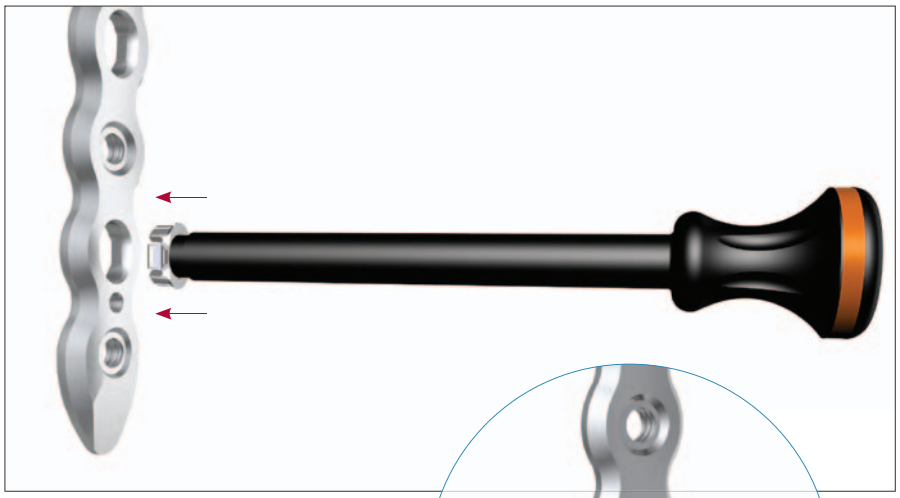


Fig. 2

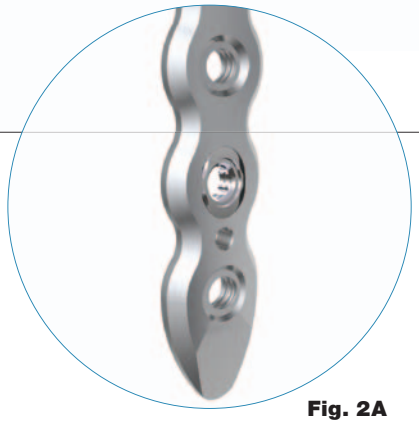


Fig. 2A

Step 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 should then be discarded, as it should not be reused.

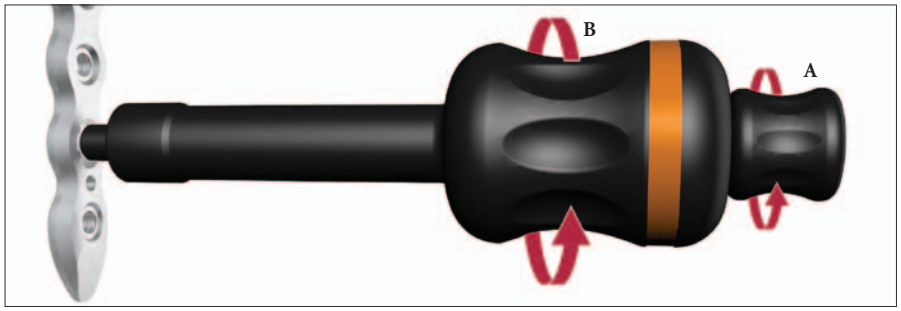


Fig. 2B

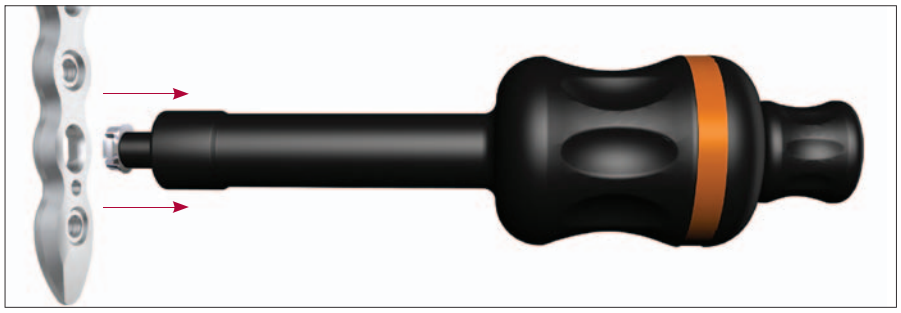


Fig. 2C

Step 2b – Intra-Operative Locking Insert Application

If desired, a Locking Insert can be applied in a standrad 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. 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.

Last, apply the Locking Insert by triggering the forceps handle. Push the button on the forceps to remove the device. At this time, remove the centering pin (Fig. 3B).

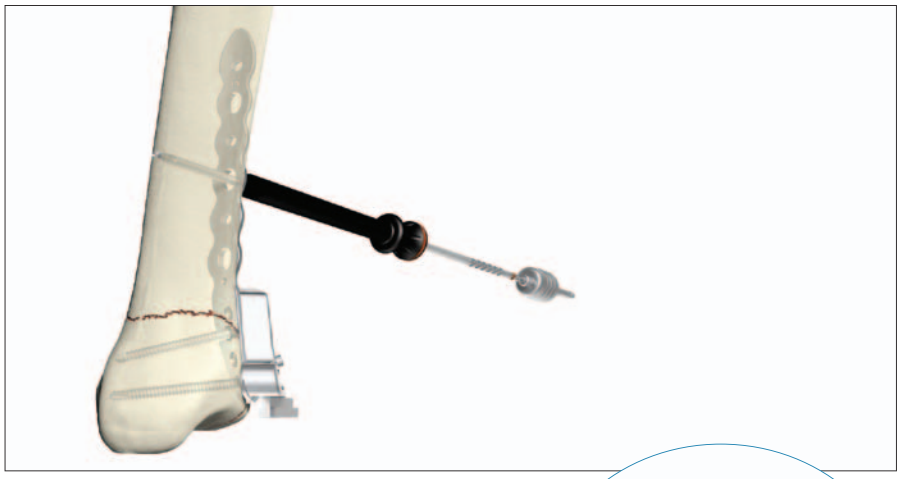


Fig. 3A

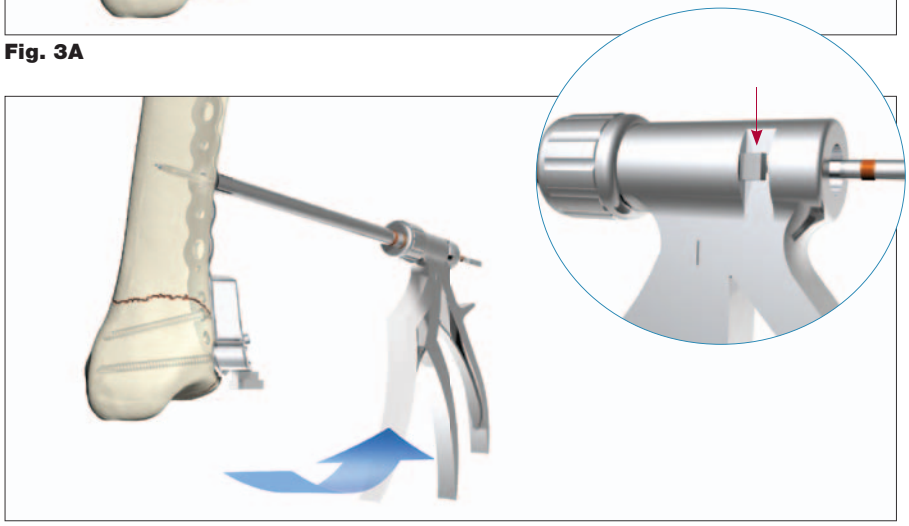


Fig. 3B

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 4).

Fig. 4

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. 5).

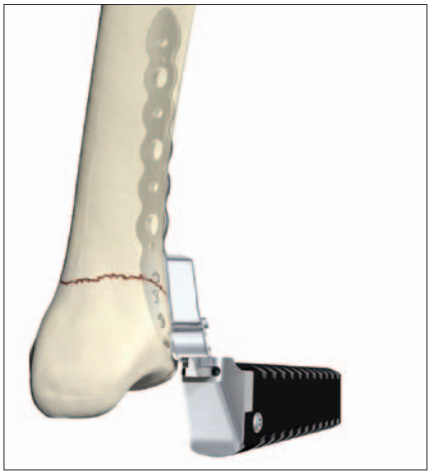


Fig. 5 – Medial View

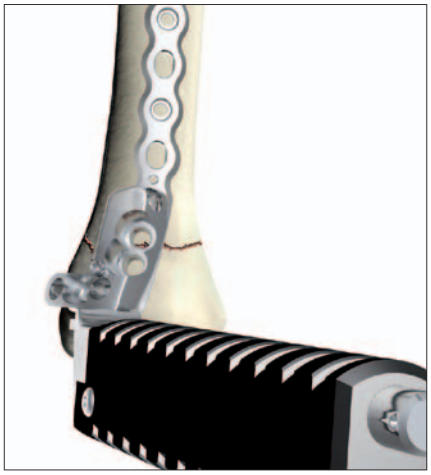


Fig. 5 – Lateral View

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 2.0×230mm K-Wire can then be inserted into one of the distal Locking Screw holes (Fig. 6). This step shows the position of the screw in relation to the joint surface and confirms the screw will not be intra-articular.

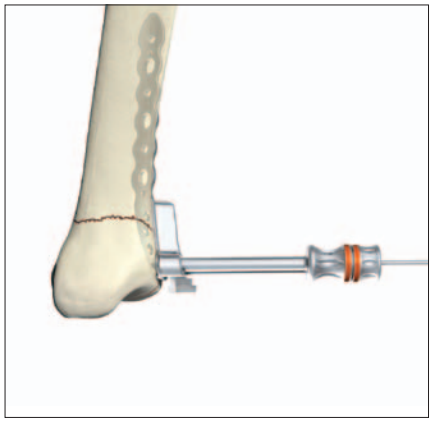


Fig. 6

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 re-confirmed at this point to make sure that the plate shaft is properly aligned over the lateral surface of the tibial shaft (Fig. 7). 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 achieved, 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.

Additional 2.0×150mm K-Wires (REF 390192) 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.

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.

Using a 2.5mm Drill Bit (REF 700347-125mm or REF 700355- 230mm) and Double Drill Guide (REF 702418), drill a core hole to the appropriate depth in the first non-threaded 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 the 2.5mm hexagonal Screwdriver (REF 702841) together with the Screw Holding Sleeve (REF 702490) (Fig. 8).

If inserting a Cancellous Screw, the near cortex must be pre-tapped using the Tap (REF 702805) and the Tear-drop Handle (REF 702428).

Any K-Wires in the shaft can be removed upon adequate screw fixation.

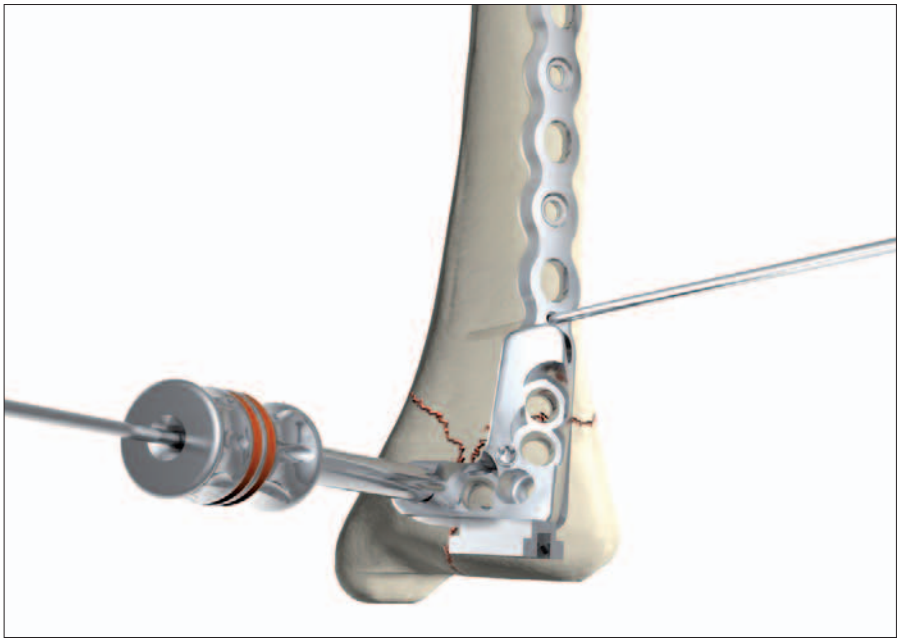


Fig. 7

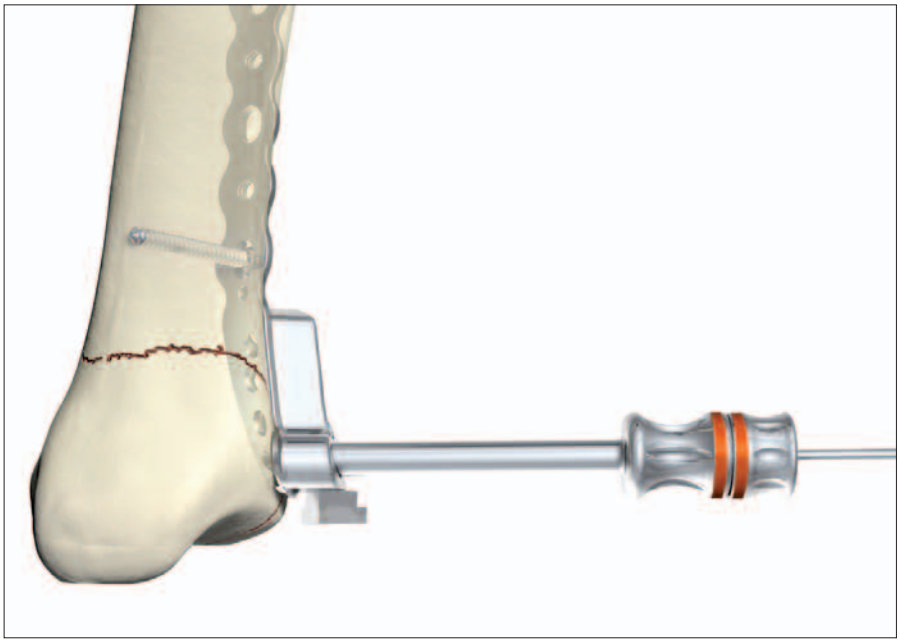


Fig. 8

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 Cortex Screw or 4.0mm cancellous Screw using the standard technique.
- A 4.0mm Locking Screw in the pre-threaded locking holes or with a Locking Insert in the standard holes (see Step 8 – Shaft Fixation).
- The Temporary Plate Holder (REF 702776) in the last unthreaded shaft hole.

In addition to providing temporary fixation, the 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. 9).

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.

The Temporary Plate Holder can also be used for indirect reduction anywhere along the fracture site using the "Pull Reduction Method".

Note:

A Locking Insert and Locking Screw should not be used in the hole where the Temporary Plate Holder is used.

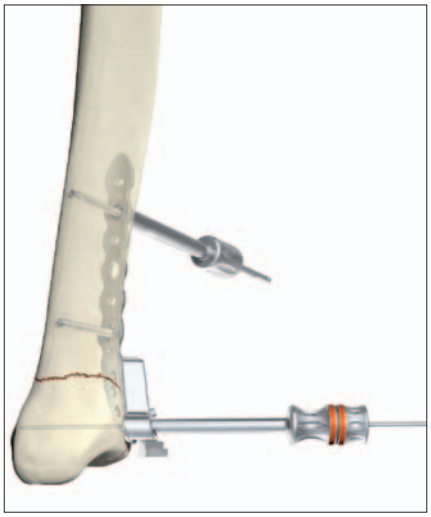


Fig. 9

Step 7 – Metaphyseal Locking

Locking Screws cannot act as Lag Screws. Should interfragmentary compression be desired, a 4.0mm Standard cancellous Screw or a 3.5mm Standard 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. 11).

Fig. 10

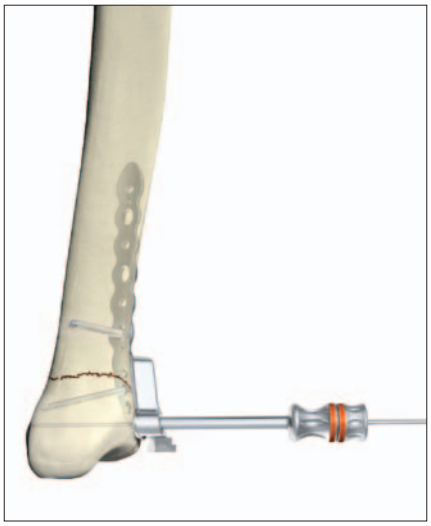


Fig. 11

Operative Technique

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 Measure 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. 12).

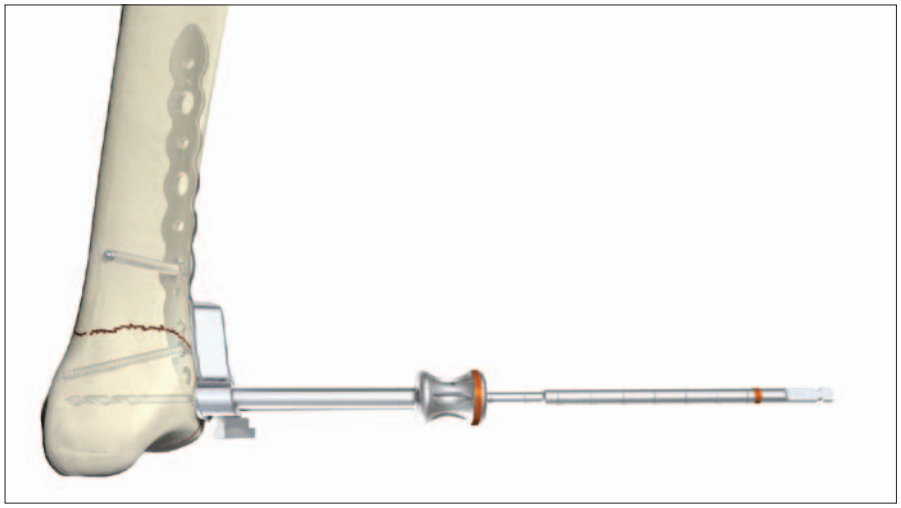


Fig. 12

Using Fluoroscopy, check the correct depth of the drill, and measure the length of the screw using the Depth Gauge for Locking Screws (REF 702884).

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. 13).
Locking Screws should initially be inserted manually to ensure proper alignment.

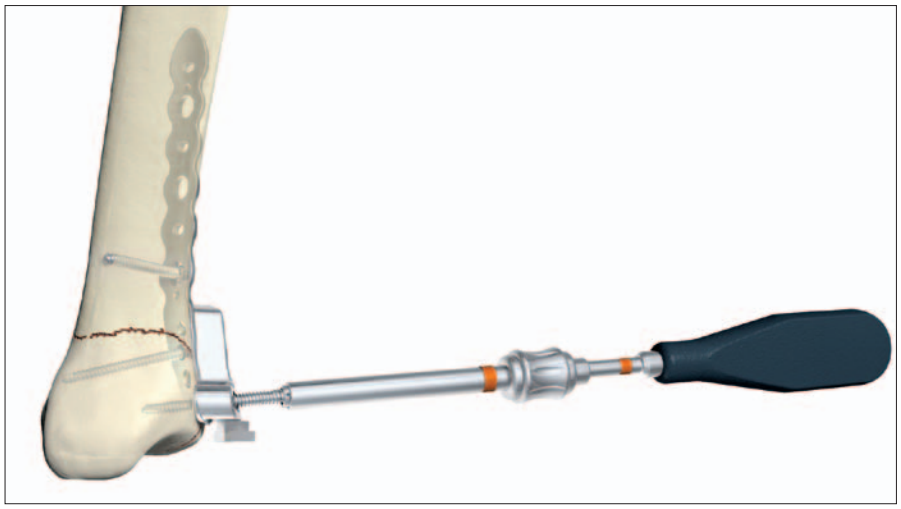


Fig. 13

Note:

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

Operative Technique

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. 14). 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 4.0Nm.

Note:

- **The Torque Limiters require routine maintenance. Refer to the instructions for Maintenance of Torque Limiters (REF V15020).**

If inserting Locking Screws under power, make sure to use a low speed drill setting to avoid damage to the screw/plate interface and potential thermal necrosis. Perform final tightening by hand, as described above.

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.

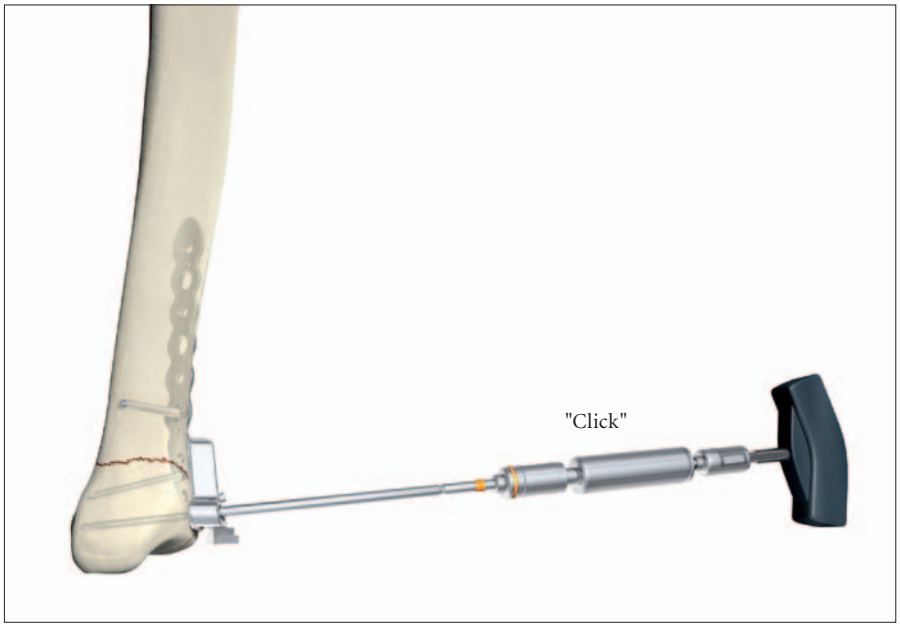
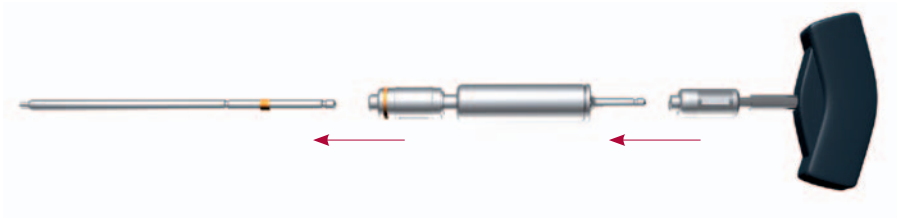


Fig. 14



Operative Technique

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. Locking Screws can be inserted in the predrilled locking holes or together with the corresponding Locking Inserts.

Note:

If a combination of Standard and Locking Screws is used in the shaft, the plate fixation should begin with Standard Cortical Screws prior to the Locking Screws. Always lag before you lock.

Locked Hole

70° Axial Angulation **14° Transverse Angulation**

(Non-locked holes only)

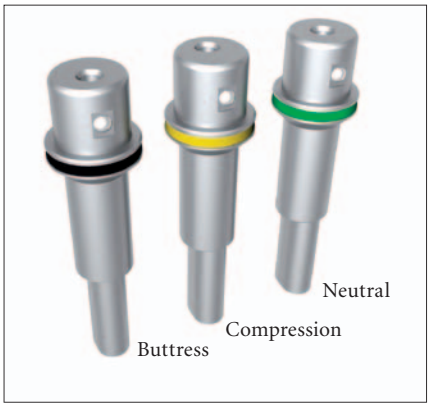
Option 1 – Standard Screws

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.

Note:

This is only possible in non-threaded holes.



Option 2 – Locking Screws

4.0mm Locking Screws can be placed in the threaded shaft holes or holes with pre-placed Locking Inserts.

Use the Drill Sleeve (REF 702707) to pre-drill the core hole for subsequent Locking Screw placement. The Drill Sleeve should be fully inserted into the pre-threaded hole or Locking Insert to ensure initial fixation of the Locking Insert into the plate.

A 3.1mm Drill Bit (REF 702742) is used to drill through both cortices (Fig. 15).

Note:

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.

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.

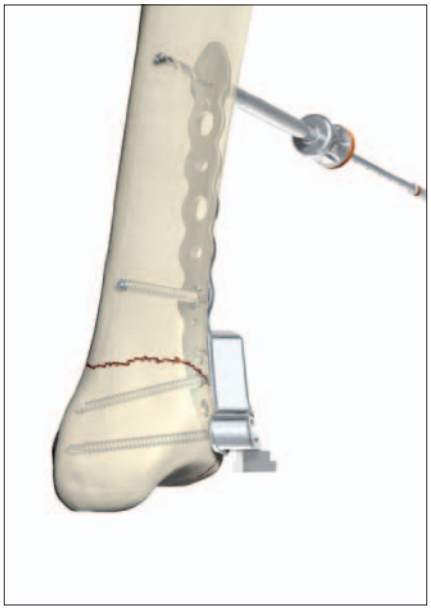


Fig. 15

Step 9 – Kick-Stand Screw Placement

The oblique 'Kick-Stand' Locking Screw provides strong triangular fixation to the opposite fragments.

It should be the last screw in the metaphyseal portion of the plate.

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 6 for insertion guidelines).

The Aiming Block should now be removed.

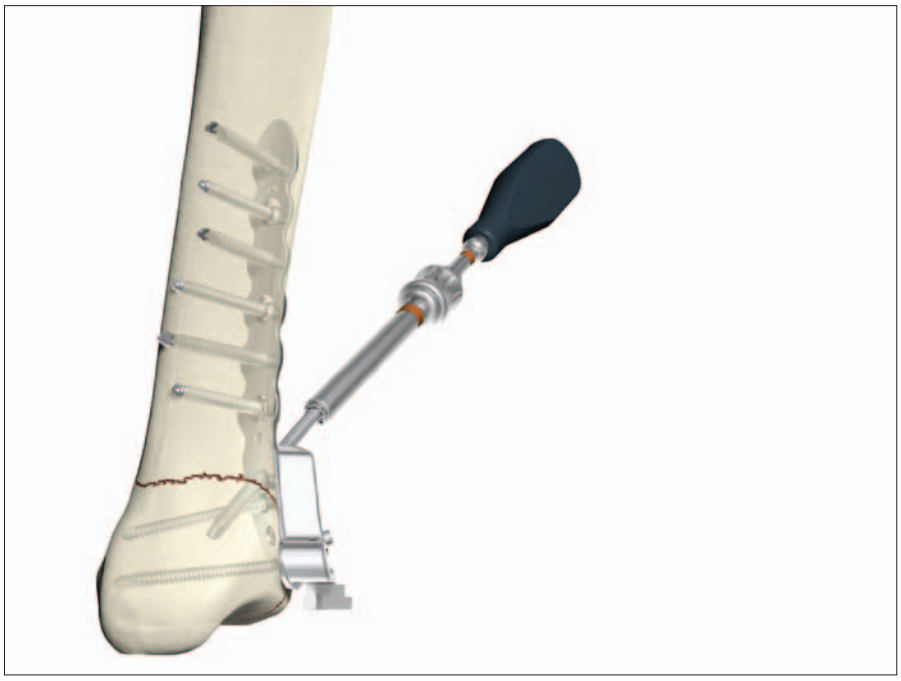


Fig. 16

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 over the periosteum (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 an 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 Shaft Hole Locator can then be rotated out of the way or removed.

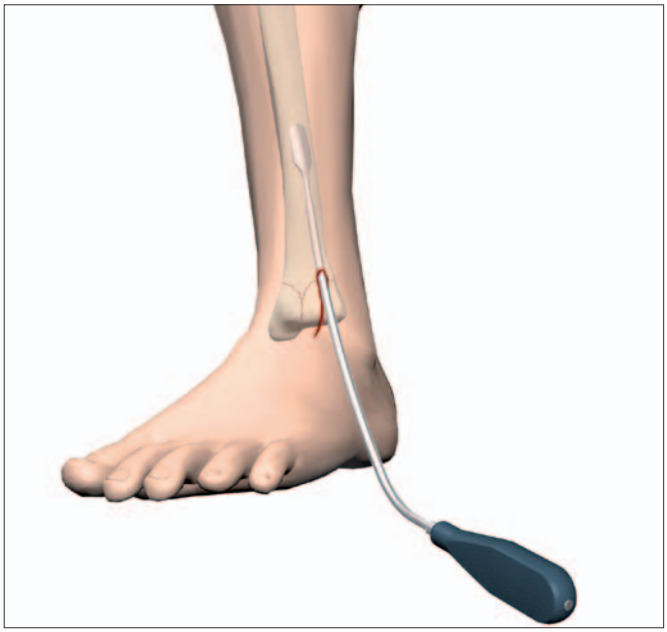


Fig. 17

Fig. 18

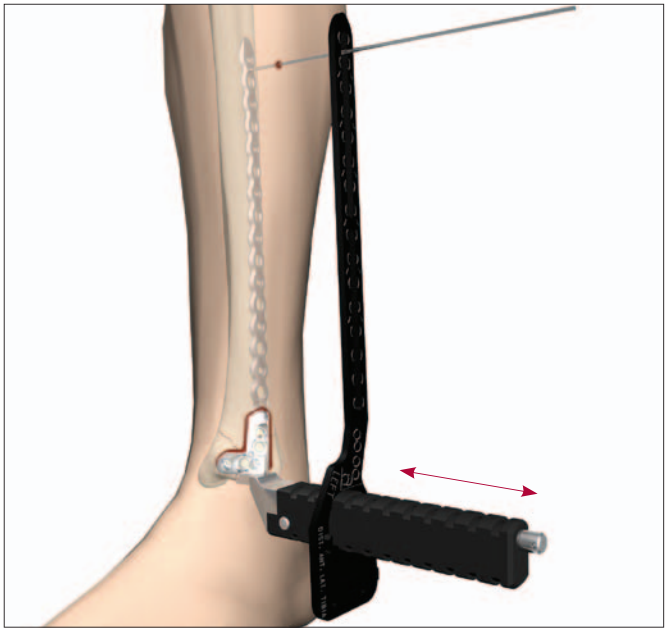
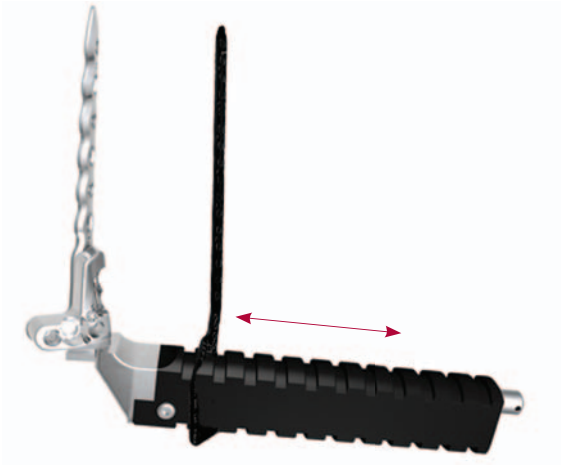


Fig. 19



Operative Technique

With the aid of the Soft Tissue Spreader (REF 702919) and Trocar (REF 702961), the skin can be opened to form a small window (Fig. 20–21) through which either a Standard Screw or Locking Screw can be placed.

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).

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.

Fig. 20

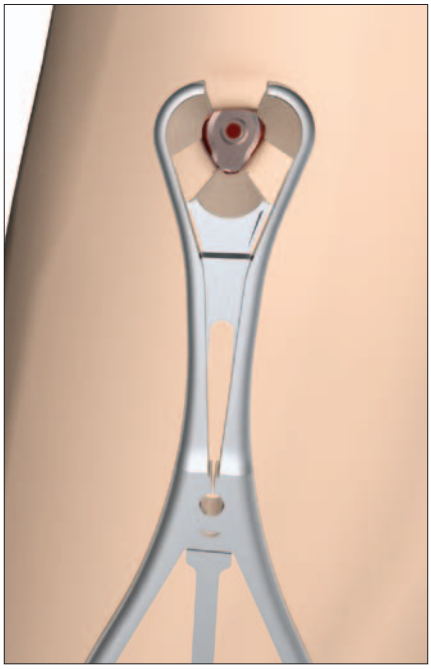


Fig. 21

Operative Technique

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

Fig. 22

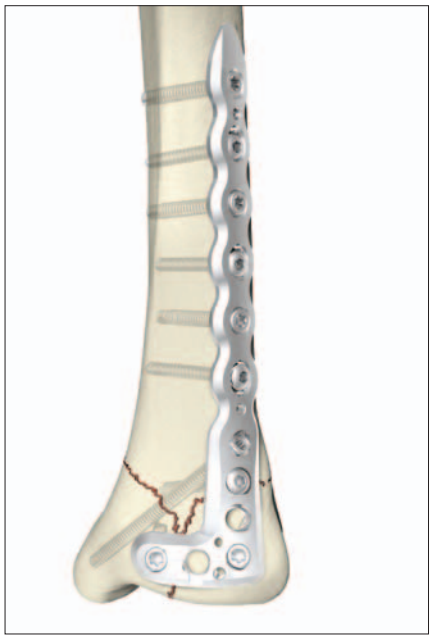


Fig. 23

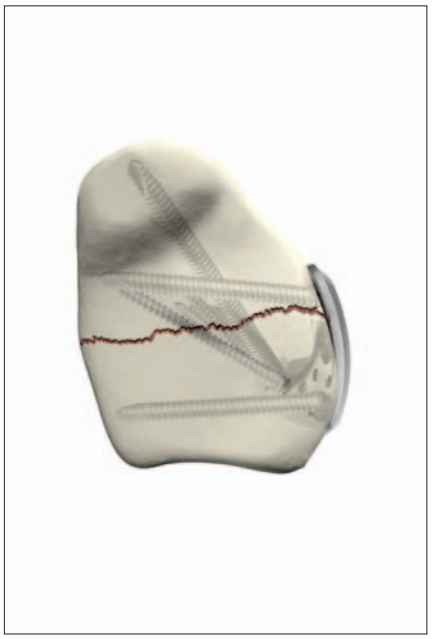


Fig. 24

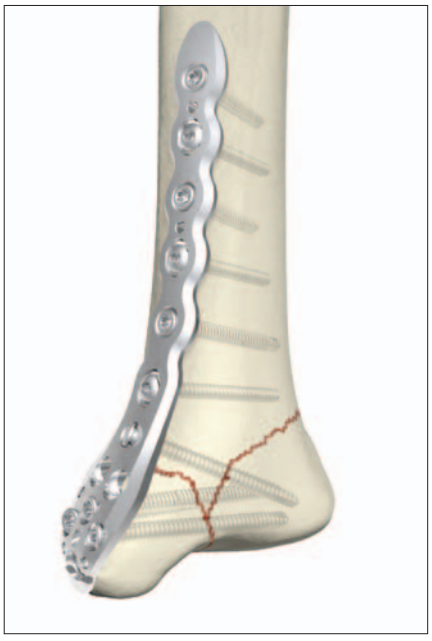


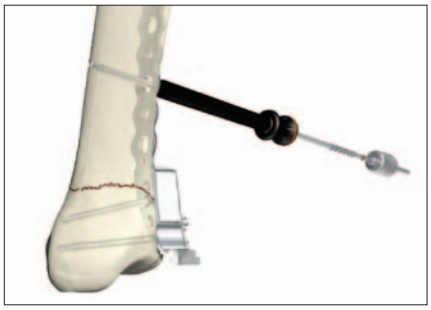
Fig. 25

Fig. 26

Fig. 27

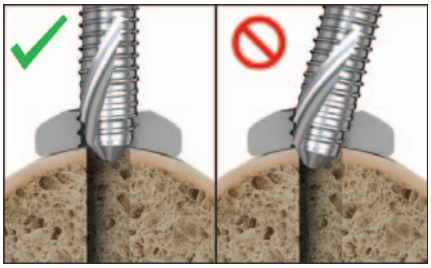
Additional Tips

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.

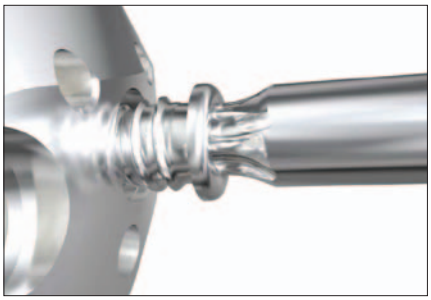


If the Locking Screw thread does not immediately engage the plate thread, reverse the screw a few turns and re-insert the screw once it is properly aligned.

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.

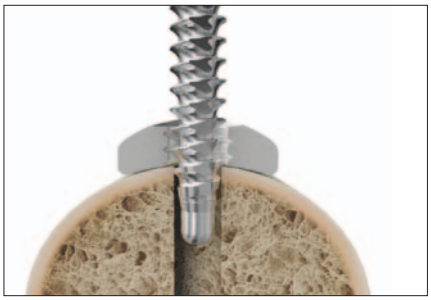
Allow the single, continuous threaded screw design to engage the plate and cut the thread in the bone on its own, as designed.

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.

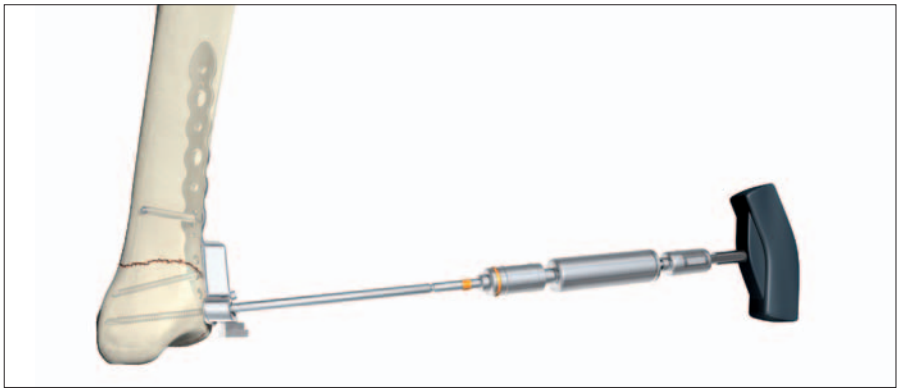
4. It is advisable to **tap hard** (dense) **cortical bone** before inserting a Locking Screw.
Use 4.0mm Tap (702772).



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 4.0mm
Standard Screws 3.5, 4.0mm

Stainless Steel REF Left	Stainless Steel REF Right	Plate Length mm	Shaft Holes	Locking Holes Metaphyseal	Locking Holes Shaft
437404	437424	97	4	3	2
437406	437426	123	6	3	3
437408	437428	149	8	3	4
437410	437430	175	10	3	5
437412	437432	201	12	3	6
437414	437434	227	14	3	7
437416	437436	253	16	3	8

DISTAL MEDIAL TIBIA

Locking screws 4.0mm
Standard Screws 3.5, 4.0mm

Stainless Steel REF Left	Stainless Steel REF Right	Plate Length mm	Shaft Holes	Locking Holes Metaphyseal	Locking Holes Shaft
437204	437224	94	4	4	2
437206	437226	120	6	4	3
437208	437228	146	8	4	4
437210	437230	172	10	4	5
437212	437232	198	12	4	6
437214	437234	224	14	4	7
437216	437236	250	16	4	8

4.0MM LOCKING INSERT

Stainless Steel REF	System mm
370002	4.0

4.0MM CABLE PLUG

Stainless Steel REF	System mm
370004	4.0

Note:

For Sterile Implants, add "S" to the REF.

Ordering Information – Implants

4.0MM LOCKING SCREW, SELF TAPPING

T15 Drive

Stainless Steel REF	Screw Length mm
371514	14
371516	16
371518	18
371520	20
371522	22
371524	24
371526	26
371528	28
371530	30
371532	32
371534	34
371536	36
371538	38
371540	40
371542	42
371544	44
371546	46
371548	48
371550	50
371555	55
371560	60
371565	65
371570	70
371575	75
371580	80
371585	85
371590	90
371595	95

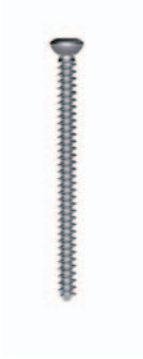
4.0MM CANCELLOUS SCREW, PARTIAL THREAD

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

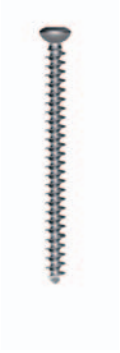
2.5mm Hex Drive



Stainless Steel REF	Screw 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

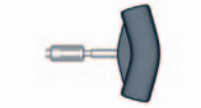


Stainless Steel REF	Screw Length mm
345414	14
345416	16
345418	18
345420	20
345422	22
345424	24
345426	26
345428	28
345430	30
345432	32
345434	34
345436	36
345438	38
345440	40
345445	45
345450	50
345455	55
345460	60
345465	65
345470	70
345475	75
345480	80
345485	85
345490	90
345495	95

Note:

For Sterile Implants, add "S" to the REF.

Ordering Information – Instruments

	REF	Description
		4.0mm Locking Instruments
	702742	Drill Ø3.1mm × 204mm
	702772	Tap Ø4.0mm × 140mm
	702747	Screwdriver T15, L200mm
	702753	Solid Screwdriver Bit T15, L115mm
	702732	Screw Holding Sleeve
	702702	K-Wire Sleeve
	702707	Drill Sleeve
	702884	Direct Depth Gauge for Locking Screws
	702750	Universal Torque Limiter T15 / 4.0mm
	702762	Locking Insert Inserter 4.0mm
	702427	T-Handle Small, AO Fitting
	38111090	K-Wire (Trocar Point Steinmann Pin Ø2.0mm × 230mm)
	702767	Locking Insert Extractor
	702778	Handle for Plate Insertion
	702712	Drill/K-Wire Measure Gauge
	702776	Temporary Plate Holder
	702776-1	Spare Shaft for Temporary Plate Holder
	702919	Soft Tissue Spreader
	702961	Trocar (for Soft Tissue Spreader)
	702782	Soft Tissue Elevator
	702756	Bending Irons (×2)

Ordering Information – Instruments

	REF	Description
		4.0mm Locking Instruments
	702968	Locking Insert Forceps
	702671	Guide for Centering Pin
	702673	Centering Pin
	702675	Adapter for Centering Pin
	702723	Aiming Block, Distal Anterolateral Tibia, Left
	702722	Aiming Block, Distal Anterolateral Tibia, Right
	702725	Aiming Block, Distal Medial Tibia, Left
	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
		Optional Instrument
	703616	Drill Ø3.1 × 204mm, flat Tip

Ordering Information – Instruments

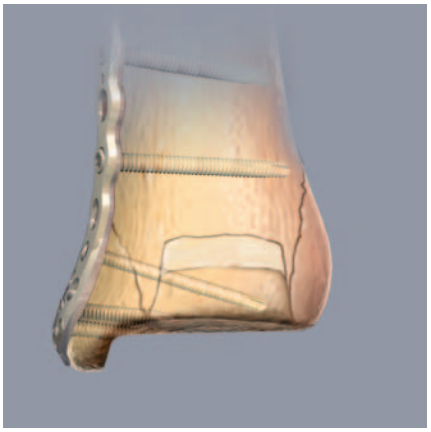
REF	Description
SPS Standard Instruments	
700347	Drill Bit Ø2.5mm×125mm, AO
700355	Drill Bit Ø2.5mm×230mm, AO
700353	Drill Bit Ø3.5mm×180mm, AO
702804	Tap Ø3.5mm×180mm, AO
702805	Tap Ø4.0mm×180mm, AO
702418	Drilling Guide Ø3.5/2.5mm
702822	Drill Sleeve Handle
702825	Drill Sleeve Ø2.5mm Neutral
702829	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 Ø2.7/3.5/4.0mm
702841	Screwdriver Hex 2.5mm for Standard Screws L200mm
702485	Solid Screwdriver Bit, Hex 2.5mm for Standard Screws L115mm
702490	Holding Sleeve for Screwdrivers For Screwheads: Ø6.0mm
702428	Tear Drop Handle, small, AO Fitting
900106	Screw Forceps
390164	K-Wires 1.6mm×150mm (optional)
390192	K-Wires 2.0mm×150mm
Other Instruments	
 702755	Torque Tester with Adapters
981082	X-Ray Template, Distal Medial Tibia
981083	X-Ray Template, Distal Anterolateral Tibia
Cases and Trays	
902955	Metal Base - Instruments
902929	Lid for Base - Instruments
902930	Instrument Tray 1 (Top)
902931	Instrument Tray 2 (Middle)
902963	Instrument Tray 3 (Bottom incl. Locking Insert Forceps)
902932	Screw Rack
902949	Metal Base - Screw Rack
902950	Metal Lid for Base - Screw Rack
902947	Metal Base - Implants
902972	Implant Tray - Distal Anterolateral Tibia
902977	Lid for Implant Tray - Distal Anterolateral Tibia
902973	Implant Tray - Distal Medial Tibia
902978	Lid for Implant Tray - Distal Medial Tibia
902958	Locking Insert Storage Box 4.0mm

Additional Information – HydroSet Injectable HA

Indications

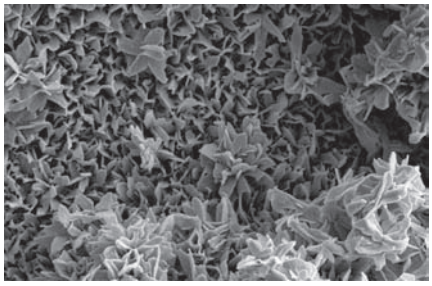
HydroSet is a self-setting calcium phosphate cement indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, craniofacial, spine, and pelvis). These defects may be surgically created or osseous defects created from traumatic injury to the bone. HydroSet is indicated only for bony 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.**
- **For more detailed information refer to Litterature No. 90-07900.**



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 properties[1]. 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
1. 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)
3. Dickson, K.F., et al. The Use of BoneSource Hydroxyapatite Cement for Traumatic Metaphyse

Ordering Information

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

stryker®

Joint Replacements

Trauma, Extremities & Deformities

Craniomaxillofacial

Spine

Biologics

Surgical Products

Neuro & ENT

Interventional Spine

Navigation

Endoscopy

Communications

Imaging

Patient Care & Handling Equipment

EMS Equipment

Manufactured by:

Stryker Trauma AG
Bohnackerweg 1
CH - 2545 Selzach
Switzerland

www.osteosynthesis.stryker.com

Literature Number: **982300**
LOT **E4110**