

OxBridge™

Ankle Fusion Nail

Design Rationale & Surgical Technique



OrthoSolutions 
Group

Advancing Foot & Ankle Care



Clinical Design Team



Mr Paul Cooke
MB ChB FRCS ChM

Consultant Orthopaedic Surgeon
in Foot & Ankle Surgery at Nuffield
Orthopaedic Centre, Oxford. UK



Mr Robert Sharp
BMBch MA FRCS
(Trauma & Ortho)

Consultant Orthopaedic Surgeon
in Foot & Ankle Surgery at Nuffield
Orthopaedic Centre, Oxford. UK



Mr Andrew Robinson
BSc FRCS (Orth)

Consultant Orthopaedic & Trauma
Surgeon, Addenbrookes Hospital NHS
Trust, Cambridge. UK



Design Goal - Simplifying the Complex

Tibiototalcalcaneal arthrodesis is a successful treatment for patients with severe pain and functional disability. Combined fusion of the ankle and subtalar joints is often used in the complex case, with significant bone loss or deformity.

Stable fixation can be achieved in many ways using a range of fixation devices. Nevertheless it is important that the hindfoot alignment is stably fixed, preferably with compression. Retrograde tibiototalcalcaneal nailing is a powerful surgical option for patients who require secure fusion of the ankle and subtalar joint.

In developing the OxBridge Ankle Fusion Nail the aim was to develop a simple and versatile system to internally fix the ankle and subtalar joints. The three design surgeons are all experienced and have witnessed the evolution of the hindfoot nail.

Based on their experience the OxBridge Ankle Fusion Nail has been designed to provide an instrument system that offers a simple and reproducible surgical technique. This is particularly important for this group of patients who present with complex anatomy, compromised bone quality and significant deformity.

Design Rationale

1 Dynamic or Static Locking Options

Choice of dynamic and static proximal locking screw options allow dynamic loading of the nail if required.





3 Material

The nail is made from Titanium alloy (Ti6Al4V), Type II anodised. The material offers improved modulus of elasticity, fatigue strength and biocompatibility compared to stainless steel.

4 Nail Sizing

Three nail diameters (10mm, 11mm & 12mm) and three nail lengths (150mm, 180mm & 250mm) accommodate anatomical variation and reduce inventory requirements.

N.B. 250mm nail lengths to be locked freehand in the proximal tibia.

5 PA and ML Distal Screw Placement

Two posterior anterior distal screw options and two medial lateral screw options are available. This ensures that the distal screws can be positioned accurately in the calcaneum and talus, for secure fixation.

6 End Caps

Two end cap designs are available
– impinging and non impinging. The impinging design prevents migration of the PA screw. The caps also protect the distal thread from tissue ingrowth.

2 Low Profile Cortical Screws

- Ultra low profile heads and soft tips of 5.0mm cortical screws minimise the likelihood of soft tissue irritation at the subcutaneous border.
- Choice of insertion point – medial to lateral or lateral to medial.
- Self tapping for ease of insertion.
- Fully threaded to achieve fixation in both cortices
- 2mm length increments of proximal cortical screws to accommodate size variation of tibia.



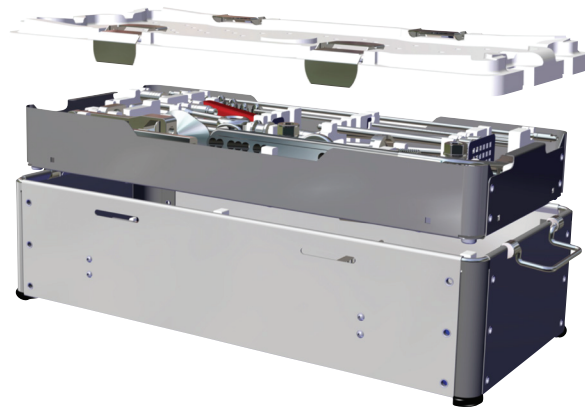
7 Supplementary Rotational Stability & Axial Compression

- Independent 6.5mm cannulated compression screw can be inserted obliquely with the miss- a-nail jig to increase rotational stability and axial compression.
- These cancellous screw options ensure compression can be augmented across the fusion sites.

Instrumentation – Key Advantages

Instrumentation System

The OxBridge instrument set and surgical technique have been designed to be as simple and straightforward as possible. All the instruments are supplied in one tray and laid out for quick access and ease of use.



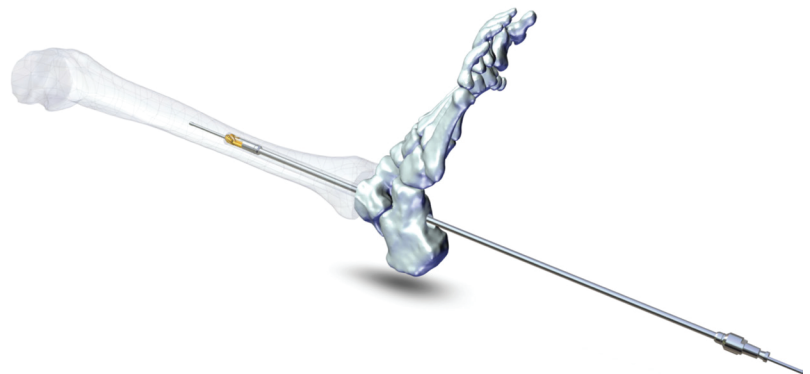
Primary Jig - Nail Entry Site

Correct positioning of the rigid 3.9mm guide wire, and ultimately the nail, is essential to ensure that the calcaneum and tibia are aligned and the tibial cortex is not breached. The primary jig is easy to use and helps ensure that the guide wire is accurately positioned and reduces the likelihood of malpositioning of the nail.



Reaming

A Ø2.6 x 900 mm olive tipped reaming rod is utilised to ensure accurate reamer positioning. The instrument set contains a flexible nitinol reamer shaft and associated modular heads which have been specifically designed to allow for the Ø2.6 x 900 mm olive tipped reaming rod to be withdrawn through the nail after insertion, eliminating the need for an exchange step and saving time.





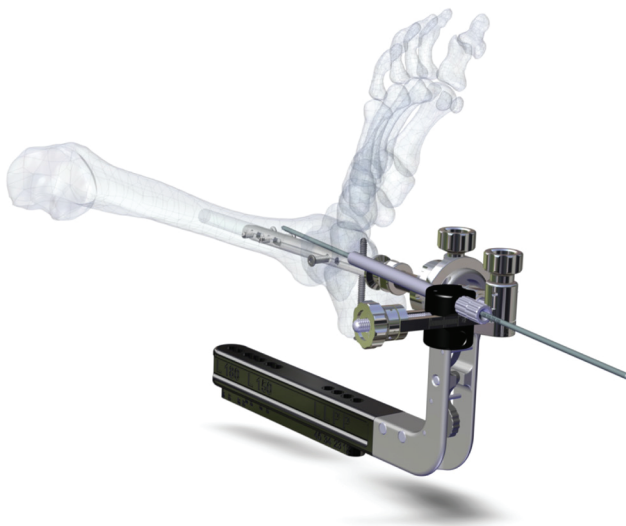
Outrigger Jig

The outrigger jig has been designed to be simple, accurate and easy to use. The trigger mechanism allows for quick and easy rotation of the radial arm through medial, posterior and lateral positions around the nail axis. The radial arm is made from radiolucent PEEK to facilitate full X-Ray visualisation in multiple planes.



External Compression Options

External compression can be applied to the fusion site through the outrigger jig. Where patients have compromised bone quality the heel cushion compression plate can be utilised. Compression can therefore be applied to the resected surfaces of the fusion site irrespective of bone quality.



Miss-a-Nail Screw Placement

Additional compression and rotational stability of the fusion site can be augmented by positioning a cannulated screw either anterior, or posterior to the nail, or both. The jig ensures that the insertion of the cannulated screw is a simple procedure and the screw can be positioned in the most appropriate bone stock for the best possible fixation.

This surgical technique guide is intended as a reference for trained orthopaedic surgeons. It does not replace the full Instructions for Use (IFU), which contains material/allergen/ biocompatibility information, indications, contraindications, warnings and precautions, sterilisation/processing instructions, an MRI safety statement and other information critical to safe and effective device usage. Surgeons should consult the IFU before use. The IFU for the OxBridge™ Ankle Fusion Nail is available electronically at www.orthosol.com/eIFU or in paper form upon request by contacting regulatory@orthosol.com.

Preoperative Planning

A full preoperative clinical assessment is made with attention to general and local comorbidities with particular attention to previous incisions, neurological and vascular status.

Mortise and lateral radiographs, usually weight bearing, are essential. CT or MRI imaging may assist in preoperative planning.

X-Ray templates are provided for implant sizing.

Patient Positioning

Patient positioning is based on surgeon preference / surgical approach and the procedure specific needs of the case. General, spinal or epidural anaesthesia, with or without a regional block is used.

The patient is positioned supine, semi-supine with a sandbag under the ipsilateral buttock or in the lateral decubitus position on a radiolucent operating table. Ensure adequate and effective, padding is used for patient protection.

Apply a well-padded tourniquet to the upper thigh of the operated leg, prepare and drape accordingly. Experience has shown that immediately following insertion of the nail, the tourniquet may be safely

released as the hindfoot fixation provided by the nail helps to control blood loss. Operative and tourniquet times can be minimised by performing locking and closure of the wound after tourniquet release in most cases. For cases with vascular compromise consider not using a tourniquet.

TIP: Ensure the lower tibia and foot are clear of radiopaque areas. It is helpful to position the calf in a raised position on an upturned bowl or equivalent. This decreases the tendency for the lower limb to rotate and prevents malposition as a result of the heel resting on the table, pushing the foot anteriorly relative to the tibia. It also safeguards the posteromedial neurovascular bundle.

Surgical Exposure

Formal preparation of both the ankle and subtalar joints is recommended. Anterior, lateral (transfibular) or medial approaches for open preparation of the joint surfaces can be used. Arthroscopic burr preparation can be used by those familiar with the technique, allowing percutaneous nail insertion.

This Ortho Solutions operative guide is based on a transfibular lateral approach.

The upper limit of the fibular incision should be at least 1 finger's breadth (2cm) above the level of the tibial plafond. Continue the incision over the fibula curving anteriorly at the tip of the fibula towards the base of the 4th metatarsal.

The fibula is divided proximal to the tibial plafond. The fibula is then mobilised, and the distal ligaments transected. The fibula is removed allowing access to

the subtalar joint. Cancellous bone can be harvested from the resected fibula and utilised as bone graft. It can be easier to section the fibula with a saw in 2 to 3mm "salami" sections during removal, to ease bone graft preparation.

A separate anteriomedial approach to prepare the medial malleolus is sometimes required.

TIP: In choosing the correct approach, try to utilise old incisions. Often the best approach is the one that the surgeon is most familiar with. Correction of deformity is most easily corrected by approaching the ankle and subtalar joints from the long side of the deformity - the lateral side for varus deformity, from anterior in equinus deformity (ankle only) and the medial side in valgus.

Fusion Site Preparation

An ankle arthrodesis is now performed in the standard manner, thoroughly preparing the joint surfaces using osteotomes, chisels or a saw according to preference. Image intensifier guidance can be helpful. A separate anteromedial incision over the medial gutter often helps. The medial malleolus is preserved, as a medial buttress.

The subtalar joint is prepared in a similar fashion, paying attention to the anterior, middle and posterior facets.

It is essential that the hindfoot is reduced and aligned beneath the tibia. The foot should be positioned such that with the patient standing the foot is flat to the ground in all planes. Inability to reduce the subtalar joint may mean that the anterior or middle facet or the posteromedial corner of the posterior facet have not been sufficiently resected.

The foot should be positioned in neutral or slight external rotation referencing from the tibial tuberosity at the knee.

The Ortho Solutions system uses a rigid guide wire. It is impossible to pass this wire anatomically aligned through the talus and tibia if the deformity is not fully corrected, and attempts to do so will either lead to failure to pass the wire or malposition of the nail.

TIP: Ankle and subtalar joint preparation is crucial to successful fusion. Take care to avoid excessive bone resection which may result in limb shortening or inadequate talar fixation.

1 /

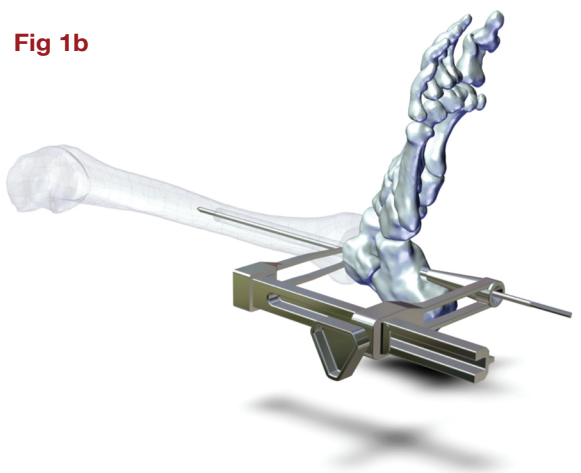
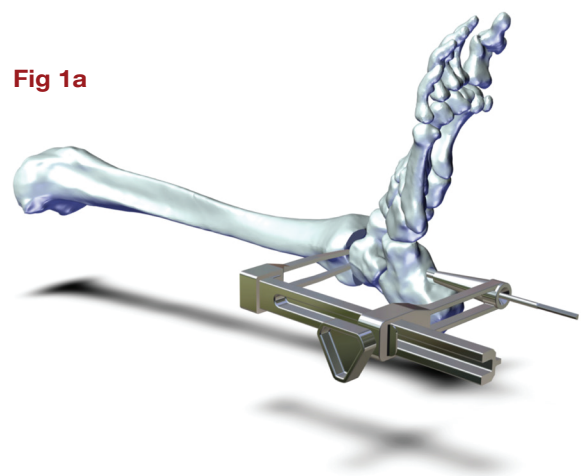
Nail Entry Site

The heel incision is carefully marked. A line is drawn in the sagittal plane from the centre of the calcaneum, to the second toe. The incision runs along this longitudinal line backwards from the anterior aspect of the heel pad for a distance of approximately two centimetres (one third of the heel pad).

The incision is deepened to the inferior surface of the calcaneum and the 3.9mm guide wire is passed through the centre of the wound. Evolution of the system has proven a rigid 3.9mm guide wire is easier and more accurate to place in the centre of the calcaneum. The central point can be found by walking the tip of the wire medially and laterally to the margins of the calcaneum. The entry portal is midway between the two points.

NOTE: *The importance of accurate placement of the entry point cannot be overemphasised.*

The primary jig (OS333002) can be used to ensure that the guide wire exits through correct site in the superior surface of the talus, in open cases. – **Fig 1a**



The 3.9mm guide wire OS333016 is advanced up the tibia under image intensifier control - **Fig 1b**

2 / Reaming

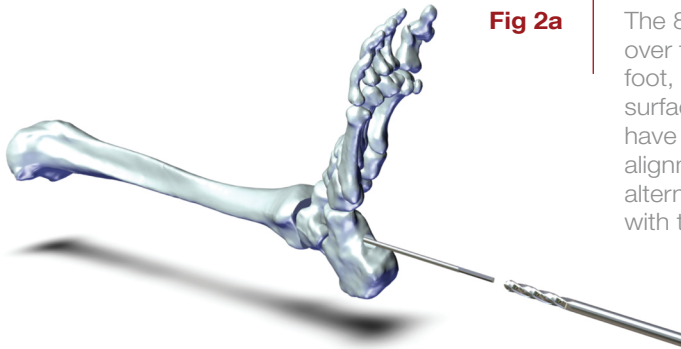


Fig 2a

The 8.0mm cannulated starter reamer is advanced over the 3.9mm guide wire through the sole of the foot, reaming through the subtalar and tibiotalar surfaces, into the tibia (**Fig 2a**). It is useful to have an assistant hold the foot in the appropriate alignment during the transmedullary reaming, alternatively the foot position can be stabilised with threaded wires.

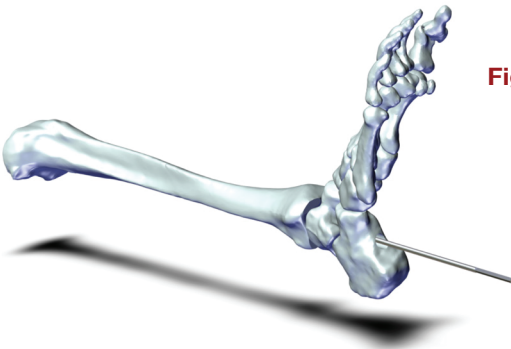


Fig 2b

Holding the foot in the correct alignment, the cannulated starter reamer is withdrawn, leaving the guide wire in place (**Fig 2b**).

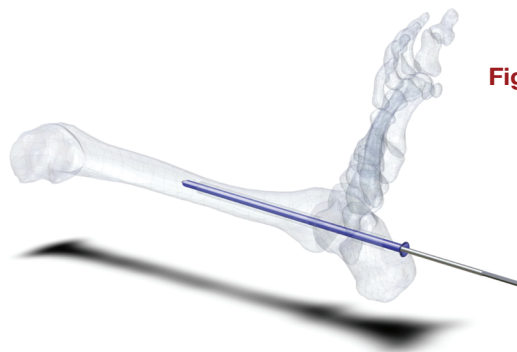


Fig 2c

The exchange tube is now passed over the guide wire into the tibia. The exchange tube is left in place whilst the guide wire is removed (**Fig 2c**).

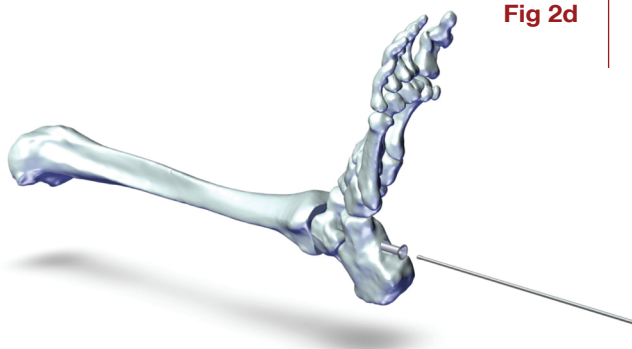


Fig 2d

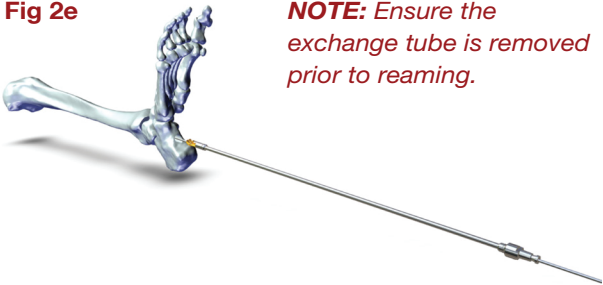
The 2.6 x 900mm olive tipped reaming rod (OS201526) is introduced through the exchange tube (**Fig 2d**), into the medullary canal of the tibia. The olive is directed proximally up the tibia. Image intensification is used to check that the guide wire remains within the tibia on both AP and lateral views.

Remove the exchange tube. Sequential reaming is now carried out, using the flexible nitinol reamer shaft and modular heads (contained within the set). The canal is opened up (**Fig 2e**) in 0.5mm increments until reaming becomes tight, or the canal is reamed to 1mm greater than the diameter of the selected nail (**Fig 2f**).

- Ensure forward gear is selected for all reamer operations – even when withdrawing the reamer.
- Make sure the 2.6 x 900mm olive tipped reaming rod (OS201526) is left in the tibia when the reamers are removed.

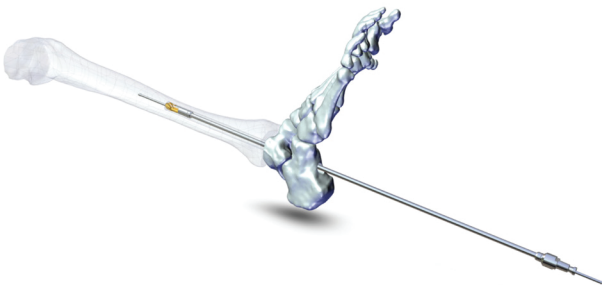
NOTE: The bone debris from reaming can used as bone graft at the end of the procedure.

Fig 2e



NOTE: Ensure the exchange tube is removed prior to reaming.

Fig 2f



Nail Size Selection

From the preoperative radiological templating and intra-operative assessment, the appropriate nail size should now be selected.

OS331150N	10mm x 150mm NAIL
OS331180N	10mm x 180mm NAIL
OS331115N	11mm x 150mm NAIL
OS331118N	11mm x 180mm NAIL
OS331125N	11mm x 250mm NAIL
OS332150N	12mm x 150mm NAIL
OS332180N	12mm x 180mm NAIL
OS332250N	12mm x 250mm NAIL

The proximal end of the nail should ideally be at least 50mm past any suspected stress risers, including fractures; non-union sites; resection sites and pre-existing holes.

The selected nail of appropriate length and diameter is assembled on the jig.

TIP: Selecting a nail 1.0mm less than the diameter reamed is suggested to reduce the need for excessive impaction during nail insertion and the consequent risk of fracture.

3 / Jig Assembly

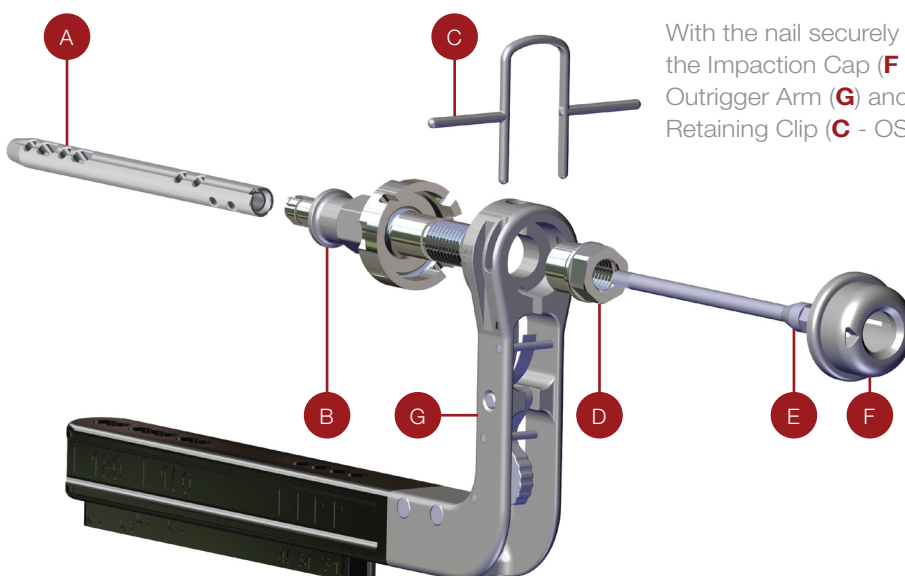
The outrigger is designed for quick and simple assembly. Firstly, locate the Nail Alignment Shaft (**B** – OS333503) in the main Outrigger Arm (**G** – OS333502). The Alignment Shaft is secured within the Outrigger Arm with the Locking Collar (**D** – OS333509) and tightened using the dedicated spanner (OS333511).

The alignment shaft has four keys cut into the surface which mates with the main Outrigger Arm.

Ensure the nail is orientated in the jig with the correct rotation, with the A/P and M/L screw holes correctly aligned, as shown in “rotating the radial arm around the nail axis.

Once tightened, the nail (**A**) is fully engaged on the alignment shaft (**B**). The alignment shaft (**B**) has a position key to ensure correct orientation. The alignment jig bolt (**E** – OS333508) is then passed through the alignment Shaft and screwed into the nail, drawing the nail securely onto the alignment shaft. Again, use the dedicated spanner (OS333511).

TIP: Before definitively tightening the nail to the assembly it is good practice to do an alignment check to verify the targeting system for screw positioning. Rotate the outrigger arm to either the medial or lateral position, and insert the guide tube (OS333005) into the furthest most screw position (for the selected nail length) on the radial arm. Insert a drill guide (OS333004) into the guide tube and thread them together. Now pass the 4.0mm drill from the disposable pack through the drill guide and verify the drill passes freely and centrally through the chosen hole in the nail.

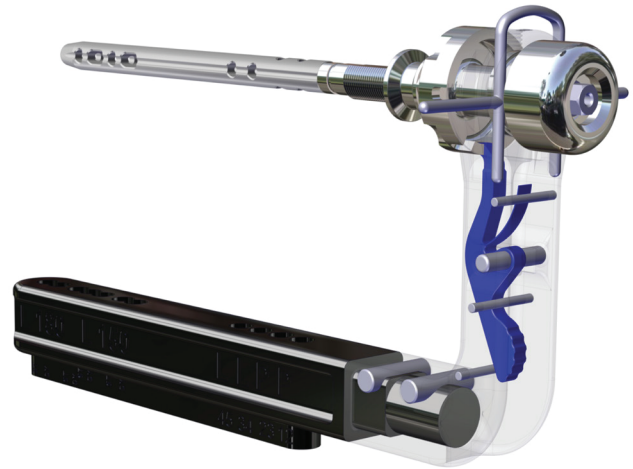


With the nail securely fastened to the main jig, position the Impaction Cap (**F** - OS333506) onto the main Outrigger Arm (**G**) and secure it in position with the Retaining Clip (**C** - OS333507).

4 /

Rotating the Radial Arm around the Nail Axis

To rotate the Main Outrigger Arm about the axis of the nail, and position the outrigger radial arm posteriorly, medially or laterally, depress the trigger (highlighted in blue) until the key disengages from the nail alignment shaft. This will allow the radial arm and the alignment shaft to freely rotate around the longitudinal axis of the nail. There are four key positions located at 90 degree intervals.



5 /

Nail Insertion

Having completed the alignment check, the outrigger radial arm should be positioned medial to the nail to allow the proximal tibial screws to be inserted from medial to lateral (**Fig 5a**). This is the default position, as the screw heads are low profile and designed not to cause soft tissue problems. If the medial skin over the tibia prevents this, for example if it is atrophic, then the radial arm can be orientated laterally and the screws inserted from lateral to medial.

Fig 5a





Fig 5b

The nail is advanced, through the sole of the foot, over the olive tipped reaming rod (**Fig 5b**).

Usually the nail can be advanced manually over the olive tipped reaming rod with gentle rotational movements and forward pressure. Gentle impaction with a mallet against the impaction cap (OS333506) may be used. Never impact against the alignment bolt (OS333508).

The PEEK outrigger arm should never be hammered. Vigorous hammering should always be avoided. You will only ever need to hammer if reaming has been inadequate.

The nail is advanced, monitoring its progress in the final stages by taking lateral or oblique views on the image intensifier. The nail should be inserted until its end is recessed between 5 and 10mm within the calcaneum. It is important to ensure that the nail is within the calcaneum, as during compression the calcaneum moves upwards, which can result in painful prominence of the nail end.

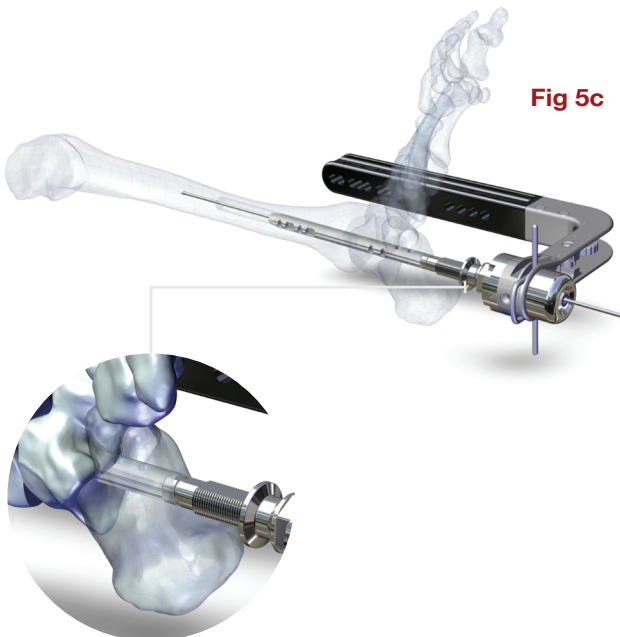


Fig 5c

There is a depth indicator notch on the alignment device (**Fig 5c**). When the indicator is level with the inferior aspect of the calcaneum, the ideal position has been achieved.

6 /

Proximal Tibial Screw Placement

The outrigger is already orientated medially for the placement of the proximal tibial screws.

NOTE: The nail's depth and orientation are established once the first proximal tibia locking screw is introduced. It is good practice to verify the position of the talar and PA locking screw(s) in the talus and calcaneum prior to inserting the first proximal tibia locking screw. The Retaining Clip has been specifically designed to show the orientation of where the posterior locking screws will lie whilst the main jig is in the medial / lateral position.

The alignment jig trocar (OS333006) is inserted into the alignment jig guide tube (OS333005) and screwed together in the locked position. This is then inserted through the appropriate jig hole to lie flush on the tibial surface (**Fig 6a**), after making an appropriate short incision in the skin. If in doubt, image guidance can be used to confirm positioning.

The trocar is then removed and the drill sleeve (OS333004) inserted into the jig guide tube. The assembly is advanced again to ensure contact with the tibia (**Fig 6b**).

TIP: Partly withdraw the olive tipped reaming rod from inside the nail so it does not interfere with the locking screw drills.

Use the short drill (OS333003) to drill the proximal tibial locking holes.

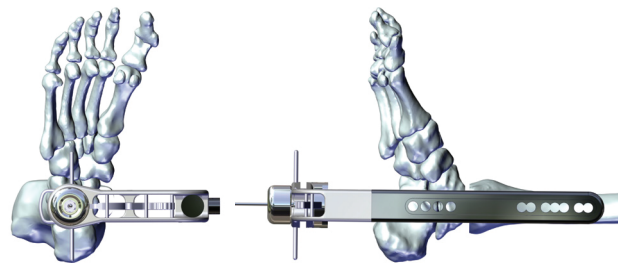


Fig 6a

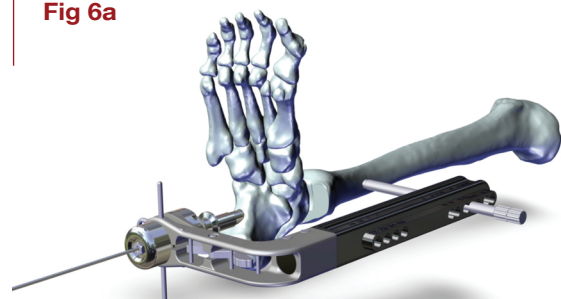
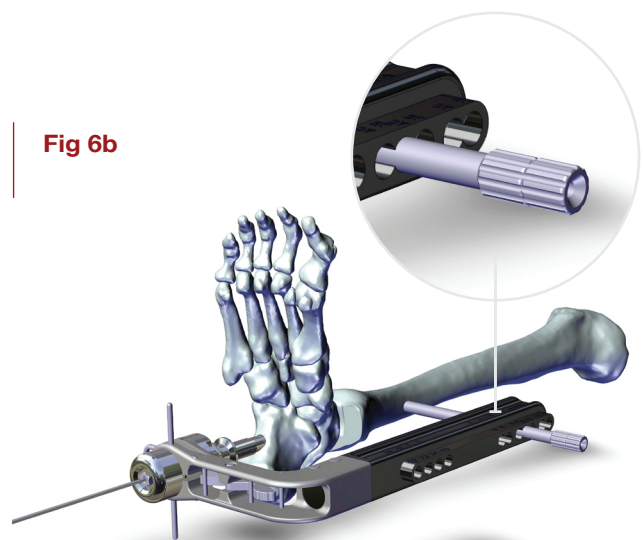


Fig 6b



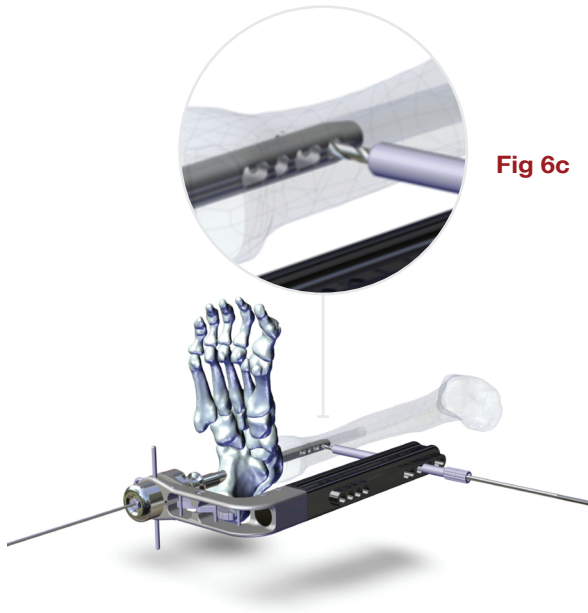


Fig 6c

Drill until you feel drill penetration just through the lateral tibial cortex (**Fig 6c**). Then stop drilling. If necessary confirm the position of the tip of the drill and then note the desired screw length from the mark on the 4.0mm drill against the drill guide.

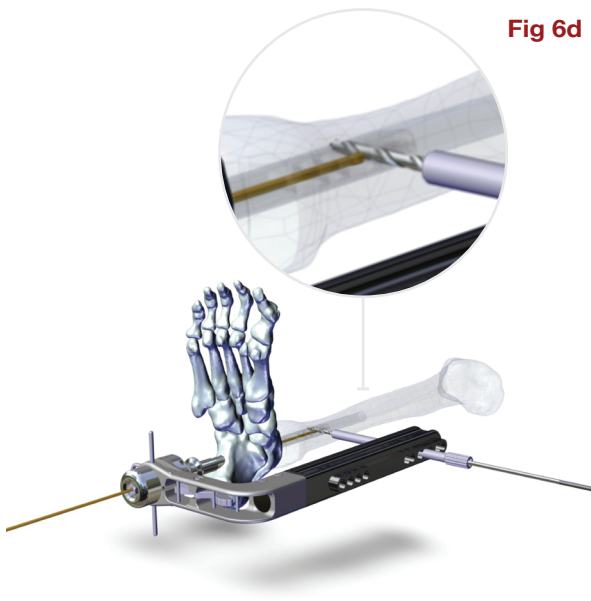


Fig 6d

Use the olive tipped reaming rod to confirm the drill has been correctly targeted through the nail. The wire, when reinserted up the nail, will be stopped by the drill if the drill is through the nail (Fig 6d)

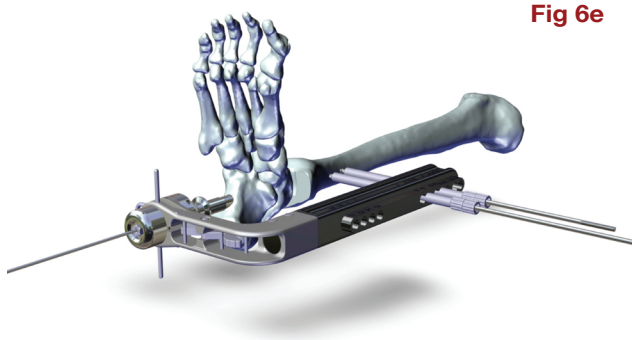


Fig 6e

Next withdraw the olive tipped reaming rod a further two or three centimetres. Following the procedure described above, repeat the drilling process through the lower of the tibial guide holes. This time use the long drill (OS333003L). Again read off the depth of screw required (**Fig 6e & 6f**).

WARNING: Leave the 4.0mm drill in place as it ensures construct stability.

TIP: If the guide wire is passed again from distal to proximal, it will be stopped at an earlier depth, indicating that the second drill has also passed through the nail.

The long drill is removed. The drill guide is unscrewed from within the jig guide tube (again ensuring the guide tube remains in contact with the tibial cortex). Couple the pear shaped handle (OS333025) and the self-retaining screwdriver shank. Load the tip of the driver with the selected 5mm cortical screw (**Fig 6g**). Advance the screw through the guide tube (**Fig 6h**).

TIP: You can double check screw lengths with the depth gauge. Screws should be selected which engage both cortices, but are not prominent. This is especially important if the screw has been inserted from lateral to medial, as the screw tip will be subcutaneous. At this point the olive tipped reaming rod is completely removed.

Remove the drill and drill guide from the proximally positioned guide tube and insert the proximal screw through the drill guide tube. The length of the screws and insertion position are verified with the image intensifier. The low profile screw head should be flush against the medial tibial cortex and the screw tip must transverse the lateral cortex (**Fig 6i**).

TIP: The screwdriver shaft can be left engaged in the lower screw through the guide tube – (**Fig 6i**) and (**Fig 6j**) - while the second tibial screw is inserted.

Fig 6f

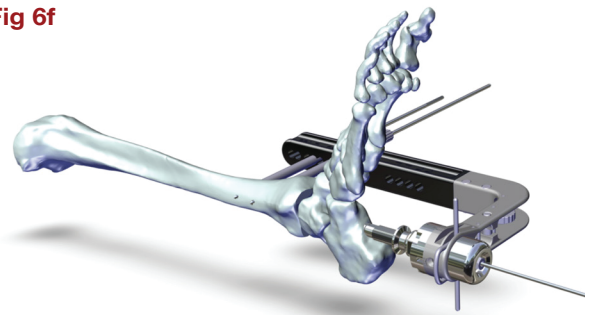


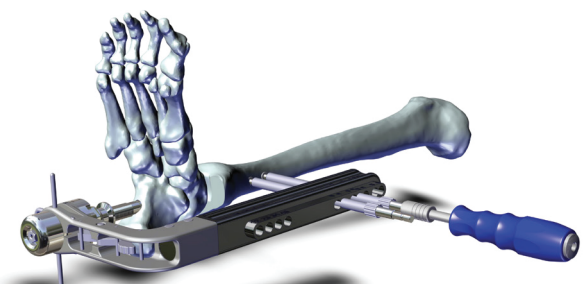
Fig 6g



Fig 6h



Fig 6i



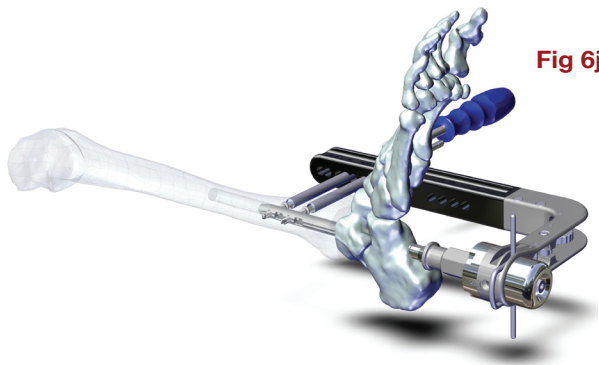


Fig 6j

7 / External Compression



Fig 7

Compression is applied by tightening the heel plate bone compression nut (OS333504) using the spanner (OS333511) allowing the end of the nut to firmly compress the calcaneum (**Fig 7**). Each turn is undertaken slowly to avoid over-tightening.

Using image intensifier control, identify the demarcation mark 5mm below the bottom of the nail / jig interface. Ideally the distal portion of the nail should not protrude from the calcaneum after compression.

Certainly never tighten such that the end of the nail is more than 5mm below the inferior margin of the calcaneum, nail prominence will irritate the heel pad.

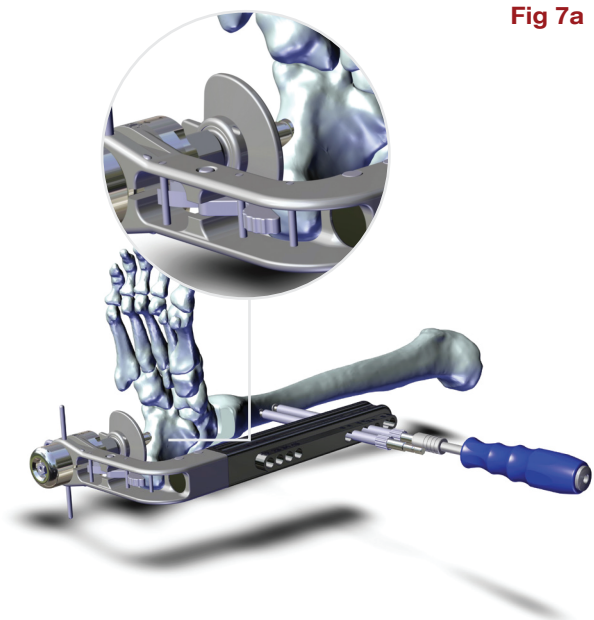


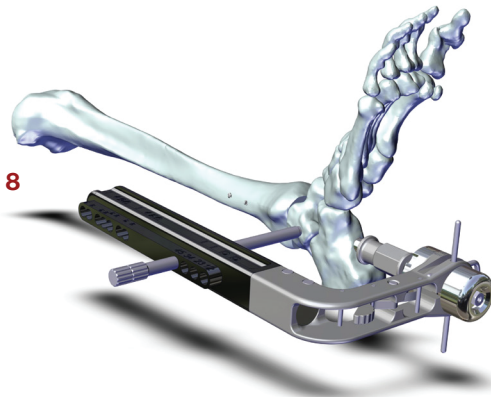
Fig 7a

Extra care must be exercised in osteoporotic bone as the nut may sink into the calcaneum in soft bone. In severely osteoporotic bone, the optional heel cushion compression plate (OS333505) can be used to apply pressure through the heel pad, rather than the calcaneum (**Fig 7a**).

8 / LM Distal Screw Placement

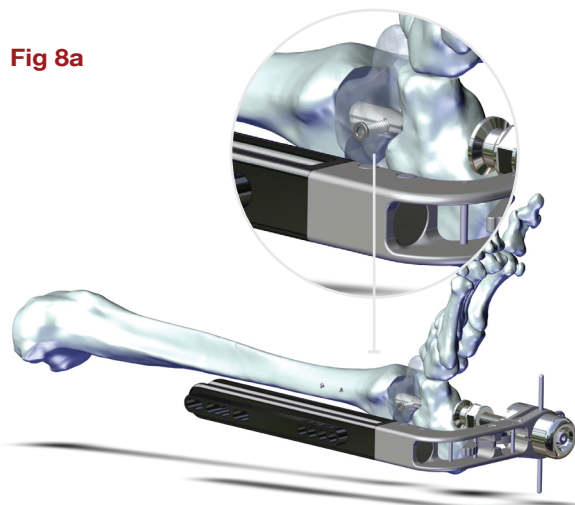
Once compression has been applied, the radial arm is rotated to a lateral orientation (**Fig 8**).

Fig 8



Using image intensification confirms that the distal screw positions will be in bone, distal to the ankle joint. The trocar and drill guide stack are passed through the holes marked L and an AP image is taken. The screws are inserted using the same technique described above for the tibial holes (**Fig 8a**).

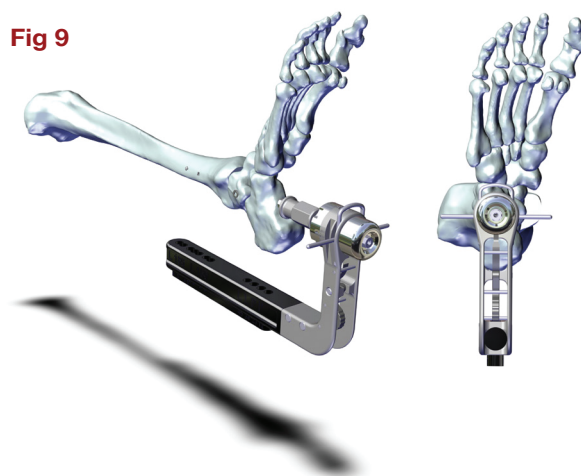
Fig 8a



9 / PA Screw Placement

The main jig radial arm is now rotated to the posterior position (**Fig 9**).

Fig 9



The previously described technique is again used to insert the posterior screw(s) (**Fig 9a & 9b**). The posterior screws should be long enough to pass through the nail, but should not breach the anterior calcaneum, unless a calcaneocuboid arthrodesis is being performed, in which case they may pass into the cuboid. Their length and positioning is assessed using the image intensifier. Two posterior screw options are available. It may be possible to use both screw holes depending on the anatomy.

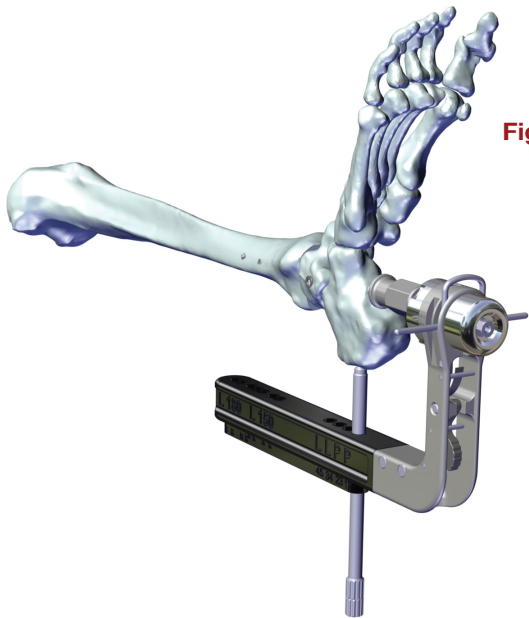


Fig 9a

Once all screws have been inserted, check radiographs should be taken using the image intensifier, and images stored.

If the preoperative planning included the insertion of the additional and independent anti-rotation and compression screw, proceed with the “OxBridge™ AFN miss-a-nail screw technique”.

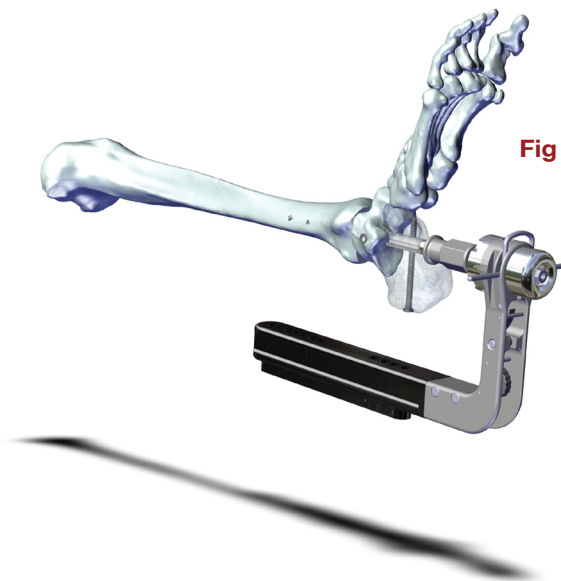


Fig 9b

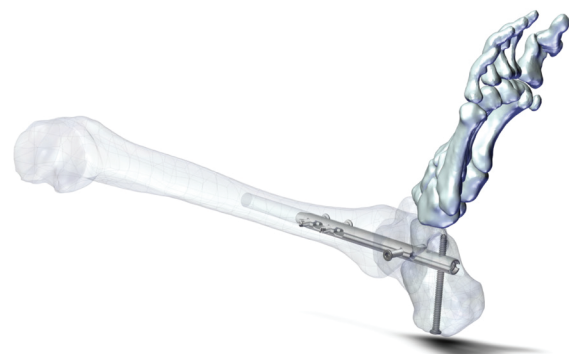


Fig 9c

If the planned procedure does not include the miss-a-nail, the jig can now be removed from the inferior end of the nail. It is recommended that an end cap is inserted. The purpose of the end cap is to inhibit fibrous and bony in-growth into the nail, which makes removal (if needed) difficult (Fig 9c) the wounds are closed with the surgeon’s preferred method and a cast or fitted splint applied.

10 / Oxbridge™ AFN – MISS-A-NAIL Technique

Miss-a-Nail – LATERAL APPROACH

The Ortho Solutions AFN has a modular miss-a-nail screw targeting system which provides additional compression and rotational stability. The miss-a-nail jig allows accurate positioning of an additional 6.5mm cannulated compression screw, from the lateral side.

After the nail has been locked proximally and distally the jig is set up to allow miss-a-nail screw insertion. With the outrigger in the posterior position and still coupled to the nail, remove the C-CLIP (OS333507) and Impaction Cap (OS333506) (**Fig 10**).

The miss-a-nail jig has a simple guide rail and locking bolt which allows it to couple to the main arm. Simply align the guide rails of the jig with the two guide rails in the main outrigger and lower until the jig sits flush on the outrigger. Then secure it in place by tightening the thumb screw (**Fig 10a**).

To establish the trajectory of the screw insert the “angel wing” OS33516C into the miss-a-nail jig drill guide holes.

To position the screw targeting arm it is rotated around the nail axis to the lateral side.

The guide is then positioned by rotating the thumb screw at the end of the targeting arm until a suitable entry position is achieved. The trajectory of the miss-a-nail screw is then checked with image intensification in the AP plane, using the angel wing (**Fig 10b & Fig 10c**).

TIP: Correct positioning allows screw passage through the calcaneus and into the tibia.

Fig 10

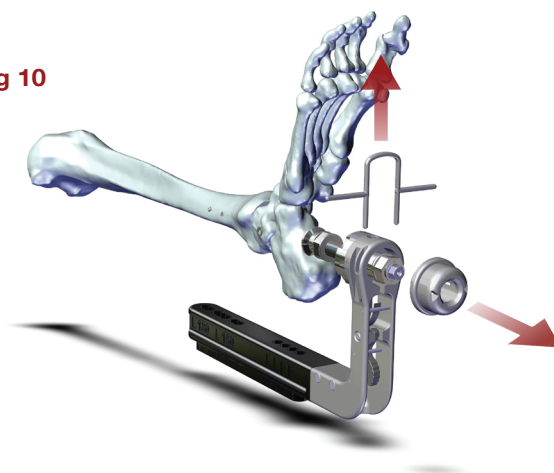


Fig 10a

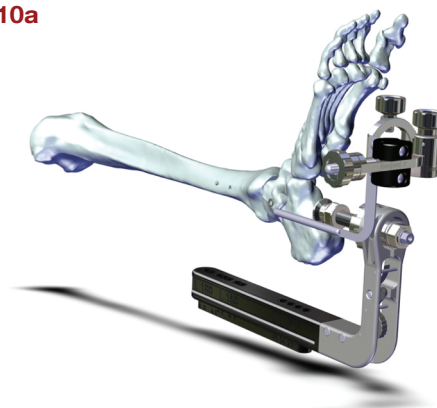


Fig 10b

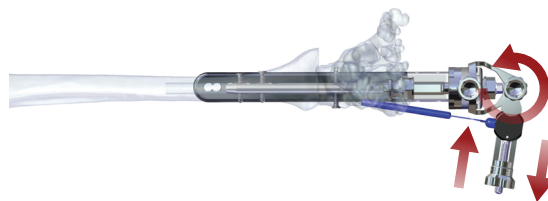


Fig 10c



Miss-a-Nail Screw Placement (Cannulated Compression Screw Described)



Fig 10d

Once the jig has been locked in position the angel wing is removed. It is possible to pass a screw anterior to the nail, posterior to the nail or both. The decision as to which position to use is up to the surgeon and is based upon the amount of tibia in front of, or behind the nail, on the lateral radiograph.

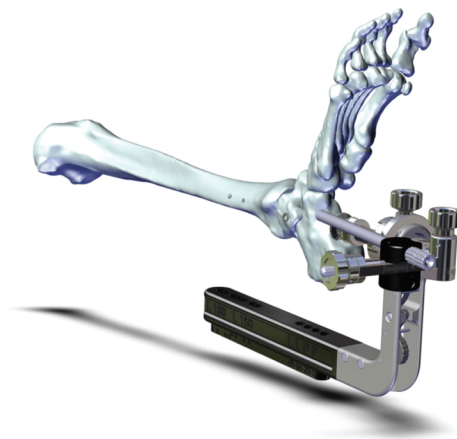


Fig 10e

Using the Trocar from the main tray and guides from the miss-a-nail caddy the alignment jig trocar (OS333006) is inserted into the alignment jig guide tube (OS333520). The two are screwed together. The construct is inserted through the appropriate holes in the screw targeting arm.

A small incision is made and the trocar is advanced to the lateral wall of the os calcis.

The trocar is removed and the 3.2mm wire guide (OS333521) inserted into the jig guide tube (**Fig 10d & 10e**).

Fig 10f

The 3.2mm calibrated guide wire (OS333523) is advanced through the wire guide to the desired depth. The wire depth and corresponding screw length can be read off the measurement scale on the wire. The trajectory can be checked using the image intensifier (**Fig 10f & 10g**).



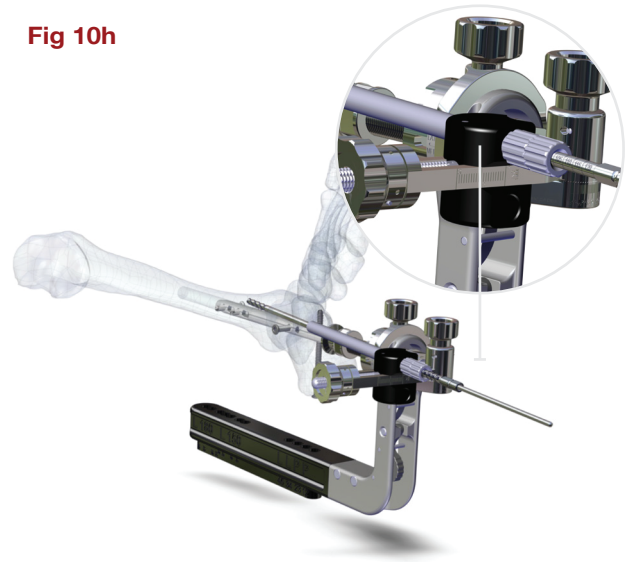
Fig 10g

Leave the guide wire in place and remove the wire guide sleeve. Insert the 5mm cannulated drill guide (OS333522) by advancing it over the guide wire and threading it into the guide tube.

Using this construct, the 5mm cannulated drill is now advanced over the guide wire to the depth previously measured (**Fig 10h**).

TIP: The guide wire may come out with the drill. If it does withdraw, loosely reinsert it down the guide and check the position using image intensification.

Fig 10h

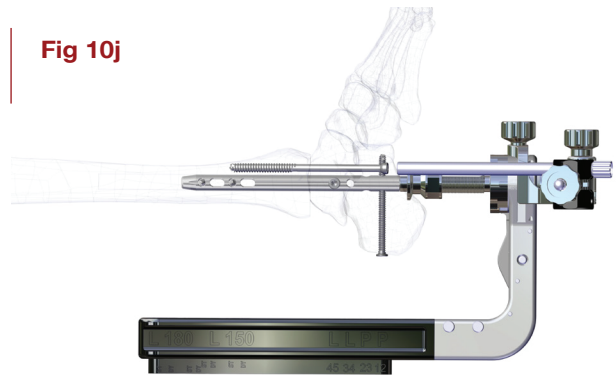


Unscrew and remove the drill guide and insert the 6.5mm cannulated compression screw. Advance the screw until the mark on the driver shank is level with the guide and the head of the is flush to the calcaneum on tangential views (**Fig 10i – 10j**).

Fig 10i

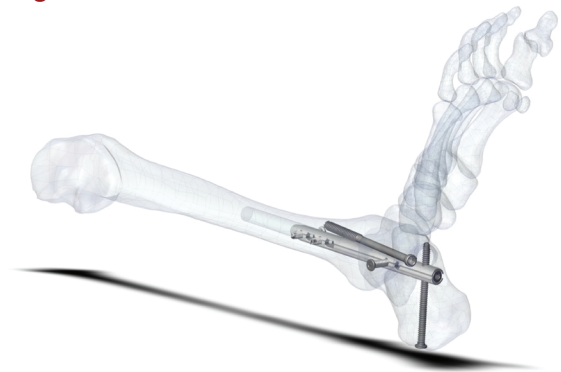


Fig 10j



The jig can now be removed from the inferior end of the nail. It is recommended that an end cap is inserted. The purpose of the end cap is to inhibit fibrous and bony in-growth into the nail, which makes removal (if needed) difficult. The wounds are closed with the surgeon's preferred method and a cast or fitted splint applied (**Fig 10k**).

Fig 10k



Post-Operative Management

It is suggested that patients are placed into a post-operative back slab or similar splint with strict elevation for the first 24 hours. Weight bearing is restricted according to surgeon's instructions for at least the first six weeks. This may not be possible with patients who have other musculoskeletal problems.

At six weeks patients may be allowed to follow a graduated weight bearing plan.

Check X-Rays are taken at six to eight weeks, three months and one year. As the compression of this device is substantial, visualising the fusion site may be difficult from the day of surgery. The patients, PA X-rays and possibly CT scan are all used as guides to union.

It is recommended that patients do not smoke and avoid non-steroidal anti-inflammatory drugs during the perioperative period where possible.

OxBridge™ Ankle Fusion Nail Extraction

If it is necessary to revise or remove the nail, remove the end cap using the pear handled screwdriver coupled to the screwdriver shaft.

Remove all of the 5.0mm cortical locking screws. Then engage and thread the extraction bolt into the distal end of the nail. Engage the slap hammer rod and the slap hammer into the end of the extraction bolt. Gently using the slap hammer withdraw the nail.

Sterilisation

The Ortho Solutions OxBridge™ Ankle Fusion Nail implants are single use and supplied sterile packaged clearly marked "STERILE" on the packaging. These implants have been sterilised using Gamma Irradiation and should not be used after the expiry date on the packaging.

Further Information

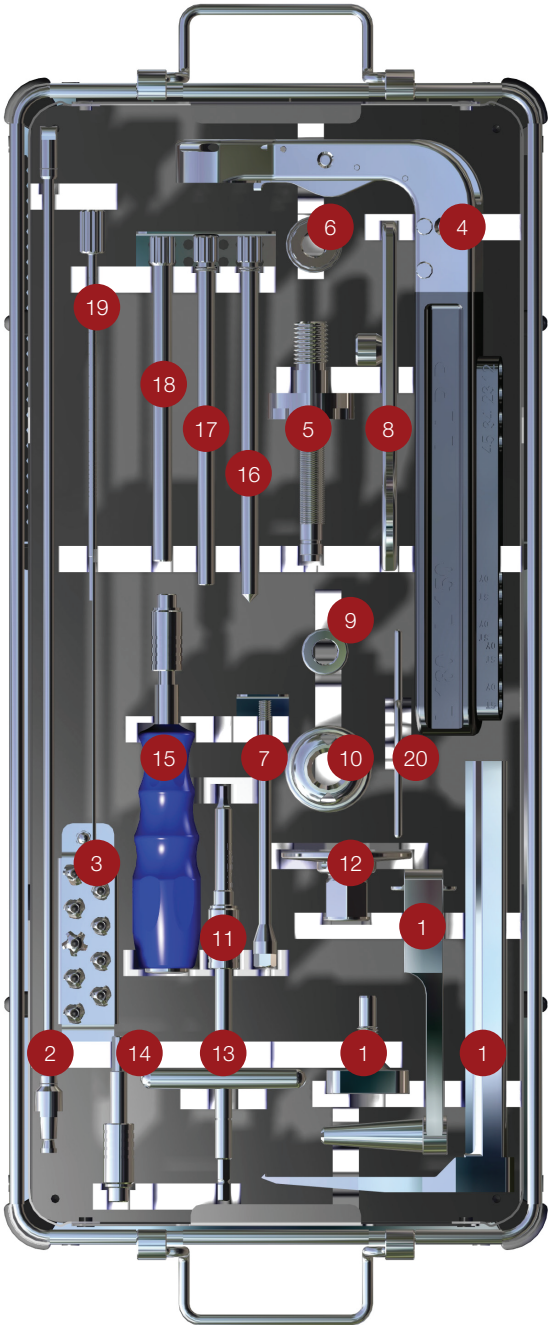
This operative technique has been written in conjunction with Mr Paul H Cooke ChM, FRCS, Mr Robert Sharp BMBCh, MA, FRCS (Tr & Orth) and Mr Andrew (Fred) Robinson BSc, FRCS (Orth), Consultant Orthopaedic Surgeons of the Nuffield Orthopaedic Centre, Oxford, UK & Cambridge University Hospitals NHS Trust, Cambridge UK.

Ortho Solutions as the manufacture of this device, does not practice medicine and does not intend to recommend this or any other surgical technique for use on a specific patient. The surgeon performing the procedure is responsible for determining and selecting the appropriate technique for any such procedure. Ortho Solutions is not responsible for the selection of any surgical technique for an individual patient.

OxBridge™ Ankle Fusion Nail System

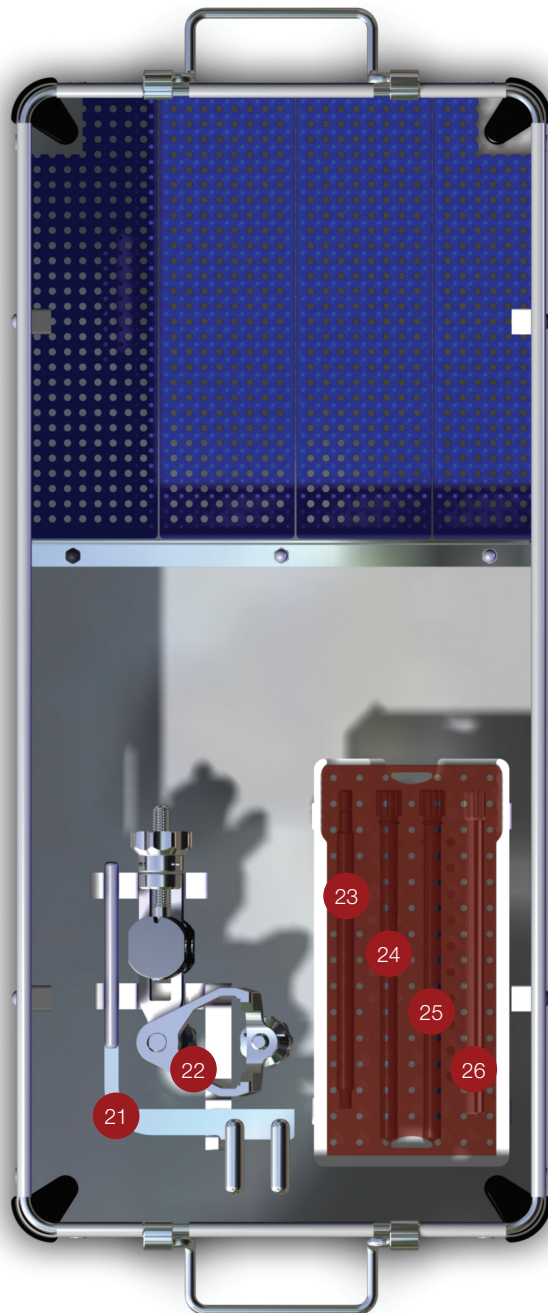
Tray Layout (Top Level)

- 1 OS333002 Primary Jig
- 2 T3713 Nitinol Flexible Reamer Shaft
- 3 Ø9.0 to Ø13mm Modular Reaming Heads
- 4 OS333502 Outrigger
- 5 OS333503 Nail Alignment Shaft
- 6 OS333509 Locking Collar
- 7 OS333508 Alignment Bolt
- 8 OS333511 Nail Spanner
- 9 OS333504 Compression Nut
- 10 OS333506 Impaction Cap
- 11 Self-Retaining Shank x 2
- 12 OS333505 Heel Plate
- 13 OS333024 T-Handle
- 14 OS333023 Power Adaptor



OxBridge™ Ankle Fusion Nail System

Tray Layout (Bottom Level)



- | | | |
|----|------------------|-----------------------------|
| 15 | OS333025 | AFN QC Driver |
| 16 | OS333006 | Trocar |
| 17 | OS333005 | Guide Tube x 2 |
| 18 | OS333004 | Ø4.0mm Drill Guide x2 |
| 19 | OS333017 | Depth Gauge |
| 20 | OS333507 | Retaining Clip |
| 21 | OS333516C | Angel Wing |
| 22 | OS333516 | Miss-a-Nail Jig |
| 23 | OS333526 | 6.5 Miss-a-Nail screwdriver |
| 24 | OS333522 | Miss Ø5.0mm Drill Guide |
| 25 | OS333521 | Ø3.2 Calibrated Wire Guide |
| 26 | OS333005 | Guide Tube |

OxBridge™ Ankle Fusion Nail System

Implant Product Listing

OS331150N	10mm x 150mm NAIL
OS331180N	10mm x 180mm NAIL
OS331115N	11mm x 150mm NAIL
OS331118N	11mm x 180mm NAIL
OS331125N	11mm x 250mm NAIL
OS332150N	12mm x 150mm NAIL
OS332180N	12mm x 180mm NAIL
OS332250N	12mm x 250mm NAIL

OS330020	5mm x 20mm cortical screw	OS330060	5 x 60 mm cortical screw
OS330022	5mm x 22mm cortical screw	OS330065	5 x 65 mm cortical screw
OS330024	5mm x 24mm cortical screw	OS330070	5 x 70 mm cortical screw
OS330026	5mm x 26mm cortical screw	OS330075	5 x 75 mm cortical screw
OS330028	5mm x 28mm cortical screw	OS330080	5 x 80 mm cortical screw
OS330030	5mm x 30mm cortical screw	OS330085	5 x 85 mm cortical screw
OS330032	5mm x 32mm cortical screw	OS330090	5 x 90 mm cortical screw
OS330034	5mm x 34mm cortical screw	OS330095	5 x 95 mm cortical screw
OS330036	5mm x 36mm cortical screw	OS330100	5 x 100 mm cortical screw
OS330040	5mm x 40mm cortical screw	OS330105	5 x 105 mm cortical screw
OS330045	5mm x 45mm cortical screw	OS330110	5 x 110 mm cortical screw
OS330050	5mm x 50mm cortical screw	OS330115	5 x 115 mm cortical screw
OS330055	5mm x 55mm cortical screw	OS330120	5 x 120 mm cortical screw

Ø6.5 X 18MM THREAD LENGTH CANNULATED SCREW

OS309020A	Ø6.5 X 18 THREAD X 20mm	OS309075	Ø6.5 X 18 THREAD X 75mm
OS309025	Ø6.5 X 18 THREAD X 25mm	OS309080	Ø6.5 X 18 THREAD X 80mm
OS309030	Ø6.5 X 18 THREAD X 30mm	OS309085	Ø6.5 X 18 THREAD X 85mm
OS309035	Ø6.5 X 18 THREAD X 35mm	OS309090	Ø6.5 X 18 THREAD X 90mm
OS309040	Ø6.5 X 18 THREAD X 40mm	OS309095	Ø6.5 X 18 THREAD X 95mm
OS309045	Ø6.5 X 18 THREAD X 45mm	OS309100	Ø6.5 X 18 THREAD X 100mm
OS309050	Ø6.5 X 18 THREAD X 50mm	OS309105	Ø6.5 X 18 THREAD X 105mm
OS309055	Ø6.5 X 18 THREAD X 55mm	OS309110	Ø6.5 X 18 THREAD X 110mm
OS309060	Ø6.5 X 18 THREAD X 60mm	OS309115	Ø6.5 X 18 THREAD X 115mm
OS309065	Ø6.5 X 18 THREAD X 65mm	OS309120	Ø6.5 X 18 THREAD X 120mm
OS309070	Ø6.5 X 18 THREAD X 70mm		

AFN END CAPS

OS331100	AFN END CAP
OS331101	END CAP Ø10 x 5mm LONG
OS331102	END CAP Ø10 x 10mm LONG
OS331103	END CAP Ø11 x 5mm LONG
OS331104	END CAP Ø11 x 10mm LONG
OS331105	END CAP Ø12 x 5mm LONG
OS331106	END CAP Ø12 x 10mm LONG
OS331107	AFN END CAP LOCKING

STERILE, SINGLE USE DISPOSABLES

	AFN Disposable Pack (8 mm Starter Reamer; Ø4mm Drill Short; Ø4mm Drill Long; Ø3.9 mm Guide Pin; Exchange Tube)
OS333523	MISS Graduated K-Wire
OS333525	AFN MISS 5mm Cannulated Drill
OS201526	Reaming Rod 2.6mm x 900mm Olive Tipped

Notes



Advancing Foot & Ankle Care



OrthoSolutions UK Limited,
West Station Business Park,
Spital Road, Maldon, Essex.
CM9 6FF, United Kingdom

Tel: +44 (0)1621 843 599
Email: sales@orthosol.com

Ortho Solutions Inc
209 10th Avenue South
Suite 416,
Nashville, TN 37203

Tel: +1 (303) 495 5407
Email: us.sales@orthosol.com

www.orthosolutions.com

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*1. CE/ UKCA marking and the Notified/ Approved Body number is applied per
part number and appears on the device packaging, or the device if applicable

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Rx only

Caution: Federal Law
(USA) restricts this device
to sale by or on the order
of a physician



Consult
instructions
for use

CE
2797^{*1}



Surgeon must be
fully trained in the
surgical technique