OrthoSolutions Group

Advancing Foot & Ankle Care

System 26

Cannulated Extremity Screws

Not All Screws Are Created Equal

Design Rationale and Surgical Technique

Not All Screws Are Created Equal

System Overview

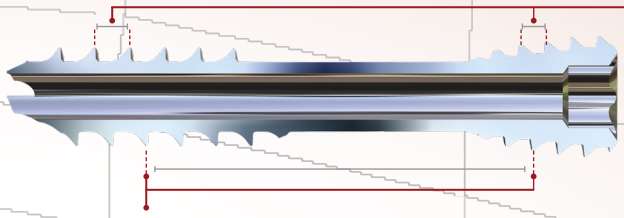
Cannulated and non cannulated bone fixation screws have been used successfully in a broad range of orthopaedic procedures for a number of years. They are technologically stable devices, and as such, design improvements are incremental in nature. Notwithstanding the mature nature of bone screw technology, a combination of improved features and design enhancements mean that not all bone screws are necessarily created equal, especially when intended for use in specific orthopaedic sub specialty areas, such as extremity surgery.

The System26 screw range has been designed to help clinicians treat an array of extremity conditions that require surgical intervention. The System26 Foot & Ankle range, has been configured to meet the specific needs of lower extremity clinicians enabling the treatment of simple to complex Forefoot, Midfoot and Hindfoot procedures, which require bone fixation.

System26 has been designed to facilitate compression at the fusion site and offers self drilling and self tapping, headless and headed, screws from 2.0mm to 8.0mm in diameter, with cannulated and non cannulated options, in a range of lengths and thread variants. The comprehensive instrumentation and implant sets offer modularity and simplicity so that surgery can be carried out effectively and efficiently across a range of Foot & Ankle indications, with one system.

Anatomy Of The System26 Screw

Compression Across The Osteotomy Site



1. Differential Thread Pitch

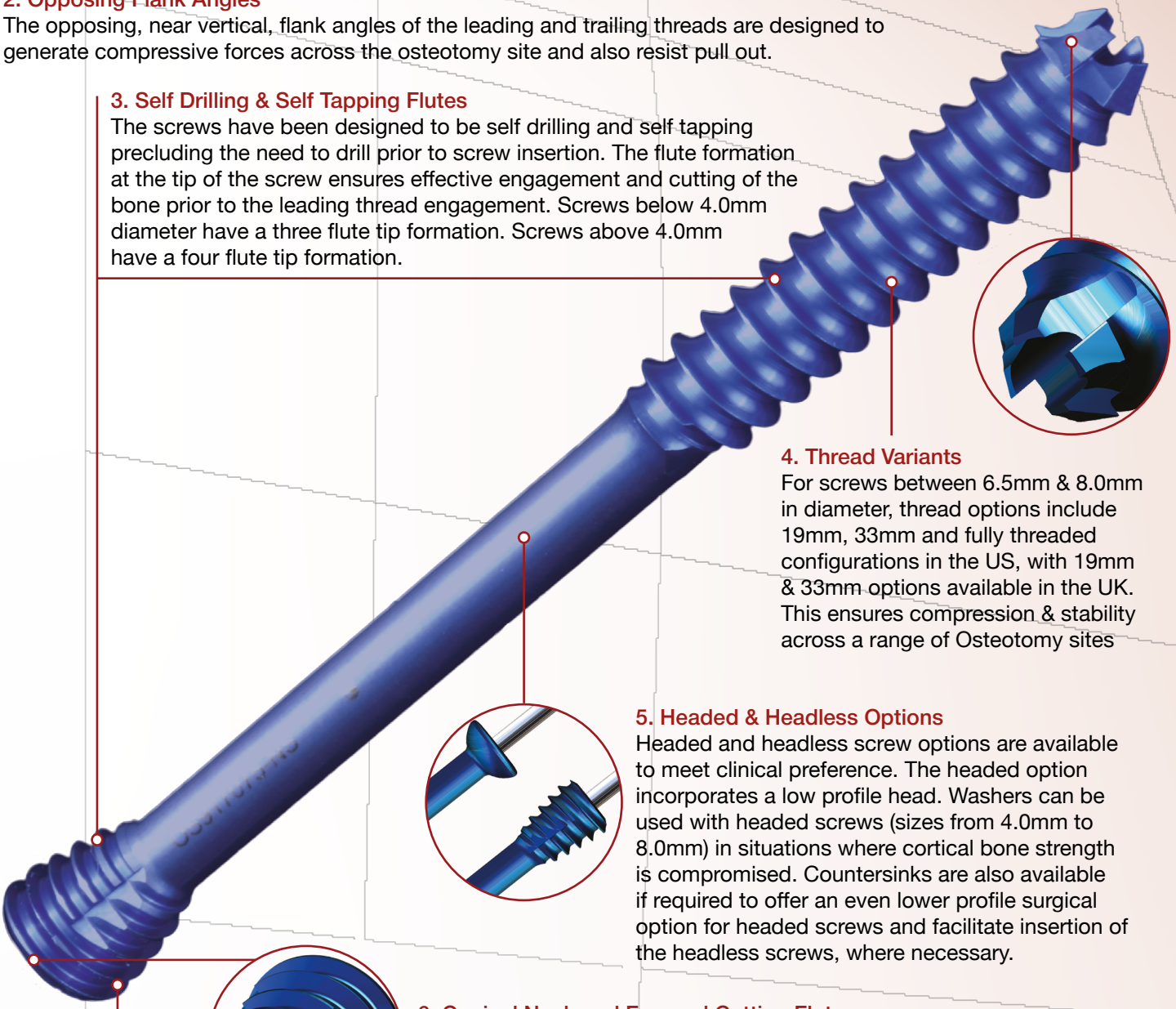
Headless screws achieve compression across the osteotomy site by utilising a differential thread pitch in the leading and trailing threads. The larger pitch in the leading thread also helps to resist pull out of the cancellous bone whilst the finer thread pitch of the trailing thread ensures an effective cutting action in the harder cortices.

2. Opposing Flank Angles

The opposing, near vertical, flank angles of the leading and trailing threads are designed to generate compressive forces across the osteotomy site and also resist pull out.

3. Self Drilling & Self Tapping Flutes

The screws have been designed to be self drilling and self tapping precluding the need to drill prior to screw insertion. The flute formation at the tip of the screw ensures effective engagement and cutting of the bone prior to the leading thread engagement. Screws below 4.0mm diameter have a three flute tip formation. Screws above 4.0mm have a four flute tip formation.

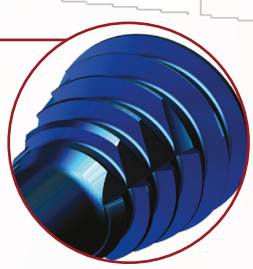


4. Thread Variants

For screws between 6.5mm & 8.0mm in diameter, thread options include 19mm, 33mm and fully threaded configurations in the US, with 19mm & 33mm options available in the UK. This ensures compression & stability across a range of Osteotomy sites

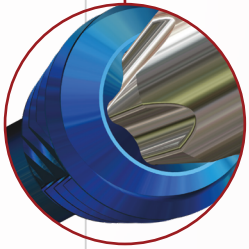
5. Headed & Headless Options

Headed and headless screw options are available to meet clinical preference. The headed option incorporates a low profile head. Washers can be used with headed screws (sizes from 4.0mm to 8.0mm) in situations where cortical bone strength is compromised. Countersinks are also available if required to offer an even lower profile surgical option for headed screws and facilitate insertion of the headless screws, where necessary.



6. Conical Neck and Forward Cutting Flutes

A smooth tapered neck engages the proximal bone and augments the reduction of the osteotomy prior to the engagement of the trailing thread with the cortex. The forward cutting flutes ensure effective self tapping into the proximal cortex.



7. Torx Drive

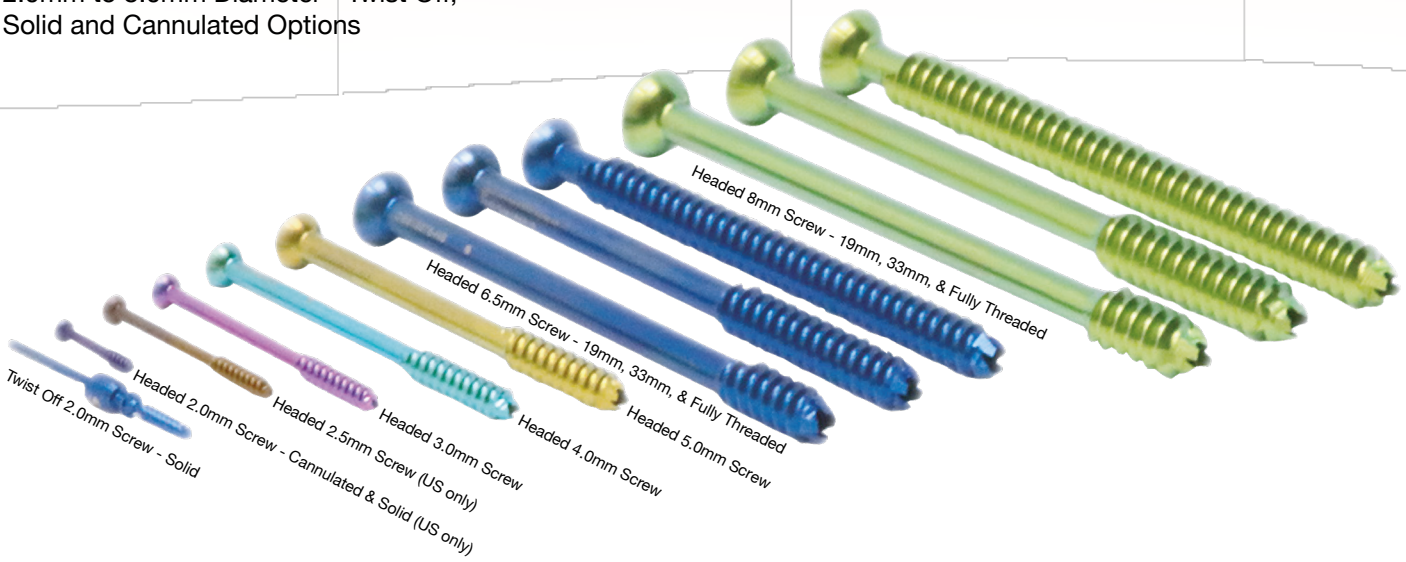
The screw range includes a Torx drive feature, designed to support multi-point contact between the driver and screw during insertion. This may help improve engagement and reduce the risk of screw-head damage during use.

One Screw System. All Your Fixation Needs

Comprehensive screw range facilitates surgical treatment of simple to complex foot disorders with one system.

Headed Screws

2.0mm to 8.0mm Diameter - Twist Off,
Solid and Cannulated Options



Headless Screws

2.0mm to 8.0mm Diameter
- Solid and Cannulated Options

The System26 Foot and Ankle screw range has been configured to offer the clinician a comprehensive selection of screw types and sizes for forefoot, midfoot and hindfoot surgical procedures. There are 25 screw types available in the system. The screw variants include headed and headless, solid and cannulated and a twist off version in the forefoot set.

The 6.5mm and 8.0mm diameter headed and headless screws offer multiple thread configurations - 19mm, 33mm and fully threaded (US only). For all the remaining screw diameters, the thread represents 35% of the screw length. Lengths vary from 10mm to 120mm across the range of screw diameters.

The screws and associated instruments are colour coded for easier identification by the operating room team ensuring ease of use and efficient time utilisation. Washers are also available for headed screws from 4.0mm to 8.0mm for situations where proximal bone quality may be compromised: The forefoot set also includes a range of varisation staples - 90 and 26 degrees (as standard only in the UK/EU system).

Screw Options (US Standard System)

Screw Diameter (mm)	Lengths (mm)	Thread	Colour	Washer (Headed only)
2 (Twist Off)	10–18 in 1mm increments	75% length	Dark Blue	X
2	10–30 in 2mm increments	35% length	Vector Purple	X
2.5	10–30 in 2mm increments	35% length	Bronze	X
3	10–40 in 2mm increments	35% length	Magenta	X
4	10–50 in 2mm increments 55–70 in 5mm increments	35% length	Teal	✓
5	30–50 in 2mm increments 55–90 in 5mm increments	35% length	Gold	✓
6.5	35–120 in 5mm increments*1	19mm, 33mm, fully threaded	Dark Blue	✓
8	35–120 in 5mm increments*1	19mm, 33mm, fully threaded	Green	✓

*1 – Available lengths within the stated range may vary according to the selected thread length/screw head configuration.

Screw Options (UK/EU Standard System)

Screw Diameter (mm)	Lengths (mm)	Thread	Colour	Washer (Headed only)
2 (Twist Off)	10–18 in 1mm increments	75% length	Dark Blue	No
2 (Headless Only)	10–30 in 2mm increments	35% length	Vector Purple	No
2.5 (Headless Only)	12–30 in 2mm increments	35% length	Bronze	No
3 (Headless Only)	12–40 in 2mm increments	35% length	Magenta	No
4	10–50 in 2mm increments (Headed Range) 14–50 in 2mm increments (Headless Range) 50–70 in 5mm increments	35% length	Teal	Yes
5	30–50 in 2mm increments 55–90 in 5mm increments	35% length	Gold	Yes
6.5	35–120 in 5mm increments*1	19mm, 33mm	Dark Blue	Yes
8	35–120 in 5mm increments*1	19mm, 33mm	Green	Yes

*1 – Available lengths within the stated range may vary according to the selected thread length/screw head configuration.

Enabling Effective And Efficient Fusion Surgery

The instrument and implant sets have been modularised to ensure ease of use and the most efficient use of time by all the operating room team.

The instrumentation system has been designed to ensure that it is intuitive and easy to use for all those involved in the surgical procedure. All size specific instruments are colour coded to align with the associated screw sizes. The layout of the sets ensures that the instruments are easy to identify and access. Instruments which interface with other instruments, or implants, are easy to assemble.

Ratcheting drivers have quick couples and ergonomically designed handles to ensure that manual insertion of the screw is controlled and effective. Distraction devices and clamps have been included to assist with the preparation and fixation of osteotomy sites.

The system is divided into sets for forefoot, midfoot and hindfoot for ease of use. These sets offer headed and headless screw options and can be customised for the needs of the user so that the surgeon's preference for a particular type of screw can be accommodated.

In situations where the system is being used by multiple users the set offers a comprehensive range of screw types to meet the needs of the individual clinicians and the range of surgical procedures that they undertake. Non-sterile screws are available in the US trays for ease of screw selection and insertion. In the UK and EU, implants and consumables are provided sterile packaged and available in bespoke trolleys to optimise space utilisation and presentation in the operating theatre.

Surgical Technique

The following surgical technique guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on their personal medical training and experience.

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 System26 is available electronically at www.orthosol.com/eIFU or in paper form upon request by contacting regulatory@orthosol.com.

Chevron Osteotomy

The following technique illustrates the use of the System26 cannulated screw system for fixation following a Chevron osteotomy.

Reduce and prepare the osteotomy site using surgeon preferred technique.

Plantar Cut

The plantar cut is typically performed at a ± 60° angle towards the metatarsal base, and the dorsal ± 45° towards the dorsal cortex. Figure 1.

The Chevron osteotomy allows for transverse displacement of the metatarsal head equal to approximately half of the width. Displacement greater than half of the metatarsal width may compromise stability and ultimately healing.

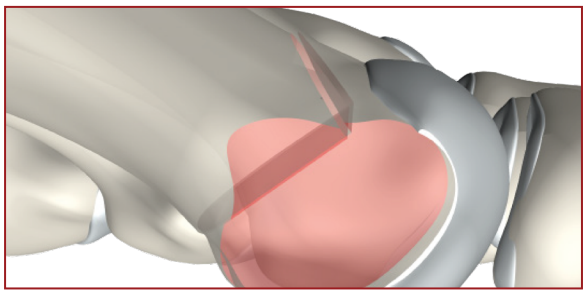


Figure 1

Screw & K-Wire Selection

Once displacement is achieved insert the appropriately sized k-wire for the selected screw diameter (see Table 1), using the k-wire and drill guide for targeting and verify the wire and ultimate screw trajectory with a lateral fluoroscopic view. Care should be taken not to pass the wire through the metatarsal head cartilage.

Screw Diameter (mm)	K-Wire Diameter (mm)
2.0	0.7
2.5	0.8
3.0	1.0

Table 1

K-Wire & Drill Guide

K-wire and drill guides for the 2.0mm, 2.5mm and 3.0mm screws are positioned on opposite ends of the guide handle. Figure 2. It is recommended to use wire and drill guides with small diameter k-wires to prevent distortion and ensure accurate final trajectory and straightness of the k-wire. Figure 3.

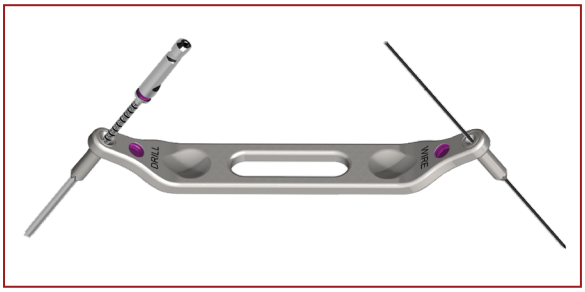


Figure 2

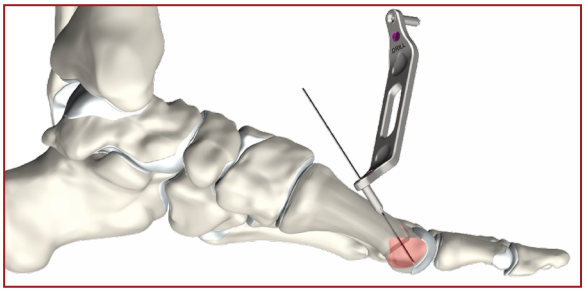


Figure 3

Surgical Technique

Determining Screw Length Without Drilling

Withdraw the wire guide over the k-wire and place the depth gauge rule over the k-wire, ensuring contact with the bone near cortex.

For the 2mm screw read the required screw length directly from the depth gauge rule by referencing the location of the end of the guide wire in relation to size indicators etched on the rule. Figure 4.

US only: for the 2.5mm and 3.0mm screw read the required screw length directly from the marking on the k-wire itself referencing this marking on the guide wire in relation to size indicators etched on the depth gauge rule. Figure 5.

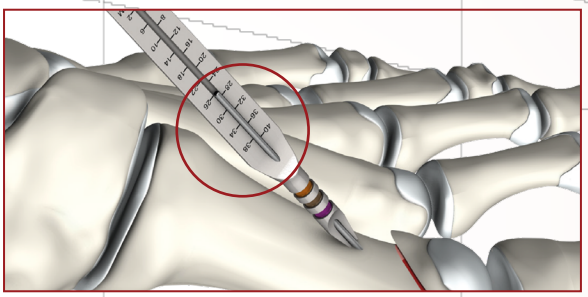


Figure 4

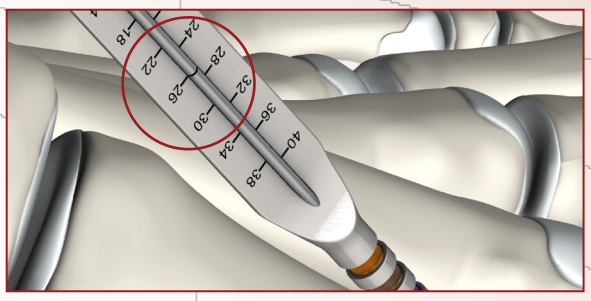


Figure 5

Determining Screw Length With Drilling

Verify under imaging the drill position being representative of screw length, and directly read the required screw length from the calibrated markings on the drill against the back face of the drill guide. Figure 6.

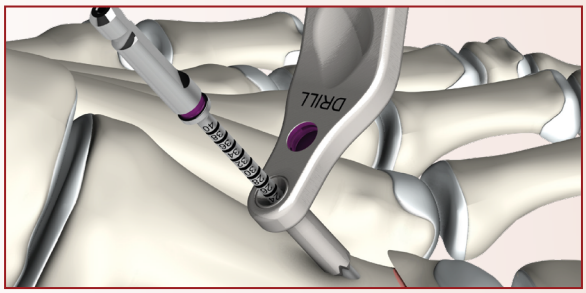


Figure 6

Countersinking the Screw Head

Remove the drill and drill guide and advance the appropriate colour-coded cannulated countersink over the k-wire. Care must be taken to ensure the cortex is not countersunk beyond its capacity. Do not use power. Figure 7.

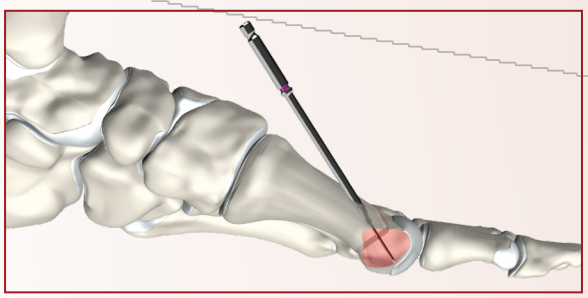


Figure 7

Screw Insertion

Insert the appropriate length cannulated screw over the guide wire using cannulated torx driver. Once the screw is seated, remove the guide wire. Confirm the final screw position as well as the adequacy of reduction and stability of fixation with fluoroscopy. Figure 8.

Closure of the incision is based on the surgeon's preferred approach.

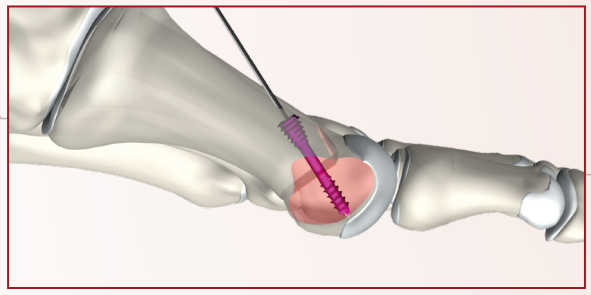


Figure 8

Surgical Technique

Triple Arthrodesis

Triple arthrodesis involves the fusion of talonavicular, subtalar and calcaneocuboid joints; System26 may be used for bone fixation to facilitate osteosynthesis in foot and ankle arthrodesis.

Prepare and reduce the osteotomy sites using the surgeon's preferred technique.

Alignment of Subtalar Joint

It is common to start posteriorly, aligning the subtalar joint and fixing with a solitary guide pin from the heel across the superior facet, aiming for just anterior to the tibial lip of the ankle joint. This alignment avoids damaging the subchondral bone of the ankle joint. The position of the subtalar guide pin should be checked on the lateral fluoroscopic view and also on the ankle anteroposterior view to ensure fairly central (medial and lateral) placement in the talar dome region. Figure 9.

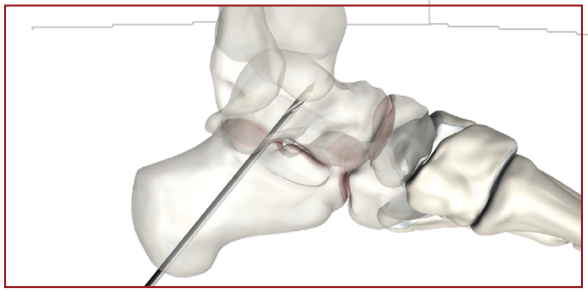


Figure 9

Drill Guide Placement

For a percutaneous approach, make a stab incision at the screw site then bluntly dissect down to bone. Thread the colour coded k-wire insert into its corresponding colour coded drill guide and then insert the assembled guide into the incision, ensuring contact with the cortex is made. Figure 10.

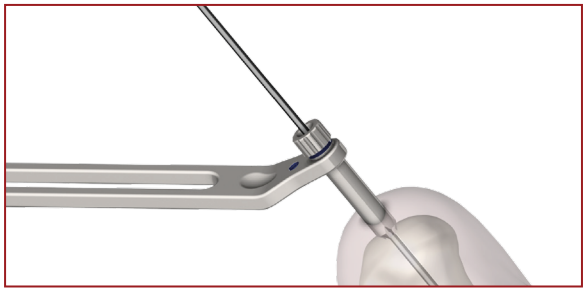


Figure 10

Determining Screw Length Without Drilling

Remove the appropriate assembled colour coded drill guide and slide the depth gauge rule over the guide wire, ensuring contact with cortical bone.

Read the required screw length directly from the depth gauge rule by referencing the location of the end of the guide wire in relation to size indicators etched on the rule. Figures 11 & 12.

Figure 11

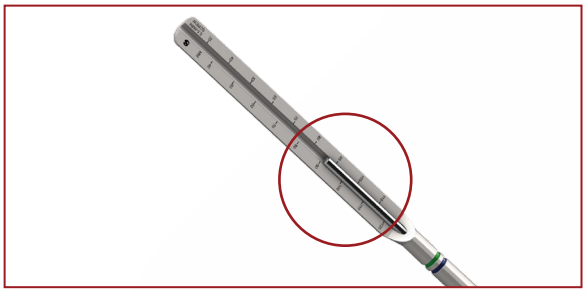


Figure 12

Surgical Technique

Drilling

System26 cannulated screws are self-drilling and self-tapping however, drilling is recommended in circumstances of hard cortical bone, or to relieve stress where the trailing thread is close to a cortical margin. Tapping is not required. Unthread the k-wire insert to remove it from the drill guide and slide the drill guide over the k-wire. Figure 13.

The appropriately-sized colour coded drill is applied over the k-wire and through the drill guide. Drill depth is read from the calibrated drill markings against the back of the drill guide. Figure 14.

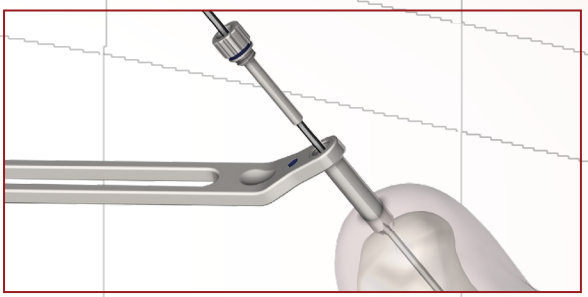


Figure 13

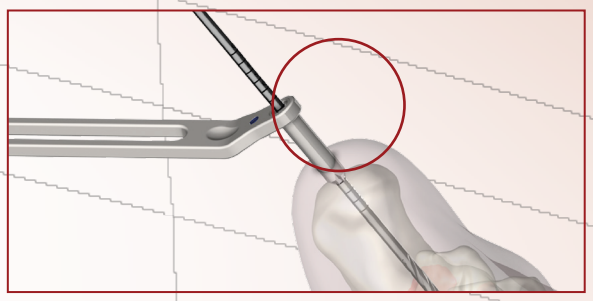


Figure 14

Countersinking Screw Head

Countersinking may be used with headed screws to seat the screw head, and with headless screws to assist with screw seating, where considered appropriate based on the surgical technique, bone quality and cortical preparation. Care should be taken to avoid countersinking beyond cortical capacity. In situations where countersinking of a headed screw is undertaken it is advisable to re-measure the screw size after countersinking. Remove the drill and drill guide and advance the appropriate, colour coded cannulated countersink over the k-wire. Care must be taken to ensure the cortex is not countersunk beyond its capacity. Do not use power. Figure 15.

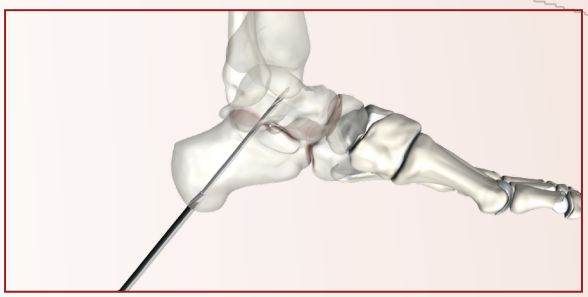


Figure 15

Screw Insertion

Insert the appropriate length cannulated screw over the guide wire using cannulated torx driver. Once the screw is seated, remove the guide wire. Confirm the final screw position as well as the adequacy of reduction and stability of fixation with fluoroscopy. Figure 16.

The screw insertion technique for the calcaneocuboid joint and the talonavicular joint is performed in the same manner as described above for the subtalar joint. Figure 17.

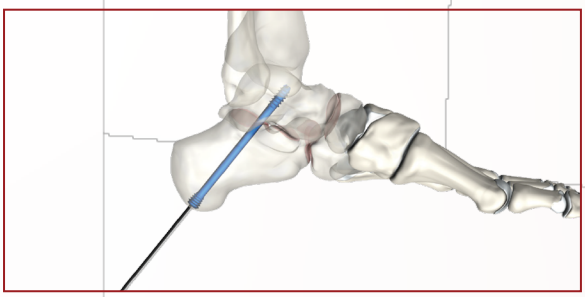


Figure 16

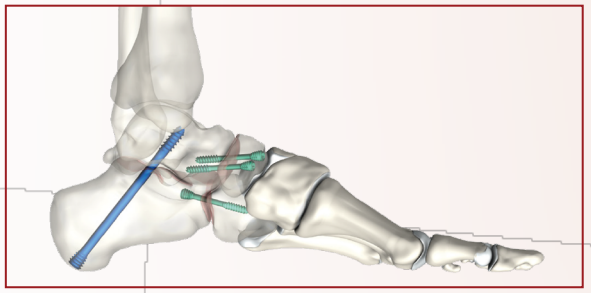


Figure 17

Closure of the incision is based on the surgeon's preferred approach.

Notes:

Notes:

OrthoSolutions Group

Advancing Foot & Ankle Care

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Consult instructions for use

CE 2797 [2]

Surgeon must be fully trained in the surgical technique