

K2-II

Ankle Arthrodesis Fusion Nailing System
with Internal Compression Mechanism

Surgical Technique

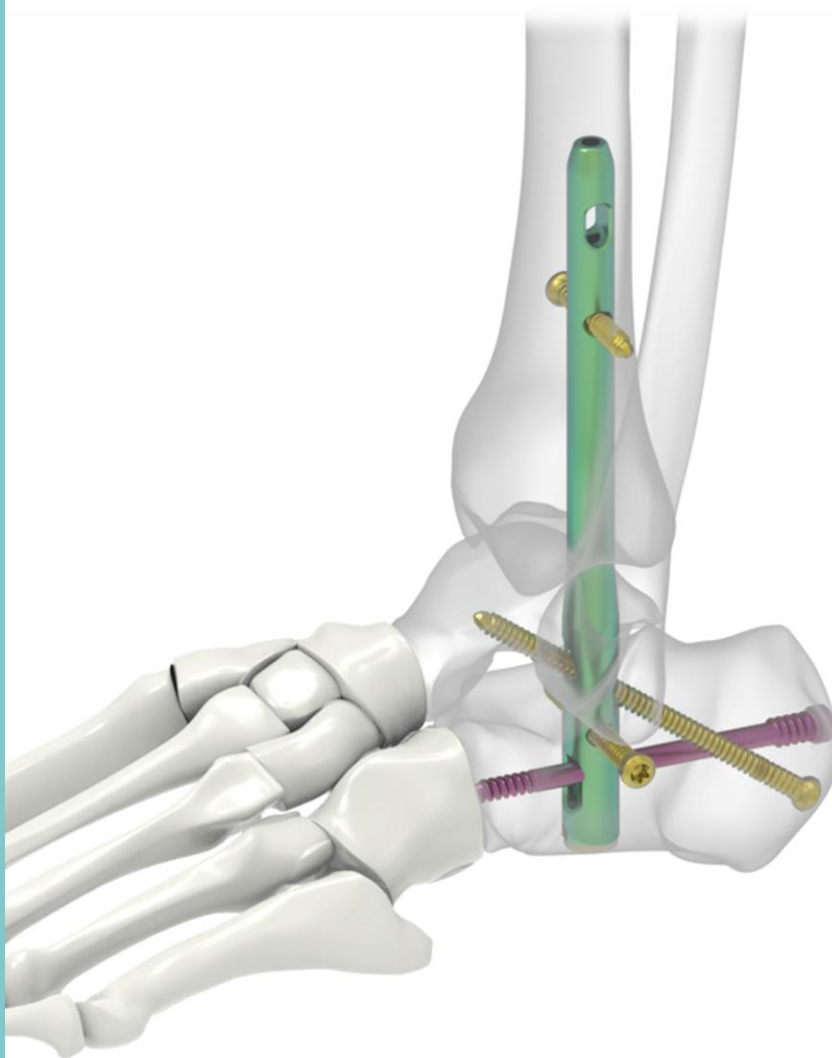


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Warning

The contents of this manual are intended to be only a guide and are not intended to set a standard of care. Instruction by a surgeon experienced in handling these instruments is highly recommended.

INTRODUCTION

The K2-II™ Ankle Arthrodesis Nail is designed to provide the option for tibiototalcalcaneal fusion with a retrograde intramedullary nail. The main advantages of the technique are limited soft tissue damage in the ankle area, high primary stability allowing early weight bearing, as well as compression of the subtalar and tibiotalar joints.

Achieving and maintaining compression at the arthrodesis site is critical, especially for the unstable ankle and subtalar joints. The K2-II™ Ankle Arthrodesis Nail provides two methods for intra- and postoperative compression — an Internal Compression Mechanism and a Dynamization Screw:

- Through the initial placement of a Proximal Dynamic Screw, dynamized compression can be achieved postoperatively.
- The system's primary means of compression is the Internal Compression Mechanism, which can achieve up to 7 mm of compression intraoperatively. Advancing the Compression Rod against the dynamic cuboid locking screw, thereby achieving compression of both the subtalar and ankle joints.

Features and Benefits

Dynamic compression slot allows up to 5 mm of compression postoperatively

Rotational stability achieved with proximal static locking hole or dynamic compression slot

Anatomically designed implants

Unique screw configuration

Diverging screw angles allow the surgeon to target specific bones and joints

Active compression slot allows up to 7 mm of compression intra-operatively

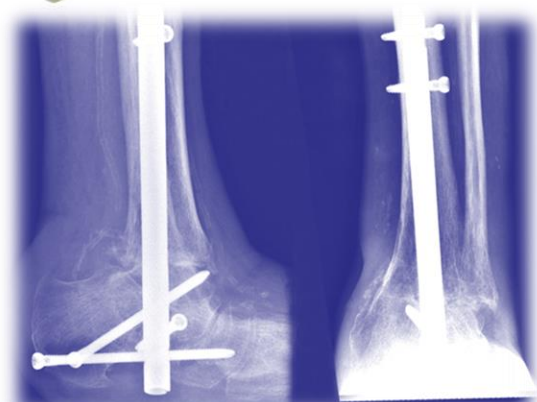
Proximal static locking hole

Nail length 160mm, 200mm and 250mm

Distal threaded screw holes help to reduce risk of screw back out while adding stability

Indications

The K2-II™ is indicated for degeneration, deformity, or trauma of both the tibiotalar and talocalcaneal articulations in the hindfoot; tibiocalcaneal arthrodesis; combined arthrodesis of the ankle and subtalar joints; avascular necrosis of the ankle and subtalar joints; failed total ankle replacement with subtalar intrusion; failed ankle arthrodesis with insufficient talar body; rheumatoid arthritis; severe deformity secondary to untreated talipes equinovarus or neuromuscular disease; and severe pilon fractures with trauma to the subtalar joints.



SURGICAL TECHNIQUE

I

Preoperative Planning

The appropriate K2-II™ implant length and diameter can be estimated through X-ray projection.

2

Patient Positioning

Position the patient prone on a radiolucent operating table (Figure 1). Position the C-arm to allow visualization of the tibiotalar and subtalar joints in both the AP and ML views.

The prone position is preferred, but lateral and supine positions are acceptable if needed. Patient positioning is determined based on the type of arthrodesis procedure performed and is therefore at the surgeon's discretion.

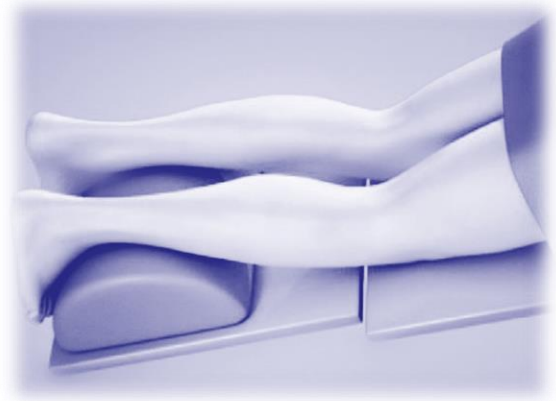


Figure 1

3

Approach

The approach chosen for the debridement, preparation and alignment of the hindfoot joint surfaces is based on factors such as surgical preference, patient positioning, and anatomy.

The simplest approach is usually through a lateral incision over the fibula and into the sinus tarsi. Full access to the joint surfaces requires a fibular osteotomy above the tibiotalar joint. This allows direct visualization and access to both the tibiotalar and sub-talar joints for debridement and subsequent alignment for fixation. This approach can be extended distally if access to the calcaneocuboid joint is needed (Figure 2).



Figure 2

4

Determine Entry Point

Once all the joint surfaces have been prepared and aligned in the desired position of fusion, the C-arm is brought into position laterally, and the **Guide Wire 3.0 mm (MOI 2401001)** is placed on the plantar surface of the foot in line with the tibia, talus, and calcaneus. The use of provisional guide wire fixation to maintain correct position of the respective arthrodesis is recommended. The Guide Wire will start slightly lateral to midline, in line with the tibial medullary canal axis.

Using this as the center of the planned insertion point, a 3 cm longitudinal incision is made on the plantar aspect of the heel (Figure 3).

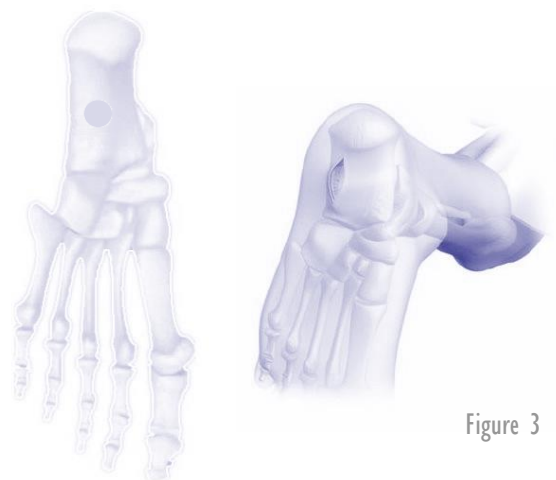


Figure 3

5

Insert Guide Wire through Calcaneus and Talus

With the hindfoot in the position of desired fusion, place the **Wire Guide Sleeve 3.2 mm** (MOI 2401017) through the incision to bone, the **Guide Wire 3.0 mm** is powered in from the calcaneus to the tibia under fluoroscopic control (Figure 4).

The C-arm is rotated into the AP/PA position to verify that the **Guide Pin** is positioned centrally within the tibia. Any deviation from a central position can affect the final fusion position.

Once the desired position is confirmed, advance the **Guide Wire** until it is 2-3 cm beyond the desired length of the nail to ensure adequate proximal reaming.

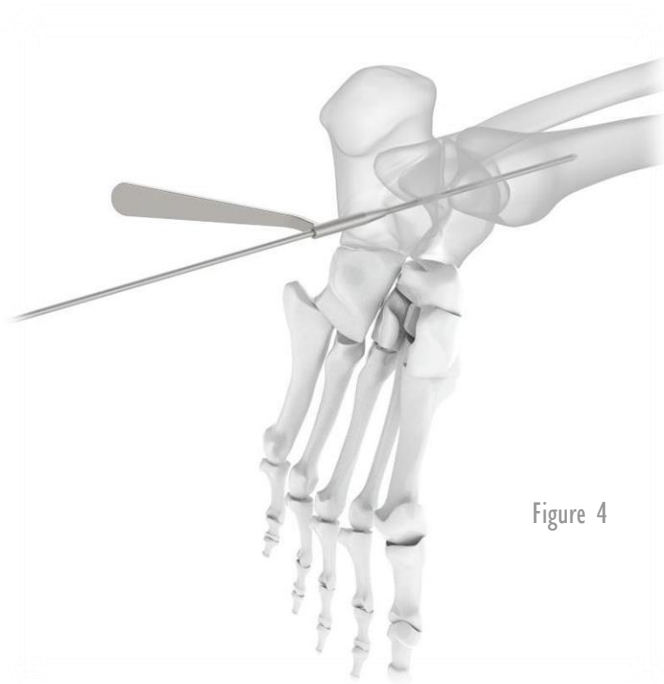


Figure 4

6

Open the Canal — Reaming

Place the combination of **Wire Sleeve 12.5/3.2 mm** (MOI 2401016) and **Protection Sleeve 15.0/12.7 mm** (MOI 2401018) over the **Guide Wire** and through the incision to bone (Figure 5).

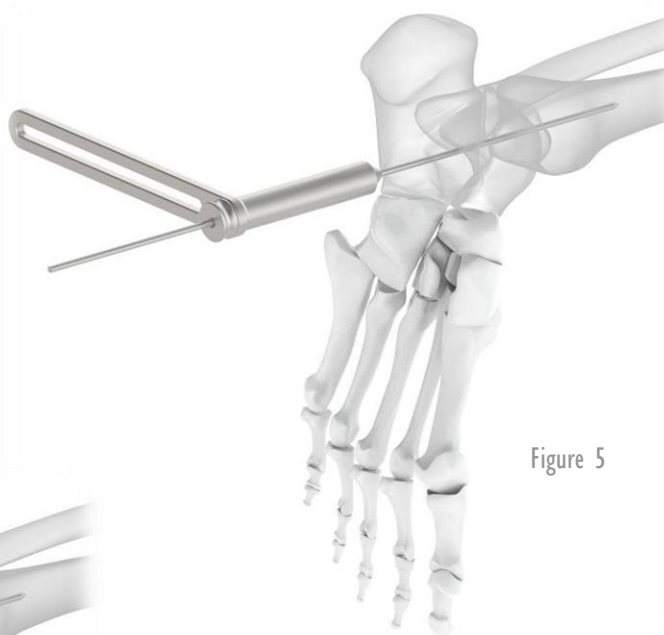


Figure 5

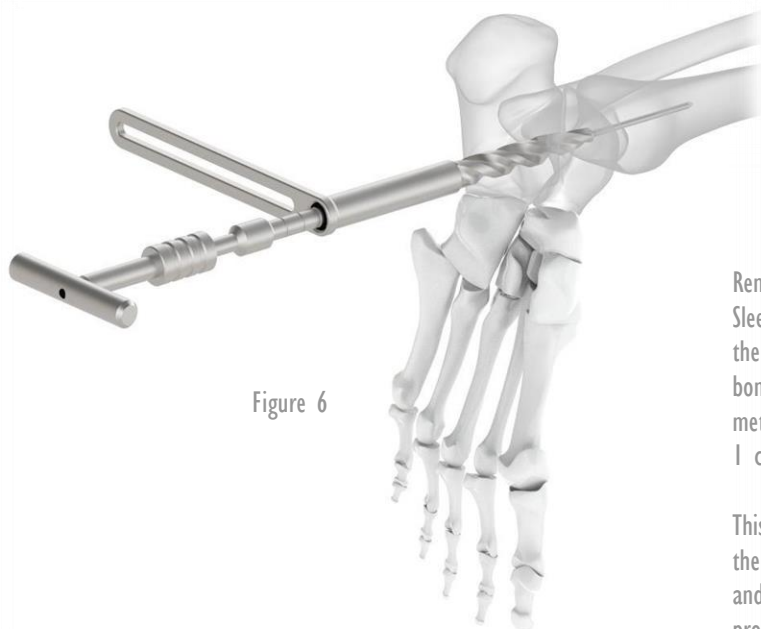


Figure 6

Remove the **Wire Sleeve with Trocar Tip** from the **Protection Sleeve**. Place the **Reamer 12.5/3.2 mm** (MOI 2401003) over the **guide wire** and through the **protection sleeve** to the bone. Drill through the calcaneus and talus into the metaphyseal region of the tibia. Ream to a depth of about 1 cm beyond the tibial articular surface.

This should ensure adequate reaming of the canal beyond the chosen length of the nail and allow room for impaction and compression of the construct without binding the nail proximally (Figure 6).

7

Place Guide Wire with Ball Tip

Remove the Guide Wire.

In most cases, the **Guide Wire with Ball Tip 1.8 mm** (MOI 0504020A) can now be easily inserted through the initial portal made by the entry Reamer and placed into the center of the tibia. Attach the **Guide Wire Holding Clamp** (MOI 0100024A), and tighten (Figure 7). Insert the guide wire with ball tip through the initial portal. Once the guide wire with ball tip has been fully inserted, the holding clamp is removed.

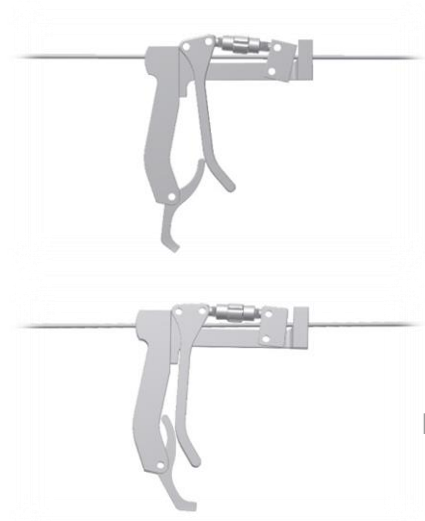


Figure 7

8

Ream the Canal

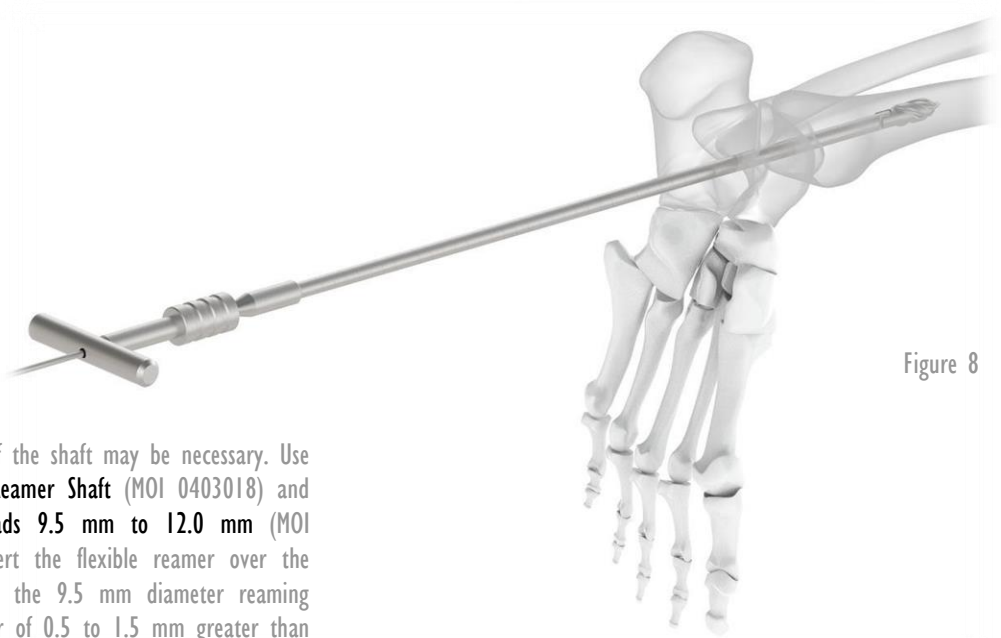


Figure 8

In some cases, reaming of the shaft may be necessary. Use the cannulated **Flexible Reamer Shaft** (MOI 0403018) and **Replaceable Reaming Heads 9.5 mm to 12.0 mm** (MOI 2401007) to do so. Insert the flexible reamer over the guide wire. Starting with the 9.5 mm diameter reaming head, ream to a diameter of 0.5 to 1.5 mm greater than the nail diameter. Ream in 0.5 mm increments and advance the reamer with steady, moderate pressure. Do not force the reamer. Partially retract the reamer repeatedly to clear debris from the medullary canal (Figure 8).

9

Assemble the Insertion Instruments

Assemble the nail to the **Insertion Handle** (MOI 2401020) using the **Nail Holding Screw** (MOI 2400030) and **Pin Wrench** (MOI 2401009). The nail is keyed and can only be assembled to the Insertion Handle in the correct way (Figure 9).



Figure 9

10

Insert the Nail

Using hand force, insert the nail through the incision into the reamed canal and seat flush to the plantar surface of the calcaneus.

Once proper entry depth is obtained, the **Hammer Guide for Nail Impactor/Extractor** (MOI 2401004) may be attached to the Insertion Handle. Initial manual compression may be achieved by flexing the knee and using the **Sliding Hammer** (MOI 0302025A) to tap the construct (Figure 10).

Position the C-arm to obtain an M/L view of the nail's driving end. Maintain the foot in the anatomical position and rotate the nail until the transverse hole can be visualized as a perfect circle. Under fluoroscopy, use the shadows of the cuboid and talus screw holes as alignment guides for screw placement.



Figure 10

Apposition/Compression Locking Mode

The K2-II™ Ankle Arthrodesis Nailing System has two proximal screw options — a Static Screw and a Dynamic Compression Screw. The Static Screw mitigates axial and rotational motion, while the oblong Compression Slot allows for either static locking or dynamic settling of the Nail (dynamization). Utilization of both screws is recommended to provide optimal rotational stability, and the possibility of postoperative dynamization in the case of delayed fusion. To achieve postoperative dynamization, remove the Proximal Static Screw, which will then permit axial compression during weight-bearing.

The K2-II™ Ankle Arthrodesis Nail provides the option to achieve active mechanical apposition/compression.

11

Guided Dynamic Locking of the Cuboid Screw

Attach the **Aiming Arm** (MOI 2400032) to the posterior side of the Insertion Handle. Lock the aiming arm firmly into place by using **Allen Wrench SW4.0** (MOI 2401008) (Figure 11).

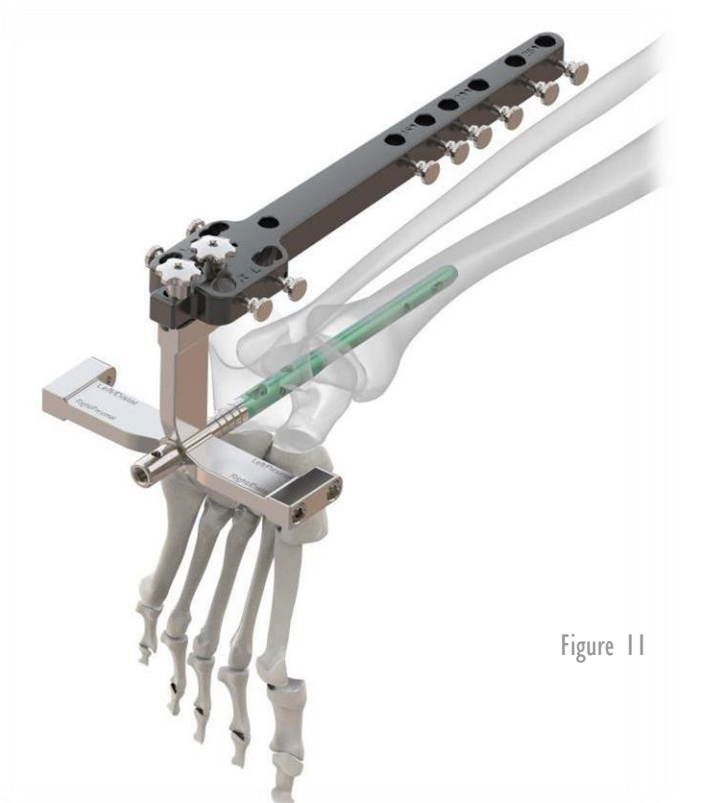


Figure 11

Insert the trocar combination of **Protection Sleeve 10.0/8.2 mm** (MOI 2401010), **Drill Sleeve 8.0/4.2 mm** (MOI 2401011) and **Trocar 4.0 mm** (MOI 2401012) through the distal Dynamic Position of Cuboid Hole on the aiming arm (Figure 12). The sleeve assembly end should sit on the lateral side of the calcaneal tuberosity and not on the lateral face of the calcaneus. Rotate the nail assembly if needed to keep the screws on the posterior surface. Make a stab incision and insert the trocar to the bone. Secure the protection sleeve in place with the lock nut (Figure 13).

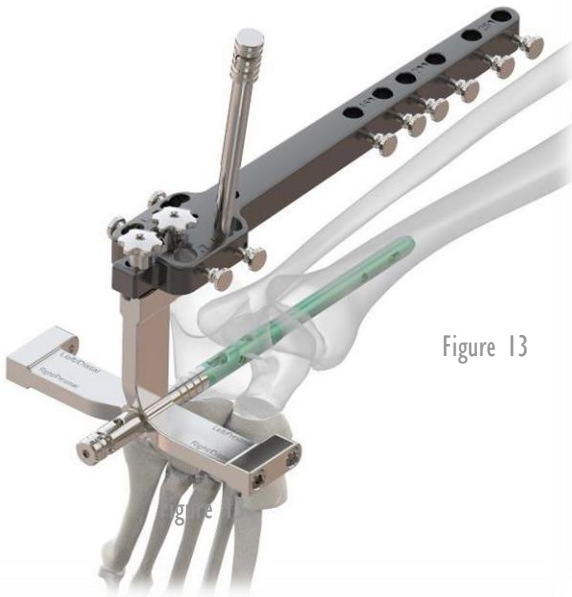


Figure 13

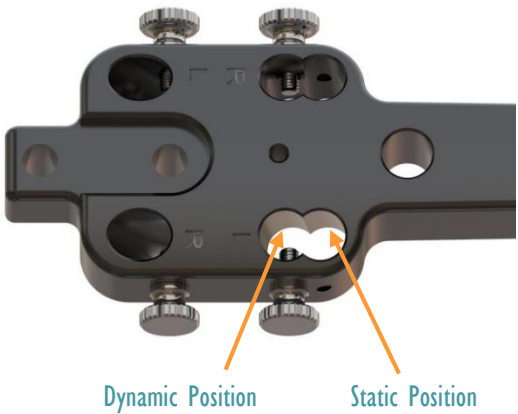


Figure 12

Withdraw the Drill Sleeve 8.0/4.2 mm and Trocar 4.0 mm, insert **Drill Sleeve 8.0/5.2 mm** (MOI 1400004) into the protection sleeve, advance the **Drill Bit 5.0 mm** (MOI 1400002) through the drill sleeve to the desired depth. The drill bit should be oriented posterior-medial in the calcaneus to anterior-lateral in the cuboid (Figure 14).

Confirm drill bit position radiographically.

The drill bit and drill sleeve are removed. The **T-Handled Tap 6.5 mm** (MOI 1400010) is inserted into the Protection Sleeve to tap the proximal cortex (Figure 15).

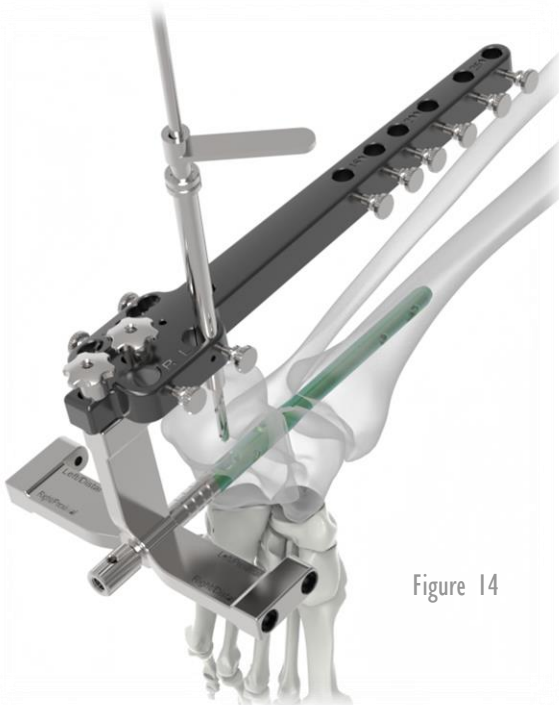


Figure 14



Figure 15

Remove the drill bit and the drill sleeve.

Screw length is determined by using the screw **Depth Gauge** (MOI 0201008A).

Insert the appropriate length **Locking Screw 5.0 mm** for subtalar compression through the protection sleeve using the **T-Handled Screwdriver SW3.5, Long** (MOI 0200007) (Figure 16).

Remove the protection sleeve. Verify locking screw length under image intensification.

12 Guided Locking of the Proximal Screws

Remove the Aiming Arm and attach it on the medial aspect of the Insertion Handle. Markings on the Insertion Handle will help ensure proper orientation.

Insert the Insert the trocar combination of **Protection Sleeve 10.0/8.2 mm**, **Drill Sleeve 8.0/4.2** and **Trocar 4.0 mm** into the appropriate hole for locking the static proximal hole of the selected Nail length.

Make a small skin incision in front of the Trocar and push the assembly until the Protection Sleeve is in contact with the medial cortex of the tibia.

The Trocar is removed, with the Tissue Protection Sleeve and the Drill Sleeve remaining in position. Drill both cortices by using **Drill Bit 4.0 mm** (MOI 2401002) (Figure 17).

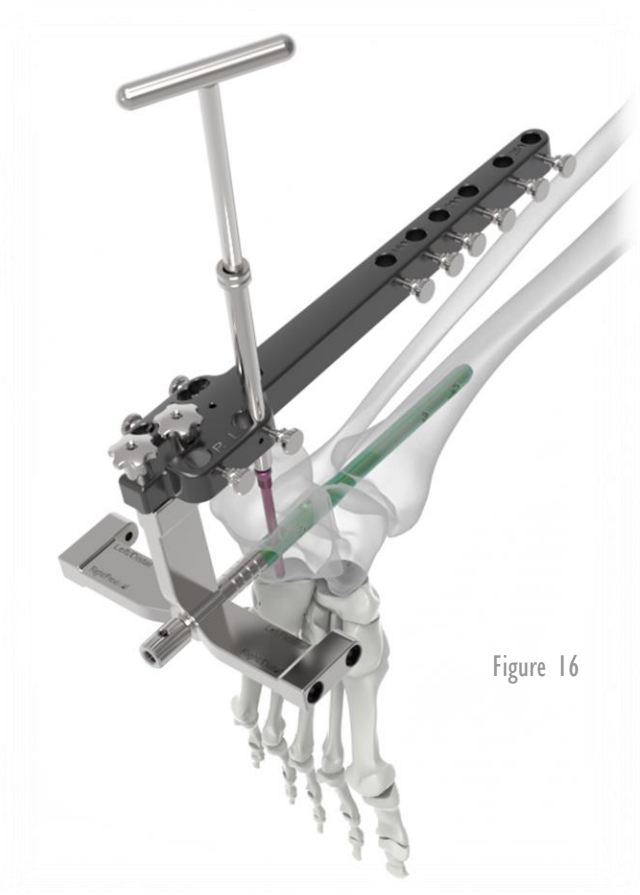


Figure 16

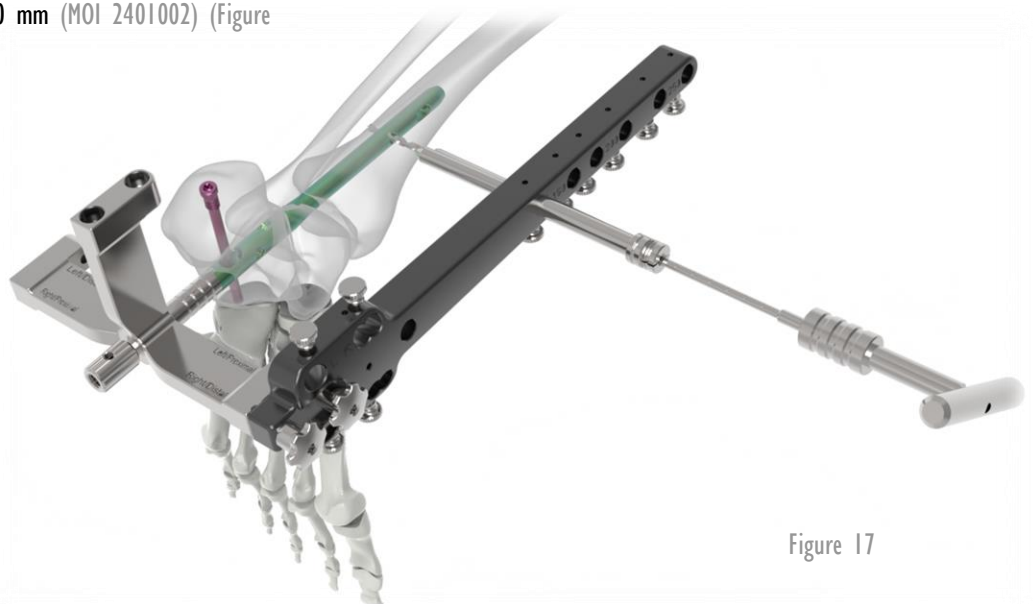


Figure 17

Remove the drill bit and the drill sleeve.

Insert the **Depth Gauge** into the protection sleeve. Make sure that the hook grasps the far cortex and that the protection sleeve is flush to the bone.

Read the measurement from the back of the outer sleeve of depth gauge, which corresponds to the appropriate length of the locking screw (Figure 18).

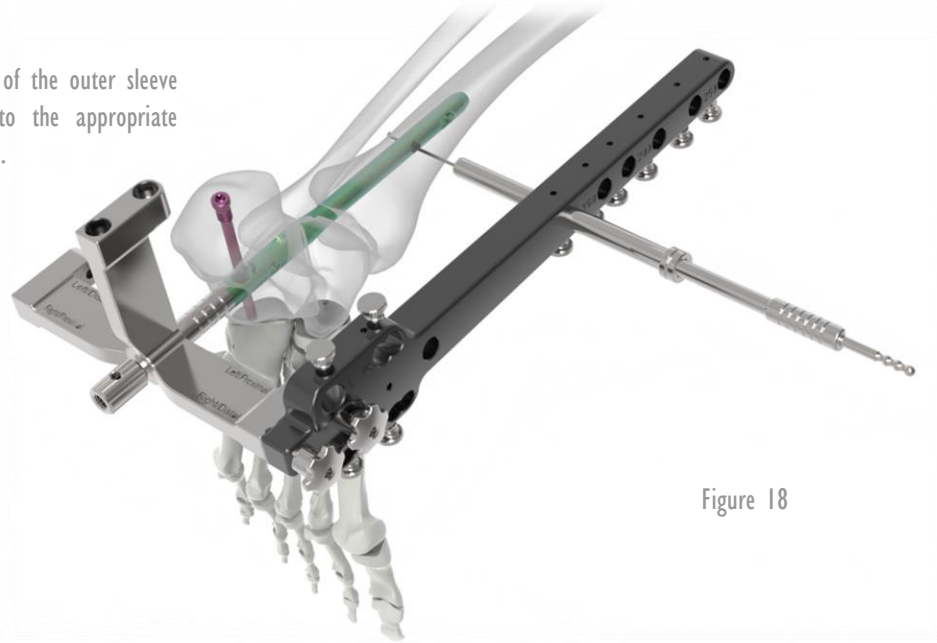


Figure 18

When the Depth Gauge is removed, the correct fully threaded Locking Screw 5.0 mm is inserted through the Protection Sleeve using the **Stardrive Screwdriver 4.5** (MOI 2401006). The screw is advanced through both cortices (Figure 19).

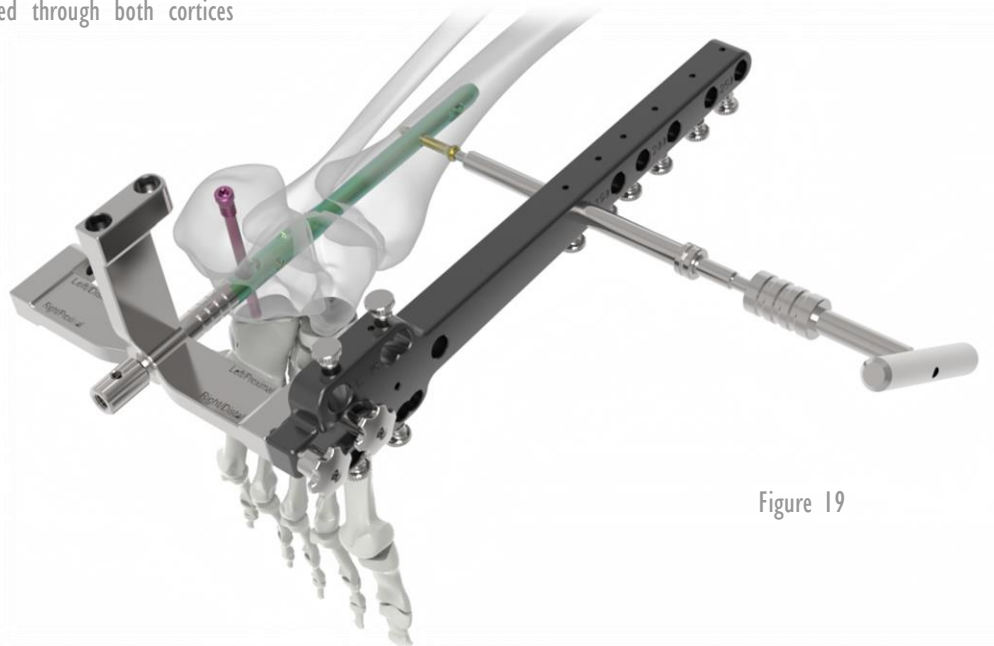


Figure 19

Repeat the locking procedure for the second Locking Screw in the proximal oblong hole (Figure 20). The dynamic option allows for up to 5 mm of late settling of the nail.

Remove the Protection Sleeve and proceed with the tibiotalar compression.

NOTE:

Proximal static locking with two fully threaded Locking Screws must be performed prior to applying active, controlled tibiotalar apposition/compression.

13
Tibio-talar Apposition/Compression

Insert the **Compression Rod** (MOI 2400031) through Nail Holding Screw and into the nail using the Allen Wrench SW4.0. The Compression Rod will then contact the dynamic locking screw.

Start turning the Compression Rod clockwise using the Pin Wrench. As the Compression Rod is advanced against the dynamic locking screw, it draws the talus towards the proximal tibial segment, employing active apposition/compression (Figure 21). Image intensification will enable the surgeon to visualize active compression.

Caution: Do not over-tighten the Compression Rod, it may bend the locking screw.

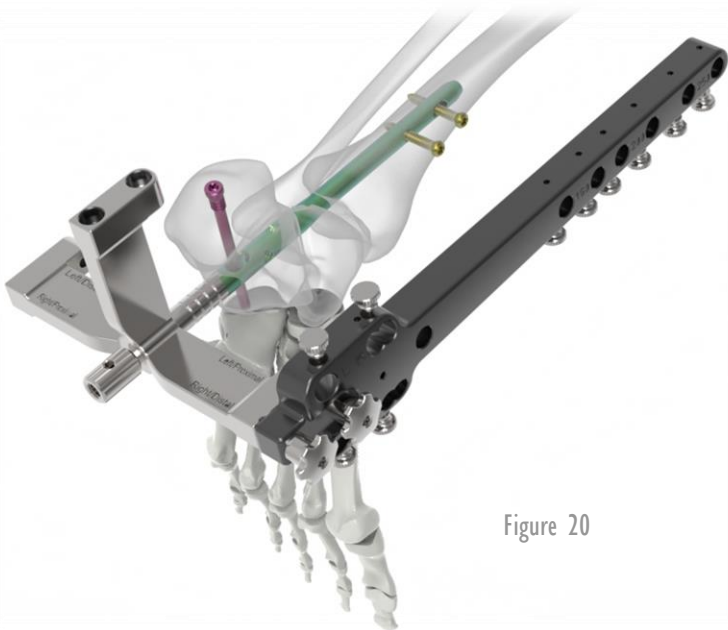


Figure 20

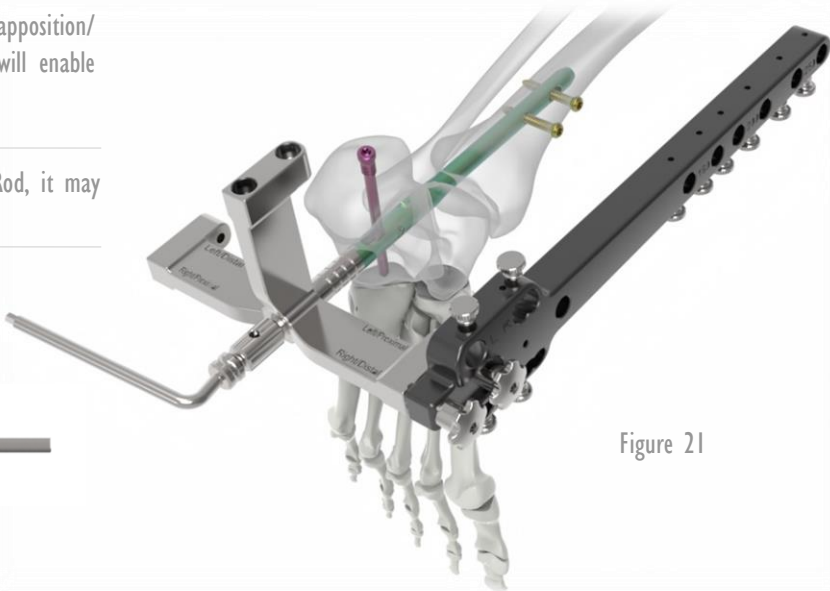


Figure 21

14
Guided Locking of the Talus Screw

Attach the **Aiming Arm** to the posterior side of the Insertion Handle again. Lock the aiming arm firmly into place. Insert the three-part trocar combination assembly through the **Talus Hole** on the aiming arm (Figure 22). Make a stab incision and insert the trocar to the bone.



Figure 22

Withdraw the trocar, insert the Drill Sleeve 8.0/4.2 mm into the protection sleeve.

Drill to the anterior side of the talus, using the Drill Bit 4.0 mm. Confirm drill bit position radiographically.

Remove the drill bit and the drill sleeve.

Insert the **Depth Gauge** into the protection sleeve. Make sure that the hook grasps the far cortex and that the protection sleeve is flush to the bone.

Read the measurement from the back of the outer sleeve of depth gauge, which corresponds to the appropriate length of the locking screw.

Insert the appropriate length Locking Screw 5.0 mm through the protection sleeve using the **Stardrive Screwdriver 4.5** (Figure 23). The talus screw should be inserted from posterior-inferior and lateral in the calcaneus to anterior-medial in the talar dome. This screw will sit approximately perpendicular to the subtalar joint.

Remove the protection sleeve. Verify locking screw length under image intensification.



Figure 23

15

Guided Locking of the Transverse Screw

Once the cuboid and talus screws are in place, a third transverse distal locking option can be used at the surgeon's discretion.

Remove the Aiming Arm and attach it on the lateral aspect of the Insertion Handle. Remove the Pin Wrench.

Insert the three-part trocar combination assembly into the **Transverse Hole** on the aiming arm (Figure 24) and repeat the above procedure for Transverse Screw insertion (Figure 25).

Verify locking screw length under image intensification.

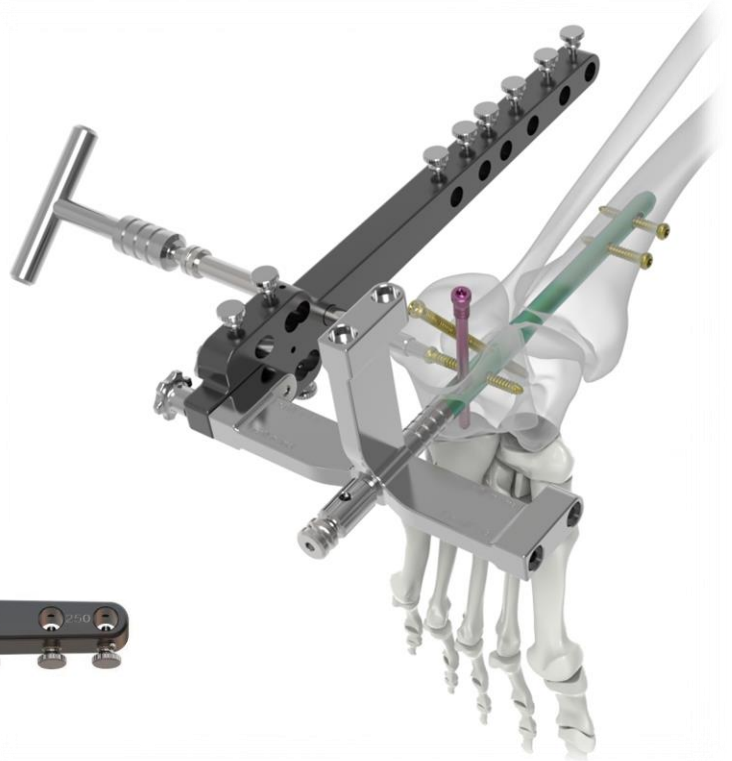


Figure 25



Figure 24

16

End Cap Insertion

Remove the nail insertion instruments.

Once the Nail Holding Screw and the Insertion Handle have been removed, a nail **End Cap** is placed over the end of the nail. The nail end cap is screwed tight with the **T-Handled Screwdriver SW3.5 mm, Short (MOI 2401005)** (Figure 26).

The end caps for the K2-II™ Ankle Arthrodesis Nails are available in extension lengths of 0 mm, 5 mm, 10 mm, 15 mm and 20 mm.



Follow standardized procedures for closure.



Figure 26

IMPLANT REMOVAL (optional)

It is not recommended to remove the nail unless deep infection occurs or if the patient is symptomatic.

However if removal is required, then dissect the plantar soft tissue to expose the distal end of the nail. Clear the Stardrive recess of the end cap and the locking implants of any tissue ingrowth. Remove the end cap using the T-Handled Screwdriver SW3.5 mm.

Thread the **Hammer Guide for Nail Impactor/Extractor** into the distal end of the nail before screw removal to restrict nail movement. It is important to avoid crossing the thread in the nail.

Make stab wounds over the original incisions. The locking screws are now all removed.

The nail is then removed by reverse hammering (Figure 27).

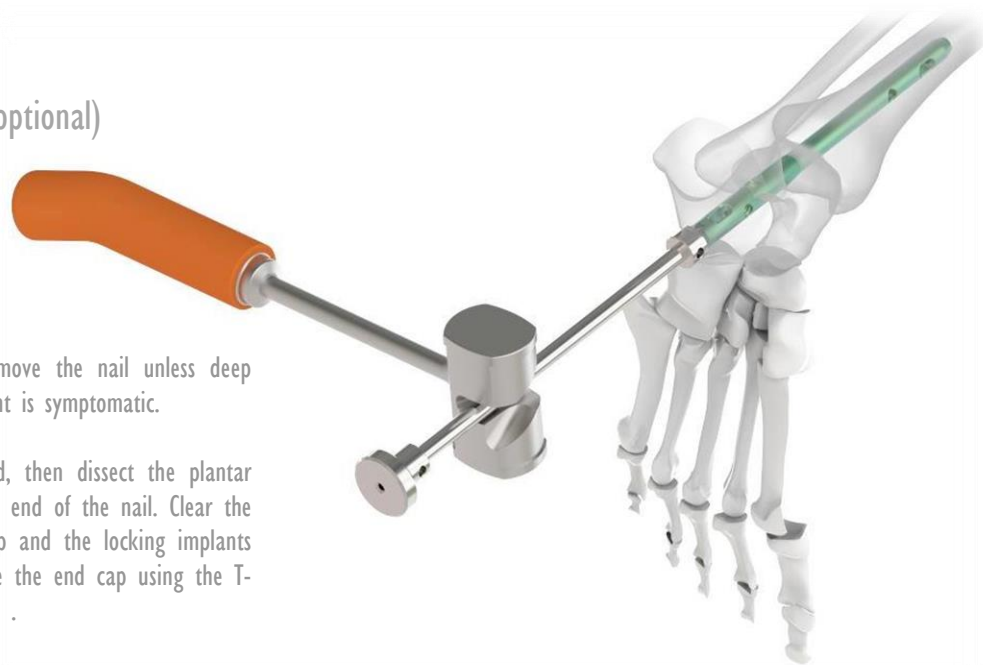


Figure 27

IMPLANT INFORMATION



K2-II™ Fusion Nails, Cannulated

REF (SS)	REF (TIT)	DIA (mm)	LEN (mm)	DIRECTION
MOI 11376160X	MOI 31376160X	10.0	160	Left
MOI 11376200X	MOI 31376200X	10.0	200	Left
MOI 11376250X	MOI 31376250X	10.0	250	Left
MOI 11377160X	MOI 31377160X	11.50	160	Left
MOI 11377200X	MOI 31377200X	11.50	200	Left
MOI 11377250X	MOI 31377250X	11.50	250	Left
MOI 11384160X	MOI 31384160X	10.0	160	Right
MOI 11384200X	MOI 31384200X	10.0	200	Right
MOI 11384250X	MOI 31384250X	10.0	250	Right
MOI 11385160X	MOI 31385160X	11.50	160	Right
MOI 11385200X	MOI 31385200X	11.50	200	Right
MOI 11385250X	MOI 31385250X	11.50	250	Right



K2™ Locking Screw 5.0 mm, fully threaded

REF (SS)	REF (TIT)	DIA (mm)	LEN (mm)
MOI 11529025	MOI 31529025	5.0	25
MOI 11529030	MOI 31529030	5.0	30
MOI 11529035	MOI 31529035	5.0	35
MOI 11529040	MOI 31529040	5.0	40
MOI 11529045	MOI 31529045	5.0	45
MOI 11529050	MOI 31529050	5.0	50
MOI 11529055	MOI 31529055	5.0	55
MOI 11529060	MOI 31529060	5.0	60
MOI 11529065	MOI 31529065	5.0	65
MOI 11529070	MOI 31529070	5.0	70
MOI 11529075	MOI 31529075	5.0	75
MOI 11529080	MOI 31529080	5.0	80
MOI 11529085	MOI 31529085	5.0	85
MOI 11529090	MOI 31529090	5.0	90
MOI 11529095	MOI 31529095	5.0	95
MOI 11529100	MOI 31529100	5.0	100
MOI 11529105	MOI 31529105	5.0	105
MOI 11529110	MOI 31529110	5.0	110

Locking Screw 5.0 mm,
(used for subtalar compression)



REF (SS)	REF (TIT)	DIA (mm)	LEN (mm)
MOI 11503060	MOI 31503060	5.0	60
MOI 11503065	MOI 31503065	5.0	65
MOI 11503070	MOI 31503070	5.0	70
MOI 11503075	MOI 31503075	5.0	75
MOI 11503080	MOI 31503080	5.0	80
MOI 11503085	MOI 31503085	5.0	85
MOI 11503090	MOI 31503090	5.0	90
MOI 11503095	MOI 31503095	5.0	95
MOI 11503100	MOI 31503100	5.0	100
MOI 11503105	MOI 31503105	5.0	105
MOI 11503110	MOI 31503110	5.0	110
MOI 11503115	MOI 31503115	5.0	115
MOI 11503120	MOI 31503120	5.0	120

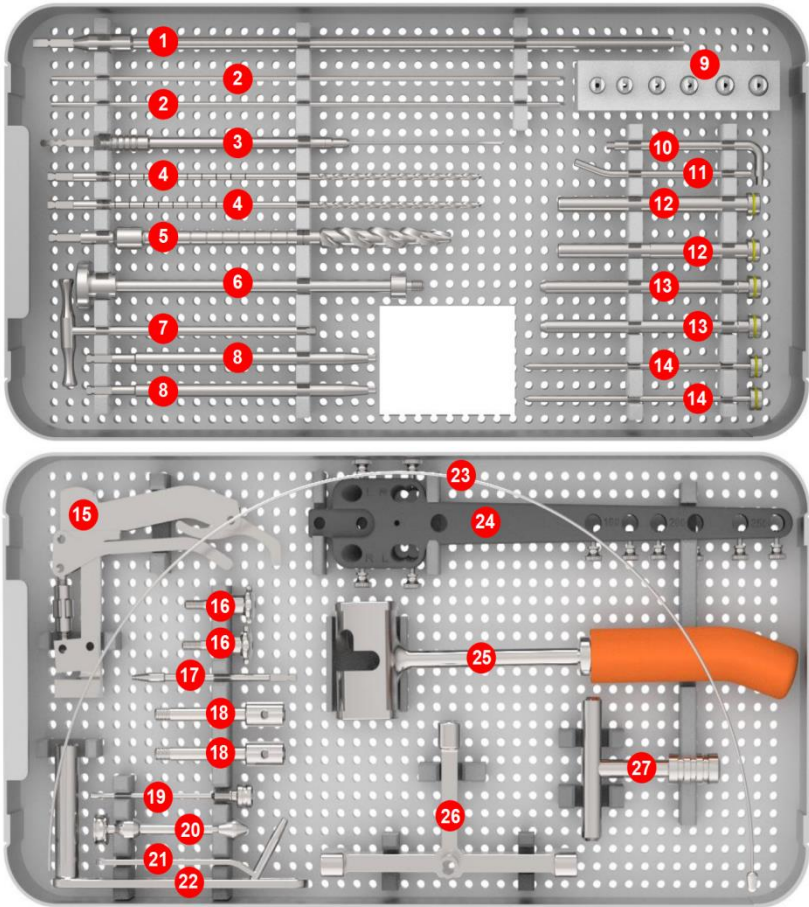


End Cap, for K2-II™ Fusion Nails

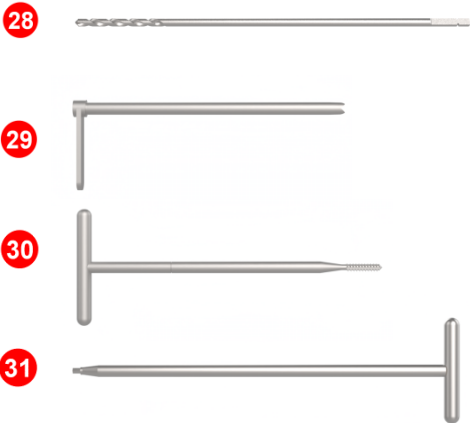
REF (SS)	REF (TIT)	SIZE (mm)
MOI 11715000X	MOI 31715000X	0
MOI 11715005X	MOI 31715005X	5
MOI 11715010X	MOI 31715010X	10
MOI 11715015X	MOI 31715015X	15
MOI 11715020X	MOI 31715020X	20

INSTRUMENTS INFORMATION

K2-II™ Ankle Arthrodesis Fusion Nailing System Instrument Set (MOI K2-II-01R)



REF	DESCRIPTION	UNITS
1 MOI 0403018	Flexible Reamer Shaft	1
2 MOI 2401001	Guide Wire 3.0 mm	2
3 MOI 0201008A	Depth Gauge for Locking Screw	1
4 MOI 2401002	Drill Bit 4.0 mm	2
5 MOI 2401003	Reamer 12.5/3.2 mm	1
6 MOI 2401004	Hammer Guide, for Nail Impactor/Extractor	1
7 MOI 2401005	T-Handled Screwdriver SW3.5, Short	1
8 MOI 2401006	Screwdriver Shaft 4.5, Stardrive	2
9 MOI 2401007	Replaceable Reaming Heads, 9.5/10.0/10.5/11.0/11.5/12.0 mm	1
10 MOI 2401008	Allen Wrench SW4.0	1
11 MOI 2401009	Pin Wrench	1
12 MOI 2401010	Protection Sleeve 10.0/8.2 mm	2
13 MOI 2401011	Drill Sleeve 8.0/4.2 mm	2
14 MOI 2401012	Trocar 4.0 mm	2
15 MOI 0100024A	Guide Wire Holding Clamp	1
16 MOI 2401013	Wheel Lock, for Aiming Arm	2
17 MOI 2401014	Extraction Screw Shaft	1
18 MOI 2400030	Nail Holding Screw	2
19 MOI 2400031	Compression Rod	1
20 MOI 2401016	Wire Sleeve 12.5/3.2 mm	1
21 MOI 2401017	Wire Guide Sleeve 3.2 mm	1
22 MOI 2401018	Protection Sleeve 15.0/12.7 mm	1
23 MOI 0504020A	Guide Wire with Ball Tip 1.8 mm	1
24 MOI 2400032	Aiming Arm	1
25 MOI 0302025A	Sliding Hammer	1
26 MOI 2401020	Insertion Handle	1
27 MOI 2401021	Quick Coupling T-Handle, Triangular Coupling	1
28 MOI 1400002	Drill Bit 5.0mm	1
29 MOI 1400004	Drill Sleeve 8.0/5.2 mm	1
30 MOI 1400010	T-Handled Tap 6.5 mm	1
31 MOI 0200007	T-Handled Screwdriver SW3.5, Long	1
* MOI 2401000K	Trays and Container	1





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