

1. Description of medical device

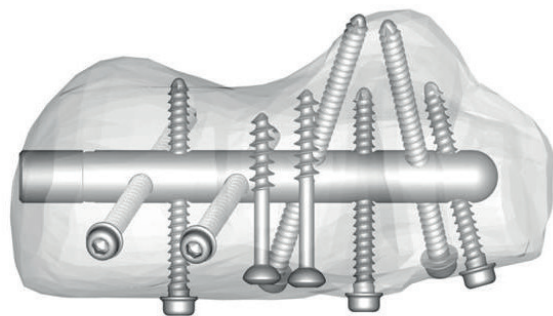
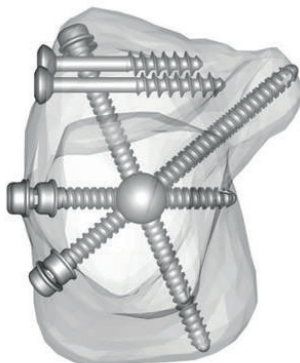
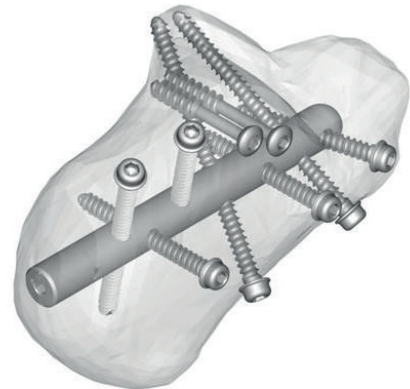
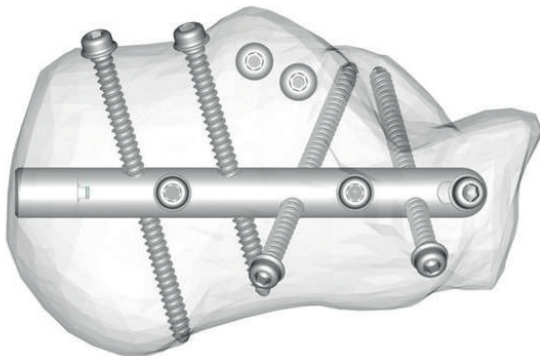
C-NAIL is an intramedullary nail for minimal-invasive fixation of intraarticular calcaneal fractures. The principle is to stabilize with the nail the four to five main fragments of the fractured calcaneus in conjunction with up to seven interlocking screws and thus creating angular stable fixation. The maximum of stability is achieved by fixing the sustentacular fragment towards the nail with two interlocking screws guided by a very precise aiming device.

The design of the nail is separated of the left leg (indicated by "L") and the right leg (indicated by "R"). The nail length is 65 mm with a diameter of 8 mm. The nail can be extended and closed by an end cap with sizes: 0 mm; 5 mm; 10 mm; 15 mm; 20 mm.

The implants are all supplied unsterile and must be sterilized before operative use.

2. Indication

Intraarticular fractures of the calcaneus according to Sanders I-IV; B and C – types according ICI-AO-ASIF Classification.



3. Preoperative planning and principle of surgical technique

Within the framework of preoperative planning one must verify the appropriateness of this surgical technique. **One of the parameters that must be verified is the length of the calcaneus, which must not be shorter than 65 mm.** Preoperative X-rays of the lateral, axial and dorsoplantar broken calcaneus are recommended as well as a CT-scan in two planes eventually shown additionally in 3D reconstruction. For knowing the individual Böhler's angle a comparative lateral X-ray of the healthy calcaneus should be taken.

The underlying principle of the operation is the minimal-invasive fixation of a fractured calcaneus with an interlocking nail which is introduced by stab incisions after initial anatomic reduction of the posterior facet. This joint reduction is performed by subtalar arthroscopy or a lateral 3 cm long intramalleolar incision. Through this approach the tuberosity fragment is reduced to the sustentacular fragment by help of a small raspatorium fixing it temporarily with a 1.8/2.0 mm K-wire. Then the lateral part of the posterior facet fragment is reduced towards the medial part of the posterior facet and temporarily fixed with two K-wires (1.8/2.0 mm) below but parallel to the joint level. If there is an additional intermediate joint fragment (type Sanders IV) the inside-out-inside K-wire technique should be performed for anatomic joint reduction. After restoring the posterior subtalar joint and Böhler's angle, controlling the result with fluoroscopy especially with a Broden's projection the aiming wire for the nail is drilled below the attachment of the Achilles tendon towards the centre of the calcaneocuboid joint. Controlling this K-wire fluoroscopically to be also in the middle axes of the calcaneus over drilling then for introduction of the nail is done. The nail is connected before introduction to the aiming device. Fix then with the help of the radiolucent arms of the aiming device first the sustentacular fragment towards the introduced C-Nail by inserting first a K-wire through the signed **"SUSTENTACULUM"** guiding arm into the sustentaculum. Only after K-wire positioning exactly into the sustentaculum close to the middle facet, controlled by fluoroscopy, the first sustentacular interlocking screw is inserted. The second sustentacular screw and then consequently the three lateral and two superior screws using the signed **"LATERAL"** and **"SUPERIOR"** guiding arms are brought in place.



4. Preparation of instrumentation and implants

Prior to the operation, it is necessary to check the completeness and functionality of all parts of the instrumentation.

On the basic body of the aiming device, aiming device arms are set into a position based on the chosen side of the operated extremity. The aiming device arms are fixed with fixation screws, which are tightened reasonably to the basic body with the help of wrench rods.

The nail is placed in the aiming device grooves, and is firmly fixed using the aiming device screw.

Prior to use, inspection must be performed of the position of the aiming device arms against the tight nail. Inspection is performed for all seven holes.



5. Operating technique

5.1. Position of patient

The patient is in a lateral position with a slightly flexed knee. The involved extremity is supported by a soft cylindrical pillow from the medial side. The other extremity is bent in the knee joint to not interfere with using fluoroscopic equipment.



5.2. Drawing of the position of the bones

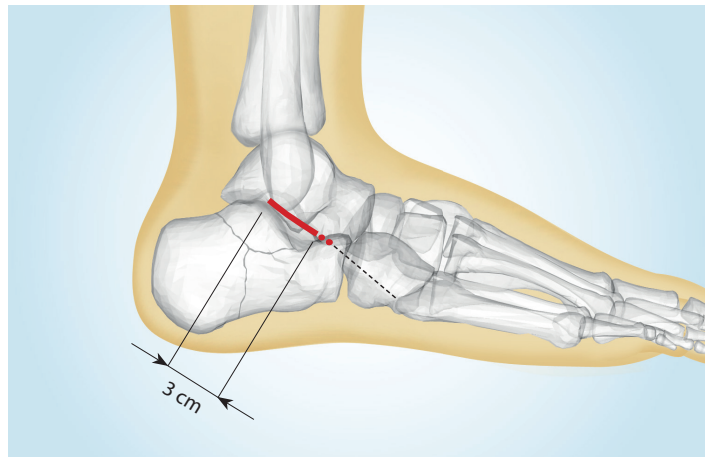
The landmarks of the lateral malleolus, calcaneus and cuboid are drawn laterally on the skin.



5.3. Incision for mini-open reduction of the posterior joint surface

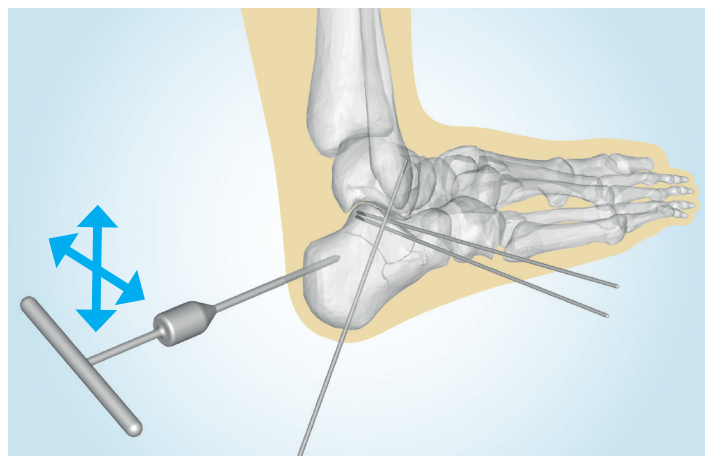
For reduction of the posterior facet a 3 cm long incision below the tip of the lateral malleolus in direction to the base of the fifth metatarsal bone is marked.

When making the incision caution is recommended not to damage the peroneal tendons.



5.4. Reduction manoeuvre for restoring Böhler's angle and the posterior joint surface

Reduction of the tuberosity fragment towards the sustentacular fragment is most often achieved by inserting a 6.5 mm cancellous Schanz-screw with handle through a stab incision into the tuberosity or tongue type fragment by correcting lateral translation, varus or valgus malposition or and/or plantar tilting of the tuberosity. Sometimes a small raspatorium is additionally needed to be introduced below the broken posterior facet to mobilize the tuberosity fragment from impaction into the sustentacular fragment. After this initial reduction manoeuvre with keeping the tuberosity fragment towards the sustentacular fragment with a 1.8/2.0 mm K-wire the reduction of posterior facet is performed using an elevator or small raspatorium.

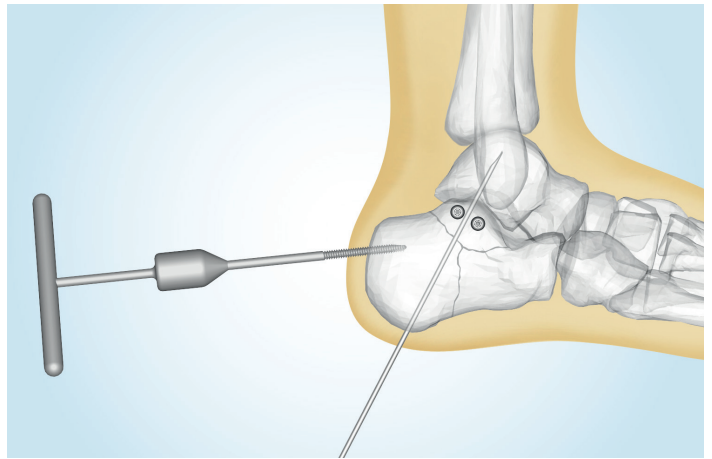


5.4.1. Temporary fixation using K-wires

After initial temporary fixation of the reduced tuberosity fragment towards the sustentacular fragment with a K-wire the lateral part of the reduced posterior facet fragment is fixed with two K-wires (1.8/2.0 mm) to the medial part of the posterior facet. In case of a dislocated intermediate fragment of the posterior facet (type Sanders IV) the inside-out-inside K-wire fixation manoeuvre is recommended. Correctness of the congruency of the posterior subtalar joint is now checked fluoroscopically with the Broden's projection.

5.4.2. Fixation using cancellous screws

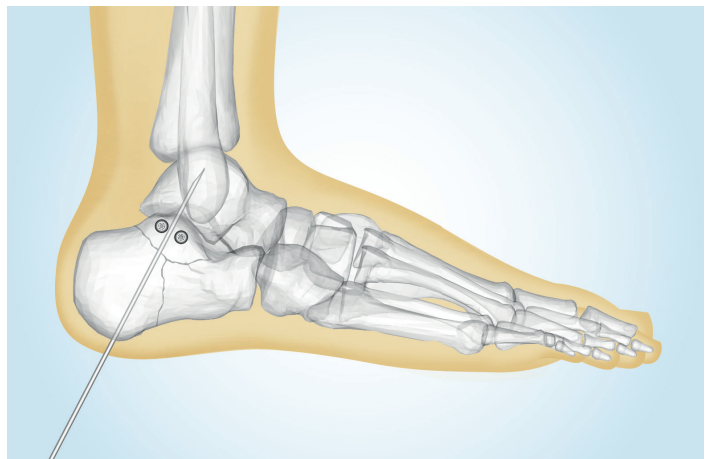
Definitive fixation of the posterior facet is usually achieved by inserting two separate 4.0 mm cancellous screws which substitute and run like the previous K-wires below the joint in direction to the sustentaculum, closing due to compression any given interfragmentary gap.



5.5. Removal of Schanz-screw, control and/or reduction of the calcaneo-cuboidal joint

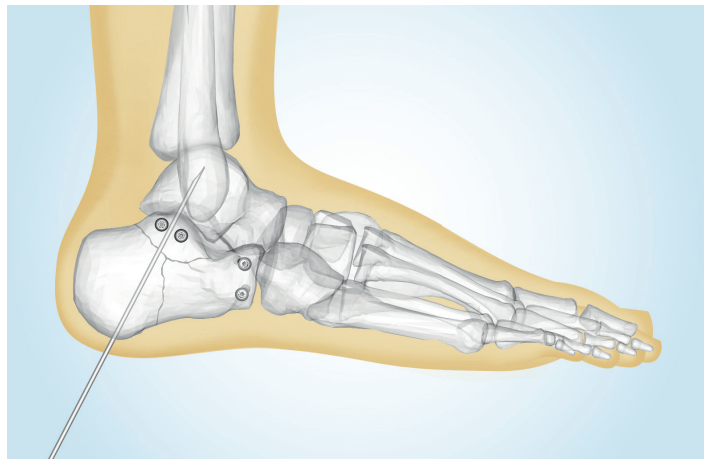
5.5.1. Removal of the Schanz screw

The Schanz-screw with handle is removed as soon as congruency of the subtalar joint is seen fluoroscopically or by open arthroscopy.



5.5.2. Control and/or reduction of the calcaneo-cuboidal joint

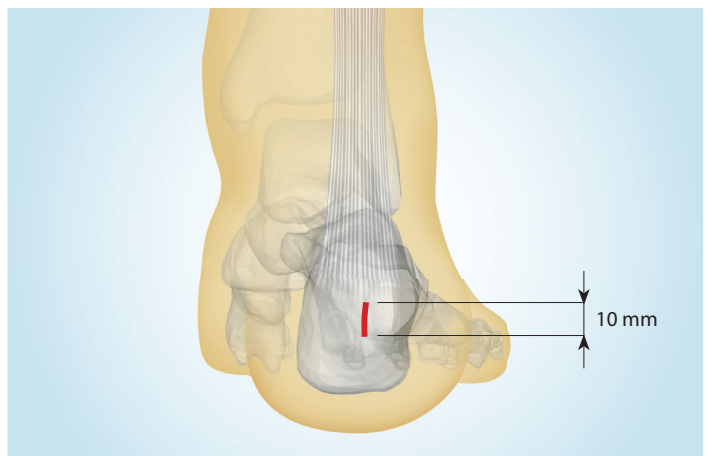
In case of a B2 fracture with a broken calcaneo-cuboidal joint, lateral and dorso-plantar fluoroscopic projection should show an indirectly reduced cuboidal facet. This intraarticular fracture can be secured by 1 or 2 percutaneously inserted 4.0 mm cancellous screws close to the calcaneo-cuboidal joint but positioned more in the dorsal and plantar height of the calcaneus not to hinder the following insertion of the nail. If incongruence is given an additional small Ollier's approach will help to achieve anatomic reduction before stabilizing the cuboidal facet with screws.



5.6. Introducing of the nail

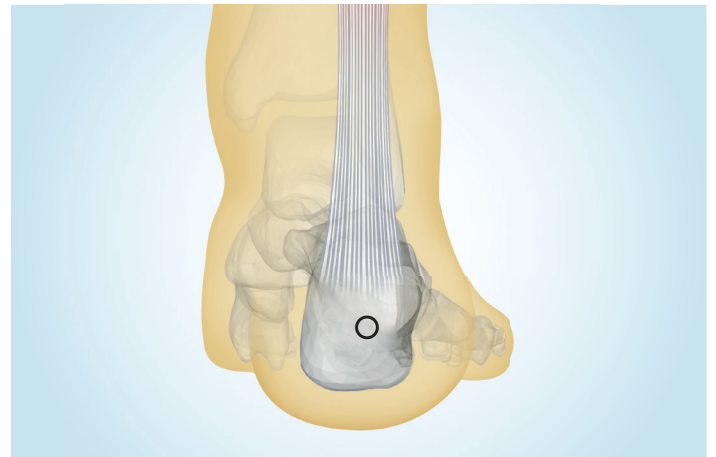
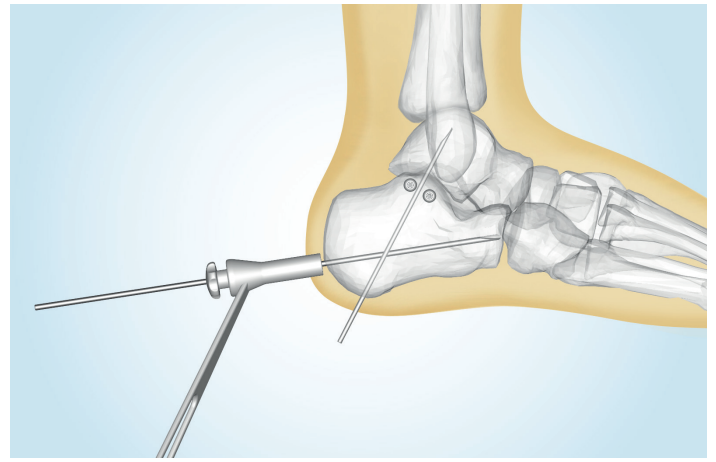
5.6.1. Incision

For inserting the nail a 10 mm vertical incision under the attachment of the Achilles tendon is made slightly lateral to the center of the dorsal heel aspect.



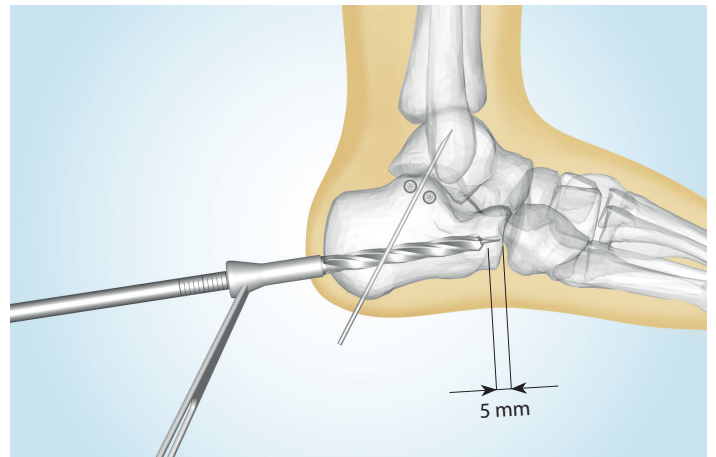
5.6.2. Drilling the guide wire for the nail hole

The direction of drilling the guide wire is determined by the center of the calcaneo-cuboidal joint. Drilling is performed using a guide wire through a protective sleeve in which the guide wire is centralized. The position of the guide wire is controlled fluoroscopically by lateral and dorso-plantar projections.



5.6.3. Drilling the hole for the nail

Drilling is performed with the cannulated 8 mm drill bit. The soft tissues are protected during drilling by the guide sleeve. The depth of drilling ends approximately 5 mm in front of the calcaneo-cuboidal joint. It is possible to read the drilling depth on the cutter scale at the level of the guide sleeve. After drilling the hole, the cutter and guide wire are extracted.



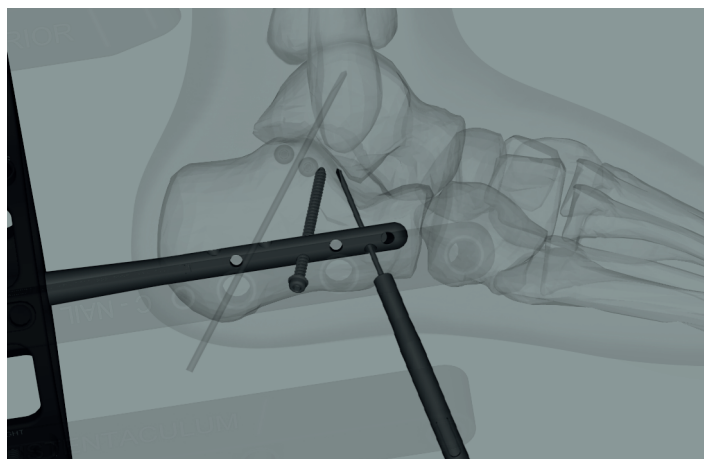
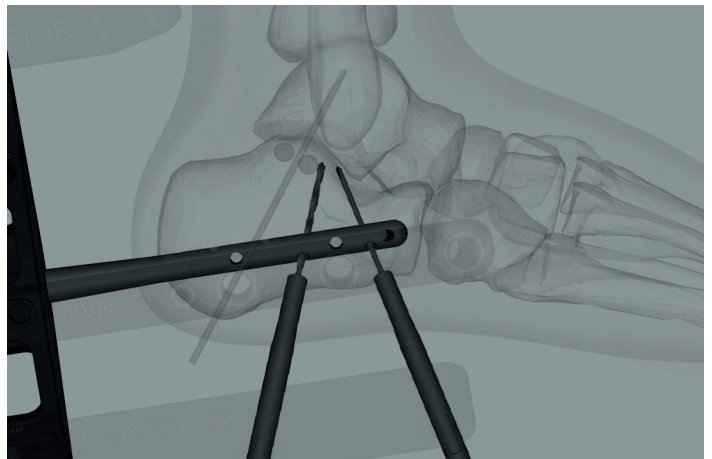
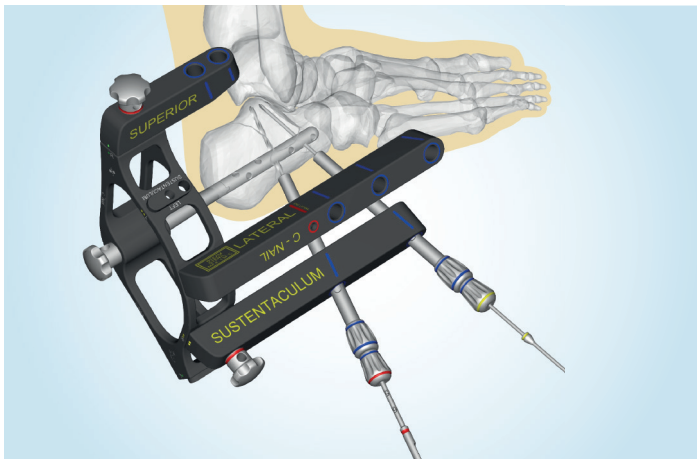
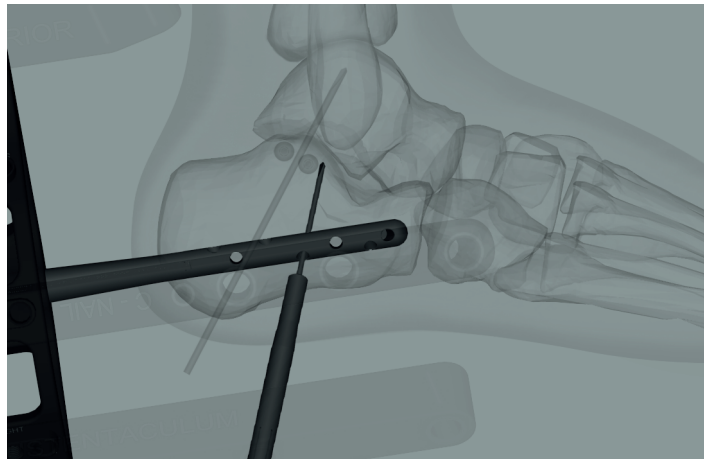
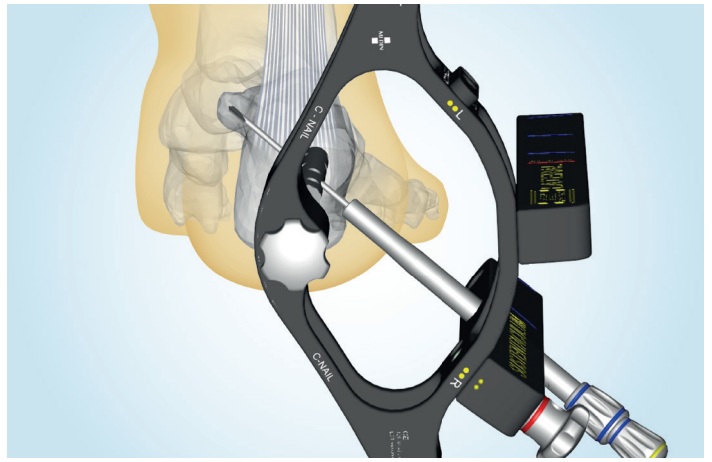
5.6.4. Introducing of the nail with the attached aiming device

The nail with the attached aiming device is introduced into the drilled hole. This is performed by mild axial pressure and rotational motion of the aiming device with the nail.



5.6.5. Adjusting the nail position and introducing K-wires to the sustentaculum

The correct rotational position of the nail is given as soon as the first K-wire with olive (2.0 mm) is positioned under fluoroscopic control through the guiding sleeve which is positioned in the posterior hole of the "sustentaculum" named guiding arm exactly into the sustentacular fragment ending close to the middle facet. After this temporary K-wire fixation the screw drill bit is introduced through the guiding sleeve which is positioned through the anterior hole of the "SUSTENTACULUM" guiding arm forward close to the bone. This is enabled after stab incision by using the conical trocar for deviating the soft tissues and allowing firm contact of the guiding sleeve to the bone while drilling and measuring length for the screw on the drill bit scale. Before inserting the screw check the position of the drill bit by fluoroscopic axial projection to be sure that the sustentaculum is hit well. If positing is right the screw is inserted and the initial positioned K-wire through the posterior aiming hole is substituted by a screw with proper length. If positioning is not correct, it is necessary to remove the initially used K-wire and correct rotation of the aiming device to have at least 2 screws optimally positioned in the sustentaculum.



5.6.6. Introducing the remaining interlocking screws

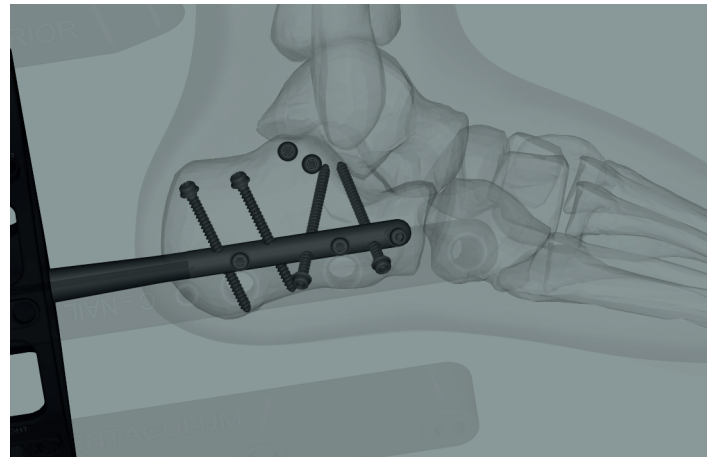
The remaining interlocking screws are then introduced using the "SUPERIOR" guiding arm for the tuberosity or tongue type fragment. As soon as this is done the first inserted K-wire can be removed. At least the "LATERAL" guiding arm of the aiming device is used for fixing the anterior process fragment being aware that there is no step left in the cuboidal facet. During introduction of the guiding sleeve it is always necessary to measure carefully the length of the needed screws so that they run bicortically. Screws should not protrude through the second cortex in order to minimize irritation of soft tissue. The screws are specially designed with a flat head to prevent their undesired embedding into the bone. Screws are placed on the screwdriver and introduced to the drilled hole through the guide sleeve (blue strip). The screw head rests upon the cortex by gently tightening with the screwdriver. In the correct position of the sleeve resting against the cortex, the screw depth is given by the scale on the screwdriver handle. A hand-held screwdriver is used exclusively for introducing screws.

NOTE: When introducing the screw is necessary to take extra care to avoid damaging the nerves and tendons. Increased risk of peroneal tendon damage occurs, while introducing the center screw of lateral aiming shoulder „LATERAL“.



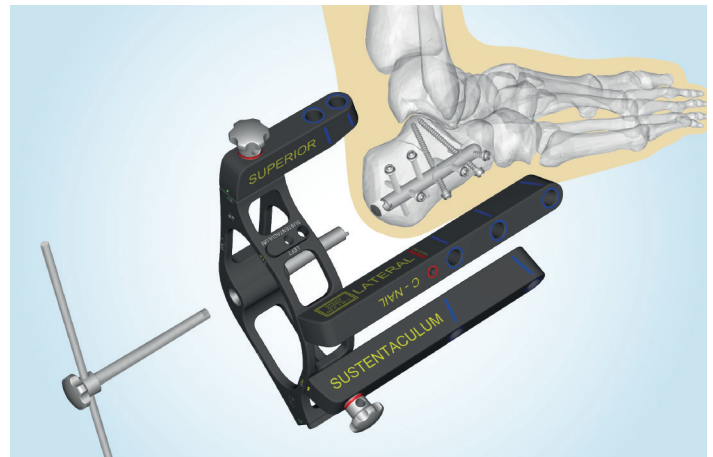
5.6.7. Verification of fixation

After introducing all screws the fixed calcaneus is checked proofing joint reduction, Böhler's angle as well as position and length of all screws by fluoroscopic Broden's, lateral, axial and dorso-plantar projections.



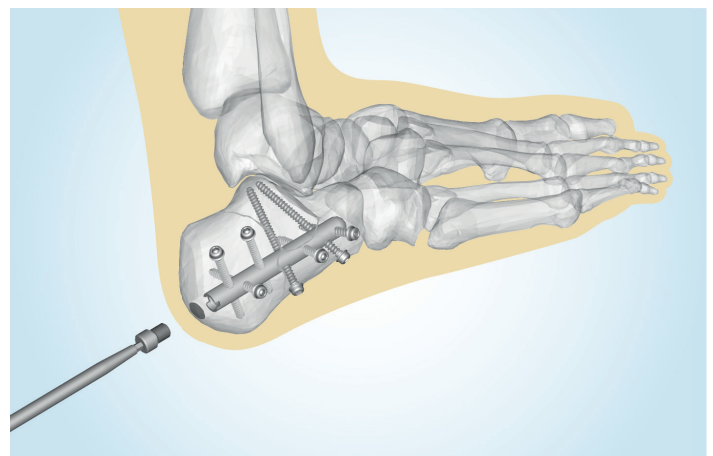
5.6.8. Removing the aiming device

The aiming device is released from the nail by loosening the clamping screw. Release is performed by using a wrench rod in the screw head hole.



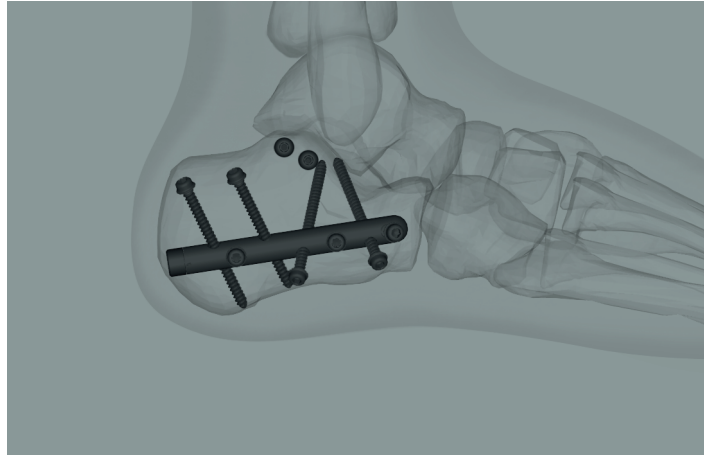
5.6.9. Introducing the end cap

An end cap is introduced into the hole at the end of the nail. The end cap length (0 mm; 5 mm; 10 mm; 15 mm; 20 mm) is chosen as long as prolongation of the nail is needed to end flush with the dorsal cortex of the calcaneus.



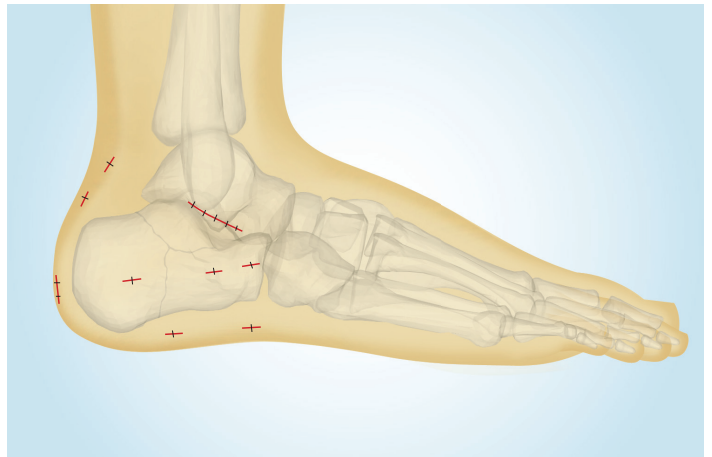
5.7. Final documentation performing fluoroscopic or x-ray views

To document reduction of the subtalar and calcaneo-cuboidal joint, the restored Böhler's angle, the position and length of the nail and all used screws Broden's, lateral, axial and dorso-plantar projections are taken by fluoroscopic or x-ray views, fixed digital and/or printed.



5.8. Completion of operation

The wounds are rinsed with a sufficient quantity of physiological solution. Due to the minimal-invasive procedure a Redon drainage is usually not needed. The small subtalar joint approach may need a subcutaneous suture, the stab incisions only a skin suture. At least a sterile dressing, a prefabricated splint or an elastic bandage is applied.



5.9. Final notes

- When using the C-nail set it cannot be used in combination with various materials.
- Combination with implants of other manufacturers must be avoided
- Implants are designed for one-time use only



6. Recommended procedure for extracting the implant

Implants may stay permanently in the calcaneus. If removal of nail and screws is indicated it should regularly performed after 6 to 12 months after implantation having proofed proper bone healing by taking x-rays or CT-scan before.

6.1. Extraction procedure

- Loosen end cap
- Remove all screws
- Extract nail with the foreseen device

7. Recommended method of cleaning instrumentation

- Remove the arms from the aiming device body
- Perform mechanical cleaning with water and brush
- Rinse the instruments with pressurized water
- Submerge the instruments in a disinfecting solution for 20 to 30 minutes. The recommended disinfection agent is Sekusept. Danger of damaging instruments exists if a different solution is applied
- Rinse again with pressurized water until only clean water runs off. Rinsing may be performed in a conventionally supplied pressurized washer for connecting instruments to the jets
- Dry

8. Recommended method of sterilization of instrumentation and implants

Prior to use, it is necessary to thoroughly wash and disinfect the instruments and implants. Steam sterilization is recommended. The sterilization temperature may not exceed 135 °C. In temperatures in excess of 135 °C causes damage to the plastic parts and the color-coding of instruments. Such damaged instruments may not be permitted for use.

C-NAIL

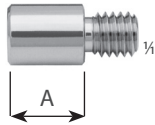
CALCANEAL NAILS



RIGHT
SSt
129 78 4160

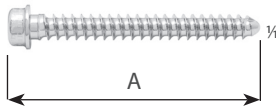
LEFT
SSt
129 78 4170

END CAPS



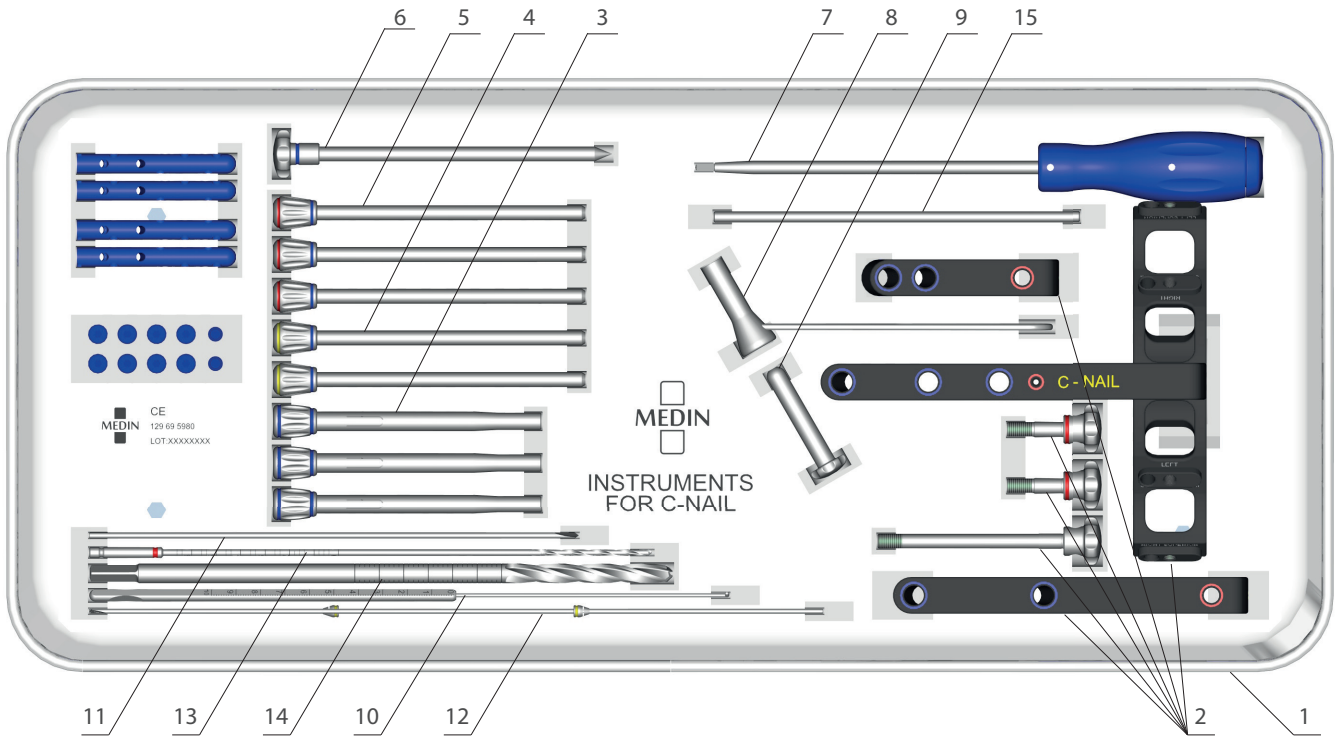
SSt	A	
129 77 2210	0 mm	Fig. 0
129 77 2220	5 mm	Fig. 5
129 77 2230	10 mm	Fig. 10
129 78 8880	15 mm	Fig. 15
129 78 8890	20 mm	Fig. 20

SELF-TAPPING CORTICAL BONE SCREWS WITH FLANGED HEAD – HA 3,5

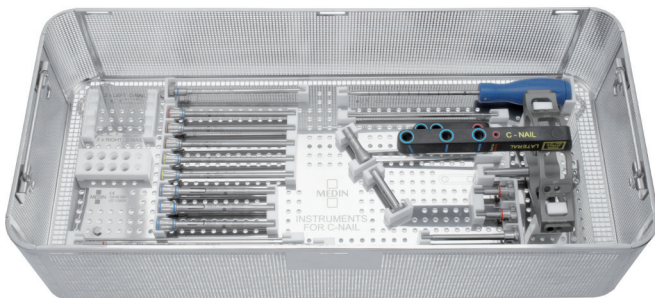


SSt	A
129 78 5651	22 mm
129 78 5661	24 mm
129 78 5671	26 mm
129 78 5681	28 mm
129 78 5691	30 mm
129 78 5701	32 mm
129 78 5711	34 mm
129 78 5721	36 mm
129 78 5731	38 mm
129 78 5741	40 mm
129 78 5751	42 mm
129 78 5761	44 mm
129 78 5771	46 mm
129 78 5781	48 mm
129 78 5791	50 mm
129 78 5801	55 mm
129 78 5811	60 mm
129 78 5821	65 mm
129 78 5831	70 mm

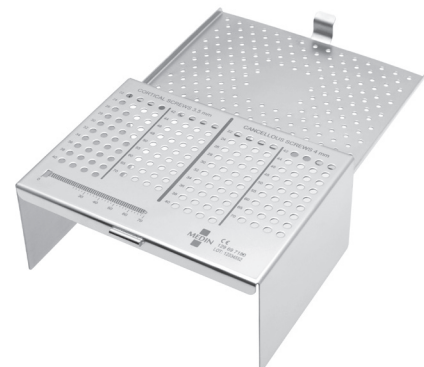
NOTES: SSt – stainless steel in accordance with ISO 5832-1
The implants are supplied unsterile.



	INSTRUMENTS	ks
1	129 69 5980 Sieve for instruments	1
2	129 69 4910 Aiming device C-Nail	1
3	129 69 6340 Sleeve Ø 8/6,1	3
4	129 69 6670 Sleeve Ø 6,1/2	2
5	129 69 6350 Sleeve Ø 6,1/2,7	3
6	129 69 6300 Trocar Ø 6 mm	1
7	129 69 5800 Screwdriver; hexagonal 2,5	1
8	129 69 5810 Drilling sleeve	1
9	129 69 5840 Sleeve for K-wire; Ø 8/2,5	1
10	129 69 5830 Gauge	1
11	129 78 6750 Guide K-wire Ø 2,5 × 200 mm	2
12	129 69 6680 K-wire with olive Ø 2 × 300 mm	2
13	129 69 6291 Drill Ø 2,7 × 230	1
14	129 69 5851 Drill Ø 8/2,5 × 240	1
15	129 69 6100 Wrench rod	1



SET OF INSTRUMENTS FOR C-NAIL
139 09 0545
 540 × 240 × 130 mm
 sieve with instruments, without implants



STAND FOR SCREWS FOR C-NAIL
129 69 7180
 160 × 125 × 81 mm
 without implants

REFID