



1. Medical device description

C-NAIL is an intramedullary calcaneal nail for minimally invasive fixation of intraarticular and extraarticular calcaneal fractures. The principle is to stabilize fragments of the broken calcaneus with the nail in connection with seven locking screws with which it forms an angularly stable fixation. Maximum stability is achieved by fixation of the sustentacular fragment through the nail by two locking screws, which are guided using the aiming device.

The nail is designed in two lengths separately for the left side (marked by "L") and the right side (marked by "R"). Nail length is 65 mm and diameter 8 mm. The nail can be extended and closed with the end cap of size: 0 mm; 5 mm; 10 mm; 15 mm; 20 mm.

The implants are supplied as nonsterile versions. It is necessary to ensure their sterilization before use.

2. Indication

Extraarticular fractures, intraarticular fractures of calcaneus according to Sanders I–IV; B and C types - according to ICI-AO-ASIF classification.











3. Preoperative planning and surgical technique principle

A suitability of this surgical technique must be verified within the preoperative planning. **One parameter, which has to be verified, is the calcaneus length. It must not be shorter than 65 cm.** A preoperative X-ray of a broken bone from the lateral, axial and dorsoplantar projections is recommended. At the same time a CT scan with 3D reconstruction is appropriate. It is desirable to perform a comparative lateral X-ray image of healthy calcaneus to determine the individual Böhler angle.

The principle of surgery is the mini-invasive fixation of the broken calcaneus with the locked nail, which is introduced through the incision after the initial anatomical reduction of the posterior facet. Joint reduction is performed by subtalar arthroscopy or lateral 3 cm long inframaleolar incision. Posterior facet is repositioned through the incision. Tuberosity fragment is repositioned on the sustentacular fragment using a small raspatory. Temporary fixation is ensured with K-wires of 1.8 / 2.0 mm. The lateral part of the posterior facet fragment is repositioned to the medial part of the posterior facet and temporarily fixed with two K-wires of 1.8/2.0 mm introduced parallel under the joint level. The inside-out-inside technique of the K-wire introduction should be used for the anatomic joint repositioning if an additional middle joint fragment (type Sanders IV) is present. X-ray check of the performed reduction is carried out after the repositioning of the posterior subtalar joint and Böhler angle. Broden projection is recommended for the check. Guide wire for the nail introduction is drilled under the Achilles tendon insertion in the direction to the centre of the calcaneocuboid joint. Check the K-wire introduction and the subsequent drilling of the hole for the nail using X-rays. The nail is connected to the aiming device and is introduced into the drilled hole in the calcaneus. It is followed by fixation of the sustentacular fragment using drill with stopper through the "SUSTENTACULUM" arm of the aiming device. The first screw into the sustentacular fragment is introduced only after the X-ray check of the correct position of the guide drill with stopper, which has to be exactly into the sustentaculum tali. The second sustentacular screw is introduced subsequently. Lateral and superior screws are introduced using the guide arms marked as "LATERAL" and "SUPERIOR".

4. Preparation of instrumentation and implants

It is necessary to check the completeness and functionality of all instrumentation components before the actual surgery. The aiming arms are positioned to the aiming device body according to the selected side of the operated limb. The aiming arms are fastened by the fixing screws that are reasonably tightened to the basic arm using a rod wrench.

The nail is attached to the grooves of the aiming device and is firmly secured by the aiming device screw.

Position of the holes in the aiming arms against the attached nail is checked prior to use. All seven holes have to be checked.







5. Surgical technique

5.1. The patient's position

The patient lies on his/her side so that the operated limb is slightly flexed in the upper position. The operated limb is supported from the medial side by a soft roller. The other unoperated limb is flexed in the knee so that it does not block the use of the X-ray amplifier.



5.2. Drawing of the bone position

Drawing of the lateral malleolus, calcaneus and cuboid is performed on the skin from the lateral side.



5.3. Incision for the miniinvasive reduction of the posterior facet

A straight incision of the length of about 3 cm from the apex of the lateral ankle to the base of the V. metatarsal bone is performed for repositioning of the posterior articular surface. When making the incision caution is recommended not to damage the peroneal tendons.

5.4. Reduction procedure to restore the Böhler angle and posterior facet

The reduction of the calcaneal tuberosity fragment against the sustentacular fragment is most often achieved by introduction of a 6.5 mm Schanz screw with a handle through incision into the calcaneal tuberosity fragment or tongue type fragment. A lateral translation, varus or valgus deformity are corrected and the Böhler angle is restored by that. It is sometimes necessary to introduce a small raspatory under the broken posterior facet to release the fragment of the calcaneal tuberosity impressed into the sustentacular fragment. An auxiliary fixation using the K-wires of $1.8 / 2.0 \,\mathrm{mm}$ followed by the repositioning of the posterior facet by an elevator or a small raspatory are performed after this initial repositioning maneuver to preserve the calcaneal tuberosity fragment position against the sustentacular fragment.

5.4.1. Temporary fixation using K-wires

The lateral part of the reduced posterior facet is fixed using two K-wires of 1.8 / 2.0 mm to the medial part of the posterior facet after the initial temporary fixation of the calcaneal tuberosity reduced fragment against the sustentacular fragment The K-wire fixation using inside-out-inside technique is recommended in case of a dislocated intermediate fragment of the posterior facet (type Sanders IV). The correctness of the posterior subtalar joint reduction is checked using X-ray in Broden projection or arthroscopy.





5.4.2. Fixation using cancellous screws

The final fixation and compression of the posterior facet fragments is performed using two separate cancellous screws HB4 with the short thread. The screws are introduced under the posterior facet.



5.5. Removal of the Schanz screw, reduction of the calcaneocuboid joint

5.5.1. Removal of the Schanz screw

The Schanz screw with handle is removed as soon as the correct position of the single fragments is achieved. An X-ray or arthroscopy is used for check.



5.5.2. Reduction of the CC-joint

Reduction check in the lateral and dorsoplantar projections is performed in case of the combination of B2 fracture with the calcaneocuboid joint fracture. The intraarticular fracture can be fixed using one or two percutaneously introduced cancellous screws of 4.0 mm in the area of the calcaneocuboid joint. It is possible to place them in the dorsal and plantar level of the calcaneus to keep a free access for the following nail introduction. It is possible to use a short Ollier approach to achieve the anatomical repositioning, if the joint surface is incongruent.



5.6. Nail introduction

5.6.1. Incision

The vertical incision of about 10 mm under the Achilles tendon insertion slightly laterally towards the centre of the heel dorsal side is performed to introduce the nail.



5.6.2. Drilling of the guide wire for the nail hole

The drilling direction of the guide wire is determined by the centre of the calcaneocuboid joint. Drilling is done using the guide wire through the protection sleeve, in which is placed the insert with the hole for the guide wire. The guide wire position is checked using the lateral and dorsoplantar projections.





5.6.3. Drilling the hole for the nail

Drilling is performed with the cannulated cutter of 8 mm diameter along the guide wire. The soft tissues are protected with the guide sleeve during drilling. The drilling depth is measured about 5 mm in front of the calcaneocuboid joint using the lateral X-ray projection. The drilling depth can be read on the cutter scale against the guide sleeve. Remove the cutter and guide wire after drilling the hole.



5.6.4. Introduction of the nail with the aiming device

Nail with the aiming device is placed into the drilled hole. The introduction is done using the slight axial pressure with the oscillating axial movement of the aiming device with the nail.



5.6.5. Nail position setting and Drill with stopper introduction into the sustentaculum tali

The correct nail position is done by the direction of the guide drills with stopper into the sustentacular fragment, which are introduced through the yellow marked sleeve. It is necessary to correctly set depth and position of the rotation of the aiming device with nail before the introduction of these drills with stopper into sustentacular fragment. It is necessary to introduce the drilling sleeve into the incision together with the conical trocar to pull apart the soft tissues when drilling all holes (through the red sleeve). **The sleeve has to be firmly pushed to the bone before the introduction of the drill and drill with stopper**. Check of the position and depth of the auxiliary drill with stopper is performed using the X-ray amplifier in two planes (lateral and axial, possibly in Broden projections) after the hole drilling. It is necessary to remove the drill with stopper and to ensure the correction of the sustentacular fragment is drilled subsequently. The second hole for the screw into the sustentacular fragment is drilled subsequently. The screw length is measured using calibrated drill or by reading the length from the guide sleeve edge. The screw introduction is checked in two projections using the X-ray amplifier.















5.6.6. Introduction of the other fixation screws

The remaining locking screws are introduced through the sleeves using the **"SUPERIOR"** arm.

The posterior fragment of the calcaneal tuberosity is fixed to the nail by that and possibly the tongue type fragment fixation is performed. It is possible to subsequently remove the k-wire. The front fragment is fixed with screws from the lateral side using aiming (through the sleeves) and the "LATERAL" arm. It is necessary to take care of the correct repositioning of the joint surface fragment of the calcaneocuboid joint. It is always necessary to carefully measure the length of the screws needed when introducing the guide sleeve so that they can be introduced bicortically. The screws must not protrude from the second corticalis to minimize soft tissue irritation. The screws have a flat head to prevent undesirable insertion into the bone. The screws are placed into the screwdriver and introduced into the drilled hole through the blue guide sleeve. The screw head will rest on the corticalis by gentle tightening with the screwdriver. The depth of screwing is given in the correct position of the sleeve resting against the corticalis by the scale on the screwdriver shaft. Use exclusively a hand screwdriver for the screw introduction.

Warning: It is necessary to be increasingly cautious when introducing the screw to prevent nerve and ligament damage. The higher risk of damage of the peroneal tendons is when introducing the middle screw from the lateral part through the "LATERAL" arm.

5.6.7. Check of the fixation

Check of the fixation is performed after introduction of all screws using the projections: Broden, lateral, axial and dorsoplantar.







The aiming device is loosened from the nail by loosening the aiming device screw. The loosening is performed by the auxiliary rod in the screw hole.





The end cap is inserted into the hole at the nail end. The end cap length is selected according to the depth of the nail introduction (0 mm; 5 mm; 10 mm; 15 mm; 20 mm). The end cap should end at the level of the dorsal corticalis of calcaneus.



5.7. Final check of the reduction

It is suitable to perform X-ray image in Broden, lateral, axial and dorsoplantar projections for documentation of the repositioning of the subtalar and calcaneocuboid joint, of the reconstructed Böhler angle, of the position and length of the nail and all used screws.

5.8. Closure of the operation

Irrigation of the wounds is performed by sufficient quantity of the physiological solution. Redon drain introduction is usually not needed thanks to the minimally invasive procedure. The approach through the subtalar joint may require subcutaneous suture. Skin sutures only can be used at the incision for the nail and screw introduction. A sterile dressing, plaster splints or elastic bandage is applied at the end. A selected option is based on the decision of the attending doctor according to the stability of the fracture fixation and the soft tissue condition.



5.9. Final notes

- Never combine different materials in one patient when using the set of calcaneal nail.
- Implants from different companies must never be combined.
- Implants are intended for single-use



6. Recommended procedure of implant removal

Implants are mostly retained in the calcaneus permanently. Any potential extraction is recommended after 6–12 months after implantation, after a proper healing of the broken bone verified by X-ray or CT.

6.1. Extraction procedure

- End cap loosening
- Loosening of the fixation screws
- Extraction of nail

7. Recommended way of the instrumentation cleaning

- To remove the arms from the aiming device body.
- To mechanically clean with water using brush.
- To rinse the instruments with pressurized water.
- To immerse the instruments into the disinfecting solution for 20 to 30 minutes. Sekusept is the recommended as disinfecting agent. The instrument damage can happen when used a different solution.
- To repeatedly rinse with the pressurized water until the draining water is clean. Rinsing is possible to perform in commonly supplied pressure washers at the instrument connection to the jets.
- To dry

8. Recommended way of the instrumentation and implant sterilization

It is necessary to thoroughly wash and disinfect the instruments and implants prior to use. A steam sterilization is recommended. A sterilization temperature must not exceed the value of 135 °C. The plastic parts and instrument colour coding will deteriorate when the temperature of 135 °C will be exceeded. The instruments must not be used when damaged as described above.

CALCANEAL NAILS



END CAPS

	SSt	A	
	397 129 77 2210	0mm	Fig. 0
1/1	397 129 77 2220	5 mm	Fig. 5
	397 129 77 2230	10 mm	Fig. 10
	397 129 78 8880	15 mm	Fig. 15
	397 129 78 8890	20 mm	Fig. 20

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



SSt	A
397 129 78 5651	22 mm
397 129 78 5661	24 mm
397 129 78 5671	26 mm
397 129 78 5681	28 mm
397 129 78 5691	30 mm
397 129 78 5701	32 mm
397 129 78 5711	34 mm
397 129 78 5721	36 mm
397 129 78 5731	38 mm
397 129 78 5741	40 mm
397 129 78 5751	42 mm
397 129 78 5761	44 mm
397 129 78 5771	46 mm
397 129 78 5781	48 mm
397 129 78 5791	50 mm
397 129 78 5801	55 mm
397 129 78 5811	60 mm
397 129 78 5821	65 mm
397 129 78 5831	70 mm

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

INSTRUMENTS FOR C-NAIL



		INSTRUMENTS	ks
1	397 129 69 5980	Sieve for instrumenents	1
2	397 129 69 4910	Aiming device C-Nail	1
3	397 129 69 6340	Sleeve Ø 8/6,1	3
4	397 129 69 6670	Sleeve Ø 6,1/2	2
5	397 129 69 6350	Sleeve Ø 6,1/2,7	3
6	397 129 69 6300	Trocar Ø 6 mm	1
7	397 129 69 5800	Screwdriver; hexagonal 2.5	1
8	397 129 69 5810	Drilling sleeve	1
9	397 129 69 5840	Sleeve for K-wire; Ø 8/2.5	1
10	397 129 69 5830	Gauge	1
11	397 129 78 6750	Guide K-wire Ø 2.5 × 200 mm	2
12	397 129 69 6680	Drill with stopper 2.0 $ imes$ 300 mm	2
13	397 129 69 6291	Drill Ø 2.7 × 230	1
14	397 129 69 5851	Drill Ø 8/2.5 × 240	1
15	397 129 69 6100	Wrench rod	1



SET OF INSTRUMENTS FOR C-NAIL 397 139 09 0545 $540 \times 240 \times 130\,mm$ sieve with instruments, without implants



397 129 69 7180 $160 \times 125 \times 81\,\text{mm}$ without implants

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