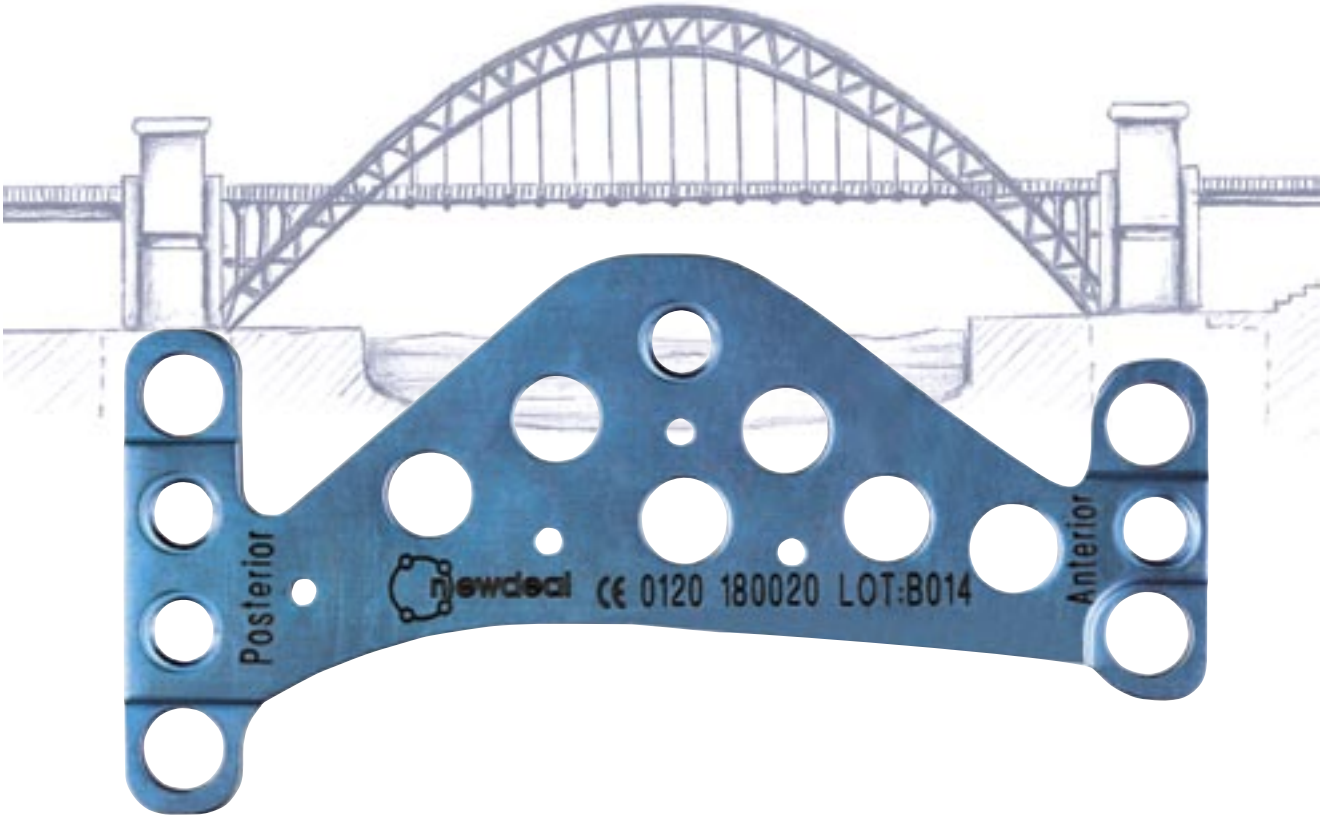
CALCANEA®

SURGICAL TECHNIQUE



Calcaneal fracture plate

MID & HINDFOOT SOLUTIONS™

INTEGRA™

newdeal®
An Integra LifeSciences Company

TECHNICAL DESCRIPTION

Calcaneal fractures are usually caused by a high-velocity impact to the heel. The most common mechanism of injury is a fall from a height of 2 meters or more, but calcaneal fractures also result from motor vehicle accidents.
Calcaneal fractures may be extra or intra-articular. Surgical treatment with open reduction and internal fixation (ORIF) is now well accepted to be the method which gives recognized clinical results, especially for type II and type III calcaneal fractures according to the Sanders classification. The aim of the surgical procedure is to restore the articular surface of the calcaneus and to obtain an anatomic reconstruction (height and width of the calcaneus).

However, clinical and technical problems can occur due to the thickness and the stiffness of the plates, in particular superficial necrosis of the surgical wounds and peroneal tendinitis. These problems are related to the traction onto the skin flap during surgery and to the thickness of the plates that may cause ischemic problems to the skin and impingement of the peroneal tendons.

Moreover, most plates have a limited number of holes and do not allow for significant moulding because of their thickness. In this situation, the screws have to be inserted in predetermined sites of the calcaneal wall, and especially in the fractured zones of the lateral calcaneal wall, in the comminuted fractures. Sometimes this can lead to insufficient grip of the screws and therefore insufficient mechanical resistance of the implant. In those circumstances, early movement to prevent joint stiffness and enhance fractured soft tissue healing is not possible.

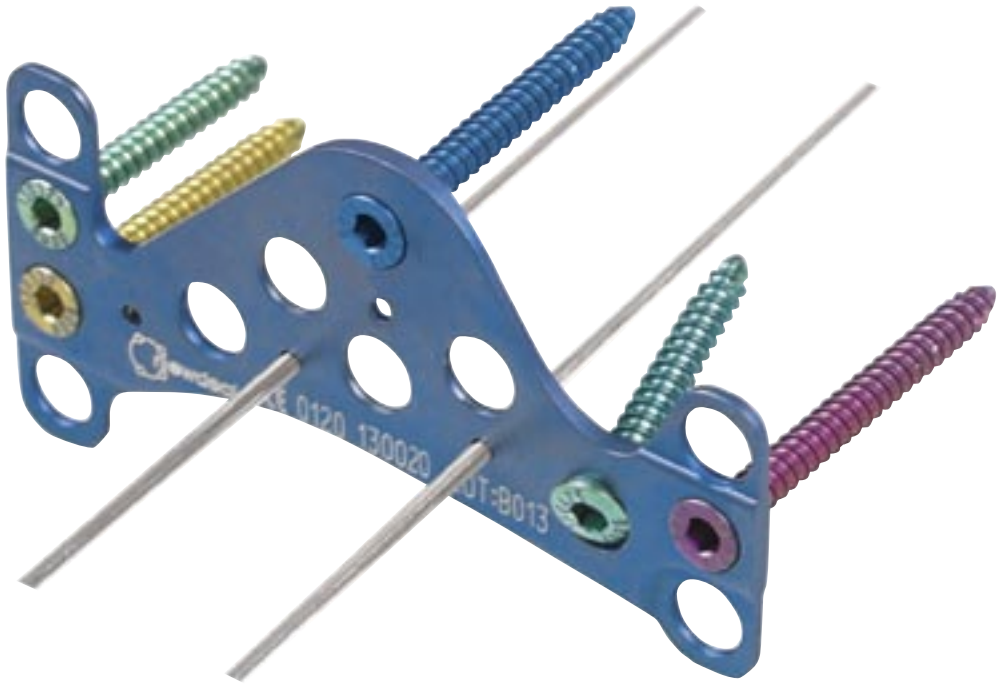
The CALCANEA® plate is the solution of choice for the ORIF treatment of calcaneal fractures.
This plate is made of titanium alloy (TAl6V4), has an anatomical shape corresponding to the anatomy of the calcaneus. It is available in three different sizes, to better fit the calcaneus shape (5.5 cm long for size small, 6.5 cm long for size medium and 7.5 cm long for size large). Its thickness is 1 mm in the middle, and 1.80 mm in the sites of main fixation. 3-4 holes are present in its anterior, posterior and upper parts for fixation screws with threaded heads, and 9-10 holes for variable orientation of the screws. The plate is fixed using 3.5 mm screws. Holes in the plate provide fixation with up to 4 screws in the posterior tuberosity, 3 screws in the anterior process, and 7 screws in the middle. The limited thickness permits to mould the plate and to eventually cut it if the plate is overstuffing anatomically the calcaneus. The upper part of the posterior and anterior borders can sometimes be cut off, or bent for a dorso-plantar screw fixation. Before the definitive fixation of the plate, autologous or synthetic bone grafts may be inserted, if necessary, in the os trigonum of the calcaneus.

Advantages:

- Increased stability by locking screw fixation and “bridging” of the primary fracture line
- Low profile plate
- Thickness allows remodeling according to the lateral wall of the calcaneus
- Low irritation of soft tissues and tendons
- Reconstruction of height and width of the calcaneus
- Large number of holes for versatile fixation
- Dual screw fixation system (locking & variable) allowing stable fixation regardless of bone conditions
- Angulation of the screws up to 30°
- Bi-cortical or mono-cortical fixation
- Color coded for the plate and the screws

It is always possible to fix the Calcanea® plate in a good cortical area of the lateral calcaneal wall with locking screws, thus improving the mechanical resistance of the implant. The plate exerts a compression effect when screws are tightened, reducing the width of the posterior tuberosity. Therefore, it allows the connection of the thalamus portion to the inferior segment. This improved mechanical resistance may make it possible to reduce the period of partial weight bearing after the operation.

The Calcanea® plate has been successfully tested* in an experimental calcaneus fracture model on synthetic bone, showing high stability and low plate deformation when loading.
(* M. Richter MD, PhD, Trauma department Hannover medical school, Germany)



SURGICAL TECHNIQUE

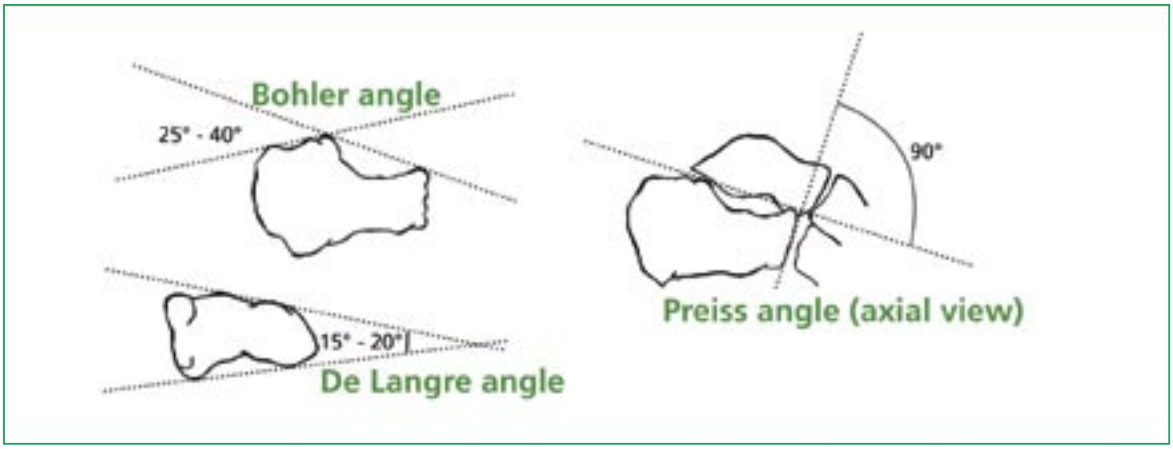
AS SUGGESTED BY PROF. THERMANN, M.D., HEIDELBERG, GERMANY

Newdeal® as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

Preoperative planning

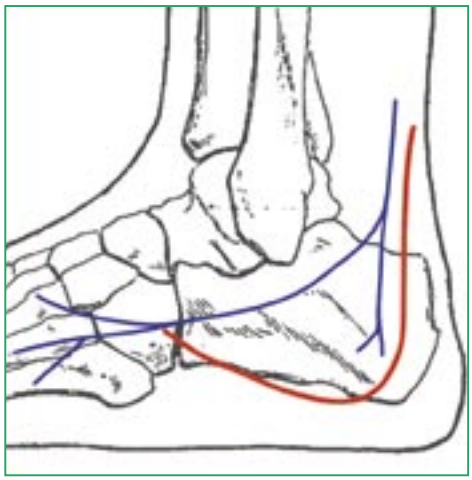
The indication for surgery is based on lateral and axial radiographs, tangential Broden views of the posterior facet. CT scan in the axial and coronal plans is analyzed to evaluate displacement and reduction strategies.

The Bohler, De Langre and Preiss angles are measured.

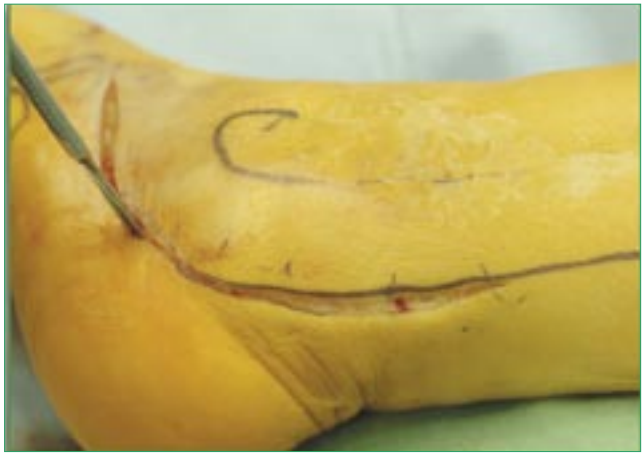


1st step: Calcaneal reconstruction

The patient is positioned in a lateral decubitus position. Safe support is needed so that the table can be tilted for fluoroscopy or for an additional reduction maneuver. The landmarks for incision are the distal fibula, the anterior process of the calcaneus, the calcaneocuboid joint and the base of the 5th metatarsal. A large L-shaped (right side) or J-shaped (left side) surgical incision is made beginning approximately 4 cm above the tip of the lateral malleolus, midway between the posterior border of the fibula and the Achilles tendon.



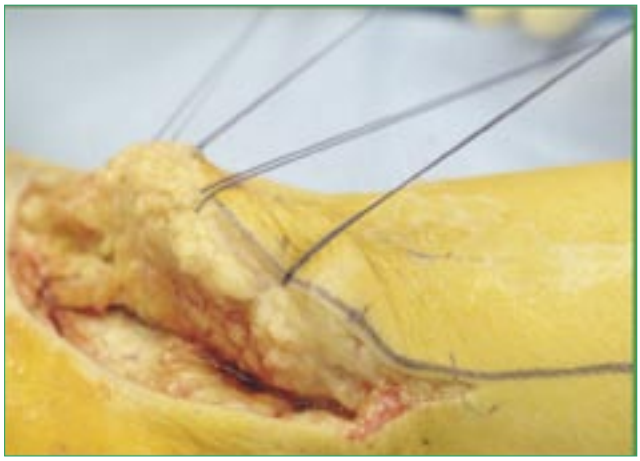
The lateral incision allows direct access and easier reduction of the displaced lateral fragment, compared to medial approach. The incision begins proximally, curves below the sural nerve, and then moves upward to the calcaneocuboid joint. It is imperative to avoid harming the sural nerve and prevent skin flap difficulties.



The incision is made down to the bone in order to make a cutaneous - subcutaneous flap that includes the peroneal tendons. The flap is developed anteriorly to expose the posterior subtalar joint.

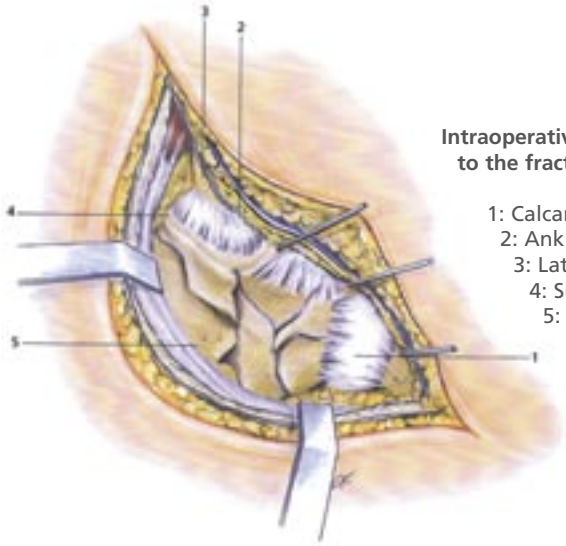
The flap is elevated, along with the sural nerve and peroneal tendons. Pins are then inserted and bent to hold the flap and the soft tissues. The subtalar joint is opened and the fractures of the lateral calcaneal wall are dissected, in order to expose the fractured and depressed articular fragments.

The reduction maneuver usually begins at the posterior articular surface and proceeds to the Gissane angle and to the body of the calcaneus. However, if varus tilt of the calcaneus prevents anatomic reduction of the posterior facet, the alignment of the body may need to be corrected prior to the reduction of the joint surface.



The fractured lateral wall of the calcaneus is gently opened, leaving the fracture fragments within their periosteal envelope.

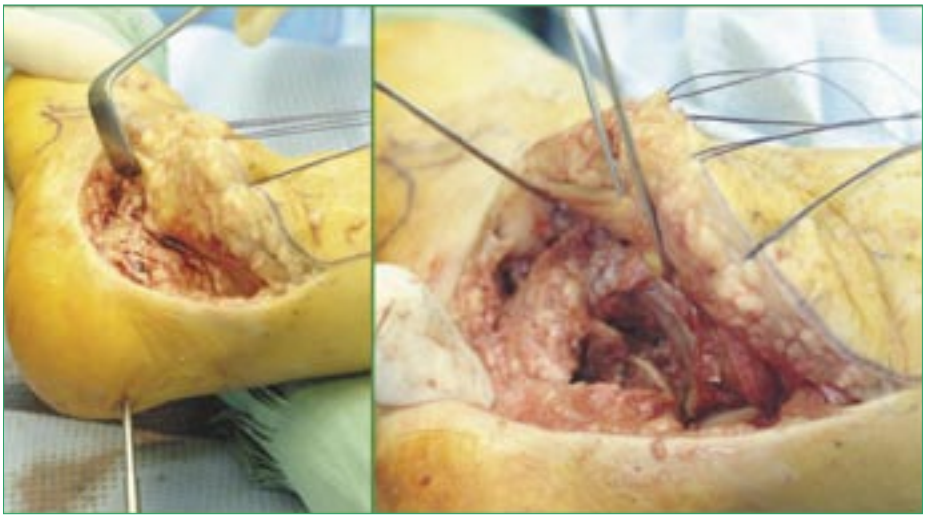
The fragments are elevated, the articular surface is reduced, and fixation is made using temporary Kirschner wires.



Intraoperative aspect of extended lateral approach to the fractured calcaneus

1: Calcaneocuboid joint
2: Ankle joint capsule
3: Lateral malleolus
4: Subtalar joint
5: Lateral wall of calcaneus (fractured)

Most of the time, the posterior facet is first restored, with the medial facet in relation to the sustentaculum tali, the anterior facet and at last the posterior tuberosity. These steps should enable the surgeon to restore the length and width of the calcaneus.



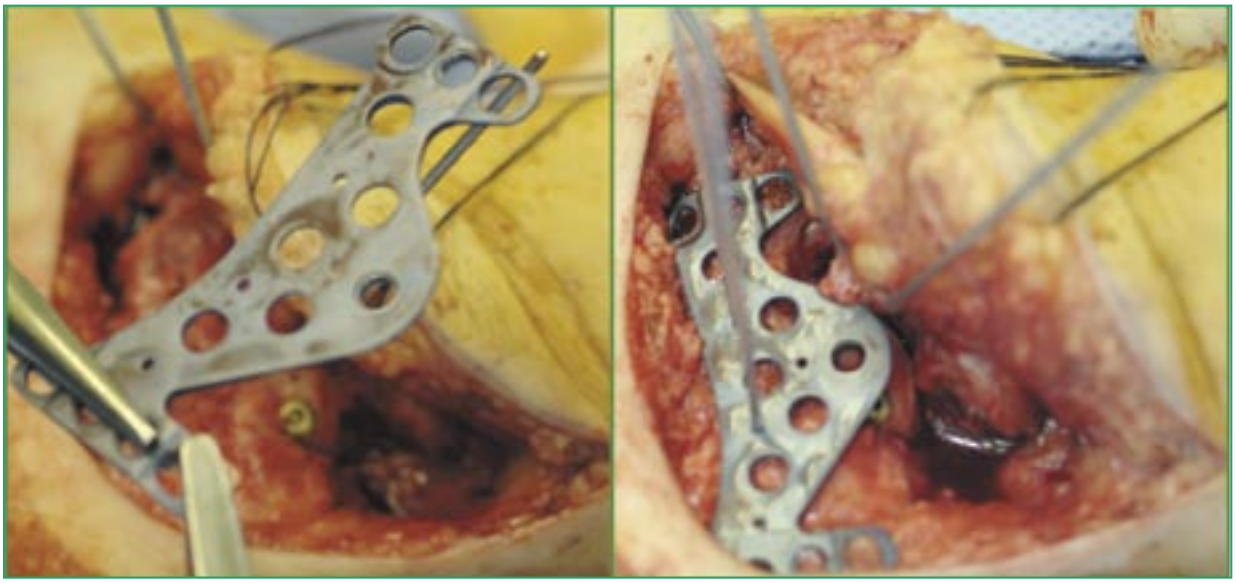
Three areas of dense cortical bone will hold fixation well:

- distal portion of the calcaneus (near the calcaneocuboid joint),
- below the angles of Gissane (below the posterior facet),
- the tuberosity.

A triangle of soft cortical bone in the middle portion of the calcaneus is a neutral triangle that will not hold a screw well.

2nd step: Calcanea® plate positioning

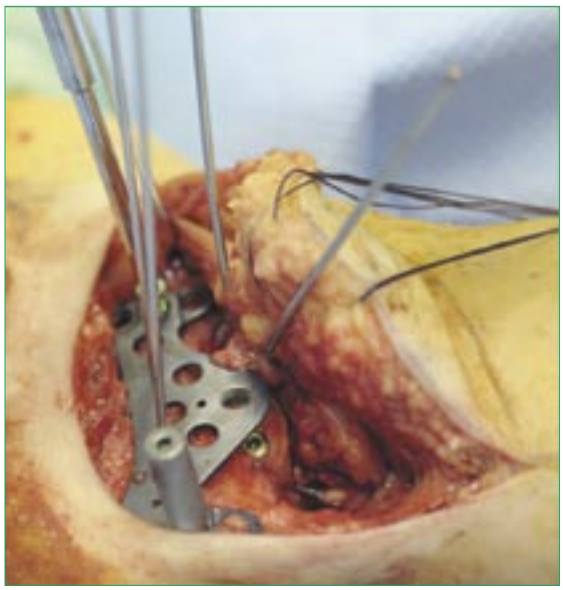
At this point, the Calcanea® plate is used. The size that best fits the calcaneal anatomy is chosen: size small, medium or large. Each plate is anatomical and suitable for either left or right side. The Calcanea® plate is then positioned at the appropriate location on the lateral calcaneal wall.

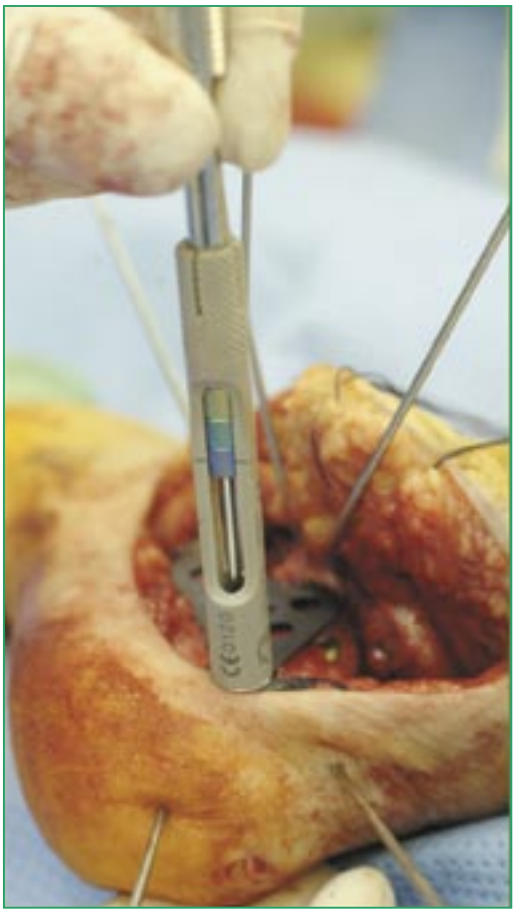


If necessary the Calcanea® plate can be moulded and contoured to the lateral aspect of the anterior process, the posterior facet and to the tuberosity. The upper part of the posterior and anterior borders can sometimes be cut off, or be bent for a dorso-plantar screw fixation. Plate benders (2 x 129 139ND) should be used for this bending procedure.

3rd step: Calcanea® plate fixation with locking screws

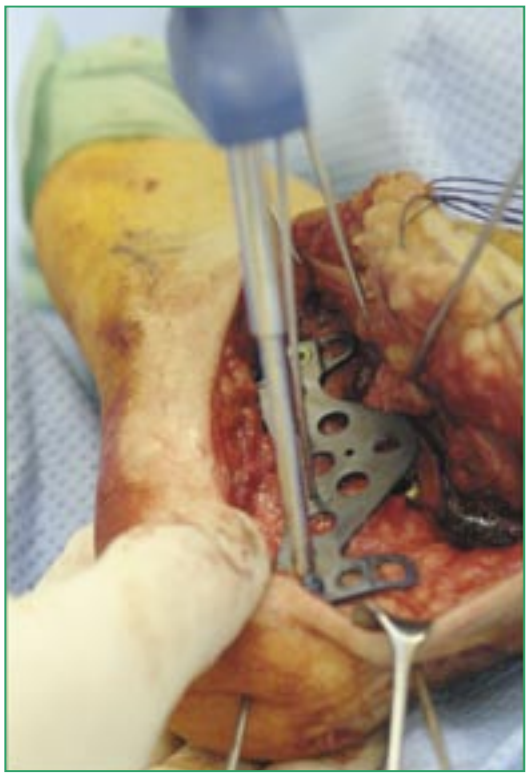
The drilling sleeves (129 135ND) are first screwed in the hole located on the anterior extremity and in the 2 holes on the posterior extremity of the plate. They allow axial drilling and perfect insertion of the locking screws. The holes for fixation screws are drilled using the 2.2 mm drill (119 006ND) through the drilling sleeves.

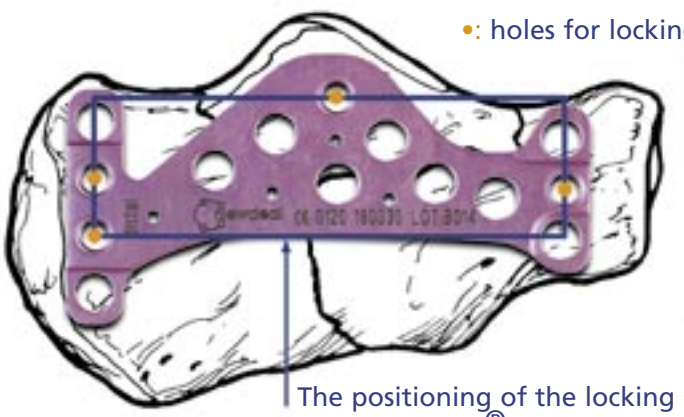




The plate is fixed using specific 3.5 mm screws (180 XXXND). The appropriate length of the screws to be inserted is evaluated using the depth gauge (129 134ND).

Color coding of each size of screw allows for quick choice of the adequate length to be used.



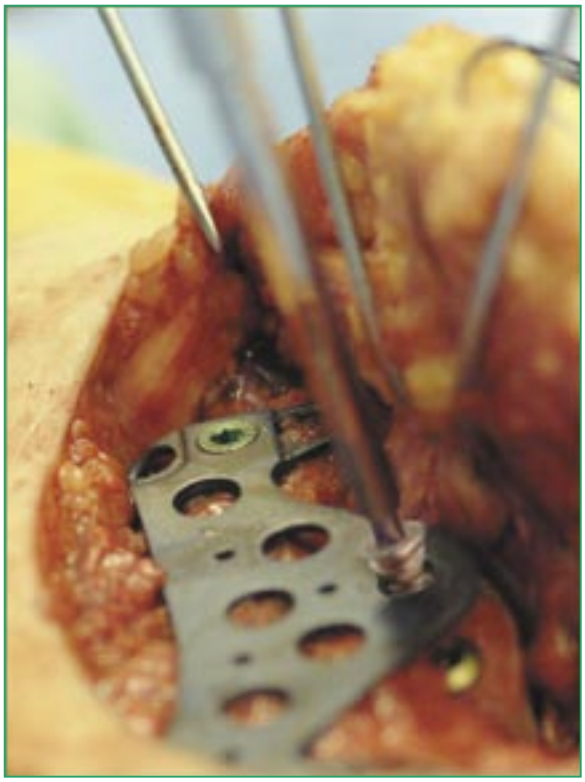


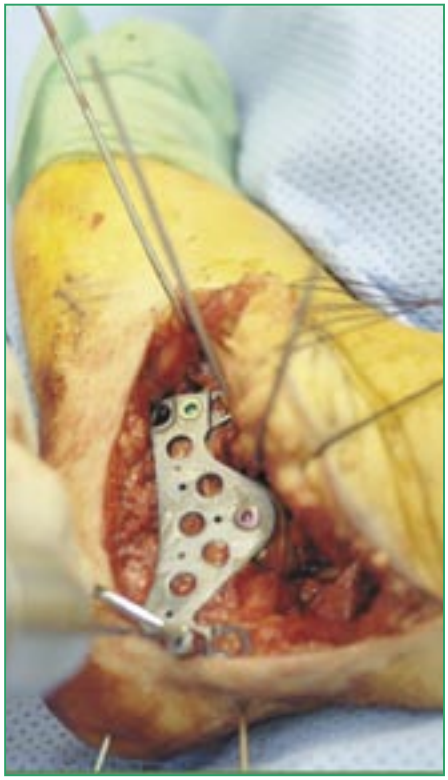
•: holes for locking screws (size large)

The positioning of the locking screws on the CALCANEA® plate creates a frame through which the stress forces are running and kept to a minimum.

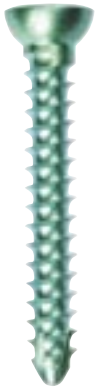
Holes in the plate allow fixation with up to 4 screws in the posterior tuberosity (2 locking screws and 2 variable angle screws), and 3 screws in the anterior process (1 locking screw and 2 variable angle screws). If there is a fracture of the anterior process of the calcaneus, it will be temporarily stabilized with Kirschner wires.

The screws are inserted with the specific screwdriver (129 132ND) in a normal way, and introduced in the bone until the base of their head is blocked against the plate.



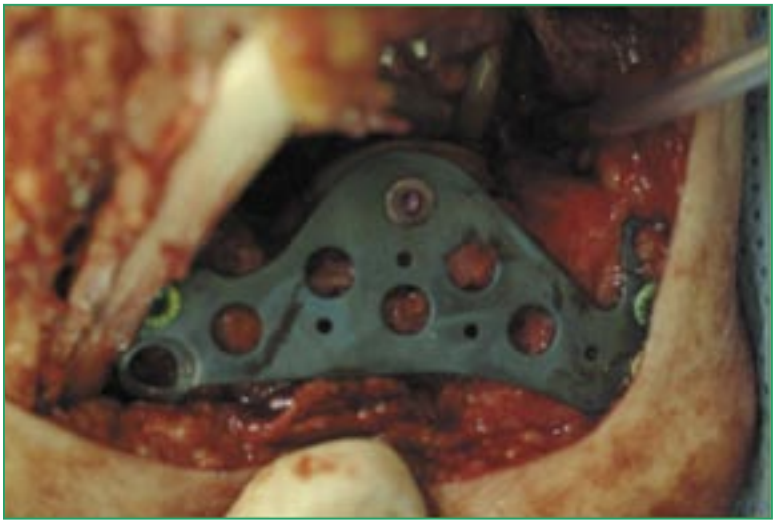


4th step: Calcanea® plate fixation with variable angle screws



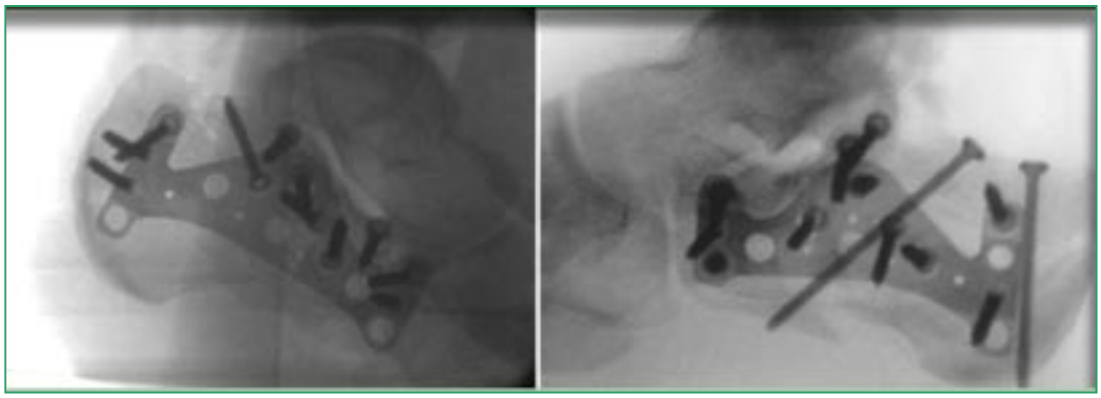
The variable angle screws can be introduced in the other holes (non-threaded) of the plate, depending on the bone fragments to be fixed. The drill guide (129 130ND) and the drill diameter 2.2 mm (119 006ND) are used to perform the holes and adjust the orientation of the screws.

The appropriate length of the 3.5 mm screws (180 XXXND) to be inserted is evaluated using the depth gauge (129 134ND).



Postoperative care

The patient should receive antibiotic and antithrombotic prophylaxis. Before the wound suture, suction drainage is performed and will be carried out for two days. The postoperative care consists of partial weight-bearing, for 4 to 6 weeks, depending on the comminution, and then physiotherapy and progressive loading. Sagittal ankle joint motion is started after suction drain removal. Eversion and inversion movements are started after stable wound healing.



Removal of the material

After 1 year, it is advised to remove the material. The Calcanea® plate has been designed to enable easy removal. All the screws inserted in the plate can be removed using a regular 3.5 mm screwdriver. An arthrolysis for improvement of the subtalar joint motion is mandatory.

Instructions for Use

NON-STERILE IMPLANTS • SINGLE USE
In accordance with EEC directive 93/42 relative to medical devices, this product must be handled and/or implanted by WELL-TRAINED, QUALIFIED PERSONS, AWARE OF THESE DIRECTIONS FOR USE.

1 - Description of the medical devices:
The implants - delivered non-sterile - are:
- Osteosynthesis plates, existing in different models and sizes
- They are made out of Titanium alloy within the frame of the standard ISO 5832-3 and ASTM F136

2 - Indications:
The CALCANEA® plate is indicated for use in fixation of:
- fractures or osteotomies of the calcaneus.

3 - Contraindications:
The implant should not be used in a patient who has currently, or who has a history of:
- Local or systemic acute or chronic inflammation;
- Active infection or inflammation;
- suspected or documented metal allergy or intolerance;

4 - Warnings:
Serious post-operative complications may occur from use of the implant in a patient who:
- Has severe osteoporosis;
- Has immunological responses, sensitization, or hypersensitivity to foreign materials;
- Lacks good general physical conditions;
- Demonstrates physiologic or anatomic anomalies that might result in significant post-operative complications;
- Systemic or metabolic disorders;

5 - Precautions for use:
Physician must determine if implant is appropriate for patients who have any of the following conditions:
- Drug and/or alcohol and/or smoke addiction and/or abuse;
- Infectious disease;
- Malignancy;
- Local bone tumors;
- Systemic or metabolic disorders or replacement;
- Compromised wound healing;;
- Obesity;
- Demonstrated psychological instability, displayed a lack of understanding, inappropriate motivation, or attitude;
- Unwillingness to accept the possibility of multiple surgeries for revision or replacement;
- Lacks an understanding that a metallic implant is not as strong as normal healthy bone and will bend, loosen, or fracture if excessive demand is placed on it;
- Lacks an understanding that their preoperative capacity may not be fully recovered even after successful implantation;
Knowledge of surgical techniques, proper reduction , selection and placement of implants, and post-operative patient management are considerations essential to a successful outcome.
Criteria for patient selection is the responsibility of the surgeon. Information contained within this document should be taken into consideration during the selection process. Recognition of the appropriate indications and contraindications and the selection of the proper surgical procedures and techniques determined to be best for the patient are the responsibility of the surgeon. Each surgeon must evaluate the appropriateness of the procedure and instruments used during the procedure based on his or her own training and experience.
The surgeon should discuss with the patient prior to surgery possible risks, precautions, warnings, consequences, complications, and adverse reactions associated with the surgical procedure and implantation of the device.
Each patient must be evaluated by the surgeon to determine the specific risk/benefit relationship in light of the patient's condition and the surgeon's practice, training, experience, and knowledge of the related medical literature.
Complications with the use of osteosynthesis plates have been reported in the medical literature. Any patient undergoing a surgical procedure is subject to intra-operative and post-operative complications. Each patient's tolerance to surgery, medication, and implantation of a foreign object may be different.
Possible risks, adverse reactions, and complications associated with surgery and the use of the osteosynthesis plates should be discussed with and understood by the patient prior to surgery. The implant is composed of titanium alloy materials; therefore, it is subject to possible reactions and complications, including those listed herein. The patient should not be led to unrealistic expectations as to the performance or results that the surgery and implant can provide. The patient should be informed that the life expectancy of the device is unpredictable once implanted, and that successful results cannot be guaranteed.
IT IS THE RESPONSIBILITY OF THE SURGEON TO PROVIDE THE PATIENT WITH INFORMATION PRIOR TO SURGERY.

Complications may include but are not limited to:
– Pain, discomfort, or abnormal sensations due to presence of the implant;
– Bending, loosening , and/or breakage, which could make removal impracticable or difficult;
– Risk of additional injury from post-operative trauma;
– Migration of the implant position or implant material resulting in injury;
– Bone loss due to stress shielding;
Side effects may include but are not limited to:
– Infections;
– Hematoma;
– Allergy;
– Thrombosis;
– Bone non union or delayed union .
Adverse effects may necessitate re-operation, revision or removal surgery , arthrodesis of the involved joint, and /or amputation of the limb.
Implant removal should be followed by adequate postoperative management to avoid fracture or re-fracture.
Interference risks during medical imaging: MRI/SCANNER: ask the patient to systematically mention that he/she was implanted with a metallic device.

6 - Instructions for reprocessing:
This product is sold non-sterile.
Check the integrity of the packaging and labeling before opening the packing.
Remove all the products from their packaging prior to sterilization
All products should be cleaned, decontaminated, and sterilized before use.
Always immediately clean and decontaminate all devices that have been soiled.
Repeated reprocessing has little effect on these products.
Preparation: Double instruments (ex. Internal screwdriver and associated external screwdriver) should be separated prior to cleaning.
Cleaning: Cleaning can be performed manually, automatically or ultrasonically in accordance with the specifications designated by the manufacturer of the hospital's equipment.
Manual cleaning:
Manual cleaning consists of using aldehyde free cleaners (neutral or alkaline), applied with a soft brush, taking special care to threaded parts and parts difficult to reach.
Note: Certain solutions such as those containing bleach or formalin may damage the devices, and they must not be used.
Use of metallic brushes or other abrasive products is also forbidden.
Cleaning should be immediately followed by profusely rinsing with deionized water. Check that water flows out the cannulated parts.
Automatic cleaning:
Automatic cleaning is performed in a cleaning/disinfecting machine using neutral cleaners, with a cleaning cycle of 5 minutes minimum and a rinsing cycle of 3 minutes.
Check the complete removal of visible dirt, especially in the cannulated parts.
If necessary, repeat the full process or proceed to a manual cleaning.
Disinfection: If an automatic cleaning is used, final rinsing at 80°C during 10 minutes can be performed.
Drying: Drying temperature should not exceed 95°C.
Controls, servicing and tests: No specific requirements. The implants are single use. They should therefore never be re-used.
Packaging: No specific requirements.
Sterilization: Newdeal's implants and instruments are recommended to be sterilized by the steam autoclaving procedure regularly used in the hospital.
The following two methods have been validated by the manufacturer and can thus be used:

Method: steam	Method: steam
Cycle: wrapped gravity	Cycle: wrapped gravity
Temperature: 132°C	Temperature: 134°C
Exposure time: 45 minutes	Exposure time: 18 minutes

Other sterilization method and cycles may also be used. However, individuals or hospitals not using the recommended method are advised to validate the alternative method using appropriate laboratory techniques.
EtO sterilization or cold sterilization techniques are not recommended.

7 - Use of the implant:
The surgeon must use the instrumentations recommended in accordance with the operative technique available from the manufacturer. The medical device must be used in compliance with the use of the profession and the standard of art. Do not attempt a surgical procedure with faulty, damaged or suspect instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively.
Opening of the instruments set must be done according to aseptic condition.
When handling the implants, avoid any contact with other material or tools which may damage the implant surface. Under no circumstances should the implant be modified.
The plates should never be excessively bent, nor reverse bent after a first bending procedure.
The Newdeal plates should be fixed using Newdeal appropriate fixation screws. Implants manufactured by Newdeal must not be used in conjunction with those of any other manufacturer as component parts may not be compatible. The company accepts no responsibility for such use.

8 - Re-use of the implants:
Orthopedic implants already implanted must never be re-used.
The company accepts no responsibility for such re-use.

9 - Re-sterilization of non implanted products:
Re-sterilization is only allowed for non implanted products. Such non implanted products can be sterilized several times in the same conditions as those described above.

10 - Preventative actions for the patient to avoid post-operative complications:
- Avoid extreme position such as flexion-extension
- Wear orthopedic shoes / external immobilization (plaster, plint ...) according to the surgeon's prescription
- Receive prompt medical attention for any infection that could occur, whether at the operated-member level or elsewhere in the body.

11 - Storage: Store in dry place

12 - Liability:
Newdeal shall not be liable for any incidental or consequential loss, damage, or expense, directly, or indirectly arising from the use of this product. Newdeal neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product. Newdeal intends that this device should be used only by physicians having received appropriate training in orthopedic surgery techniques.

WARNING: Federal law (USA) restricts this device to sale by or on the order of a physician.

WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

INFORMATION: Should any information regarding the products or their uses be required, please contact your representative or distributor or directly contact the manufacturer.

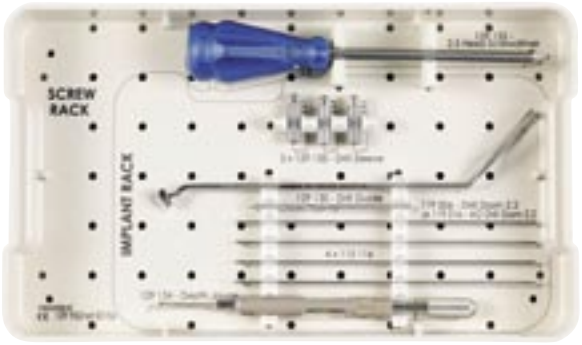
CALCANEA®

CALCANEA®

Catalog Number	Description
180 010ND	Calcanea plate - small - green
180 020ND	Calcanea plate - medium - blue
180 030ND	Calcanea plate - large - purple

SCREWS

Catalog Number	Description
180 320ND	Locking screw - length 20 mm
180 325ND	Locking screw - length 25 mm
180 330ND	Locking screw - length 30 mm
180 335ND	Locking screw - length 35 mm
180 340ND	Locking screw - length 40 mm
180 345ND	Locking screw - length 45 mm
180 420ND	Variable angle screw - length 20 mm
180 425ND	Variable angle screw - length 25 mm
180 430ND	Variable angle screw - length 30 mm
180 435ND	Variable angle screw - length 35 mm
180 440ND	Variable angle screw - length 40 mm
180 445ND	Variable angle screw - length 45 mm



INSTRUMENTS

Catalog Number	Description
129 950ND	Sterilisation container
129 951ND	Implants tray
129 130ND	Drilling guide
129 132ND	2.5 mm hexagonal screwdriver
129 134ND	Depth gauge
129 135ND	Drilling sleeve
115 116ND	K-wire diam. 1.6 mm - L. 150 mm
or 119 006ND	Drill 2.2 mm
or 119 016ND	AO attachment drill 2.2 mm

Upon request

129 139ND	Bender

- *The products are manufactured and referenced within the frame of the standards in force.*
- *Implantation procedures are described in the surgical technique.*
- *Non-contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.*
- *WARNING: Federal law (USA) restricts this device to sale by or on the order of a physician.*

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