newdeal®
New ideas for foot surgery™

T.T.C.
Tibio-Talo-Calcaneus plate

ADVANSYS™
Midfoot plating system

Surgical technique

ORTHOPAEDICS
LOWER
EXTREMITY

INTEGRA™
EXTREMITY RECONSTRUCTION

Introduction

Indications

The Newdeal TTC plate are intended for arthrodesis of the ankkle joint and distal tibia, fractures, osteotomies, fusions and replantations of small bones in the foot and ankle.

Contraindications

The implant should not be used in a patient who has currently, or who has a history of:

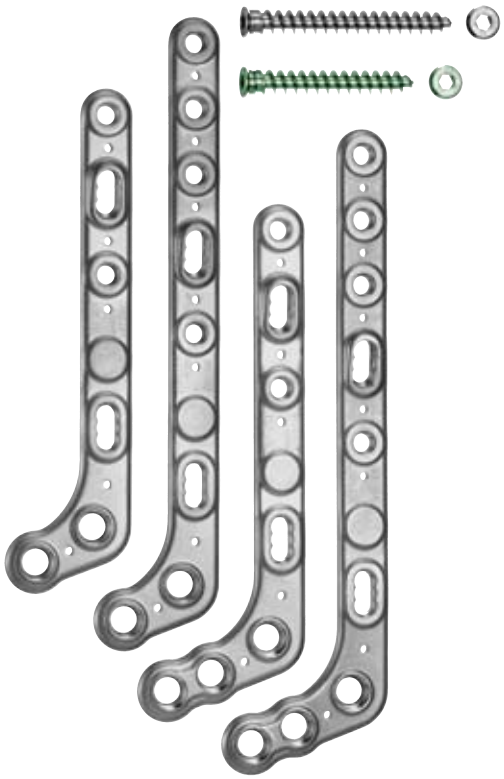
- Intact asymptomatic subtalar joint
- Active local or systemic infection
- Severe peripheral vascular disease
- Severe longitudinal deformity
- Insufficient quantity or quality of bone to permit stabilization of the arthrodesis
- Conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process
- Suspected or documented metal allergy or intolerance

Description

Implants:

4 sizes of implants :

- 4 right & 4 left plates (in 6,7,8,9 holes configurations)
- 4.5mm diam. Surfix® screw for fixation of the tibia and talus – Length 14 mm to 65 mm
- 6.5mm diam. Surfix® screw for fixation of the calcaneus - Length 20 mm to 65 mm
- Lock-screws for 4.5 mm diam. screws.
- Lock-screws for 6.5 mm diam. screws.



Instruments:

The hindfoot instrument set is composed of generic and specific instruments.

- The generic instruments are used to implant the 4.5 and 6.5mm screws and lock-screws.
- Specific tools include plate trials, drill guides, plate benders and compression forceps.

Please refer to Instrument Set Diagram (P. 16) for additional information.

T.T.C.

Surgical technique

Designed in conjunction with Robert Anderson, MD, Bruce Cohen, MD, Hodges Davis, MD and Carroll Jones, MD

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.

1 • Articular surfaces preparation

The articular surfaces should be prepared using standard procedure, for cartilage resection and/or bone graft placement. ***(fig. 1-a)***

If necessary, deformity correction and alignement should also be performed.

Compression with separate fixation screws may be done prior to plate application, should this be required, one should take care that these separate fixation scews do not hinder late positioning of the T.T.C.P. and screws.

The final plate placement is shown in figure 1-b.

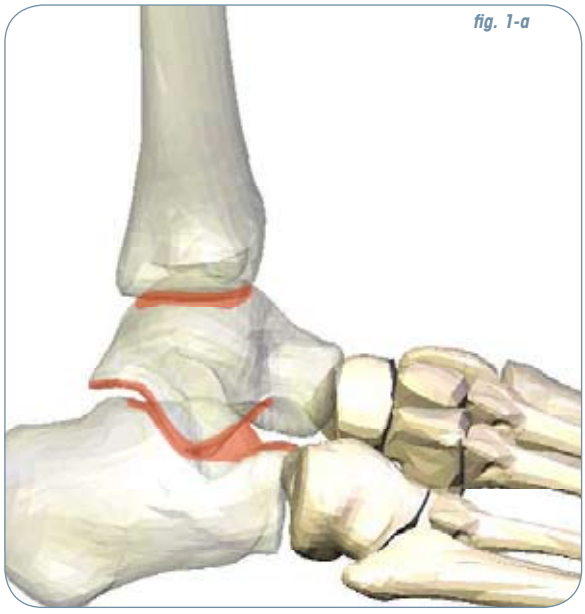


fig. 1-a

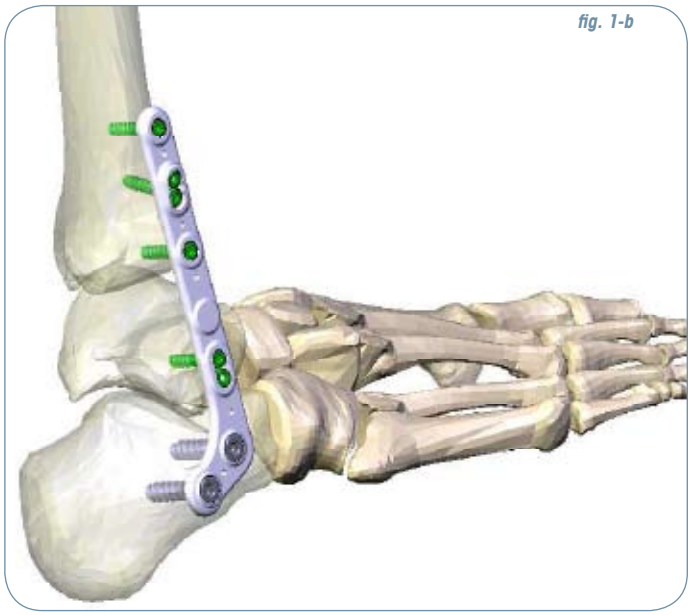


fig. 1-b

2 • trials positioning

Trials *(169 001, 169 002, 169 003, 169 004)* are used to determine the appropriate implant size.

The trial should be positioned laterally, in order to provide:

- 2 to 3 holes in the short J-shaped or L-shaped part of the plate facing the calcaneus.
- The oblong central hole facing the talus, if any is present
- The long part of the plate aligned with the tibia .

115 216
K-wire

169 001 to 169 004
Trial implants

129 765
Plate benders

K-wires *(115 216)* are used for temporary fixation of the trial, and implant.

The trials are flexible and allow contouring to the lateral surface of the calcaneus, the talus and the tibia. The contoured trial may be used as a template for contouring the final implant later in the procedure.

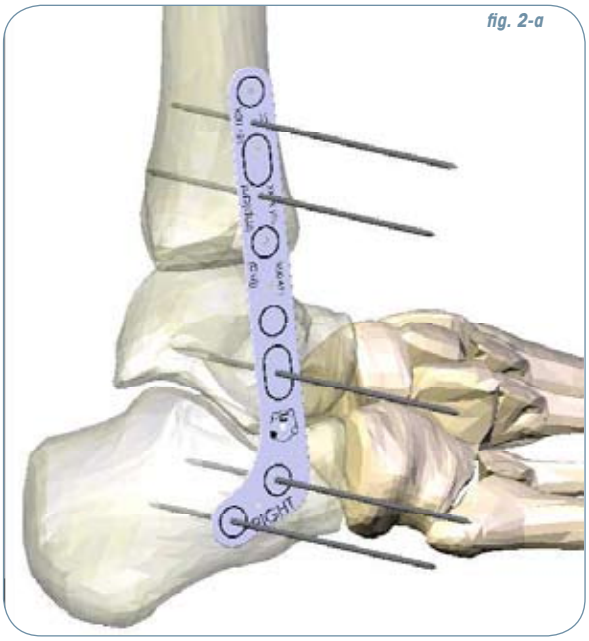


fig. 2-a

3 • Plate contouring

The plates are pre-bent to better fit the lateral aspect of the hindfoot. However, when deemed necessary by the surgeon, the plate may be further contoured using plate benders *(129 765)* as shown in figures 3-a and 3-b.

Warning :
It is imperative that the bending be implemented between two consecutive lipped holes. If not, the intermediate threaded holes may be damaged or deformed and the locking function minimized or lost.

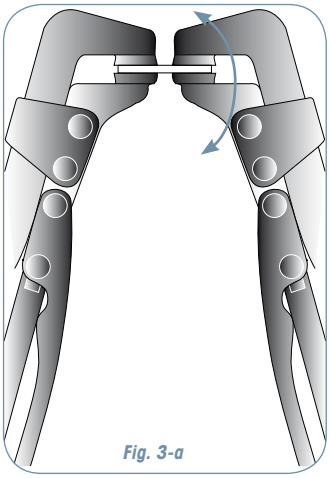


Fig. 3-a

Fig. 3-b

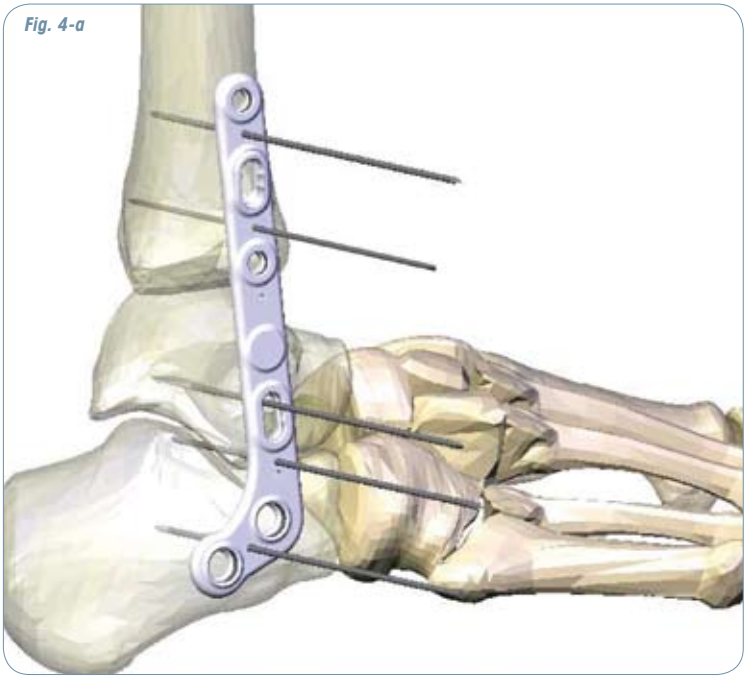
219 665
Drilling guides

219 865
Screwdriver

4 • implant positioning

The implant is selected, based on the size defined using the trial plate.
The plate can slide along the k-wire(s) used to position the trial plate ***(Fig. 4-a)***.
The k-wires serve as temporary fixation during preparation of the screw holes.

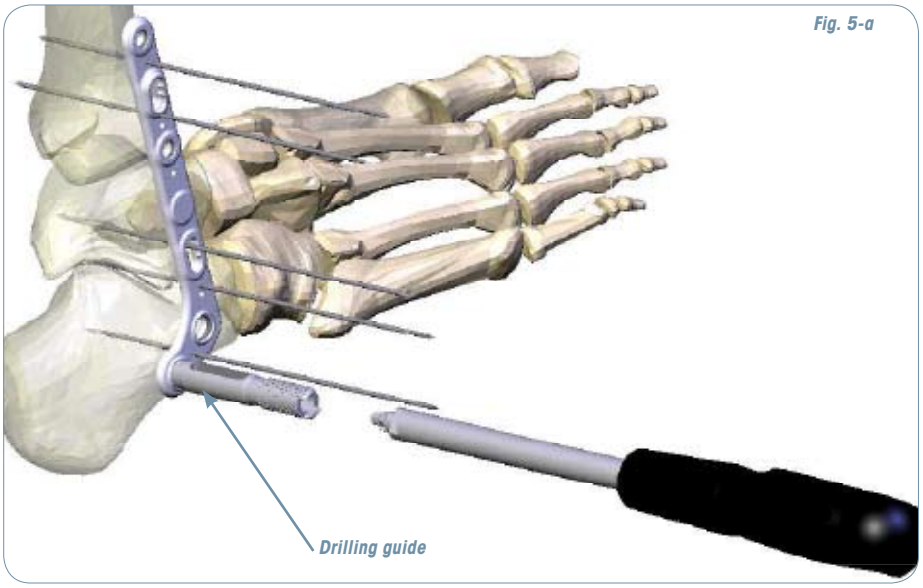
Fig. 4-a

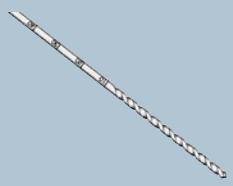


5 • Drill screw holes

Holes should be prepared, starting with the calcaneal screw holes as shown in figure 5-a.
K-wires may be used to temporarily hold the plates in position until the screws are inserted.
Drilling guides *(219 665)* are fixed to the plate on the appropriate threaded holes using the screwdriver *(219 865)*.

Fig. 5-a

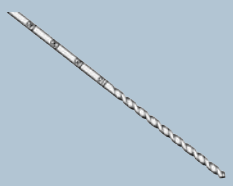




219 545
4.5 mm drill

219 345
Depth gauge

Diam.
4.5 mm



219 565
6.5 mm drill

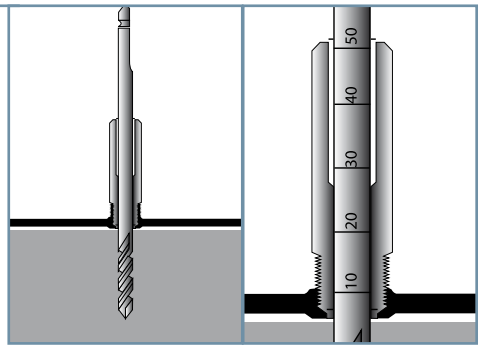
219 365
Depth gauge

Diam.
6.5 mm

6 • Screw insertion

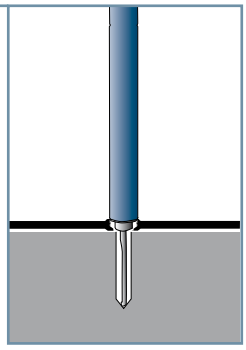
For each hole, the following steps must be followed as shown in figures 6-a to 6-f:

Fig. 6-a



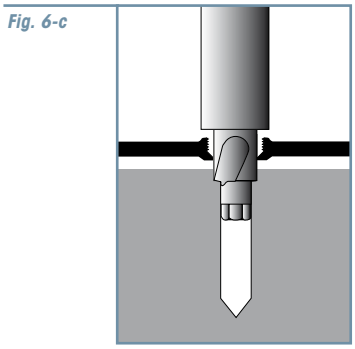
A Drilling with ref *(219 545 for screws diam. 4.5mm – or ref 219 565 for screws diam. 6.5mm)* through the drill guide. The screw length can be read from the calibrated scale on the drill. The length is read from the top side of the drill guide.

Fig. 6-b



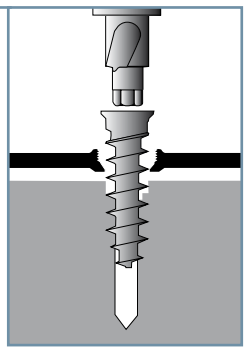
B Alternately, the screw length can be measured using the depth gage *(219 345 for screws diam. 4.5mm – or ref 219 365 for screws diam. 6.5mm)*.

Fig. 6-c



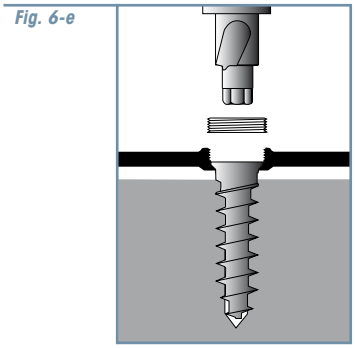
C Chamfer the drill hole with the screwdriver *(219 845 for screws diam. 4.5mm – or ref 219 865 for screws diam. 6.5mm)*.
Ensure that the threaded hole is not damaged when performing the chamfering.

Fig. 6-d



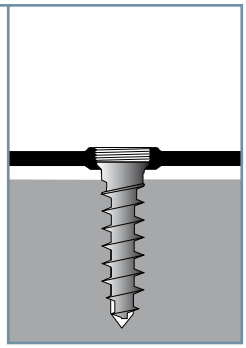
D Insert the screw into the prepared hole until it reaches the end. Clean the threaded hole before and after introducing the screw. Maintain axial alignment between the screw and the threaded hole.

Fig. 6-e



E Positioning the lock-screw.
Assemble the lock-screw to the appropriate screwdriver or power driver. The screw and lock-screw should be inserted in each hole before starting preparation of the next screw hole

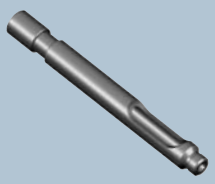
Fig. 6-f



F Locking: Fully seat the lock-screw with the screwdriver. The lock-screw should be flush with the top of the plate when it is fully inserted.

Warning

Steps A to F should be completed for each screw before starting preparation of the subsequent screw(s). If not, the axes of the screw and the prepared hole may be misaligned.



219 645
Drilling guides

115 425
K-wire

219 900
Compression clamp

7 • Join space reduction

After insertion of the calcaneal screws, compression is applied and maintained to reduce the arthrodesis ***(Fig. 7-a)***.

- A drill guide *(219 645)* is fixed to the most proximal hole.
- A 2.5mm K-wire *(115 425)* is inserted in the tibial diaphysis, 20mm from the plate
- The compression clamp *(219 900)* is fixed, in a open position, to the drilling guide and the K-wire
- Temporary K-wires are removed.

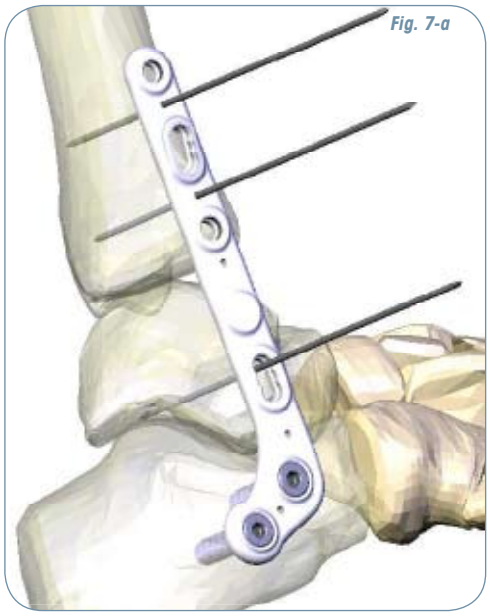


Fig. 7-a

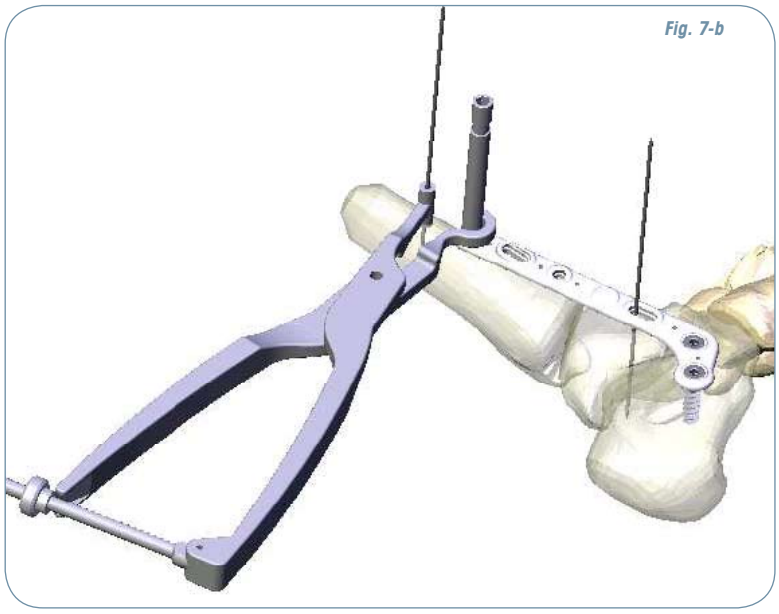


Fig. 7-b

Compression is applied with the compression clamp *(219 900)* as shown in figure 7-c.

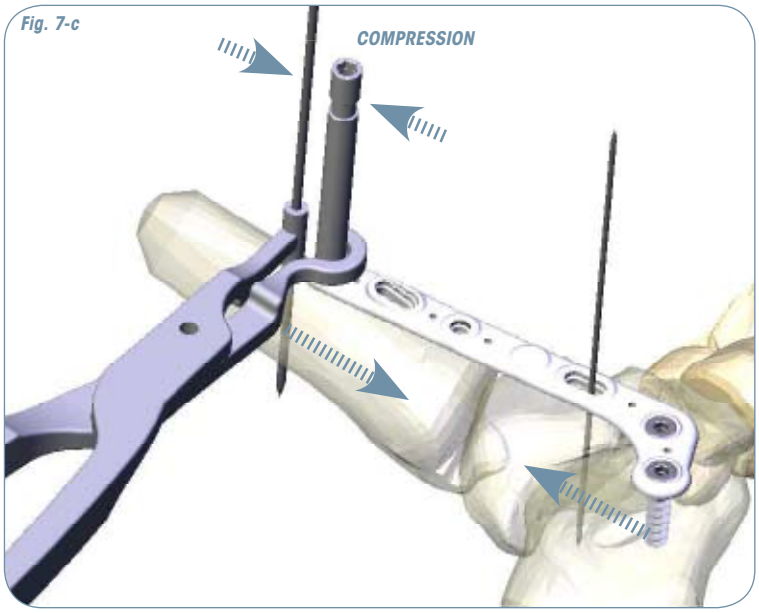


Fig. 7-c

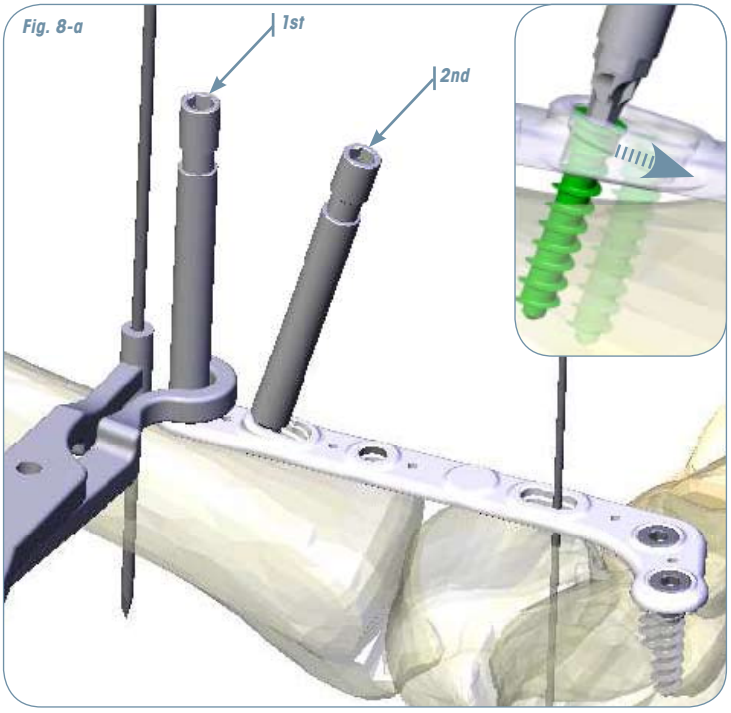
219 645
Drilling guides

219 845
Screwdriver

8 • Tibial fixation

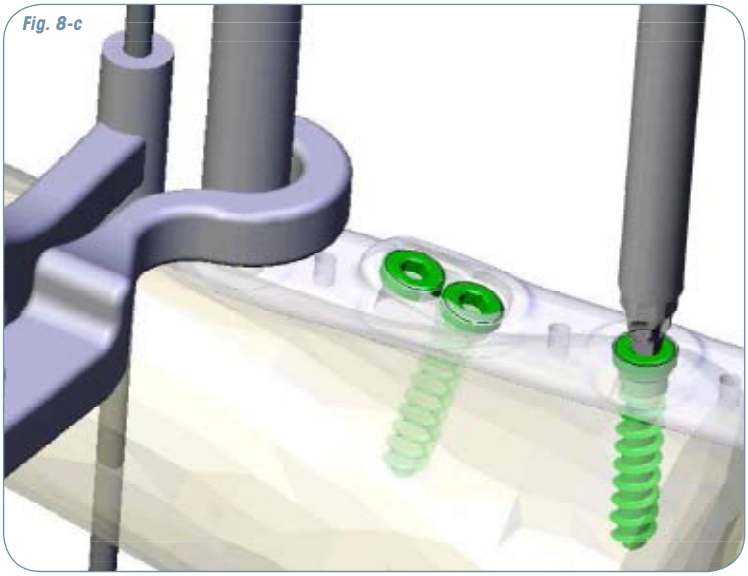
Connect a 2nd guide *(219 645)* and proceed with screw insertion (as described in section 6) at the upper part of the inclined oblong hole first.

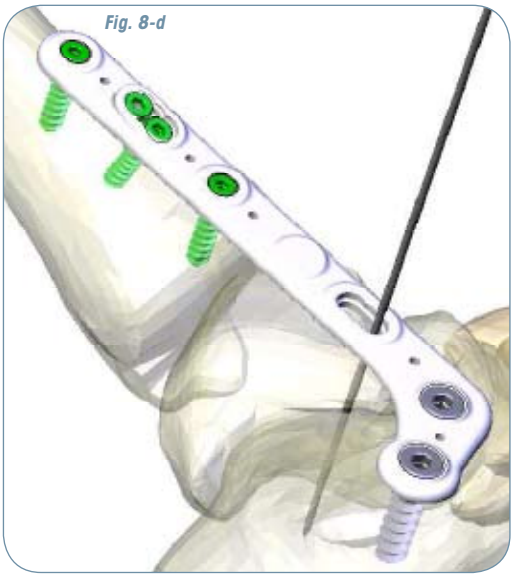
This enables the application of additional compression during screw insertion as shown in figures 8-a and 8-b.



Once compression has been applied, and the screw tightened, use 2 lock-screws to lock the oblong hole.

Insert the remaining screws into the tibia as shown in figures 8-c and 8-d.





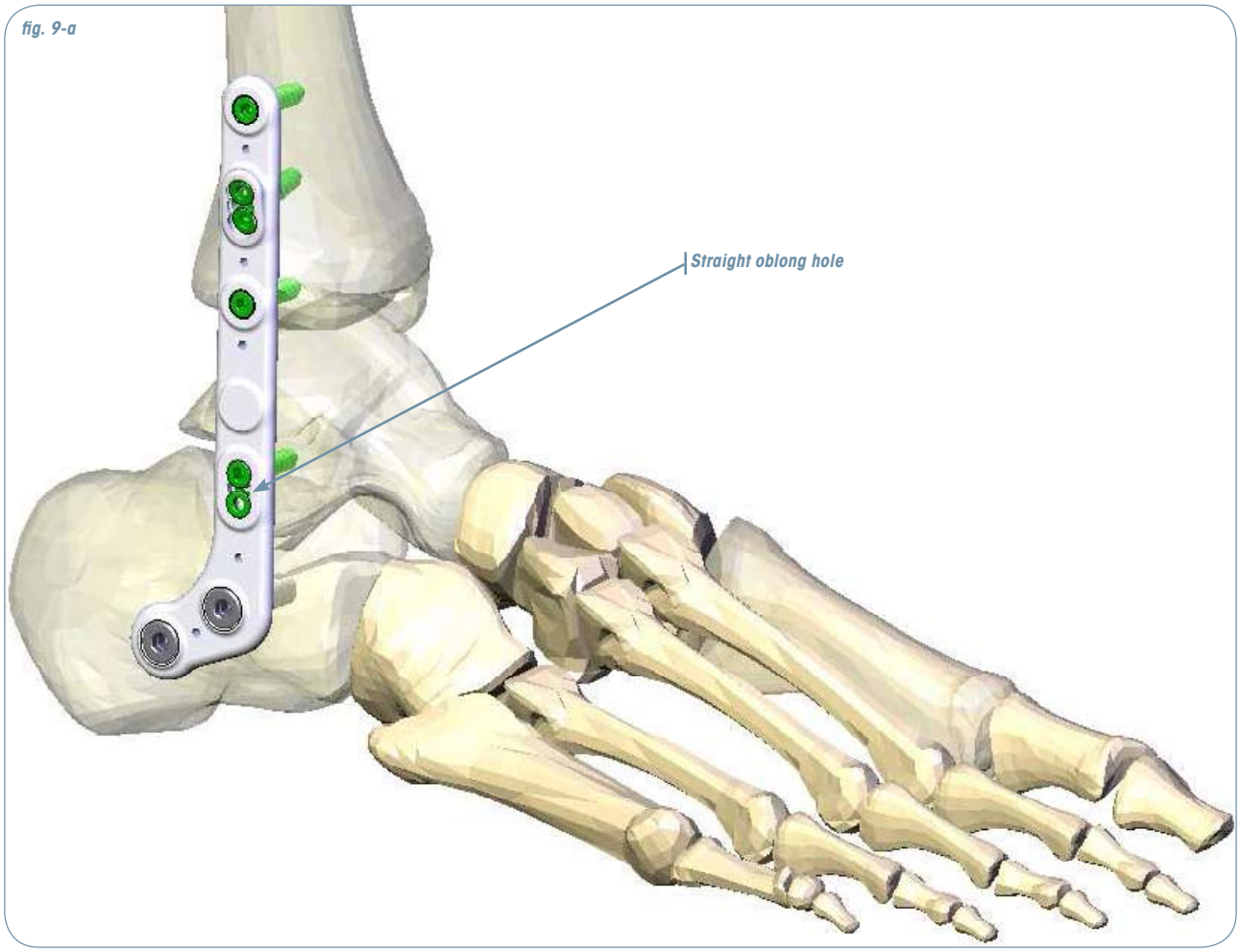
219 845
Screwdriver

9 • Talar fixation

If talus is present, its fixation should be performed using 2 screws in the straight oblong hole, and 2 lock-screws.

If no talus remains, this straight oblong hole faces the distal tibia. Insertion of a screw is recommended, with 2 lock-screws.

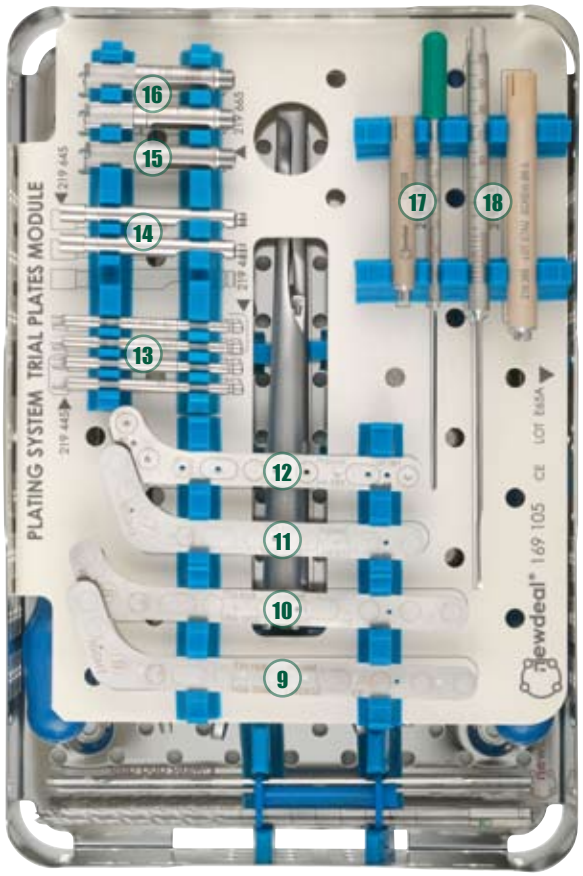
fig. 9-a



Instruments set diagram

Instruments

	Reference	Description
1•	219 845	Hex screwdriver for diam. 4.5 Screw
2•	219 865	Hex screwdriver for diam. 6.5 Screw
3•	219 765	Bending forceps, diam. 6.5 hole, L. 193 mm
4•	219 900	Compression forcep, L. 260 mm
5•	219 545	3.0 diam drill for diam. 4.5 screw
6•	219 565	3.5 diam drill for diam. 6.5 screw
7•	115 216	K-wire, diam. 1.6 mm, L. 150 mm
8•	115 425	K-wire, diam. 2.5 mm, L. 200 mm



Instruments

	Reference	Description
9•	169 004	Trial TTC implant, 9 holes
10•	169 002	Trial TTC implant, 8 holes
11•	169 003	Trial TTC implant, 7 holes
12•	169 001	Trial TTC implant, 6 holes
13•	219 445	Screwdriver / AO, hex. diam. 2.5 mm, L. 76 mm
14•	219 465	Screwdriver / AO, hex. diam. 3.5 mm, L. 76 mm
15•	219 645	Drilling guide, diam. 3.0 mm
16•	219 665	Drilling guide, diam. 3.5 mm
17•	219 345	Depth gauge, diam. 4.5 mm screws
18•	219 365	Depth gauge, diam. 6.5 mm screws

Instructions for use

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

• Description

Newdeal®'s osteosynthesis systems are designed for the fixation of fractures, fusions and osteotomies, more especially for foot, ankle and hand surgery.

Material: 316L (ISO 5832-1 / ASTM F138&139)

• Indications

For fixation of bone fractures or for bone reconstruction. Examples include:

- Arthrodesis in hand or foot surgery
- Fractures management in the foot or hand
- Mono or Bi-cortical osteotomies in the foot or hand
- Distal or proximal metatarsal or metacarpal osteotomies
- Fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.)

The size of the chosen staple should be adapted to the specific indication.

The ADVANSYS™ Plates have to be fixed with the Newdeal® Locking System screws and washers diam. 3.5 mm.

• 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.

Warnings

Serious post-operative complications may occur from use of the implant in a patient who:

- Lacks good general physical condition;
- Has severe osteoporosis;
- Demonstrates physiologic or anatomic anomalies;
- Has immunological responses, sensitization, or hypersensitivity to foreign materials;
- Systemic or metabolic disorders.

• 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;
- 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 are 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 systems 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 osteosynthesis systems should be discussed with and understood by the patient prior to surgery. The implant is made from metallic alloys; 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.

• Packaging - sterility

This product is sold either sterile or non sterile.

The sterilization method is specified on the packaging. Components sterilized by radiation are exposed to a minimum of 25 kGy of gamma irradiation.

If the product is not labeled « STERILE», it must be sterilized prior to use, in compliance with current regulations.

If the product has been removed from packaging but not used, it may be re-sterilized.

Check packaging and labeling integrity before use. The sterility is guaranteed as long as the packaging has not been damaged or opened and before the expiration date.

Do not use any implant for which the packaging has been opened or damaged outside the operating theatre.

Inner packaging should be handled under sterile conditions (persons/instruments).

• Use of the products

The surgeon must use the instrumentation 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 multi-component devices (such as plates-screws systems) should only associate the appropriated Newdeal® products and should never be used in conjunction with components of any other manufacturers, as these products may not be compatible. The company accepts no responsibility for such use.

Specific cautions for plates

The plates should never been excessively bent, nor reverse bent.

• Re-use of the implants

Orthopedic implants already implanted must never be re-used. The company accepts no responsibility for such re-use.

• Re-sterilization of non-implanted implants and sterilization of non-sterile products

Unless supplied sterile and clearly labeled as such, all implants and instruments must be steam autoclaved prior to use in surgery. Re-sterilization is only allowed for non-implanted products. Remove delivery packaging in compliance with current regulations to sterilize non-sterile products. Newdeal®'s osteosynthesis implants are recommended to be sterilized by the steam autoclaving procedure regularly used in the hospital. The implants can be sterilized several times in the same conditions.

The following two methods have been validated by the manufacturer:

Newdeal® Plastic (Radel®) sterilization trays

Cycle Type: Gravity Displacement
5 pulses
[Maximum 900 mbar; Minimum 200 mbar]
Minimum Temperature: 134°C (273° F)
Exposure Time: 18 minutes
20 minute vacuum drying

Cycle Type: Pre-Vacuum
3 pulses
[Maximum 26.0 psig (2.8 bar); Minimum 10 inHg (339 mbar)]
Minimum Temperature: 132°C (270° F)
Exposure time: 9 minutes
2-3 minute purge
20 minute vacuum drying

For the Forefoot tray in a pre-vacuum cycle, the user MUST disassemble the locking nuts for devices 119401 and 119403 within the Forefoot Set and place them in the base of the container prior to sterilizing. Devices 119401: 90° Solustaple Holder & Impactor and 119403: 26° Solustaple Holder & Impactor are located in the middle level of the tray system.

Newdeal® Stainless Steel sterilization trays

Cycle Type: Gravity Displacement
5 pulses
[Maximum 900 mbar; Minimum 200 mbar]
Minimum Temperature: 134°C (273° F)
Exposure Time: 18 minutes
20 minute vacuum drying

Cycle Type: Pre-Vacuum
3 pulses
[Maximum 26.0 psig (2.8 bar); Minimum 10 inHg (339 mbar)]
Minimum Temperature: 132°C (270° F)
Exposure time: 4 minutes
2-3 minute purge
20 minute vacuum drying

These sterilization parameters assume that all instruments have been properly decontaminated prior to sterilization. The parameters are validated to sterilize specific configurations as noted in the tray markings. If other products are added to the tray or to the sterilizer, the recommended parameters may not be valid and new cycle parameters may need to be validated by the user. The autoclave must be properly installed, maintained and calibrated.

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.

• Information related to postoperative care

- The patient should be advised that a second more minor procedure for the removal of the implants is usually necessary
- While the surgeon must make the final decision regarding implant removal, wherever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. In the absence of a bursa or pain, removal of the implant in elderly or debilitated patients is not suggested.
- Postoperative instructions to patients and appropriate nursing care are critical. Early weight bearing substantially increases implant loading and increases the risk of loosening, bending, or breaking the device. Patients who are obese or non-compliant, as well as patients who could be predisposed to delayed or non-union must have auxiliary support.
- Even after full healing, the patient should be cautioned that re-fracture is more likely with the implant in place and soon after its removal, rather than later, when the voids in the bone left by implant removal have been filled in completely.
- Patients should be cautioned against unassisted activity that requires walking or lifting.
- Postoperative care and physical therapy should be structured to prevent loading of the operative extremity until stability is evident.
- The patient should be encouraged to report to his/her surgeon any unusual changes of the operated extremity. If evidence suggests loosening of the implant (particular pain and progressive changes in the radiographs) an intensified schedule of check-ups is advised and new warning and instructions to the patient may be appropriate regarding further activity restrictions.
- The patient should be encouraged to receive prompt medical attention for any infection that could occur, whether at the operated-member level or elsewhere in the body.

• Storage

Store in dry place.

• Product information disclosure Liability

Newdeal®, an Integra LifeSciences Company, has exercised reasonable care in the selection of materials and the manufacture of these products. Newdeal® excludes all warranties, whether expressed or implied, including but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Newdeal® shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from use of this product. Newdeal® neither assumes nor authorizes any person to assume for it any other or additional liability or responsibility in connection with these products. Newdeal® intends that this device should be used only by physicians having received proper training in orthopedic surgery technique for use of the device.

• 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.

ADVANSYS®
Compression plate

Compression stainless steel plate

Reference	Description
181 001s	Right - 6 holes
181 002s	Right - 7 holes
181 003s	Right - 8 holes
181 004s	Right - 9 holes
181 011s	Left - 6 holes
181 012s	Left - 7 holes
181 013s	Left - 8 holes
181 014s	Left - 9 holes

Container for non sterile implants

Reference	Description
188 201	Container
188 211	Base
188 215	Rack
169 103	Lid

Container for ancillary

Reference	Description
169 100	Container
169 111	Base
169 103	Lid
169 104	Cylinder
169 15	Module

Instruments

Reference	Description
219 845	Screwdriver / Hex. diam. 2.5 mm, L. 191 mm
219 865	Screwdriver / Hex. diam. 3.5 mm, L. 230 mm
219 445	Screwdriver / AO, hex. diam. 2.5 mm, L. 76 mm
219 465	Screwdriver / AO, hex. diam. 3.5 mm, L. 76 mm
219 645	Drilling guide, diam. 3.0 mm
219 665	Drilling guide, diam. 3.5 mm
219 545	Drill, diam. 3.0 mm, L. 190 mm
219 565	Drill, diam. 3.5 mm, L. 200 mm
219 900	Compression forcep, L. 260 mm
219 765	Bending forceps, diam. 6.5 mm hole, L. 193 mm
219 345	Depth gauge, diam. 4.5 mm screws
219 365	Depth gauge, diam. 6.5 mm screws
115 216	K-wire, diam. 1.6 mm, L. 150 mm
115 425	K-wire, diam. 2.5 mm, L. 200 mm
169 001	Trial TTC plate, 6 holes
169 002	Trial TTC plate, 8 holes
169 003	Trial TTC plate, 7 holes
169 004	Trial TTC plate, 9 holes

Surfix® Titanium screw diam. 4.5 mm + lock screw

Reference	Length
285 414s	12 mm
285 416s	14 mm
285 418s	18 mm
285 420s	20 mm
285 422s	22 mm
285 424s	24 mm
285 426s	26 mm
285 428s	28 mm
285 430s	30 mm
285 435s	35 mm
285 440s	40 mm
285 445s	45 mm
285 450s	50 mm
285 455s	55 mm
285 460s	60 mm
285 465s	65 mm
185 400s	Lock screw, diam. 4.5 mm

Surfix® Titanium screw diam. 6.5 mm + lock screw

Reference	Length
285 620s	20 mm
285 625s	25 mm
285 630s	30 mm
285 635s	35 mm
285 640s	40 mm
285 645s	45 mm
285 650s	50 mm
285 655s	55 mm
285 660s	60 mm
285 665s	65 mm
185 600s	Lock screw, diam. 6.5 mm

Distributed by

CE 0120

- 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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ND 03322-01-08

PRODUCTS FOR SALE IN EUROPE, MIDDLE-EAST AND AFRICA ONLY

- *See instructions for use*
- *Single use*
- *Sterile* — STERILE | R

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