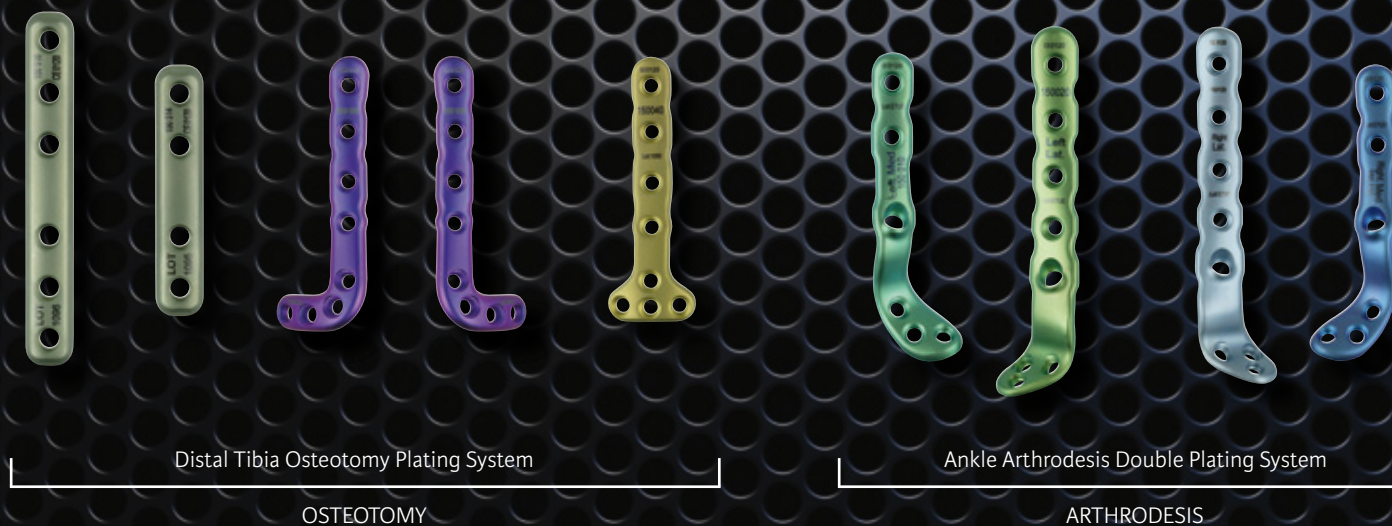


Integra®

TIBIAXYS® Osteotomy - Arthrodesis

SURGICAL TECHNIQUE

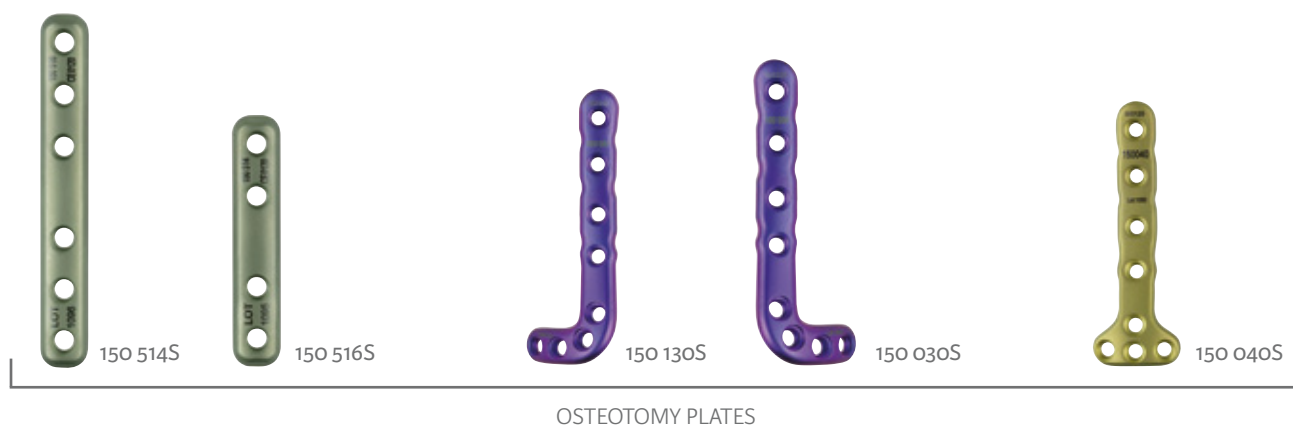


INTEGRA®
LIMIT UNCERTAINTY

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■ Osteotomy ■ Arthrodesis



■ ■ Description

Material

- Plates: Titanium alloy TA6V.
- Screws: Titanium alloy TA6V.

System Features

Plate Description

- Arthrodesis, 3 mm thickness:
 - Right side (blue color coded)
 - Left side (green color coded)
- Osteotomy.

Screw Description

- Surfix® diam. 3.5 mm, lengths from 10 to 50 mm:
 - Standard
 - Variable angle
- Transarticular cortical screw diam. 4.0 mm, lengths from 40 to 100 mm.



■ ■ Main Features of the Plates

Anatomically Contoured Plates

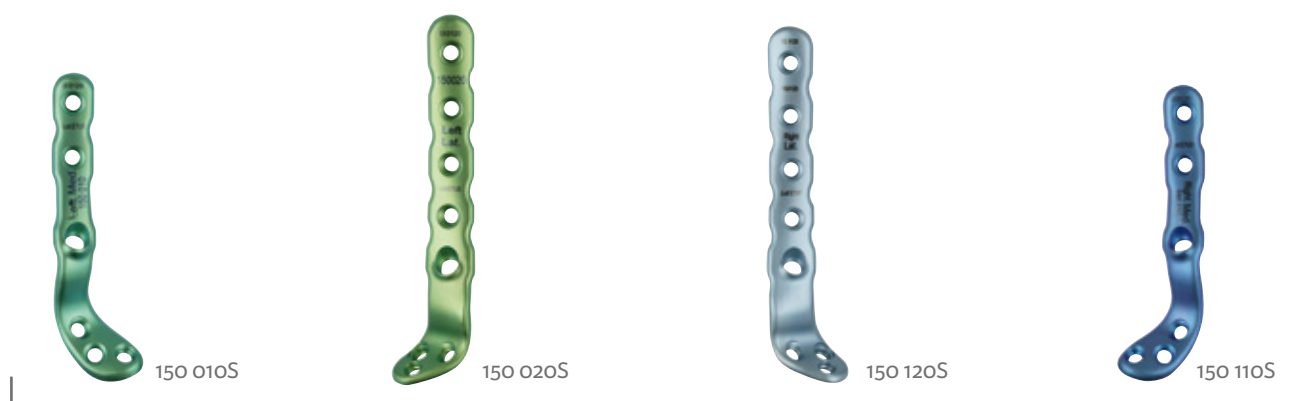
- Compliant with the patient's tissues and bone.

Adaptive Plates (Orientable or Non-Orientable Surfix® Fixed Angle Screws)

- Let you choose the right way to position the screws: no compromise between locking and orientation.

Surfix® Fixed Angle Locking System

- Reliability: monobloc fixation (screw/plate/bone).
- Stability.



ARTHRODESIS PLATES

Benefits

Versatile and Adaptive System

- All implants are possibly implanted with the same instrumentation set.

Easy, Reliable and Reproducible Surgery

- Anatomically contoured plates, complete instrumentation set.

■ Allows Rigid Fixation Particularly in the Case of:

- Open wedge/closing wedge osteotomies.
- Complex fractures.

■ Ankle Fusion

- High stability and less complication risk.

■ Allows Rigid Fixation Particularly in the Case of:

- Bad bone stock.
- Bad bone quality.
- Misalignment.

Indications of the TIBIAXYS® System (Osteotomy and Arthrodesis Plates)

Arthrodesis, osteotomies and fractures of ankle joint, distal tibia and fibula. The Newdeal TIBIAXYS® Plates have to be fixed with the SURFIX® fixed angle Locking System screws and washers diam. 3.5 mm. Anterior plates for ankle arthrodesis have to be fixed with the TIBIAXYS® cortical screws diam. 4 mm too.

Possible Uses for Osteotomy Plates

Internal Fixation after Osteotomies of Distal Tibia and/or Fibula for Correction of:

- Varus/valgus (frontal plane) misalignment.
- Retrocurvatum/antecurvatum (sagittal plane) misalignment.
- Malrotation deformity.

Internal Fixation of Distal Tibia and Fibula for Treatment of:

- Fractures.
- Nonunions/pseudarthroses.

Notes

Integra®

TIBIAXYS® Osteotomy - Arthrodesis

SURGICAL TECHNIQUE
OSTEOTOMY



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.

This surgical technique is presenting the positioning of a medial osteotomy plate in the treatment of a valgus ankle osteoarthritis (closing wedge osteotomy). Same principle and use of the instrumentation set can be applied to the antero-lateral and anteromedial plates and for opening wedge osteotomy.

■ Surgical Technique Osteotomy

1 Patient Positioning

- The patient is in a supine position on a radiolucent operating table.
- Tourniquet at the thigh.
- Pad under lower leg for elevation.
- Heel flush with the operation table.

2 Ankle Arthroscopy

Ankle arthroscopy can be done at the beginning of surgery, particularly for:

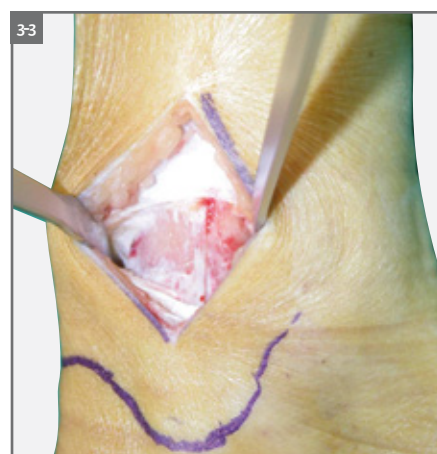
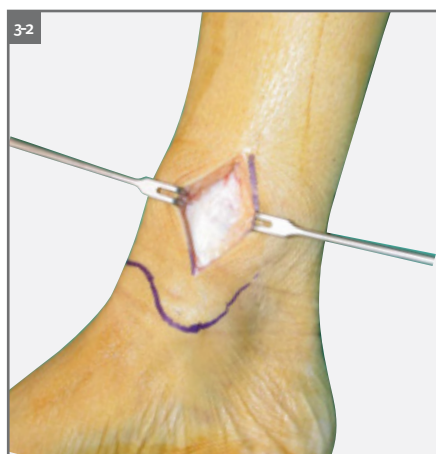
- Assessment of cartilage, ligaments and instability pattern.
- Shaving of scarred and inflammatory soft tissues in case of soft tissue impingement.
- Osteophytes debridement in case of impingement or restricted range of motion.
- Microfracturing in case of circumscribed confined chondral lesions.

3 Exposure

For tibial osteotomy, a medial skin incision (length 7-8 cm) is performed directly over the distal tibial metaphysis.

Saphenus vein and nerve run posteromedially to the incision and usually do not hinder direct bone approach.

Soft tissues are retracted at once with a retractor.



4 Tibial Osteotomy

Note

The use of fluoroscopy is highly recommended to check the correct positioning of the K-wires, bones, plates and screws.

4-1 Preparation of the Osteotomy

Two K-wires (115 225) are inserted under fluoroscopy to guide the saw blade. Their direction is perpendicular to the cortical bone, thus running typically slightly distally (Fig. 4-1), aiming direct contact of medial cortex after closing the osteotomy. A goniometer may be used.



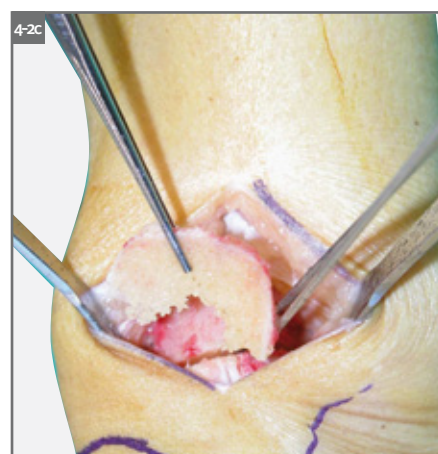
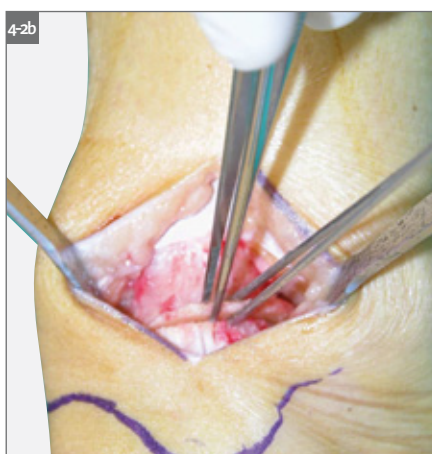
4-2 Performing the Osteotomy

Osteotomy is performed following the K-wires with the saw blade (Fig. 4-2a).

The bone wedge is mobilized (Fig. 4-2b) and removed (Fig. 4-2c).

Note

Bone matrix may be used to improve bone healing.



The lateral cortex at the tip of the wedge is preserved to enhance stability of fixation and to use it as a hinge to translate the heel contact point to the convex side of the deformity. The osteotomy is slowly closed by manual compression.

Note

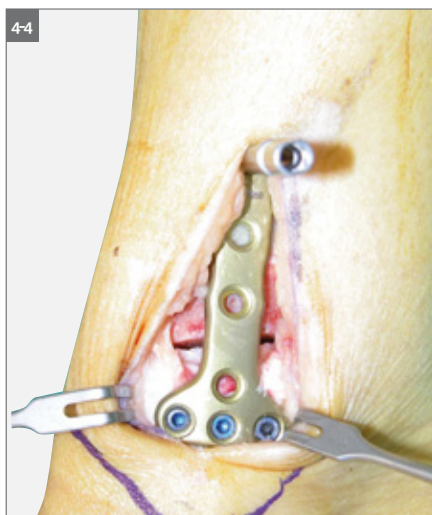
In closing wedge tibial osteotomy with a base of more than 10 mm thickness closing of the osteotomy may cause relevant zigzag deformity of the distal tibia. In such case the lateral cortex is not preserved to allow adjustment by translation of the distal tibial fragment. Usually translation is not necessary in wedges with smaller than 10 mm base.

4-3 Positioning and Fixation with the Medial Plate

- The plate is first fixed to the distal part of the tibia (distally to the osteotomy cut) with 3.5 mm Surfix® fixed angle standard locking screws.
- Then the compression can be achieved using the specific compression forceps before the fixation of the proximal part of the plate to the tibia diaphysis.
- This fixation of the plate to the tibia diaphysis is achieved thanks to either 3.5 mm Surfix® fixed angle or 3.5 mm Surfix® variable angle locking screws.

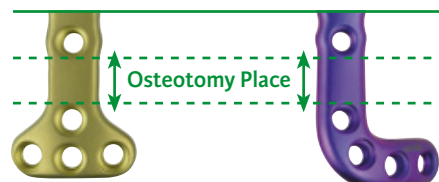
4-4 Distal Fixation

The anatomically shaped medial plate providing angular stabilization is prepared to be positioned. The distal fragment is fixed first (Fig. 4-4).



Positioning of the plate on the sides of the osteotomy:

The distance between the 2 holes that have to be positioned on the two different sides of the osteotomy is higher than the distance between two consecutive holes.





219 635
Drilling
guide
dia. 2.7 mm



219 845
Screwdriver
HEX
dia. 2.5 mm
L. 191 mm



219 835
Screwdriver
HEX
dia. 2 mm
L. 180 mm



219 435
AO Screwdriver
HEX
dia. 2 mm
L. 76 mm



219 535
Drill AO
dia. 2.7 mm
L. 125 mm

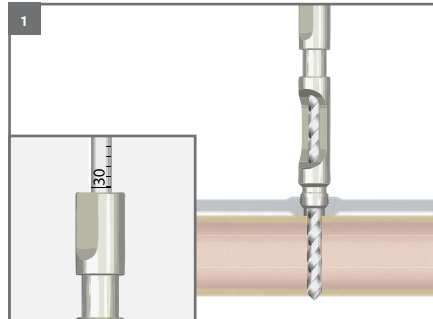


219 335
Length Gauge
dia. 3.5 mm
screws

4-5

Surfix® Fixed Angle Locking Screw Insertion

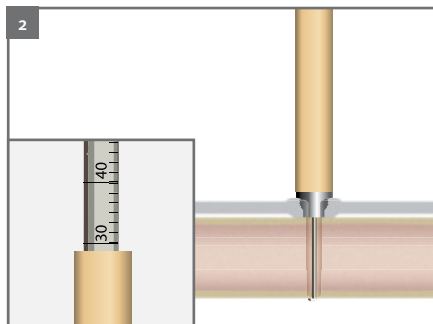
1. Prepare holes with the 2.7 mm drill (219 535) through the drilling guide (219 635). The screw length can be read from the calibrated scale on the drill. The depth is read from the top side of the drilling guide.



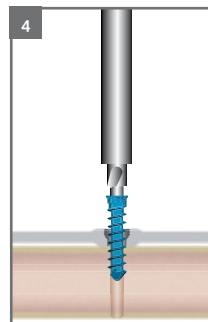
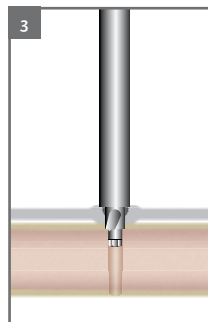
Caution

Steps 1 to 6 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.

2. Alternately, measure the necessary screw length using the length gauge (219 335), after having removed the drilling guide.

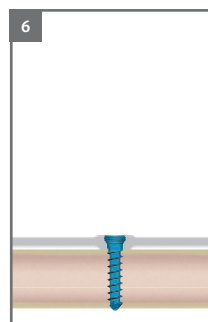
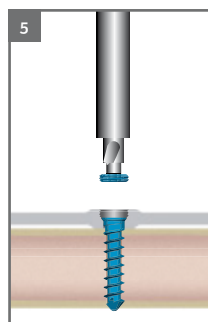


3. Chamfer the drill hole with the screwdriver (219 835). Ensure that the threaded hole is not damaged when performing the chamfering.

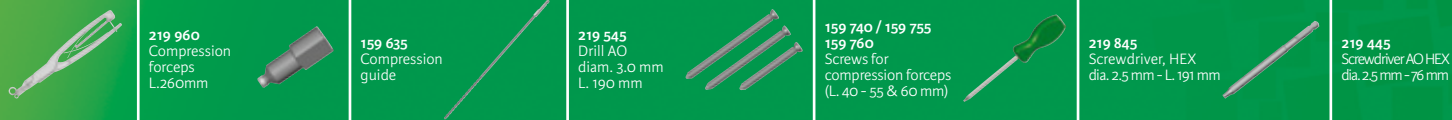


4. Using the hexa screwdriver (219 835 – 219 435), insert the screw into the prepared hole until the plate is at the desired position relative to the bone. The screw should be fully seated in the plate. Clean the threaded hole before and after introducing the screw. Maintain co-axiality between the screw and the threaded hole.

5. Assemble the lock-screw to the appropriate screwdriver (219 835). The lockscrew should be inserted after each screw, and before preparation and insertion of the subsequent screw. This prevents potential damage to thread.



6. 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.

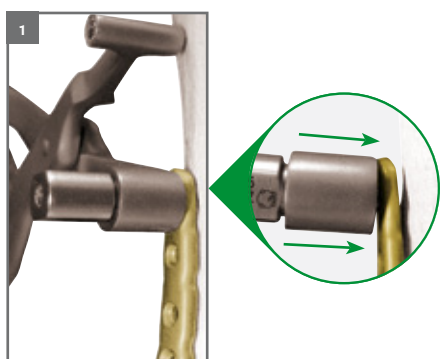


4-6 Compression/Closing the Osteotomy

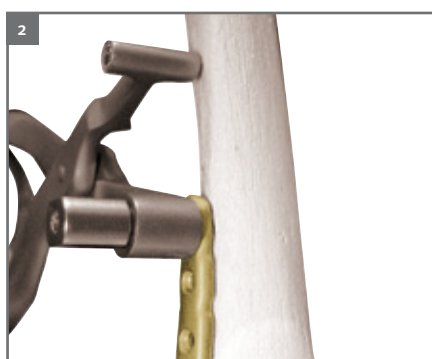
The osteotomy is closed by varus stress to the foot and/or using the compression forceps fixed to the proximal side of the plate.

Note

The second most proximal threaded hole of the plate can also be used if the skin incision does not allow to have enough space to further position the compression forceps onto the tibia.



1. Put the compression guide (159 635) through the specific hole of the compression forceps (219 960) and screw this guide in the most proximal threaded hole of the plate.



2. Position the most proximal extremity of the compression forceps on the tibia diaphysis respecting the alignment with the tibial axis of the plate. The distance between the 2 extremities of the compression forceps should be around 2 cm to allow a sufficient compression.



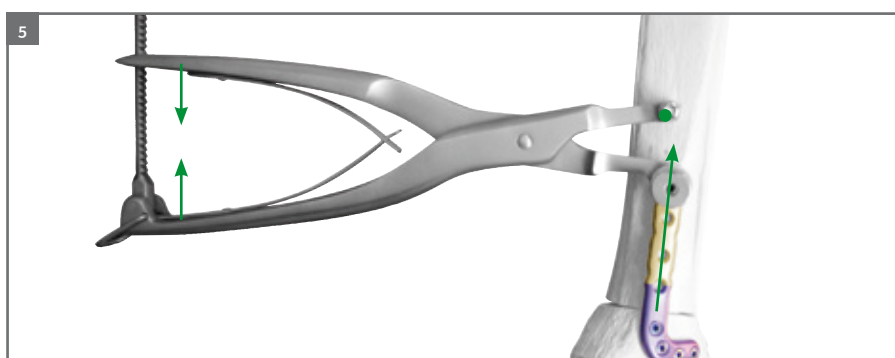
3. Prepare the compression screw insertion (159 740 / 159 755 / 159 760) using the 3 mm drill (219545) through the hole of the proximal extremity of the compression forceps.

Caution

Ensure compression guide is fully threaded and seated properly into the plate prior to applying compression.



4. Insert the compression screw (159 740 / 159 755 / 159 760) into the tibia through the hole of the proximal extremity of the compression forceps (219960) using the screwdriver (219845 / 219445). The compression forceps is fixed, in an open position, to the plate and the tibia.



5. Apply compression with the compression forceps as shown in the figure.

219 035
Drilling guide
variable angle
screw



219 835
Screwdriver HEX
diam. 2.0 mm -
L. 180 mm



219 435
AO Screwdriver HEX
diam. 2.0 mm - L. 76 mm



219 535
Drill AO
diam. 2.7 mm -
L. 125 mm



219 335
Length Gauge
diam. 3.5 mm
screws



219 135
Screwdriver
hexalobular tto

4-7 Fixation to the Tibial Diaphysis

Keeping the compression forceps in place to maintain the compression, the tibial part of the medial plate is fixed with 4 bi-cortical Surfix® fixed angle or Surfix® variable angle locking screws to the medial aspect of the tibial diaphysis. The choice of the use of Surfix® fixed angle or Surfix® variable angle locking screws depends on the need for angulation of the screws. If the use of Surfix® variable angle locking screws is needed, using the same number of Surfix® fixed angle and Surfix® variable angle locking screws is recommended. It is also recommended to use a Surfix® fixed angle locking screw into the most proximal threaded hole.

For the Surfix® fixed angle locking screw insertion, report to the Part 4-4 "Distal Fixation" (p.10).

Note

Oblique screw insertion into the tibial diaphysis may provide additional compression to the closed osteotomy.

4-8 Surfix® Variable Angle Screw Insertion 4-8a Drill Screw Holes:

The drilling guide (219 035) specifically designed for the variable angle screws is inserted into the chosen threaded hole to obtain a variation of the angle (+/- 15°) between the plate and the position of a standard Surfix® fixed angle screw (90°).

Caution

Steps 1 to 6 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.

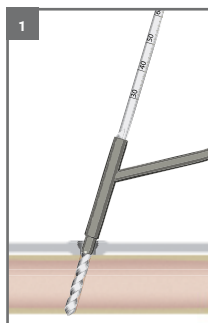
Note

If the angle is less than 75° or more than 105°, the drilling guide will not fit into the hole.

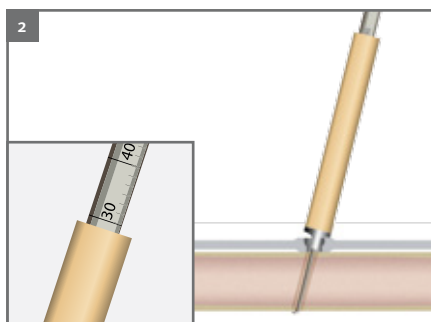
4-8b Screw Insertion

1. Screw Insertion

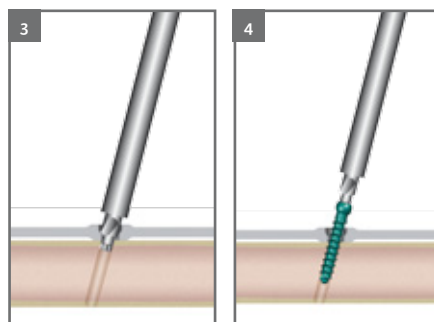
Prepare holes with the 2.7 mm drill (219 535) through the drilling guide. The screw length can be read from the calibrated scale on the drill. The depth is read from the top side of the drilling guide.



2. Alternately, measure the necessary screw length using the depth gauge (219 335).

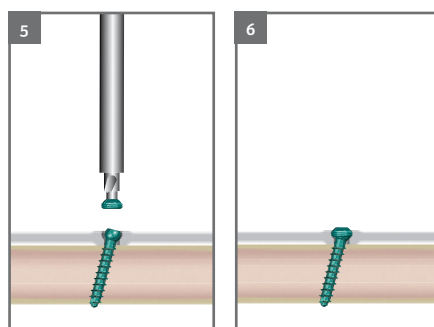


3. Chamfer the drill hole with the screwdriver (219 835). Ensure that the threaded hole is not damaged when performing the chamfering.



4. Insert the screw with the screwdriver (219 835 - 219 435) into the prepared hole until the plate is at the desired position relative to the bone. The screw should be fully seated in the plate. Clean the threaded hole before and after introducing the screw.

5. Assemble the lock-screw to the hexalobular screwdriver (219 135). The lock-screw should be inserted after each screw, and before preparation and insertion of the subsequent screw. This prevents potential damage to thread. Note that this spherical shaped lock-screw has to be inserted perpendicularly to the plate in order to be screwed properly.



6. Locking: Fully seat the lock-screw with the screwdriver. The lock-screw should close in a curved manner the hole of the plate onto the screw head.

7. Insert a first screw into the tibia to fix the plate in the correct position ; this will be enough to maintain the compression. X-ray is then done to check overall position of osteotomy and implant (Fig. 7) before further insertion of the screws into the tibial diaphysis. The internal fixation is finished when all the screws have been inserted into the plate holes.



Note

The intact fibula does not hinder isolated tibial correction. A collapsed lateral malleolar gutter is usually decompressed by closing the medial tibial wedge. Sagittal plane deformity of the distal tibial joint surface can be addressed by adding anterior closing wedge to correct the flexion deformity and a posterior closing wedge to correct the extension deformity. The rotational center of the ankle in lateral view should be in line with the mid-diaphyseal axis of the tibia. Otherwise translational adjustment has to be done.

5 Fibular Osteotomy

Additional distal fibular osteotomy may be needed consequently to distal tibial osteotomy. This can be performed with a lateral approach and use of the fibular plate for the stabilization of the osteotomy.

5-a Exposure

The fibula is approached with a longitudinal lateral skin incision. Potential branches of the superficial peroneal nerve are retracted. The distal tibia is exposed by further preparation anteriorly to the fibula.



Note

In some instances, there is no talofibular impingement, as it is typically the case after malunited ankle fractures. Lateral opening wedge osteotomy is thus preferred to preserve the ankle congruency, or to correct position of fibula.

5-b Preparation and Performing of the Osteotomy

To lengthen the fibula, two K-wires are inserted to mark the horizontal cuts of the Z-shaped osteotomy of fibula. The distal horizontal cut is performed anteriorly whereas the proximal horizontal cut is done posteriorly. The vertical cut is usually 2 cm longer than the planned lengthening to assure a 2 cm overlap. To rotate the fibula, an oblique cut from the dorsal-proximal point to the anterior-distal one is done, which allows to rotate, shorten or lengthen the distal fibula. The fixation of the plate is performed in the same way as for the tibial plates.

6 Closure and End of the Procedure

- Final check by fluoroscopy (Fig. 6-1 & 6-2)
- The skin is closed with interrupted nonabsorbable 3-0 sutures.
- A drain is not used routinely.
- A thick compressive dressing is applied and the foot placed in a reusable prefab splint.
- The tourniquet is deflated.



7 Postoperative Care

- The foot is protected by a removable short leg cast in neutral foot position for 6 to 8 weeks.
- Mobilisation on crutches with partial weight-bearing of 15 to 20 kg.
- Rehabilitation program starts immediately postoperatively, depending on achieved wound healing. It includes:
 - passive continuous motion.
 - active motion without weight-bearing.
- Once bone healing is achieved, usually after 8 weeks, free weight-bearing as tolerated is allowed.
- Thereafter, a walker or stabilizing shoe may be recommended to be used during other 4 to 8 weeks for walks on uneven ground and for professional work outside.
- Athletes should anticipate to return to sport in 8 to 12 months after their reconstruction.

Note

Removal of hardware is not recommended earlier than 8 months after surgery. Undercorrection of the valgus deformity is corrected by redo realignment surgery. Overcorrection is unlikely. Progressive ankle arthritis may need further surgical treatment. However, total ankle arthroplasty and ankle fusion are facilitated in the well aligned arthritic ankle.

Notes

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.
Newdeal's products are made from Titanium alloy Ti-6Al-4V (ISO 5832-3 / ASTM F136).

Indications

For fixation of bone fractures or for bone reconstruction.
Examples include:
Arthrodesis, osteotomies and fractures of ankle joint, distal tibia and fibula.

The Newdeal TIBIAXYS Plates have to be fixed with the SURFIX® Locking System screws and washers diam. 3.5 mm.
Anterior plates for ankle arthrodesis have to be fixed with the TIBIAXYS cortical screws dia.4 mm too.o.

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 be 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 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 and warrant that the products are free from manufacturing defects. Newdeal excludes all other 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.

Notes

Integra®

TIBIAXYS® Osteotomy - Arthrodesis

SURGICAL TECHNIQUE
ARTHRODESIS

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.

Note

In case of gross deformity or bone defects, reconstruction with allograft or an autograft from iliac crest or other anatomic regions may be necessary. Excessive length of the fibula causing lateral impingement may make shortening necessary. This can be easily done through the same anterior approach.

Surgical Technique Arthrodesis

1 Patient Positioning

- The patient is in a supine position on a radiolucent operating table.
- The ipsilateral pelvis should be underplayed by cushions to control external rotation of the leg, so that the patellar is directed upward to allow easier operation.
- Tourniquet at the thigh.

2 Exposure 2-1 Skin Incision

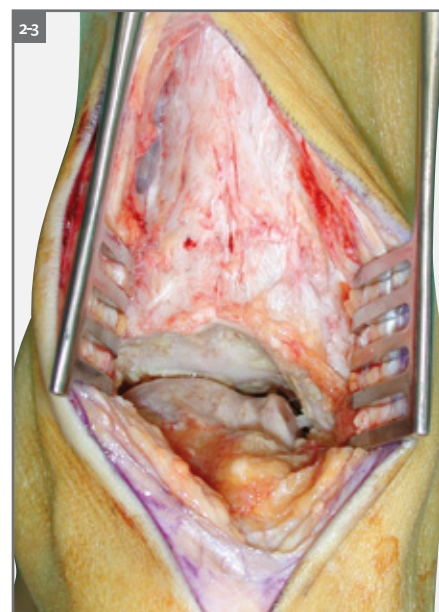
- 10 to 12 cm anterior longitudinal incision is performed directly laterally to the tibialis anterior tendon.

2-2 Dissection is Performed as Following:

- Division of the subcutaneous tissues to the extensor retinaculum paying attention to the medial branches of the superficial peroneal nerve and the veins.
- Longitudinal dissection of the extensor retinaculum along the lateral border of anterior tibial tendon.

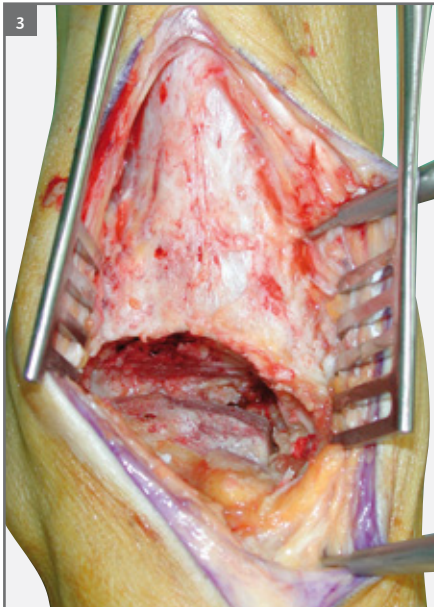
2-3 Exposure of Tibia and Talus

- Expose the distal tibia beneath the anterior tibial tendon which is held medially by a small blunt retractor, and expose sub-periosteal distal tibia using 2 small Hohmann retractors.
- Arthrotomy of the ankle joint and removal of scared capsule, and loose bodies.
- Exposure of the neck of the talus.
- One or two Hintermann® retractors can be inserted to open the tibiotalar joint and to facilitate the following cleaning work.



Note

Preservation of the convexity of the talar dome and concavity of the distal tibia may increase obtained stability after internal fixation, particularly against rotational forces. In any case, anterior and posterior rims of distal tibia should be preserved to get high contact stress at the anterior and posterior aspects of arthrodesis which will increase intrinsic stability of the arthrodesis. The lateral gutter does not need to be cleaned. In very sclerotic cases or talus necrosis, opening the tourniquet during operation may help evaluation of the vitality of the bone. Using a sharp curved chisel allows easier removal of the cartilage and preserves anatomic shape of the bones.



3 Preparation of the Joint

Using a hintermann® distractor may help exposing the tibiotalar joint.

- Remaining cartilage is removed from the talar dome, the tibial plafond and the medial gutter using chisel and curettes, paying attention to preserve the anatomic configuration of surfaces.
- After debridement to the subchondral bone, a 2.5mm drill or a burr is used to break sclerotic bone areas.
- In the case of bone defect (e.g. after failed total ankle arthroplasty), an autologous bone graft or allograft is inserted to fill the defect while the foot is strictly held in neutral position. The use of one or two Hintermann® spreaders may be helpful to obtain desired distraction of the tibiotalar joint.
- Cysts are cleaned and filled with cancellous bone graft or bone matrix.

4 Temporary Fixation of the Bones

Crucial for success of the surgery is the obtained position before internal fixation. Optimal position in all planes must be achieved. The use of X-rays or fluoroscopy is highly recommended to check the correct positioning of the bones, plates and screws.

- The positioning of the tibio talar joint will be determined through the help of the anatomical trial plates. Their purpose will allow to check the allocate space for the definite implant.
- Once desired reduction is obtained, a 2.5mm K-wire (115 225) is inserted through the joint, from distal tibia into the talus.
- It is adviced to place the k-wire in the centre of the tibia and in the sagittal plane in order not to interfere with the plates position later on.
- This K-wire will temporarily maintain the position of the talus against the tibia while positioning and fixating the lateral plate.



5 Positioning and Fixation of the Plates

First the lateral plate is positioned and fixed to the talus. Rigid fixation is achieved by 3.5 mm diam. Surfix® fixed angle locking screws. Direction of each screw is given by the precontoured holes. Once the plate is rigidly fixed against the lateral aspect of talar head, angular stability is achieved by insertion of the lock-screws. The k-wire is removed.

Thereafter, the compression forceps is fixed to the first or second proximal hole of the plate and the tibia with a monocortical screw, respectively. By applying compression the talus is moved against the tibia. Once desired compression is achieved, the plate is fixed to the tibia by using either 3.5 mm diam. Surfix® fixed angle or 3.5 mm diam. Surfix® variable angle locking screws; thereby, the talus is pushed medially against the medial malleolus.



5-1 Antero-Lateral Plate

The antero-lateral plate (150 120S or 150 020S depending on the operated side) is fixed first.

- Residual osteophytes hampering the plate positioning have to be removed before positioning properly the plate onto the bone.
- The use of the wedges to be screwed into the tibial holes of the plate (159 103, 159 106, 159 109) can be useful to act as a spacer between the tibia and the plate while positioning correctly the distal part of the plate onto the talus.



Note

The second most proximal threaded hole of the plate can also be used if the skin incision does not allow to have enough space to further position the compression forceps onto the tibia.

5-1a Talar Fixation

The distal part of the lateral plate is fixed with 3 Surfix® fixed angle locking screws to the lateral aspect of the talar neck. In the case of posterior position of the tibia, the provided wedges of various thicknesses (159 103, 159 106, 159 109) can be screwed to the tibial holes of the plate to get it fixed to the talar head with desired distance to the tibia. Thereafter, the wedges can be removed and the tibia will then be pulled anteriorwards against the plate.

1. Drill Screw Holes.

Drilling guides (219 635) are fixed to the plate on the 3 most distal threaded holes using the screwdriver (219 845). (fig.5-1).

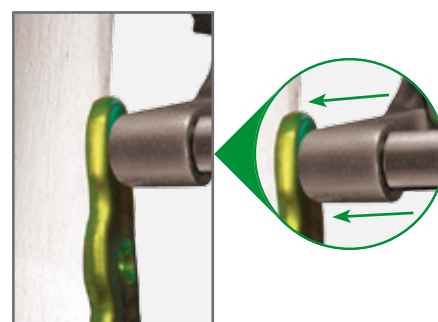
2. Surfix® Fixed Angle Locking Screw Insertion.

Report to the part 4-5 (p. 11).

5-1b Compression of the Joint

Compression of the talus against the tibia and the medial malleolus is achieved with the compression forceps (219 960) attached to the plate with the compression guide (159 635) and to the tibia diaphysis with the compression screw (159 7xx).

1. Insert the compression guide (159 635) through the specific hole of the compression forceps (219 960) and screw this guide in the most proximal threaded hole of the plate.



Caution

Ensure compression guide is fully threaded and seated properly into the plate prior to applying compression.



219 960
Compression
forceps
L. 260 mm



159 635
Compression
guide



219 545
Drill AO
diam. 3.0 mm
L. 190 mm



**159 740 / 159 755
159 760**
Screws for
compression
forceps
L. 40 - 55 & 60 mm



219 845
Screwdriver HEX
dia. 2.5 mm - L. 191 mm



219 445
Screwdriver
AO HEX
dia. 2.5 mm
- L. 76 mm

2. Position the most proximal extremity of the compression forceps on the tibia diaphysis respecting the alignment with the tibial axis of the plate. The distance between the 2 extremities of the compression forceps should be around 2 cm to allow a sufficient compression.



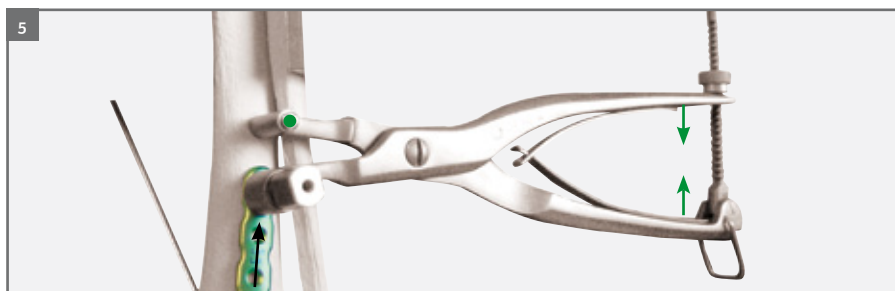
3. Prepare the compression screw insertion (159 740 / 159 755 / 159 760) using the 3 mm drill (219 545) through the hole of the proximal extremity of the compression forceps.



4. Insert the compression screw (159 740 / 159 755 / 159 760) into the tibia through the hole of the proximal extremity of the compression forceps (219 960) using the screwdriver (219 845 / 219 445). The compression forceps is fixed, in an open position, to the plate and the tibia.



5. Compression is applied with the compression forceps as shown on the figure.



5-1C Tibial Fixation

Keeping the compression forceps in place to maintain the compression, the tibial part of the lateral plate is fixed with 4 bicortical Surfix® fixed angle or Surfix® variable angle locking screws to the lateral aspect of the tibial diaphysis. The choice of the use of Surfix® fixed angle or Surfix® variable angle locking screws depends on the need for angulation of the orientation of the screws. If the use of Surfix® variable angle locking screws is needed, using the same number of Surfix® fixed angle and Surfix® variable angle locking screws is recommended. It is also recommended to use a Surfix® fixed angle locking screw into the most proximal threaded hole.

For the Surfix® fixed angle locking screw insertion, report to the Part «Talar Fixation» (p.19).

Note

If the angle is less than 75° or more than 105°, the drilling guide will not fit into the hole.

5-1C Insertion of Surfix® Variable Angle Screw

1. Drill Screw Holes

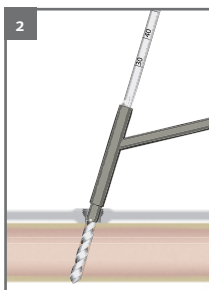
The drilling guide (219 035) specifically designed for the variable angle screws is inserted into the chosen threaded hole to obtain a variation of the angle (+/- 15°) between the plate and the position of a Surfix® fixed angle screw (90°).

Caution

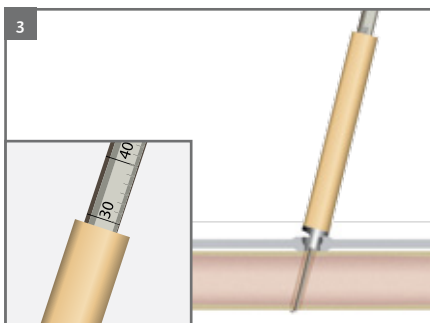
Steps 1 to 6 should be completed for each screw before starting preparation of the subsequent screw(s). If not, the axes of the screw and the prepared hole may be misaligned.

2. Screw Insertion

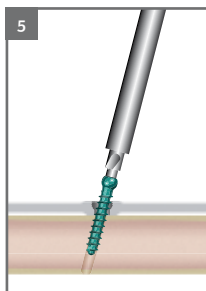
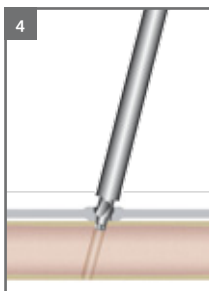
Prepare holes with the 2.7 mm drill (219 535) through the drilling guide (219 635). The screw length can be read from the calibrated scale on the drill. The depth is read from the top side of the drilling guide.



3. Alternately, measure the necessary screw length using the depth gauge (219 335).

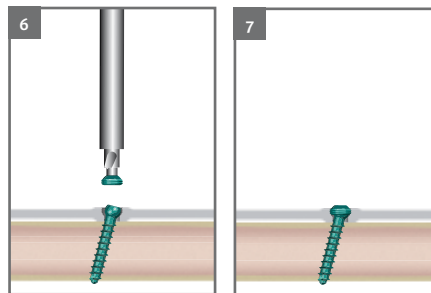


4. Chamfer the drill hole with the screwdriver (219 835). Ensure that the threaded hole is not damaged when performing the chamfering.



5. Insert the screw with the screwdriver (219 835 - 219 435) into the prepared hole until the plate is at the desired position relative to the bone. The screw should be fully seated in the plate. Clean the threaded hole before and after introducing the screw.

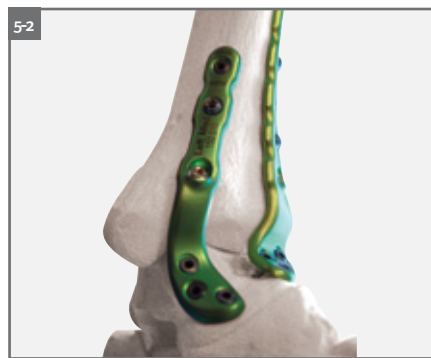
6. Assemble the lock-screw to the hexalobular screwdriver (219 135). The lock-screw should be inserted after each screw, and before preparation and insertion of the subsequent screw. This prevents potential damage to thread. Note that this spherical shaped lock-screw has to be inserted perpendicularly to the plate in order to be screwed properly.



7. Locking: Fully seat the lock-screw with the screwdriver. The lock-screw should close in a curved manner the hole of the plate onto the screw head.

5-2 Antero-Medial Plate

The antero-medial plate (150 010S or 150 110S depending on the operated side) is fixed secondly. Positioning and fixation of this plate is performed exactly in the same way as it has been done with the antero-lateral plate (repeat step 5-1, p.21). Except compression step (compression already performed on the lateral plate).



6 Locking of the Joint

Additional 4mm cortical screws (150 2xxS) crossing and compressing the tibio-talar joint are placed through the tibia to the dorsal part of the talus. This allows a further stabilization of the joint with a more posterior fixation, and also fixation of the bone graft in the cases it has been needed with a transarticular fixation.



1. Drill the Screw Holes

The drilling guide (159 130) is inserted into the most distal tibial hole (non threaded). The orientation of the guide should allow the drill to go from the tibia to the posterior aspect of the talus.

Prepare the insertion of the screw using the 3mm drill (219 545) through the drilling guide. The drill should not be inserted too deeply in order to avoid the 2nd cortical aspect of the talus, which is part of the sub-talar joint. Use of X-Ray or fluoroscopy is recommended to check the good positioning of the drill.





159 130
Drilling guide
diam. 3.0 mm



219 545
Drill AO
diam. 3.0 mm
L. 190 mm



219 845
Screwdriver HEX
dia. 2.5 mm - L. 191 mm



219 445
Screwdriver AO HEX
dia. 2.5 mm - 76 mm



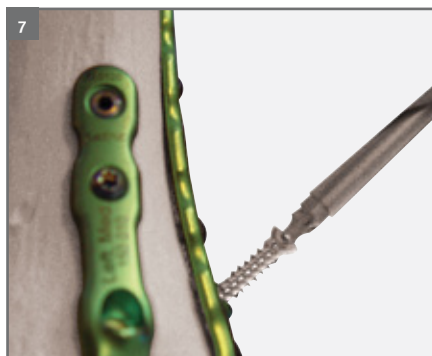
219 335
Length gauge
dia. 3.5 mm
screws

2. Screw insertion

Insert the screw into the prepared hole using the screwdriver (219 445 / 219 845).

7 Closure and End of the Procedure

- Final check by fluoroscopy.
- The longitudinal incision of the extensor retinaculum is closed by continuous absorbable 0 suture.
- The skin is closed with interrupted non-absorbable 3-0 sutures.
- A drain is not used routinely.
- A thick compressive dressing is applied and the foot placed in a reusable prefab splint.
- The tourniquet is deflated.



8 Postoperative Care

- At the second postoperative day, the compressive dressings and prefabricated splint are replaced by a removable cast. This allows the use of an inflatable footpump in case of substantial postoperative swelling.
- After subsidence of the swelling (mostly between day 6 and 14 days postop), a below-knee walking cast is applied and left in place until the eighth postoperative week included.
- Removal of the stitches should not be done before the 14th postoperative day.
- Once the walking cast is applied properly, weight-bearing is allowed as tolerated; usually full weightbearing is achieved after 10 to 14 days postoperatively.
- At eight weeks, the cast is removed and standard radiographs are made. If bony fusion is considered not to be sufficient, a removable walking cast is applied for another 4 to 6 weeks. If the fusion is considered to be sufficient, the patient is allowed for free ambulation on custom shoes.
- Low molecular heparin or oral anticoagulants should be given, as long as the walking cast is in place or free full weight bearing is not granted.

Notes

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.

Newdeal®'s products are made from Titanium alloy Ti-6Al-4V (ISO 5832-3 / ASTM F136).

Indications

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

Arthrodesis, osteotomies and fractures of ankle joint, distal tibia and fibula.

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

Anterior plates for ankle arthrodesis have to be fixed with the TIBIAXYS cortical screws dia. 4 mm too.o.

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 be bent excessively, 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 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 and warrant that the products are free from manufacturing defects. Newdeal excludes all other 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.

References



Osteotomy Plates

Reference	Description
150 130S	Medial right / Lateral left osteotomy plate
150 030S	Lateral right / Medial left osteotomy plate
150 040S	Medial osteotomy plate

Fibula Plates


Reference	Description
150 514S	4 Holes fibula plate
150 516S	6 Holes fibula plate

Container = 159 991


Reference	Description
159 960	Base
996 200	Lid
119 909	Silicone wedge



Cortical Screw Diam. 4.0 mm + Diam. 6.0mm Head	
Reference	Length
150 240S	40 mm
150 242S	42 mm
150 246S	46 mm
150 250S	50 mm
150 255S	55 mm
150 260S	60 mm
150 265S	65 mm
150 270S	70 mm
150 275S	75 mm
150 280S	80 mm
150 285S	85 mm
150 290S	90 mm
150 200S	100 mm



Surfix® Fixed Angle Screw Diam. 3.5 mm + Lock Screw	
Reference	Length
285 310S	10 mm
285 312S	12 mm
285 314S	14 mm
285 316S	16 mm
285 318S	18 mm
285 320S	20 mm
285 322S	22 mm
285 324S	24 mm
285 326S	26 mm
285 328S	28 mm
285 330S	30 mm
285 332S	32 mm
285 334S	34 mm
285 336S	36 mm
285 338S	38 mm
285 340S	40 mm
285 344S	44 mm
285 348S	48 mm
285 350S	50 mm



Surfix® Variable Angle Screw Diam. 3.5 mm + Lock Screw	
Reference	Length
295 310S	10 mm
295 312S	12 mm
295 314S	14 mm
295 316S	16 mm
295 318S	18 mm
295 320S	20 mm
295 322S	22 mm
295 324S	24 mm
295 326S	26 mm
295 328S	28 mm
295 330S	30 mm
295 332S	32 mm
295 334S	34 mm
295 336S	36 mm
295 338S	38 mm
295 340S	40 mm
295 344S	44 mm
295 348S	48 mm
295 350S	50 mm



150 010S



150 020S



150 120S



150 110S

Ankle Arthrodesis Plates

Reference	Description
150 010S	Left medial anterior plate
150 020S	Left lateral anterior plate
150 110S	Right medial anterior plate
150 120S	Right lateral anterior plate

Container: 159 970

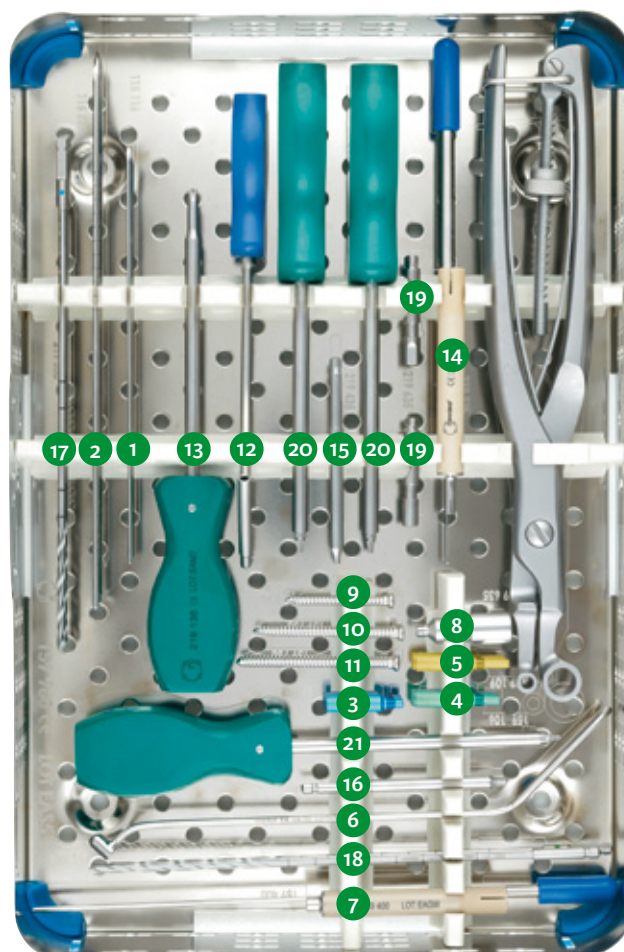
Reference	Description
159 010	Left medial anterior trial plate
159 020	Left lateral anterior trial plate
159 110	Right medial anterior trial plate
159 120	Right lateral anterior trial plate

Container: 159 970

Reference	Description
159 071	Base
309 942	Lid

Instruments

#	Reference	Description
1	115 116	K-wire - diam. 1.6 mm - L. 150 mm
2	115 225	K-wire - diam 2.5 mm - L. 200 mm
3	159 103	Wedge thickness 3 mm
4	159 106	Wedge thickness 6 mm
5	159 109	Wedge thickness 9 mm
6	159 130	Drilling guide - diam. 3.0 mm
7	159 400	Length gauge - diam. 4.0 mm screws
8	159 635	Compression guide
9	159 740	Screw for compression forceps diam. 4 mm - L. 40 mm
10	159 755	Screw for compression forceps diam. 4 mm - L. 55 mm
11	159 760	Screw for compression forceps diam. 4 mm - L. 60 mm
12	219 035	Drilling guide - variable angle screw
13	219 135	Screwdriver hexalobular t10
14	219 335	Length gauge diam. 3.5 mm screws
15	219 435	Screwdriver AO - diam. 2.0 mm - L. 76 mm - HEX
16	219 445	Screwdriver AO - diam. 2.5 mm - L. 76 mm - HEX
17	219 535	Drill AO - diam. 2.7 mm - L. 125 mm
18	219 545	Drill AO - diam. 3.0 mm - L. 190 mm
19	219 635	Drilling guide - diam. 2.7 mm
20	219 835	Screwdriver - diam. 2.0 mm - L. 180 mm - HEX
21	219 845	Screwdriver diam. 2.5 - L. 191 mm - HEX
22	219 960	Compression forceps - L. 260 mm



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