ENG

Integra®

Advansys® Midfoot Plating System

SURGICAL TECHNIQUE

INTEGRA®
LIMIT UNCERTAINTY

Products for sale in Europe, Middle-East and Africa only.

Table of Contents

Indications

The Dorsal Lisfranc Plates are intended for fractures, fusions, osteotomies and replantations of small bones at the tarsometatarsal joints (Lisfranc Joints).

Contraindications

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

- Active local or systemic infection.
- Severe peripheral vascular disease.
- 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:

3 sizes of implants:

- 3 right & 3 left plates (small, medium and large).
- 3.5 mm diameter Surfix® screws available in lengths from 8 to 34 mm in 2 mm increments.
- 3.5 mm lock-screws.

Material:

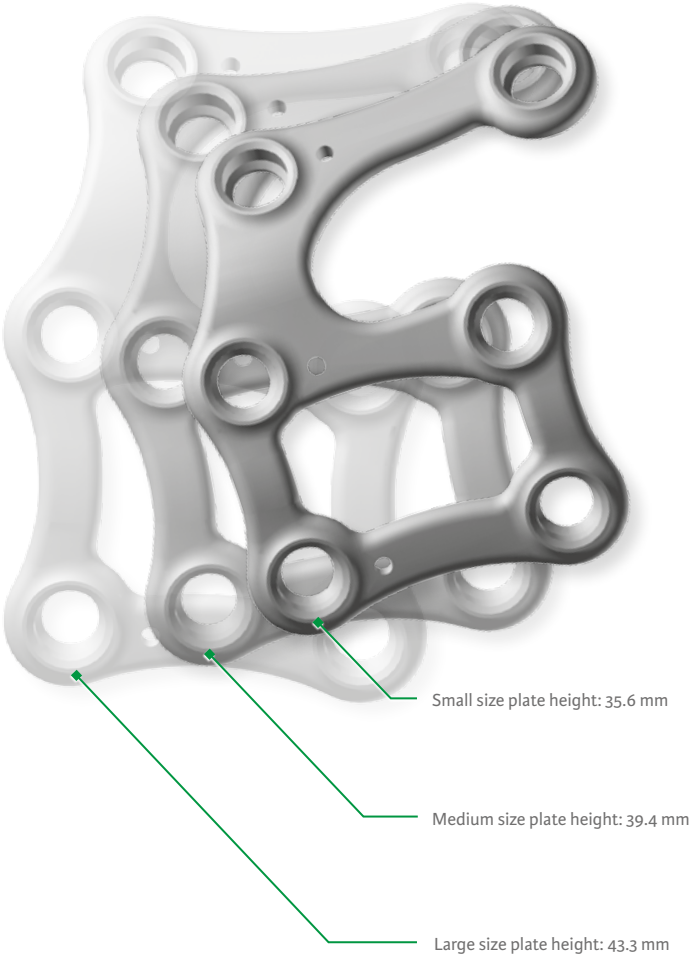
- Plates: Stainless steel 316L (ISO 5832-1 / ASTM F138&139).
- Screws: Titanium alloy Ti-6Al-4V (ISO 5832-3 / ASTM F136).

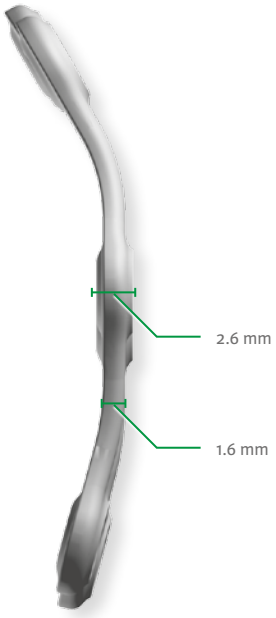
Instruments

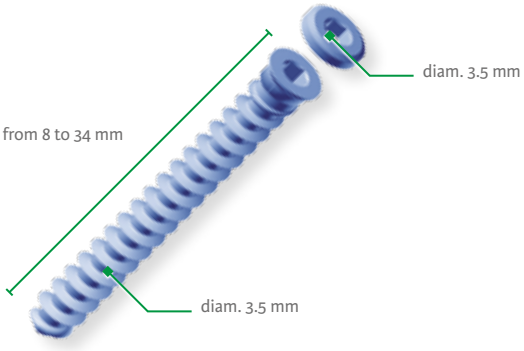
Some generic and specific instruments are available in the mid-foot set.

- The generic instruments include screwdrivers and drills used to implant the 3.5 mm screws and lock-screws.
- Specifically designed instruments include the plate benders, drill guides and plate trials.

Note
Please refer to Instrument Set Diagram (P. 17) for additional information.





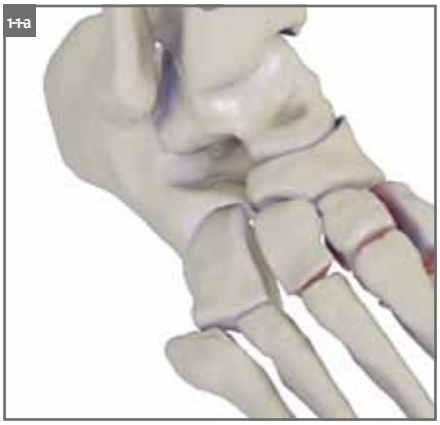


Introduction

As the manufacturer of this device, Newdeal 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 procedure is responsible for determining and using the appropriate technique in each patient.
Designed in conjunction with Robert Anderson, MD, Bruce Cohen, MD and Hodges Davis, MD

Preparation

1-1 **Articular surfaces preparation**
The articular surfaces should be prepared using standard technique to resect the necessary amount of cartilage and, if necessary, to remove bone graft material. (Figure 1-1-a).
The final plate placement is shown in figure 1-1-b.

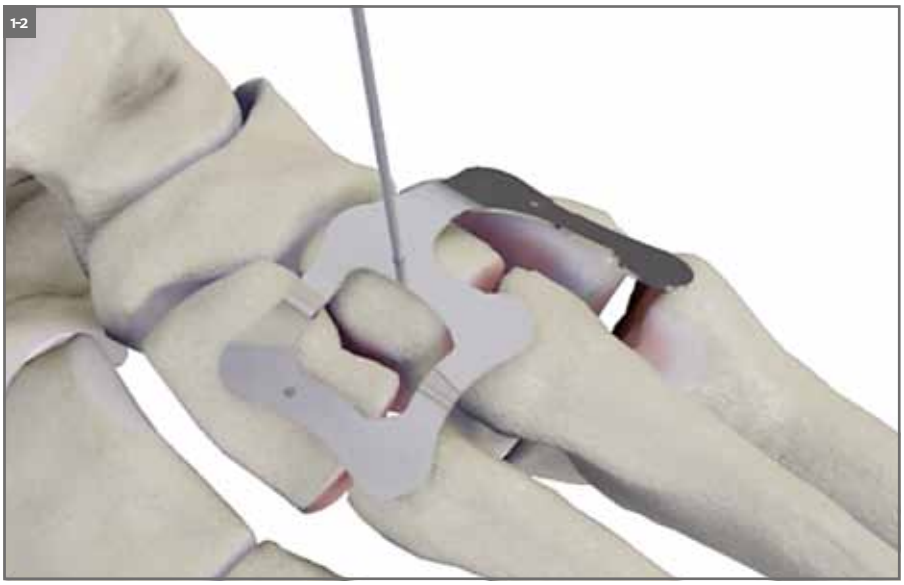

1-1-a


1-1-b

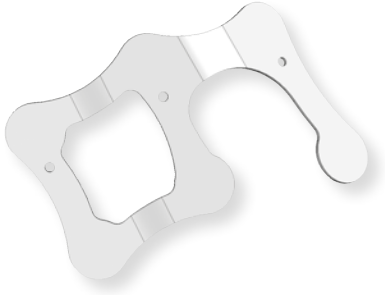
1-2 **Trials positioning**
Trials (169 021, 169 022, 169 023, 169 031, 169 032 and 169 033) are used to determine the appropriate implant size.
Trials are positioned dorsally (Figure 1-2), in order to provide:

- 3 distal holes facing anterior toward the bases of the 1st, 2nd and 3rd metatarsals,
- 3 proximal holes facing the 3 cuneiforms.

A k-wire (115 100) is used for temporary fixation of the trial, or the plate.
Additional k-wires may be used to provide additional stability.
The trials are flexible and allow contouring to the dorsal surface of the cuneiforms and metatarsals.
The contoured trial may be used as a template for contouring the final implant later in the procedure.


1-2

Trials (169 021, 169 022, 169 023, 169 031, 169 032 and 169 033)



1-3

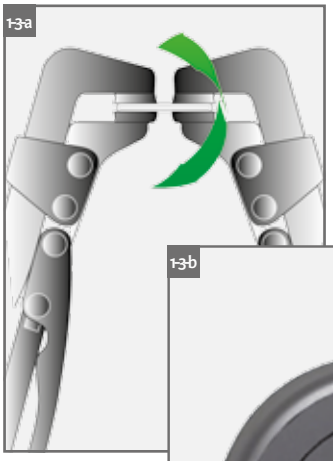
1.3.a • Plate contouring

The plates are pre-bent to better fit the anatomy of the midfoot. However, when deemed necessary by the surgeon, the plate may be further contoured using plate benders (219 735). (Fig. 1.3-a & 1.3-b)

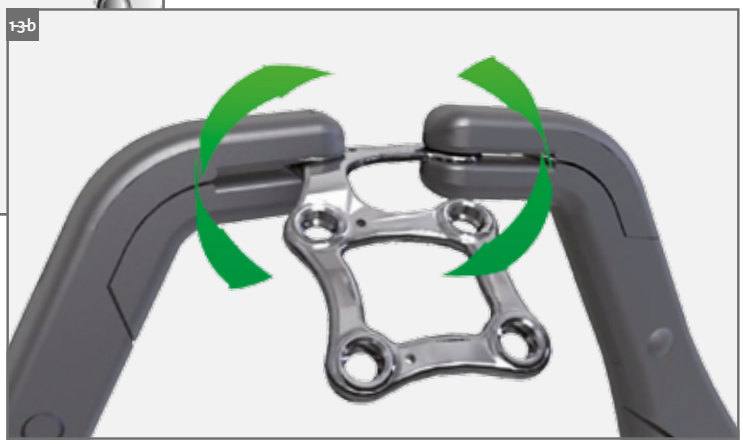
Caution

It is imperative that the bending be implemented between two consecutive lipped holes. If this is not the case, the intermediate locking threads may be damaged or deformed and prevent optimal functioning of the lock-screw mechanism. Bend the plate only once, and not excessively.

1-3a



1-3b

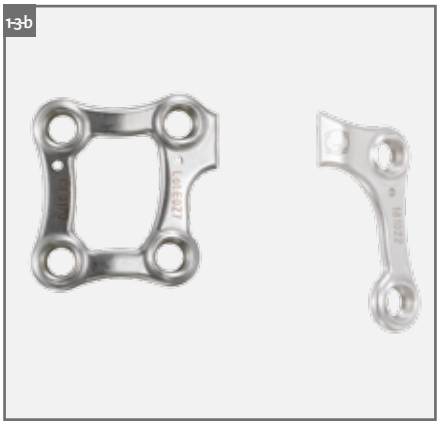


1-3

1.3.b • Optional plate cutting

An optional plate cutter may be used to remove the medial flange of the plate as shown in figure 1-3-b. Care should be taken to cut the flange as close as possible to the raised area around the middle posterior screw (2nd cuneiform screw).

1-3b



1-4

Implant positioning

The implant is selected, based on the size defined by the trial plate. The plate can slide along the k-wire used to position the trial plate (Fig. 1-4). The k-wire provides a temporary fixation during preparation of the screw holes.

1-4

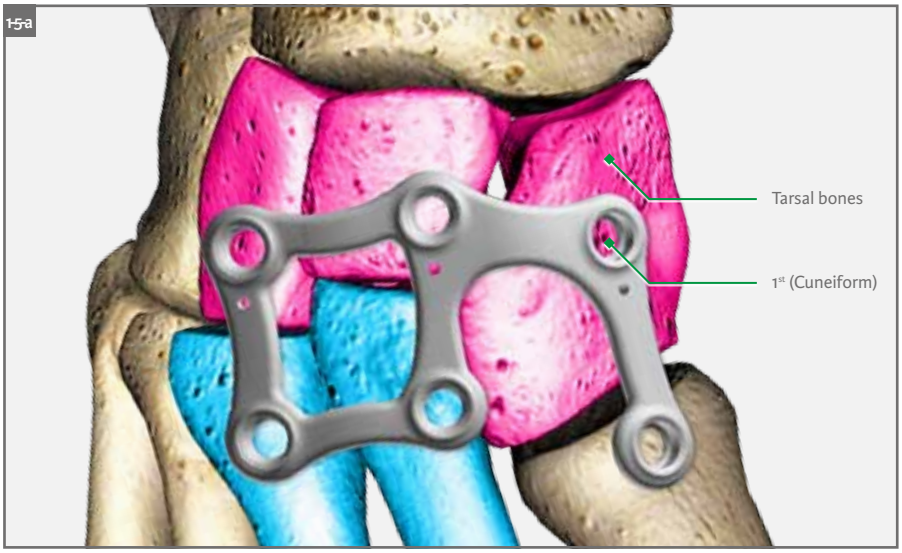
1-5

Drill screw holes

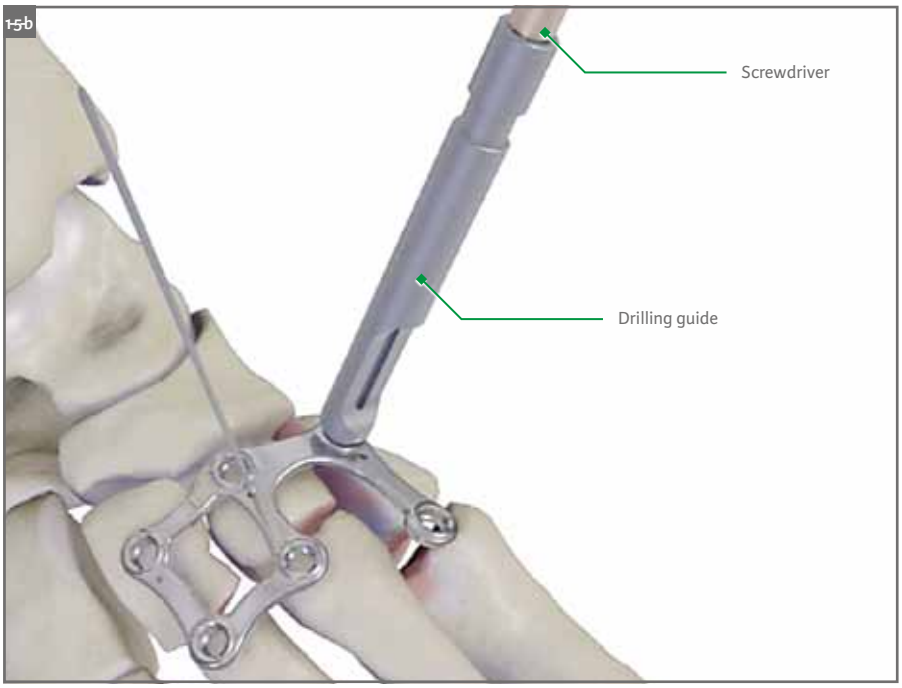
Holes are prepared starting with the 1st cuneiform, as shown in figures 1-5-a and 1-5-b.
K-wires may be used to temporarily hold the plate in position until the screws are inserted.
Drilling guides (219 635) are fixed to the plate on the appropriate lipped socket, using the screwdriver (219 835).

Note
The screws should be mono-cortical.

1-5a



1-5b

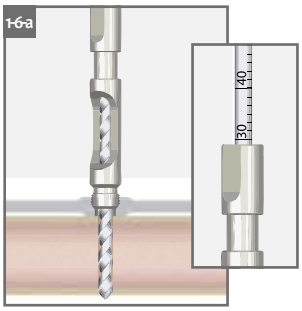


1-6 Screw insertion

For each hole, the following steps must be followed as shown in figures 1.6-a to 1.6-f:

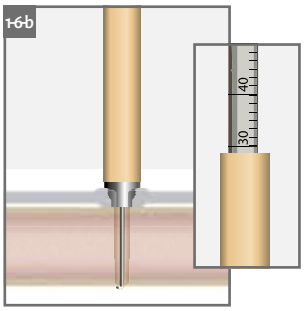
Caution
Steps a to f should be completed for each screw before starting preparation of the subsequent screw(s). If not, the axes of the screw and the prepared hole may be misaligned.

1-6a



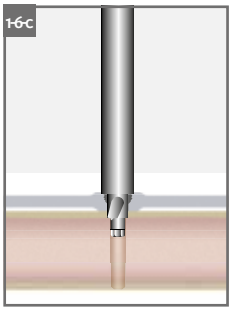
Prepare holes with the 2.7 mm drill (219 535) through the drilling guide. The screw length can be read from the calibrated scale on the drill. The depth is read from the top side of the drilling guide.

1-6b



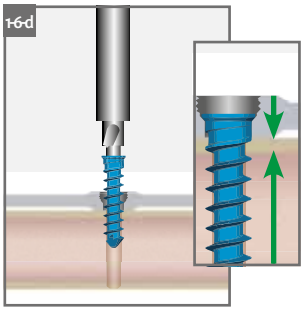
Alternately, measure the necessary screw length using the length gauge (219 335), after having removed the drilling guide.

1-6c



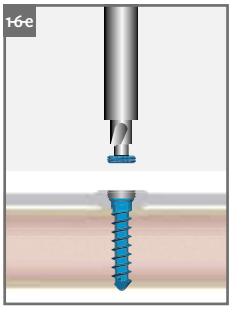
Chamfer the drill hole with the screwdriver. Ensure that the threaded hole is not damaged when performing the chamfering.

1-6d



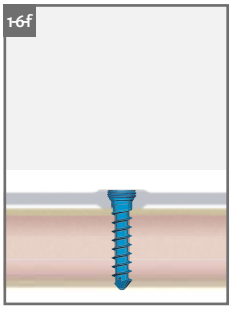
Insert the screw into the prepared hole until the plate is at the desired position relative to the bone. The screw should be fully seated in the plate. Clean the threaded hole before and after introducing the screw. Maintain co-axiality between the screw and the threaded hole.

1-6e



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

1-6f



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.

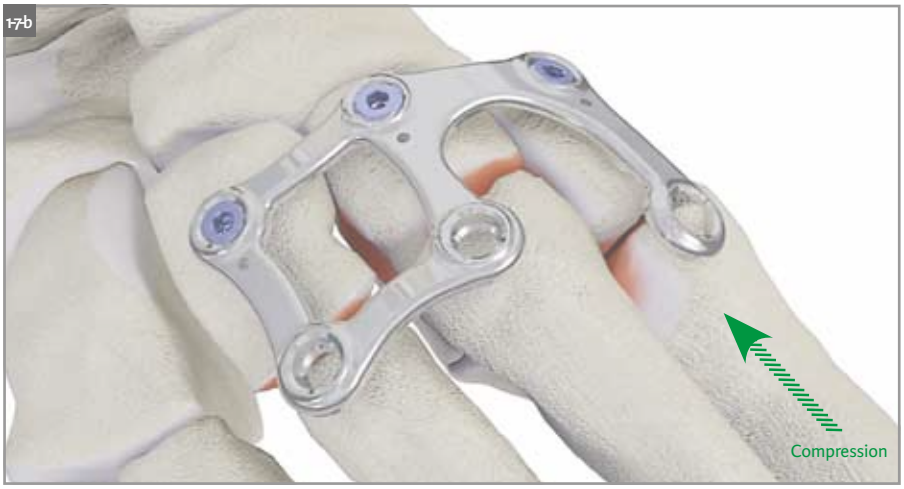
1-7

Arthrodesis reduction

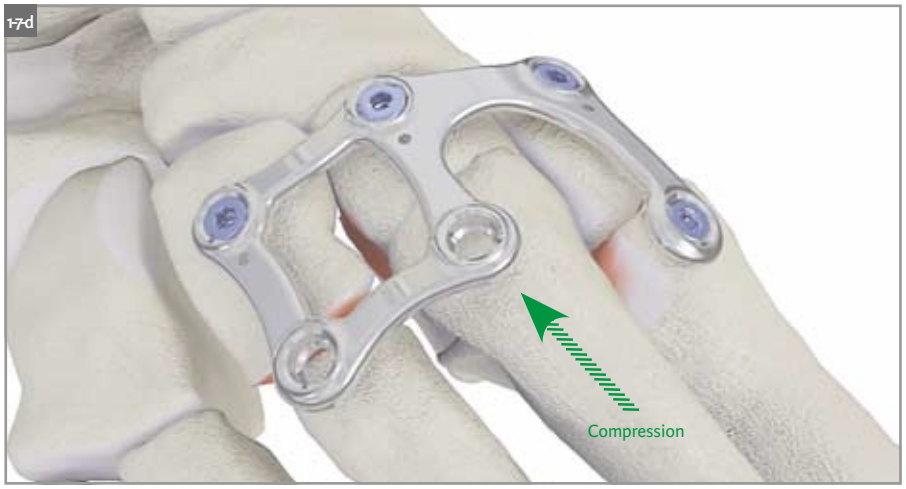
After insertion of the cuneiform screws (Fig. 1-7-a), remove any k-wires used for temporary fixation, compression is applied manually and is maintained to reduce the arthrodesis (Fig. 1-7-b).
Repeat the insertion process for each hole in the base of the 1st, 2nd and 3rd metatarsals (Fig. 1-7-c > 1-7-g).

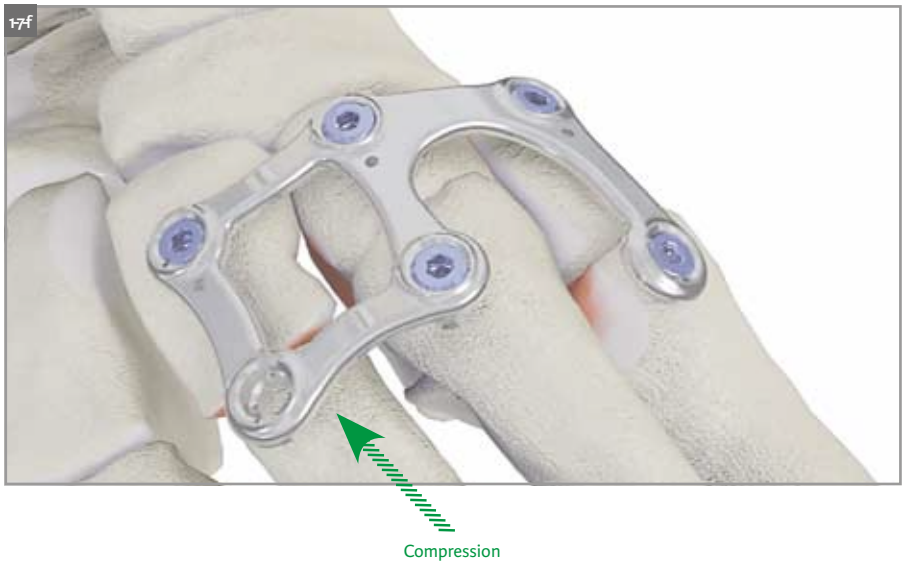
1-7-a

1-7-b

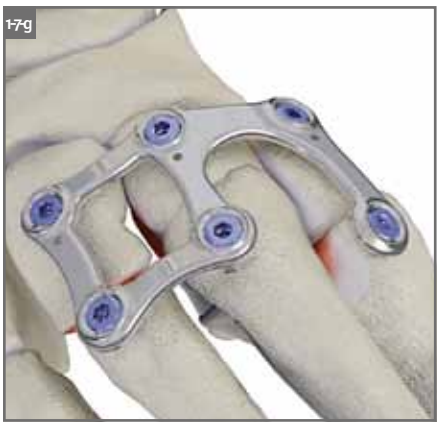


1-7-c





A representative view of the final plate placement is shown in figure 1-7-g.



Indications

For bone fixation such as:

- arthrodesis of the 1st metatarsocuneiform joint to reposition and stabilize a metatarsus primus varus,
- Lisfranc arthrodesis,
- Mono or bi-cortical osteotomies or fractures near the 1st metatarsocuneiform joint.

Contraindications

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

- active local or systemic infection,
- severe peripheral vascular disease,
- 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:

2 sizes of implants:

- 2 right & 2 left plates (small and large sizes)
- 3.5 mm diameter Surfix® screws available in lengths from 8 to 34 mm in 2 mm increments
- 3.5 mm lock-screws

Material:

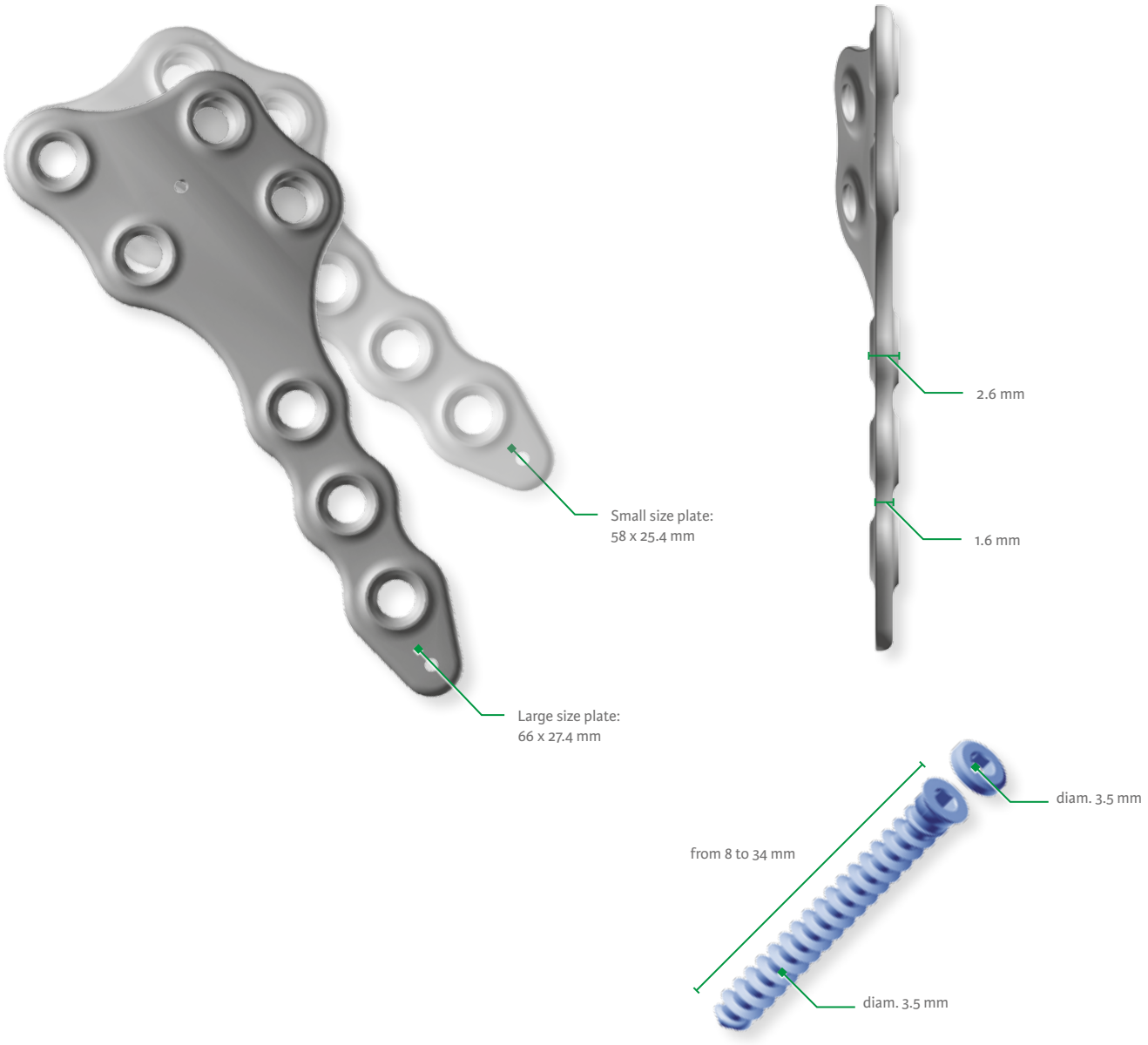
- Plates: Stainless steel 316L (ISO 5832-1 / ASTM F138&139)
- Screws: Titanium alloy Ti-6Al-4V (ISO 5832-3 / ASTM F136)

Instruments

Some generic and specific instruments are available in the mid-foot set.

- The generic instruments include screwdrivers and drills used to implant the 3.5 mm screws and lock-screws.
- Specifically designed instruments include the plate benders, drill guides and plate trials.

Note
Please refer to Instrument Set Diagram (P. 17) for additional information.



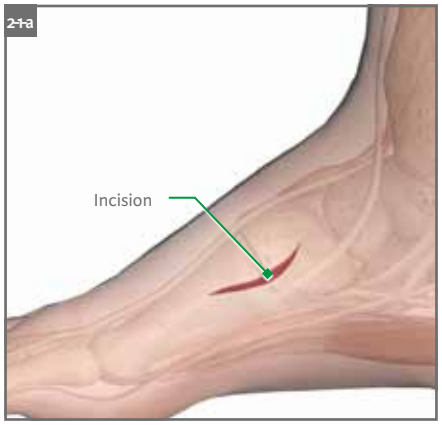
Introduction

As the manufacturer of this device, Newdeal 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 procedure is responsible for determining and using the appropriate technique in each patient.
Designed in conjunction with Robert Anderson, MD, Bruce Cohen, MD and Hodges Davis, MD

Preparation

2-1 **Articular surfaces preparation**

The articular surfaces should be prepared using standard technique to resect the necessary amount of cartilage and, if necessary, to remove bone graft material. (fig 2-1-a).
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 M.L.P. and screws.
The implant placement is shown in figure 2-1-b.



Caution
- Dorso-medial incision has to be performed. The bone of the proximal metatarsal and the medial cuneiform is exposed with care of the overlying structures (Fig. 2-1-a).
- The plate is to be placed on the bone and has to be implanted beneath the tibialis anterior tendon (Fig. 2-1-b).

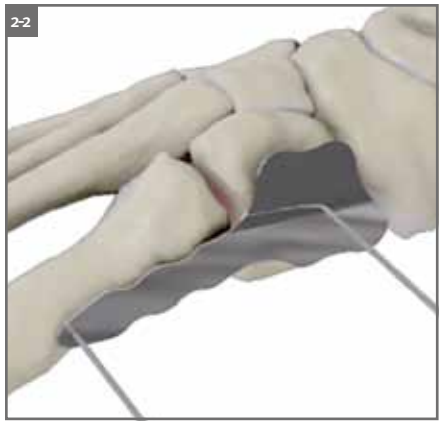
Caution
⚠ Never implant the screw Ø3.5 through the tibialis anterior tendon (Fig. 2-1-b).
⚠ During surgery care should be taken to maintain the attachment of tibialis anterior tendon.
⚠ Never detach the tibialis anterior tendon but if necessary unstuck it from the bone.

2-2 **Trials positioning**

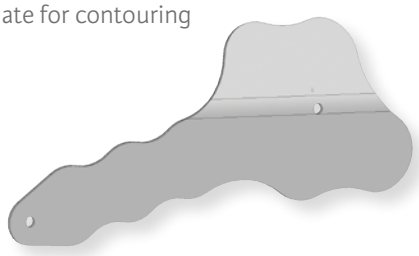
Trials (169 041, 169 042, 169 051, 169 052) are used to determine the appropriate implant size.
Trials are positioned medially as shown in figure 2.2, in order to provide:

- 3 distal holes in the proximal part of the 1st metatarsal.
- 4 proximal holes in the 1st cuneiform. Two k-wires (115 100) are used for temporary fixation of the trial, and plate.

The trials are flexible and allow contouring to the medial surface of the cuneiform, metatarsal and potentially the navicular bone.
The contoured trial may be used as a template for contouring the final implant later in the procedure.



Trials (169 041, 169 042, 169 051, 169 052)



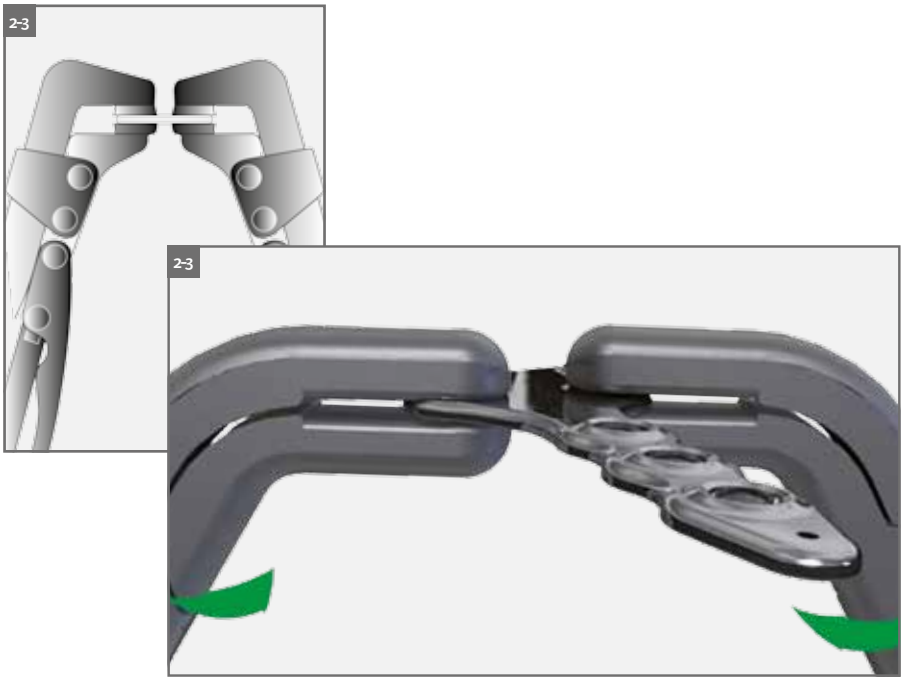
2-3

Plate contouring

The plates are pre-bent to better fit the anatomy of the midfoot. However, when deemed necessary by the surgeon, the plate may be further contoured using plate benders (219 735).

Caution

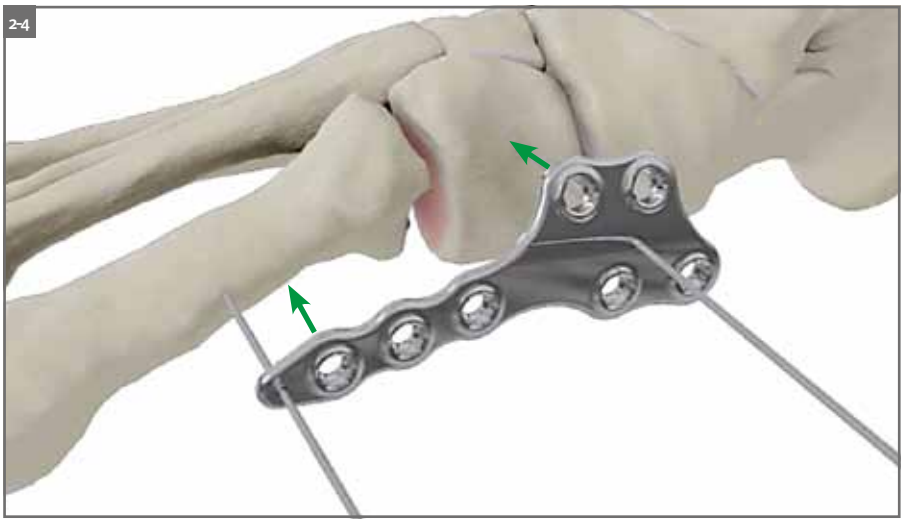
It is imperative that the bending be implemented between two consecutive lipped holes. If this is not the case, the intermediate locking threads may be damaged or deformed and prevent optimal functioning of the lock-screw mechanism. Bend the plate only once, and not excessively.



2-4

Implant positioning

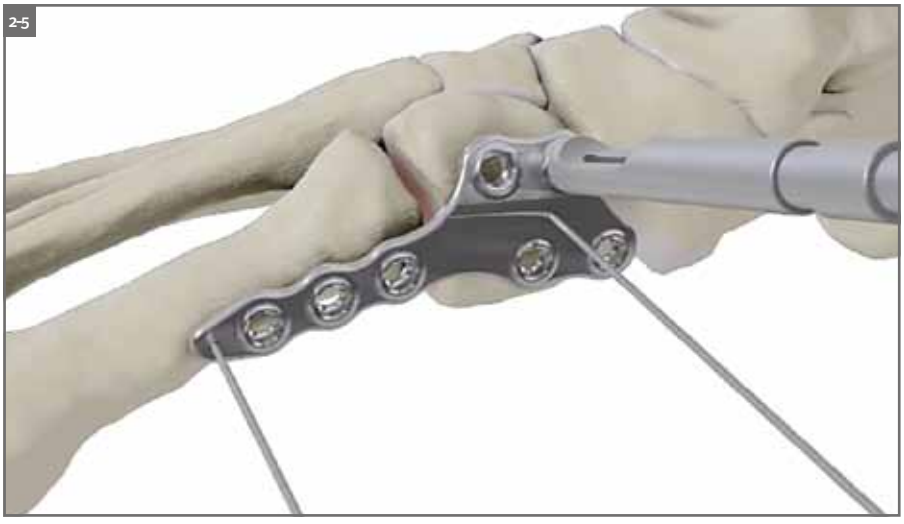
The final plate is selected, based on the size defined using the trial plate. The plate can slide along the k-wires used to position the trial plate (Fig. 2-4).
The k-wires serve as temporary fixation during preparation of the screw holes.



2-5

Drill screw holes

Holes should be prepared, starting with one of the dorsal proximal screw holes as shown in figure 2-5. K-wires may be used to temporarily hold the plates in position until the screws are inserted.
Drilling guides (219 635) are fixed to the plate on the appropriate threaded holes using the screwdriver (219 835).



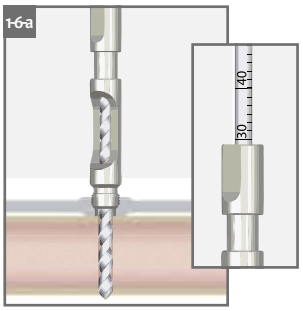
2-6

Screw insertion

For each hole, the following steps must be followed as shown in figures 2.6-a to 2.6-f:

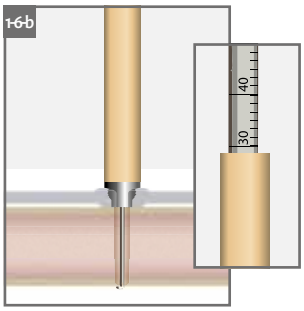
Caution
Steps a to f should be completed for each screw before starting preparation of the subsequent screw(s). If not, the axes of the screw and the prepared hole may be misaligned.

1-6a



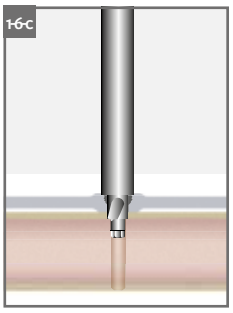
Prepare holes with the 2.7 mm drill (219 535) through the drilling guide. The screw length can be read from the calibrated scale on the drill. The depth is read from the top side of the drilling guide.

1-6b



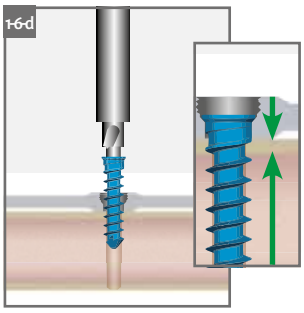
Alternately, measure the necessary screw length using the length gauge (219 335), after having removed the drilling guide.

1-6c



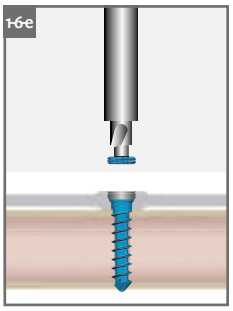
Chamfer the drill hole with the screwdriver. Ensure that the threaded hole is not damaged when performing the chamfering.

1-6d



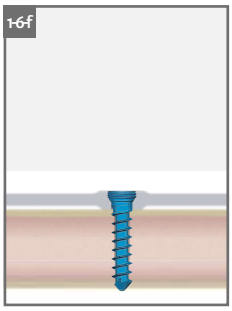
Insert the screw into the prepared hole until the plate is at the desired position relative to the bone. The screw should be fully seated in the plate. Clean the threaded hole before and after introducing the screw. Maintain co-axiality between the screw and the threaded hole.

1-6e



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

1-6f



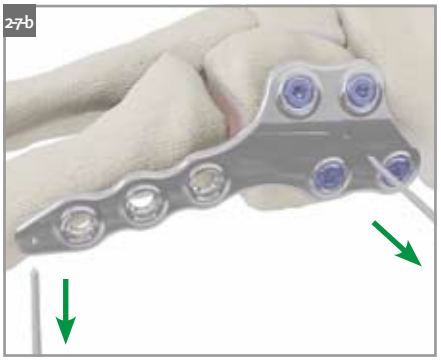
Locking:
Fully seat the lock-screw with the screwdriver.The lock-screw should be flush with the top of the plate when it is fully inserted.

2-7 Arthrodesis reduction

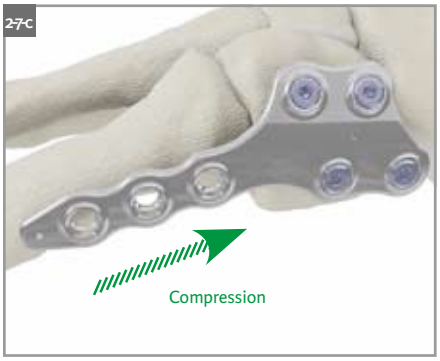
After insertion of the cuneiform screws, remove all k-wires used for temporary fixation (Fig. 2-7-b), compression is applied manually and is maintained to reduce the arthrodesis (Fig. 2-7-c). Repeat the screw insertion procedure for the holes in the base of the 1st metatarsal (Fig. 2-7-d & 2-7-e).

2-7a

2-7b



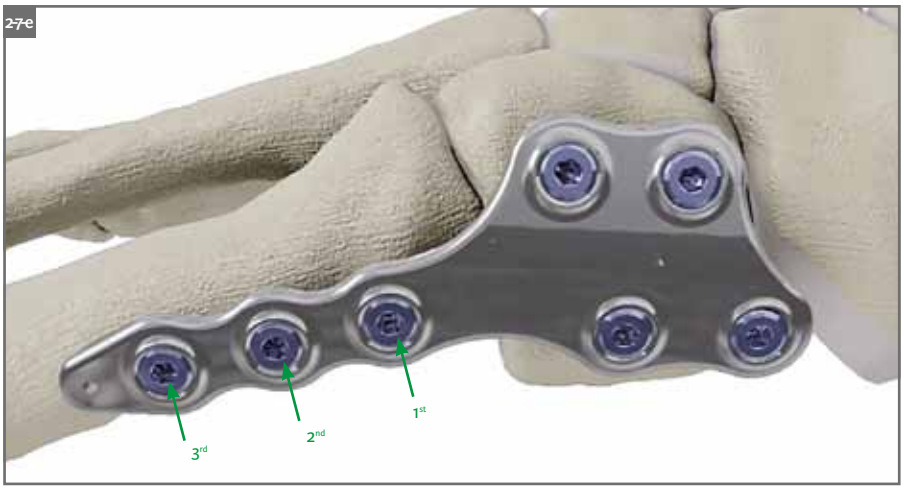
2-7c



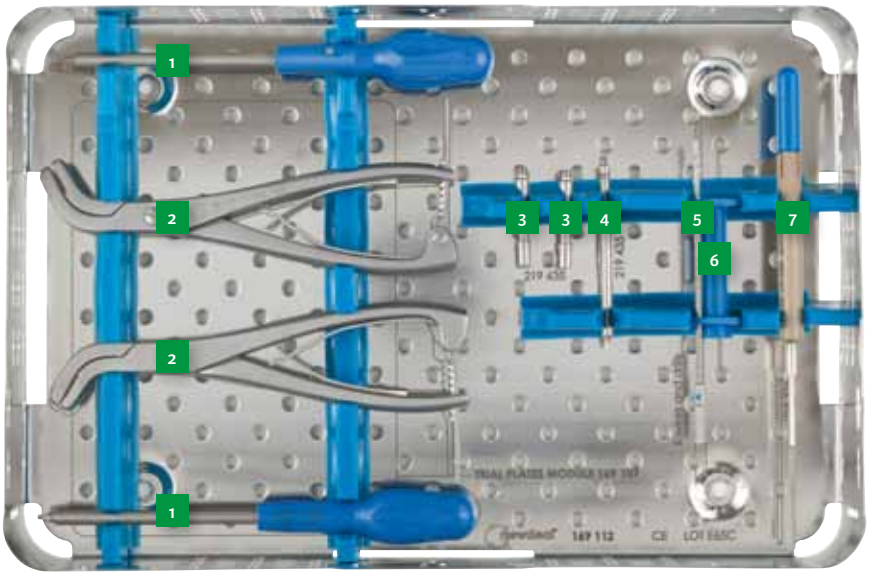
2-7d

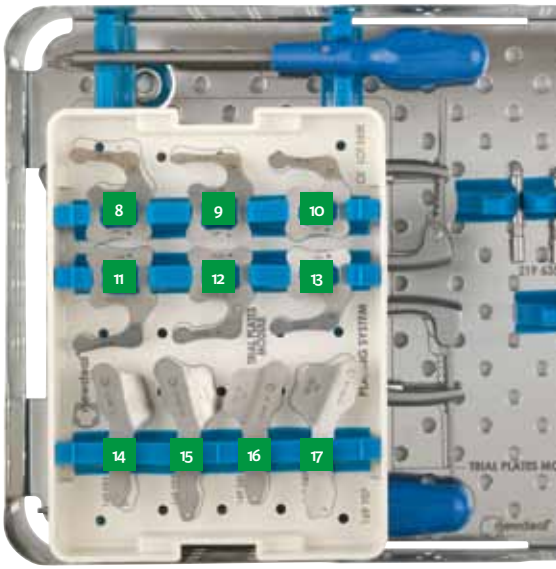
A representative view of the final plate placement is shown in figure 2-7-e.

2-7e



Notes





Instruments

	Reference	Description
1	219 835	Screwdriver / Hexa 2.0 mm, L. 180 mm
2	219 435	Screwdriver / AO, hexa 2.0 mm, L. 76 mm
3	219 635	Drilling guide, diam. 2.7 mm
4	219 535	Drill, diam. 2.7 mm
5	219 735	Bending forceps, diam. 3.5 hole, L. 171 mm
6	219 335	Depth gauge, diam. 3.5 mm screws
7	115 100	K-wire, diam. 1.0 mm, L. 100 mm
8	169 021	Dorsal trial plate, right, small
9	169 022	Dorsal trial plate, right, medium
10	169 023	Dorsal trial plate, right, large
11	169 031	Dorsal trial plate, left, small
12	169 032	Dorsal trial plate, left, medium
13	169 033	Dorsal trial plate, left, large
14	169 041	Medial trial plate, right, small
15	169 042	Medial trial plate, right, large
16	169 051	Medial trial plate, left, small
17	169 052	Medial trial plate, left, large

Integra
Advansys® Midfoot Plating System

References

Advansys® Dorsal Lisfranc Plates

Reference	Description
181 021S	Right - Small size
181 022S	Right - Medium size
181 023S	Right - Large size
181 031S	Left - Small size
181 032S	Left - Medium size
181 033S	Left - Large size

Advansys® Medial Lisfranc Plates

Reference	Description
181 041S	Right - Small size
181 042S	Right - Large size
181 051S	Left - Small size
181 052S	Left - Large size

Surfix® Locking Screw diam. 3.5 mm + lock-Screw

Reference	Description
285 308S	08 mm
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
185 300S	Lock-Screw diam. 3.5 mm

Instruments

Reference	Description
219 835	Screwdriver / Hexa 2.0 mm, L. 180 mm
219 435	Screwdriver / AO, hexa 2.0 mm, L. 76 mm
219 635	Drilling guide, diam. 2.7 mm
219 535	Drill, diam. 2.7 mm
219 735	Bending forceps, diam. 3.5 hole, L. 171 mm
219 335	Depth gauge, diam. 3.5 mm screws
115 100	K-wire, diam. 1.0 mm, L. 100 mm
169 021	Dorsal trial plate, right, small
169 022	Dorsal trial plate, right, medium
169 023	Dorsal trial plate, right, large
169 031	Dorsal trial plate, left, small
169 032	Dorsal trial plate, left, medium
169 033	Dorsal trial plate, left, large
169 041	Medial trial plate, right, small
169 042	Medial trial plate, right, large
169 051	Medial trial plate, left, small
169 052	Medial trial plate, left, large

Container = 169 102

Reference	Description
169 112	Base
169 103	Lid
169 106	Cylinder
169 107	Module

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