Integra™

Uni-CP Compression Plating System

SURGICAL TECHNIQUE

INTEGRA™
LIMIT UNCERTAINTY

Table of contents

Indications

The UNI-CP compression plates are indicated for fixation of bone fractures or for bone reconstruction:

- Arthrodesis in foot and ankle surgery.
- Fractures management in the foot and ankle.
- Mono or bi-cortical osteotomies in the foot and ankle.

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.

Description

- 3 plate configurations:
  - » 2 hole design (17, 20, 25, and 30 mm interaxis)
  - » 4 hole design (20, 25, and 30 mm interaxis)
  - » 4 hole T-shape design (20 mm interaxis)
- Range of screw lengths
  - » 12 mm to 40 mm in 2 mm increments
- Surfix® Locking Technology
- Material:
  - » Plates: Stainless steel 316L (ISO 5832-1 / ASTM F138&139)
  - » Screws: Titanium alloy Ti-6Al-4V (ISO 5832-3 / ASTM F136)

339 004
Trial plate t et u

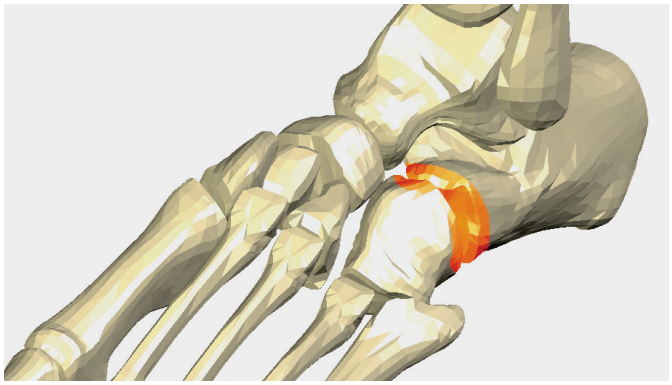
339 005
Implant sizer 2 and 4 holes

Surgical technique

This technique has been developed with the help of Stephen Conti, 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. Surgical approach

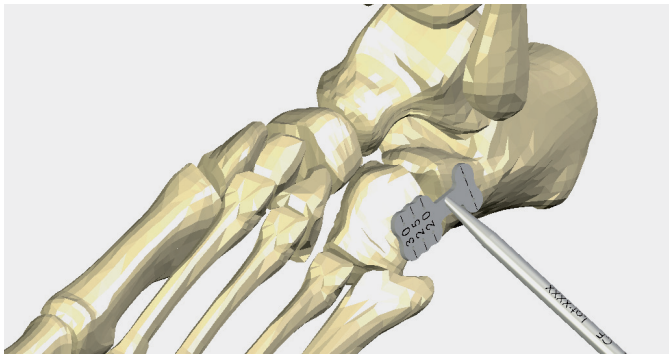
The articular surfaces should be prepared using standard technique to resect the necessary amount of cartilage and, if necessary, to remove bone graft material. Obtain adequate reduction and provisional fixation using guide wires or reduction forceps.



2. Positioning trial plate

Use the trial implant (339 005, 339 004) to determine the ideal plate configuration and position. Depending on the indication, the surgical exposure may not accommodate the trial plate. Place the graduated end of the trial over the larger bone (fragment), under the soft tissue to minimize irritation.

HINT
1mm guide wires can be placed through the trial to maintain plate alignment if desired.




115 101
K-wire
diam. 1.0 mm,
L. 100 mm


219 735
Bending Forceps
diam. 3.5 mm hole,
L. 171 mm

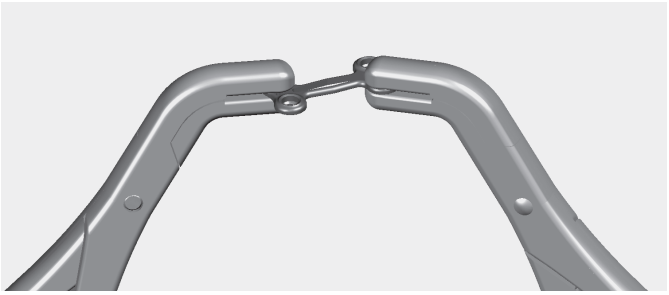

219 635
Drilling guide
diam. 2.7 mm


219 835
Screwdriver/Hex.
diam. 2.0 mm,
L. 180 mm


339 003
Holder

3. Plate contouring

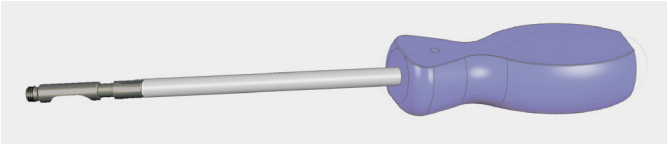
The chosen plate can be contoured, prior to application, to better fit the patient's anatomy. A set of two plate benders (219 735) are included to aid in this process. **It is important to position the benders in the locking holes to protect the locking mechanical properties of the plate design. If this is not the case, the intermediate locking threads may be damaged or deformed, thus preventing optimal functioning of the lock-screw mechanism.**



WARNING
The plate will weaken with excessive bending.
The Uni CP plate may be bent only once and should not be bent excessively.
Attach the drill guides to the appropriately contoured plate.

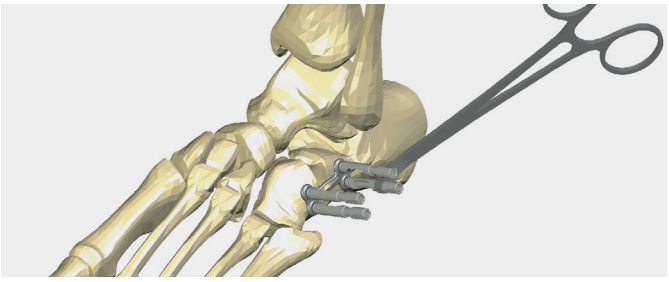
4. Assembling the drill guides

Assemble the drilling guides to the bended plate.

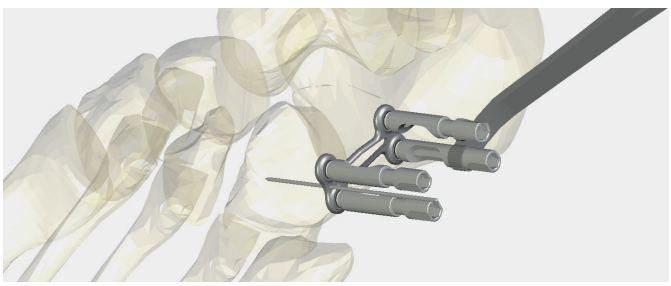


5. Drilling and hole preparation

Position the plate in the desired location. An implant holder (339 003) can be secured to any one of the drill guides to aid in this process.
1 mm guide wires can then be inserted into the wire holes in the plate for temporary fixation.



HINT
If 1mm guide wires were introduced through the trial instrument, the plate can be introduced over them.



219 535
Drill AO
diam. 2.7 mm,
L. 190 mm

219 335
Depth gauge
diam. 3.5 mm
screws

219 835
Screwdriver/Hex.
diam. 2.0 mm,
L. 180 mm

219 435
Screwdriver/
AO hex.
diam. 2.0 mm,
L. 76 mm

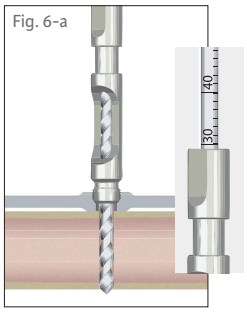
339 001
Compression
forceps

219 635
Drilling guide

6. Screw insertion

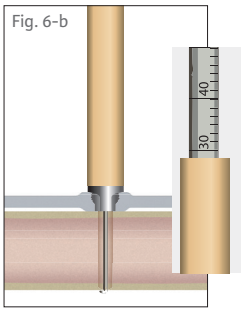
For each hole, the following steps must be followed as shown in figures A to F:

Fig. 6-a



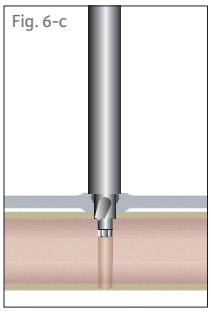
Prepare holes with the 2.7 mm drill (219 635) through the drilling guide. The screw length can be read from the calibrated scale on the drill.
The depth is read from the top side of the drilling guide.

Fig. 6-b



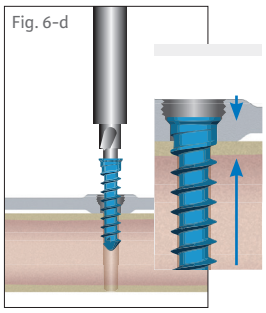
Alternately, measure the necessary screw length using the length gauge (219 335), after having removed the drill guide.

Fig. 6-c



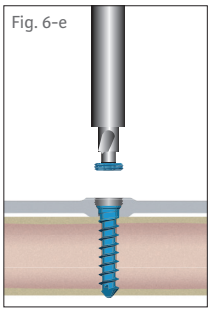
Chamfer the drill hole with the screwdriver. Ensure that the threaded hole is not damaged when performing the chamfering.

Fig. 6-d



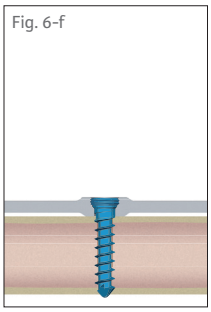
Insert the screw into the prepared hole until the plate is at the desired position relative to the bone. The screw should be fully seated in the plate. Clean the threaded hole before and after introducing the screw. Maintain co-axiality between the screw and the threaded hole.

Fig. 6-e



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.

Fig. 6-f

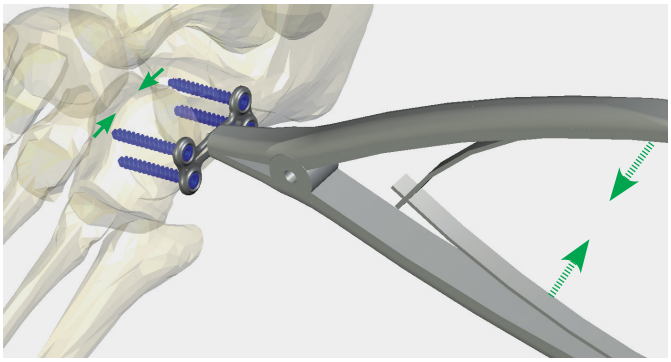


Locking: Fully seat the lock-screw with the screwdriver.
The lock-screw should be flush with the top of the plate when it is fully inserted.

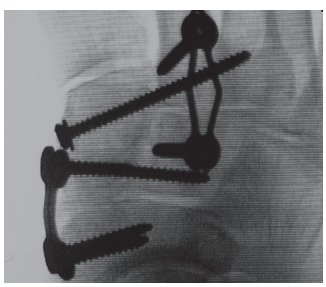
WARNING
Steps a to f should be completed for each screw before starting preparation of the subsequent screw(s). If not, the axes of the screw and the prepared hole may be misaligned.

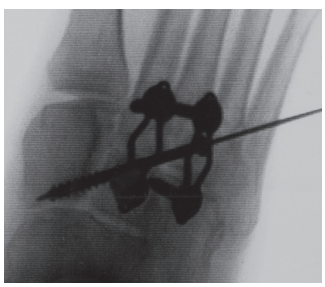
7. Compression

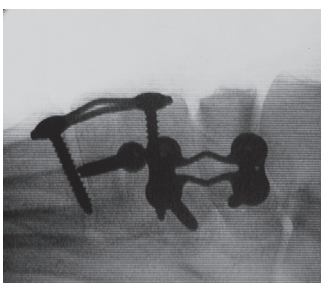
After all screws are locked in place, compress the Uni-CP plate using the compression forcep (spreading) instrument (339 001).
Upon opening the diamond designed bridge, the compressive forces will pull the ends of the plate toward one another.

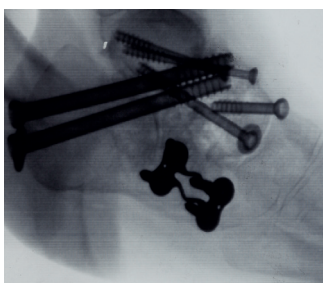


8. X-Rays









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 INSTRUCTIONS FOR USE.

Description

The osteosynthesis systems manufactured by Newdeal, are designed for the fixation of fractures, fusions and osteotomies, more especially for foot, ankle and hand surgery.

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

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 UNI-CP Plates have to be fixed with the Surfix® 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 postoperative 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. Ostesynthesis implants manufactured by Newdeal 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	Gravity Displacement 5 pulses [Maximum 900 mbar; Minimum 200 mbar]	Pre-Vacuum 3 pulses [Maximum 26.0 psig (2.8 bar); Minimum 10 inHg (339 mbar)]
Minimum Temperature	134°C (273° F)	132°C (270° F)
Exposure Time	18 minutes	4 minutes
purge	-	2-3 minute
vacuum drying	20 minutes	20 minute

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 warrants 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.

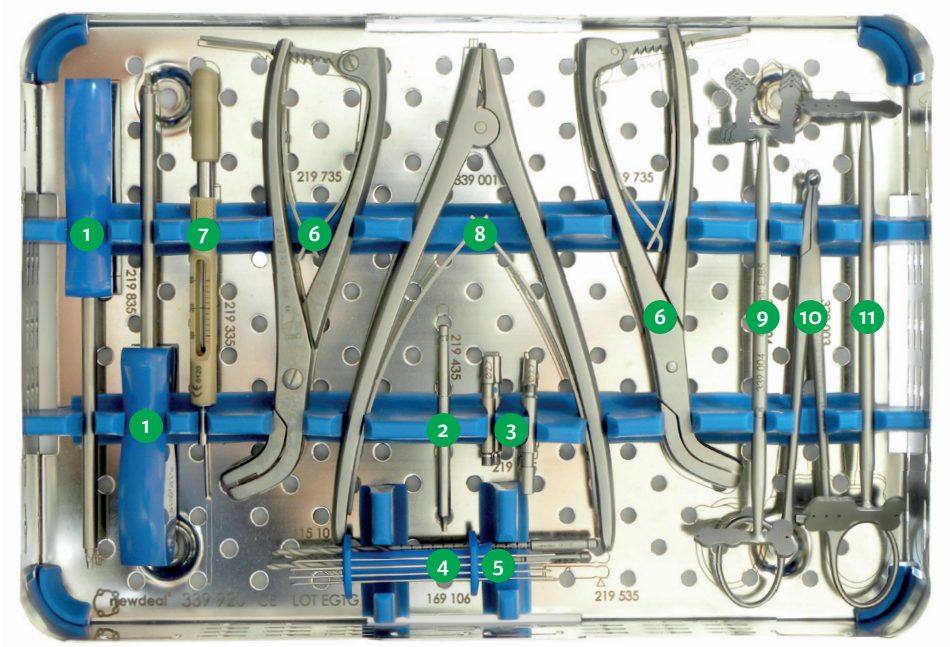
INFORMATION

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

Uni-CP
Compression Plating System

Surfix® Titanium screw diam. 3.5 mm + lock screw

Reference	Description
285 312S	Length 12 mm
285 314S	Length 14 mm
285 316S	Length 16 mm
285 318S	Length 18 mm
285 320S	Length 20 mm
285 322S	Length 22 mm
285 324S	Length 24 mm
285 326S	Length 26 mm
285 328S	Length 28 mm
285 330S	Length 30 mm
285 332S	Length 32 mm
285 334S	Length 34 mm
285 336S	Length 36 mm
285 338S	Length 38 mm
285 340S	Length 40 mm
185 300S	Lock-screw diam. 3.5 mm



Compression stainless steel plate

Reference	Description
330 217S	2 holes - 17 mm
330 225S	2 holes - 25 mm
330 230S	2 holes - 30 mm
330 420S	4 holes - 20 mm
330 425S	4 holes - 25 mm
330 430S	4 holes - 30 mm
330 030S	4 holes - 20mm T-shape

Instruments

	Reference	Description
1	219 835	Screwdriver / Hex. diam. 2.0 mm, L. 180 mm
2	219 435	Screwdriver / AO, hex. diam. 2.0 mm, L. 76 mm
3	219 635	Drilling guide, diam. 2.7 mm
4	219 535	Drill, AO diam. 2.7 mm, L. 190 mm
5	115 101	K-wire, diam. 1.0 mm, L. 100 mm
6	219 735	Bending forceps, diam. 3.5 mm hole, L. 171 mm
7	219 335	Depth gauge, diam. 3.5 mm screws
8	339 001	Compression forceps
9	339 004	Implant sizer for T and U plates *
10	339 003	Holder
11	339 005	Trial plate for 2 and 4 holes plates

Container

Reference	Description
339 950	Container
339 920	Base
996 200	Lid
169 106	Module

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