Ostéo France Ortho

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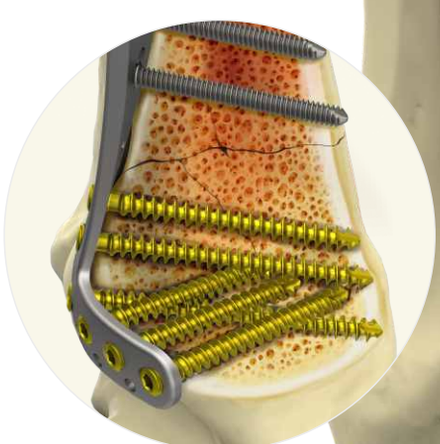
LOCKING 3.5mm

DISTAL **TIBIA**

ANTEROLATERAL PLATE



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DISTAL TIBIA ANTEROLATERAL PLATE

CONTENS

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ISO 9001:2015
ISO 13485:2016
CE 1984

1.1 Proximal Tibia Anterolateral Plate

1.1.1.Specification

The Locking Distal Anterolateral Tibial Plate is a specialized orthopedic implant designed for the stabilization of fractures in the distal tibia. These plates are anatomically contoured to match the unique shape of the tibia and feature Combi holes that accommodate both locking and cortex screws, offering flexibility in fixation methods. The design allows for easier reduction and less surgical time, adapting to the complex anatomy of the tibia which varies from person to person. Such plates are part of advanced systems that integrate locking screw technology with conventional plating techniques, providing surgeons with versatile options for treating tibial fractures.

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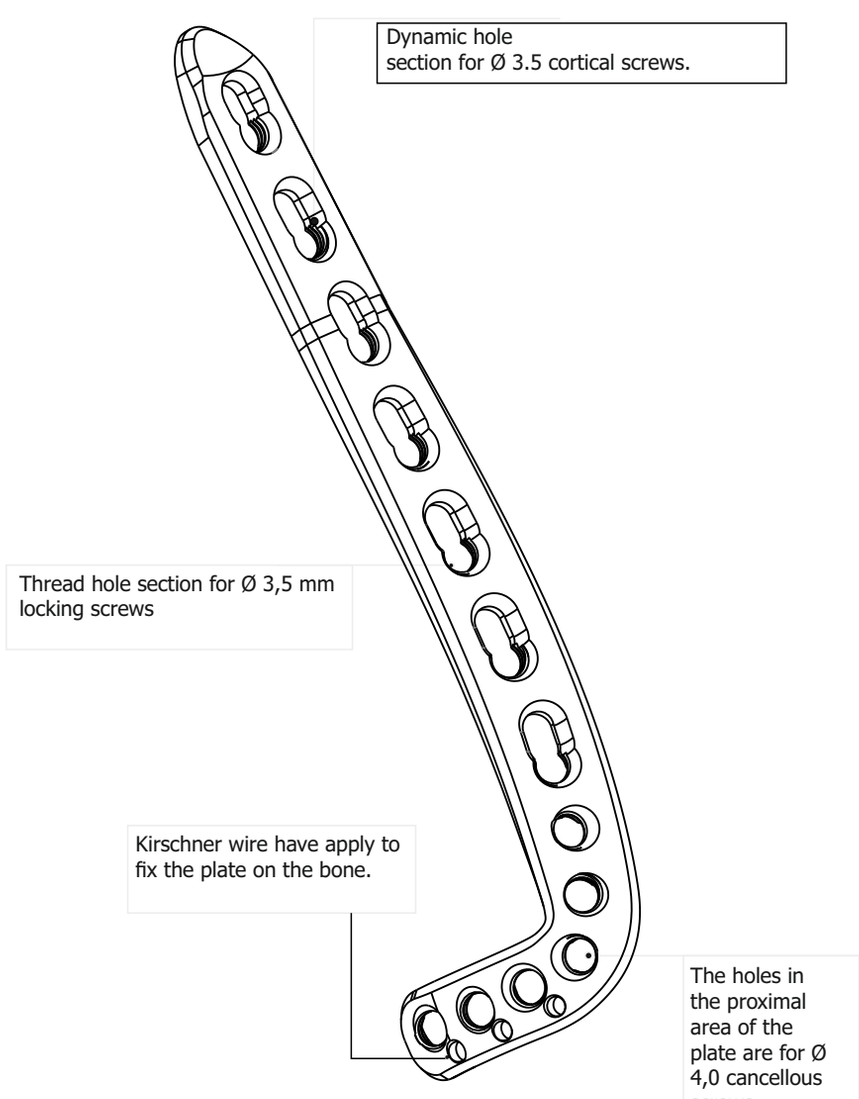
PROXIMAL TIBIA
ANTEROLATERAL PLATE

REF NO	HOLES
10132-10010	10 - R
10132-10012	12- R
10132-10014	14 - R
10132-10016	16 - R
10132-10018	18- R
10132-20010	10 - L
10132-20012	12 - L
10132-20014	14 - L
10132-20016	16 - L
10132-20018	18 - L

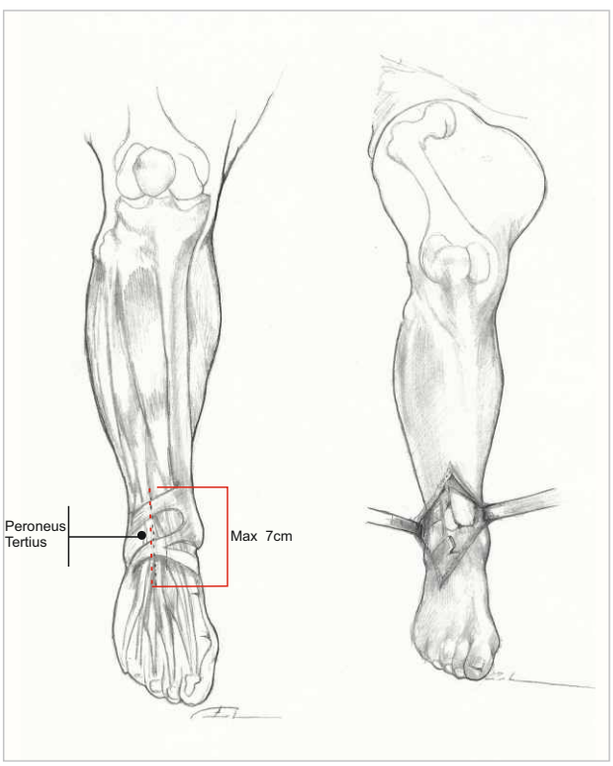
Locking distal Anterolateral tibial plate is indicated for fixation of distal tibia fractures, osteotomies and nonunions in patients with osteopenic bone tissue. It is used together with Ø3.5 locking screw, Ø3.5 locking cannulated screw, Ø3.5 cortical screw, Ø4.0 cancellous screw, Ø4.0 locking cannulated screw. The locking distal anterolateral tibial plate is manufactured from ISO 5832-2 TiGr3 (ASTM F 67) material.

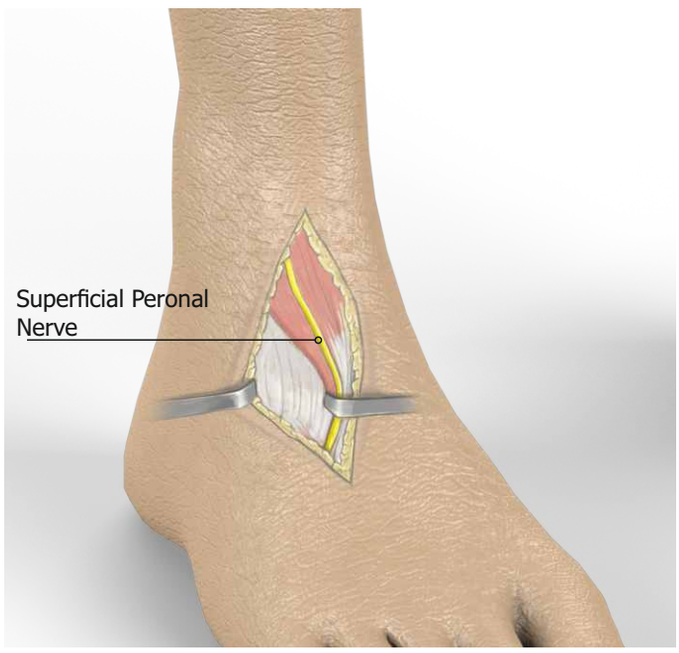


2.1 Approach

The anterolateral approach offers visualization of the tibial articular surface as far as the medial malleolus,

The fascia over the anterior compartment of the distal tibia is incised sharply, beneath the superficial peroneal nerve. Distally, the extensor retinaculum is incised, and the anterior compartment tendons are all retracted medially.





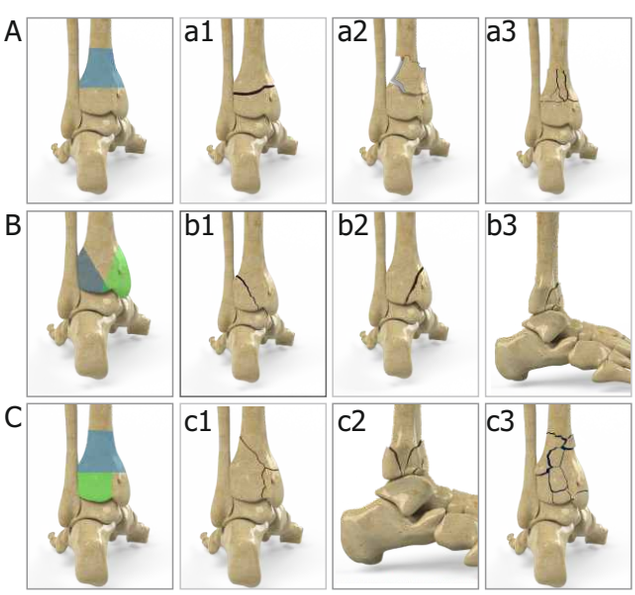
This incision is centered on the ankle joint. Distally, it should be parallel to the fourth metatarsal and parallel to the tibia and fibula. It is done proximally between the two *(Fibula and tibia)*.

The incision should not be extended more than 7 cm from the ankle joint.

Care should be taken not to damage the superficial peroneal nerve located just under the skin.

Added distractors can be used to facilitate joint reduction

2.2 Fracture



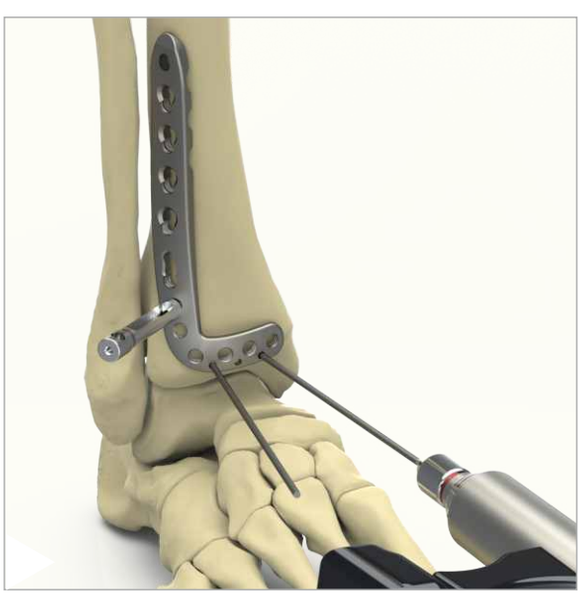
Extra-articular and simple intra-articular distal tibia fractures
—Distal tibia fracture, percutaneous or reducible by limited arthrotomy
—Distal tibia fracture extending into the diaphyseal area

2.3 Proximal Tibia Anterolateral Plate

2.3.1.Locating plate,and placement

Plate is located under imaging and by other methods. Depending on the fracture, fixations may be required first.*(Fig.1-2)*

Drill guide is attached to the plate . Hold the guide and place the plate on the bone *(Fig.3)*

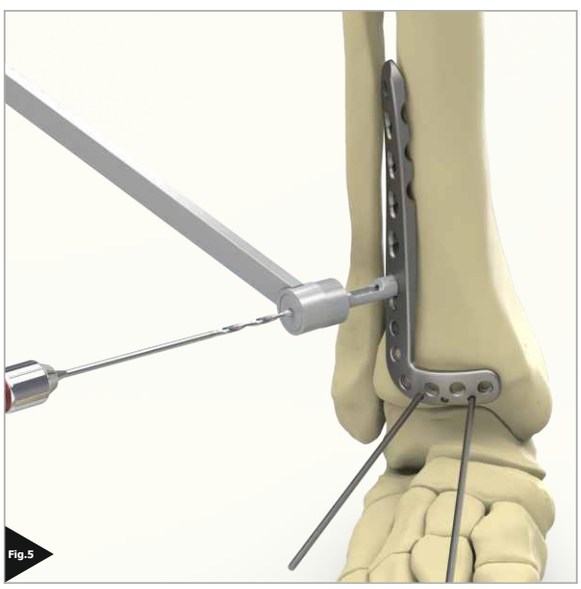


After the location of the plate is decided, 1. Kirshner wire is attached.*(Fig.4)*

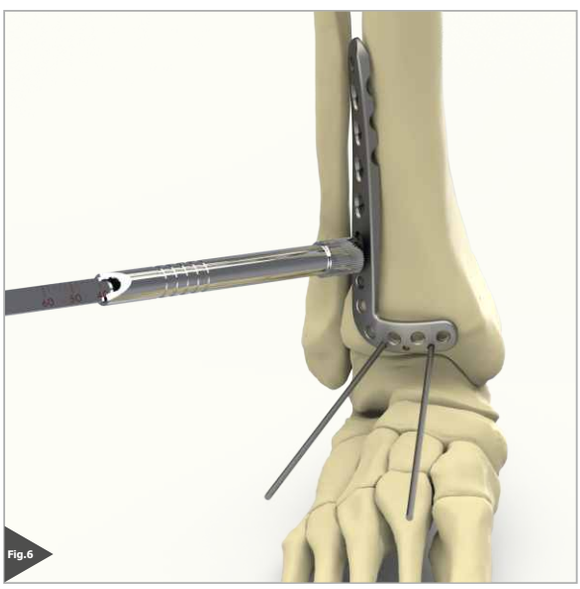
The location is checked again. Some more adjustments are made. Temporarily fixed with Second Kirschner wire. *(Fig.4)*

2.3 Proximal Tibia Anterolateral Plate

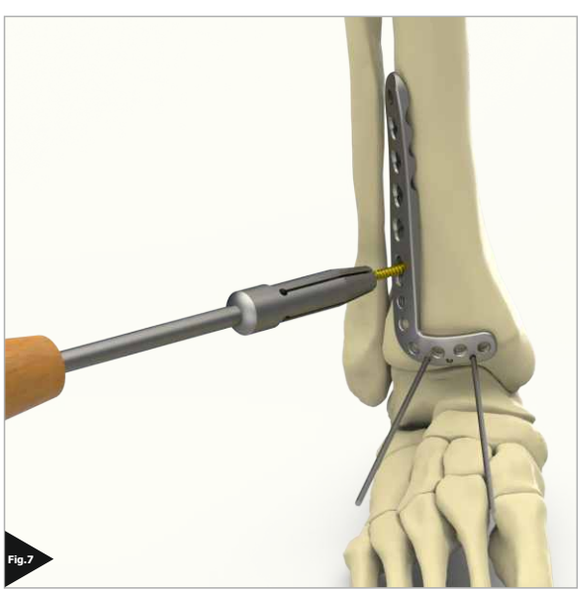
2.3.1. Ø3.5 Cortical Screw



Drilling is done with a ***(Eccentric Double Drill Guide Ø 3.5 mm 9108-0017)*** with a drill Dril ***(Ø 2.6 x 180 mm Ref.9108-0014)***.*(Fig.5)*

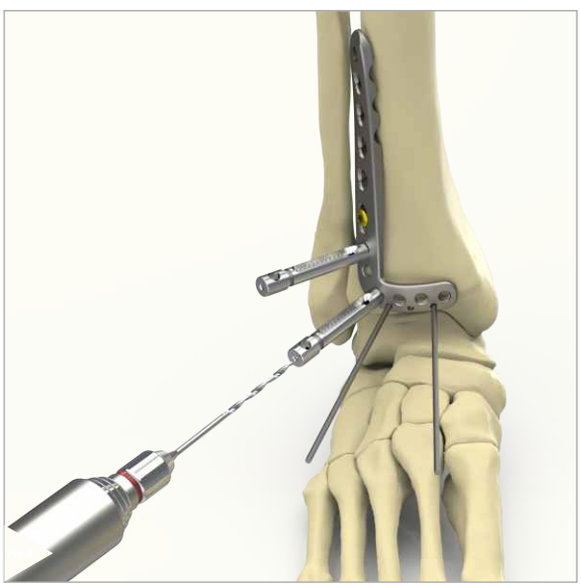


Screw length is determined with a ***(depth guide Ø 3.5 mm Ref.9108-0009)***. *(Fig.6)*

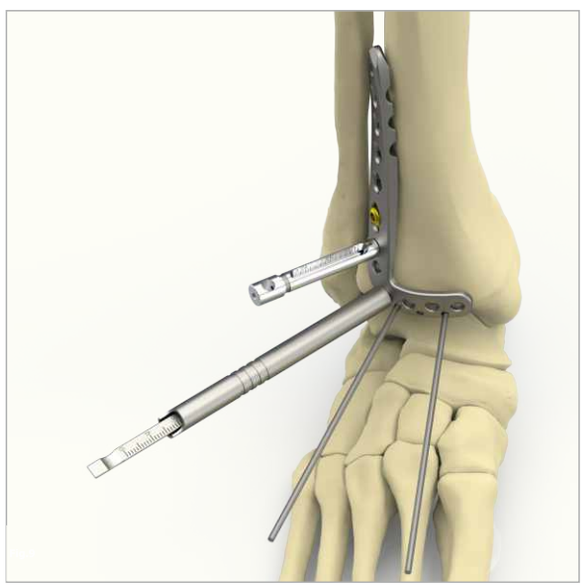


Ø3.5 Cortical screw attached with ***(Screwdriver Holder Ø 3.5 mm ref.9108-0007 &Screwdriver Bit Ø 3.5 mm.ref.9108-0008)*** *(Fig.7)*

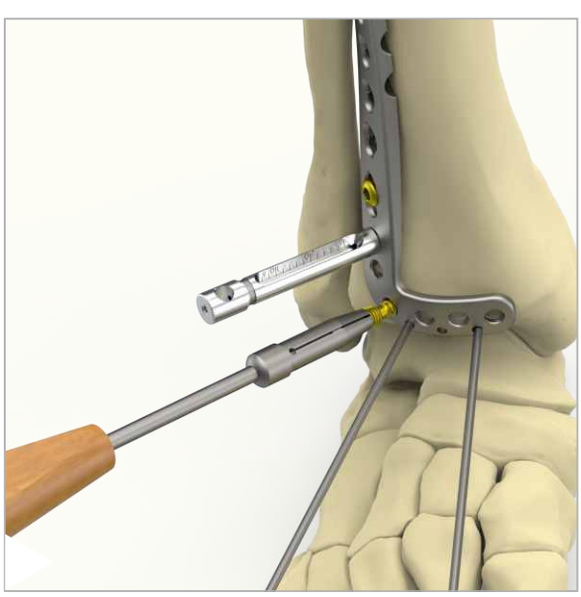
2.3.2. Ø4.0mm Locking Cancellous Screw



Drill with ***(Drill tip Ø 2.0 x 160 mm. ref.9108-0011)*** inside from ***(Drilling guide Ø 2.0 mm ref.9108-0012)*** *(Fig.8)*



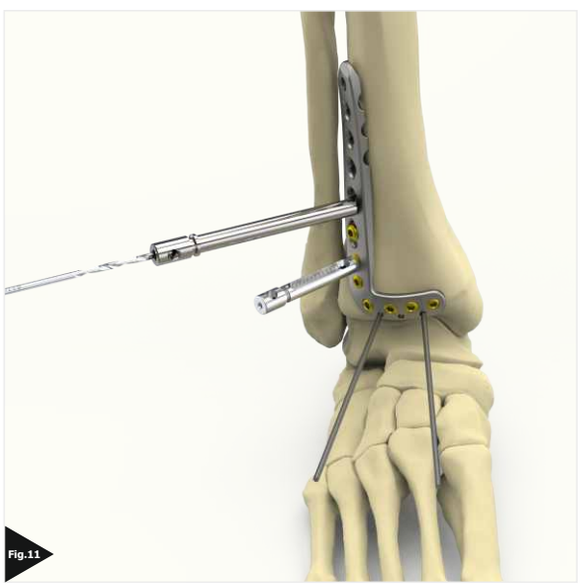
Measure the length of the screw you will install. ***(Depth Guide Ø 3,5 mm ref.9108-0009)*** *(Fig.9)*



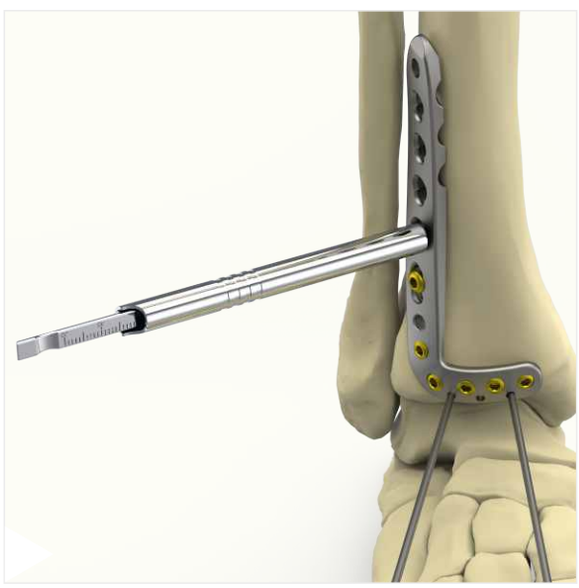
Ø4.05 Locking screw attached with ***(Screwdriver Holder Ø 3.5 mm ref.9108-0007 &Screwdriver Bit Ø 3.5 mm.ref.9108-0008)*** *(Fig.10)*

Ø4.05 Locking screw attached with ***(Screwdriver Holder Ø 3.5 mm ref.9108-0007 &Screwdriver Bit Ø 3.5 mm.ref.9108-0008)*** *(Fig.11)*

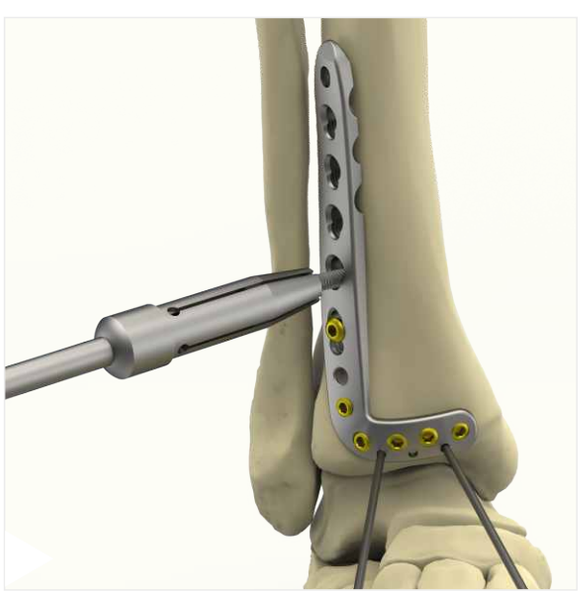
2.3.3. Ø3.5mm Locking Locking Screw



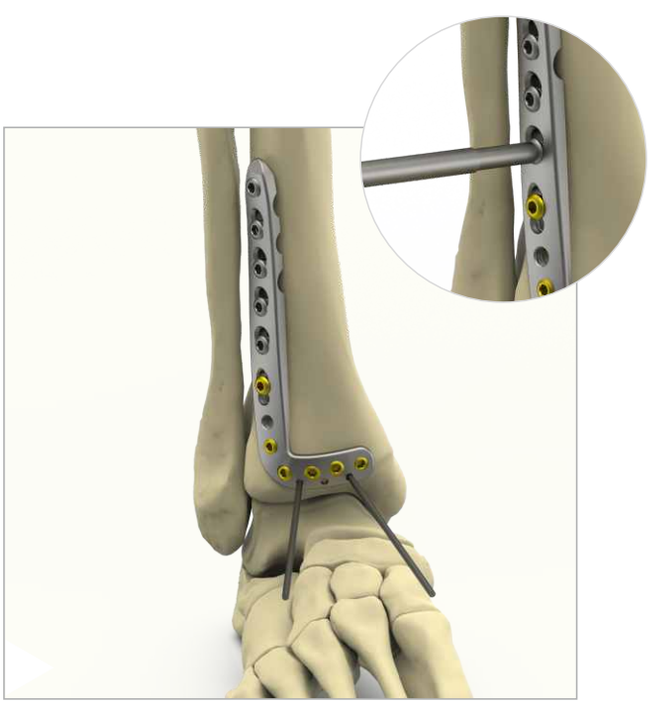
Proximally, the plate is fixed. can be passed for shaft region. First, the cortical screws on the plate will be inserted. Drilling is done from the part of the drill guide for neutral holes*(Fig.11a)*



Screw length is determined with a depth guide. *(Fig.12)*



The cortical screw of the appropriate size is sent with a Ø3.5mm screwdriver. *(Fig.13)*



After the cortical screw in the distal* of the plate is sent, the locked screw stage is started. Locking screws should not be used without inserting cortical screws. If you start with locking screws, there will be a gap between the plate and the bone*(Fig.14)*.

3.1 DEVICE CLEANING CONDITIONS

Do not use metal brushes or rubbing pads during Decontamination of the tools should be performed immediately after the surgical procedure is completed. Contaminated tools must not be allowed to dry before reprocessing.

Excessive blood or debris must be removed in order to prevent the drying on the surface. All users must be qualified staff with documented evidence of training and competence. Training should include the current guidelines, standards and hospital policies. Even if they are made of high-grade stainless steel, the surgical tools must be thoroughly dried in order to prevent rust formation. Prior to sterilization, all the tools should be examined for the cleanliness of the lumens of the joints of the surfaces. manual cleaning process. Use cleaning agents with low-foam surfactant to be able to see the tools in the cleaning solution. Rinse the cleaning materials easily from the tool in order to prevent residue formation.

Mineral oil or silicon lubricants should not be used

materials are recommended for cleaning the reusable instruments. It is very important to neutralize and rinse the alkaline cleaning materials thoroughly from the tools. Anodized aluminum should not contact with certain cleaning or disinfectant solutions. Avoid strong alkaline cleaners and disinfectants and solutions containing iodine, chlorine or certain metal salts.

Manual Cleaning/Disinfection

Prepare the enzymatic and cleaning materials at the dilution rates and temperatures as recommended by the manufacturer. New solutions should be prepared when the existing solutions are heavily contaminated. Place the tools in the enzymatic solution so that they are completely immersed. Operate all the movable parts so that the detergent contacts with all the surfaces.

Keep in the fluid for minimum 20 min. Use a nylon, soft-bristled brush to gently rub the tools until all visible debris is cleaned. Pay particular attention to the accessible areas and use a suitable bottle brush. In order to remove the dirt in the open springs, coils or flexible parts, wash the recesses with plenty of cleaning solution. Rub the surface with a scrubbing brush to remove all the visible dirt from the surface and the recesses. To ensure that all the recesses are cleaned, turn the component while rubbing. Remove the tools and rinse them for minimum 3 min. under running water. Pay particular attention to the cannulas and use a syringe to pass the fluid through the hard-to-reach areas. Place all the tools that are completely immersed in water, in an ultrasonic unit containing teh cleaning solution. Operate all the movable parts so that the detergent contacts with all the surfaces. Expose the tools to sonification process for minimum 10 min..

Remove the tools and rinse with deionized water for at least 3 minutes or unless all the blood or dirt traces are eliminated in the rinsing water. Examine the tools under normal light to verify that visible dirt is removed. If visible dirt is present, repeat the above mentioned sonification procedure and the rinsing steps. Remove the excessive moisture on the tool with a clean, absorbent, lint-free cloth.

Combination Manual / Automated Cleaning and Disinfection

Prepare the enzymatic and cleaning materials at the dilution rates and temperatures as recommended by the manufacturer. New solutions should be prepared when the existing solutions are heavily contaminated. Place the tools in the enzymatic solution so that they are completely immersed. Operate all the movable parts so that the detergent contacts with all the surfaces. Keep in the fluid for minimum 10 min. Use a nylon, soft-bristled brush to gently rub the tools until all visible debris is cleaned. Pay particular attention to the accessible areas and use a suitable bottle brush. A sonicator will help to clean the instruments thoroughly. The use of a syringe or a water fountain will facilitate passing of the liquid from the low-spaced areas and difficult-to-access areas. Remove the tools from the enzyme solution and rinse them for minimum 1 min. under deionized water. Place the tools in a suitable washer / disinfector basket and perform a standard washer / disinfector cycle. Specific minimum parameters are essential for a complete cleaning and disinfection. These parameters are given in a below mentioned table.

Automated Cleaning and Disinfection

Automated washing / drying systems are not recommended as the only cleaning method for surgical tools. An automated system can be used as a follow-up operation after manual cleaning. To ensure an effective cleaning, tools must be thoroughly examined before sterilization. For detailed information on Washing and Disinfection see

Specific minimum parameters used for a complete cleaning and disinfection:

	Definition
1	Pre-washing for 2 minutes with cold tap water
2	enzyme sprey for 20 seconds with hot tap water
3	Immersion in enzyme after 1 minute
4	rinsing for 15 seconds with cold tap water (Should be repeated twice)
5	Washing with detergent for 2 minutes with hot tap water
6	rinsing for 15 seconds with hot tap water
7	Rinsing with 10 seconds with optional lubricated purified water
8	Drying for 7 minutes with hot air

Note: Follow the isntruction of the washer/disinfector manufacturer

Medical, as the manufacturer of this device, and their surgical consultants do 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 utilizing the appropriate techniques for implanting the device in each individual patient. and their surgical consultants are not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.

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