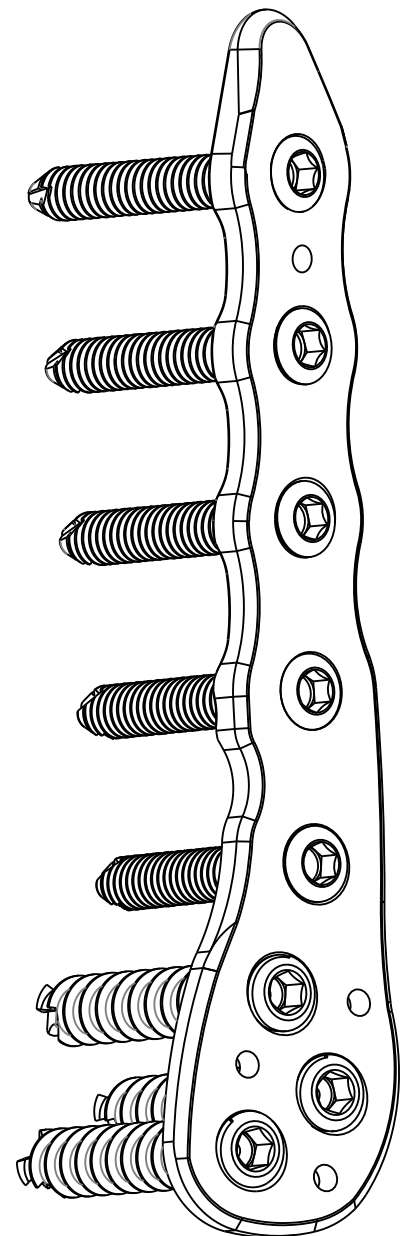




www.osteofrance-ortho.fr

Locking DISTAL LATERAL TIBIAL PLATE

SURGICAL TECHNIQUE



Locking DISTAL LATERAL TIBIAL PLATE

Contents

1. Introduction

1.1. Locking Distal Lateral Plate.....	3
1.1.1. Specification.....	

2. Surgical Technique

2.1. Locking Distal Lateral Plate.....	4
2.1.1. Distal Tibia Fracture.....	
2.1.2. Anterolateral Approach to Distal Tibia.....	
2.1.3. Plate Placement.....	
2.1.4. Ø 5.0 Locking Cortical Screw.....	5
2.1.5. Ø 6.5 Locking Cancellous Screw.....	
2.1.6. Finishing.....	

3. Screw

3.1 Ø 5.0 Locking Screw, Ø6.5 Cancellous Screw.....	6
---	---

4. Instrument Set

4.1 5.0 Instrument Set.....	7
4.1.1. Tray 1.....	
4.1.2. Tray 2.....	

5. Disinfection

5.1. Device Cleaning Conditions.....	10
5.1.1. Manual Cleaning/Disinfection.....	
5.1.2. Combination Manual / Automated Cleaning.....	
and Disinfection:.....	
5.1.3. Automated Cleaning and Disinfection.....	



1. Introduction

1.1. Distal Lateral Tibial Plate



1.1 Locking Distal Lateral Tibial Plate

1.1.1. Specification

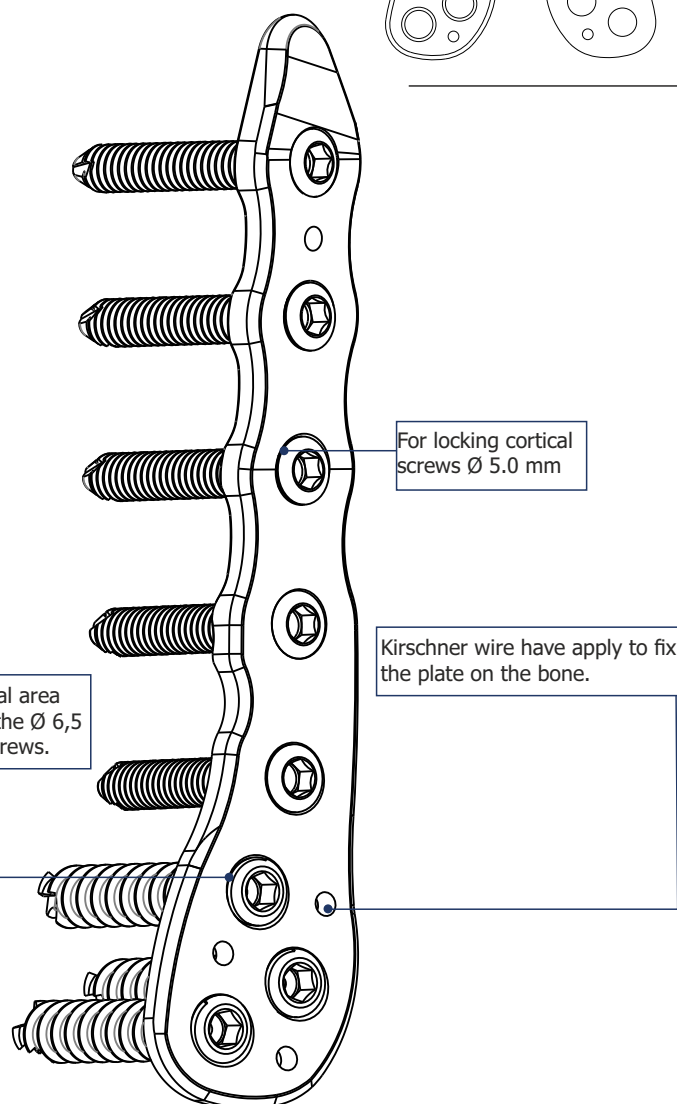
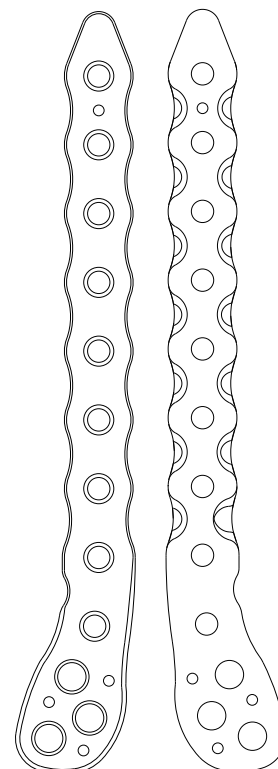
Locking Distal Lateral Tibial Plate is indicated for distal tibial fractures either extra-articular or simple intra-articular, extending to the diaphyseal region. The plate is designed for Ø5.0 locking cortical screws and Ø6,5 locking cancellous screws. 8, 10, 12, 14, 16 hole right and left length options are available. Distal Lateral Tibia Plate is manufactured in titanium alloy manufactured according to ISO 5832-2.



Locking
DISTAL LATERAL TIBIAL PLATE
 (with Ø 5,0 / 6.5mm screw)

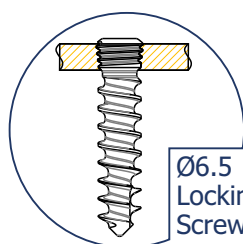
REF. NO	HOLES
1582-1008	8-R
1582-1010	10-R
1582-1012	12-R
1582-1014	14-R
1582-1016	16-R
1582-2008	8-L
1582-2010	10-L
1582-2012	12-L
1582-2014	14-L
1582-2016	16-L

HOLES	8	10	12	14	16
L(mm)	113	145	177	209	241



Ø5.0 Locking Cortical Screw

Ø5.0 Locking Cortical Screw are in 12 to 95mm size



Ø6.5 Locking Cancellous Screw

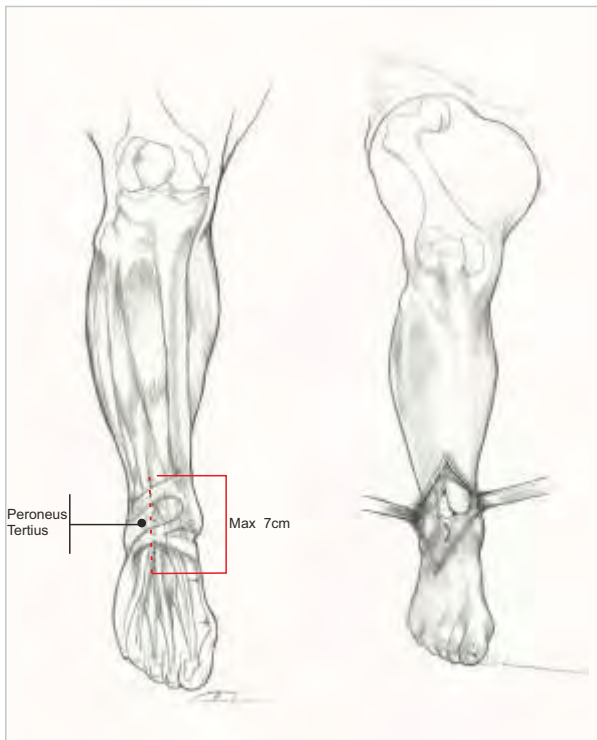
Ø6.5 Locking Cancellous Screw are in 30 to 120mm size



2.1.1 Distal Tibia Fracture

Distal tibia fractures are complex injuries caused by compression and rotational forces, extending from the distal metaphysis of the tibia to the joint surface. Open fractures are common as a result of thin soft tissue coverage at the ankle level. The treatment of such fractures with soft tissue injuries, involves great difficulties compared to other fractures due to complications ranging from infection and union problems to amputation. Distal Lateral Tibia Plate is designed to reduce surgical trauma in the damaged area in appropriate type distal tibia fractures.

2.1.2 Anterolateral Approach to Distal Tibia



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

2.1.3 Plate Placement



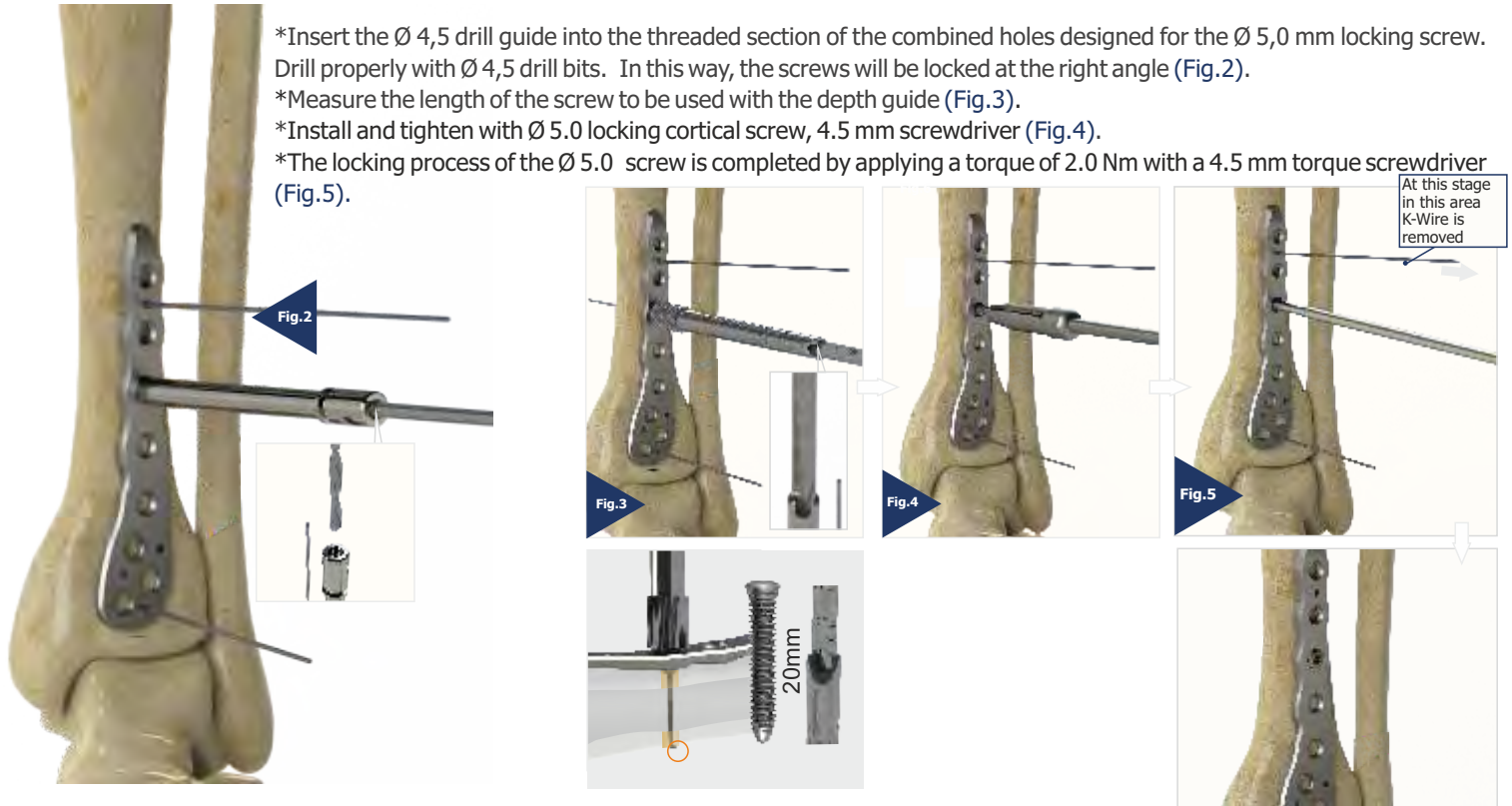
The plate is placed according to the bone anatomy and fracture (Fig.1).

*The plate is fixed to the bone with Kirschner Wire (Fig.2)



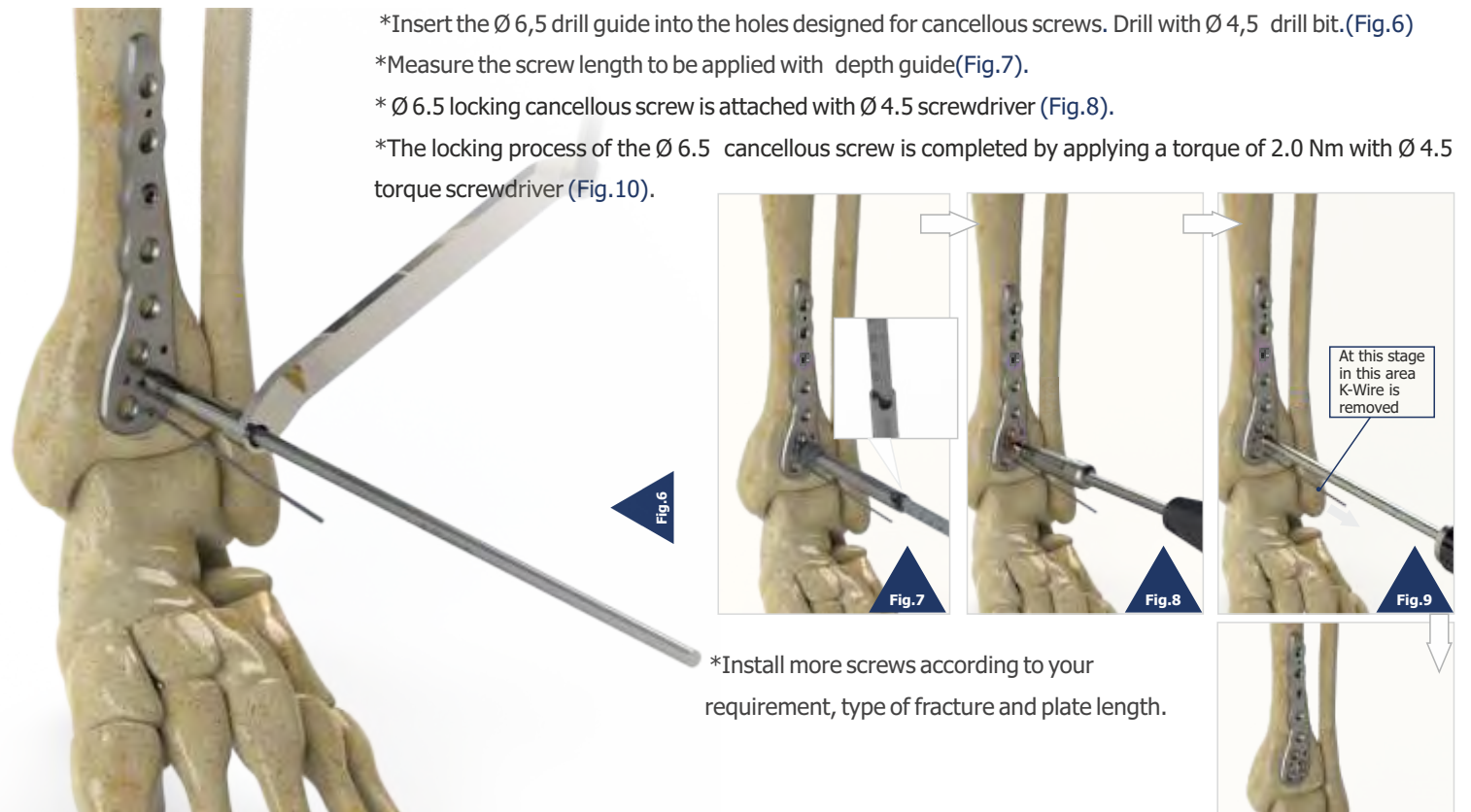
2.1.4 Ø5,0 Locking Cortical Screw

- *Insert the Ø 4,5 drill guide into the threaded section of the combined holes designed for the Ø 5,0 mm locking screw. Drill properly with Ø 4,5 drill bits. In this way, the screws will be locked at the right angle (Fig.2).
- *Measure the length of the screw to be used with the depth guide (Fig.3).
- *Install and tighten with Ø 5.0 locking cortical screw, 4.5 mm screwdriver (Fig.4).
- *The locking process of the Ø 5.0 screw is completed by applying a torque of 2.0 Nm with a 4.5 mm torque screwdriver (Fig.5).



2.1.5 Ø6,5 Locking Cancellous Screw

- *Insert the Ø 6,5 drill guide into the holes designed for cancellous screws. Drill with Ø 4,5 drill bit. (Fig.6)
- *Measure the screw length to be applied with depth guide (Fig.7).
- *Ø 6.5 locking cancellous screw is attached with Ø 4.5 screwdriver (Fig.8).
- *The locking process of the Ø 6.5 cancellous screw is completed by applying a torque of 2.0 Nm with Ø 4.5 torque screwdriver (Fig.10).

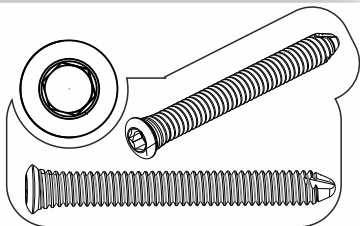


*Install more screws according to your requirement, type of fracture and plate length.



3.1

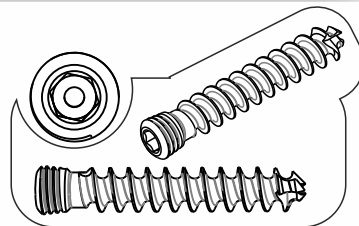
Ø5,0 Locking Screw



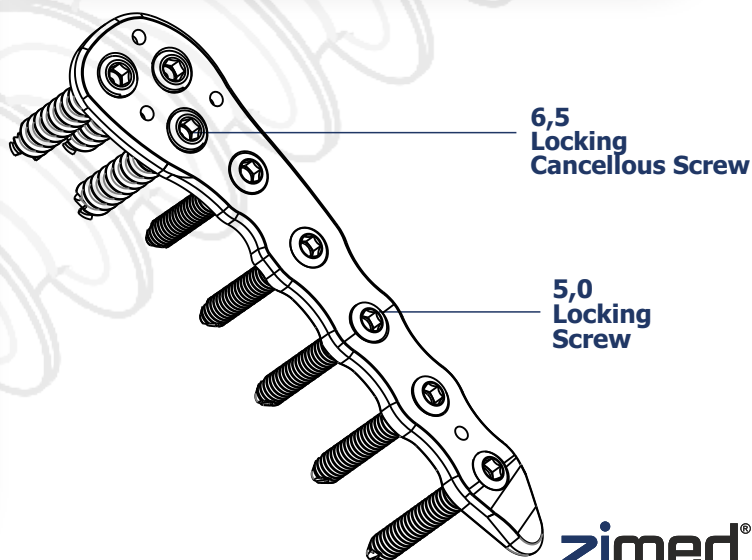
REF. NO	SIZE
2052-5012	12
2052-5014	14
2052-5016	16
2052-5018	18
2052-5020	20
2052-5022	22
2052-5024	24
2052-5026	26
2052-5028	28
2052-5030	30
2052-5032	32
2052-5034	34
2052-5036	36
2052-5038	38
2052-5040	40
2052-5042	42
2052-5044	44
2052-5046	46
2052-5048	48
2052-5050	50
2052-5052	52
2052-5054	54
2052-5055	55
2052-5056	56
2052-5058	58
2052-5060	60
2052-5065	65
2052-5070	70
2052-5075	75
2052-5080	80
2052-5085	85
2052-5090	90
2052-5095	95

3.2

Ø6,5 Locking Cancellous Screw



REF. NO	SIZE
2182-0030	6.5x30
2182-0035	6.5x35
2182-0040	6.5x40
2182-0045	6.5x45
2182-0050	6.5x50
2182-0055	6.5x55
2182-0060	6.5x60
2182-0065	6.5x65
2182-0070	6.5x70
2182-0075	6.5x75
2182-0080	6.5x80
2182-0085	6.5x85
2182-0090	6.5x90
2182-0095	6.5x95
2182-0100	6.5x100
2182-0105	6.5x105
2182-0110	6.5x110
2182-0115	6.5x115
2182-0120	6.5x120



6,5
Locking
Cancellous
Screw

5,0
Locking
Screw

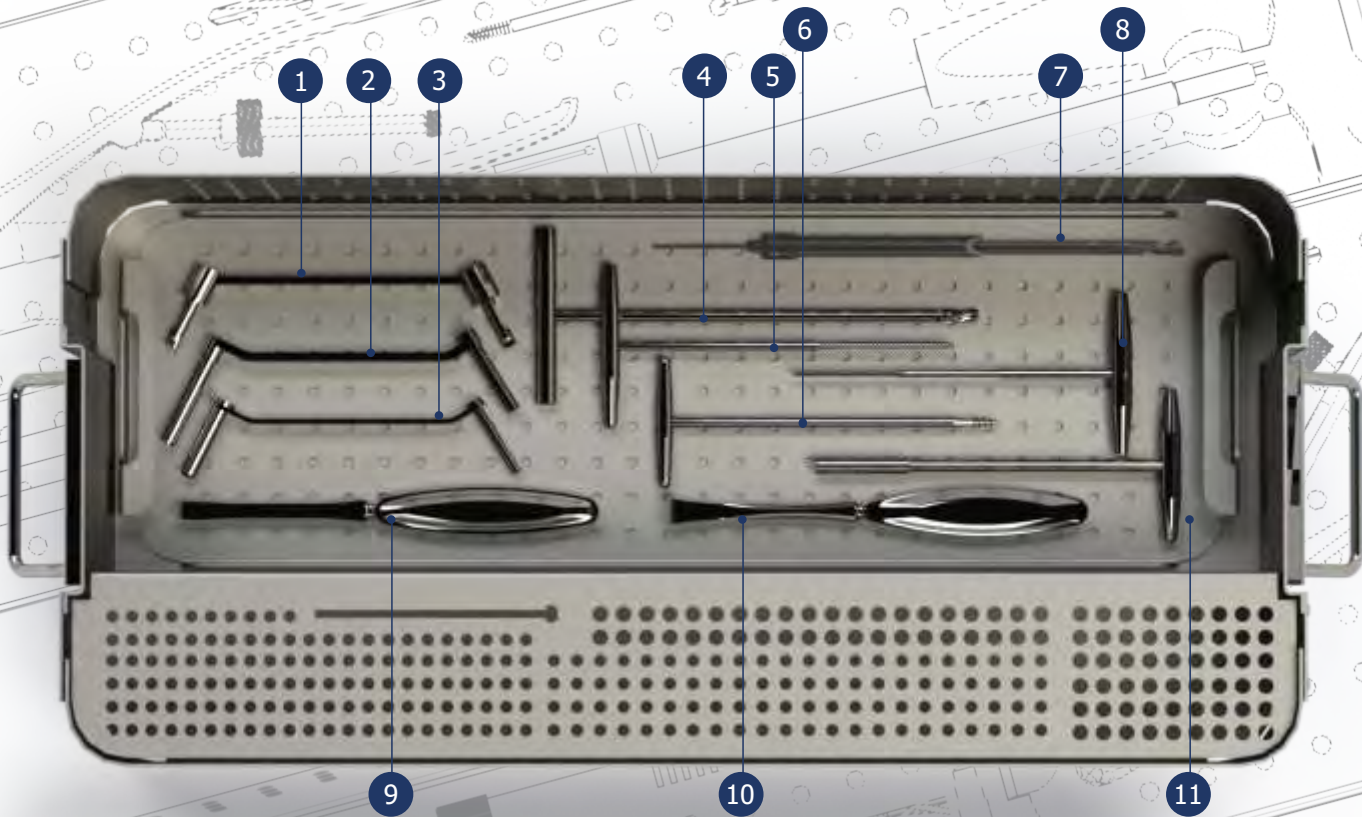


zimed[®]

Large Fragment Locking
Plate Instrument Set

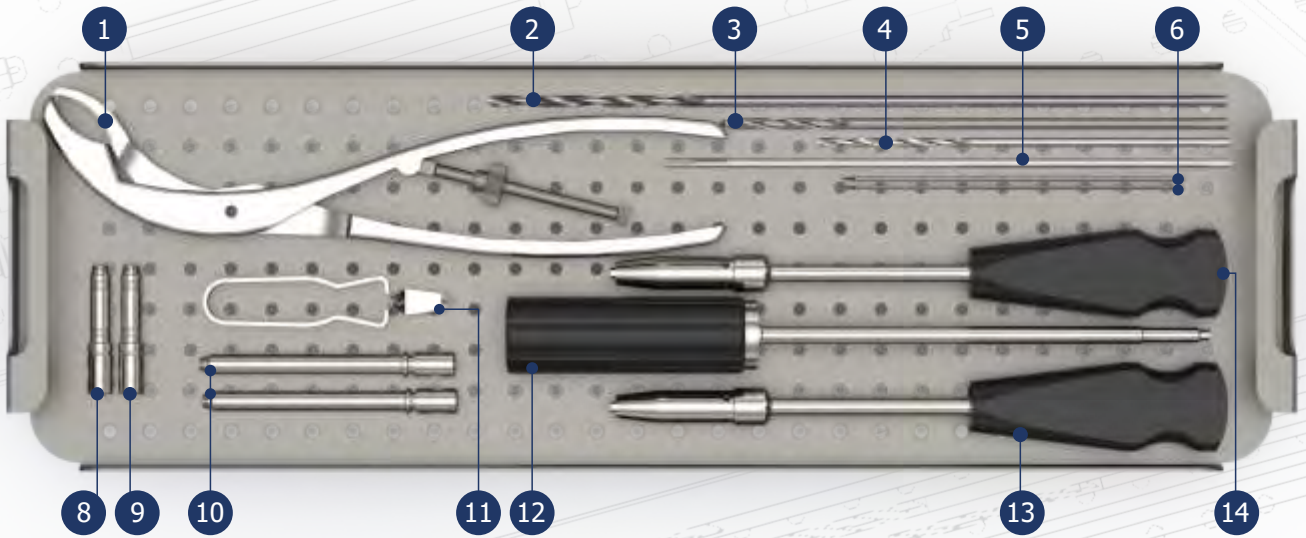
5,0_{mm}





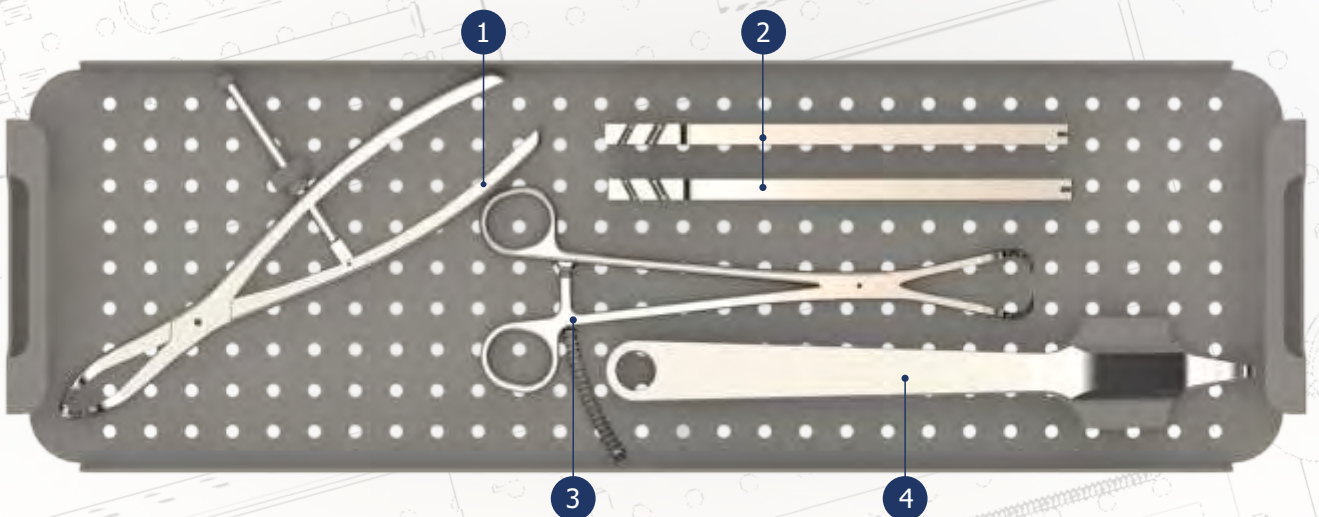
1	9102-0055	Double Drill Guide Ø 4,5 Ø 6,5 mm
2	9102-0056	Double Drill Guide Ø 3.2 (Angled Tube)
3	9102-0057	Double Drill Guide Ø 3.2 (Straight Tube)
4	9102-0024	Tap Ø 6.5 mm (for Cancellous Screw)
5	9102-0024	Tap Ø 6.5 mm (for Cancellous Screw)
6	9102-0017	Screw Extractor

7	9102-0007	Depth Guide
8	9102-0025	Tap Ø 4.5 mm (For Cortical Screw)
9	9102-0004	Bone Scraper Small 5,0 mm
10	9102-0003	Bone Scraper Large 5,0 mm
11	9102-0030	Bone Reamer 5,0 mm



1	9102-0013	Bone holding forceps
2	9102-0021	Drill Ø 4,3 x 220 mm
3	9102-0020	Drill Ø 3,2 x 160 mm
4	9102-0022	Drill Ø 4,5 mm
5	9102-0023	Threaded Guide Ø 2,3 mm
6	9702-0080	3.2 DRILL
7		

8	9102-0026	Drill Guide Ø 4,5 mm
9	9102-0032	Drill Guide Ø 4,5 mm
10	9102-0019	Drill Guide Ø 4,3
11	9102-0018	Screw Holder
12	9102-0010	Torque Limiting Screwdriver 4.0 Nm
13	9102-0005	Screwdriver Ø 3.5 mm
14	9102-0002	Star Screwdriver T25



1	9102-0011	Reduction Forceps
2	9102-0001	Plate Bender
3	9102-0012	Reduction Forceps with Points
4	9102-0009	Retractor Large



5.1 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.

5.1.1 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 the 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.

5.1.2 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 / disinfectant basket and perform a standard washer / disinfectant cycle. Specific minimum parameters are essential for a complete cleaning and disinfection. These parameters are given in a below mentioned table.



5.1.3 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 spray 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 instruction of the washer/disinfectant manufacturer

●  **Ostéo France Ortho** 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.  surgical consultants are not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.



Ostéo France Ortho

ISO 9001
ISO 13485

