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Locking

CLAVICLE PLATE SYSTEM

SURGICAL TECHNIQUE

zimed®

Locking

CLAVICLE PLATE SYSTEM

Contents

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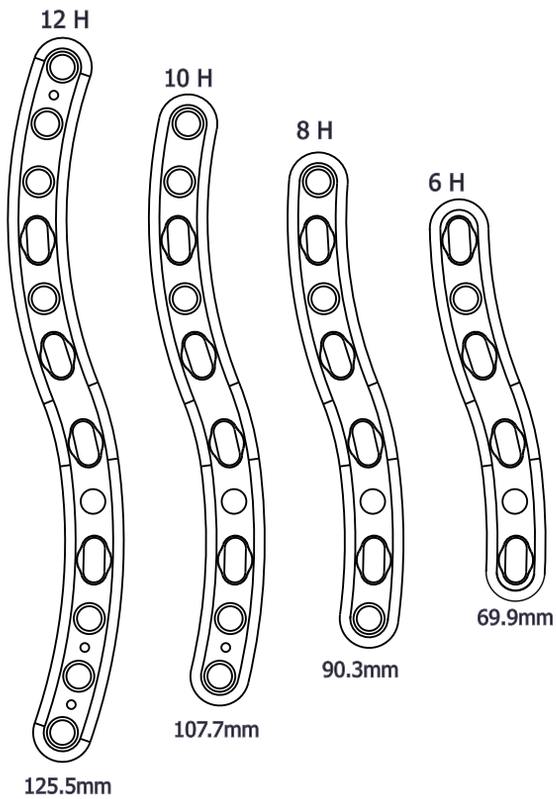
ISO 9001
ISO 13485 CE 1984

1.1.Clavicle Plate

1.1.1.Specification

Locked Clavicle Plate is indicated for fractures and osteotomies on the shaft of the clavicle bone. Used in combination with Ø3,5 mm locking screw and Ø3,5 cortical screw. 6, 8, 10, 12 hole right and left size options are available. Clavicle Plate is manufactured from titanium alloy manufactured according to ASTM F136.



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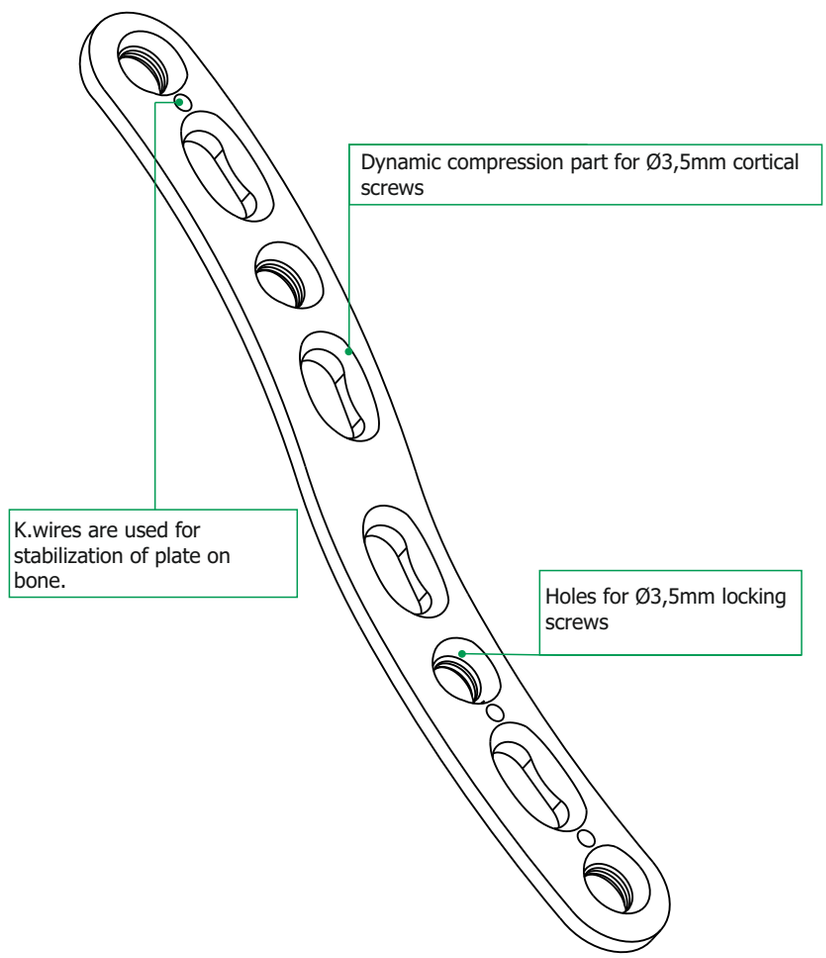
Locking

CLAVICLE PLATE

(with Ø 3,5 screw)

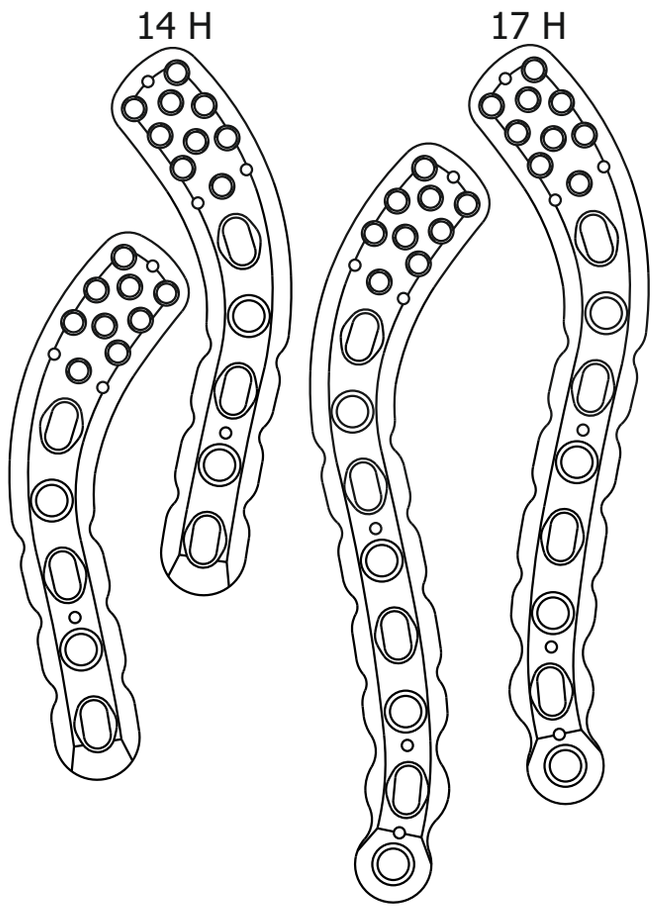
REF. NO	HOLES
1632-1006	6-R
1632-1008	8-R
1632-1010	10-R
1632-1012	12-R
1632-2006	6-L
1632-2008	8-L
1632-2010	10-L
1632-2012	12-L



1.2.Distal Clavicle Plate

1.2.1.Specification

Distal Clavicle Plate is indicated for fractures and osteotomies of lateral clavicle bone. Used in combination with Ø3,5 mm locking screw, Ø3,5 cortical screw and Ø 2,4mm locking screw.14 ,17 hole right and left size options are available.Distal Clavicle Plate is manufactured from ISO 5832-2 TiGr3 (ASTM F 67)



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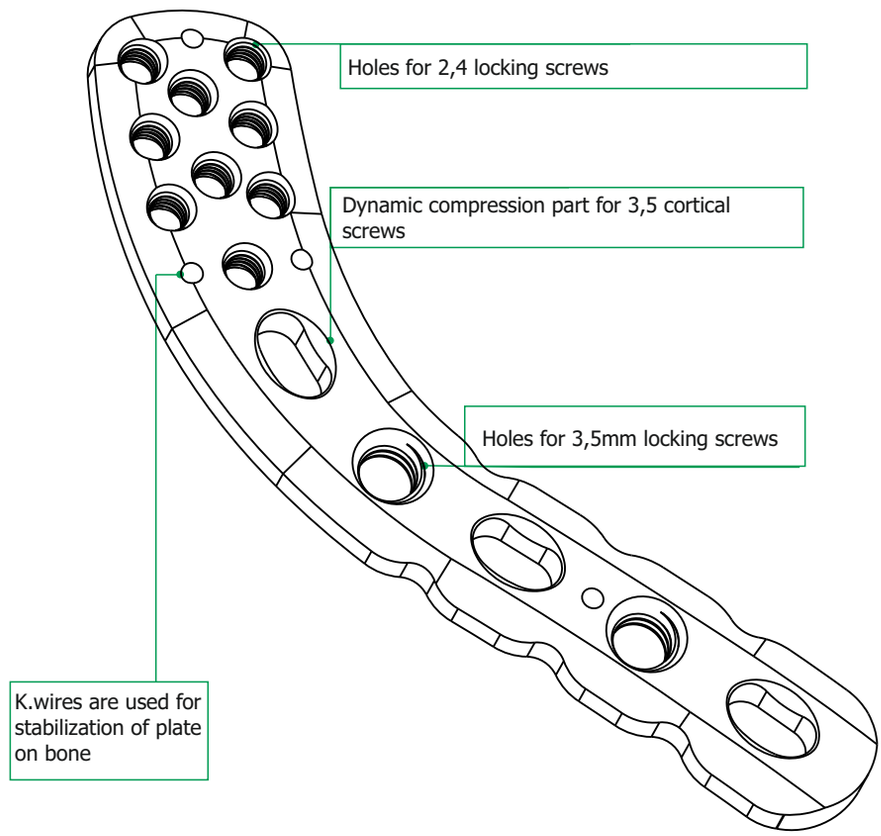
Locking
DISTAL
CLAVICLE
PLATE

(with Ø 3,5 and Ø2.4 screw)

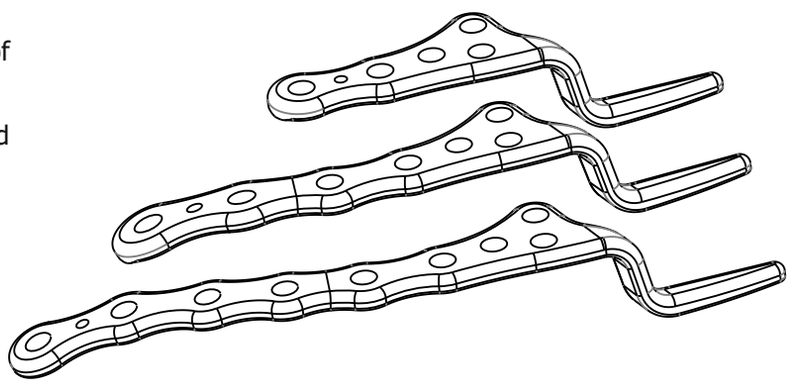
REF. NO	HOLES
1492-1014	14-R
1492-1017	17-R
1492-2014	14-L
1492-2017	17-L



1.3.Clavicle Hook Plate

1.3.1.Specification

Locking clavicular hook plate is indicated for dislocation of acromial fractured joint and fixation of lateral clavicles. It is used with Ø3.5 mm locking screw and Ø3.5 cortical screw. 5, 7, 9 hole right and left guides are available. Clavicular hook plate is manufactured from ISO 5832-2 TiGr3 (ASTM F 67) material.

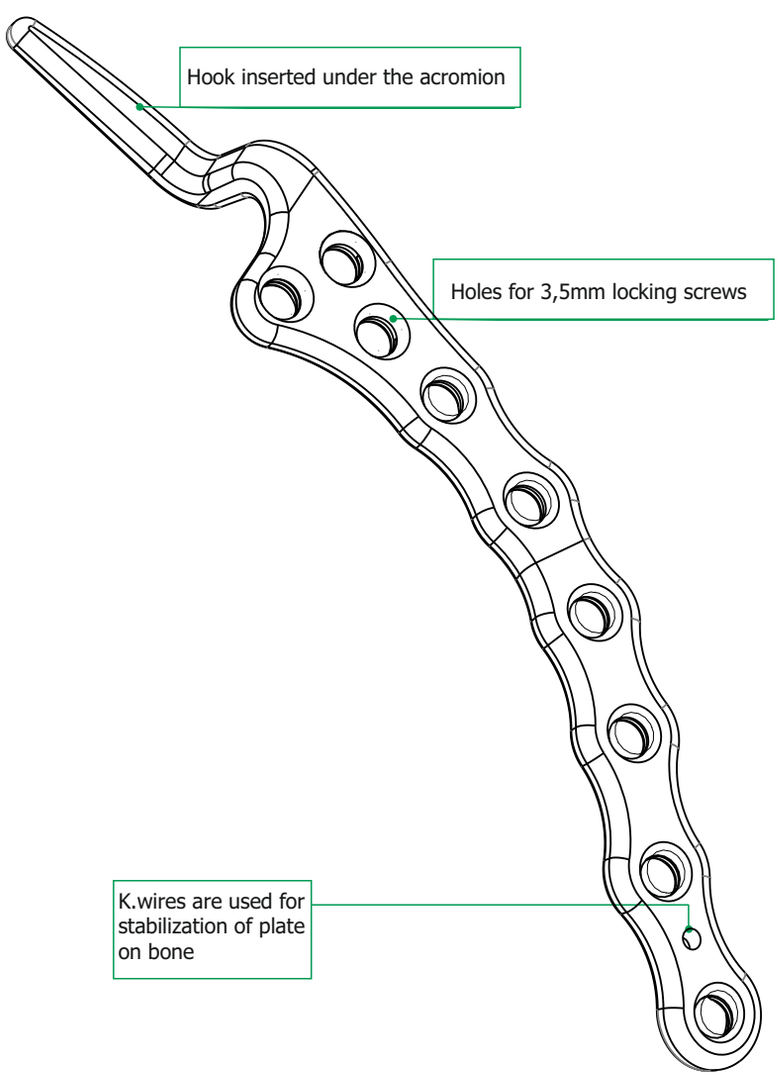


zimed®

Locking

CLAVICLE HOOK PLATE

REF. NO	HOLES
1622-1005	5-R
1622-1007	7-R
1622-1009	9-R
1622-2005	5-L
1622-2007	7-L
1622-2009	9-L

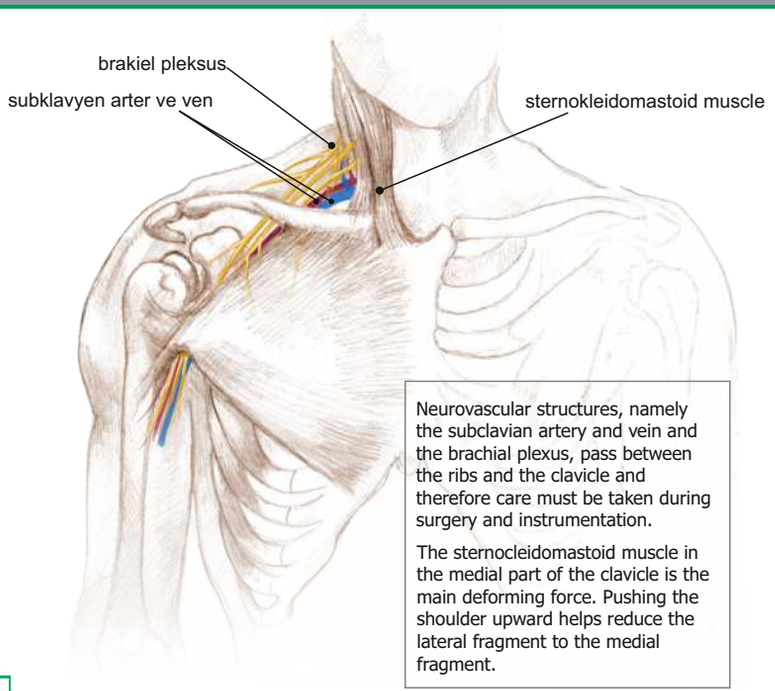


2.1.Fracture

2.1.1.Clavicle Fractures

Fractures of the clavicle constitute 15% of all clavicle fracture types. It is usually seen as a closed fracture. The open fracture type is rarely seen (it is seen in extreme stress and extreme sports types). The deformity occurs as shortening, angulation and medial rotation.

Clavicle fractures occur as a result of falling on the shoulder, unnecessary periosteal scraping should be avoided in surgery, and care should be taken to protect the neurovascular structure.



Neurovascular structures, namely the subclavian artery and vein and the brachial plexus, pass between the ribs and the clavicle and therefore care must be taken during surgery and instrumentation.

The sternocleidomastoid muscle in the medial part of the clavicle is the main deforming force. Pushing the shoulder upward helps reduce the lateral fragment to the medial fragment.

2.1.2.Fracture Types

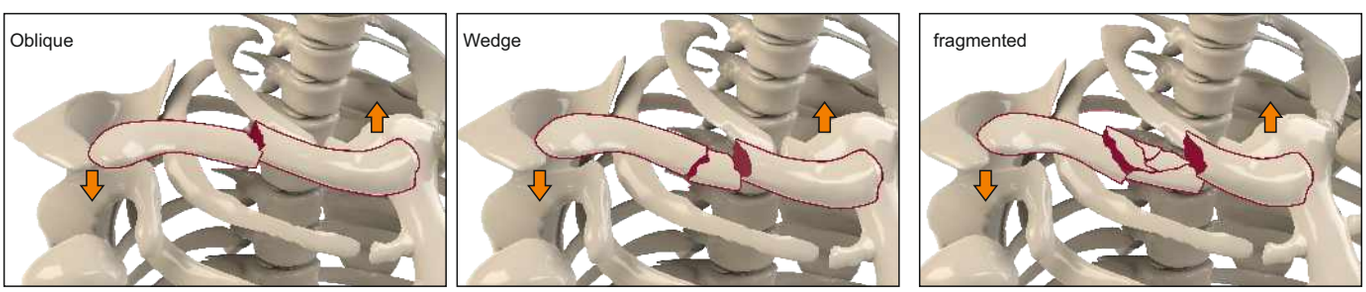
Clavicle fractures are classified from inside to outside (horizontal) because of the way they are positioned in the skeletal system. Clavicle fractures can be classified according to the anatomical structure, including displacement, angulation, and pattern. (oblique, transverse, segmented)

2.1.2.1 Medial Clavicle

Medial fractures are usually treated non-surgically.

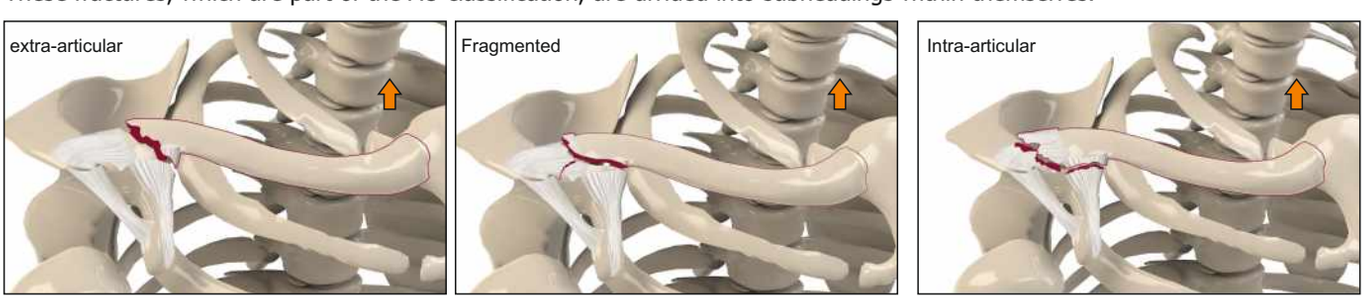
2.1.2.2 Clavicle Shaft

Most shaft fractures can be treated without surgery. Diaphyseal fractures are subject to rotation due to ligaments. Clavicular plate may be preferred in oblique, wedged and comminuted fractures. Below are some examples of these fractures. These fractures, which are part of the AO classification, are divided into subheadings within themselves.



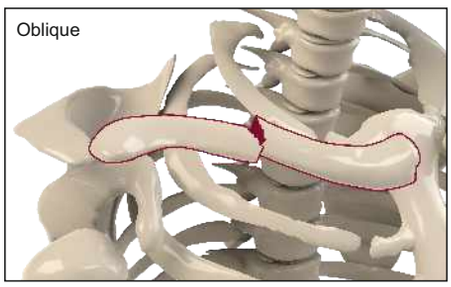
2.1.2.3 Lateral Clavicle

Simple, undisplaced lateral fractures that do not involve the joint can be healed by non-surgical methods. However, fractures that are not related to the displaced joint and related to the joint may require surgery. Distal clavicular plate can be used for displaced extra-articular and comminuted fractures. If the coracoclavicular ligaments are broken in intra-articular lateral clavicle fractures, a hook plate may be preferred. Reduction before plaque placement may require methods such as temporary fixation. These fractures, which are part of the AO classification, are divided into subheadings within themselves.



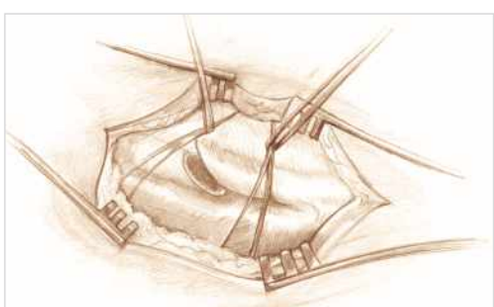
2.2.Clavicle Plate

2.2.1.Diaphyseal Clavicle Fracture



It is the most common type of fracture. exposed to external deforming force and pulling of muscles medially and weight of upper extremity. The clavicle plate, which is produced in accordance with the anatomy of the clavicle, allows the patient to regain their former health with a correct operation.

2.2.2.Approach



An oblique 8-10 cm incision centered on the fracture site is made just below the clavicle.
Supraclavicular nerves must be identified and protected.
Care must be taken to preserve soft tissue attachments to all bone fragments to ensure proper bone healing.

2.2.3.Plate Positioning and Kirschner Wire

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

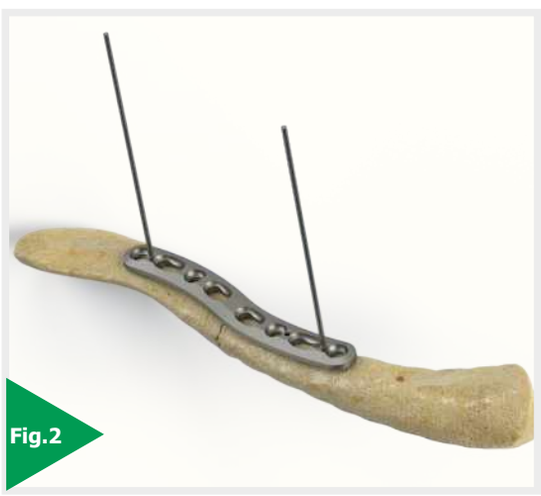


*Plate is temporarily fixed on bone with K.wire.(Fig.2)

2.2.Clavicle Plate

2.2.4.Ø3,5 Cortical Screw

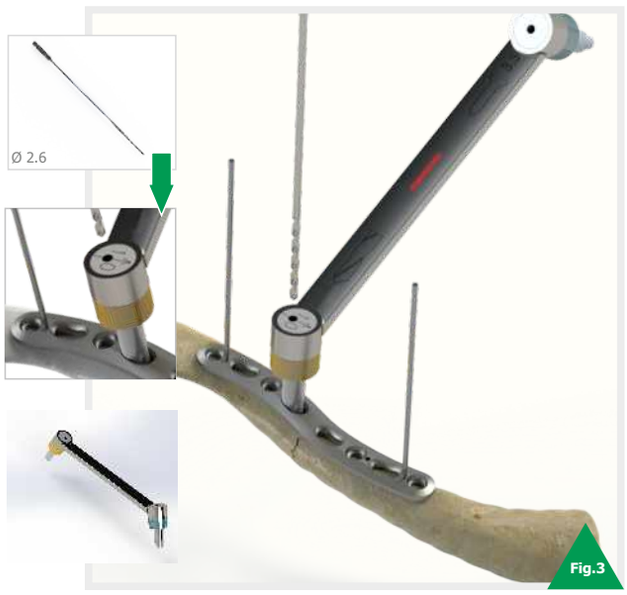


Fig.3

*Put the Ø 2.6 mm drill guide on cortical screw hole. (Fig.3)
*Open the way for cortical screw with using Ø2.6 mm drill bit (Fig.4)

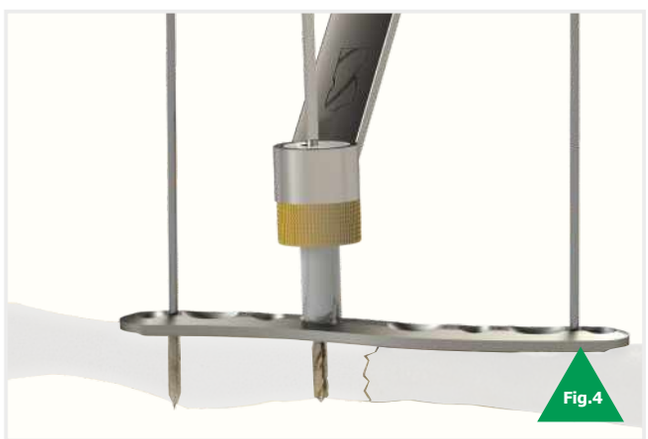


Fig.4

*Decide to size of screws with using depth guide. (Fig.5)
*Make tap with 3,5 mm Tap (Fig.6)

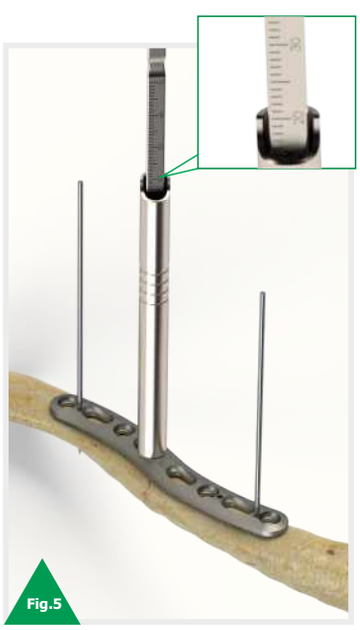


Fig.5

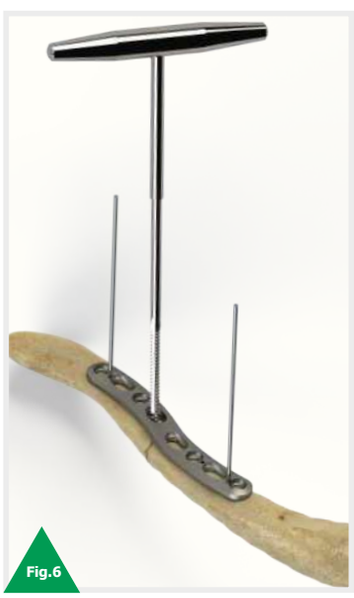


Fig.6

2.2.Clavicle Plate

2.2.4.Ø3,5 Cortical Screw

2a

Chosen size of cortical screw is sent to hole (not fully) (Fig.7-8)

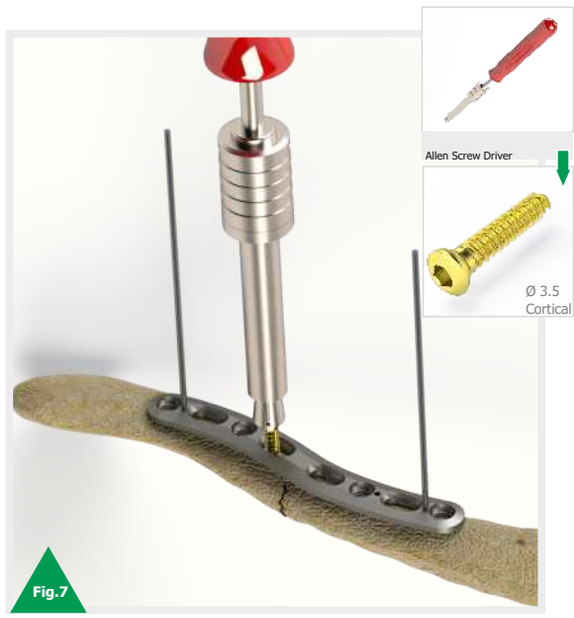


Fig.7

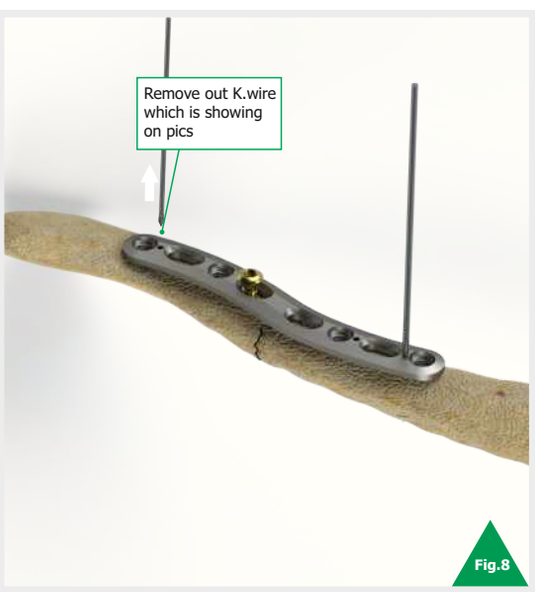


Fig.8

Note : Please look at shape 1 ,page 8 if you need to more information about sent cortical screws(not fully). Full screwing process has been showed at page 8.

2.2.Clavicle Plate

2.2.5. Ø3,5 Locking Screw

*Put the Ø 2.6 mm drill guide on locking screw hole. (Fig.9)
*Open the way for locking screw with using Ø 2.6 mm drill bit (Fig.10)

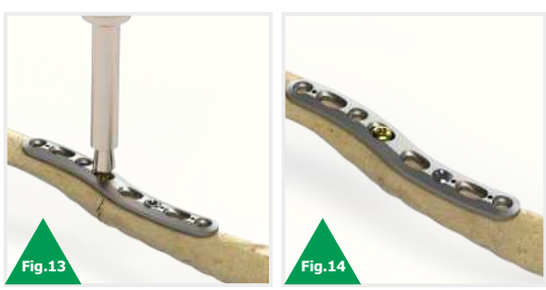
*'For Ø 3,5locking screws, you can decide to size of locking screws while drilling process.' There is black strip on the drill. In this way, you can decide screws size with usign measure which is on guide. (Fig.10)

Note : You should use non-deformed drill for perfect screws match

2.2.Clavicle Plate

2.2.5. Ø3,5 Locking Screw

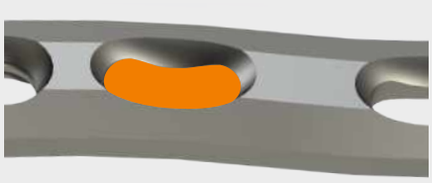
*Send Ø 3.5 mm locking screw with Ø 2.5 mm allen screwdriver (Fig.11)
*Complete the screwing process with using Ø 2.5 mm torque allen screwdriver. (1.5Nm torque) (Fig.12). After this step you should remove the k-wires.



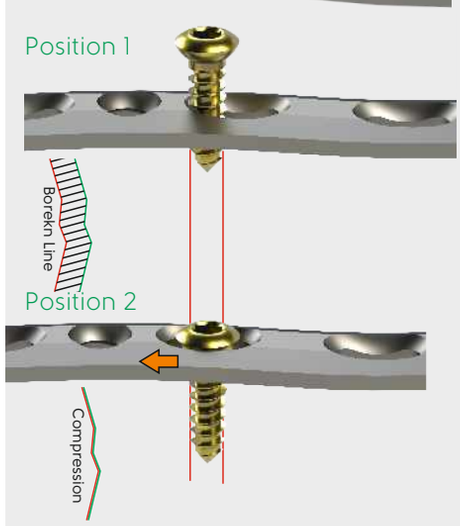
2a step : Send rest of the Ø3,5 cortical screws. In this way, you has been finished compression and plate positioning. (Fig.13-14)

*If you need , you can send Ø3,5mm screws to other holes. At the scopy view dynamic screw holes has been empty. (Near of fracture) (Fig.15)

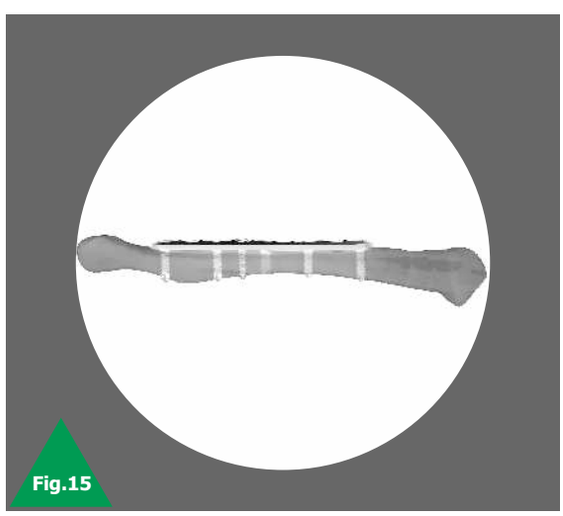
Dynamic Compression Zone and One-way Compression



The structure of dynamic compression part on plate is gived to make compression possibilty/opportunity.

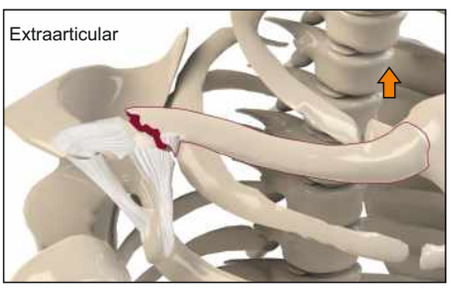


You can see how compression will be completed at left (position 1 to position 2) (For compression, you should not send cortical screws full.)



2.3. Distal Clavicle Plate

2.3.1.Lateral Clavicle Fracture



In displaced lateral clavicle fractures, the distal lateral plate adapts to the distal of the bone thanks to its anatomical structure and 2.4 locking screws. It can be applied in this and similar cases.

2.3.2.Plate Positioning and Kirschner Wire

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

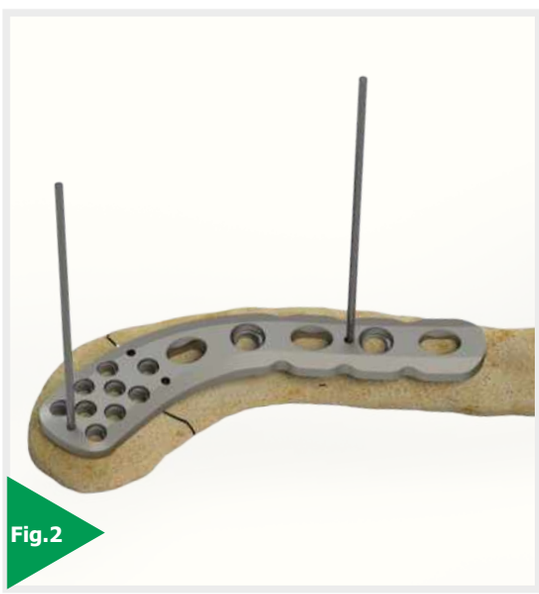


*Plate is temporarily fixed on bone with

2.3. Distal Clavicle Plate

2.3.3.Ø3,5 Cortical screw

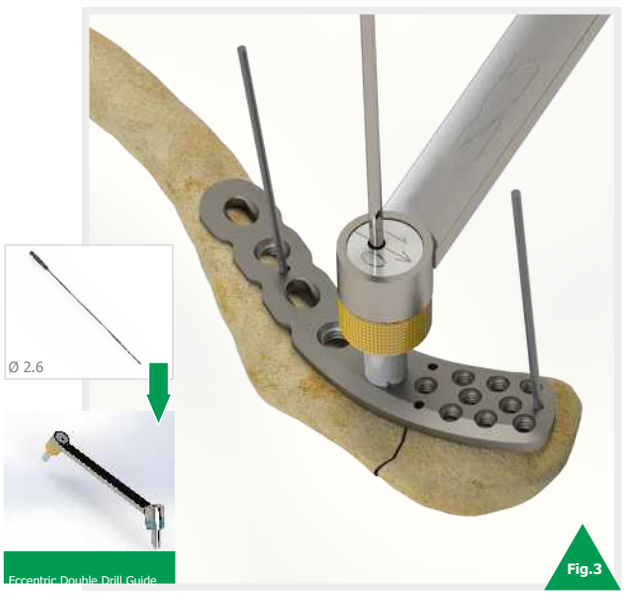


Fig.3

*Put the Ø2.6 mm drill guide on cortical screw hole (Fig.3)
*Open the way for cortical screw with using Ø2.6 mm drill bit (Fig.4)

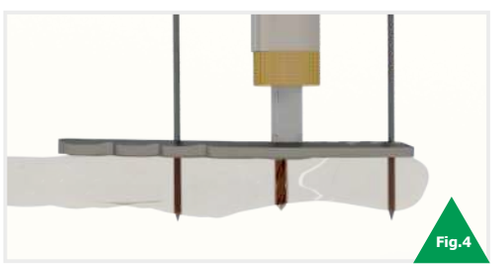


Fig.4

*Decide to size of screws with using depth guide. (Fig.5)
*Make tap with Ø3,5 mm Tap (Fig.6)

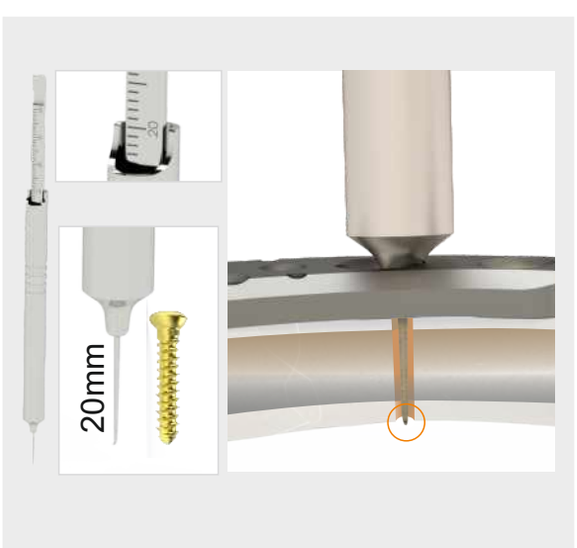



Fig.5


Fig.6

2.3. Distal Clavicle Plate

2.3.3.Ø3,5 Cortical screw

2a *Chosen size of cortical screw is sent to hole (not fully) (Fig.7-8)

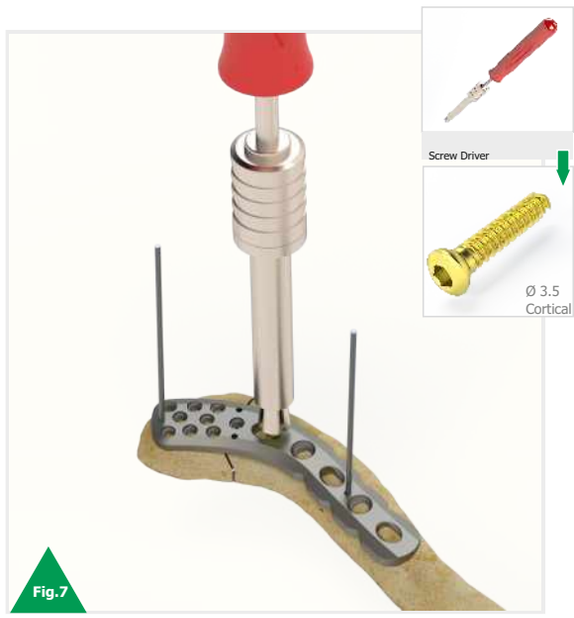


Fig.7

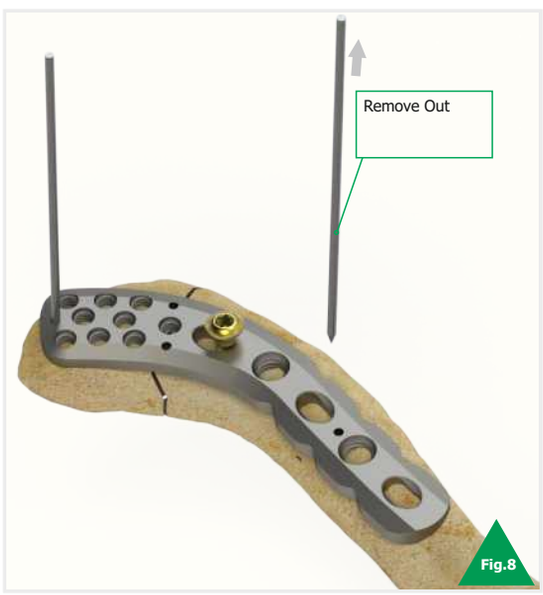
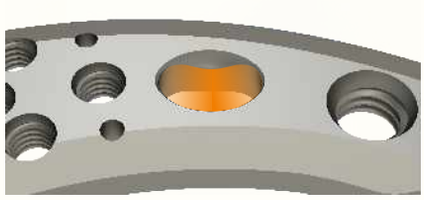


Fig.8

*.Remove out K.wire which is showing on pics (Fig.8)

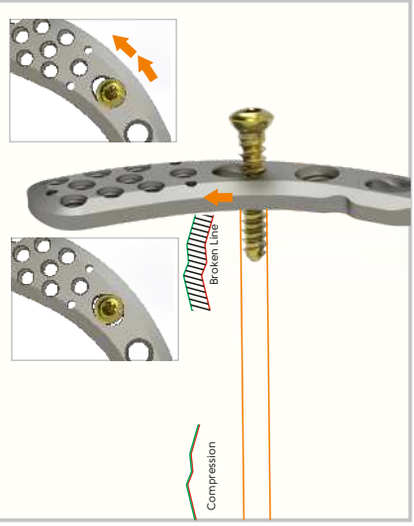
Note : Please look at shape 1 ,page 6 if you need to more information about sent cortical screws(not fully). Full screwing process has been showed at page 8.

Dynamic Compression Zone and one-way compression



The structure of dynamic compression part on plate is gived to make compression possibilty/opportunity.

You can see how compression will be completed at left (position 1 to position 2)
(For compression, you should not send cortical screws full.)



2.3. Distal Clavicle Plate

2.3.4. Ø 2.4 Locking Screw

*Put the Ø1.75 mm drill guide on distal part holes (Fig.9).
*Open the way for locking screw with using Ø1.75 mm drill bit (Fig.10).

"*For Ø2,4 locking screws, you can decide to size of locking screws while drilling process.' There is black strip on the drill. In this way, you can decide screws size with usign measure which is on guide.((Fig.10)"

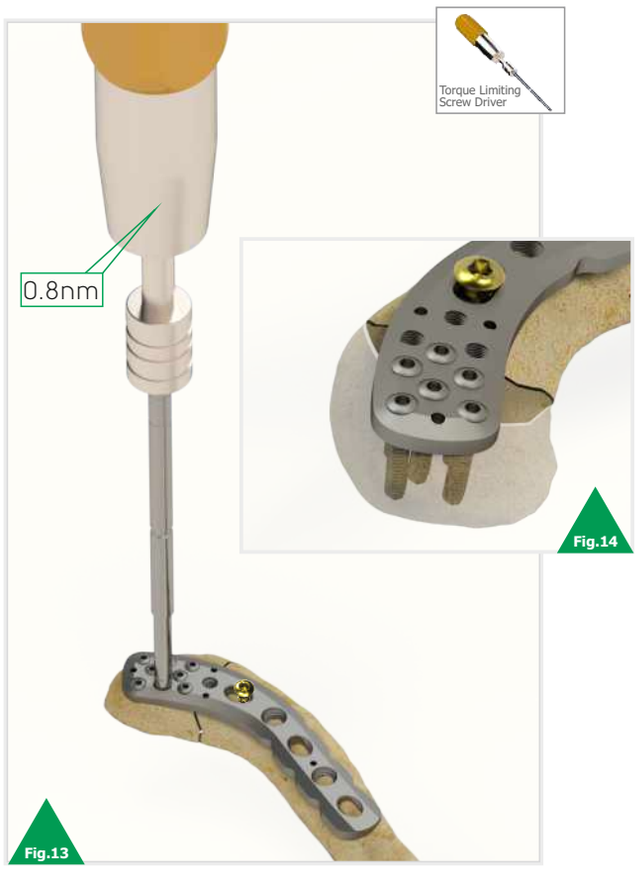
Note : You should use non-deformed drill for perfect screws match

*Send Ø2.4 mm locking screw with 1.5 mm allen screwdriver (Fig.11).

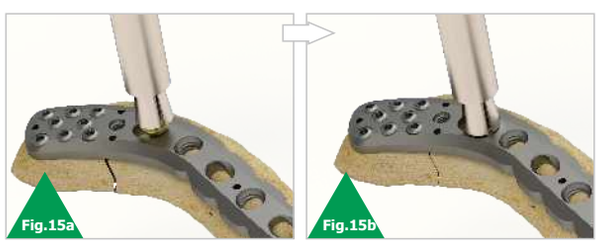
2.3. Distal Clavicle Plate

2.3.4. Ø 2.4 Locking Screw

*Remove out rest of the K-wires. (Fig.13). Complete the screwing process with using 1.5 mm torque allen screwdriver. (0.8Nm torque) (Fig.13-14).



*2a step : Send rest of the Ø3,5 cortical screws. In this way, you has been finished compression and plate positioning. (Fig.15-a-b)



2.3. Distal Clavicle Plate

2.3.5. Ø 3.5 Locking Screw

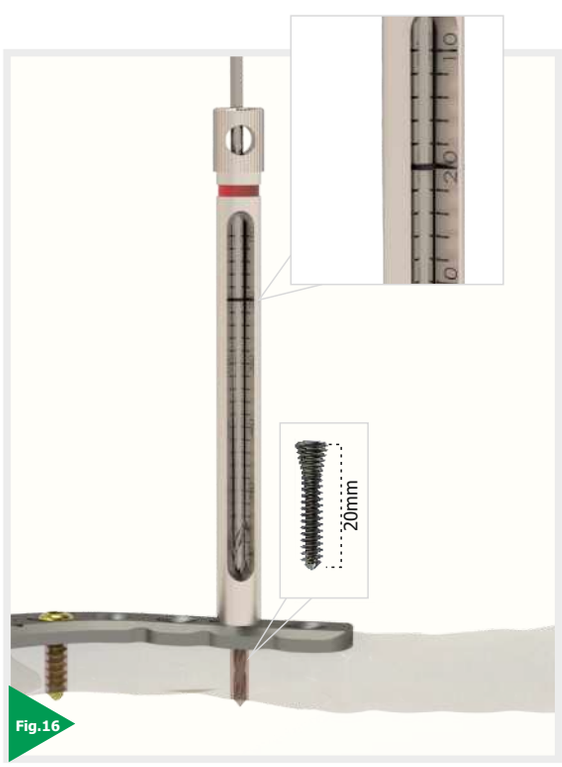
*Put the Ø2.6 mm drill guide on locking screw hole. (Fig.15)
*Open the way for locking screw with using Ø2.6 mm drill bit (Fig.16)

"

*'For Ø3,5 locking screws, you can decide to size of locking screws while drilling process.'There is black strip on the drill. In this way, you can decide screws size with usign measure which is on guide. (Fig.16)

"

Note : You should use non-deformed drill for perfect screws match



2.3. Distal Clavicle Plate

2.3.4.Ø 3.5 Locking Screw

Fig.17

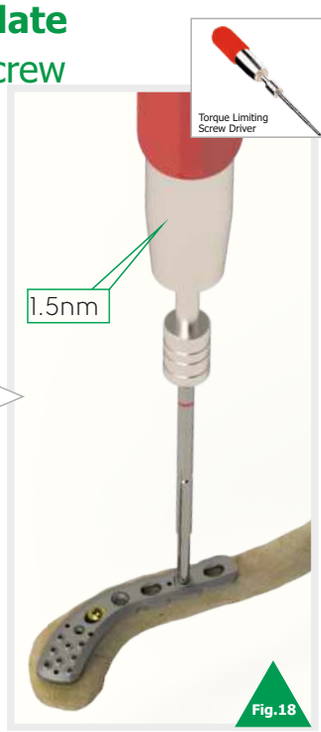


Fig.18

*Send Ø3.5 mm locking screw with Ø 2.5 mm allen screwdriver. (1.5Nm torque) .(Fig.17-18)

*If you need , you can send Ø3,5mm screws to other holes and complete process. (Fig.19-20)


Fig.19

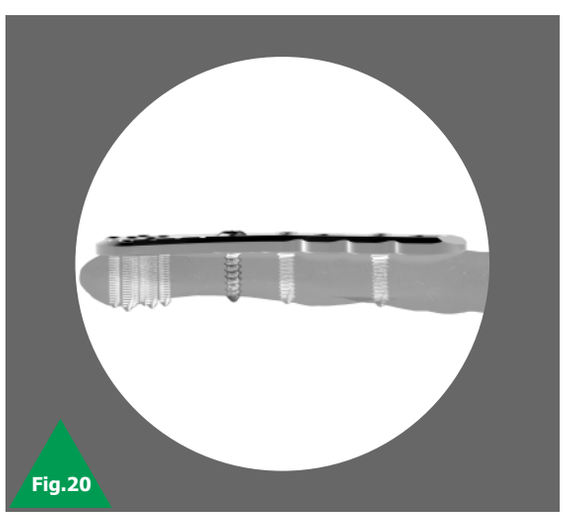
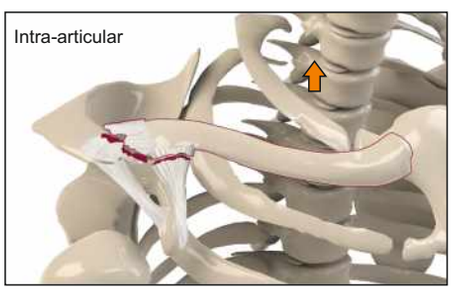
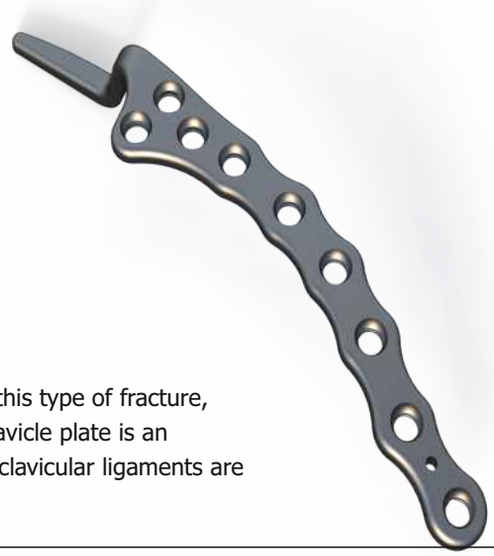


Fig.20

2.4.Clavicle Hook Plate

2.4.1. Lateral Clavicle Fracture





This type of fracture is a type of fracture involving the joint. In this type of fracture, the distal clavicle plate is sometimes insufficient. The hooked clavicle plate is an alternative designed to be used in situations where the acromioclavicular ligaments are broken and the distal clavicular plate is insufficient for fixation.

2.4.2.Fracture reduction

*The fracture should be reduced and temporarily fixed before plate placement. Fig.1).

*Reduced fracture with reduction forceps is temporarily fixed with Kischner Wire. If deduction is not made with a plate, it can be fixed with screws as an alternative (Fig.2).

2.4.Clavicle Hook Plate

2.4.3.Plate Placement

The hook part of the plate is passed through the lower part of the acromion and the medial of the plate is temporarily fixed with a Kishner wire (Fig.3)

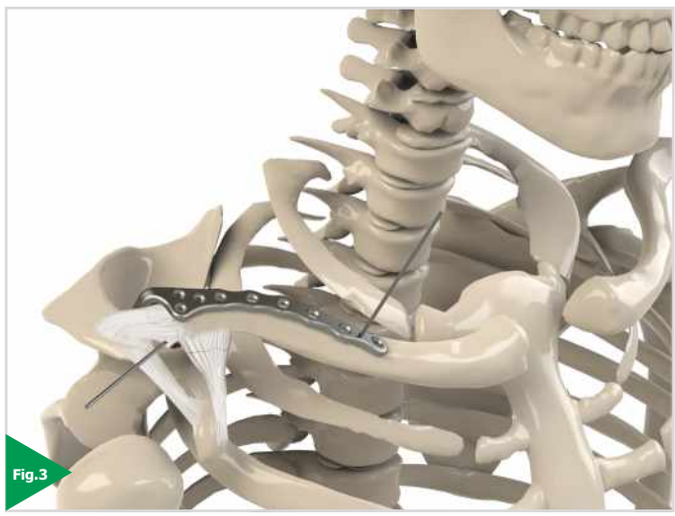


Fig.3

Drill for 3.5 locking screws from the plate shank. At the same time, identify the appropriate size screw (Fig.4)

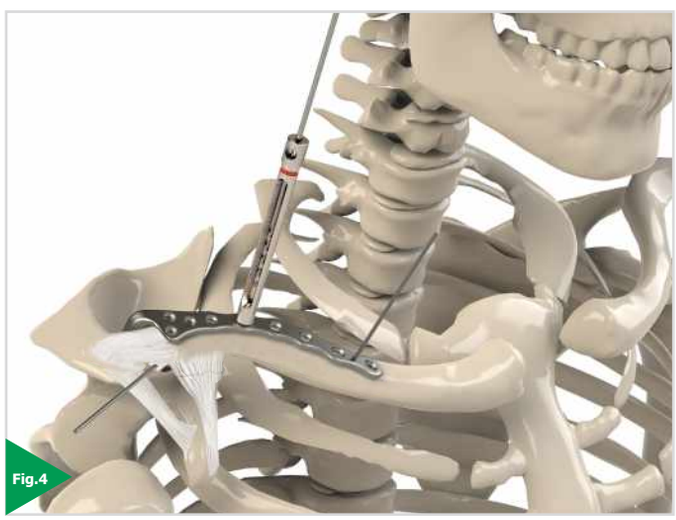


Fig.4

Install the appropriate size screw with a 3.5 screwdriver (Fig.5). Send the sufficient number of locking screws.

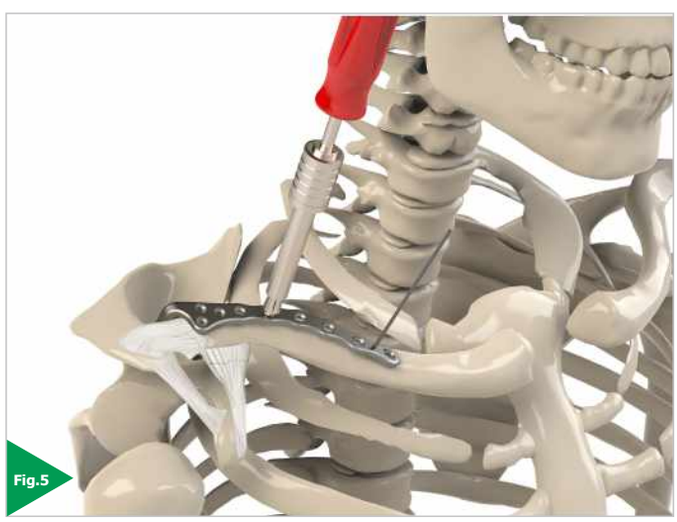


Fig.5

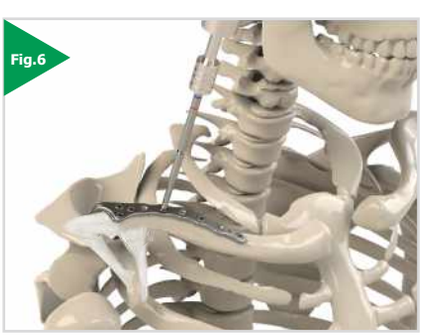


Fig.6

Check the tightening of the 3.5 screws for each with a torque screwdriver (Fig.6).

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 on Zimed tools. Neutral pH enzymatic and cleaning 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.

3.1.1 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 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.

3.1.2 *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 / 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.

3.1.3 *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 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

Zimed 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. Zimed 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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