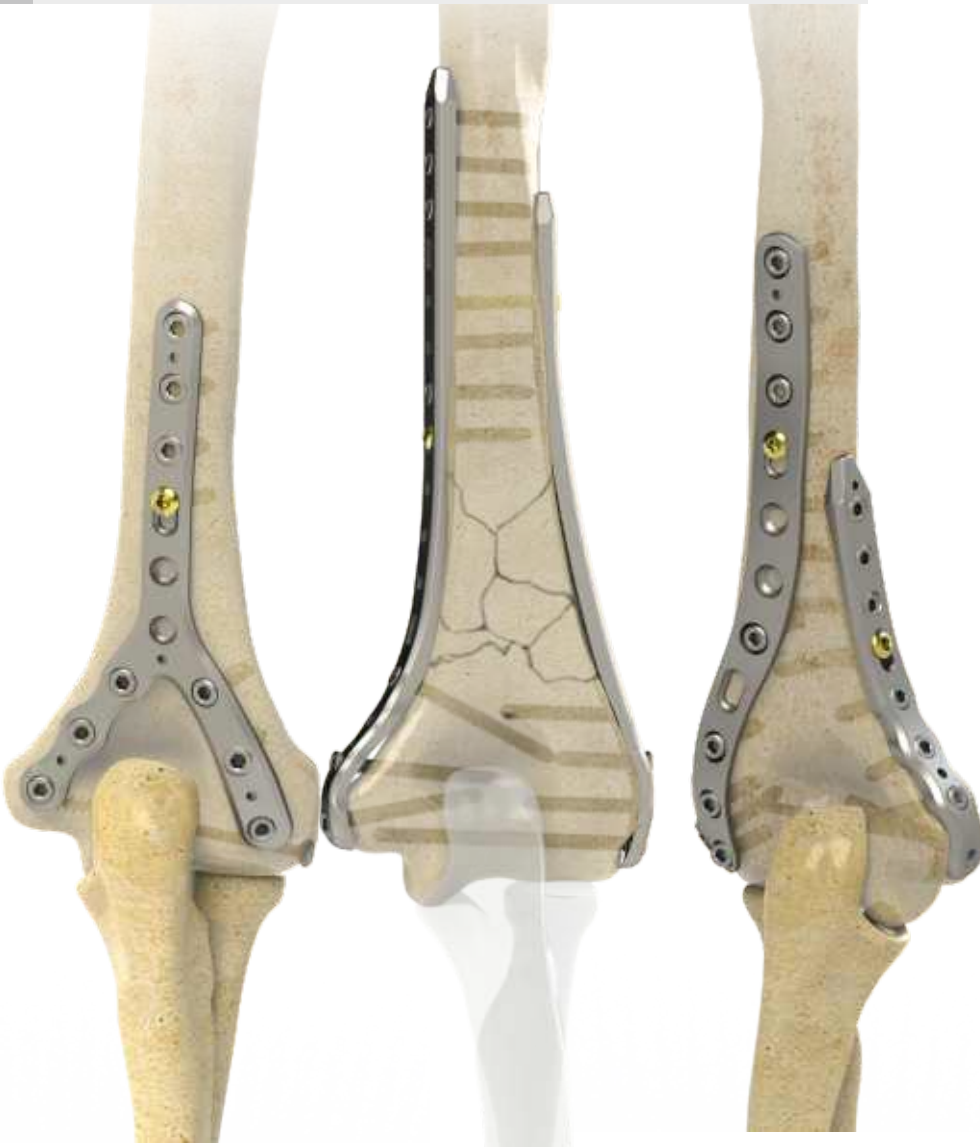




www.zimed.com.tr

Locking **ELBOW PLATE SYSTEM**

SURGICAL TECHNIQUE



zimed[®]

Locking

ELBOW

PLATE SYSTEM

Contents

1. Introduction

1.1.Locking Distal Posterior Humeral Plate	
1.1.1.Specification	3
1.2.Locking Distal Lateral Humeral Plate	
1.2.1.Specification	4
1.3.Locking Distal Medial Humeral Plate	
1.3.1.Specification	5
1.4.Locking Distal Y Humeral Plate	
1.4.1.Specification	6

2. Surgical Technique

2.1.Elbow Joint	7
2.2.Distal Humerus Fracture.....	
2.2.1.Approach	9
2.3.Plate Application.....	10
2.3.1.Perpendicular double plating.....	
2.3.1.1. Fixation with Kirschner Wire and Headless Cannulated Screw.....	
2.3.1.2. Plate placement and locking screw for distal posterior plate.....	
2.3.1.3. Ø3.5 mm Cortical screw for posterior plate.....	
2.3.1.4. Ø3.5mm Cortical Screw for the medial plate.....	
2.3.1.5. Removing Kirschner Wires and Distal Locking Screws.....	
2.3.1.6. Tightening and Compression of Cortical Screws.....	
2.3.1.7. Installation and Torque of Proximal Locking Screws.....	
2.3.2.Y Plate.....	14
2.3.2.1. Fixation of the Fracture,Cancellous screw and plate placement	
2.3.2.2. Ø3.5mm Cortical Screw	
2.3.2.3.Ø3.5mm Locking Screw (Distal)	
2.3.2.2. Tightening and Compression of Cortical Screws	
2.3.2.3. Ø3.5mm Locking Screw (Proximal)	
2.3.3. Paralel Plating.....	17
2.3.3.1. Fixation of the Fracture,	
2.3.3.2. Plate Placement and cortical screw for medial plate ,	
2.3.3.2. Plate Placement and cortical screw for medial plate ,	
2.3.3.2. Lateral Plate Cortical Screw ,	
2.3.3.2. Locking Screw (Distal)crew	
2.3.3.2. Tightening and Compression of Cortical Screws	

3. Disinfection

3.1. Device Cleaning Conditions.....	20
3.1.1. Manual Cleaning/Disinfection.....	
3.1.2. Combination Manual / Automated Cleaning.....	
and Disinfection:.....	
3.1.3. Automated Cleaning and Disinfection.....	

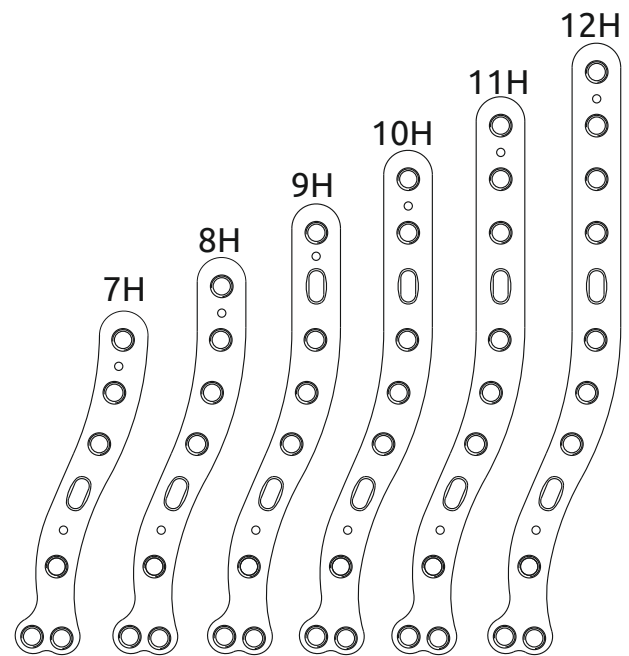




1.1. Locking Distal Posterior Humeral Plate

1.1.1. Specification

It is indicated for fixation of distal posterior humerus articular fractures and osteotomies. It is produced from ISO 5832-2 TiGr3 (ASTM F 67) material. 7-12 holes, 84, 97, 110, 123, 136, 150 mm length options are available. It is used with Ø 3,5 mm locking screw and Ø 3,5 mm cortical screw.



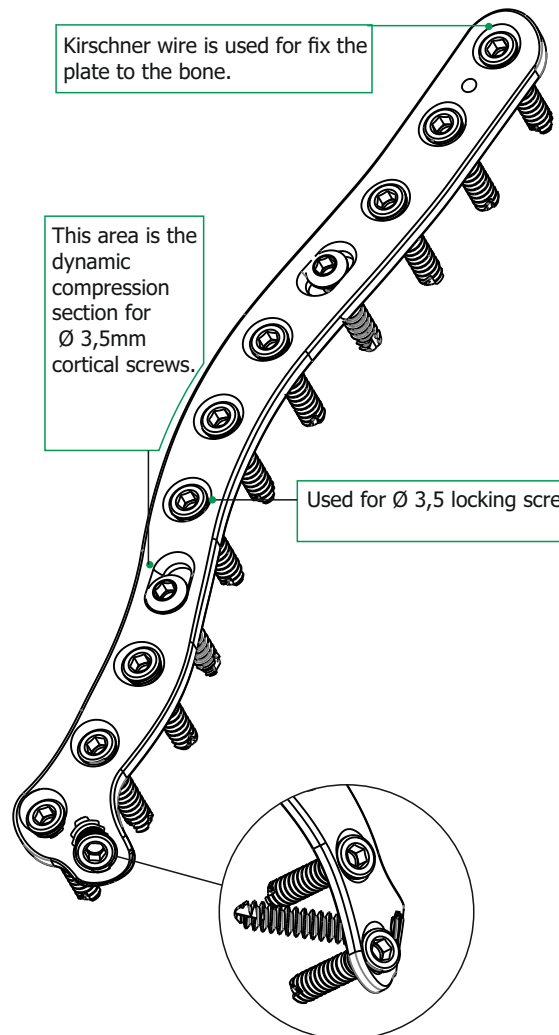
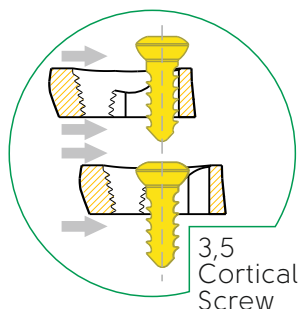
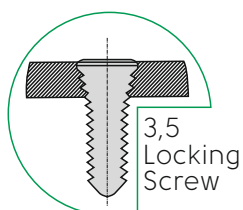
zimed®
Locking
 DISTAL POSTERIOR
 HUMERAL PLATE

REF. NO	HOLES
1502-1008	8-R
1502-1010	10-R
1502-1012	12-R
1502-2008	8-L
1502-2010	10-L
1502-2012	12-L

Kirschner wire is used for fix the plate to the bone.

This area is the dynamic compression section for Ø 3,5mm cortical screws.

Used for Ø 3,5 locking screws.

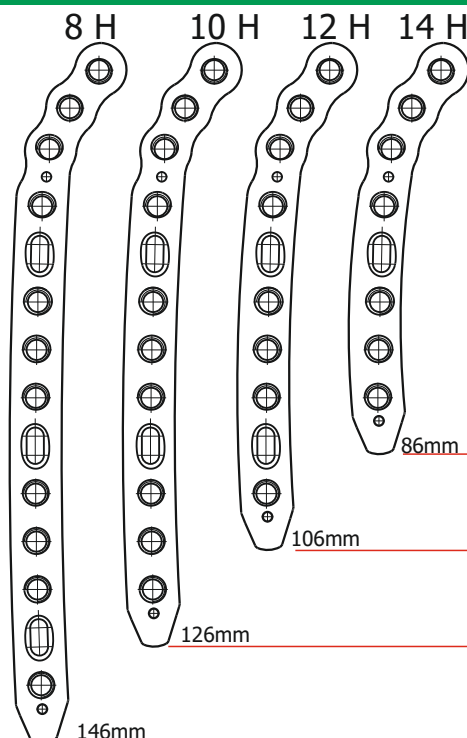




1.2. Locking Distal Lateral Humeral Plate

1.2.1. Specification

It is indicated for the fixation of the distal humerus fractures and osteotomy after fracture malunions and nonunion of the distal humerus fracture. 8, 10, 12, 14, 16 holes, 87, 107, 127, 147, 167 mm length options are available. Right-left feature is available. It is used with Ø3,5 mm locking screw, Ø3,5 mm Cortical screw and Ø4,0 mm cancellous screw, Ø4,0 locking cancellous screw. Locking Distal Medial Plates are manufactured from titanium alloy manufactured according to ASTM F136.

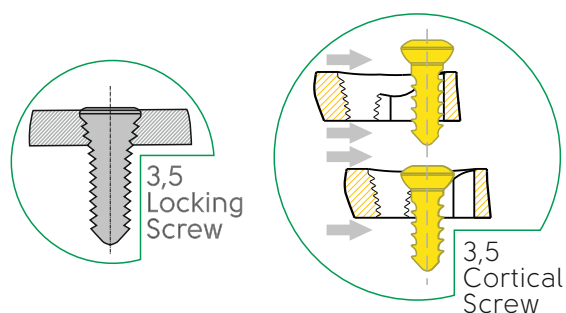


zimed®

Locking

DISTAL LATERAL HUMERAL PLATE

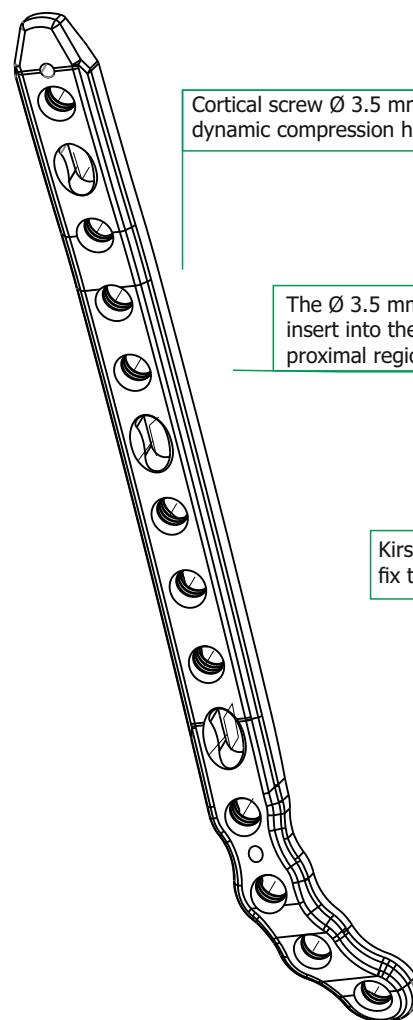
REF. NO	HOLES
1682-1008	8-R
1682-1010	10-R
1682-1012	12-R
1682-1014	14-R
1682-2008	8-L
1682-2010	10-L
1682-2012	12-L
1682-2014	14-L



Cortical screw Ø 3.5 mm have insert into the dynamic compression holes.

The Ø 3.5 mm locking screw have insert into the plate holes in the proximal region of the plate.

Kirschner wire have apply to fix the plate on the bone.





1.3. Locking Distal Medial Humeral Plate

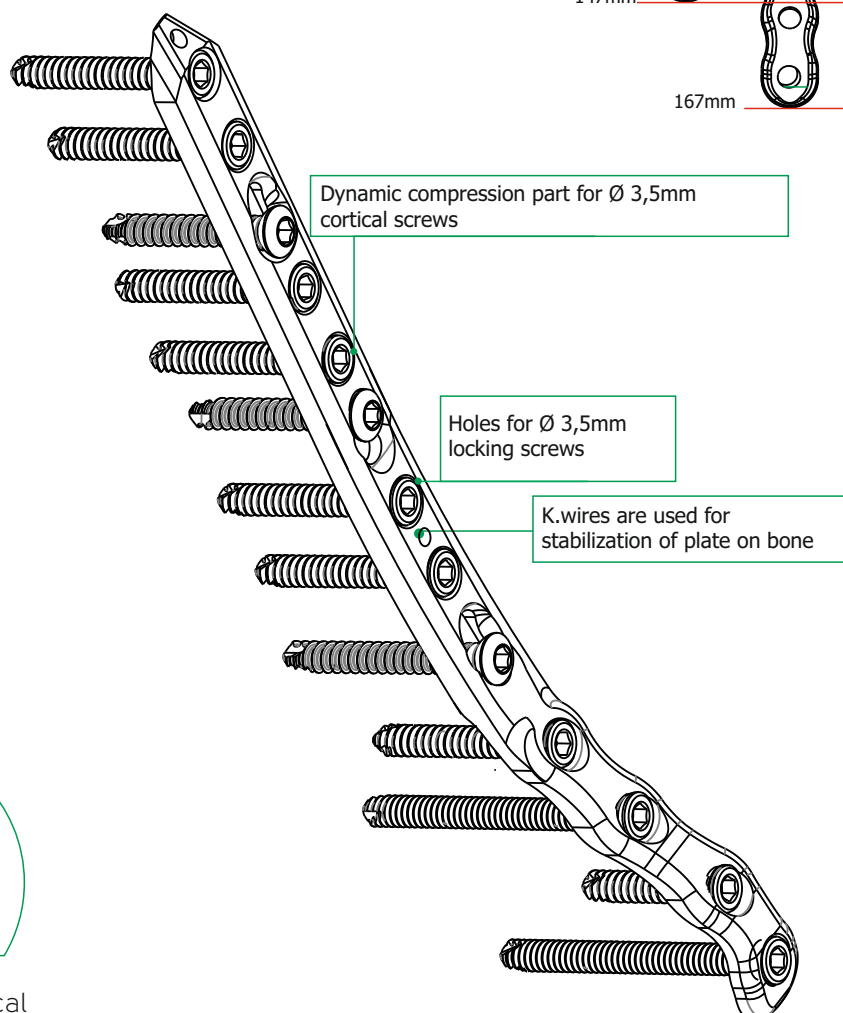
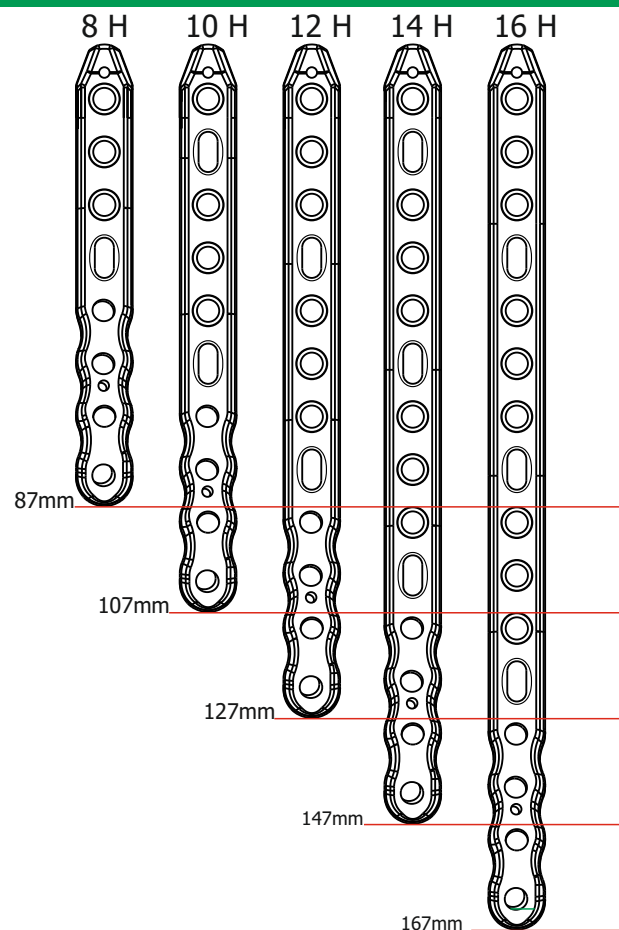
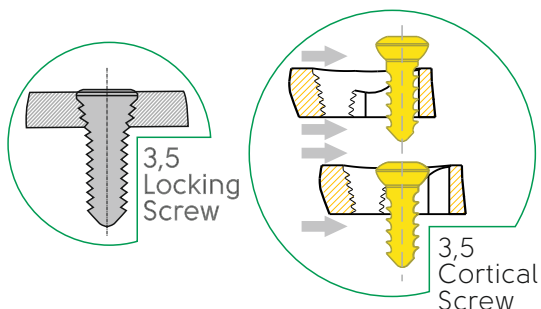
1.3.1. Specification

It is indicated for the fixation of the distal humerus fractures and osteotomy after fracture malunions and nonunion of the distal humerus fracture. 8, 10, 12, 14, 16 holes, 87, 107, 127, 147, 167 mm length options are available. Right-left feature is available. It is used with Ø3,5 mm locking screw, Ø3,5 mm Cortical screw, Ø4,0 mm cancellous screw, Ø4,0 locking cancellous screw. Locking Distal Medial Plates are manufactured from titanium alloy manufactured according to ASTM F136.

zimed[®]

Locking Distal Medial Humeral Plate

REF. NO	HOLES
1532-1008	8-R
1532-1010	10-R
1532-1012	12-R
1532-1014	14-R
1532-1016	16-R
1532-2008	8-L
1532-2010	10-L
1532-2012	12-L
1532-2014	14-L
1532-2016	16-L

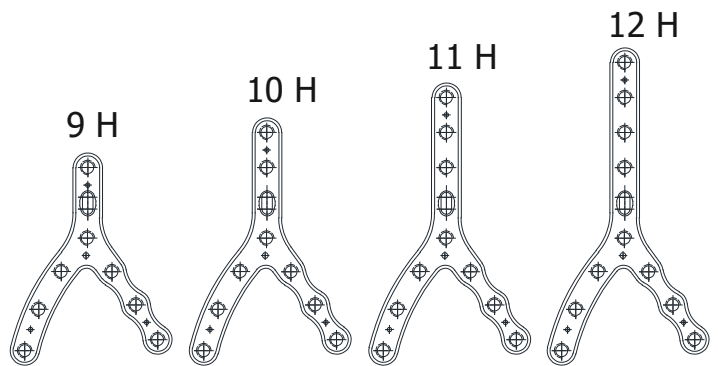




1.4. Locking Distal Y Humeral Plate

1.4.1. Specification

It is indicated for the fixation of the distal humerus intraarticular, supracondylar fractures and non-union situations of the distal humerus. It's used with Ø3.5 Locking and Ø3.5 Cortical Screw. Locking Distal Humeral Y Plate is manufactured from ISO 5832-2 TiGr3 (ASTM F 67) material. 9-16 holes, 73, 85, 97, 109, 121, 133, 145, 157 mm length options are available.

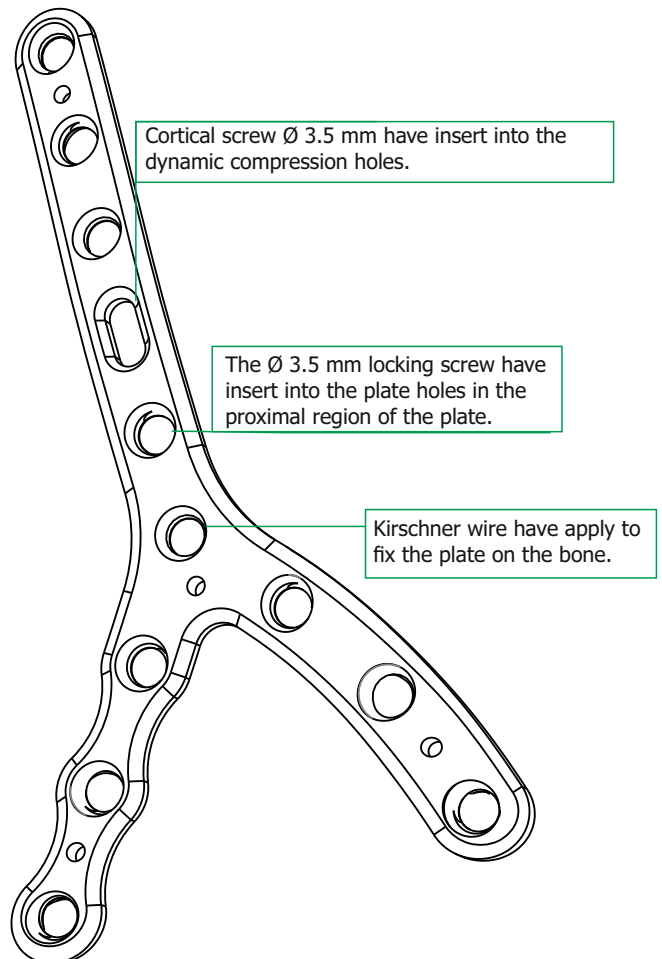
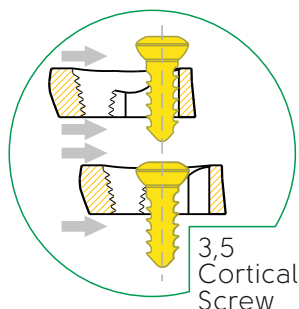
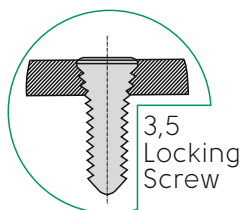


zimed[®]

Locking

Distal Humeral
Y Plate

REF. NO	HOLES
1512-1009	9-R
1512-1010	10-R
1512-1011	11-R
1512-1012	12-R
1512-2009	9-L
1512-2010	10-L
1512-2011	11-L
1512-2012	12-L

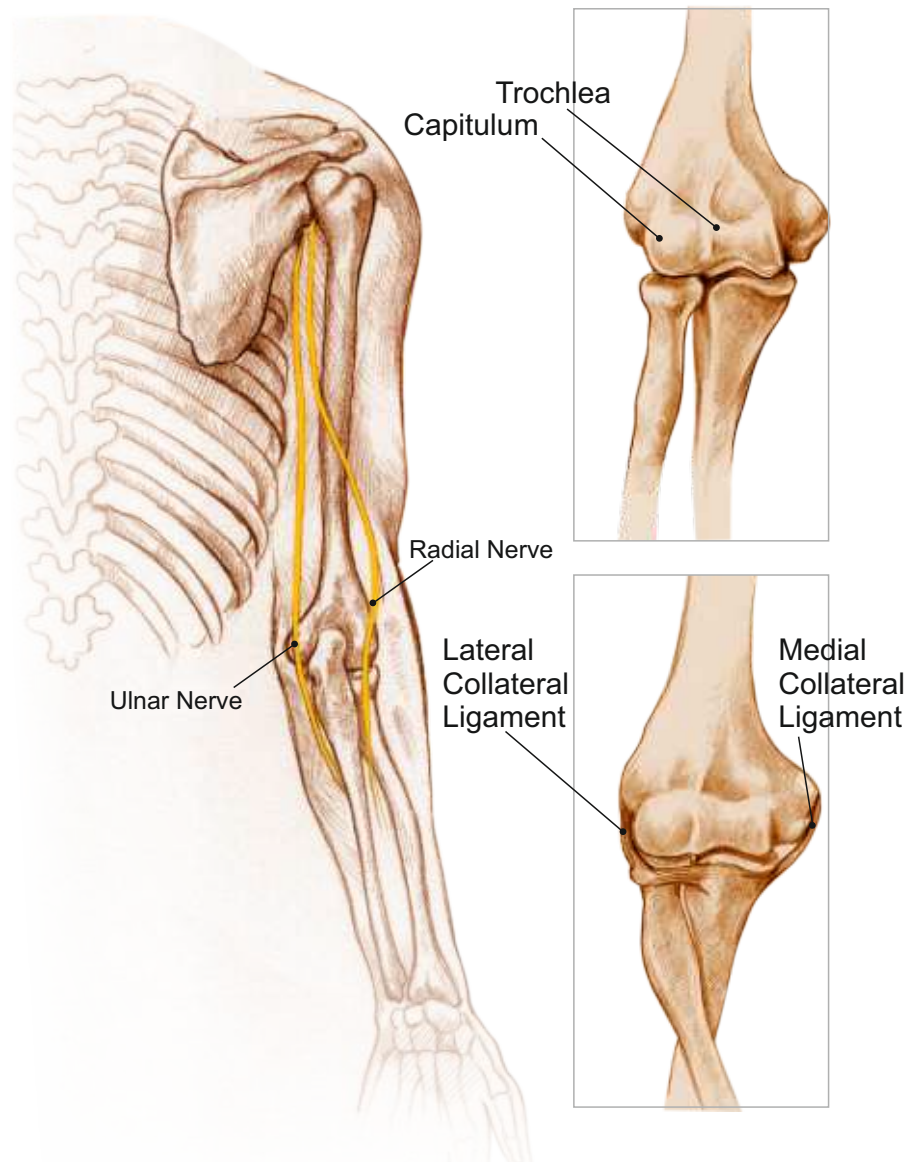




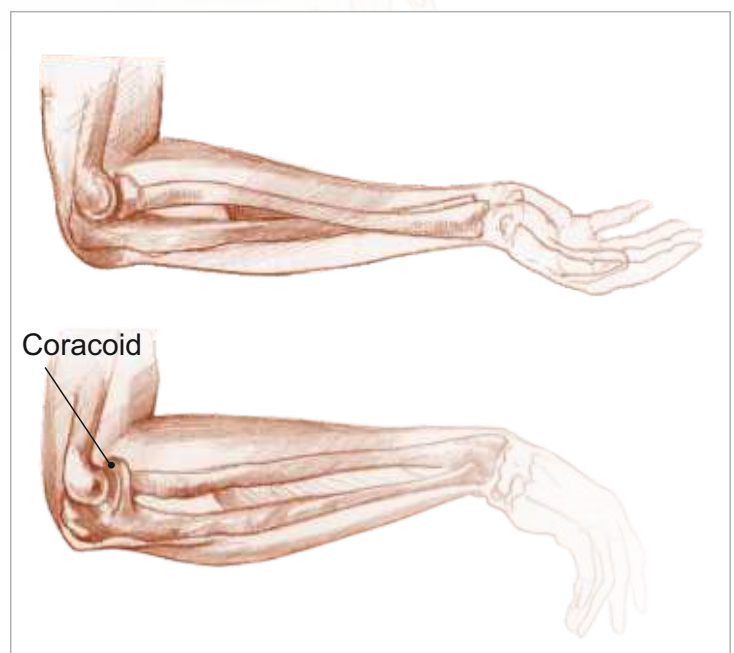
2.1. Elbow Joint

The humerus has two articular surfaces, the round-headed capitellum, the roller-shaped Trochlea.

They articulate with the articular surfaces of the radial head and the trochlear notch of the ulna. This whole unit acts as a hinge joint with the biceps and brachialis flexing and the triceps extending it.



The elbow is a restricted structure consisting of two joints:
Ulnohumeral - flexion and extension of the forearm.
Radiocapitellar - forearm pronosupination.

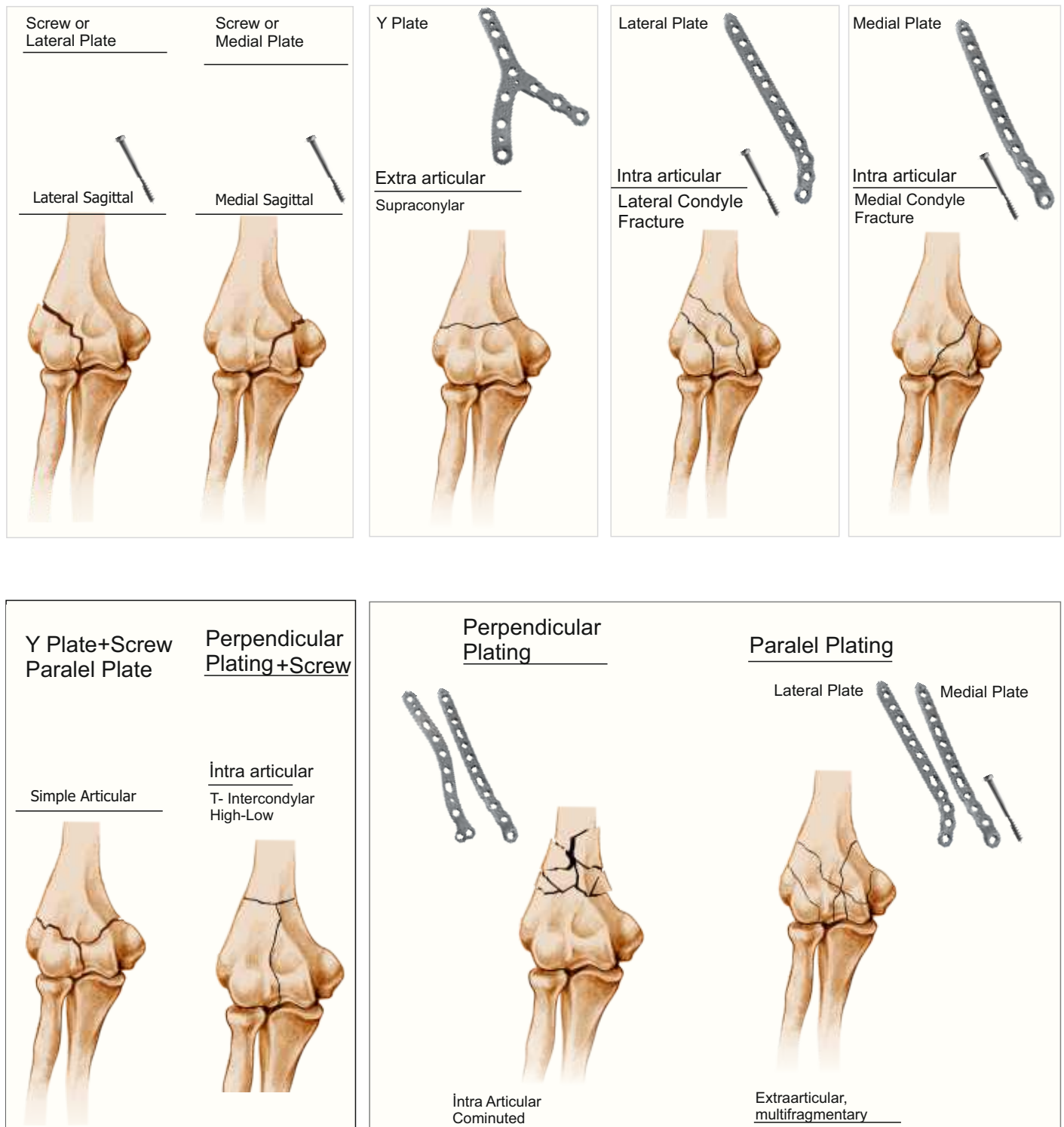




2.2. Distal Humerus Fractures

Distal humerus fractures account for about half of elbow fractures. The most common form of fracture in adults is double-column and intra-articular. .

There are various classifications for distal humerus fractures. Some examples of these classifications are given. Plate application is recommended for some fracture types.



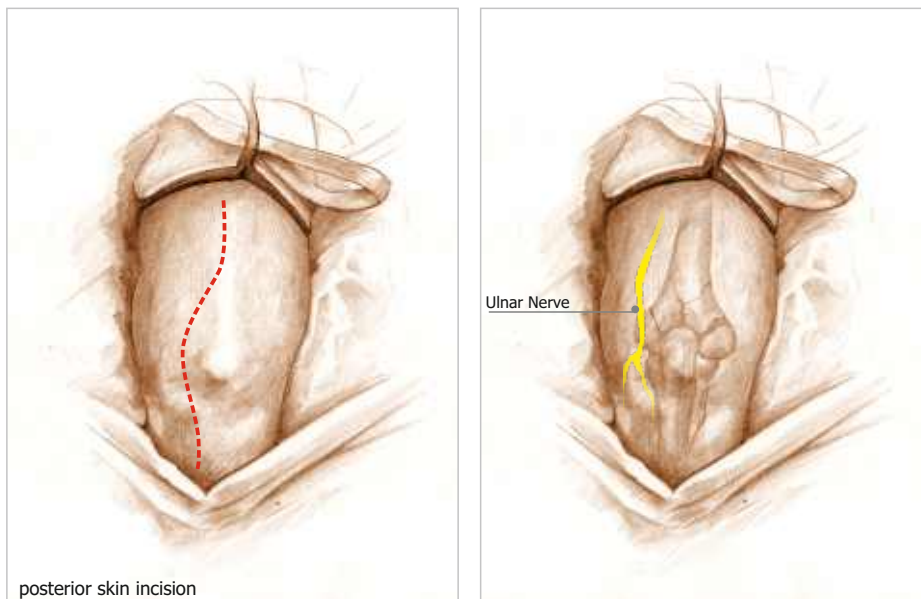
These are only a general suggestion. Every patient needs individual treatment, surgeon should take this into account



2.2. Distal Humerus Fractures

2.2.1. Approach

All approaches to fixation of distal humeral fractures begin with a posterior skin incision through the triceps muscle or with various dissections protecting it.





2.3. Plate Application

2.3.1. Perpendicular double plating

The main advantage of perpendicular plating is that screws can be placed more distally to the posterolateral plate to capture coronal fractures involving the capitellum.

It can be used on comminuted intra articular fracture

Distal Posterior Humeral Plate
Medial Humeral Plate,
and cancellous screw



2.3.1.1

Fixation with Kirschner Wire and Headless Cannulated Screw

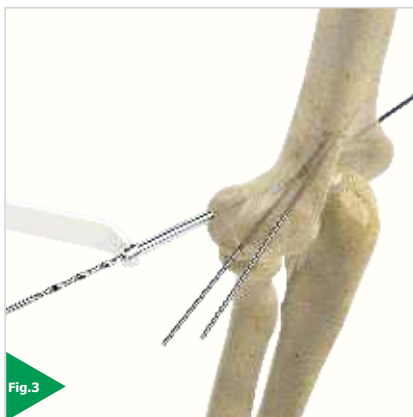
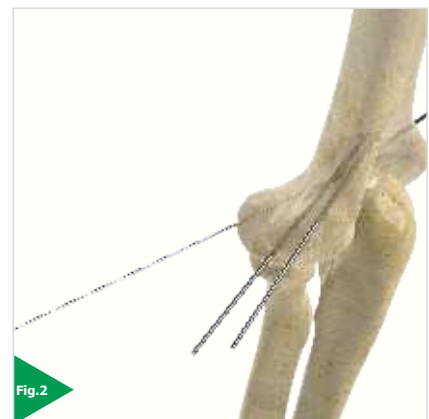
Fracture should be reduced with distractors

The fracture is temporarily fixed with Kirschner Wires (Fig.1).

It may be necessary to send a screw according to the fracture form. In this case an appropriate size headless cannulated screw is sent from the the lateral epicondyle.

To send the screw;
Send Kirschner wire for guidance purposes(Fig.2).
Insert drill guide and Drill with a cannulated drill(Fig.3).
Determine the screw length (Fig.4).
Insert the headless cannulated screw (Fig.5).

Intra Articular
Cominuted Fractures





2.3. Plate Application

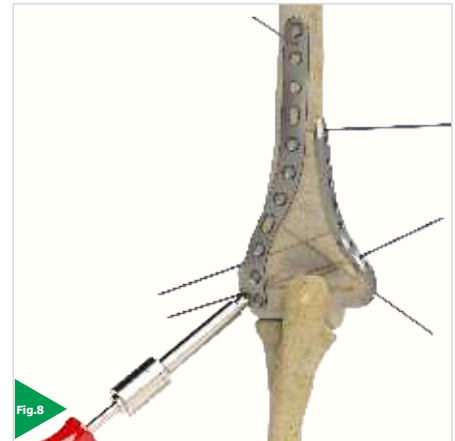
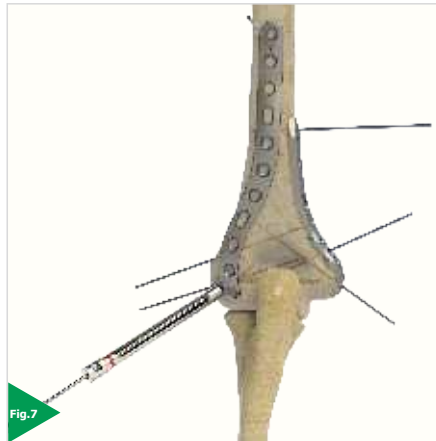
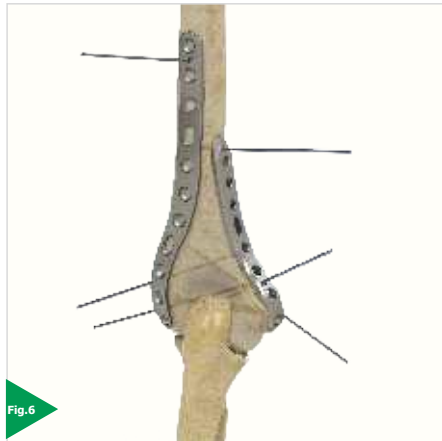
2.3.1. Perpendicular double plating

Fracture is fixed with the help of screws and Kirschner wires on previous stage. Plate placement is possible now.

2.3.1.2 Plate placement and locking screw for distal posterior plate

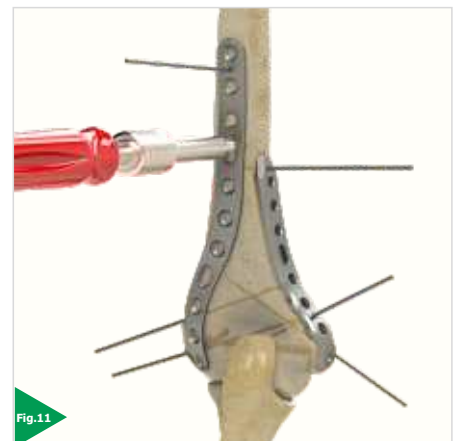
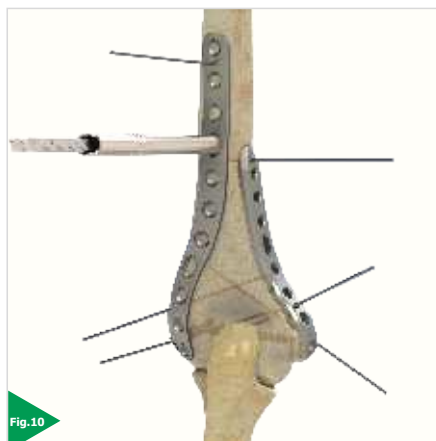
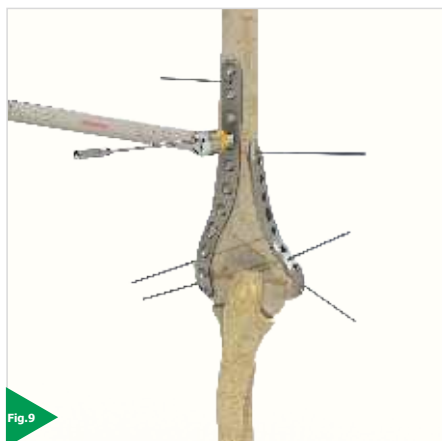
Posterior plate and medial plate are temporarily fixed with Kirschner wires according to the anatomy of the bone (Fig. 6).

First, a locking screw can be sent distally for the posterior plate. Drilling is done and while drilling, its length is measured with calibrated drill guide (Fig. 7). Ø3.5mm locking screw inserted with a Ø3.5 screwdriver. (Fig. 8).



2.3.1.3 Ø3.5 mm Cortical screw for posterior plate

Drilling is made for the cortical screw (Fig. 9). Determine screw length with depth guide (Fig. 10). It is sent with a 3.5 screwdriver that will not be fully tightened. (For compression) (Fig. 11).



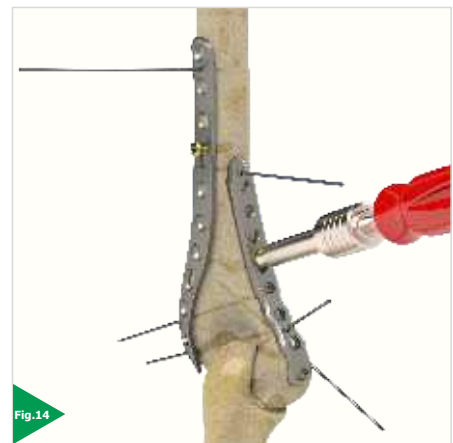
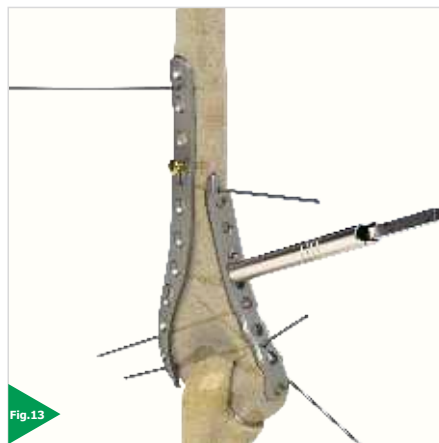
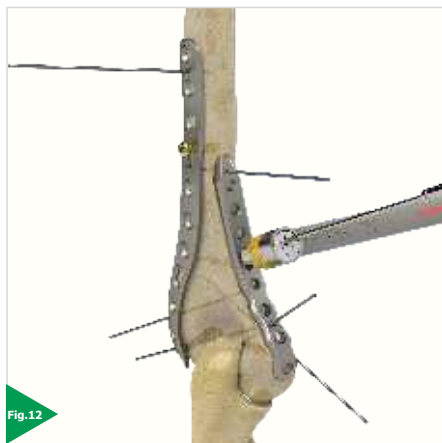


2.3. Plate Application

2.2.3. Perpendicular double plating

2.2.3.4 Ø3.5mm Cortical Screw for the medial plate

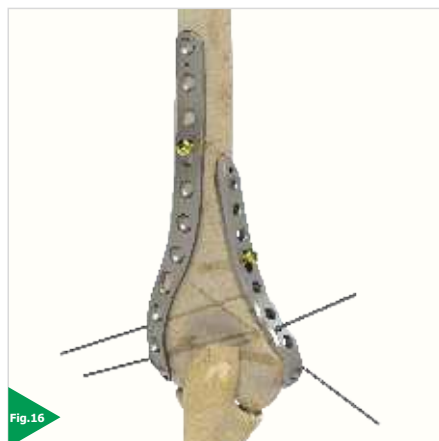
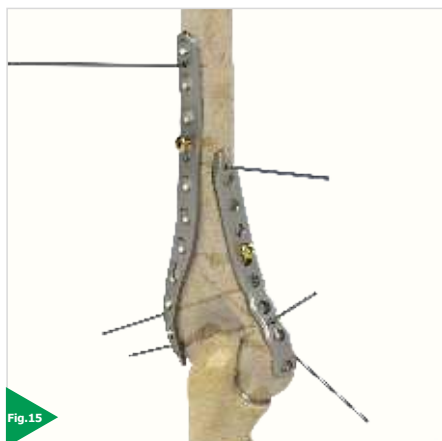
Drilling is made for the cortical screw (Fig. 12). Determine screw length with depth guide (Fig. 13). It is sent with a 3.5 screwdriver that will not be fully tightened. (For compression) (Fig. 14).



2.2.3.5 Removing Kirschner Wires and Distal Locking Screws.

In this way, the proximal Kirschner wires are removable (Fig. 16).. When the distal locking screws are sent all of the Kirschner wires become removable (Fig. 17).

You must remove the Kirschner wires at this stage so that you can perform dynamic compression. If it is not done, it can be removed at the end of the surgery.



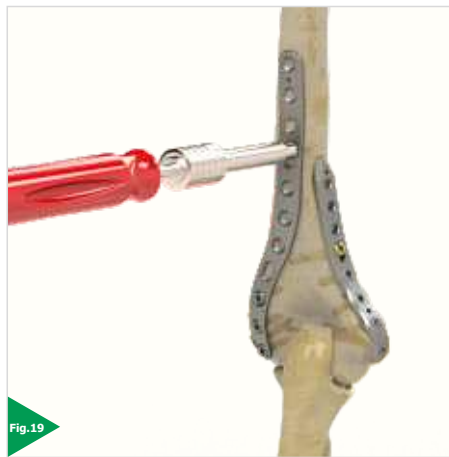


2.3. Plate Application

2.3.1. Perpendicular double plating

2.3.1.6. Tightening and Compression of Cortical Screws

Some compression can be done by completing the tightening process of the cortical screws that we sent half in the previous stage (*Fig.18-19*).



2.3.1.7 Installation and Torque of Proximal Locking Screws

Fracture is fixed with plate and screws now. When the proximal locking screws are sent, we get the necessary support from the shaft area of the bone and complete the perpendicular plating system. (*Fig.20-21*)



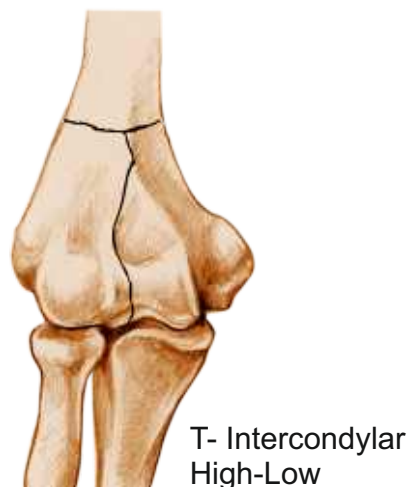
Torque operation of Locking Screws should be checked and completed. (*Fig.22*)



2.3. Plate Application

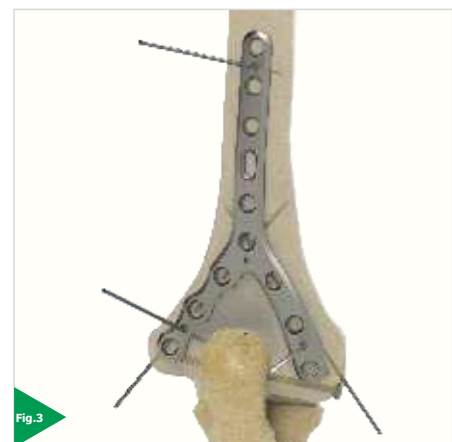
2.3.2. Y Plate

Y plate can be used to articular fracture and Intercondylar t fractures. If it support with screws on horizontal plane, by type of fracture more sturdy structure can be obtained.



2.3.2.1 Fixation of the Fracture, Cannulated screw and plate placement

The reduced fracture is temporarily fixed with Kirschner Wires (Fig. 1). Cannulated screw which is sent from distally fixed permanently (Fig. 2). Y plate is placed according to bone anatomy with the Kirschner wires (Fig. 3).



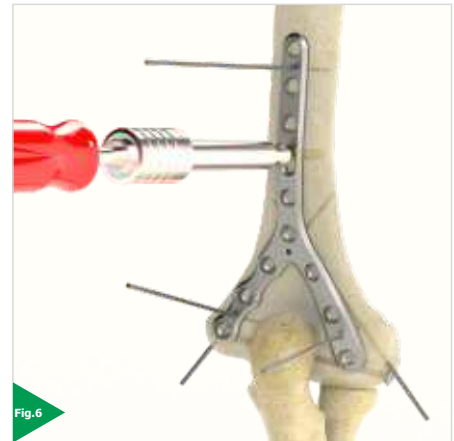
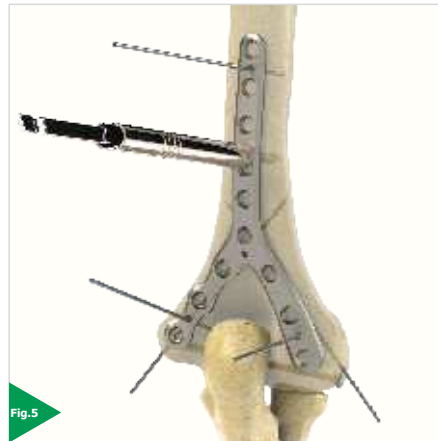
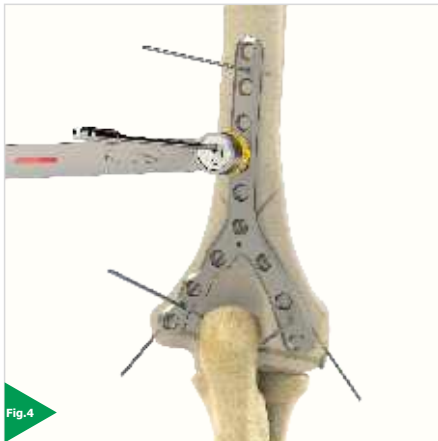


2.3. Plate Application

2.3.2. Y Plate

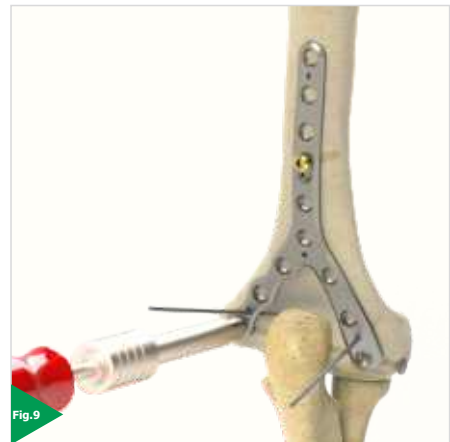
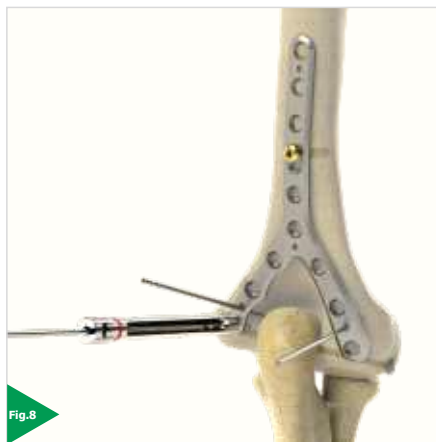
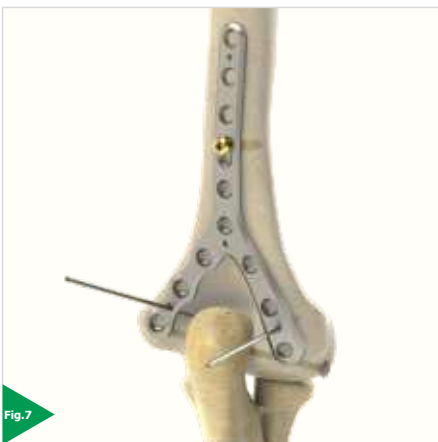
2.3.2.2. Ø3.5mm Cortical Screw

Drilling is made for the cortical screw (Fig.4). Determine screw length with depth guide (Fig.5). It is sent with a 3.5 screwdriver that will not be fully tightened. (For compression) (Fig.6). Kirschner wire on the proximally can be remove. (Kirschner wire must be removed so that the plate can move during the compression process.)



2.3.2.3. Ø3.5mm Locking Screw (Distal)

Locking screw can be sent on distally in this section. (If no compression will be done, all the locking screws can be sent.)



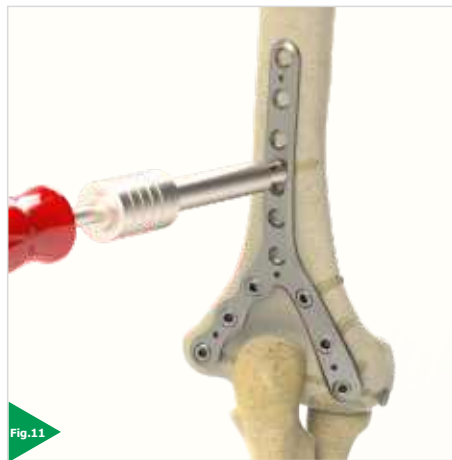
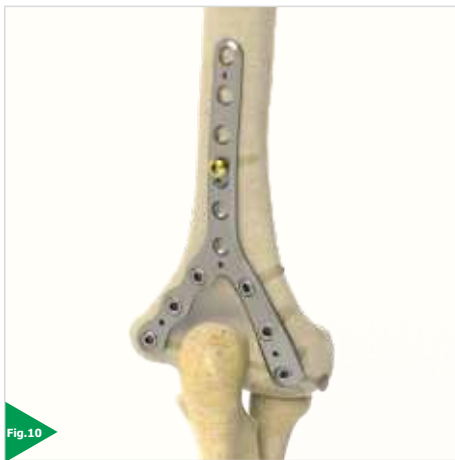


2.3. Plate Application

2.3.2. Y Plate

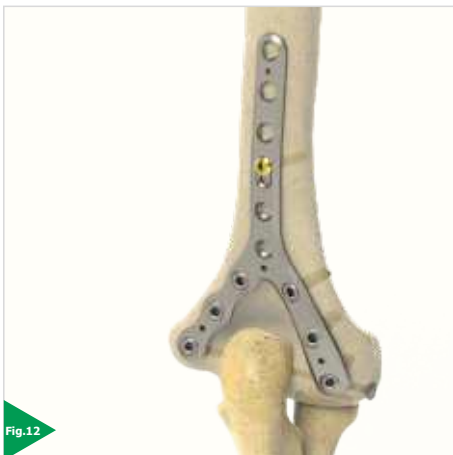
2.3.2.4 Tightening and Compression of Cortical Screws

Some compression can be done by completing the tightening process of the cortical screws that we sent half in the previous stage (2.2.4.2)(Fig. 10-11).



2.3.2.5 Ø3.5mm Locking Screw (Proximal)

Fracture is fixed with plate and screws now. For complete stabilization, we need to install the proximal locking screws. Determine the number of screws according to the need and plate size (Fig. 12-13). Don't forget torque all locking screw end the process





2.3. Plate Application

2.3.3. Parallel plating

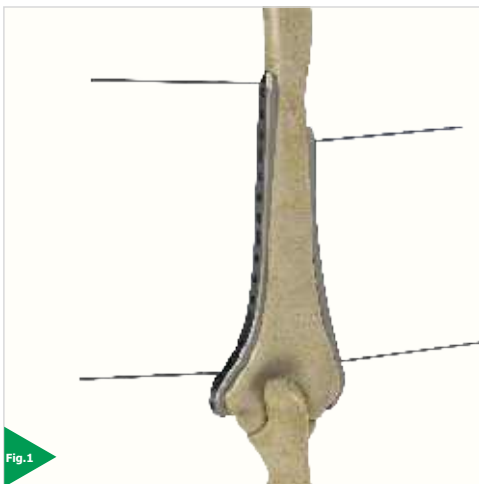
The advantage of parallel plate application is that it is theoretically more stable against varus stress.

2.3.3.1 Fixation of the Fracture

The fracture should be reduced and, if necessary, fixed with Kirschner wires and screws before the plates are placed.

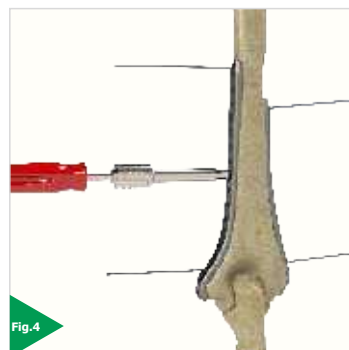
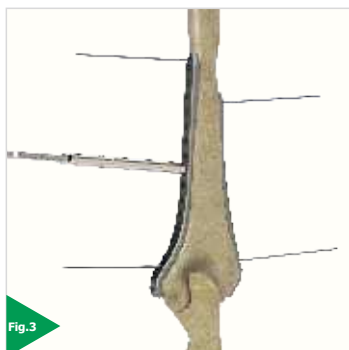
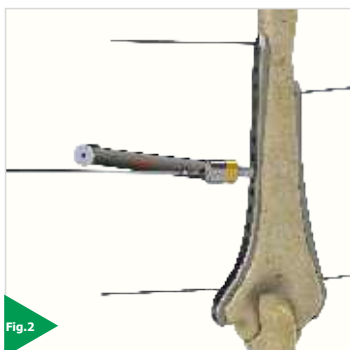


2.3.3.2 Plate Placement and cortical screw for medial plate



The lateral plate and the medial plate are placed according to the anatomy of the bone. It is temporarily fixed with Kirschner wires (Fig. 1).

For the Medial Plate, it can be started with a cortical screw. Drill guide is placed on the dynamic compression hole. Drilling is done with drill bit. (Fig. 2). Screw length is determined with a Depth guide (Fig. 3). The appropriate size screw is sent with a Ø3.5 screwdriver (Fig. 4) in a way that it cannot be tightened completely.

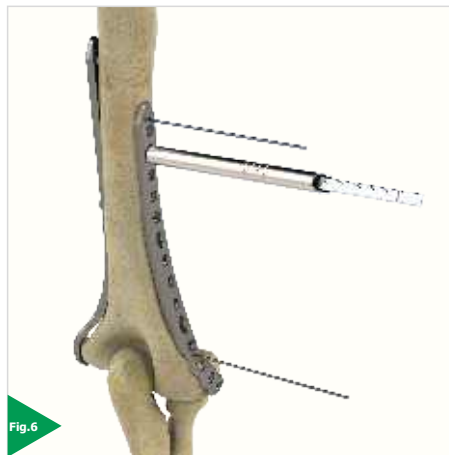
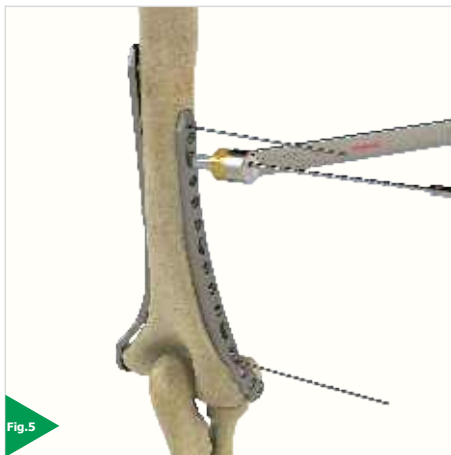




2.3. Plate Application

2.3.3. Parallel plating

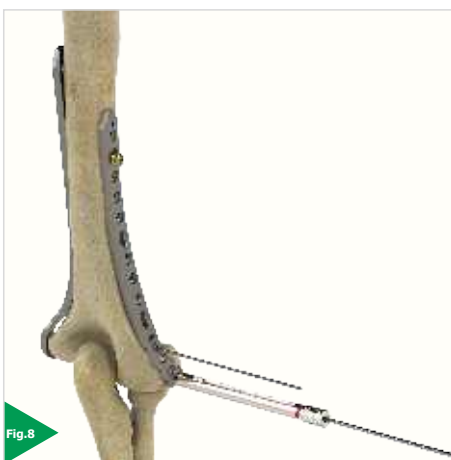
2.3.3.3 Lateral Plate Cortical Screw



For the Lateral Plate, it can be started with a cortical screw. Drill guide is placed on the dynamic compression hole. Drilling is done with a drill bit. (Fig. 5). Screw length is determined with a Depth guide (Fig. 6). The appropriate size screw is sent with a Ø3.5 screwdriver (Fig. 7) in a way that it cannot be tightened completely

2.3.3.4 Ø3.5 Locking Screw (Distal)

Locking screw can be sent on distally in this section (Fig. 9-10). (If no compression will be done, all the locking screws can be sent.)



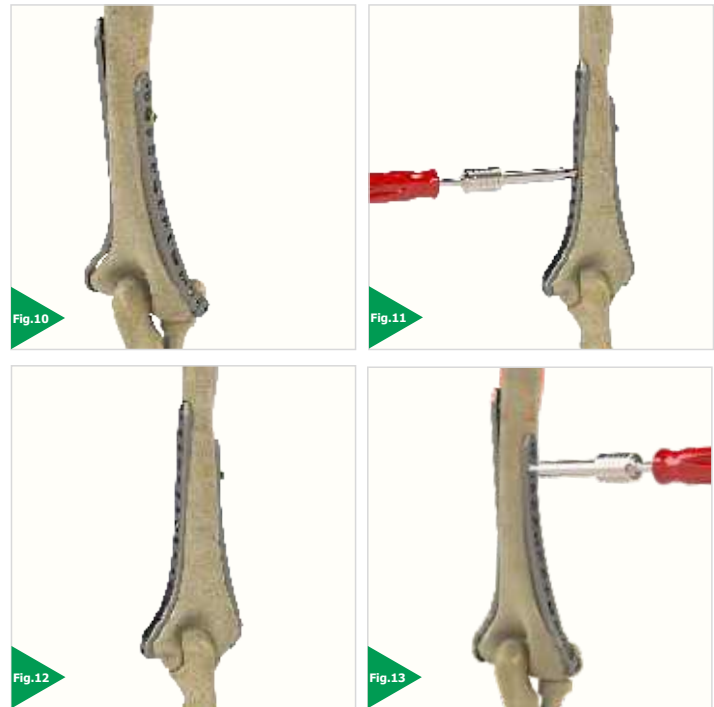


2.3. Plate Application

2.3.3. Parallel plating

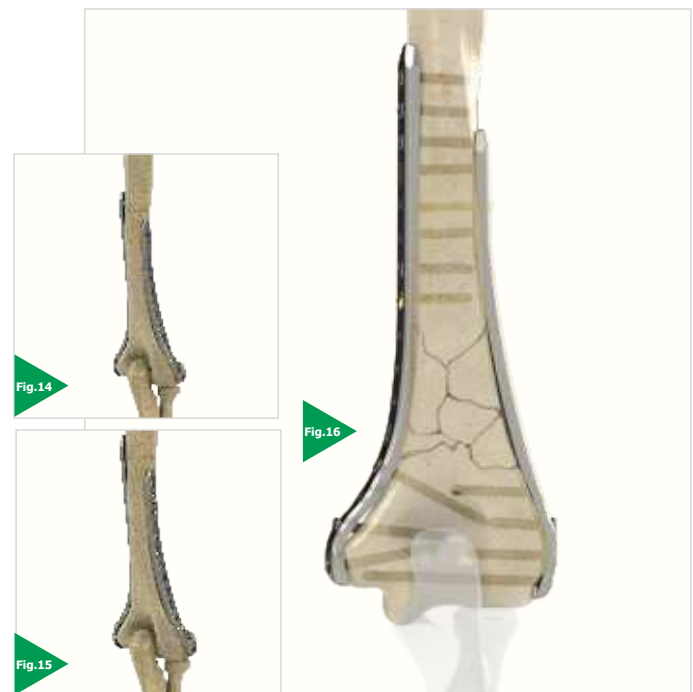
2.3.3.5 Tightening and Compression of Cortical Screws

Some compression can be done by completing the tightening process of the cortical screws that we sent half in the previous stage (2.2.5.2) and (2.2.5.3) (Fig. 10-11 and 12-13).



2.3.3.6 Proximal locking screw and finish

Install sufficient number of locking screws according to the need and the length of the plate. (Fig. 14-16).





4.1 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.

4.1.1 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.

4.1.2 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.

4.1.3 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

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.

zimed®

ISO 9001
ISO 13485

CE 1984

www.zimed.com.tr

ST.01.08-1 Rev.00 - 6.08.2021