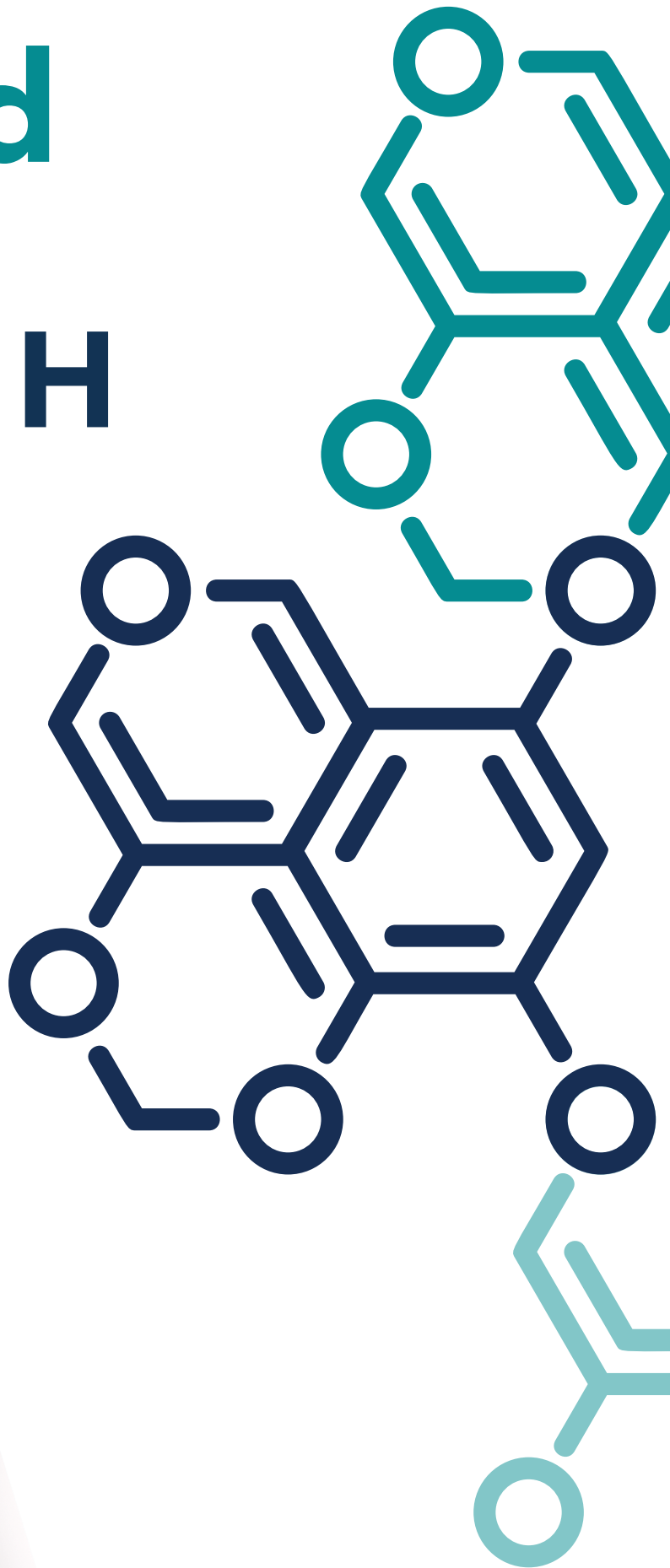
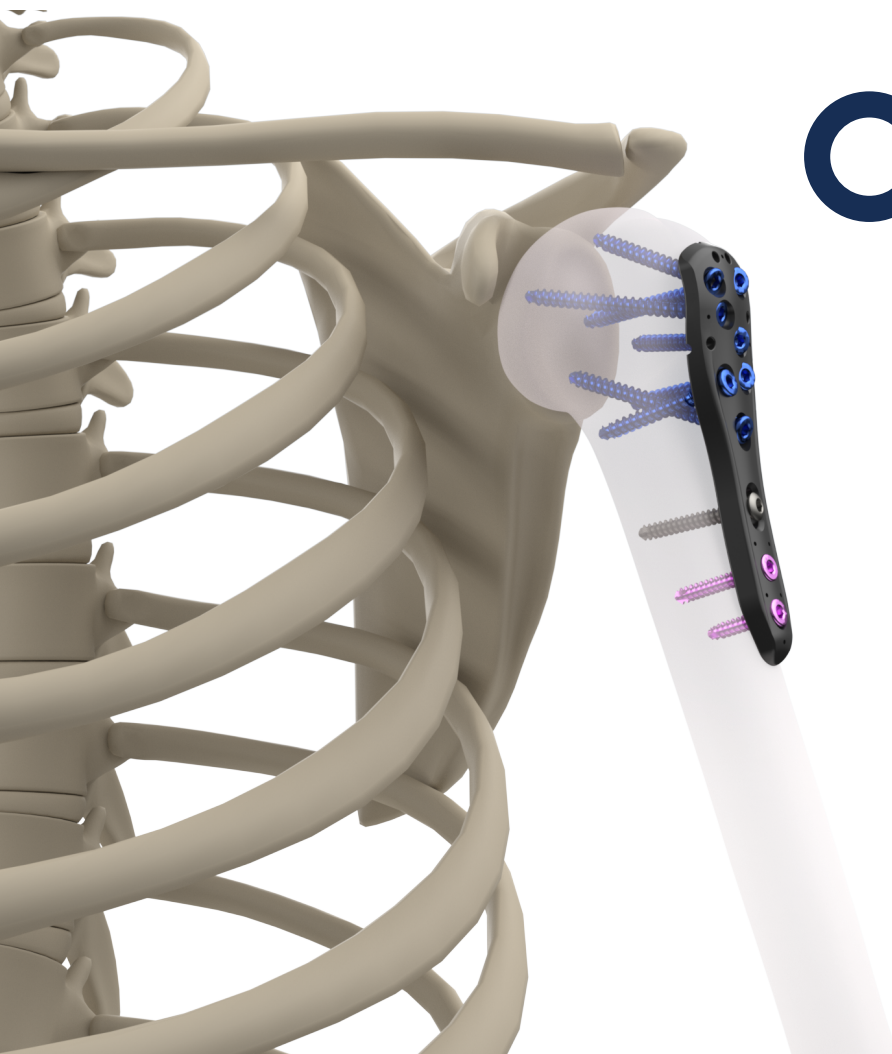


**LSMMed**

# DiPHOS H

Humeral plate

Product description  
& surgical technique





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**LSM-Med S.r.l.** is a manufacturer of implants and as such does not perform medical procedures. This documentation concerning surgical techniques, which provides surgeons with general guidelines for implanting the DiPHOS H Humeral Plate, was developed with the advice of a team of surgical experts. All decisions as to the type of surgery and most suitable technique are obviously the responsibility of the health care professional. Surgeons must make their own decisions as to the adequacy of each planned implant technique based on their training, experience and the clinical condition of the patient.

**INDICATIONS**

DiPHOS H Proximal Humeral Plate and Bone Screws are indicated for fractures, fracture dislocations and non unions of the proximal humerus.

Bone screws are designed to be used to treat bone fractures in combination with osteosynthesis devices.



Please follow the instructions for use enclosed in the product packaging.

**CONTRAINDICATIONS**

These devices must not be used in cases of:

1. insufficient quantity or quality of bone;
2. acute or chronic, local and/or systemic infections;
3. serious muscular, neurological or vascular diseases involving the arm in question;
4. advanced osteoporosis;
5. bone malformations;
6. gsevere soft tissue damage;
7. manifest allergy to the device material;
8. physiologically or psychologically impaired patients;
9. skeletally immature patients.

**ALLOWED/PROHIBITED COMBINATIONS**

**Use only bone screws for plate fixation manufactured by LSM-Med.**

**Select the correct screw type for central, proximal and distal holes as indicated in the present surgical technique. Any other option must be considered improper.**

**RISK FACTORS**

The following risk factors may result in poor results with DiPHOS H Plate:

1. strenuous physical activities (active sports, heavy physical work);
2. incorrect implant positioning;
3. medical disabilities which can lead to an unnatural loading of the joint;
4. muscle deficiencies;
5. multiple joint disabilities;
6. refusal to modify postoperative physical activities;
7. patient's history of infections or falls;
8. systemic diseases and metabolic disorders;
9. local or disseminated neoplastic diseases;
10. drug therapies that adversely affect bone quality, healing, or resistance to infection;
11. drug use or alcoholism;
12. marked osteoporosis or osteomalacia;
13. patient's resistance generally weakened (HIV, tumour, infections);
14. severe deformity leading to impaired anchorage or improper positioning of implants.



**MATERIALS**

Plate: PEEK OPTIMA LT1 CA30.

Radiographic markers: tantalum (ASTM F 560),

Screws: titanium alloy Ti6Al4V in conformity with ISO 5832-3.



**CLINICAL CASES**

1. 3-part proximal humerus fracture.



2. A/P view.



Courtesy of Dr. R. Rotini, Istituto Ortopedico Rizzoli, Bologna.

**PLATE IN CFR PEEK 30%**

- Since PEEK is a plastic material, no galvanic corrosion phenomena can occur between plate and screws, thus permitting an easier removal.
- Slotted hole at diaphyseal level allows adjustment during the positioning phase.



- PEEK material is radiolucent, thus allowing the intra-op fracture reduction and post-op following of the healing process. Perimetral tantalum radiographical markers are embedded into the plate to allow easier radiographical evaluation.



**ANGULAR STABILITY SCREW**

- Angular stability screw in Ti6Al4V.
- Type 3 anodic oxidation treatment for diameter identification.
- Polyaxial screw: the screw head will 'tap' the hole, allowing oblique insertion. It is allowed to completely insert the screw in the non threaded holes of the plate one time only.
- $\varnothing$  4 mm angular stability cancellous screw for epiphyseal stabilization.
- $\varnothing$  3.5 mm angular stability cortical screw for diaphyseal stabilization.

**NOTE.** It is recommended not to tight completely the screw before checking the correct lenght and positioning.





Figure 1

**TECHNIQUE WITHOUT ALIGNMENT MASK**

Reduce the fracture and fix the fragments with K wires. After fracture reduction select the proper implant size with the trial plates (Fig. 1).

Position the 1.5 mm K wires in order to stabilize the plate (Fig. 2).

If necessary bend the K wires to avoid any interference with the following steps of the technique (Fig. 3).



Figure 2



Figure 3



Figure 4

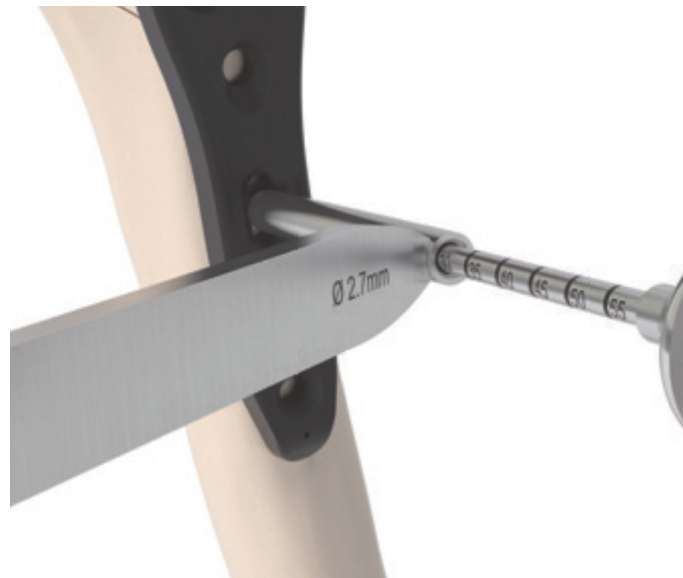


Figure 5

**CENTRAL SLOTTED HOLE**

Starting from the slotted hole of the plate, drill both cortices using the 2.7 mm drill bit with the 2.7 mm double drill guide (Figs. 4-5).

Remove the 2.7 mm drill bit and the corresponding sleeve and determine the screw length using the measuring device. Before setting the correct measure mind to hook the head of the measuring device out of the second cortex (Fig. 6).



Figure 6



Read on the indicator the length of the screw to be selected (Fig. 7).

Insert the 3.5 mm cortical screw with spherical head, with the hex 2.5 mm screwdriver. Before complete locking, adjust the plate positioning (Figs 8-9).

In case a power tool is used the final tightening shall be done manually.

**NOTE.** In this step use screws with spherical head coded 8930.15.XXX only. Do not use the plate and screws for reduction, this system is not suitable to be used as lever to reduce fragments.

Figure 7

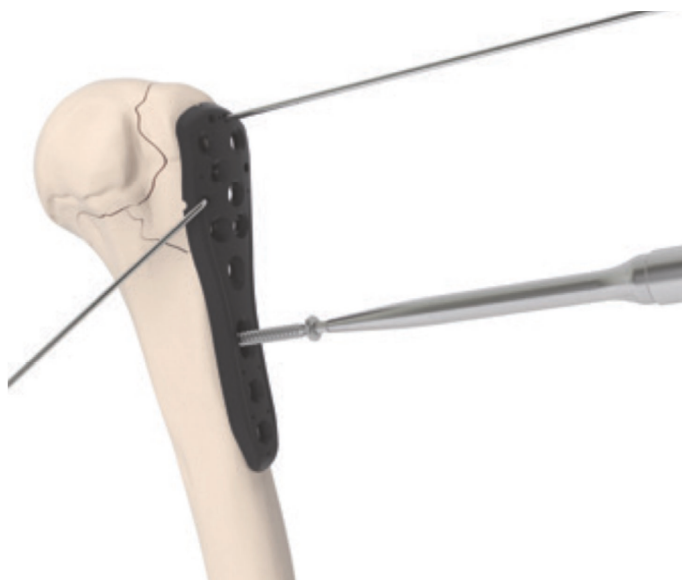


Figure 8



Figure 9

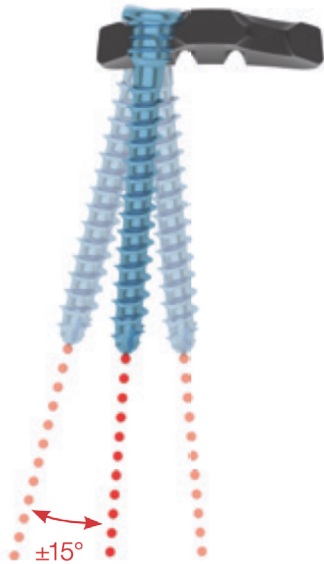


Figure 10

**PROXIMAL HOLES**

Proximal screws may be positioned in multiaxial directions in a range of  $\pm 15^\circ$  (Fig. 10).

Prepare the holes for proximal screws using the 2.7 mm drill bit and the corresponding double drill guide (Fig. 11).

Remove the 2.7 mm drill bit and the corresponding double drill guide and determine the screw length using the measuring device (Fig. 12).

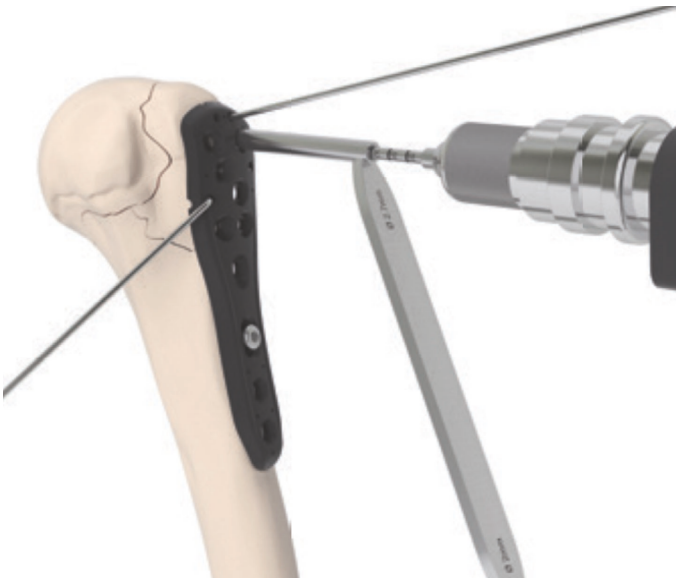
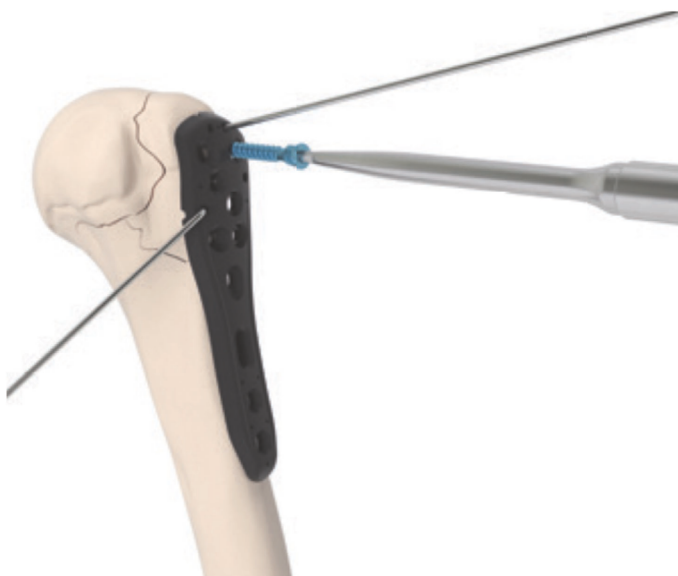


Figure 11



Figure 12





Insert the Ø 4 mm angular stability screws with the hex 2.5 mm screwdriver. If a power tool is used the final tightening shall be done manually (Fig. 13).

Repeat the same procedure for all the proximal screws.

**NOTE.** In this step use cancellous screws threaded head coded 8910.15.XXX only.

Figure 13



Figure 14

**DISTAL HOLES**

Prepare the holes for the distal screws using the 2.7 mm drill bit and the corresponding double drill guide (Fig. 14).

Remove the 2.7 mm drill bit and the corresponding double drill guide and determine the screw length using the measuring device.

Before setting the correct measure mind to hook the head of the measuring device out of the second cortex (Fig. 15).

Read on the indicator the length of the screw to be selected (Fig. 16).

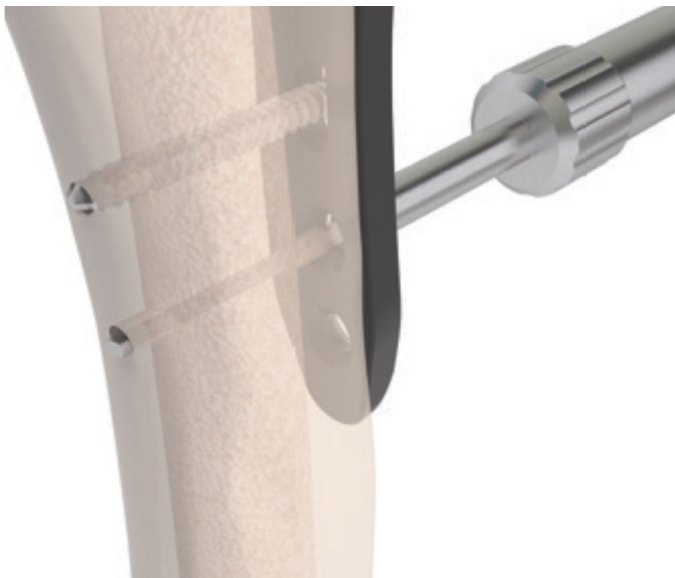


Figure 15



Figure 16



Insert the 3.5 mm cortical screw with threaded head with the hex 2.5 mm screwdriver (Fig. 17).

If a power tool is used the final tightening shall be done manually.

Repeat the same procedure for all the distal screws.

**NOTE.** In this step use threaded head cortical screws coded 8920.15.XXX only.

Reinsert the rotator cuff and both tuberosities. The holes are used to insert needle and suture wire for fixation (Fig. 18).

Figure 17



Figure 18



Figure 1



Figure 2

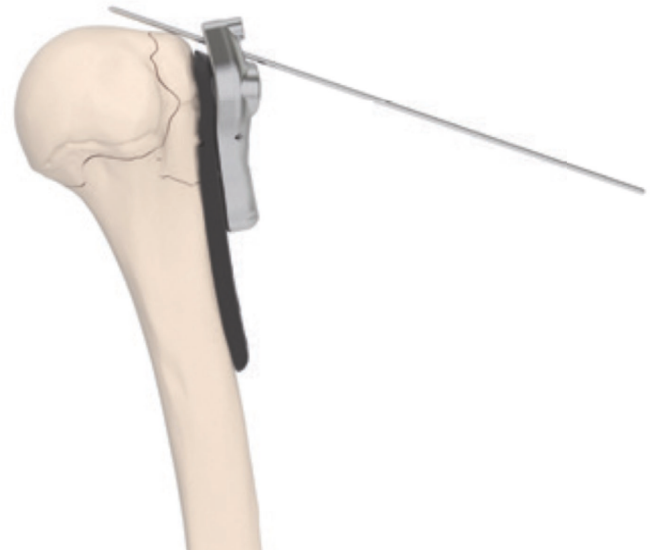


Figure 3

**TECHNIQUE WITH ALIGNMENT MASK**

The use of the alignment mask allows to place proximal screws in monoaxial direction only.

Reduce the fracture and fix the fragments with K wires. After fracture reduction select the proper implant size with the trial plates.

Assemble the alignment mask on the plate (Figs. 1-2).

Position the plate 10 mm below the upper end of the greater tubercle. Insert a  $\varnothing$  1.5 mm. K wire into the proximal hole of the mask. The placing is correct if the K wire aims the proximal joint surface (Fig. 3).



Use two 1.5 mm Dia. K wires to stabilize plate and mask in the correct position (Fig. 4).

If necessary, bend the K wires to avoid any interference with the following steps of the technique (Fig. 5).

**NOTE.** Start screws application from the central slotted hole and proceed as reported on pages 10-11.

Assemble the sleeve for drill in the sleeve for screws as shown in Fig. 6.

Figure 4



Figure 5

Figure 6

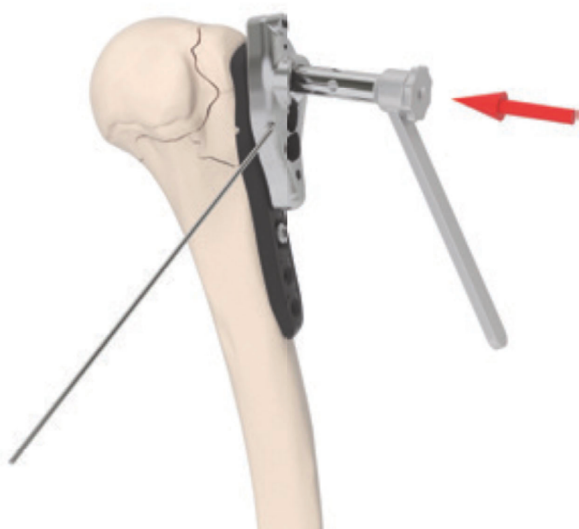


Figure 7

Insert the two assembled sleeves in the selected hole of the alignment mask (Fig. 7).

Start drilling, then remove the drill and the sleeve for drill, leaving the sleeve for screws in position (Figs. 8-9).

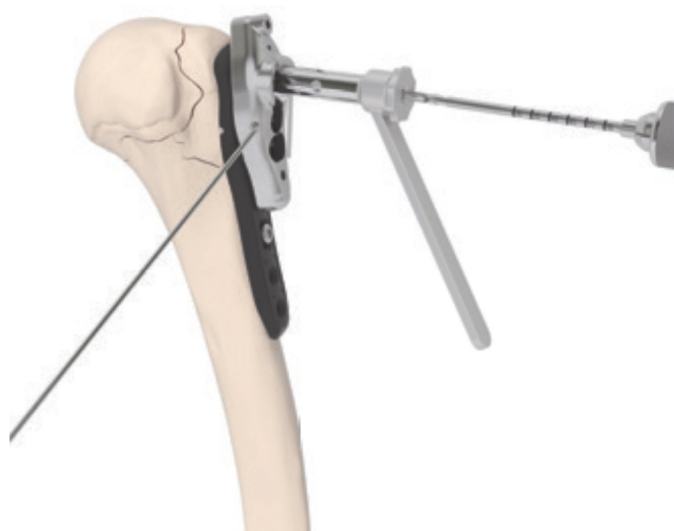
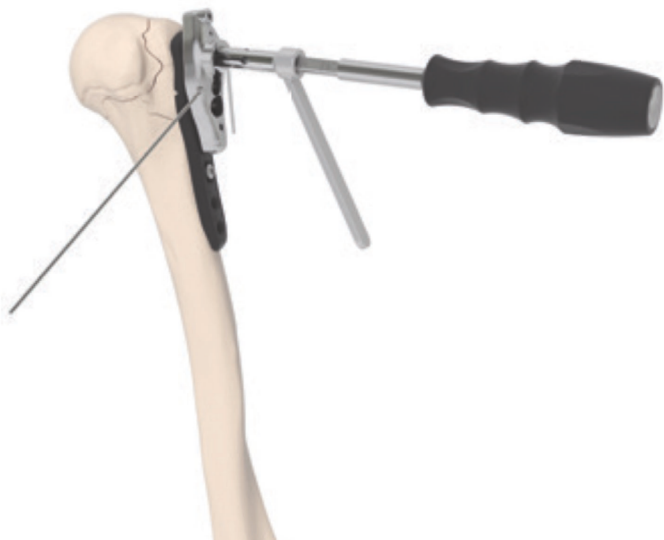


Figure 8



Figure 9

**DiPHOS H SURGICAL TECHNIQUE**  
Technique with Alignment Mask



Insert the depth gauge for proximal holes in the sleeve for screw and read on the indicator the length of the screw to be selected (Figs. 10-11).

Remove the depth gauge for proximal holes from the sleeve for screws.

Insert the screw in the sleeve and proceed tightening (Fig. 12).

If a power tool is used the final tightening shall be done manually.

Repeat the same procedure for all proximal screws.

**NOTE.** In this step use threaded head cancellous screws coded 8910.15.XXX only.

Figure 10



Figure 11

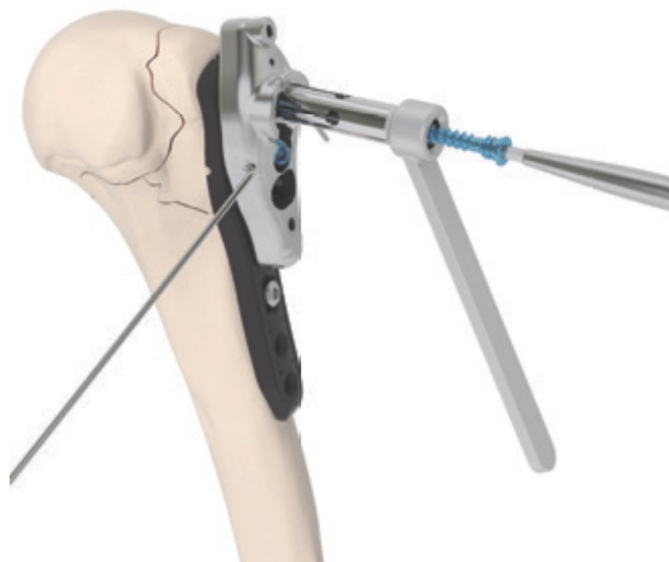


Figure 12



When application of all proximal screws is completed the alignment mask can be disassembled (Figs. 13-14).

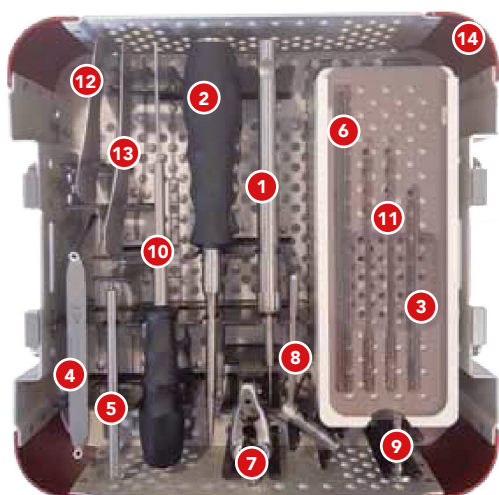
**NOTE.** Proceed with screws application on distal holes as indicated on pages 14-15.

Figure 13



Figure 13





9087.10.000			
1	9087.10.010	Measuring device	
2	9087.10.020	Hexagonal screwdriver	⌀ 2.5 mm
3	9087.10.021	Hexagonal terminal screwdriver *	⌀ 2.5 mm
4	9087.10.031	Double drilling guide	⌀ 2 mm ⌀ 2.7 mm
5	9087.10.033	Handle for mask	
6	9087.10.034	Guide wire (10 pcs)	⌀ 1.5 mm L. 155 mm
7	9087.10.035	Alignment mask for screws	
8	9087.10.036	Sleeve for screws	⌀ 6 mm
9	9087.10.037	Sleeve for drill ⌀ 2.7 mm	
10	9087.10.038	Depth gauge for proximal holes	
11	9087.10.040	Long drill bit (2 pcs) *	⌀ 2.7 mm
12	9087.10.103	Trial plate	3 holes
13	9087.10.105	Trial Plate	5 holes
14	9087.10.990	Tray	

\* Small AO coupling

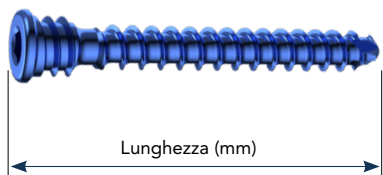
⌀ Hexagon



**PLATE**

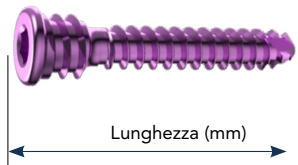
	Code	Holes
<b>CFR PEEK 30%</b>	8710.02.003	3
	8710.02.005	5

Sterile single packaging.



CANCELLOUS SCREW, THREADED HEAD			
	Code	Length (mm)	Diameter Ø (mm)
<b>Ti6Al4V</b>	8910.15.030.S	30	4.0
	8910.15.032.S	32	4.0
	8910.15.034.S	34	4.0
	8910.15.036.S	36	4.0
	8910.15.038.S	38	4.0
	8910.15.040.S	40	4.0
	8910.15.042.S	42	4.0
	8910.15.044.S	44	4.0
	8910.15.046.S	46	4.0
	8910.15.048.S	48	4.0
	8910.15.050.S	50	4.0
	8910.15.055.S	55	4.0
	8910.15.060.S	60	4.0

Sterile single packaging.



**CORTICAL SCREW, THREADED HEAD**

	Code	Length (mm)	Diameter Ø (mm)
<b>Ti6Al4V</b>	8920.15.016.S	16	3.5
	8920.15.018.S	18	3.5
	8920.15.020.S	20	3.5
	8920.15.022.S	22	3.5
	8920.15.024.S	24	3.5
	8920.15.026.S	26	3.5
	8920.15.028.S	28	3.5
	8920.15.030.S	30	3.5
	8920.15.032.S	32	3.5
	8920.15.034.S	34	3.5
	8920.15.036.S	36	3.5
	8920.15.038.S	38	3.5
	8920.15.040.S	40	3.5

Sterile single packaging.



CORTICAL SCREW, SPHERICAL HEAD			
	Code	Length (mm)	Diameter Ø (mm)
<b>Ti6Al4V</b>	8930.15.016.S	16	3.5
	8930.15.018.S	18	3.5
	8930.15.020.S	20	3.5
	8930.15.022.S	22	3.5
	8930.15.024.S	24	3.5
	8930.15.026.S	26	3.5
	8930.15.028.S	28	3.5
	8930.15.030.S	30	3.5
	8930.15.032.S	32	3.5
	8930.15.034.S	34	3.5
	8930.15.036.S	36	3.5
	8930.15.038.S	38	3.5
	8930.15.040.S	40	3.5

Sterile single packaging.

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