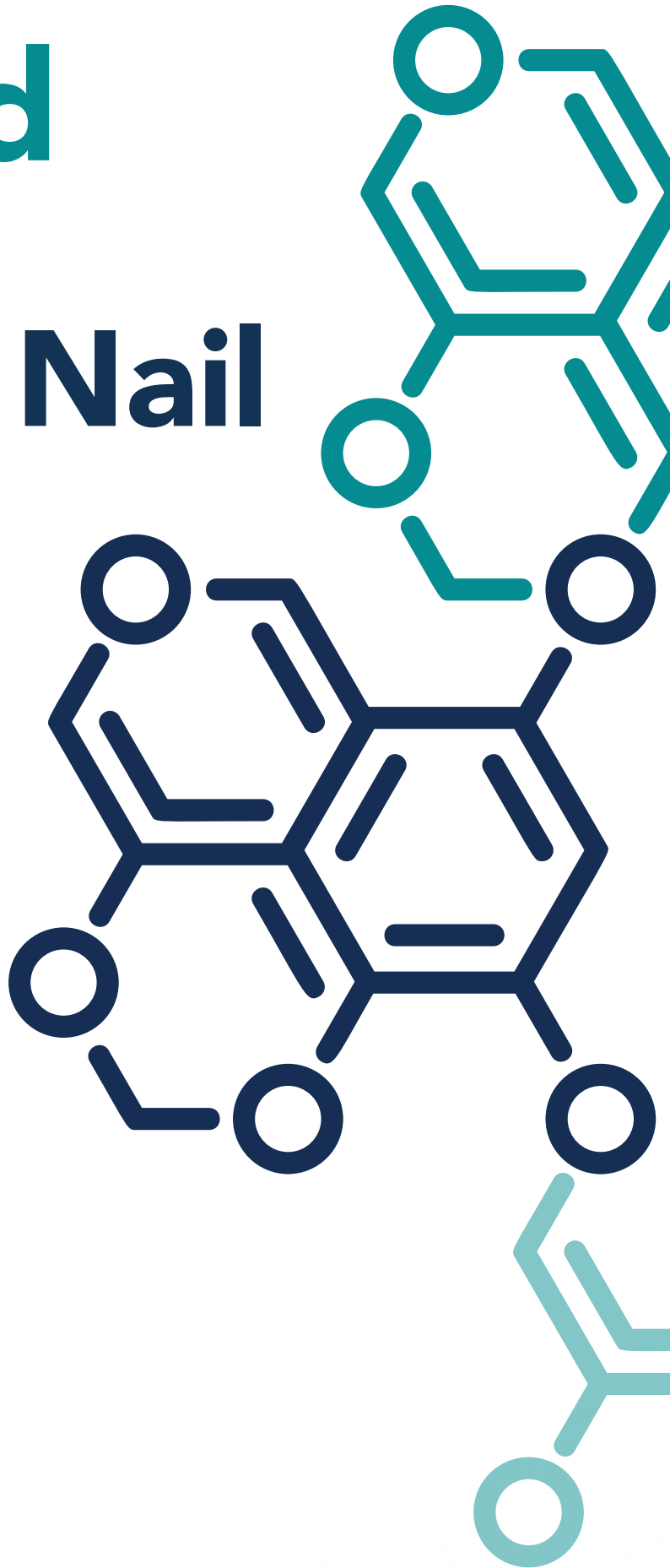
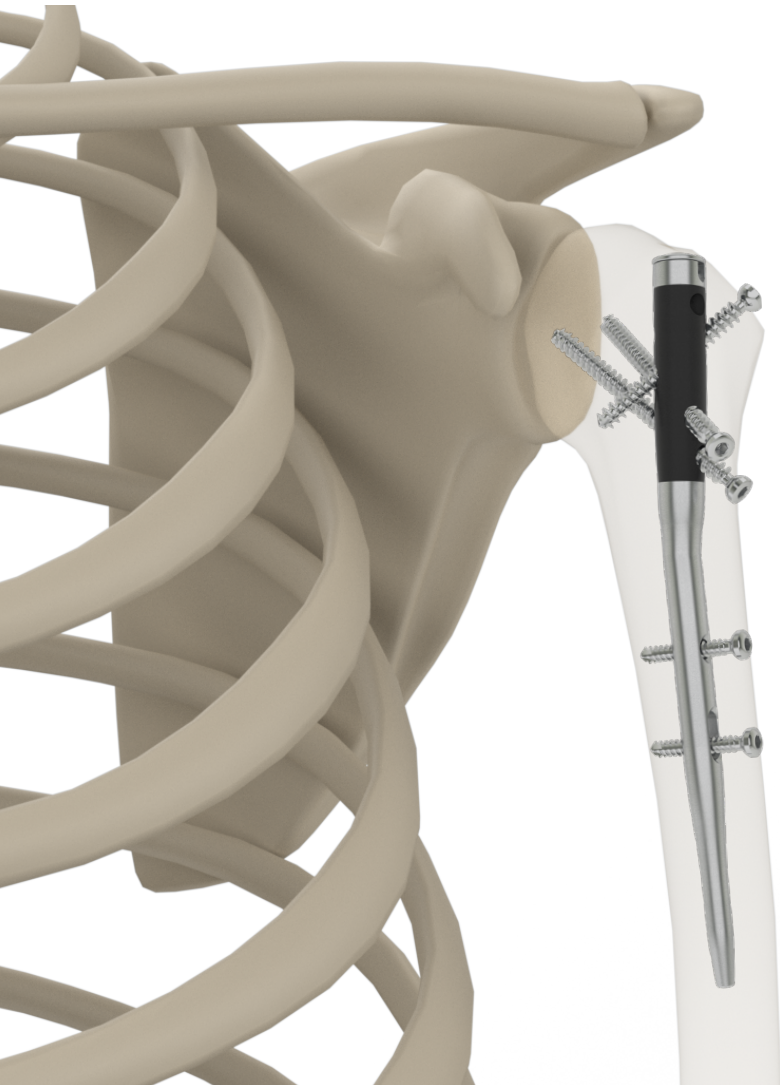




# DiPHOS Nail

Humeral Nail

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 Humeral Nail, 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 Nail Short is indicated for two and three parts fractures of proximal humerus.

DiPHOS Nail Long is indicated for diaphyseal fractures of the humerus with or without two, three and four parts fractures 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. serious lack of bone substance which would affect the success of the synthesis;
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. manifest allergy to the device material;
7. physiologically or psychologically impaired patients;
8. skeletally immature patients.

#### ALLOWED/PROHIBITED COMBINATIONS

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

**Select the correct screw type for 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 Nail:

1. strenuous physical activities (active sports, heavy physical work) in the early post-operative time;
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**

Nail, screws and locking plug are made of titanium alloy Ti6Al4V in conformity with ISO 5832-3.

Proximal nail coating is made of PEEK OPTIMA LT1CA30.



**CASE 1**

1. Humeral Fracture with complete detachment of the greater tuberosity.



2. Fixation with the DiPHOS Nail according to assembly scheme "A".



**CASE 2**

1. Humeral Fracture with head deformation in valgus.



2. Fixation with the DiPHOS Nail according to assembly scheme "B".



Courtesy of Dr. P. Maniscalco, Ospedale Guglielmo da Saliceto, Piacenza.

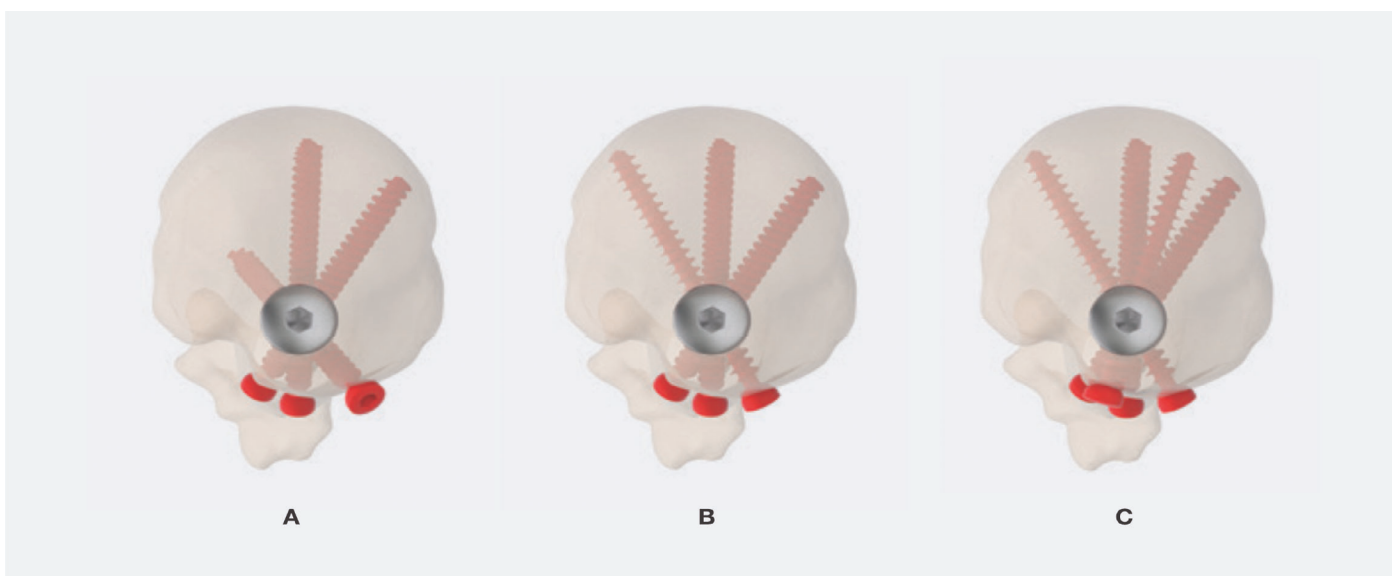
**FEATURES:**

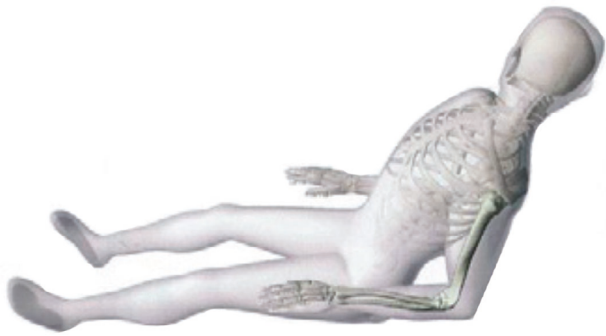
- Angular stability screws
- Anti-pull out system
- No cold welding
- Multiplanar Fixation
- Multiple configuration of screw positioning



**MULTIPLE CONFIGURATION OF SCREW POSITIONING**

- Screw dedicated to greater tuberosity stabilization (A)
- Calcar support (B)
- Fixation of surgical neck (C)



**PATIENT POSITIONING**

The patient is placed semi-reclined in “beach chair position” or supine on radiolucent table.

Patient positioning should be checked to ensure that imaging and access to the entry site are possible without excessive manipulation of the fractured extremity.

**ENTRY POINT 1/2**

DiPHOS Nail is designed to be inserted through a medial (**A**) or lateral (**B**) entry point.

**ENTRY POINT 2/2**

Use the cannulated awl (A2) to prepare the entry approach and to insert the guide wire 9087.30.003 (Figs. 1, 2).



Figure 1

Figure 2



Figure 3

**REAMING**

Insert the rasp (A4) or the initial reamer (A1) on the guide wire and proceed by reaming proximally (Fig. 3, 4).

If the initial reamer is used drill up the medullary canal.

It is recommended to use the soft tissue protector (A10) while using the initial reamer (Fig. 4).



Figure 4



**SHORT NAIL INSERTION**

Assemble the short nail (B1) with the nail holder using the locking bolt (B2). Complete the blocking using the wrench (B5) (Fig. 5).

**⚠️ ⚡ WARNING**

Do not use the nail holder as counter torque during the assembly (Fig. 5a).

Sink the nail on the guide wire and insert it into the medullary canal (Fig. 6). Extract the guide wire.

Figure 5



**⚠️ ⚡ WARNING**

Figure 5a



Figure 6



Figure 7

#### **POSITIONING CHECK**

The nail must be sunk at least up to the first circumferential groove on the nail holder but not deeper than the second groove.

It is possible to insert a pin through the nail holder as a marker during the fluoroscopy for assessment of the correct sinking (Fig. 7).



**ALIGNMENT CONTROL**

Place a graduated pin (A5) in the proper hole (left or right) of the nail holder and align it with the forearm, it indicates the anatomical 30° retroversion of the humeral head (Fig. 8).



Figure 8

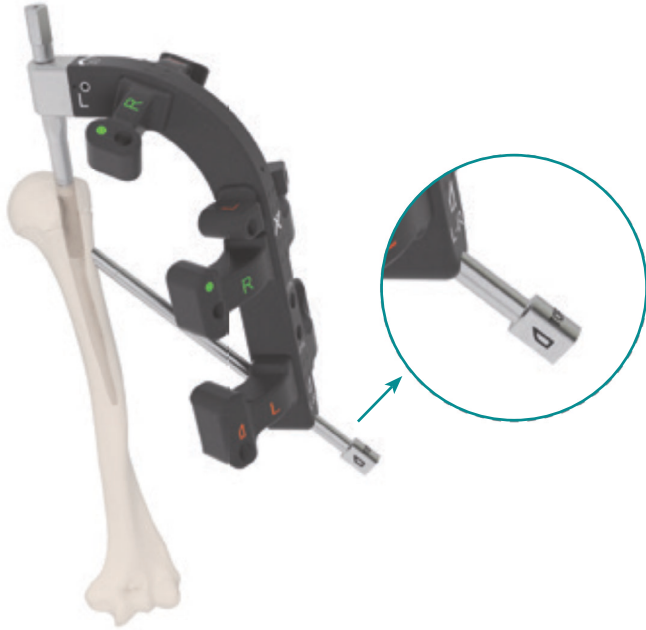


Figure 9

**PROXIMAL STABILIZATION**

Prepare the screw site starting from the most distal hole.

Assemble the internal sleeve for pin (B4) into the external sleeve oblique tip (B10) and insert them in the proper hole on the nail holder. Proceed drilling with the graduated pin (A5) (Figs. 9, 10, 11).



Figure 10



Figure 11



Figure 12

### COMPLETION OF THE DRILLING PROCEDURES

Proceed with the other pins (Fig. 12) according to the following schemes (Figs. 13, 14, 15).

Mind to use the external sleeve oblique tip (B10) for distal holes and the external sleeve flat tip (B3) for proximal holes.



Figure 13a

**ASSEMBLY 'A' (EG. LEFT NAIL)  
GREATER TUBEROSITY STABILIZATION**

The insertion of the screws according to the assembly scheme here illustrated, allows the proximal nail locking with stabilization of the greater tuberosity (Figs. 13a, 13b, 13c).

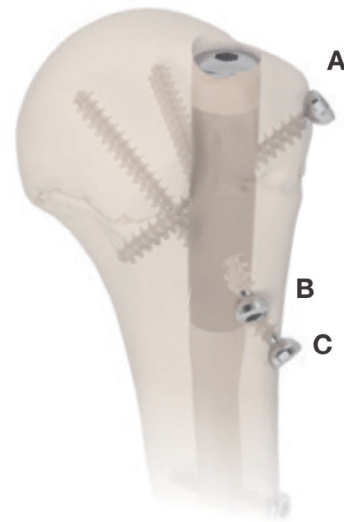


Figure 13b

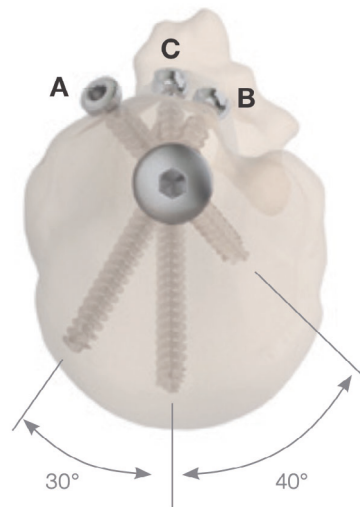


Figure 13c

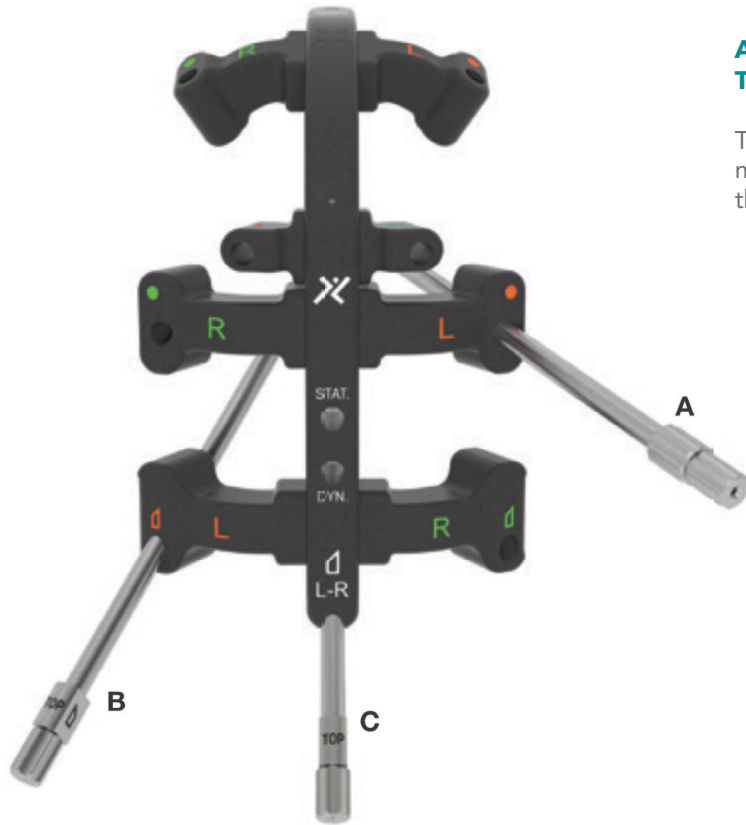


Figure 14a

**ASSEMBLY 'B' (EG. LEFT NAIL) WITH THREE STABILIZATION POINTS IN THE HUMERAL HEAD**

The insertion of the screws according to the assembly scheme here illustrated, allows the proximal nail locking with three grip points on humeral head (Figs. 14a, 14b, 14c).

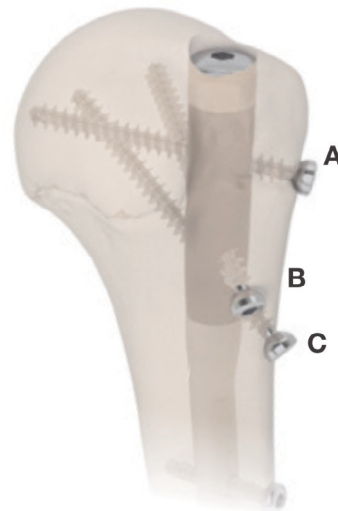


Figure 14b

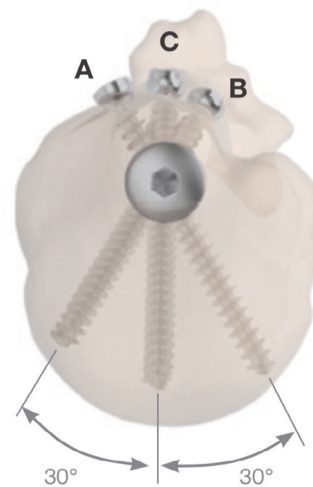


Figure 14c

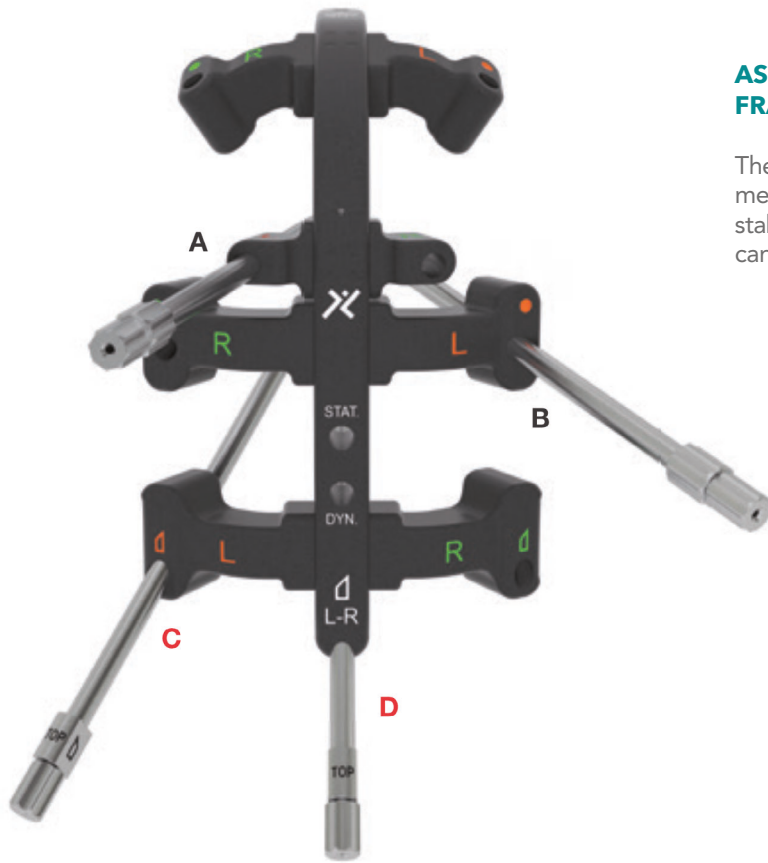


Figure 15a

**ASSEMBLY 'C' (EG. LEFT NAIL) SURGICAL NECK FRACTURES**

The insertion of the screws according to the assembly scheme here illustrated, allows the proximal nail locking with two stabilization points in the humeral head. Optional stabilization cancellous screws are highlighted in red (Figs. 15a, 15b, 15c).

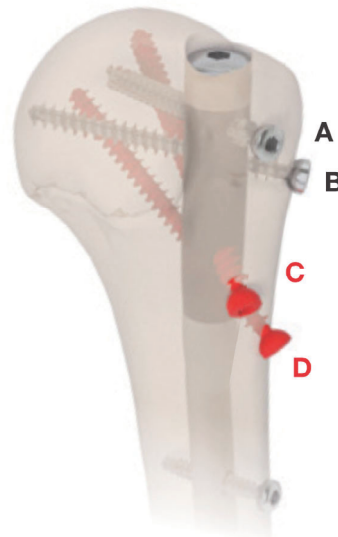


Figure 15b

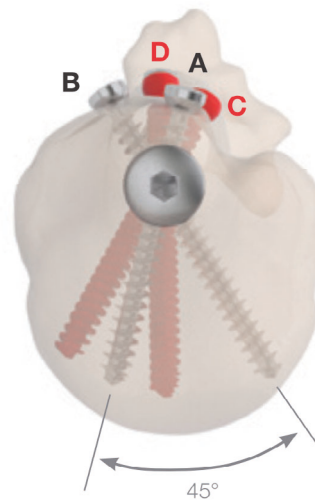


Figure 15c

**⚠ WARNING**

The design of the nail allows insertion of the proximal screws ONLY in one of the two positions marked with a dot on the targeting device (Fig. 16).

Before drilling check the positioning of the external sleeves (Fig. 17). In case they are both inserted in a marked position, one must be removed and another hole must be selected.



Figure 16

**✓ CORRECT POSITIONING**



Figure 17

**✗ WRONG POSITIONING**

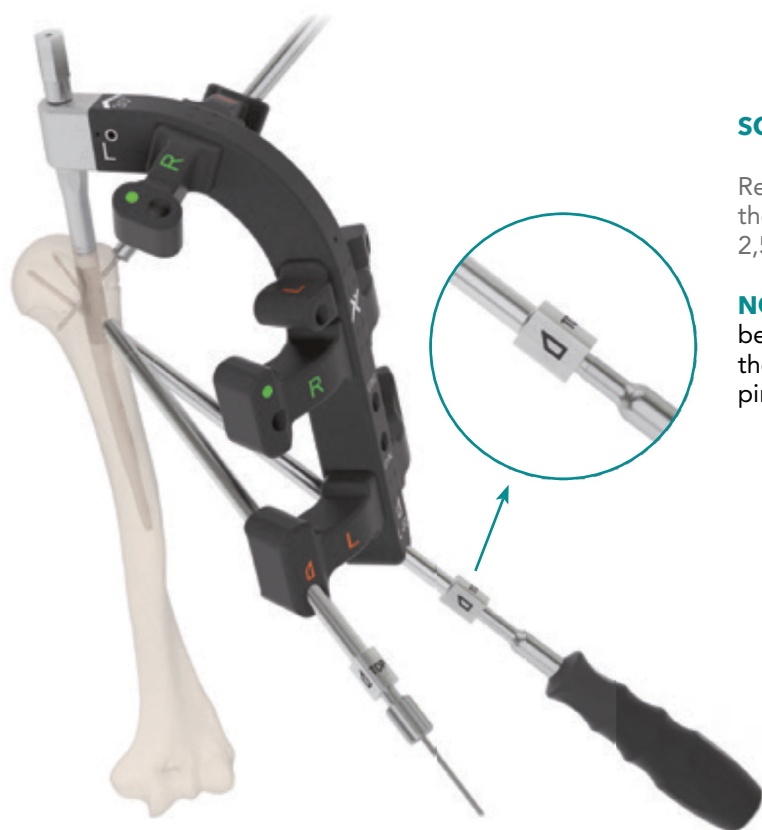


**MEASURING**

Select the screw length reading the corresponding measure on the graduated pin and/or the gauge for pin (A6) (Fig. 18).

Figure 18



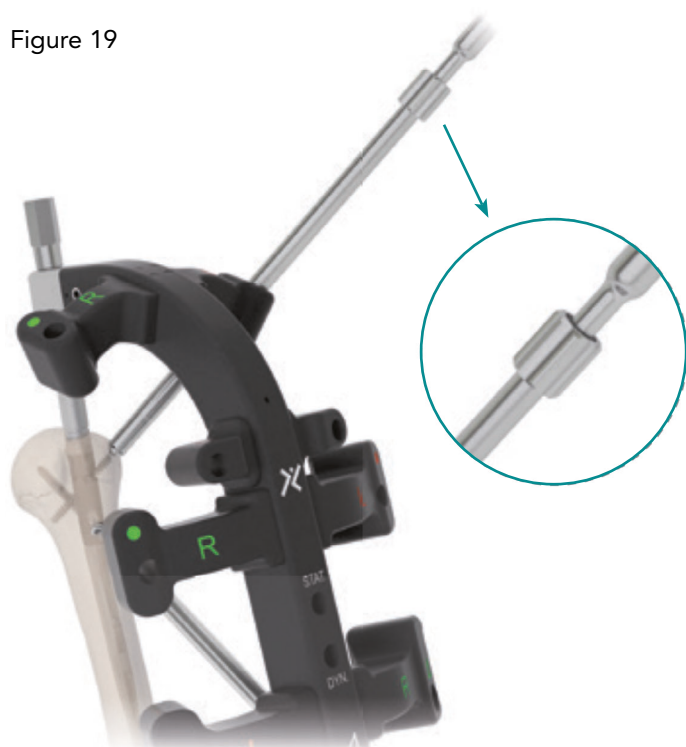


**SCREW INSERTION**

Remove pin (A5) and the internal for pin (B4) then insert the screw previously measured (8990.15.XXX.S) with the 2,5 mm long hexagonal screwdriver (G30) (Fig. 19).

**NOTA.** It is recommended to remove pins one by one before inserting every screw to enhance the stability of the assembly; do not remove 2 or more pins at the same time.

Figure 19



The marking circular ring is the reference to indicate when the screw head stops on the cortical bone (Fig. 20).

**NOTA.** Proximal fixation have to be performed using 4,5 mm proximal cancellous screws code 8990.15.XXX.S only.

Figure 19



Figure 21

### DISTAL LOCKING

Insert the two distal screws (8980.15.XXX.S) as previously done for the proximal ones, minding to use the external sleeve flat tip (B3) (Fig. 21).

**NOTE.** Distal locking have to be performed using 3,5 mm distal cortical screw code 8980.15.XXX.S only.

### CONCLUSION

In the final step disassemble the locking bolt from the nail holder using the wrench, and insert the plug, using the 3,5mm short hexagonal screwdriver (A8) (Fig. 22).

### SECONDARY DYNAMIZATION

Depending on fracture type, secondary dynamization can be achieved by extracting the static distal locking screw (Fig. 23).



Figure 22



Figure 23



Figure 24



Figure 25

**REDUCE FRACTURE AND WIRE REPLACEMENT**

For humeral shaft fractures, if reaming is needed, use guide wire with olive tip (code 9087.30.016) and if necessary use also the reduction rod (A13) to facilitate wire insertion (Figs. 24-25).

Before proceeding with nail insertion mind to replace the olive tip wire with the smooth tip one (code 9087.30.003) using the guide wire exchange tube (A12).

- A)** insert the guidewire exchange tube (Fig. 26a);
- B)** remove the olive tip wire (Fig. 26b);
- C)** replace with smooth tip wire (Fig. 26c);
- D)** remove the guide wire exchange tube (Fig. 26d).

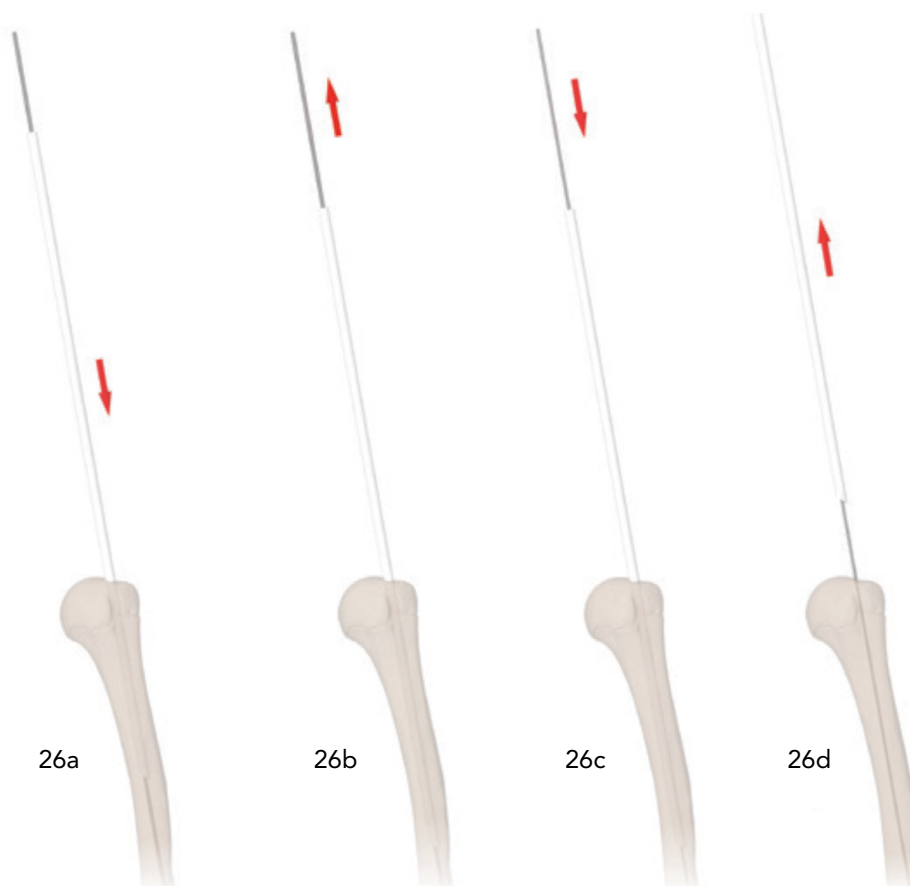


Figure 26

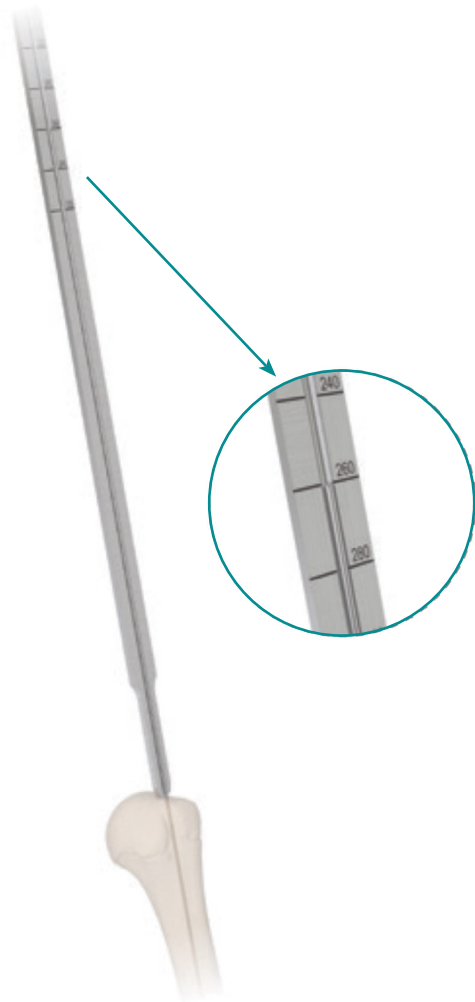


Figure 27

**LONG NAIL SIZE DETERMINATION**

Select the correct measure of the Long Nail reading the corresponding length on the gauge for long nails (A15), after a complete sinking of the wire into the medullary canal (Fig. 27).



**PROXIMAL LOCKING**

Proceed as indicated on pages 10-21.

**DISTAL LOCKING (FREE HAND TECHNIQUE)**

**WARNING**

In case of A.P. distal locking in order to prevent injuries of Radial Nerve proceed with careful dissection and with the nerve identification (Fig. 28).

1. Assemble the internal distal sleeve for wire (B11) in free hand distal drilling guide (B7) (Fig. 29).
2. Insert a K-wire (A18) in the internal distal sleeve for wire (B11) and using the C-Arm place the K-wire inside the distal hole of the Long Nail (Fig. 30).

Figure 28



Figure 29

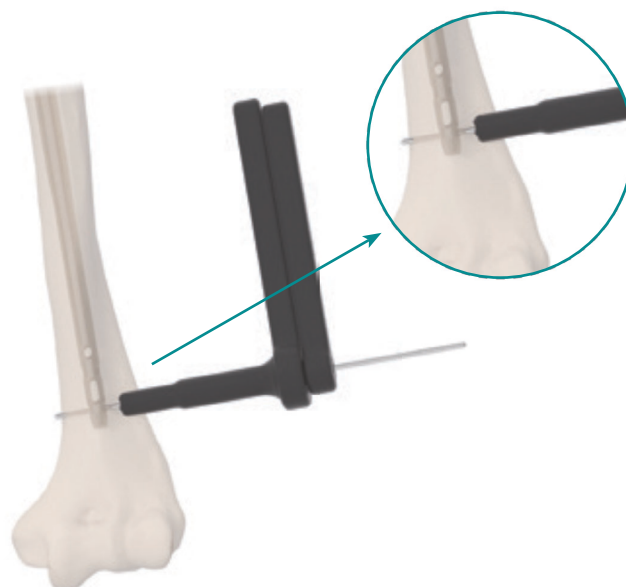


Figure 30



Figure 31

3. Remove the internal distal sleeve for wire (B11) (Fig. 31).
4. Before drilling, prepare the bone surface using the countersink for distal holes (B8) (Fig. 32).



Figure 32



Figure 33

5. Assemble the internal sleeve for drill (B9) in free hand distal drilling guide (B7), and remove the K-wire (**Fig. 33**).
6. Use the two sleeves as guide and then proceed drilling with drill for distal holes (A14). Select the screw length reading the corresponding measure on the graduated drill (A14) (**Fig. 34**).



Figure 34



Figure 35

**DISTAL LOCKING**

Remove the internal distal sleeve for drill (B9) and proceed with screw application using 3,5mm distal cortical screws as previously measured (codes 8980.15.XXX.S) (Fig.35).



**NAIL REMOVAL**

Remove the plug, if present, using the 2,5 mm short hexagonal screwdriver (A16) and assemble final extractor (A9) on the proper proximal thread.

**WARNING**

It's mandatory to position the extractor before proceeding with screw's removal in order to avoid nail migration.

Remove all stabilization screws, from the most distal to the most proximal using the 2,5 mm long hexagonal screwdriver (A7) (Fig. 36).

Extract the nail with Diapason hammer (A3) (Fig. 37).

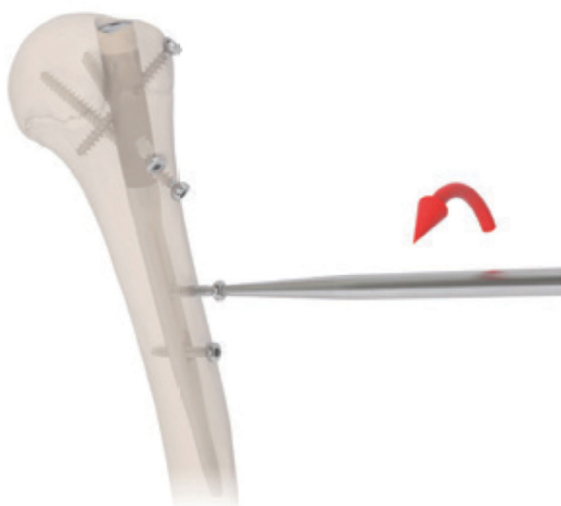


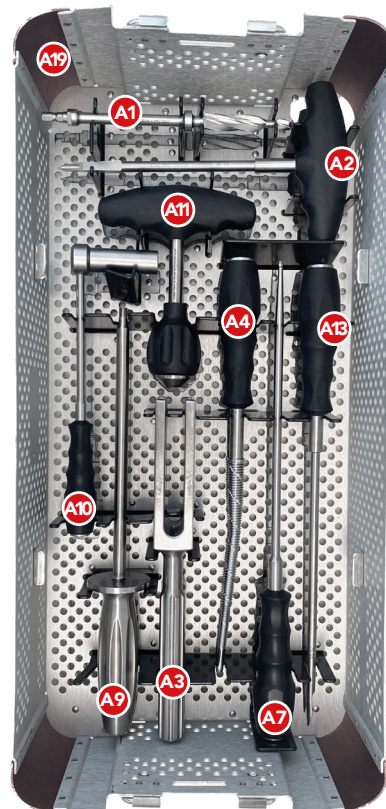
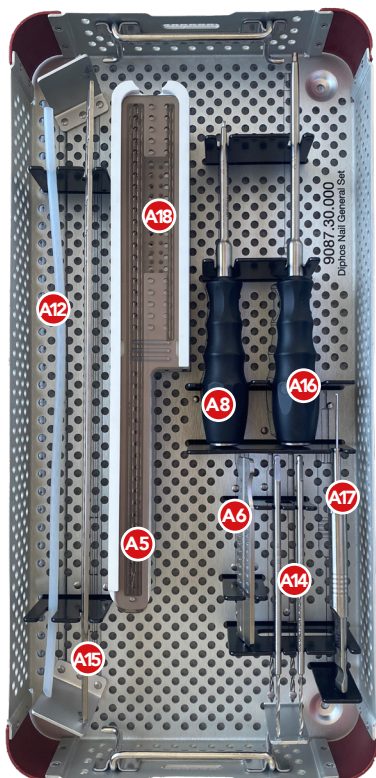
Figure 36



Figure 37

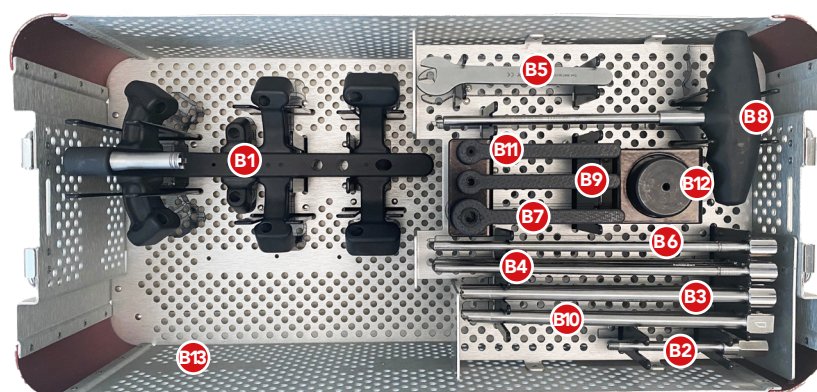
**9087.30.000 DiPHOS Nail GENERAL SET**

Ref.	Code	Description	Q.ty
A1	9087.30.001	Initial reamer	1
A2	9087.30.002	Cannulated Awl	1
A3	9087.30.004	Diapason Hammer	1
A4	9087.30.005	Rasp	1
A5	9087.30.010	Pin Ø 2.5 mm x L. 320 mm	4
A6	9087.30.011	Gauge for Pin	1
A7	9087.30.013	2,5 mm Long Hexagonal Screwdriver	1
A8	9087.30.014	3,5 mm Hexagonal Screwdriver	1
A9	9087.30.015	Extractor	1
A10	9087.30.018	Protection Device for Initial Reamer	1
A11	9087.30.019	Self-Locking Chuck	1
A12	9087.30.020	TGuide Wire Exchange Tube Ø 6 mm x L. 400 mm	1
A13	9087.30.021	Reduction Rod	1
A14	99087.30.022	Drill for Distal Holes Ø 2.7mm	2
A15	9087.30.024	Gauge for Long Nails	1
A16	9087.30.031	2.5 mm Short Hexagonal Screwdriver	1
A17	9087.10.010	Gauge for Distal Holes	1
A18	9087.10.030	Wire Ø 2 mm L. 155 mm	1
A19	9087.30.990	Instrument Tray	1



### 9087.31.000 DiPHOS Nail Targeting Set

Ref.	Code	Description	Q.ty
<b>B1</b>	9087.30.106	Nail Holder	1
<b>B2</b>	9087.30.007	Locking Bolt	2
<b>B3</b>	9087.30.008	External Sleeve Flat Tip	2
<b>B4</b>	9087.30.009	Internal Sleeve for Pin	4
<b>B5</b>	9087.30.012	Wrench	1
<b>B6</b>	9087.30.017	Trocar for Proximal Holes	1
<b>B7</b>	9087.30.025	Free Hand Distal Drilling Guide	1
<b>B8</b>	9087.30.026	Countersink for Distal Holes	1
<b>B9</b>	9087.30.027	Internal Distal Sleeve for Drill	1
<b>B10</b>	9087.30.028	External Sleeve Oblique Tip	2
<b>B11</b>	9087.30.029	Internal Distal Sleeve for Wire Ø 2 mm	1
<b>B12</b>	9087.30.030	Protection for Locking Bolt	1
<b>B13</b>	9087.31.990	Instrument Tray	1



### 9087.32.000 Wires Set

Code	Description	Q.ty
9087.30.003	Guide Wire Ø 2 mm x L. 600 mm Smooth tip	2
9087.30.016	Guide Wire Ø 2,5 mm x L. 600 mm Olive tip	1



Proximal Ø 11 mm  
Distal Ø 5.5 mm

**DiPHOS NAIL SHORT**

Ti6Al4V CFR Peek 30%	Code	Angle	Length (mm)	Type
	8730.15.100	6°	150	L
	8730.15.101	6°	150	R

Sterile single packaging.

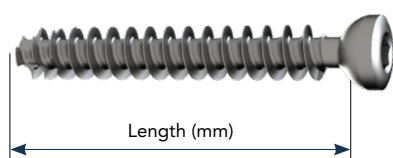


Proximal Ø 11 mm

**DiPHOS NAIL LONG**

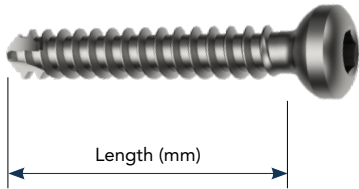
	Right	Left	Length (mm)	Distal Ø (mm)
Ti6Al4V CFR Peek 30%	8730.15.008	8730.15.002	200	7
	8730.15.009	8730.15.003	220	7
	8730.15.010	8730.15.004	240	7
	8730.15.011	8730.15.005	260	7
	8730.15.012	8730.15.006	280	7
	8730.15.013	8730.15.007	300	7
	8730.15.020	8730.15.014	200	8
	8730.15.021	8730.15.015	220	8
	8730.15.022	8730.15.016	240	8
	8730.15.023	8730.15.017	260	8
	8730.15.024	8730.15.018	280	8
	8730.15.025	8730.15.019	300	8

Sterile single packaging.



Ø 4.5 mm PROXIMAL CANCELLOUS SCREW			
	Codice	Length (mm)	Diameter Ø (mm)
<b>Ti6Al4V</b>	8990.15.250.S	25	4.5
	8990.15.275.S	27.5	4.5
	8990.15.300.S	30	4.5
	8990.15.325.S	32.5	4.5
	8990.15.350.S	35	4.5
	8990.15.375.S	37.5	4.5
	8990.15.400.S	40	4.5
	8990.15.425.S	42.5	4.5
	8990.15.450.S	45	4.5
	8990.15.475.S	47.5	4.5
	8990.15.500.S	50	4.5
	8990.15.525.S	52.5	4.5
	8990.15.550.S	55	4.5
	8990.15.575.S	57.5	4.5
	8990.15.600.S	60	4.5

Sterile single packaging.



Ø 3.5 mm DISTAL CORTICAL SCREW			
	Code	Length (mm)	Diameter Ø (mm)
<b>Ti6Al4V</b>	980.15.018.S	18	3.5
	8980.15.020.S	20	3.5
	8980.15.022.S	22	3.5
	8980.15.024.S	24	3.5
	8980.15.026.S	26	3.5
	8980.15.028.S	28	3.5
	8980.15.030.S	30	3.5
	980.15.032.S	32	3.5
	8980.15.034.S	34	3.5
	8980.15.036.S	36	3.5
	8980.15.038.S	38	3.5
	8980.15.040.S	40	3.5

Sterile single packaging.



LOCKING PLUG		
	8731.15.100	+ 0
<b>Ti6Al4V</b>	8731.15.101	+ 2
	8731.15.102	+ 4

Sterile single packaging.

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Lima Corporate Orthopaedic Motion.





Info

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