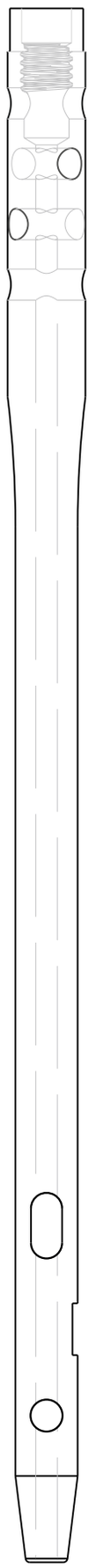
Ostéo France Ortho



Intramedullary

Humeral Nail

Surgical Technique

Ostéo France Ortho

Intramedullary
Humeral Nail
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Ostéo France Ortho

ISO 9001:2015
ISO 13485:2016
CE 1984

1.1 HUMERAL NAIL

1.1.1.Specifications

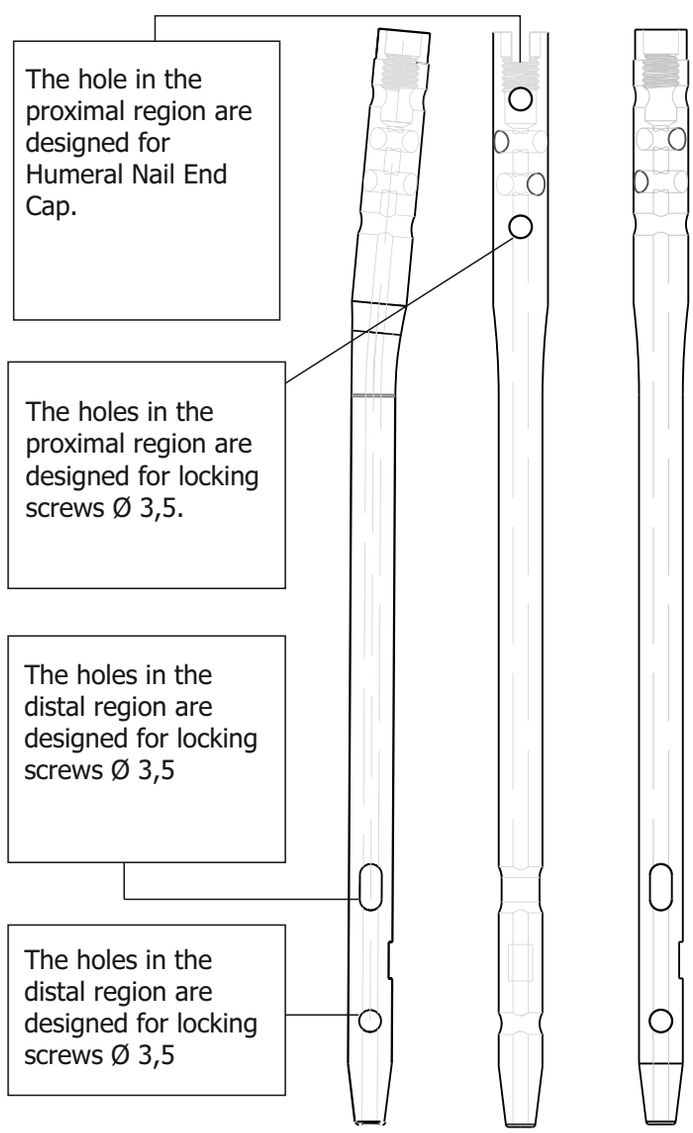
The intramedullary nail is designed to treat fractured humeral head and humeral shaft fractures. The humeral nail is designed with a 5 ° lateral angle and a distal dynamic hole. It has diameters of Ø 7, 8 and 9 mm and is available in variable lengths from 160 mm to 280 mm The End Cup screw is standard and there are no size options. The cortical distal locking screw is Ø 3,5 mm in diameter and is available in 18 mm - 50 mm length options. All components of the intramedullary nail system are manufactured from titanium alloy manufactured in accordance with ISO 5832-3.

Ostéo France Ortho

CANNULATED INTRAMEDULLARY

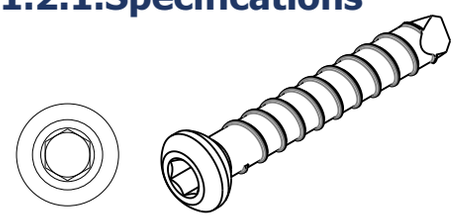
HUMERAL NAIL

REF. NO	SIZE
4102-0716	7x160
4102-0718	7x180
4102-0720	7x200
4102-0722	7x220
4102-0724	7x240
4102-0726	7x260
4102-0728	7x280
4102-0816	8x160
4102-0818	8x180
4102-0820	8x200
4102-0822	8x220
4102-0824	8x240
4102-0826	8x260
4102-0828	8x280
4102-0916	9x160
4102-0918	9x180
4102-0920	9x200
4102-0922	9x220
4102-0924	9x240
4102-0926	9x260
4102-0928	9x280



1.2 screw

1.2.1.Specifications



Ø3.5mm Locking Screw

REF. NO	SIZE
4042-0018	18mm
4042-0020	20mm
4042-0022	22mm
4042-0024	24mm
4042-0025	25mm
4042-0026	26mm
4042-0028	28mm
4042-0030	30mm
4042-0032	32mm
4042-0034	34mm
4042-0035	35mm
4042-0036	36mm
4042-0038	38mm
4042-0040	40mm
4042-0042	42mm
4042-0044	44mm
4042-0045	45mm
4042-0046	46mm
4042-0048	48mm
4042-0050	50mm

Humeral Nail End Cap

REF. NO
4112-0000

2.1. Safe Area For Humerus

Due to the anatomy of the region where the humeral bone is located, Shanz and Kirscher or screw can only be applied to certain areas. Needing attention; The axillary nerve, the radial nerve, and the bicitibal groove in the anterior. *(In addition, it should be considered in the rotation of the radial nerve from the posterior to the anterior on the humerus.* In the images below, safe areas in average sizes are shown.

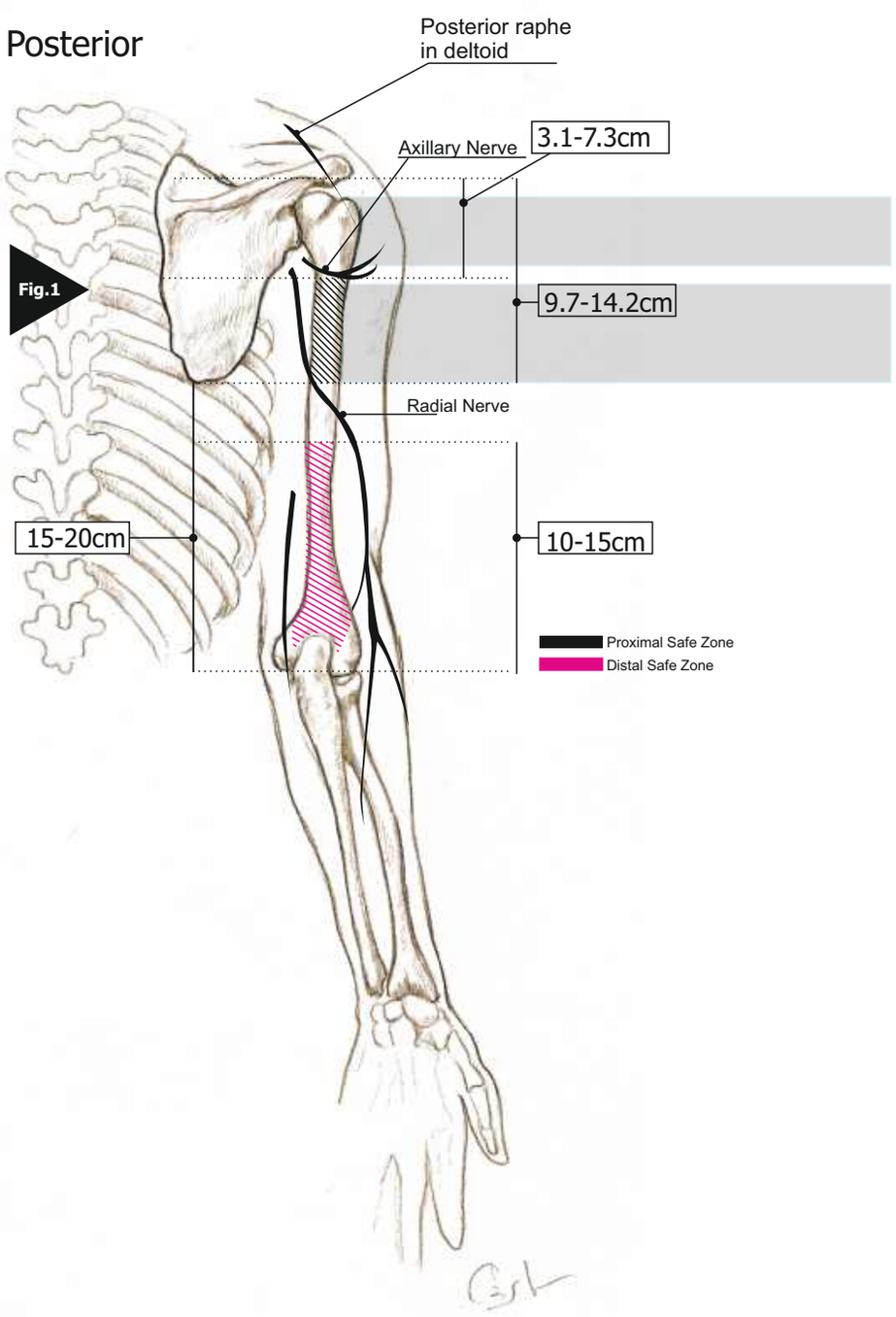


Fig.1

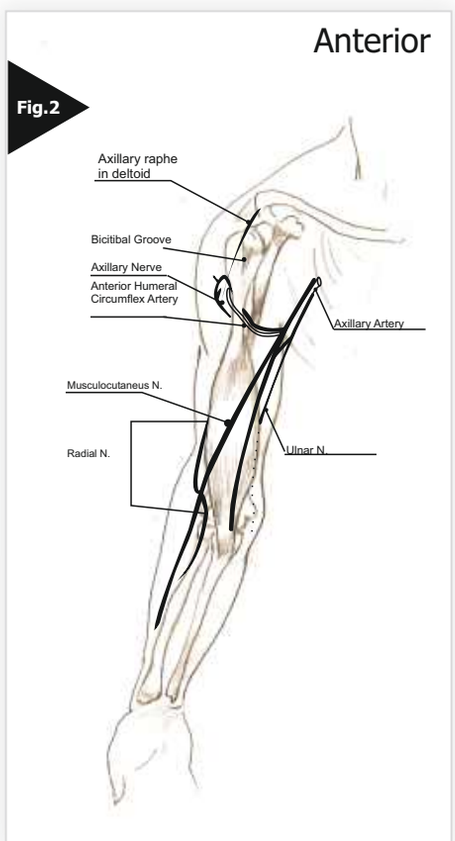
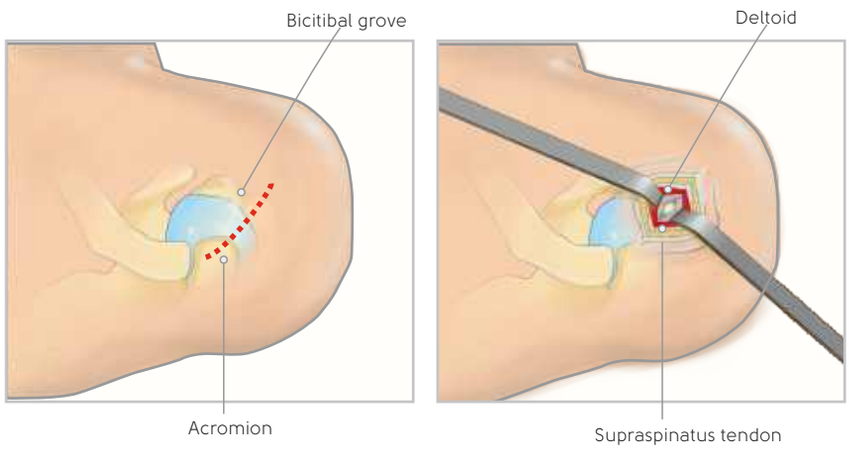


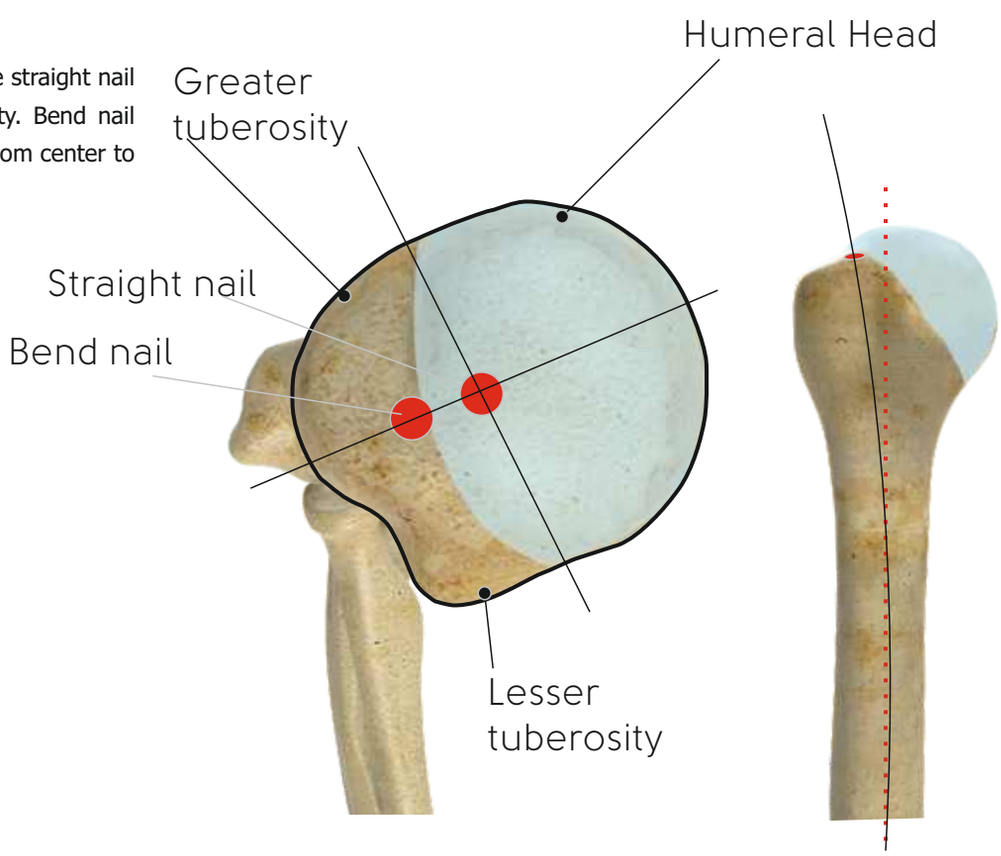
Fig.2

2.2. Entry Point

Make a small skin incision from the anterolateral edge of the acromion



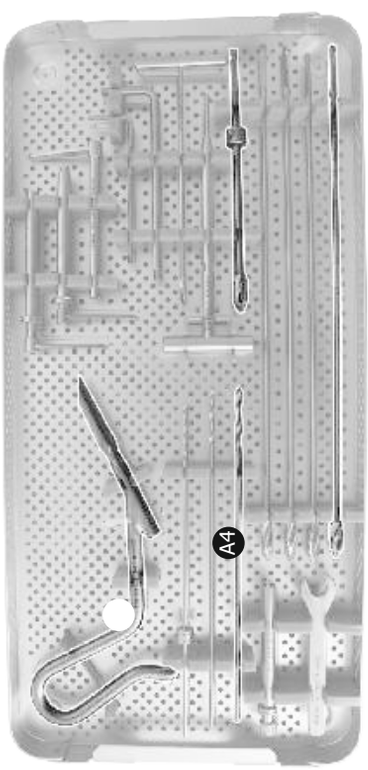
The insertion point for the straight nail is in line with the medullary cavity. Bend nail insterion point is 1-2cm distance from center to distally.



2.3. Insert Nail

Drill with *(A4 Drill Ø3.6)* from entry point.(Fig.1)

Expand entry point with *(A8,AWL)* (Fig.2)



2.3. Insert Nail

2.3.1 Remaing

Combine *(A16, proximal reamer)* with *(B13 T handle)* (Fig.3).

Prepare nail entry with the *(A16, proximal reamer)*(Fig.3)

Combine (A18-21, reamer) with *(B13 T handle)* (Fig.3).

Open the canal with*(A18-21, reamer)* (Fig.4) *(proceed from small to large one)*
Determine nail lenght while reaming. Use numbers on the reamer for determining. This dimension will used instaling targeting device in the later stages

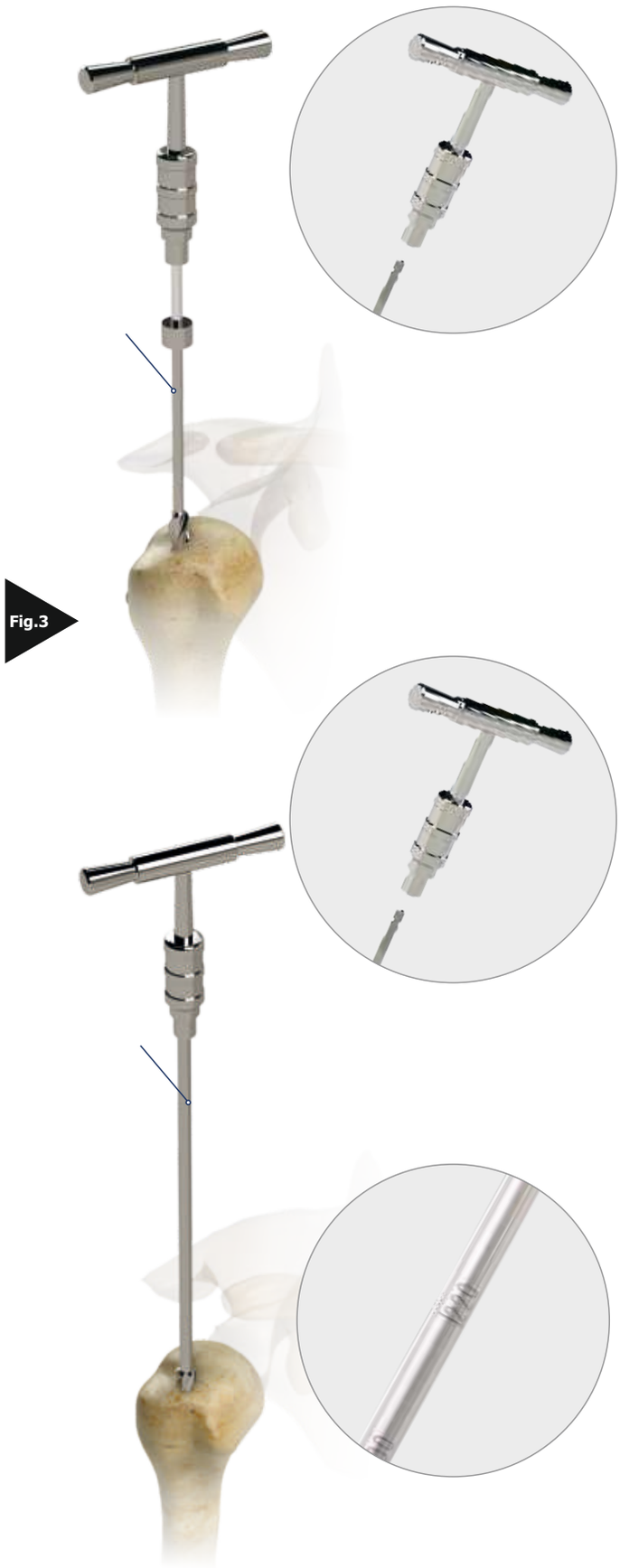


Fig.3

2.3. Insert Nail

2.3.2 Nail and Handle

The nail is combined with the *(B8 nail support handle)*.(Fig.5)Fixed with*(B9 Nail Suppert Handle Screw)* Use *(A1 Wrench)* fix for screw.(Fig.6)

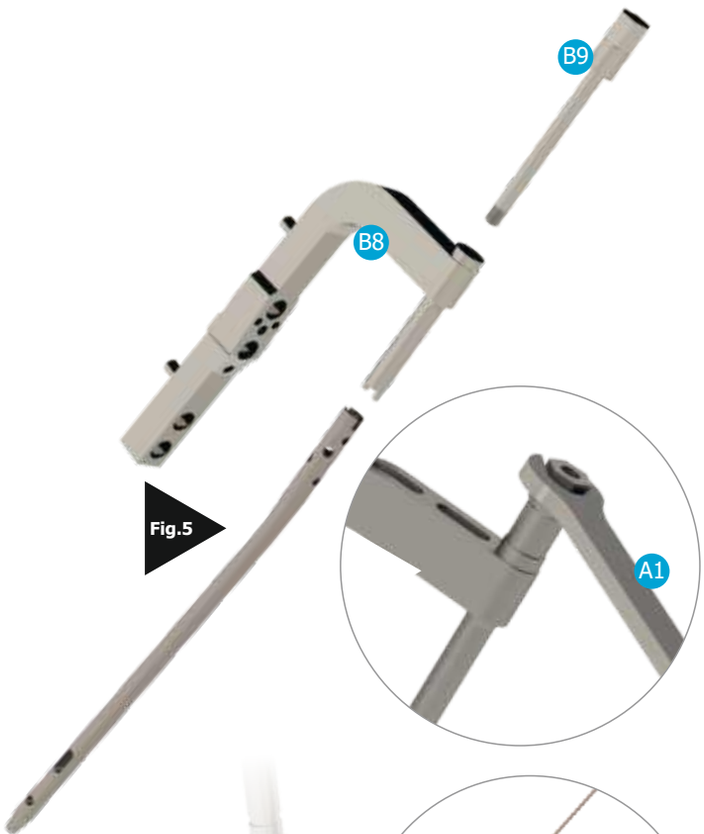
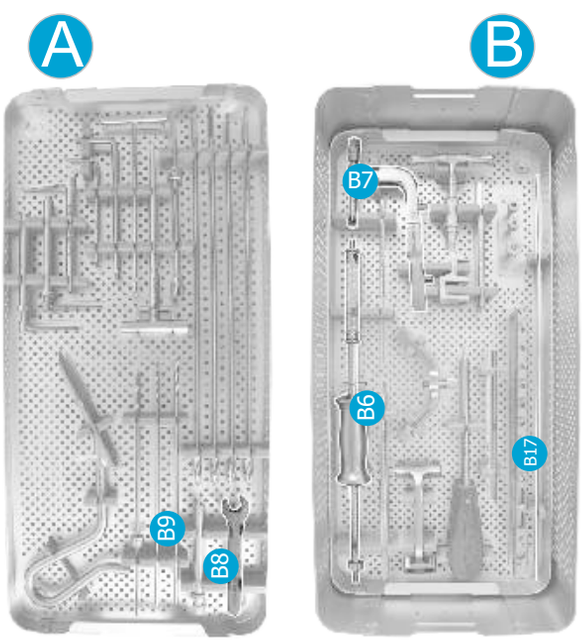


Fig.5

Gripper is used for to insert*(B17 guidewire)t*o inside canal.(Fig.7-8)

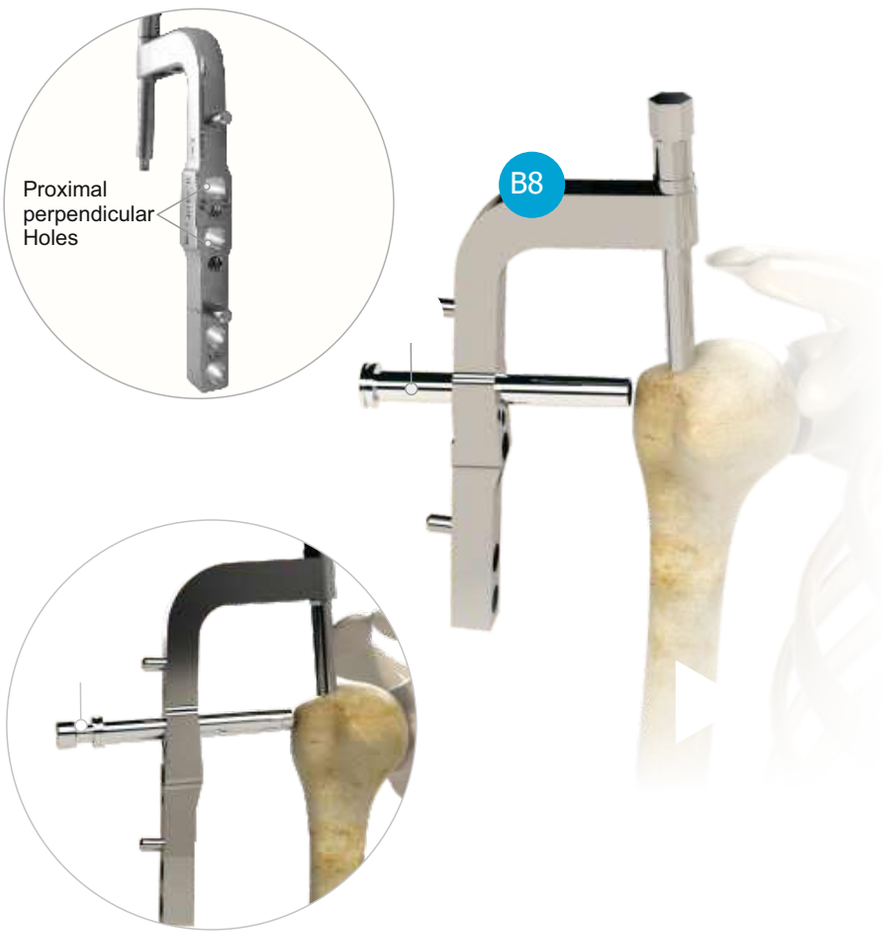
The nail is placed using the *(B17 guidewire)* and with the help of the *(B8 nail support handle)*.(Fig.9)



2.4. Proximal Fixing

2.4.1 Screw

is placed to *(B8 Nail Support Handle)*(Fig.8). *(A2 Point Marker)* is placed inside to *(A3 or A10 Centering Tube)*(Fig.9) and the place is marked on the bone for the the drill. *(A2 Point Marker)* remove.

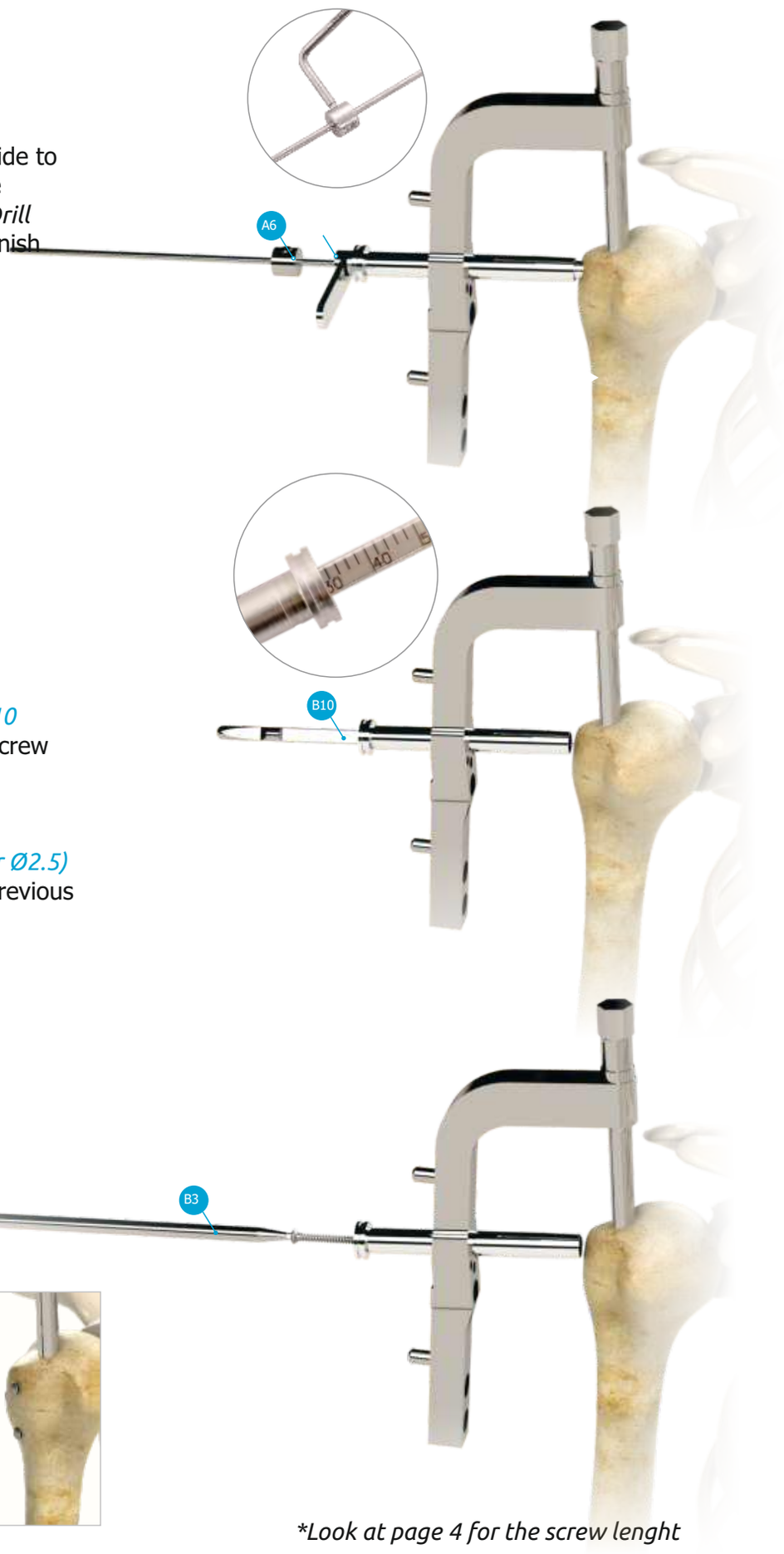


(A9 Drill guide Ø2.9) is placed inside to the *(A3 or A10 Centering Tube)*(Fig.10)

2.4. Proximal Fixing

2.4.1 Screw

is placed inside to the *(A9 Drill guide Ø2.9)*. Drill to the second cortex an then set the *(A7 Drill Stopper)*. Fix with *(A12 L Wrench)*. Finish the drilling (Fig.11).



(*A9 Drill guide Ø2.9)* is removed. *(B10 Depth Guide)* is placed. Determine Screw lenght*.*(B10 Depth Guide)* is removed(Fig.12).

Send the screw with *(B3 Screwdriver Ø2.5)* which is determined lenght on the previous step(Fig.13).

Apply same prodecure for second scew (Fig.14)


Fig.14

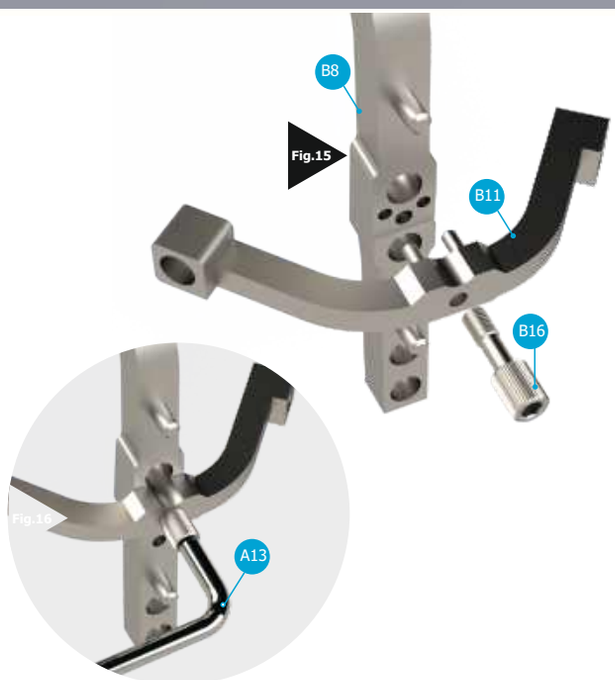
**Look at page 4 for the screw lenght*

2.4. Proximal Fixing

2.4.2 Angled Screw

(B11 Proximal Aiming Guide Angled) is placed *(B8 Nail Support Handle)* (Fig.15). Fix with *(A13 L wrench)* and *(B16 Guide Stopper)*(Fig.16).

(A3 or A10 Centering Tube) is placed (Fig.17).
(A2 Point Marker) is placed inside to *(A3 or A10 Centering Tube)*.Mark for the drill. *(A2 Point Marker)* is removed (Fig.18).



2.4. Proximal Fixing
2.4.2 Angled Screw

(A9 Drill guide Ø2.9) is placed inside to the *(A3 or A10 Centering Tube)*(Fig.19)

(A5 or A6 Drill Bit Ø2.9) is placed inside to the *(A9 Drill guide Ø2.9)*. Drill up to the second cortex an then set the *(A7 Drill Stopper)*. Fix with *(A12 L Wrench)*. Finish the drilling(Fig.20).

(A9 Drill guide Ø2.9) is removed. *(B10 Depth Guide)* is placed. Determine Screw lenght*.*(B10 Depth Guidde)* is removed (Fig.21).

2.4. Proximal Fixing
2.4.2 Angled Screw

Send the screw with *(B3 Screwdriver Ø2.5)* which is determined lenght on the previous step(Fig.22).

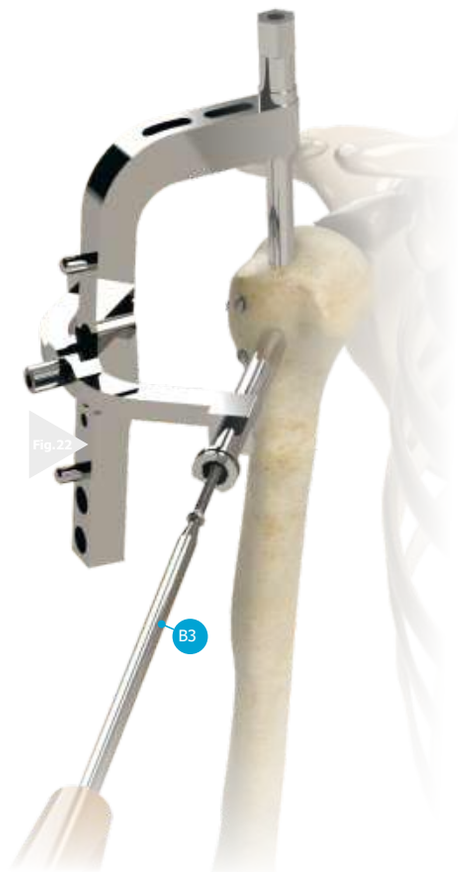


Fig.22

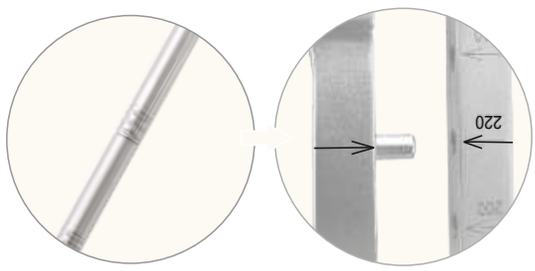
Apply same prodecure for angled second scew (Fig.23) Remove *(B11 Proximal Aiming Guide Angled).*(Fig.24)

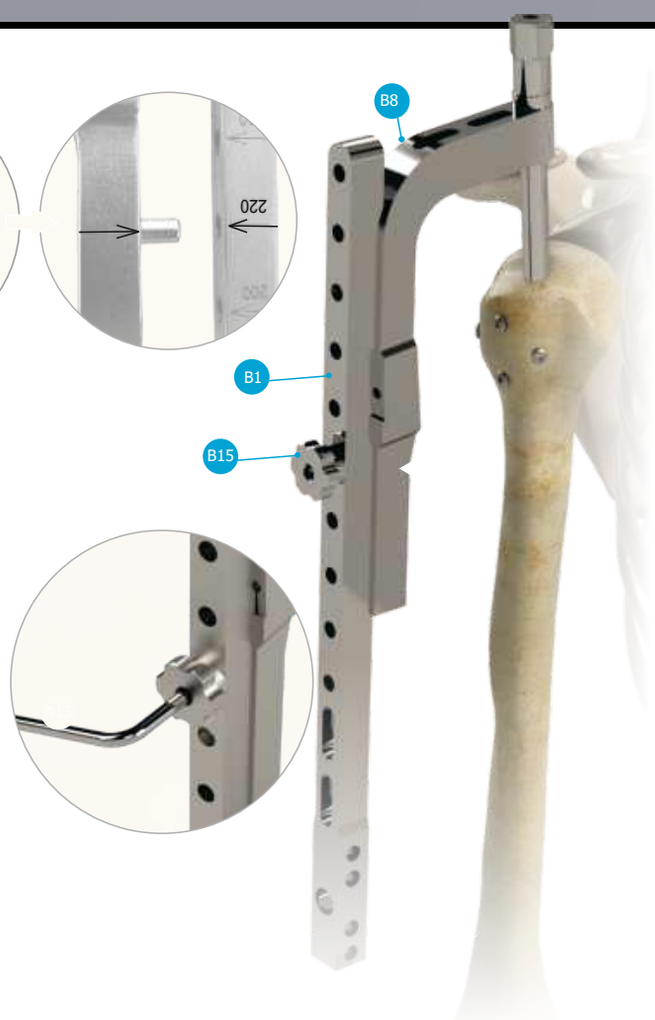

Fig.23

2.5. Distal Fixing

2.5.1 Distal Fixing Device

Combination of the targeting device is made according to the nail lenght. Use the lenght which is determined in the

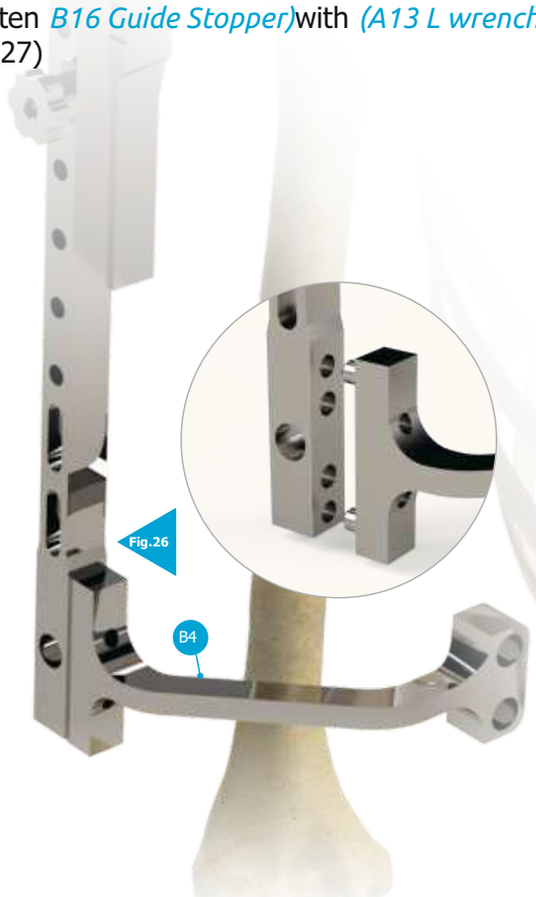


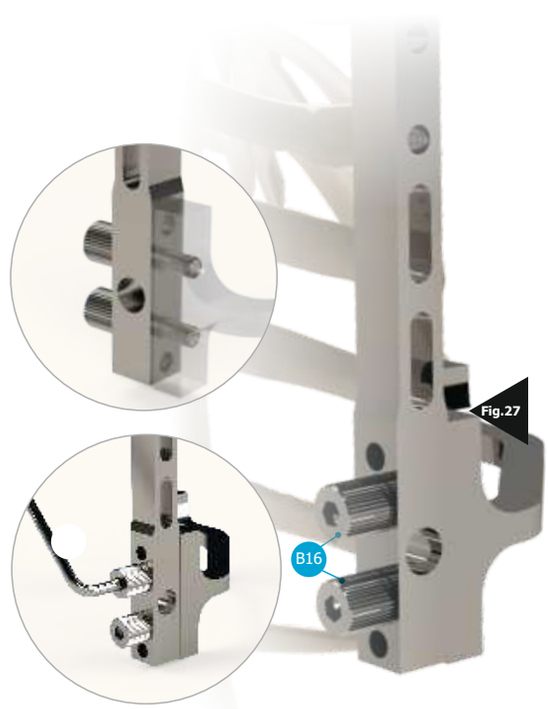


(B1 Targeting Device) is placed to *(B8 Nail Support Handle). (B1 Targeting Device)* is fixed with *(B15 Targeting Guide Screw)* and *(A13 L wrench)* (Fig.25).

(B4 Distal Aiming Guide) is placed on distal hole of *(B1 Targeting Device)*(Fig.26)

Use *(B16 Guide Stopper)* to fix *(B4 Distal Aiming Guide)* with *(B1 Targeting Device).*
Tighten *B16 Guide Stopper)*with *(A13 L wrench)* (Fig.27)





2.5. Distal Fixing

2.5.1 Distal Fixing Device

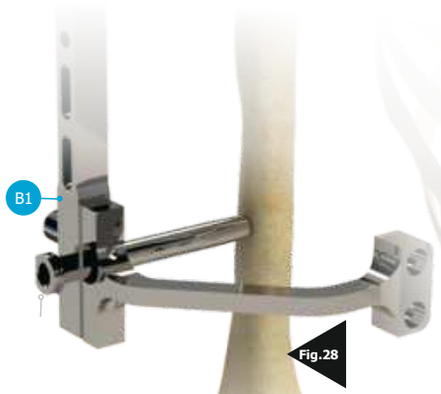


Fig.28

(A3 Centering Tube) is placed on *(B1 Targeting Device)* (Fig.28)

(A2 Point Marker) is placed inside to the *(A3 Centering Tube)* and marked for drill. Remove *(A2 Point Marker)*(Fig.29)

(A11 Drill Guide Ø3.6) is placed inside *(A3 Centering Tube)*(Fig.30)

Drill with (A4 Ø3.6 Drill Bit)(Fig.27)

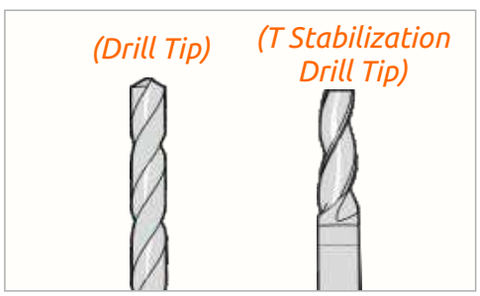
Remove (A11 Drill Guide Ø3.6)

2.5. Distal Fixing

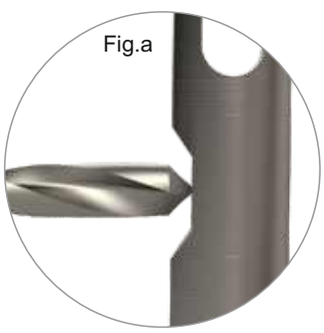
2.5.1 Distal Fixing Device

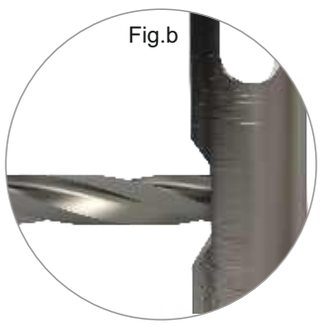
Drill with *(A4 Ø3.6 Drill Bit)* (Fig.31)

It is important (A14 T Drill Ø3.6) is used for after drilling process. Because Drill tip point is triangle shape. (A14 T Drill Ø3.6) Drill tip point is straight. So for the best distal locking use (A14 T Drill Ø3.6) in this section.(Fig.32)



Make sure that the drilled area is fully opened with *(A14 T Drill Ø3.6) The importance of this stage is that it enables the drilling of the area of the drill bit, which is close to the triangle, in a smooth form, and allows a more uniform fixation in the distal.(Fig.a-b).*





2.5. Distal Fixing

2.5.1 Distal Fixing Device

(A15 T stabilization Device) is placed inside *(A3 Centering Tube)*(Fig.32)
(B12 U Stabilization Device) is placed for fixing *(A15 T stabilization Device)*.(Fig.33)

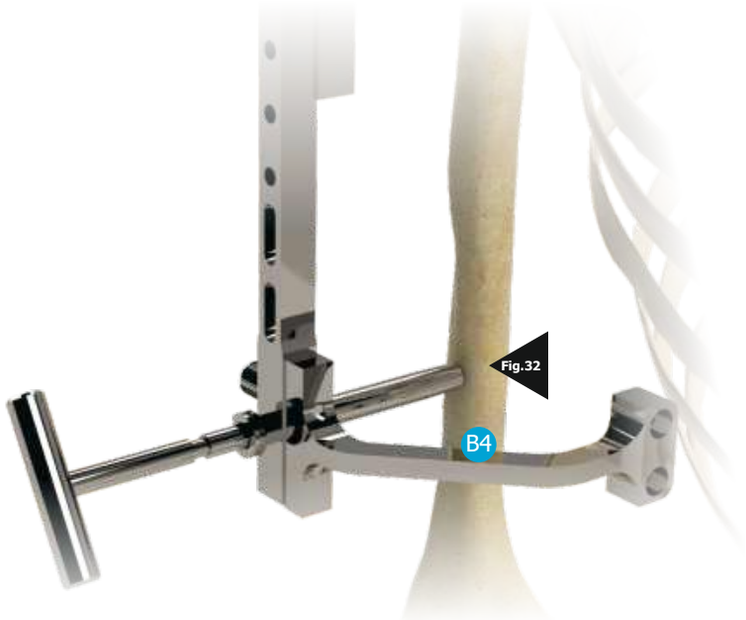
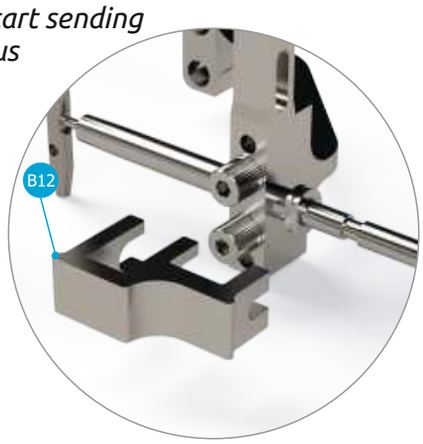


Fig.32

make sure the part (B12 U Stabilization Device) fits well . it is important for the right stabilization . Aftar that you can start sending screw for distal area of the humerus



2.5. Distal Fixing

2.5.2 Distal Screw

(A10 Centering Tube) is placed to the *(B4 Distal Aiming Guide)* (Fig.34)
(A2 Point Marker) is placed inside to the(A10 Centering Tube). Mark for drill. *(A2 Point Marker)* is removed(Fig.35).
is placed inside to the *Centering Tube)*(Fig.36)

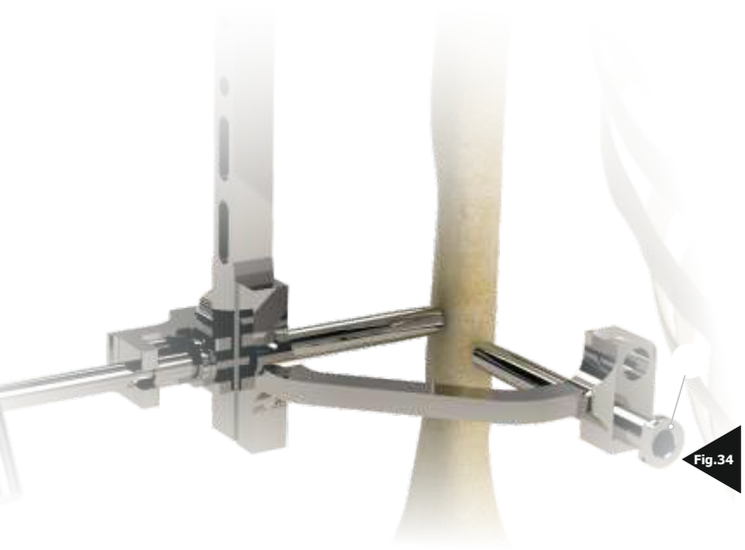
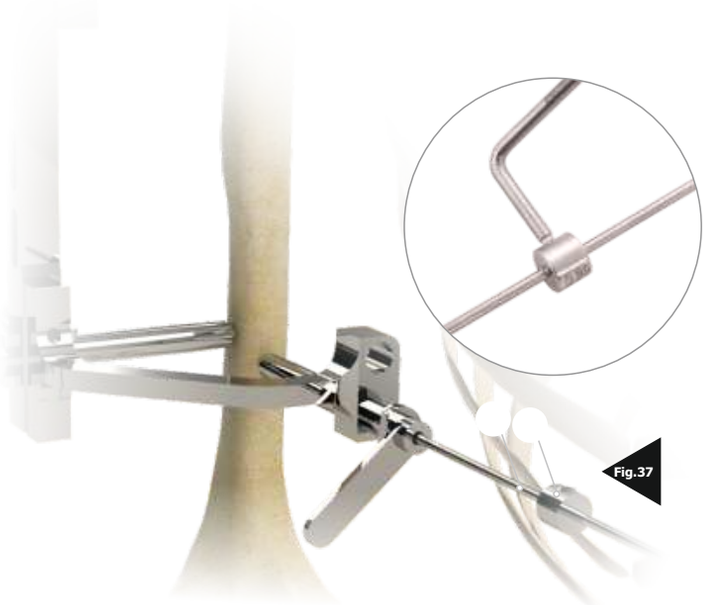
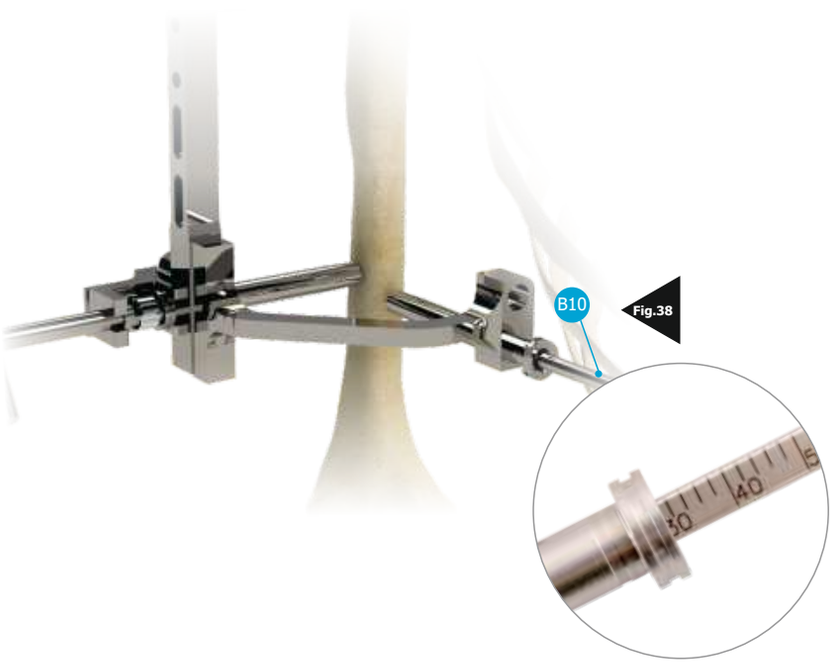


Fig.34

2.5. Distal Fixing
2.5.2 Distal Screw



is placed inside to the Drill guide Ø2.9).Drill up to the second cortex an then set the (A7 Drill Stopper). Fix with (A12 L Wrench). Finish the drilling (Fig.37).



is removed. (B10 Depth Guide) is placed. Determine Screw lenght*.(B10 Depth Guidde) is removed (Fig.38).

**Look at page 4 for the screw lenght*

2.5. Distal Fixing
2.5.2 Distal Screw

Send the screw with *(B3 Screwdriver Ø2.5)* which is determined lenght on the previous step(Fig.39).

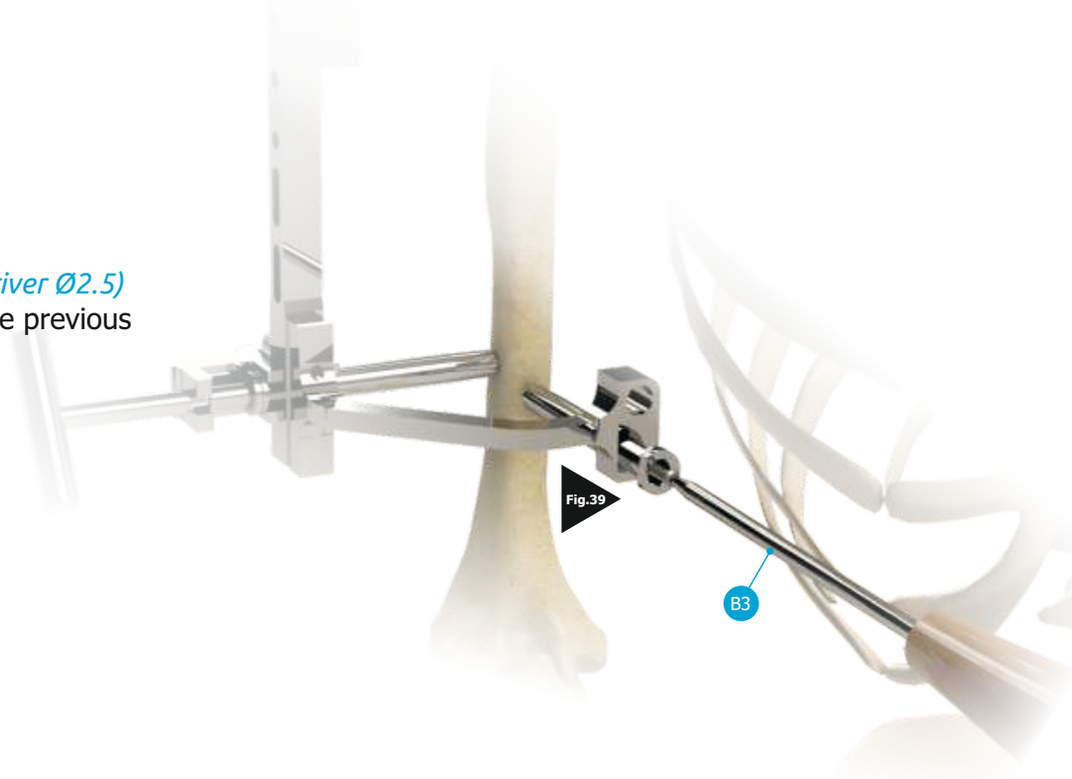
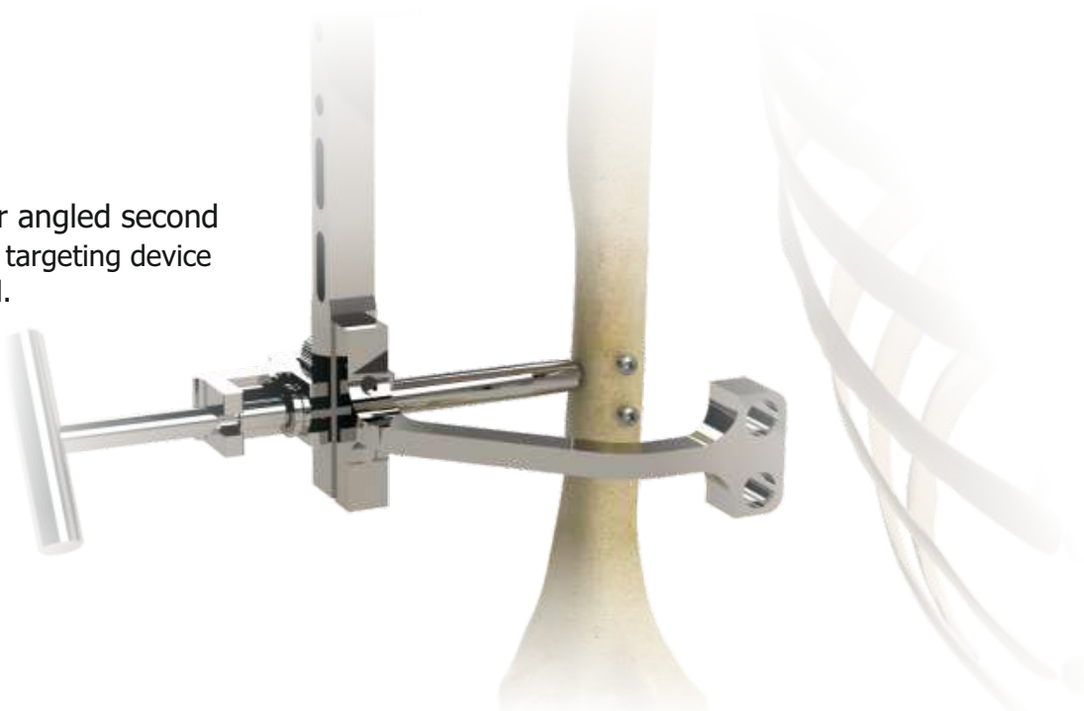


Fig.39

Apply same prodecure for angled second scew (Fig.40) After that all targeting device and guides can be removed.



2.6. Removing

2.6.1 Removing targeting devices

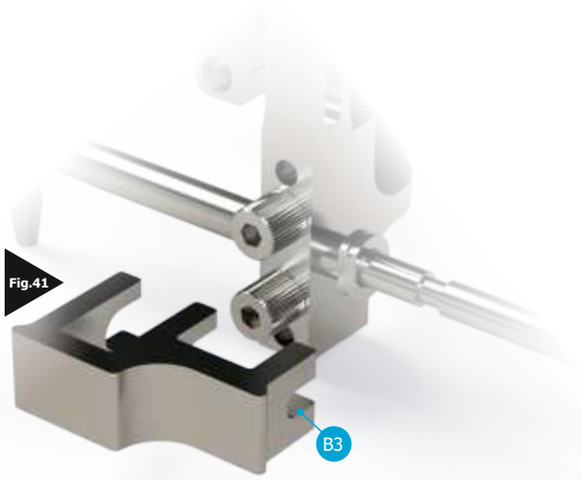
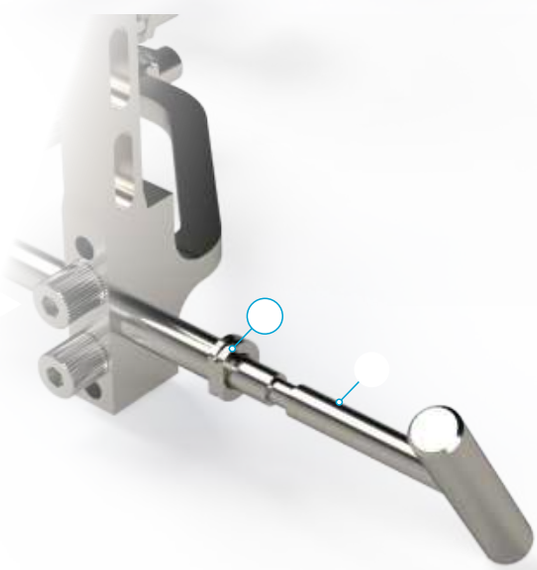


Fig.41

Remove *(B12 U stabilization device)* (Fig.41)



Remove *(A15 T Stabilization device)* and *(A10 Centering tube)* (Fig.42)

(B6 Guide Stoper) is loosen with *(A13 L Wrench)* (Fig.43)
Remove *(B6 Guide Stoper)* and *(B4 Distal Aiming Guide)*

Fig.43

2.6. Removing

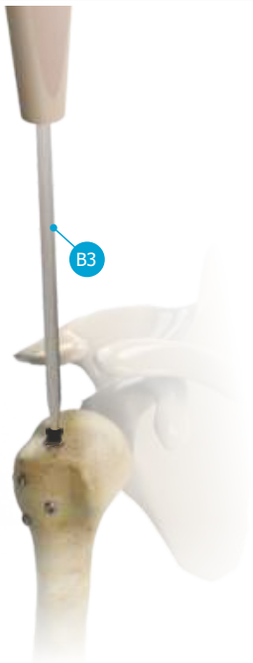
2.6.1 Removing targeting devices

(B15 Targeting Guide Screw) is loosen with *(A13 L Wrench)* (Fig.44)
Remove *(B15 Targeting Guide Screw)* and *(B1 Targeting Device)* (Fig.45)

(B9 Nail Support Handle Screw) is loosen with *(A1 Wrench)* (Fig.46)
(B8 Nail support handle) and *(B9 Nail Support Handle Screw)* can be removed (Fig.47)

2.6. Removing
2.6.2 Endcap

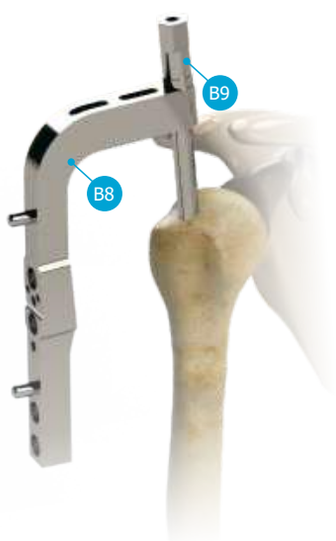
after All targeting device and guides removed, endcap is can be send with *(B3 Screwdriver)* (Fig.49)



2.6. Removing
2.6.3 Removing Nail

At first, end cup have tobe removed it is can be remove with *(B3 Screwdriver)* (Fig.50)

insert *(B8 Nail Support Handle)* and *(B9 Nail Support Handle screw)* connect with nail (Fig.51)



2.6. Removing

2.6.3 Removing Nail

Connect *(B7 Cannulated Slidding Hammer)* with *(B9 Nail Support Handle Screw).* Tighten with *(B6 Cannulated Slidding Hammer Nut)*(Fig.52)

After stabilization, Ø3.5mm screws are can be removed.(Fig.53)
Use *(B7 Cannulated Slidding Hammer)* for remove nail (Fig.54)

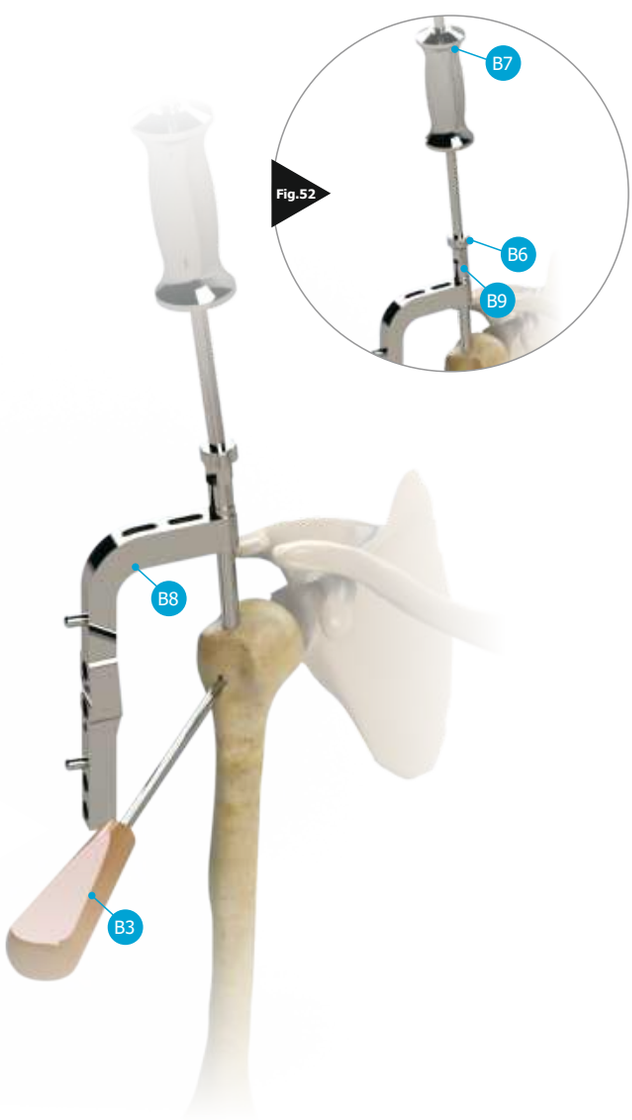
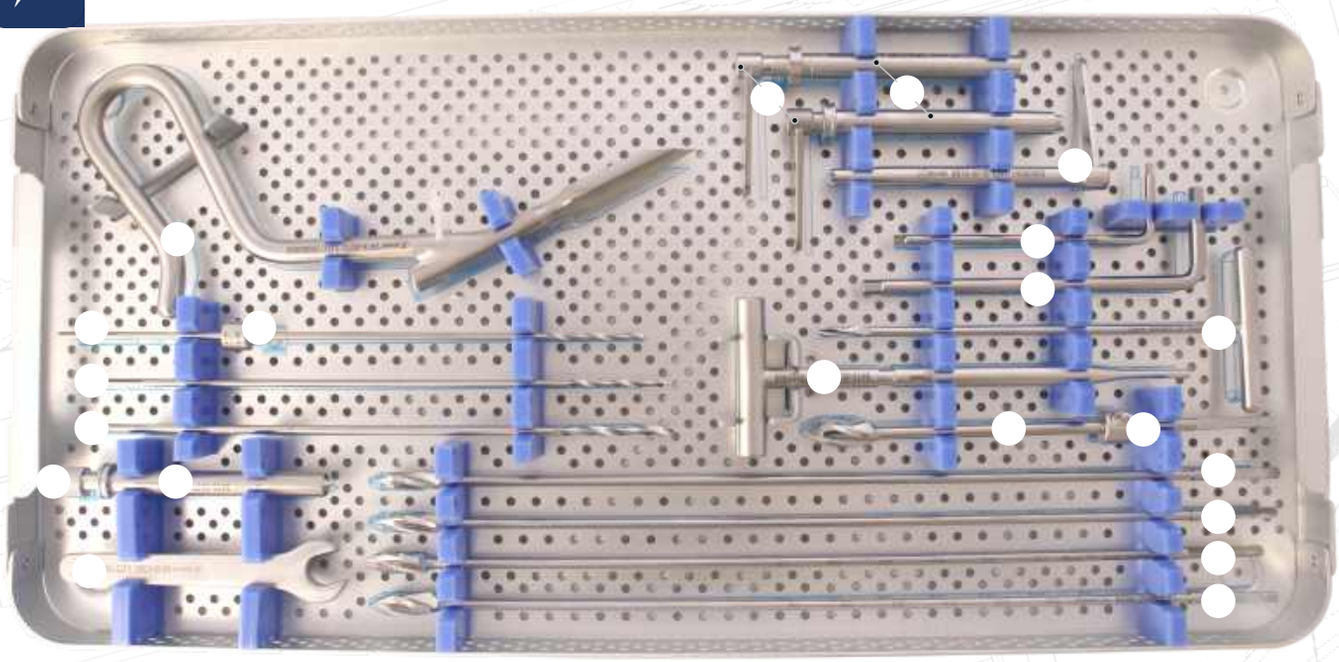


Fig.52

3.1. Set Tray A

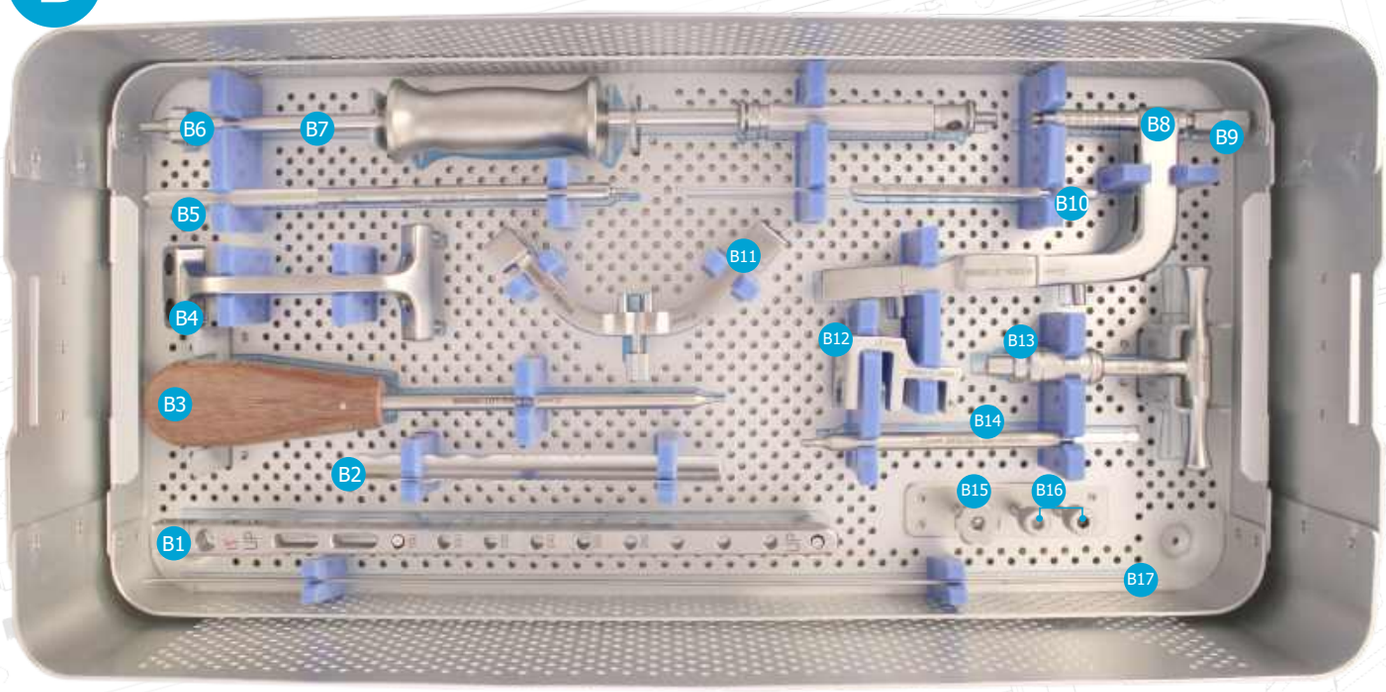


A1		Wrench
A2		Point Marker
A3		Screw Guide Ø 10 / Ø 8 mm
A4		Drill Ø 3,6 mm
A5		Drill Ø 2,9mm
A6		Drill Ø 2,9 mm
A7		Stopper
A8		AWL

A9		Drill Guide Ø 2,9 mm
A10		Centering Tube
A11		Drill Guide Ø 3,6 mm
A12		L Wrench 3 mm
A13		L Wrench 5 mm
A14		T Drill Ø3.6
A15		T Stabilization Device
A16		Proximal Reamer
A17		Stopper
A18		Reamer Ø 7 mm
A19		Reamer Ø 8 mm
A20		Reamer Ø 8.5 mm
A21		Reamer Ø 9 mm

3.2. Set Tray B

B



B1		Targeting Device
B2		Measurement Device
B3		Screwdriver Ø 2.5
B4		Nail Distal Aiming Guide
B5		Sliding Hammer
B6		Cannulated Sliding Hammer Nut
B7		Cannulated Sliding Hammer
B8		Nail Support Handle
B9		Nail Support Handle Screw

B10		Depth Guide
B11		Nail Proximal Aiming Guide
B12		U Stabilizing Device
B13		Cannulated T Handle
B14		Ø2.5 Screwdriver
B15		Targeting Guide Screw
B16		Guide Stopper Ø 2,9
B17		Guide Wire

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

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.

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.

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.

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

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. 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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