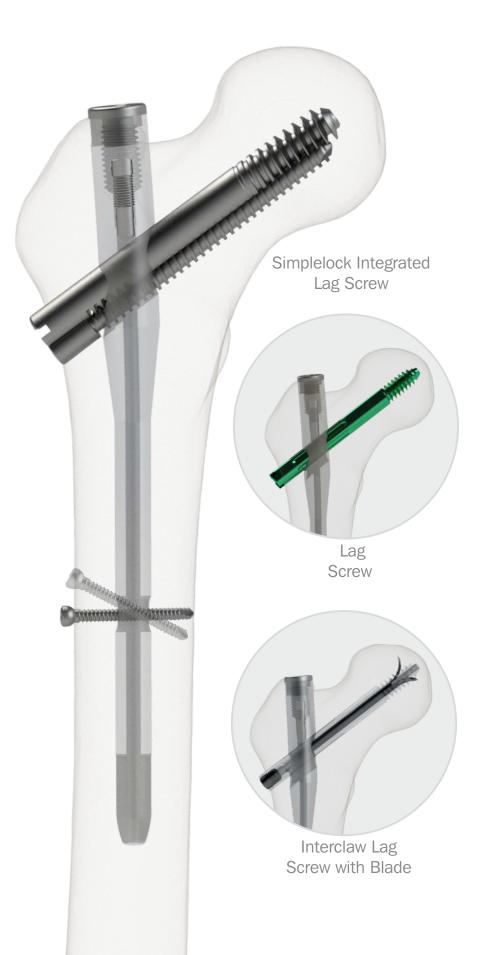


SIMPLELOCK / INTERCLAW /LAG

PFNA

Anti-Rotation Proximal Femoral Nail

Surgical Technique







Lag Screw
Proximal Femoral
Nail

1.1.1.Specification

PFN-A Intramedullary Nail

The PFN-A Nail is used in the treatment of unstable intertrochanteric fractures. Intertrochanteric femur fractures are common in the elderly population. This is because of osteoporosis. Due to the decrease in bone quality and deterioration of its microstructure, fractures often develop with very lowenergy trauma

Lag is the most important feature of the nail. There are three types.
They come to the forefront with their features such as screw thread structures, compression, blade features and they have their own unique application forms.

Lag Screw

Can be used in low-energy unstable intertrochanteric fractures and in patients with non osteoporosis and younger

REF. NO	LENGTH (mm)
4582-0080	80
4582-0085	85
4582-0090	90
4582-0095	95
4582-0100	100
4582-0105	105
4582-0110	110
4582-0115	115
4582-0120	120





-Proximal diameter Ø16mm

-Distal diameter Ø10mm - Ø11mm -

Ø12mm - Ø13mm - Ø14mm

-Proximal – Distal angle 5°

-Lag screw center angle 55° to proximal body

-Cannula diameter Ø3,7mm for all diameters of PFN-A nails

-Distal antirotation (Ø2,5mm X 25mm)

-Ø5mm locking screw dynamic locking screw

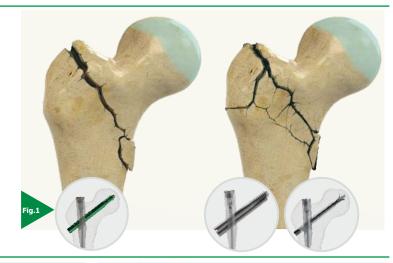
******** *******



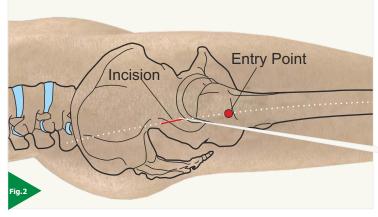
1.1.2. Fracture

Evan's classification system divides intertrochanteric fractures into stable and unstable fracture patterns. The distinction between stable and unstable fractures is based on the integrity of the posterior medial cortex. Other intertrochanteric fracture classifications are variations of Evan's classification, including AO.

In general, when the posterior medial cortex is fragmented, fractures are considered unstable due to the possibility of the fracture collapsing into varus and retroversion. (Fig. 1)

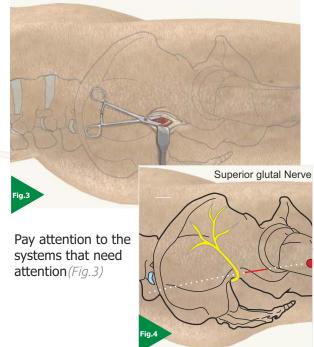


1.1.3. Approach



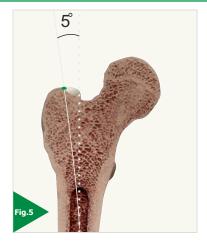
A 3-5 cm skin incision is made a few centimeters proximal to the tip of the greater trochanter. It is located in the proximal extension of the curved axis of the femoral shaft. The exact location of the skin incision depends on the type of holder and the nail.

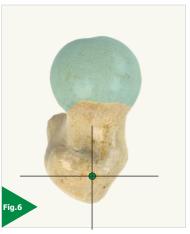
may show changes. (Fig. 2)



1.1.4.Entry Point

Determine the appropriate entry zone for the nail (Fig.4)

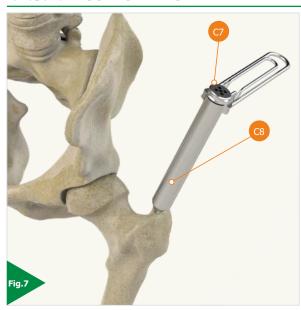




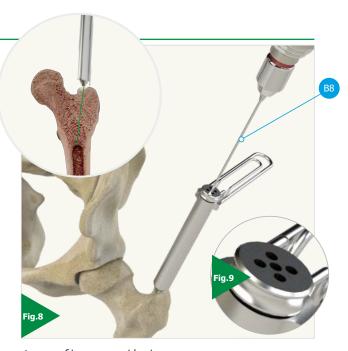


1.1.5. Opening the Proximal Femur

1.1.5.1.Kirschner Wire



The guide tool *(C7-C8)* is inserted from the incision to the bone. *(Fig.7)*.Insert the guide wire *(B8)*. Place 2-3 cm in the trachantoric region. Provide control from the AP and Lateral planes *(Fig.8)*.



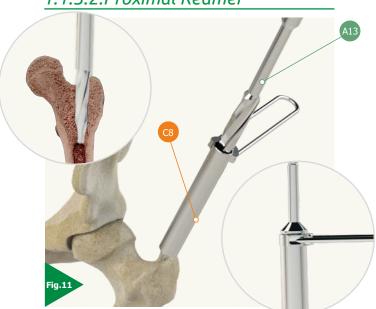
In case of improper guide pin placement, rotate the guide and repeat with a new guide wire in suitable hole (Fig.9).

1.1.5.1.Kirschner Wire



Remove the inner guide (C7) (Fig. 10)

1.1.5.2.Proximal Reamer



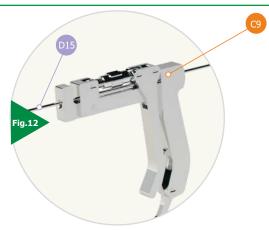
Insert the proximal reamer *(A13)* into the guide *(C8)*. Remaing up to the stoper on the reamer *(Fig.11)*



1.1.PFNA Nail System For Long PFNA Nail

1.1.6.Intramedullary reaming

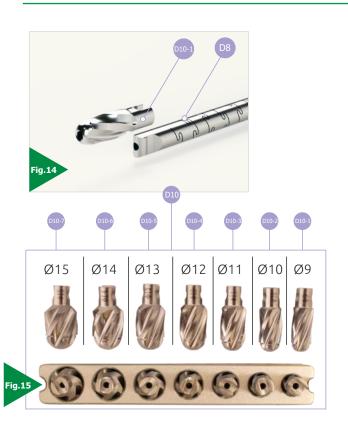
1.1.6.1.Guide Wire





attach it to the gripper *(C9)* with guide wire *(D15).(Fig.12)* insert the guide wire through the opened inlet channel, and advance it through the opened channel. *(Fig.13)*

1.1.6.2.Opening the Canal



Nail length can be determined with a reamer. (Fig. 16)



In order to place the nail, it is necessary to ream the bone canal properly. For this, flexible reamer (D8) and reamer heads (D10) are used (Fig. 14). Carving is started from a small size suitable for the nail (D10-1)(Fig. 15). The nail size can be made at this stage with a length reamer holder (Fig. 16).

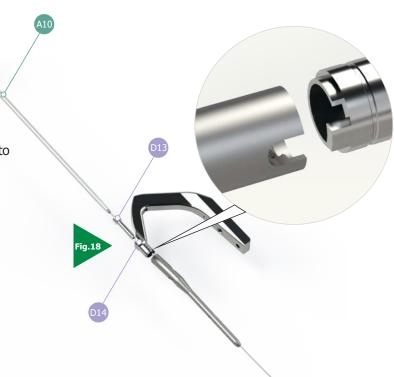
Nailing section

1.1.PFNA Nail System

1.1.7.Nail Insert

1.1.7.1.Preparing Nail

For the nail, the fracture is reduced and the channel is opened. The length of the nail was also determined. To be able to insert the nail into the canal, it must be combined with the holder. The connecting screw (D13) is attached to the holder (D14). It is fixed with screwdriver (A10) (Fig. 18).



1.1.7.2.Inserting Nail



For a precise placement, it can be placed in the channel with the rotation movement shown in the picture. (Fig. 19).



Do not fully insert the nail for proper positioning and control of the proximal screws .(Fig. 20).

1.1.7.Nail Insert



After it is attached to the holder *(D14)*, the driving apparatus *(C6)* (*Fig.21*) and the hammer swing shaft *(C13)* (*Fig.22*) are combined. It is advanced in the channel with the help of hammer *(C11)* (*Fig.23-24*)



1.1.7.2.Inserting Nail







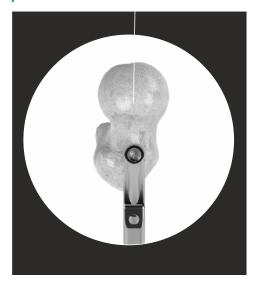
System 1- Lag Screw

1.1.PFNA Nail System

1.1.8. Proximal Screw *Lag screw*

1.1.8.1 location and preparation

In order to attach the proximal screws, the proximal holder (D4) must be attached first. Proximal retainers are of two types. It is in the form of a bladed lag screw and a compression and sliding lag screw. This part (D6) is used since the sliding lag screw will be attached at this stage. (Fig. 25-26)





1.1.8.2.Connection devices







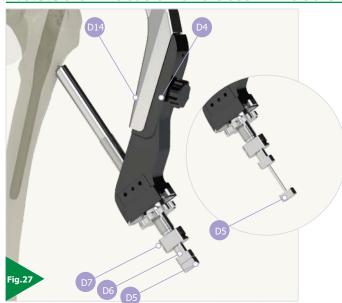


System 1- Lag Screw

1.1.PFNA Nail System

1.1.8.Proximal Screw *Lag screw*

1.1.8.3.Screw Location and determine screw length

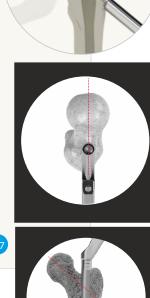


Insert the group sleeve (D5Point Marker, D6 Kirschner and D7 drill sleeve)(Fig:27)

Mark with point marker (D5) and remove it



Insert the (B7 or B8 Kirschner) to (D6 Kirschner sleeve) Control under the image place of Kirchner wire. Right place important Beacuse Lag screw will send over this wire. (Fig:28)



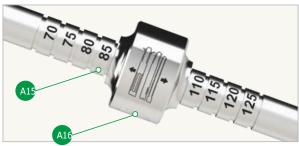


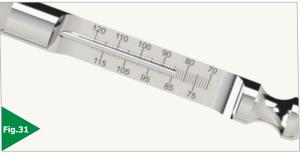
Remove (D6 Kirschner Sleeve)(Fig:29)



Use the (C5 Lag screw gauge), determine scew lenght over the Kirschner wire (Fig:30)

1.1.8.Proximal Screw *Lag screw* 1.1.8.4 *Drilling for the lag screw*.

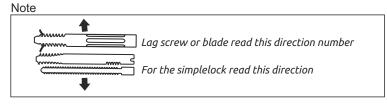




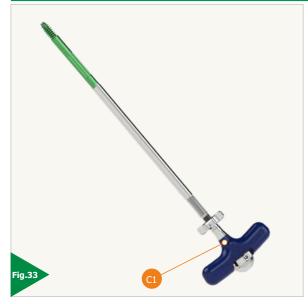
Prepare (A15 Ø10.8xØ3.2mm Cannulated Drill Bit) for drilling. Adjust (A16 drill stoper) according to prestage size measurement (Fig:31)



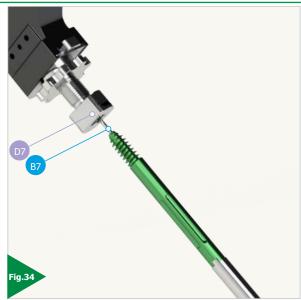
Insert the (A15 Cannulated Drill Bit) to (D7 Drill Sleeve) (Fig:32)



1.1.8.5 *Lag screw*



Attached the lag screw with (C1 Lag screw driver)(Fig:33)



Insert over the (B7 Kirschner wire) to lag screw from the Drill Sleeve (D7 drill sleeve)(Fig:34)



System 1- Lag Screw

1.1.PFNA Nail System

1.1.8.Proximal Screw *Lag screw*

1.1.8.5 *Lag Screw*

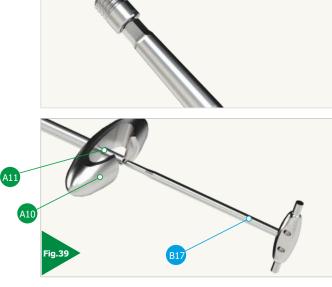


Slide inside to the guide and make compression if it needs. (Fig:36)

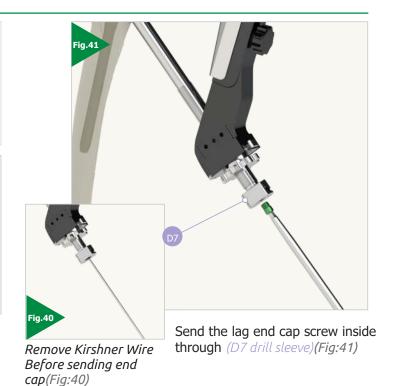


Remove lag screw driver (C1 Lag screw driver)(Fig:38)

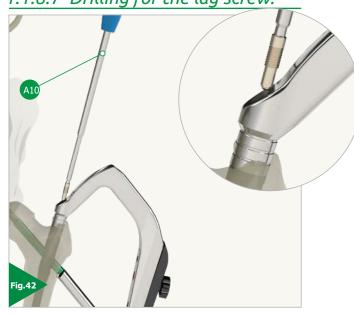
1.1.8.6 Lag End Cap



Prepare (A10 Screwdriwer Ø4.0 and A11 inner shaft) attached screw with (B17 Screwdriver) (Fig:39)

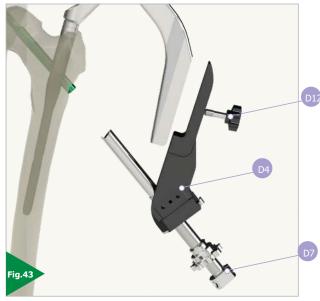


1.1.8. Proximal Screw Lag screw 1.1.8.7 Drilling for the lag screw.



Prepare (A10 Lag Fixing Screw Driver Ø4.0mm) Lag fixing screw (Fig:42)

1.1.8.8 Removing Targeting Device.

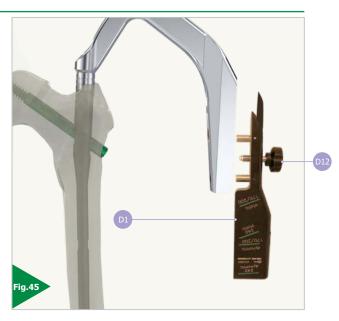


Remove before (D12 locking bolt) than (D7 Drill Guide) and (D4 Proximal Lag Screw Targeting Device Handle) (Fig:43)

1.1.8.9 Installing Targeting Device.



Prepare targeting device for the distal locking scew (Fig:44)



Attach the (D1 distal targeting device) to handle with (D12 Locking Bolt) to the appropriate holes. (Fig:45)



System 1- Lag Screw

1.1.PFNA Nail System

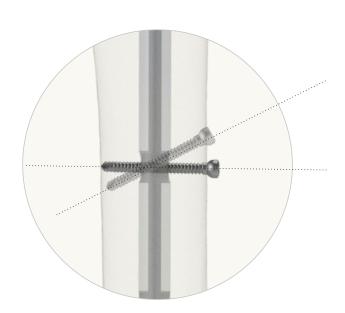
1.1.9.Distal Screw

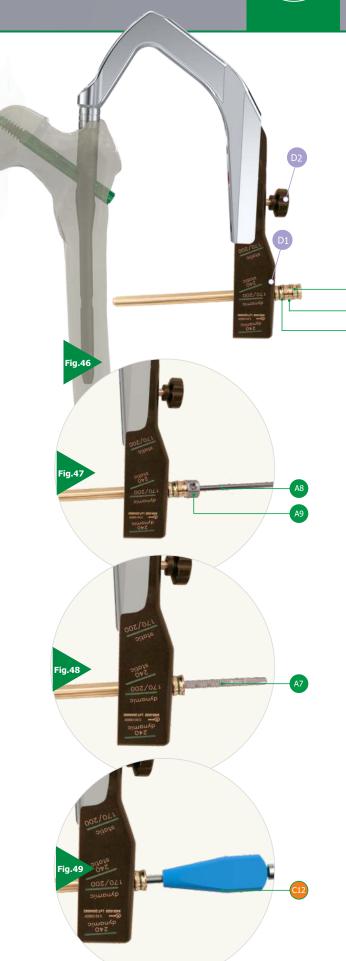
1.1.9.1.Distal guide and screw

For the distal screw, a distal screwing guide is attached (D1). It is fixed with a connecting screw (D2). If necessary, a dynamically static distal screw can be sent. The guide, which is in the set of 3, is placed in its place. Marking is done and marker (A4) is removed. With (A3) and (A2) attached, the Drill uv (A8) is attached. The drill stopper is adjusted (A9) and drilling is done. (Fig.46)-(Fig.47)

(A3) The drill guide is removed. With (A2) installed, the screw length is determined by the size meter (A7). (Fig. 48)

With *(A2)* installed, after the screw length is determined *(A7)*, the screw is sent with a screwdriver. *(Fig.49)*





1.1.10.End Cap

1.1.10.1.Removing targetin device

Remove (distal targeting device & handle device) before sending end cap (Fig.50) -(Fig.51)



End Cap

REF. NO	LENGTH (mm)
4562-0000	0
4562-0005	5
4562-0010	10



1.1.10.2.End Cap Screw

Complete the process by inserting the End Cap screw *(A10)* with a screwdriver. Make the final check under Imaging and complete the process.



1.1.PFNA Nail System

PFNA

Anti-Rotation Proximal Femoral Nail

1.1.11.Specification

PFN-A Intramedullary

The PFN-A Nail is used in the treatment of unstable intertrochanteric fractures. Intertrochanteric femur fractures are common in the elderly population. This is because of osteoporosis. Due to the decrease in bone quality and deterioration of its microstructure, fractures often develop with very lowenergy trauma

Simplelock Lag Screw

may be preferred in high-energy and unstable fractures if more compression is needed

Simplelock Lag Screw

REF. NO	LENGTH (mm)
4782-0065	65
4782-0070	70
4782-0075	75
4782-0080	80
4782-0085	85
4782-0090	90
4782-0095	95
4782-0100	100
4782-0105	105
4782-0110	110
4782-0115	115
4782-0120	120

Simplelock Anti-Rotation Compression Screw

REF. NO	LENGTH (mm)
4792-0060	60
4792-0065	65
4792-0070	70
4792-0075	75
4792-0080	80
4792-0085	85
4792-0090	90
4792-0095	95
4792-0100	100
4792-0105	105
4792-0110	110
4792-0115	115

PFN-A Nail Technical Specifications

-Proximal diameter Ø16mm

-Distal diameter Ø10mm - Ø11mm -

Ø12mm - Ø13mm - Ø14mm

-Proximal – Distal angle 5°

-Lag screw center angle 55° to proximal body

-Cannula diameter Ø3,7mm for all diameters of PFN-A nails

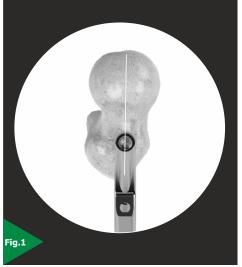
-Distal antirotation (Ø2,5mm X 25mm)

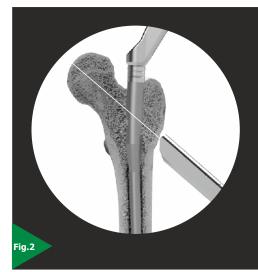
-Ø5mm locking screw dynamic locking screw

1.1.PFNA Nail System

1.1.12.Proximal Screw Simplelock Lag Screw 1.1.12.1.Positioning

Note the position of the Alignment Handle under fluoroscopy. The radiolucent socket in the middle of the arm should be center-to-centre on the femoral neck and head.

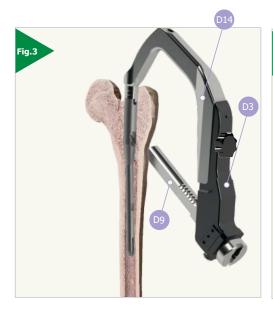


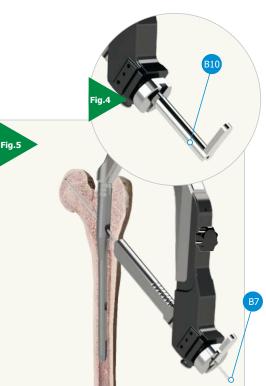


1.1.12.2.Guides and Kirschner Wire

In order to attach the proximal screws, the proximal holder (D3) must be attached first to (D14) handle. (Fig.3)Proximal retainers are of two types. It is in the form of a bladed lag screw and a compression and sliding lag screw. This part (D9) is used since the sliding lag screw will be attached at this stage. (Fig.3)

The guide (B10) for the wire is attached .(Fig.4) After the position is verified, the guide wire (B7) to be used for the Lag screw can be sent(Fig.5).







1.1.PFNA Nail System

1.1.12.Proximal Screw Simplelock Lag Screw

1.1.12.3.Determine Screw Lenght



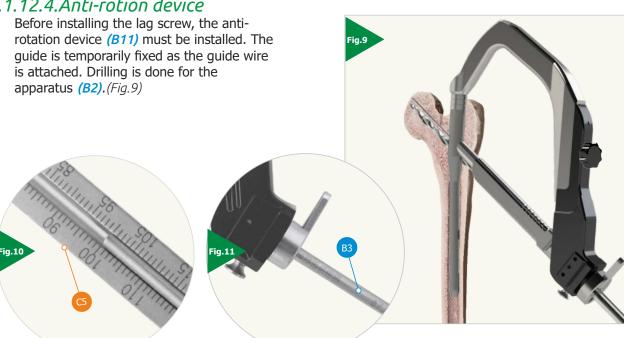


Kirschner wire location has been determined and sent. Kirshner Wire location is important beacuse it is use for like a guide for the lag screw and size decision tool (*Fig.*6)

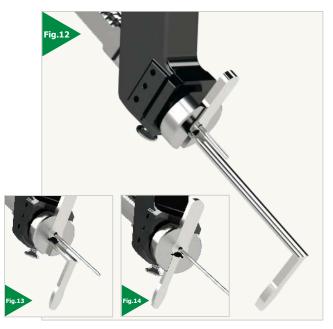
For the lag screw, a height measurement *(C5)* is made before drilling

1.1.12.Proximal Screw Simplelock Lag Screw

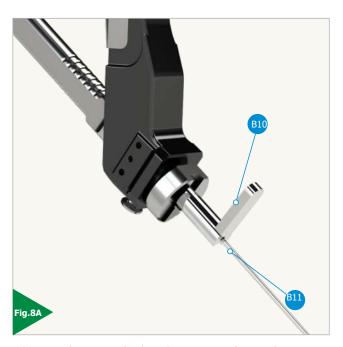
1.1.12.4.Anti-rotion device



Note:Please rate the number 5 minus the measured height. (Fig. 10-11)



Then the device is attached. After this stage, drilling can be done to send the lag screw and the screw can be sent. (Fig. 12-14)



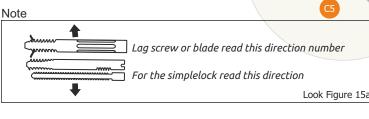
the Kirschner Guide (B10) is removed. Kirschner wire (B7) is at place in this process. (Fig.8A)



1.1.PFNA Nail System

1.1.12.Proximal Screw Simplelock Lag Screw

1.1.12.5.Lag screw

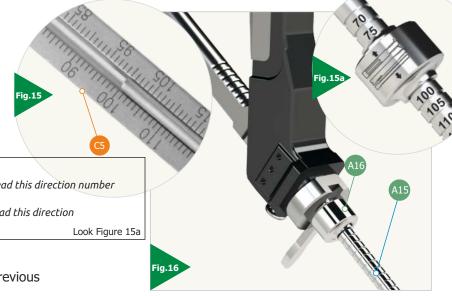


Use (A16 stopper) adjust based on previous measurements (*Fig. 15*)

Drill with (A15, Ø10.8xØ3.2mm Cannulated Drill Bit) (Fig.16)



Drilling was done for the lag screw and the screw length was determined. Screw can be sent. For this, first the Lag screw screwdriver (B9) and the lag screw must be combined. It is sent from within the guide. (Fig. 17-19)







1.1.12.Proximal Screw Simplelock Lag Screw

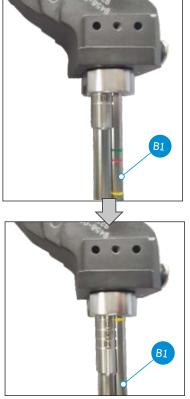




The lag screw is inserted and the nail is fixed proximally. The anti-rotation / compression screw can be sent. The anti-rotation apparatus (B11) is removed. Antirotion screw send with (B1). (Fig. 20)

If you do not want compression, set it to zero. Move to these positions for 5 and 10 mm compression





always set the yellow mark on the screwdriver to the zero position to complete the compression

1.1.12.Proximal Screw Simplelock Lag Screw

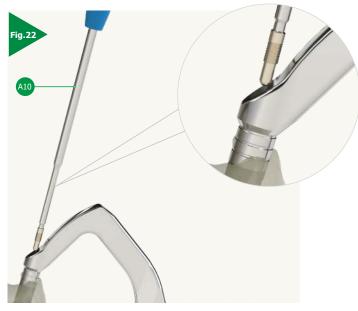
1.1.12.7.Lag Fixing Screw



The anti rotation screw is send accordingly. In this way, the proximal fixation is completed. for the Distal screw can be passed. For this, the proximal guide (D3) is removed.(Fig.25)



Prepare (A10 Lag Fixing Screw Driver Ø4.0mm) Lag Fixing screw (Fig:21)



Send the lag fixing screw (Fig:22)

1.1.9.8.Remove Targeting Device



Lag scew and compression scew is sent Remove (D9) first and loosen up (D12) then remove (D3) (Fig.23)

1.1.PFNA Nail System

2.1.8.Distal Screw

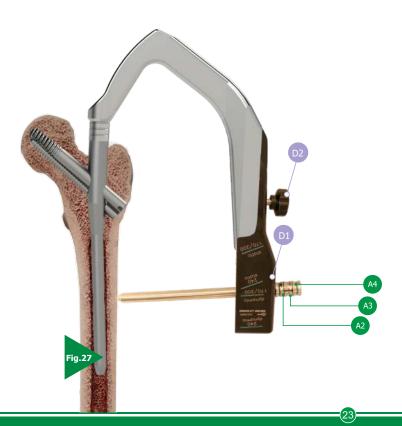
2.1.8.1.Distal guide and screw



For the distal screw, a distal screwing guide is attached (D1). It is fixed with a connecting screw (D2). If necessary, a dynamically static distal screw can be sent. The guide, which is in the set of 3, is placed in its place. Marking is done and marker (A4) is removed. With (A3) and (A2) attached, the Drill uv (A8) is attached. The drill stopper is adjusted (A9) and drilling is done. (Fig.27)

(A3) The drill guide is removed. With (A2) installed, the screw length is determined by the size meter (A7).

With (A2) installed, after the screw length is determined (C12), the screw is sent with a screwdriver.





1.1.12.Proximal Screw Simplelock Lag Screw

1.1.12.8.Remove targeting device

Remove (distal targeting device & handle device) before sending end cap (Fig.50) -(Fig.51)



1.1.13.End Cap 1.1.13.1.End Cap Screw

REF. NO	LENGTH (mm)
4562-0000	0
4562-0005	5
4562-0010	10



Complete the process by inserting the End Cap screw *(A10)* with a screwdriver. Make the final check under Imaging and complete the process.





1.1.PFNA Nail System

PFNA

Interclaw Lag Screw with Blade Proximal Femoral Nail

1.1.14.Specification

PFN-A Intramedullary

The PFN-A Nail is used in the treatment of unstable intertrochanteric fractures. Intertrochanteric femur fractures are common in the elderly population. This is because of osteoporosis. Due to the decrease in bone quality and deterioration of its microstructure, fractures often develop with very lowenergy trauma

Interclaw Lag Screw with Blade

Can be used in high-energy unstable intertrochanteric fractures and in patients with osteoporosis and older

acienes with osceoporosis and otaer

Interclaw LAG Screw

Intorol	~	1 10	Dlac	٦,
Intercl	aw	LAG	DIGC	ıе

REF. NO	LENGTH (mm)	REF. NO	LENGTH (mm)
4642-0080	80	4592-0080	80
4642-0085	85	4592-0085	85
4642-0090	90	4592-0090	90
4642-0095	95	4592-0095	95
4642-0100	100	4592-0100	100
4642-0105	105	4592-0105	105
4642-0110	110	4592-0110	110
4642-0115	115	4592-0115	115
4642-0120	120	4592-0120	120

PFN-A Nail Technical Specifications

- -Proximal diameter Ø16mm
- -Distal diameter Ø10mm Ø11mm -
- Ø12mm Ø13mm Ø14mm
- -Proximal Distal angle 5°
- -Lag screw center angle 55° to proximal body
- -Cannula diameter Ø3,7mm for all diameters of PFN-A nails
- -Distal antirotation (Ø2,5mm X 25mm)
- -Ø5mm locking screw dynamic locking screw

1.1.PFNA Nail System

1.1.15.Proximal Screw 2 Interclaw Lag Screw with Blade

1.1.15.1.Connection devices

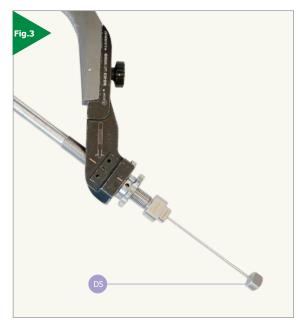
Attached (D14)insertion Handle) with (D4) Proximal lag screw targeting device handle Blade. (Fig:1)

1.1.15.2 location and preparation



insert through (D4) Proximal lag screw targeting device handle Blade to Interclaw sleeve*(Fig:2)





Mark with (D5) Point maker and take out (Fig:3)

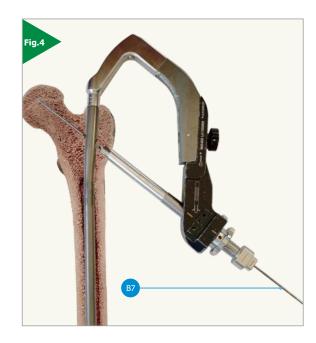
*Interclaw slew include D5 Point Maker, D6 Kirschner Sleeve, D7 Lag screw drill sleeve

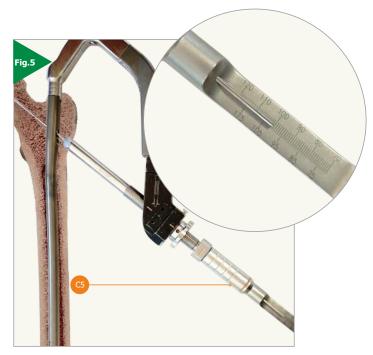
1.1.PFNA Nail System

1.1.15.Proximal Screw 2 Interclaw Lag Screw with Blade

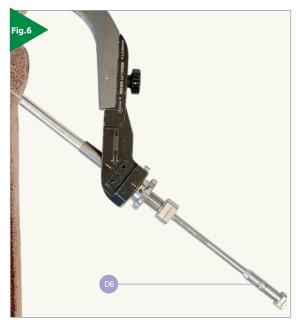
1.1.15.3 Determine Screw Lenght.

Send the (B7) or (B8) Kirschner wire trough the Sleeve (Fig:4)





Use the (C5 Lag screw gauge), determine scew lenght over the Kirschner wire(Fig:5)



After determining the screw Length, (D6)Kirschner sleeve must be removed for drilling. Kirschner wire will stand (Fig:6)



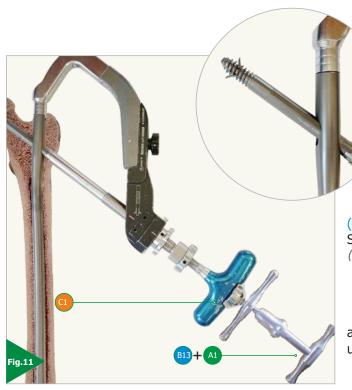
1.1.PFNA Nail System

1.1.15.Proximal Screw 2 Interclaw Lag Screw with Blade

1.1.15.6 Openning Blade

<u>Combine (B13 Pusher)</u> with (A1 Cannulated Handle) Its use for open blade (Fig:10)







(B13),(A1) passes through Lag Screwdriver and attached to lag screw (Fig:11)

apply some compression and contol under image

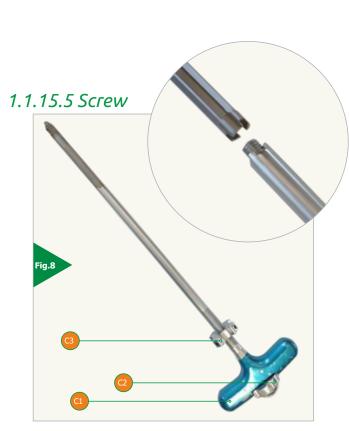


1.1.PFNA Nail System

1.1.15.Proximal Screw 2 Interclaw Lag Screw with Blade

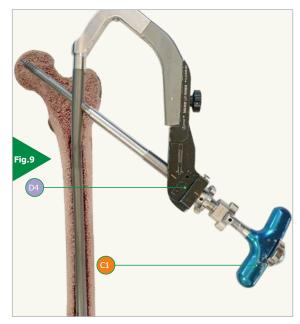
1.1.15.4 Drilling for the lag screw.

(A15)Ø10.8XØ3.2mmCannulated Drill Bit Drilling will be done according to the screw whose size you have determined. Adjust the drill (A16)stoper stop to the size you specified for screw and drill (Fig:7)



Prepare *C1lag screw driver for blade* and lag screw *(Fig:8)*





Send the *C1lag screw driver for blade* trough (*D4* Targeting Device) (*Fig:9*)

Lag screw driver include 3 piece device C1

C2

C3



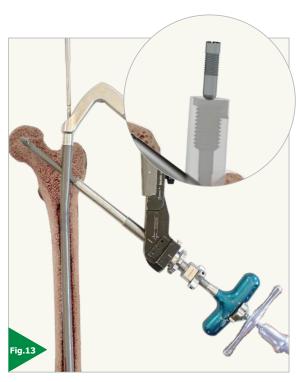
1.1.PFNA Nail System

1.1.15.Proximal Screw 2 Interclaw Lag Screw with Blade

1.1.15.7 Lag Fixing Screw

Prepare (A10 Lag Fixing Screw Driver Ø4.0mm) Lag Fixing screw (Fig:12)





Send to the screw inside the nail (Fig:13)



pass to the lag end cap stage. For this before remove to the Lag screw driver and pusher (Fig:14)



1.1.PFNA Nail System

1.1.15.Proximal Screw 2 Interclaw Lag Screw with Blade

1.1.15.8 Lag End Cap
The lag screwdriver is removed. Continue with the interclaw slide in place. (Fig:13)

Lag end cap and screwdriver are prepared. (Fig:14) It is inserted into the lag screw through the interclav sleeve and tightened (Fig:14-15)









1.1.PFNA Nail System

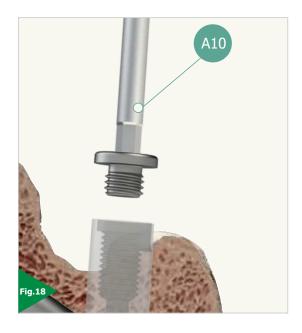
1.1.15.Proximal Screw 2 Interclaw Lag Screw with Blade

2.1.15.9 Finish

The placement and fastening of the screw is complete. Interclave slide and screw guide are removable. The operation will be completed by sending the nail end cup before the holder is removed. Send the end cap screw with (A10) Ø4.0 Screwdriver (Fig:18)







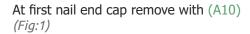


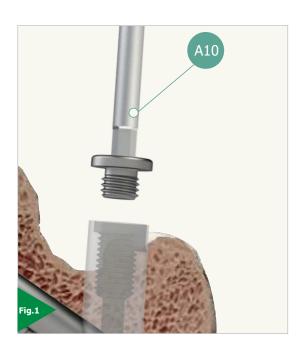
1.1.PFNA Nail System

1.1.16.Proximal Screw 2 Interclaw Lag Screw with Blade Removing

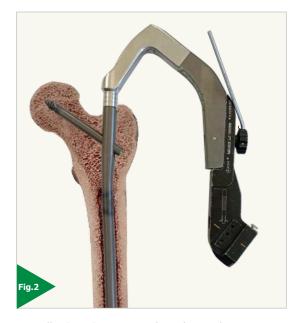
1.1.16.1 End Cap Removing

There are minor details, although the reverse of the insertion procedure is used to remove the interclave screw. Proceed according to procedure





1.1.16.2 Targeting device attachment



Handle (D14) is attaced to the nail and then attached (D4)targeting device. (Fig:2)



Interclav sleeve (D7)Lag screw drill sleeve is attached through targeting device with nail. (Fig:3)



1.1.PFNA Nail System

1.1.16.Proximal Screw 2 Interclaw Lag Screw with Blade Removing

1.1.16.3. Lag Screw Removing

Insert the removal screwdriver through the slide. (Fig:4)

After allowing the screwdriver to hold onto the screw, remove the end cap screw. (Fig:5)





1.1.PFNA Nail System

1.1.16.Proximal Screw 2 Interclaw Lag Screw with Blade Removing

1.1.16.4. Blade closing

Attached lag screw driver through from interclav sleeve. (Fig:6)
Ensure its assembly with the screw





Prepare device for close blade. (B12) Tractor Apparatus (Fig:7)

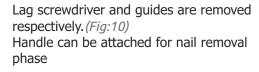


attached inside from lag screw driver and let the blade loosen then close the blade (Fig:8)

1.1.16.Proximal Screw 2 Interclaw Lag Screw with Blade Removing

1.1.16.5 Lag Fixing Screw Removing

Unscrew the clamping screw used to tighten the lag screws with a screwdriver. After this process, the lag screw can be removed. Unscrew the lag screw(Fig:9)











1.1.PFNA Nail System

1.1.16.Proximal Screw 2 Interclaw Lag Screw with Blade Removing

1.1.16.6 Preparing for remove

The handle must be attached to the nail to remove the nail. The end cup was previously removed. The connecting screw (D13) is attached to the holder (D14). It is fixed with screwdriver (A10) (Fig. 12).

1.1.16.7.Removing Nail

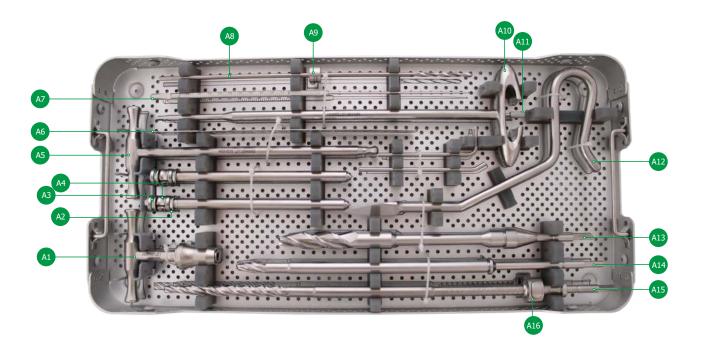
After it is attached to the holder (D14), apparatus (C6) and the hammer swing shaft (C13) are combined. It is removed from the canal with the help of a hammer. (C11) (Fig. 13).





2.1.Tray A





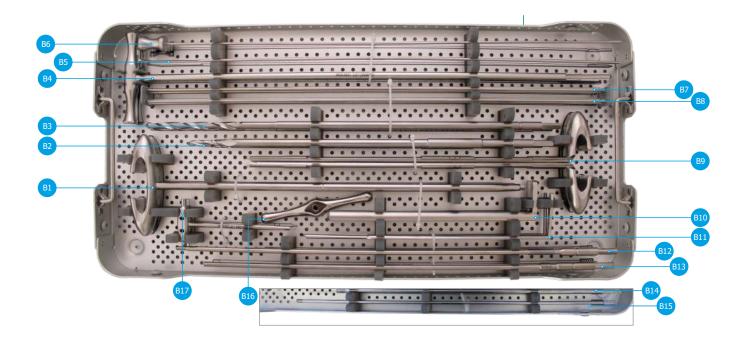
A1	Cannulated T Handle	9455-0031
A2	Ø4.0mm Pointer	9455-0021
А3	8/Ø4.3mm Inner Sleeve	9455-0020
A4	11/Ø8.0mm Protecting Sleeve	9455-0019
A5	Screwdriver SW8	9455-0018
A6	Radiographic Ruler	9455-0010
A7	Depth Guide (locking Screw)	9455-0045
A8	Ø 4.3 x300mm Drill	9455-0008
A9	Ø4.3mm Stopper	9455-0009
A10	Screwdriver Ø4.00mm	9455-0055
A11	Inner Shaft for Screwdriver Ø4.00mm	9455-0056

A12	Cannulated AWL	9455-0016
A13	Ø17mm Cannulated Reamer	9455-0047
A14	Lag Screw first entry drill	9455-0064
A15	Ø10.8xØ3.2mm Cannulated Drill Bit	9455-0042
A16	Stopper	



2.2.Tray B



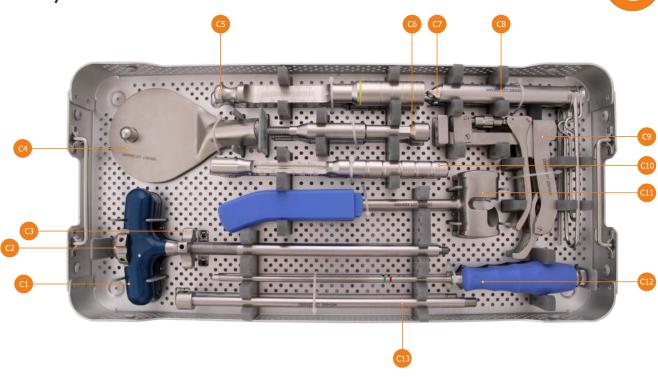


В1	Anti-Rotation (Compression) Screwdriver	9455-2065
B2	(AWL)for compression screw	9455-0062
В3	Drill Bit for compression screw	9455-0063
B4	T anatomic chisel	9455-0001
B5	Guide Wire Curved TipØ2.8 (Cannula Cleaning Probe)	9455-0003
В6	Cannulated Drill Cleaning Probe	9455-0007
В7	Ø2.7x440mm Threated Kirschner	9455-0022
В8	Ø2.7x440mm Kirschner	9455-0023
В9	Lag Screwdriver (PFNA ISS)	9455-2066
B10	Kirschner Guide	9455-0061
B11	Anti-Rotation Guide (PFNA ISS)	9455-0060

B12	Tractor apparatus	9455-0005
B13	Pusher apparatus	9455-0006
B14	Lag Screwdriver Inner Sleeve (PFNA ISS)	9455-0067
B15	Anti-Rotation Screwdriver Inner Sleeve (PFNA ISS)	9455-0064
B16	Handle	9455-0011
B17	Screwdriwer	9455-0068



2.3.Tray C



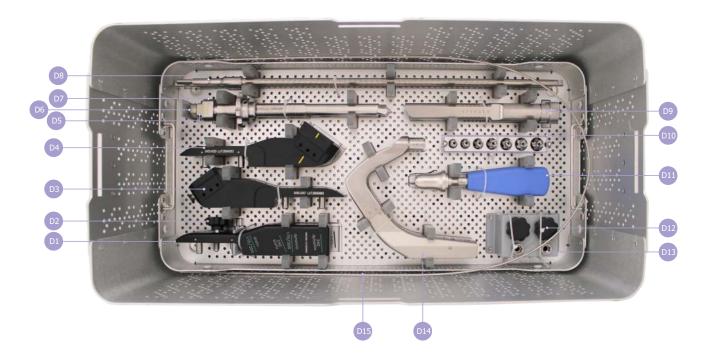
C1	0	9455-0065
C2	0	9455-0062
C3	0	9455-0063
C4	Tissue Protector	9455-0017
C5	Lag Screw Gauge (Depth Guide)	9455-0046
C6	Nail Extract Rot	9455-0044
C7	Proximal K-Wire Guide Ø3.5x5mm	9455-0050
C8	Proximal Drill Guide Handle Ø17mm	9455-0051
C9	Gripper	9455-0027
C10	Lag Screw Height Gauge	9455-0059
C11	Slidding Hammer	9455-0032

C12	Distal locking screw driver	9455-0049
C13	Combine Hammer Bar	9455-0043



2.4.Tray 4





D1	Distal Dynamic&Static Locking Targeting Device	9455-0028
D2	Guide Screw	9455-0053
D3	Proximal Lag Screw Targeting Device Handle (Twin Screw)	9455-0057
D4	Proximal Lag Screw Targeting Device Handle (Blade)	9455-0029
D5	Point Marker	9455-0026
D6	Kirschner Sleeve	9455-0025
D7	Lag Screw Drill Sleeve	9455-0024
D8	Flexiable Reamer	9455-0004
D9	Lag Screw Drill Guide	9455-0058
D10	Flexiable Reamer Tips	9455-0061

D10-1 Reamer Head Ø9mm	9455-0033
D10-2 Reamer Head Ø10mm	9455-0034
^{D10-3} Reamer Head Ø11mm	9455-0035
D10-4 Reamer Head Ø12mm	9455-0036
D10-5 Reamer Head Ø13mm	9455-0037
D10-6 Reamer Head Ø14mm	9455-0038
D10-7 Reamer Head Ø15mm	9455-0039

D11	Distal Locking Screw, screw driver	9455-0049
D12	Locking Bolt	9455-0053
D13	Connection Screw	9455-0041
D14	Insertion Handle	9455-0030
D15	Guide Wire with ballØ2.5x1100	9455-0002



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. Combination Manual / 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.



