PATENTED

A-PFN

Antirotator Proximal Femoral Nail

tst Medical Devices

Table of Contents

Warning:
This descriptive catalog is not sufficient as being unaided for proper use of the products intraoperatively. It is highly recommended that implantation and instrument sets must be used by a surgeon who is trained-experienced about the product performances and usage.

Introductions

Intertrochanteric femoral fractures constitute 10% of all the bone fractures. They are frequently seen in elderly patients above 65 years.

Proximal femoral fractures frequently occur as a result of ordinary traumas in elderly patients with osteoporosis. Besides, these kinds of fractures rarely occur in young patients who have high energy trauma.

Fractures take place in proximal femur area have an effect on patients' general health and on their psychological, social, economical conditions. Treatment of these fractures may end up with worse results than expected, despite the advanced patient care and surgical techniques in recent years.

In some cases, ideal treatment is determined contentiously because of having poor bone quality may accompany systemic diseases.

The purpose of the hip fracture treatment in elderly patients is to return them to their health condition in the pre-fracture level by enabling them to move within the shortest time and avoid complications that can occur due to immobility.
In today, sufficient amount of reduction and rigid internal fixation are the most valid treatment methods for unstable intertrochanteric femoral fractures.

Proximal Femoral Nail (PFN) System usage becomes prevalent for fixation among orthopedic surgeons in recent years by means of having anatomical and mechanical biocompatibility.

Intramedullary implants provide better weight distribution over the calcar by means of their medial position when compared to extramedullary implants (DHS-Dynamic Hip Screw) that have usage indications in the treatment of proximal femur fractures. They reduce the risk of implant failure by decreasing the tensile strengths that act on the implant by virtue of their short motion arms. They provide controlled impaction as sliding nails. A closed entry through the entrance hole brings some theoretical advantages such as short operation time, less soft tissue dissection, less bleeding and as the most important one; protection of fracture hematoma which is the main element of bone fusion.

Patients are easily rehabilitated in consequence of weight bearing as early as possible in the postoperative period.

This feature of the nail brings too many advantages.
As a result of sliding, fracture lines are converged thus provides reinforcement to the bone union process.

The length of the moment arm is decreased by telescopic effect which ensures a decrease in bending force over the implant. As a result, fixation failure rate becomes less.

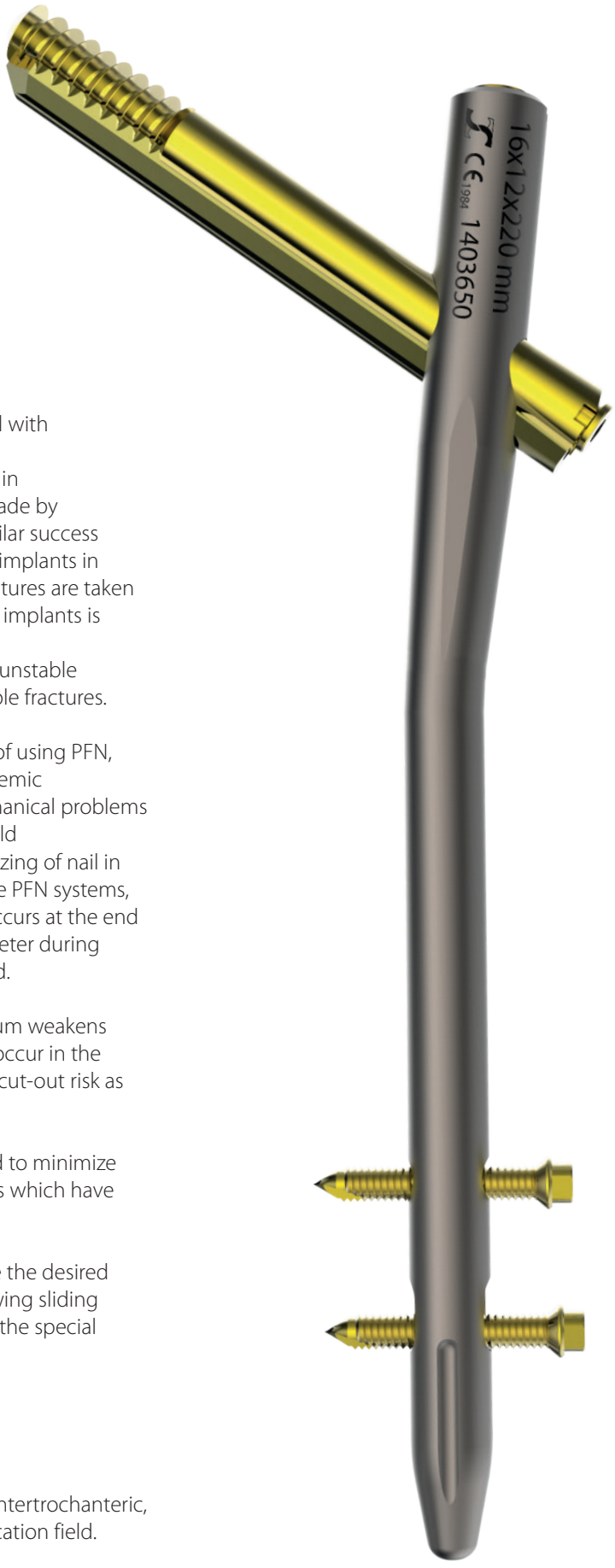
Compressive forces that press to medial are equal with tensile forces that press lateral in stable fractures. However; pressure on the lateral cortex increases in unstable fractures. According to these results -made by considering the hip biomechanics-, there is a similar success rate for using intramedullary and extramedullary implants in stable fractures. Nevertheless, when unstable fractures are taken into consideration, success rate of intramedullary implants is higher and the complication rate is lower.
The system has an indication for both stable and unstable fractures, however it is more important for unstable fractures.

Although there are some important advantages of using PFN, considering the amount of bleeding, local or systemic complications, stripping, implant inefficacy, mechanical problems and operation time. Femur diaphysis fracture could be seen owing to different reasons such as squeezing of nail in the medulla because of the nail thickness in some PFN systems, usage of a hammer to send the nail, stress that occurs at the end of the nail due to thickness of the nail distal diameter during these operations and in the post-operative period.

Likewise, sending one proximal screw to the collum weakens stability and can not prevent rotation which will occur in the proximal area. It also increases -stress forces thus cut-out risk as well.

Design of proximal femur nails has been changed to minimize complications and improve benefits of these nails which have been used nowadays.

A-PFN which is developed by TST aims to achieve the desired results, enables impaction of the fracture by allowing sliding compression and increases rotational stability by the special blade.



Indications

Proximal femur upper fractures; pertrochanteric, intertrochanteric, subtrochanteric fractures are included in the indication field.

Features

A-PFN nail is developed via making important additions to PFN system. A-PFN nail ensures rotational stability through a special blade which can be sent over the cannulated proximal screw that fronts to the neck with an angle of 125°, allows impaction of fracture by means of sliding compression. Other features of A-PFN are written below.

A body which has a 6° of anatomical angle provides an easy insertion to the trochanter major tip with a little incision.

The proximal diameter of the nail is 16 mm thus minimizes the bone loss.

Cannulated proximal screw that goes to the neck has a collodiaphyseal angle of 125°.

The nail has 4 diameter options of 9, 10, 11, 12 mm and 2 length options of 160-220 mm.

The cannulated structure of the screw enables a guide wire with the diameter of 2.5 mm to pass through itself.

Design of the nail enables to compress femur neck and intertrochanteric space. There is a cannulated proximal lag screw present in the system.

Cannulated proximal lag screw has a special blade gutter to inhibit the femur head rotation.

Special anti-rotator blades with different lengths which are compatible with their proximal cannulated screws can be driven through the gutter so that they provide complete rotational stability.

Cannulated proximal Lag Screw which can be sent over a guide wire and by means of broad cancellous threads of Ø 10 mm, proximal fragment fixing is much better and stronger. A special designed oval hole operating with tap screw enables locking and compression. It has a sliding compression feature nevertheless, it has a special tap screw to inhibit this function. Besides standard tap screws are available too.

Through the unique design of distal locking screw, it is fixed to the driver and possible undesirable conditions such as dropping and wrong way dispatching problems are removed.

The nail driven is facilitated by the inventively head design of distal end and the distal end is formed with distal slit to enable flexibility thus reduce stress focusing.

According to literature, stress forces at the distal part of the short nail may induce femur diaphysis breakage.
It is prevented in virtue of this new design.

By means of external modular targeting guide arm and other helper instruments, fast and troubleless placing is ensured.

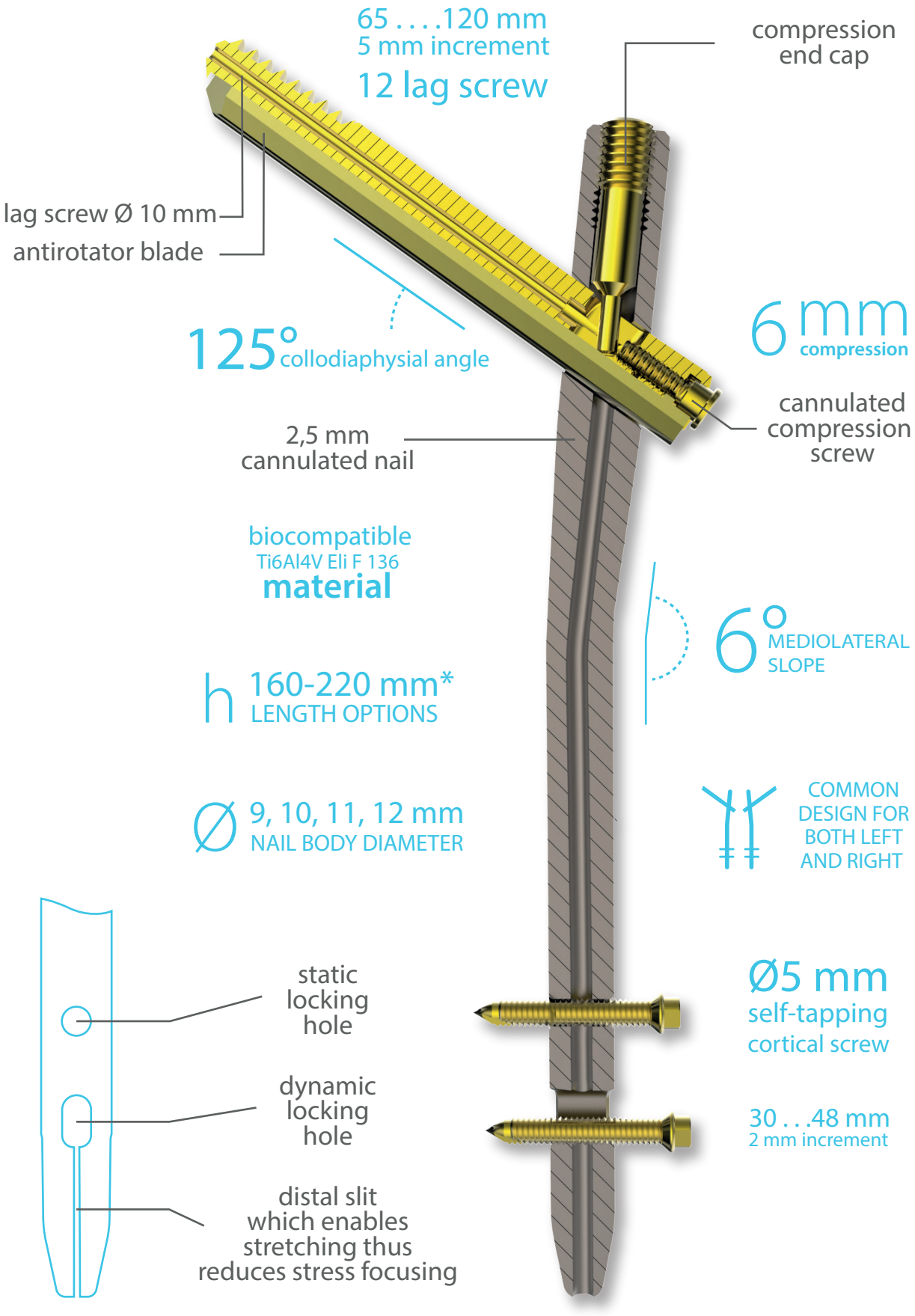
Nail distal locking is realized by considering condition of the fracture via the static and dynamic holes present at the distal part by self-tapping cortical screws in the diameter of Ø 5 mm.

By means of the short external guide system, distal locking is accomplished easily.

All of the implants are made of robust and biocompatible implant material which meets the requirements of Ti6Al4V Eli 136 standards.

Lag screw and the blade operates as a monoblock by means of the special locking mechanism in this system, thus the 'Z effect' is removed.

In the A-PFN System the compression can be realized in three different ways:
Primary compression by the lag screw, secondary compression by the Cannulated Compression Screw and tertiary compression by the sliding effect.

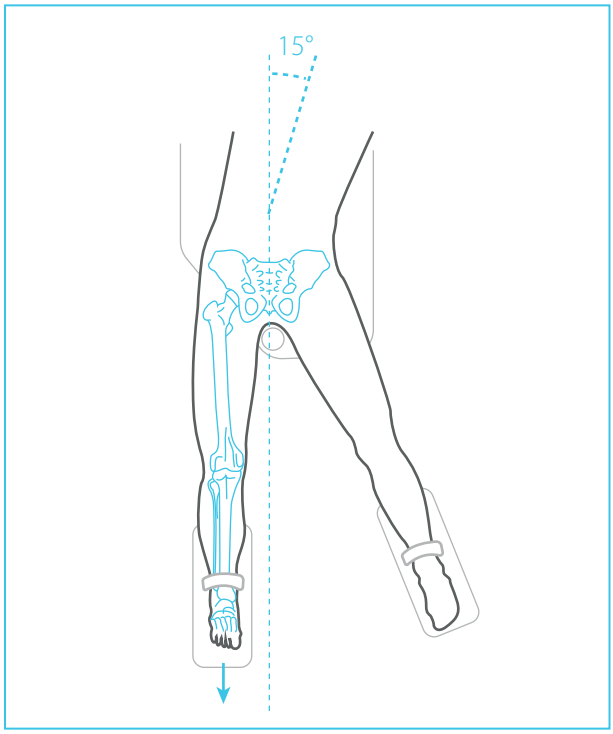


*optional 320, 340, 360 mm

Surgical Technique

1 PATIENT POSITION

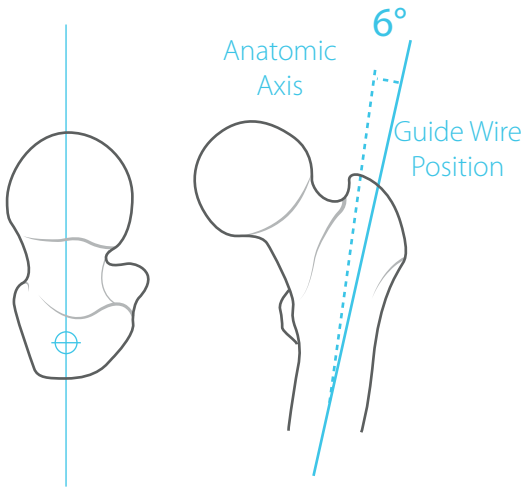
The patient is placed on the traction table in supine position. Trochanter major is palpated and 5 cm longitudinal incision is made from top to the proximal. Then the reduction is controlled under the fluoroscopy. After achieving the suitable position, it is reached to trochanter major by incision of the skin, subcutaneous and tensor fasciae latae. Gluteus medius is incised parallel to the muscle fibers.



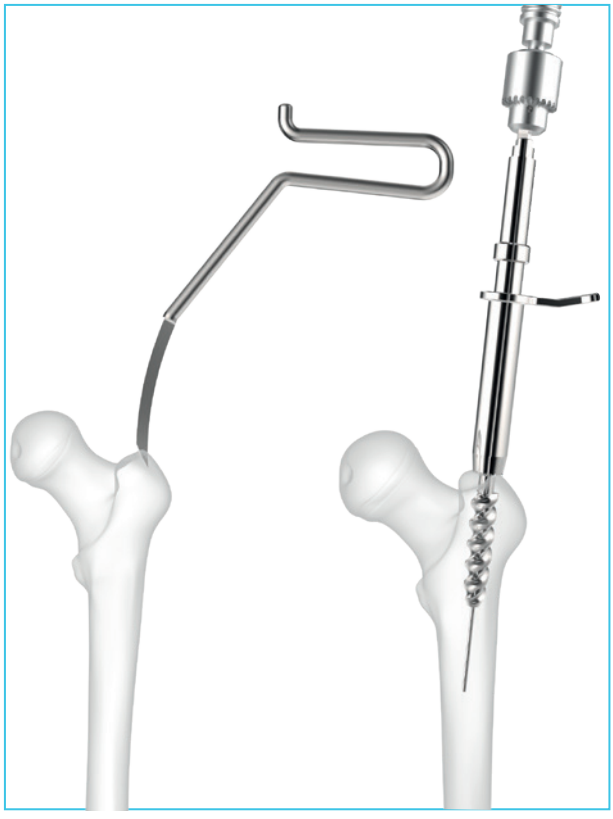
2 NAIL ENTRY POINT

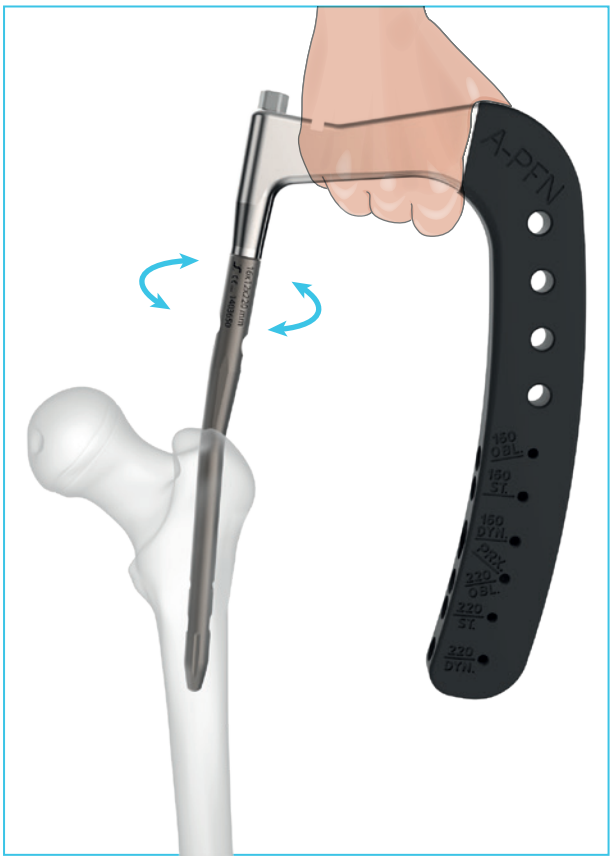
A ***Ø 2.5 x 400 mm K wire*** is sent via IM from tip of the trochanter major.

After conforming that the ***K-Wire*** is in the medulla from the standpoint of both two plans, femur proximal is carved using ***AWL*** over the ***K-Wire*** or ***Trochanteric Reamer*** with soft tissue protector.



*Axial ve AP View of the Guide Wire Entrance





3 NAIL INSERTING

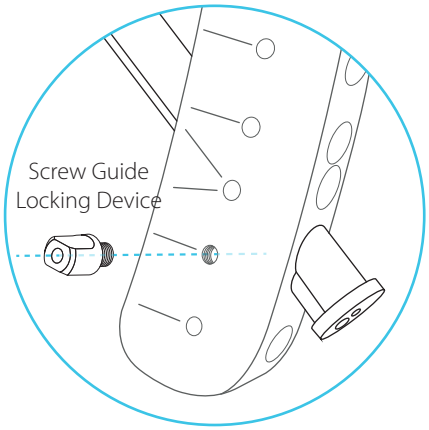
After designating proper nail with regard to diameter and length, the nail is fixed to ***Insertion Handle***.

The nail is sent under rotational forces through the trochanteric major tip. ***Hammer should not be used at this stage.*** If it is not possible to send the nail, one size smaller nail should be sent. If the medullar canal is still tight, the medulla should be widen up to 10 mm.

4 TISSUE PROTECTOR PLACEMENT FOR PROXIMAL SCREW-BLADE

If the nail is placed over the guide wire, ***K-Wire*** is taken out.

After sending the nail, tissue protector system ***(A-PFN Blade Drill & Proximal Screw K-Wire Guide***) is placed to send ***Proximal Lag Screw*** and the ***Antirotator Blade.***

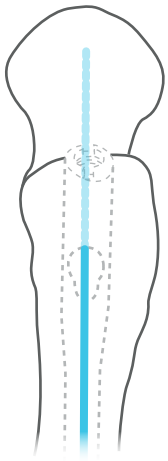


System is fixed by PFN Screw Guide Locking Device when tissue protector and the bone are in contact.

5 K -WIRE PLACEMENT FOR BLADE

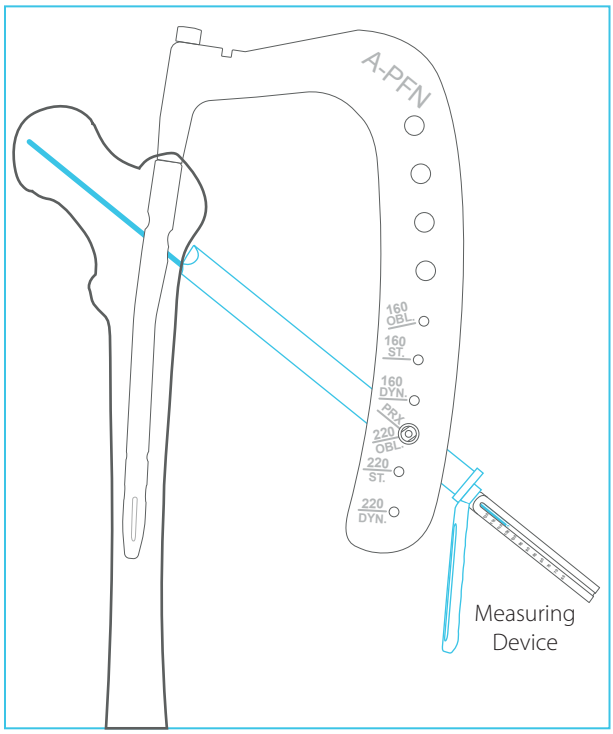
Before sending the screw and blade, the anteversion of the nail should be considered.

To send neck screw and blade, ***A-PFN Blade K-Wire Guide*** is placed into the tissue protector, then Ø 2 x 340 mm of K-Wire is sent through it until arriving subchondral part.



After sending **Ø 2 x 340 mm of K-Wire,** fluoroscopy control is achieved. The ***K-Wire*** should be at the down half part of the femoral head on the AP view and be at the center on the lateral view.

If the position is convenient, length is measured by ***Measuring Device*** over the ***K-Wire*** for proximal screw. The ***Blade K-Wire Guide*** is taken off.



6 K-WIRE PLACEMENT FOR PROXIMAL SCREW

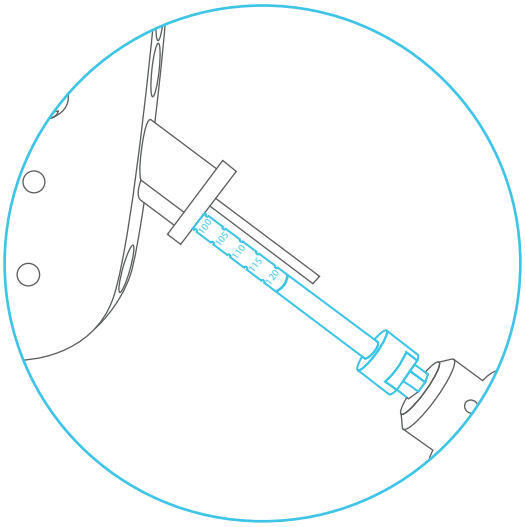
To send the proximal lag screw, ***Threaded End Ø 2,5 x 340 mm K-Wire*** is sent until subchondral area through proximal ***K-Wire*** hole which is in the tissue protector. After that, the position is controlled by fluoroscopy.

The K-Wire is always sent 5 mm longer than the planned screw size.

**It is important to pay attention that instruments belong to external targeting guide system such as tissue protector, screw-blade, guide-sleeve should be in complete contact with the bone during applications.*

7 CARVING OPERATION FOR BLADE

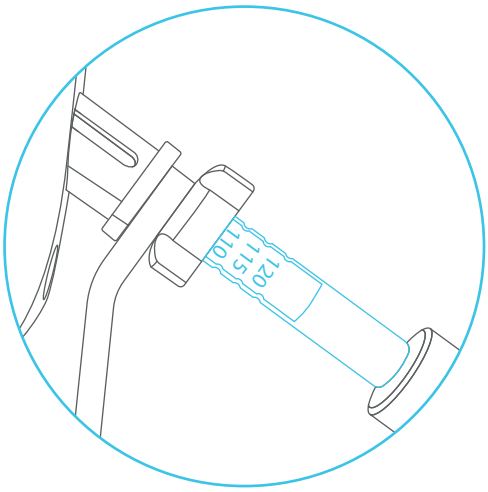
Guide hole is opened by ***A-PFN Blade Drill*** over the ***Ø 2x340 mm of K-Wire*** exists at the distal for blade.



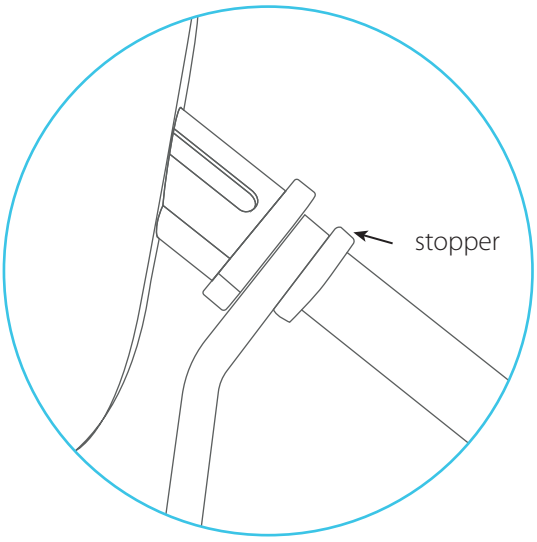
8 CARVING OPERATION FOR PROXIMAL LAG SCREW

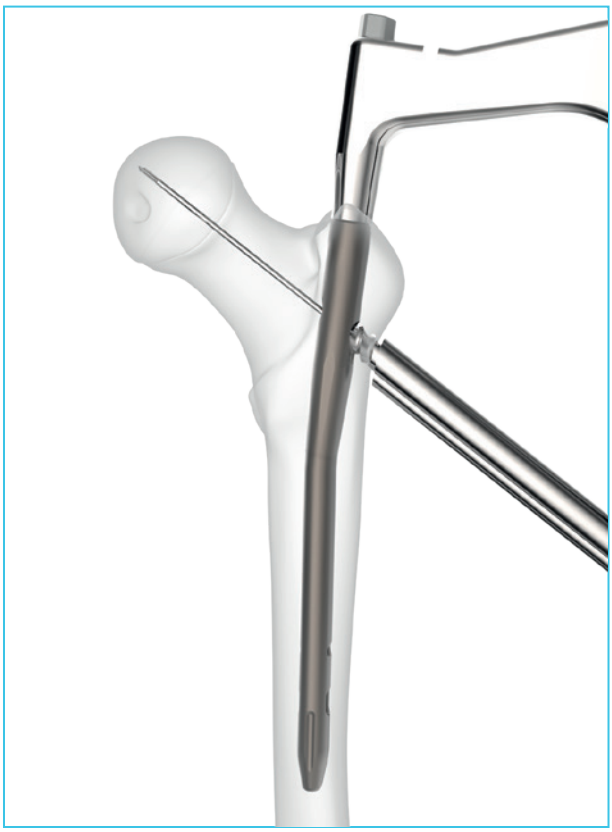
Tissue protector system is changed. ***A-PFN Blade Drill & Prox. Screw K-Wire Guide is*** taken off and ***A-PFN Proximal Screw-Blade Guide*** is placed instead.

A-PFN Proximal Screw-Reamer Guide is fixed into it then 1. Reamer and 2. Reamer are sent until determined depth thus carving operation is realized.



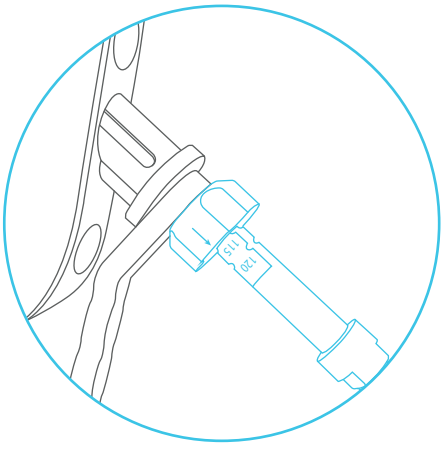
2. Reamer is used just for widening lateral cortex. A stopper exists on the drill.





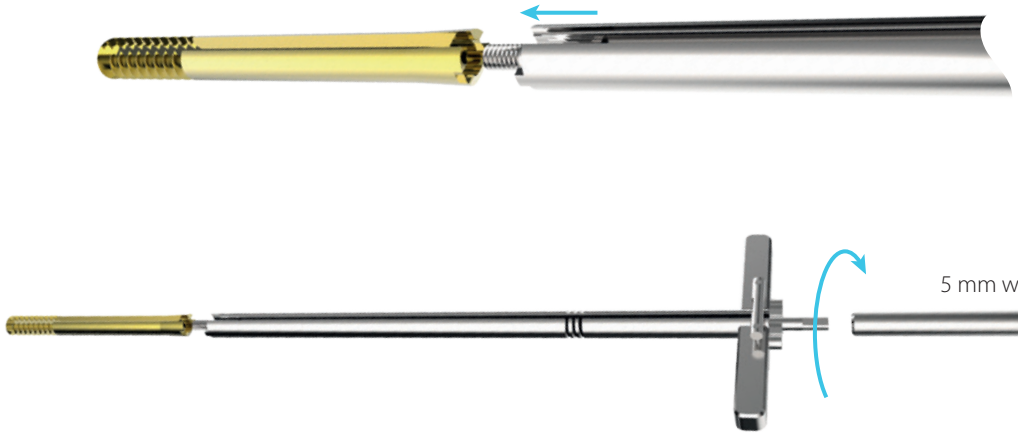
9 TAP OPERATION FOR PROXIMAL SCREW

For the ***Proximal Lag Screw,*** a threaded guide way is opened by ***Tap*** held to the ***T-Handle.*** Tapping operation should be done especially on the young patients because of their hard bone structure.



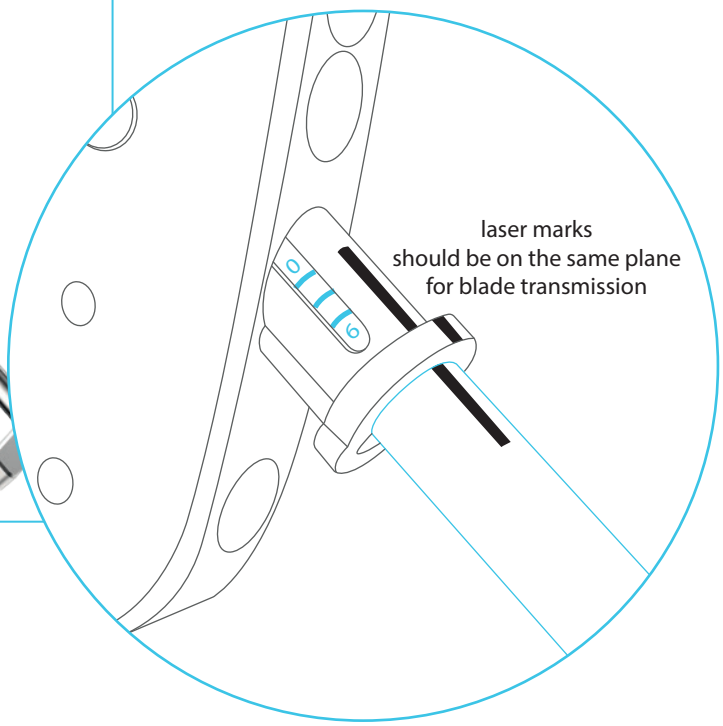
10 INSERTING OF THE PROXIMAL SCREW

A ***Proximal Screw*** in the proper length is fixed to ***A-PFN Proximal Screw Inserter*** as in the figure.



After pulling out the ***Proximal Screw Reamer Guide,*** the ***Proximal Screw*** is sent over the ***K-Wire*** toward the head. The position of the proximal screw is controlled by the fluoroscopy. Required compression amount (0, 3, 6 mm) is determined by checking window on the tissue protector.

For an accurate placement, laser marks on the Inserter and the Tissue Protector should be on the same plane.

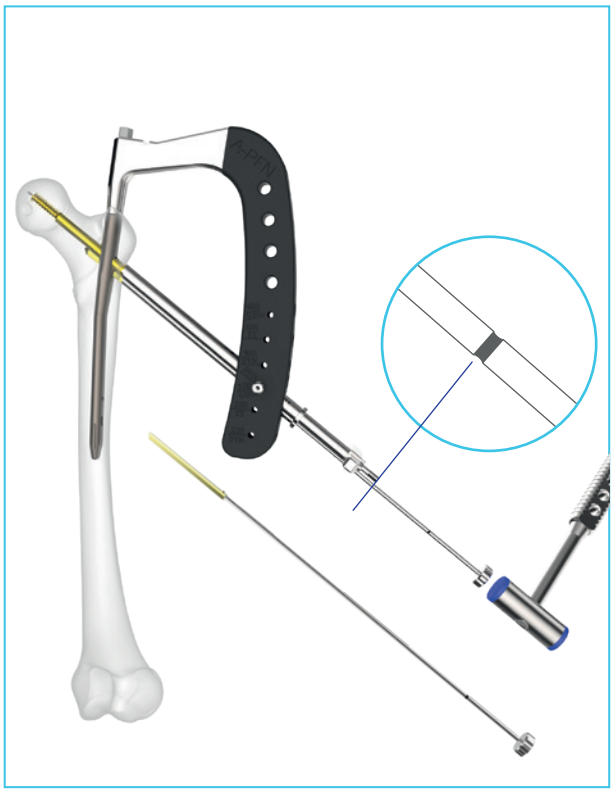


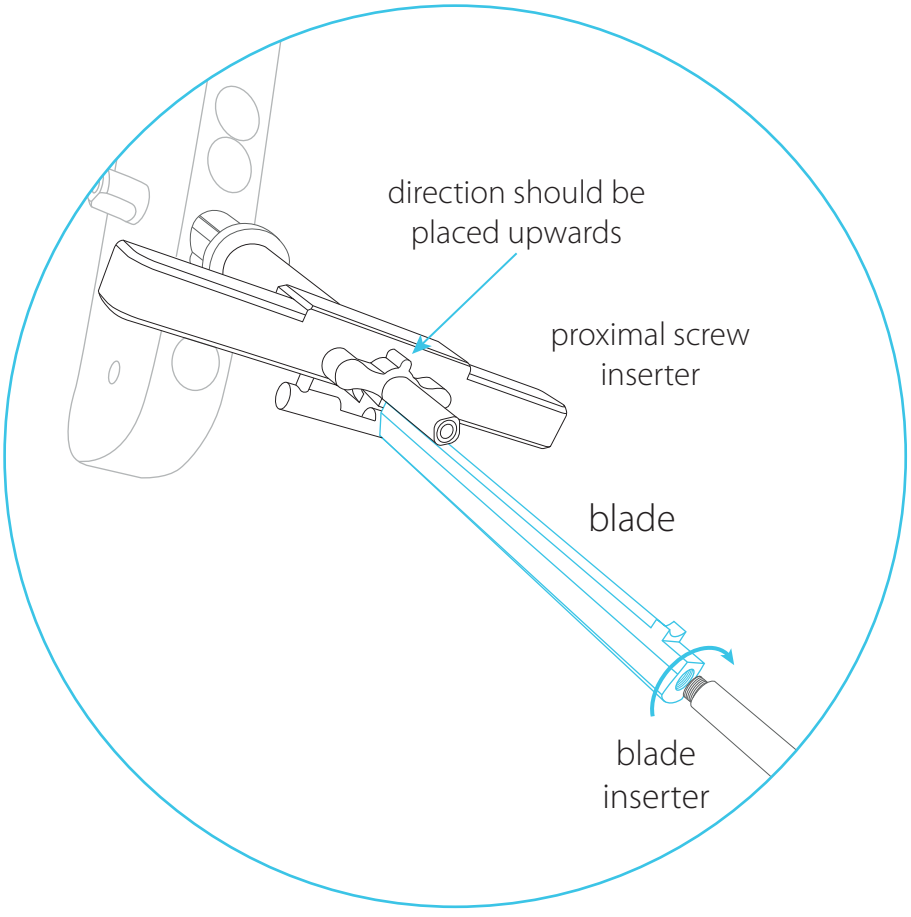
11 INSERTING OF THE BLADE

A-PFN Antirotator Blade which is in the same length with the proximal screw is assembled to the ***Blade Inserter*** as in the figure.

Blade is sent after placing to the slide which is in the inferior of ***Proximal Screw Inserter.*** It is sent until the sign on the blade inserter that arrives ***Screw Inserter*** level with the help of slight ***Hammer*** strikes.

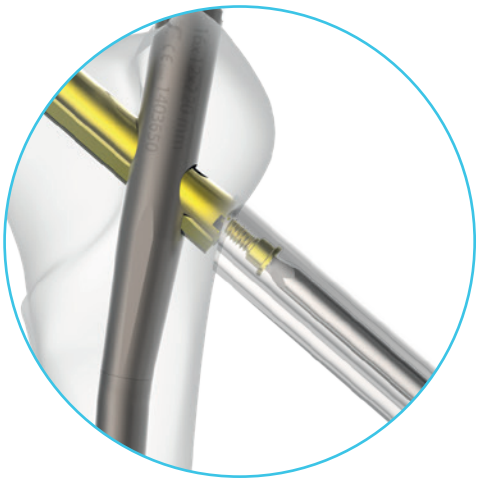
In this system, the ***Blade*** is settled to blade gutter exists in the inferior of ***Proximal Screw*** thus provides rotational stability.





12 COMPRESSION SCREW INSERTION

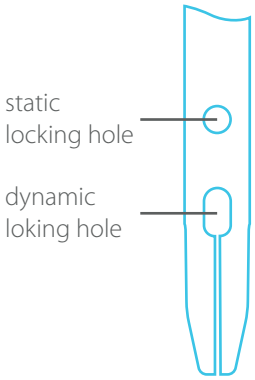
A-PFN Blade Inserter and ***Inner Part of the Proximal Screw Inserter*** are removed. Cannulated Compression Screw is sent by ***Ø 4 mm Cannulated Screw Driver*** inside of the ***Proximal Screw Inserter*** to **Proximal Screw** as providing 3 or 4 threads held.



13 REAMERIZATION FOR DISTAL LOCKING

Proximal Tissue Protector is removed. ***K-Wire*** is shortened by cutting until 2-3 cm remains outside the skin.

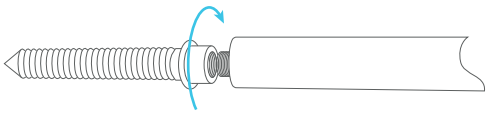
Distal locking changes according to condition of the fracture, however locking is made from proximal screw hole for static locking and distal screw hole for dynamic locking. Locking can be made using 2 screws for subtrochanteric fractures. According to the static locking or dynamic locking construction, carving is operated for cortical screw over ***Tissue Protector*** by ***4.2 mm of Drill.***



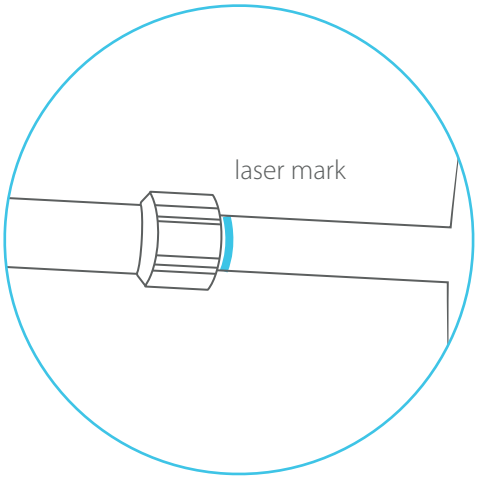
Length is measured for ***Ø 5 mm of Cortical Screw*** over ***Drill Guide***, therefore ***Depth Gauge*** is available in the set.

14 DISTAL LOCKING

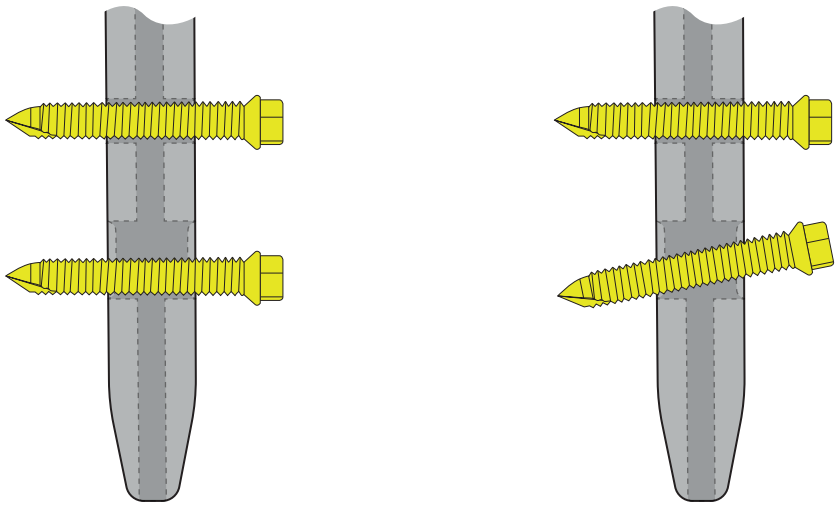
Distal locking is completed after the transfer of ***Cortical Screw*** which is assembled to ***T-Handle Screw Inserter,*** in available length, through ***Tissue Protector.*** It is sent until laser line on the ***T-Handle Screw Inserter***.

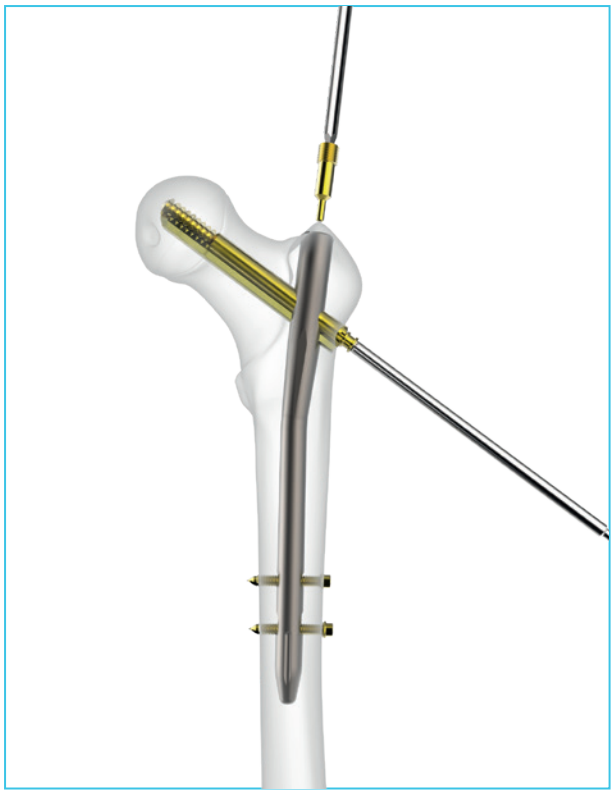


assembling of the distal locking screw to t-handle screw inserter



static and dynamic locking options





15 END CAP INSERTION AND COMPRESSION

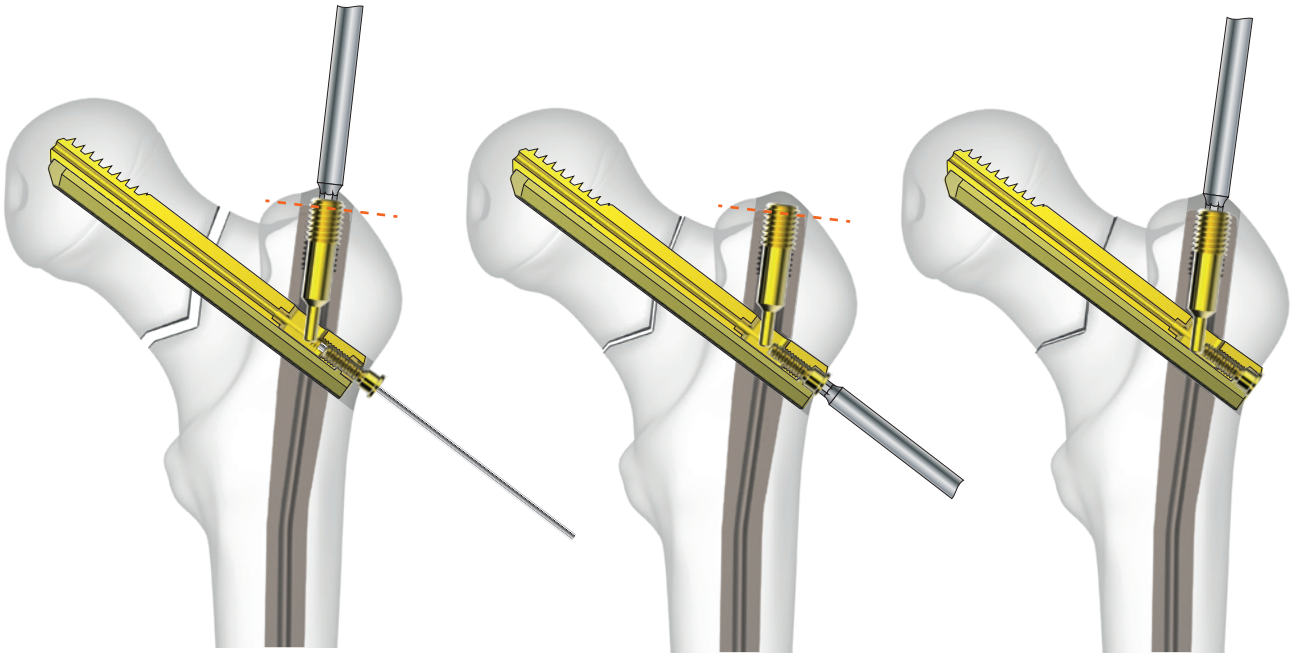
Insertion Handle is removed. ***K-Wire*** is pulled back until ***Compression Screw*** to avoid overlapping with ***End Cap***. ***End Cap*** is placed to screw top from proximal of the nail.

Proximal of the end cap should be placed meticulously considering to leave 1-2 mm of it from nail top point, from the standpoint of AP and it should not squeeze completely. Because in this system, compression is ensured by ***Compression Screw*** that operates in interaction with ***Proximal Screw*** and ***End Cap***.

After that, required compression is realized from lateral using ***Screw Driver Ø 4x175 mm***. This operation can be realized using ***Cannulated Screwdriver*** over ***K-Wire*** in overweight patients.

End Cap screw should be squeezed completely after compression.

Whether the screws are in screw holes, the lenght and final position of the fracture are controlled via fluoroscopy. After the approval process, the incision area is closed considering subcutaneous layers anatomy.



K-Wire pulls back until ***Compression Screw*** to avoid overlapping with ***End Cap***. On the AP view, End Cap should place 1-2 mm above the nail top point and it should not squeeze completely. Because in this system, compression is realized by the Compression Screw operates in interaction with Proximal Screw and End Cap.

Required compression is realized from lateral using Screw Driver Ø 4x175 mm.

End Cap should be squeezed after compression.

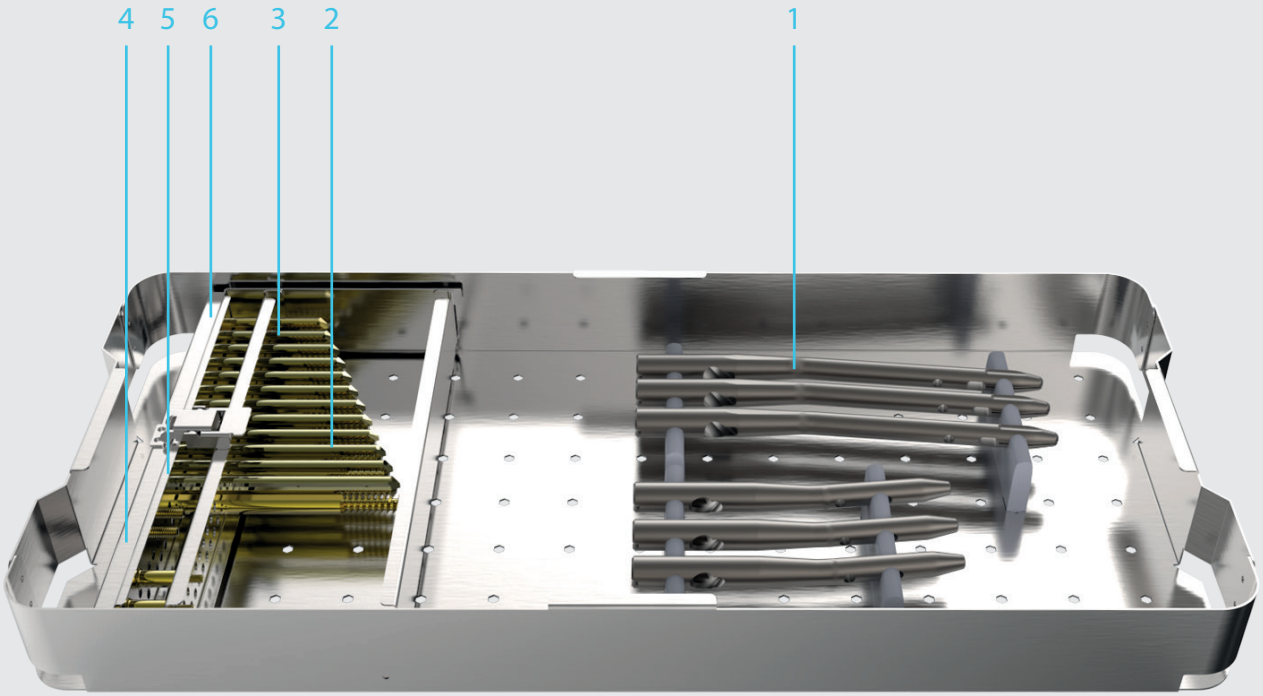
*In cases where the fracture impaction is needed End Cap is not squeezed completely thus sliding effect of the system is allowed.

Set Detail

Implant Tray

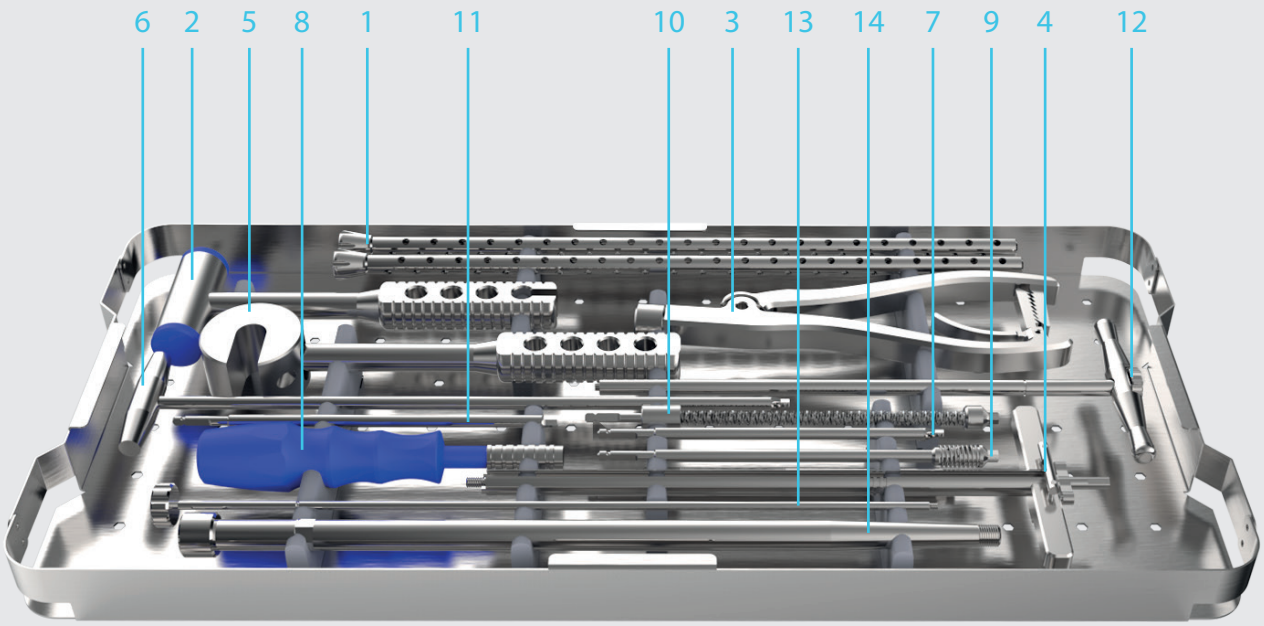
No	Code	Barcode	Description	Qty
1	80220159160	8699931024265	A-PFN (ANTIROT.-PROX. FEM. NAIL) TI Ø9x160 MM	1
	80221510160	8699931024210	A-PFN (ANTIROT.-PROX. FEM. NAIL) TI Ø10x160 MM	1
	80221511160	8699931024234	A-PFN (ANTIROT.-PROX. FEM. NAIL) TI Ø11x160 MM	1
	80221510220	8699931024227	A-PFN (ANTIROT.-PROX. FEM. NAIL) TI Ø10x220 MM	1
	80221511220	8699931024241	A-PFN (ANTIROT.-PROX. FEM. NAIL) TI Ø11x220 MM	1
	80221512220	8699931024258	A-PFN (ANTIROT.-PROX. FEM. NAIL) TI Ø12x220 MM	1
2	80220650010	8699931022568	A-PFN PROXIMAL SCREW TI Ø10x65	1
	80220700010	8699931022575	A-PFN PROXIMAL SCREW TI Ø10x70	1
	80220750010	8699931022582	A-PFN PROXIMAL SCREW TI Ø10x75	1
	80220800010	8699931022599	A-PFN PROXIMAL SCREW TI Ø10x80	1
	80220850010	8699931022605	A-PFN PROXIMAL SCREW TI Ø10x85	1
	80220900010	8699931022612	A-PFN PROXIMAL SCREW TI Ø10x90	1
	80220950010	8699931022629	A-PFN PROXIMAL SCREW TI Ø10x95	1
	80220100010	8699931022636	A-PFN PROXIMAL SCREW TI Ø10x100	1
	80220105010	8699931022643	A-PFN PROXIMAL SCREW TI Ø10x105	1
	80220110010	8699931022650	A-PFN PROXIMAL SCREW TI Ø10x110	1
	80220115010	8699931022667	A-PFN PROXIMAL SCREW TI Ø10x115	1
	80220120010	8699931022674	A-PFN PROXIMAL SCREW TI Ø10x120	1
3	21521000065	8699931022681	A-PFN ANTIROTATOR BLADE 65 MM	1
	21521000070	8699931022698	A-PFN ANTIROTATOR BLADE 70 MM	1
	21521000075	8699931022704	A-PFN ANTIROTATOR BLADE 75 MM	1
	21521000080	8699931022711	A-PFN ANTIROTATOR BLADE 80 MM	1
	21521000085	8699931022728	A-PFN ANTIROTATOR BLADE 85 MM	1
	21521000090	8699931022735	A-PFN ANTIROTATOR BLADE 90 MM	1
	21521000095	8699931022742	A-PFN ANTIROTATOR BLADE 95 MM	1
	21521000100	8699931022759	A-PFN ANTIROTATOR BLADE 100 MM	1
	21521000105	8699931022766	A-PFN ANTIROTATOR BLADE 105 MM	1
	21521000110	8699931014143	A-PFN ANTIROTATOR BLADE 110 MM	1
	21521000115	8699931022773	A-PFN ANTIROTATOR BLADE 115 MM	1
	21521000120	8699931022780	A-PFN ANTIROTATOR BLADE 120 MM	1

No	Code	Barcode	Description	Qty
4	20220100100	8699931022797	A-PFN CANNULATED COMPRESSION SCREW TI	2
	80220100002	8699931022827	A-PFN END CAP FOR COMPRESSION AND LOCKING	1
	80220100000	8699931022810	A-PFN END CAP	1
5	20124300050	8699931022339	CORTEX SCREW FOR NAILS TI Ø5x30 MM	2
	20124320050	8699931022346	CORTEX SCREW FOR NAILS TI Ø5x32 MM	2
	20124340050	8699931022353	CORTEX SCREW FOR NAILS TI Ø5x34 MM	2
	20124360050	8699931022360	CORTEX SCREW FOR NAILS TI Ø5x36 MM	2
	20124380050	8699931022377	CORTEX SCREW FOR NAILS TI Ø5x38 MM	2
	20124400050	8699931022384	CORTEX SCREW FOR NAILS TI Ø5x40 MM	2
	20124420050	8699931030945	CORTEX SCREW FOR NAILS TI Ø5X42 MM	2
	20124440050	8699931030952	CORTEX SCREW FOR NAILS TI Ø5X44 MM	2
	20124460050	8699931030969	CORTEX SCREW FOR NAILS TI Ø5X46 MM	2
	20124480050	8699931030976	CORTEX SCREW FOR NAILS TI Ø5X48 MM	2
6	0604000	8699931026566	A-PFN SCREW BOX	1
	0604100	8699931026573	A-PFN IMPLANT 1.DESIGN TRAY	1



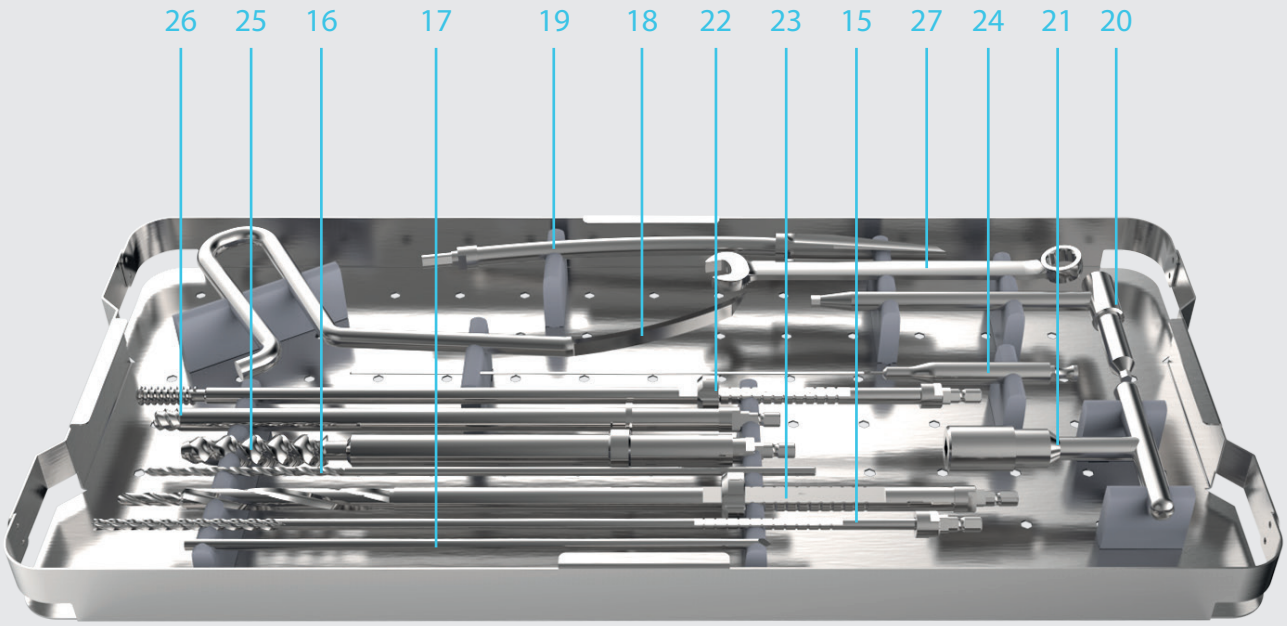
Instrument Tray 1

No	Code	Barcode	Description	Qty
1	04551000350	8699931030686	K-WIRE TUBE Ø10XØ8X350 MM	2
	23410060025	8699931028744	KIRSCHNER WIRE Ø2,5x600 mm	1
	23412340025	8699931022834	KIRSCHNER WIRE THREADED POINT Ø2,5x340 MM	1
	23412340020	8699931014099	KIRSCHNER WIRE THREADED POINT Ø2x340 MM	1
	23410340125	8699931026344	KIRSCHNER WIRE TROCAR POINT Ø2,5x340 MM	2
	23410340120	8699931013993	KIRSCHNER WIRE TROCAR POINT Ø2x340 MM	2
2	01194002009	8699931028164	BONE HAMMER MEDIUM WITH SLOTTED END	1
3	08300000025	8699931021738	GUIDE WIRE PUSHER	1
4	00250005002	8699931022902	A-PFN PROXIMAL SCREW INSERTER	1
5	01195001009	8699931028195	HINGED SLOTTED HAMMER LARGE	1
6	00250040330	8699931022971	CANN. T-SCREW DRIVER HEXAGONAL 4X330 MM	1
7	00250040175	8699931022964	SCREW DRIVER QUICK TIP HEGZAGONAL Ø4x175MM	1
8	02010101002	8698673493308	SOFT SCREW DRIVER QUICK LARGE	1
9	02050101050	8699931029031	QUICK SCRW DRVR SHAFT WITH SWIVEL 5MM HX.BIT	1
10	02020111005	8699931030372	QUICK FLEXIBLE SCREW DRIVER BIT Ø5 MM	1
11	02060018050	8680858405886	SCREW DRIVER QUICK TIP HEGZAGONAL Ø5.0X180 MM	1
12	00250100010	8699931023015	T HANDLE SCREW INSERTER 260 MM	1
13	00250031002	8699931022957	A-PFN BLADE INSERTER	1
14	08061000030	8680858408399	PFN NAIL EXTRACTOR	1
	0604200	8699931026580	A-PFN INSTRUMENT 1.DESIGN TRAY	1



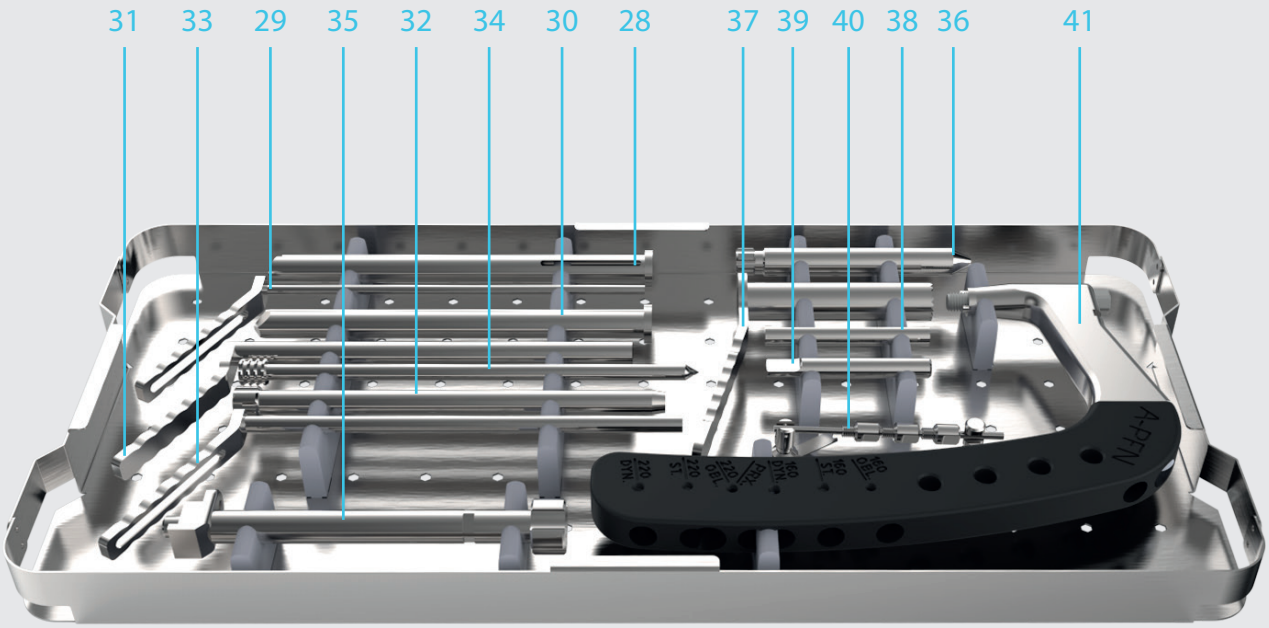
Instrument Tray 2

No	Code	Barcode	Description	Qty
15	00250041002	8699931022988	A-PFN BLADE DRILL	1
16	01210030042	8699931030747	GRADUATED DRILL BIT Ø4,2 MM x300 MM (PFN)	2
17	21510250150	8698673454149	STEINMANN PINS 5X250 MM	1
18	08201000003	8698673496248	AWL	1
19	00250200001	8699931023046	AWL (A-PFN)	1
20	02025100500	8699931005172	T-SCREW DRIVER 5 MM	1
21	01193000023	8698673493780	T QUICK HANDLE	1
22	00250004102	8699931022896	A-PFN PROXIMAL SCREW TAP	1
23	00250001002	8699931022865	A-PFN PROXIMAL SCREW 1.REAMER	1
24	00250120050	8699931023039	DEPTH GAUGE - PROFIN & A-PFN 0-50 MM	1
25	00250200102	8699931023060	A-PFN TROCHANTERIC REAMER	1
26	00250002002	8699931022872	A-PFN PROXIMAL SCREW 2.REAMER	1
27	08044000012	8699931015744	WRENCH Ø 12 MM	1
	0604300	8699931026597	A-PFN INSTRUMENT 2.DESIGN TRAY	1



Instrument Tray 3

No	Code	Barcode	Description	Qty
28	00250024002	8699931022940	A-PFN PROXIMAL SCREW-BLADE GUIDE	1
29	00250200802	8699931023145	A-PFN BLADE KIRSCHNER WIRE GUIDE	1
30	00250008002	8699931022919	A-PFN BLADE DRILL-PROX. SCREW K-WIRE GUIDE	1
31	00250004002	8699931022889	A-PFN PROXIMAL SCREW REAMER GUIDE	1
32	00250100602	8699931023022	SLEEVE FOR CORTEX SCREW OF NAILS (A-PFN&PFN)	1
33	00250008101	8699931022926	DRILL GUIDE FOR CORTEX SCRW OF NAILS (A-PFN&PFN)	1
34	08060080220	8699931032253	DISTAL TROCAR (A-PFN&PFN) Ø 8 X 220 MM	1
35	00250001031	8699931026658	PFN INSERTION KNOB	1
36	00250250600	8699931023084	A-PFN KIRSCHNER WIRE GUIDE Ø2.5X600MM	1
37	00250200032	8699931023053	A-PFN TROCHANTERIC SLEEVE	1
38	0250040001	8680858430710	LENGTH MEASURING DEVICE - A PFN	1
39	00250080345	8699931023008	WRENCH 5 MM (A-PFN)	1
40	00250020001	8699931022933	PFN SCREW GUIDE LOCKING DEVICE	3
41	00250000002	8699931022858	INSERTION HANDLE FOR A-PFN	1
	0604400	8699931026603	A-PFN INSTRUMENT 3.DESIGN TRAY	1
	00560270170	8699931010787	KONTEYNER 560X270X170	1



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