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Introduction

Humerus InSafeLOCK Nail is an innovative intramedullary nailing system, developed for humerus problems.

Humerus fractures have 5-6 % incidence of all bone fractures. Nowadays, conservative and surgical methods are used for the treatment of humerus fractures. Other surgical options have negative effects as; plate-screw fixation, an oversized opening of soft tissue and radial nerves damage risk. Multiple Elastic Pins and unlocked nails (like Küntscher) have the risk of insufficient stability and dislocation.

Features

Humerus InSafeLOCK Nail;

Perforated and rounded,

Titanium flexible and biocompatible,

Usable for both right and left humerus fractures,

No need to fluoroscopy for distal and proximal locking,

New, ergonomic, easy instruments for insertionextraction and locking,

Advantage of application as carved and non-carved,

Humerus InSafeLOCK nail shaft diameter; 7 mm, 8 mm, 9 mm,

Length options; 180, 200, 220, 240, 260, 280, 300 mm,

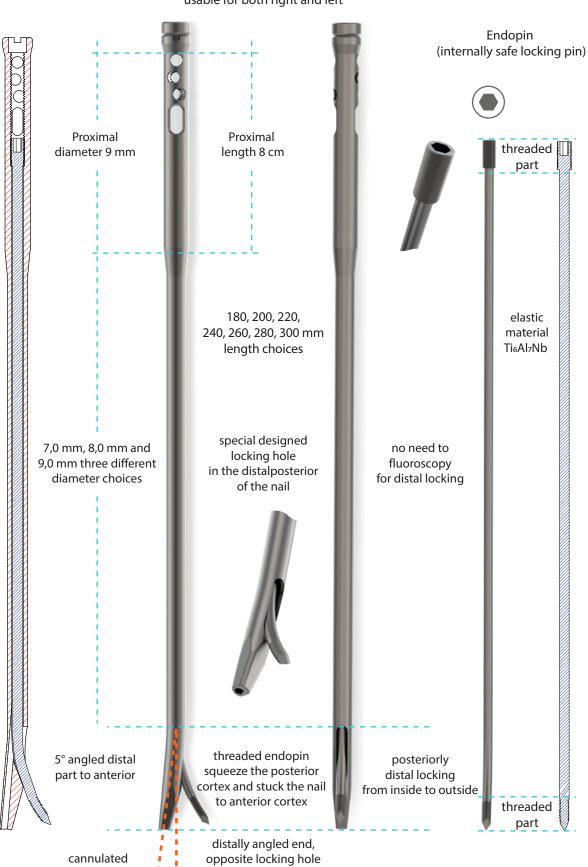
Proximal diameter is 9 mm of all nails and 8 cm of proximal part length.

3 cm of the distal tip was angled 5° anteriorly for nail can be easily distracted and contributes to rotational stability.

The distal part of the nail with oval shaped designed hole in the posterior direction, the hole is designed for endopin. No soft tissue damage at the distal part and no need to use fluoroscopy for the distal locking.

Warning

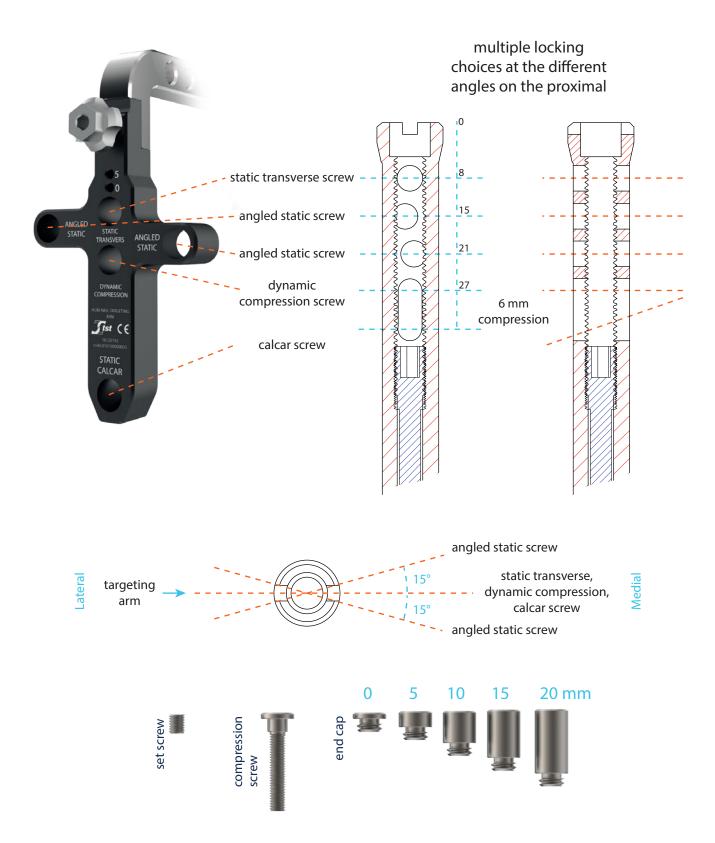
This description is not sufficient by itself for direct and proper use of the instrument set intraoperatively. Instruction by a surgeon who is thoroughly trained and experienced in handling these instruments and in doing the procedure are highly recommended.



on the posterior

usable for both right and left

4 locking holes in the proximal, three holes are static and the other one is dynamic. 4 mm diameter locking screws allow multiple locking in different planes at the humerus head.



Features of InSafeLOCK Nail

Usable for both right and left,

Can be placed to the most distal part (until the proximal edge of the olecranon fossa),

No need to fluoroscopy or extra guide usage for distal locking,

No distal locking complications as indicated below;

- No tissue incision,
- No radial nerves damaged (radial, median and musculocutaneous nerves),
- No distal locking screw loosening, migration and irritation problems,
- Shorter application period and operation time.



Proximal humerus fractures (2, 3, 4 parts),

Metaphyseal, Metaphyseal diafizer, and diaphyseal all fractures (3 cm from end of the olecranon fossa to proximal), In tumor resections, Shortening osteotomies,

In deformity correction surgeries.

Contraindications;

Active systemic infection, Local infection at the entrance of the nail, Sensitivity and allergy of implant material, The bone is excessively contaminated of open fractures.

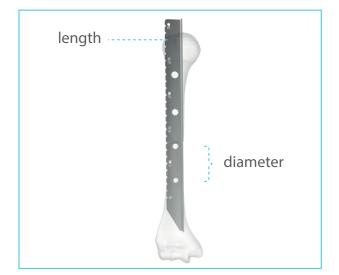
Surgical Technique

Humerus InSafeLOCK Nail applied with the technique of antegrade operation

DETERMINATION OF NAIL'S DIAMETER AND LENGHT ARE:

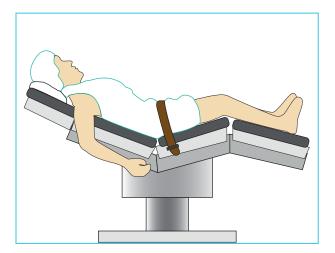
a) Sturdy humerus is measured digitally.

b) After measuring the humerus canal, humerus length is determined through the *Surgical Ruler* before the pre-operative time.



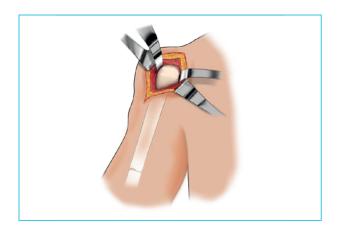


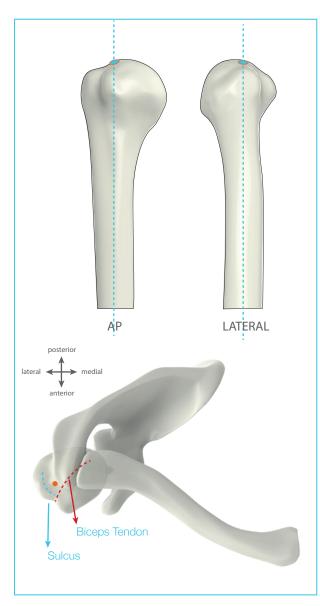
The patient is positioned 'supine' or 'sunbed' on the table. The fracture is reducted.





It is reached to humerus top in 3 cm incision from acromion to distal with the anterolateral approach.





4 NAIL ENTRY POINT:

Entering the medulla directly from the top of the head. Showed in the figure; Entry point of the nail is positioned posterolateral of biceps tendon between big tubercule and humerus head in the medial of the groove.

The *K-wire 3X400 mm Ø* should be placed metaphyseal in the medulla canal with fluoroscopic control.

5 OPENING NAIL ENTRY POINT:

Entry Reamer opened under the guidance of *K-Wire* in the *Entry Reamer Sleeve*.

All nail diameters are 9 mm. *Entry Reamer* is designed for this diameter. The nail holder diameter is 11 mm and enlargement process is performed from top of the bone to 10 mm depth with the reamer (11 mm).



6 SENDING THE GUIDE WIRE:

The Long Guide Wire (Ø3X650 mm) is inserted into the intramedullary canal after opening the entry point if carving of diaphease will be done. *Reduction Device* can be used by fixated to *T-handle* in order to pass easily the fracture line and assist in reduction.







7 DETERMINING NAIL LENGHT:

The Guide Wire is transmitted to the distal humerus, the tip of the wire is positioned at the top of the olecranon fossa, with a reamer.

The length of the nail is determined by *Length Measuring Device* of the wire outside the bone with the aid of length measurement device. Nail size should be 6-10 mm shorter than the measured size if compression is applied in the fracture line. Otherwise, there is a risk of overflowing the bone surface of the nail after compression.



8 UNREAMED TECHNIQUE:

If the unreamed technical to be preferred; first of all *Guide Wire (Ø 2X650 mm)* should be placed in the canal and The nail should be attached to the *Targeting Arm* must be inserted into the canal via this wire.

9 CARVED TECHNIQUE:

The canal carving process is started through *Guide Wire (Ø 3X650 mm)* with the smallest *Flexible Reamer (Ø 7 mm)* and the size is continued by 0.5 mm increment.

While the *Reamer* is removing, the *Guide Wire Pusher* is used behind the reamer to prevent the *Thick Guide Wire* going back.

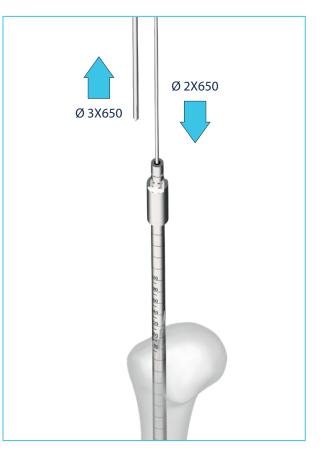
The carving process continues until the cortex contact is felt.

The nail diameter should be 1-1.5 mm smaller than the last used reamer.



10 GUIDE-WIRE CHANGING:

At the end of the canal carving process, *Guide-Wire* (Ø 2X650 mm) which is compatible with the inner diameter of the nail is placed through the *Reamer* while the last *Reamer* is in the humerus, the *Guide Wire* (Ø 3X650 mm) is removed.





1 1 TARGETING DEVICE-NAIL ASSEMBLY

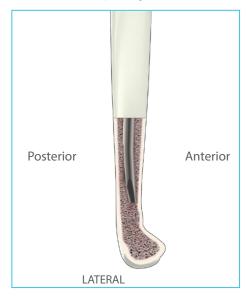
The determined nail is attached to the *Targeting Arm* as shown in the picture and the other instrument is checked.

The laser marks on the top of the nail help to matchup the direction of the nail (L (Left) or R (Right)). *Nail Holder* and nail are connected by **Connection** *Screw. The 12 mm Wrench* is used to tighten the bolt. The *Targeting Arm* is attached tightly to the *Nail Holder* with the *Wrench*.



2 NAIL PLACEMENT:

The nail that is set up to the *Targeting Arm*, is taken forward through as the distal tip is sloped to anteriorly straight (distal on the humerus), the channel from insertion site (through the guide wire in the channel). The nail is improved by hand and by rotational movements with passing the broken line.





13 NAILING:

In the case of nailing needed, *Connection Screw* is attached to the threaded slot on the *Nail Holder*. Nail Hammer (inside threaded end) is tightly connected to the *Connection Screw* by *12 mm Wrench*. Nail clamping is applied with the *Sliding Hammer* which is located on the *Sliding Hammer Impactor*. This process should be done with soft impacts which will not damage the cortex.

For slight forward movements; the process should be applied by hitting the nail and screw with *U Hammer* through *K-Wire*.



14 NAIL PROXIMAL POSITION:

Nail placement could be tracked with 0, 5, 10, 15 and 20 mm nail marks on the *Nail Holder*.

With this aim, *K-wire (Ø 3X250 mm)* to be sent from 0 to 5 levels on the *Targeting Arm*, indicates the nail connection point (0 mm) and nail placement depth (5 mm).

Regarding the levels of the proximal tip of the nail in the bone; If the compression needed the nail placement is applied at a depth of 10 mm from the bone surface.

When the nail passes to the distal fragment, the *Guide Wire* is removed.





15 PREPARATION FOR DISTAL LOCKING:

For distal locking, there is no need to use fluoroscopy or guide.

Internal locking is performed without the incision. In this way, tissue nerve injury and aesthetic disadvantages that may occur are prevented in the patient, the duration of surgery will be significantly reduced.

The elbow is placed in a supine position with a 90° flexion before the distal pin, which provides distal fixation, is delivered. *Nail Holder* should be target tub. Major in proximal and epithelium condyle in distal. For endopin holding point, posterior cortex is drilled through the top of the nail (through nail channel) with Ø 3X400 mm K-wire (with motor aid).



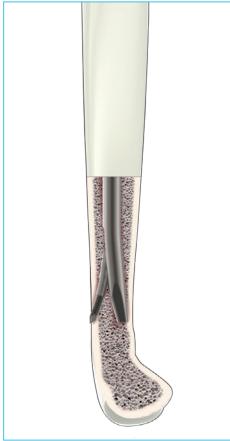
16 DISTAL LOCKING:

Endopin 2,5x200 mm is sent through with the *Screwdriver* from the *Connection Screw for Nail Holder* insertion site. The grooves in the tip of the *Endopin* are matched with the grooves in the nail channel. *Endopin* is improved to distal tip by clockwise rotation of the inserter

Final placement is determined by considering the laser mark on the inserter.



Endopin; Distal nail tip makes compress to the anterior cortex and performs distal locking by providing attachment holding point of posterior cortex with grooved tip.



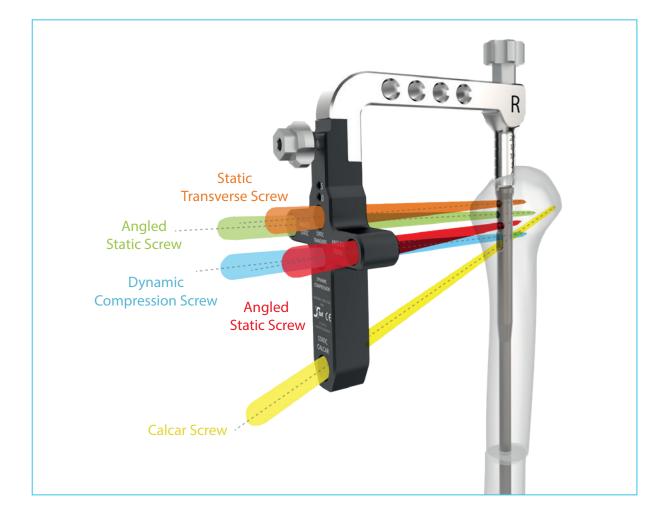


17 PROXIMAL LOCKING DEFINITION:

The humeral nail could be used for non-stabilized or fragmented humerus fractures. Proximal locking, depending on the choice of the surgeon, performed with the aid of a guide through 4 screw holes designed at different angles.

The targeting arm is designed to provide four options for locking over the nail in the proximal direction. These are; Static Transverse, Static Angle, Dynamic Compression and Calcar Screw.

When necessary, the dynamic hole in the distal could be compressed to 6 mm by applying a transverse screw for compression purposes.



PREPARATION:

Static locking will help to protect the length of the bone and the rotational stability of the fracture.

For this purpose, the *Proximal Screw Guide* with a *Trocar* inserted into the hole defined in the *Targeting Arm* is marked to skin. Following the incision, the soft tissue is passed and the contact with the bone is provided. The *Trocar* is removed, replaced with the *Proximal Drill Guide* and the hole is opened for the nail lock screw by drilling the lateral cortex to the appropriate depth with *3.2x300 mm Measured Drill*. On counter-cortex connection, the screw size is determined by the measure of the *Drill Guide* tip. If the direction of the drilling is towards the joint surface, the bone density is taken into consideration and care should be taken to avoid subchondral penetration. The use of scoping is recommended in this step.

Depth Gauge (through the drill guide) could be used to determine the length of the proximal screws as an alternative.



18 PROXIMAL LOCKING:

The *Drill Guide* is removed and the Ø 4 mm Proximal Locking Screw, which is determined via the Screw Guide, is inserted into the bone with the Screwdriver (Ø4X9x150 mm).

For the exact placement, the laser mark on the screwdriver must be at the guide alignment.

Other *Proximal Locking Screws* are applied following the same steps.

At the humerus, the suitability and length of the screw sites are checked on both plans.



COMPRESSION TECHNIQUE:

The distal fragment is approximated to the main fragment with 4 mm compression screws (or direct compression device) which is based on 4 mm screw inserted transversally through the oblong hole and the fracture gap is closed. 6 mm compression could be provided with the system.

Compression could be done in 3 different ways;

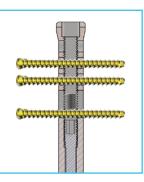
WITH COMPRESSION HEAD SCREW;

Before implementation, the *Targeting Arm* should be separated. *Compressed Head Screw* is applied with *4x9x150 mm Hexagon Screwdriver*.

Locking screws could not be applied to the other proximal holes after this application.

WITH SET SCREW;

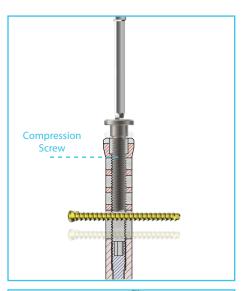
When the *Set Screw* is a small piece, it is placed to grooved canal in the nail with a *2.5x200 mm Screwdriver* over the *Targeting Screw*. Then the compression is performed with a *2.5 x 200 mm Normal Screwdriver* (due to risk of tip fracture). Locking screws could be applied to the other proximal holes after this application. The process is completed by inserting the appropriate head bolt after the nail has been detected.

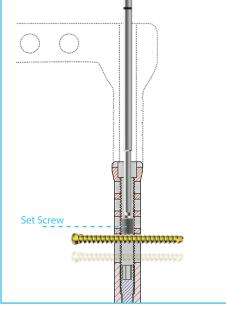


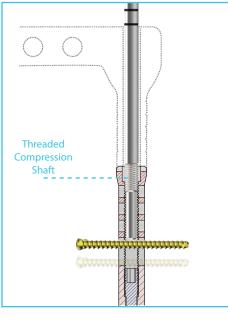
WITH THREADED COMPRESSION SHAFTS

Threaded Compression Shaft is applied over the *Targeting Arm* by attaching to the *Screwdriver*. Compression is performed paying attention to the laser marks on *Compression Shaft*. During this application, temporary detection of the proximal fragment is provided with the drill bit sent to the static hole without the *Compression Shaft* removed. After *Compression Shaft* is removed, the lock screws are applied from the other proximal holes

Trying to improve more than 6 mm while applying compression, or applying too much force could cause bending of the transverse going screw in the oblong hole. It is recommended that this procedure be performed at the time of scopy control. The process is completed by attaching the appropriate top screw after the nail detection is done.







19 CLOSING THE WOUND:

Incision wound is closed by using the standard technique.

20 REMOVING NAIL PROCESS:

The removal operation should be performed by applying the reverse of the nail placement procedure.

The *End Cap* is removed.

The connection is made between *Targeting Arm* and the nail.

The screws located in the proximal part of the nail are removed.

If the set screw is available, must be removed before the compression screw.

Endopin is reached from the top of the Targeting Arm using a Screwdriver Ø 2.5X200 mm. The Endopin should provide a complete fitting with the Screwdriver recess by turning the screwdriver clockwise and Endopin in the nail channel is removed. Ø 2.5X200 mm Screwdriver with holder tip could be used in order to catch and remove the Endopin which is released in the nail inner channel during removal.

The *Nail Extractor* is connected to the nail by *Connection Screw for Nail Extractor. The Nail is* removed from the humerus channel by *Hammer* which is located on *Sliding Hammer Rod*. When extra power required during removal, *Sliding U Hammer* could be used over the *Nail Extractor*.



Set Detail Implants

Barcode

Code

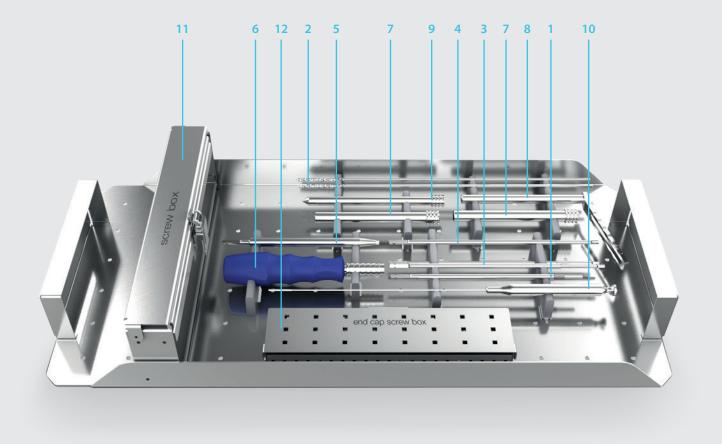
Description

HIN - HUMERUS INSAFELOCK NAIL Ø 7.0 X 180 MM
HIN - HUMERUS INSAFELOCK NAIL Ø 7.0 X 200 MM
HIN - HUMERUS INSAFELOCK NAIL Ø 7.0 X 220 MM
HIN - HUMERUS INSAFELOCK NAIL Ø 7.0 X 240 MM
HIN - HUMERUS INSAFELOCK NAIL Ø 7.0 X 260 MM
HIN - HUMERUS INSAFELOCK NAIL Ø 7.0 X 280 MM
HIN - HUMERUS INSAFELOCK NAIL Ø 7.0 X 300 MM
HIN - HUMERUS INSAFELOCK NAIL Ø 8.0 X 180 MM
HIN - HUMERUS INSAFELOCK NAIL Ø 8.0 X 200 MM
HIN - HUMERUS INSAFELOCK NAIL Ø 8.0 X 220 MM
HIN - HUMERUS INSAFELOCK NAIL Ø 8.0 X 240 MM
HIN - HUMERUS INSAFELOCK NAIL Ø 8.0 X 260 MM
HIN - HUMERUS INSAFELOCK NAIL Ø 8.0 X 280 MM
HIN - HUMERUS INSAFELOCK NAIL Ø 8.0 X 300 MM
HIN - HUMERUS INSAFELOCK NAIL Ø 9.0 X 180 MM
HIN - HUMERUS INSAFELOCK NAIL Ø 9.0 X 200 MM
HIN - HUMERUS INSAFELOCK NAIL Ø 9.0 X 220 MM
HIN - HUMERUS INSAFELOCK NAIL Ø 9.0 X 240 MM
HIN - HUMERUS INSAFELOCK NAIL Ø 9.0 X 260 MM
HIN - HUMERUS INSAFELOCK NAIL Ø 9.0 X 280 MM
HIN - HUMERUS INSAFELOCK NAIL Ø 9.0 X 300 MM
HIN INSAFELOCK ENDOPIN SCREW 180 MM
HIN INSAFELOCK ENDOPIN SCREW 200 MM
HIN INSAFELOCK ENDOPIN SCREW 220 MM
HIN INSAFELOCK ENDOPIN SCREW 240 MM
HIN INSAFELOCK ENDOPIN SCREW 260 MM
HIN INSAFELOCK ENDOPIN SCREW 280 MM
HIN INSAFELOCK ENDOPIN SCREW 300 MM

Qty

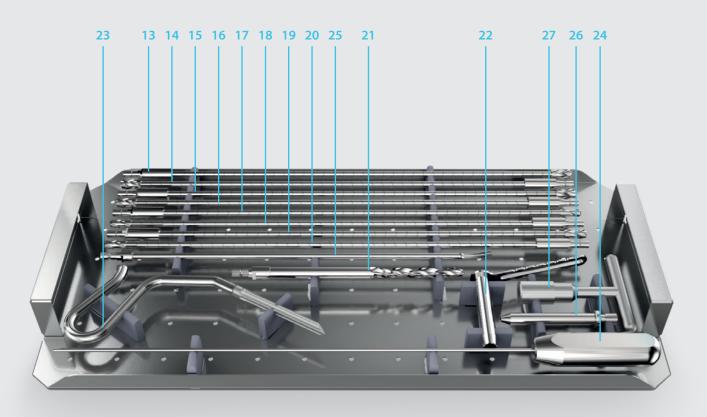
Tray 1

No	Code	Barcode	Description	Qty
	808100	8680858431274	HIN 1.DESIGN TRAY	1
1	02381000010	8680858431946	THREADED COMPRESSION SHAFT	1
2	01610030032	8680858424184	GRADUATED DRILL BIT Ø3.2X300 MM	2
3	01610020025	8680858430130	SCREW DRIVER QUICK TIP 2.5X200 MM	2
4	01611020025	8680858430147	SCREW DRIVER QUICK TIP HOLDER 2.5X200 MM	1
5	02000409150	8680858431861	SCREW DRIVER QUICK HEX. TIP 4X9x150 MM	1
6	02010101002	8698673493308	SOFT SCREW DRIVER QUICK LARGE	1
7	01610000006	8680858424153	HUM. NAIL PROXIMAL SCREW SLEEVE	2
8	01610000007	8680858424160	HUM. NAIL PROXIMAL DRILL GUIDE	1
9	01610000008	8680858424177	HUM. NAIL TROCAR	1
10	02001400100	8680858430307	DEPTH GAUGE - HIN PROX. SCREW LENGTH	
11	808700	8680858431304	HIN LOCK. SCREW BOX	1
	22124040018	8680858422340	CORTEX SCREW FOR NAILS TI Ø4.0X18 MM	2
	22124040020	8680858422357	CORTEX SCREW FOR NAILS TI Ø4.0X20 MM	2
	22124040022	8680858422364	CORTEX SCREW FOR NAILS TI Ø4.0X22 MM	2
	22124040024	8680858422371	CORTEX SCREW FOR NAILS TI Ø4.0X24 MM	2
	22124040026	8680858422388	CORTEX SCREW FOR NAILS TI Ø4.0X26 MM	2
	22124040028	8680858422395	CORTEX SCREW FOR NAILS TI Ø4.0X28 MM	2
	22124040030	8680858422401	CORTEX SCREW FOR NAILS TI Ø4.0X30 MM	2
	22124040032	8680858422418	CORTEX SCREW FOR NAILS TI Ø4.0X32 MM	2
	22124040034	8680858422425	CORTEX SCREW FOR NAILS TI Ø4.0X34 MM	2
	22124040036	8680858422432	CORTEX SCREW FOR NAILS TI Ø4.0X36 MM	3
	22124040038	8680858422449	CORTEX SCREW FOR NAILS TI Ø4.0X38 MM	3
	22124040040	8680858422456	CORTEX SCREW FOR NAILS TI Ø4.0X40 MM	3
	22124040042	8680858422463	CORTEX SCREW FOR NAILS TI Ø4.0X42 MM	3
	22124040044	8680858422470	CORTEX SCREW FOR NAILS TI Ø4.0X44 MM	3
	22124040046	8680858422487	CORTEX SCREW FOR NAILS TI Ø4.0X46 MM	3
	22124040048	8680858422494	CORTEX SCREW FOR NAILS TI Ø4.0X48 MM	3
	22124040050	8680858422500	CORTEX SCREW FOR NAILS TI Ø4.0X50 MM	2
	22124040052	8680858422517	CORTEX SCREW FOR NAILS TI Ø4.0X52 MM	2
	22124040054	8680858422524	CORTEX SCREW FOR NAILS TI Ø4.0X54 MM	2
	22124040056	8680858422531	CORTEX SCREW FOR NAILS TI Ø4.0X56 MM	2
	22124040058	8680858422548	CORTEX SCREW FOR NAILS TI Ø4.0X58 MM	2
	22124040060	8680858422555	CORTEX SCREW FOR NAILS TI Ø4.0X60 MM	2
	22124040062	8680858422562	CORTEX SCREW FOR NAILS TI Ø4.0X62 MM	2
	22124040064	8680858422579	CORTEX SCREW FOR NAILS TI Ø4.0X64 MM	2
	22124040066	8680858422586	CORTEX SCREW FOR NAILS TI Ø4.0X66 MM	2
	22124040068	8680858422593	CORTEX SCREW FOR NAILS TI Ø4.0X68 MM	2
	22124040070	8680858422609	CORTEX SCREW FOR NAILS TI Ø4.0X70 MM	2
12	808800	8680858431311	HIN END CAP SCREW BOX	1
	81520000001	8698673427983	HUMERUS INSAFELOCK NAIL SET SCREW	2
	21120028500	8680858421268	HUMERUS INSAFELOCK LOCK. COMPRESSION SCREW (TI)	1
	82120000000	8680858421275	HUMERUS INSAFELOCK END CAP (TI) STANDARD	2
	82120000005	8680858421282	HUMERUS INSAFELOCK END CAP (TI) + 5 MM	2
	82120000010	8680858421299	HUMERUS INSAFELOCK END CAP (TI) + 10 MM	1
	82120000015	8680858421305	HUMERUS INSAFELOCK END CAP (TI) + 15 MM	1
	82120000020	8680858421312	HUMERUS INSAFELOCK END CAP (TI) + 20 MM	1



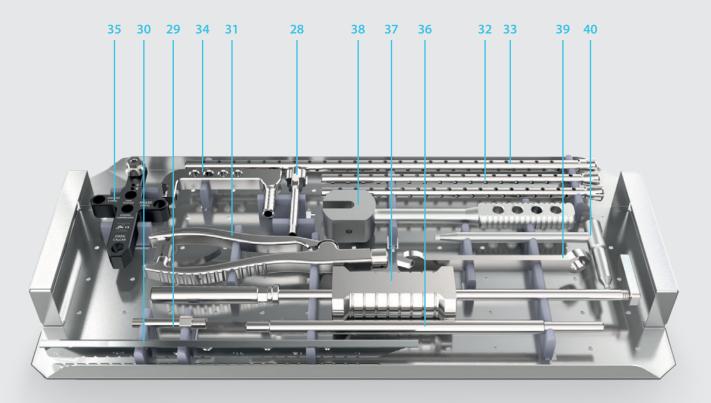
Tray 2

No	Code	Barcode	Description	Qty
	808200	8680858431281	HIN 2.DESIGN TRAY	1
13	08050000012	8698673497245	FLEXIBLE REAMER Ø 7	1
14	01610001075	8699931026740	FLEXIBLE REAMER Ø 7.5	1
15	08050000013	8698673497252	FLEXIBLE REAMER Ø 8	1
16	01610000085	8699931017090	FLEXIBLE REAMER Ø 8.5	1
17	08050000014	8698673497269	FLEXIBLE REAMER Ø 9	1
18	01610000095	8699931017106	FLEXIBLE REAMER Ø 9.5	1
19	08050000015	8698673497214	FLEXIBLE REAMER Ø 10	1
20	01610000105	8699931017113	FLEXIBLE REAMER Ø 10.5	1
21	01610000001	8680858424078	HUM. NAIL ENTRY REAMER	1
22	08201100001	8680858432417	INTRAMED. NAIL ENTRY REAMER SLEEVE Ø10X80MM	1
23	01610000012	8680858424511	INTRAMED. NAIL CANNULE AWL	1
24	08011000000	0080110000008	PUSH ROD	1
25	01610000005	8680858424146	HUM. NAIL REDUCTION DEVICE	1
26	01610000010	8680858424214	INTRAMED. NAIL K-WIRE GUIDE Ø3X105MM	1
27	01193000023	8698673493780	T QUICK HANDLE	1



Tray 3

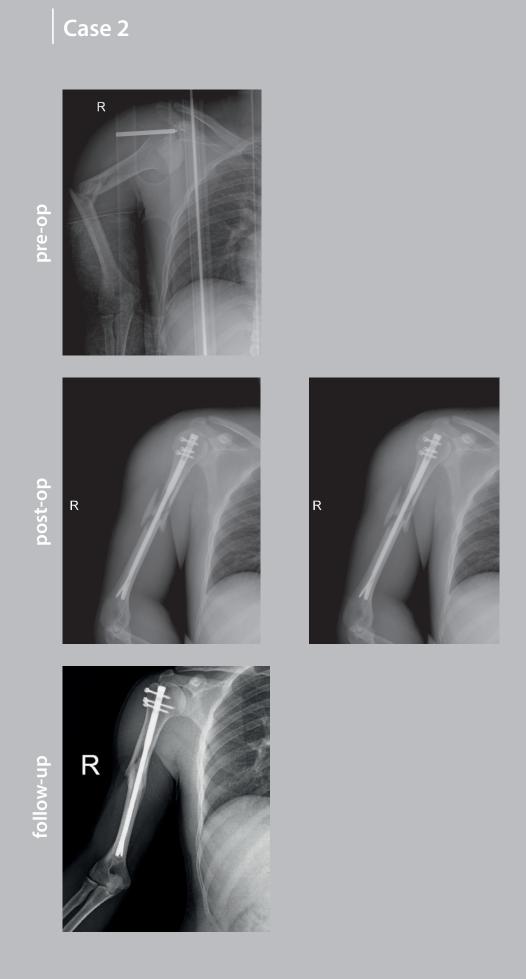
No	Code	Barcode	Description	Qty
	808300	8680858431298	HIN 3.DESIGN TRAY	1
28	08211000010	8680858432424	CONNECTION SCREW FOR HUM. NAIL HOLDER	1
29	08211000020	8680858432431	CONNECTION SCREW FOR HUM. NAIL EXTRACTOR	1
30	01610003000	8680858424054	SURGICAL RULER S.S 300 MM	1
31	0830000025	8699931021738	GUIDE WIRE PUSHER	1
32	04551208260	8699931029628	K-WIRE TUBE Ø12XØ8X260 MM	1
	23410250130	8698673453272	KIRSCHNER WIRE TROCAR POINT 3X250 MM	4
33	04551208400	8699931032406	K-WIRE TUBE Ø12XØ8X400 MM	1
	01610040030	8680858424139	KIRSCHNER WIRE TROCAR POINT Ø3X400 MM	3
34	01610000002	8680858424085	HUM. NAIL HOLDER	1
35	01610000003	8680858424092	HUM. NAIL TARGETING ARM	1
36	01610000011	8680858424221	HUM. NAIL LENGTH MEASURING DEVICE	1
37	01610000004	8680858424108	SLIDING NAIL IMPACTOR&EXTRACTOR HIN	1
	01194000009	8699931028171	SLIDING HAMMER	1
	01194020008	8680858431847	SLIDING HAMMER STOPPER HIN	1
38	01194000099	8680858430123	SLIDING U-HAMMER	1
39	08044000012	8699931015744	WRENCH 12 MM	1
40	02025100500	8699931005172	T SCREW DRIVER Ø 5 MM	1
	00560270170	8699931010787	CONTAINER 560x270x170	1
	01610065020	8680858424061	GUIDE WIRE 2X650 MM	2
	01610065030	8680858424535	GUIDE WIRE 3X650 MM	1



Sample Cases

Case 1





Case 3

pre-op

R













Case 4

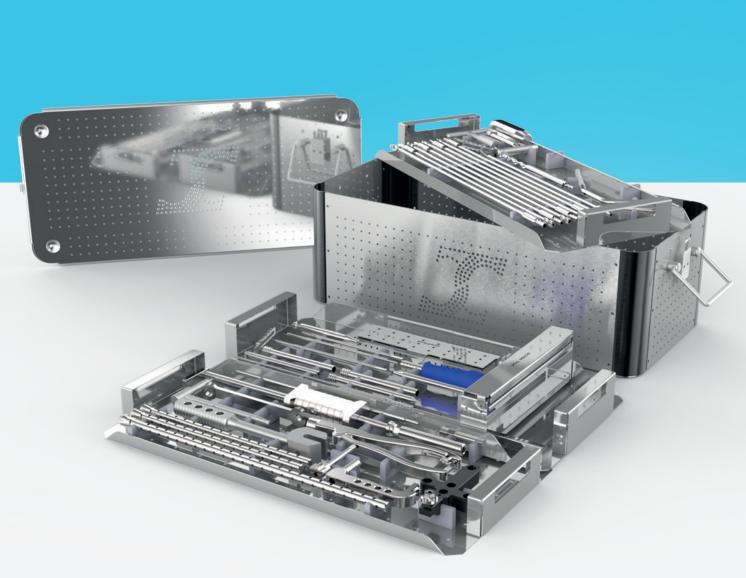
















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