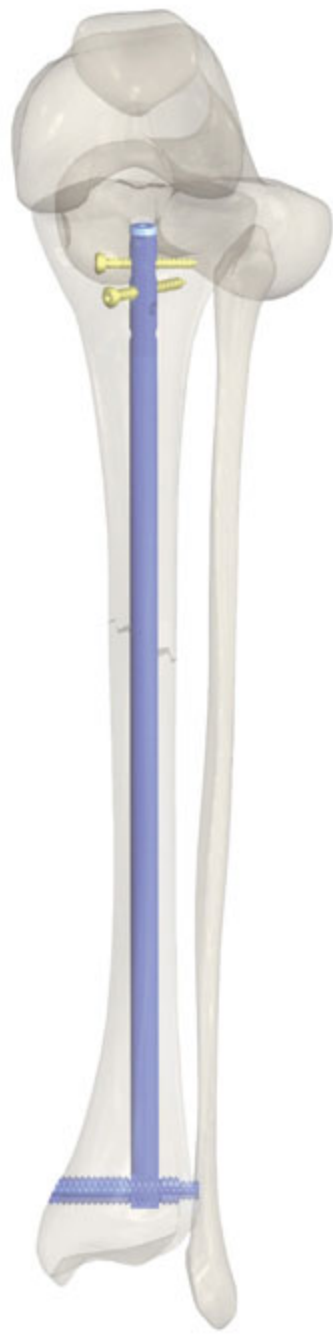
TIBIA

Intramedullary Nail (TIN)

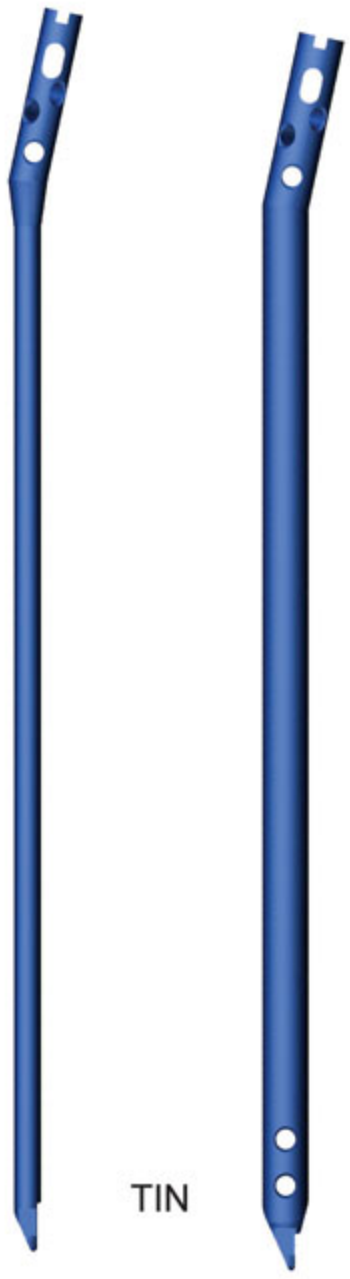
Patented

titanium

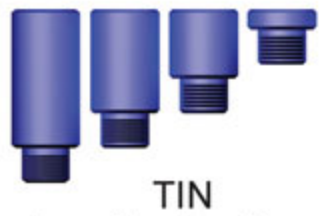
Contents



Implants and Instruments

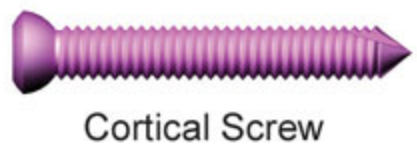


TIN



TIN
Lengthening Screw

Compression
Screw



Cortical Screw

DSBLS

Set Screw

Flexible Reamer

Bone Drill Bit Ø 4.2 X 250 mm

Cannulated Drill Bit Ø 5 mm

Graded Cannulated Drill Bit Ø 8.5 X 5.0 mm

Nail Extracter

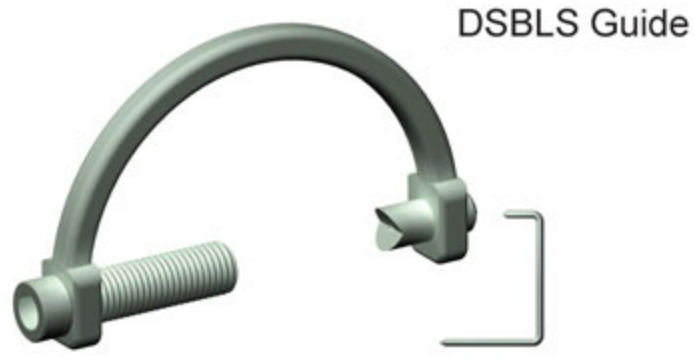
Screw Length Gauge

Distal Screw Length Gauger

Kirschner Wire 2 x 250mm

Stainless Ruler

Proximal
Drill Guide



DSBLS Guide

Distal K.Wire
Guide

Distal Drill Guide
Ø 5 mm

Proximal Locking
Screw Guide

Nail Holder - Inserter

Nail Driver

Proximal Guide

DSBLS Holder-Inserter

AA 2,5 Screw Driver

AA 3,5 Screw Driver

Articulated
Hammer

Patella
Protector

AWL

Hammer

Tibia Intramedullary Nails

81520280710	TIBIA INTRAMEDULLARY NAIL (TIN) 10X7X280 mm Ti
81520300710	TIBIA INTRAMEDULLARY NAIL (TIN) 10X7X300 mm Ti
81520320710	TIBIA INTRAMEDULLARY NAIL (TIN) 10X7X320 mm Ti
81520340710	TIBIA INTRAMEDULLARY NAIL (TIN) 10X7X340 mm Ti
81520340710	TIBIA INTRAMEDULLARY NAIL (TIN) 10X7X360 mm Ti
81520340710	TIBIA INTRAMEDULLARY NAIL (TIN) 10X7X380 mm Ti
81520280810	TIBIA INTRAMEDULLARY NAIL (TIN) 10X8X280 mm Ti
81520300810	TIBIA INTRAMEDULLARY NAIL (TIN) 10X8X300 mm Ti
81520320810	TIBIA INTRAMEDULLARY NAIL (TIN) 10X8X320 mm Ti
81520340810	TIBIA INTRAMEDULLARY NAIL (TIN) 10X8X340 mm Ti
81520360810	TIBIA INTRAMEDULLARY NAIL (TIN) 10X8X360 mm Ti
81520360810	TIBIA INTRAMEDULLARY NAIL (TIN) 10X8X380 mm Ti
81520360810	TIBIA INTRAMEDULLARY NAIL (TIN) 10X8X400 mm Ti
81520300910	TIBIA INTRAMEDULLARY NAIL (TIN) 10X9X300 mm Ti
81520320910	TIBIA INTRAMEDULLARY NAIL (TIN) 10X9X320 mm Ti
81520340910	TIBIA INTRAMEDULLARY NAIL (TIN) 10X9X340 mm Ti
81520360910	TIBIA INTRAMEDULLARY NAIL (TIN) 10X9X360 mm Ti
81520380910	TIBIA INTRAMEDULLARY NAIL (TIN) 10X9X380 mm Ti
81520380910	TIBIA INTRAMEDULLARY NAIL (TIN) 10X9X400 mm Ti
81520301010	TIBIA INTRAMEDULLARY NAIL (TIN) 10X10X300 mm Ti
81520321010	TIBIA INTRAMEDULLARY NAIL (TIN) 10X10X320 mm Ti
81520341010	TIBIA INTRAMEDULLARY NAIL (TIN) 10X10X340 mm Ti
81520361010	TIBIA INTRAMEDULLARY NAIL (TIN) 10X10X360 mm Ti
81520381010	TIBIA INTRAMEDULLARY NAIL (TIN) 10X10X380 mm Ti
81520381010	TIBIA INTRAMEDULLARY NAIL (TIN) 10X10X400 mm Ti
81520301111	TIBIA INTRAMEDULLARY NAIL (TIN) 11X11X300 mm Ti
81520321111	TIBIA INTRAMEDULLARY NAIL (TIN) 11X11X320 mm Ti
81520341111	TIBIA INTRAMEDULLARY NAIL (TIN) 11X11X340 mm Ti
81520361111	TIBIA INTRAMEDULLARY NAIL (TIN) 11X11X360 mm Ti
81520381111	TIBIA INTRAMEDULLARY NAIL (TIN) 11X11X380 mm Ti
81520381111	TIBIA INTRAMEDULLARY NAIL (TIN) 11X11X400 mm Ti
81520341212	TIBIA INTRAMEDULLARY NAIL (TIN) 12X12X340 mm Ti
81520361212	TIBIA INTRAMEDULLARY NAIL (TIN) 12X12X360 mm Ti
81520381212	TIBIA INTRAMEDULLARY NAIL (TIN) 12X12X380 mm Ti
81520401212	TIBIA INTRAMEDULLARY NAIL (TIN) 12X12X400 mm Ti
81520003411	DISTAL SUPPORTIVE BOLT LOCKING SCREW 11X34 mm
81520003511	DISTAL SUPPORTIVE BOLT LOCKING SCREW 11X35 mm
81520003611	DISTAL SUPPORTIVE BOLT LOCKING SCREW 11X36 mm
81520003711	DISTAL SUPPORTIVE BOLT LOCKING SCREW 11X37 mm
81520003811	DISTAL SUPPORTIVE BOLT LOCKING SCREW 11X38 mm
81520004011	DISTAL SUPPORTIVE BOLT LOCKING SCREW 11X40 mm
81520004211	DISTAL SUPPORTIVE BOLT LOCKING SCREW 11X42 mm

Screws

81521500001	SET SECREW 15 mm
81521700001	SET SECREW 17 mm
81521900001	SET SECREW 19 mm
81522000001	SET SECREW 20 mm
81522300001	SET SECREW 23 mm
20228250045	SELF TAPPING CORTICAL SCREW 5X25 mm
20228300045	SELF TAPPING CORTICAL SCREW 5X30 mm
20228350045	SELF TAPPING CORTICAL SCREW 5X35 mm
20228400045	SELF TAPPING CORTICAL SCREW 5X40 mm
20228450045	SELF TAPPING CORTICAL SCREW 5X45 mm
20228500045	SELF TAPPING CORTICAL SCREW 5X50 mm
20228550045	SELF TAPPING CORTICAL SCREW 5X55 mm
20228600045	SELF TAPPING CORTICAL SCREW 5X60 mm
20228650045	SELF TAPPING CORTICAL SCREW 5X65 mm
20228700050	SELF TAPPING CORTICAL SCREW 5X70 mm
81520001000	TIN COMPRESSION SCREW 0 mm
81520001000	TIN LENGTHENING SCREW 5 mm
81520001000	TIN LENGTHENING SCREW 10 mm
81520001500	TIN LENGTHENING SCREW 15 mm
81520002000	TIN LENGTHENING SCREW 20 mm

Instruments

08050000000	NAIL HOLDER-INSERTER
08050000005	DSBLS GUIDE
08050000007	PROXIMAL LOCKING SCREW GUIDE
08050000006	PROXIMAL DRILL BIT GUIDE
22310250042	BONE DRILL BIT 4.2 X 250 mm
08050000008	AA 3,5 SCREWDRIVER
08050000009	AA 2,5 SCREWDRIVER
08201000003	PROXIMAL ENTRY HOLE OPENING DEVICE (AWL)
08050000018	GRADED CANNULATED DRILL BIT 8.5 X 5.0 mm
08050000010	0 ALUMINIUM PLATE (PATELLA PROTECTOR)
08050000011	400 mm LONG STAINLESS RULER
08050000012	FLEXIBLE REAMER Ø 7 mm
08050000013	FLEXIBLE REAMER Ø 8 mm
08050000014	FLEXIBLE REAMER Ø 9 mm
08050000015	FLEXIBLE REAMER Ø 10 mm
08050000016	FLEXIBLE REAMER Ø 11 mm
08050000017	FLEXIBLE REAMER Ø 12 mm
08050000019	DISTAL KIRSCHNER WIRE GUIDE
23410250120	KIRSCHNER WIRE 2 X 250 mm
02051000450	CANNULATED DRILL BIT Ø 5 mm
08050000023	DISTAL GUIDE FOR CANNULATED DRILL BIT Ø 5 mm
08050000024	DISTAL GUIDE FOR GRADED DRILL BIT
08040000400	HAMMER
08050000004	NAIL EXTRACTER
08201000006	ARTICULATED HAMMER
08050000002	NAIL DRIVER
08050000001	DSBLS HOLDER-INSERTER
08050000021	SCREW LENGTH GAUGE
08050000022	DISTAL SCREW LENGTH GAUGE

Introduction

A lot different fixation methods are used in problems regarding Tibia bone. As in the other long bones (tubular), Intramedullary locking nail fixation for Tibia too is widespread used in the most recent years as indications are getting expanded.

Nail systems which they function as providing locking in the proximal and distal with the interlocking screws is preferable. However elimination studies of nail and screw breakage problems and of difficulties in placing the distal locking screws (intensive scopy usage) are getting continued.

New nail system searchings are for that ideal intramedullary fixation method has not be able to be developed. New intramedullary locking nail system which can include the advantages of the intramedullary fixation method the most, which its distal locking design is too different and can perform any required function with only one screw in every directions, has been developed for Tibia.

Aims (Need for Development)

- To decrease the numbers of the surgical devices (tool-equipment, instrument) which will be used.
- To be able to insert and extract easily and so to decrease the operation time.
- To be able to perform controlled compression.
- To provide the maximum necessary resistance against to the rotation and angulation (bending)forces.
- To be able to be perform the locking in both ends (proximal and distal) easily as eliminating the need of scopy and guide or decreasing it to the least (to minimize).
- To eliminate the nail migration on the ends (proximal and distal migration).
- To prevent the breakage of the screw and nail.
- To prevent screw removal.
- To prevent translation as the nail being at the single plan (profile) and with the single distal locking screw.
- To provide necessary and possible the most strong fixation (maximum stabilization) on all of the planes.
- To eliminate the need of external fixation, and to perform intramedullary fixation which allows early movement and loading.

Indications

- For all of the Tibia fracture as from 4.5cm distal of Tibia proximal joint surface to 2.5cm proximal of the distal joint surface.
- In the events of malunion or non-union (pseudoarthrosis)
- Osteotomies for shorthening
- Osteotomies for lengthening
- Tumor resection

Features(Definition of the Nail-Design)

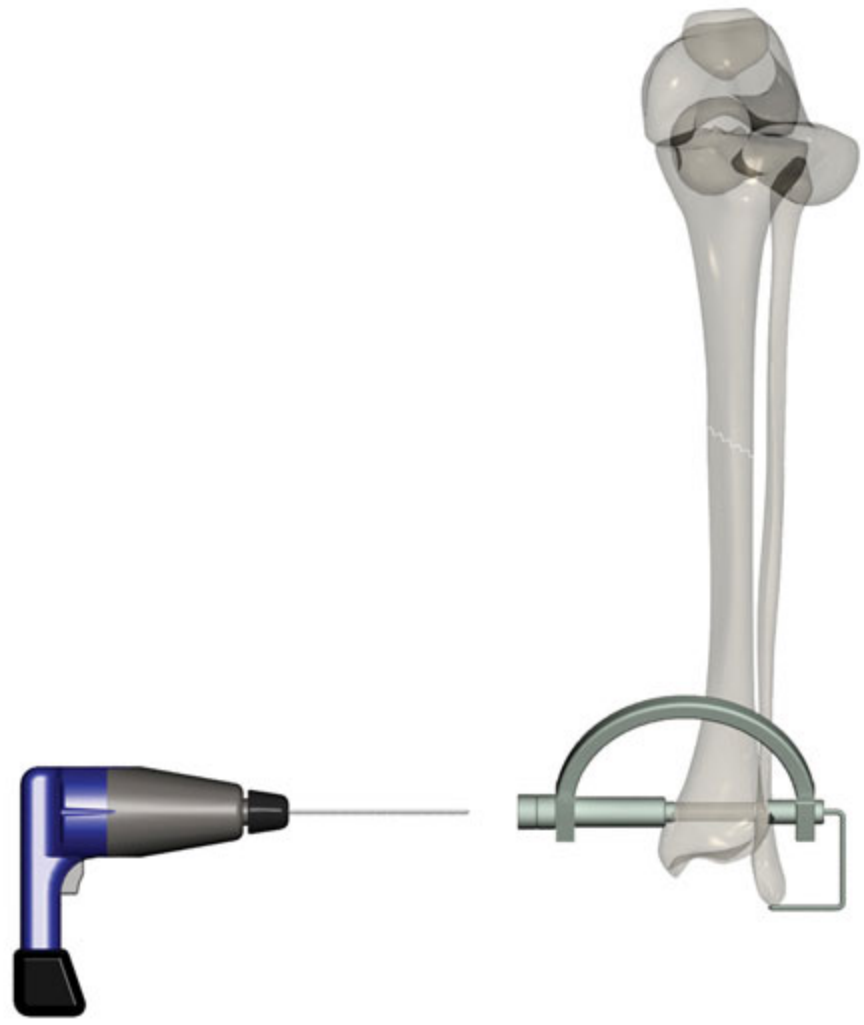
- Solid -Round
- Unreamed – Reamed
- Wedge formed distal end
- Titanium flexibility and biocompatibility
- 4.5cm part as from the proximal has 10mm diameter (for 6-10mm nails), 11mm,12mm,13mm diameter
- Including 3 holes that have 5.3mm diameter and provide locking on multi plans and 1 hole that has 5.3x10mm dimention and allows compression, total are 4 locking holes on the proximal
- There are choices in lengths as 280mm,300mm,……400mm for the diameters 6mm, 7mm, 8mm, 9mm, 10mm of the distal part; as 300-400mm lengths for the diameters 11mm, 12mm of the distal part
- Distal Supportive Bolt Locking Screw (DSBLS)' which is a special design is used for the distal locking.
- The same nail system is used for the left and the right
- **There is no need of usage of scopy or guide for the distal locking (if desired, this option of usage of scopy or guide is applied)**
- Guide is used for the proximal locking
- New, ergonomic and simple driving, extracting and locking system is designed

The differences which are superior to the other nails

- Proximal locking screws which are on different directions provide stability on multi-plane
- Because of that there isn't any distal locking screw hole on the nail, the solid nails which have less diameters can be used as unreamed for tibias which have narrow medulla. Even full loading are delayed as making them internal athel function, early knee and ankle movements can be performed
- Because of that there isn't any distal locking screw hole on the nails which have small diameters, nail breakage complication on the side of the screw hole which can be seen on the classic nails doesn't happen.
- **Due to ' Distal Supportive Bolt Locking Screw (DSBLS);**
  - Distal locking screw breakage and migration of interior of the joint don't exist even on the nails which have small diameters
  - The nail can also be used safely for the breaks till 2.5cm proximal from the distal joint surface
  - Distal locking is provided on all planes, with DSBLS which is placed from a single hole.
  - Maximum resistance to axial loading, rotation, translation and angulation forces is provided with DSBLS (without breakage of nail and screw)
  - No need for scopy and guide for locking with DSBLS. For the fractures which reposition has been provided, when the nail is moved forward from proximal towards distal, it places to DSBLS easily
  - Providing locking with DSBLS can be checked with the setscrew inside it
  - If usage of scopy is preferred, It's exposed to the X-Rays the least time according to the other nail systems

- Two sided graphy of the healthy tibia is taken from 1 meter distance pre-operation.
- The diameter of the narrowest medullar region is measured, the enlargement ratio that is approximately 10 % is subtracted and so the diameter of the nail is determined.
- Tibia bone length is measured between the joint surfaces. The length of the nail is determined as subtracting the enlargement ratio that is approximately 10 % and extra 2cm (The length of the nail is also determined when the distance between the most projected part of the medial malleolar of the healthy tibia and the most projected part of the tuberositas tibia is measured externally).
- Medial-lateral intercortical distance for the length of DSBLS is measured from 2 cm proximal of the distal tibia joint surface on the antero-posterior graphy.
- The nails which have the next smaller and the next bigger diameters and the lengths than the diameter and the length of the measured nail are prepared. If there is no scopy or it won't be used; DSBLS is first placed to the fractured tibia distal of the patient to be operated.
- As holding the foot at neutral (the ankle is neutral at 90 degree and in the way the big toe will look to the ceiling.

The lateral of the guide with C handle is placed to the fibula at 4cm proximal from lateral malleolar end, and medial of it is placed to the tibia medial at the middle line at the 2.5cm prox of the med. mal.



3mm kirschner wire is entered transvers to the ankle joint on the middle line from 2.5cm proximal medial of the most extruded part of the medial malleolar (If desired DSBLS is determined with the distal screw length measuring gauge via kirschner wire and distal kirschner wire guide).

Both cortex is drilled with a drill bit of 5mm via K..wire. (Care is taken for the fibula not to be holed)

Drilling is made, with a special graded length justifier drill bit via K.wire, in the way that lateral cortex will be 5mm, medial cortex will be 8.5mm

DSBLS (Distal Supportiv Bolt Locking Screw) in measured length is placed in the way that the nail placing slot's wider side will look at the proximal.

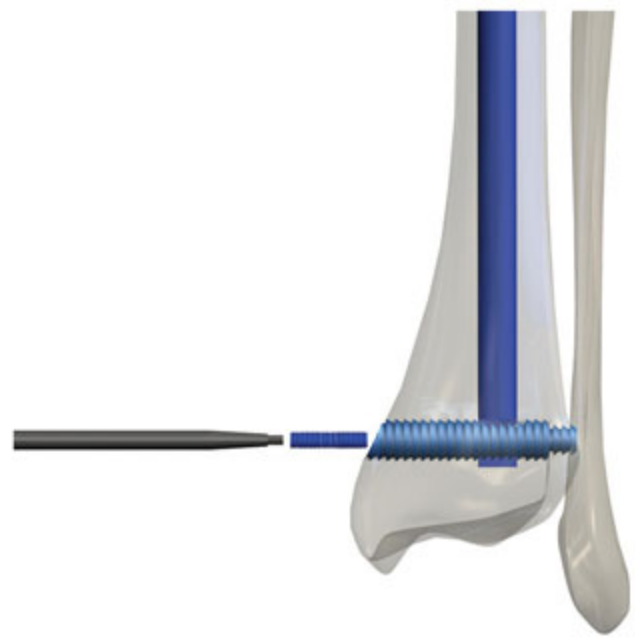
- Standard med parapatellar or anterior 5 cm longitudinal incision is performed on proximal.
- It's reached to tibia medulla from the middle of the anterior intercondylar region (Universal entry point) with an awl or 3mm K.wire. It's moved ahead as expanding the medulla entry hole with a cannulated drill bit via the wire.

P.s.: **If the nail is desired to be used with the reamer system, the diameter of the medulla can be expanded with the reamers**

Previously prepared nail is moved ahead into the distal part by partial rotations by means of its holder-inserter-driver- external guide.

If the reduction has been able to be provided by hand, when the nail is moved ahead, it's moved to the distal fragment. If the reduction hasn't been provided, the nail is inserted to the most possible distal by means of scopy control; if it doesn't happen again, it's done by mini incision following reduction. In the meantime, it's felt or seen that the nail was placed in the DSBLS.
If desired, it's checked with a setscrew that if locking happened or not.
P.s: DSBLS inserter is not used for traction.

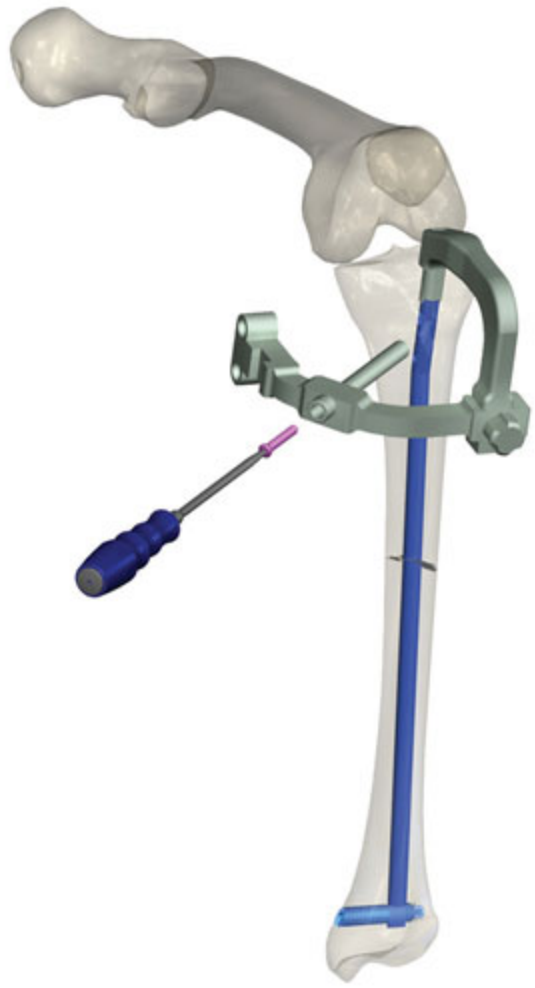
The nail end has been exactly placed to the DSBLS.



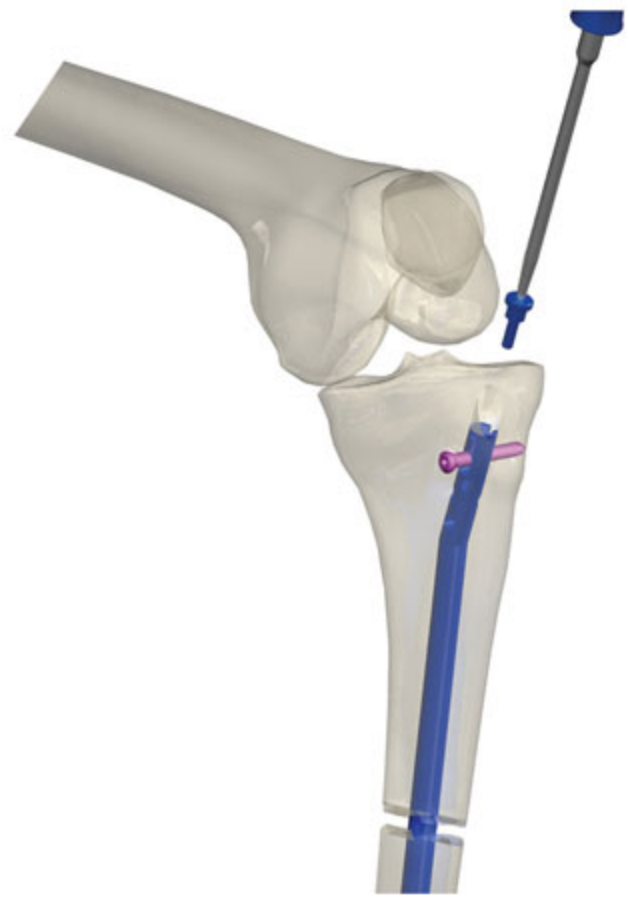
Distal locking is provided with a set screw in suitable length (the length of the set screw=the length of DSBLS-18mm)

Proximal locking can be made easily in any desired way. If primer compression, dynamization or auto-compression are required, the oval hole is used; if static locking is required, round holes are used

After extremity alignment control, proximal locking screws are placed in any desired way and numbers (Inserting screw to the dynamic locking hole)



Inserting screw as oblique (from antero-medial to postero-laterale)



Suitable top screw (neutral,lengthening or compression screw) is placed (placing the top screw which makes compression)

View which compression has been applied

Transverse and oblique static locking has been provided

Locking has been completed on proximal and distal

Post Operation;

- Every kind of bed exercises is started beginning from the time that the patient has regained his/her consciousness after anesthesia.
- The patient gets allowed to walk as suggested the most possible loading (for the patients who the nail with 8mm diameter and with those over that are used on) at the shortest time that his/her general health condition allows this.

If scopy usage is desired;

- After reduction, the nail in suitable diameter and length is inserted till 2cm from proximal.
- Distal end is seen by scopy on lateral plan, Kirchner wire is entered to 1 cm distal from the nail end and parallel to the joint.
- DSBLS is placed via K.wire.
- It's entered in the DSBLS as driving the nail.
- Locking is provided with a setscrew.

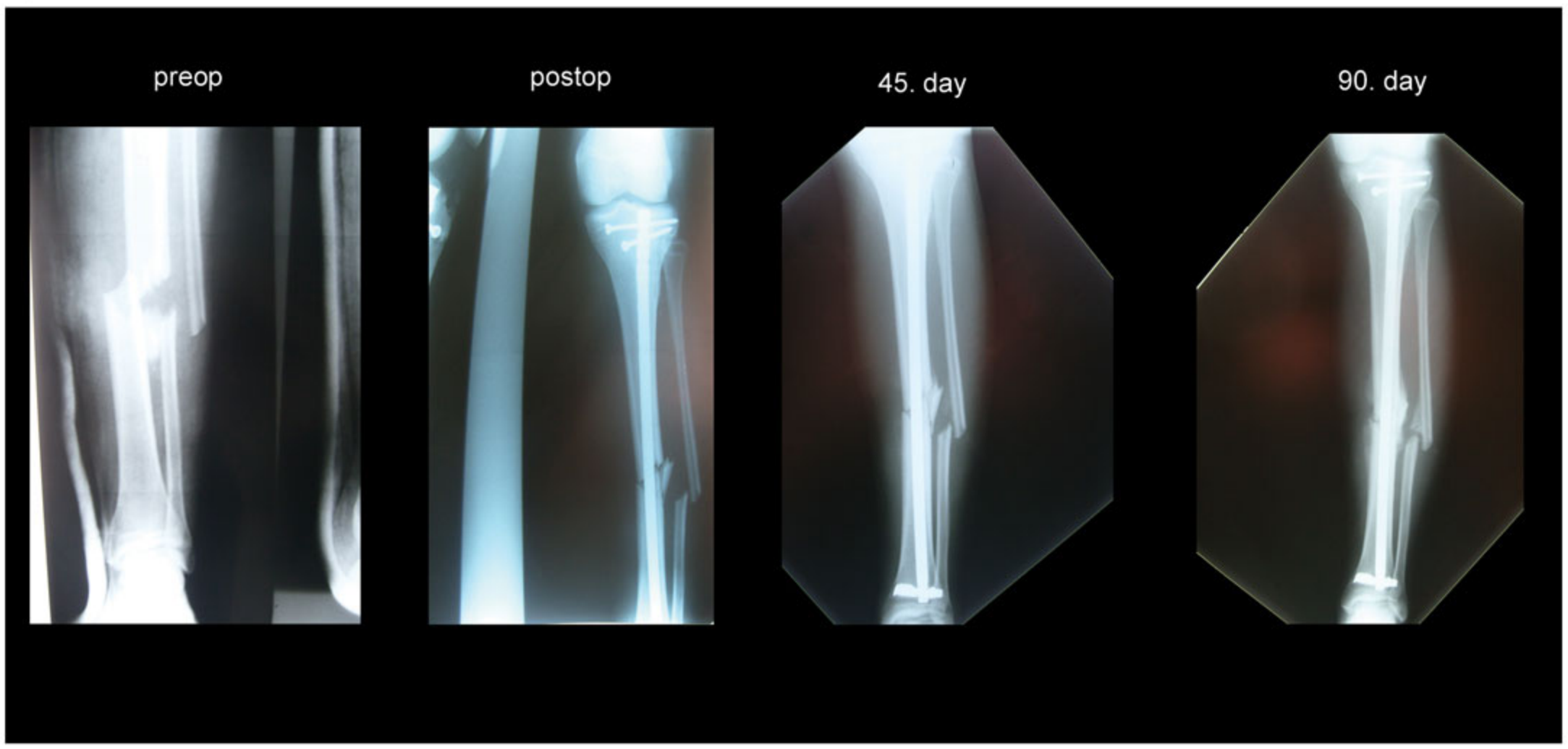
CAUTION!!!

Important notes about surgical technique which is needed to be keept in mind;

- During preparation before operation, Ap-Lat graphy of healthy tibia is definitely taken and;
  - Bone anatomy must be carefully inspected. If extremely narrow medullar canal or extremely anterior bowing exists or not must be checked.
  - The diameter and the length of the nail planned to be placed must be determined.
- Care must be taken for the choice of entry point.
- Nail must be moved ahead by hand till entering to the cortical region from metaphyseal region.
- It shouldn't be forgotten for fragments that medullar opening of the distal main fragment could be closed with pieces or could be narrowed.
- During the nail is directed to the distal, the holder must be checked as thinking that screw loosening could be happened.
- Care must be taken as placing the DSBLS, fibula mustn't be drilled.
- If the nail end is ;
  - Directed to the medial of the DSBLS groove, DSBLS is taken back 2-3mm.
  - Directed to the lateral of the DSBLS groove, DSBLS is moved ahead 2-3mm.
  - Directed to the anterior or posterior of the DSBLS groove, as directing DSBLS reamer from the same medial entry to anterior and posterior, and so a 5mm new hole is opened on lateral and DSBLS is placed in there. (Nail direction can be changed by manipulation for the distal metaphyseal fractures as needed no new hole

Operation X-Ray

I



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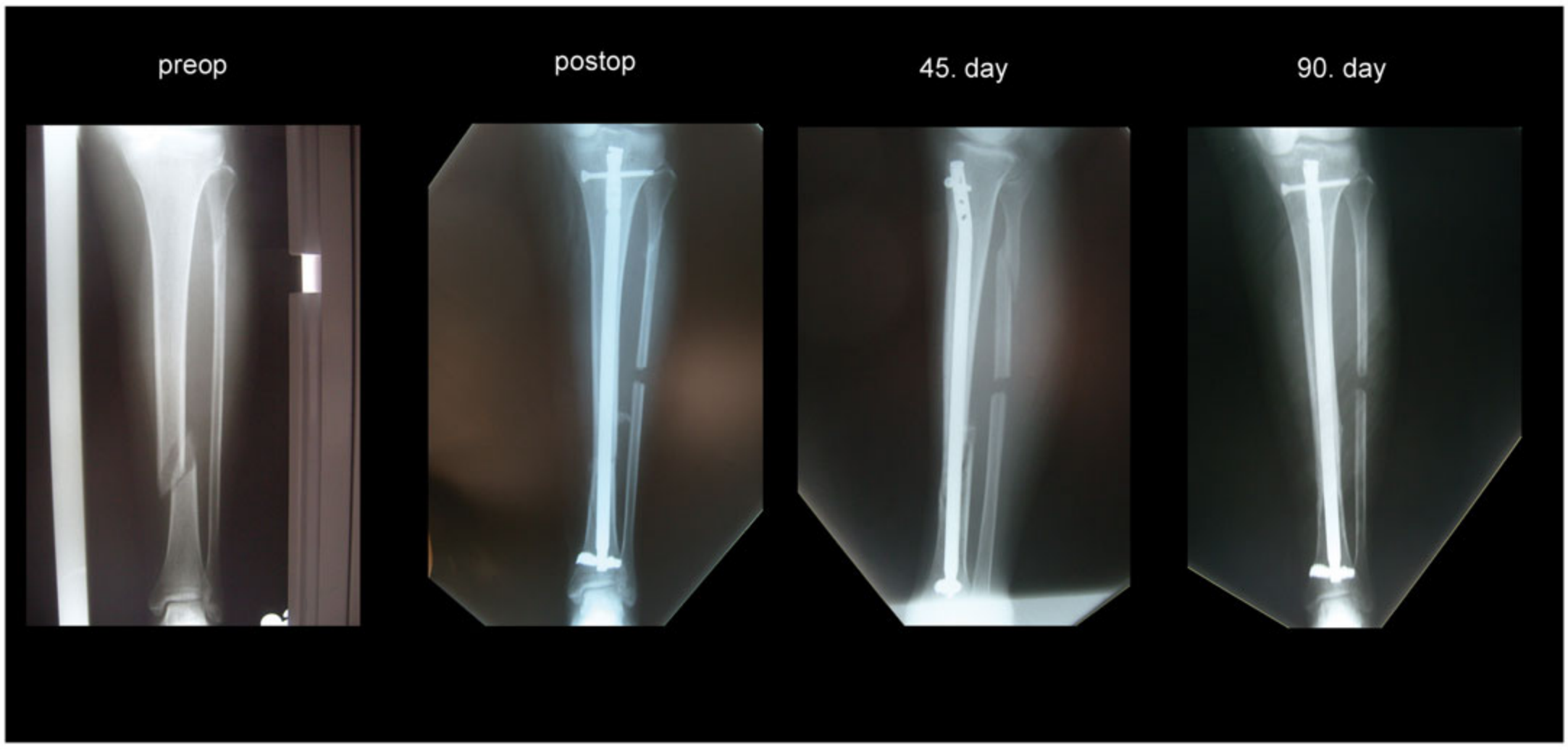

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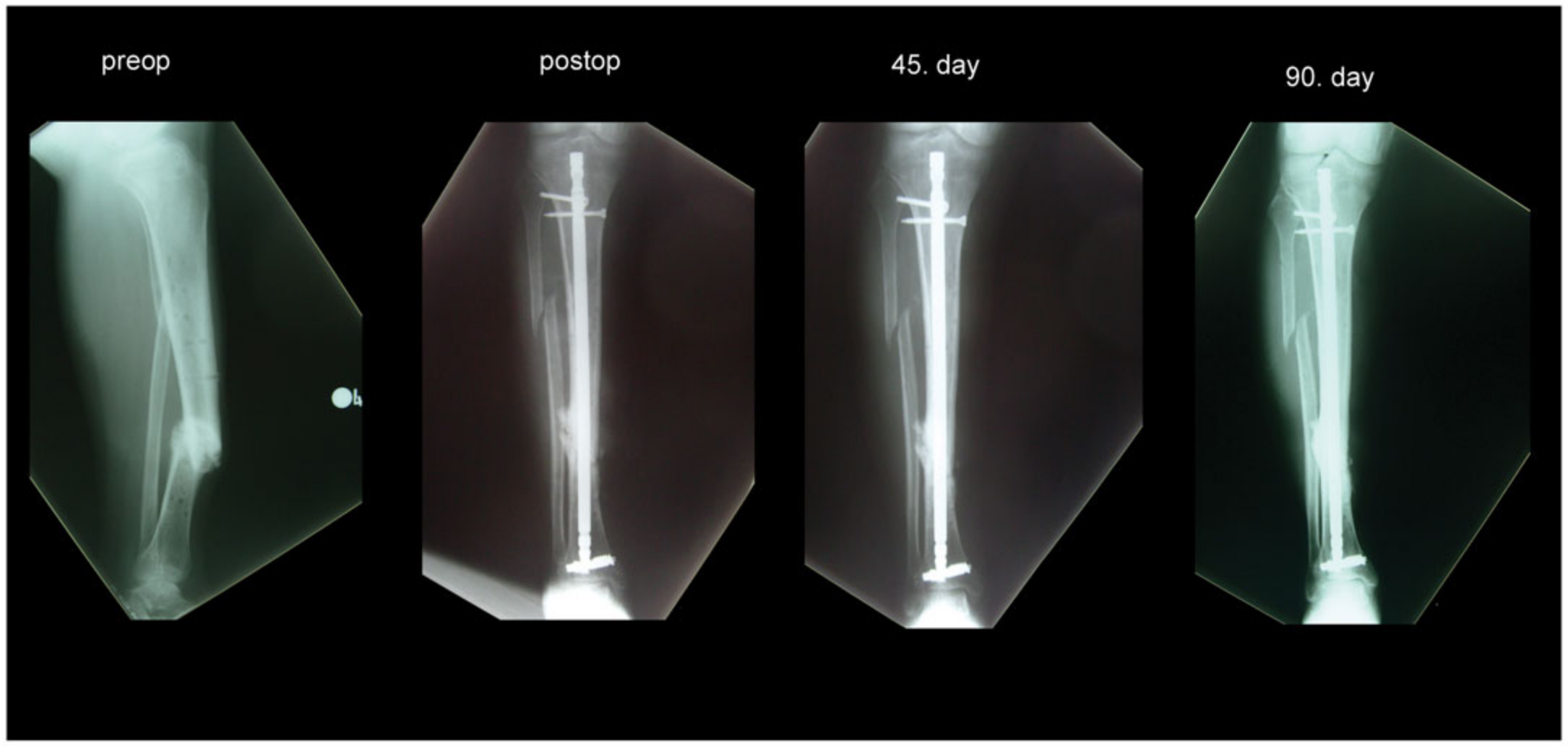

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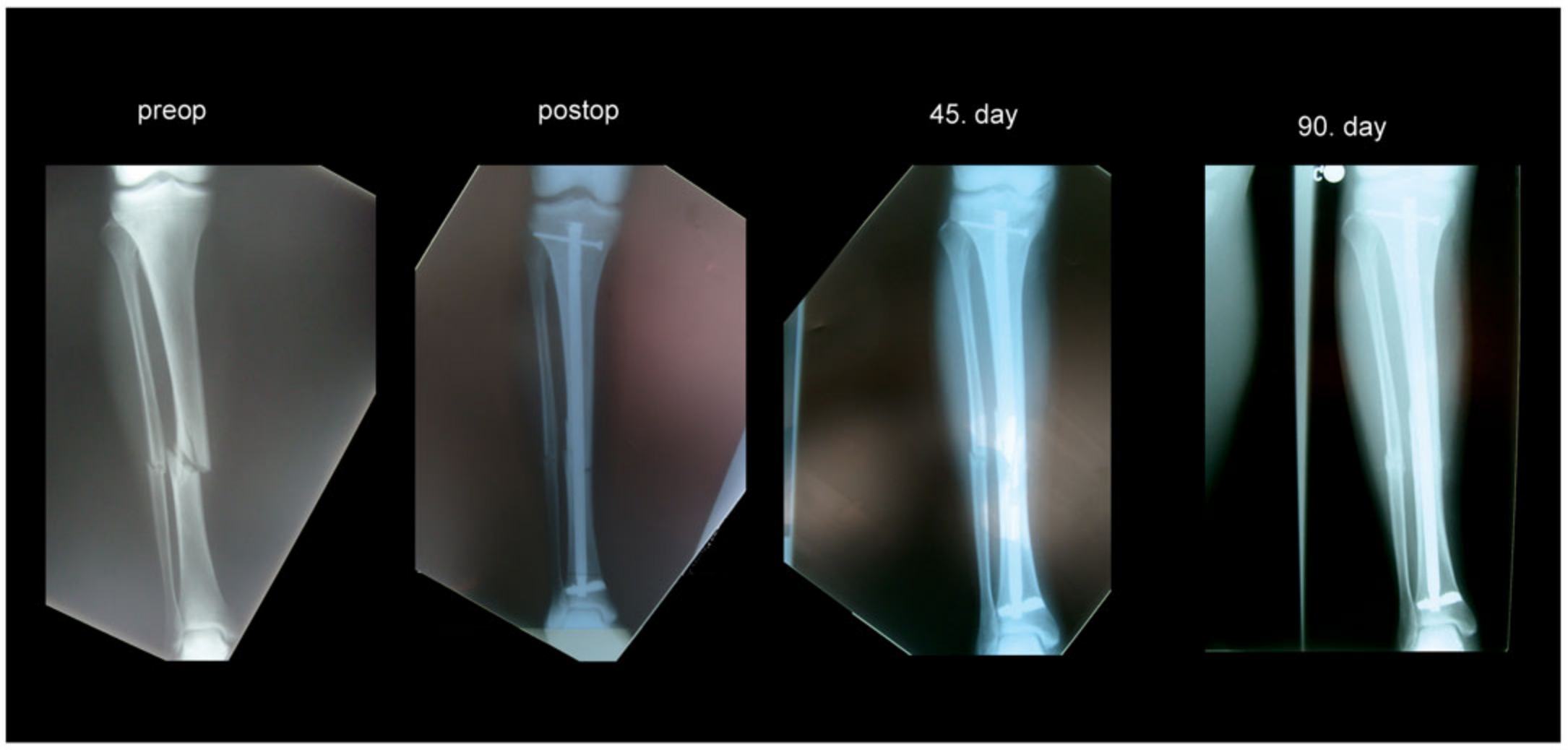
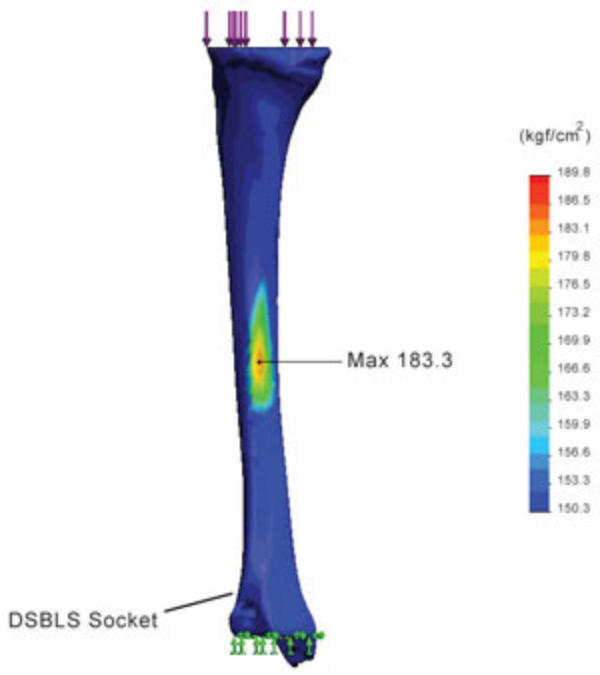


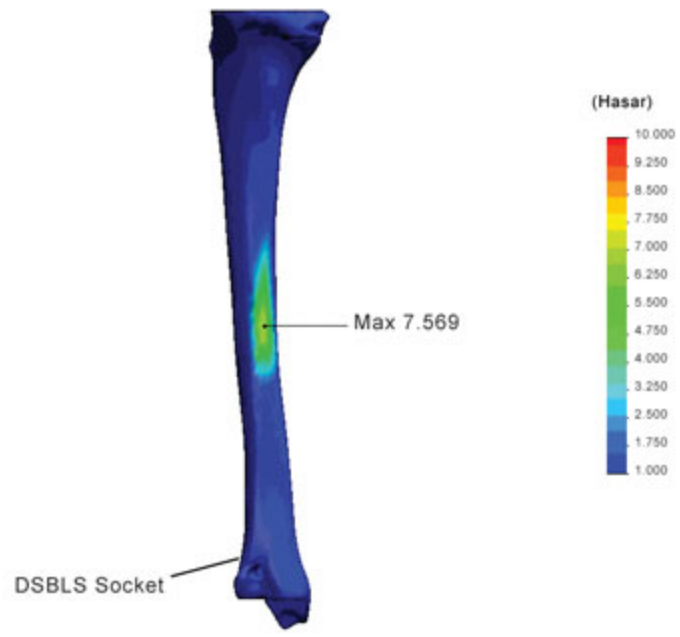
The Analysis of the Tibia

Model: Left Tibia
Type : Static Nodal Stress



Material: Bone (Tibia)
Material Yield Strength : is taken as189.8 kgf/cm2
Max. Loading: 170 kg (1700 N)
Because of that the yield strength at the max. point is 184.3 kgf/cm2, the bone is safe.
The region with the most stress is the dyaphyseal region of the bone as it's seen on the figure.

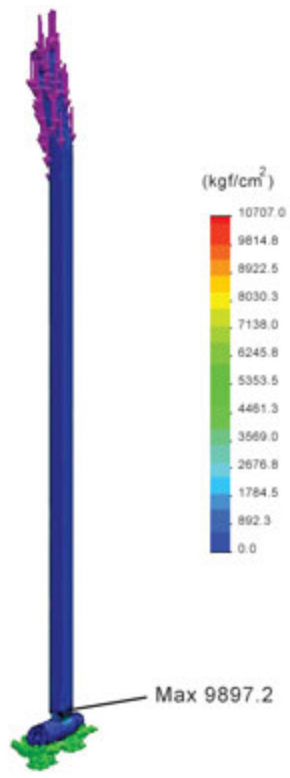
Model: Left Tibia
Type: Static Nodal Stress



Loading : 250 kg (2500N)
Number of cycles : 1.000.000
When this test was applied, region with stress hasn't existed at the DSBLS appling place on distal tibia. Again, diaphyse has been determined as region with the most stress

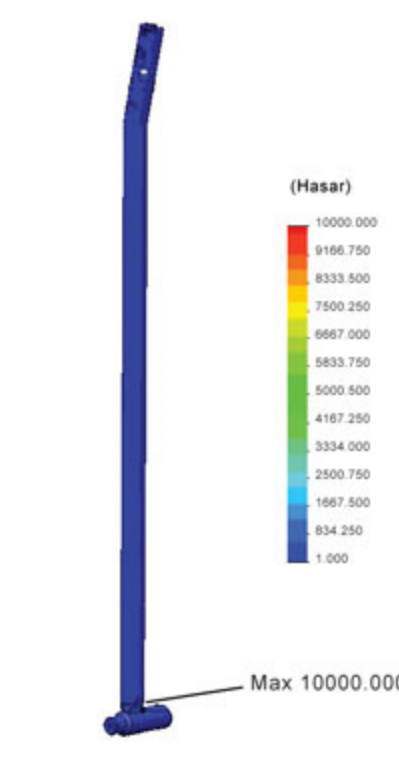
The Analysis of The TIN Nail

Model: Nail of Tibia11x11x320mm
Type: Static Nodal Stress



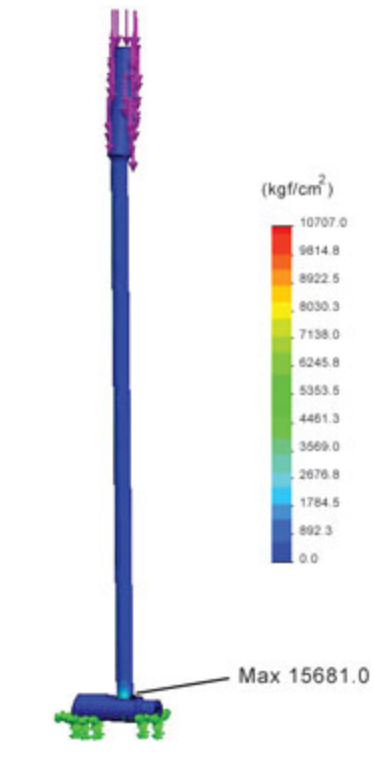
Material: T16Al4V
Material Yield Stress: is taken as10707 kgf/cm2
Max. Loading : 170 kg
Because of that the yield strength at the max. point is 9897.2 kgf/cm2, the TIN nail is safe

Model: Nail of Tibia 11x11x320mm
Type: Fatigue



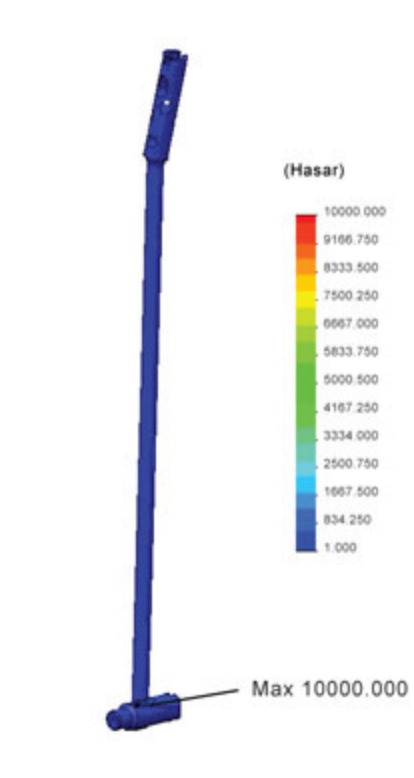
Material: Ti6Al4V
Loading :170 kg (1700N)
Number of Cycles: 1.000.000
When this test was applied, damaged area hasn't existed at the DSBLS appling place on distal tibia

Model: Nail of Tibia 10x7x280mm
Type: Static Nodal Stress



Material: Ti6Al4V
Material Yield Stress: is taken as
10707 kgf/cm2
Max. Loading :102 kg

Model: Nail of Tibia 10x7x280mm
Type: Fatigue



Material: T16Al4V
Loading: 102 kg
Number of Cycles: 1.000.000

Literature

Giri SK. Achieving distal locking without an image intensifier. Nepal Med Coll J. 2007 Dec;9(4):275-7.

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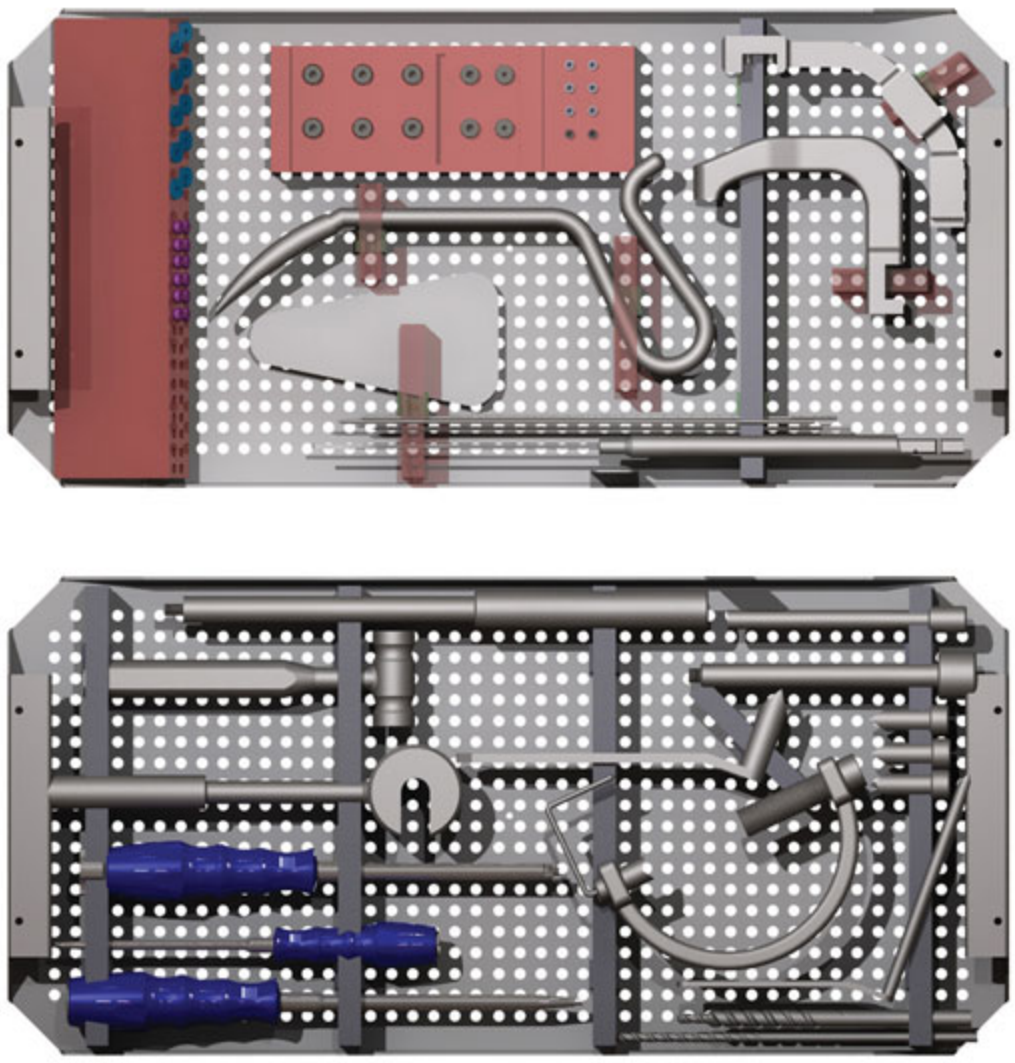

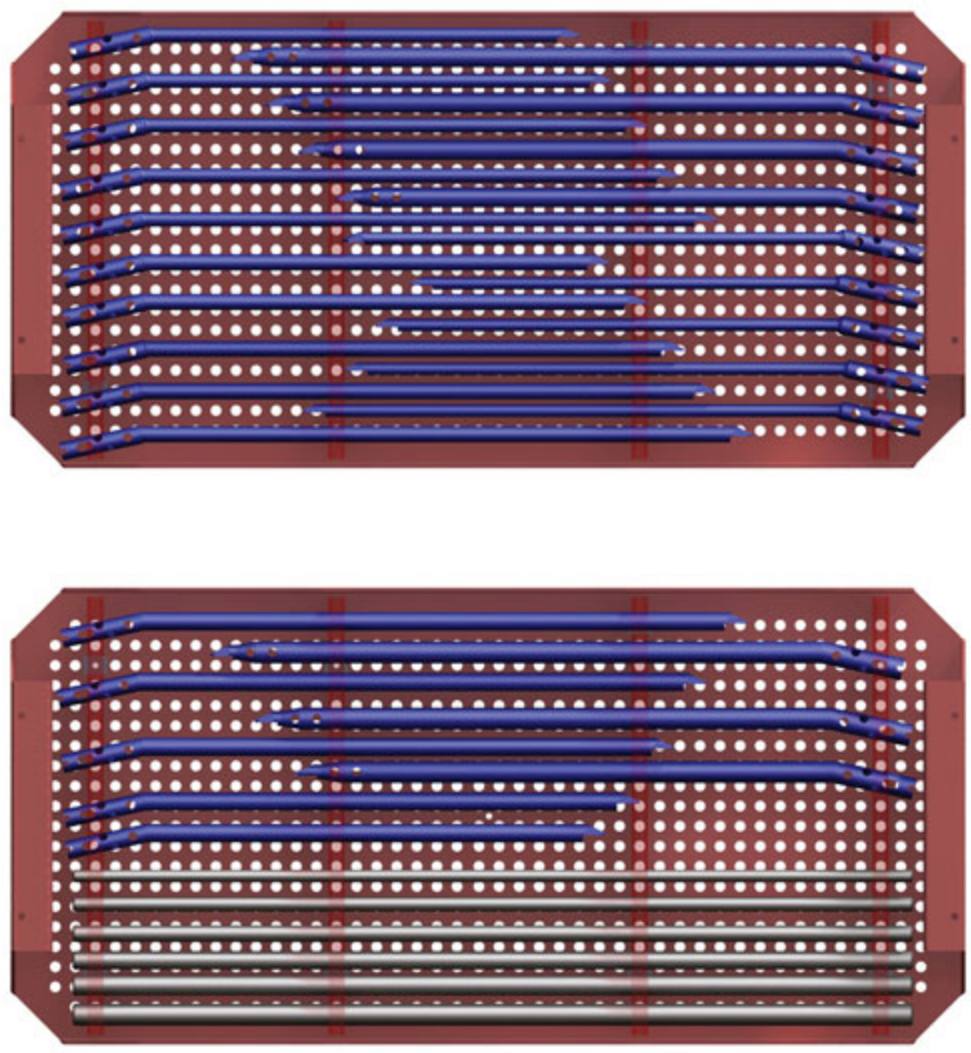

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