ETN 胫骨髓内钉
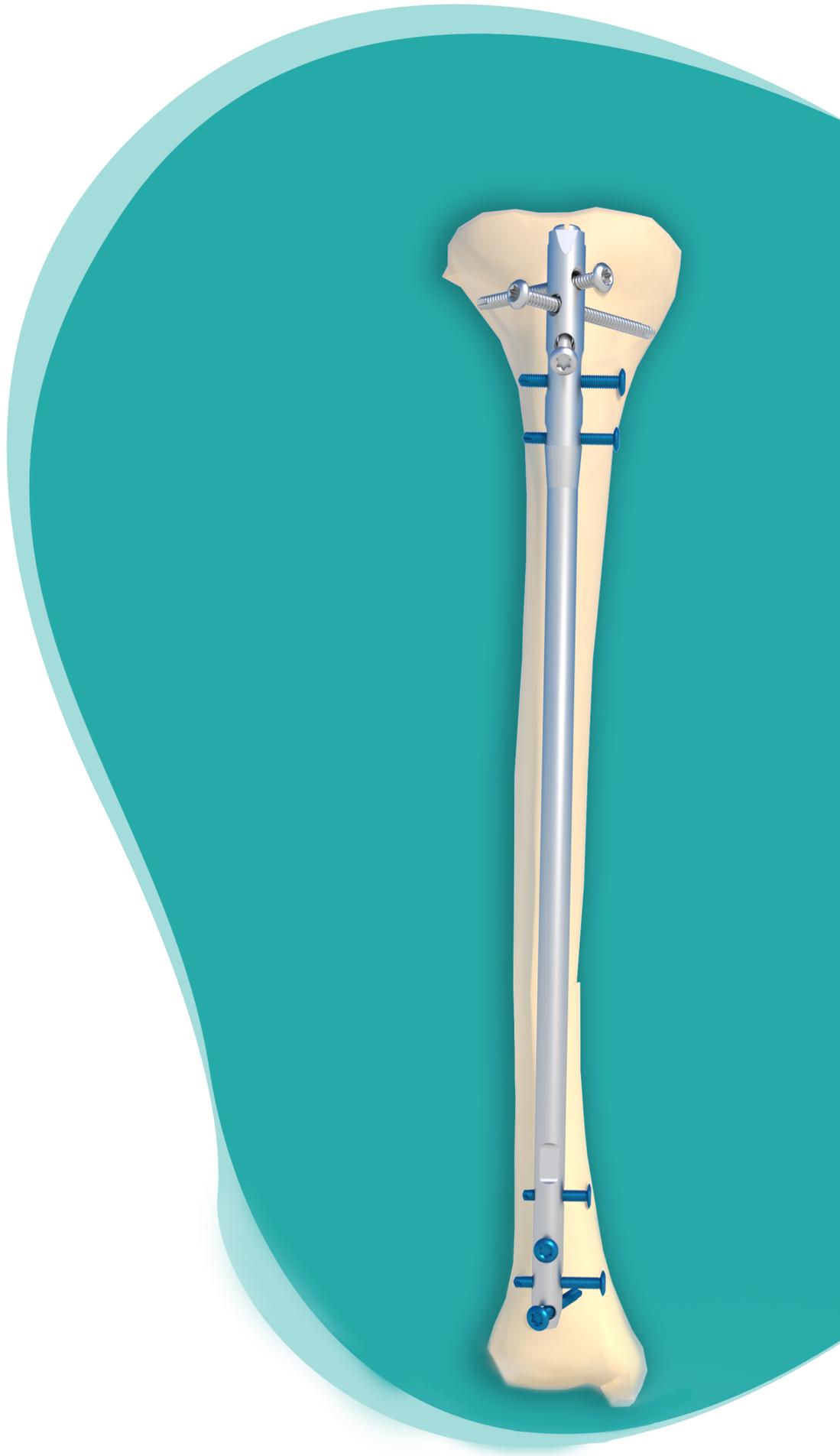
Tibia Intramedullary Nail

Why choose Fule?

Our strengths

- The company is a national high-tech enterprise that integrates research and development,production, and sales of medical devices,with a fully intelligent processing equipment production line.

- The establishment of the Academician Expert Studio helps to enhance the R&D capabilities of Fule and further deepen the cooperation between industry, academia, and research;Approved postdoctoral researchworkstation.

- The hardware facilities are complete, the R&D team is excellent, and we work closely withclinical experts, obtaining more than 100 domestic and foreign patents.

- Based on the agent cooperation model, establish a nationwide sales and service network, supply products to nearly a thousand tertiary hospitals nationwide, and export to more than 20 overseas countries.

CONTENTS

Product advantages

Characteristic

Design features of locking nails

-Double lead thread, more contact points, increased stability, and convenient placement;

-The thread is closer to the screw head, providing better grip near the cortical bone and improving stability;

-Titanium alloy materials improve mechanical and fatigue performance;

-T25 plum blossom head enhances torque transmission and ensures safe grip.
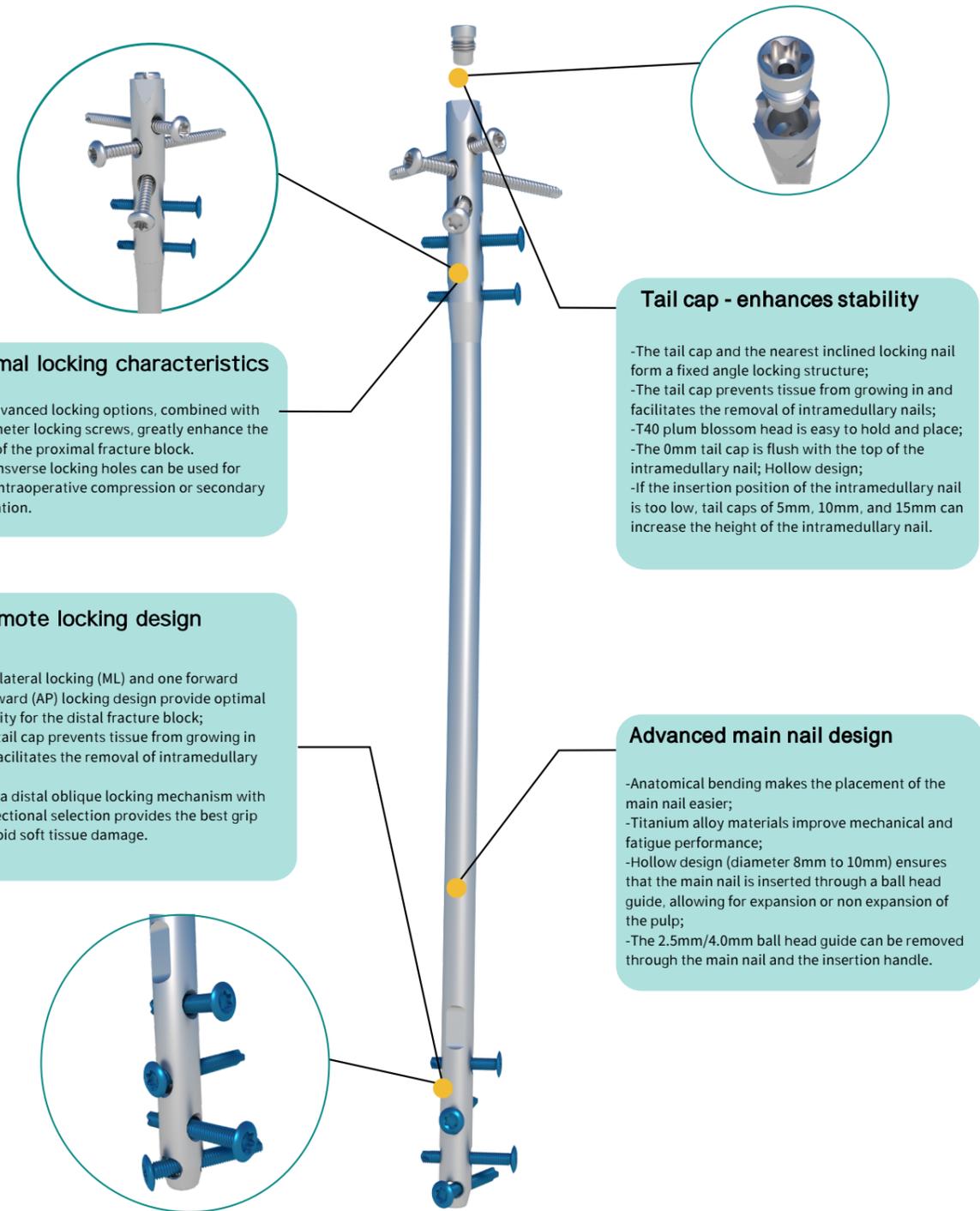
Cancellous bone locking nail

-All ETNs have three unique and innovative trabecular bone locking holes at the proximal end.

-Double diameter design: The smaller diameter provides better grip on trabecular bone, while

 the larger diameter can with stand greater loads.

- Single cortical fixation;

- Length: 25-90mm.

Standard locking nail

-Larger cross-sectional area increases mechanical resistance;

- 4.0mm locking nails are suitable for φ8.5 and φ9mm tibial intramedullary nail, length: 24-80mm;

- 5.0mm locking nails are suitable for φ10mm tibial intramedullary nail, length: 26-100mm.

Proximal locking characteristics

-Three advanced locking options, combined with dual diameter locking screws, greatly enhance the stability of the proximal fracture block.
- Two transverse locking holes can be used for primary intraoperative compression or secondary dynamization.

Remote locking design

-Two lateral locking (ML) and one forward backward (AP) locking design provide optimal stability for the distal fracture block;
-The tail cap prevents tissue from growing in and facilitates the removal of intramedullary nails;
-Aultra distal oblique locking mechanism with bidirectional selection provides the best grip to avoid soft tissue damage.

Tail cap - enhances stability

-The tail cap and the nearest inclined locking nail form a fixed angle locking structure;
-The tail cap prevents tissue from growing in and facilitates the removal of intramedullary nails;
-T40 plum blossom head is easy to hold and place;
-The 0mm tail cap is flush with the top of the intramedullary nail; Hollow design;
-If the insertion position of the intramedullary nail is too low, tail caps of 5mm, 10mm, and 15mm can increase the height of the intramedullary nail.

Advanced main nail design

-Anatomical bending makes the placement of the main nail easier;
-Titanium alloy materials improve mechanical and fatigue performance;
-Hollow design (diameter 8mm to 10mm) ensures that the main nail is inserted through a ball head guide, allowing for expansion or non expansion of the pulp;
-The 2.5mm/4.0mm ball head guide can be removed through the main nail and the insertion handle.

Instructions for use

● 【Indications】

Stable proximal, distal, and tibial shaft fractures, open and closed tibial shaft fractures, tibial malunion and non union.

—— 41-A2/A3

—— All diaphyseal fractures

—— 43-A1/A2/A3

—— Composite fractures in the above three situations

The treatment of the following types of fractures requires ETN combined with other implants (not indicated in the figure).

- 41-C1/C2

- 43-C1/C2

Attention: In cases of pseudarthrosis, tumor formation, malunion, and non union, it is recommended to use larger diameter hollow intramedullary nails combined with medullary expansion techniques to provide stronger stability.

Surgical procedure

【Step1】   Reduction of the fracture

● Use closed reduction technique, apply traction, external fixation frame or percutaneous reduction forceps for temporary fixation. Platform fractures or Pilon fractures should be first reduced and fixed.

Surgical procedure

【Step2】 Patient Position

- The patient is lying supine on a surgical bed with X-ray transparency, ensuring that the knee joint flexion is at least 90 ° to 100 °. Place the image enhancer in an appropriate position to facilitate anteroposterior and lateral fluoroscopy of the joint surfaces of the proximal and distal tibia.

Attention: The knee joint support pad can be placed slightly distal to the affected thigh to avoid obstruction of the support pad to the tibial plateau during orthopedic fluoroscopy.
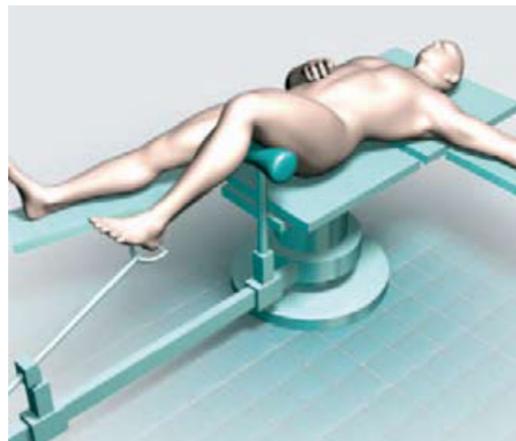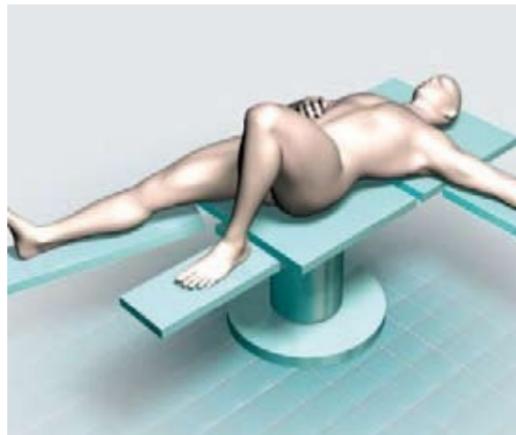
Figure 2a

Surgical procedure

【Step3】 Determine the nail insertion point

- The incision is located on the axis of the medullary cavity (Figure 3a).

- The insertion point determines the final position of the intramedullary nail in the medullary cavity, which is very important (Figure 3b).

- On the anteroposterior view, the insertion point is located on the line connecting the medullary cavity axis and the lateral tuberosity of the intercondylar protrusion.

- On the lateral view, the insertion point is located at the anterior edge of the tibial plateau.
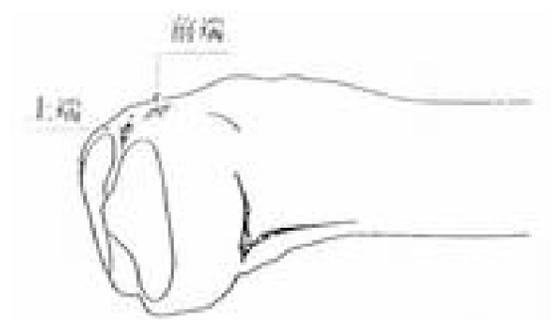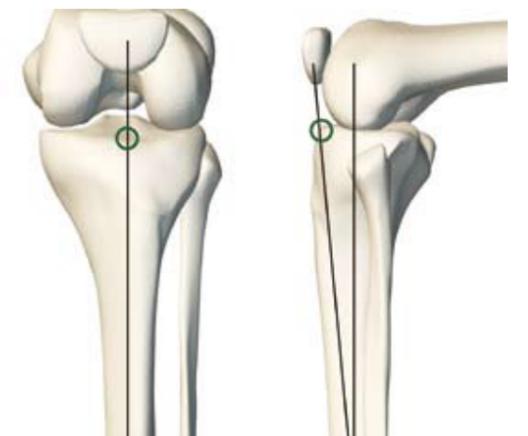
Figure 3a

Figure 3b

Surgical procedure

Surgical procedure

【Step4】   Insert guide pin

【Step5】   Open the medullary cavity

- Use the guide pin holder to hold the threaded guide pin and gently tap it, mark the insertion point, and insert the guide pin. On the lateral film, the guide needle forms a 10 ° angle with the axis of the tibial shaft.

Figure 4a

- The hollow hole opener opens the medullary cavity through a threaded guide needle 8-10mm. Skincare boards provide protection for soft tissues (Figure 5a).

Figure 5a

- Alternatively, use a quick change handle to connect the proximal reamer through a threaded guide and protective sleeve to open the medullary cavity (Figure 5b).

Figure 5b

Surgical procedure

【Step6】 Reduction of the fracture

- Insert the reduction rod towards the distal end of the medullary cavity to reduce the fracture. Connect the ball head guide to the guide holder, allowing the ball head guide to enter the medullary cavity through the resetting rod. Once the guide pin is in place, remove the guide pin holder in order to remove the reset rod.

Figure 6a

Surgical procedure

【Step7】 Medullary cavity preparation

- The preparation of the medullary cavity is determined before surgery. If using the technique of expanding the medullary cavity, the soft expanding blade can be sequentially connected to the soft expanding guide rod from small to large starting from 7.5mm, and the medullary cavity can be expanded through a ball head guide needle, increasing by 0.5mm each time until the desired diameter is reached. You can also choose to use a pulp expander to gradually expand the pulp from small to large. The diameter of the expanded pulp should exceed the diameter of the intramedullary nail by 0.5-1mm.

Figure 7a

- Advance and retreat must be clockwise.

Surgical procedure

Surgical procedure

【Step8】 Implantation of intramedullary nails

- Assembly of intramedullary nails:

  Connect the handle and bolts to the

  intramedullary nail through a bolt

  wrench. Ensure that the connecting

  bolts tightly bite the intramedullary nail.

Figure 8a

【Step9】 Implantation of intramedullary nails

- Slowly insert the intramedullary nail along the ball head guide needle, and observe the progress of the nail with an image enhancer. Ideally, gently insert without any obstruction sensation. If you feel a slight obstruction, fix the main pin pull-out connector on the handle and gently tap it with a sliding hammer. If greater force is required for insertion, connect the sliding hammer guide rod to the main pin pull-out connector and tighten it with an open-ended wrench or a small wrench.

The sliding hammer technique can further penetrate the intramedullary nail into the medullary cavity. If further placement is not possible, a suitable intramedullary nail should be selected and the above operation should be repeated. After confirming the position, remove the ball head guide pin.

Figure 9a

Attention: The scale on the handle is 5mm apart, corresponding to the specifications of the tail plug. This design feature is used to adjust the over insertion depth of intramedullary nails and correct the length of intramedullary nails. If the plan is for initial compression or later motorization, it is recommended that the depth of intramedullary nail over insertion exceed 7mm, which is consistent with the design of the locking nail sliding hole.

Surgical procedure

Surgical procedure

【Step10】 Install positioning rod for remote positioning

- Install the long guide rod and lock it with bolts (Figure 10a)

- Make all openings under the guide drill sleeve, bluntly separate and reach the bone cortex, without damaging nerves and blood vessels. Insert the soft tissue separator into the guide sleeve and push the soft tissue separator until it reaches the surface of the tibia. Then remove the soft tissue separator and use a positioning rod bone drill to drill holes in the tibia. When the bone drill comes into contact with the intramedullary nail, stop drilling and immediately use a positioning rod flat head drill to clean the bone debris on the surface of the intramedullary nail, without damaging the surface of the intramedullary nail (Figure 10b).

Figure 10a

Figure 10b

【Step11】 Positioning rod positioning

- Take out the positioning rod flat head drill and the positioning rod drill sleeve. Insert the positioning rod and install the positioning block on the guide rod.

Figure 11a

Surgical procedure

【Step12】 Remote vertical hole locking or temporary fixation

- Make all openings under the outer sheath, bluntly separate and reach the bone cortex, without damaging nerves and blood vessels. Insert the guide sleeve and soft tissue separator into the outer sheath, and push the soft tissue separator until it reaches the surface of the tibia (Figure 12a).

Figure 12a

Figure 12b

- Drill the tibia with a 3.2mm or 4.0mm drill bit, when the diameter of the main nail is Φ At 10 o'clock, use a 4.0mm drill bit, otherwise use a 3.2mm drill bit. When drilling, use a limiter to control the depth of the drill bit (Figure 12b).

Surgical procedure

【Step13】 Remote vertical hole locking or temporary fixation

- Depth measurement: Remove the drill bit and guide sleeve, and use a depth gauge to determine the specifications of the interlocking nail.

Figure 13a

- Implantation of interlocking screws: Use a ring wrench to insert the interlocking nail corresponding to the diameter of the main nail. When the diameter of the main nail is 10mm, use a 5.0mm interlocking nail. When the diameter of the main nail is 8.5 or 9, use a 4.0mm interlocking nail (Figure 13a).

Surgical procedure

【Step14】 Remote vertical hole locking or temporary fixation

- Temporary fixation, temporary fixation can be performed according to surgical conditions. After removing the guide drill sleeve, insert a right angle positioning pin with two specifications of 3.2 and 4.0mm, and use the same as above.

Figure 14a

Surgical procedure

【Step15】 Ultra remote locking

- Installation of aiming frame: The long guide rod is engraved with the indicator letter A, locate the instrument with the letter A engraved on the far end aiming frame, install it on the long guide rod, and fix it with bolts (Figure 15a).

Figure 15a

- Implantation of bilateral locking nails: Following the above steps, perform blunt separation of soft tissue, drill holes (using a diameter corresponding to the main nail specification, and use a 4.0 drill bit when the main nail diameter is 10mm), measure depth, and implant interlocking nails (Figure 15b).
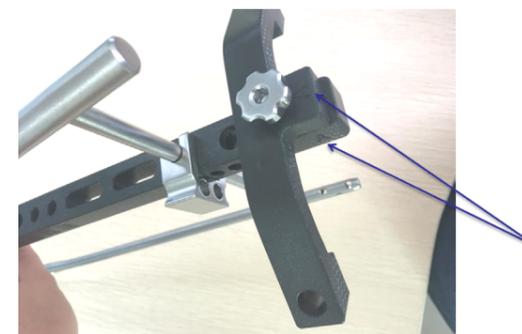

Figure 15b

Surgical procedure

【Step16】 Remote locking

- Installation of aiming frame: Use instruments with the letter B to install them in the position where the letter B is engraved on the long guide rod, and fix them with bolts (Figure 16a).

Figure 16a

- Implantation of locking nails: Following the above steps, perform blunt separation of soft tissues, drill holes (using a diameter corresponding to the main nail specification, and use a 4.0 drill bit when the main nail diameter is 10mm), measure depth, and implant interlocking nails (Figure 16b).

Figure 16b

Surgical procedure

【Step17】 Proximal locking

- Install the near end aiming frame with the identification letter C, and place it on the handlebar with the letter C engraved on it. Tighten and secure it with bolts. Place the protective sheath and guide drill sleeve into the aiming frame, and use a soft tissue separator to separate the soft tissue.

Figure 17a

Surgical procedure

【Step18】 Proximal locking

- Drilling: Use a 4.0mm drill bit to drill holes (Figure 18a);

- Depth measurement and implantation of 5.0mm interlocking nails (Figure 18b).

Figure 18a

Figure 18b

【Step19】 Proximal locking

- Compression: If it is necessary to apply pressure to the fracture line, a compression bolt can be screwed in from the handle for compression, as shown in the figure on the right. After the compression is completed, follow the above operation to complete the implantation of another screw.

Figure 19a

Surgical procedure

【Step20】 Proximal locking

- Drilling: Use a 4.0mm drill bit to drill holes (Figure 20a);

- Depth measurement and implantation of 5.0mm interlocking nails (Figure 20b).

Figure 20a

Figure 20b

Surgical procedure

【Step21】 Proximal trabecular bone locking

- Install the proximal cancellous bone aiming frame: Remove the proximal aiming frame, insert the proximal cancellous bone aiming frame into the handle, mark the frame with the letter D, and tighten it with bolts (Figure 21a).

Figure 21a

- Insert the cancellous bone screw sleeve assembly: Use a guide drill sleeve to insert it into the aiming frame guide hole (Figure 21b).

Figure 21b

Surgical procedure

Surgical procedure

【Step22】　　　Proximal trabecular bone locking

- Drilling: Use a 3.2mm drill bit to drill holes and follow the above steps for depth measurement. Implant 5.0 cancellous bone screws for operation (Figure 22a).

- Follow the above steps to implant the remaining 2 positions of cancellous bone screws.

Figure 22a

【Step23】　　　Implantation of tail cap

- Remove the proximal cancellous bone sight frame, connecting bolts, and handle. Hold the tail cap with a plum blossom holding rod and insert it into the proximal end of the intramedullary nail. Rotate the tail plug counterclockwise until its thread aligns with the thread of the intramedullary nail to avoid misalignment. Rotate clockwise, screw the tail plug into the intramedullary nail two to three turns, remove the tail cap and plum blossom holding rod, and use a T-shaped wrench or straight plum blossom screwdriver to lock the tail cap.

Surgical procedure

Product information

【Step24】 Implant removal

- Postoperative treatment: Within 40 days after surgery, joints can be moved and functional exercises can be performed, but weight-bearing is not allowed. After 4 weeks of surgery, X-rays showed continuous callus growth in the fracture, and the patient's limbs were raised in an extended position without pain. Only then can partial weight-bearing be carried under the protection of the stent. Complete weight-bearing should only be performed after postoperative X-ray shows bone healing.

Figure 24a

- Remove the locking pin and tail plug: Remove the growing tissue from the holding groove of the locking pin and tail plug, use a locking pin wrench to remove the locking pin, and use a T-shaped wrench to remove the tail plug (Figure 24a).

Remove the intramedullary nail: Use the main nail to remove the connecting rod and screw it into the intramedullary nail. Connect the slide hammer guide rod (or directly use the slide hammer guide rod) and gently tap the slide hammer back to remove the intramedullary nail.

● 【Intramedullary nail I】

Product Code	Diameter	Length	Code	Diameter	Length	Code	Diameter	Length
9211085260	Φ8.5	255	9211090260	Φ9	255	9211010260	Φ10	255
9212085270	Φ8.5	270	9212090270	Φ9	270	9212010270	Φ10	270
9211085290	Φ8.5	285	9211090290	Φ9	285	9211010290	Φ10	285
9212085300	Φ8.5	300	9212090300	Φ9	300	9212010300	Φ10	300
9211085320	Φ8.5	315	9211090320	Φ9	315	9211010320	Φ10	315
9212085330	Φ8.5	330	9212090330	Φ9	330	9212010330	Φ10	330
9211085350	Φ8.5	345	9211090350	Φ9	345	9211010350	Φ10	345
9212085360	Φ8.5	360	9212090360	Φ9	360	9212010360	Φ10	360
9211085380	Φ8.5	375	9211090380	Φ9	375	9211010380	Φ10	375
9212085390	Φ8.5	390	9212090390	Φ9	390	9212010390	Φ10	390
9211085410	Φ8.5	405	9211090410	Φ9	405	9211010410	Φ10	405

● 【Titanium bone screws (single thread)】

Product Code	specifications	Code	specifications	Code	specifications	Code	specifications
3532040024	Φ4.0×24	3532040040	Φ4.0×40	3532040056	Φ4.0×56	3532040072	Φ4.0×72
3532040026	Φ4.0×26	3532040042	Φ4.0×42	3532040058	Φ4.0×58	3532040074	Φ4.0×74
3532040028	Φ4.0×28	3532040044	Φ4.0×44	3532040060	Φ4.0×60	3532040076	Φ4.0×76
3532040030	Φ4.0×30	3532040046	Φ4.0×46	3532040062	Φ4.0×62	3532040078	Φ4.0×78
3532040032	Φ4.0×32	3532040048	Φ4.0×48	3532040064	Φ4.0×64	3532040080	Φ4.0×80
3532040034	Φ4.0×34	3532040050	Φ4.0×50	3532040066	Φ4.0×66		
3532040036	Φ4.0×36	3532040052	Φ4.0×52	3532040068	Φ4.0×68		
3532040038	Φ4.0×38	3532040054	Φ4.0×54	3532040070	Φ4.0×70		

● 【LHC Hollow screw】

Code	specifications	Remarks
3144035018	0 extend	Φ3.5×18

Product information

● 【Titanium bone screws (single thread)】

Code	Specifications	Code	Specifications	Code	Specifications	Code	Specifications
3533050024	Φ5.0×24	3533050042	Φ5.0×42	3533050060	Φ5.0×60	3533050078	Φ5.0×78
3533050026	Φ5.0×26	3533050044	Φ5.0×44	3533050062	Φ5.0×62	3533050080	Φ5.0×80
3533050028	Φ5.0×28	3533050046	Φ5.0×46	3533050064	Φ5.0×64	3533050085	Φ5.0×85
3533050030	Φ5.0×30	3533050048	Φ5.0×48	3533050066	Φ5.0×66	3533050090	Φ5.0×90
3533050032	Φ5.0×32	3533050050	Φ5.0×50	3533050068	Φ5.0×68	3533050095	Φ5.0×95
3533050034	Φ5.0×34	3533050052	Φ5.0×52	3533050070	Φ5.0×70	3533050100	Φ5.0×100
3533050036	Φ5.0×36	3533050054	Φ5.0×54	3533050072	Φ5.0×72		
3533050038	Φ5.0×38	3533050056	Φ5.0×56	3533050074	Φ5.0×74		
3533050040	Φ5.0×40	3533050058	Φ5.0×58	3533050076	Φ5.0×76		

● 【Interlocking screw III（φ5.0）】

Code	Specifications	Code	Specifications	Code	Specifications	Code	Specifications
9210050025	Φ5.0×25	9210050045	Φ5.0×45	9210050065	Φ5.0×65	9210050085	Φ5.0×85
9210050030	Φ5.0×30	9210050050	Φ5.0×50	9210050070	Φ5.0×70	9210050090	Φ5.0×90
9210050035	Φ5.0×35	9210050055	Φ5.0×55	9210050075	Φ5.0×75		
9210050040	Φ5.0×40	9210050060	Φ5.0×60	9210050080	Φ5.0×80		

● 【LHC Hollow screw】

Code	Specifications	Remarks	Code	Specifications	Remarks
3144035012	0	Φ3.5×12	3144035017	5	Φ3.5×17
3144035022	10	Φ3.5×22	3144035027	15	Φ3.5×27

Tool information

● 414-270
Template（Ⅰ）
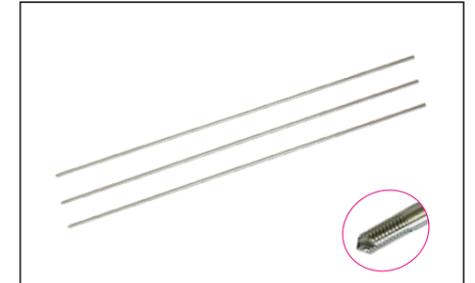
● 414-280
Bone positioning needle (threaded)

● 414-290
Puller (guide pin II)

● 414-300
Guide drill (III)

● 414-310
Bone chisel (opening)

● 414-320
Open cone

● 414-330
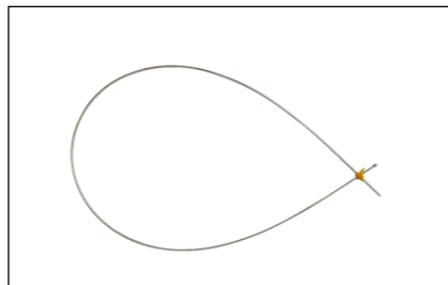Enlarged medullary cavity drill (proximal II)
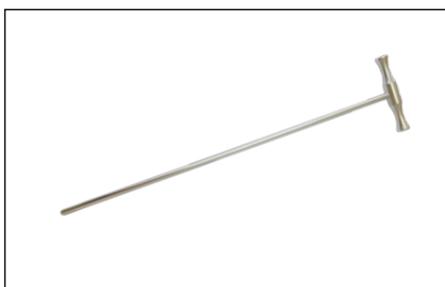

● 425-210
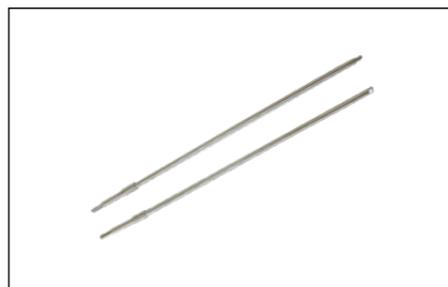Quick fit handle (T-shaped)

Tool information

Tool information

● 414-350
Bone distractor (small)

● 425-010
Bone guide needle (ball head)

● 414-440
Orthopedic wrench (connecting bolt)

● 414-450
Puller (connection block)

● 414-370
Bone pry

● 414-380
Flexible pulp expander (unidirectional II)

● 414-460
Puller (connecting rod)

● 414-470
Orthopedic wrench (open end)

● 414-390~392
Marrow cavity reamer (I)

● 414-400~406
Marrow cavity reamer (II)
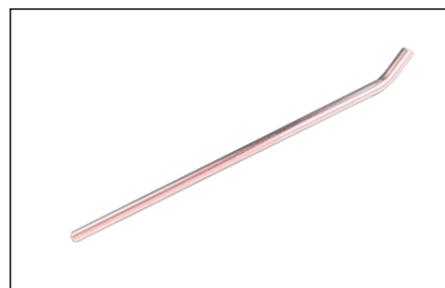
● 425-610
Orthopedic wrench (rod type)

● 414-490
Puller (slide hammer I)

● 414-420
Quick connecting rod (handle)

● 425-361
Bone hammer

● 414-511
Quick connecting rod (sight lock wheel)

● 425-580
Orthopedic wrench (hexagonal)
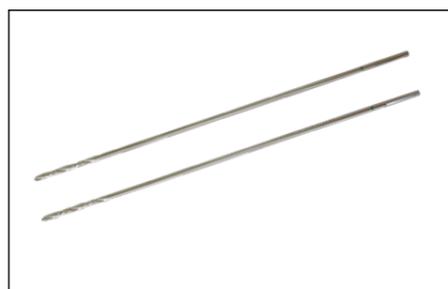
Tool information

● 414-530
Sheath (I)

● 414-540/560
Sheath （II）

● 414-550
Bone cone

● 425-080
Orthopedic drill bits

● 425-090
Orthopedic drill bit (limiter)

● 425-140
Orthopedic drill bits

● 425-170
Orthopedic drill bit (flat head)

● 425-100
Orthopedic wrench (hexagonal))

Tool information

● 414-660
Sounder (II)

● 414-670
Bone positioning needle (right angle)

● 414-671
Bone positioning needle (right angle)

● 414-680
Orthopedic wrench (handle locking II)

● 414-690
Orthopedic wrench (plum blossom quick change)

● 414-710
Orthopedic wrench (plum blossom)

● 414-720
Orthopedic drill bits (versatile)

● 414-780
Quick connecting rod (pressurized)

Tool information

● 414-790
Orthopedic wrench (hexagonal universal joint)

● 414-800
Orthopedic gripper

● 414-821
Orthopedic positioning frame (handle)

● 414-822
Orthopedic positioning frame

● 414-823
Orthopedic positioning frame (remote sight I)

● 414-824
Orthopedic positioning frame (ultra distal)

● 414-827
Orthopedic positioning frame (proximal sight I)

● 414-828
Orthopedic positioning frame (proximal cancellous bone)

Tool information

● 414-825
Orthopedic positioning frame (positioning needle)

● 414-826
Orthopedic positioning frame (locator I)