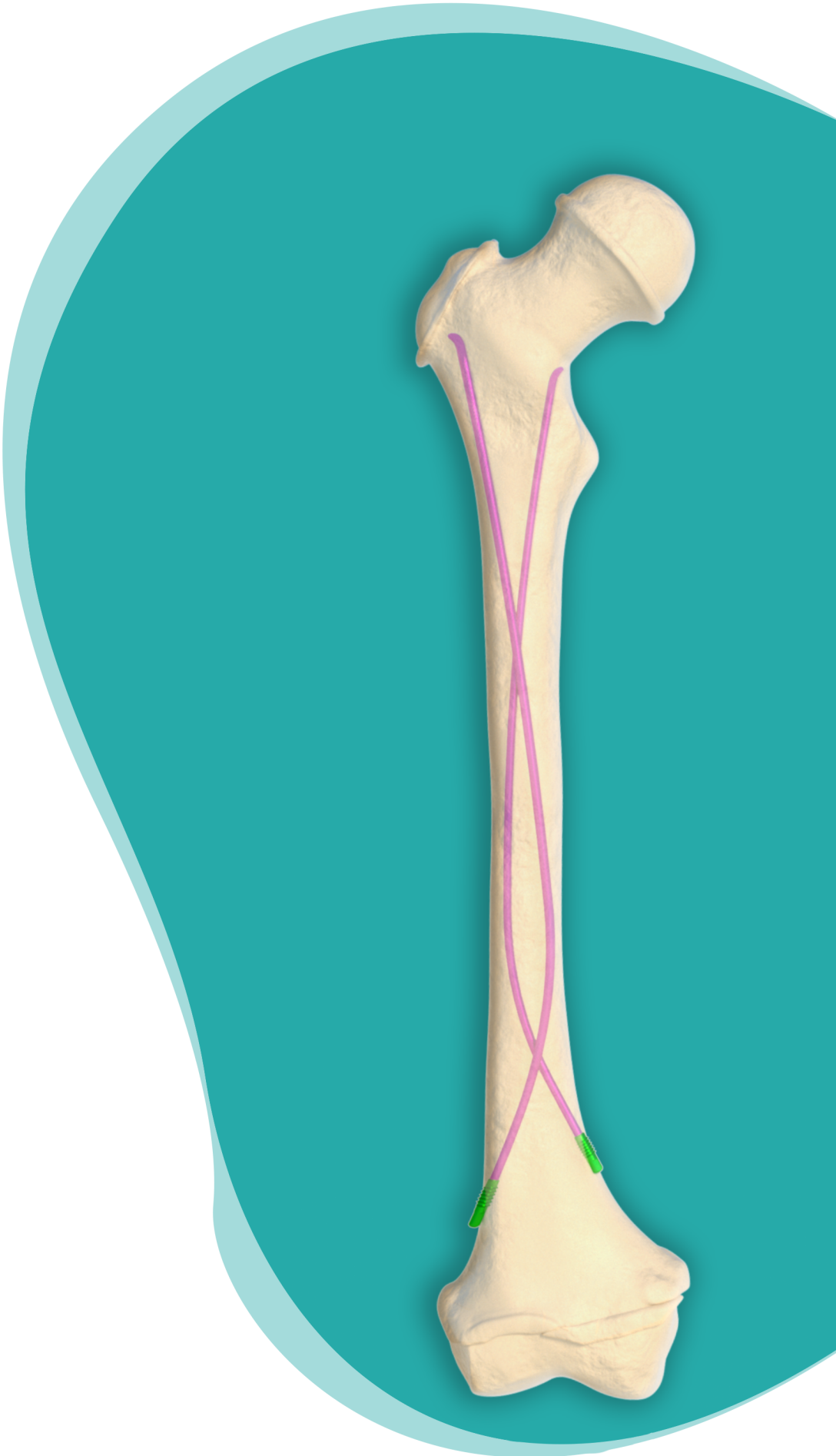
金属髓内针

Metal Intramedullary Needle



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专注骨科事业

Why choose Fule?

Our strengths

- The company is a national high-tech enterprise integrating research and development, production and sales of medical devices, with a full 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,andresearch; Approved postdoctoral research workstation.
- The hardware facilities are complete, the R&D team is excellent, and we work closely with clinical 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.

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Product Advantages

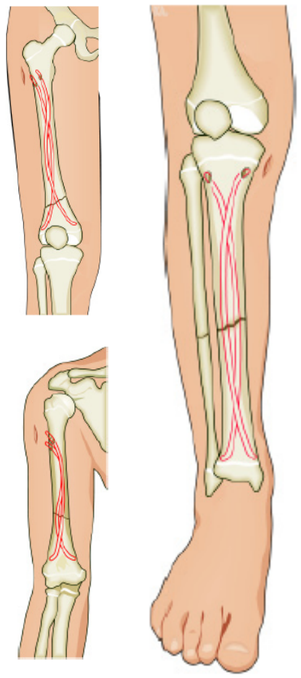
- -The curved tip was designed to facilitate the insertion and working reduction of the intramedullary needle.
  -Provide a variety of diameter and length specifications;
  -Anodized treatment, easy to distinguish specifications.

- - Diameter

  1.5 mm — Rose purple　　2.0 mm — Light green
  2.5 mm — R o s e r e d　　3.0 mm — Golden yellow
  3.5 mm — L i g h t b l u e　　4.0 mm — Rose purple

- -Length: 440mm, capable of being cut during surgery
- - Material: TC4

Product Advantages



Elastic intramedullary needle mean:

- Minimally invasive
- Sufficient stability during activities and when carrying some weight
- It is more suitable for children's long bones in terms of both physiological and clinical adaptability.
  Horizontal fracture
  Short oblique fracture
  Short spiral fracture
- Can be used for adult clavicle and upper limb fractures
  For fractures in school-age children, biological minimally invasive fixation is carried out, which can achieve satisfactory reduction and fixation.

Product Advantages

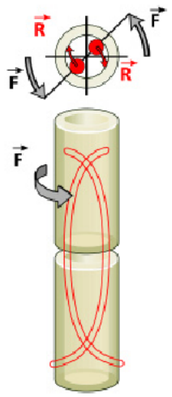
Biomechanical Diagram:

$\vec{F}$ = The load acting on the bone

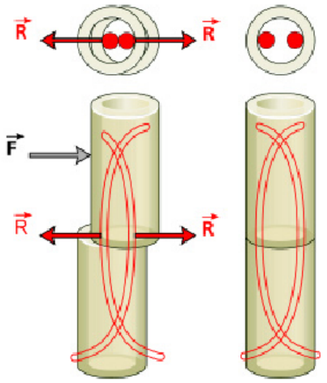
$\vec{R}$ = The load borne by the intramedullary needle

$\vec{S}$ = Compression force

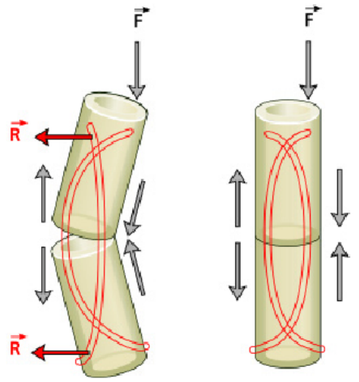
$\vec{C}$ = Pressure



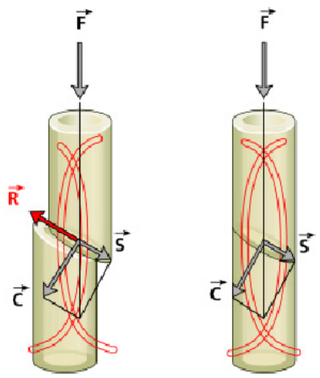
- Rotational stability



- Lateral stability



- Bending resistance stability



- Axial stability

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Product Advantages

Biomechanical Diagram:

$\vec{F}$ = The load acting on the bone

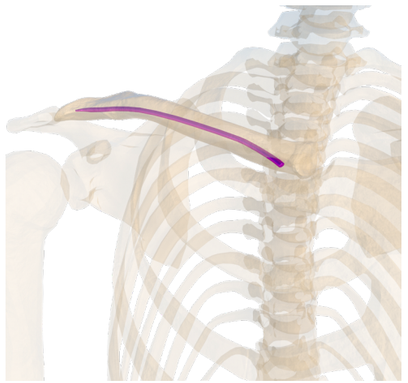
$\vec{R}$ = The load borne by the intramedullary needle

$\vec{S}$ = Compression force

$\vec{C}$ = Pressure

Instruction For Use

Indications



- Used for treating fractures of the diaphysis and epiphyseal ends in children. The treatment plan is determined based on the different ages, the different fracture sites and the different types of fractures.
- Type of fracture

  Horizontal fracture;

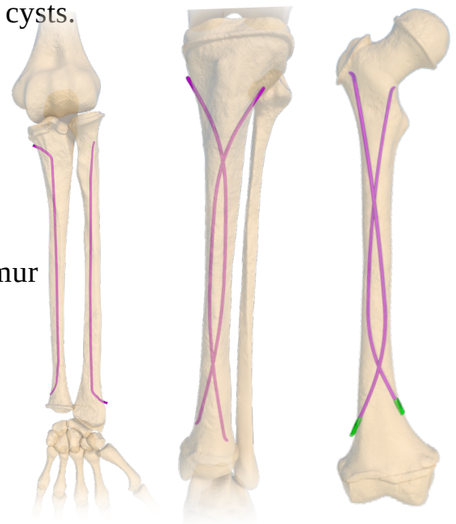
  Short oblique or horizontal fractures with wedge-shaped bone fragments;

  Long oblique fractures with cortical bone support;

  Spiral fracture;

  Multiple fractures and double-site fractures;

  Pathological fractures caused by juvenile bone cysts.



- Fracture site

  Femoral shaft

  The distal metaphyseal region of the femur

  The subtrochanteric region of the proximal femur

  The lower part of the shinbone

  The distal epiphysis of the lower leg

  The shaft and head region of the humerus

  The supracondylar region of the humerus

  The shaft of the radius and ulna bones

  Radial neck and radial head

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Instruction For Use

Contraindications

-Intra-articular fractures

-Completely unstable complex forearm fractures or lower limb fractures without any cortical bone support, especially for those who need to bear weight or are elderly.

Surgical Procedures

【Step 1】 The surgical position of pediatric patients

Standard surgical techniques (taking the femur as an example)

- The child lies on the transparent operating table on his back. For children with a taller body, a traction bed can be used. For young children, it is safer to fix them on the operating table.
- The free movement of the affected limb is beneficial for controlling the position of the intramedullary needle and correcting the rotational deformity of the affected limb. The C-arm machine should be able to ensure the accurate positioning of the anteroposterior and lateral views of the entire femur during fluoroscopy.

Surgical Procedures

【Step 2】 Reposition of a fracture

- Try to use the closed reduction method to initially reset the fracture. For complex fractures, both lower limbs should be disinfected and dressed to facilitate the comparison of length and rotation.

Surgical Procedures

【Step 3】 Determination of the entry point of the intramedullary needle

- The diameter of the narrowestern part of the medullary cavity on the X-ray film was measured, and the diameter of the intramedullary needle was selected to be at least 1/3 of its diameter.

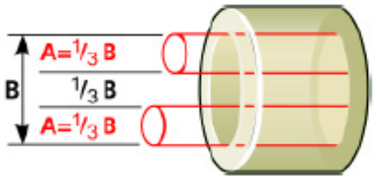


Figure3a

- If the intramedullary needle needs to be driven in a retrograde direction (i.e., from the distal femur to the proximal end), the entry point should be I-2 cm proximal to the epiphyseal plate of the distal femur. In children, this position is approximately at the position of a transverse finger proximal to the superior border of the patella during knee extension.

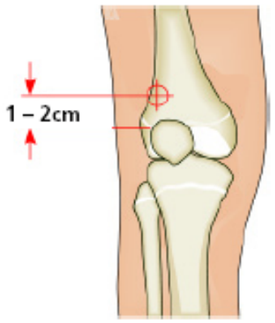


Figure3b

Surgical Procedures

【Step 4】 Surgical incision

- Based on the patient's body size, make an incision 3-4 centimeters in length on both the inner and outer sides of the puncture point plane, extending towards the distal end. It is important that the puncture point should be on the outer side of the joint capsule to avoid damaging the epiphyseal plate.

Surgical Procedures

【Step 5】 Open pulp

- Accurate and symmetrical opening of the bone marrow cavity on both sides is an important parameter to achieve ideal symmetric clamping fixation in the future. Adequate dissection of the tensor fasciae lata was performed, and at the proximal end of the incision, the opening cone was inserted perpendicular to the bone cortex, slowly rotated to Pierce the bone cortex, and then the entry direction was slowly at a 45 degree Angle to the long axis of the femur, and then continued upward through the bone cortex. The hole should be slightly larger in diameter than the chosen intramedullary needle. (You can use the C-arm machine to check the position of the bone cone and the depth of entry.)
  Caution: Do not damage the epiphyseal plate.

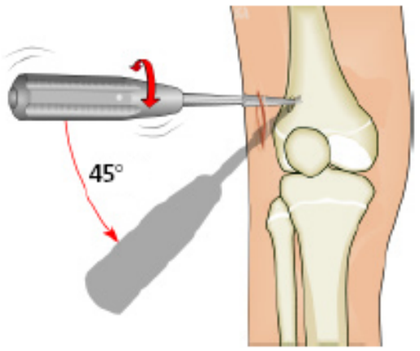


Figure5a

- If the cortical bone is thick, an appropriate bone drill can be used, along with a guide drill to perform the pulp cavity opening. (The position and depth of the bone drill can be checked using an X-ray machine.)

Surgical Procedures

【Step 6】 Prebending of the intramedullary needle

- It is recommended to perform pre-bending of the intramedullary needle before inserting it. The pre-bending arc should be three times the diameter of the medullary cavity. The apex of the arc should be located at the fracture area. The needle tip of the intramedullary needle should be consistent with the arc shape. Both intramedullary needles should be pre-bent beforehand.

Figure6a

Surgical Procedures

【Step 7】 Insertion of the intramedullary needle

- The intramedullary needle was first installed on the impeller and tightened. The laser mark on the intramedullary needle should be flush with one end of the inserter. This allows the direction of the intramedullary needleing to be controlled without the use of a C-arm machine.

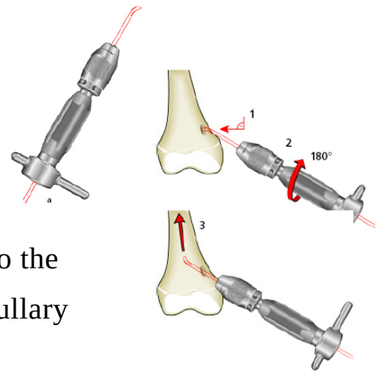


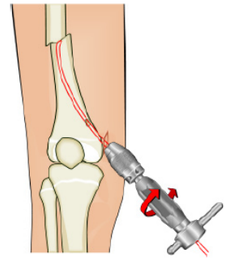
Figure7a

- The first intramedullary thorium was inserted to the fracture end. As shown, the tip of the intramedullary needle
is inserted perpendicular to the bone cortex into the medullary cavity. The intramedullary needle was then rotated 180 degrees so that it was parallel to the medullary cavity. If needed, the position of the intramedullary needle was checked using a C-arm machine. The laser marker on the intramedullary needle should be flush with one end of
the inserter, which facilitates directional control and reduces intraoperative X-ray exposure.
- Rotate or gently tap, gradually inserting the intramedullary needle into the fracture end. (Be careful not to tap the T-shaped handle of the inserter.) If it is necessary to consciously insert and withdraw the intramedullary needle during the insertion process, it is recommended to connect the extraction device.

Surgical Procedures

【Step 8】 Insertion of the intramedullary needle

- If the advance of the intramedullary needle is blocked at the fracture end, the fracture can be reduced first by rotating the intramedullary needle ,
stretching the leg, or using an adjustable reduction device. With the help of X-ray film, one side of the intramedullary needle can be advanced and passed through the medullary cavity of the fracture end.



The second intramedullary needle was inserted the same procedure.

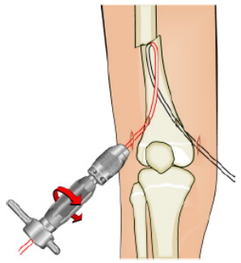


Figure8a

Surgical Procedures

【Step 9】 Confirm the position of the tip of the intramedullary needle

- Under the C-arm machine, check the anteroposterior position of the tip of the intramedullary needle within the proximal fracture fragment's medullary cavity. Ensure that the tip of the intramedullary needle remains in the correct position within the medullary cavity, which should be parallel to the coronal plane.

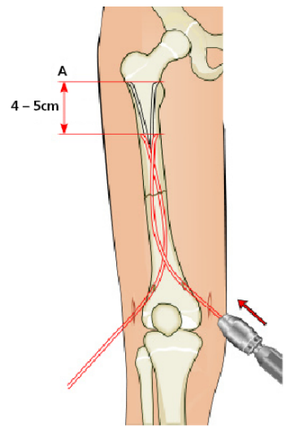


Figure9a

- If the tip of the intramedullary needle is positioned correctly, the needle is advanced another 4-5 cm until the tip reaches position A distal to the proximal epiphyseal plate. It is necessary to ensure that the two intramedullary needles pass through the fracture end to
complete the cross fixation again.

Note: The tip of the medial intramedullary needle should not pass through the future position of the calcar femoris.

Surgical Procedures

【Step 10】 Check the rotation

- After completing the temporary fixation of the fracture, rotation was checked and, if needed, good alignment of the tip of the intramedullary needle was completed before final fixation of the proximal metaphysis of the intramedullary needle.

- When a traction table is used, the traction of the lower limb is relaxed under aseptic operation so that it can rotate freely to check for correction of rotational deformity. The C-arm was used simultaneously to control the alignment of the proximal femur.

Surgical Procedures

【Step 11】 Cut the intramedullary needle

- According to the future need to fix the length to the A position! (X), the intramedullary needleing was cut, taking care to retain approximately 1 cm of residual length (Y) for future removal of the intramedullary needle
- The stump should not be too long to avoid the occurrence of pseudocyst and not affect the normal activity of the knee joint. Too long can sometimes break through the skin and cause infection.

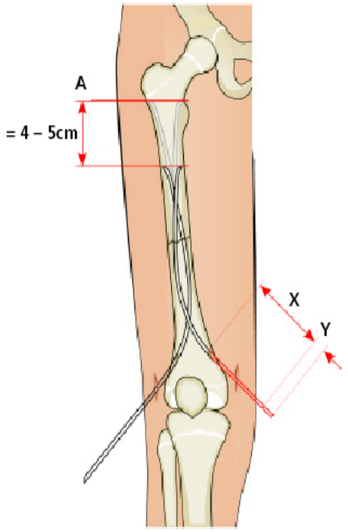


Figure11a

Surgical Procedures

【Step 12】 Check the position of the intramedullary needle

- Finally, the oblique impeller was used to gently strike the intramedullary needle to the desired position. Ensure that the end of the oblique impinger is in contact with the cortical bone. This keeps the stump of the intramedullary needle around 1 cm for future removal of the needle. An oblique impeller can be used to slightly bend the stump of the needle for future removal.
- If it is necessary to strike the intramedullary needle deeper, a straight impeller can be used carefully.
- Tighten the tail cap. Tighten the tail cap with a three-edge wrench, put the tail cap into the needle tail, advance and screw the tail cap thread completely into the bone cortex.

  Note: Tail caps are not recommended for procedures other than femoral procedures.

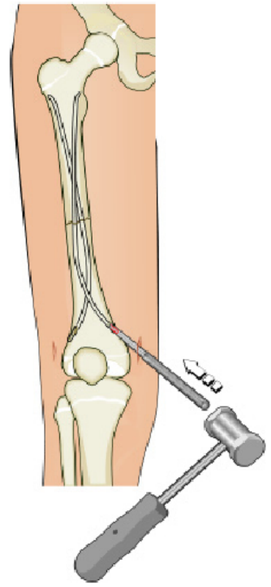


Figure12a

【Step 13】 Femur -Proximal to distal fixation technique

Other techniques - femur

- The proximal-to-distal femoral fixation technique is suitable for distal femoral metaphyseal or distal 1/3 femoral fractures. The biomechanical principles of intramedullary fixation of metaphyseal fractures are different from those of diaphyseal fractures. Then, it is also necessary to ensure the in-support for the tip of the intramedullary needle and the fixation of the fracture fragment

Note the differences from the standard operation:

- For the treatment of femoral fractures from proximal to distal, the entry point is located at the anterolateral side of the femoral trochanter, and the two holes are separated by 1-2 cm on the longitudinal line, with a deviation of 0.5 to 1 cm from each other. If the insertion points are too close together, the cortical bone may burst when the intramedullary needle is inserted.

【Step 14】 Prebending of the intramedullary needle

- Skin incision length is 4-5 cm to expose the proximal femur (FIG. 14a)

- To ensure proper internal fixation (three-point fixation), an intramedullary needle is prebent into an S-shape so that it has internal fixation at the level of the fracture area (FIG. 14b).

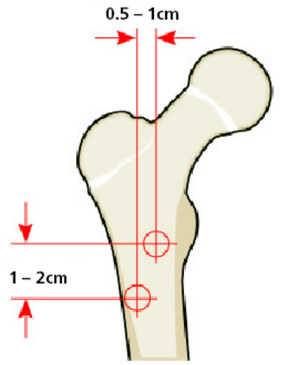


Figure14a

Figure14b

Surgical Procedures

【Step 15】 Insert the intramedullary needle

- A prebent intramedullary needle was inserted and an intramedullary target was used
  The fracture was reduced and initial stability was obtained.
- A prebent S-shaped intramedullary needle (1) was inserted. Once it is in contact with the contralateral side, the intramedullary needle is rotated 180 degrees (2) and the prestress can be increased if needed (FIG. 15)
  Continue to drive the needle in the direction of the epiphyseal plate, and adjust the position and orientation of the tip of the needle so that they are separated in opposite directions (Figure 15b).

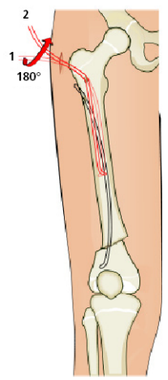


Figure15a

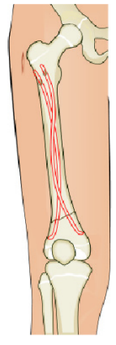


Figure15b

Surgical Procedures

【Step 16】 The ulna and radius

Other techniques-ulna and radius

- Since the radius and ulna form a whole through the interosseous membrane, only one intramedullary needle is needed to be inserted into the radius and ulna in the forearm.

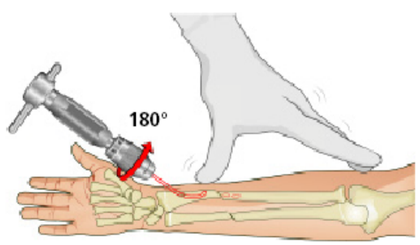
Note the following differences from the standard femoral manipulation

- 1. Determine the diameter of the intramedullary needle:
  The diameter of the intramedullary needle was approximately 2/3 of the diameter of the isthmus of the medullary cavity

Surgical Procedures

【Step 17】 Determine the intramedullary needle insertion point/surgical incision

- 2. Determine the intramedullary needle entry point/surgical incision



Radius: The radius was fixed using the far-to-near technique. The insertion point was located approximately 2 cm proximal to the epiphyseal plate of the distal radius, and a dorsal radial incision of about 2-3 cm in length was made. Care should be taken to avoid injury to the superficial branch of the radial nerve with this incision.

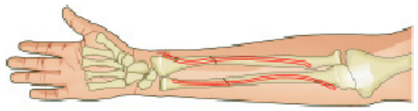


Figure17a

Ulna: Fixed using the near-to-far technique. A radial dorsal incision was made distal to the olecranon epiphyseal plate. The insertion point is approximately 2 cm distal to the epiphysis.

Surgical Procedures

【Step 18】 Insert the intramedullary needle

- The intramedullary needle was continued along the radius and/or ulna to the fracture site. It is recommended to reduce the more difficult fracture (usually the radius) first, so that the whole forearm fracture can be better reduced.

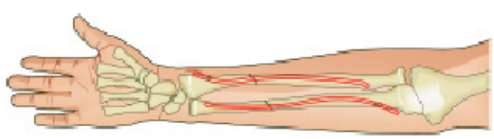


Figure18a

Note: if the radius or bone after several efforts still! If the reduction is not achieved, it is most likely a muscle incarceration. A small incision can be made at the fracture site on one side of the ulna or radius for open reduction.

【Step 19】 Determination of the final position and fixation of the intramedullary needle

- The position of the needle was adjusted so that the tips of the needleing

could face each other, thus providing an arc of support to the IOM.

Forearm bones are also able to regain their physiologically bent shape.

In order to avoid skin irritation, the length of the end of the intramedullary needle should not be more than 5-6 mm outside the bone.

【Step 20】 Other techniques - radial neck

Other techniques-ulna and radius

- Due to the elasticity of the intramedullary needle itself, the intramedullary needle is well suited for closed reduction and fixation of radial neck and head fractures. Do not prebend the intramedullary needle in the use of this indication.

Note the following differences from the standard femoral manipulation:

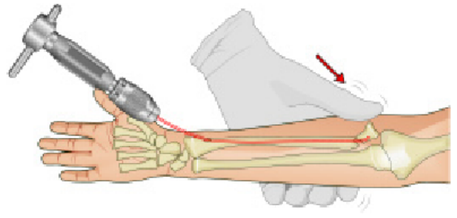
- 1. Determine the diameter of the intramedullary needle
A 2.0 or 2.5 mm diameter intramedullary needle was selected to reduce the radial neck fracture.

Surgical Procedures

【Step 21】 Insert the intramedullary needle

- 2. Insert the intramedullary needle
  An intramedullary needle was inserted as in a radial fracture

- 3. Insert the intramedullary needle into the fracture area
  Provides gentle hammering and rotational activity to insert the intramedullary needle into
  the fracture area. In severe dislocation of the radial head, external force may be used to press the radial head just anterior to the tip of the intramedullary needle.
  A 1.2 or 1.6 mm diameter Kirschner wire can be used to sled the severely dislocated radial head for assisted reduction



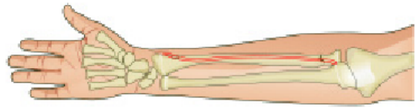


Figure21a

- 4. Determination of the final position of the intramedullary needle
  Gentle axial stress was applied to the intramedullary needle to release the impaction of the fracture end, and then the reduction was
  completed by rotating the intramedullary needle 180 degrees.

Surgical Procedures

【Step 22】 Humerus -fixation technique from far to near

Other techniques - humerus

- Proximal humeral and humeral shaft fractures can be treated using the lateral cortical needle technique from far to near. In contrast, "proximal-to-distal humeral fixation techniques can be used for treatment
  Fracture of the distal humerus.
  Note the following differences from the standard femoral manipulation:

- 1. Fixation technique from far to near
  This technique is similar to the proximal-to-distal fixation of the femur.

【Step 23】Determine the entry point of the intramedullary needle

- 2. Determine the entry point of the intramedullary needle

  A radial incision was chosen for the operation. Do make an incision on the ulnar side to avoid injury t ulnar nerve.

  The distal needle entry point was located 1-2 cm proximal to the epiphyseal plate. The second needl entry point is located 1-2 cm proximal to the distal needle entry point and offset 0.5-1 cm to the media side (Figure 23a).

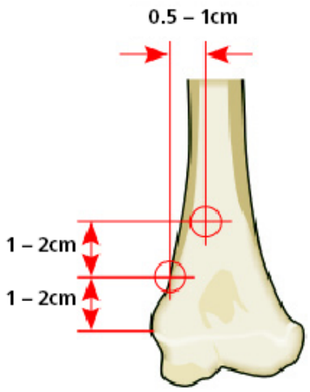


Figure23a

- 3. Make surgical incisions

  A -4-5 cm long incision was made in the radial condyle of the humerus. The lateral margin of the radius was exposed through the ventral muscular septum.

- 4. Opening of the medullary cavity

  It is best to use a drill to make a hole in the hard cortical bone.

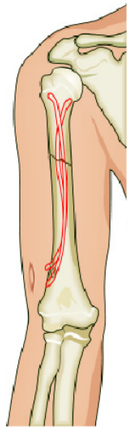


Figure23

【Step 24】Humerus - Proximal to distal fixation technique

- This technique corresponds to the distal to proximal fixation of the humerus.

  Note the following fixation technique with the humerus from far to near! Do something different:

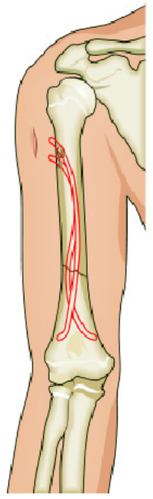


Figure24a

- 1. Determine the entry point of the intramedullary needle

  In the near-to-far fixation technique, the insertion point is lateral to the humerus at the attachment of the deltoid muscle. The insertion points of intramedullary needles were 1-2 cm apart longitudinally and 0.5-1 cm apart laterally. If the insertion point is too deep, the radial nerve may be injured.

- 2. Make the surgical incision

  A -4-5 cm long incision was made on the radial side of the proximal humerus to expose the distal subperiosteal dissection of the needle point.

【Step 25】 Fixation technique for calf fractures

Other techniques - tibia and fibula

- It is best to use plaster external fixation for stable calf fractures or simple tibial fractures.

- Clinical indications for intramedullary needle:
  1. Closed unstable fracture of the lower leg, children over 10 years old
  2. Fractures that are difficult to reduce and maintain
  3. Multiple injuries and/or combined craniocerebral injury

Figure25a

Because the tibia has a triangular medullary cavity, special care should be taken when intramedullary needleing is performed. An eccentric position of the tibia relative to the surrounding muscles can adversely affect intramedullary needleing.

The near-to-far technique must be used in the fixation of the tibia and the far-to-near fixation cannot be performed.

【Step 26】 Determine the entry point of the intramedullary needle

- Note the following differences from the standard femoral fixation technique:

- 1. Determine the entry point of the intramedullary needle
  The intramedullary needle entry points were located medial and lateral to the tibial tuberum (FIG. 26a).
  Note: It is necessary to avoid injury to the tibial epiphysis and epiphyseal plate when crossing the cortical bone.

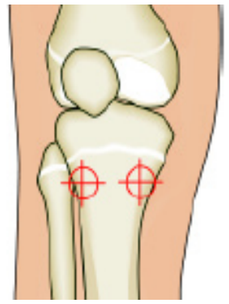


Figure26a

- 2. Check the position of the tip of the intramedullary needle
  Because the tibia has a triangular medullary cavity, the two intramedullary pins have a tendency to slide to the dorsal side, which can easily lead to the occurrence of retroflexion deformity. So turn the tips of the two intramedullary needles slightly back before finally inserting them! Side, so as to maintain the normal physiological radian of the tibia (Figure 26b)
  Note: Tap the fracture end to avoid separation of the fracture end.

Figure26b

Surgical Procedures

【Step 27】 Cut the intramedullary needle

- 3. Cut the intramedullary needle
  Due to soft tissue coverage problems, the end of the intramedullary needle was cut short and slightly bent laterally.

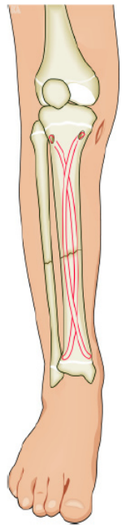


Figure27a

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Surgical Procedures

【Step 28】 Remove the intramedullary needle

- The following procedures for intramedullary needle removal are independent of indication
- The original incision was made to expose the tail end of the intramedullary needle. The tail end of the intramedullary needle was tightly clamped with the removal forceps and gently pulled outward, and then the intramedullary needle was removed with a bone hammer. Beveled cone sled is sometimes used to pull the end of the intramedullary needle if it fits the bone surface very tightly.

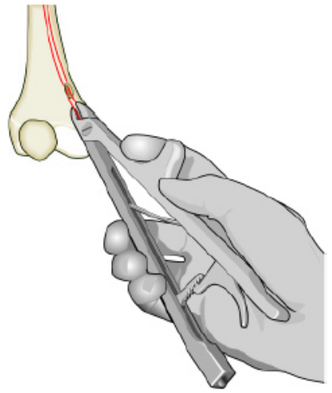


Figure28a

Product Information

【Metal Instramedullary Needle】

Non-sterilized product code	Sterilization product code	Specification
4301615300	4304615300	ϕ1.5×300
4301620440	4304620440	ϕ2.0×440
4301625440	4304625440	ϕ2.5×440
4301630440	4304630440	ϕ3.0×440
4301635440	4304635440	ϕ3.5×440
4301640440	4304640440	ϕ4.0×440

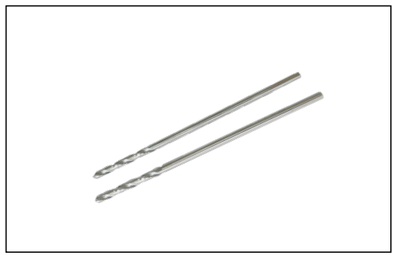
【End cap】

Non-sterilized product code	Sterilization product code	Tail cap	Remarks
4302600025	4303600025	ϕ2.5	Use with ϕ1.5/2.0/2.5 elastic needle
4303600040	4302600040	ϕ4.0	Use with ϕ3.0/3.5/4.0 elastic needle

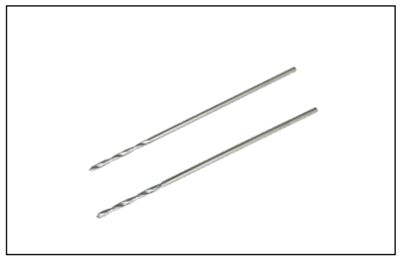
Surgical Instruments

● 427-011
Open cone (straight)

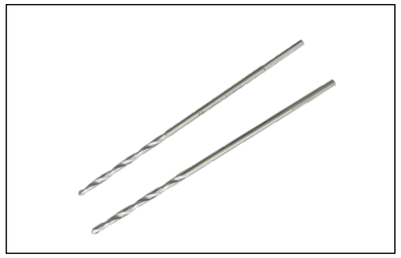
● 427-010
Open cone (arc)



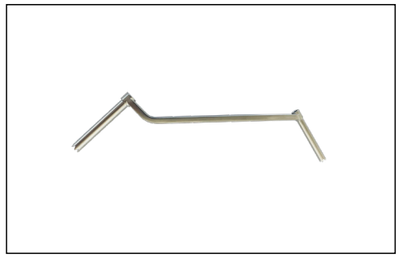
● 427-020
Bone drill (Φ2.7)



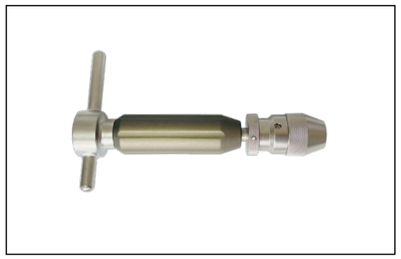
● 427-030
Bone drill (Φ3.2)



● 427-040
Bone drill (Φ4.5)



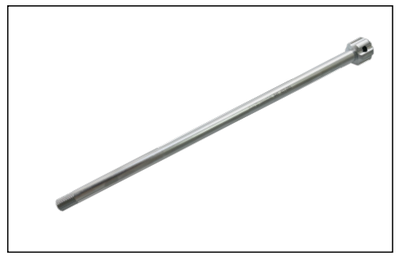
● 418-050
Guide drill (double head)



● 427-060
Insertion tool

● 427-070
Bone hammer

Surgical Instruments



● 427-080
Drill chuck

● 427-090
Scissors (body)

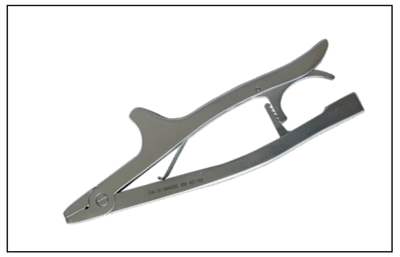
● 427-100
Scissors (Wrench)

● 427-110
Insertion tool (straight type)

● 427-120
Intrusion device (inclined shape)

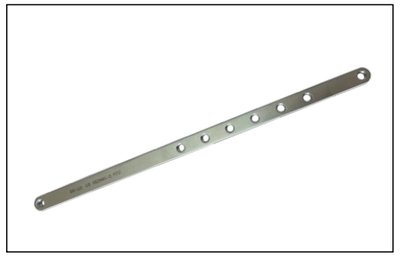
● 427-130
Wrench (Φ3.5)

● 427-140
Wrench (Φ5.0)



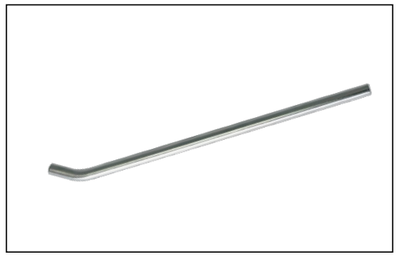
● 427-150
Extracting forceps

Surgical Instruments

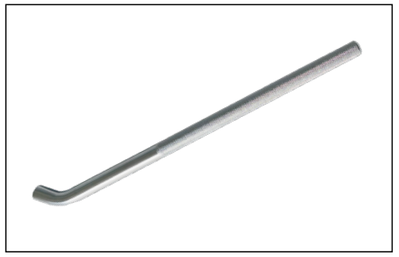


● 427-160
Pliers (repositioning plate)

● 427-170
Pliers (repositioning rod)



● 427-180
Wrench (Φ4.5)



● 427-190
Bending rod device

● 427-200
Steel needle cutter