

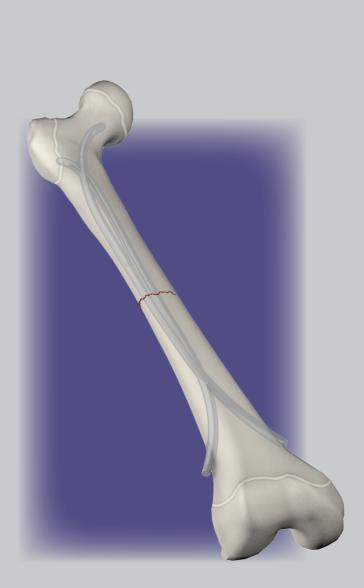
T2 Kids Flexible Nailing System

Operative Technique



Femur

Tibia & Fibula



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This publication sets forth detailed recommended procedures for using Stryker Osteosynthesis devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required. A workshop training is recommended prior to first surgery. All nonsterile devices must be cleaned and sterilized before use. Follow the instructions provided in our reprocessing guide (L24002000). Multi-component instruments must be dis-assembled for cleaning. Please refer to the corresponding assembly / dis-assembly instructions.

See package insert (L22000007) for a complete list of potential adverse effects, contraindications, warnings and precautions. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

Introduction

In 1979, Professor Jean Prévot and his young team of surgeons - Dr Métaizeau, Dr Ligier and Dr Lascombes of the Centre Hospitalier Universitaire of Nancy, France, developed and introduced a technique for the treatment of long bone fractures in children using flexible IM nailing.

In 1994, Professor Prévot passed his torch of pediatric orthopaedic leadership of the University Hospital in Nancy to Professor Pierre Lascombes, who has continued to improve and teach the flexible intramedullary nailing technique around the world.

In order to share the expertise acquired over more than 30 years in Nancy and with the intention to unite the culmination of experience of many renowned surgeons, Professor Lascombes published one of the most complete books about this flexible nail technique to date. The book, entitled Flexible Intramedullary Nailing in Children¹ describes the technique for all bones and provides numerous illustrated tips and tricks. The illustrations found in this document are used with the permission of the publisher¹.

Rationale

What is the concept behind flexible nailing which makes it not only biomechanically advantageous to more rigid fixations but also more demanding to learn as a technique?

The technique consists of bending nails of appropriate diameter in such a manner that, when inserted into a fractured bone, the nails may reduce the fracture, splint the cortices with optimal force at the fracture site and maintain the elastic energy to continually brace against rotational and angular forces of the muscles.

An effort is required of the surgeon to consider not only the choice of implant but also the manner in which the frame is to be constructed in his or her hands, according to the indication. It is the aim of Stryker to provide surgeons with the best possible materials and instruments to ease the task of reducing and stabilizing fractures in children. Much consulting has been done, drawings made and explained in detail, surgeries observed, laboratory studies and testing performed to determine the optimal materials, the dimensions and the shape of the nails as well as the effectiveness, ergonomics and necessity of each instrument. The operating room staff's needs have not been forgotten, as we have also considered the practicalities of the cleaning, storage and easy identification of our products.

It is our desire that the T2 Flexible Nail system helps each surgeon gain not only confidence but also joy in his or her ability to bring children back to good health.

Indication, Precautions & Contraindications

Indication

The T2 Flexible Nail is intended for the temporary stabilization of bone segments or fragments until bone consolidation has been achieved.

This includes upper extremity fractures and lower extremity fractures of pediatric patients.

Specific indications include:

- Fixation of mid-diaphyseal, proximal and distal fractures of the femur, tibia, and fibula.
- Fixation of mid-diaphyseal, proximal and distal fractures of humerus and forearm fractures.

Precautions

Stryker Osteosynthesis systems have not been evaluated for safety and compatibility in MR environment and have not been tested for heating or migration in the MR environment, unless specified otherwise in the product labeling or respective operative technique.

Contraindications

The physician's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment.

Conditions presenting an increased risk of implant failure include:

- Any active or suspected latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhabit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, infection or prior implantation that can not proved adequate support and/or fixation of the devices.
- Material sensitivity, documented or suspected.
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or failure of the device itself.

- Patients having inadequate tissue coverage over the operative site.
- Implant utilization that would interfere with anatomical structures or physiological performance.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in post-operative care.
- Other medical or surgical conditions which would preclude the potential benefits of surgery.

Detailed information is included in the instructions for use being provided with each implant.

See package insert for a complete list of potential adverse effects and contraindications.

The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, child's parents or guardian.

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Features & Benefits

Nails

Materials

The T2 Flexible Nail is offered in two materials¹⁶⁻²⁰:

Titanium:

Grade 5 Ti6Al4V ELI conforming with ASTM F136, EN ISO=5832-3 Type II anodized with laser-etched bands for easy identification of nail diameter.

Stainless Steel:

1.4441 (316 LVM) conforming with EN ISO 5832-1 and ASTM F-138 with laser-etched bands for easy identification of nail diameters.

Diameters

Diameters:

ø1.5; ø1.75; ø2.0; ø2.25mm with length 300mm.

Diameters:

ø2.5; ø3.0; ø3.5; ø4.0mm with length 450mm. We offer an extensive diameter range for optimal patient treatment.

Tapered Tips and Concave Side

Tapered tip and concave inner side for anchoring in metaphyseal bone and capturing fracture fragments.

Pre-curved Shaft

The T2 Flexible Nail features an additional insertion bend to assure the maximum ease of insertion. This bend saves one step during the surgical procedure as such a curved shaft is added in most cases to ease insertion.

Note:

This pre-curved proximal shaft does not preclude the need for the surgeon to bend the nail to create the three point cortical contact.

Curved Tip

Curved nail tip with optimized height for maximal guidance and reduced potential of blocking in the intramedullary canal.

Design rationale:

IF the selected nail diameter (d) is 2/5 or 40% of the IM canal diameter (D) AND the nail tip height is a factor of 2.2d - THEN there remains a clearance between the IM canal and the nail tip.

Example: D=10mm d=0.4 \times 10=4mm Nail tip height =8.8<10mm

Packaging

All nails are offered single packed in sterile as well as in non-sterile packaging.

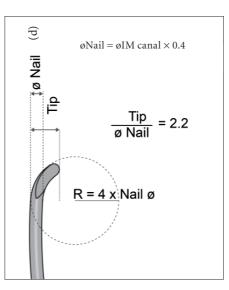
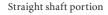


Fig. 1 Nail Tip Outer curve (convex) Inner curve Tapered (concave) extremity Curved Nail tip or nail tip curvature

Pre-curved shaft portion

It can be bent back with the bending instrument, if the indication asks for it.



Nail end (Driving end)

Features & Benefits

Instruments

The Stryker T2 Flexible Nail instruments are based on the T2 IM Nailing instrument platform.

More than that, the T2 Flexible Nail system instruments are designed to distinguish between small and large bone treatment characteristics to pediatric orthopaedics.

This optimizes the instrument-topatient precision maneuvering while maintaining the Stryker signature ergonomic handles.



Image 1a

Trays

Tray layout according to operative steps:

- 1) Nail bending: Bending Instrument
- 2) Bone opening: Awl (Large and Small) and Tissue Protection Sleeve.Drills can be found on top tray insert
- 3) Nail Insertion and Tip Impaction: Universal Chuck, Slotted Hammer
- 4) Nail Cutting: Cutters
- 5) Nail End Impaction: Final Impactors (Large and Small) and Slotted Hammer
- 6) Nail Removal: Forceps and Slotted Hammer



Image 1b

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Features & Benefits

Material Advantages

All Stryker T2 implants are made of Type II anodized titanium alloy (Ti6Al4V) $^{19\,\&\,20}.$

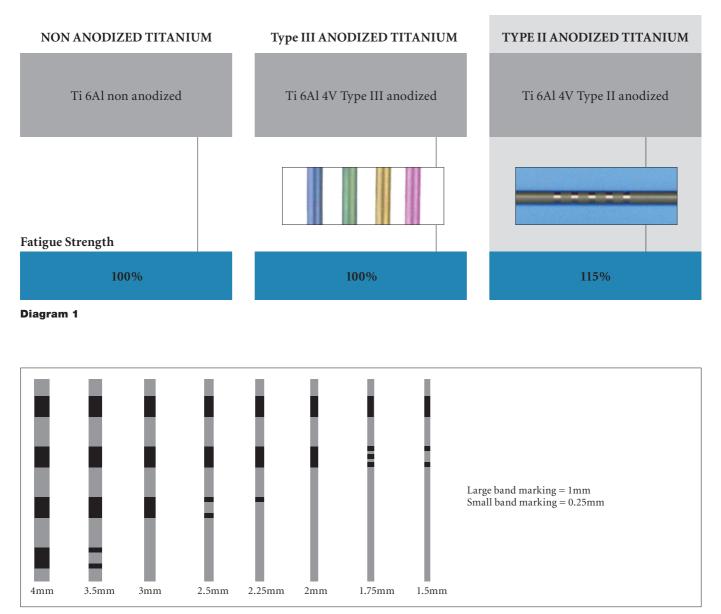


Diagram 2

All Stryker T2 Flexible Nail ends are laser-etched with bands for easy diameter identification. Thick bands indicate 1mm diameter and thin bands indicate 0.25mm diameter. Verify the nail diameter by inserting the nail end into the designated hole in the tray insert.

Nail Selection

The diameter of the implants should be about 40% of the diameter of the intramedullary canal measured on the X-Ray.

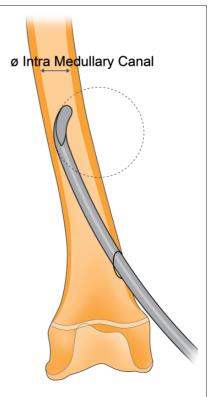
The formula is therefore:

 \emptyset Nail = 0.4 x \emptyset IM canal

Some individual adaptations are tolerated but experience has shown that when hesitating between two diameters, the greater diameter should be preferred over the lesser diameter, which may lead to a deformation caused by a less stable construct.

In the majority of cases, the two nails should have matching diameters to prevent iatrogenic valgus or varus deformities. Verify the selected nail diameter in at least one of the three possible ways:

- Packaging information
- Laser band markings at the end of the nail
- · Measuring holes on the metal tray insert





Fracture Reduction

Instrument: Reduction Instrument

Check if the fracture can be reduced in a closed manner prior to setting up the sterile field.

Assemble the Reduction Instrument by threading the two radiolucent bars into the handle at the appropriate levels according to the limb to be treated and the patient's size (Images 2 & 3).

Slide the Reduction Instrument over the limb with a bar on each side and reduce the fracture by maneuvering the handle of the tool. Verify the reduction through bi-planar fluoroscopy over the radiolucent reduction bars.



Image 2



Image 3

Nail Bending

Instrument: Bending Instrument

The Bending Instrument is a multi-purpose instrument with specifically designed bending slots. The following possibilities are provided:

- creating identical fracture bends for two nails (Image 4)
- increasing or decreasing the radius of the pre-manufactured curved shaft (Image 5 & 6)

The fracture bend is created by the surgeon to ensure a continued correctional force within the intramedullary canal at the fracture level. This correctional force is a result of the characteristic memory of the metal (found in titanium and to a lesser degree in stainless steel). This metal memory, called elasticity, is a potential energy which causes the nail to strain against the cortex in an effort to regain the pre-operative bend which was produced by the surgeon and which afterwards is contained in an area too narrow to permit the bend to be physically expressed.

Engage the nail into the appropriate dimension slot. Bend the nails according to the situation with the apex at the fracture level. Bending both nails identically ensuring matching curves permits an optimal stability of the frame.

Warning:

- Avoid both over-bending the nail and creating any notches on the nail surface²⁰
- Consider not using the nail if overbending made it necessary to bend the nail in reverse over its natural position as it might reduce the fatigue strength²⁰

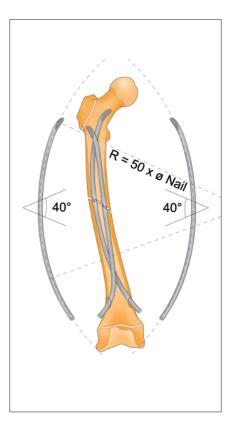




Image 4 Creating the fracture bend using the slots



Image 5 Decreasing the pre-curved shaft



Image 6 Increasing the pre-curved shaft

Determining the Incision and Insertion Points

The insertion site can be determined by placing the Awl perpendicular to the bone and above the skin then taking a fluoroscopy image in the frontal view to confirm. The skin is incised where the cortex will be opened, allowing for extra space to permit maneuvering of the nail upon insertion without irritating the skin.

To fully benefit from the flexible intramedullary nailing technique, respect the following guidelines:

- 1) The apex of the (40°) bend is situated at the fracture level
- 2) The two nails are aligned face-to-face in the canal
- 3) The two nails cross each other above and below the fracture site.

See the diagrams on the following pages which depict the opening and final constructs for several procedures.

Warning:

When opening the medial site, be careful not to let the Awl or Drill Bit slip posteriorly into the region of the femoral artery.

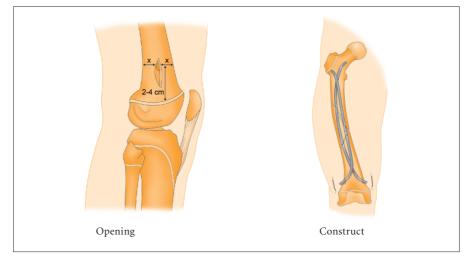


Fig. 4 Femoral Retrograde

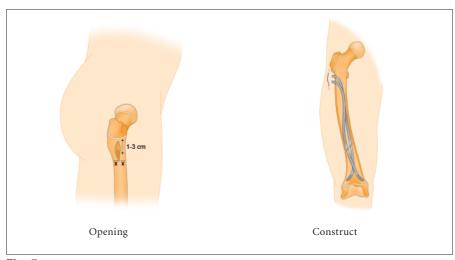


Fig. 5

Femoral Antegrade

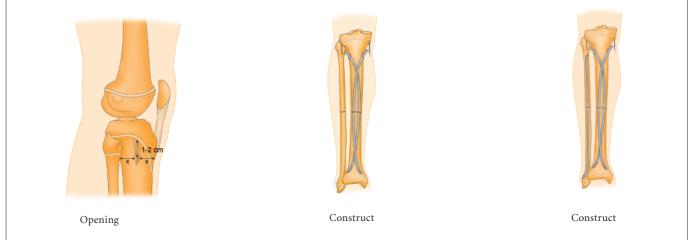
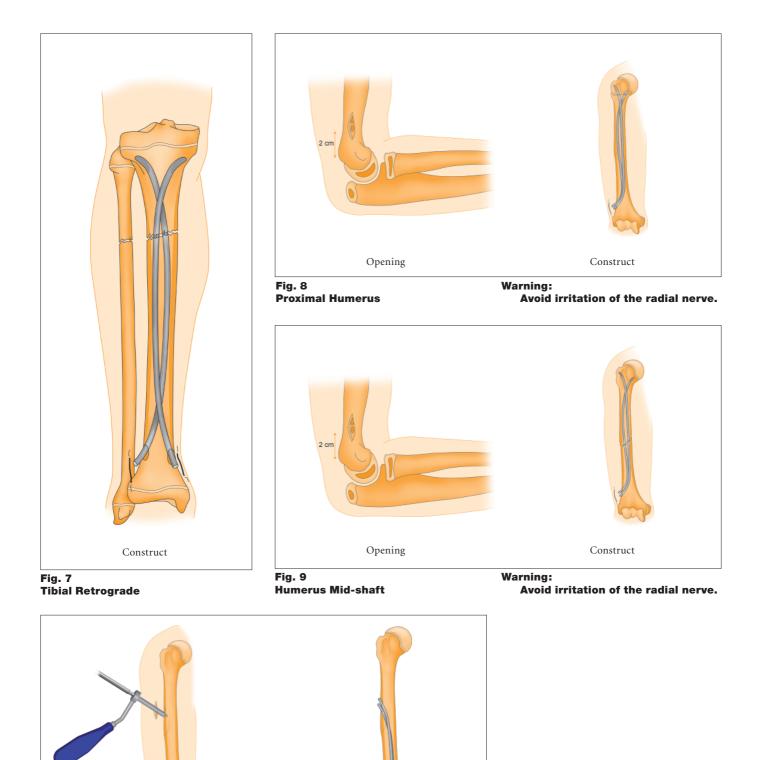
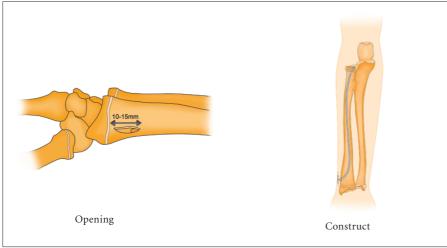


Fig. 6 Tibial/Fibial Antegrade





Construct





Warning: Avoid irritation of the extensor tendons and superficial radial nerve.

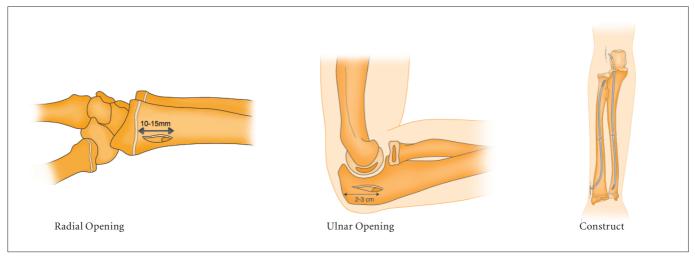


Fig. 12 Forearm

Warning: Avoid irritation of the extensor tendons and superficial radial nerve.

Cortical Opening - Femoral Shaft

Instruments: Straight ø5.0mm Awl or ø5.0mm Drill Bit, Tissue Protection Sleeve

The Tissue Protection Sleeve accepts both the Awl or Drill Bit. The front is serrated for better grip on bone.

The length of the Tissue Protection Sleeve limits the functional length of Awl or Drill Bit to 20mm. This is designed to avoid penetration of the far cortex by the Awl or Drill Bit as well as protect the adjacent soft tissue.

The Straight ø5.0mm Awl or large ø5.0mm Drill Bit is recommended when nails of the following diameters are used:

ø2.5mm; ø3.0mm; ø3.5mm and ø4.0mm.

The smaller nails use the ø3.2mm Awl or ø3.2mm Drill Bit.

The cortical insertion hole is made with the Awl or Drill Bit which is first applied at a 90° angle (perpendicular) to the cortex.

Once the first cortex is penetrated, the instrument-to-bone angle is lowered to shape an oblique opening in the direction of the fracture.

An optional ø5.0mm Curved Awl is available to further enlarge the insertion hole and align the insertion hole with the IM canal.

Warning:

Do not use the Curved Awl for the initial opening of the bone as a sharp curved instrument is difficult to prevent from damaging soft tissue.

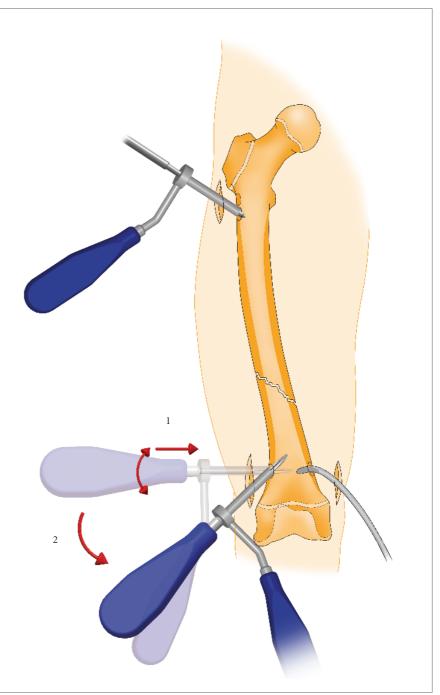


Fig. 13 Cortical opening

First Nail Insertion and Progression

Instrument: Universal Chuck with T-Handle

The Universal Chuck with T-Handle can be used for all nail diameters.

Engage the selected nail with the Universal Chuck by sliding its end into the center of the opening. Locking the grip on the nail can be achieved by holding the front part of the Chuck firmly and turning the T-Handle clockwise (Fig. 14a).

For optimal grip make sure that the nail is captured in the center of the Chuck as it can happen that the nail is clamped with a slight offset.

To unlock the nail pull the ring on the back side of the Chuck first and turn the Chuck counter-clockwise (Fig. 14b).

Optionally, the Strike Plate can be threaded into the Strike Plate of the Universal Chuck T-Handle. The Strike Plate offers a bar extending to the side facilitating the adjustment of the inserted nail in the reversed direction by tapping it with cautious hammer blows (Fig. 14c).

Make sure that the Strike Plate is sitting flush with the Strike Plate of the Universal Chuck T-Handle and is tightly threaded on. Monitor nail manipulation with fluoroscopy.

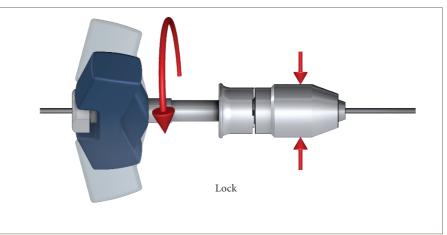
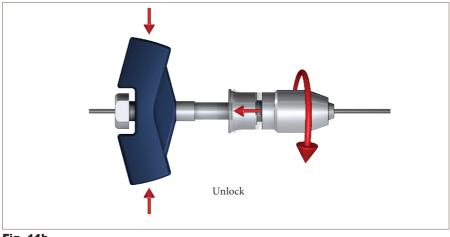


Fig. 14a





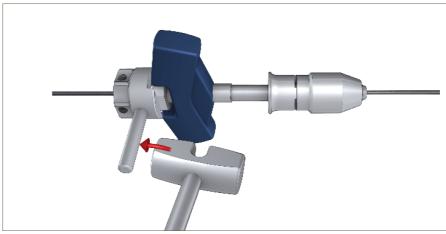


Fig. 14c

First Nail Insertion and Progression

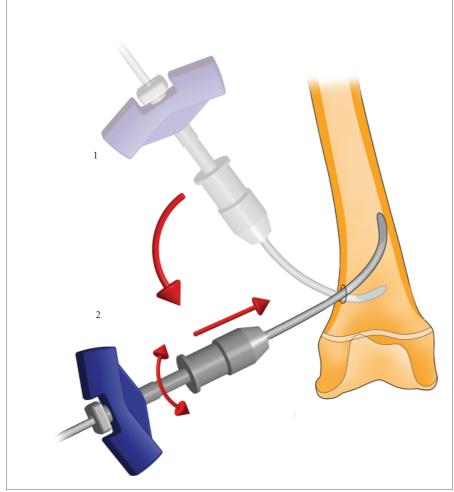


Fig. 16 Nail insertion

Crossing the Fracture Site with the First Nail

Instruments: Universal Chuck with T-Handle or Slotted Hammer

The Slotted Hammer is designed to fit over the nail and slide along it to tap with controlled blows onto the Universal Chuck with T-Handle and drive the nail forward in the intramedullary canal. Make sure to only tap on the strike surface for an insertion force in line with the nail.

Check the progression of the nail with fluoroscopy to ensure that the tip is advancing with each blow.

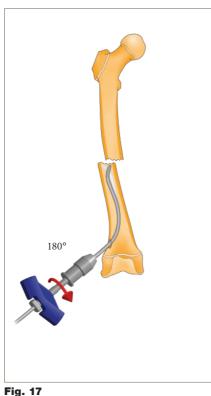
When the fracture site is reached, the nail tip must be rotated 180° so that it is oriented just below the opposite fragment in both frontal and lateral fluoroscopic views (Fig. 17). The fracture is reduced and reduction is checked using fluoroscopy once again. Drive the nail across the fracture site using the Slotted Hammer (Fig. 18).

Make sure that the Strike Plate is sitting flush with the Strike Plate of the Universal Chuck T-Handle and is tightly threaded on. Monitor nail manipulation with fluoroscopy .

How far up the fragment should the first nail be inserted?

Option 1:

Verify the reduction and nail position with frontal and lateral fluoroscopy. Advance the nail a few centimeters further in the far fragment. By advancing the first nail just slightly into the second fragment there is less stability but more reduction potential, given that the communication between the two fragments is with only one unanchored nail. This also facilitates passage of the second nail.



Crossing the fracture site

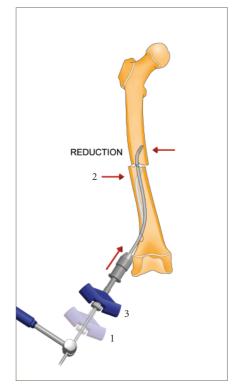


Fig. 18 Crossing the fracture site

Option 2:

If the first nail is advanced much further up the canal, there is a heightened stability of the primary reduction but the passage of the second nail is not as simple, as the space in the intramedullary canal has been reduced. In this case, more space can be gained by rotating the nail.

Crossing the Fracture Site with the Second Nail

Instruments: Universal Chuck with T-Handle Slotted Hammer

The Slotted Hammer is designed to fit over the nail and slide along it to tap with controlled blows onto the Universal Chuck with T-Handle and drive the nail forward in the intramedullary canal. Make sure to only tap on the strike surface for an insertion force in line with the nail.

Check the progression of the nail with fluoroscopy to ensure that the tip is advancing with each blow.

When the fracture site is reached, the nail tip must be rotated 180° so that it is oriented just below the opposite fragment in both frontal and lateral fluoroscopic views (Fig. 17). The fracture is reduced and reduction is checked using fluoroscopy once again. Drive the nail across the fracture site using the Slotted Hammer (Fig. 18).

Make sure that the Strike Plate is sitting flush with the Strike Plate of the Universal Chuck T-Handle and is tightly threaded on. Monitor nail manipulation with fluoroscopy .

Varus/valgus angulation caused by a transverse fracture can be addressed by directing the nail tips medially or laterally as appropriate to counter the angulation forces. A varus angulation can be corrected by directing the nail tip laterally whereas a valgus angulation can be corrected by directing the nail tip medially.

Similarly, in the sagittal plane, a recurvatum angulation can be corrected by directing the nail tips posteriorly and a flexion angulation by directing the nail tips so that the concave sides face anteriorly.

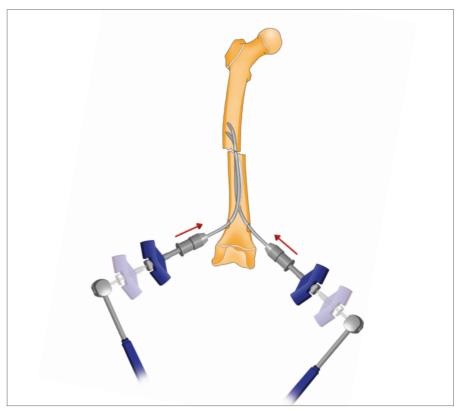


Fig. 19 Second nail crossing the fracture site

There are of course possibilities of combined deformities as well as biomechanical factors to be considered. The surgeon must choose the optimal position of the nails in the intramedullary canal to provide a stable frame in spite of the constraints.

During all moments of fracture reduction, great vigilance must be taken to avoid a rotational malunion, as the remodeling is limited in this axis.

Impacting the Nail Tips

Instruments: Universal Chuck with T-Handle Slotted Hammer

Once the position and orientation of both nails are satisfactory, they are impacted into the cancellous bone of the metaphysis while maintaining reduction. Use the Large Slotted Hammer on the Universal Chuck with T-Handle to impact the nails (Fig. 20).

Attention should be paid to the horizontal plane at all times during this reduction step so as to prevent rotational malunion.

Impaction of the fracture plays an important role in final reduction. All transverse fractures must be impacted to minimize the potential for later leg length discrepancy. In oblique and spiral fractures and even fractures with a third fragment, impaction provides stabilization of the fracture site at the expense of slight shortening (5 to 10mm) which is readily compensated for by post-operative overgrowth.

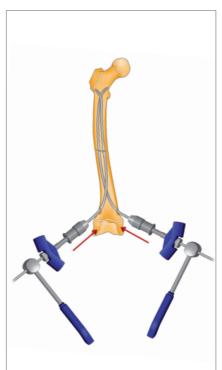


Fig. 20 Impacting the nail tips

Bending the Nails Prior to Cutting

Instrument: Universal Chuck with T-Handle

At this point, the Universal Chuck with T-Handle OR Inserter is still on the nail. There are three options for bending the trialing ends prior to cutting off the excess material:

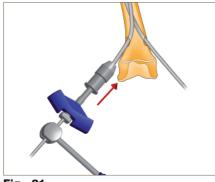


Fig. 21

Option 1:

In some cases, the trialing ends are not bent at all; they are simply left to lie against the cortical wall after trimming (Fig. 21).

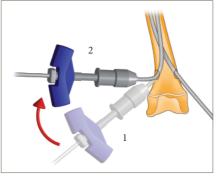
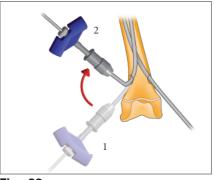


Fig. 22



For ease of future removal, the nail ends may be bent away from the cortex at an angle of approximately 30-60°, according to the limb involved and the surrounding soft-tissue coverage (Fig. 22).





Option 3:

The third option is to sharply bend the trialing ends (>90°) with the intention to fully recess them into the bone later in the procedure. Be aware that removal of a sunken nail is more difficult than a protruding nail (Fig. 23).

Cutting the Nail Ends

Instrument: Large Cutter, for ø2.5 - 4.0 nails

Remove the Universal Chuck from the nail.

Make sure the Large Cutter is assembled as shown and the inner sleeve is rotated counter-clockwise to the fully open position. In this position the engraved lines on the inner sleeve and handle are aligned (Fig. 24a).

Slide the Cutter over the nail selecting the appropriate hole as indicated. Push the Cutter down over the nail to the desired cut-off point. A groove off the frontal plane of the Cutter indicates where the nail will be cut (Fig. 24b & 24c).

After you have positioned the Cutter at the correct position, slide the handle piece over the key on top of the assembly.

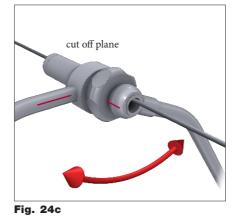
The position to engage the handle with the assembly is when both handle pieces are at an angle of about 90° and the engraved lines are aligned (Fig. 24c).

Cut the nail by moving the handles smoothly towards each other. The trimmed portion of the nail is captured within the cutter (Fig. 24d & 24e).

If access to the cut-off point is difficult, you may also mark the nail at the planned cut-off point with a pen or clamp. Retract the nail far enough to access the cut-off point. The cut nail end is pushed back into the intramedullary canal using the Final Impactor as described next.







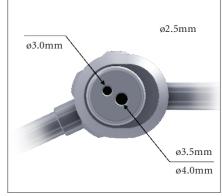






Fig. 24d



Fig. 24e

Final Impaction

Instruments: Final Impactor, Slotted Hammer, Forceps

The Large Final Impactor will leave from 7 to 12mm of nail length protruding from the outer cortex, according to the position in which it is placed on the bone. For the femur, it is recommended to leave 12mm of nail protruding from the bone but less is better tolerated if the child is small or slender. Turn the Impactor so that the desired length of the protruding nail is indicated on the side which is closest to and faces the cortex (the opposite length will be facing the surgeon). Impact the nails into the metaphyseal bone while firmly maintaining the reduction (Fig. 25).

2

If the nail has been over inserted use the Forceps to retract the nail. Final fluoroscopic verification in both frontal and lateral planes is made prior to wound closure.

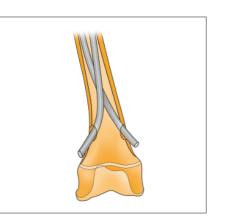


Fig. 26 Option for nail impaction

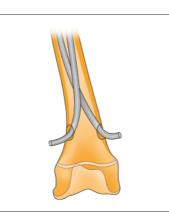


Fig. 27 Option for nail impaction

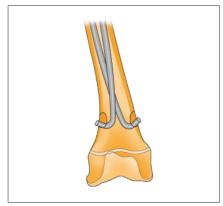


Fig. 28 Option for nail impaction

Fig. 25

Impacting the nail ends

Incision and Insertion Points for Radial Shaft Fracture

Forearm Mid-Shaft

Cortical Opening (Fig. 29)

Instruments: Straight ø3.2mm Awl or, ø3.2mm Drill Bit, Tissue Protection Sleeve

The Tissue Protection Sleeve accepts the ø3.2mm Drill Bit. The front is serrated for better grip on bone.

The length of the Tissue Protection Sleeve limits the functional length of the Drill Bit to 15mm. This avoids penetration of the far cortex by the Drill Bit and protecting the adjacent soft tissue.

The Straight ø3.2mm Awl or the ø3.2mm Drill Bit are recommended when nails of the following diameters are used:

ø1.5mm; ø1.75mm; ø2.0mm and ø2.25mm.

The cortical insertion hole is made with the Awl or Drill Bit which is first applied at a 90° angle (perpendicular) to the cortex. Once the first cortex is penetrated, the instrument-to-bone angle is lowered to shape an oblique opening in the direction of the fracture (Fig. 29).

An optional Curved ø3.2mm Awl is available to further enlarge the insertion hole.

Warning:

Do not use the Curved Awl for the initial opening of the bone as a sharp curved instrument is difficult to prevent from damaging soft tissue.

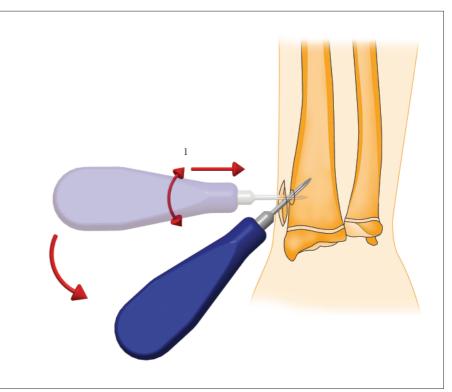


Fig. 29 Cortical opening

Radial Nail Insertion

Instrument: Universal Chuck with T-Handle

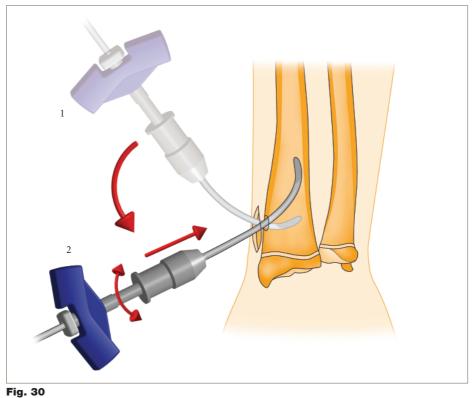
Engage the selected nail with the Universal Chuck by sliding its end into the center of the opening. Locking the grip on the nail can be achieved by holding the front part of the Chuck firmly and turning the T-Handle clockwise. For optimal grip make sure that the nail is captured in the center of the Chuck as it can happen that the nail is clamped with a slight offset.

To unlock the nail pull the ring on the back side of the Chuck first and turn the Chuck counter-clockwise.

Introduce the nail into the bone opening with the hook facing away from the fracture. When the opposite cortex is felt, rotate the nail 180° so that the hook now faces the fracture and is ready to be glided progressively through the intramedullary canal (Fig. 30).

Warning:

Do not grip the T-Handle with your palm over the center of the strike plate, as the nail end will protrude from there.



Radial nail insertion

Crossing the Fracture Site with the Radial Nail

Instruments: Universal Chuck with T-Handle, Slotted Hammer

The nail is pushed forward in the canal using slight rotational movements to avoid blockage.

When the fracture site is reached, the nail tip must be rotated 180° so that it is oriented just below the opposite fragment (Fig. 31). Drive the nail through the fracture site into the fragment, using the Slotted Hammer (Fig. 32). Continue inserting the nail up to the metaphysis. The concave bow of the nail must be facing the ulna (Fig. 33).

Monitor nail advancement with fluoroscopy.

180°

Fig. 31-33 Crossing the fracture site with the radial nail

REDUCTION

Cortical opening for the Ulnar Nail

Instrument: Straight ø3.2mm Awl or ø3.2mm Drill Bit, Tissue Protection Sleeve

Perform the skin incision for the ulnar nail. Prepare the insertion site in the ulnar bone for the second nail. The ulnar entry site is on the posterolateral aspect of the olecranon so that the end of the nail will be buried in the short elbow extensor muscle (anconeus) and permits leaning the elbow on the table (Fig. 34).

Warning:

The medial approach is to be avoided as there is a risk of damaging the ulnar nerve.

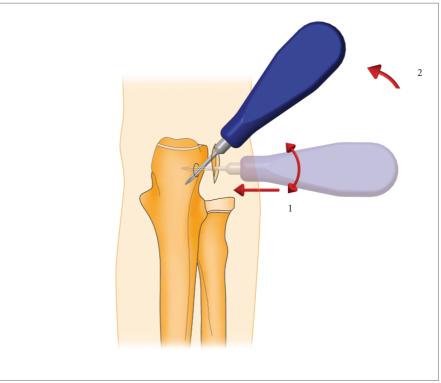


Fig. 34

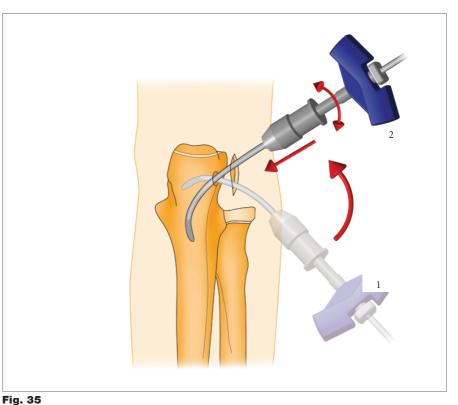
Cortical opening for the ulnar nail

Insertion of Ulnar Nail

Instrument: Universal Chuck with T-Handle

Engage the selected nail with the Universal Chuck by sliding its end into the center of the opening. Locking the grip on the nail can be achieved by holding the front part of the Chuck firmly and turning the T-Handle clockwise. For optimal grip make sure that the nail is captured in the center of the Chuck as it can happen that the nail is clamped with a slight offset.

Advance the nail just down to the fracture site (Fig. 35).



Cortical opening for the ulnar nail

Crossing the Fracture Site with the Ulnar Nail

Instruments: Universal Chuck with T-Handle, Slotted Hammer

Cross the ulnar fracture site with the second nail in the same manner as that of the radial nail: Advance to the fracture site, orient the curved tip to enter the IM canal of the further fragment and hammer the second nail through the fracture site into the further fragment (Fig. 36).

Continue inserting the ulnar nail down to the distal ulnar metaphysis and orient the concave bow of the nail towards the radius.

Ascertain that the nails are oriented correctly. The curved tip of the radial nail must be oriented towards the medial aspect whereas the curved tip of the ulnar nail must be oriented towards the lateral aspect. Thus the two concave aspects of the nails are face-to-face and the construct is further stabilized by the spreading of the intraosseous membrane.

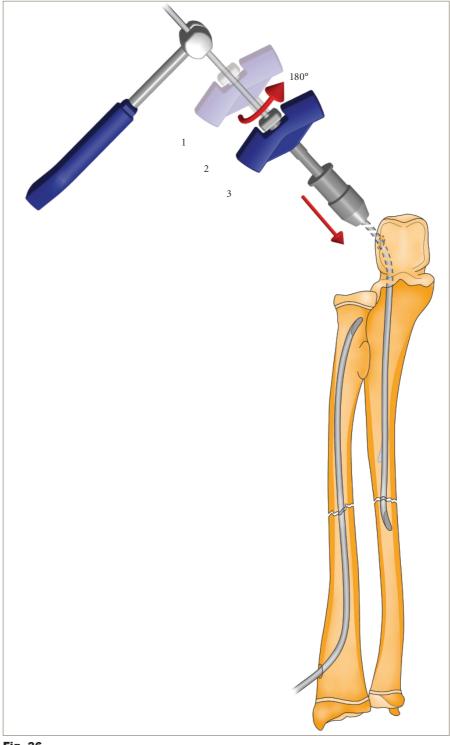


Fig. 36 Crossing the fracture site with the ulnar nail

Impacting the Nail Tips

Instruments: Universal Chuck with T-Handle, Slotted Hammer

Use the Slotted Hammer to impact the nails into their respective metaphyses for the final reduction.

Once the position and orientation of both nails are satisfactory, they are impacted into the cancellous bone of the metaphysis while maintaining reduction. Use the Slotted Hammer on the Universal Chuck with T-Handle to impact the nails. Make sure to only tap on the strike plate of the TA-Handle for an insertion force in line with the nail (Fig. 37).

Attention should be paid to the horizontal plane at all times during this reduction step to prevent rotational malunion.

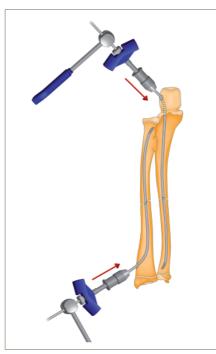


Fig. 37 Impacting the nail tips

Bending the Nail Ends Prior to Cutting

Instrument: Universal Chuck with T-Handle

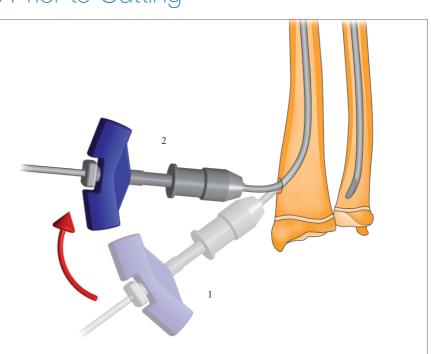
At this point, the Universal Chuck is still on the nail. There are two options for bending the trialing ends prior to cutting off the excess material (Fig. 38):

Option 1:

In some cases, the trialing ends are not bent at all; they are simply left to lie against the cortical wall after trimming.

Option 2:

For ease of future removal, the nail ends may be bent away from the cortex at an angle of approximately 30-60°, according to the limb involved and the surrounding soft-tissue coverage.





Cutting the Nail Ends

Instrument: Small Cutter, for ø1.5-2.5mm nails

Remove the Universal Chuck from the nail.

Cut the end of the nail with the Cutter, facing the golden cutting blades towards the cortex. The black rubber jaws are facing the operator and are holding the clipped nail end preventing it from flying off when the nail end is cut (Fig. 39a & 39b).

Cut the nail end as close as possible to the cortex leaving at least 3mm of the nail end protruding from the cortex.

Warning:

Although there is a rubber grip designed to keep the clipped nail end from flying out of the Cutter, use of eye protection is advised.

If access to the cut-off point is difficult, you may also mark the nail at the cut-off point with a pen or clamp. Retract the nail far enough to access the cut-off point. The cut nail end is pushed back into the intramedullary canal using the Final Impactor as described next.

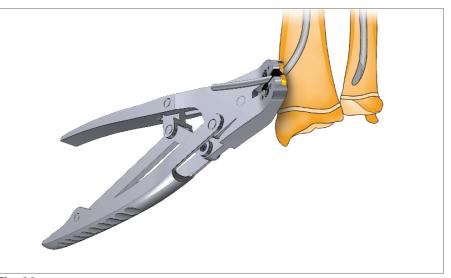


Fig. 39a Cutting the nail ends



Fig. 39b Cutting the nail ends

Final Impaction

Instruments: Small Final Impactor, Slotted Hammer

The Small Final Impactor will leave from 3 to 5mm of the nail length protruding from the outer cortex, according to the position in which it is placed on the bone.

Turn the Impactor so that the desired length of protruding nail is indicated on the side which is closest to and faces the cortex (the opposite length will be facing the surgeon) (Fig. 40). Impact the nails into the metaphyseal bone while firmly maintaining the reduction (Fig. 41).

It is fundamental to completely pronate and supinate the forearm to ascertain full range of motion.

Final fluoroscopic verification in both frontal and lateral planes is made prior to wound closure.

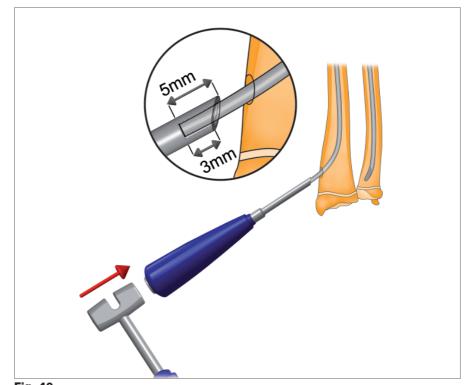


Fig. 40 Impacting the nail ends

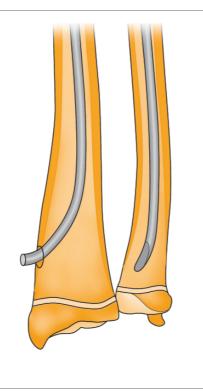


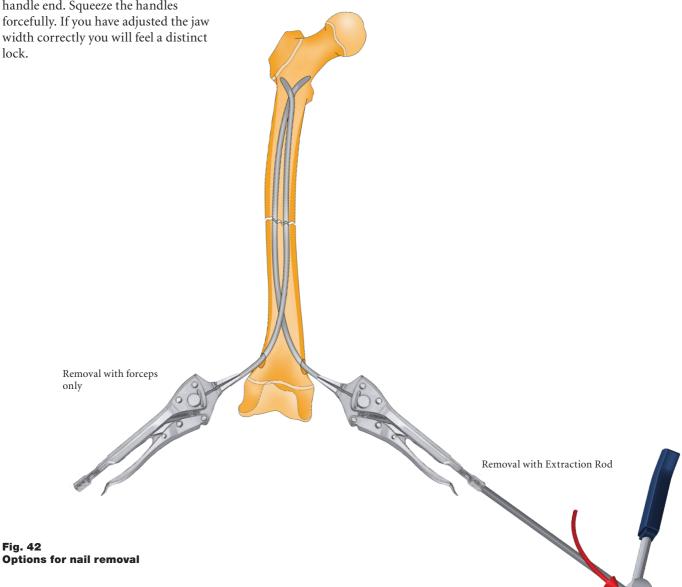
Fig. 41 Impacting the nail ends

Removing the Nails

Instruments: Forceps, Slotted Hammer, Extraction Rod

Engage the Forceps to the exposed nail end. The Forceps requires only a few millimeters of the nail end for removal in most cases. Engage the Forceps in line with the nail straight on.

Adjust the Forceps jaw width by turning the adjustment knob at the handle end. Squeeze the handles forcefully. If you have adjusted the jaw width correctly you will feel a distinct lock.



Care and Maintenance

After each use, all instruments must be cleaned. Instruments with removable parts should be dis-assembled prior to cleaning. Steel brushes must not be used to clean the instruments.

Cannulated instruments must be thoroughly cleaned and opened prior to washing and disinfection. Standard proprietory detergents and disinfectants can be used in accordance with the manufacturer's recommendation.

Prior to autoclaving, instruments should be checked for cleanliness. Instruments with moving parts must be lubricated with autoclavable oil.

Universal Chuck with T-Handle

Clean the Universal Chuck with T-Handle after every use. Use a soft brush and neutral pH detergent to wash the debris from the Chuck and cannulation. It is essential to lubricate the Universal Chuck with T-Handle with autoclaveable oil to maintain smooth operation of the chuck.

After cleaning, apply a single drop of oil to each Chuck jaw and rear bushing (Images 7a–7c).

Open and close the Chuck several times and wipe away the excess oil with a dry towel. Sterilize the Inserter before use.

Oiling the Universal Chuck with T-Handle



Fig. 7a



Fig. 7b



Fig. 7c

Care and Maintenance

Large Cutter

The Cutter has movable parts. To dis-assemble the Cutter, unscrew the Stop Nut and remove the cutting Inner Sleeve from the Sleeve Handle piece (Fig. 8a–8c).

Following the cleaning, and before autoclaving, lubricate the cutting sleeve with autoclavable oil. The cutting sleeve must be adequately lubricated to ensure smooth cutting (Fig. 8d & 8e).

Store the single parts in the metal tray. Sterilize the Cutter before use.

For more information see "Instructions for Cleaning, Sterilization, Inspection and Maintenance of Osteosynthesis Medical Devices" L24002000.

Oiling the Large Cutter



Fig. 8a



Fig. 8d



Fig. 8b



Fig. 8e



Fig. 8c

Ordering Information – Implants

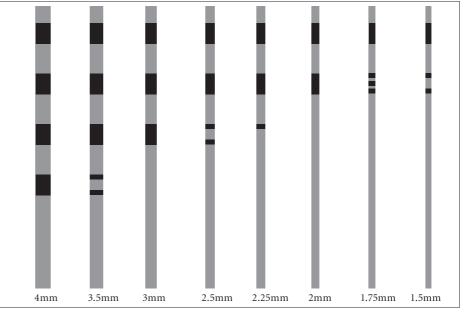
FLEXIBLE NAIL

Titanium Alloy REF	Diameter mm	Total Length mm	Stainless Steel REF
0194-1500S	1.50	300	0195-1500S
0194-1750S	1.75	300	0195-1750S
0194-2000S	2.00	300	0195-2000S
0194-2250S	2.25	300	0195-2250S
0194-2500S	2.50	450	0195-2500S
0194-3000S	3.00	450	0195-3000S
0194-3500S	3.50	450	0195-35008
0194-4000S	4.00	450	0195-4000S

Note:

For non sterile implants, please remove "S" from the reference number.

Laser-etched ends for easy identification



Large band marking = 1mm Small band marking = 0.25mm

Please note that these pictures are an indication only and are not to scale.

Ordering Information – Instruments

	REF	Description		REF	Description
		<u> </u>			
	0193-1000	Awl, Straight, ø5.0mm		0193-1100	Awl Curved, ø3.2mm
	0193-1200	Awl, Straight, ø3.2mm		0193-1300	Awl, Curved, ø5.0mm
	0193-1400	Final Impactor, ø4.0mm		0193-3200	Reduction Instrument, Small
	0193-1600	Final Impactor, ø2.5mm		0193-3800	Chisel
	0193-1900	Cutter, Large	8	0193-3900	Extraction Rod
				0193-4000	Strike Plate
R.C.	0193-2000	Cutter, Small		0193-4600	Hohmann Retractor, 6mm
	0193-2400	Bending Instrument			omm
	0193-2600	Protection Sleeve		0193-4700	Periosteal and Freer Elevator
	0193-2800	Universal Chuck with T-Handle		1806-6102	Teardrop Handle, AO coupling
	1806-0170	Slotted Hammer		1806-6165	Crown Drill, ø3mm
- Contained	0193-3400	Forceps		1806-6166	Crown Drill, ø4mm
				1806-6167	Crown Drill, ø5mm
	0193-4350(S)	Drill, AO (sterile), ø3.2 × 180mm		1806-6183	Conical xtractor, female, left hand,
	0193-4500(S)	Drill AO (sterile),			ø3mm
		ø5.0 × 180mm		1806-6184	Conical Extractor, female, left hand, ø4mm

BASIC INSTRUMENTS

OPTIONAL INSTRUMENTS

-6

6983-5000

REF

0193-1910

0193-1920

0193-1930

0193-1940

0193-2001

Slotted Hammer, Small

Sleeve for Large Cutter

Handle for Large Cutter

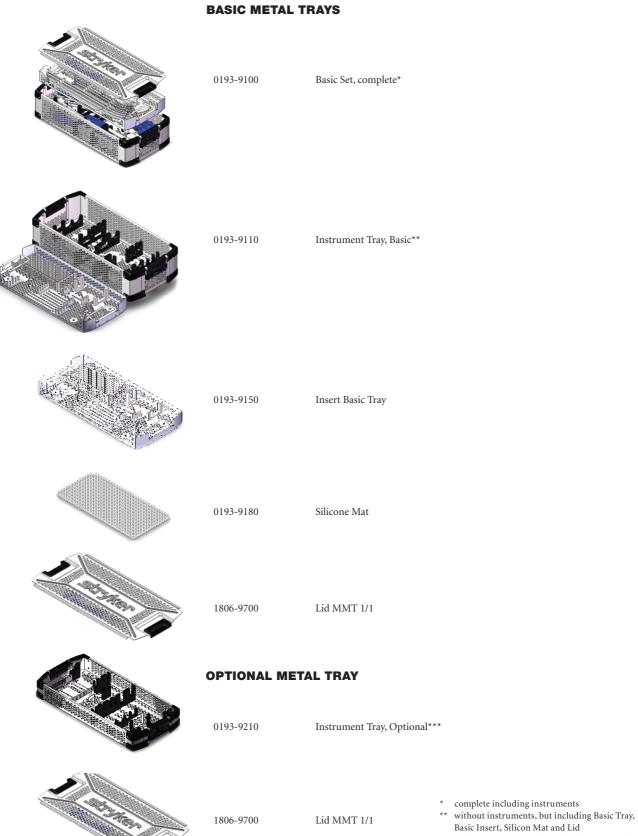
Wrench for Large Cutter

Blades for Small Cutter

Nut for Large Cutter

Description

Ordering Information – Trays



*** without instruments, but including Optional Tray and Lid

Please note that these pictures are an indication only and are not to scale.

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