



# MJ-FLEX

The New Metaizeau Nail™

Operative Technique

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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see Instructions for Use for the complete list of indications, warnings,precautions, and other important medical information.

Operative Technique Contributing Surgeon:  
J-D Metaizeau, M.D.

## General Description

The MJ-FLEX THE NEW METAIZEAU NAIL™ (MJ-FLEX) is an intramedullary implant system specifically designed for Elastic Stable Intramedullary Nailing (ESIN) fracture fixation. The principle of ESIN involves balanced nailing to provide elasticity and stability at the fracture site.

## Intended Use

The MJ-FLEX is intended for the treatment of diaphyseal fractures of long bones.

## Indications for Use

The MJ-FLEX is indicated to treat:

- upper extremity and clavicle fractures in all patients except newborns and infants;
- lower extremity fractures in pediatric patients, except newborns and infants, where the flexibility of the implant is paramount not to disrupt the growth plate;
- lower extremity fractures in small adults where the medullary canal is narrow.

## Features and Benefits

- Dedicated for the treatment of diaphyseal long bones fractures in pediatric patients, except new born and infants, and in small adults where the small size and minimally invasiveness of the device is the main priority
- The patented shape allows to insert a strong nail to optimally fill the medullary canal
- Titanium and stainless steel options
- Strong, elastic and easy to bend
- Sterile implants
- Nails are supplied in different diameters and lengths to assure compatibility with anatomy of the patient

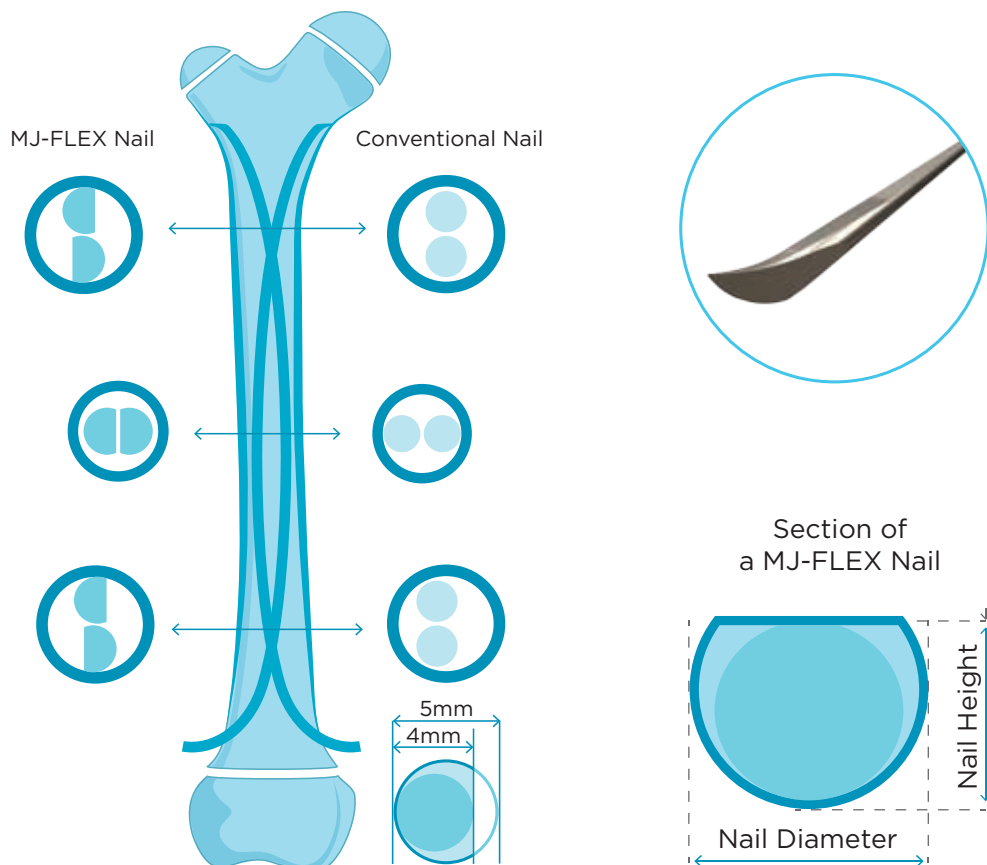
## Surgeon Benefits

- Developed to allow a direct visual control of the alignment of the nail tip in the medullary canal, thus potentially reducing exposure to the image intensifier during insertion of the nail and the surgery time
- The flat surface allows to bend the nail on a proper plane
- Dedicated instrumentation for a streamlined operative technique
- A great variety of nails in several diameters both in titanium and stainless steel

## Patient Benefits

- Stability of the osteosynthesis in all planes due to the superior medullary canal filling than standard cylindrical nails<sup>1</sup>
- Developed to limit X-ray exposure during insertion due to the unique shape that allows visual control of nail orientation
- A minimal invasiveness of the device

<sup>1</sup>Bah M, Suchier Y, Denis D, Metaizeau JD (2017) *Pre-clinical analysis of the performance of a new elastic stable intramedullary nail design*. Orthopaedic Proceedings vol. 99-B no. SUPP 3 24

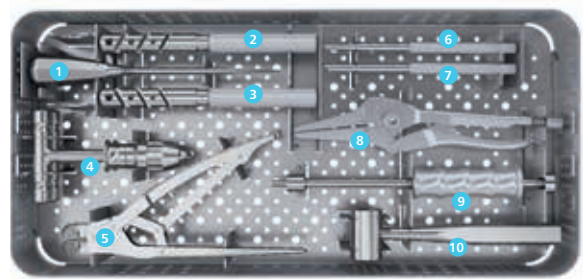


## Equipment Required

### 166990C MJ-FLEX Sterilization Box, complete

Part#	Description
166990	MJ-FLEX Nail Sterilization Box, empty
166260	① Bone Awl
166300	② Bender - Right
166301	③ Bender - Left
166955	④ Nail Inserter
W1003	⑤ Wire Cutter
166381	⑥ Nail Impactor - 2/3
166383	⑦ Nail Impactor - 4/5
166978	⑧ Extraction Pliers
166370	⑨ Slap Hammer
166380	⑩ Hammer
166305*	Nail Cutter

\* Nail Cutter is packaged individually (out of the tray), delivered together with the complete Box.



### IMPLANTS - STERILE - Titanium

Part#	Description
99-T662540	MJ-FLEX Ti Nail L400mm D2.5mm Sterile
99-T663040	MJ-FLEX Ti Nail L400mm D3mm Sterile
99-T663540	MJ-FLEX Ti Nail L400mm D3.5mm Sterile
99-T664045	MJ-FLEX Ti Nail L450mm D4mm Sterile
99-T664545	MJ-FLEX Ti Nail L450mm D4.5mm Sterile
99-T665045	MJ-FLEX Ti Nail L450mm D5mm Sterile

### IMPLANTS - STERILE - Stainless Steel

Part#	Description
99-664045	MJ-FLEX Ss Nail L450mm D4mm Sterile
99-664545	MJ-FLEX Ss Nail L450mm D4.5mm Sterile
99-665045	MJ-FLEX Ss Nail L450mm D5mm Sterile

## Implant Principles

The elasticity of the pre-bent nails provides the potential energy that causes the nails to strain against the cortex generating three-point fixation (**Fig.1**) and correctional forces. When inserted into a fractured bone, nails of appropriate diameter should reduce the fracture by continually counteracting rotational and angular forces of the muscles.

The following guidelines are recommended with respect to implant principles and proper operative technique:

1. The apex of the fully inserted nail is at the level of the fracture site (this allows optimal correctional forces).
2. When fully inserted, the tips of the nail should be on the opposite epiphysis with respect to the entry point (this ensures three-point fixation).
3. Theoretically, the two nails cross each other two times, once below and once above the fracture site.

## Nail selection



**NOTE:** The flat part of the MJ-FLEX nail leads to two different measures on the transverse section (**Fig.2**), that are the diameter (D) and the height (H) of the nail. When selecting the nail consider  $H = 80\% D$ .

The laser marked size reported on each nail and on packaging information is intended as the diameter (D) of the nail.



**PRECAUTION:** Ideally, the two nails should have the same diameter so that the opposing forces are equal, limiting iatrogenic valgus or varus deformities



**NOTE:** In rare cases, i.e. when different opposite forces are necessary to maintain fracture reduction, it is accepted to insert two nails with different diameters always ensure that a correct reduction is achieved at the end of the procedure.

When using two MJ-FLEX nails of the same size, the diameter (D) of the selected nail should be about 50% of the intramedullary canal measured at the level of the isthmus ( $\emptyset$  IM canal). Considering the height (H) of the nail, this automatically corresponds to 40% of the  $\emptyset$  IM canal allowing adequate clearance for the second nail of same dimension (**Fig. 3**).

Fig. 1

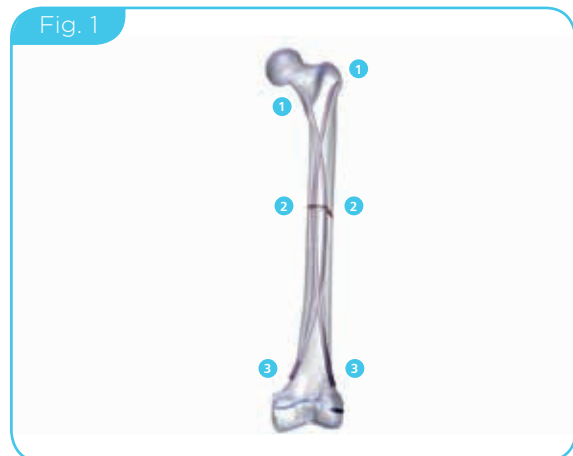
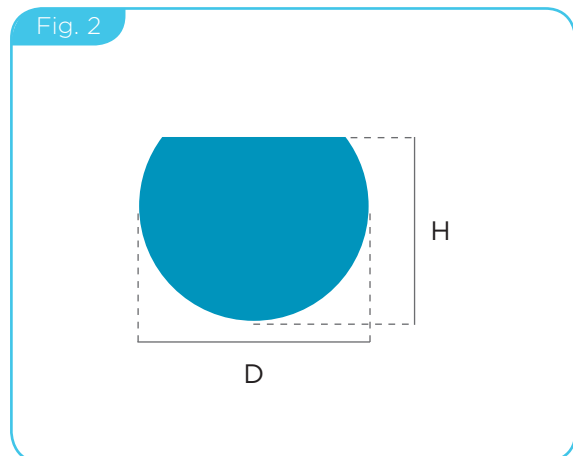
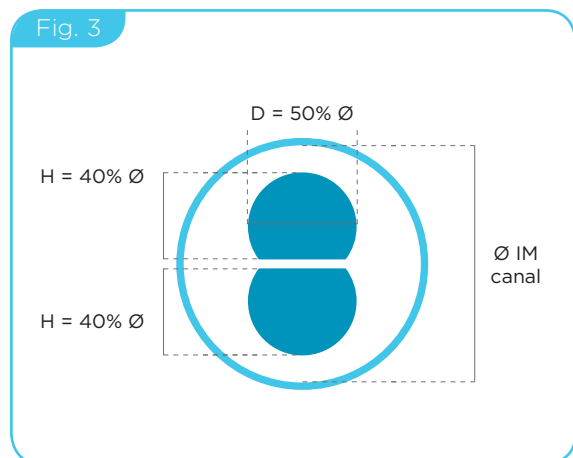


Fig. 2



Transverse section of the MJ-FLEX nail

Fig. 3



Medullary canal filling

According to Ø IM canal, two calculations are therefore equivalent to select the appropriate size of the nail (Table 1):

$$D = 0.5 \times \text{Ø IM canal}$$

or

$$H = 0.4 \times \text{Ø IM canal}$$



**PRECAUTION:** The diameter of the selected nail should be no more than 50% of the width of isthmus. In case two nails with different diameters are used, the sum of the two diameters should not be more than the width of the isthmus.

Ø IM canal	Nail size	
	D (laser marked)	H
5.0	2.5	2.0
6.0	3.0	2.4
7.0	3.5	2.8
8.0	4.0	3.2
9.0	4.5	3.6
10.0	5.0	4.0

Table 1

## Prior to Use Information

The product is intended for professional use only. Surgeons who supervise the use of the product must have full awareness of orthopedic fixation procedures and should be familiar with the devices, instruments and surgical procedure, including the application and removal.



### WARNING:

- Preoperative procedures, knowledge of surgical technique and proper selection and placement of the implant are important aspects for the successful use of the device by the surgeon.
- Do not combine MJ-FLEX nails with components from other systems.
- Do not combine MJ-FLEX nails of dissimilar metals, since this may cause an electrolytic reaction.
- Never insert more than two nails in the same medullary canal.
- Nails must not be reused. If any implant has come into contact with any body fluid it should be considered to have been used. Loosening, cracking or breakage of the implants can cause loss of stabilization.
- This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.
- In skeletally immature patients, it is recommended to avoid crossing open epiphyseal plates to decrease the probability of consequent growth disturbance.



### PRECAUTION:

- Ensure that all components needed for the operation are available in the operating theatre.
- Examine all components carefully prior to use. Product integrity, sterility (in the case of sterile products) and performance are assured only if the packaging is undamaged.
- Do not use if packaging is compromised or if a component is believed to be faulty, damaged or suspect.
- Careful handling and storage of the product is required. Scratching or damage to the component can significantly reduce the strength and fatigue resistance of the products.
- Check the fit and functioning of nails and instruments assembly prior to implantation.
- Ideally, two nails should be used. Where the medullary canal is very narrow, (e.g. for clavicular, metacarpal, phalangeal and metatarsal fractures, fibula, ulna, radius), only one nail might be used taking care to fill the canal as much as possible.

## MRI safety information

ORTHOFIX MJ-FLEX Nail has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of The ORTHOFIX MJ-FLEX Nail in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

## Cleaning Sterilization and Maintenance

Important information - please read prior to use MJ-FLEX The New Metaizeau Nail™ - PQ MJF.

## Surgical steps for retrograde femoral insertion



**NOTE:** The following steps describe in detail the more common retrograde technique for femoral fractures stabilization with two nails inserted from a lateral and a medial entry points above the distal physis. Nails positioning for different entry points and/or anatomical sites follows the same implant principles and the same surgical steps.

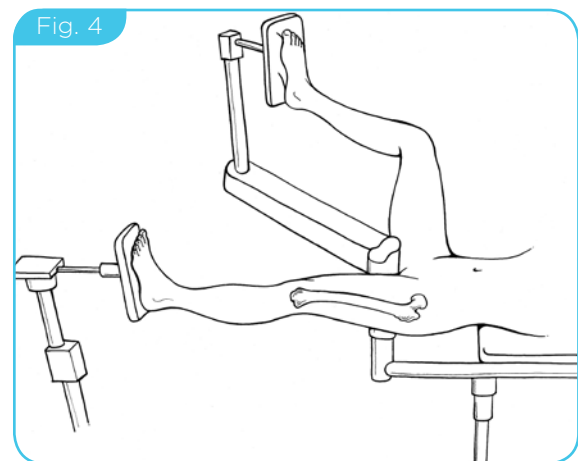
## Patient positioning



**NOTE:** Fracture reduction should be achieved according to the normal reduction-philosophy of the surgeon. However, the following procedure may help achieving this goal.

### Fracture reduction in the frontal plane

The patient is placed supine on a fracture table (**Fig.4**), and initial reduction obtained by traction under image intensification. Traction and abduction are then adjusted if necessary, to achieve anatomic reduction.



Patient positioning



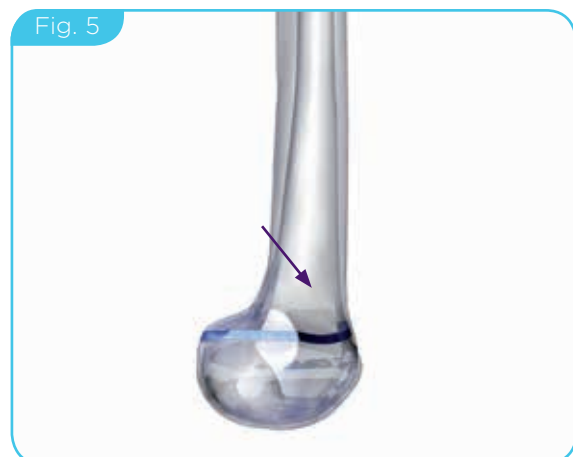
## Entry point targeting and opening

### Entry point targeting

The entry points will vary with individual anatomy and they are on the medial and lateral aspect of the distal femur, at the metaphyseal-diaphyseal junction, 2 to 3 cm proximal to the distal physis (**Fig 5**).

Position the C-arm to allow visualization of the distal femur in the AP plane and place a radiopaque tool above the skin and perpendicular to the bone to find and mark the level of entry points.

Make a 2-3 cm incision on the lateral or medial aspect of the distal femur at the marked level. Gently dissect down to the periosteum to exhibit the bone allowing extra space to permit maneuvering of the nail upon insertion.



Entry point targeting

### Entry points opening

Open the first entry point by gently advancing the bone awl (Code: 166260) perpendicular to the bone (**Fig. 6A**) with a twisting motion. Alternatively, the cannulated awl (Code: 183260) can be used.

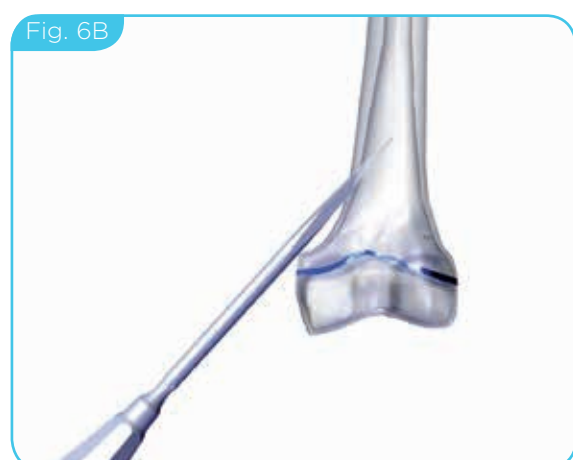
Once the first cortex is penetrated, lower the awl to a 45° instrument-to-bone angle to shape an oblique opening in the direction of the fracture (**Fig. 6B**). Circular movement of the awl can help widening the entry point.



First cortex penetration

**NOTE:** It is suggested to insert first the nail which most effectively aids reduction of the fracture pulling the proximal fragment into alignment or the one that may be the most difficult to insert. Open the medial or the lateral point first accordingly.

Repeat the same procedure on the opposite side when opening the second entry point.



Oblique opening shaping

## Nail Contouring



**NOTE:** There are two different benders specifically designed for right (Code: 166300) or left (Code: 166301) hand. Each bender has three different holes and three different bending slots (**Fig. 7**) for the different sizes of the nails. Holes and slots can be alternatively used to engage the bender to the nail.

Fig. 7

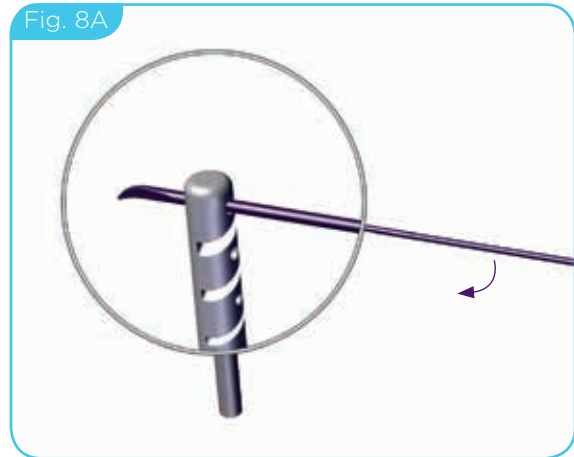


LEFT and RIGHT benders

Nail counterung can be done by hand or using one bender and one hand (**Fig. 8A**), or using two benders (**Fig. 8B**).

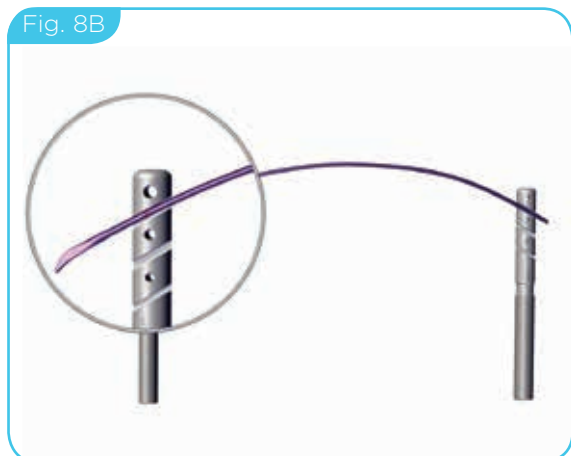
Engage the nail into the appropriate hole or slot of the bender/s according to selected size of the nail.

Fig. 8A



Nail counterung using one bender

Fig. 8B



Nail counterung using two bender

## Nail Insertion

Insert the selected nail in the nail inserter (Code: 166955) with a length of about 10 cm protruding the chuck. Lock the nail by holding the chuck firmly and turning the T-handle clockwise (Fig. 9).

Fig. 9



Nail matching on nail inserter



**PRECAUTION:** For optimal control of the nail, make sure that one jaw of the chuck is positioned exactly over the flat part of the nail (Fig. 10).

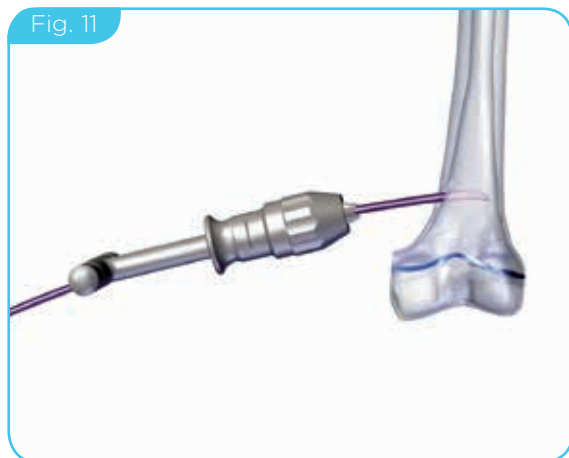
Fig. 10



Optimal jaw-nail matching

Insert the nail in the entry point directing the tip distally (Fig. 11).

Fig. 11



Nail insertion

As soon as the first cortex has been crossed, rotate the tip of the nail 180° towards the fracture site (**Fig. 12**).

Advance the nail until the inserter is near the skin, ensuring that the convex side of the bent nail is glancing off the far cortex (opposite to the entry point). Unlock the nail and slide back the inserter until a length of about 10 additional centimeters is protruding from the chuck.



**PRECAUTION:** During insertion, check the progression of the nail under fluoroscopy to ensure the tip is advancing without any impediment. If the implant is not advancing properly, the surgeon should never persist in the insertion, but should review the situation and consider the following options:

- Withdraw a little the nail turning it before trying to insert it again;
- Make sure the tip of the nail has the proper orientation;
- Increase the contour angle near the tip of the nail;
- Gently hammer the nail;
- Change the nail for the next-smaller diameter.

Vigorous hammering should never be necessary. The nail should advance blow by blow. If the nail does not advance properly, the surgeon should never persist with hammering.

Continue advancing the nail until the fracture site is reached (**Fig. 13**).



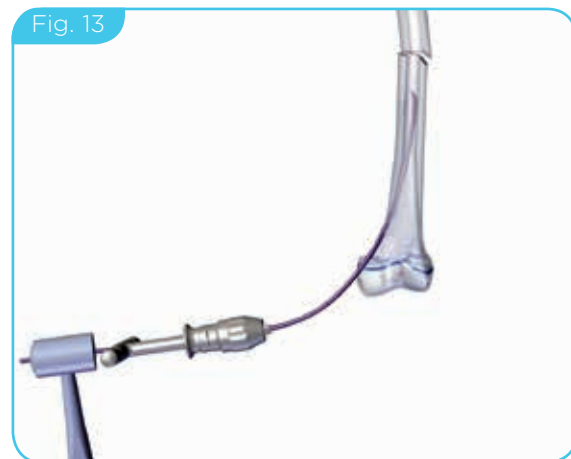
**NOTE:** The flat part of the MJ-FLEX nail follows the same plane of the bow providing a reference for the tip of the nail orientation during the insertion.

Once the fracture site is reached, under fluoroscopy achieve a partial reduction and advance the nail a few centimeters across the fracture site into the second fragment.

If necessary, rotate the tip of the nail towards the medullary canal of the opposite fragment (**Fig 14**). This maneuver often aids in crossing the fracture site avoiding any impingement of the tip of the nail in the broken cortices.



Nail insertion



Nail advancing up the first fragment



Nail rotation at the level of the fracture site

If rotation of the nail was needed to cross the fracture line, turn it back to re-orient the tip towards the entry point-side cortex and continue advancing the nail as appropriate. If necessary, drive the nail by gently hammering on the T-handle of the inserter.



**NOTE:** Ideally, the tip of the nail should be placed underneath the metaphyseal section (**Fig. 15**).

Fig. 15



Nail advancing up the second fragment

Repeat the same procedure to insert the second nail through the opposite entry point. Advance the second nail to the level of the first one crossing the fracture site.

To aid advancing the tip of the second nail can be rotated in anterior or posterior direction to avoid it spiraling up the first nail.



**WARNING:** Make sure not to twist the tip of the second nail more than 180° to avoid the second nail spiral up around the first nail (“corkscrew effect”).



**NOTE:** If traction was applied for reduction purposes, it needs to be released before the following steps.

Fig. 16



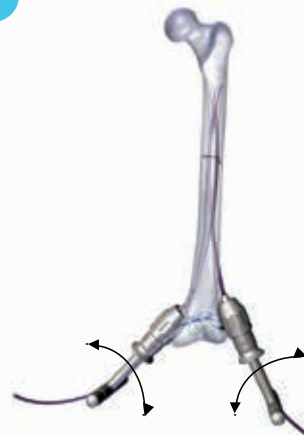
Second nail insertion

Under fluoroscopy, check the rotation of the femur and, if needed, orientate anatomically the fragments one to the other by external maneuver. Once rotational malalignments are corrected, continue advancing both nails alternatively until they are into the cancellous bone of the metaphysis of the second fragment (**Fig. 16**).



**NOTE:** Nails can act as reduction tools as well as countering angulation forces to achieve the final satisfactory reduction. If necessary, angulations of the proximal fragment can be addressed by maneuvering the nail inserters to direct the tips of the nails as appropriate (**Fig. 17**). Once the reduction is obtained, the nails should be gently hammered further in the epiphysis to anchor the device.

Fig. 17



Final reduction

Theoretically, a varus angulation can be adjusted by directing the tip laterally whereas a valgus angulation can be adjusted by directing the tip medially. On the sagittal plane, a recurvatum angulation can be adjusted by directing the tip posteriorly, and a flexion angulation can be adjusted by directing the tip anteriorly.

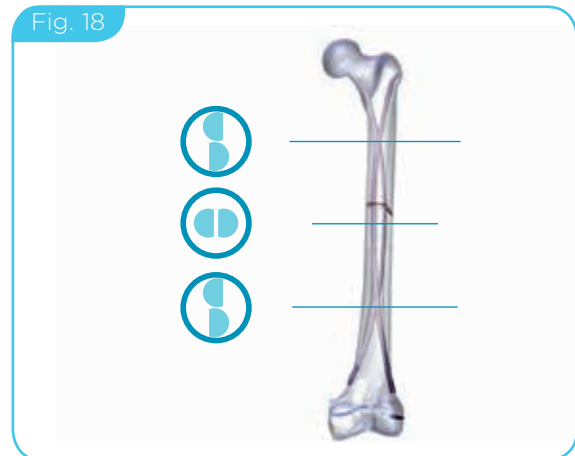
Ideally, when fully inserted, the tip of the laterally inserted nail should be placed just above the greater trochanter growth plate, and the tip of medially inserted nail just above the lesser trochanter. Consider that after the final impaction the nail will be further advanced 2 to 5 mm (**Fig. 18**).



**PRECAUTION:**

- Under fluoroscopy, verify the final position of the tip of the nail to prevent inadvertent damage to the physis. It is recommended to stop nail insertion at least 1 cm before the physis to allow adequate clearance for optional final impaction of the nail.
- Improper positioning of the nails may result in loosening, cracking, or fracture of the device or bone or both.

Fig. 18



Fully inserted nail

## Nail Cutting



**NOTE:** Two different cutters are provided: for small diameters (D = 2.5 and 3 mm) it is recommended to cut nails with the wire cutter (**Fig.19**) (Code: W1003), whereas for the greater diameters it is recommended to use the nail cutter (Code: 166305) which allows 3 different openings (**Fig. 20**).



**PRECAUTION:** Ensure selection of the appropriate cutter and cutter hole according to the selected diameter of the nail.

Fig. 19



Wire cutter

Fig. 20



Nail cutter

In order to avoid sharp bending of the nail at the bone level, hold the very end of the nail whilst bending it in a smooth 90 degree parabola, then cut to length. Mark the planned cut-off points with a pen or with a clamp. Ideally, for the femur the cut-off point should be 1 cm of nail protruding from the bone for removal purposes. The 1 cm protruding nail will decrease after final impaction.

Cut the nails at the level of the marked cut-off points with the appropriate cutter (**Fig. 21**).

Repeat the same procedure to cut the second nail.



**NOTE:** If access to cut-off point is difficult, retract the nail far enough to access the cut-off point from outside the incision.



Nail cutting

## Final Impaction

If necessary, reinsert the nail slightly to leave an appropriate amount of protruding nail from the bone.



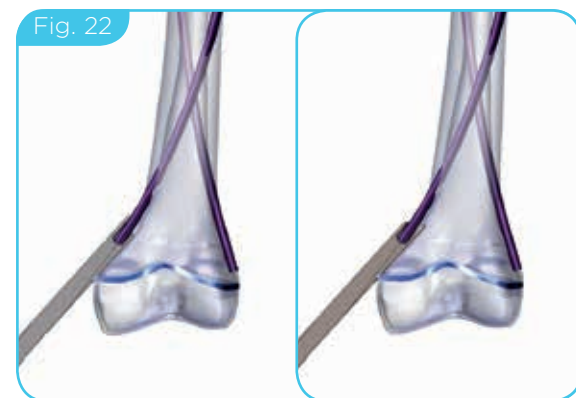
**NOTE:** Two different nail impactors are provided for final impaction of the nails. For small diameter nails ( $D = 2.5$  and  $3$  mm) it is recommended to use the small nail impactor 2/3 (Code: 166381), whereas for greater nails the greater nail impactor 4/5 (Code: 166383) is recommended.



**PRECAUTION:** Ensure selection of the appropriate impactor according to the selected diameter of the nail.



**NOTE:** When driven flush to the periosteum, depending on its orientation the small nail impactor will leave approximately 3 to 5 mm of nail protruding from the cortex, whereas the greater impactor will leave 7 to 12 mm (**Fig 22**).



Turn the impactor to achieve the desired length of protruding nail, capture the end of the nail with the selected nail impactor and impact the nail while firmly maintaining the reduction by gently hammering (**Fig. 23**).

If the nail has been over inserted, use the extraction pliers (Code: 166978) to pull out the nail.



**PRECAUTION:** Multiple re-positioning of the nail may lead to poor anchoring of the nail tip. Close the wound.



Final impaction

## Post-Operative Care

Carefully monitor the healing progress in all patients. Choose the appropriate post-operative care for each patient and application. The following are suggestions given by Orthofix, however, post-operative care will always remain the full responsibility of the surgeon:

- Usually, there is no need for a cast. For less stable fractures, if clinically significant deflection (more than 5° from varus or valgus) is noted a single leg spica cast is recommended.
- Use of crutches is recommended for comfort and allows progressive weight bearing.
- Mobility and progressive weight bearing should be encouraged as early as possible, within pain limits, and according to the surgeon's discretion. Regulate the amount of weight bearing, depending on the compaction and/or callus formation.
- Physical therapy is seldom required.
- Patients should be instructed to report any adverse or unanticipated effects to the treating surgeon.



**NOTE:** The nail can be over bent, crack or even break when subjected to the increased loading associated with delayed union, non-unions and/or improper alignment. Internal fixation devices are load-sharing devices which are intended to hold fractured bone surfaces in position to facilitate healing. Loads on the device produced by load bearing and the patient's activity level will dictate the longevity of the device.



### PRECAUTION:

- If callus is slow to or fails to develop, the implant may eventually break due to metal fatigue: to avoid this, further measures may be required, including replacement of the implant.
- When appropriate the implants should be removed at conclusion of treatment.

## Nails Positioning for Different Entry Points and/or Anatomical Sites



Femur (antegrade)



Forearm



Humerus (antegrade)



Humerus (retrograde)



Humerus supracondylar



Radius (retrograde)



## Nails Removal

Once the fracture is healed, nails can be removed.

Make a 2-3 cm incision on the lateral or medial aspect of the distal femur at the level of the entry point. Gently dissect down to the periosteum to exhibit the protruding nail allowing extra space to permit maneuvering of the extraction pliers (Code: 166978) upon removal.

Engage the extraction pliers to the exposed nail end (Fig. 24). In most cases the plier requires only a few millimeters of the engagement with the nail for removal.

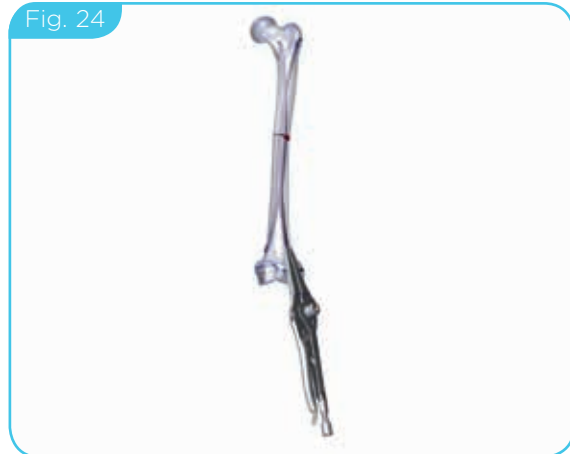


**NOTE:** Engage the plier in line with the nail strength. Once the nail is engaged, to preserve the grip avoid moving the plier left or right.

Retract the nail with the extraction pliers. If the nail is difficult to remove, the slap hammer (Code: 166370) can be matched to the pliers (Fig. 25) and used to complete removal (Fig. 26).

Close the wound and repeat the same procedure to extract the second nail.

Fig. 24



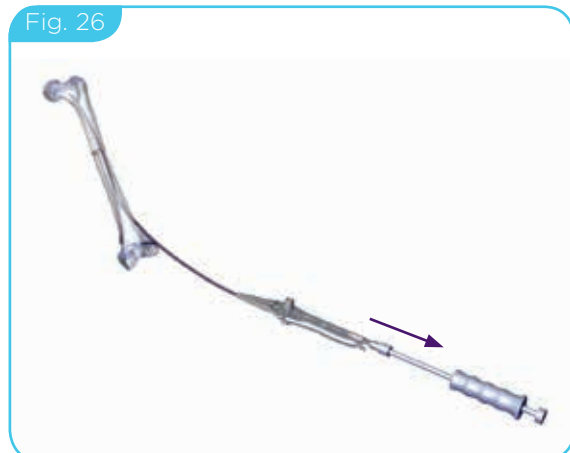
Exposed nail engagement

Fig. 25



Slap hammer matching

Fig. 26



Nail removal





Electronic Instructions for use available at the website <http://ifu.orthofix.it>

Electronic Instructions for use - Minimum requirements for consultation:

- Internet connection (56 kbps)
- Device capable to visualize PDF (ISO/IEC 32000-1) files
- Disk space: 50Mbytes

Free paper copy can be requested to customer service (delivery within 7 days):  
tel +39 045 6719301, fax +39 045 6719370, e-mail: [customerservice@orthofix.it](mailto:customerservice@orthofix.it)



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Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. This manual is furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience. Please refer to the MJ-FLEX Instructions for Use (PQ MJF) supplied with the products for specific information on indications for use, contraindications, warnings, precautions, adverse effects and sterilization.