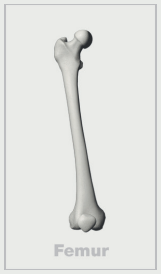
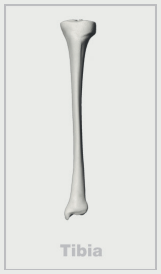


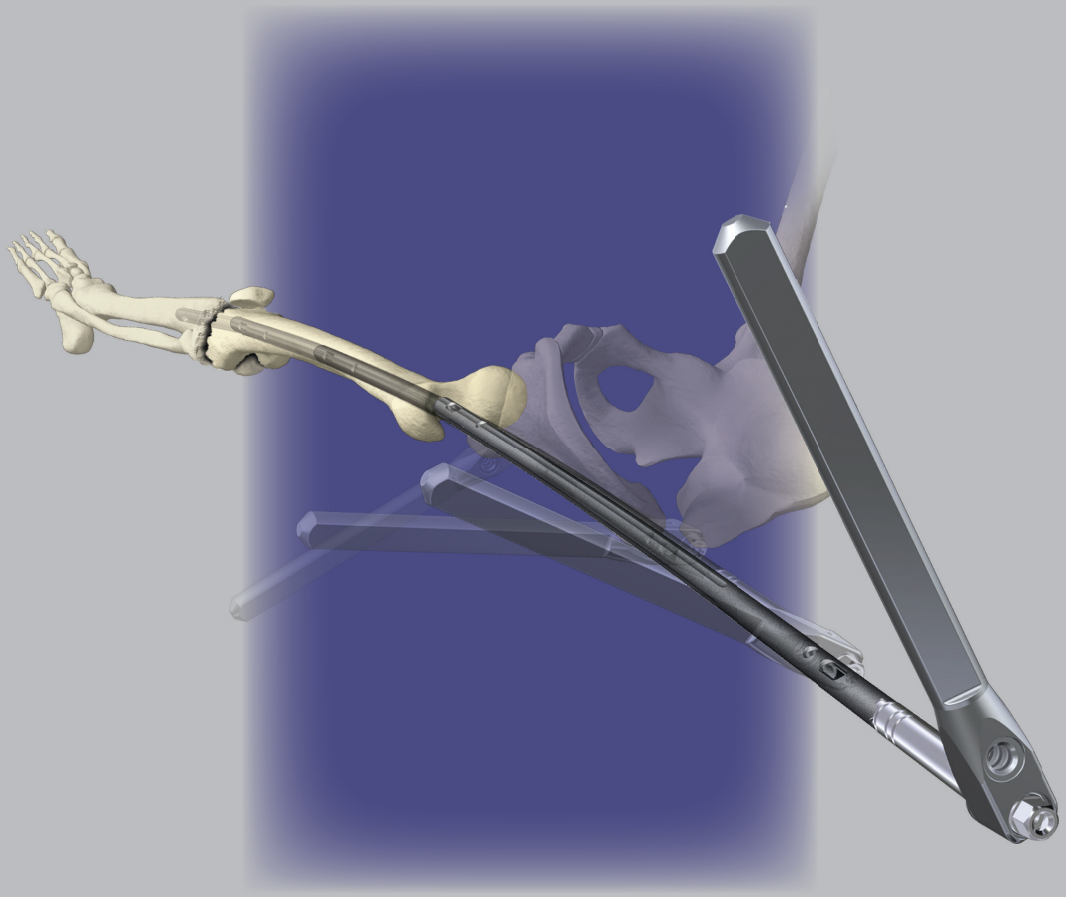


stryker

T2®

Arthrodesis Nailing System

Operative Technique



IM Nailing

T2 Knee Arthrodesis Nailing System

Contributing Surgeons

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This publication sets forth detailed recommended procedures for using Stryker 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.

⚠ WARNING

- Follow the instructions provided in our cleaning and sterilization guide (OT-RG-1).
- All non-sterile devices must be cleaned and sterilized before use.

⚠ WARNING

Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/ disassembly instructions.

Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.

Consult Instructions for Use (www.ifu.stryker.com) for a complete list of potential adverse effects and adverse events, contraindications, warnings and precautions.

The surgeon must advise patients of surgical risks, and make them aware of adverse effects and alternative treatments.

⚠ WARNING

- The patient should be advised that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma and that the device has a finite expected service life.
- Removal or revision of the device may be required sometime in the future due to medical reasons.

References

1. Incavo S., Lily J. ,Churchill Bartlett C., Arthrodesis of the Knee: Experience with Intramedullary Nailing. Journal of Arthroplasty 15 (7) 871–876, 2000
2. Hofmann G.O., Therapeutische Optionen bei persistierendem Kniegelenkinfekt, Trauma Berufskrankheit 5 (2003), 221–224

Contents

Indications & Contraindications

Indications

The T2 Arthrodesis Nail is indicated for long bone internal fixation, which may include the following:

- Aseptic failed total knee arthroplasty
- Open and closed femoral fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures and tumor resections
- Ipsilateral femur fractures
- Failed external fixation, nonunions and malunions
- Periarticular fractures where repair is not possible
- Knee Arthrodesis

Contraindications

The physician's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

- Any active or suspected latent infection or marked local inflammation in or about the affected area
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site
- Bone stock compromised by disease, infection or prior implantation that can not provide 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 to 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 postoperative care
- Other medical or surgical conditions which would preclude the potential benefit of surgery

⚠ WARNING

The T2 Arthrodesis Nailing System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of T2 Arthrodesis Nailing System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

Technical Details

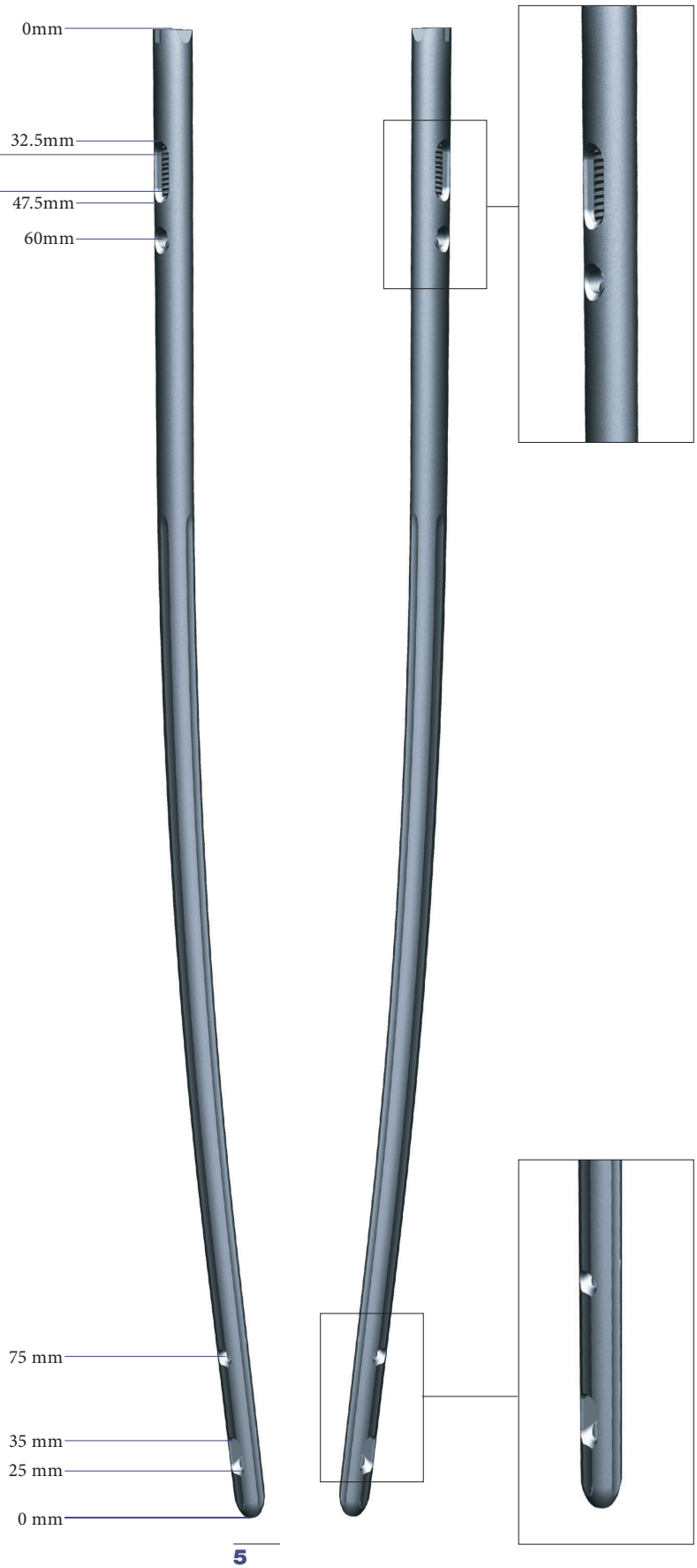
System Specifications

Two Nails, Left and Right

Diameters: 10, 11.5, 13mm
Lengths: 540 – 780mm
in 40mm increments

Compression Range:

Total Length of Slot	15mm
Less Screw Diameter (–)	5mm
Maximum Movement of	10mm



Operative Technique

Pre-operative Planning

An X-Ray Template (1806-0011) is available for pre-operative planning. Implant sizing is best determined using full length A/P and Lateral X-Rays of both the affected and contralateral legs. C.T. Scan for canal diameter and leg length may be useful. The knee should be placed in 5–10˚ of flexion and 5˚ valgus. The leg should be 1cm shorter than the opposite side. This position allows for more normal gait and foot clearance during walking.

Ultimately, 1 cm of leg shortening is the goal, therefore in cases with more significant bone loss, additional flexion should be avoided to minimize additional shortening.

Nail Length

The nail length is surgeon dependent with regards to the individual situation of the patient and with regards on how long the nail should extend into the Tibia.

Patient Positioning

Patient positioning is surgeon dependent. The patient may be positioned supine (elevate the affected hip), lateral or semi-lateral on a radiolucent table.

⚠CAUTION

Use image intensification (A/P and Lateral) for confirmation throughout each step.

Knee Incision

A vertical skin incision is made extending from the femoral condylar region to the tibial tubercle, followed by a parapatellar capsular incision. In cases with a previous incision, this one could be used. Knee arthroplasty instruments may be used to recut tibial and femoral surfaces.

Hip Incision and Entry Point

A skin incision is made beginning at the level of the Greater Trochanter extending proximal and slightly posterior, in line with the Gluteus Muscle, exposing the Piriformis Fossa. Alternatively, the Tip of the Greater Trochanter can be located by palpation, and a horizontal skin incision is made from the Greater Trochanter to the Iliac Crest. The medullary canal is opened with the curved awl (1806-0040), or with a 3x285mm K-Wire (1806-0050) and Ø12mm Rigid Reamer (1806-2014) combination.

Alternatively, a minimal skin incision of the hip region can be made if the femoral canal is reamed in retrograde fashion from the knee joint. To accomplish this, the 3x1250mm Ball Tip Guide Wire (1806-1250S) is advanced from the distal femoral canal proximally to the greater trochanteric/ piriformis fossa region.

⚠WARNING

Avoid the femoral neck. The Guide Wire is then gently advanced through the cortex by gently tapping the strike plate on the Guide Wire Handle/Chuck assembly. Fluoroscopic visualization is necessary for this step. Once the Guide Wire exits the bone, it is retrieved through a small skin incision made over the tip of the Guide Wire.

Noting any deformity of the axis of the tibial shaft, and using either the Awl or Rigid Reamer over the K-Wire, open the anterior central medial aspect of the tibia using the tibial tubercle as a reference to the medullary canal.

Insert the 1250mm Ball Tip Guide Wire (1806-1250S) from the hip through the knee and advance into the tibial shaft to the depth at which you want the nail to end.

The Guide Wire Ruler (1806-0022) features dedicated marks to identify the to be chosen nail length when using the 1250mm Guide Wire.

⚠CAUTION

Use image intensification (A/P and Lateral) for confirmation throughout each step.

⚠WARNING

Thorough evaluation of pre-operative radiographs of the affected extremity is critical. Careful radiographic examination can prevent intra-operative complications.

Operative Technique

Reaming

Using a 885mm Bixcut Modular Reamer Shaft (0227-8885S), reaming is commenced in 0.5mm increments. Generally, the femur is reamed 1.5 – 2.0mm larger than the diameter of the nail selected, and the tibia is reamed line to line.

The proximal end of the tibial shaft may be over-reamed if there is any question of final Femoral-Tibial alignment. Final determination of how much to ream either the femur or the tibia must be made by the surgeon based on many factors including bone quality and whether the nail will be cross-locked with screws distally in the tibia. As stated above, in some cases, surgeons may opt to use standard length Guide Wires and Reamers and ream the femur in retrograde fashion first and then the tibia separately.

Nail Assembly

The selected nail is assembled onto the Target Device (1806-1005) with the Femoral Holding Screw (1806-0165) (Fig. 1). Tighten the Nail Holding Screw with the Universal Socket Wrench (1806-0400) securely so that it does not loosen during nail insertion.

Alternatively, the Fixation Screw Clamp (1806-0273) can be used to fix the Targeting Arm to the Nail Handle. After clamping it on the Targeting Arm the knob will tighten the sleeve to the Targeting Arm.

⚠CAUTION

Curvature of the nail must match the curvature of the femur and knee valgus.

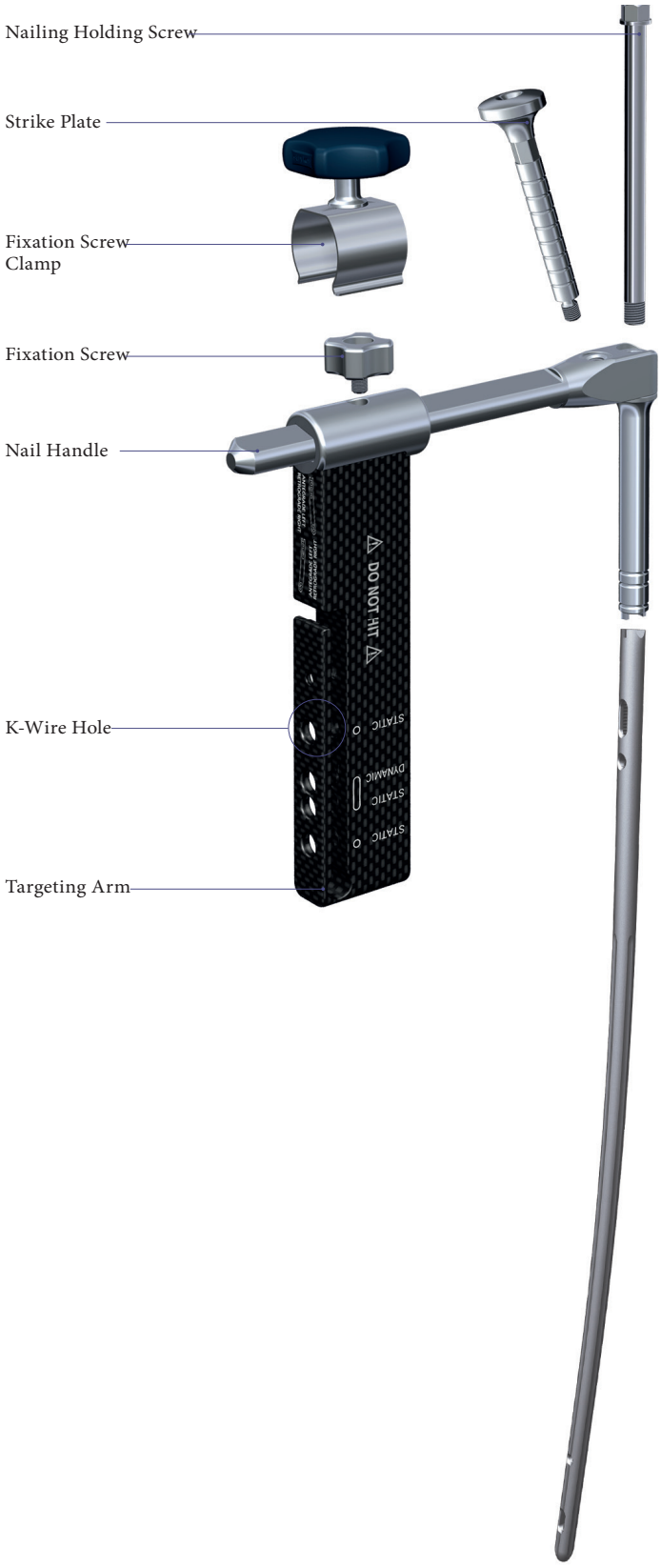


Fig. 1

Operative Technique

Nail Insertion Preparation

Upon completion of reaming, the appropriate size nail is ready for insertion over the 3x1250mm Ball Tip Guide Wire (1806-1250S).

⚠ CAUTION

The diameter of the selected nail should be 1.5 – 2.0mm smaller than that of the last reamer used.

The Slotted Hammer can be used on the Strike Plate, or if dense bone is encountered, the Universal Rod (1806-0110) may be attached to the Nail Holding Screw and used in conjunction with the Slotted Hammer to insert the nail (Fig. 2).

Fig. 2

⚠ CAUTION

- Prior to insertion, check for correct assembly into the nail by passing a drill bit through the Target Device and through the nail holes to help check alignment.
- DO NOT hit the target device. Only hit on the strike plate.

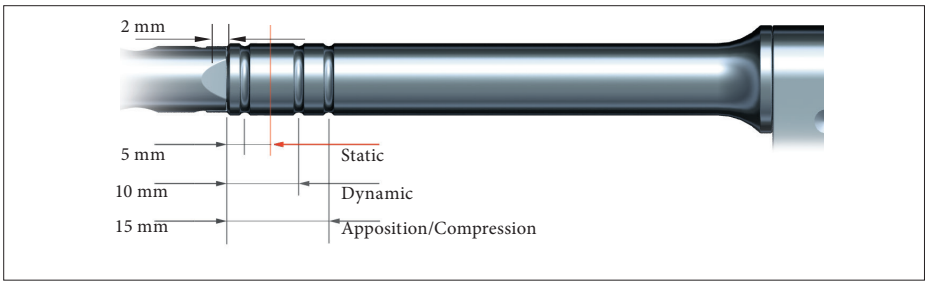


Fig. 3

When locking the nail in the Static Mode, the nail is countersunk a minimum of 5mm (Fig. 4). When the implant is inserted in the dynamic mode, without active apposition/ compression, or when the implant is inserted with active apposition/ compression, the recommended depth of insertion is 15mm (Fig. 5).

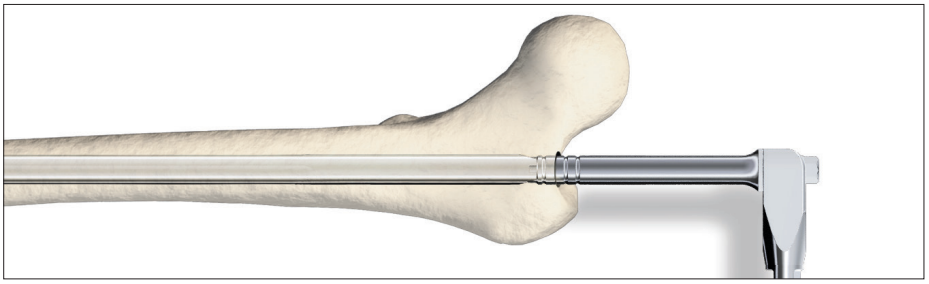


Fig. 4

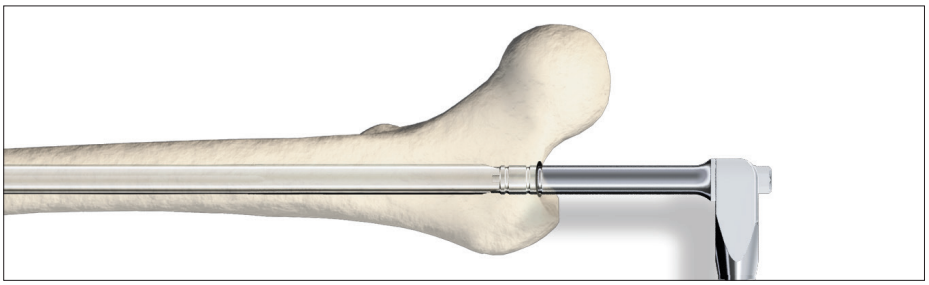


Fig. 5

⚠ CAUTION

- The system offers the option of different locking modes. In addition to static locking, a controlled dynamization or a controlled apposition/compression can be mechanically applied with an optional internal compression screw.
- In cases where the compression feature is used, the tibia must be locked with cross-locking screws before the compression is applied proximally. Up to 10mm of mechanical compression can be applied.
- Additionally, the 3x285mm K-Wire may be inserted through the Target Device which indicates the junction of the nail and insertion post (see Fig. 1).

Operative Technique

Nail Insertion

To start the insertion of the nail, it is recommended that the Target Device is internally rotated to accommodate the individual patient's anatomy (see Fig. 6, Position 1 for approximated example).

As the nail is passed down the femur towards the knee, a controlled external rotation of the Target Device is applied to better accommodate the unique dual curvature of the nail passing through the medullary canal (Fig. 7 position 2, 3, 4).

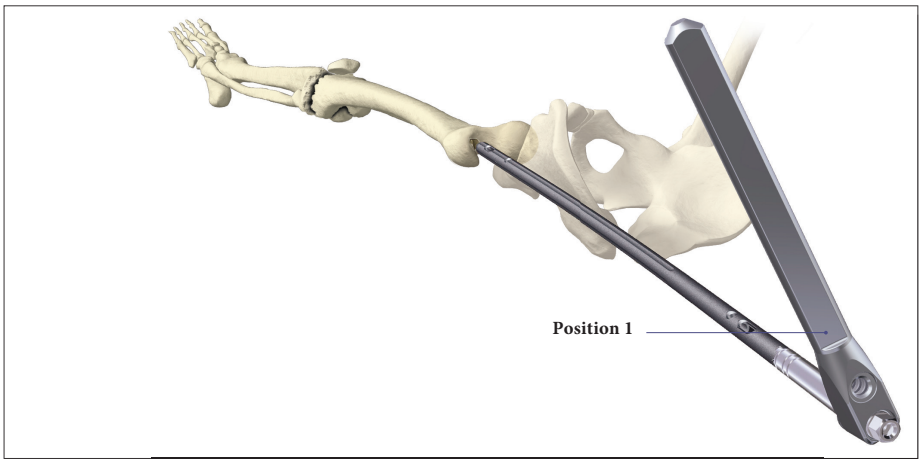


Fig. 6

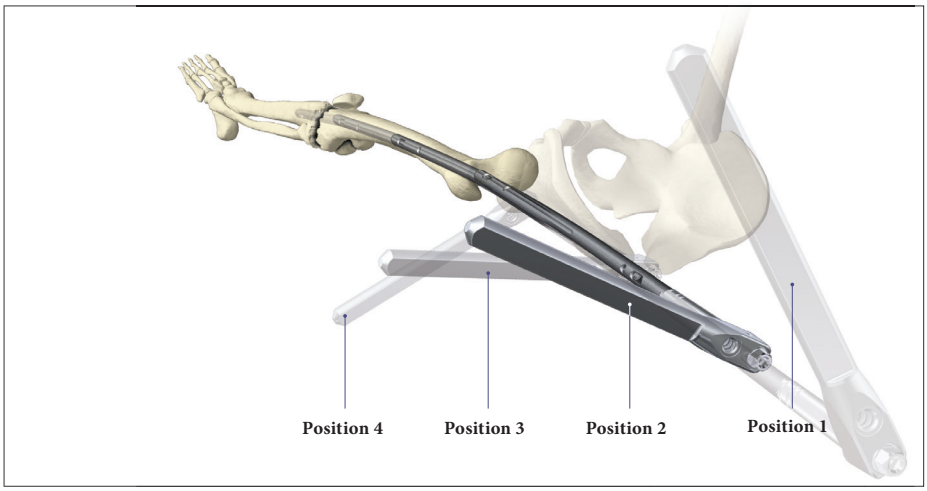


Fig. 7

⚠CAUTION

- The amount of internal rotation, and the timing of the external rotation is based on the individual patient's anatomy and as such, the surgeon's judgement.
- The final position of the Target Device must be directly lateral to the femur. In this final position, the hole pattern of the nail is properly lined up for screw insertion.
- Since every Arthrodesis case is different, the choice of whether to dynamize, actively compress, or statically lock the nail is up to the surgeon based on the individual patient's indications.

Check the alignment of the leg in all axis with proper full length X-Rays and throughout the surgery (Fig. 8).

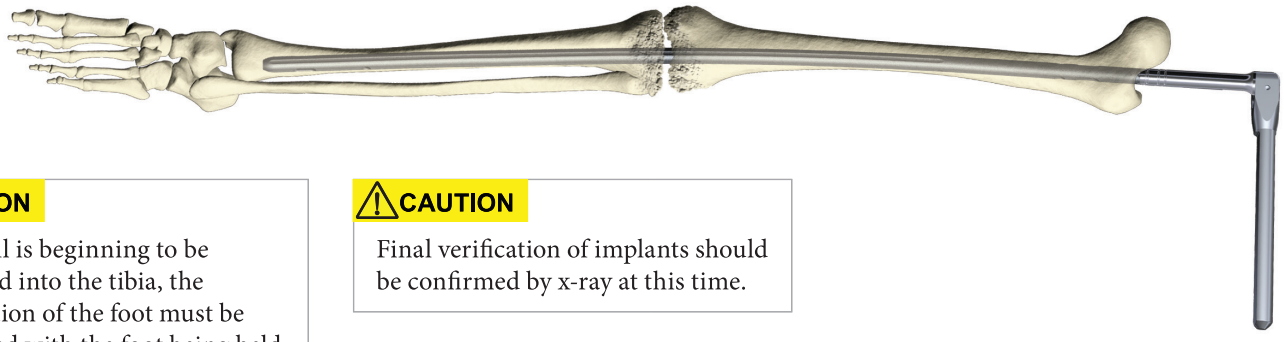


Fig. 8

⚠CAUTION

As the nail is beginning to be introduced into the tibia, the final position of the foot must be determined with the foot being held in place accordingly as the nail is impacted to its final position. The amount of external rotation of the foot, generally 0 – 10˚, is left to the surgeon's discretion.

⚠CAUTION

Final verification of implants should be confirmed by x-ray at this time.

Guided Locking Mode (via Target Device)

In controlled Dynamic Mode, and/or controlled Apposition/Compression Mode, the dynamic hole is required (Fig. 9).
4. Dynamic

In Advanced Locking Mode, the dynamic hole is required. After utilizing compression with the Compression Screw, the distal static hole is used. (Fig. 10).
3. Static
4. Dynamic

In Static Locking Mode, the distal static hole and the static position of the oblong hole are required (Fig. 10).
2. Static
3. Static

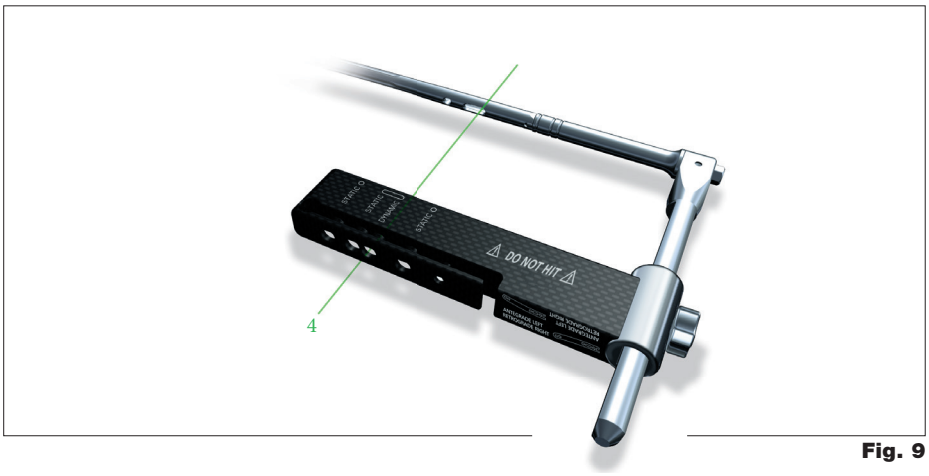


Fig. 9

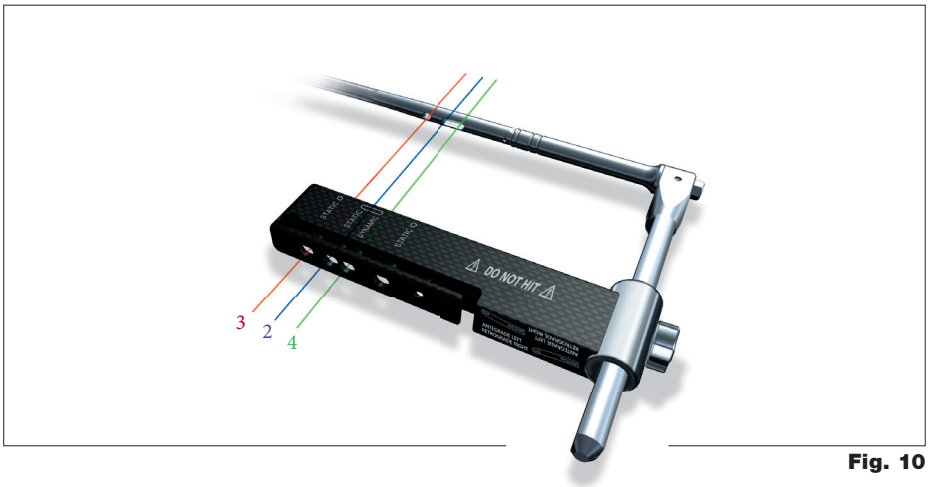


Fig. 10

⚠ CAUTION

Never use the most proximal static hole of the Target Device! There is no corresponding hole in the Arthrodesis Nail.

The Long Tissue Protection Sleeve (1806-0185) together with the Long Drill Sleeve (1806-0215) and the Long Trocar (1806-0315) is inserted into the Target Device by pressing the safety clip (Fig. 11). The mechanism will keep the sleeve in place and prevent it from falling out. It will also prevent the sleeve from sliding during screw measurement. To release the Tissue Protection Sleeve, the safety clip must be pressed again.

⚠ CAUTION

Remove the Guide Wire prior to drilling and inserting the Locking Screws.

⚠ CAUTION

In order to prevent damage during drilling and insertion of the most proximal locking screw, the advanced compression screw has to be placed between the oblong hole and the most proximal locking hole.

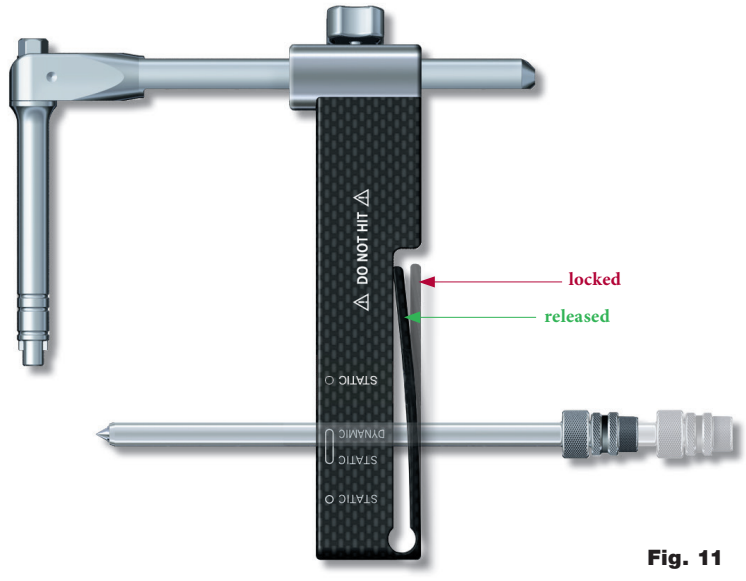


Fig. 11

Static Locking Mode

The Long Tissue Protection Sleeve together with the Long Drill Sleeve and Long Trocar, are positioned through the most distal static locking hole on the Target Device. A small skin incision is made, and the assembly is pushed through until it is in contact with the lateral cortex of the femur (Fig. 12).

Alternatively, the Trocar (1806-0311) can be advanced together with the Tissue Protection Sleeve. Push the assembly down to the bone.

The paddle tip design may help to pass the soft tissue and prepare the way for drilling. Remove the Trocar to insert the Drill Sleeve.

⚠CAUTION

Make sure the Tissue Protection Sleeve/Drill Sleeve Assembly is seated on bone prior to selecting final screw length.

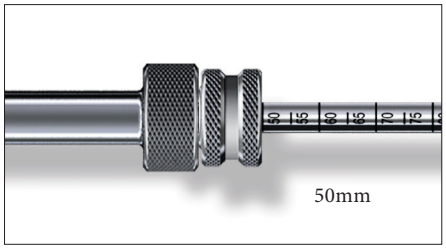


Fig. 13a

The Trocar is removed, with the Tissue Protection Sleeve and the Drill Sleeve remaining in position.

To help ensure accurate drilling and easy determination of screw length, use the center tipped, calibrated Ø4.2x340mm Drill (1806-4260S). The centered Drill is forwarded through the Drill Sleeve and pushed onto the cortex.

After drilling both cortices, the screw length may be read directly off of the calibrated Drill at the end of the Drill Sleeve (Fig. 13a).

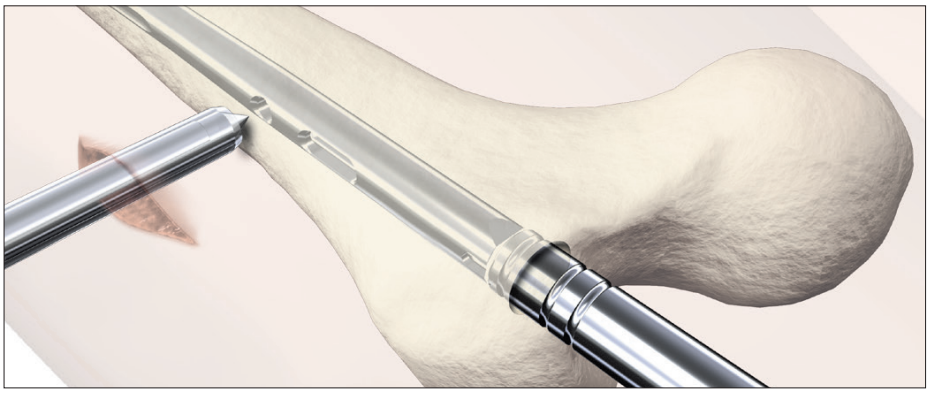


Fig. 12

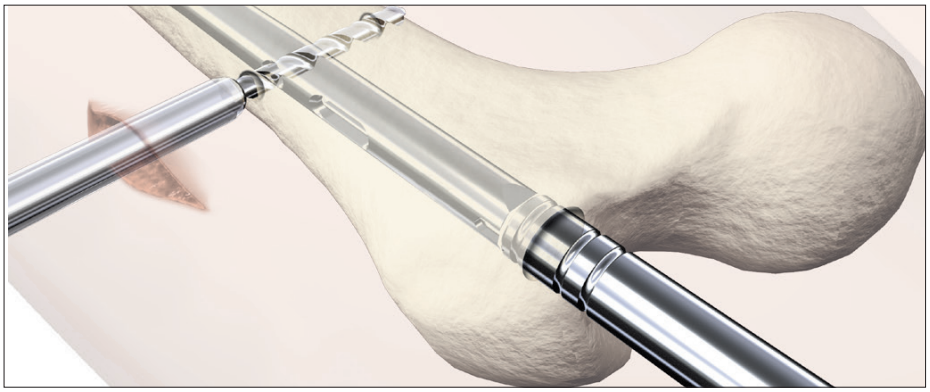


Fig. 13

Operative Technique

When the Drill Sleeve is removed, the correct Locking Screw is inserted through the Tissue Protection Sleeve using the Long Screwdriver Shaft (1806-0227) with Teardrop Handle (702429) (Fig. 14).

⚠CAUTION

- The coupling of Elastosil handles contains a mechanism with one or multiple ball bearings. In case of applied axial stress on the Elastosil handle, those components are pressed into the surrounding cylinder resulting in a complete blockage of the device and possible bending.
- To avoid intra-operative complications and secure long-term functionality, we mandate that Elastosil handles be used only for their intended use.
- DO NOT HIT any Elastosil handles.

The screw is advanced through both cortices. The screw is near its proper seating position when the groove around the shaft of the screwdriver is approaching the end of the Tissue Protection Sleeve.

Repeat the locking procedure for the other statically positioned Locking Screw (Fig. 15).

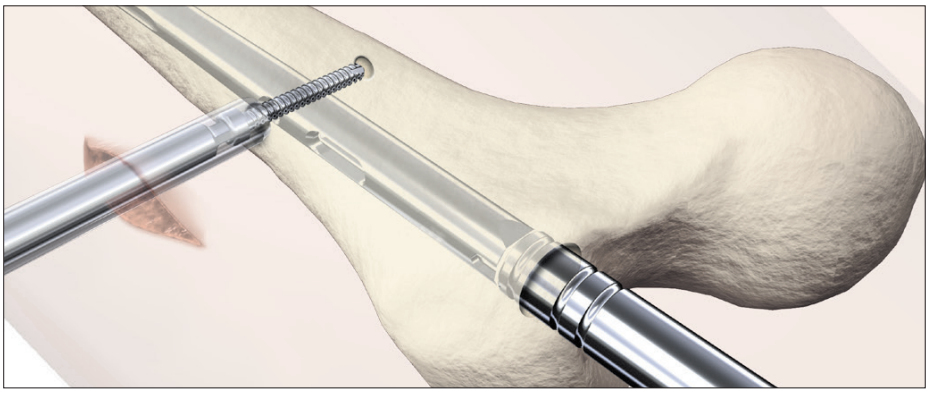


Fig. 14

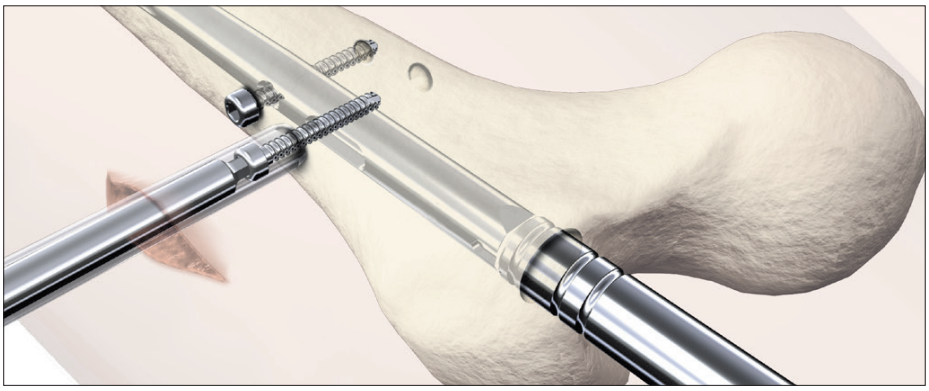


Fig. 15

Apposition/Compression Locking Mode

⚠CAUTION

Distal freehand static locking with at least two Fully Threaded Locking Screws must be performed prior to applying active, controlled apposition/compression to the fusion site.

If active apposition/compression is required, a Partially Threaded Locking Screw (Shaft Screw) is inserted via the Target Device in the dynamic position of the oblong hole. This will allow for a maximum of 10mm of active, controlled apposition/compression.

⚠CAUTION

Care should be taken that the shaft of the advanced compression screw does not extend into the area of the oblong hole. ONLY the advanced compression screw allows reattachment of the targeting device without extending in the area of the oblong hole.

In order to insert the Shaft Screw, drill both cortices with the Ø4.2x340mm Drill (1806-4260S). Next, drill the near cortex, ONLY, with the Ø5.0x230mm Drill (1806-5000S).

After the opposite cortex is drilled with the Ø4.2x340mm Drill, the correct screw length can be read directly off of the calibrated Drill at the end of the Drill Sleeve.

After the Shaft Screw is inserted, the Nail Holding Screw securing the nail to the insertion post is removed, leaving the insertion post intact with the nail (Fig. 16). This will act as a guide for the Compression Screw. The Compression Screw is inserted with the Screwdriver Shaft (1806-0227) assembled on the Teardrop Handle through the insertion post (Fig. 17 & 18).

As the Compression Screw is advanced against the 5mm Partially Threaded Screw (Shaft Screw), active apposition/compression is applied at the knee site.

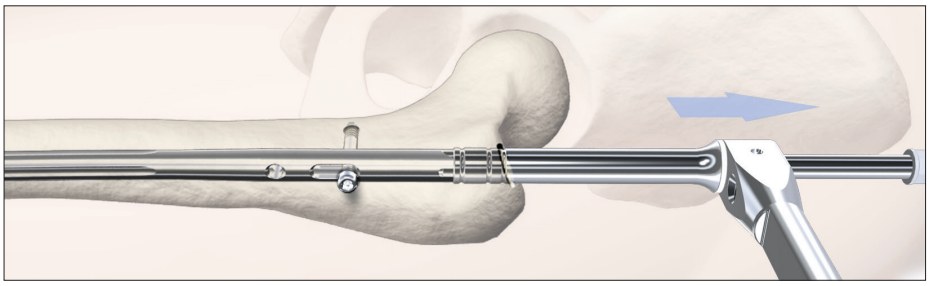


Fig. 16

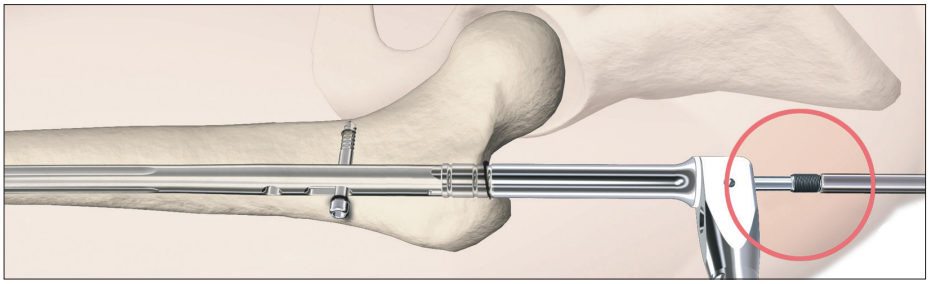


Fig. 17

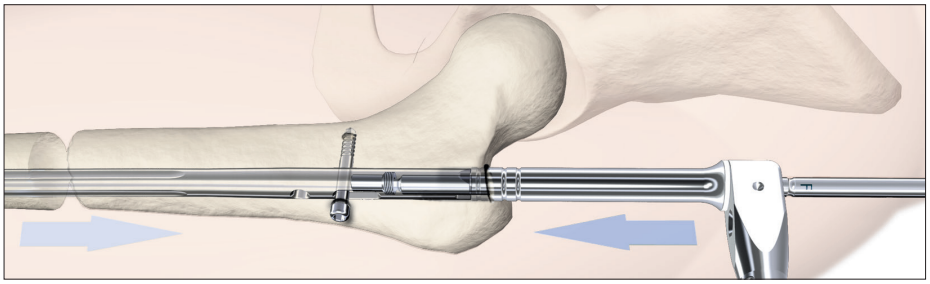


Fig. 18

⚠CAUTION

- When compressing the nail, the implant must be inserted a safe distance from the entry point to accommodate for the 10mm of active compression. The three grooves on the insertion post help attain accurate insertion depth of the implant.
- Apposition/compression must be carried out under x-ray control. Over compression may cause the nail or the shaft screw to fail.
- An End Cap cannot be inserted if a Compression Screw has been used.

For optional apposition/compression using the external compression device, please refer to the T2 Femur Operative Technique (B1000004).

Freehand Distal Locking

The freehand technique is used to insert Locking Screws into the M/L holes in the nail. Rotational alignment must be checked prior to locking the nail statically.

Multiple locking techniques and radiolucent drill devices are available for freehand locking. The critical step with any freehand locking technique is to visualize a perfectly round locking hole with the C-Arm.

The center-tipped Ø4.2x230mm Drill (1806-4290S) is held at an oblique angle to the center of the locking hole (Fig. 19). Upon X-Ray verification, the Drill is placed perpendicular to the nail and drilled through the medial cortex. Confirm in both the A/P and M/L planes by X-Ray that the Drill passes through the hole in the nail.

After drilling both cortices the screw length may be read directly off of the calibrated Screw Scale, Long (1806-0365) at the green ring on the center-tipped Drill.

Alternatively, the Screw Gauge can be used to determine the screw length.

⚠ CAUTION

The position of the end of the drill is equal to the end of the screw as they relate to the far cortex.

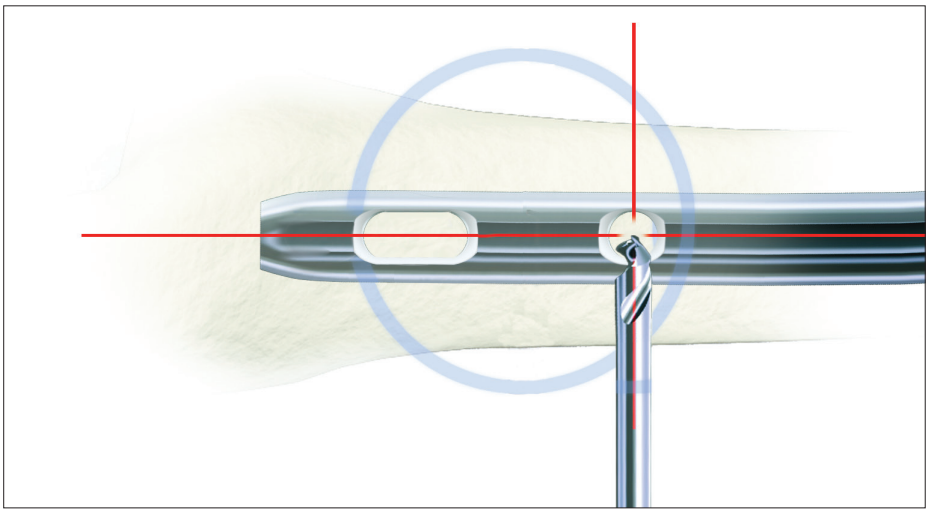


Fig. 19

Routine Locking Screw insertion is employed with the assembled Screwdriver Shaft and Teardrop Handle.

⚠ CAUTION

- Distal locking should always be performed with two screws, locking the hole nearest the fracture site first.
- On the Standard T2 Arthrodesis nails, always lock the most proximal M/L hole.
- T2 Arthrodesis nails must always be locked distally with 5mm Fully Threaded Screws.

Notes

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This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

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Content ID: T2-ST-8, Rev. 1, 09-2022

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