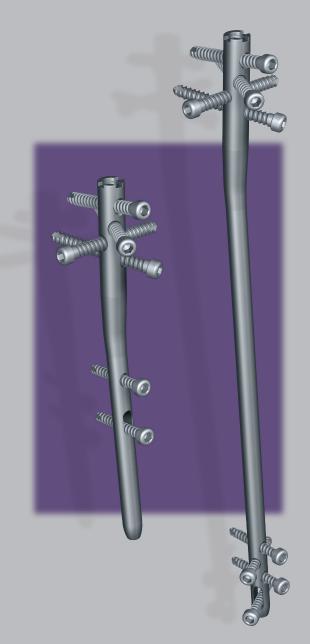


stryker

Trauma & Extremities

# T2® Proximal Humeral Nailing System

### **Operative Technique**



Humeral Fractures

# **T2 Proximal Humeral Nailing System**

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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 non-sterile devices must be cleaned and sterilized before use. Follow the instructions provided in our reprocessing guide (L24002000). Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/ disassembly 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.

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# Introduction

# Introduction

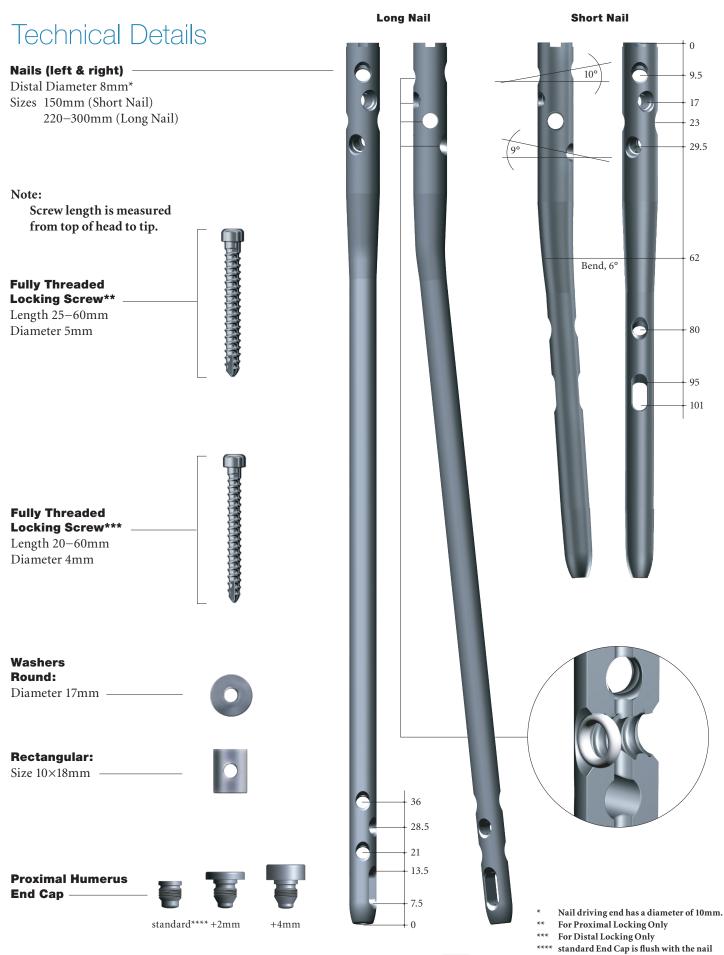
**Proximal humeral fractures** can be difficult to treat, particularly multifragmented fractures in osteopenic bone. A large number of treatment modalities have been developed over the years.

Treatments range from conservative measures such as swathe, to percutanous procedures using pins, wires and screws onwards to open procedures with plate fixation and even joint replacement.

Problems lie in the difficulty of obtaining fixation of one or several fragments and achieving rotator cuff stability to allow early motion. **Reduction and fixation must be performed without disturbing** the blood supply to the fracture fragments. Finally, the **implants** used should be not interfere with surrounding soft tissue or the acromion. Additionally, the risk of implant migration should be minimized.

To complement the **T2 Nailing System**, Stryker has created a humeral implant: the T2 Proximal Humeral Nail for the treatment of proximal humeral fractures, and those with diaphyseal extension.

# **System Overview**



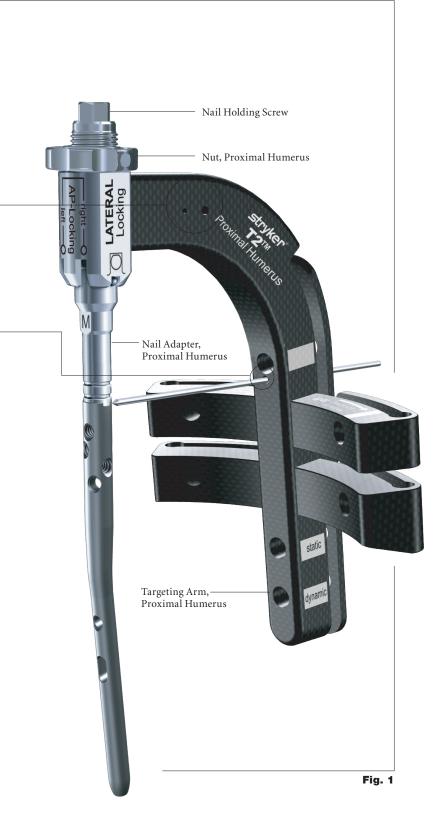
# Introduction

# Instrument Features

The majority of the instruments come from the existing T2 platform. A specific Targeting Device has been designed, unique for the T2 Proximal Humeral Nail.

The instrumentation is characterized as follows:

- A carbonfiber, radiolucent Targeting Device (Fig. 1) that allows exact placement of all Proximal Screws, and Distal Locking Screws of the short nail.
- A K-Wire inserted through the Targeting Device and aligned with the forearm indicates the correct rotational alignment of the Targeting Device and Nail. Alignment is based on the assumption that anatomical retroversion of the humeral head is 30°.
- A second K-Wire inserted through the Targeting Device indicates the exact top end of the nail to aid achieving the correct insertion depth.
- A Friction Locking Mechanism firmly holds the Drill Sleeves in their required position. The Drill Sleeves, when locked into the targeting device, will also help to stabilize the nail and may temporarily stabilize fragments during fixation.
- Scaled Drill bits give correct measurements of screw length.
- **Proximal screw holes are manually drilled**. This may improve the surgeons "**feel**" of the bone.
- Two sets of Tissue Protection Sleeves and Drill Sleeves provide the **technique to temporarily fix the nail** with one set, while the other set can be used for placing the first screw.



### **Indications, Precautions & Contraindications**

### Indications

The T2 Proximal Humeral Nail is intended to be used for various types of proximal and/or diaphyseal fractures of the humerus. The nails are inserted using an opened or closed technique and can be statically and dynamically locked. The T2 Proximal Humeral Nail is intended for single use only. Examples of specific indications according to AO classification include Type A-Fractures, dislocated, Type B-Fractures, dislocated, Type C-Fractures, with intact calotte, or Humeral Fractures according to Neer-Classification.

### Precautions

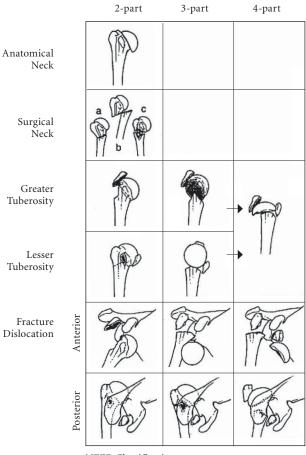
Stryker systems have not been evaluated for safety and use in MR environment and have not been tested for heating or migration in the MR environment, unless specified otherwise in the product labeling.

# **Relative 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.



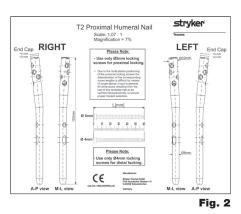
NEER Classification

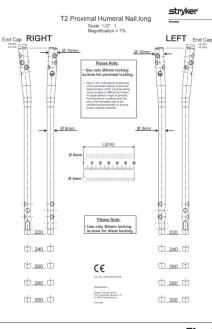
### **Pre-Operative Planning**

X-Ray Templates are available for pre-operative planning (Fig. 2 & 3).

- X-Ray Template, Short PHN (1806-2008)
- X-Ray Template, Long PHN (1806-2007)

Thorough evaluation of pre-operative radiographs of the affected Upper Arm and Shoulder is critical. Careful radiographic examination of the Humeral head region may prevent intraoperative complications.







# **Locking Options**

# Locking Option Examples:

#### **T2 Proximal Humeral Nail**



# Patient Positioning and Fracture Reduction

The patient is placed semi-reclined in the "beach chair position" or supine on a radiolucent table. Patient positioning should be checked to ensure that imaging and access to the entry site are possible without excessive manipulation of the affected extremity (Fig. 4).

#### Note:

Closed reduction by "Joysticktechnique" with K-Wires to manipulate fragments can be used.

If closed reduction was not successful, open reduction should be performed.

### Incision

A small incision is made in line with the fibers of the deltoid muscle anterolateral to the acromion. The deltoid is split to expose the subdeltoid bursa (Fig. 5). The supraspinatus tendon is then incised in line with its fibers.

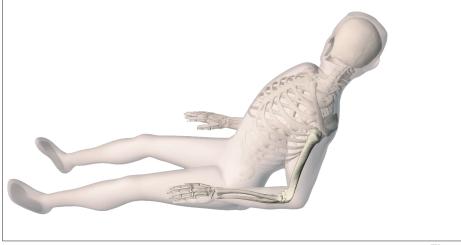
### Entry Point

To indicate the exact entry point before incising the supraspinatus tendon, a K-Wire (1806-0050S) can be placed through the tendon into the bone at the expected entry point (Fig. 6):

Confirmation should be made with the image intensifier, in both lateral and A/P views.

The T2 Proximal Humeral Nail is designed to be inserted either through a lateral (A) or a central (B) entry point (Fig. 6).

The lateral entry point (A) is located just inside the Greater Tuberosity (as seen on the A/P view) and aligned with the humeral axis (as seen on the lateral view). Verify with the image intensifier. The central entry point (B) is located at the very top of the humeral head, in the articular surface, in line with the humeral axis (in both A/P and lateral views).









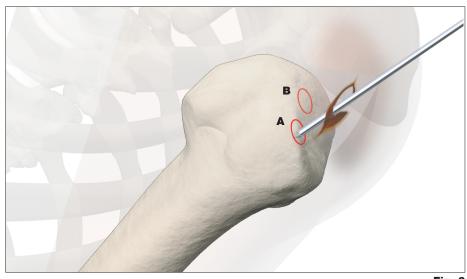


Fig. 6

#### Note:

If the greater tuberosity is fractured or compromised, the central entry point is recommended to achieve stability between the humeral head fragment and the proximal end of the nail.

The entry point is made with the cannulated 10mm Awl, Straight (1806-0045) or by using the Small K-Wire (1806-0050) with the Guide Wire Handle (1806-1095 and 1806-1096) (Fig. 7a, b, c). Image intensification is required to identify the correct entry point. The proximal metaphysis should be reamed with the Rigid Reamer, 10mm (1806-2010) through the Rigid Reamer Sleeve, 10mm (1806-0410).

Alternatively, the optional Crown Drill (1806-2020) may be used over the K-Wire with Washer (1806-0051S) for entry point preparation. The K-Wire will help to guide the Crown Drill centrally.

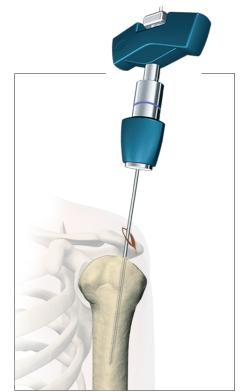
#### Note:

During opening of the entry point with the Awl, dense cortex may block the tip of the Awl. An Awl Plug (1806-0032) can be inserted through the Awl to avoid penetration of bone debris into the cannulation of the Awl shaft.

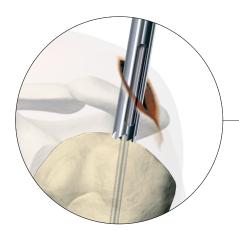
Further reaming is not necessary with the Short PHN. The nail may be inserted directly. Caution:

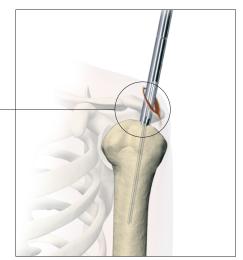
The coupling of Elastosil handles contains a mechanism with one or multiple ball bearings. In case of applied axial stress on the Elastosil handle, those components are pressed into the surrounding cylinder resulting in a complete blockage of the device and possible bending. To avoid intra-operative

complications and secure long-term functionality, we mandate that Elastosil handles be used only for their intended use. DO NOT HIT any Elastosil handles.









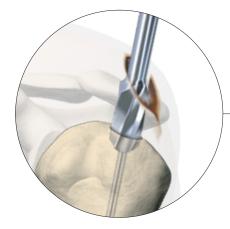
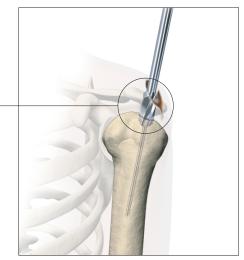


Fig. 7b



# Reamed Technique

For insertion of the Long PHN, reaming of the medullary canal may be necessary.

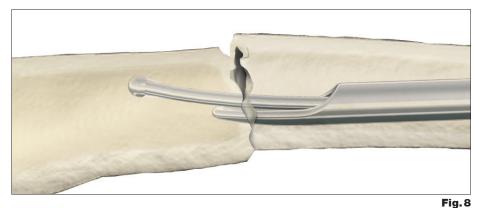
For reamed techniques, the 2.5×800mm Ball Tip Guide Wire (1806-0083S) is inserted across the fracture site. The Reduction Rod (1806-0363), may be used as a fracture reduction tool to facilitate guide wire insertion across the fracture site (Fig. 8).

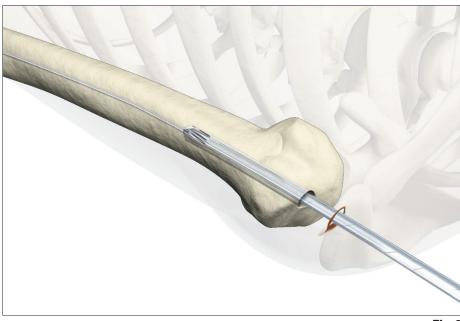
Reaming is commenced in 0.5mm increments. Final reaming should be 1mm–1.5mm larger than the diameter of the nail to be used (Fig. 9).

The Guide Wire Pusher can be used to help keep the Guide Wire in position during reamer shaft extraction. The metal cavity at the end of the handle pushed on the end of the power tool facilitates to hold the Guide Wire in place when starting to pull the power tool. When close to the Guide Wire end place the Guide Wire Pusher with its funnel tip to the end of the power tool cannulation. While removing the power tool the Guide Wire Pusher will keep the Guide Wire in place (Fig. 9a and 9b).

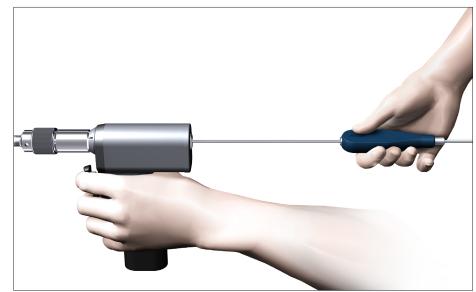
When reaming is completed, the Teflon Tube (1806-0073S) should be used to exchange the Ball Tip Guide Wire (1806-0083S) with the Smooth Tip Guide Wire (1806-0093S) for nail insertion (Fig. 10).

An unreamed technique can be considered in cases, where the medullary canal has the appropriate diameter. In these cases, the nail can be introduced over the 2.2×800mm Smooth Tip Guide Wire (1806-0093S).



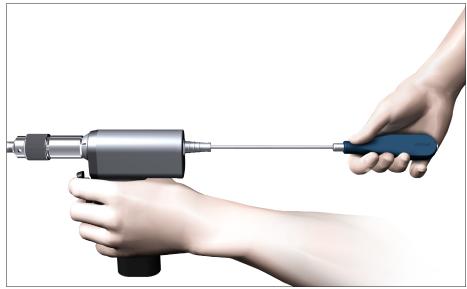




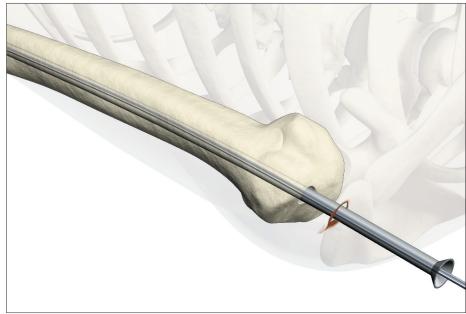


#### Note:

X-Ray Templates should be used pre-operatively to determine the canal size radiographically.









### Nail Selection

The T2 PHN is available in left and right, short and long.

#### Diameter

Both the Short and the Long version have a proximal diameter of 10mm and a shaft diameter of 8mm (Fig. 11).

#### Length

The Short PHN is available in 150mm length only. The Long PHN are available in five different lengths (220–300mm).



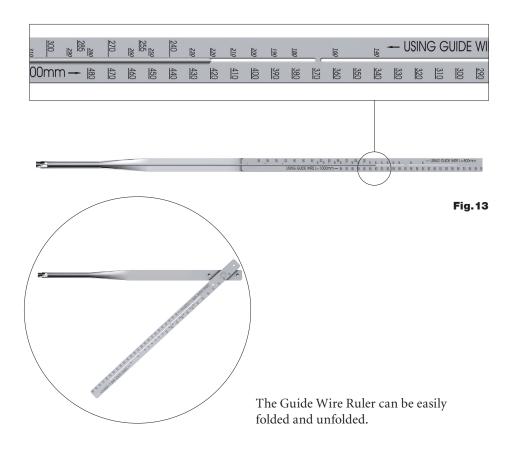


Short Nail

The Guide Wire Ruler (1806-0022) may be used by placing it on the Guide Wire and reading the correct nail length at the end of the Guide Wire on the Guide Wire Ruler (Fig. 12 & 13).

Confirm the position of the tip of the Guide Wire prior to measurement.





### Nail Insertion

The selected nail is attached to the Nail Adapter (1806-2025) until its three connection teeth engage into the corresponding slots of the Nail (Fig. 14).

The Nail Holding Screw (1806-0163) is placed through the Nail Adapter, and tightened securely with the Insertion Wrench (1806-0135) or Wrench 8/10mm (1806-0130) to avoid loosening during Nail insertion. Engravings on the Nail Adapter will indicate lateral and medial direction (Fig. 15).

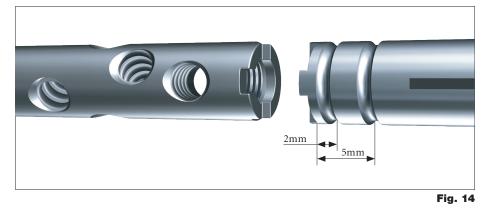




Fig. 16

Note:

- Two circumferential grooves are located on the insertion post at 2mm and 5mm from the driving end of the nail (Fig. 14). Depth of insertion may be visualized with the aid of fluoroscopy.
- The Strike Plate (1806-0150) (Fig. 16) or the Short Universal Rod (1806-0113) may be used to improve handling during insertion. These are screwed into the Nail Holding Screw and have to be removed if the Targeting Arm (1806-2035) is to be mounted after introduction of the nail.

Please ensure that the nail holding screw is still securely tightened.

Alternatively, the Targeting Arm is assembled onto the Nail Adapter with the Nut (1806-2030) (Fig. 17a). Hand tighten the Nut so that it does not loosen during nail insertion.

#### Note:

- Before inserting the nail, verify that the assembly is locked in the appropriate position: the smaller peg of the Nail Adapter engaged into the smaller slot of the Targeting Arm indicated by the "LATERAL Locking" sign (Fig. 17a) and the larger peg into the larger slot on the opposite side (Fig. 17b).
- Prior to nail insertion please check correct alignment by inserting a drill bit through the assembled Tissue Protection - and Drill Sleeve placed in the required holes of the targeting device (Fig. 18).

The nail is ready for insertion. All nails are cannulated and can be inserted over the 2.2×800mm Smooth Tip Guide Wire. Advance it through the entry point (Fig. 19). The nail should be advanced with

manual pressure.





Aggressiveness can result in additional fractures or fragment displacements. If the nail does not advance easily, use the image intensifier to identify the problem.

#### Note:

#### Do not hit the Targeting Device and/or the Nail Holding Screw.

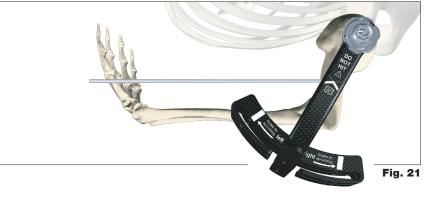
The nail should be inserted at least up to the first circumferential groove on the Nail Adapter but not deeper than the second groove.





### Proximal Guided Locking





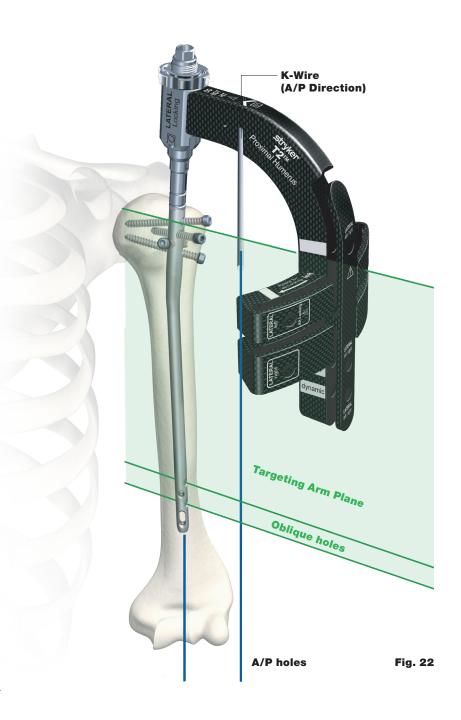
Prior to guided locking via the Target Device, the Nail Holding Screw and the Nut must be firmly tightened to ensure that the nail is in correct alignment with the Targeting Device (Fig. 20).

Remove the Strike Plate if used. Withdraw the guide wire if used.

Two sets of Tissue Protection Sleeves, Drill Sleeves and Trocars can be used at the same time. The tight fit of the friction lock mechanism provides the opportunity to temporarily stabilize the nail and the fragment with one set, while using the second to perform locking.

#### Note:

- A K-Wire placed through the Targeting Device and aligned with the forearm indicates anatomical 30° retroversion of the humeral head (Fig. 21).
- Prior to proximal locking of the Long PHN, ensure correct alignment of the distal holes as these are locked by freehand technique. The K-Wire placed through the targeting device is in the same plane as the AP locking holes at the nail tip whereas the plane of the targeting arm is the same for the distal oblique holes (Fig. 22).



Except for the A/P Proximal Locking Screw, all of the Proximal and Distal Locking procedure (Short PHN only) can be performed without changing position of the Targeting Arm.

#### Note:

### For the use of an A/P Locking Screw see page 22.

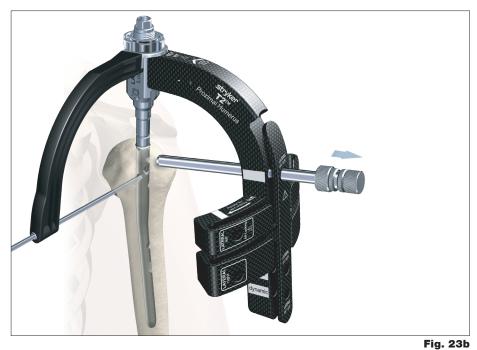
To ensure correct rotational alignment of the nail and avoid penetration of the biceps tendon with the proximal anterior screw, the Anterior Aiming Adapter (1806-2036) may be utilized. Slide the Anterior Aiming Adapter on the targeting device as shown in Fig. 23a and ensure secure tightening with the Nut. Both rotational alignment and temporary fixation may be achieved by introducing a K-Wire (1806-0050S) through the Adapter in the lesser tuberosity. The insertion point of this K-wire should not interfere with the biceptal groove as it will determine the final position of the proximal anterior screw (Fig. 23b).

The Short Tissue Protection Sleeve (1806-0180) together with the Short Drill Sleeve (1806-0210) and the Short Trocar (1806-0310) are inserted into the Targeting Arm by pressing the Safety Clip (Fig. 23c). Advance the assembly until bony contact is achieved and the trocar backs out.

The friction locking mechanism is designed to keep the sleeve in place. It will also stop the sleeve from sliding during screw measurement. To release the Tissue Protection Sleeve, the Safety Clip must be pressed again.



Fig. 23a





The Trocar is removed, while the Tissue Protection Sleeve and the Drill Sleeve remain in position. The T-Handle (702427) is assembled with the 3.5×230mm Drill (1806-3540S). Drilling is preferably done manually to improve feel of resistance in soft bone. The Drill is forwarded through the Drill Sleeve and pushed onto the cortex (Fig. 24).

Advance the Drill until it is in contact with the subchondral bone. The appropriate screw length may be read directly off of the Drill at the end of the Drill Sleeve (Fig. 24). 50mm

#### Note:

Drill the lateral cortex only. In cases where the nail is inserted close to the lateral cortex, manual drilling will help to avoid nail contact.



#### Caution:

Do not drill through the far cortex as this will penetrate the joint. The position of the Drill tip placed in the subchondral bone is equal to where the end of the screw will be.

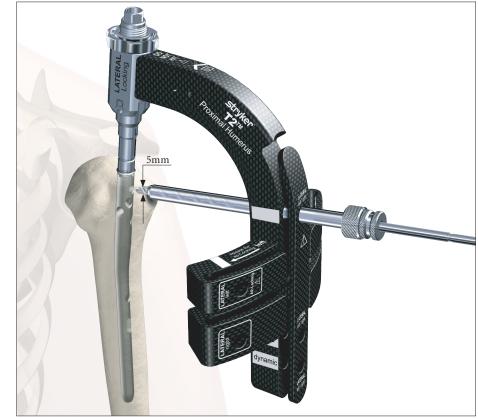
#### Note:

The Locking Screw length determination is very important and must be carried out carefully.

#### Caution:

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

In cases with dense bone, the cortex of the proximal locking holes may be opened with the  $5.0 \times 180$  mm Drill (1806-5010S).



When the Drill Sleeve is removed, the correct 5.0mm Fully Threaded Locking Screw is inserted through the Tissue Protection Sleeve using the Screwdriver Shaft Short (1806-0222) with the Teardrop Handle (702429) (Fig. 26).

#### Note:

- In order to optimize screw insertion in the threaded screw hole, push the Locking Screw without turning through the first cortex until it is in contact with the nail. Then start turning the Locking Screw with gentle axial pressure to engage the internal thread of the nail. In cases with dense bone where the screw cannot be pushed forward, the lateral cortex may be opened with the 5.0×180mm Drill to ease screw insertion as described above.
- To avoid loss of reduction or position of the nail when the Drill is removed, you may leave the first Drill in the bone. Then, using the second set of Sleeves, drill the second hole and insert this screw while the nail is stabilized by the first Drill.

The Locking 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 (Fig. 27).

#### Note:

- Fluoroscopic visualisation during Locking Screw insertion is absolutely necessary to place the tip of the Locking Screw in the subchondral bone, to stabilize the head fragment and avoid penetration of the Locking Screw into the articular surface.
- In four-part fractures, the role of the first Proximal Screw is to obtain fixation of the Head Fragment and not of the Greater Tuberosity.

Repeat the locking procedure for all lateral Proximal Locking Screws (Fig. 28).

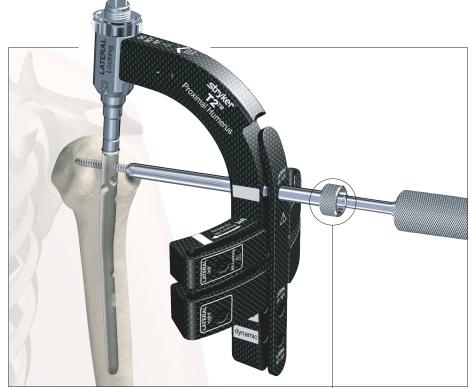
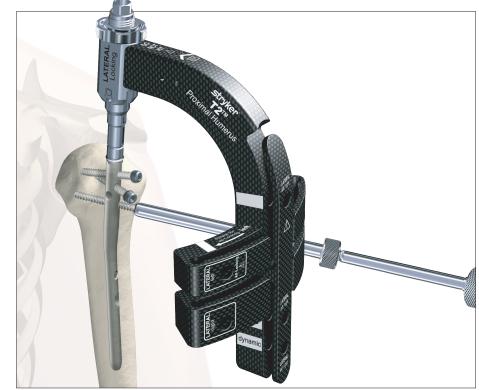


Fig. 26







Washers, either Rectangular or Round, can be used for patients with osteoporotic bones. They can be used in conjunction with a screw for fixing fragmented tuberosities. However, they can also be used to stabilize the nail, allowing compression of the surrounding bone against the nail. Sutures are particularly helpful for tuberosity reattachment (3 and 4-part fractures) helping neutralize the muscle forces acting on the humeral head.

#### Note:

Do not use a Washer with the most Proximal Locking Screw as it may cause Acromial impingement.

### Proximal A/P Locking

#### Note:

The A/P Screw is designed to fix the Lesser Tuberosity. If an A/P Screw is inserted, it is recommended to perform the A/P Screw locking after all other required screws are inserted.

To place the A/P Locking Screw, the Targeting Arm must be rotated.

#### Note:

If the Anterior Aiming Adapter has been used, the inserted K-Wire must be withdrawn and the Nut must be released in order to remove it prior to rotating the targeting device.

The Nut must be released with four complete turns. Pull up the Targeting Arm and turn it anteriorly around the Nail Adapter (Fig. 29). Push down the Targeting Arm and lock the system in the appropriate position indicated on the Targeting Arm (Fig. 30a). **For the left nail**, the larger peg of the Nail Adapter engages into the larger slot indicated by the "A/P locking left" sign (Fig. 30a) and the smaller peg into the opposite smaller slot (Fig. 30b).

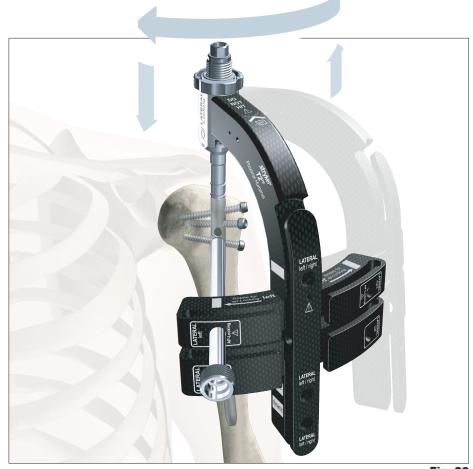


Fig. 29

(For the right nail, the smaller peg must be engaged into the smaller slot, indicated by the "AP Locking right" sign and the larger peg into the opposite larger slot.) Hand tighten the Nut to ensure it does not loosen during locking procedure.

Routine locking procedure is performed as described on page 18 to 22.





Fig. 30a

Fig. 30b

# Distal Locking

#### Distal Guided Locking (Short PHN only)

The Targeting Device is designed to provide two Distal Locking Options; Static Mode or Dynamic Mode.

For Static Locking Mode, two Distal Locking Screws should be used (round and oblong hole).

The Short Tissue Protection Sleeve together with the Short Drill Sleeve and the Short Trocar are inserted into the Targeting Arm in the static hole.

A small skin incision is made and the assembly is pushed through until it is in contact with the lateral cortex.

The Trocar is removed, while the Tissue Protection Sleeve and the Drill Sleeve remain in position.

#### Caution:

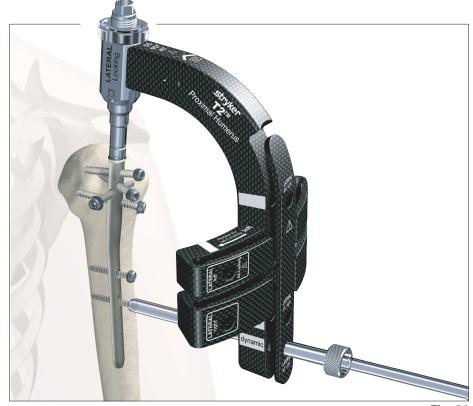
Make sure the Tissue Protection Sleeve/Drill Sleeve Assembly is seated on bone prior to selecting final screw length

After drilling both cortices with the calibrated 3.5×230mm Drill (1806-3540S), the screw length may be read directly off of the calibrated Drill at the end of the Drill Sleeve.

Alternatively, after removal of the Drill Sleeve, the Screw Gauge, Short can be used for screw length measurement.

A 4mm Locking Screw is inserted with the assembled Short Screwdriver Shaft and the Teardrop Handle.

For the second distal Locking Screw, routine Screw insertion is employed using the dynamic hole on the Targeting Arm.



#### Fig. 31

#### Note:

The dynamic hole on the Targeting Arm will allow placement of the Locking Screw in a Dynamic Locking Mode (at the bottom of the oblong hole) (Fig. 31).

Depending on the fracture type, secondary dynamization can be achieved by extracting the static distal Locking Screw (round hole) (Fig. 32).



#### Distal Freehand Locking (Long PHN only)

#### Note:

#### Never use the the distal holes (Static/Dynamic) of the Targeting Device. There are no corresponding holes in the Long PHN.

The freehand technique is used to insert Locking Screws into both the A/P and Oblique holes in the nail. Rotational alignment must be checked prior to distal locking.

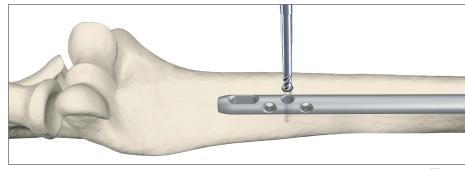
Multiple locking techniques and radiolucent drill devices are available for freehand locking. The critical step with any freehand locking technique, proximal or distal, is to visualize a perfectly round locking hole with the C-Arm.

#### Note:

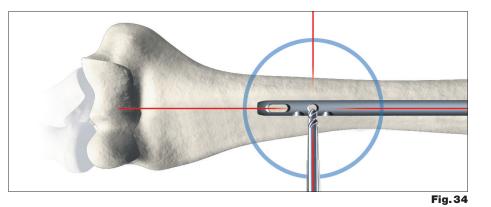
- In order to avoid damage to the neurovascular structure, a limited open approach should be considered.
- Leaving the targeting device attached in lateral position can facilitate the freehand locking procedure. The K-Wire placed through the targeting device is in the same plane as the AP locking holes at the nail tip whereas the plane of the targeting arm is the same for the distal Oblique holes (Fig. 22, p. 18).

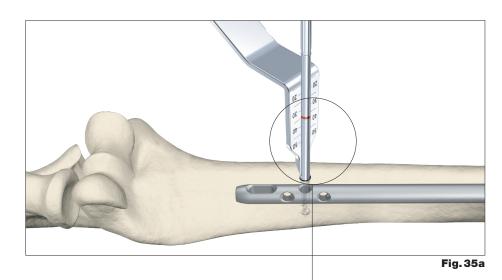
The  $\emptyset 3.5 \times 130$ mm Drill (1806-3550S) is held at an oblique angle to the center of the locking hole (Fig. 33, 34). Upon X-Ray verification, the Drill is placed perpendicular to the nail and drilled through the anterior cortex. Confirm these views in both the A/P and M/L planes by X-Ray.

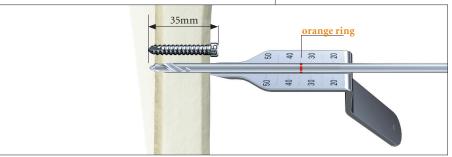
After drilling both cortices, the screw length may be read directly off of the Screw Scale, Short (1806-0360) at the orange color coded ring on the centertipped Drill (Fig. 35a & b). Alternatively, the Screw Gauge can be used to determine the screw length. As with proximal locking, the position of the end of the drill is equal to the end of the screw as they relate to the far cortex.











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

#### Note:

The A/P oblong hole (Long PHN) in the nail tip will allow placement of the Locking Screw in a Dynamic Locking Mode (at the bottom of the oblong hole).

If possible, the Long PHN should be locked distally with two Fully Threaded Locking Screws. Additional locking of the Oblique hole(s) is possible if the image intensifier can be adjusted (Fig. 36).

#### Note:

Use image intensification to confirm screw position through the nail as well as screw length.

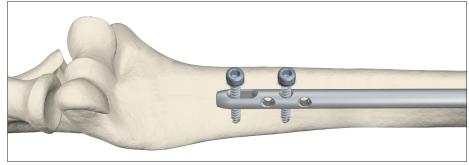


Fig. 36

# End Cap Insertion

After removal of the Targeting Device, an End Cap may be inserted. End Caps are available in three sizes.

The End Cap is inserted with the Screwdriver Shaft, Short assembled on the Teardrop Handle (Fig. 37). Fully seat the End Cap to minimize the risk of loosening.

#### The End Cap may be used to:

- Lock and stabilize the Proximal Locking Screw.
- Adjust the height of the nail for optimal purchase of the nail at the entry point.

#### Note:

To avoid impingement, carefully select the length of the End Cap.

Close the wound using standard technique.



+2mm

standard



+4mm



Fig. 37

# Nail Removal

Nail removal is an elective procedure. The End Cap, if used, is removed prior to removing the most proximal Locking Screw with the Screwdriver Shaft, Short and the Teardrop Handle.

#### Note:

Attaching the Universal Rod, Short to the nail before removal of all other Locking Screws, will prevent nail migration.

The Short Universal Rod is inserted into the driving end of the nail. All Locking Screws are removed with the Short Screwdriver Shaft and the Teardrop Handle (Fig. 38).

The nail may then be removed with the Slotted Hammer (Fig. 39).



Fig. 38



### **Notes**

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