stryker

T2 Alpha®
Humerus Nailing System

Operative technique

T2 Alpha

Humerus Nailing System

Contents

⚠ 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.

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.

Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling. Consult instructions for use (ifu.stryker.com) for a complete list of potential adverse effects, contraindications, warnings and precautions.

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

⚠ 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

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

⚠ WARNING

Stryker bone screws are not approved or intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Indications and contraindications

Intended use & Indications

The T2 Alpha Humerus Nailing System is indicated for the treatment of humerus fractures. Fractures can include, but are not limited to, non-unions, malunions, malalignments, pathological fractures, and impending pathological fractures.

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.
- 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.

Additional Information

T2 Alpha Humerus Nailing System

Humeral Nail (short) and Humeral Nail (long)
Left and right specific

Nail diameter
Humeral Nail (short): Ø8mm
Humeral Nail (long): Ø7mm–Ø10mm[1] in 1mm increments

Driving end diameter
Driving end diameter of the 7–9mm is Ø10mm;
nail size 10mm has a constant diameter

Nail length
Humeral Nail (short): 150mm
Humeral Nail (long): 180–315mm[1] in 15mm increments
Note: Screw length is measured from top of head to tip.

Locking Screw[2]
Ø4mm, 20–60mm length in 2.5mm increments

Advanced Locking Screw[2]
Ø4mm, 20–60mm length in 2.5mm increments

Compression Screw Humerus

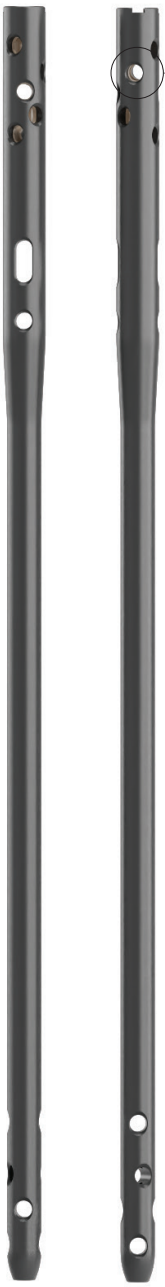
End Caps

Washers[3]

Drills[4]
3.5mm – orange
4.5mm – orange (counterbore drill)

1. Check with local representative regarding availability of implant sizes.
2. Product from IMN Screws System.
3. Includes product from T2 Nailing System.
4. Product from IMN Instruments System.

Humeral Nail (short)

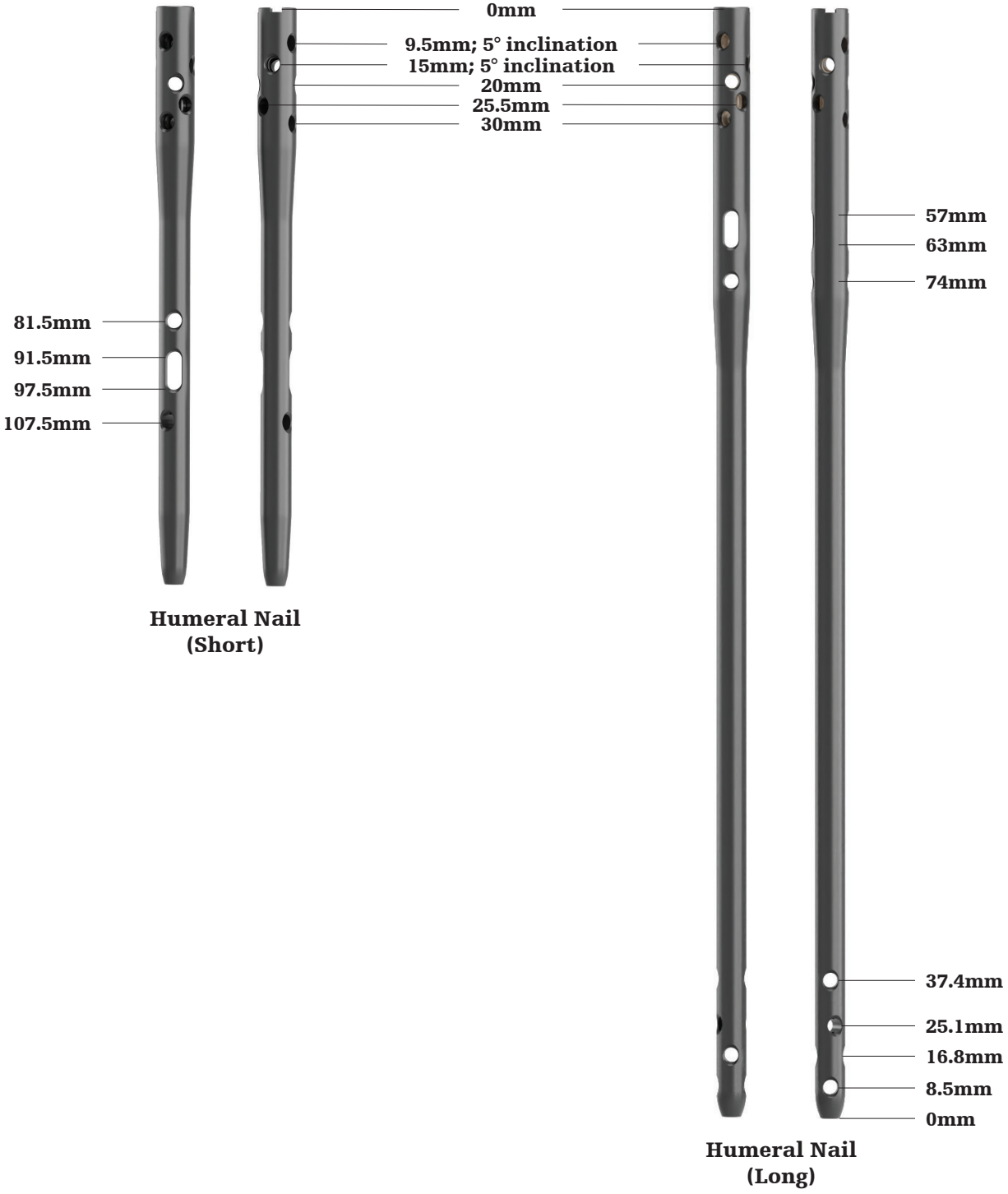


Humeral Nail (long)

Pre-inserted PEEK Sleeve designed to prevent back-out of the 5 most proximal screws

Additional Information

T2 Alpha Humerus Nailing System
Nailing Dimensions



Additional Information

T2 Alpha Humerus Nailing System Locking Options

Short Nail

Static locking

Dynamic locking

Long Nail

Static locking

Internal or External compression

Additional information

Packaging

The implants in the T2 Alpha Humerus Nailing System and IMN Screws System include packaging that minimizes user contact with the implant prior to implantation. After the pouch is opened, all implants include a sheath that is introduced into the sterile field.

Example 1: Nail is removed from pouch, sheath is opened, then the sterile nail is attached to the Nail Adapter (2353-1103) with the Nail Holding Screw (2353-1104) (Fig. 1, 2, 3).

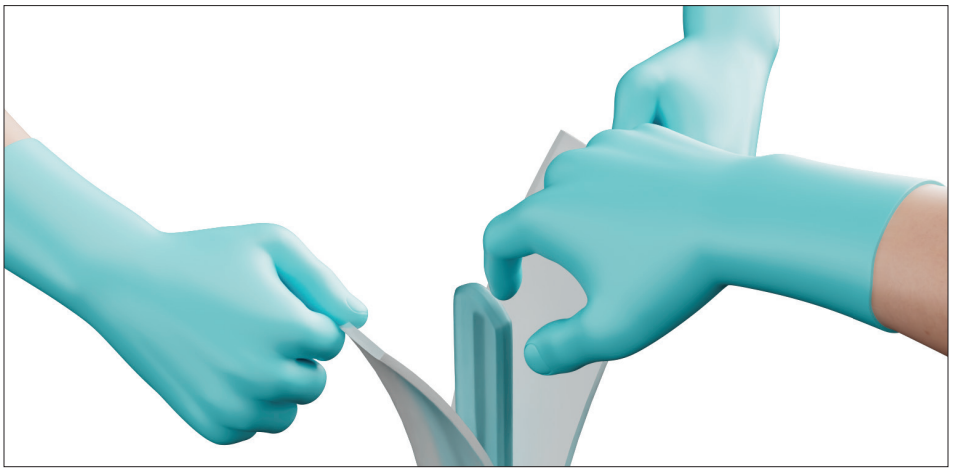


Fig. 1

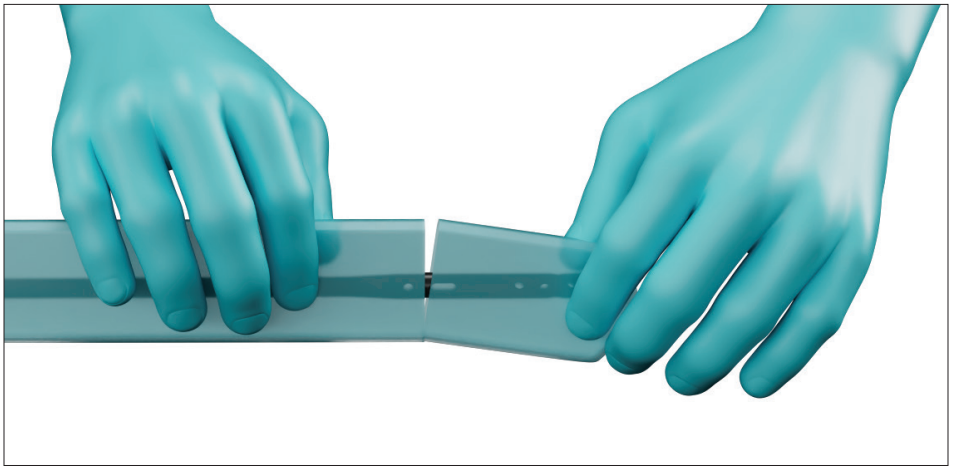


Fig. 2

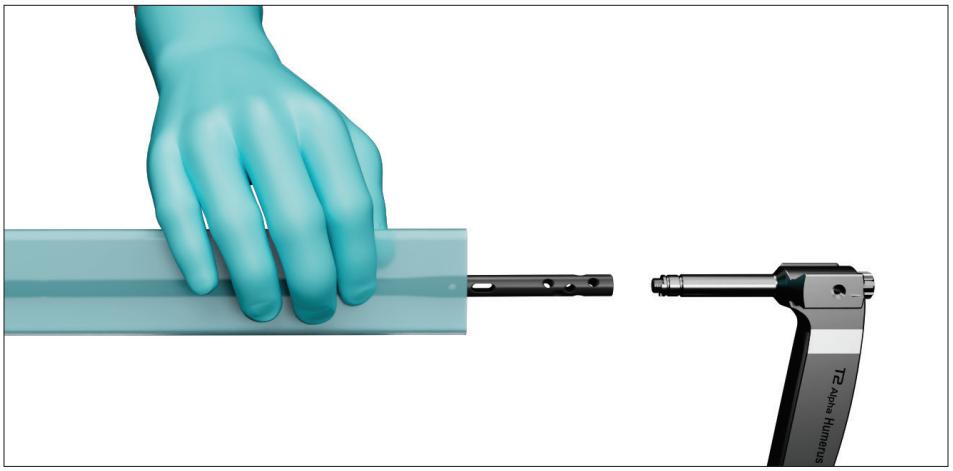


Fig. 3

Additional Information

Packaging

Example 2: After removal from pouch, screw or other implant (Fig. 4, 5) is attached to the corresponding screwdriver (Fig. 6).

Fig. 4

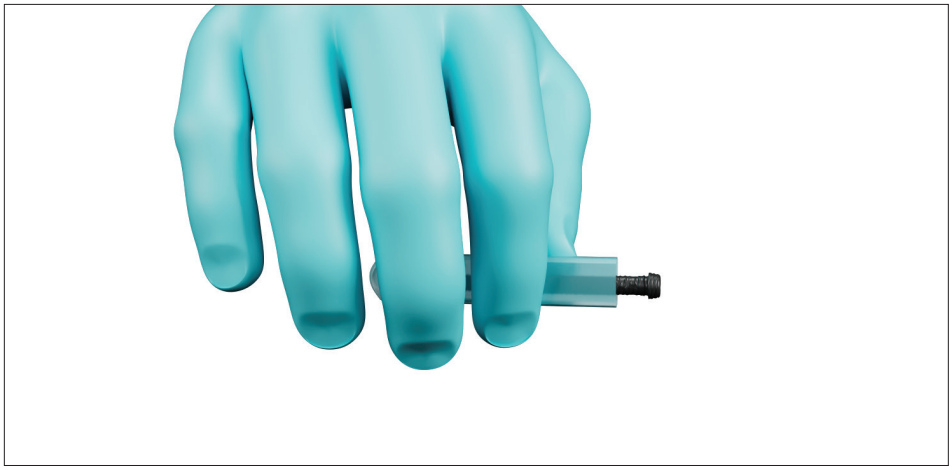


Fig. 5

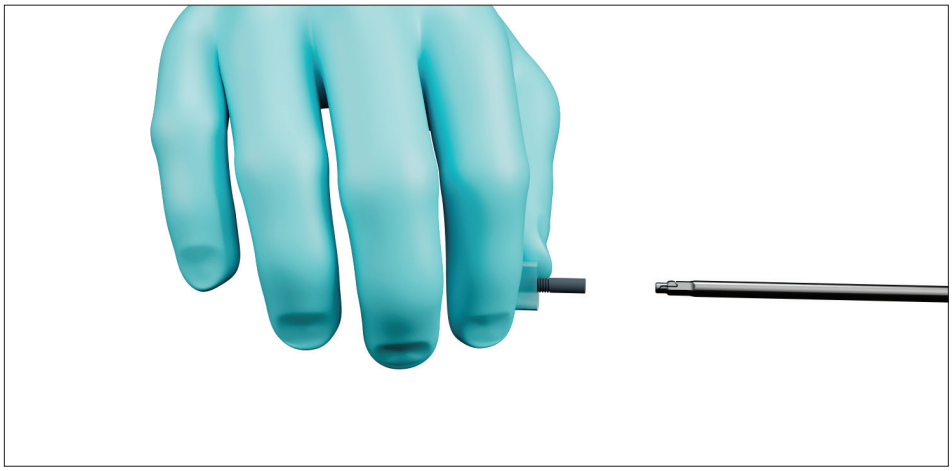


Fig. 6

Operative technique

Patient positioning

Surgery may be performed in either the supine or beach chair position. For both approaches, care must be taken to position the arm in slight extension at the shoulder to allow proper nail insertion into the apex of the humeral head. This may require use of a scapular bump (Fig. 8) or table positioning techniques that enable extension.

For both positions, it is critical to obtain orthogonal radiographs. The recommended views are:

- True AP (Grashey) View (Fig. 11)
- Scapular Y / Lateral Humerus View (Fig. 12)

These radiographic views can be obtained with the C-arm positioned on the same or opposite side of the operative arm. A variety of setups may be used based on table configuration and surgeon preference.

The C-arm may be introduced from either the head or side of the table and then rotated to obtain both AP and lateral views. The monitor should be positioned to avoid obstructing the fluoroscope and allow optimal surgeon visibility.

(See Figures 9-20 for representative positioning and radiographs.)

Fig. 7

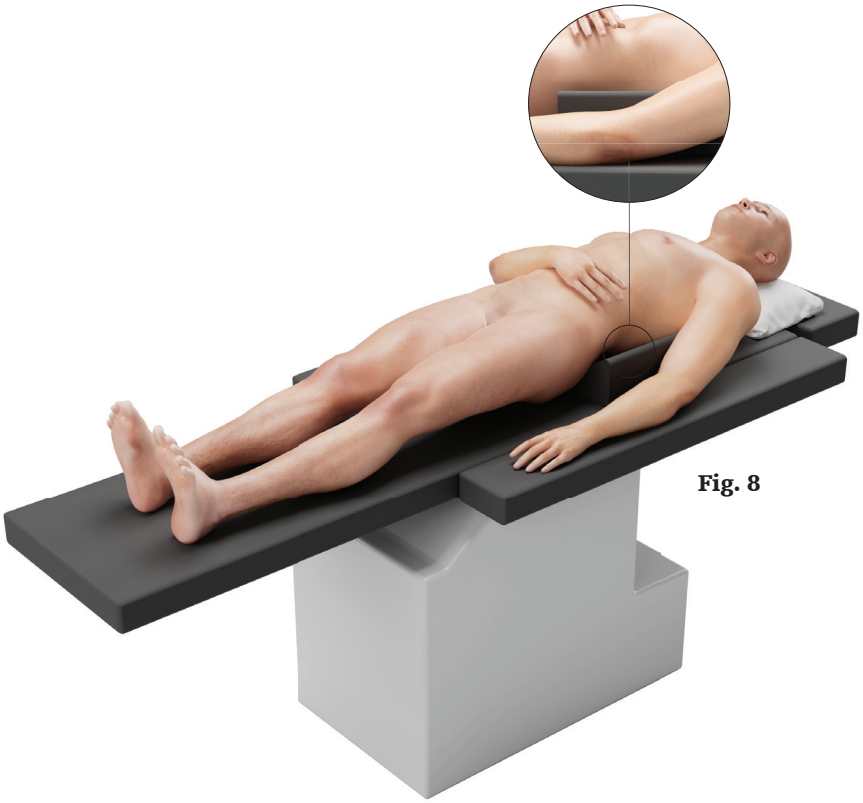


Fig. 8

Operative technique

Patient positioning

Beach chair position

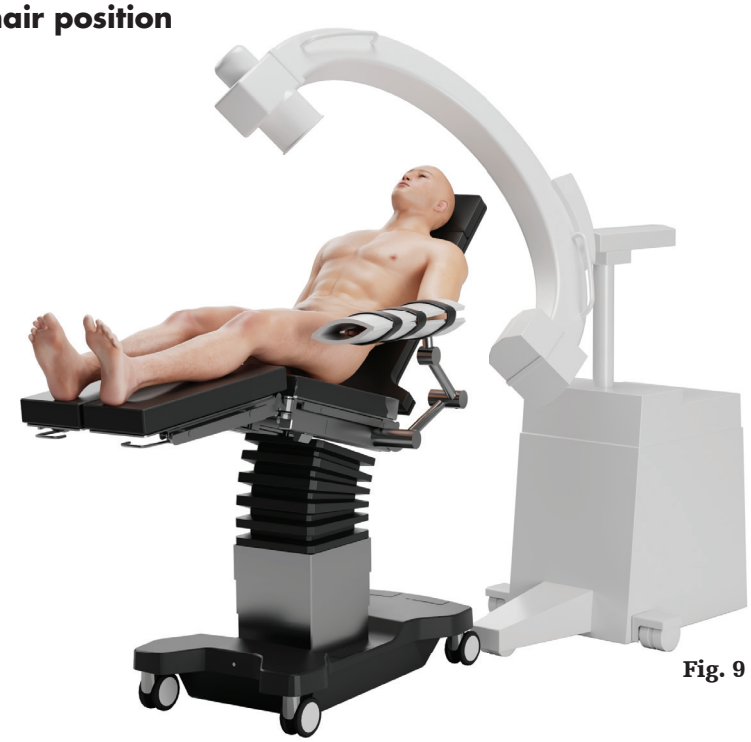


Fig. 9

Fig. 11

Fig. 10

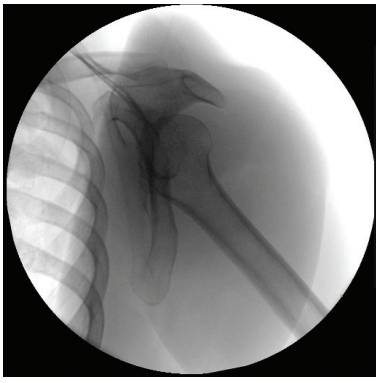


Fig. 12

Operative technique
Patient positioning

Beach chair position – continued

Fig. 13

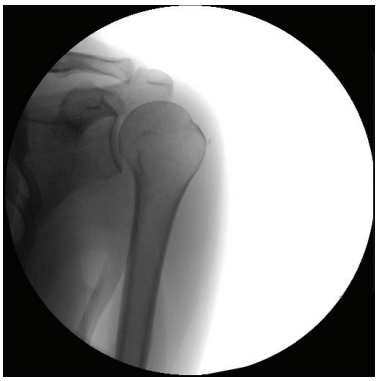


Fig. 15

Fig. 14

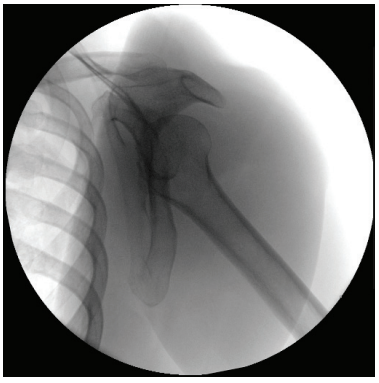


Fig. 16

Operative technique

Patient positioning

Modified supine

Fig. 17

Fig. 19

Fig. 18

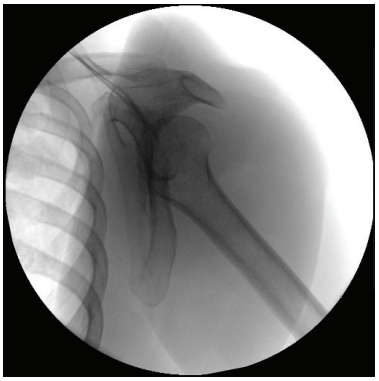


Fig. 20

Operative technique

Incision and entry point

Reduction

Reduction / reposition is required prior to nail insertion.

A small rasp, periosteal elevator, and/or hook can be used to lift the head and reduce the tuberosities, which can then be fixed with small K-wires. Percutaneous reduction by "Joystick-technique" with K-wires to manipulate fragments can be used.

If closed reduction is not possible/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. The supraspinatus tendon is then incised in line with its fibers.

Percutaneous Approach

Using an incision on the upper arm, the deltoid muscle is bluntly split to expose the rotator cuff (Fig. 21).

Alternative Approaches

The Superior Transdeltoid Approach

The anterior deltoid is detached from the anterior acromion to expose the rotator cuff (Fig. 22, Fig. 23).

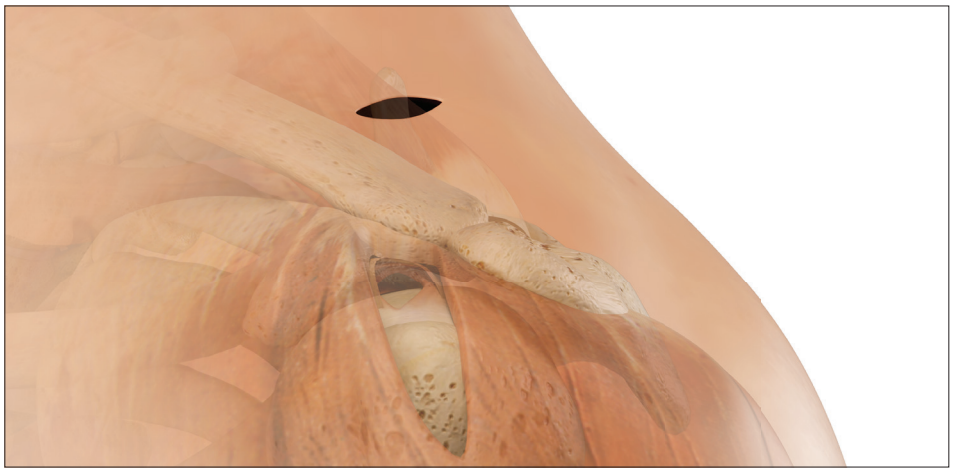


Fig. 21

Fig. 22

Fig. 23

Operative technique

Incision and entry point

Entry Point

To indicate the exact entry point before incising the supraspinatus tendon, a K-wire (2351-3028S) can be placed through the tendon and into the bone at the expected entry point.

Confirm the K-wire position with the image intensifier, in both lateral and A/P views.

The Humeral Nail is designed to be inserted into the central entry point. The central entry point 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).

Insert the K-wire into the diaphyseal area of the bone, as shown in the X-ray image below (Fig. 25).

Fig. 24

⚠CAUTION

Ensure incision is large enough to avoid excessive pressure on the soft tissue.

Fig. 25

Operative technique

Incision and entry point

After incision and entry point identification with the K-wire, protect the surrounding tissue prior to opening of the entry point.

Insert the Opening Reamer Sleeve (2351-5210) and Rigid Reamer Trocar (1806-0411) assembly over the K-wire until it is seated on the bone (Fig. 26). Remove the trocar and insert the Opening Reamer (2351-5110) (Fig. 27). Carefully ream the proximal metaphysis with the Opening Reamer until the depth stop of the reamer (Fig. 28).

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

Optional

To aid with placement of the Opening Reamer Sleeve and Rigid Reamer Trocar assembly, a Cuff Spreader (2351-5010) can be used over the K-wire to evacuate the cuff and surrounding tissue. The Cuff Spreader can be extended to enable insertion of the sleeve and trocar assembly over the K-wire. Lock the sleeve to secure the final seated position (Fig. 25, Fig. 30, Fig. 31).

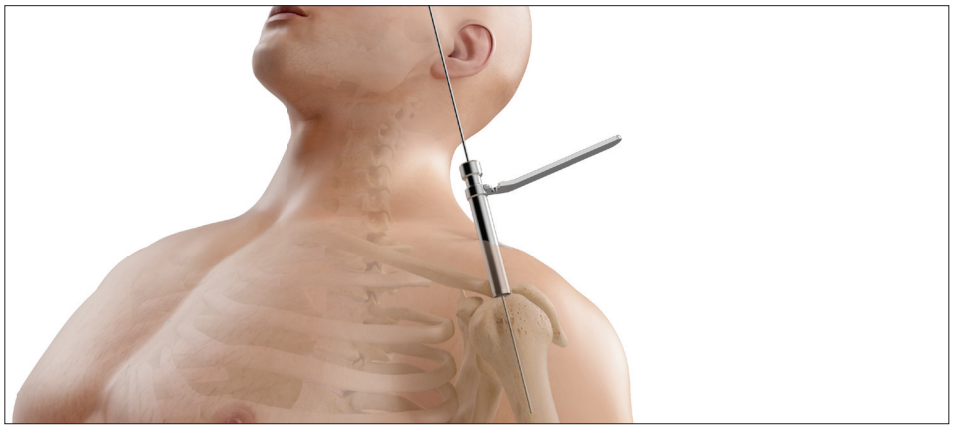


Fig. 26

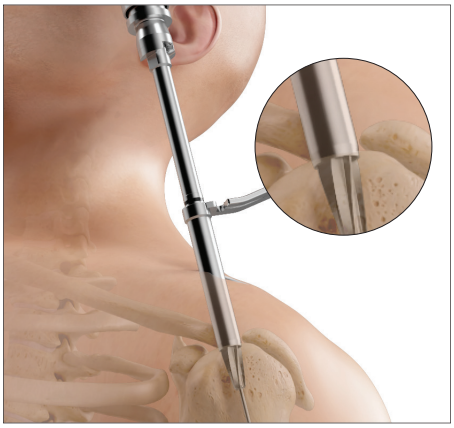


Fig. 27

Fig. 28

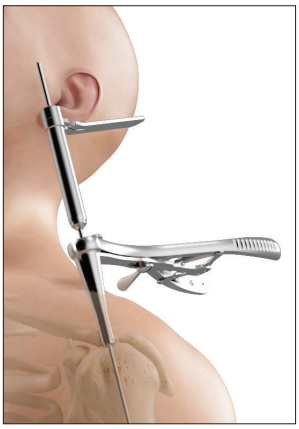


Fig. 29

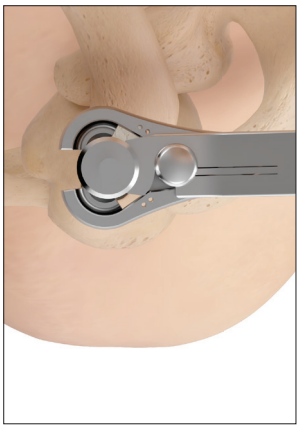


Fig. 30

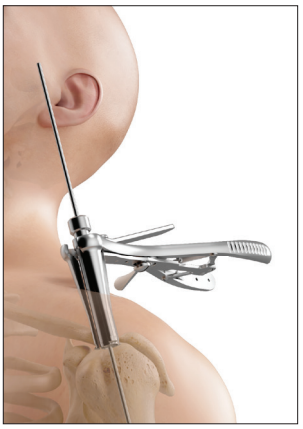


Fig. 31

⚠ CAUTION

Use of the Opening Reamer Sleeve is required to protect the soft tissue.

⚠ CAUTION

Guide or K-wires are single use products and therefore must be discarded at the end of a surgical procedure and not be re-used, even if they appear to be undamaged.

Operative technique

Reaming

For insertion of the Humeral Nail (long), reaming of the medullary canal is recommended.

Guide Wire insertion

Insert the Ball Tip Guide Wire 2.5 x 800mm (1806-0083S) through the Guide Wire Handle (Fig. 32). The Guide Wire Handle can accommodate guide wires and K-wires with diameters from 1.8mm–4mm. To calibrate, loosen the adjustment wheel completely, then close the fixation lever and tighten the adjustment wheel to decrease the diameter of the insertion hole.

Advance the Ball Tip Guide Wire through the fracture site and to the desired insertion depth (approximately 20mm proximal to the olecranon fossa). The guide wire should lie in the center of the metaphysis and the diaphysis in both the AP and lateral views to avoid offset positioning of nail. The Reduction Rod (2351-0020) and Quick-Lock Delta Handle (2351-0140) assembly may be used as a fracture reduction tool to facilitate guide wire insertion through the fracture site (Fig. 34). If the reduction rod is used, the guide wire should be pre-loaded through the tip of the reduction rod before insertion.

⚠CAUTION

Confirm correct position of Ball Tip Guide Wire in the distal fragment prior to reaming.

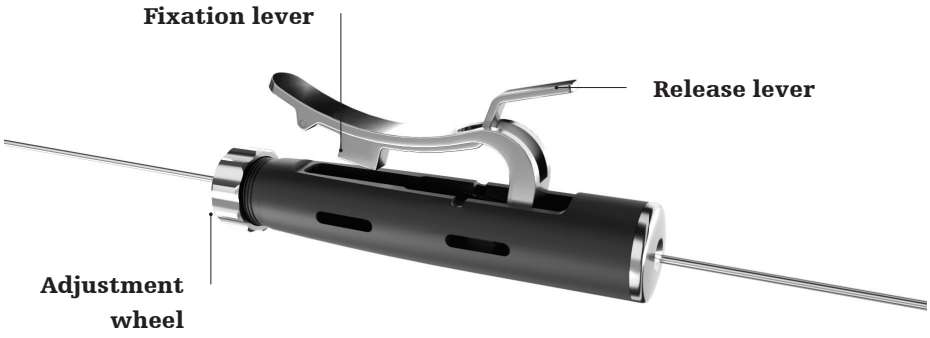


Fig. 32

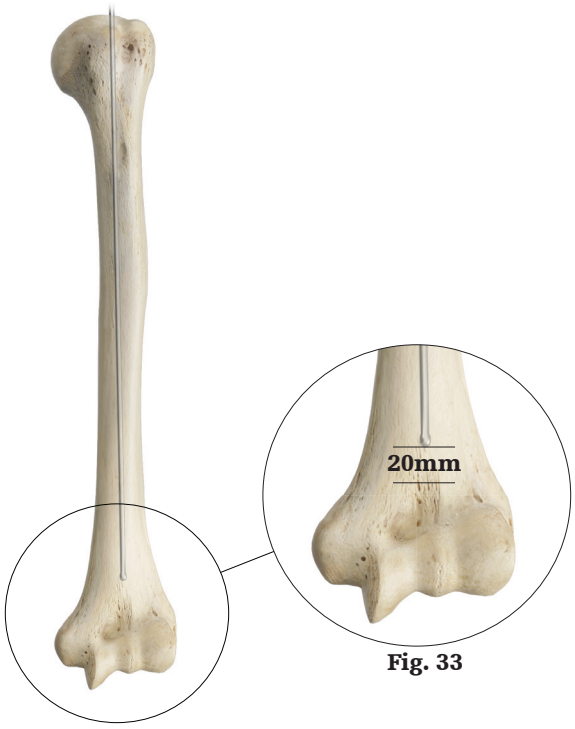


Fig. 33

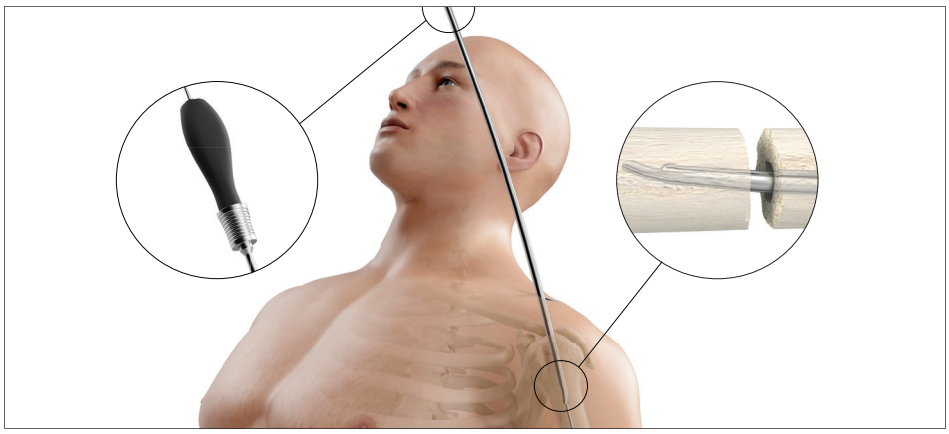


Fig. 34

Operative technique
Reaming

Reaming (long nail only)

Commence reaming in 0.5mm increments until the desired diameter has been achieved. To help maintain the position of the guide wire during reamer extraction, press the funnel tip end of the guide wire pusher at the end of the wire while extracting the reamer from the medullary canal (Fig. 37). The diameter of the selected humeral nail should be 1–1.5mm smaller than that of the last reamer used. When reaming is completed, the Teflon Tube (1806-0073) should be used to exchange the Ball Tip Guide Wire with the Smooth Tip Guide Wire 2.2 x 800mm (1806-0093S) for nail insertion.

A guide wire exchange is required to enable the guided insertion of the humeral nail. The Ball Tip Guide Wire does not fit through the cannulation of the humeral nail.

Note: The ball tip at the end of the guide wire will stop the reamer head.

⚠CAUTION

Care must be taken to ensure that the entry portal is not extended during reaming. This could lead to an offset position for the nail.

⚠CAUTION

Excessive heat generation during reaming/drilling can cause soft tissue or bone damage.

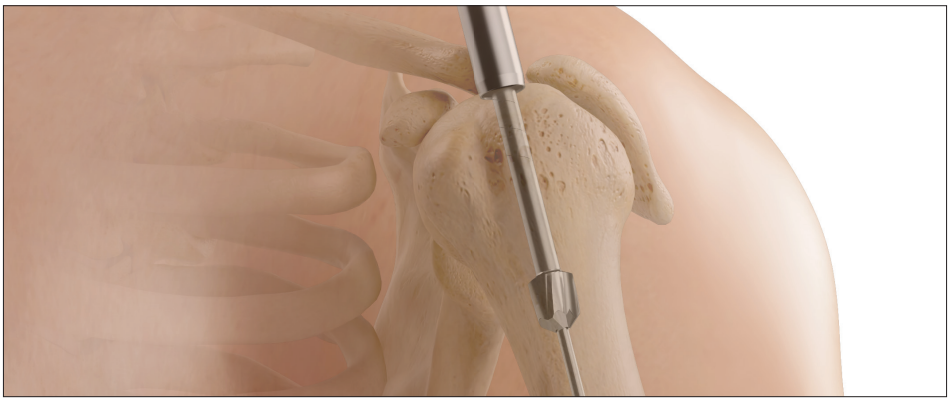


Fig. 35

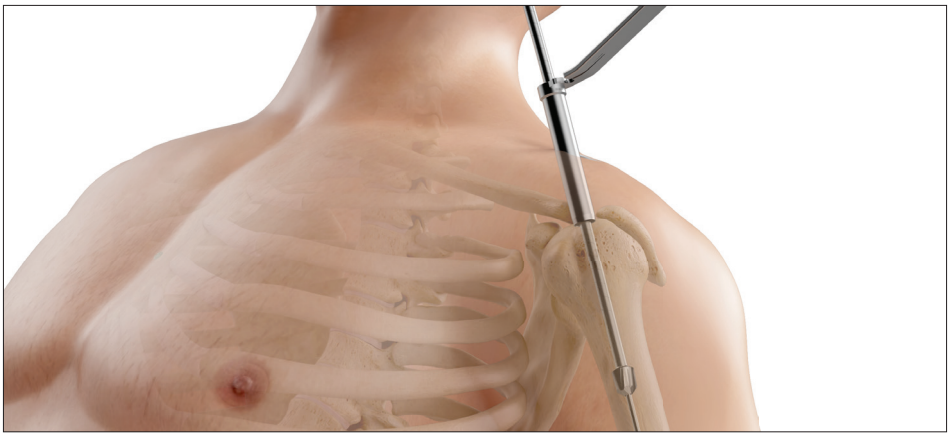


Fig. 36

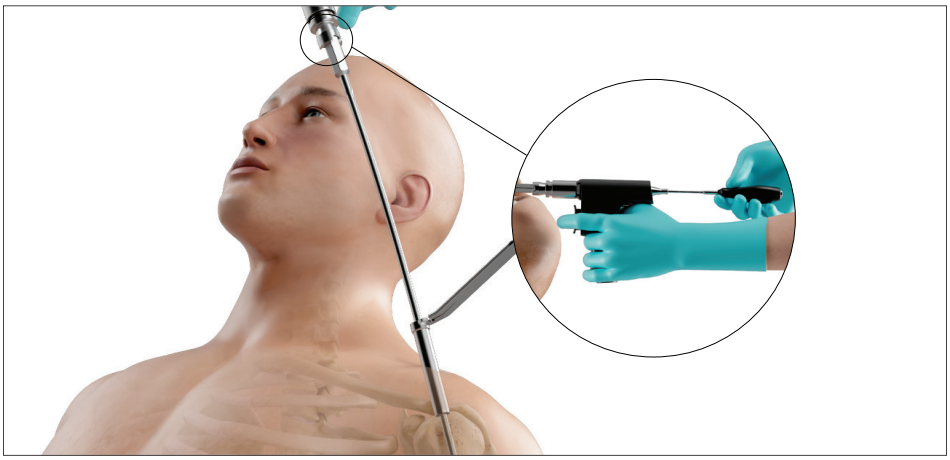


Fig. 37

NOTICE

The smallest diameter nail available is 7mm. The diaphyseal bone must be large enough to allow for reaming of the medullary canal up to at least 8mm.

Operative technique

Nail selection

Length

Determine appropriate nail length by measuring the remaining length of the guide wire.

Confirm the position of the tip of the guide wire prior to measurement.

Place the Guide Wire Ruler (1806-0022) on the guide wire and read the correct nail length at the end of the guide wire on the Guide Wire Ruler (Fig. 39). Ensure that the tip of the Guide Wire Ruler is fully seated on the bone prior to determining measurement (Fig. 38).

If the measurement is between markings, use of the shorter nail is recommended.

Fig. 38

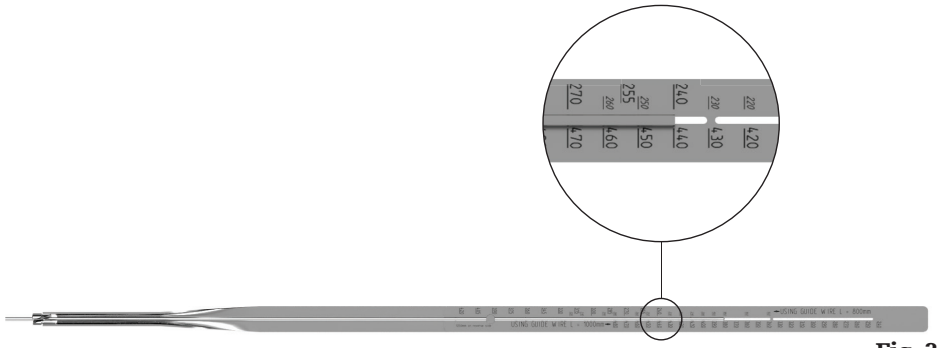
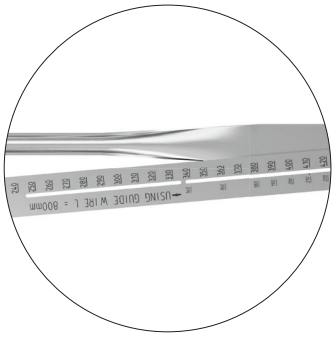


Fig. 39



The Guide Wire Ruler can be easily folded and unfolded.

⚠ CAUTION

Use fluoroscopy to ensure that the guide wire and Guide Wire Ruler are correctly positioned and verify nail length measurement prior to nail insertion.

⚠ CAUTION

If the fracture is suitable for apposition / compression the implant selected should be at least 6 mm shorter than measured to help avoid migration of the nail beyond the insertion site.

NOTICE

The end of the Guide Wire Ruler should align with the proximal end of the nail once inserted.

NOTICE

The Guide Wire Ruler is calibrated for 800mm and 1000mm guide wires.

Operative technique

Nail insertion

The selected nail is assembled onto the Nail Adapter with the Nail Holding Screw. Pre-tighten the screw to the nail by hand then use the Ball Tip Screwdriver (2351-0040) to tighten the assembly (Fig. 40).

Preoperative assembly of the targeting devices is recommended prior to nail insertion, refer to targeting device assembly on page 21 and Distal Targeting Device assembly on page 28.

Remove all targeting devices from the Nail Adapter prior to inserting the nail. Insert the nail by hand over the Smooth Tip Guide Wire and into the entry site of the proximal humerus. Advance the nail past the fracture site. Insert the nail so that it is countersunk below the articular surface. Do not leave the nail proud as this could damage the joint surface. Remove the guide wire once the nail is appropriately positioned.

If dense bone is encountered, first confirm that sufficient reaming has been achieved. If hammering is desired, thread the Strike Plate (1806-0150) into the Nail Adapter and deliver light blows with the Slotted Hammer (2351-0060) to advance the nail further (Fig. 41).

NOTICE

Do not hit the Nail Adapter with the Slotted Hammer; only hit the Strike Plate.

Fig. 40

Fig. 41

⚠ CAUTION

Prior to nail insertion, ensure that the following measures are taken:

1. Verify that the nail is tightly secured to the Nail Adapter.
2. Ensure that both the head of the Nail Holding Screw and the driving end of the nail completely align with the Nail Adapter.
3. Verify correct alignment by inserting a drill through the sleeve and targeting arm assembly. The drill must pass through the holes of the nail.
4. If guided distal locking is to be performed, follow the pre-operative assembly instructions as described in this operative technique.

Operative technique

Nail insertion

If the nail has been inserted too far, reposition as needed. Repositioning of the nail should be carried out either by hand or by using the Universal Rod (1806-0110).

Backslapping may be performed using the Slotted Hammer to extract the assembly.

Two circumferential grooves are located on the insertion post of the Nail Adapter at 2mm and 8mm from the driving end of the nail (Fig. 42, 43). Depth of insertion may be visualized with the aid of fluoroscopy.

When apposition/compression is desired, the recommended depth of insertion is at least 6mm to avoid protrusion of the nail.

Do not insert the nail with a targeting device attached to the Nail Adapter.

Optional: The Nail Height Stop (2351-5310) may also be inserted through the Nail Adapter after insertion of the nail to help prevent plunging of the nail through the proximal humerus. The Nail Height Stop must be loosened to sink the nail further down in the bone.

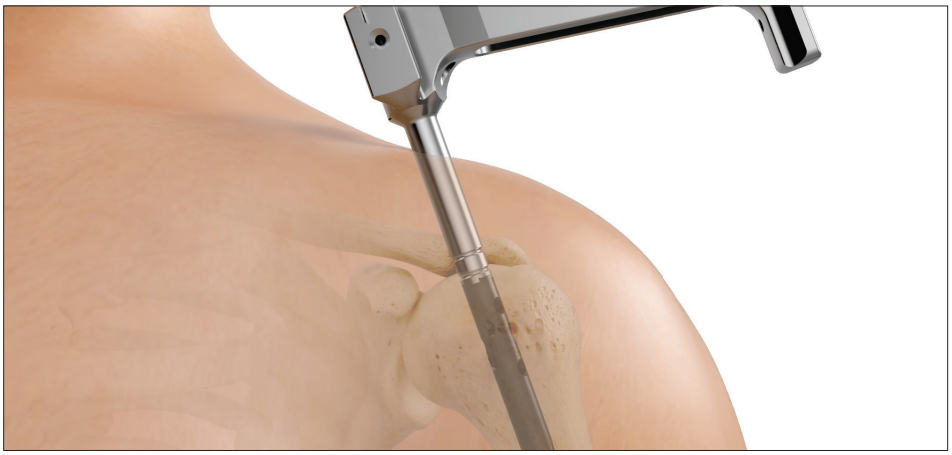


Fig. 42

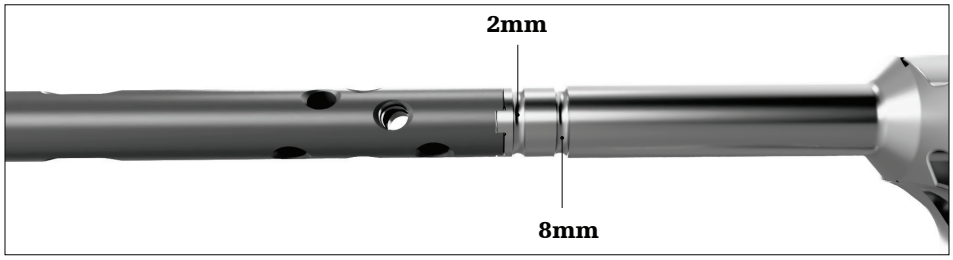


Fig. 43

Fig. 44

⚠ CAUTION

To avoid impingement, check the proximal nail depth with the image intensifier before locking the nail, especially if an End Cap will be used.

⚠ CAUTION

Do not impact or backslap the nail while a targeting device is attached to the Nail Adapter.

⚠ CAUTION

Do not apply excessive force during nail insertion. If severe resistance is encountered, removal of the nail and additional reaming or selection of a nail with a smaller diameter is recommended.

Operative technique

Targeting device assembly

Attach the Targeting Device (left/right specific) to the Nail Adapter, ensuring the knob on the Targeting Device is in the unlocked position and sliding the targeting device down the interface of the Nail Adapter until it hits the stop. Turn knob to lock (Fig. 46). Insert the Tissue Protection Sleeve (2351-0070) together with the Drill Sleeve (2351-4280) into the holes of the targeting devices and insert the Locking Drill Ø3.5 x 360mm (2352-3536S) to confirm that the devices have been assembled properly. Repeat the procedure with the Anterior Targeting Device (2353-1107), which can be used for either the left or right side.

If guided distal locking is to be performed, follow the pre-operative assembly instructions as described in this operative technique, refer to page 28.

Fig. 45

Fig. 46

Fig. 47

Fig. 48

Fig. 49

Operative technique

Targeting device assembly

Prior to locking the nail proximally, verify that the Nail Holding Screw is securely tightened and that the Targeting Device (Left or Right) or Anterior Targeting Device is properly attached to the Nail Adapter.

Proximal locking

1. Static Greater Tuberosity
2. Static Lesser Tuberosity
3. Static Greater Tuberosity
4. Static Greater Tuberosity
5. Static Calcar

Shaft locking

The Humeral Nail (long) allows for active compression using a compression screw (internal compression) or an external compression device (external compression)

6. Compression
7. Static Shaft

Distal locking

The Humeral Nail (short) can be locked with the targeting devices.

8. Static
9. Dynamic
10. Static oblique

4.0mm Locking Screws (2360-40XXS) and Advanced Locking Screws (2361-40XXS) require the 3.5mm drill (orange color-code drill).

Fig. 50

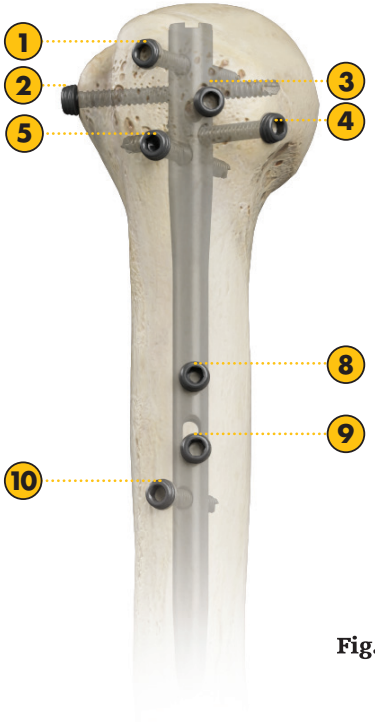


Fig. 51

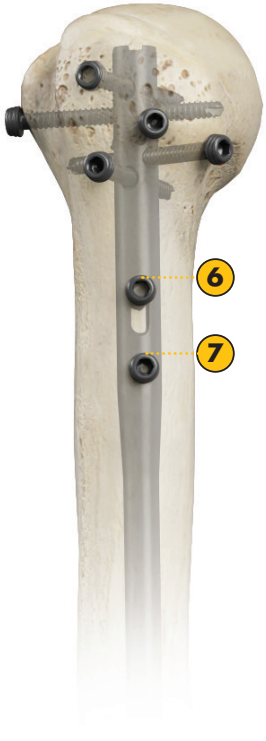


Fig. 52

Note: Numeric markings are for illustration only. Not all positions on the targeting device are marked with numbers. All circles marked on targeting device indicate potential locking options. Dynamic / compression locking options are marked accordingly.

Operative technique

Implant positioning

Ensure the humeral head is anatomically reduced to the shaft, rotate the nail to allow screw insertion into the Greater and Lesser Tuberosities then position the Nail Adapter on the ML plane and insert a K-wire through the adapter; the wire represents the AP plane. Align the wire with the forearm to achieve approximately 30° humeral-head retroversion. In fractures with persistent neck instability, insert the first proximal screw to secure the head fragment, then confirm or adjust rotation with the K-wire.

It is recommended to place the most proximal screw first, as it dictates positioning for all subsequent screws. The most proximal screw is positioned within the triangle formed by the posterior border of the bicipital groove and the cranial border of the Greater Tuberosity, which is where the Tissue Protection Sleeve should be sitting. Once all planned screws are inserted into the humeral head, any torsion between the head and the shaft can be adjusted before securing the distal fragment using the targeting device.

⚠CAUTION

Ensure nail depth persists after rotational alignment.

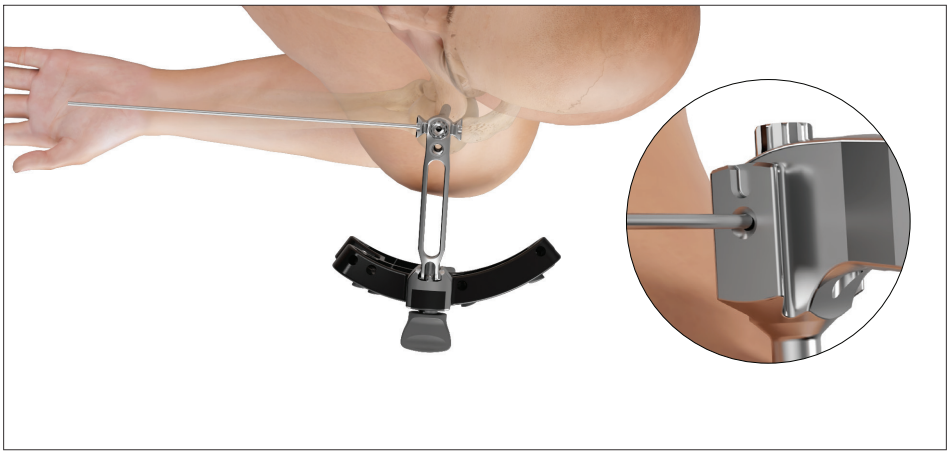


Fig. 53

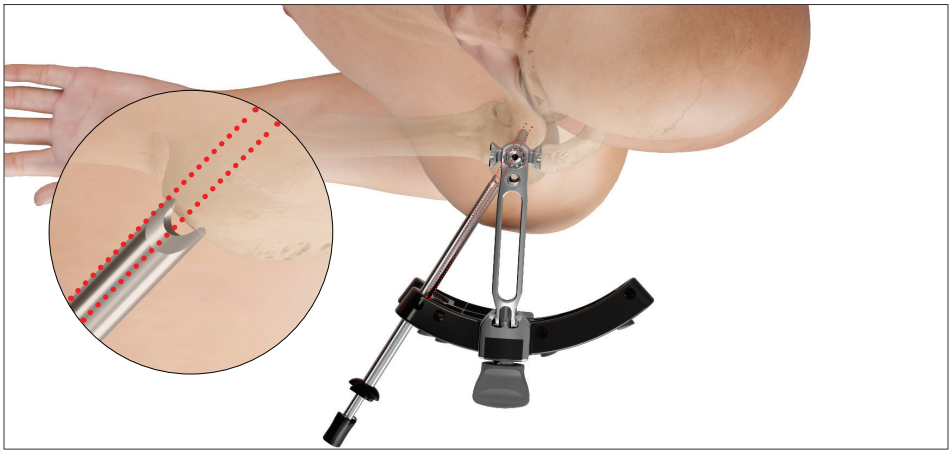


Fig. 54

Fig. 55

Operative technique
Guided proximal locking

All of the proximal screws can be targeted through the Targeting Device (as well as the distal screws for the 150mm short nail), except for the Static Lesser Tuberosity Screw (screw #2 in Fig. 51). Insert the Tissue Protection Sleeve, Locking Drill Sleeve and trocar assembly into the desired locking hole in the Targeting Device (or Anterior Targeting Device if placing the static lesser tuberosity screw). Mark the position on the skin and create an incision. Ensure nail orientation and height is suitable prior to the creation of the incision. Insert the sleeve assembly until it touches the bone. Ensure a sharp drill bit is used to minimize resistance during drilling. A dull bit may require increased force, which can compromise accuracyor damage bone. Remove the trocar and insert the Locking Drill. Drill through the first cortex and advance the drill without rotating through the nail until it is in contact with the subchondral bone. The appropriate screw length can be measured with the sleeve assembly. To maintain targeting accuracy during screw insertion, it is recommended to utilize temporary fixation after initial targeting.

⚠CAUTION

Ensure sleeve assembly is seated on bone and verify correct position under imaging prior to drilling and screw length measuring.

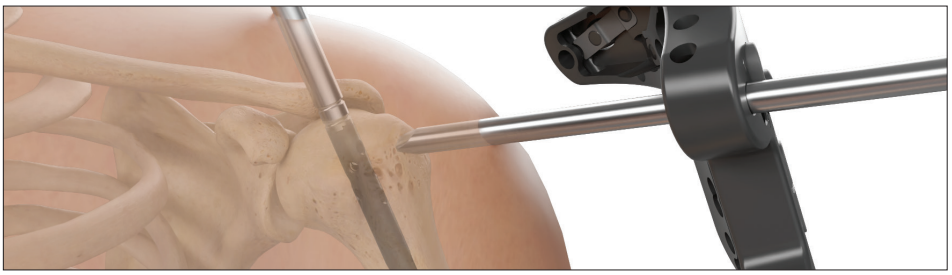


Fig. 56a

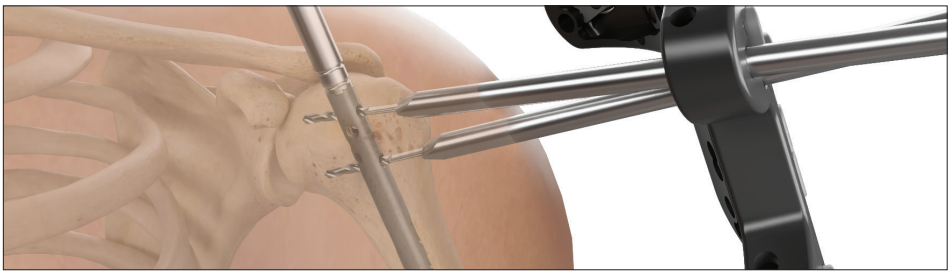


Fig. 56b

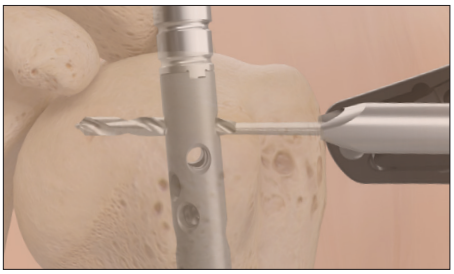


Fig. 57

Insert a second drill bit through the sleeve assembly into an additional proximal hole and keep it in position during insertion of the first screw. This should help stabilize the targeting arm and maintain alignment (Fig. 56b).

Fig. 58

The gray friction lock mechanism is designed to maintain the position of the Tissue Protection Sleeve. To remove the sleeve assembly from the targeting device, press the gray mechanism while pulling the sleeves and trocar.

⚠CAUTION

Remove guide wire prior to drilling.

⚠CAUTION

Do not drill through the far cortex of the humeral head as this will penetrate the joint. The position of the drill tip in the subchondral bone corresponds to the final position of the screw tip.

Operative technique
Guided proximal locking

Remove the Locking Drill and Locking Drill Sleeve and insert the selected Locking Screw (2360-40XXS) through the Tissue Protection Sleeve using the Screwdriver Bit and Quick-Lock Delta Handle (Fig. 60).

When the marking on the screwdriver nears the head of the Tissue Protection Sleeve, the screw is close to its final position. Use imaging to confirm placement of the screw. The paddle tip of the Tissue Protection Sleeve allows the user to visually verify that the screw head is seated on the bone under X-ray without retracting the sleeve from the bone.

Alternatively, the sleeve can be pulled away from the bone to verify that the screw is fully seated. Repeat the procedure for all proximal screws.

NOTICE

Fluoroscopic visualization during Locking Screw insertion is 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.

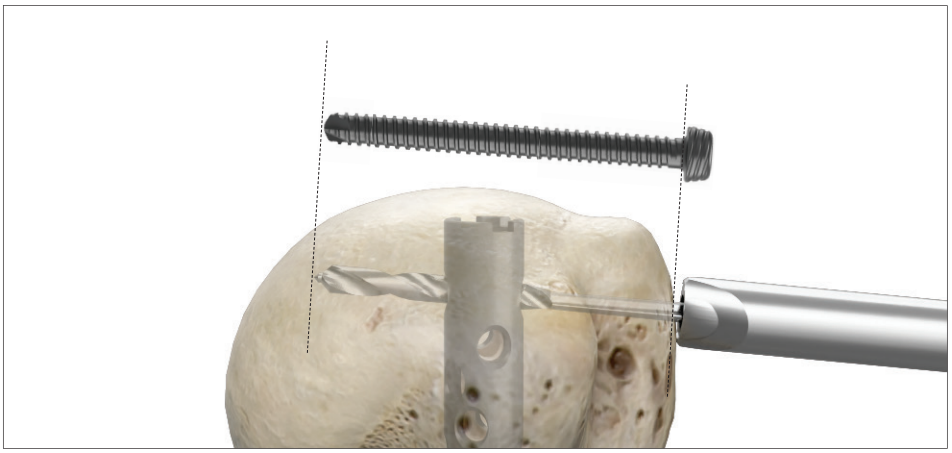


Fig. 59

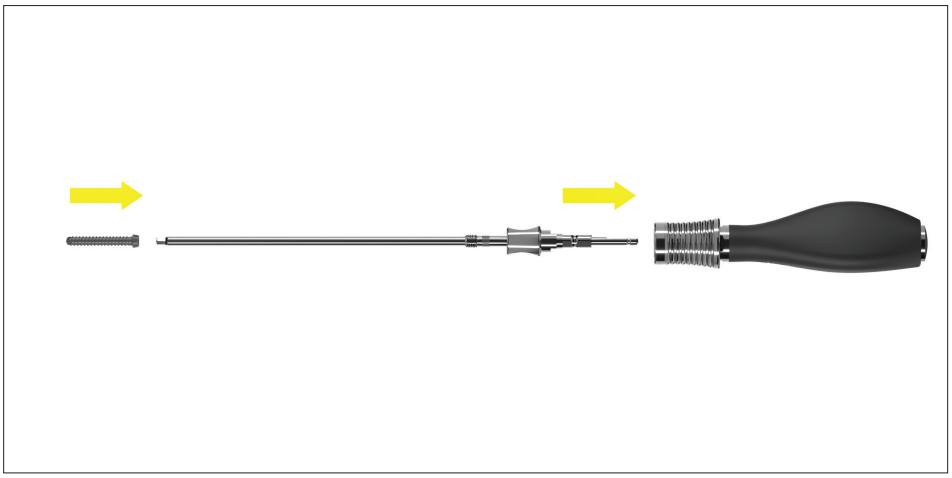


Fig. 60

Fig. 61

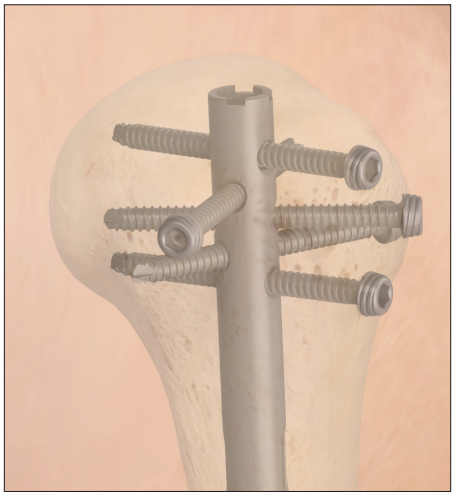


Fig. 62

Operative technique
Guided distal locking (short nail)

The targeting device is designed to provide three Distal Locking Options; two Static Mode options and one Dynamic Mode option.

For static mode: Place screws in both round holes (add a screw in the oblong hole for additional support, if needed).

For dynamic mode: Place a screw in the oblong hole (Fig. 64).

To place screws distally, use the same technique for placement of proximal locking (page 23), but ensure bi-cortical fixation.

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

Fig. 63

Fig. 64

Operative technique
Guided distal locking (long nail)

Distal locking

11. Static AP (anterior to posterior)
12. Static Oblique (Left or Right)
13. Static LM (lateral to medial) (non guided)
14. Static AP

Fig. 65

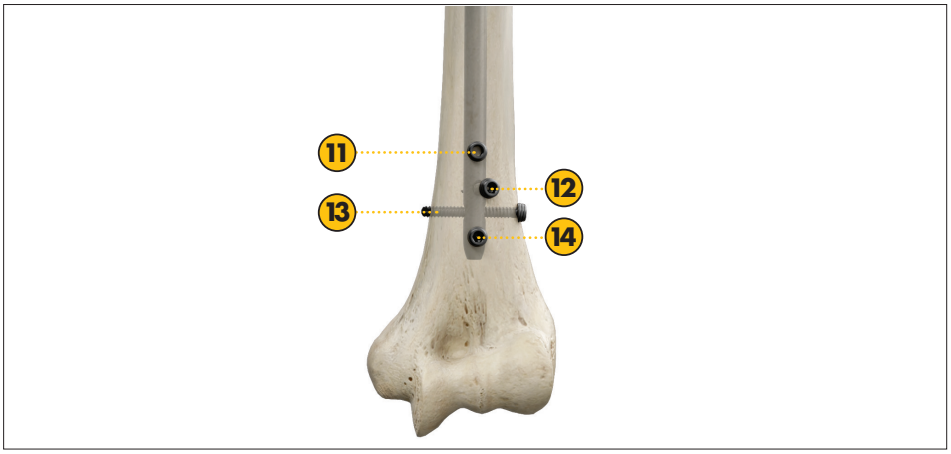


Fig. 66

Operative technique
Guided distal locking (long nail)

Use of the Distal Targeting Device (2353-1108) is recommended when performing distal locking of the AP and oblique screws. The distal LM screw is not targeted and requires freehand distal locking. Pre-operative assembly is recommended prior to nail insertion.

Preoperative assembly steps include:

1. Attach the DTD Adapter (2353-1109) to the Distal Targeting Device in the slot corresponding with the correct nail length (Fig. 67, 68).
2. Attach the Distal Targeting Device to the Anterior Targeting Device and turn the knob of the DTD Adapter to secure (Fig. 69, Fig. 70).
3. If not already secured, attach the Anterior Targeting Device to the Nail Adapter and tighten the knob.

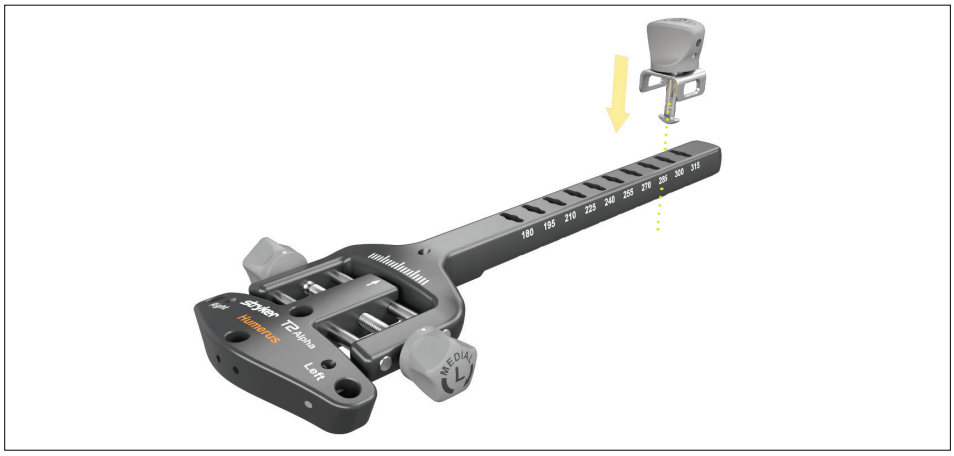


Fig. 67

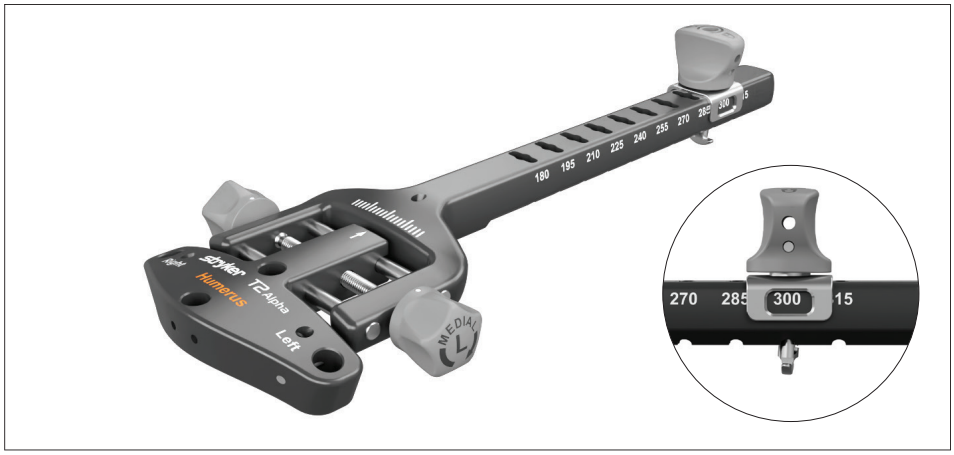


Fig. 68

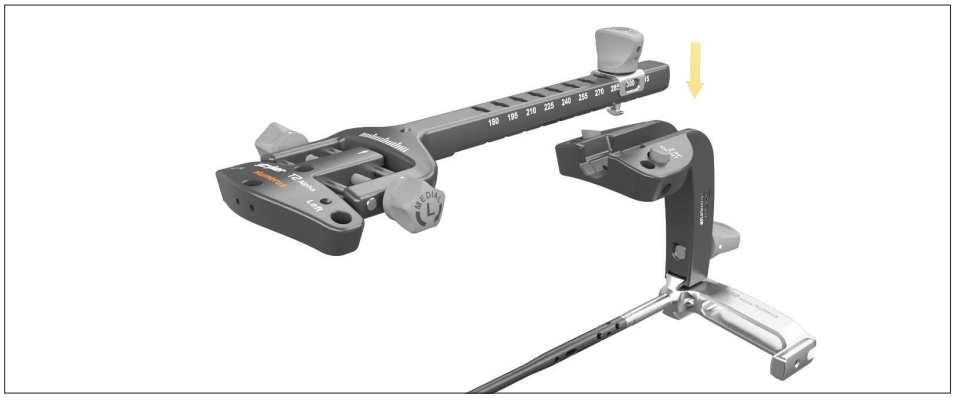


Fig. 69

Operative technique
Guided distal locking (long nail)

4. Insert the Tissue Protection Sleeve into a hole in the Distal Targeting Device. Verify correct assembly by ensuring the drill passes through both the Tissue Protection Sleeve, Locking Drill Sleeve assembly, and the corresponding nail hole (Fig. 71, 72).

5. If properly positioned, remove the sleeve then detach the Nail Adapter from the Anterior Targeting Device and set the assembly aside. Keep the DTD Adapter attached to the Distal Targeting Device, to maintain correct length. Proceed with nail and proximal screw insertion (see pages 19-25). Distal screw insertion may be done prior to proximal locking based on the preferred locking configuration. Reattach the distal targeting assembly to the Nail Adapter. Insert the sleeve assembly through the appropriate hole of the Distal Targeting Device, ensuring the sleeves do not contact the patient's skin. Do not make an incision until the C-arm and sleeves are properly positioned (see next page).

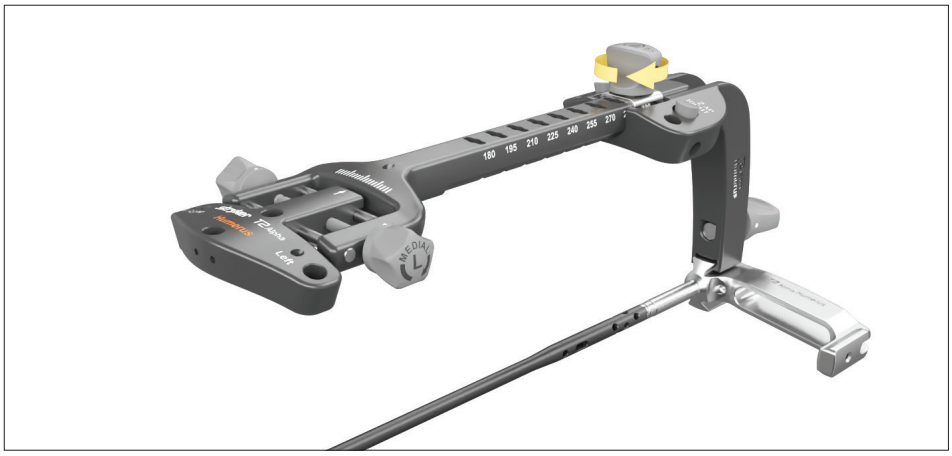


Fig. 70

Fig. 71

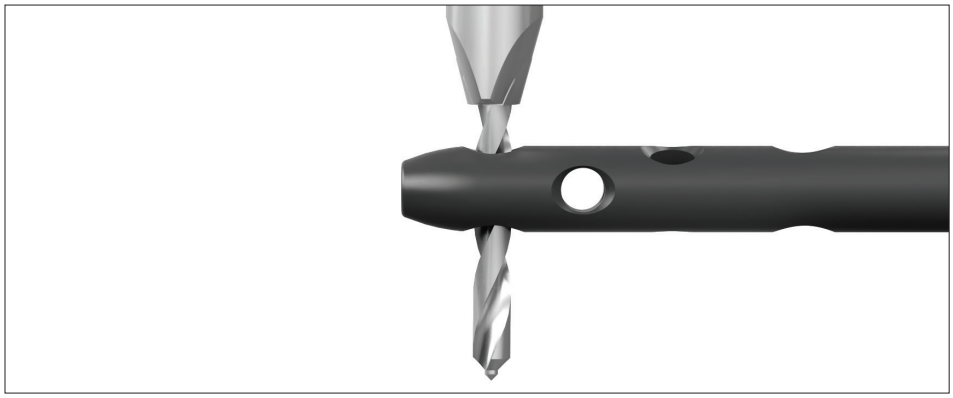


Fig. 72

Operative technique
Guided distal locking (long nail)

The following three steps must be taken prior to drilling.

1. Oblique positioning of C-arm
2. Orbital rotation and second plane of rotation adjustment of the C-arm
3. Sleeve adjustment to the nail position

To perform guided distal locking, it is essential to place the X-ray beam of a C-arm approximately 30° oblique to the axis of the drill sleeve assembly (Fig. 73). As an option, the 3 x 285mm K-wire (2351-3028S) or Oblique Alignment Wire (1320-5395) can be inserted into the hole of the Distal Targeting Device.
The wire indicates a 30° axis to the drill sleeve assembly to aid in correct C-arm positioning.

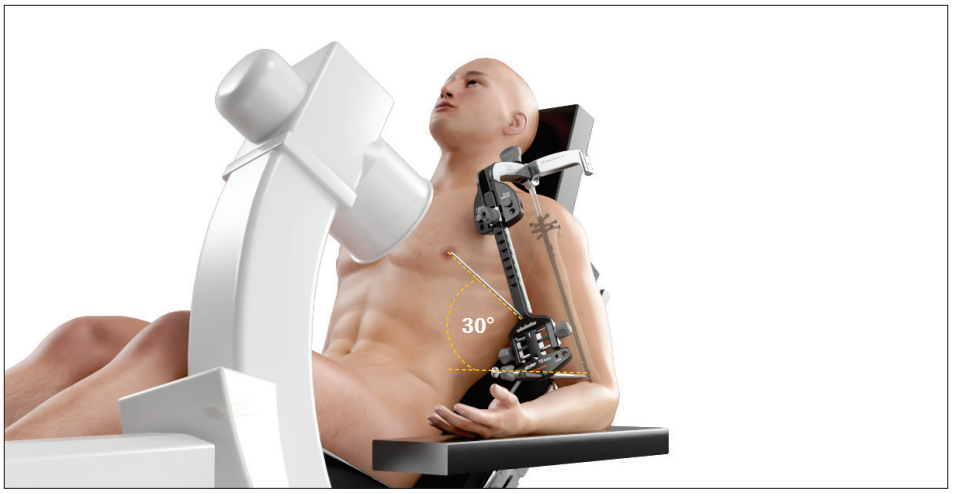


Fig. 73

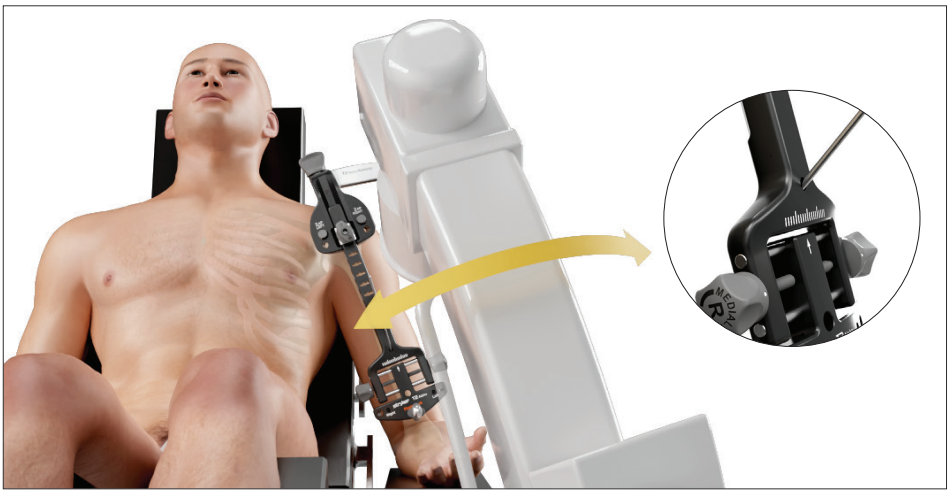


Fig. 74

Oblique positioning of C-arm

In this step, it is important to position the C-arm so that the nail tip and the sleeve axis are seen parallel in the fluoroscopic image.

After oblique C-arm positioning, adjust the height and orbital rotation of the X-ray beam at the same plane as the drill sleeve assembly. Take an X-ray.

Operative technique
Guided distal locking (long nail)

If the sleeve and nail tip are parallel (Fig. 75) or colinear in the X-ray image, the C-arm is correctly positioned and no adjustments to the C-arm position are necessary. If the sleeve and nail tip are not parallel, the C-arm is incorrectly positioned (Fig. 76, Fig. 77).

Adjust the rotation of the C-arm until the tip of the nail and sleeve are parallel or colinear in the X-ray (Fig. 75).

This step requires appropriate C-arm positioning only. Do not turn the knob of the Distal Targeting Device before the nail and sleeve are parallel.

Note: There are different C-arm positions and subsequent oblique alignment wire positions for the AP holes and oblique hole.

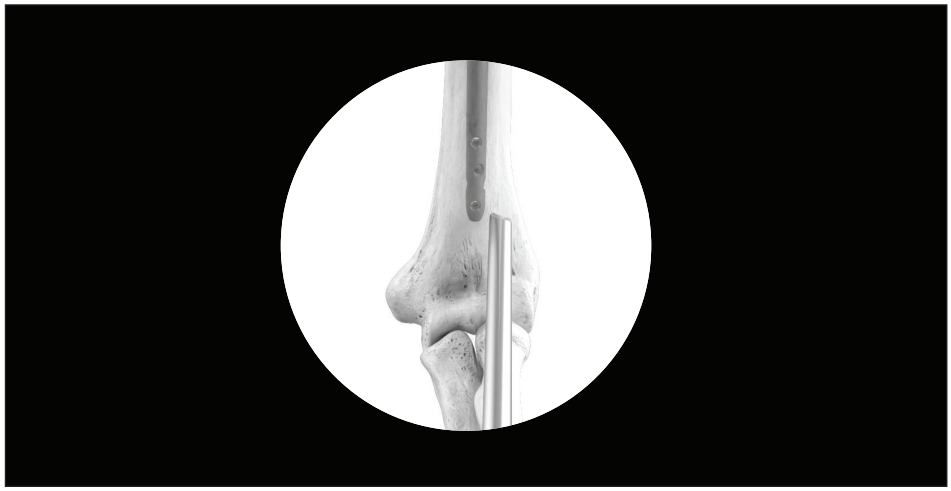


Fig. 75

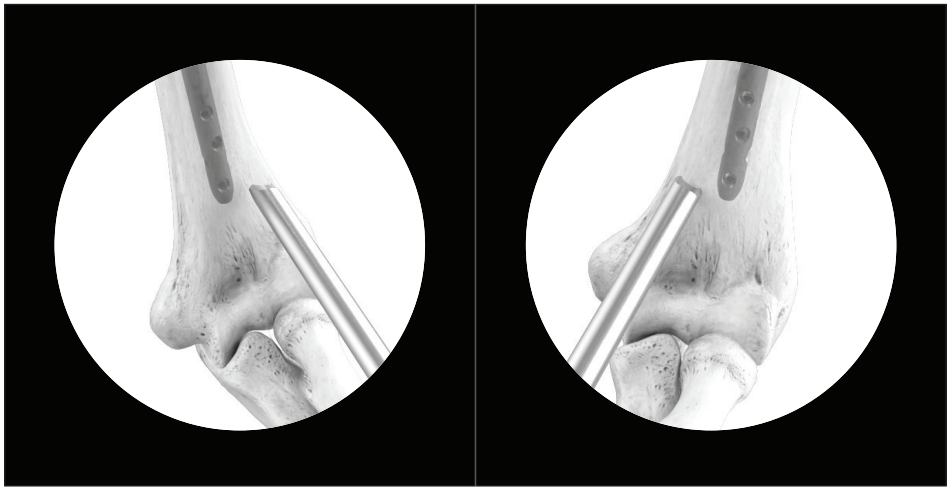


Fig. 76 **Fig. 77**

Sleeve adjustment to the nail position

Once the C-arm has been adjusted so that nail and sleeve are shown in parallel (Fig. 75), the deviated image will show the sleeve either medial or lateral to the nail. If the sleeve and the nail are shown parallel and collinear no further adjustment of the sleeve is needed.

Fig. 78

Operative technique
Guided distal locking (long nail)

If the sleeve and nail tip are not seen on the same axis (Fig. 75), sleeve adjustment is required by turning the knob of the Distal Targeting Device (Fig. 79).
By turning the adjusting knob, the sleeves move medially or laterally.

Distal drilling and locking

Begin with the most proximal of the distal screw set to help maintain targeting accuracy and reduce the potential for nail deformation.

When placing the first screw distally, always begin with a standard bicortical Locking Screw to help prevent skiving.

Once the correct nail and sleeve adjustment has been obtained, make a small skin incision at the sleeve entry point. Ensure that the incision is aligned with the sleeve to avoid excess force. Advance the Tissue Protection Sleeve, Locking Drill Sleeve, and Locking Trocar, assembly through the incision until the sleeve tip is close to the cortex.

⚠CAUTION

To prevent skiving of the sleeve, gently seat the sleeve on the bone and don't apply excessive forces to the sleeve.

Care should be taken to avoid applying load or downward pressure on the targeting device or sleeves, as this may shift the sleeve's alignment relative to the locking hole.

Take an X-ray to confirm correct position of the sleeve as sleeve alignment could be compromised by soft tissue or slippage on the bone. Adjust sleeve position if needed.

Replace the drill bit if there is any indication of dullness prior to distal screw insertion, particularly in hard cortical bone. Once sleeve position has been confirmed, commence distal drilling and screw insertion as outlined in the proximal locking section. Repeat these steps for the insertion of a second AP screw or an oblique screw.

Fig. 79

NOTICE

Patient anatomy, entry point or other factors may result in excessive nail bending that cannot be compensated by design or with the adjustment function. In these instances, freehand distal locking must be performed.

⚠CAUTION

Avoid applying soft tissue pressure to the sleeve assembly.
Do not make skin incision until correct alignment of screw trajectory is confirmed.

⚠CAUTION

Identify the radial nerve position to protect the nerve during distal locking.

Operative technique

Distal freehand locking (long nail)

An alternative to guided distal locking for screw insertion is the freehand technique. 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 (i.e. perfect circles).

Once the C-arm is correctly positioned, make a skin incision that is in line with the distal hole of the nail (Fig. 82).

⚠CAUTION

To avoid damage to the neurovascular structure, consider a limited open approach.

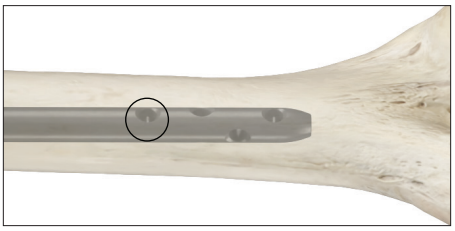


Fig. 80

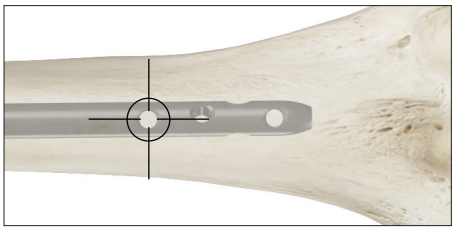


Fig. 81

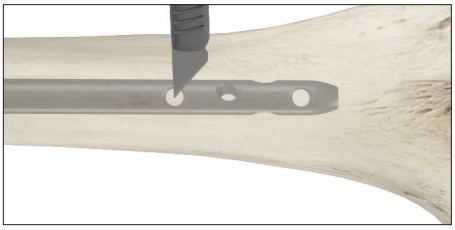


Fig. 82

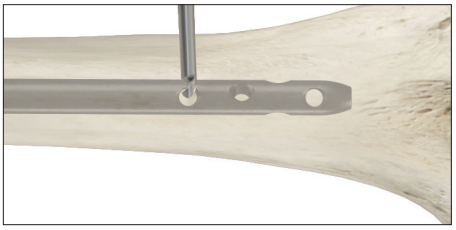


Fig. 83

Fig. 84

Operative technique
Distal freehand locking (long nail)

The freehand drill is held at an oblique angle to the center of the locking hole (Fig. 83). Upon X-Ray verification, the drill is placed perpendicular to the nail and drilled through the near cortex. Confirm these views in both the A/P and M/L planes with X-Ray. After drilling both cortices, the screw length may be read directly off of the Screw Scale (2351-0340).

Alternatively, the Depth Gauge can be used to determine the screw length. 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 Bit (2351-0100) and the Delta Handle.

⚠CAUTION

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

The self-retaining screwdriver assembly may be used to facilitate freehand locking. To use, assemble the Self-retaining Screwdriver Sleeve to the Self-Retaining Screwdriver Bit / quick-lock delta handle assembly (Fig. 87) and attach the screwdriver to the screw and secure the connection by turning the screwdriver sleeve counter-clockwise.

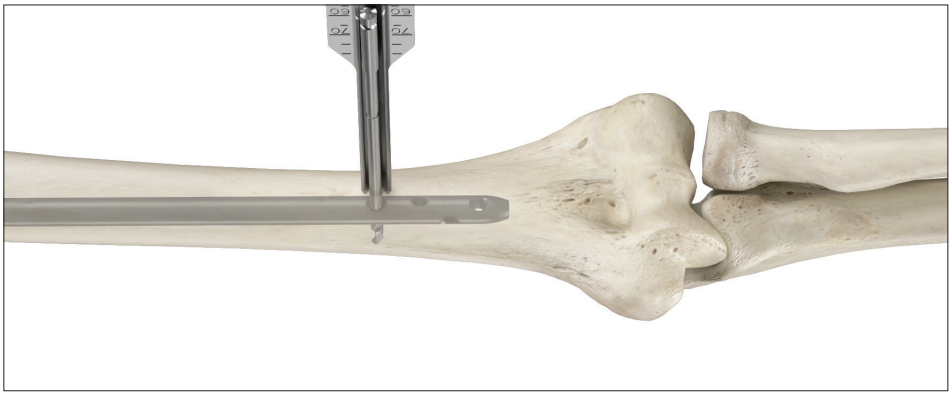


Fig. 85

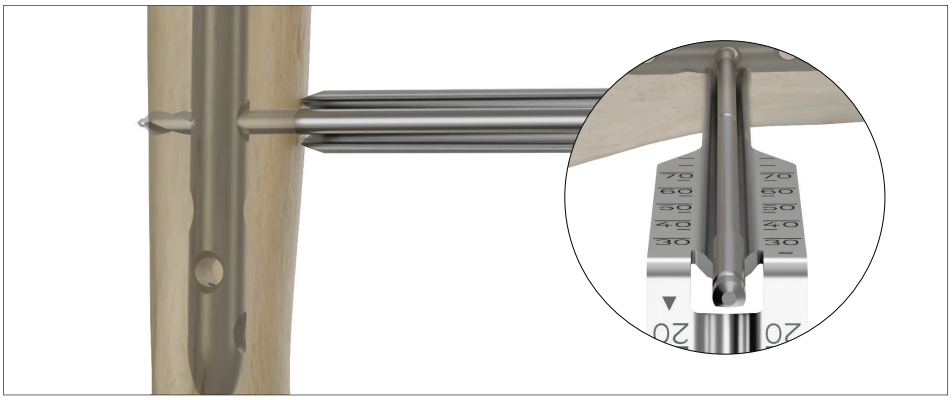


Fig. 86

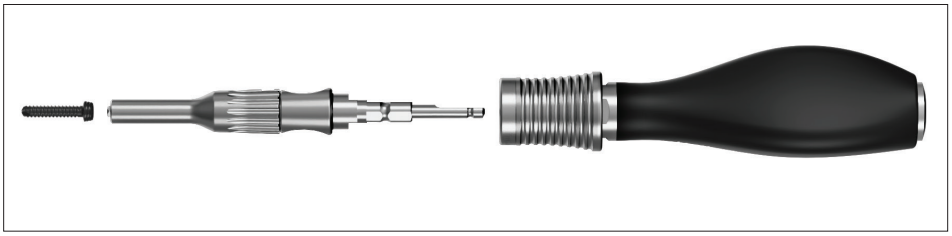


Fig. 87

Fig. 88

Operative technique
Compression

Internal apposition / compression mode (long nail only)

In transverse, axially stable fracture patterns, active mechanical apposition / compression may be desired. The Compression Screw (2311-0010S) can be used to apply apposition / compression. When compressing the fracture, the implant must be inserted at an appropriate distance from the entry point to accommodate for the 6mm of active compression. The two grooves on the insertion post of the Nail Adapter help obtain accurate insertion depth of the implant. After inserting two distal Locking Screws, insert a Locking Screw proximally in the oblong hole. To apply compression, attach the Compression Screw to the Compression Screwdriver (2351-0405) and Quick-lock Delta Handle assembly. Insert the Compression Screwdriver through the Nail Holding Screw and apply apposition / compression (Fig. 89, 90). Once apposition / compression has been applied, the compression screwdriver can be removed. Insertion of the second proximal shaft locking screw is recommended (Fig. 91).

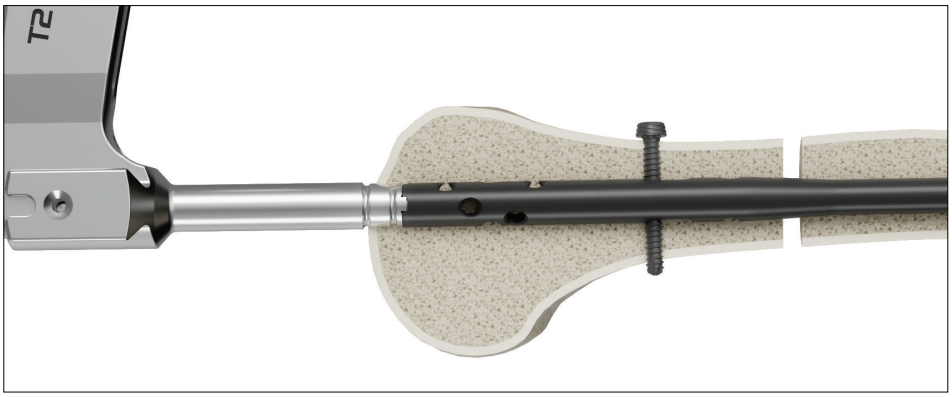


Fig. 89

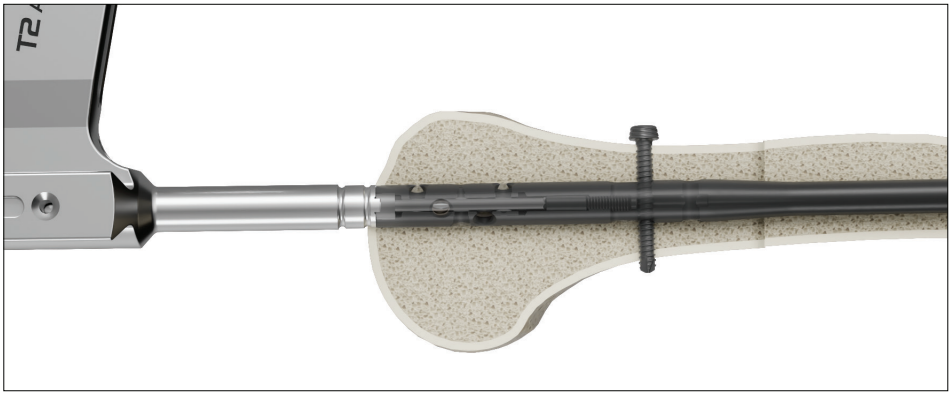


Fig. 90

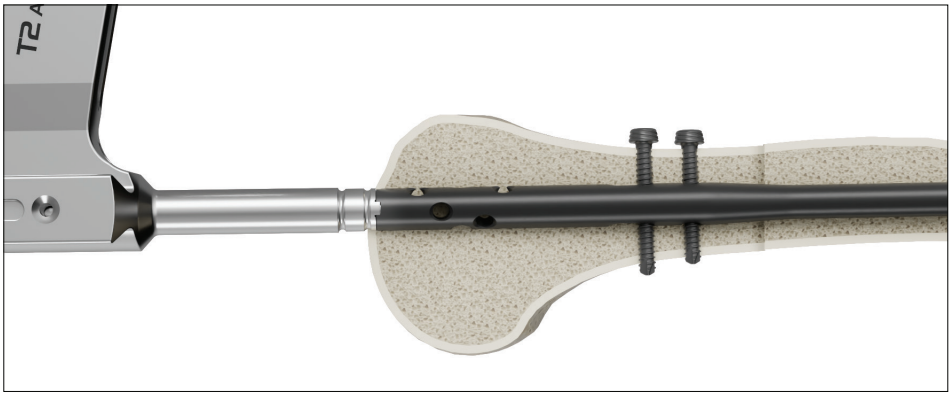


Fig. 91

⚠CAUTION

Apposition / compression must be carried out under X-ray control. Once initial signs of bending of the Locking Screw is observed, further compression should be limited to one additional turn of the Compression Screw. Over compression may cause the nail or screw to fail.

Operative technique
Compression

External apposition / compression mode (long nail only)

As an alternative to internal compression, the External Compression Device (Fig. 92) can be used to apply apposition / compression. When compressing the nail, the implant must be inserted at an appropriate distance from the entry point to accommodate for the 6mm of active compression. The two grooves on the insertion post of the Nail Adapter help attain accurate insertion depth of the implant. After insertion of two distal Locking Screws, insert a Locking Screw proximally in the oblong hole.

To apply compression, attach the External Compression Device to the Quick-Lock Delta Handle and insert the External Compression Device through the Nail Holding Screw to engage the internal threads of the nail. Rotate to apply compression (Fig. 93, 94). Once apposition / compression has been applied, insert the second shaft locking screw. Once the second screw has been inserted, the External Compression Device can be detached.

Fig. 92

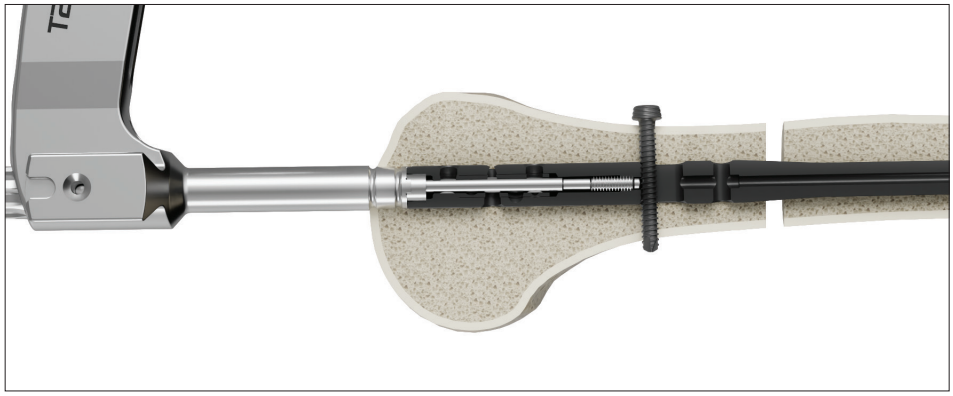


Fig. 93

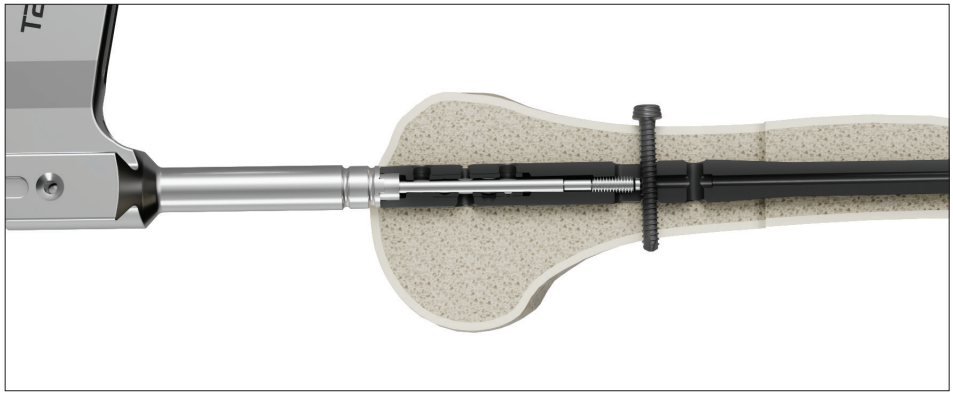


Fig. 94

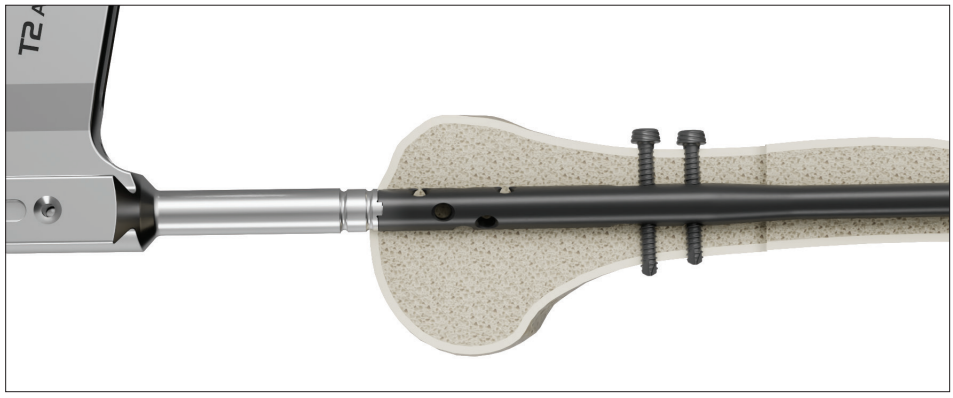


Fig. 95

Operative technique

Advanced Locking Screws

Advanced Locking Screws (2361-40XXS) can be used as an alternative to the Locking Screws in all round holes.

The Advanced Locking Screws are designed with oversized threads (Fig. 96) that engage with the internal threads of the humeral nail to facilitate axial stability in the nail and screw construct.

Advanced Locking Screws may be preferred in instances of poor bone quality and in other instances when axial stability is desired.

Insertion characteristics of the Advanced Locking Screw might be susceptible to user related parameters such as drilling angulation or translational offsets during the predrilling and insertion processes. Anatomic conditions such as bone quality and cortical bone dimensions might also influence screw insertion.

⚠CAUTION

If too much torque is required while using the Advanced Locking Screw, exchange for a standard Locking Screw.

NOTICE

Do not place an Advanced Locking Screw in an oblong hole.

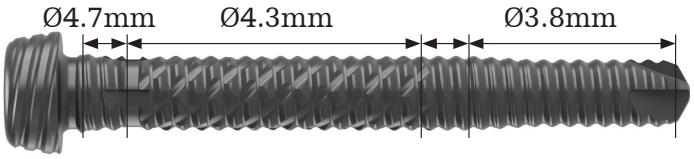


Fig. 96

Fig. 97

Fig. 98

Operative technique

Advanced Locking Screws

Drill both cortices and determine screw length in a guided or freehand manner as described in sections 'Guided distal locking', 'Proximal locking', or 'Distal freehand locking' (Fig. 99). Once screw length has been determined, open the near cortex using the Counterbore Drill, Manual (2351-4515) in combination with the Quick-Lock Delta Handle to ensure that the cortex and the passage to the nail is sufficiently widened. Turn the drill in a gentle clockwise motion with moderate axial pressure until the pathway to the nail has been opened.

⚠CAUTION

Do not use the Manual Counterbore Drill with a power tool in order to avoid implant damage.

⚠CAUTION

Overdrilling the first cortex with a Counterbore Drill is required prior to Advanced Locking Screw insertion.

Fig. 99

Fig. 100

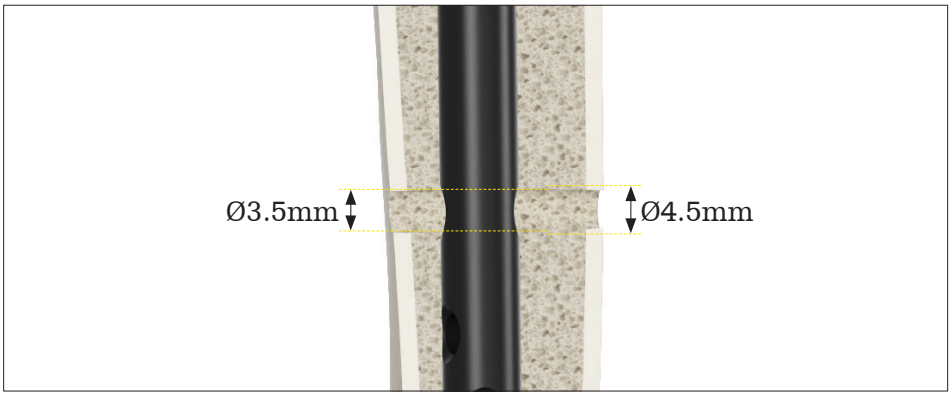


Fig. 101

Operative technique
Advanced Locking Screws

Once drilling has been completed, insert the Advanced Locking Screw with gentle axial force using the appropriate screwdriver through the near cortex without turning the screw, ensuring the axis of the screw is aligned with the corresponding locking hole.

Proximal screws

Insert the screw by rotating clockwise until the screw is fully seated.

For distal and shaft screw

Push the screw until the leading tip is fully engaged with the nail hole.

To confirm correct starting point and axial alignment of the screw, gently rotate the screw counterclockwise while applying gentle axial force (Fig. 102).

A click sound or snapping of the thread indicates that the screw is in the correct position. Once position has been confirmed, insert the screw by rotating clockwise until the screw is fully seated (Fig. 103).

⚠CAUTION

Carefully observe the nail position during Advanced Locking Screw insertion using X-ray.

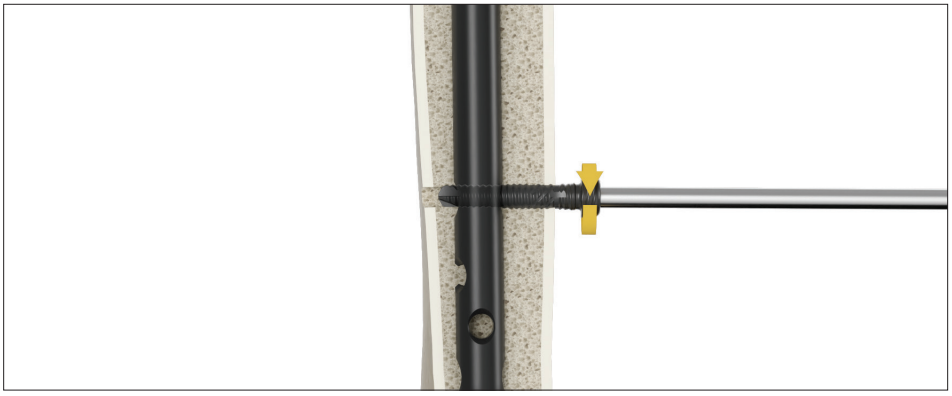


Fig. 102

Fig. 103

Operative technique
Washers

Optional washer use

Washers can be used with Locking Screws or Advanced Locking Screws in instances where increased surface contact on the bone is desired.

The low-profile Humerus Washer (2311-0030S) shall only be used in proximal metaphyseal bone. Use in cortical diaphyseal bone is not recommended and may result in washer failure.

After drilling and measuring, withdraw the Tissue Protection Sleeve. Position the washer below the tip of the Tissue Protection Sleeve and slide the screw through the Tissue Protection Sleeve and the washer. Hold the washer until the screw tip touches the bone. Insert the screw under X-ray control until the washer is fully seated on the bone.

Humerus Washer

Fig. 104

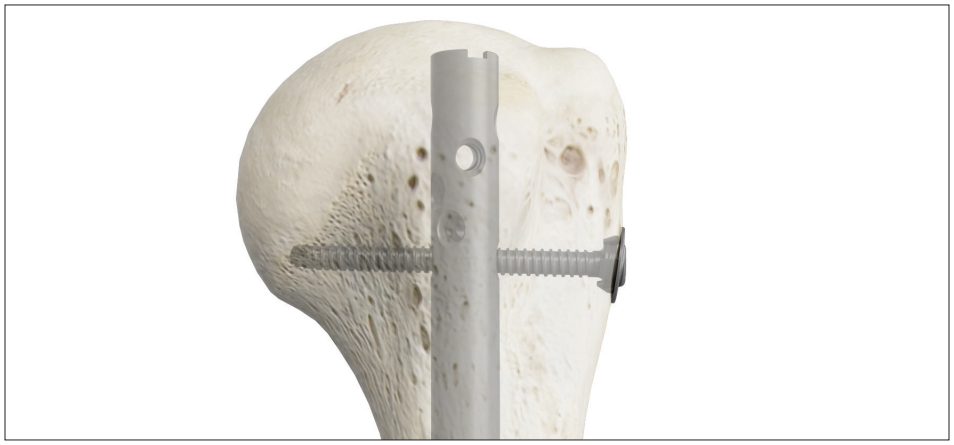


Fig. 105

⚠WARNING

When utilizing the Humerus Washer (2311-0030S), the selected screw size should be at least 1.5mm shorter than the measured length to avoid damage of the joint, as the washer is designed to sit flush with the bone surface.

NOTICE

The utilization of a washer might require a slightly larger incision to avoid capturing the surrounded tissue.

⚠CAUTION

Do not use a washer with the most proximal locking screw as it may cause acromial impingement.

Operative technique

End Cap insertion

After removal of the Nail Adapter and Nail Holding Screw, an End Cap may be inserted. End Caps are available in three sizes.

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

The End Cap is inserted with the Screwdriver, Self-Holding, Short, 3.5mm (1806-0238). Fully seat the End Cap to minimize the risk of loosening.

The End Cap may be used to adjust the height of the nail for optimal purchase of the nail at the entry point.

Close the wound using standard technique.

Fig. 106

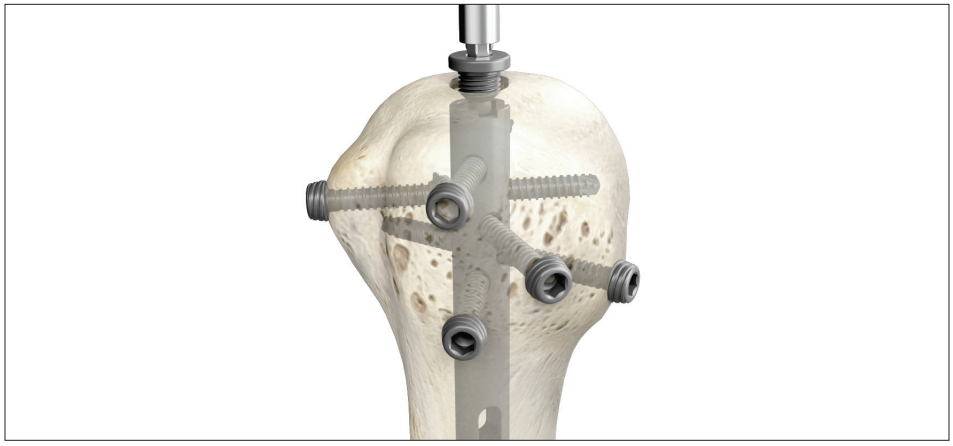


Fig. 107

Fig. 108

Operative technique

Extraction

Nail removal is an elective procedure. The End Cap, if used, is removed prior to removing the most proximal Locking Screw with the screwdriver (e.g. Screwdriver Bit, Short + Self- Retaining Screwdriver Sleeve, Short + Quick-Lock Delta Handle, Modified Trinkle). The Screwdriver, Self-Holding might be used to remove the End Cap. In case a Compression Screw is used, untightening of the Compression Screw with the Compression Screwdriver is required prior to removal of the compressed Locking Screw.

NOTICE

Attaching the Extraction Shaft to the nail before removal of all other Locking Screws should prevent nail migration.

The Extraction Shaft (2351-5410) is inserted into the driving end of the nail. The Universal Rod is attached to the Extraction Shaft. All Locking Screws are removed with the screwdriver. Further remove all washers, if used.

The nail may then be removed with the Slotted Hammer.

Fig. 109

Fig. 110

Fig. 111

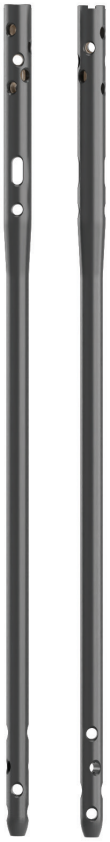
System components

Humeral Nail – short

Left Ref #	Right Ref #	Diameter (mm)	Length (mm)
2311-0815S	2313-0815S	Ø8.0	150.0

Note: The information in the section is not intended to be used for sales and/or promotional purposes.
This information is solely intended to be used as a reference for clinical usage.

System components



Humeral Nail – long

Left Ref #	Right Ref #	Diameter (mm)	Length (mm)
2311-0718S	2313-0718S	Ø7.0	180.0
2311-0719S	2313-0719S	Ø7.0	195.0
2311-0721S	2313-0721S	Ø7.0	210.0
2311-0722S	2313-0722S	Ø7.0	225.0
2311-0724S	2313-0724S	Ø7.0	240.0
2311-0725S	2313-0725S	Ø7.0	255.0
2311-0727S	2313-0727S	Ø7.0	270.0
2311-0728S	2313-0728S	Ø7.0	285.0
2311-0730S	2313-0730S	Ø7.0	300.0
2311-0731S	2313-0731S	Ø7.0	315.0
2311-0818S	2313-0818S	Ø8.0	180.0
2311-0819S	2313-0819S	Ø8.0	195.0
2311-0821S	2313-0821S	Ø8.0	210.0
2311-0822S	2313-0822S	Ø8.0	225.0
2311-0824S	2313-0824S	Ø8.0	240.0
2311-0825S	2313-0825S	Ø8.0	255.0
2311-0827S	2313-0827S	Ø8.0	270.0
2311-0828S	2313-0828S	Ø8.0	285.0
2311-0830S	2313-0830S	Ø8.0	300.0
2311-0831S	2313-0831S	Ø8.0	315.0
2311-0918S	2313-0918S	Ø9.0	180.0
2311-0919S	2313-0919S	Ø9.0	195.0
2311-0921S	2313-0921S	Ø9.0	210.0
2311-0922S	2313-0922S	Ø9.0	225.0
2311-0924S	2313-0924S	Ø9.0	240.0
2311-0925S	2313-0925S	Ø9.0	255.0
2311-0927S	2313-0927S	Ø9.0	270.0
2311-0928S	2313-0928S	Ø9.0	285.0
2311-0930S	2313-0930S	Ø9.0	300.0
2311-0931S	2313-0931S	Ø9.0	315.0

System components

Humeral Nail – long

Left Ref #	Right Ref #	Diameter (mm)	Length (mm)
2311-1018S	2313-1018S	Ø10.0	180.0
2311-1019S	2313-1019S	Ø10.0	195.0
2311-1021S	2313-1021S	Ø10.0	210.0
2311-1022S	2313-1022S	Ø10.0	225.0
2311-1024S	2313-1024S	Ø10.0	240.0
2311-1025S	2313-1025S	Ø10.0	255.0
2311-1027S	2313-1027S	Ø10.0	270.0
2311-1028S	2313-1028S	Ø10.0	285.0
2311-1030S	2313-1030S	Ø10.0	300.0
2311-1031S	2313-1031S	Ø10.0	315.0

System components

Locking Screw

Ref #	Diameter (mm)	Length (mm)
2360-4020S	Ø4.0	20.0
2360-4022S	Ø4.0	22.5
2360-4025S	Ø4.0	25.0
2360-4027S	Ø4.0	27.5
2360-4030S	Ø4.0	30.0
2360-4032S	Ø4.0	32.5
2360-4035S	Ø4.0	35.0
2360-4037S	Ø4.0	37.5
2360-4040S	Ø4.0	40.0
2360-4042S	Ø4.0	42.5
2360-4045S	Ø4.0	45.0
2360-4047S	Ø4.0	47.5
2360-4050S	Ø4.0	50.0
2360-4052S	Ø4.0	52.5
2360-4055S	Ø4.0	55.0
2360-4057S	Ø4.0	57.5
2360-4060S	Ø4.0	60.0

System components

Advanced Locking Screw

Ref #	Diameter (mm)	Length (mm)
236l-4020S	Ø4.0	20.0
236l-4022S	Ø4.0	22.5
236l-4025S	Ø4.0	25.0
236l-4027S	Ø4.0	27.5
236l-4030S	Ø4.0	30.0
236l-4032S	Ø4.0	32.5
236l-4035S	Ø4.0	35.0
236l-4037S	Ø4.0	37.5
236l-4040S	Ø4.0	40.0
236l-4042S	Ø4.0	42.5
236l-4045S	Ø4.0	45.0
236l-4047S	Ø4.0	47.5
236l-4050S	Ø4.0	50.0
236l-4052S	Ø4.0	52.5
236l-4055S	Ø4.0	55.0
236l-4057S	Ø4.0	57.5
236l-4060S	Ø4.0	60.0

System components

Washer

Ref #	Description	Size (mm)
2311-0030S	Washer Humerus Round	Ø11
1832-0007S*	Washer, Round	Ø17mm
1832-0008S*	Washer, Rectangular	10 × 18mm
1832-0009S*	Washer, Small	14.7 × 8mm

End Cap

Ref #	Diameter (mm)	Length(mm))
2311-0000S	Ø7.0	0.0
2311-0002S	Ø10.0	2.0
2311-0004S	Ø10.0	4.0

Compression Screw

Ref #	Diameter (mm)
2311-0010S	Ø4.0mm

* Implants from the T2 system

System components

Indication Specific Instruments

	Ref #	Description
	2355-1000	Humerus Indication Tray Kit
	2351-5110	Opening Reamer Ø10.0
	2351-5210	Opening Reamer Sleeve Ø10.0
	1806-0411	Rigid Reamer Trocar T2 Humerus
	2351-0405	Compression Screwdriver Humerus
	2351-0260	External Compression Device Humerus
	2351-5310	Nail Height Stop Humerus
	2351-5410	Extraction Shaft Humerus
	1806-0203	Screwdriver, Self-Holding, Short, 3.5mm
	2353-1103	Nail Adapter Humerus
	2353-1104	Nail Holding Screw Humerus
	2353-1107	Anterior Targeting Device Humerus
	2353-1105	Targeting Device Humerus, Left
	2353-1106	Targeting Device Humerus, Right

Optional Indication Specific Instruments

	Ref #	Description
	2351-5010	Cuff Spreader Humerus
	1806-2020	Crown Drill T2 Prox. Hum. Ø10 × 195mm
	2353-1109	DTD Adapter Humerus
	2353-1108	Distal Targeting Device Humerus
	1320-5395	Oblique Alignment Wire Gamma3® Distal Targeting Ø3.2 × 180mm

System components

IMN Basic Instruments*

	Ref #	Description
	2356-0580	IM Nailing Basic Instruments Kit
	2351-0020	Reduction Rod
	2351-0030	Guide Wire Handle
	2351-0040	Ball Tip Screwdriver
	2351-0060	Slotted Hammer
	2351-0070	Tissue Protection Sleeve, Long
	2351-0100	Screwdriver Bit, Short
	2351-0101	Self-Retaining Screwdriver Sleeve, Short
	2351-0105	Screwdriver Bit, Medium
	2351-0106	Self-Retaining Screwdriver Sleeve, Medium
	2351-0110	Screwdriver Bit, Long
	2351-0140	Quick-Lock Delta Handle, Modified Trinkle
	2351-0150	Guided Depth Gauge
	2351-0160	Freehand Depth Gauge, Short
	2351-0170	Freehand Depth Gauge, Long
	2351-0340	Screw Scale
	2351-0380	Guide Wire Pusher
	2351-0420	X-ray Ruler
	2351-4280	Locking Drill Sleeve, Long
	2351-4290	Locking Trocar, Long
	2355-5000	Basic Instruments Tray
	2355-5005	Basic Tray Base
	2355-5010	Basic Tray Insert
	1500-0040	Full Size Tray Lid
	1806-0022	Guide Wire Ruler
	1806-0110	Universal Rod
	1806-0150	Strike Plate

* Existing part from the IMN Instruments System

System components

Disposables

	Ref #	Description
	1806-0051	K-wire with Washer T2 Prox. Hum. Ø7.8 × Ø3 × 285mm
	1806-0050	K-wire T2 Femur Ø3 × 285mm
	2351-3028S	K-wire IMN Instruments Ø3 × 285mm
	2351-4515	Counterbore Drill, Manual IMN Instruments Ø4.5mm × 280mm
	2352-3536S	Locking Drill IMN Instruments Ø3.5 × 360mm
	2352-3513S	Freehand Drill IMN Instruments Ø3.5 × 130mm
	2352-3518S	Freehand Drill Ø3.5 × 180mm
	1806-0073	Teflon Tube
	1806-0083S	Ball Tip Guide Wire 2.5 x 800mm
	1806-00935S	Smooth Tip Guide Wire 2.2 x 800mm
	2351-0390S	Locking Scalpel

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.

The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the product label and/or Instructions for Use, including the instructions for Cleaning and Sterilization (if applicable), before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

The Instructions for Use, Operative Techniques, Cleaning instructions, patient information leaflets and other associated labeling maybe requested online at www.ifu.stryker.com or www.stryker.com. If saving the Instructions for Use, Operative Techniques, Cleaning instructions from the above mentioned websites, please make sure you always have the most up to date version prior to use.

This document is only applicable to US and Canada.

Content ID: TR-T2AL-SURGP-2363750, 09-2025

Manufacturer:
Stryker GmbH
Bohnackerweg 1
2545 Selzach,
Switzerland
www.stryker.com