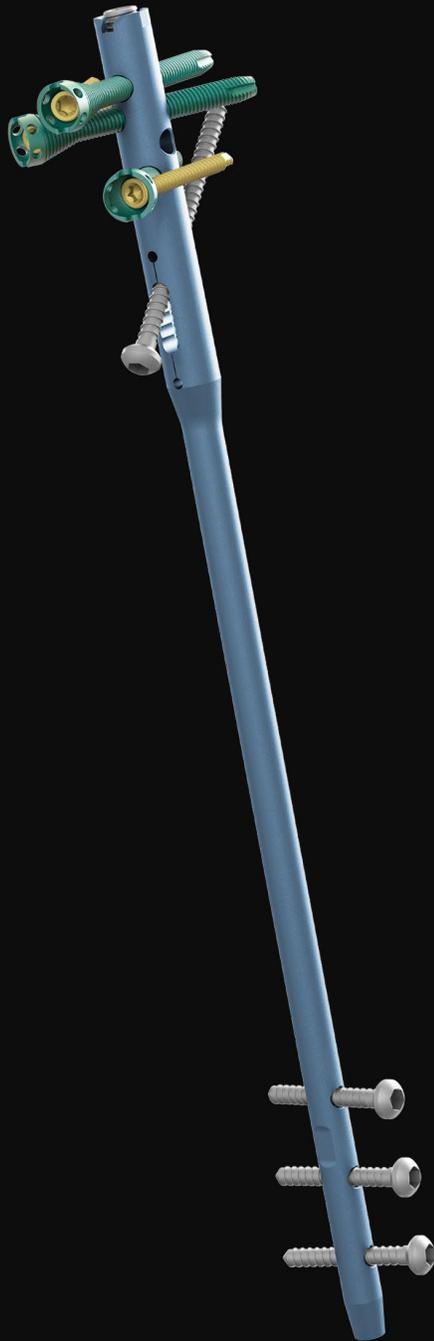


SURGICAL TECHNIQUE

# H-Fix™ Humeral Nail System



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## INTRAMEDULAR H-FIX HUMERAL INTRAMEDULAR NECK SYSTEM SURGICAL TECHNIQUE

### System description

The Traufix H-Fix Humerus Intramedullary Nail System is designed to treat simple and complex fractures of the humerus, both proximal and diaphyseal. This system is innovative with multiple locking options and advanced features that provide superior stability and OPTIMIZE biomechanics in the osteosynthesis of humeral fractures.

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### Implant Options

- ▶ **Short nail:** Available for right and left humerus, with a diameter of 9.0 mm and a length of 160 mm
  - ▶ **Long Nail:** Available for right and left humerus, with diameters of 7.0 mm and 8.0 mm, with lengths of 200 - 300 mm of 20 in 20 mm.
  - ▶ **Locking plug:** Available in sizes 0, 5, 10, 15 and 20
  - ▶ **DuoFix screw (4.5):** Available in lengths from 20 to 60 mm by 5 in 5 mm
  - ▶ **Screw 3.5 DCP:** Available in lengths from 25 to 55 mm in 5 by 5 mm.
  - ▶ **3.5 ALP Screw:** Available in lengths from 25 to 55 mm in 5 in 5 mm increments
-

## Short Nail Screw Configuration

### Levels A to D

#### Proximal Locking

The three lateral screws (greater tubercles [trochiter], levels **A**, **B** and **D**) should be used in all fractures, regardless of their location, as they guarantee the basic stability of the assembly.

Screw type:

-4.5mm DuoFix screw (emerald green)

The **anterior screw** (minor tubercle [trochlea], level **C**) increases the stability of the assembly. It can be used in fractures with a trochlear fragment, provided it is large enough to accommodate the screw head. Never insert a 3.5 mm locking screw at this level.

Screw type:

-4.5mm DuoFix screw (emerald green).

Additional **locking screws** ("screws on screw") (major tubercle, levels **A**, **B** and **D**) can also be inserted through the head of the lateral screws to increase the stability of the osteosynthesis. These additional screws are particularly useful in case of poor bone quality (e.g. osteoporosis)\*.

Screw type (optional):

-Locking screw 3.5 mm (yellow)

### E-levels

#### Ascending screw

The ascending screw provides support for the medial calcar region, which may be useful in fractures with medial comminution.

Screw type:

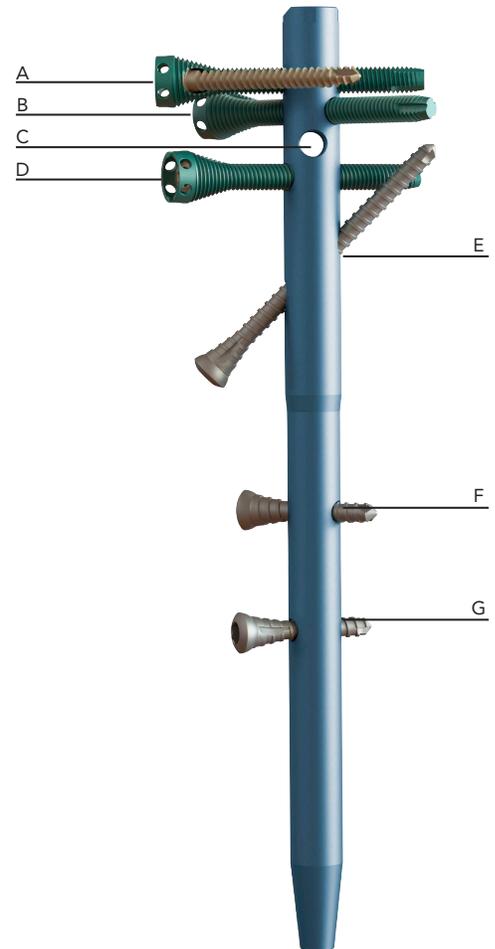
-Locking screw 3.5 mm (gray).

### Levels F and G

#### Distal locking

The two distal locking screws are placed in different planes to reduce implant tilting in the medullary cavity of the humerus. Screw type:

-3.5 mm locking screw (gray).



## Screw Configuration Long Nail

### Levels A to D

#### Proximal Locking

For fractures of the proximal humerus with extension to the diaphysis and combined fractures of the proximal humerus and humeral diaphysis, the three lateral screws (greater tubercle [trochlea], levels **A, B and D**) should be used to ensure basic stability of the assembly.

For humeral diaphysis fractures, two of the three **lateral screws** (greater tubercle [trochiter], levels **A, B or D**) may be sufficient, depending on the type of fracture.

Screw type:

-4.5mm DuoFix screw (emerald green)

The anterior screw (minor tubercle [trochlea], level **C**) increases the stability of the assembly. It can be used in fractures with a trochlear fragment, provided it is large enough to accommodate the screw head. Never insert a 3.5 mm locking screw at this level.

Screw type:

-4.5mm DuoFix screw (emerald green).

Additional locking screws ("screws on screw") (major tubercle, levels **A, B and D**) can also be inserted through the head of the lateral screws to increase the stability of the osteosynthesis. These additional screws are particularly useful in case of poor bone quality (e.g. osteoporosis)\*.

Screw type (optional):

-Locking screw 3.5 mm (yellow).

### Level E

#### Option 1: Ascending screw

The ascending screw provides support for the medial calcar region, which may be useful in fractures with medial comminution.

Screw type:

-3.5 mm locking screw (gray).



### Option 2: Compression Screw

Compression screw may be used to apply compression to short oblique or transverse fractures.

Screw type:

-Locking screw 3.5 mm (gray).

#### Cautions:

- The ascending screw should not be combined with compression.

**Note:** The ascending screw and the compression screw should not be used simultaneously.

### Levels F to H

#### Distal Locking

The three distal locking screws are positioned in two different planes to reduce implant tilting and increase the stability of the osteosynthesis. The locking planes are placed in an anatomical anteroposterior direction (levels **F** and **H**) and lateral oblique (level **G**), at 25° to each other.

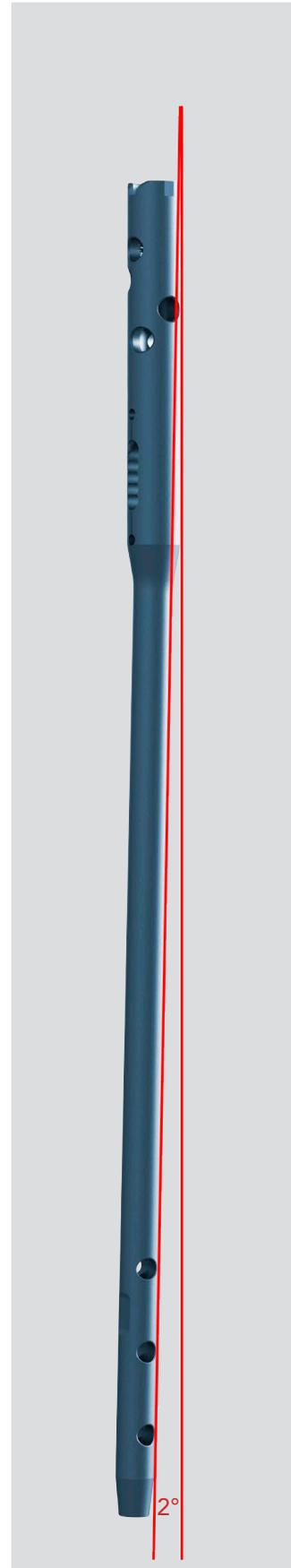
Screw type:

-3.5 mm locking screw (grey)



## Innovative Design Features

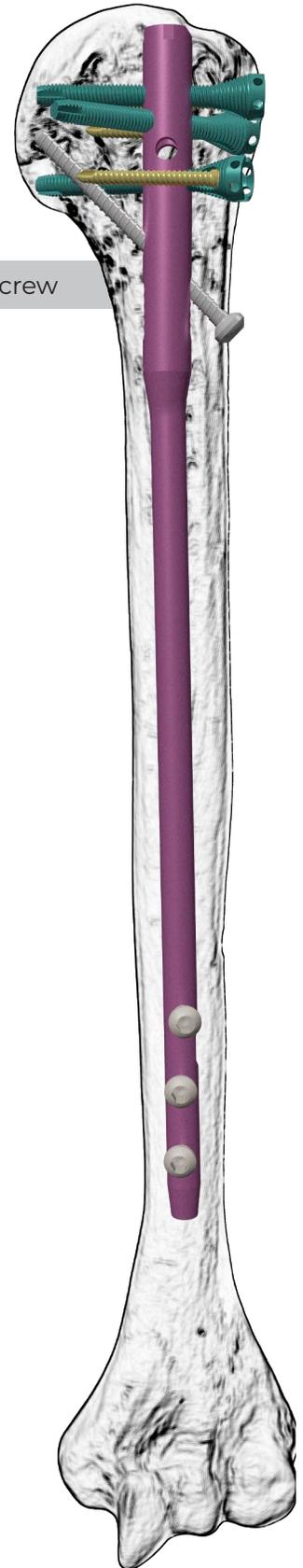
1. **Anatomical design of the nail:** The nail starts with a straight design, but in its distal part there is an angulation which follows the shape of the humerus. Increasing biomechanical stability and reducing the risk of complications during insertion, the angle is directed laterally



**2.DuoFix Screws:** The screws feature a screw-in-screw option to improve stability, especially in osteopenic bone. The screw tips are blunt, which reduces the risk of secondary perforation, and each screw has four holes for rotator cuff tendon attachment.

**3.Improved proximal fixation:** The ascending screw in calcar and 3.5 mm screws, with screw-in-screw option, are designed to resist humeral head migration and prevent varus deformity as well as rotation of the greater tuberosity

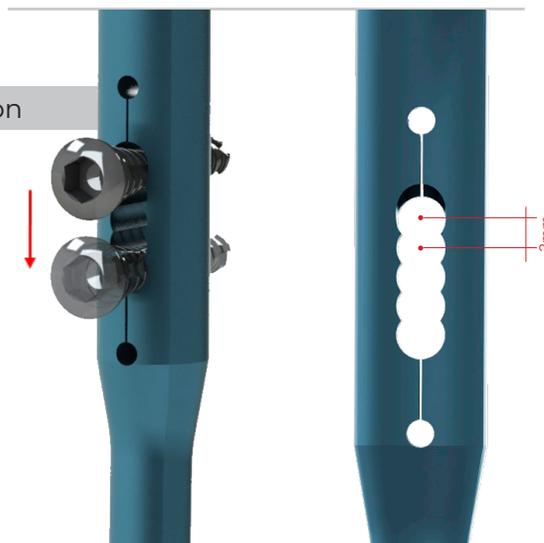
**4.Bicortical Compression with Long Nail:** Designed to increase stability in transverse and short oblique fractures of the humerus, bicortical compression is a simple and innovative possibility of the HFix (long) humeral nail that improves stability against rotation in transverse and short oblique fractures to promote bony healing. A locking screw is inserted bicortically and securely below the axillary nerve. This simple and reliable mechanism allows the compression to be maintained intraoperatively before inserting the remaining screws in the proximal fragment. 2mm hole spacing.



DuoFix



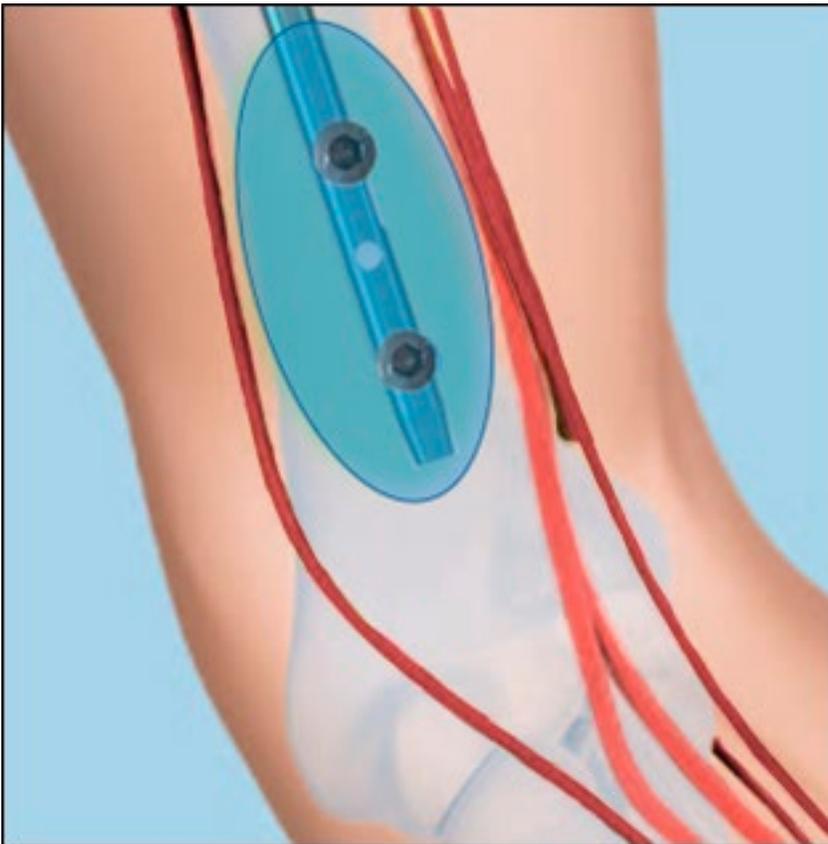
Bicortical Compression



**5. Distal block in the safe zone:** Distal block is performed in the anatomically safe zone between the median and radial nerves, with three distal blocking options in the AP direction to facilitate manual blocking

**6. Multiplanar distal block in the safe zone:**

Multiplanar distal locking reduces implant tilting in the proximal humeral nailing. The H-Fix (long) humeral nail has safe and easily identifiable distal block planes that respect neurovascular structures.



## Patient Positioning and Approach

### 1. Patient Positioning

Place the patient in a semi-sitting position on a radiolucent table. It is recommended that shoulder pads be used to support the shoulder and the fractured arm be positioned on an adjustable side table or arm support. It is essential that the arm can be reclined sufficiently to expose the head of the humerus in front of the acromion.

Ensure that the C-arm allows visualization of the entire humerus in two planes.

**Alternative:** A modified supine position on a fully radiolucent table can be used, as long as the C-arm allows visualization in the AP and lateral planes.

### 2. Determination of H-Fix Humeral Nail Length (length)

Using the image intensifier, obtain an AP view of the proximal humerus. Place the graduated ruler along the humerus and mark the desired entry point on the skin. Then move the intensifier to the distal humerus and take another AP image to verify fracture reduction.

Read the length of the nail directly from the radiographic image, selecting a length that is at least 1 cm proximal to the upper edge of the fracture 2.5 cm proximal to the superior border of the olecranal fossa.

### Instruments

- 16.03.01 Graduated Ruler  $\varnothing$  7 -  $\varnothing$  9.5 x 160 - 300 mm

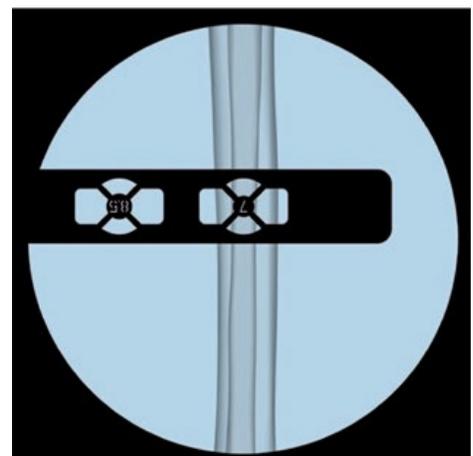
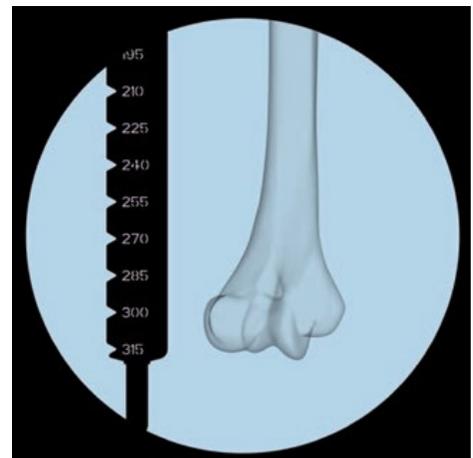
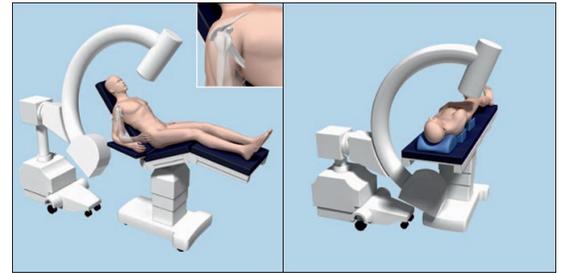
### Notas:

- The length can be correctly determined on the fractured arm only after the fracture has been correctly reduced.

### 3. Determining the Diameter of the H-Fix Humeral Nail (long)

Use the radiographic caliper to determine the diameter of the nail, focusing on the narrowest part of the medullary canal. Read the diameter on the circular gauge that best fits the canal.

**Note:** The caliper does not have the same depth as the humerus, which may affect the accuracy of the measurement.



## Surgical Approach and Fracture Reduction

### 1. Anterolateral Approach

Make an anterolateral incision from the tip of the acromion and along the deltoid muscle. Divide the deltoid fibers at the tendinous intersection between the anterior and middle third. In cases of complete fractures, it may be necessary to partially detach the deltoid from the anterior border of the acromion for better exposure.

**Caution:** Do not extend the incision too distally to avoid iatrogenic injury to the axillary nerve. This nerve can be identified by gentle palpation or careful dissection.

### 2. Fracture Reduction

Fracture reduction can be performed by indirect maneuvers, such as the use of traction sutures, elevators or K-wires acting as guides.

If necessary, use guide wires (K-wires) to temporarily hold the fragments in place during implant insertion. Make sure that the wires do not block the nail insertion.

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#### Instruments

- 16.01.15 Guide wire  $\varnothing$  1.5 x 250 mm
- 

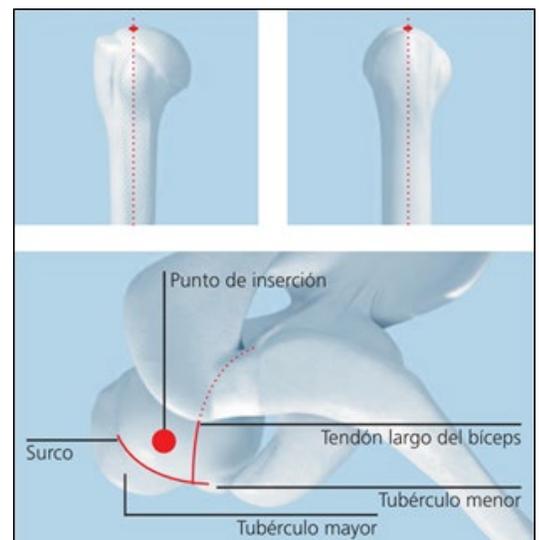
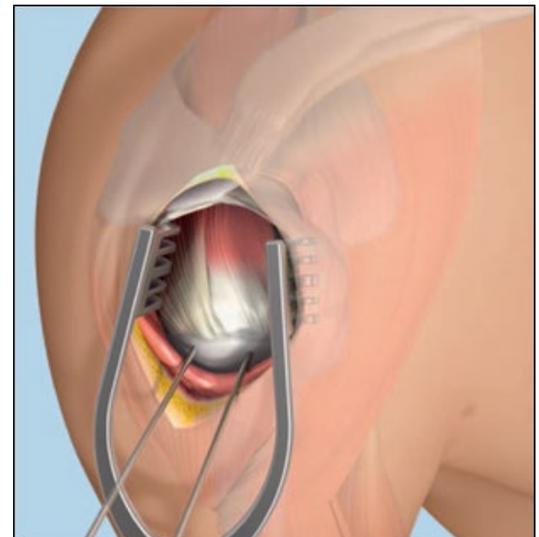
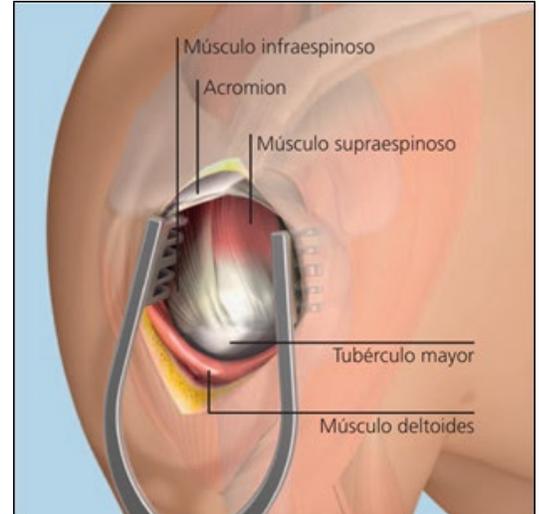
## Medullary Canal Opening

### 1. Entry point

The ideal entry point is located at the apex of the humeral head, in line with the medullary canal in both AP (anteroposterior) and lateral views. It is located posterolateral to the biceps tendon and medial to the groove between the greater tuberosity and the humeral head.

#### Note:

In the event that the acromion is obstructing the ideal insertion point, the shoulder should be reclinod or extended slightly to move the apex of the humeral head in front of the acromion.



## 2. Limited Guide Wire Insertion (for reamer)

Partially insert the guide wire into the entry point using the cannulated T-handle. Be sure to verify the position of the guide wire in the AP and lateral views.

Make a 1-2 cm longitudinal incision through the supraspinatus tendon, using traction sutures and retractors to improve exposure.

Advance the guide wire until its stop reaches the bony surface.

Remove the T-handle.

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### Instruments

- 16.04.25 Guide wire limited  $\varnothing$  2.5 x 200 mm
- 12.12.08 Cannulated T-Handle  $\varnothing$  8

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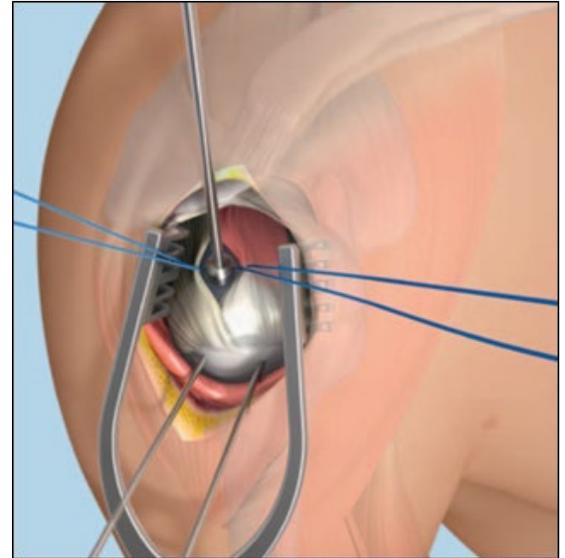
### Alternative Technique: Guide Wire Insertion (for cannulated punch)

In case you prefer to use the cannulated PUNCH to open the medullary cavity, it is necessary to insert a 2.5 mm guide wire INSTEAD of the limited guide wire.

---

### Instruments

- 16.01.25 Guide Wire  $\varnothing$  2.5 x 250 mm
- 



### 3. Medullary Canal Opening

#### Option A: Reamer

Sliding the reamer inside the single guide and over the guide wire, down to the bone, drill to the desired depth and remove the drill bit.

#### Instruments

- 20.03.10 Cannulated reamer  $\varnothing$  10 x 60 mm, or
- 20.03.115 Cannulated reamer  $\varnothing$  11.5 x 60 mm
- 18.05.115 Single guide

#### Option B: With cannulated punch

Slide the cannulated punch into the guide wire up to the bone. Using a smooth rotary motion, advance the punch deep into the medullary cavity.

Finish by removing the punch and guide wire.

#### Instruments

- 31.11.35 Cannulated Punch

#### Note:

When using the cannulated punch, take care not to displace the fracture, especially if a complex fracture is encountered.

-Use the 11.5 mm reamer for the 9.5 mm H-Fix (short) proximal humeral nail

- For all other nails, use the 10.0 mm reamer.

NAIL	Nail $\varnothing$ (mm)	Reamer $\varnothing$ (mm)
Proximal Humeral Nail H-Fix (Short)	9.5	11.5
Humeral Nail H-Fix (long)	7.0	10.0
Humeral Nail H-fix (long)	8.0	10.0

### Fracture reduction and reaming. Humeral Nail H-Fix (long).

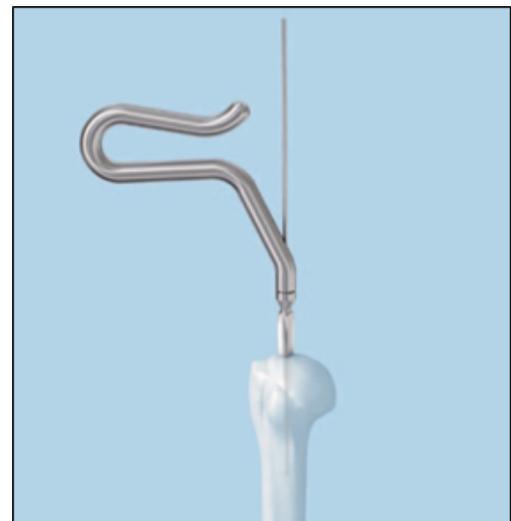
#### 1. Fracture Reduction

Insert the cannulated reduction rod into the medullary cavity. Continue inserting the olive-tipped guide wire into the reduction instrument.

Facilitate the passage of the olive-tipped guide wire through the fracture line by rotating the reduction instrument.

Having reduced the fracture, advance the olive-tipped guide through the medullary cavity.

Finish by removing the reduction instrument, leaving the olive-tipped guide in place.



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### Instrument set

- 54.01.33 Cannulated reduction rod with T-handle.
  - 23.07.01 Olive-tipped guide wire  $\varnothing$  2.5 x 680 mm, or
  - 23.13.25 Guide wire with olive tip (Nitinol alloy)  $\varnothing$  2.5 x 680 mm.
- 

### Notes:

- Do not remove the olive-tipped guide wire when removing the reduction instrument
- Any manipulation of the fat-filled medullary cavity leads to increased intramedullary pressure. It is therefore advisable to reduce manipulations in this area, e.g. reduce the fracture only with the aid of the reaming guide.

## 2. Milling (Optional)

Verify with the image intensifier that the fracture reduction is maintained.

Then ream to a diameter at least 1.0 mm larger than the nail diameter. Continue reaming in 0.5 mm increments and advancing with constant, moderate force.

- 
- 
- 24.06.07 Flexible Shaft for rhyme tips  $\varnothing$  7 mm
  - 24.06.08 Flexible Shaft for rhyme tips  $\varnothing$  8 mm
  - 24.06.09 Flexible Shaft for rhyme tips  $\varnothing$  9 mm
  - 24.06.10 Flexible Shaft for rhyme tips  $\varnothing$  10 mm
- 
- 



**Important:** Do not force the bur. Gently remove the bur to clean out any debris from the medullary cavity.

Remove the reamed assembly, leaving the olive-tipped guide wire in place. All H-Fix (long) humeral nails can be inserted over the olive guide wire.

**Note:** Be sure to wash the surgical site upon completion of reaming to remove debris and minimize the risk of heterotopic ossification as much as possible.

**Important:** In cases of comminuted fracture where the area where the radial nerve is in contact with the bone in the radial nerve groove, reaming should be avoided.

## Nail Insertion and Fixation

### 1. Mounting the Insertion Instruments

Position the U-locking clamp laterally and match the geometric shape of its free end to that of the intramedullary nail. Using the clamp, screw the cannulated long screw into the nail, and tighten it with the wrench to fix the assembly.

#### Instruments

- 40.03.01 U-locking Clamp
- 39.07.345 Cannulated long screw M6/  $\varnothing$  3.45/ SW11
- 27.01.11 Spanner wrench SW11

### 2. Nail Insertion

Insert the nail over the olive-tipped guide wire (if used) and advance it over the spinal canal with twisting movements, avoiding the use of hammers to reduce the risk of iatrogenic fractures.

Inspect the passage of the nail by the fracture line and by radiological control in two planes to minimize alignment defects. Caution should be exercised to avoid any injury to the radial nerve, especially in fractures in the area between the middle and distal thirds of the humeral diaphysis.

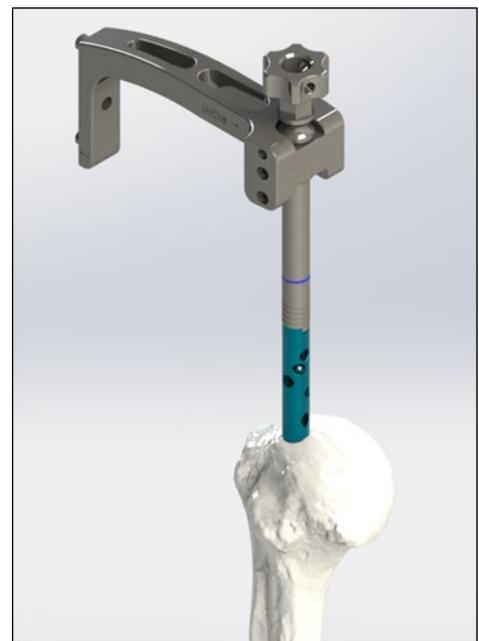
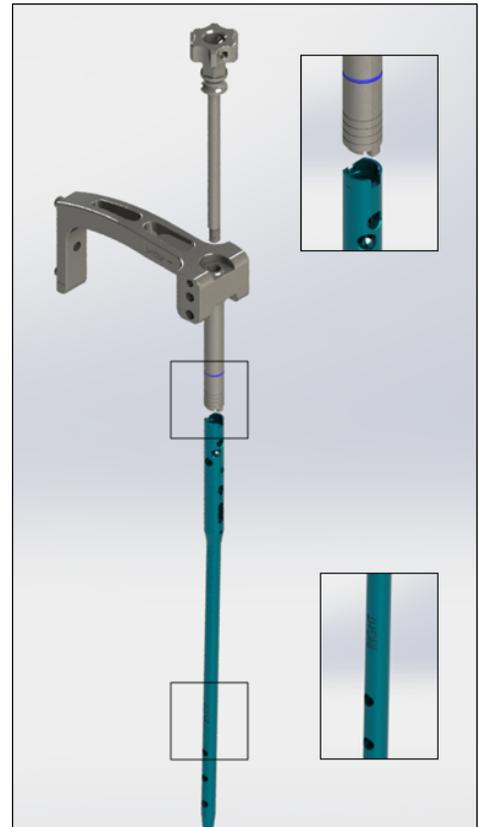
The following is how the procedure should be approached in special cases:

- **Metaphyseal Fracture:** Advance the nail to the fractured area, perform fracture reduction and pass the nail into the diaphysis.
- **Preoperative Distal Nerve Paresis:** Initiate exploration of the nerve by making a short anterolateral incision at the transition zone between the middle and distal thirds of the diaphysis.

If you have used the olive-tipped guide wire, remove it before proceeding with the block.

#### Notes:

- If difficulties are encountered when inserting the nail, select a smaller diameter nail or proceed to ream the medullary cavity to enlarge its diameter
- The pressure against the elbow that is present when advancing the nail prevents traction diastasis and consolidation problems.



## Nail Placement

### 1. Assembly of the Proximal Rail

By inserting the connection screw into the proximal strip, orient the proximal strip correctly. Connect the proximal strip to the U-locking strip and tighten the connection screw.

---

#### Instrument set

- 40.06.01 Proximal clamp

#### Notes:

Check that the proximal clamp shows the marking "RIGHT" in case of a right humerus and that it shows "LEFT" if used for left humerus.

**Optional technique: assembly of the proximal locking arm for anterior screw placement (level C) or determination of ascending screw height (level E).**

If the anterior screw (lesser tubercle) or ascending screw is required, attach the proximal locking arm to the U-locking rail and tighten the connecting screw.

---

#### Instrument set

- 40.09.01 Proximal Locking Arm

### 2. Nail Placement: Adjusting the Insertion Depth

Position the proximal end of the nail 2 to 3 mm below the cartilage to combine minimal risk of conflict with maximum stability. This provides the insertion depth of the implant.

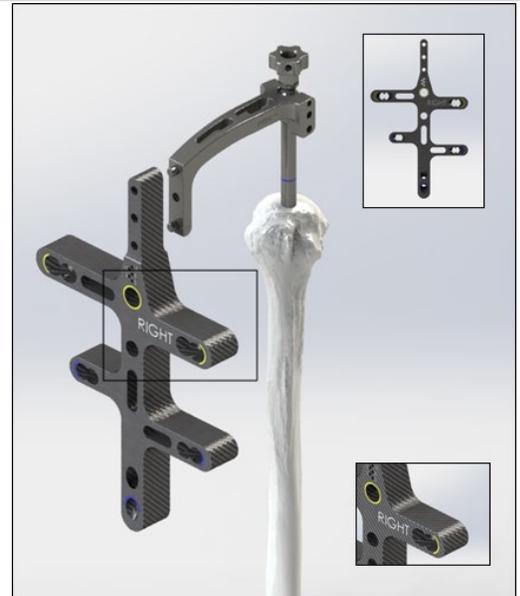
Verify the proximal nail site clinically and use image intensifier support in pure anteroposterior projection

**Note:** Improve the way to identify a proximal end of the nail by placing a 2.5 mm guide wire through the hole of the distal clamp with the "0" mark.

---

#### Instrumentation

- 16.01.25 Guide Wire  $\varnothing$  2.5 x 250



### Optional Technique: Ascending Screw (level E)

If the use of the ascending screw is planned, it is required to insert a 2.5 mm guide wire through the hole in the proximal locking arm.

Adjust the position of the image intensifier, or the patient's arm, to align the circle of the proximal locking arm with the anterior screw hole in the intramedullary nail. The position of the ascending screw is indicated by the guide wire.

Adjust the nail insertion depth so that the ascending screw is placed in the calcar region.

### 3. Nail Placement: Adjustment of the rotation.

Insert a three-piece trocar assembly (consisting of outer sleeve, screw extension and long punch) through the most proximal hole of the distal clamp (Level A).

Then insert a second trocar assembly into the anterior hole of the distal clamp (Level D).

It is important that the screw at Level D is placed as anteriorly as possible, without impinging on the long biceps tendon, as this will determine proper rotation of the implant.

Press the punch down into the bone. Remove the punch.

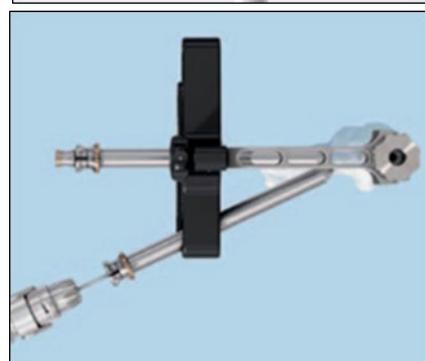
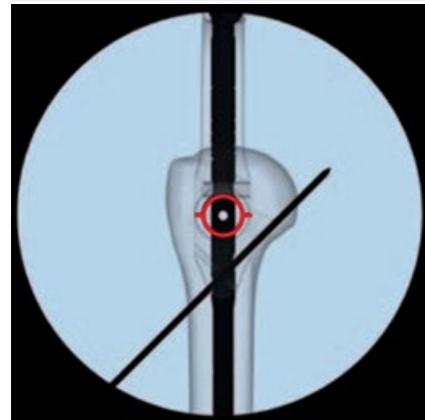
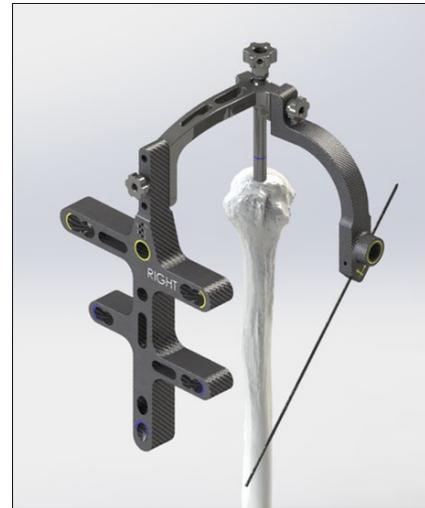
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#### Instruments

- 18.11.13 Outer Sleeve  $\varnothing$  13/  $\varnothing$  10 x 150 mm
  - 55.01.10 Screw extension  $\varnothing$  10/  $\varnothing$  3.8 x 162 mm
  - 31.04.38 Long punch  $\varnothing$  3.8
  - 16.01.25 Guide wire  $\varnothing$  2.5 x 250
- 

**Remark:** Avoid placing screws in the bicipital slide.

**Nota:** The holes for the DuoFix screws are marked with a yellow circle.



### Optional technique: Anterior screw (level C)

If using the anterior screw (lesser tubercle), make a small incision with blunt dissection of the soft tissue. Proceed by inserting the second trocar assembly through the proximal locking arm

**Note:** Confirm that the tip of the punch is in contact with the tip of the lesser tubercle. This reduces the risk of the screw irritating the long biceps tendon or the ascending branch of the anterior humeral circumflex artery.

**Note:** In case the lesser tubercle is not large enough to place a DuoFix screw, opt for other modes of fixation, such as smaller independent screws or apply bone sutures.



### Proximal Locking

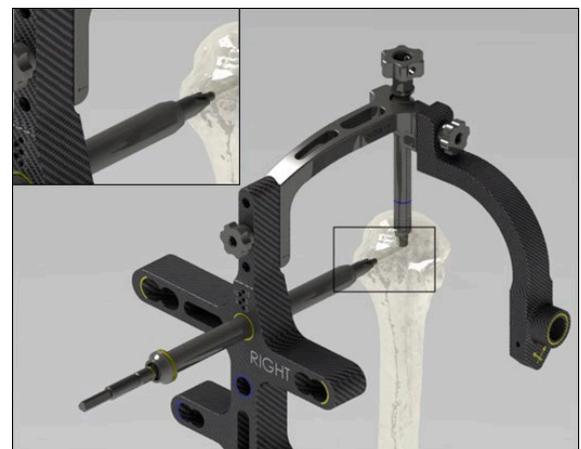
#### DuoFix Screws

##### 1. Drilling and determining the screw length.

Insert the graduated drill bit and drill carefully until the subchondral bone is reached. Check the position of the drill bit with the image intensifier. The appropriate screw length is directly indicated by the graduated drill bit on the back of the screw extension. Press the drill guide firmly onto the cortex to ensure correct measurement.

Remove the drill bit and extension.

The **solid countersink Ø 8mm** can be used to insert the DuoFix screw head, it is inserted into the outer sleeve and the hole is countersunk to accommodate the DuoFix screw head, add the **solid countersink Ø 8mm** to the instrument part **21.05.08**



#### Instrument set

- 13.08.38 Graduated Drill 0-60 Ø 3.8mm

**Note:** Before placing the DuoFix Screw in level D, identify and take care of the axillary nerve and its branches. Also be cautious not to perforate the articular surface.

### Alternative technique: Determination of length with Depth Gauge.

Another way to determine the length of the screw is by means of the depth gauge.

The depth gauge is placed with its outer sleeve.

Insert the depth gauge through the outer sleeve and advance it until the resistance of the subchondral area is felt. Perform a check with the image intensifier. Apply firm pressure on the outer sheath of the depth gauge against the cortex to ensure an accurate measurement. The screw length can be read directly on the back of the outer sheath of the depth gauge.

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#### Instrumentation

- 16.01.90 Depth Gauge 0-90 mm

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**Remark:** The yellow mark on the depth gauge must be aligned with the entry hole in the outer sleeve.

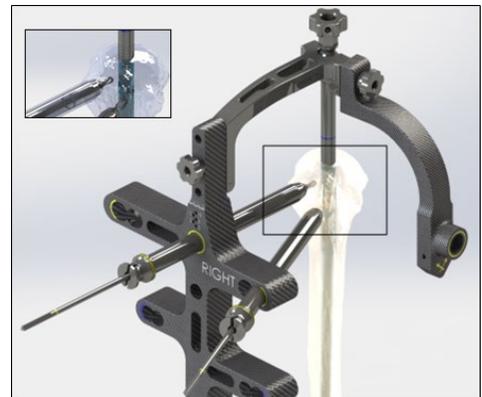
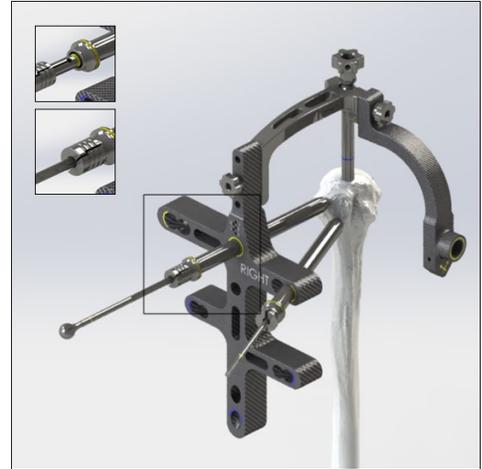
#### 2. Optional: Drilling in case of dense bone

If dense bone is encountered, the lateral cortex should be re-drilled with the graduated drill to conceal the DuoFix screw.

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#### Instruments

- 13.06.38 Graded drill bit with stop 0-60  $\varnothing$  3.8 mm
- 

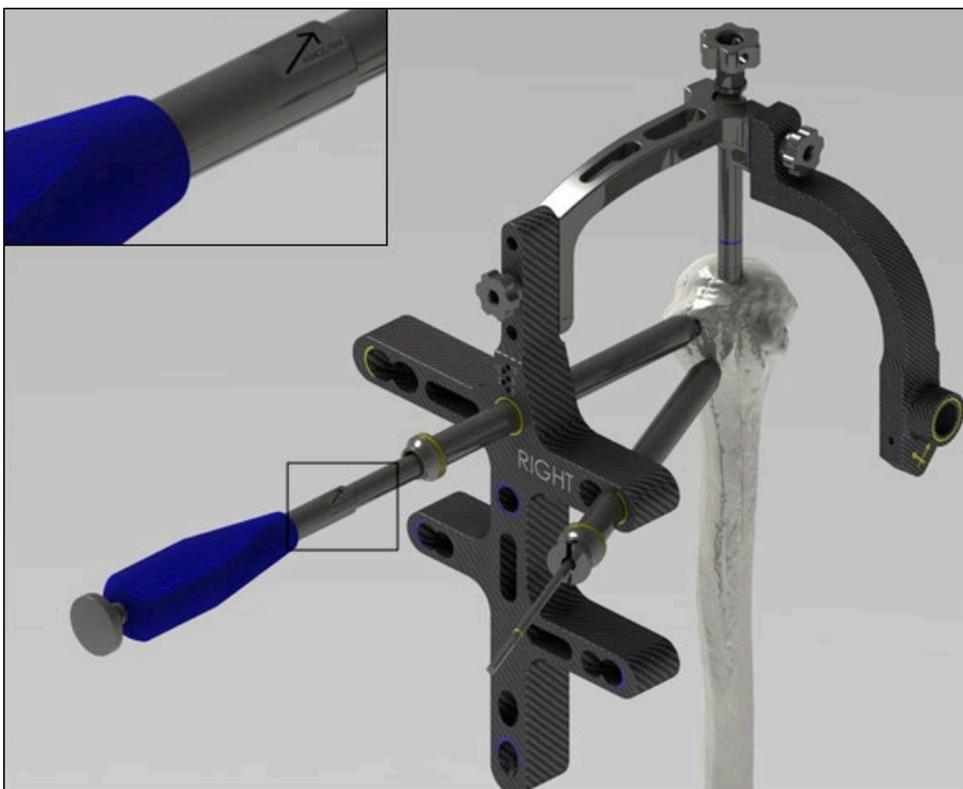
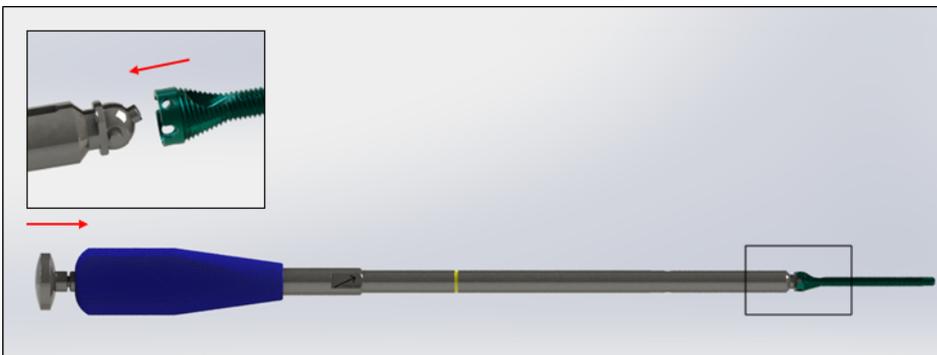


### 3. Inserting the DuoFix screw.

Pull the handle of the multilock screwdriver backwards and engage the appropriate DuoFix screw. Then push the handle forward to lock the screw in place. Insert the screw through the outer sleeve until it is completely concealed.

Verify that the screwdriver handle is in the final position perpendicular to the nail, with the arrow pointing backwards. Use the image intensifier to confirm the position of the screwdriver.

Finally, pull the handle back to release the screwdriver.



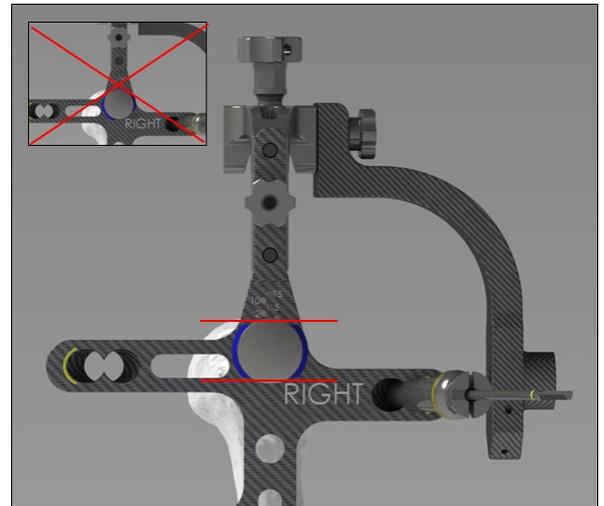
### 3. Inserting the DuoFix screw.

Pull the handle of the multi-lock screwdriver back and engage the appropriate DuoFix screw. Then push the handle forward to lock the screw in place. Insert the screw through the outer sleeve until it is completely concealed.

---

#### Instruments

- 11.17.01 Multilock Screwdriver
- 



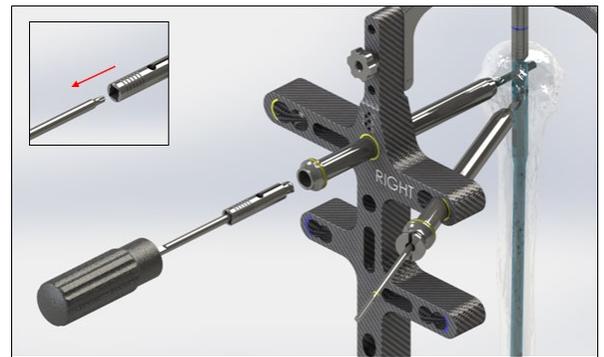
### 4. Optional: Nail extension connection for 3.5 mm locking screws ("screw on screw").

If you plan to combine a 3.5 mm locking screw ("screw on screw") with a DuoFix screw, place a nail extension on the T15 hex screwdriver (torx tip) and insert the assembly into the outer sleeve.

Turn the screwdriver slightly until the extension aligns with the star shape of the screw. Press the screwdriver to lock the extension onto the DuoFix screw. Finally, remove the screwdriver and the outer sleeve.

Remark:

- Avoid insertion of 3.5 mm locking screw by the above screw (level c).
- Another way to insert the nail extension is also by hand.



---

#### Instrument set

- 55.03.10 Nail extension  $\varnothing$  10/  $\varnothing$  5.8
  - Hexagonal Screwdriver T15
- 

### 5. Insertion of the remaining DuoFix Screws

To insert the remaining screws, repeat steps 1 through 4.

Use the image intensifier at different angles to carefully check the final position of all DuoFix screws to ensure that none cross the articular surface. If you used the proximal locking arm, remove it now.

**Notes:**

- H-Fix proximal humeral nail (short): In all fractures, regardless of location, it is essential to use all three lateral screws (greater tubercle [trochiter], levels A, B and D) to ensure basic stability of the assembly.
- H-Fix Humeral Nail (long): In fractures of the proximal humerus extending into the diaphysis or in combined fractures of the proximal humerus and diaphysis, all three lateral screws (greater tubercle [trochlea], levels A, B and D) should be used to ensure adequate stability. In the case of fractures limited to the humeral diaphysis, two of the three lateral screws (greater tubercle [trochiter], levels A, B or D) may be sufficient, depending on the type of fracture.

**3.5 mm locking screws (screw on screw).**

**1. Positioning the centering guide**

Remove the distal clamp.

If not already done, place a nail extension on the DuoFix screw.

Carefully tilt the centering guide forward and engage the extension with handle until a click is heard.

Make sure that both handles of the T-extension are perfectly perpendicular to the intramedullary nail. If necessary, rotate the assembly to achieve the correct position.

---

**Instrument set**

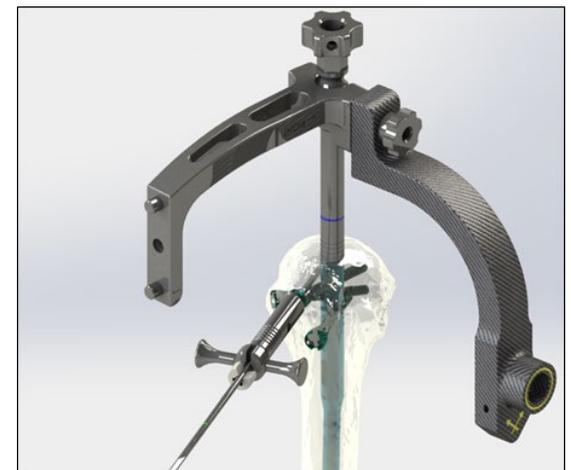
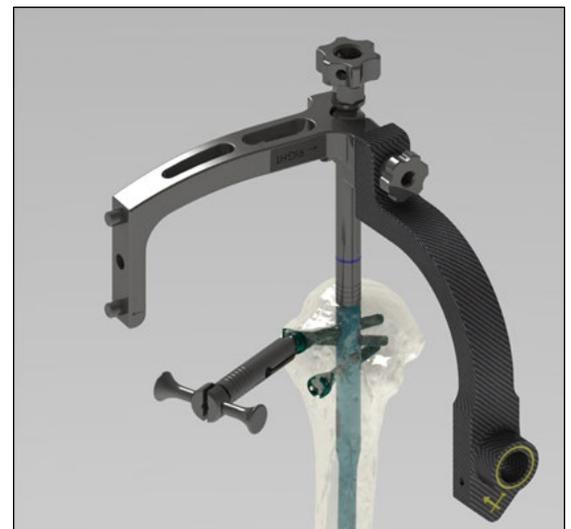
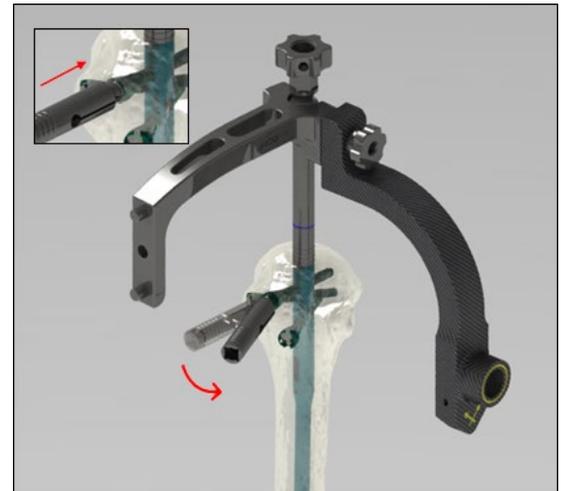
- 55.03.10 Extension for Nail  $\varnothing$  10/  $\varnothing$  5.8
  - 55.02.58 T-Handle Extension  $\varnothing$  5.8/  $\varnothing$  2.8 x 62 mm
- 

**2. Drilling and Determination of Screw Length**

Insert the drill bit and drill cautiously until reaching the subchondral bone. Verify the position of the drill bit using the image intensifier. The correct screw length can be read directly on the graduated drill bit on the back of the drill guide.

Finally, remove both the drill bit and the drill guide.

**Warning:** Avoid drilling into the articular surface.



### Notes:

- It is only possible to insert the drill bit when the T-extension is properly locked in the nail extension.
- Do not reposition the nail extension.
- Do not squeeze the two T-extension handles during bit insertion

---

### Instruments

- 13.06.28 Graduated drill bit with stop 20-60  $\varnothing$  2.8
- 

### Alternative technique: length determination with depth gauge

Another option is to use the depth gauge to determine the length of the screw.

Mount the depth gauge together with its outer sleeve. Insert the depth gauge through the T-extension and advance until resistance is felt in the subchondral space. Check with the image intensifier. Read the screw length on the fenestrated scale of the depth gauge.

Then, remove the T-extension.

**Observation:** Avoid changing the position of the nail extension

---

### Instrumentation

- 16.01.90 Depth Gauge 0-90 mm
- 

### 3. Insertion of the 3.5 mm locking screw

Select a 3.5 mm locking screw of the appropriate length and insert it through the centering guide. Tighten the screw until you hear a click. Finally, remove the centering guide

**Note:** The centering guide should not be removed until the 3.5 mm locking screw is fully seated.

---

### Instruments

- 11.04.15 Hexagon-head screwdriver 1.5 N.m
- 



#### 4. Insertion of the remaining 3.5 mm locking screws and mounting of the distal clamp

To insert the remaining 3.5 mm locking screws, repeat the procedure described in steps 1 to 3.

Carefully check the final position of all 3.5 mm locking screws using the image intensifier in different planes, making sure that none cross the articular surface.

If an H-Fix (short) proximal humeral nail has been used, reposition the distal clamp on the U-locking clamp and tighten the connecting screw.

**Note:** Check that the distal rail shows the marking "RIGHT" for the right humerus and "LEFT" for the left humerus.

---

#### Instrument set

- 40.06.01 Distal Clamp
- 

### Ascending Screw

#### 1. Inserting the Trocar Assembly

Insert the three-piece trocar assembly (which includes the outer sleeve, screw extension and long awl) through the ascending screw hole in the distal clamp. Make a skin incision and dissect down to the bone, taking care not to damage the neurovascular structures or surrounding soft tissues

Advance the trocar assembly and press the PUNCH against the bone. Then remove the punch.

**Caution:** Prior to insertion of the ascending screw, locate and protect the axillary nerve. Make an incision limited to the skin and proceed with blunt dissection to avoid injury to the axillary nerve or its nerve branches.

#### Notes:

- In case the humerus is too small, avoid using the ascending screw to avoid damaging the humeral head
- The hole in the directional arm marked with a blue circle is intended for the ascending screw.



---

### Instrument set

- 18.11.11 Outer sleeve  $\varnothing$  11/  $\varnothing$  8.2 x 175 mm
  - 55.01.82 Screw extension  $\varnothing$  8.2/  $\varnothing$  3 x 187 mm
  - 31.04.30 Punch long  $\varnothing$  3.0
- 

### 2. Drilling and determination of screw length

Insert the graduated drill bit and drill carefully until you reach the subchondral bone. Check the position of the drill bit with the image intensifier.

The correct screw length is indicated directly on the graduated drill bit on the back of the screw extension.

Press the screw extension firmly onto the cortex to ensure accurate measurement. Then remove both the drill bit and the extension.

**Note:** Make sure not to perforate the articular surface.

---

### Instruments

- 13.08.30 Drill bit graduated 0-70  $\varnothing$  3.0
- 

### Alternative technique: Determining the length with depth gauge

The depth gauge can also be used to determine the length of the screw.

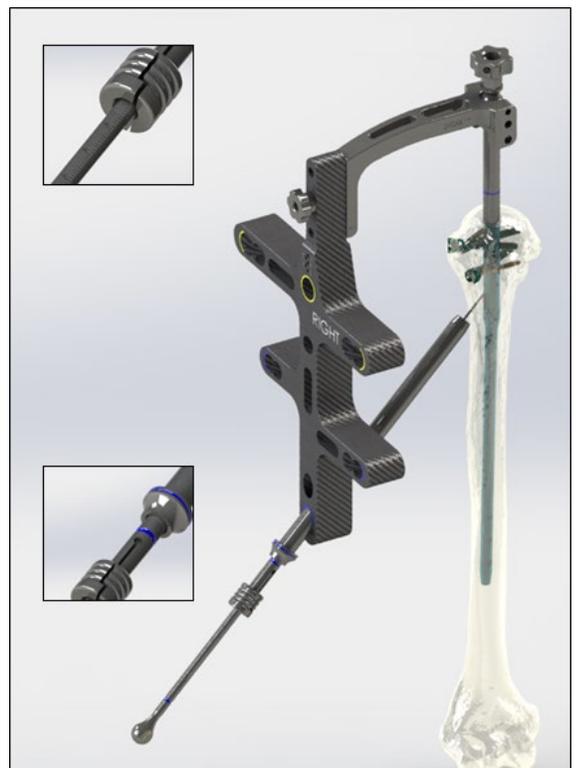
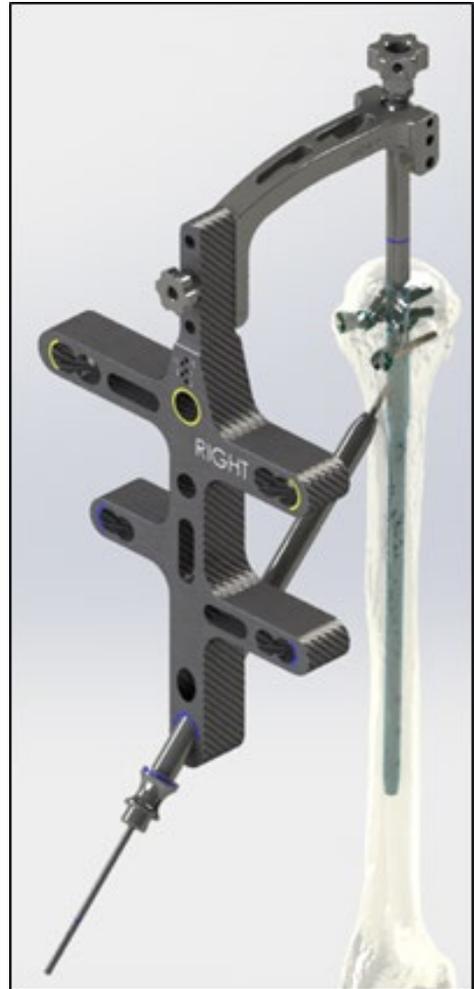
Assemble the depth gauge together with its outer sleeve and insert IT through the outer sleeve, ADVANCING IT until the resistance of the subchondral space is felt. Verify its position with the image intensifier. Press the depth gauge firmly onto the cortex to ensure an accurate measurement. The screw length can be read directly on the depth gauge.

**Remark:** The blue mark on the depth gauge must coincide with the leading edge of the tissue protection sheath.

---

### Instruments

- 16.01.90 Depth Gauge 0-90 mm
- 



### 3. 3.5 mm locking screw insertion

Insert the 3.5 mm locking screw with the appropriate length through the tissue protection sleeve using the hexagon-tipped screwdriver SW3.5.

---

#### Instrument set

- 11.04.35 Hexagonal Screwdriver SW3.5
- 

### Guided Distal Locking - H-Fix Proximal Humeral Nail (Short)

#### 1. Inserting the Trocar Assembly

Insert the three-piece trocar assembly (Outer Sleeve, Screw Extension and Long Punch) through one of the distal holes of the distal clamp. Make an incision in the skin and design until the bone is reached, taking care not to damage nearby neurovascular structures or soft tissues.

Advance the trocar assembly and press the punch against the bone. Then remove the punch.

**Remark:** The holes in the distal strip marked with blue are intended for the distal locking screws.

---

#### Instrument set

- 18.11.11 Outer Sleeve  $\varnothing$  11/  $\varnothing$  8.2 x 175 mm
  - 55.01.82 Screw extension  $\varnothing$  8.2/  $\varnothing$  3 x 187 mm
  - 31.04.30 Long punch  $\varnothing$  3.0
- 

#### 2. Drilling and determination of screw length

Insert the graduated drill bit and drill carefully until the tip barely protrudes from the medial cortex. Verify the position of the drill bit using the image intensifier.

The appropriate screw length is indicated directly on the back of the drill guide. Press the guide firmly onto the cortex to ensure accurate measurement.

Then remove both the drill bit and the screw extension.

---

#### Instruments

- 13.08.30 Drill bit graduated 0-70  $\varnothing$  3.0
- 



### Alternative technique: Determining the length with depth gauge

You may also choose to use the depth gauge to determine the length of the screw.

Place the depth gauge with its outer sleeve and insert it through the outer sleeve.

Press the gauge firmly onto the cortex to ensure an accurate measurement. The screw length is displayed directly on the depth gauge.

**Remark:** The blue mark on the depth gauge should be aligned with the entry hole in the outer sleeve.

### 3. Insertion of the 3.5 mm locking screw

Using the SW3.5 hex screwdriver, insert the 3.5 mm locking screw of the appropriate length through the outer sleeve.

---

#### Instruments

- 11.04.35 Hexagon socket screwdriver SW 3.5
- 

### 4. Inserting the second locking screw 3.5 mm

To insert the second 3.5 mm locking screw, repeat the procedure described from 1 to 3

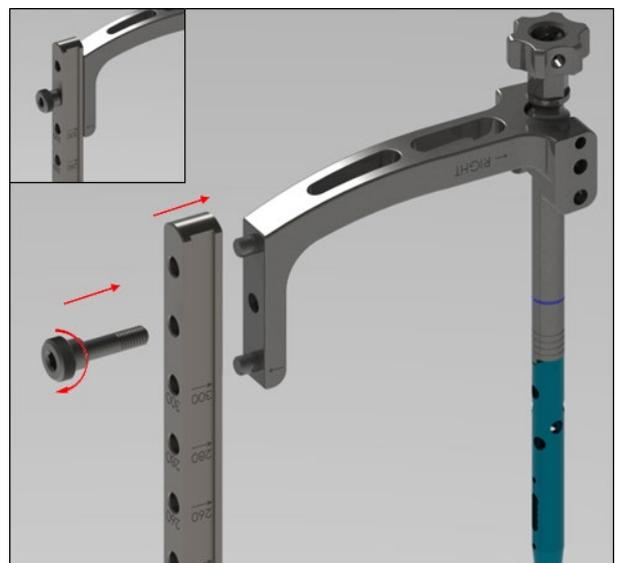
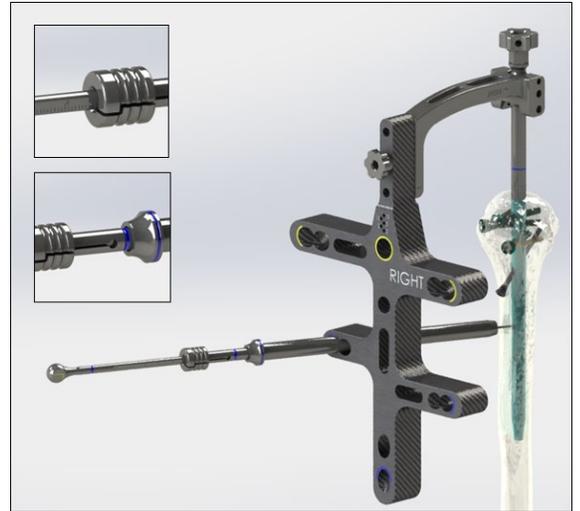
Remove the distal clamp.

## Distal Guided Locking - H-Fix Proximal Humerus Nail (Long)

### 1. Distal Guide Placement

In the first instance place the Clamp (200-300) on the U-Lock Clamp according to the nail size, in order to correctly perform the distal locking

Insert the Outer Sleeve through the hole in the distal part of the URing (200-300).



Then insert in the Outer Sleeve the T-Handle Probe, which will be adjusted and fixed with the support of the Distal Probe Lock.

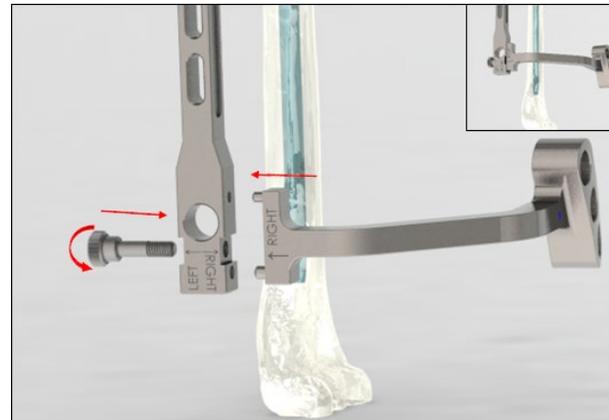
Next, attach the Distal Locking Arm corresponding to the type of nail being used (Left or Right)

**Note:** Make sure that the distal guide has the engraving indicating the correct orientation of the nail.

---

### Instrument Set

- 40.03.01 U-Lock Clamp
  - 41.01.02 Locking for Distal Probe
  - 40.04.20 Clamp 200 - 300 mm
  - 40.08.01 Distal Locking Arm
  - 42.01.01 T-Handle Stylus with T-Handle
  - 18.11.13 Outer Sleeve  $\varnothing$  13/  $\varnothing$  10 x 150 mm
- 



### 2. Screw Insertion 3.5 (without threaded head)

Using the distal Locking ARM, INSERT the Outer Sleeve into the Screw Extension. And in each of the holes of the Locking Arm place this assembly so that the Drill  $\varnothing$  3.0 can be inserted.

---

### Instrument

- 18.11.11 Outer Sleeve  $\varnothing$  11/  $\varnothing$  8.2 x 175
  - 55.01.82 Screw extension  $\varnothing$  8.2/  $\varnothing$  3 x 187
  - 13.08.30 Graduated Drill 0-70  $\varnothing$  3.0
- 



## Hands Free Distal Locking - H-Fix Humeral Nail (long)

Distal locking using the Radiolucent Attachment is detailed below.

### 1. Adjust the image

Recheck the fracture reduction in AP and lateral projection. Align the image intensifier with the nail hole until it appears as a perfect circle in the center of the screen.

**Warning:** To visualize round holes, always adjust the position of the image intensifier instead of the arm, as moving the ARM may cause significant rotational disturbance.

**Note:** It is recommended to block the most proximal distal hole first.

### 2. Incision

Locate the center of the hole with a guide wire to mark the insertion point and incise the skin. Dissect the white tissues to clear the area and expose the bone. Place spacers to protect the neurovascular structures from damage

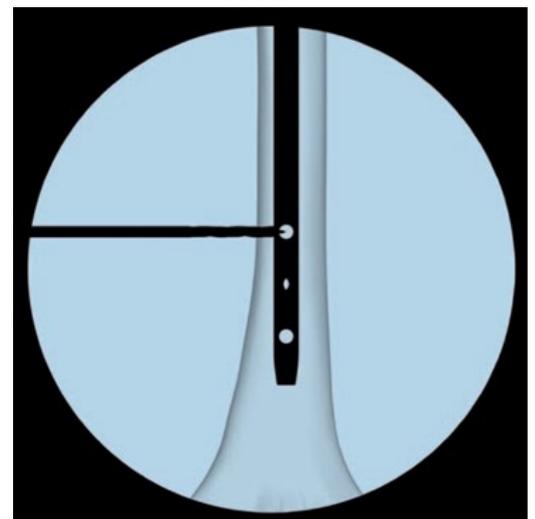
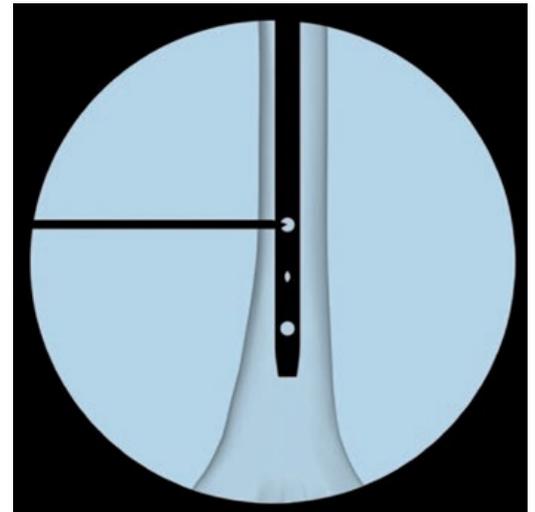
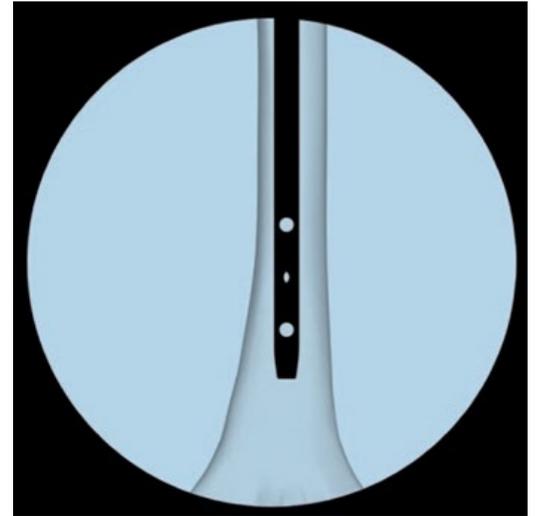
**Note:** Make only one skin incision and then perform a blunt dissection down to the bone to avoid injury to the median and radial nerves and the brachial artery.

### 3. Drilling

With radiological control using the image intensifier, insert the tip of the drill bit through the skin incision until it reaches the bone. Hold the drill at an oblique angle to the radiation axis until the tip is centered in the locking hole.

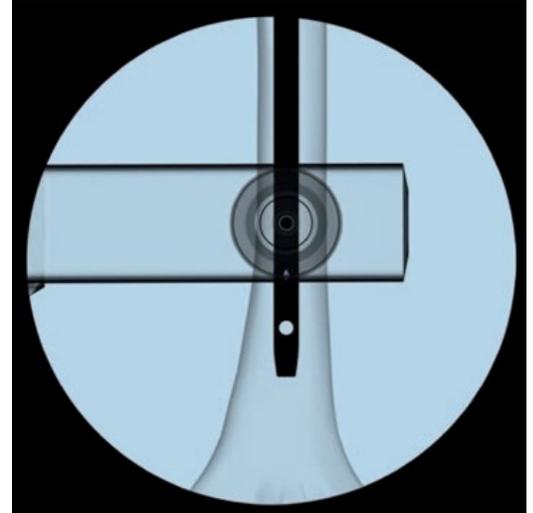
**Note:** Be sure to use a sharp drill bit to prevent slippage and ensure greater accuracy.

Tilt the surgical motor until the drill bit is aligned with the radiation axis so that it appears centered in the locking hole on the screen, occupying almost the entire image of the hole. Hold the drill firmly in this position and drill through both cortices



Monitor the drill bit insertion with the image intensifier, as the position of the tip directly indicates where the screw will be placed in the bone.

**Note:** For better control of the drill bit, turn off the motor after drilling the first cortex. Manually guide the drill bit through the nail and then turn the motor back on to drill the opposite cortex.



---

### Instruments

- 13.06.30 Graduated drill bit with stop 0-70 ø 3.0
- 

### 4. Determination of screw length

Assemble the depth gauge with its outer sleeve.

Insert the depth gauge and engage the hook on the opposite cortex of the bone. Firmly press the depth gauge onto the cortex to ensure an accurate measurement. The length of the screw can be read directly on the depth gauge.

---

### Instruments

- 16.01.90 Depth Gauge 0-90 mm
- 

### 5. Insertion of 3.5 mm locking screw

Insert a 3.5 mm locking screw of the corresponding length using the hexagon-tipped screwdriver SW3.5.

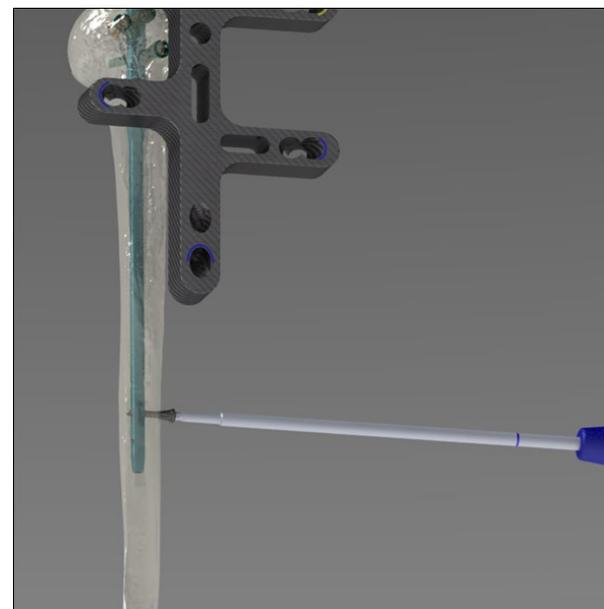
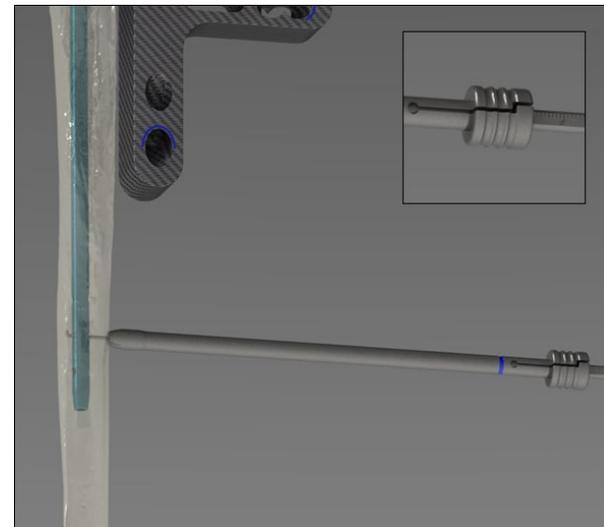
---

### Instruments

- 11.04.35 Hexagonal Screwdriver SW3.5
- 

### 6. Inserting the remaining 3.5 mm locking screws

To insert the remaining 3.5 mm locking screws, repeat the procedure described in steps 1 to 5.



## Compression Locking (optional) Humeral Nail H-Fix (long)

Compression locking of the H-Fix Humeral Nail (long) allows closure of diastasis in short oblique or transverse fractures up to 8 mm. It also provides moderate interfragmentary compression which improves the strength of the nail-bone assembly against bending and torsional forces. It is important to insert the nail at least the same distance provided for interfragmentary displacement, since, when compression is applied, the nail retracts at the point of insertion

### Caution:

- The axillary nerve must be located and isolated before activating the compression function.
- If there is suspicion of possible compression or risk to the radial nerve, the radial nerve should be explored and isolated before inserting the intramedullary nail or activating compression

### Observation:

It is necessary to perform the distal block before proceeding with compression.

### 1. Distal nail locking

Insert the nail beyond the planned distance for interfragmentary displacement. The compression slot allows a maximum of 8 mm of travel.

The nail should be locked into the distal fragment as described in the section "Hands-Free Distal Locking– H-Fix (Long) Humeral Nail" (page 16).

### 2. Compression

Using the traditional insertion technique, insert a 3.5 mm locking screw through the appropriate hole, orienting it toward the upper end of the nail compression slot. Refer to the section "Guided Distal Locking– H-Fix (Short) Proximal Humeral Nail" (page 14).

**Note:** Check that the nail does not protrude after purchase, as this may cause impingement.

**Warning:** Before inserting the 3.5 mm locking screw, locate and protect the axillary nerve. Make a limited skin incision and continue with blunt dissection to avoid injury to the axillary nerve or its branches.



Insert the compression screw through the connection screw. Advance the compression screw using the SW3.5 hex screwdriver or the SW11 open end wrench. The tip of the compression screw will contact the 3.5 mm locking screw, which will cause the nail to elevate and the locked distal fragment to move toward the proximal fragment, thus compressing the fracture

Continue to advance the compression screw, monitoring the inter-fragment displacement radiologically, until the desired compression is achieved. Monitor the compression with the image intensifier, as the proximal end of the nail may recede at the point of insertion, causing a gap conflict.

Remove the compression screw and ensure that the nail remains securely attached to the U-locking clamp. If necessary, re-tighten the connection with the Spanner wrench.

**Observation:**

During the compression process, check both the fracture line and the 3.5 mm locking screw. If the fragments do not compress or if the 3.5 mm locking screw is displaced or deformed excessively, stop the compression locking procedure.

**Note:** Each complete rotation (360°) of the compression screw corresponds to an axial displacement of 1 mm.

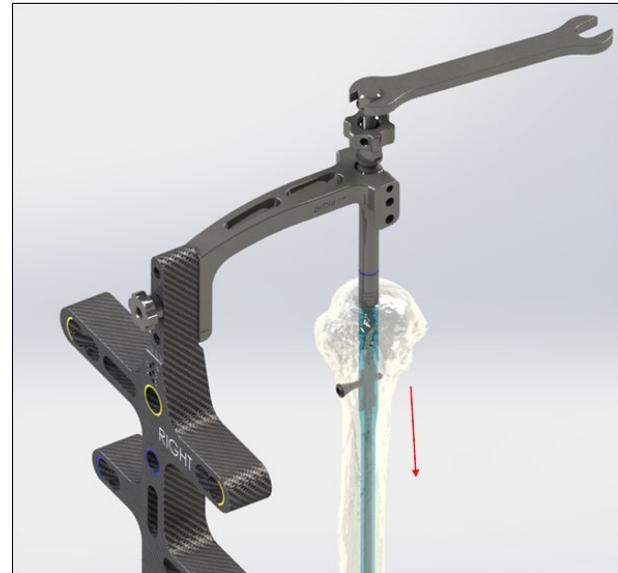
---

**Instruments**

- 39.03.32 Compression screw
  - 11.04.35 Screwdriver with hexagonal tip SW3.5
  - 27.01.11 Spanner Wrench SW11
- 

**3. Proximal Locking of the Nail**

Insert the proximal locking screws according to the procedure described in the section "Proximal Locking" (page 8).



## Inserting the Locking Plug

### 1. Determining the Length of the Locking Plug

It is suggested to use a locking plug to prevent penetration of neoformed bone tissue into the proximal end of the nail, or to extend the nail to improve the stability of the osteosynthesis in case the nail is over-inserted.

Slide the temporary placement rod along the proximal slot of the Ulocking strip. Press the rod down against the bone and refer to the appropriate length of the locking plug directly on the rod. Then remove the temporary positioning rod, the connecting screw and the U-lock clamp. If you encounter any difficulty in removing the connecting screw, use the spanner wrench.

**Observation:** The proximal end of the nail and the locking screw should be placed at least 2 to 3 mm below the cartilage to minimize the risk of conflict and maximize stability.

---

#### Instruments

- 54.02.10 Temporary Placement Rod
  - 27.01.11 Spanner Wrench SW11
- 

#### Alternative Technique: Length Determination with Distal Clamp and Guide Wire

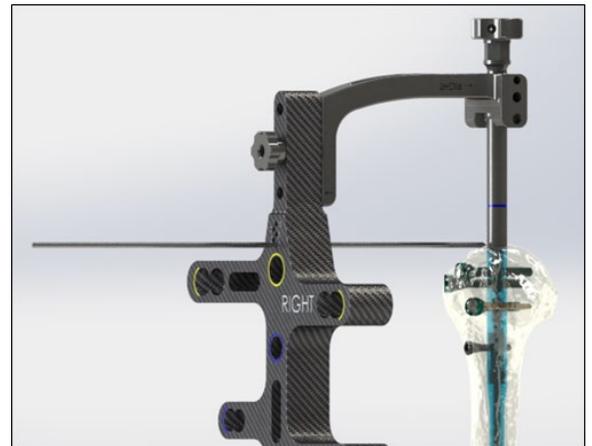
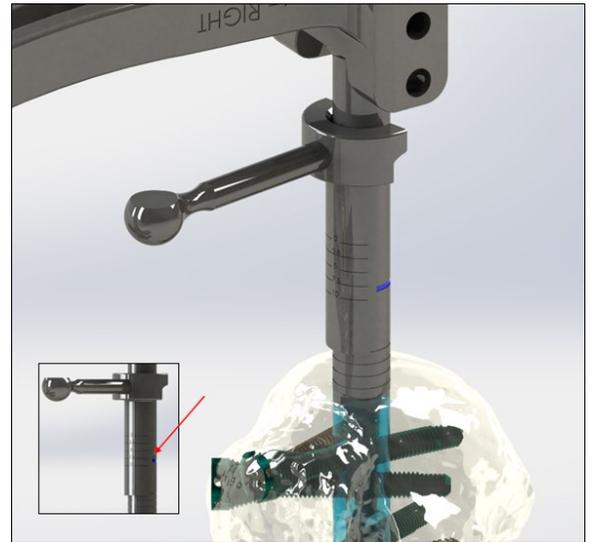
Place the distal clamp on the U-locking clamp and tighten the connecting screw. Insert a 2.5 mm guide wire through the corresponding hole for the locking screw in the proximal part of the distal rail. Determine the extension length on a pure anteroposterior image of the proximal end of the nail. Then remove the guide wire and the distal clamp.

---

#### Instruments

- 40.06.01 Distal Clamp
  - 16.01.25 Guide Wire  $\varnothing$  2.5 x 250 mm
- 

**Observation:** The slots on the U-locking strip are useful for determining the insertion depth on the image intensifier screen. In addition, the proximal end of the nail and the locking screw should be positioned at least 2 to 3 mm below the cartilage for minimum risk of conflict and maximum stability.



## 2. Insertion of the Locking Cap

Be sure to tighten the locking plug securely using the Hexagon Screwdriver SW3.5.

### Caution:

- The closure plug should be inserted well below the surface of the humeral head to avoid space problems. If in doubt, choose a shorter stopper.
- To minimize the risk of cross-threading, turn the locking plug counterclockwise until its thread is properly aligned with that of the nail.

---

### Instruments

- 11.04.35 Screwdriver with hexagonal tip SW3.5

## 3. Use of Sutures (optional)

For better osteosynthesis stability, place one or more strong nonabsorbable sutures in the tendon insertion zone of the supraspinatus, infraspinatus and subscapularis muscles. Secure the sutures to the DuoFix screws through the specific holes in the screw head.

## Implant removal (optional)

### 1. Removal of the cover cap

Carefully design the soft parts to visualize all the locking implants.

Remove the locking cap using the SW3.5 hex-tipped screwdriver.

Then, screw the connecting screw into the intramedullary nail.

**Note:** Always mount the connecting screw before proceeding to remove the screws.

---

### Instrumental

- 11.04.35 Screwdriver with hexagonal tip SW3.5
- 39.06.25 Connecting screw M6/  $\varnothing$  2.5/ SW11



## 2. Removal of the 3.5 mm locking screws ("screw on screw")

Proceed to remove all 3.5 mm locking screws by placing the screwdriver part in the handle

---

### Instruments

- 11.04.15 Hexagon-head screwdriver 1.5 N.m
- 

## 3. Removing the DuoFix screws

Place the extraction shaft in the handle and then remove all DuoFix screws.

**Remark:** If 3.5 mm locking screws are used, remove them first.

---

### Instruments

- 11.17.01 Multilocking Screwdriver
- 

## 4. Removal of the 3.5 mm locking screws

Remove all 3.5 mm locking screws using the SW3.5 hexagon-tipped screwdriver.

---

### Instruments

- 11.04.35 Hexagonal Screwdriver SW3.5
- 

**Remark:** Make sure that the extraction screw is fixed to the nail before removing the last locking screw

## 5. Nail Removal

Before removing the intramedullary nail, make sure that all locking screws have been removed. Then remove the nail. If resistance is encountered, tap gently with a hammer to facilitate removal.

---

### Instruments

- 32.01.01 Sliding Hammer
- 



## Implants

### Nails

#### Design:

Straight, cannulated, right or left

#### Material:

Titanium alloy containing 6% Aluminum and 4% Vanadium, grade 23.

#### Diameter:

##### Humerus Nail (short).

9.0 mm (Ø proximal 9.5 mm)

##### Humerus Nail (short)

7.0 mm (Ø proximal 9.5 mm)

8.0 mm (Ø proximal 9.5 mm)

#### Color:

Blue (right nail) / Pink (left nail)

#### Lengths:

##### Humerus Nail (short)

160 mm

##### Nail for humerus (long)

200 mm

220 mm

240 mm

260 mm

280 mm

300 mm



## DuoFix screw Ø4.5 mm

---

### Material:

Titanium alloy containing 6% Aluminum and 4% Vanadium, grade 23.

### Color:

Emerald green

---

### Dimensions:

---

- Length from 20 to 60 mm with 5 mm increments
  - DuoFix, screw-on-screw entry
  - Self-tapping design
- 

### Lengths

---

20 mm  
25 mm  
30 mm  
35 mm  
40 mm  
45 mm  
50 mm  
55 mm  
60 mm



**Locking screw Ø3.5 mm, ALP**

---

**Material:**

Titanium alloy containing 6% Aluminum and 4% Vanadium, grade 23.

**Color:**

Yellow

**Dimensions:**

---

- Length from 20 to 55 mm with 5 mm increments.
  - Torx T15
  - Thread to head
  - Self-tapping design
- 

**Lengths**

---

20 mm  
25 mm  
30 mm  
35 mm  
40 mm  
45 mm  
50 mm  
55 mm  
60 mm



## Locking screw Ø3.5 mm DCP

---

### Material:

Titanium alloy containing 6% Aluminum and 4% Vanadium, grade 23.

### Color:

Gray

### Dimensions:

---

- Length 20 to 55 mm with 5 mm increments.
- Hexagon 3.5 mm
- Self-tapping design
- Self-tapping head

### Lengths

---

20 mm  
25 mm  
30 mm  
35 mm  
40 mm  
45 mm  
50 mm  
55 mm  
60 mm



## Locking plug

---

### Material:

Titanium alloy containing 6% Aluminum and 4% Vanadium, grade 23.

### Color:

Gray

---

### Without extension (0 mm)

---

- Prevents adjacent tissues from penetrating the nail thread.
- Hexagon 3.5 mm
- Diameter 6.0 mm
- Hexagon 3.5 mm

---

### With 5mm, 10mm, 15mm and 20mm extension.

---

- Extends the height of the nail in case of over-insertion.
- Prevents adjacent tissues from penetrating the nail thread.
- Diameter 9.5 mm
- Hexagon 3.5 mm

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### Extensions

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0 mm

5 mm

10 mm

15 mm

20 mm



## INSTRUMENTAL

### TRAY 1

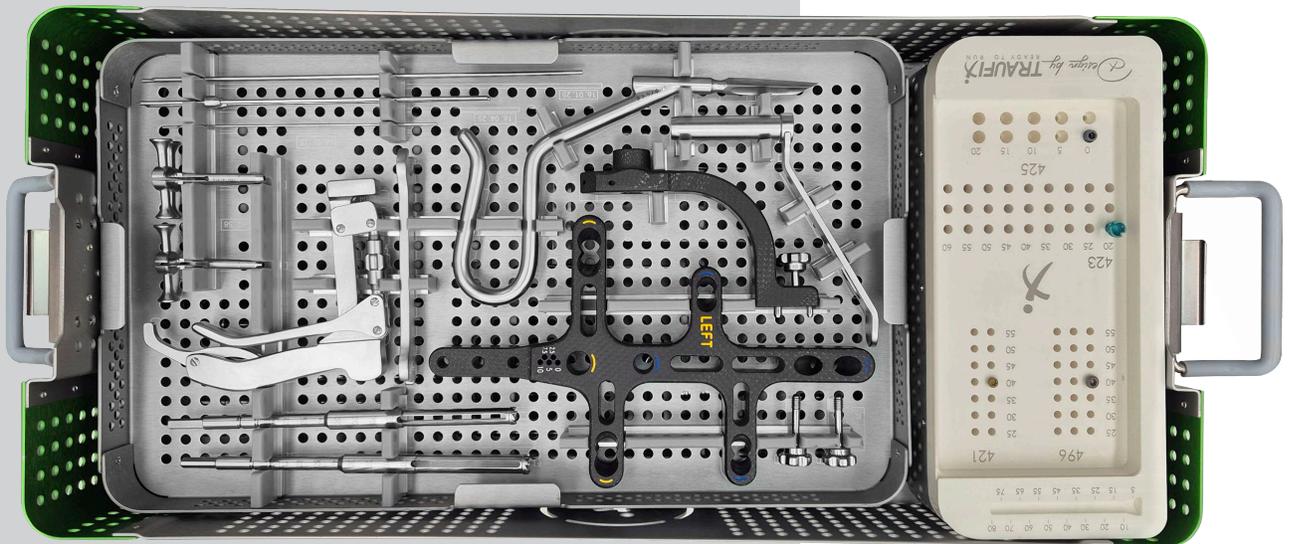
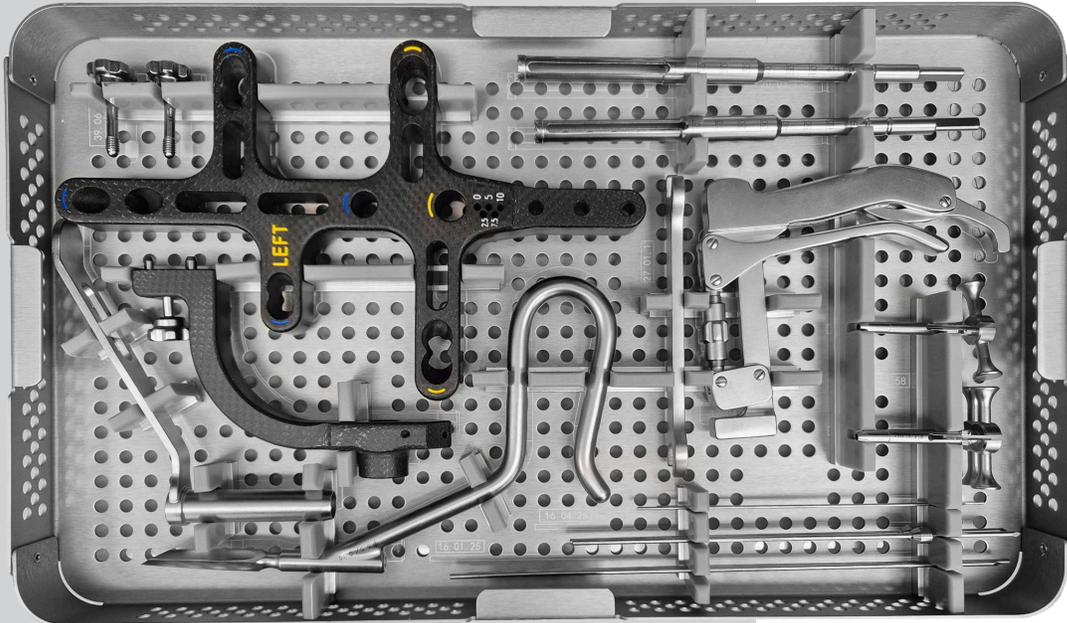
- 16.01.25 Guide wire  $\varnothing$  2.5 x 250
- 16.04.25 Guide wire limited  $\varnothing$  2.5 x 200
- 16.01.15 Guide wire  $\varnothing$  1.5 x 150
- 18.05.115 Single guide wire  $\varnothing$  11.5 x 70mm
- 20.03.115 Cannulated reamer  $\varnothing$  11.5 x 60
- 20.03.10 Cannulated reamer  $\varnothing$  10 x 60
- 31.11.35 Cannulated punch  $\varnothing$  3.5/ $\varnothing$ 10
- 12.04.02 Guide wire clamp handle
- 27.01.11 Spanner wrench SW11
- 40.09.01 Proximal locking arm
- 40.06.01 Distal clamp
- 39.06.05 Connecting screw M6/SW5 Engraved with measure
- 55.02.58 Extension with T-handle  $\varnothing$  5.8/  $\varnothing$  2.8 x 62

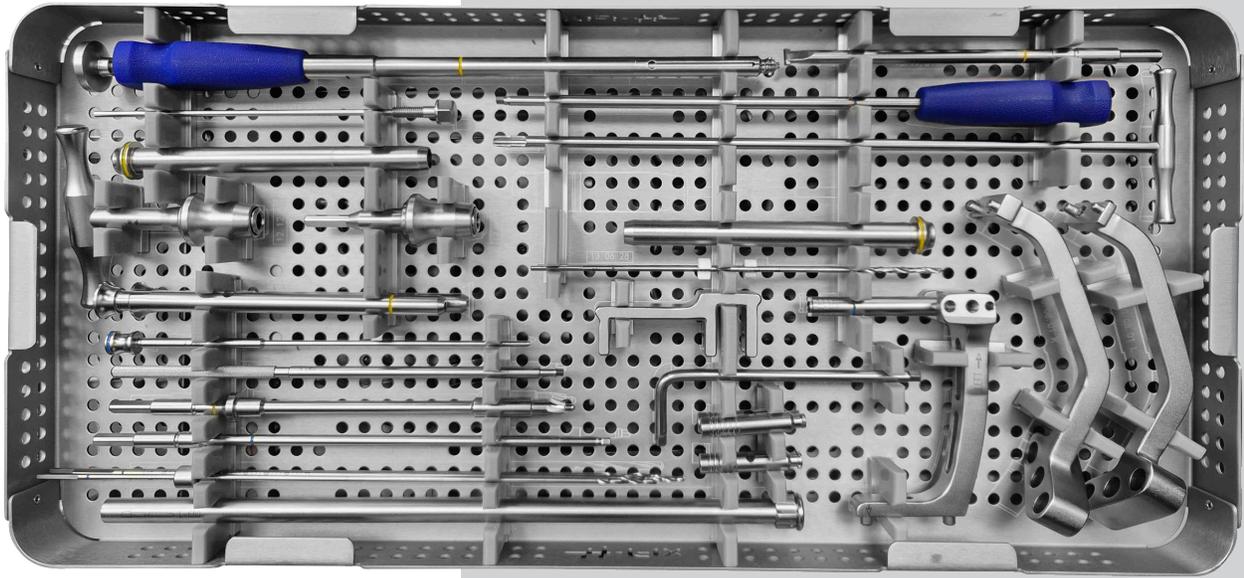
### TRAY 2

- 54.01.33 Cannulated reduction rod with T-handle, L: 33cm
- 55.03.430 Graduated rod 120-430
- 12.12.08 Cannulated T-handle  $\varnothing$  8
- 23.07.01 Guide wire with olive tip  $\varnothing$  2.5 x 680mm
- 23.13.25 Guide wire with olive tip (Nitinol alloy)  $\varnothing$  2.5 x 680mm
- 12.13.01 Handle with quick coupling
- 13.06.38 Drill bit with graduated stop 0-60  $\varnothing$  3.8 mm
- 13.08.38 Drill bit 0-60  $\varnothing$  3.8 mm
- 11.17.01 Multi-lock screwdriver
- 21.05.08 Solid countersink  $\varnothing$  8
- 55.01.10 Inner sleeve  $\varnothing$  10/ $\varnothing$  3.8 x 162
- 18.11.13 Outer sleeve  $\varnothing$  13/ $\varnothing$ 10 x 150
- 40.03.01 U-shaped locking strip Engraved with an arrow
- 39.03.32 Compression screw M6/ $\varnothing$  3.2/SW11
- 40.08.01 Distal locking arm
- 41.01.02 Locking device for distal probe
- 26.02.05 Allen key SW5
- 55.01.3.5 Extension for screw SW3.5
- 13.19.01 Flat drill bit with triangular anchorage
- 55.03.10 Extension for Nail  $\varnothing$  10/ $\varnothing$  5.8
- 13.06.28 Graduated drill with stop 20-60  $\varnothing$  2.8
- 31.04.30 Long punch  $\varnothing$  3.0
- 11.04.35 Screwdriver with hexagon tip SW3.5
- 11.04.35T Hexagon screwdriver T15
- 11.19.35 Screwdriver tip with triangular anchor SW3.5

### TRAY 3

- 16.03.01 Graduated ruler  $\varnothing$  7-  $\varnothing$  9.5 x 160- 300
- 24.06.07 Flexible Shaft for rhyme tips  $\varnothing$  7
- 24.06.08 Shaft flexible for rhyme tips  $\varnothing$  8
- 24.06.09 Shaft flexible for rhyme tips  $\varnothing$  9
- 24.06.10 Shaft flexible for rhyme tips  $\varnothing$  10
- 16.01.90 Depth gauge 0-90 mm
- 31.04.38 Long punch  $\varnothing$  3.8
- 32.01.01 Sliding hammer
- 39.07.345 Cannulated long screw M6/ $\varnothing$  3.45/SW11
- 39.06.25 Connecting screw M6/ $\varnothing$  2.5/SW11
- 40.04.20 Graduated 200-300 bar
- 39.03.05 Compression screw M6/SW5 Engraved with measure
- 42.01.01 T-Handle Feeler with T-Handle
- 13.11.38 T-handle drill bit  $\varnothing$  3.8
- 31.10.02 Punch with sleeve
- 54.02.10 Temporary locating rod 0-10
- 11.04.15 Hexagon screwdriver 1.5 N.m
- 18.11.11 Outer sleeve  $\varnothing$  11/ $\varnothing$ 8.2 x 175
- 55.01.82 Screw extension  $\varnothing$  8.2/ $\varnothing$  3 x 187
- 13.08.30 Graded drill bit 0-70  $\varnothing$  3.0
- 13.06.30 Graded drill bit with stop 0-70  $\varnothing$  3.0
- 26.02.03 Allen key SW3.0
- 16.01.90 Depth gauge 0-90







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