TFN-ADVANCED™

Proximal Femoral Nailing System (TFNA)

Surgical Technique

AUGMENTATION

approved by AO Technical Commission

DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance
For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
For general information about reprocessing, care and maintenance of DePuy Synthes reusable devices, instrument trays and cases, as well as processing of DePuy Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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TFN-ADVANCED™
Proximal Femoral Nailing System (TFNA)

TFNA short
(Lengths 170 mm, 200 mm, 235 mm)

TFNA long
(Lengths 260 mm – 480 mm)

▲ WARNINGS:

- It is critical to ensure proper selection of the implant meets the needs of the patient anatomy and the presenting trauma.
- The TFNA Nail is not intended for full weight bearing in patients with complex unstable fractures until sufficient bone consolidation is confirmed in the follow up X-rays.
- Conditions that place excessive stresses on bone and implant such as severe obesity or degenerative diseases should be considered. The decision whether to use these devices in patients with such conditions must be made by the physician taking into account the risks versus the benefits to the patients.
- Use of these devices is not recommended when there is systemic infection, infection localized to the site of the proposed implantation or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
- Physician should consider patient bone quality to ensure it provides adequate fixation to promote healing.
- Compromised vascularity in the site of proposed implantation may prevent adequate healing and thus preclude the use of this or any orthopedic implant.
- Physician should take into account an increase in medullary pressure occurring during medullary nailing or reaming. This release varying amounts of bone marrow and fat into the venous blood system.
- When selecting the 235 mm length nail for subtrochanteric fractures, make sure it is suitable for the intended application and restrict use to high subtrochanteric fractures only.
- Do not augment if X-ray contrast media leaks into the joint.
- The 6 mm minimum distance is recommended to reduce the risk of thermal injury to the adjacent cartilage tissue.
- In the event that there is danger of cement leakage into the joint, fracture gap or venous system, stop injection immediately.
- If the extravasated cement conforms to the architecture of the hip joint, it may not need to be removed. However, if it does not conform and is abrasive or damages the articular surface, then the extruded cement will need to be removed.
- To remove the cement, the treating physician has the option of either hip arthroscopy, arthroplasty, or open arthrotomy to remove the extruded pieces. The timing of the removal is at the discretion of the physician after appropriate evaluation of the patient.

TFNA Augmentation

■ Note:

The perforated TFNA Screws and TFNA Helical Blades may be used with or without augmentation.

Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effect and Residual Risks.
Instructions for Use are available at www.e-ifu.com and/or www.depuysynthes.com/ifu

The AO Principles of Fracture Management

Mission

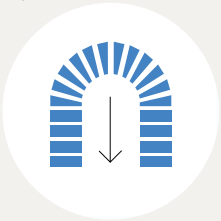
The AO's mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

AO Principles[1,2]

1.

Fracture reduction and fixation to restore anatomical relationships.

2.



Fracture fixation providing absolute or relative stability, as required by the "personality" of the fracture, the patient, and the injury.

3.

Preservation of the blood supply to soft-tissues and bone by gentle reduction techniques and careful handling.

4.

Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

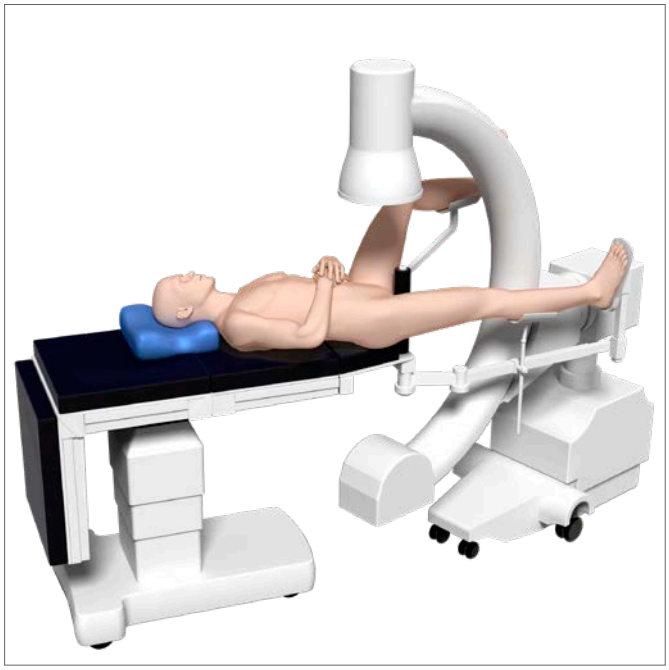
[1] Müller ME, Allgöwer M, Schneider R, Willenegger H. Manual of Internal Fixation. 3rd ed. Berlin, Heidelberg New York: Springer 1991.
[2] Rüedi TP, RE Buckley, CG Moran. AO Principles of Fracture Management. 2nd ed. Stuttgart, New York: Thieme. 2007.

Preparation

1. Position patient

Position the patient in the lateral decubitus or supine position on a fracture or radiolucent table. Position the image intensifier to enable visualization of the proximal femur in both the AP and lateral planes.

For unimpeded access to the medullary canal, abduct the upper part of the body approximately 10 – 15° to the contralateral side (or adduct the affected leg by 10 – 15°).



2. Fracture reduction

Perform closed reduction manually by axial traction under image intensifier control. The use of the large distractor (refer to Instructions for Use) may be appropriate in certain circumstances.

If reduction cannot be achieved in a closed approach, open reduction may be considered.

▲ Precautions:

- Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin.
- Handle devices with care and dispose worn bone cutting instruments in an approved sharps container.

3. Determine CCD angle

Instruments	
03.037.006	Radiographic Ruler
357.399*	Guide Wire ∅ 3.2 mm, length 400 mm
Alternative Instrument	
03.045.018*	Guide Wire ∅ 3.2 mm, w/drill tip, 400 mm

The three oblique holes in the proximal end of the radiographic ruler are used to determine the femoral neck angle (CCD angle). Select a guide wire and insert the guide wire in line with one of the grooves marked 125°, 130°, or 135°.

Position the radiographic ruler over the proximal femur and take an AP image. Select the angle that most closely matches the angle of the femoral neck and position the radiographic ruler such that the guide wire is aimed centrally in the femoral head. Mark the position of the radiographic ruler at the proximal outline of the ruler on the skin to assist the next steps.

■ Notes:

- The proximal end of the radiographic ruler represents the proximal nail end after insertion. The slot on the proximal end refers to the path of the guide wire, used for opening of the femur
- All AP images of the proximal femur are made with correction for the anteversion, either by internally rotating the femur or by adjusting the image intensifier

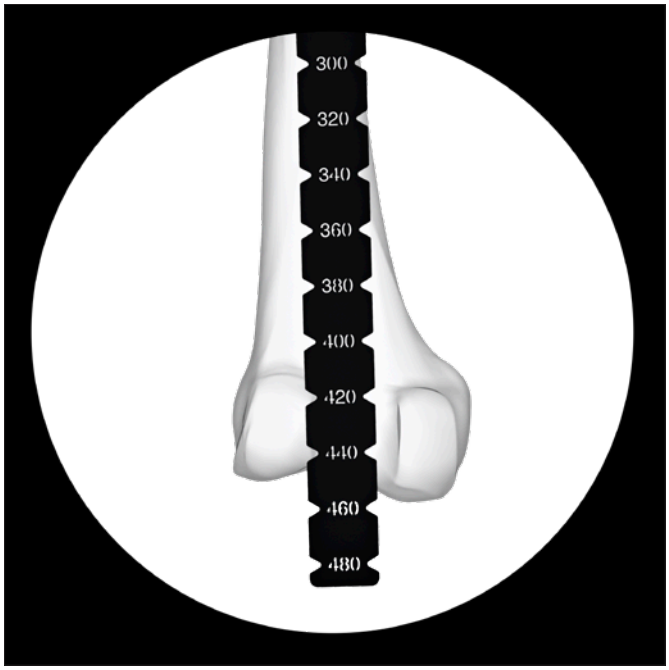
* Available non-sterile or sterile packed. Add “S” to the article number to order sterile products.

4. Determine nail length (for long nails 260 mm–480 mm)

Instrument	
03.037.006	Radiographic Ruler

Move the image intensifier to the distal femur, place the proximal end of the radiographic ruler at the skin mark, and take an AP image. Verify fracture reduction. Read nail length directly from the ruler image, selecting the measurement that places the distal end of the nail at, or just proximal to, the physeal scar, or the chosen insertion depth.

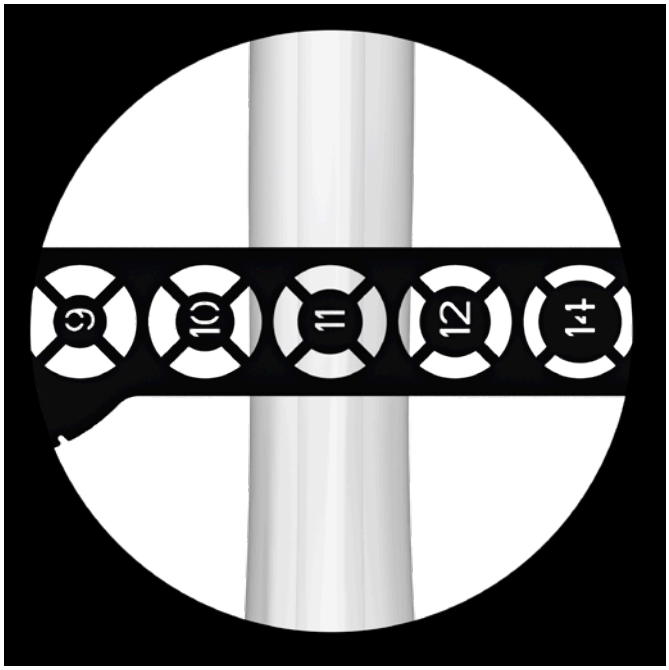
Alternative: Nail length may also be determined by using a reaming rod, refer **option: Determine nail length over reaming rod** for technique.



5. Determine nail diameter

Instrument	
03.037.006	Radiographic Ruler

To determine nail diameter, position the image intensifier for an AP view of the femur at the level of the isthmus. Hold the radiographic ruler perpendicular to the femur and position the diameter windows over the isthmus. Read the estimated diameter measurement on the circular indicator that fills the canal.



■ Note:

The distance of the radiographic ruler from the bone affects the diameter measurement.
Estimate the width as follows:

- Distance between the radiographic ruler and bone
  a. 25 mm = 1 mm larger reading
  b. 50 mm = 2 mm larger reading
  c. 100 mm = 3 mm larger reading
- If the reamed technique is used, the diameter of the largest medullary reamer applied must be 0.5 mm to 1.5 mm larger than the nail diameter
- Always choose the largest diameter nail that fits into the intramedullary canal

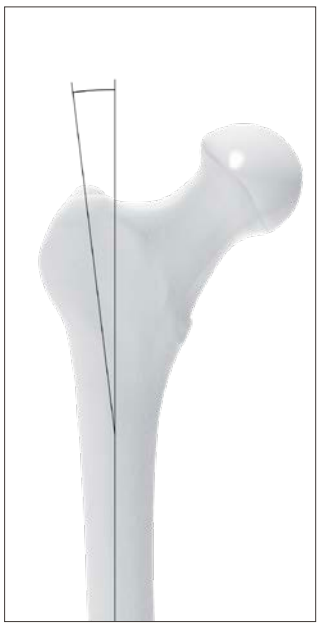
Open Proximal Femur

1. Identify nail entry point

Make a longitudinal incision proximal to the greater trochanter. Carry the dissection down to the gluteus medius fascia longitudinally in the direction of the wound. Separate the underlying muscle fibers and palpate the tip of the greater trochanter.

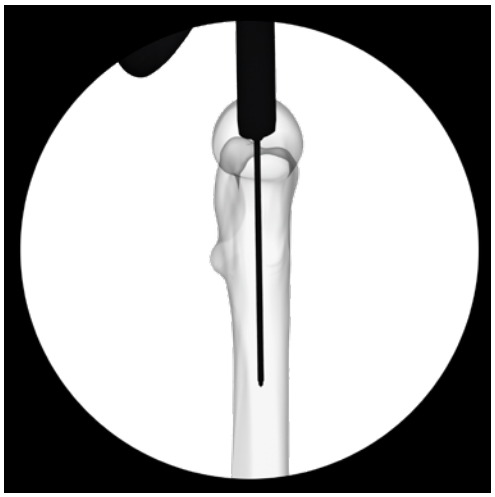
In the AP view, the nail insertion point is on the tip or slightly lateral to the tip of the greater trochanter, in the curved extension of the medullary cavity. This represents a point, 5° lateral of the femoral shaft axis, measured from a point just below the lesser trochanter, as the ml angle of the nail is 5°.

In the lateral view, the entry point for the nail is centered in the greater trochanter and in line with the medullary canal.



2. Insert guide wire

Instruments	
03.037.000	Multihole Drill Sleeve
03.037.001	Protection Sleeve
357.399*	Guide Wire ∅ 3.2 mm, length 400 mm
393.100	Universal Chuck with T-Handle
Alternative instruments	
03.037.100	Multihole Drill Sleeve, long
03.037.101	Protection Sleeve, long
09.037.010*	Guide Wire ∅ 3.2 mm, length 475 mm
03.045.018*	Guide Wire ∅ 3.2 mm, w/drill tip, 400 mm
03.043.001	Universal Chuck



Position the protection sleeve and the multi hole drill sleeve assembly at the insertion point.

Insert the guide wire through the drill sleeve. Confirm guide wire placement in both the AP and lateral planes. Insert to a depth of approximately 15 cm. Remove the drill sleeve.

Alternatively the guide wire can be inserted without the protection sleeve and multiple wire guide. The protection sleeve and wire guide can then be passed over the guide wire.

If the first guide wire is inserted in an incorrect position, a second guide wire can be inserted through one of the additional holes in the multi hole drill sleeve at either 4 mm or 6 mm from the central hole. Once the guide wire is in the desired entry point, remove the first guide wire.

* Available non-sterile or sterile packed. Add “S” to the article number to order sterile products.

Alternative technique

Instruments	
03.037.008	Awl ∅ 8/4.7 mm, curved, cannulated
or	
03.037.007	Awl ∅ 8/4.7 mm, straight, cannulated

The entry point can also be determined by using the awl. After initial opening with the awl, insert the 950 mm reaming rod through the cannulation.

3. Open canal

Instruments	
03.037.001	Protection Sleeve
03.037.002*	Drill Bit ∅16 mm, flexible, cannulated, for Quick Coupling for DHS™/DCS™
or	
03.037.003*	Drill Bit ∅16 mm, cannulated, for Quick Coupling for DHS™/DCS™

Alternative instruments	
03.037.101	Protection Sleeve, long
03.037.102*	Drill Bit ∅16 mm, long, flexible, cannulated, for Quick Coupling for DHS™/DCS™
or	
03.037.103*	Drill Bit ∅16 mm, long, cannulated, for Quick Coupling for DHS™/DCS™

Guide the flexible cannulated drill bit over the guide wire through the protection sleeve to the bone and drill to the stop.

Remove and dispose of the guide wire.

▲ Precaution:

Guide wires are single-use items, do not re-use.

* Available non-sterile or sterile packed. Add “S” to the article number to order sterile products.

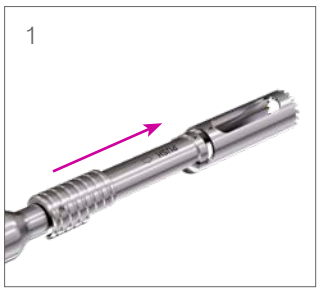
3a. Option: Hollow Reamer

Instruments	
03.037.004*	Hollow Reamer ∅ 16 mm, cannulated, for Quick Coupling for DHS™/DCS™
03.037.104*	Hollow Reamer ∅ 16 mm, long, cannulated, for Quick Coupling for DHS™/DCS™

Make sure that the centering mechanism of the Hollow Reamer is in the correct position: it must be pushed from the coupling end (1) towards the cutting end (2) of the instrument.

Guide the cannulated Hollow Reamer over the guide wire through the protection sleeve to the bone and drill to the stop.

Remove and dispose of the guide wire.



▲ Precaution:

Guide wires are single-use items, do not re-use.

■ Note:

In hard bone it might be necessary to repeat the opening process with either the flexible drill bits 03.037.002/ 03.037.102 or the solid drill bits 03.037.003/03.037.103.

▲ Precaution:

Monitor the drill depth under image intensifier throughout the procedure.

* Available non-sterile or sterile packed. Add "S" to the article number to order sterile products.

4. Option: Ream medullary canal

If necessary, enlarge the femoral canal to the desired diameter using the medullary reamer system SynReam and the corresponding surgical technique.

Use image intensification to confirm fracture reduction. Insert the reaming rod into the medullary canal to the desired insertion depth. The tip must be correctly positioned in the medullary canal since it determines the final distal position of the nail.

Reaming

Starting with the 8.5 mm diameter reaming head, ream to a diameter of 0.5 mm to 1.5 mm greater than the nail diameter. Ream in 0.5 mm increments and advance the reamer with steady, moderate pressure. Do not force the reamer. Partially retract the reamer repeatedly to clear debris from the medullary canal.

4. Option: Reamer protection tube

Instruments	
03.037.001	Protection Sleeve
03.037.005	Protection Tube for Medullary Reamers
03.037.105	Trocar for Protection Tube

The reamer tube facilitates the protection of the proximal metaphysis during reaming.

Assemble the reamer protection tube, trocar and protection sleeve. Then take the reamer protection tube assembly and insert it over the reaming rod, sliding the trocar and reamer protection tube into the bone.

Remove the inner trocar from the assembly and pass the reamer over the reaming rod and through the protection tube. Then ream per the technique described above.

When removing the reamer head through the reamer protection tube be sure to align the angle of the reamer shaft to the protection tube. This will help ensure the reamer head will not get caught on the tube upon removal.

■ Note:

The reamer protection tube can only be used with reamer heads up to 13.5 mm. Therefore it can only be used for nails up to 12 mm.

Option: Determine nail length over reaming rod

Instruments	
351.719	Elongation Tube for Reaming Rods, for Depth Gauge for Medullary Nails, for Nos. 351.717 and 03.019.001
03.037.036	Depth Gauge for Nails
Alternative Instruments	
03.045.035	Direct measuring device for IM nails
03.045.036	Tube for Direct measuring device

Nail length can be determined over a 950 mm reaming rod. Confirm reaming rod insertion depth under image intensification. Assemble the elongation tube to the depth gauge. Pass the device over the reaming rod and down to the bone. Read nail length directly from the depth gauge.

If a 1150 mm reaming rod is used, the nail length measurement should be read off the etched line on the reaming rod.

Insert Nail

1. Assemble insertion instruments

Instruments	
03.037.010	Connecting Screw for Insertion Handle
03.037.012 or 03.037.011 or 03.037.112	Insertion Handle Insertion Handle, hybrid Insertion Handle, long
03.010.517	Screwdriver, hexagonal ∅ 8.0 mm, with T-Handle, with spherical head, length 322 mm
03.037.028	Screwdriver, hexagonal 5.0 mm, flexible, cannulated
Alternative Instrument	
03.043.027	Screwdriver, hexagonal ∅ 8.0 mm, with T-handle, spherical head, cannulated

Assemble the hexagonal screwdriver with spherical head to the connecting screw until it clicks into the recess.

Match the geometry of the handle to the nail and connect the nail to the insertion handle. The nail will click in and self retain.

Pass the connecting screw through the insertion handle and securely tighten with the hexagonal screwdriver with spherical head.

To verify the appropriate position of the locking mechanism for the screw, pass the 5.0 mm flexible screwdriver through the cannulated connecting screw and turn counter-clockwise until it stops.

Remove the hexagonal screwdriver.

▲ Precautions:

- Ensure that the connection between the nail and the insertion handle is tight (retighten if necessary)
- Do not attach the aiming arm to the insertion handle yet
- If a 235 mm or longer nail is selected, reconfirm that the correct nail (right or left) is assembled

2. Insert nail

Instruments	
03.037.012	Insertion Handle
or	
03.037.011	Insertion Handle, hybrid
or	
03.037.112	Insertion Handle, long

TFNA short (170 mm, 200 mm and 235 mm)

Orient the insertion handle laterally, taking into consideration the anteversion of the femoral head and neck. Manually insert the nail into the femoral opening. When using a reaming rod, pass the cannulated nail over the reaming rod and into the femoral opening.

Under image intensification, verify fracture reduction and insert the nail as far as possible by hand. Use the insertion assembly to manipulate the nail across the fracture.

When inserting a short nail (170 mm, 200 mm and 235 mm), no hammer blows should be required.

TFNA short

TFNA long (260 mm to 480 mm)

Orient the insertion handle anteriorly until the nail reaches the isthmus. Manually insert the nail into the femoral opening. When using a reaming rod, pass the cannulated nail over the reaming rod and into the femoral opening. As the nail is advanced, rotate the handle so it is positioned laterally for final seating.

Under image intensification, verify fracture reduction and insert the nail as far as possible by hand. Use the insertion assembly to manipulate the nail across the fracture. Insertion can be aided by light hammer blows on the driving cap, as described in the step below.

If a reaming rod has been used, it should be removed once the nail has crossed the fracture site.

TFNA long

3. Insert nail with hammer (optional)

Instruments	
03.010.522	Combined Hammer, 500 g
03.010.523	Driving Cap with thread, for Insertion Handle
03.037.120	Connector for Driving Cap
03.037.031	Wrench, hexagonal socket 11/Blade-Screw
03.010.170	Hammer Guide

To use a hammer, screw the driving cap onto the hybrid insertion handle and tighten with combination wrench.

While applying light blows, monitor the tip of the nail using image intensification. Verify that there is no evidence of impingement distally. Remove the driving cap and the connector once the nail has been seated.

▲ Precautions:

- Using light blows, the hammer can also be used with the hammer guide to back slap the nail if the nail has been slightly over inserted.
- Confirm that the nail is tightly connected to the insertion handle, as hammering may loosen the connection.

When using the fully carbon fibre insertion handle 03.037.012 or 03.037.112, insert the connector for driving cap into the anterior side of the handle and screw the driving cap through the connector onto the insertion handle.

Proximal Locking

1. Choose aiming arm

Instruments	
Aiming Arms CCD: 125°	
03.037.014	(static distal locking)
03.037.114	(static and dynamic distal locking)
130°	
03.037.013	(static distal locking)
03.037.113	(static and dynamic distal locking)
135°	
03.037.035	(static distal locking)
03.037.135	(static and dynamic distal locking)

Ensure that the nail is tightly connected to the insertion handle. Retighten if necessary.

Choose the aiming arm that matches the angle of the nail inserted and securely attach to the insertion handle by tightening the thumb screw.

2. Verify nail insertion depth

Instrument	
357.399*	Guide Wire ∅ 3.2 mm, length 400 mm

Alternative Instrument	
03.045.018*	Guide Wire ∅ 3.2 mm, w/drill tip, 400 mm

Verify nail insertion depth and position for the helical blade/screw. Place a guide wire on the yellow marking of the aiming arm and radiographically check the guide wire position in AP.

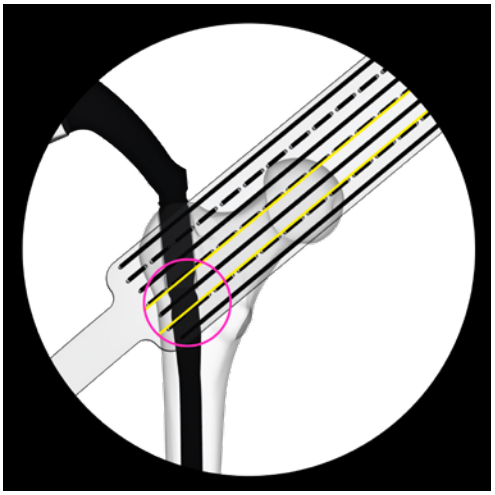
* Available non-sterile or sterile packed. Add “S” to the article number to order sterile products.

Alternative technique: Position guide wire with guide wire aiming device

Instruments	
03.010.412	Aiming Device for Guide Wire, for PFNA and TFN, for AP orientation
03.010.415	Connecting Screw for TFN, for No. 03.010.412
03.010.471	Guide Wire Aiming Device Offset Block, 100 mm

Insert the aiming device into the three holes on the aiming arm and attach it to the aiming arm using the connecting screw.

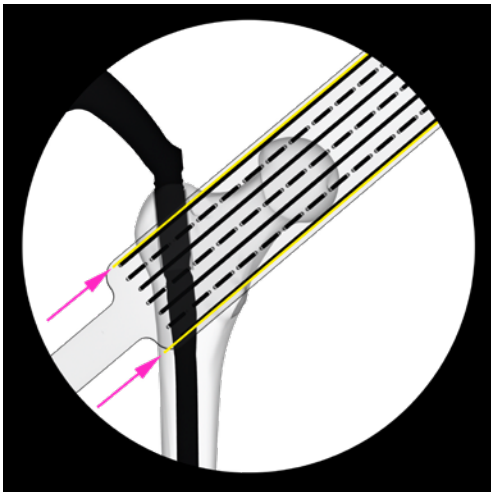
Option: The guide wire aiming device offset block can be added between the aiming arm and the guide wire aiming device to obtain an additional 10 cm of soft tissue clearance.



Position the image intensifier for an AP image. Rotate the image intensifier until any two dotted orientation lines are parallel to the proximal locking hole. The midline in between these two orientation lines represents the guide wire trajectory.

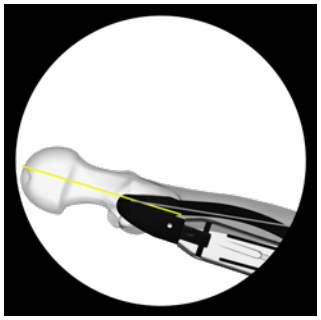
■ Note:

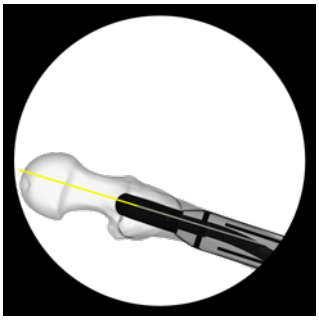
The outer lines can be used to determine the center of the femoral head.



3. Verify nail anteversion

Instrument	
357.399*	Guide Wire ∅ 3.2 mm, length 400 mm
Alternative Instrument	
03.045.018*	Guide Wire ∅ 3.2 mm, w/drill tip, 400 mm





Position the image intensifier in the true lateral view (alignment of the axis of the femoral neck congruent with the axis of the femoral shaft).

Adjust nail rotation until the two radiographic lines on the insertion handle are parallel to the nail.

Option: A guide wire can be inserted in the corresponding hole in the insertion handle to predict the location of the guide wire and helical blade/screw.

* Available non-sterile or sterile packed. Add “S” to the article number to order sterile products.

4. Insert guide sleeve

Instruments	
03.037.016	Buttress/Compression Nut
03.037.017	Guide Sleeve, yellow
03.037.018	Drill Sleeve, yellow
03.037.019	Trocar, yellow
03.010.491	Handle for Scalpel, long

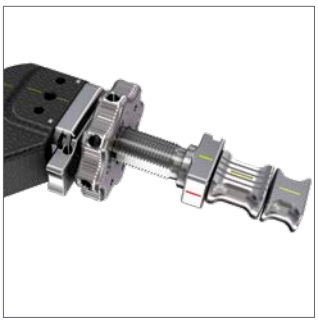
To make an incision to accommodate the path of the sleeve assembly, insert the handle with scalpel blade attached through the corresponding hole of the aiming arm. Ensure that the incision and dissection of the fascia is in line with the path of the sleeve assembly.

Thread the buttress/compression nut onto the guide sleeve, to the black marking.

Assemble the yellow marked trocar and the drill sleeve into the guide sleeve. Place the assembly through the aiming arm and through the soft tissue to the bone. Slightly rotating the assembly while pushing through the soft tissue may help facilitate insertion. Advance the assembly until the buttress/compression nut clicks into the aiming arm.

■ Note:

The Drill Sleeve 03.037.018 will not advance as far as the Guide Sleeve 03.037.017 when pushing the assembly to the bone.



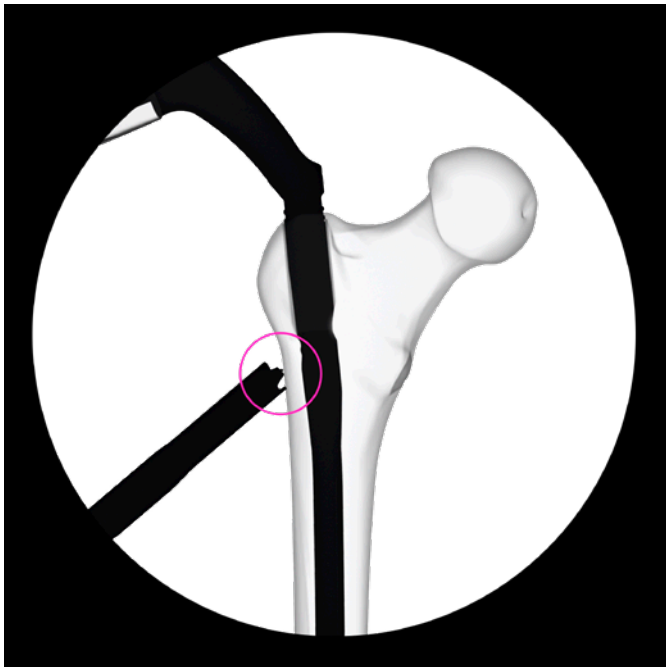
Turn the buttress/compression nut counterclockwise to advance the guide sleeve to the bone.

Take an AP image to confirm that the tooth on the guide sleeve is just touching the lateral cortex.

▲ Precautions:

- The distal tooth of the guide sleeve should rest on the lateral cortex. Do not overtighten on the cortex as this may affect the accuracy of the aiming assembly.
- The fatigue strength of the nail may be affected and may contribute to the potential for the nail to fracture if the nail is damaged during any step of the helical blade/screw reaming in addition to other factors such as fracture reduction, surgical technique, obesity, level of activity/ weight-bearing, non-union, or delayed union.

Using a light hammer blow, hit the trocar into the bone to create an indentation in the bone which will help prevent the guide wire from skiving off the bone in the next step.



Reconfirm fracture reduction using image intensification.

5. Insert guide wire for helical blade/ screw

Instruments	
03.037.019	Trocar, yellow
357.399*	Guide Wire ∅ 3.2 mm, length 400 mm
Alternative Instrument	
03.045.018*	Guide Wire ∅ 3.2 mm, w/drill tip, 400 mm

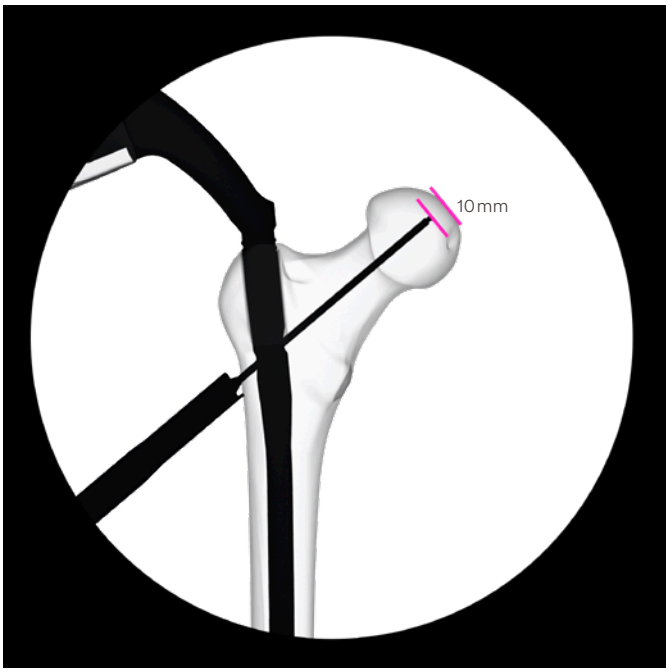
■ Note:

Instrument 09.037.010 (3.2 mm Guide Wire 475 mm) should not be used for head element placement. This instrument is etched with two bands to aid in identification and is intended only for nail entry point.

Remove the trocar and pass a new guide wire through the drill sleeve to the bone. Advance the guide wire into the femoral head, stopping approximately 10 mm below the joint level.

The guide wire should be centered in the femoral head and neck in both the AP and lateral planes. The tip of the guide wire is positioned where the tip of the head element will be when the head element is properly inserted.

Confirm guide wire placement, in both planes, using the image intensifier.



▲ Precautions:

- If the nail must be repositioned to improve guide wire placement, remove the guide sleeve assembly and adjust with the insertion handle. Make a new incision for insertion of the guide sleeve, if necessary. Do not pull on the guide sleeve or power tool to make this adjustment, as this could affect the accuracy of the aiming.
- The fatigue strength of the nail may be affected and may contribute to the potential for the nail to fracture if the nail is damaged during any step of the helical blade/ screw reaming in addition to other factors such as fracture reduction, surgical technique, obesity, level of activity/weight-bearing, non-union, or delayed union.
- Do not reuse guide wires, as they may bend during initial use. If the guide is deformed during insertion, use a new guide and discard the deformed guide wire.
- Insert the guide wire for the blade or screw carefully to avoid penetration of the guide wire into the joint. Penetration of the articular surface is a contraindication for the augmentation of the blade or screw.

■ Note:

When inserting the guide wire in patients with larger anatomies, it might be necessary to stop during wire insertion and remove the drill sleeve. This is most likely to occur in anatomies requiring helical blade/screw lengths of 120 mm or larger.

* Available non-sterile or sterile packed. Add “S” to the article number to order sterile products.

Optional technique: Rotational control of femoral head

Instruments	
357.399*	Guide Wire ∅ 3.2 mm, length 400 mm
357.413	Drill Sleeve 5.6 / 3.2, length 198 mm
Alternative Instrument	
03.045.018*	Guide Wire ∅ 3.2 mm, w/drill tip, 400 mm

In very unstable fractures, insert an additional guide wire to prevent rotation. Pass the drill sleeve through the corresponding anterior or posterior hole on the aiming arm. Make a stab incision and pass the sleeve to the bone. Advance a guide wire into the femoral head. Monitor passage with the image intensifier.

Repeat to place a second guide wire if necessary.

The guide wires will converge towards the tip of the helical blade/screw, but will not touch it. The guide wires should be used for provisional fixation only and removed once the helical blade/screw has been inserted.

* Available non-sterile or sterile packed. Add “S” to the article number to order sterile products.

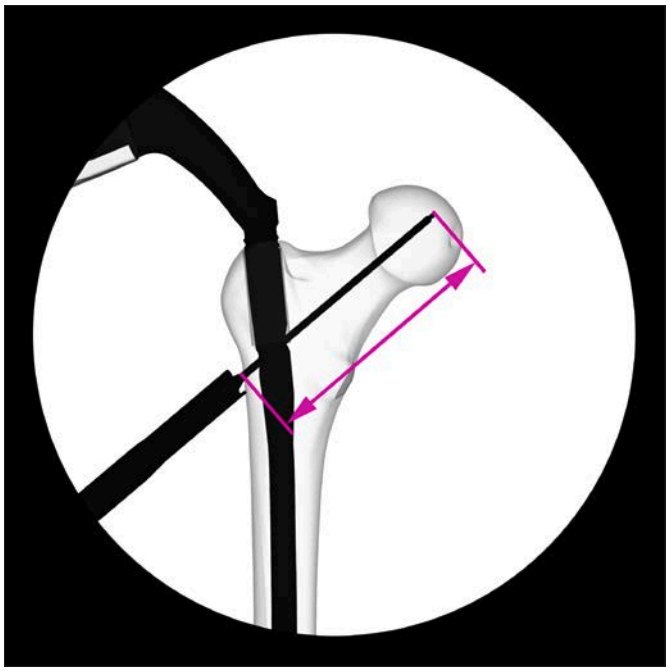
6. Measure helical blade/screw length

Instrument	
03.037.020	Direct Measuring Device, yellow

To measure the helical blade or screw length, pass the measuring device over the guide wire to the back of the guide sleeve. The length is read directly from the measuring device. No calculations are required.

■ Note:

The measurement is calibrated from the tip of the guide wire to the tip of the tooth on the guide sleeve.



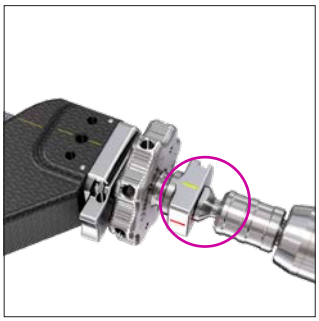
7. Open lateral cortex for helical blade/ screw insertion

Instruments	
03.037.017	Guide Sleeve, yellow
03.037.021*	Drill Bit for lateral cortex opening, for Quick Coupling for DHS™/DCS™

Remove the drill sleeve. Pass the drill bit over the guide wire, through the guide sleeve, and drill to the stop. This will open the lateral cortex.

■ Note:

If the guide wire deflected as it passed into the femoral head/neck, it may be removed before drilling and blade/ screw insertion. If the guide wire falls out or comes out when the drill bit is removed, it may be left out for blade/ screw insertion. Care should be taken to ensure the orientation of the insertion handle and aiming arm is not altered.



* Available non-sterile or sterile packed. Add “S” to the article number to order sterile products.

Option: Drilling for dense bone or when using a screw

Instruments	
03.037.022*	Stepped Reamer for TFNA Helical Blade and Screw for Quick Coupling for DHS™/DCS™
03.037.023	Fixation Sleeve for Stepped Reamer
03.010.093	Rod Pusher for Reaming Rod with Hexagonal Screwdriver ∅ 8.0 mm

For dense bone or when using a screw, the stepped reamer should be used to prepare a path for the full length of the implant. The stepped reamer should be used only after the lateral cortex has been opened.

Pass the fixation sleeve over the back end of the stepped reamer and check the fixation sleeve for wear per the instructions **checking fixation sleeve wear**. Adjust the setting to the measured implant length. Pass the reamer over the guide wire, through the guide sleeve and advance it to the stop.

Use the rod pusher through to hold the guide wire in place while removing the stepped reamer.

■ Notes:

- Clean the flutes if high resistance is felt.
- Drill always stops 5 mm short of the wire tip.
- Rod pusher can be used to hold the guide wire in the bone when the drill is retracted.

▲ Precaution:

Monitor the drill depth under image intensifier throughout the procedure.

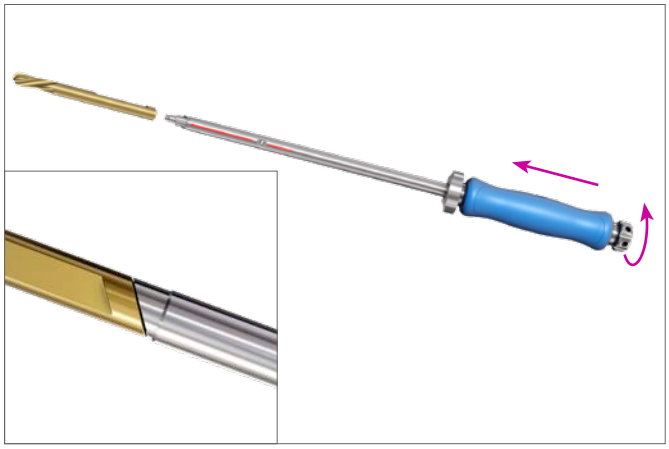
* Available non-sterile or sterile packed. Add “S” to the article number to order sterile products.

Option A: Helical Blade Insertion

8a. Assemble helical blade

Instruments	
03.037.024	TFNA Helical-Blade Impactor
03.037.026	Connecting Screw for TFNA Helical Blade and Screw

Insert the connecting screw and thread in until it is fully captured in the helical blade impactor. The connecting screw will remain attached to the instrument. Select the appropriate helical blade length as measured. Align the back end of the helical blade with the impactor. Further, thread the connecting screw into the helical blade and finger tighten the assembly.



9a. Insert helical blade

Instrument	
03.010.522	Combined Hammer, 500 g

Pass the helical blade impactor assembly through the guide sleeve and align the red line on the impactor shaft with the red line on the guide sleeve. Advance the helical blade as far as possible by hand.

Use light hammer blows on the back of the connecting screw until the impactor comes to a stop at the back of the guide sleeve.

In the final position the yellow line on the guide sleeve is in alignment to the yellow line on the impactor.

The helical blade MUST be fully inserted.

▲ Precautions:

- Image intensifier should be used during helical blade insertion to monitor positioning.
- Assure that the guide wire is in place while inserting the helical blade to prevent the cannulation from clogging, impeding an optional augmentation procedure.

Option: Intraoperative exchange of the blade

Instrument	
03.010.523	Driving Cap with thread, for Insertion Handle

To intraoperatively exchange the helical blade, attach the driving cap/threaded to the back of the coupling screw. Use the hammer to back slap if needed.

Option B: Screw Insertion

8b. Tap for screw (optional)

Instrument	
03.037.027	Tap for TFNA Screw

The tap may be used to prepare a pathway for the screw.

■ Note:

Only use the tap in dense bone.

Pass the tap over the guide wire, through the guide sleeve and through the nail. Advance the tap manually by turning clockwise until the tip of the tap reaches the desired screw placement in the femoral head.

▲ Precautions:

- There is no stop on the tap, therefore monitoring insertion via the following methods is recommended:
  - Monitor the depth under image intensifier
  - Monitor the respective graduations of the instrument shaft in relation to the guide sleeve

Remove the tap by turning counterclockwise.

9b. Assemble screw

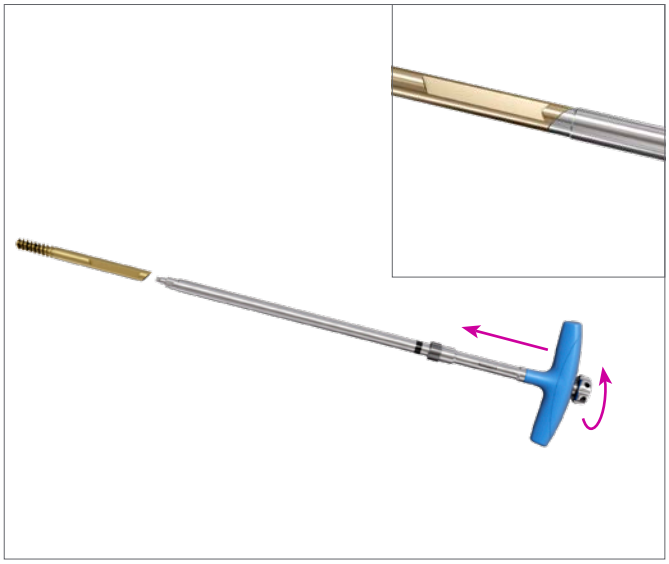
Instruments	
03.037.025	TFNA Screw Inserter
03.037.026	Connecting Screw for TFNA Helical Blade and Screw

Insert the connecting screw and thread in until it is fully captured in the screw inserter. The connecting screw will remain attached to the inserter.

Select the appropriate screw length as measured.

Align the back end of the screw with the inserter.

Further, thread the connecting screw into the screw and finger tighten the assembly.



10b. Insert screw

■ Starting notes:

- The screw advances 1.75 mm increments by turning the handle 180° (or 3.5 mm by turning 360°).
- When adjusting for final positioning, always rotate the handle clockwise, further engaging the screw in the bone. Do not rotate counterclockwise, as this will leave a gap between the screw and the bone.
- The screw can be over inserted a maximum of .1 (one) full turn.
- The etched image on the inserter indicates the orientation of the lateral oblique end of the screw.

Pass the screw insertion assembly over the guide wire, through the guide sleeve and through the nail. Advance the screw by turning the inserter clockwise until the line on the inserter meets the flange surface of the guide sleeve. At this depth the screw tip will be positioned at the tip of the guide wire. Assure that the inserter handle is aligned to the aiming arm. This is essential for proper engagement of the locking mechanism.

▲ Precautions:

- Image intensifier should be used during screw insertion to monitor positioning.
- Assure that the guide wire is in place while inserting the screw to prevent the cannulation from clogging, impeding an optional augmentation procedure.

11. Rotational locking

Engaging locking mechanism against rotation

Instrument	
03.037.028	Screwdriver, hexagonal 5.0 mm, flexible, cannulated

The preassembled locking mechanism in the nail must be advanced to control the rotation of the blade or screw. Pass the 5 mm flexible screwdriver through the cannulated connecting screw and insertion handle until it is seated in the hexagonal recess of the locking mechanism. Turn clockwise to advance the locking mechanism. Advance the screwdriver down until it stops completely, then back the screwdriver off by turning counterclockwise 1/2 turn (180 degrees). The helical blade or screw is now locked in rotation but can still slide.

▲ Precaution:

If the locking mechanism is not turned back 1/2 turn after initial tightening as described above, controlled collapse and compression of the fracture may not occur.

Option: Interfragmentary Compression

Option A: Helical blade compression

Instrument	
321.170	Pin Wrench ∅ 4.5 mm, length 120 mm

Once the helical blade has been locked in rotation, interfragmentary compression can be obtained by turning the buttress/compression nut clockwise by hand.
For additional leverage, use the pin wrench.

▲ Precaution:

Caution should be taken when using the buttress/compression nut with the pin wrench to avoid over compression that could potentially cause the helical blade to lose purchase in the bone, especially in patients with poor bone quality.

Option B: screw compression

Instruments	
03.037.116	Compression Nut for Inserter for TFNA Screw
321.170	Pin Wrench ∅ 4.5 mm, length 120 mm

Once the screw has been locked in rotation, interfragmentary compression can be obtained by mounting the compression nut onto the screw inserter. Turn it until it abuts the guide sleeve. Turn the buttress/compression nut clockwise by hand. For additional leverage, use the pin wrench.

▲ Precaution:

Caution should be taken when using the buttress/compression nut with the pin wrench to avoid over compression that could potentially cause the screw to lose purchase in the bone, especially in patients with poor bone quality.

Option: Static Locking

Option: Engage locking mechanism to restrict sliding (static locking)

Instruments	
03.037.029	Screwdriver Shaft, hexagonal 5.0 mm, with Hexagonal Coupling 6.0 mm, for static locking
03.140.023	Torque Limiter, 6 Nm, for AO / ASIF Quick Coupling for Reamer
03.010.496	T-Handle, cannulated, with Quick Coupling, Hex 12 mm
Alternative instrument	
03.231.018	Handle with Torque Limiting Function, 6 Nm

The helical blade or screw can be statically locked to restrict sliding of the blade/screw through the nail.

■ Note:

The blade or screw may slide after load is placed on the construct. The components enabling static locking are based on a friction fit, where the user tightens the locking mechanism down onto the surface of the blade/screw. In some instances, sliding may occur.

Assemble the torque limiter to the T-Handle and to the hexagonal screwdriver shaft.

Pass the static locking screwdriver assembly through the connecting screw and insertion handle until it is seated in the hexagonal recess of the locking mechanism.
Turn clockwise to further advance. Turn until the torque limiter releases. After one click, the optimal torque is reached and the helical blade or screw is statically locked.

■ Note:

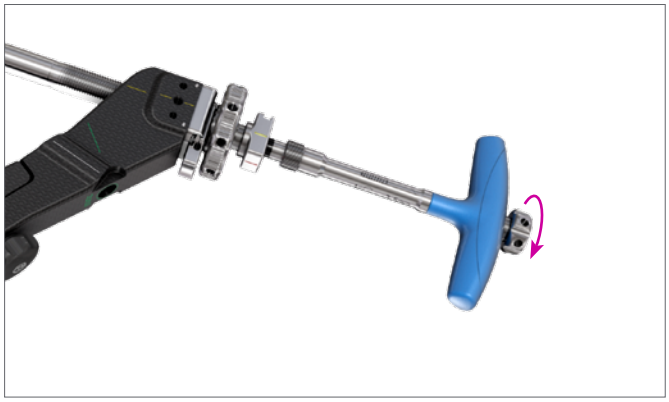
The torque limiter ensures that the correct torque is achieved to engage the locking mechanism against sliding.

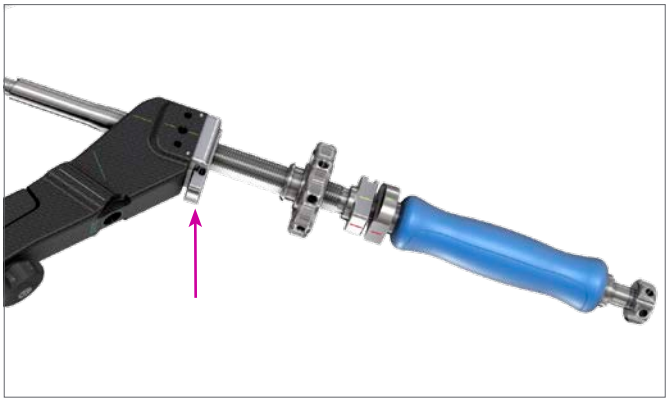
12. Remove proximal locking instruments

Disconnect the connecting screw from the helical blade or screw. If the connecting screw cannot be loosened by hand, use the flexible screwdriver or pin wrench to loosen the connection.

If no augmentation is planned, remove the guide sleeve/inserter assembly from the aiming arm by pushing the locking device on the aiming arm and pulling out the complete guide sleeve assembly. Remove guide wire.

If augmentation is planned, remove the helical blade impactor and leave the guide sleeve in place to facilitate augmentation.





Augmentation

■ Notes:

- Consult the Instructions for Use for the Intended Use, Indications/Contraindications, Warnings/Precautions of the “TRAUMACEM™ V+ Bone Cement, injectable”.
- Consult the Instructions for Use for the Intended Use, Warnings/Precautions of the “TRAUMACEM™ V+ Syringe Kit, 4 × 1 mL, 2.3 mm Adapter”.
- Consult the Instructions for Use for the Intended Use, Warnings/Precautions of the “TRAUMACEM™ V+ Syringe Kit, 4 × 1 mL, 2 × 2 mL”.
- Consult the manufacturer’s directions on Indications/ Contraindications of the radiographic contrast agent.

■ General notes:

- It is recommended to use 3 ml of cement for augmentation. The injected amount must not exceed 6 ml of cement.
- Aimed placement of cement is around the helical part of the blade/screw. The PMMA cement filling should have a distance of 6 mm–10 mm to the joint surface. Filling of the cavity lateral to the helical part of the blade/screw is not necessary.

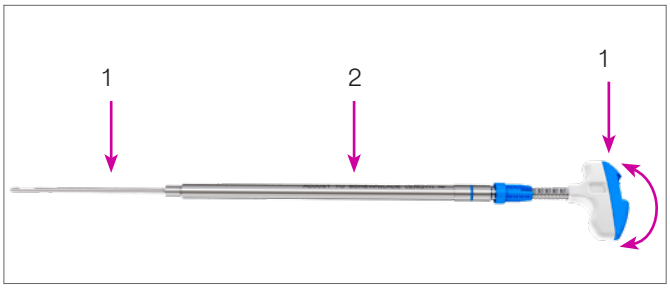
▲ Precaution:

The working time for TRAUMACEM V+ Injectable Bone Cement at room temperature (20 °C) is approximately 27 minutes. At body temperature (37 °C) the setting time is 15 minutes. After last cement injection, the patient should remain immobile for 15 minutes to facilitate proper cement curing.

1. Adjust sleeve of injection cannula

Instrument	
03.702.121S	TRAUMACEM V+ Injection Cannula, for TFNA System, sterile

Adjust the sleeve of the injection cannula to the selected head element length. Length adjustments are made by turning the injection cannula (1), while holding the sleeve (2).



2. Check for possible cement leakage into joint

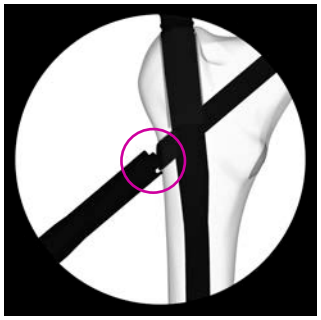
Instrument	
03.702.121S	TRAUMACEM V+ Injection Cannula, for TFNA System, sterile

Other materials
1–2 Syringes (6–10 ml) with Luer lock
Radiographic contrast agent
Saline solution

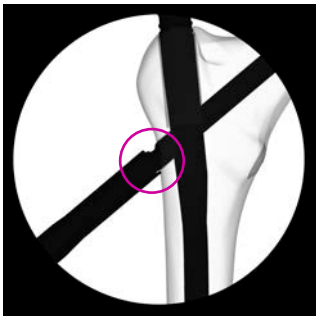
Attach the syringe with luer lock to the injection cannula and pre-fill the injection cannula with approximately 4 ml of radiographic contrast agent.

Insert the injection cannula through the guide sleeve into the helical blade/screw until the stop.

Confirm that the selected length on the injection cannula corresponds with the length of the helical blade/screw and verify under image intensification that the injection cannula is fully inserted.
At the correct position the tip of the sleeve has disappeared in the lateral end of the helical blade/screw.
Monitor the correct position of the sleeve throughout the procedure.



Wrong – tip of the sleeve visible



Correct – tip has disappeared in the screw/blade

Inject radiographic contrast agent into the femoral head and monitor the flow under image intensification.

Remove the injection cannula.

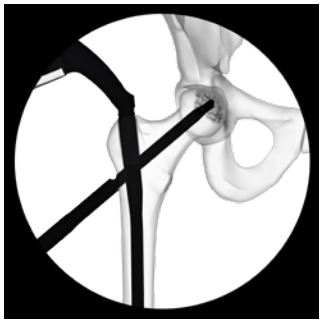
Wash the radiographic contrast agent out of the cannula and, if necessary, out of the femoral head using a saline solution and another syringe (6 – 10 ml), attached to the injection cannula.

▲ WARNING:

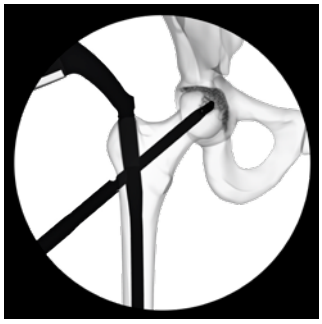
Do not augment if X-ray contrast media leaks into the joint.

▲ Precautions:

- Use only radiographic contrast agents that are indicated for this application.
- Consult the manufacturer's directions on indications, contraindications, use, precautions, warnings and side effects of the radiographic contrast agent.



No leakage into joint



Leakage into joint, do not augment

3. Prepare cement

Instrument	
07.702.040S	TRAUMACEM V+ Bone Cement, injectable, sterile

Hold the TRAUMACEM V+ Injectable Bone Cement mixer upright and gently slat with the finger tip at the top of the mixing device in order to ensure no cement powder sticks to the cartridge and sterilization lid.

Pull the handle until it is fully retracted.

■ Note:

During preparation, mixing and injection always handle the mixing device by gripping the blue part located directly below the transparent cartridge. If the transparent part is gripped, the excess body heat from the user's hand might result in a shorter working time than intended.

Open the glass ampoule by breaking the bottle neck with the plastic cap (1). Remove and dispose the mixing device sterilization lid. Pour all monomer from the glass ampoule into the cement powder (2) and close the mixing device tightly using the enclosed transferring lid.

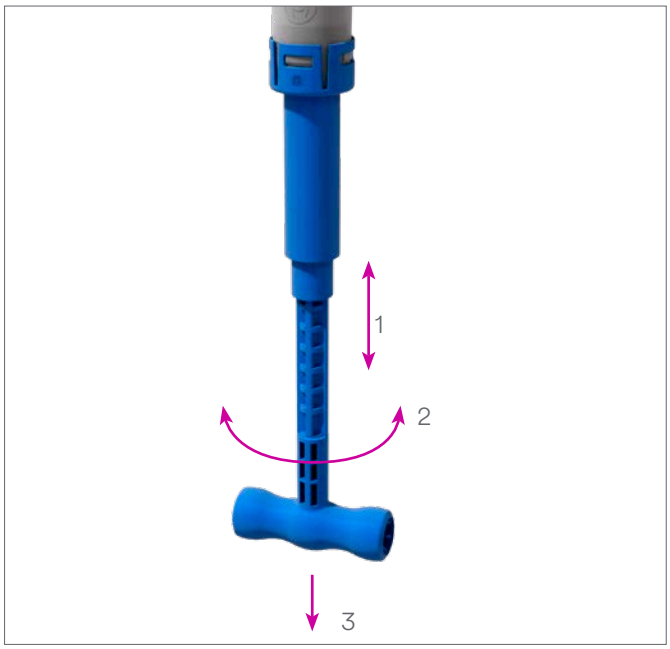
▲ Precaution:

Always use the full amounts of monomer liquid and polymer powder provided in the kit, respectively, when mixing TRAUMACEM V+ Injectable Bone Cement. Otherwise the behavior of the TRAUMACEM V+ Injectable Bone Cement can no longer be guaranteed. Using only one of the components is not permitted.

Mix the TRAUMACEM V+ Injectable Bone Cement by moving the blue handle back and forth from stop to stop approximately 20 times (1). Perform the first mixing strokes slowly with oscillating-rotating movements (2). After mixing fully retract the handle (3).

▲ Precaution:

Ensure that the powder and liquid component are thoroughly mixed before starting cement transfer.



4. Fill injection syringes

Instrument	
03.702.150S	TRAUMACEM V+ Syringe Kit, 4×1 mL, 2×2 mL, sterile

Once the cement has been prepared remove the small, transparent plug of the mixer lid (1). Connect the stop-cock (the side without the funnel) to the mixer. Ensure a tight fit between the mixer and the stop-cock (2).

▲ Precaution:

Ensure a good fit between the syringe and the stop-cock/ used access solution, but make sure to be on axis and avoid using excessive force when coupling them. They are both made of plastic and could otherwise break.

First remove the air from the system. With the valve open, gently turn the handle of the cement mixer clockwise. The mixer piston will advance in the translucent cartridge and a steady flow of cement will move into the stop-cock. As soon as the cement is visible in the stop-cock, close the valve (3).

■ Note:

Do not push to transfer cement.

Open

Close

Attach a 2 ml (white) syringe to the one way stop-cock (funnel side).

Open the one way stop-cock (the “off” sign facing away from the syringe).

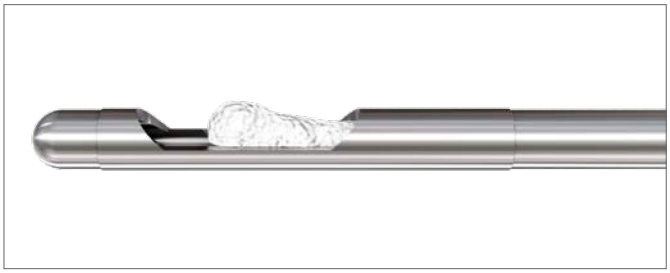
Gently turn the handle of the cement mixer clockwise to advance the piston. As soon as the syringe is filled, close the stop-cock again, by turning the “off” sign towards the mixer.

Disconnect the full syringe and attach the next syringe to be filled. Avoid spillage of cement into the funnel during the transfer process and remove excess cement to avoid accidental pollution of the protection sleeve, blade or screw. Continue to fill all the 1 ml (blue) and 2 ml (white) syringes in the same manner. Always fill all syringes.

5. Pre-fill the injection cannula with TRAUMACEM V+ Injectable Bone Cement

Instrument

03.702.121S	TRAUMACEM V+ Injection Cannula, for TFNA System, sterile



Attach a cement filled 2 ml syringe to the injection cannula. Pre-fill the injection cannula with the 2 ml of cement from the syringe. Attach another filled 2 ml syringe and fill the injection cannula until the cement is coming out of the side-opening, representing 4 ml of cement filled into the canal. Remove and discard the syringes. Attach a filled 1 ml syringe to the injectable cannula in preparation of the augmentation.

In case of cement leakage from the side opening, remove the excess cement in order to avoid accidental pollution of the protection sleeve or blade/screw.

■ Note:

1 ml syringes must be used to inject cement. The 2 ml syringes are not suited to augment the blade/screw. The force necessary to inject cement increases with time, as the cement sets. The required force also increases with increased syringe size. It is therefore advised to start using the 2 ml syringes first and the 1 mL syringes later.

6. Insert injection cannula

Confirm that the selected length on the injection cannula corresponds with the length of the helical blade/screw.

Insert the injection cannula through the guide sleeve into the blade/screw until the stop.

Verify under image intensification that the injection cannula is fully inserted.

7. Augmentation with TRAUMACEM V+ Injectable Bone Cement

Instrument	
03.702.121S	TRAUMACEM V+ Injection Cannula, for TFNA System, sterile

Injection of cement into the femoral head is performed using 1ml syringes.

Slowly inject TRAUMACEM V+ Injectable Bone Cement using 1ml syringes. Optimize the filling by rotating the handle to inject cement around the blade/screw and more medially or laterally.
A full turn of the sleeve corresponds to an adjustment of 5 mm.

▲ WARNING:

The 6-mm minimum distance is recommended to reduce the risk of thermal injury to the adjacent cartilage tissue.

Visualization of cement during injection must be assured. Continuously monitor the cement flow under image intensification.

▲ Precautions:

Do not advance the cannula more than 5 mm over the selected head element length. This would result in injection of cement in front of the head element tip where no additional stability is achieved and the risk of penetration and cement leakage is increased.

▲ WARNING:

In the event that there is danger of cement leakage into the joint, fracture gap or venous system, stop injection immediately.

■ Note:

The arrow on the handle indicates the position of the injection window of the cannula.

Options:

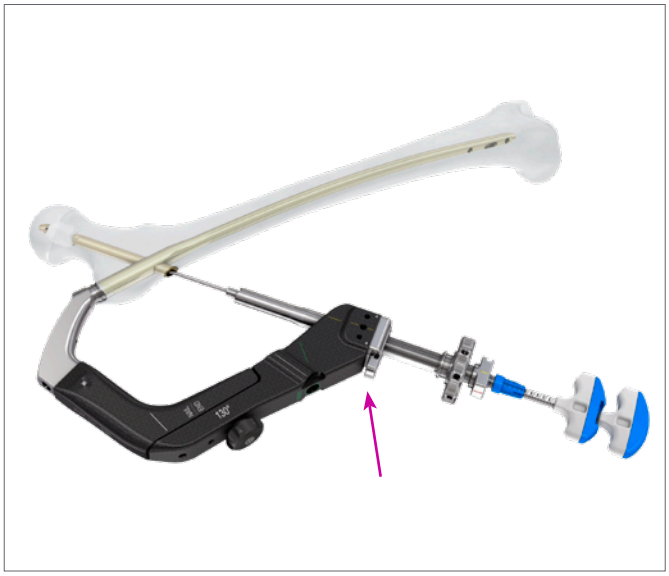
- Injection of cement can be continued using the plunger when the viscosity is increasing or the cement in the cavity of the injection cannula is necessary for augmentation. Approximately 3 ml of cement contained in the injection cannula can be injected with the plunger.
- Remove the 1 ml syringe and insert the plunger. Continue the injection using the plunger and optimize the filling by rotating the handle.

▲ WARNINGS:

- If the extravasated cement conforms to the architecture of the hip joint it may not need to be removed, however if it does not conform and is abrasive or damages the articular surface then the extruded cement will need to be removed.
- To remove the cement, the treating physician has the option of either hip arthroscopy, arthroplasty, or open arthrotomy to remove the extruded pieces. The timing of the removal is at the discretion of the physician after appropriate evaluation of the patient.

8. Remove the injection cannula

Push the locking device on the aiming arm to remove the injection cannula/guide sleeve assembly. Remove the injection cannula as soon as the injection is complete and the cement is still malleable.



Distal Locking – TFNA short

(170 mm, 200 mm and 235 mm)

1. Reconfirm reduction

Instrument	
03.010.491	Handle for Scalpel, long

Confirm reduction of the fracture with AP and lateral images.

Make a stab incision by sliding the scalpel through the hole of the aiming arm.

2. Drill and measure for locking screw

Instruments	
03.025.040	Protection Sleeve, 11.0 / 8.0, length 188 mm
03.010.065	Drill Sleeve 8.0 / 4.2, for No. 03.010.063
03.010.070	Trocar ∅ 4.2 mm, for No. 03.010.065
03.010.061*	Drill Bit ∅ 4.2 mm, calibrated, length 340 mm, 3-flute, for Quick Coupling, for No. 03.010.065
Alternative Instruments	
03.045.022*	Drill Bit ∅ 4.2 mm, calibrated, 120 mm
03.045.019	Protection Sleeve, ∅ 11/8
03.045.020	Drill Sleeve, ∅ 4.2 mm

Insert the green triple trocar assembly through the aiming arm to the bone.

■ Note:

Using a light hammer blow, hit the trocar into the bone to create an indentation in the bone which will help prevent the drill bit from skiving off the bone.

* Available non-sterile or sterile packed. Add “S” to the article number to order sterile products.

Remove the trocar and drill through both cortices using the calibrated 4.2 mm three-fluted drill bit.

Read the length of the locking screw directly from the drill bit at the back of the drill sleeve. Press the drill sleeve to the bone to ensure accurate measurement.

▲ Precaution:

Select adequate screw length to avoid protrusion of the screw tip and irritation of soft tissue.

Alternative technique

Instrument	
03.010.428	Depth Gauge for Locking Screws, measuring range to 110 mm
or	
03.010.072	Depth Gauge for Locking Screws, measuring range up to 110 mm, for No. 03.010.063
Alternative Instrument	
03.019.017	Depth gauge for Locking Screws, measuring range up to 100 mm

The depth gauge for locking screws may be used through the protection sleeve to determine locking screw length. Remove the drill sleeve and pass the measuring hook through the protection sleeve. Read locking screw length directly from the measuring device at the back of the protection sleeve.

3. Insert locking screw

Instruments	
03.010.518	Screwdriver STARDRIVE™, T25, self-holding, length 319 mm
03.025.040	Protection Sleeve 11.0 / 8.0, length 188 mm

Insert the appropriate 5.0 mm locking screw through the protection sleeve using the appropriate STARDRIVE screwdriver.

Remove the protection sleeve and aiming arm.

■ Note:

If using retaining screws please refer to addendum A for surgical technique and instruments.

Freehand Distal Locking – TFNA long

1. Distal Locking

Distal locking of the long nail is performed with the freehand technique.

There are three distal locking options:

- Two transverse, lateral to medial holes
- One of the holes is static and the other allows for static or dynamic locking options
- One oblique locking hole for stability in trochanteric fractures with a shaft fracture. This is the most distal hole.

Alternatively distal locking can be performed using the SURELOCK System and the corresponding surgical technique.

■ Note:

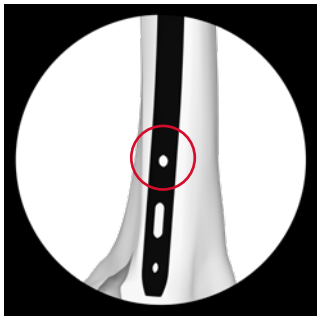
The SURELOCK System will only target the two most proximal distal locking holes in the long nail and only works with the TFNA long nails from 280 mm to 460 mm.

2. Align image

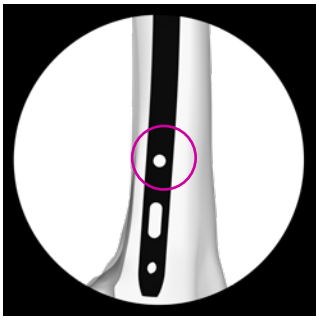
- Confirm reduction of the fracture with AP and lateral images.
- Align the image intensifier with the hole in the nail until a perfect circle is visible in the center of the screen.

▲ Precaution:

Confirm that the nail is securely connected to the insertion handle, especially after hammering.



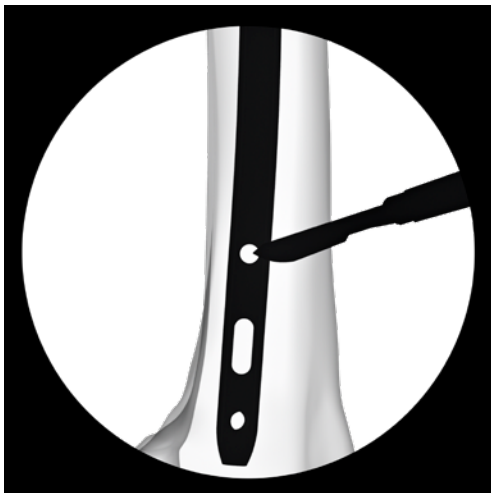
Not aligned.



Aligned.

3. Determine incision point

- Place a scalpel blade on the skin over the center of the hole to mark the incision point and make a stab incision.



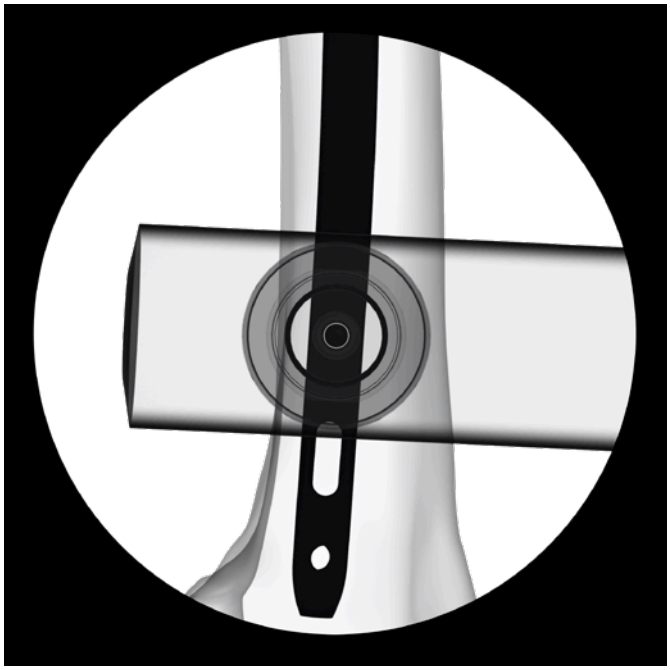
4. Drill

Instrument	
03.010.101	Drill Bit ∅ 4.2 mm, calibrated, length 145 mm, 3-flute, with Coupling for RDL

Insert the drill into the radiolucent drive and insert it, through the incision, down to the bone.

Incline the drive so that the tip of the drill bit is centered over the locking hole. The drill bit should almost completely fill the circle of the locking hole. Hold the drill bit in this position and drill through both cortices.

Stop drilling immediately after perforation of both cortices and disassemble the drill bit from the power equipment.



■ Note:

For greater drill bit control, discontinue drill bit power after perforating the near cortex. Manually guide the drill bit through the nail before resuming power to drill the far cortex.

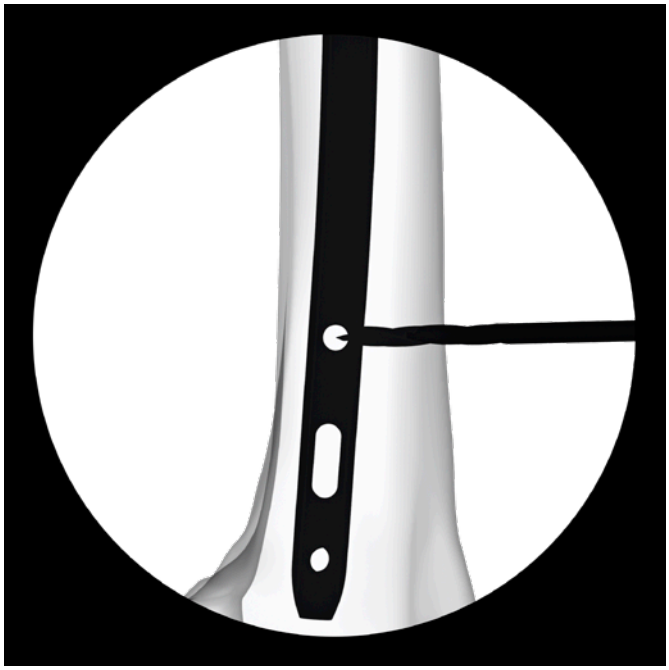
Alternative instrument

03.010.104*	Drill Bit ∅ 4.2 mm, calibrated, length 145 mm, 3-flute, for Quick Coupling

■ Note:

Before inserting the drill bit in the power tool, determine the right drilling position and fix the position with a light hammer tap on the back of the drill bit.

Stop drilling immediately after perforation of both cortices and disassemble the drill bit from the power equipment.



* Available non-sterile or sterile packed. Add “S” to the article number to order sterile products.

5. Measure for screw length

Instruments	
03.010.106	Direct Measuring Device for Drill Bits of length 145 mm, for Nos. 03.010.100 to 03.010.105
or 03.010.429	Direct Measuring Device for Drill Bits, length 145 mm

Slide the measuring device onto the drill bit.

Ensure correct position of the drill bit beyond the far cortex, and that the measuring device is against the bone.

Read the measurement on the measuring device at the end of the drill bit, not from the green line.

■ Note:

Correct placement of the drill bit and measuring device are important for accurate locking screw length measurement.

▲ Precaution:

Select adequate screw length to avoid protrusion of the screw tip and irritation of soft tissue.

Alternative instrument

03.010.428	Depth Gauge for Locking Screws, measuring range to 110 mm
or	
03.010.072	Depth Gauge for Locking Screws, measuring range up to 110 mm, for No. 03.010.063
or	
03.010.019	Depth Gauge for Locking Screws, measuring range up to 110 mm, for No. 03.010.009
or	
03.019.017	Depth Gauge for Locking Screws, measuring range up to 100 mm

Measure the locking screw length using the depth gauge. Ensure the outer sleeve is in contact with the bone and the hook grasps the far cortex.

Ensure the correct position of the depth gauge beyond the far cortex.

Read the locking screw length directly from the depth gauge at the back of the outer sleeve.

6. Insert locking screw

Instruments	
03.010.518	Screwdriver STARDRIVE™, T25, self-holding, length 319 mm
or	
03.010.473	Inter-Lock Screwdriver, combined, STARDRIVE™, T25/hexagonal ∅ 3.5, length 224 mm

■ Notes:

- If using retaining screws please refer to addendum A for surgical technique and instruments.
- For Optional Nut and Washer Technique, please refer to addendum A.

Insert the appropriate length screw using the screwdriver.

Verify locking screw length under image intensification.

Repeat steps 2 to 6 for the second and third proximal locking screw if the fracture necessitates additional distal fixation.

Insert End Cap

1. Insert end cap

Instruments	
03.010.517	Screwdriver, hexagonal ∅ 8.0 mm, with T-Handle, with spherical head, length 322 mm
03.010.520	Screwdriver STARDRIVE™, T40, with spherical head, cannulated, length 277 mm
357.399*	Guide Wire ∅ 3.2 mm, length 400 mm
Alternative instruments	
03.037.028	Screwdriver, hexagonal 5.0 mm, flexible, cannulated
03.045.018*	Guide Wire ∅ 3.2 mm, w/drill tip, 400 mm
03.043.027	Screwdriver, hexagonal ∅ 8.0 mm, with T-handle, spherical head

Use of an end cap is recommended if bony ingrowth into the proximal end of the nail is of concern. Also, in reverse oblique intertrochanteric and high subtrochanteric fractures, the nail should be slightly proud of the greater trochanter to provide an added point of fixation. If the nail has been over inserted, it should be extended by the use of an end cap of appropriate length.

■ Notes:

- The insertion depth of the nail is indicated by the rings on the insertion handle. Starting distally, each ring is an additional 5 mm from the tip of the nail. This will help in end cap selection.
- For use of retaining end caps, please refer to addendum A.

* Available non-sterile or sterile packed. Add “S” to the article number to order sterile products.

Inserting the 0 mm end cap

Remove the connecting screw using the ball hexagonal screwdriver with spherical head while leaving the insertion handle connected to the nail.

Insert the 0 mm end cap using the STARDRIVE screwdriver through the insertion handle. A guide wire can be used to help ensure alignment while inserting the end cap.

After the end cap is inserted, remove the insertion handle from the nail.

Inserting the 0 mm end cap.

Inserting the 5 – 15 mm end cap

Remove the connecting screw and insertion handle using the hexagonal screwdriver with spherical head.

Insert the end cap using the STARDRIVE screwdriver. A guide wire can be used to help ensure alignment while inserting the end cap.

■ Note:

In case of difficulties to remove the connecting screw, push the insertion handle towards medial or lateral to neutralize soft tissue pressure.

Inserting the 5–15 mm end cap.

Option: Standard Removal

1. Remove End-Cap and distal locking screw

Instruments	
03.037.030	Extraction Instrument for TFNA Helical Blade and Screw
03.037.032	Extraction Instrument for Nails, cannulated
03.010.520	Screwdriver STARDRIVE™, T40, with spherical head, cannulated, length 277 mm
356.717	Guide Wire ∅ 2.8 mm, 460 mm length, with Hook
356.715	Socket, hexagonal, ∅ 11.0/11.0 mm, cannulated, for AFN
Alternative instrument	
03.037.028	Screwdriver, hexagonal 5.0 mm, flexible, cannulated

Use the STARDRIVE screwdriver to remove the end cap, optionally assisted by use of the guide wire with hook.

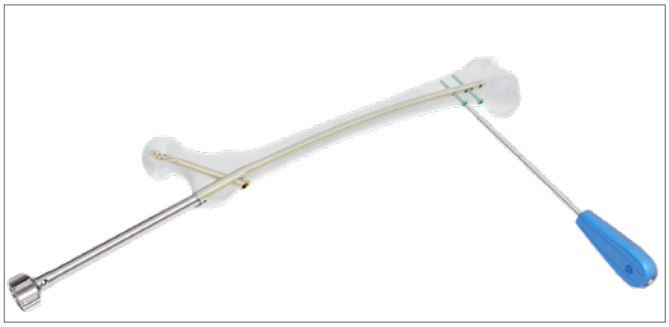
Option: For removal of 5 mm, 10 mm and 15 mm end caps, the hexagonal socket 11.0 mm (356.715) can also be used.

Thread the extraction instrument for Nails into the top of the nail.

■ Note:

It may be easier to align the nail extractor if the flexible screwdriver is passed through the nail extractor first and then both instruments engage in the top of the nail.

Remove the distal locking screws using the STARDRIVE screwdriver.



▲ Precaution:

Do not attempt to remove the nail at this point.

2. Disengage locking mechanism and remove helical blade or screw

Instruments	
03.037.030	Extraction Instrument for TFNA Helical Blade and Screw
03.010.522	Combined Hammer, 500 g
03.010.518	Screwdriver STARDRIVE™, T25, self-holding, length 319 mm
03.010.170	Hammer Guide
03.037.031	Wrench, hexagonal socket 11/Blade-Screw
03.037.028	Screwdriver, hexagonal 5.0 mm, flexible, cannulated

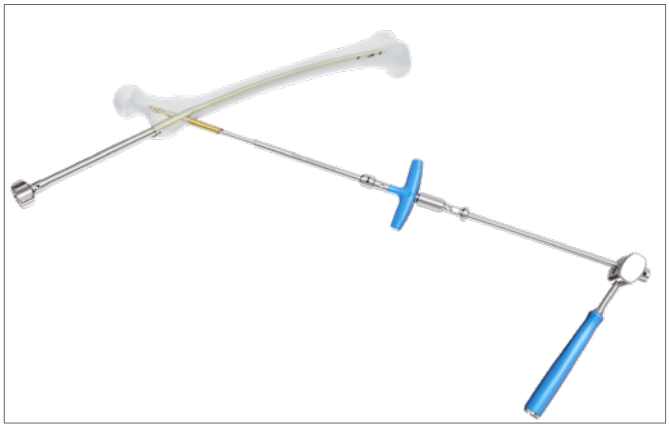
Check the recess in the helical blade or screw before attaching the extraction instrument.

In case of ingrown tissue or blockage with cement clean the recess with a sharp hook.

Thread the extraction instrument for helical blade/screw into the implant by turning counterclockwise.
Do not yet extract the helical blade/screw.

Pass the hexagonal flexible screwdriver through the instrument and engage the hex in the locking mechanism. Turn counterclockwise to the stop to disengage the locking mechanism.

For the helical blade removal, slide the hammer over the helical blade/screw extractor and use light hammer blows, hammer until the helical blade is removed from the bone.

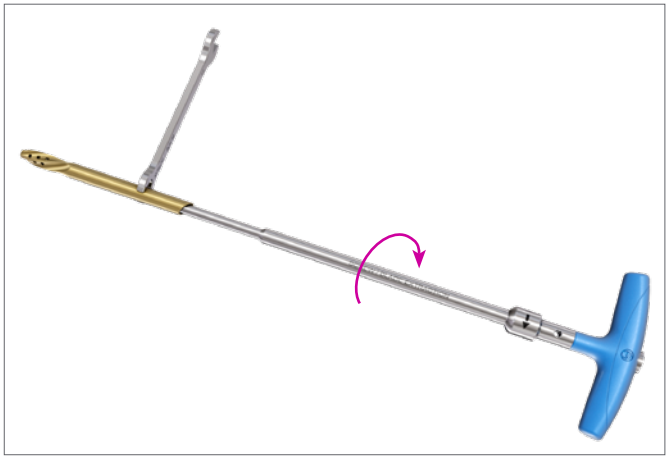


■ Note:

The hammer guide may be threaded in the back of the helical blade/screw extractor to extend the working length and thus support the removal.

For the screw removal, continue to turn counterclockwise with a slight pulling force until the screw is removed from the bone.

The end of the combination wrench marked “BLADE/SCREW” can be attached to the helical blade or screw. To remove the helical blade or screw from the extraction instrument rotate clockwise.



3. Extract nail

Instruments	
03.010.170	Hammer Guide
03.010.522	Combined Hammer, 500 g

To remove the nail, thread the hammer guide onto the back end of the nail extraction instrument. Attach the combined hammer to the hammer guide and then use light hammer blows to extract the nail.

After the nail has been extracted from the bone, dissemble the extractor from the nail.

Option: Extraction Hook (Broken Nail)

Instruments	
355.399	Extraction Hook ∅ 3.7 mm, for Cannulated Nails
393.100	Universal Chuck with T-Handle
Alternative Instrument	
03.043.001	Universal Chuck

Begin with Steps 1 and 2 of Standard Implant Removal.

Option 1

1. Assemble extraction hook and universal chuck

Insert the extraction hook into the universal chuck with T-Handle. The hook should be parallel with the T-Handle. This facilitates visualization of the hook position in the bone.

2. Insert extraction hook through nail

Remove the nails extraction instrument and pass the extraction hook through the cannula of the nail, including the distant fragment.

■ Note:

Under image intensification, verify that the hook has passed through and engaged the distant end of the nail.

3. Extract nail

Extract both nail fragments.

■ Note:

Keep the patient's limb restrained to increase the efficiency of the extraction force.

Option 2

1. Remove near nail fragment

Remove the near nail fragment using the technique described in step 3 of the implant removal.

■ Note:

The extraction hook can be used as an alternative to extraction instrumentation.

2. Ream canal

Ream the medullary canal 1mm larger than the nail diameter to clear a path for the distant nail fragment.

■ Note:

Use image intensification to verify position/depth of the reamer to avoid contacting the distant nail fragment.

3. Align extraction hook

Insert the extraction hook and explanted near nail fragment into the medullary canal. The near nail fragment aligns the extraction hook with the cannulation of the distant nail fragment.

4. Engage distant fragment

Pass the extraction hook through the cannula of the distant nail fragment.

■ Note:

Under image intensification, verify that the hook has passed through and engaged the distant end of the nail.

5. Extract nail

Extract both nail fragments.

■ Note:

Keep the patient's limb restrained to increase the efficiency of the extraction force.

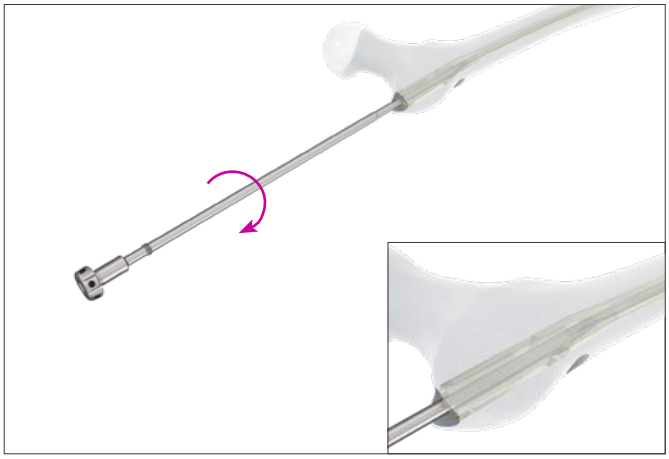
Alternative Technique – Coupling Screw for removal of broken nail

Instruments

03.037.026	Helical Blade and Screw Coupling Screw

Optional instruments

03.010.523	Driving cap threaded
03.010.522	Spiral Combination Hammer 500 Grams



■ Note:

The coupling screw may be used in instances where the nail is broken at the proximal hole and is in two pieces. For removal of the near fragment, use Steps 1 and 2 of Implant Removal. For removal of the distant nail fragment, this alternative technique may be used.

Begin with step 1 and 2 of Implant Removal.

1. Remove near nail fragment

Remove the near nail fragment using the technique described in step 3 of the implant removal.

2. Ream canal

Ream the proximal femur to 17 mm to clear a path for the distant nail fragment.

■ Note:

- Use image intensification to verify position/depth of the reamer to avoid contacting the distant nail fragment.

3. Engage distant fragment

Thread the coupling screw into the distant nail fragment.

■ Notes:

- The coupling screw is cannulated. If the extraction hook is already in the nail, the coupling screw may be inserted over the extraction hook. Once the nail is engaged with the coupling screw, the extraction hook may be removed.
- A reaming rod may also be used to help guide the coupling screw into the nail thread. If using the reaming rod, insert the end opposite of the ball tip through the back of the coupling screw before inserting the reaming rod into the nail. This will allow guided insertion of the coupling screw and the ability to remove the reaming rod before attaching the threaded driving cap.
- Under image intensification, verify that the coupling screw has engaged the distant nail fragment.

4. Extract nail

If hammering is required to remove the distant nail fragment, remove the extraction hook or reaming rod if used, and attach the threaded driving cap into the back of the coupling screw for extraction. Slide the spiral combination hammer over the driving cap and using light hammer blows, hammer until the nail is removed from the bone. Extract distant nail fragment.

Checking Fixation Sleeve Wear

Instruments

03.037.022*	Stepped Reamer for TFNA Helical Blade and Screw for Quick Coupling for DHS™/DCS™
03.037.023	Fixation Sleeve for Stepped Reamer

Possible damage

If excessive wear occurs, the fixation sleeve can slip, resulting in incorrect drilling depth.

Before use:

- Slide the fixation sleeve onto the drill bit.
- Press on the fixation sleeve with the thumb without pressing the button. If the fixation sleeve moves under pressure, replace it.
- Do the same test in the opposite direction. If the fixation sleeve moves, replace it.

Recommendations:

- Drill only under periodic image intensifier control.
- While drilling, do not force.
- Replace fixation sleeves that do not pass the described wear test.

* Available non-sterile or sterile packed. Add “S” to the article number to order sterile products.

TFNA Nails

Material

- Titanium alloy* (TiMo)
- Color: green

Locking Mechanism

- Material of Locking mechanism can be found in the corresponding TFN-ADVANCED™ Proximal Femoral Nailing System Instructions for Use
- Color: green

Lengths

TFNA short:

- 170 mm
- 200 mm
- 235 mm left/235 mm right

TFNA long:

- 260 mm–480 mm (left and right nails, 20 mm increments)

Diameters

Distal:

- Short nails: ∅ 9, ∅ 10, ∅ 11, ∅ 12
- Long nails: ∅ 9, ∅ 10, ∅ 11, ∅ 12, ∅ 14

CCD Angle

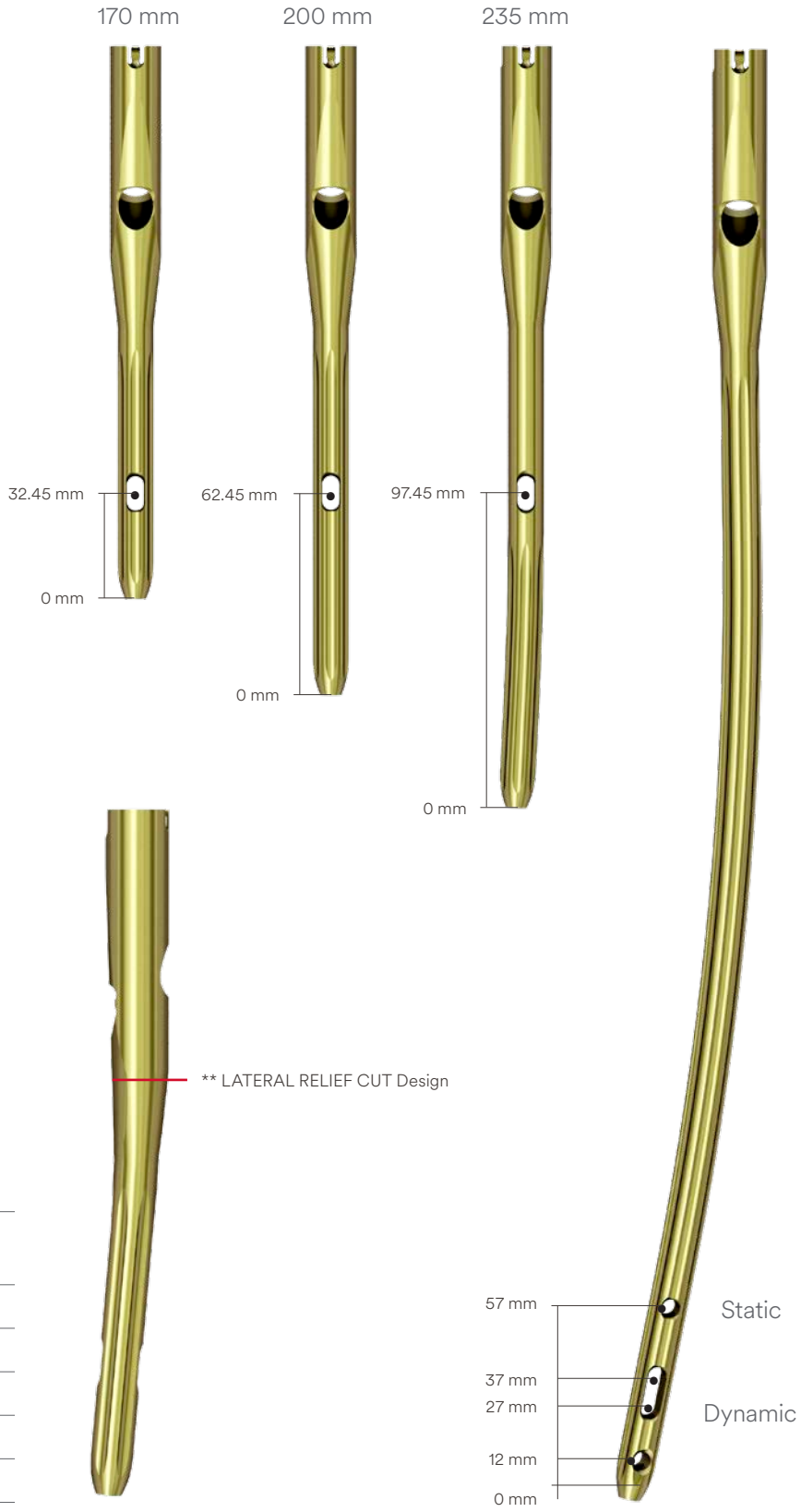
- 125°/130°/135°

Nail features

- Proximal diameter 15.66 mm
- 5° ML angle
- Preassembled locking mechanism
- Anterior Posterior bend, 1.0 m radius of curvature
- LATERAL RELIEF CUT™

TFNA Nail	LATERAL RELIEF CUT DESIGN**
9 mm	13.4 mm
10 mm	13.7 mm
11 mm	14.1 mm
12 mm	14.5 mm
14 mm	15.2 mm

* Ti-15Mo



TFNA Head Elements

TFNA Helical Blades and TFNA Screws

Material:

- Titanium alloy* (TAN)
- Color: gold

TFNA Helical Blades, perforated, sterile

	Length (mm)
04.038.370S	70
04.038.375S	75
04.038.380S	80
04.038.385S	85
04.038.390S	90
04.038.395S	95
04.038.400S	100
04.038.405S	105
04.038.410S	110
04.038.415S	115
04.038.420S	120
04.038.425S	125
04.038.430S	130

TFNA Screws, perforated, sterile

	Length (mm)
04.038.170S	70
04.038.175S	75
04.038.180S	80
04.038.185S	85
04.038.190S	90
04.038.195S	95
04.038.200S	100
04.038.205S	105
04.038.210S	110
04.038.215S	115
04.038.220S	120
04.038.225S	125
04.038.230S	130

*Ti-6Al-7Nb

TFNA, short, length 170 mm

	Dia. (mm)	Angle
04.037.912S	9	125°
04.037.942S	9	130°
04.037.972S	9	135°
04.037.012S	10	125°
04.037.042S	10	130°
04.037.072S	10	135°
04.037.112S	11	125°
04.037.142S	11	130°
04.037.172S	11	135°
04.037.212S	12	125°
04.037.242S	12	130°
04.037.272S	12	135°

TFNA, short, length 235 mm

Right	Left	Dia. (mm)	Angle
04.037.914S	04.037.915S	9	125°
04.037.944S	04.037.945S	9	130°
04.037.974S	04.037.975S	9	135°
04.037.014S	04.037.015S	10	125°
04.037.044S	04.037.045S	10	130°
04.037.074S	04.037.075S	10	135°
04.037.114S	04.037.115S	11	125°
04.037.144S	04.037.145S	11	130°
04.037.174S	04.037.175S	11	135°
04.037.214S	04.037.215S	12	125°
04.037.244S	04.037.245S	12	130°
04.037.274S	04.037.275S	12	135°

TFNA, short, length 200 mm

	Dia. (mm)	Angle
04.037.913S	9	125°
04.037.943S	9	130°
04.037.973S	9	135°
04.037.013S	10	125°
04.037.043S	10	130°
04.037.073S	10	135°
04.037.113S	11	125°
04.037.143S	11	130°
04.037.173S	11	135°
04.037.213S	12	125°
04.037.243S	12	130°
04.037.273S	12	135°

TFNA, ∅ 9 mm, long

Right	Left	Length (mm)	Angle
04.037.916S	04.037.917S	260	125°
04.037.918S	04.037.919S	280	125°
04.037.920S	04.037.921S	300	125°
04.037.922S	04.037.923S	320	125°
04.037.924S	04.037.925S	340	125°
04.037.926S	04.037.927S	360	125°
04.037.928S	04.037.929S	380	125°
04.037.930S	04.037.931S	400	125°
04.037.932S	04.037.933S	420	125°
04.037.934S	04.037.935S	440	125°
04.037.936S	04.037.937S	460	125°
04.037.938S	04.037.939S	480	125°
04.037.946S	04.037.947S	260	130°
04.037.948S	04.037.949S	280	130°
04.037.950S	04.037.951S	300	130°
04.037.952S	04.037.953S	320	130°
04.037.954S	04.037.955S	340	130°
04.037.956S	04.037.957S	360	130°
04.037.958S	04.037.959S	380	130°
04.037.960S	04.037.961S	400	130°
04.037.962S	04.037.963S	420	130°
04.037.964S	04.037.965S	440	130°
04.037.966S	04.037.967S	460	130°
04.037.968S	04.037.969S	480	130°

TFNA, ∅ 10 mm, long

Right	Left	Length (mm)	Angle
04.037.016S	04.037.017S	260	125°
04.037.018S	04.037.019S	280	125°
04.037.020S	04.037.021S	300	125°
04.037.022S	04.037.023S	320	125°
04.037.024S	04.037.025S	340	125°
04.037.026S	04.037.027S	360	125°
04.037.028S	04.037.029S	380	125°
04.037.030S	04.037.031S	400	125°
04.037.032S	04.037.033S	420	125°
04.037.034S	04.037.035S	440	125°
04.037.036S	04.037.037S	460	125°
04.037.038S	04.037.039S	480	125°
04.037.046S	04.037.047S	260	130°
04.037.048S	04.037.049S	280	130°
04.037.050S	04.037.051S	300	130°
04.037.052S	04.037.053S	320	130°
04.037.054S	04.037.055S	340	130°
04.037.056S	04.037.057S	360	130°
04.037.058S	04.037.059S	380	130°
04.037.060S	04.037.061S	400	130°
04.037.062S	04.037.063S	420	130°
04.037.064S	04.037.065S	440	130°
04.037.066S	04.037.067S	460	130°
04.037.068S	04.037.069S	480	130°

TFNA, ∅ 11 mm, long

Right	Left	Length (mm)	Angle
04.037.120S	04.037.121S	300	125°
04.037.122S	04.037.123S	320	125°
04.037.124S	04.037.125S	340	125°
04.037.126S	04.037.127S	360	125°
04.037.128S	04.037.129S	380	125°
04.037.130S	04.037.131S	400	125°
04.037.132S	04.037.133S	420	125°
04.037.134S	04.037.135S	440	125°
04.037.136S	04.037.137S	460	125°
04.037.138S	04.037.139S	480	125°
04.037.150S	04.037.151S	300	130°
04.037.152S	04.037.153S	320	130°
04.037.154S	04.037.155S	340	130°
04.037.156S	04.037.157S	360	130°
04.037.158S	04.037.159S	380	130°
04.037.160S	04.037.161S	400	130°
04.037.162S	04.037.163S	420	130°
04.037.164S	04.037.165S	440	130°
04.037.166S	04.037.167S	460	130°
04.037.168S	04.037.169S	480	130°
04.037.180S	04.037.181S	300	135°
04.037.182S	04.037.183S	320	135°
04.037.184S	04.037.185S	340	135°
04.037.186S	04.037.187S	360	135°
04.037.188S	04.037.189S	380	135°
04.037.190S	04.037.191S	400	135°
04.037.192S	04.037.193S	420	135°
04.037.194S	04.037.195S	440	135°
04.037.196S	04.037.197S	460	135°
04.037.198S	04.037.199S	480	135°

TFNA, ∅ 12 mm, long

Right	Left	Length (mm)	Angle
04.037.220S	04.037.221S	300	125°
04.037.222S	04.037.223S	320	125°
04.037.224S	04.037.225S	340	125°
04.037.226S	04.037.227S	360	125°
04.037.228S	04.037.229S	380	125°
04.037.230S	04.037.231S	400	125°
04.037.232S	04.037.233S	420	125°
04.037.234S	04.037.235S	440	125°
04.037.236S	04.037.237S	460	125°
04.037.238S	04.037.239S	480	125°
04.037.250S	04.037.251S	300	130°
04.037.252S	04.037.253S	320	130°
04.037.254S	04.037.255S	340	130°
04.037.256S	04.037.257S	360	130°
04.037.258S	04.037.259S	380	130°
04.037.260S	04.037.261S	400	130°
04.037.262S	04.037.263S	420	130°
04.037.264S	04.037.265S	440	130°
04.037.266S	04.037.267S	460	130°
04.037.268S	04.037.269S	480	130°

TFNA, ∅ 14 mm, long

Right	Left	Length (mm)	Angle
04.037.450S	04.037.451S	300	130°
04.037.452S	04.037.453S	320	130°
04.037.454S	04.037.455S	340	130°
04.037.456S	04.037.457S	360	130°
04.037.458S	04.037.459S	380	130°
04.037.460S	04.037.461S	400	130°
04.037.462S	04.037.463S	420	130°
04.037.464S	04.037.465S	440	130°
04.037.466S	04.037.467S	460	130°
04.037.468S	04.037.469S	480	130°

Locking Screws

Material

- Titanium alloy** (TAN)
- Color: light green

Drill

- 4.2 mm diameter

Lengths

- 26 mm – 80 mm (2 mm increments)
- 80 mm – 100 mm (5 mm increments)

Design

- Recess: STARDRIVE T25

Locking Screws*, ∅ 5 mm

	Length (mm)		Length (mm)
04.005.516	26	04.005.548	58
04.005.518	28	04.005.550	60
04.005.520	30	04.005.552	62
04.005.522	32	04.005.554	64
04.005.524	34	04.005.556	66
04.005.526	36	04.005.558	68
04.005.528	38	04.005.560	70
04.005.530	40	04.005.562	72
04.005.532	42	04.005.564	74
04.005.534	44	04.005.566	76
04.005.536	46	04.005.568	78
04.005.538	48	04.005.570	80
04.005.540	50	04.005.575	85
04.005.542	52	04.005.580	90
04.005.544	54	04.005.585	95
04.005.546	56	04.005.590	100

* All screws available non-sterile or in sterile packaging. Corresponding sterile article number with suffix “TS” for tube packaging or “S” for standard pouch packaging.
**Ti-6Al-7Nb

Locking Screws for Medullary Nails

Material

- Titanium alloy** (TAN)
- Color: light green

Drill

- 4.2 mm diameter

Lengths

- 26 mm–88 mm (2 mm increments)
- 90 mm–120 mm (5 mm increments)

Design

- Recess: XL25

Standard Locking Screw

Low-Profile Locking Screw

Locking Screws for Medullary Nail*, ∅ 5 mm

	Length (mm)		Length (mm)
04.045.026	26	04.045.066	66
04.045.028	28	04.045.068	68
04.045.030	30	04.045.070	70
04.045.032	32	04.045.072	72
04.045.034	34	04.045.074	74
04.045.036	36	04.045.076	76
04.045.038	38	04.045.078	78
04.045.040	40	04.045.080	80
04.045.042	42	04.045.082	82
04.045.044	44	04.045.084	84
04.045.046	46	04.045.086	86
04.045.048	48	04.045.088	88
04.045.050	50	04.045.090	90
04.045.052	52	04.045.095	95
04.045.054	54	04.045.100	100
04.045.056	56	04.045.105	105
04.045.058	58	04.045.110	110
04.045.060	60	04.045.115	115
04.045.062	62	04.045.120	120
04.045.064	64		

Low-Profile Locking Screws for Medullary Nail*, ∅ 5 mm

	Length (mm)		Length (mm)
04.045.326	26	04.045.366	66
04.045.328	28	04.045.368	68
04.045.330	30	04.045.370	70
04.045.332	32	04.045.372	72
04.045.334	34	04.045.374	74
04.045.336	36	04.045.376	76
04.045.338	38	04.045.378	78
04.045.340	40	04.045.380	80
04.045.342	42	04.045.382	82
04.045.344	44	04.045.384	84
04.045.346	46	04.045.386	86
04.045.348	48	04.045.388	88
04.045.350	50	04.045.390	90
04.045.352	52	04.045.395	95
04.045.354	54	04.045.400	100
04.045.356	56	04.045.405	105
04.045.358	58	04.045.410	110
04.045.360	60	04.045.415	115
04.045.362	62	04.045.420	120
04.045.364	64		

* All screws available non-sterile or in sterile packaging. Corresponding sterile article number with suffix “TS” for tube packaging or “S” for standard pouch packaging.
**Ti-6Al-7Nb

End Caps

Material

- Titanium alloy** (TAN)
- Color: green

Lengths

- 0 mm (sits flush with nail end)
  5 mm/10 mm and 15 mm extensions

Design

- Recess: STARDRIVE T40, Hexagonal 5.0 mm

0 mm 5 mm 10 mm 15 mm

End Caps, sterile

Extension (mm)	
0	04.038.000S
5	04.038.005S
10	04.038.010S
15	04.038.015S

Retaining End Caps

Material

- Titanium alloy** (TAN)
- Color: green

Lengths

- 0 mm (sits flush with nail end)
  5 mm/10 mm and 15 mm extensions

Design

- Recess: XL40

0 mm 5 mm 10 mm 15 mm

End Caps, sterile

Extension (mm)	
0	04.045.870S
5	04.045.875S
10	04.045.880S
15	04.045.885S

**Ti-6Al-7Nb

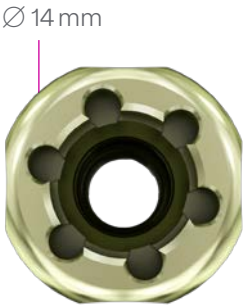
Titanium Nuts and Washers for Locking Screws

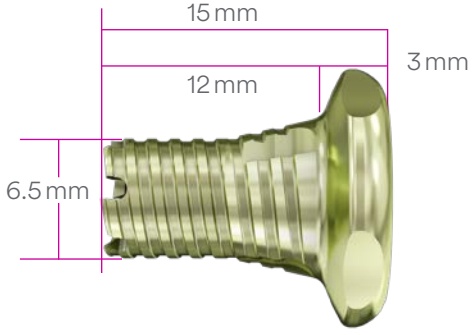
Titanium Nuts and Washers for Locking Screws

- Washers are made from Titanium, Nut is made from Titanium alloy
- Nut is inserted over standard locking screws, either at the screw tip or screw head
- Washer for Nut, 1.1 mm thickness, to increase overall diameter to 17 mm
- Washer for Screw, 1.2 mm thickness, to increase the overall diameter to 14 mm

04.045.780S	Washer for Screw
04.045.781S	Nut
04.045.782S	Washer for Nut

04.045.780S

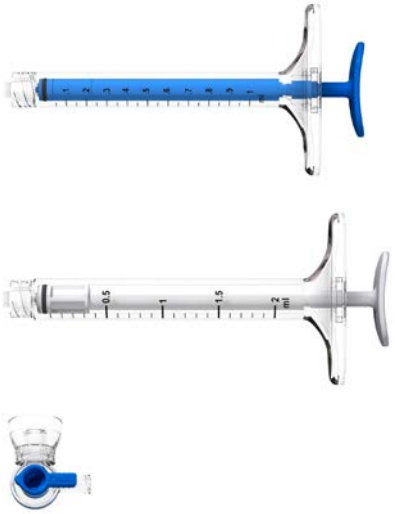
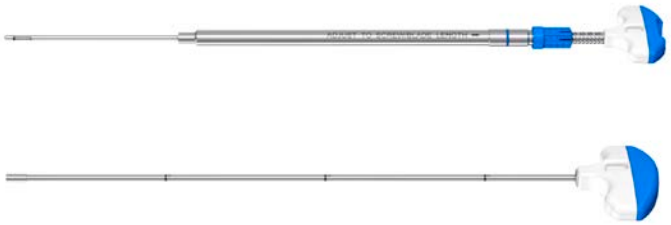




04.045.781S

04.045.782S

Implants and Instruments for Augmentation

07.702.040S	TRAUMACEM V+ Bone Cement, injectable, sterile Containing: 1 × TRAUMACEM V+ mixer with sterilization lid 1 × Monomer glass ampoule 1 × Cement mixing and transferring lid	
03.702.150S	TRAUMACEM V+ Syringe Kit, 4×1mL, 2 × 2 mL, sterile Containing: 4 × Blue 1 ml syringes 2 × White 2 ml syringes 1 × One-way stop-cock	
03.702.121S*	TRAUMACEM V+ Injection Cannula, for TFNA System, sterile Containing: 1 × Injection cannula, with Luer-lock 1 × Plunger	

Additionally required

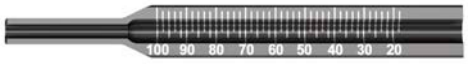
1–2 Syringes (6–10 ml) with Luer lock
Radiographic contrast agent
Saline solution

* TRAUMACEM V+ Injection Cannula: CE0482 Manufactured by:
Möller Medical GmbH, Wasserkuppenstrasse 29–31,
36043 Fulda, Germany
Distributed by: Synthes GmbH, Eimattstrasse 3, 4436 Oberdorf, Switzerland

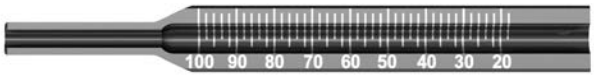
Instruments

292.120*	Kirschner Wire ∅ 1.25 mm with trocar tip, length 150 mm, Stainless Steel
292.120.01	Kirschner Wire ∅ 1.25 mm with trocar tip, length 150 mm, Stainless Steel
292.120.10	Kirschner Wire ∅ 1.25 mm with trocar tip, length 150 mm, Stainless Steel, pack of 10 units
321.160	Combination Wrench 11 mm
321.170	Pin Wrench ∅ 4.5 mm, length 120 mm
351.717	Depth Gauge for Medullary Nails
351.719	Elongation Tube for Reaming Rods, for Depth Gauge for Medullary Nails, for Nos. 351.717 and 03.019.001
03.045.036	Tube for Direct measuring device
355.399	Extraction Hook ∅ 3.7 mm, for Cannulated Nails
356.715	Socket, hexagonal, ∅ 11.0/11.0 mm, cannulated, for AFN
356.717	Guide Wire ∅ 2.8 mm, 460 mm length, with Hook
357.399*	Guide Wire ∅ 3.2 mm, length 400 mm
03.045.018*	Guide Wire ∅ 3.2 mm, w/drill tip, 400 mm
357.413	Drill Sleeve 5.6/3.2, length 198 mm
393.100	Universal Chuck with T-Handle
03.043.001	Universal Chuck with T-Handle

* Available non-sterile or sterile packed. Add “S” to the article number to order sterile products.

03.010.019	Depth Gauge for Locking Screws, measuring range up to 110 mm, for No. 03.010.009	
03.010.061*	Drill Bit ∅ 4.2 mm, calibrated, length 340 mm, 3-flute, for Quick Coupling, for No. 03.010.065	
03.010.065	Drill Sleeve 8.0/4.2, for No. 03.010.063	
03.010.070	Trocar ∅ 4.2 mm, for No. 03.010.065	
03.010.072	Depth Gauge for Locking Screws, measuring range up to 110 mm, for No. 03.010.063	
03.010.093	Rod Pusher for Reaming Rod with Hexagonal Screwdriver ∅ 8.0 mm	
03.010.101	Drill Bit ∅ 4.2 mm, calibrated, length 145 mm, 3-flute, with Coupling for RDL	
03.010.104*	Drill Bit ∅ 4.2 mm, calibrated, length 145 mm, 3-flute, for Quick Coupling	
03.010.106	Direct Measuring Device for Drill Bits of length 145 mm, for Nos. 03.010.100 to 03.010.105	
03.010.170	Hammer Guide	
03.010.412	Aiming Device for Guide Wire, for PFNA and TFN, for AP Orientation	

* Available non-sterile or sterile packed. Add “S” to the article number to order sterile products.

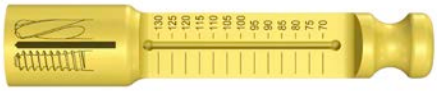
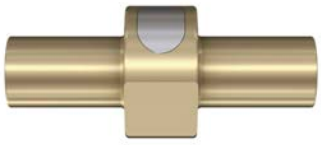
03.010.415	Connecting Screw for TFN, for No. 03.010.412	
03.010.428	Depth Gauge for Locking Screws, measuring range to 110 mm	
03.010.429	Direct Measuring Device for Drill Bits, length 145 mm	
03.010.471	Guide Wire Aiming Device Offset Block, 100 mm	
03.010.473	Inter-Lock Screwdriver, combined, STARDRIVE™, T25/hexagonal ∅ 3.5, length 224 mm	
03.010.491	Handle for Scalpel, long	
03.010.495	Intramedullary Reduction Tool, curved, with Quick Coupling, Hex 12 mm	
03.010.496	T-Handle, cannulated, with Quick Coupling, Hex 12 mm	
03.010.500	Handle, with quick coupling	
03.010.517	Screwdriver, hexagonal ∅ 8.0 mm, with T-Handle, with spherical head, length 322 mm	
03.043.027	Screwdriver, hexagonal ∅ 8.0 mm, with T-Handle, with spherical head, length 322 mm	

03.010.518	Screwdriver STARDRIVE™, T25, self-holding, length 319 mm	
03.045.001	Screwdriver XL25	
03.045.002	Retention Pin for Screwdriver XL25	
03.045.003	Screwdriver, short, XL25	
03.045.004	Retention Pin for Screwdriver, short	
03.045.005	Screwdriver XL25 Quick Coupling Hex 12 mm	
03.045.006	Retention Pin for Screwdriver Quick Coupling, Hex 12 mm	
03.045.007	Screwdriver, short, XL25 Quick Coupling Hex 12 mm	
03.045.008	Retention Pin for Screwdriver, short, Quick Coupling Hex 12 mm	
03.045.009	Sleeve for screwdriver	
03.140.027	Handle, large, cannulated, with Quick Coupling, Hex 12 mm	
03.045.010	Sleeve for screwdriver, short	
03.045.011	Screwdriver XL40	
03.045.012	Retention Pin for Screwdriver XL40	
03.010.520	Screwdriver STARDRIVE™, T40, with spherical head, cannulated, length 277 mm	
03.010.522	Combined Hammer, 500 g	
03.010.523	Driving Cap with thread, for Insertion Handle	
03.025.040	Protection Sleeve, 11.0/8.0, length 188 mm	
03.045.019	Protection Sleeve, ∅ 11/8	

03.037.000	Multihole Drill Sleeve	
03.037.001	Protection Sleeve	
03.037.002*	Drill Bit ∅ 16 mm, flexible, cannulated, for Quick Coupling for DHS™/DCS™	
03.037.003*	Drill Bit ∅ 16 mm, cannulated, for Quick Coupling for DHS™/DCS™	
03.037.004*	Hollow Reamer ∅ 16 mm, cannulated, for Quick Coupling, for DHS™/DCS™	
03.045.029*	Reamer, ∅ 5.5 mm	
03.037.005	Protection Tube for Medullary Reamers	
03.037.006	Radiographic Ruler	
03.037.007	Awl ∅ 8/4.7 mm, straight, cannulated	
03.037.008	Awl ∅ 8/4.7 mm, curved, cannulated	

* Available non-sterile or sterile packed. Add “S” to the article number to order sterile products.

03.037.010	Connecting Screw for Insertion Handle	
03.037.011	Insertion Handle, hybrid	
03.037.012	Insertion Handle	
03.037.013	Aiming Arm 130° for Static Distal Locking, for Screw	
03.037.014	Aiming Arm 125° for Static Distal Locking, for Screw	

03.037.016	Buttress /Compression Nut	
03.037.017	Guide Sleeve for No. 03.037.115 and 03.037.215	
03.037.018	Drill Sleeve, yellow	
03.045.020	Drill Sleeve, ∅ 4.2 mm	
03.045.022*	Drill Bit ∅ 4.2 mm, calibrated, 120 mm	
03.037.019	Trocar, yellow	
03.037.020	Direct Measuring Device, yellow	
03.037.021*	Drill Bit for lateral cortex opening, for Quick Coupling for DHS™/DCS™	
03.037.022*	Stepped Reamer for TFNA Helical Blade and Screw for Quick Coupling for DHS™/DCS™	
03.037.023	Fixation Sleeve for Stepped Reamer	

* Available non-sterile or sterile packed. Add “S” to the article number to order sterile products.

03.037.024	TFNA Helical-Blade Impactor	
03.037.025	TFNA Screw Inserter	
03.037.026	Connecting Screw for TFNA Helical Blade and Screw	
03.037.027	Tap for TFNA Screw	
03.037.028	Screwdriver, hexagonal 5.0 mm, flexible, cannulated	
03.037.029	Screwdriver Shaft, hexagonal 5.0 mm, with Hexagonal Coupling 6.0 mm, for static locking	
03.037.030	Extraction Instrument for TFNA Helical Blade and Screw	

03.037.031	Wrench, hexagonal socket 11/ Blade-Screw	
03.037.032	Extraction Instrument for Nails, cannulated	
03.037.035	Aiming Arm 135° for Static Distal Locking	
03.037.036	Depth Gauge for Nails	
03.045.035	Direct measuring device for IM nails	
03.037.100	Multihole Drill Sleeve, long	
03.037.101	Protection Sleeve, long	

03.037.102*	Drill Bit ∅ 16 mm, long, flexible, cannulated, for Quick Coupling for DHS™/DCS™	
03.037.103*	Drill Bit ∅ 16 mm, long, cannulated, for Quick Coupling for DHS™/DCS™	
03.037.104*	Hollow Reamer ∅ 16 mm, long, cannulated, for Quick Coupling, for DHS™/DCS™	
03.037.105	Trocar for Protection Tube	
03.037.112	Insertion Handle, long	
03.037.113	Aiming Arm 130° for Static and Dynamic Distal Locking	
03.037.114	Aiming Arm 125° for Static and Dynamic Distal Locking	
03.037.116	Compression Nut for Inserter for TFNA Screw	

* Available non-sterile or sterile packed. Add “S” to the article number to order sterile products.

03.037.120	Connector for Driving Cap	
03.037.135	Aiming Arm 135° for Static and Dynamic Distal Locking	
03.045.030*	Extractor Shaft for XL25 and T25	
03.045.031*	Curette for XL25	
03.045.032*	Extraction Screw, conical	
03.900.001	Straight Sharp Hook	
03.140.023	Torque Limiter, 6 Nm, for AO/ASIF Quick Coupling for Reamer	
03.231.018	Handle with Torque Limiting Function, 6 Nm	
09.037.010*	Guide Wire ∅3.2 mm, length 475 mm	

* Available non-sterile or sterile packed. Add “S” to the article number to order sterile products.

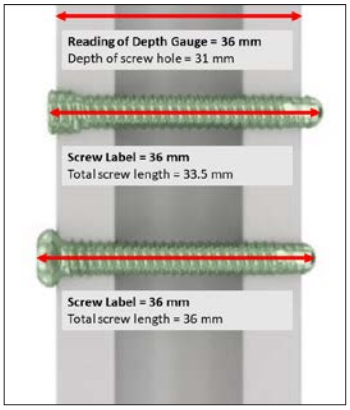
Addendum A

About Measuring Screw Length

Screw length is measured by using either of the two methods.

Read length from the calibrated drill bits Measure length using the depth gauge for locking screws

Readings do not reflect measured distance, they indicate the required screw length. The reading on the scale will correspond to the screw length as indicated on the screw label, considering the amount of screw tip protrusion required to get full screw thread engagement in the far cortex.



■ Notes:

- Drill bit location with respect to the far cortex is critical for measuring the appropriate locking screw length.
- Beware depth gauges are implant specific. Always use the appropriate depth gauge as specified in surgical technique guide.

▲ Precaution:

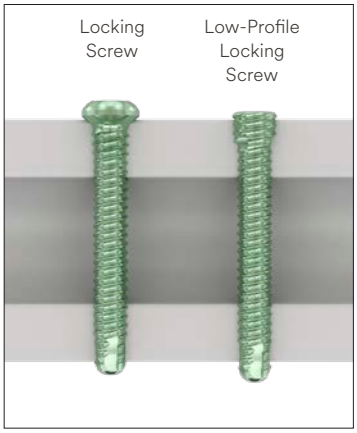
Select adequate screw length to avoid protrusion of the screw tip and irritation of soft tissue.

Screw Options

TFN-ADVANCED offers two different types of retaining screws:

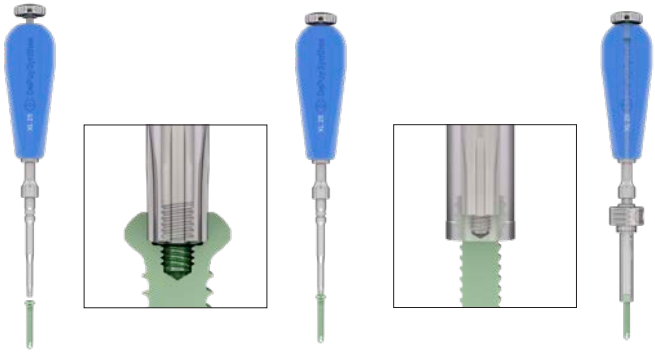
1. Locking Screw
   Standard IM nail locking screw.

2. Low-Profile Locking Screw
   The low-profile screw reduces implant prominence.



■ Note:

Both types of screws have a threaded recess and can be securely attached to the screwdriver by using the retention pins. To do so, slide the retention pin through the back of the screwdriver until it stops. Further advance it by turning it clockwise, until its tip extends out of the tip of the screwdriver.



Engage the screwdriver in the recess of the locking screw and thread the retention pin into the screw's recess to lock the screw to the screwdriver.

Alternatively, the screw can be partially inserted with a power tool, by using the screwdriver shaft with its retention pin, following the same steps as described above.

▲ Precaution:

The screw must not be fully tightened with the power tool. Disengage the power tool from the screwdriver shaft before the screw is fully seated and use the manual handle to bring the screw to its final position and tighten it as appropriate.

Option: Low-Profile Screw

The low-profile screw can be used instead of the standard locking screw, by following the same basic steps for screw insertion.

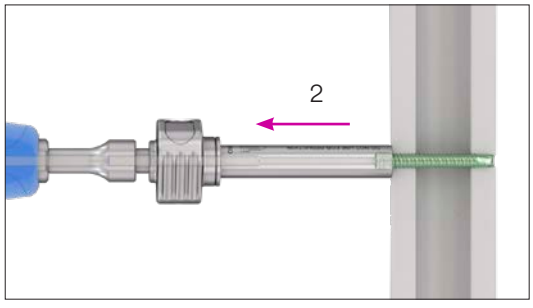
An optional sleeve is available to indicate when the screw is fully seated. Slide it over the tip of the screwdriver until it locks in place.

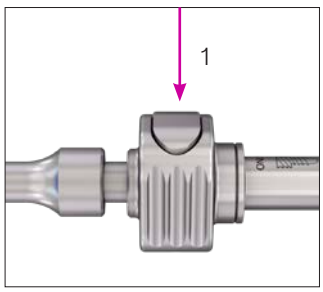
In its initial position, it will cover the head of the screw, protecting surrounding soft tissues from the screw head's cutting flutes. Advance the screw until the sleeve touches the cortex.

■ Note:

Pay attention not to damage the cortex with the sleeve

Then retract the sleeve by pushing the release button and pulling it backwards towards the screwdriver handle.





Continue to advance the screw, now sinking the threaded screw head into the bony cortex. Once the sleeve touches the cortex a second time the screw head will be 0.5 mm proud of the cortex.

The cutting flutes in the 5 mm low-profile screw's threaded head allow insertion of the screw without any extra steps. However, in hard bone it is recommended to enlarge the near cortex with the ∅ 5.5 reamer (03.045.029), to make room for the screw head, and avoid excessive insertion torque.

1. Insert locking screw, Distal Locking – Short Nails (170 mm, 200 mm and 235 mm)

Instruments	
03.045.001*	Screwdriver XL25
03.045.002	Retention Pin for Screwdriver XL25

Insert the appropriate length locking screw through the protection sleeve using the screwdriver. Verify locking screw length under image intensification.

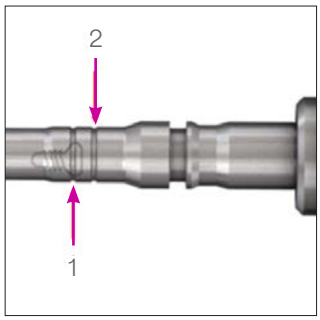
The tip of the locking screw should not project more than 4 mm beyond the far cortex.

Repeat steps for the second, antegrade locking screw if desired.

Remove protection sleeves and the aiming arm.

The shaft of the screwdriver has two lines, one of which indicates insertion depth of the locking screw (1), and the other indicating insertion depth of the low-profile locking screw (2) relative to the tip of the protection sleeve.

Screws are fully seated, when the line is flush with the head of the protection sleeve.



*Only for use with retaining screws.

1. Insert locking screw, Distal Locking – Long Nails

Refer to proximal locking screw guidance when inserting distal locking screw.

Instruments	
03.045.003*	Screwdriver, short, XL25
03.045.004	Retention Pin for Screwdriver, short

Insert the appropriate length locking screw using the screwdriver. Verify locking screw length under image intensification.

The tip of the locking screw should not project more than 2 mm beyond the far cortex.

*Only for use with retaining screws.

Option: Powered Screw Insertion

Instruments

03.045.005	Screwdriver XL25 Quick Coupling Hex 12 mm
03.045.006	Retention Pin for Screwdriver Quick Coupling, Hex 12 mm
03.045.007	Screwdriver, short, XL25 Quick Coupling Hex 12 mm
03.045.008	Retention Pin for Screwdriver, short, Quick Coupling, Hex 12 mm
03.140.027	Handle, large, cannulated, with Quick Coupling, Hex 12 mm

Alternative instrument

03.010.496	T-Handle Cannulated, with Quick Coupling

Alternatively, the screw can be partially inserted with a power tool, by using the screwdriver shaft (03.045.005 or 03.045.007) with its retention pin (03.045.006 or 03.045.008), following the same steps as described above.

▲ Precaution:

Screws must not be fully tightened with power tool. Disengage the power tool from the screwdriver shaft before the screw is fully seated and use the manual handle (03.140.027 or 03.010.496) to bring the screw to its final position and tighten as appropriate.

Option: Low-Profile Locking Screw

Instruments

03.045.009	Sleeve for Screwdriver
03.045.010	Sleeve for Screwdriver, short
03.045.029*	Reamer, ∅ 5.5 mm

The low-profile screw can be used instead of the standard locking screw, by following the same basic steps for screw insertion.

An optional sleeve is available to indicate when the screw is fully seated. Slide it over the tip of the screwdriver until it locks in place.

The use of a ∅ 5.5 mm reamer, to make room for the screw head is recommended in hard bone.

* Available non-sterile or sterile packed. Add “S” to the article number to order sterile products.

Optional Nut and Washer Technique

■ Note:

Nut and washers are intended for use with standard Ø 5.0 mm Locking Screws only (04.045.026 through 04.045.120).

The number of nuts and washers to be used is according to surgeon preference, patient anatomy, and/or clinical condition.

■ Note:

The nut includes a friction feature to secure nut onto the screw. The surgeon may experience tactile friction during nut insertion on the screw.

The use of nuts and/or washers may be limited in patients with a knee prosthesis, due to interference of the prosthesis, including the prosthesis box, pegs and borders.

The use of nuts may be limited by the location of the distal locking holes relative to the condyles.

■ Note:

Ensure sufficient insertion depth between nut and nail is available prior to nut insertion to avoid contact between nut and nail. If the nut contacts the nail before being fully seated, the nut may protrude off the bone.

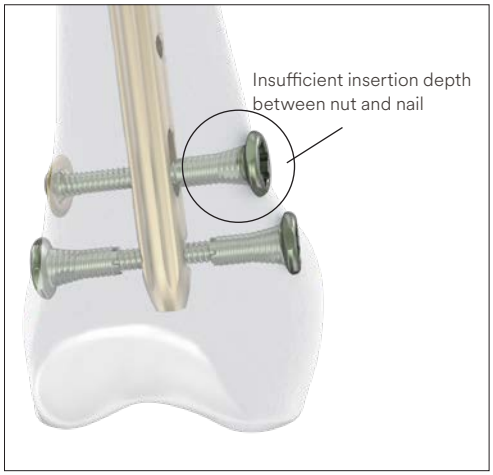
While the actual length of the nut is 15 mm, a minimum depth gauge/drill bit measurement of 20 mm from outer cortex to nail surface is needed to provide sufficient insertion depth for the nut.

■ Note:

If more than one screw with nut assembly is planned consider the final position of adjacent screws/nuts to avoid interference. A screw with nut in the dynamic locking position may interfere with a screw with nut in the most distal locking hole.

Two techniques are described for insertion of nuts and washers, “nut-over-screw” technique and “nut-over-drill bit” technique.

Pictures for reference of Nut and Washer only, not shown with TFNA implant.



Nut and Washer: Nut-Over-Screw Technique

1. Insert Locking Screw

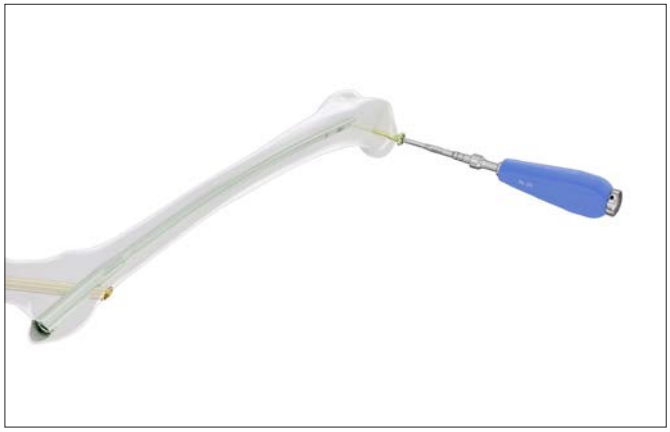
Instruments	
03.045.003	Screwdriver, short, XL25
03.045.004	Retention Pin for Screwdriver, short
Optional Instrument	
03.045.034	Countersink, QC, 7.4 mm

After drilling according to the distal locking technique, nuts and/or washers can be used with the distal, medial-lateral locking screws in the condylar region.

Countersink can be used to ease insertion of nut in patients with hard bone. Drill with countersink until the stop on the countersink contacts the cortical surface.

■ Note:

Consider anatomy and/or position the nail in the bone. A minimum distance of 20 mm measured with the drill bit/depth gauge from the surface of the bone to the outer surface of the nail is needed to ensure the nut does not contact the nail at final tightening.



Select the appropriate length screw according to the distal locking technique.

With the retention pin inserted into the screwdriver, insert the screwdriver into the screw head recess. Thread the retention pin into the screw head until secure.

■ Notes:

- If using nut at screw head, thread nut onto screw until secure, prior to inserting screw into bone.
- If using washer for screw or washer for nut, position washer prior to inserting screw into bone.
- Prior to inserting nut into bone, forceps can be used to hold nut during screw insertion. Once screw head is seated in the nut, insertion of screw and nut assembly can continue.
- There are two types of washers that can be used. Select appropriate washer based on desired construct profile and nut contact area.

Proceed with inserting screw until it is seated in the bone.

If nut is used at the screw head, the screw head should be seated flush with nut when fully inserted.

2. Insert Distal Nut and Final Tighten

Instruments	
03.045.033	Driver for Nut
03.045.003	Screwdriver, short, XL25
03.045.004	Retention Pin for Screwdriver, short

Make an incision at the contralateral position over the tip of the screw.

Attach nut to the nut driver.

■ Note:

If using washer for nut, position washer over nut prior to advancing the nut to bone.

Advance nut to the bone, ensuring alignment with the screw tip.

While holding the screwdriver in position, tighten nut with nut driver until seated. The nut should be fully seated to reduce soft tissue irritation.

Remove nut driver and screwdriver.

Nut and Washer: Nut-Over-Drill Bit Technique

1. Insert Distal Nut

Instruments	
03.010.104	4.2 mm Three Fluted Drill Bit
03.045.033	Driver for Nut

After drilling according to the distal locking technique, nuts and/or washers can be used with the distal, medial-lateral locking screws in the condylar region.

■ Note:

Consider anatomy and/or position of the nail in the bone. A minimum distance of 20 mm measured with the drill bit/depth gauge from the surface of the bone to the outer surface of the nail is needed to ensure the nut does not contact the nail at final tightening.

Select the appropriate length screw according to the distal locking technique using the drill bit.

Keep the drill bit in position in the bone.

Make an incision at the contralateral position over the tip of the drill bit.

Attach nut to the nut driver.

■ Note:

If using washer for nut, position washer over nut prior to advancing nut to the bone.

Advance nut to the bone, ensuring alignment with the tip of the drill bit.

While holding the drill bit in position, tighten nut with nut driver until seated.

Keep nut driver engaged in nut. Remove the drill bit.

2. Insert locking screw

Instruments	
03.045.003	Screwdriver, short, XL25
03.045.004	Retention Pin for Screwdriver, short

With the retention pin inserted into the screwdriver, insert the screwdriver into the screw head recess. Thread the retention pin into the screw head until secure.

Use the screwdriver to insert the appropriate length locking screw.

■ Notes:

- If using nut at screw head, thread nut onto screw until secure, prior to inserting screw into bone.
- If using washer for screw or washer for nut, position washer prior to advancing screw to the bone.
- Prior to inserting nut into bone, forceps can be used to hold nut during screw insertion. Once screw head is seated in the nut, insertion of screw and nut assembly can continue.

After insertion of screw through the nail, use radiographic imaging to ensure the screw tip is aligned with the nut in the bone.

Use nut driver to provide counter-torque to nut while inserting screw through nut. Continue insertion of screw until seated.

If nut is used at screw head, the screw head should be seated flush with nut when fully inserted.

Nut should be fully seated to reduce soft tissue irritation.

Remove nut driver and screwdriver.

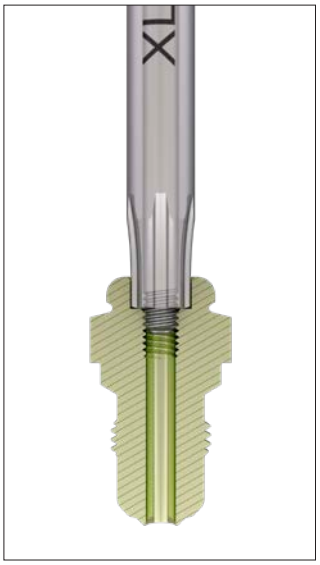
Insert Retaining End Cap

1. Insert end cap

Instruments	
03.045.011*	Screwdriver XL40
03.045.012	Retention Pin for Screwdriver XL40
03.043.027	T-Handle Ball Hex Screwdriver, Cannulated, ∅ 8 mm
Alternative Instruments	
03.045.018†	Guide Wire ∅ 3.2 mm, w/drill tip, 400 mm
357.399†	Guide Wire ∅ 3.2 mm, length 400 mm

Endcap insertion is an optional procedure.

The grooves on the insertion handle facilitate visualization of the nail position. The first, most distal groove represents the nail end. The subsequent distances between the grooves on the insertion handle represent 5 mm and correspond to the extensions of the end caps.



End caps for femoral nails are available in extension lengths of 0 mm, 5 mm, 10 mm, and 15 mm. End caps fulfill two functions: preventing bone ingrowth into the nail and extending the nail if it is over inserted.

If desired, End Caps can be locked to the screwdriver. To do so, slide the retention pin through the back of the screwdriver until it stops. Further advance it by turning the pin clockwise, until its tip extends out through the tip of the screwdriver.

Engage the screwdriver with the recess of the recon screw and thread in the retention pin to lock the screw to the screwdriver.

*Only for use with retaining end caps.
†Available nonsterile or sterile packaged. Add “S” to product number to indicate sterile product.

Inserting the 0 mm end cap

Remove the connecting screw using the ball hexagonal screwdriver while leaving the insertion handle connected to the nail.

Insert the 0 mm end cap using the screwdriver through the insertion handle.

After the end cap is inserted, remove the insertion handle from the nail by pulling the insertion handle away from the nail.

Inserting the 5–15 mm end cap

Remove the connecting screw using the ball hexagonal screwdriver, remove the insertion handle from the nail by pulling the insertion handle away from the nail.

Engage the end cap with the screwdriver. To prevent cross-threading, align the end cap with the nail axis and turn the end cap counterclockwise, until the thread of the end cap aligns with that of the nail. Turn the end cap clockwise to thread the end cap into the nail until it is fully inserted.

Remove screwdriver.

Notes:

- In case of difficulties removing the connecting screw or insertion handle, push the insertion handle towards the medial or lateral side to neutralize soft tissue pressure.
- The end cap protects the nail connection threads from bone ingrowth to facilitate removal and extends the height of the nail if over-inserted.

Implant Removal

Implant removal is an optional procedure.

1. Remove end cap and locking screws

Removal of End Caps	
03.045.011	Screwdriver XL40
03.045.012	Retention Pin for Screwdriver XL40
Alternative Instruments	
03.045.013	Screwdriver XL40, extra long
03.045.014	Retention Pin for Screwdriver XL40, extra long
Removal of Locking Screws	
03.045.001	Screwdriver XL25
03.045.002	Retention Pin for Screwdriver XL25
Alternative Instruments	
03.045.003	Screwdriver, short, XL25
03.045.004	Retention Pin for Screwdriver XL25, short

Clear the recess of the end cap and the locking implants of any ingrown tissue. Remove the end cap using the screwdriver.

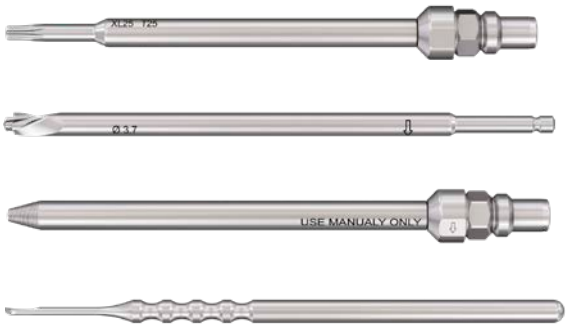
Remove all locking screws except one proximal locking screw using the screwdriver. Refer to retaining screw guidance above, to lock screws to suitable screwdrivers.

■ Note:

Retaining end caps are compatible with existing T40 screwdrivers, and retaining screws are compatible with existing T25 screwdrivers.

Screw Removal Tools

03.045.030*	Extractor Shaft for XL25 and T25
03.045.031*	Curette for XL25
03.045.032*	Extraction Screw, conical
03.900.001	Straight Sharp Hook



* Available non-sterile or sterile packed. Add “S” to the article number to order sterile products.

2. Remove final locking screw

Instruments	
03.010.000	Extraction Screw for Tibial and Femoral Nails
03.010.170	Hammer Guide
321.160	Combination Wrench ∅ 11.0 mm
Removal of Locking Screws	
03.045.001	Screwdriver XL25
03.045.002	Retention Pin for Screwdriver XL25

Before removing the final locking screw, screw the extraction screw into the nail and tighten it using the ratchet wrench. The locking screw will prevent nail rotation as the extraction screw is tightened.

Attach the hammer guide to the extraction screw. Remove the remaining screw using an XL25 screwdriver.

MRI Information

A patient implanted with the DePuy Synthes device may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient. The recommendations below only apply to the implantable devices and not to instrumentation.

Nominal values of Static Magnetic Field (Bo)	1.5 Tesla or 3 Tesla
Maximum Spatial Field Gradient (SFG)	Up to 20 T/m (2,000 gauss/cm) Note: 20 T/m is a standardized value often used in labeling
Static Magnetic Field (Bo) Orientation	Horizontal, Cylindrical Bore
RF Excitation	Circularly polarized
RF Transmit Coil Type	Transmit quadrature-driven coil only
Maximum Whole-body SAR	Normal Operating Mode or 2 W/kg for 1.5 T 2 W/kg for 3.0 T
Maximum expected temperature rise	9.5 °C in 1.5 T system 5.9 °C in a 3.0 T system
Limits on Scan Duration	1.5 T (64 MHz) environment – Scan for 6 minutes of continuous RF exposure with one or more MR imaging pulse sequences (scan or series) 3.0 T (128 MHz) environment – Scan for 15 minutes of continuous RF exposure with one or more MR imaging pulse sequences (scan or series)
MR Artifact	The presence of the device may produce an image artifact. Imaging protocol modifications may be necessary to compensate for the image artifact.

▲ Precautions:

The above-mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:

- It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
- Generally it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.
- Using the ventilation system may further contribute to reduce temperature increase in the body.

Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effect and Residual Risks. Instructions for Use are available at www.e-ifu.com and/or www.depuysynthes.com/ifu

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