

UHN/PHN

Humeral Nailing System

Surgical Technique



Discontinued – December 2018
103401-181130

 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.depuyshnthes.com/hcp/reprocessing-care-maintenance>

For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:

<http://emea.depuyshnthes.com/hcp/reprocessing-care-maintenance>

	358.590	Radiographic Ruler for UHN
	292.260	Kirschner Wire Ø 2.5 mm with trocar tip, length 280 mm, Stainless Steel
	351.120	Awl with T-Handle, cannulated, straight
	358.540	Connecting Screw for UHN
	321.160	Combination Wrench Ø 11.0 mm
	358.689	Aiming Arm for Standard Locking, for Solid Humeral Nail
	358.692	Insertion Handle for UHN and PHN
	355.750	Trocar Ø 8.0 mm
	355.700	Protection Sleeve 11.0/8.0
	359.026	Drill Sleeve 8.0/2.7
	355.722	Drill Sleeve 8.0/3.2, dark blue
	462.660–667	End Cap for Spiral Blade for UHN and PHN, extension 0–15 mm, Titanium Alloy (TAN)
	462.634–654	Spiral Blade for UHN and PHN, length 34–54 mm, Titanium Alloy (TAN)
	458.160–800	Locking Bolt Ø 3.9 mm, self-tapping, length 16–80 mm, Titanium Alloy (TAN), dark blue
	462.969–971	PHN - Proximal Humeral Nail Ø 7.5/8.0 mm, length 150 mm, Titanium Alloy (TAN), gold
	462.660–667	End Cap for Spiral Blade for UHN and PHN, extension 0–15 mm, Titanium Alloy (TAN)
	462.672–688	Spiral Blade for UHN Ø 6.7 mm, length 32–48 mm, Titanium Alloy (TAN)
	462.618–632	UHN - Solid Humeral Nail Ø 6.7 mm, length 180–325 mm, Titanium Alloy (TAN), violet
	462.416–460	Locking Bolt Ø 3.4 mm, self-tapping, length 16–60 mm, Titanium Alloy (TAN), violet
	462.660–667	End Cap for Spiral Blade for UHN and PHN, extension 0–15 mm, Titanium Alloy (TAN)
	462.634–654	Spiral Blade for UHN and PHN, length 34–54 mm, Titanium Alloy (TAN)
	467.718–732	UHN - Solid Humeral Nail Ø 7.5 mm, length 180–325 mm, Titanium Alloy (TAN), dark blue
	462.918–932	UHN - Solid Humeral Nail Ø 9.5 mm, length 180–325 mm, Titanium Alloy (TAN), dark blue
	458.160–800	Locking Bolt Ø 3.9 mm, self-tapping, length 16–80 mm, Titanium Alloy (TAN), dark blue

Available non-sterile or sterile packed. Add «S» to the catalogue number to order sterile products.

	359.031	Drill Bit \varnothing 2.7 mm, calibrated, length 210/185 mm, 3-flute, for Quick Coupling
	314.240	Screwdriver, hexagonal, small, \varnothing 2.5 mm, with Groove, length 250 mm
	315.330	Drill Bit \varnothing 3.2 mm, calibrated, length 210/185 mm, 3-flute, for Quick Coupling
	314.270	Screwdriver, hexagonal, large, \varnothing 3.5 mm, with Groove, length 245 mm
	355.790	Depth Gauge for Locking Bolts, measuring range up to 90 mm
	462.950–965	End Cap for UHN, extension 0–15 mm, Titanium Alloy (TAN), dark blue
	358.679	Aiming Arm for Spiral Blade Locking, for UHN and PHN
	358.686	Trocar \varnothing 2.0 mm, for No. 358.694
	358.694	Drill Sleeve 4.5/2.0, for No. 358.688
	358.688	Protection Sleeve 14.0/4.5
	292.650	Guide Wire \varnothing 2.0 mm with threaded tip with trocar, length 230 mm, Stainless Steel
	358.698	Measuring Device for Spiral Blades, for UHN and PHN
	358.691	Drill Bit \varnothing 4.5 mm, cannulated, for Spiral Blade for UHN and PHN
	358.696	Inserter for Spiral Blade, for UHN and PHN
	358.697	Connecting Screw for Spiral Blades, for UHN and PHN
	310.440	Drill Bit \varnothing 4.5 mm, length 145/120 mm, 2-flute, for Quick Coupling
	358.682	Projectile Burr, for Quick Coupling
	332.062	Router, length 130 mm, for Quick Coupling
	358.680	Burr \varnothing 8.5/3.5 mm, conical, length 80 mm, for Quick Coupling
	358.681	Burr \varnothing 8.5/3.5 mm, conical, length 110 mm, for Quick Coupling
	314.280	Holding Sleeve, large, for Nos. 314.190, 314.240, 314.260, 314.270 and 314.750
	358.610	Compression Connecting Screw, for No. 358.600
	358.600	Compression Device for UHN
	359.021	Connecting Piece for Extraction of UHN
	356.490	Inserter/Extractor for UTN/CTN and UHN
	332.200	Slotted Hammer
	319.970	Screw Forceps, self-holding, length 85 mm

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Description

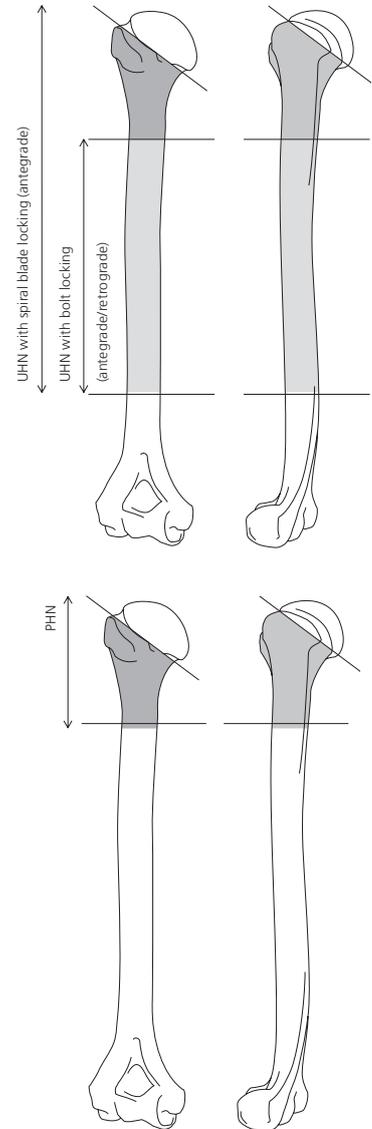
UHN – locking with bolt or spiral blade

The Solid Humeral Nail UHN can be inserted into the humeral shaft in both antegrade or retrograde directions and can be used universally for the left and the right humerus.

The special hole geometry of the nail ensures optimal positioning of the locking bolts in both approaches. The numerous locking options allow secure fixation of even short distal or proximal fragments. In the antegrade procedure using a spiral blade for proximal locking, better fixation can be achieved in osteoporotic bone. Locking with bolts offers the option of interfragmental compression for enhanced stabilisation of transverse and short oblique fractures.

PHN – standard locking with spiral blade

The Proximal Humeral Nail PHN is inserted into the proximal humeral shaft in the antegrade direction and can be used universally for the left and the right humerus. The spiral blade is used for proximal locking and produces adequate anchorage even in an osteoporotic humeral head.



Indications and Contraindications

Indications

UHN

The range of indications for the UHN includes humeral shaft fractures down to approx. 5 cm proximal to the olecranon fossa with closed epiphyseal lines for:

- stable or unstable fractures
- refractures, fractures with delayed healing and pseudoarthroses

PHN

The range of indications for the PHN includes humerus fractures in adults in the subcapital area (AO/ASIF classification: A2, A3), or with concurrent avulsion of the greater tuberosity (AO/ASIF classification: Extra-articular bifocal fractures B1, B2) for:

- stable or unstable fractures
- refractures, fractures with delayed healing and pseudoarthroses

In certain cases, joint fractures at the head of the humerus can also be managed by this technique (AO classification: C fractures), provided that the domed head fragment is large enough and that it is not itself fractured.

Contraindications

There are no specific contraindications.

Implants

1.

Solid Humeral Nail UHN

for standard locking and locking with spiral blade

violet: diameter 6.7 mm

dark blue: diameter 7.5 and 9.5 mm

Lengths: 190, 205, 220, 230, 240, 250, 260, 270, 280, 295, 310 and 325 mm

Standard locking

End Cap for UHN, extension 0–15 mm, Titanium Alloy (TAN) (462.950–965), dark blue

Locking Bolt \varnothing 3.4 mm, self-tapping, length 16–60 mm, Titanium Alloy (TAN) (462.416–460), violet

Locking Bolt \varnothing 3.9 mm, self-tapping, length 16–80 mm, Titanium Alloy (TAN) (458.160–800), dark blue

Spiral blade locking

End Cap for Spiral Blade for UHN and PHN, extension 0–15 mm, Titanium Alloy (462.660–667), gold

Spiral Blade for UHN \varnothing 6.7 mm, length 32–48 mm, Titanium Alloy (TAN) (462.672–688)

Spiral Blade for UHN and PHN, length 34–52 mm, Titanium Alloy (TAN) (462.634–652)

Locking Bolt \varnothing 3.4 mm, self-tapping, length 16–60 mm, Titanium Alloy (TAN) (462.416–460), violet

Locking Bolt \varnothing 3.9 mm, self-tapping, length 16–80 mm, Titanium Alloy (TAN) (458.160–800), dark blue

Locking of the nail tip

Locking Bolt \varnothing 3.4 mm, self-tapping, length 16–60 mm, Titanium Alloy (TAN) (462.416–460), violet

Locking Bolt \varnothing 3.9 mm, self-tapping, length 16–80 mm, Titanium Alloy (TAN) (458.160–800), dark blue



2.

Proximal Humeral Nail PHN

for spiral blade locking

Diameter 7.5 and 8.0 mm

Length 150 mm

Spiral blade locking

End Cap for Spiral Blade for UHN and PHN, extension
0–15 mm, Titanium Alloy (462.660–667), gold

Spiral Blade for UHN and PHN, length 34–52 mm,
Titanium Alloy (TAN) (462.634–652)

Locking Bolt \varnothing 3.9 mm, self-tapping, length 16–80 mm,
Titanium Alloy (TAN) (458.160–800), dark blue

Locking of the nail tip

Locking Bolt \varnothing 3.9 mm, self-tapping, length 16–80 mm,
Titanium Alloy (TAN) (458.160–800), dark blue



UHN – Retrograde insertion

1. Position patient

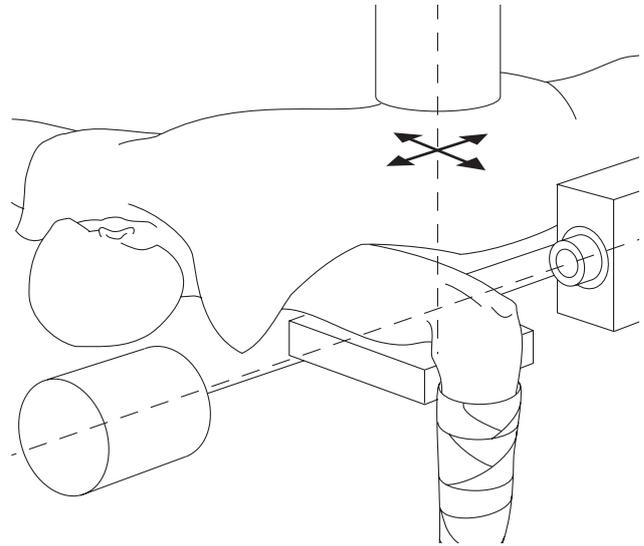
The patient is preferably placed in the prone position, supported by pads, on the ipsilateral edge of the table. Position the fractured upper arm on an additional arm board or arm rest fastened to the table. The elbow is flexed at 90°. If necessary, it should be possible to flex the elbow up to approx. 120°. In this position, the surgeon has a good view of the operating field from the dorsal side. It must be possible to view the whole upper arm, including the elbow and humeral head, in two planes in the image intensifier. The hanging forearm usually adopts the correct rotation by itself.

If the patient's general condition or injuries prevent the adoption of the prone position, the operation can also be performed with the patient in the lateral or supine positions.

If the patient is placed in the lateral position, the arm to be treated should be positioned over a foam wedge. It must be possible to bend the elbow joint up to approx. 120°. The patient must be adequately supported.

If the patient is supine, a position approximating the lateral position should be achieved by the use of supporting pads. With the elbow flexed, the humerus is held under tension by the assistant.

- The ability to view the whole of the humerus in the image intensifier should be checked preoperatively, bearing in mind that this is much more difficult with the lateral and supine positions than with the prone position.



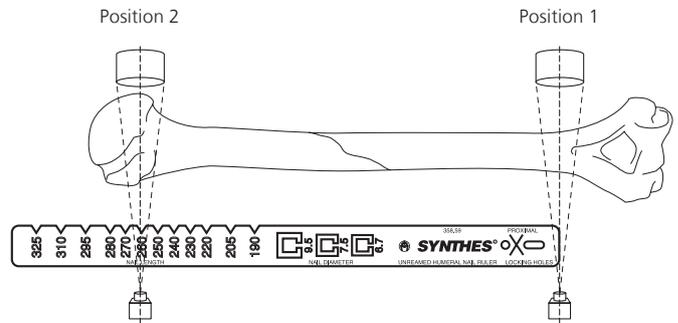
2. Determine nail length

The approximate nail length can be determined pre-operatively. Measure the length of the unfractured humerus from its head to the olecranon fossa and deduct 5–6 cm from the measured distance.

The length can only be determined correctly on the fractured arm if the fracture is correctly reduced.

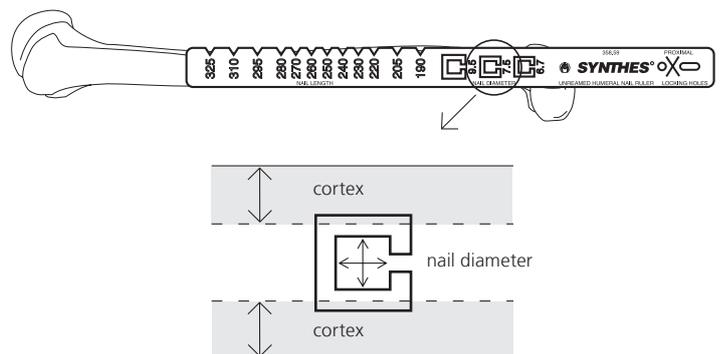
- 1 Position the image intensifier for an AP view of the distal humerus (position 1). Using long holding forceps, hold the Radiographic Ruler for UHN (358.590) parallel to the humerus so that the proximal locking holes symbolized on the ruler are located at the correct point against the distal humerus. Mark the skin over the distal humerus at the end of the ruler.
- 2 Position the image intensifier over the proximal humerus (position 2), place the distal end of the ruler next to the marked skin site and record an AP image. Check the reduction and read off the nail length from the image of the ruler.

The nail tip should only project a little way into the humeral head.



3. Determine nail diameter

- 1 Position the image intensifier for a lateromedial view of the distal humerus. Hold the ruler parallel or at right angles to the humerus so that the square "NAIL DIAMETER" marking (6.7, 7.5, 9.5) is positioned over the medullary canal. The inner square of this marking corresponds to the nail diameter. Select the nail diameter shown when the medullary canal/cortex transition is still visible at the sides of the square in the image intensifier.



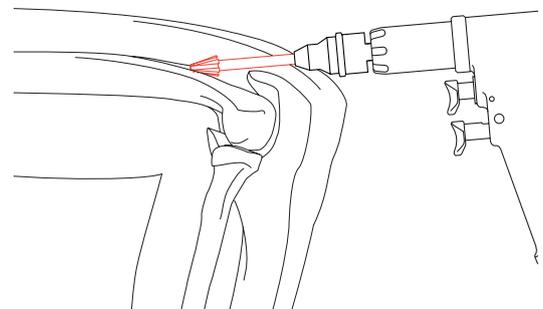
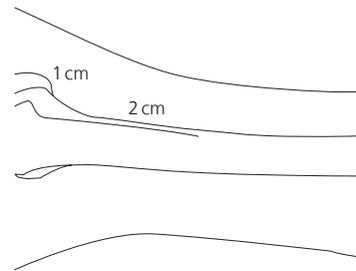
4. Open medullary canal

With the elbow flexed at 90°, the longitudinal skin incision begins slightly distal to the olecranon. Split the triceps tendon where it extends beyond the distal humeral shaft. It should be possible to view a bone area starting at the upper edge of the olecranon fossa and proceeding approx. 25 mm in the proximal direction. Do not open the elbow joint.

The insertion point in the medullary canal is located in the centre of an imagined triangle between the medial and lateral supracondylar edge and the roof of the olecranon fossa.

First drill three holes \varnothing 3.2 mm (Drill Bit \varnothing 3.2 mm [315.330]) perpendicular to the medullary canal and then widen the holes with the Drill Bit \varnothing 4.5 mm (310.440). Lower the bit until it is in line with the medullary canal in the lateral view (see illustration). Using the burs, open up an entry portal 10 mm wide and 20 mm long. The conical Burr \varnothing 8.5/3.5 mm (358.681) allows rapid reaming, while the cylindrical Projectile Burr (358.682) facilitates the shaping of the insertion point.

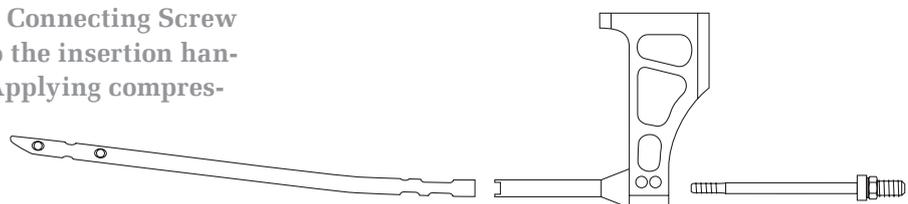
Chamfer and smooth down the distal edge of the insertion hole such that the nail can be introduced unhindered.



5. Mount nail on insertion handle

Mount the selected nail on the Insertion Handle (358.692), ensuring that the apex of the nail curvature points away from the insertion handle. Screw the Connecting Screw (358.540) through the insertion handle into the nail and tighten using the Ratchet Wrench \varnothing 11.0 mm (321.200) or the Combination Wrench \varnothing 11.0 mm (321.160).

Note: If interfragmental compression with minimizing of the fracture gap is desired for transverse or short oblique fractures, the Compression Device (358.600) and the Compression Connecting Screw (358.610) must be screwed onto the insertion handle at this point (see page 15, Applying compression).



6. Insert nail

Insert the nail with slight rotating movements of the insertion handle. It is not advisable to use a hammer when inserting the UHN since this increases the risk of iatrogenic fissures or fractures at the insertion site. Insert the nail up to the fracture site, reduce the fracture and continue beyond the fracture under image intensifier control. Proceed carefully so as to avoid injury to the radial nerve, particularly in fractures of the mid to distal third of the shaft.



If radial nerve palsy is present preoperatively, it may be necessary to explore the nerve through a short anterolateral incision at the transition of the mid and distal third of the shaft.

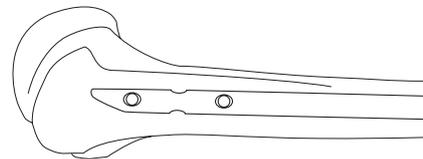
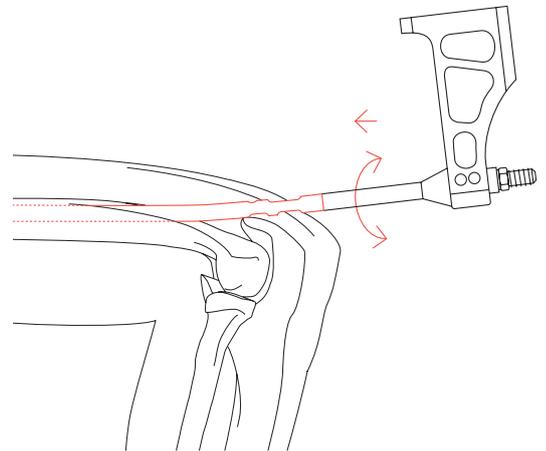
Use a reaming system intended for humeral reaming procedures. Using image intensification, ensure that fracture reduction has been maintained. This reduces the risk of iatrogenic fractures. Under no circumstances should the nail be knocked in with a hammer.

Continue advancing the nail until the tip projects slightly into the humeral head. This allows the insertion of a lateromedial bolt in the humeral head distal to the rotator cuff.



Check the nail position under the image intensifier.

Note: Pressure against the humeral head when advancing the nail prevents diastasis formation and possible associated healing problems.

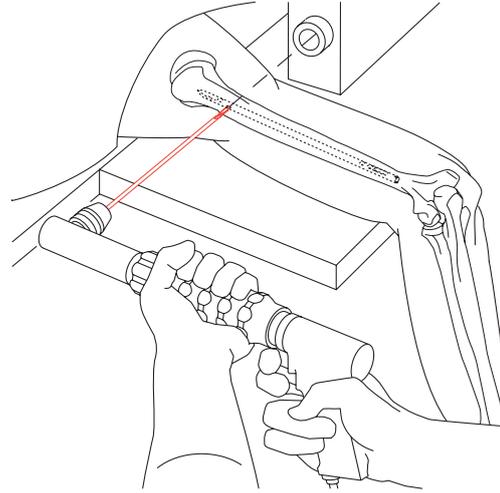


7. Proximal locking

When the nail tip has reached its definitive position in the humeral head, the nail is first locked proximally using the Radiolucent Drive (pages 20–21, steps 7–10) or the “freehand” technique.

- Check the position of the proximal fragment, since a fracture gap could have formed during nail insertion. Use Drill Bit \varnothing 3.2 mm (315.330) for the 3.9 mm bolts or Drill Bit \varnothing 2.7 mm (359.031) for the 3.4 mm bolts. Determine the length of the locking bolt with the Depth Gauge for Screws (319.010), the Depth Gauge for Locking Bolts (355.790) or read the length directly off the ring marking on the calibrated drill bit. If a depth gauge is used, add 2 mm to the measured length to ensure that the locking bolt can penetrate the anterior cortex.

Precaution: To avoid jeopardising the trunk or branches of the axillary nerve after the skin incision, the underlying muscles should be prepared by blunt dissection and spread apart carefully.



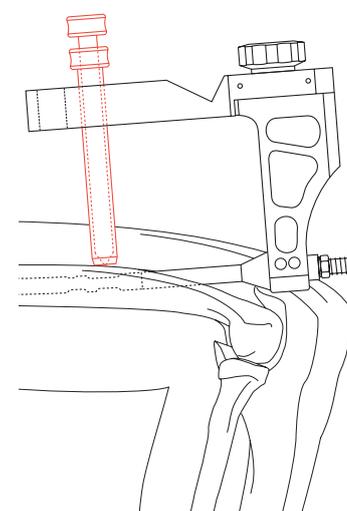
Distal locking

Distal locking is performed using the insertion handle with the attached aiming arm. Normally, double-locking in parallel is performed at the distal end, i.e. both the static and compression holes are used.

8. Mount aiming arm and insert trocar combination

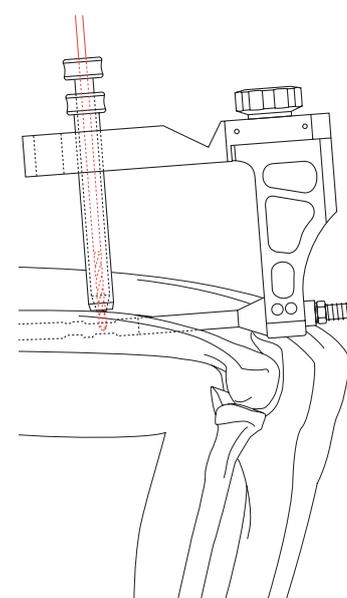
- Mount the Aiming Arm for Standard Locking (358.689) on the insertion handle. Check the insertion handle/nail connection and tighten if necessary. Likewise, check the reduction.

Insert the two-piece trocar combination (Protection Sleeve 11.0/8.0 [355.700], Trocar \varnothing 8.0 mm [355.750]) through the desired hole in the aiming arm, make a stab incision and insert the trocar down to the bone. Remove the trocar and insert the drill sleeve corresponding to the diameter of the bolt or drill (for \varnothing 3.9 mm bolts use Drill Sleeve 8.0/3.2 [355.722], for \varnothing 3.4 mm bolts use Drill Sleeve 8.0/2.7 [359.026]).



9. Drill and determine length of locking bolt

- Using the appropriate drill bit (\varnothing 3.2 mm for \varnothing 3.9 mm bolts, \varnothing 2.7 mm for \varnothing 3.4 mm bolts), drill through both cortices until the tip of the drill bit just breaks through the anterior cortex. The required length of the locking bolt can be determined either by reading it directly off the calibrated drill bit or by measuring with the Depth Gauge for Screws (319.010) or the Depth Gauge for Locking Bolts (355.790). If a depth gauge is used, add 2 mm to the measured length to ensure that the locking bolt can penetrate the anterior cortex.



10. Insert locking bolts

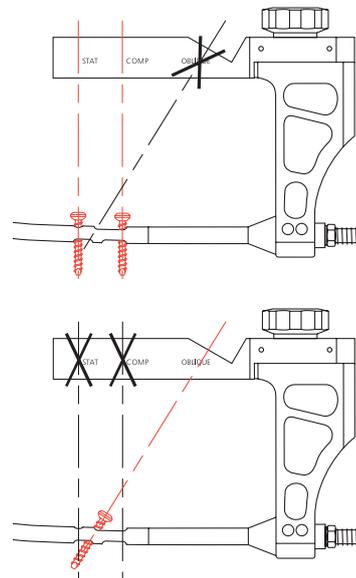
Insert a locking bolt through the protection sleeve and tighten using the Large Hexagonal Screwdriver \varnothing 3.5 mm (314.270) until the bolt head rests against the posterior cortex. The tip of the locking bolt should project beyond the anterior cortex by 1–2 mm.



Insert the second locking bolt in the same way.

Insert two locking bolts into each main fragment, particularly into short fragments.

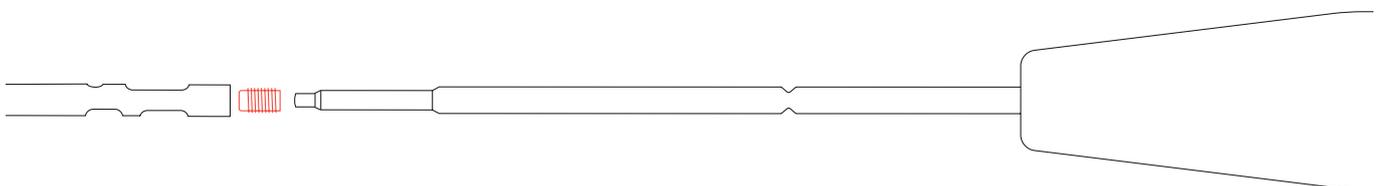
The insertion of a locking bolt through the oblique locking hole prevents the insertion of a second locking bolt through the perpendicular holes and thus the application of compression.



11. Insert end cap into nail

The end cap protects the inner thread of the nail from tissue ingrowth and facilitates subsequent implant removal. The end cap is available in four lengths (extension of 0, 5, 10 or 15 mm) and can, if necessary, be used to extend the nail and thus allow more flexible placement of the locking bolts in regions with better bone quality.

Tighten the end cap using the hexagonal screwdriver (for the 0 mm extension use the Small Hexagonal Screwdriver \varnothing 2.5 mm [314.240], for all other extensions use the Large Hexagonal Screwdriver \varnothing 3.5 mm [314.270]).



12. Postoperative management

Apply a sterile dressing with cotton wool padding post-operatively; additional splinting of the arm is not required.

Check radial nerve function when the anaesthetic has worn off.

Remove the Redon drain on the second postoperative day.

Active and passive movements and muscle-tensing exercises in the shoulder and elbow can begin immediately, although rotational movements against resistance should be avoided until the fracture has healed.

13. X-ray follow-up

- X-rays are recorded immediately after the operation. Further X-rays are recorded after two, six and twelve weeks, and beyond, depending on the course of the healing process.

Compression (optional)

Compared to the femur and the tibia, the humerus is less exposed to compressive stresses but more exposed to rotational stresses. Thus, while dynamic loading will produce fragment adaptation with certain fracture types in the femur and the tibia, healing problems can occur with corresponding fractures of the humeral shaft.

The application of compression facilitates the controlled joining of the fragments with the aim of closing the fracture gap or exerting interfragmental compression.

Interfragmental compression can therefore be applied in the following types of humeral shaft fractures:

- Transverse fractures
- Short oblique fractures

Precautions: In view of the associated loss of length and possible dislocations, compression shall not be applied for the following fracture types:

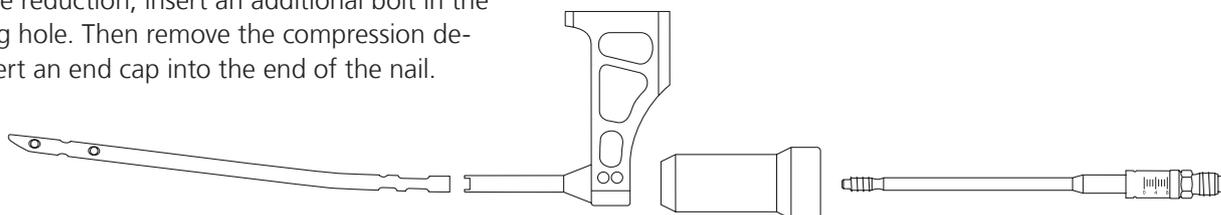
- Spiral fractures
- Long oblique fractures
- Longitudinally unstable fractures

Applying compression

Screw the Compression Device (358.600) with the Compression Connecting Screw (358.610) and insertion handle onto the nail using the Ratchet Wrench \varnothing 11.0 mm (321.200) or the Combination Wrench \varnothing 11.0 mm (321.160). Insert the nail into the medullary canal and lock distally in the compression hole. Next, lock

- 1 the nail in the proximal fragment under image intensifier control. Tightening the nut on the end of the compression connecting screw moves the bolt in the compression hole and the corresponding distal fragment in a proximal direction (by a maximum of 8 mm). The moment in which the fragments come together must be
- 2 checked under the image intensifier, bearing in mind that when the fragments approximate, the base of the nail is located slightly more distally (risk of impingement).

To secure the reduction, insert an additional bolt in the static locking hole. Then remove the compression device and insert an end cap into the end of the nail.



UHN – Antegrade insertion

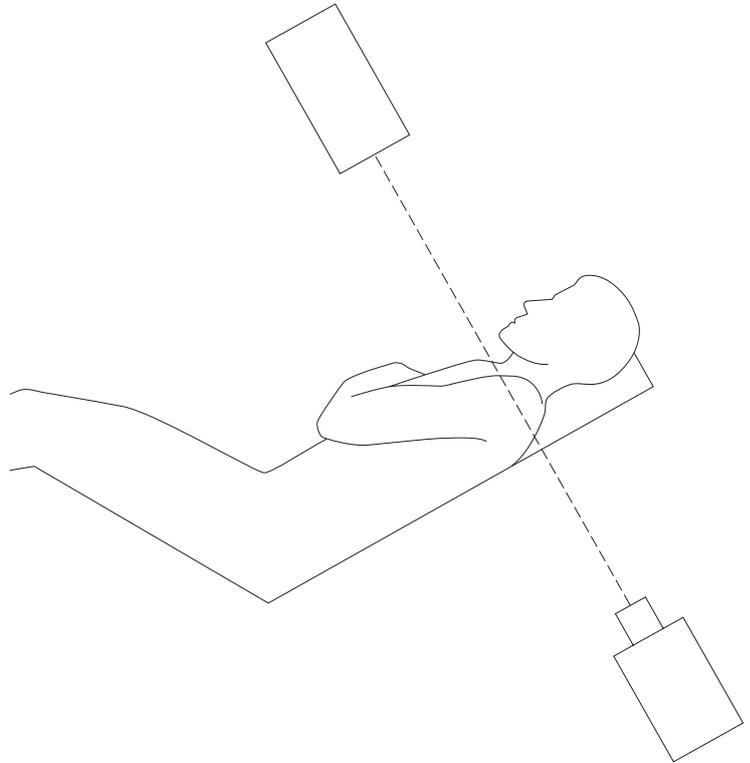
1. Position patient

Position the patient on his/her back with the upper body raised at an angle of 30°. Support the shoulder with pads. The operating table must be radiolucent in the shoulder area, or else it should be possible to remove the corresponding table section. It must be possible to view the whole upper arm, including the elbow and humeral head, in two planes in the image intensifier. Support the fractured arm on a side rest.

2. Determine nail length

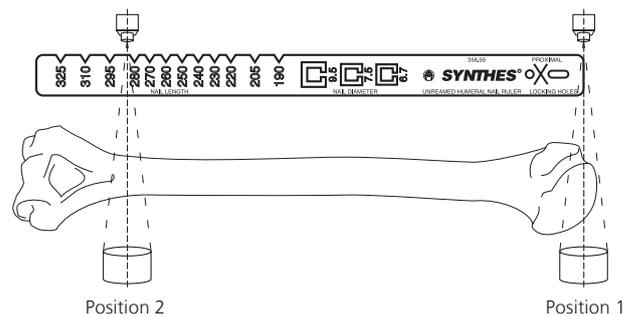
The approximate nail length can be determined preoperatively. Measure the length of the unfractured humerus from its head to the olecranon fossa and deduct 3–4 cm from the measured distance.

On the fractured arm, the correct length can only be determined correctly if the fracture is correctly reduced.



- 1 Position the image intensifier for an AP view of the proximal humerus (position 1). Hold the Radiographic Ruler for UHN (358.590) parallel to the humerus so that the locking holes symbolized on the ruler are located at the correct point against the proximal humerus. Mark the skin at the proximal end of the ruler.

- 2 Position the image intensifier over the distal humerus (position 2), place the proximal end of the ruler next to the marked skin site and record an AP image. Check the reduction and read off the nail length from the illustration on the ruler.



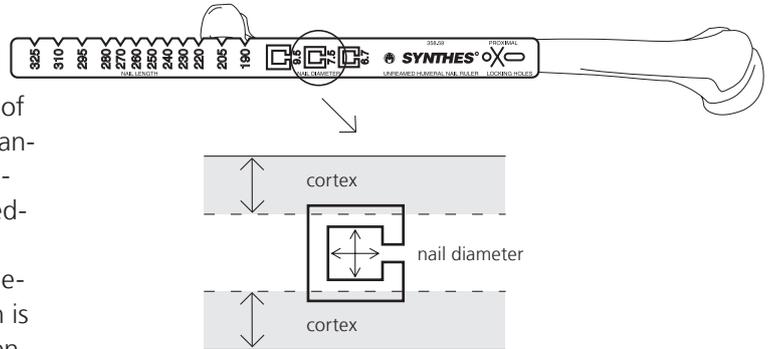
Note: The nail tip should be positioned at least 25 mm away from the cranial boundary of the olecranon fossa.

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 nail diameter

- Position the image intensifier for a lateromedial view of the distal humerus. Hold the ruler parallel or at right angles to the humerus so that the square “NAIL DIAMETER” marking (6.7, 7.5, 9.5) is positioned over the medullary canal. The inner square of this marking corresponds to the nail diameter. Select the nail diameter shown when the medullary canal/cortex transition is still visible at the sides of the square in the image intensifier.



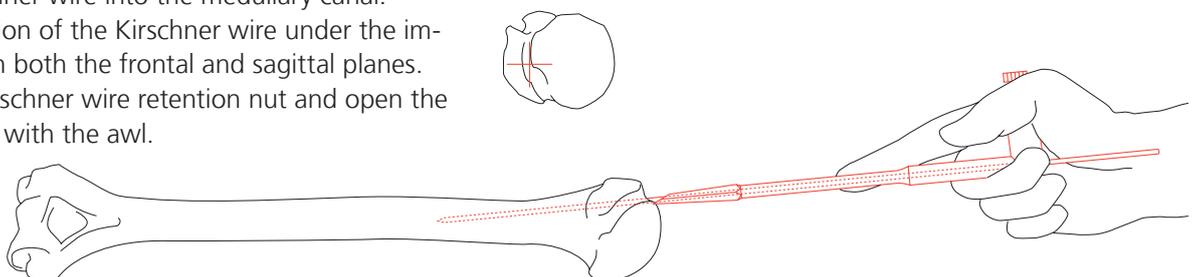
4. Open medullary canal

Make the initial incision anterolateral to the acromion process and split the deltoid muscle longitudinally. Palpate the greater tuberosity, identify – but do not expose – the supraspinatus tendon and split the mid section lengthwise. Avoid any additional injury to the rotator cuff. The arm can be adducted across the chest in order to gain better access to the proximal humerus.

The antegrade insertion point for the UHN is located on the extended axis of the central humeral shaft at the bone-cartilage transition of the humeral head and not on the greater tuberosity, otherwise the tendon attachment of the supraspinatus will be affected. With the humeral head correctly positioned, the point is located just in front of, or below, the tip of the acromion process. Find this position under the image intensifier using a Kirschner Wire \varnothing 2.5 mm with Trocar Tip (292.260). The orientation between an excessively ventral or dorsal position of the Kirschner wire can be determined where the line of the humeral head intersects the Kirschner wire. The Kirschner wire is located in the exact position if it rests in the middle of the humeral head.

Using the cannulated Awl with T-Handle (351.120), advance the Kirschner wire into the medullary canal.

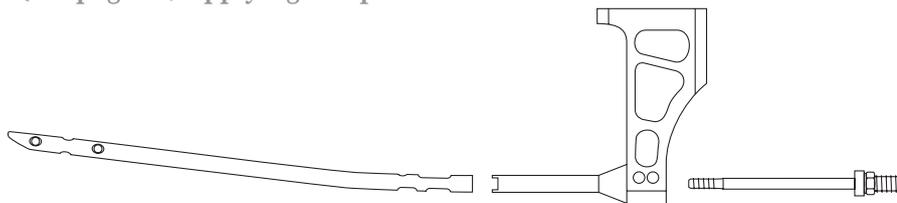
- Check the position of the Kirschner wire under the image intensifier in both the frontal and sagittal planes. Unscrew the Kirschner wire retention nut and open the medullary canal with the awl.



5. Mount nail on insertion handle

Mount the selected nail on the Insertion Handle (358.692), ensuring that the apex of the nail curvature points away from the insertion handle. Screw the Connecting Screw (358.540) through the insertion handle into the nail and tighten using the Ratchet Wrench \varnothing 11.0 mm (321.200) or the Combination Wrench \varnothing 11.0 mm (321.160).

Note: If interfragmental compression with minimizing of the fracture gap is desired for transverse or short oblique fractures, the Compression Device (358.600) and the Compression Connecting Screw (358.610) must be screwed onto the insertion handle at this point (see page 27, Applying compression).



6. Insert nail

Insert the nail with slight rotating movements of the insertion handle. It is not advisable to use a hammer when inserting the UHN since this increases the risk of iatrogenic fissures or fractures at the insertion site. Insert the nail up to the fracture site, reduce the fracture and continue beyond the fracture under image intensifier control.

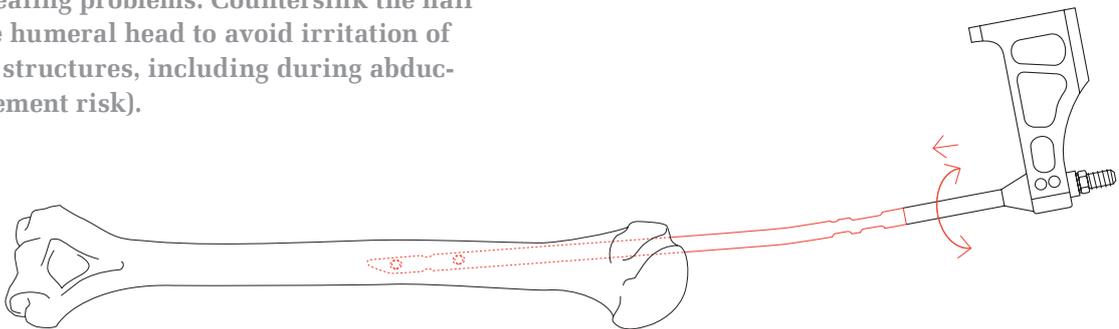
1 Proceed carefully so as to avoid injury to the radial nerve, particularly in fractures of the mid to distal third of the shaft.

If radial nerve palsy is present preoperatively, it may be necessary to explore the nerve through a short anterolateral incision at the transition of the mid and distal third of the shaft.

- 1 Check the nail position under the image intensifier.

Precautions:

- If the nail proves very difficult to advance, check whether widening of the medullary canal by using a reamer system is indicated. This reduces the risk of iatrogenic fractures. Under no circumstances should the nail be knocked in with a hammer.
- Pressure against the olecranon when advancing the nail prevents diastasis formation and possible associated healing problems. Countersink the nail fully into the humeral head to avoid irritation of the shoulder structures, including during abduction (impingement risk).



Distal locking

If the fracture gap is properly reduced, proximal locking may be carried out first. Otherwise distal locking should be implemented first: When the nail tip has reached the desired position, lock it distally. Then apply light reverse hammer blows before locking the nail proximally.

If a spiral blade is used, the nail must always be locked first at the proximal end so that the spiral blade can be placed in the optimal position.

Distal locking

Double-locking in parallel is normally performed at the distal end using the radiolucent drive or the “freehand” technique.

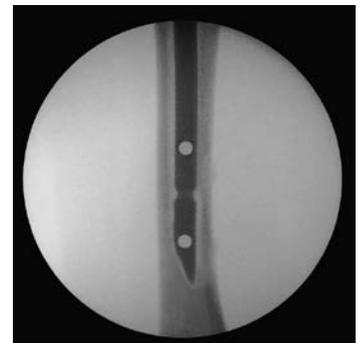
Distal locking with the Radiolucent Drive is described below.

7. Position insertion handle and adjust image

- 1 Check the insertion handle/nail connection and tighten the connecting screw if necessary. In case of proximal locking with a spiral blade, swivel the insertion handle with aiming arm approx. 20° ventrally so as to respect the retrotorsion of the humeral head. Thus, the spiral blade will be positioned in the centre of the humeral head.
- 2 Check the position of the distal fragment, since a fracture gap could have resulted from nail insertion.
- 3 Align the image intensifier with the distal nail holes such that the holes appear perfectly round in the image.



Incorrect

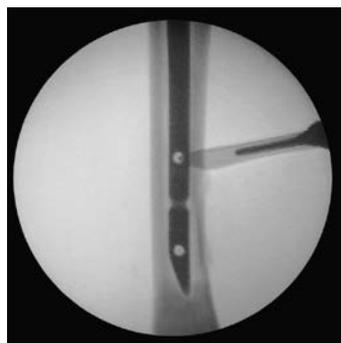


Correct

8. Perform incision

- 1 Determine the entry point on the skin and perform a stab incision with the scalpel.

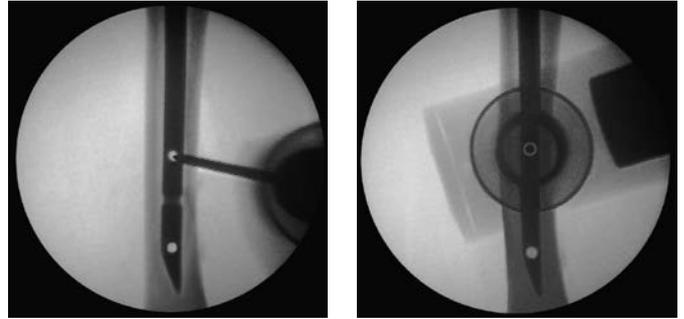
Precaution: To avoid injury to the brachial artery or median nerve, perform blunt dissection down to the bone.



9. Drill

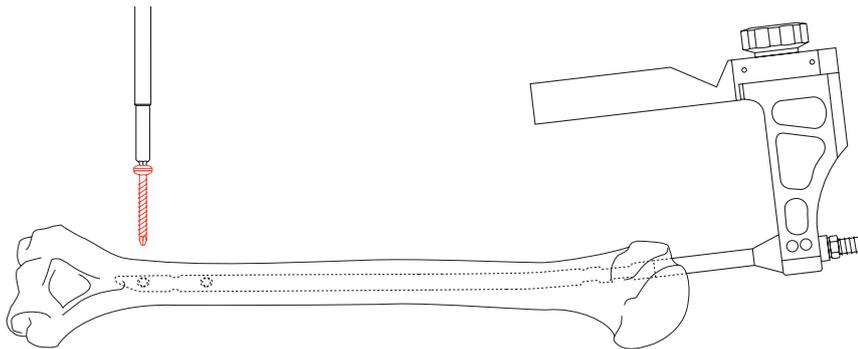
Using Drill Bit \varnothing 3.2 mm (315.330) for the \varnothing 3.9 mm bolts or Drill Bit \varnothing 2.7 mm (359.031) for the \varnothing 3.4 mm bolts, insert the corresponding bit into the radiolucent drive and introduce through the incision down to the bone.

- 1 Incline the radiolucent drive such that the tip of the drill bit is centered over the locking hole. The bit should almost completely fill the circular locking hole. Holding the drill bit in this position, drill through both cortices until the tip just penetrates the posterior cortex.



10. Determine length of locking bolts and insert locking bolts

If the calibrated drill bit is used, read the correct bolt length directly off the ring marking or use the Depth Gauge for Screws (319.010) or the Depth Gauge for Locking Bolts (355.790). If a depth gauge is used, add 2 mm to the measured length to ensure that the locking bolt can penetrate the posterior cortex.



Proximal locking with bolt (standard locking)

Proximal locking is performed using the insertion handle with the attached aiming arm, which should be aligned precisely in the mediolateral plane.

Single-hole oblique locking is considered to be the standard locking method for antegrade insertion, since it does not interfere with the dome of the humerus and offers better purchase medially thanks to the stronger cortical bone.

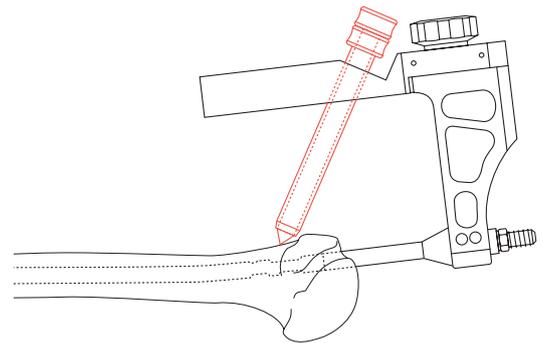
For proximal locking with the spiral blade see pages 28–32, steps 11b–17b.

11a. Mount aiming arm and insert trocar combination

Mount the Aiming Arm for Standard Locking (358.689) on the insertion handle. Confirm the reduction.

Insert the two-piece trocar combination (Protection Sleeve 11.0/8.0 [355.700], Trocar \varnothing 8.0 mm [355.750]) through the desired hole in the aiming arm, make a stab incision and insert the trocar down to the bone. Remove the trocar and insert the drill sleeve corresponding to the bolt/drill diameter (for \varnothing 3.9 mm bolts use Drill Sleeve 8.0/3.2 [355.722], for \varnothing 3.4 mm bolts use Drill Sleeve 8.0/2.7 [359.026]).

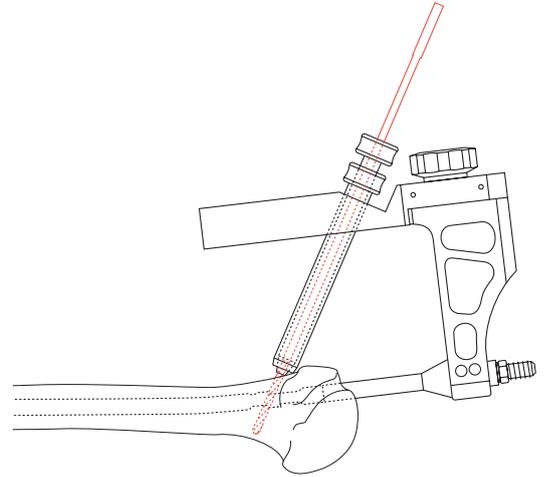
Precaution: Only incise the skin and then perform blunt dissection so as to avoid injury to the axillary nerve and its branches.



12a. Drill and determine length of locking bolt

- 1 Drill through the lateral cortex using the appropriate drill bit (\varnothing 3.2 mm for \varnothing 3.9 mm bolts or \varnothing 2.7 mm for \varnothing 3.4 mm bolts). Monitor drill bit insertion radiographically, since the position of the drill bit tip directly represents locking bolt tip position in the bone. This locking bolt may be bicortical or unicortical depending upon its placement relative to the articular surface.

The required length of the locking bolt can be determined either by reading it directly off the calibrated drill bit or by measuring with the Depth Gauge for Screws (319.010) or the Depth Gauge for Locking Bolts (355.790). If a depth gauge is used for bicortical locking, add 2 mm to the measured length to ensure that the locking bolt can penetrate the medial cortex.

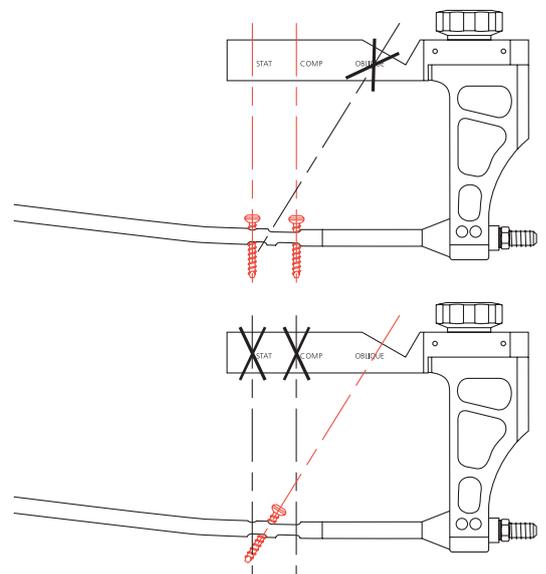


13a. Insert locking bolts

- 1 Insert a locking bolt through the protection sleeve and tighten using the Large Hexagonal Screwdriver \varnothing 3.5 mm (314.270) until the bolt head rests against the lateral cortex. The tip of the locking bolt should project beyond the medial cortex by 1–2 mm for bicortical locking.

Follow the same procedure for inserting the second locking bolt when locking transversely.

Note: The insertion of a locking bolt through the oblique locking hole prevents the insertion of a second bolt through the perpendicular holes and the application of compression.



14a. Insert end cap into nail

The end cap protects the inner thread of the nail from tissue ingrowth and facilitates subsequent implant removal. The end cap is available in four lengths (extension of 0, 5, 10 or 15 mm) and can, if necessary, be used to extend the nail and thus allow more flexible placement of the locking bolts in regions with better bone quality.

Tighten the end cap using the hexagonal screwdriver (for the 0mm extension use the Small Hexagonal Screwdriver \varnothing 2.5 mm [314.240], for all other extensions use the Large Hexagonal Screwdriver \varnothing 3.5 mm [314.270]).

Ensure that the nail and the end cap are fully counter-sunk in the humeral head, so that shoulder function remains unhindered, including during abduction. For this reason, an end cap without extension should be used where possible.

Note: If the compression device is used, bear in mind that the base of the nail will be located close to the surface of the domed head. It is preferable to insert the base of the nail deeper into the humeral head and, if necessary, to offset the excessive distance from the dome surface with an appropriate end cap.



15a. Postoperative management

Apply a sterile dressing with cotton wool padding post-operatively; additional splinting of the arm is not required.

Check radial nerve function when the anaesthetic has worn off.

Remove the Redon drain on the second postoperative day.

Active and passive movements and muscle-tensing exercises in the shoulder and elbow can begin immediately, although rotational movements against resistance should be avoided until the fracture has healed.

16a. X-ray follow-up

- ❶ X-rays are recorded immediately after the operation. Further X-rays are recorded after two, six and twelve weeks, and beyond, depending on the course of the healing process.

Compression (optional)

Compared to the femur and the tibia, the humerus is less exposed to compressive stresses but more exposed to rotational stresses. Thus, while dynamic loading will produce fragment adaptation with certain fracture types in the femur and the tibia, healing problems can occur with corresponding fractures of the humeral shaft.

The application of compression facilitates the controlled joining of the fragments with the aim of closing the fracture gap or exerting interfragmental compression.

Interfragmental compression can therefore be applied in the following types of humeral shaft fractures:

- Transverse fractures
- Short oblique fractures

Precautions: In view of the associated loss of length and possible dislocations, compression shall not be applied for the following fracture types:

- **Spiral fractures**
- **Long oblique fracture**
- **Longitudinally unstable fractures**

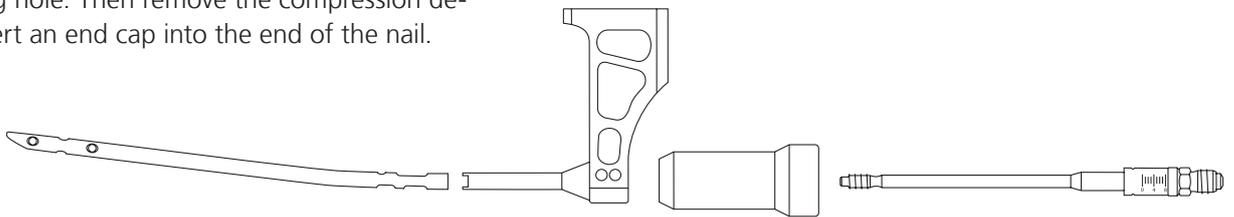
The compression device is designed primarily for the retrograde procedure, since two parallel bolts are required at the base of the nail. In the antegrade procedure, only one bolt is locked obliquely as a rule. Nevertheless, it is still possible to use the compression device in the antegrade procedure. It should be noted, however, that the bone purchase for these two bolts, now aligned in parallel, will be reduced as a result of the minimal cortical thickness and that the compression bolt produces less compression in the cancellous bone compared to the retrograde technique.

Applying compression

Screw the Compression Device (358.600) with the Compression Connecting Screw (358.610) and insertion handle onto the nail using the Ratchet Wrench \varnothing 11.0mm (321.200) or the Combination Wrench \varnothing 11.0mm (321.160). Insert the nail into the medullary canal and lock proximally in the compression hole.

- ① Next, lock the nail in the distal fragment under image intensifier control. Tightening the nut on the end of the compression connecting screw moves the bolt in the compression hole, together with the whole distal fragment, in a proximal direction. The moment in which the fragments come together must be checked under the
- ① image intensifier, bearing in mind that, when the fragments approximate, the base of the nail is located slightly more proximally (risk of impingement).

To secure the reduction, insert an additional bolt in the static locking hole. Then remove the compression device and insert an end cap into the end of the nail.



Proximal locking with spiral blade

Spiral blade locking offers greater stability in the proximal fragment compared to locking bolts, particularly in the following cases: shaft fractures extending well into the proximal section, combinations of shaft fractures with an ipsilateral, subcapital humerus fracture, and in patients with osteoporotic bone.

11b. Mount aiming arm and insert trocar combination

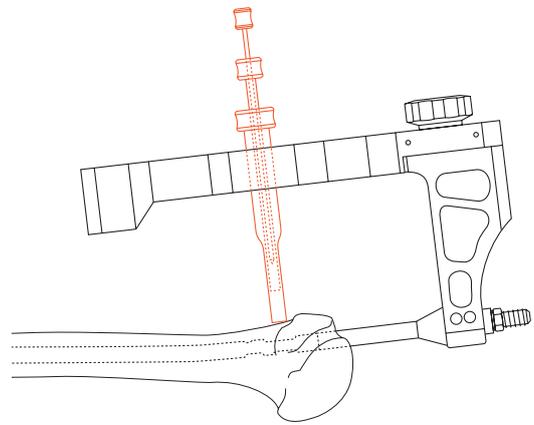
Mount the Aiming Arm for Spiral Blade Locking (358.679) on the insertion handle.

- If starting with proximal locking, tighten the connecting screw if necessary. Likewise, check the reduction. Swivel the insertion handle with aiming arm approx. 20° ventrally so as to respect the retrotorsion of the humeral head. Thus, the spiral blade will be positioned in the centre of the humeral head.

Make a skin incision and insert the three-piece trocar combination (Protection Sleeve 14.0/4.5 [358.688], Drill Sleeve 4.5/2.0 [358.694], Trocar Ø 2.0 mm [358.686]) through the hole in the aiming arm marked "Spiral Blade" and insert the trocar down to the bone.

Remove the trocar.

Precaution: Only incise the skin and then perform blunt dissection so as to avoid injury to the axillary nerve and its branches.



12b. Determine length of spiral blade and drill

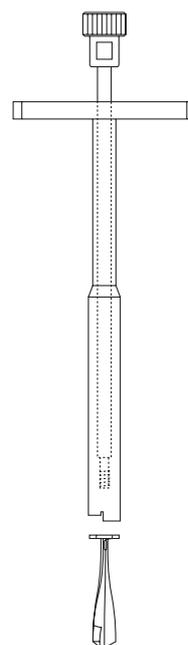
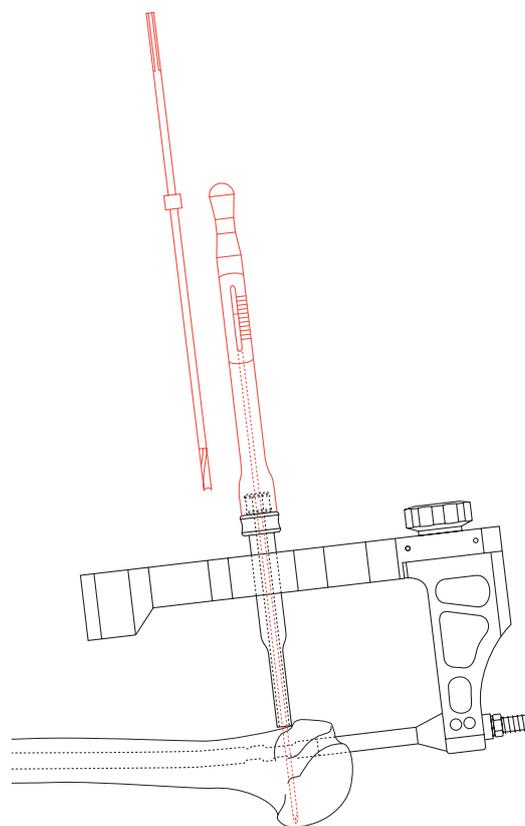
- Insert a Guide Wire \varnothing 2.0 mm (292.650) through the Drill Sleeve 4.5/2.0 (358.694) into the humeral head
- and use the image intensifier to check the definitive position at the transition of the medial and lower third of the humeral head. The wire should extend almost to the cortex on the opposite side, but should not perforate it down to the subchondral space. Pass the Depth Gauge for Spiral Blades (358.698) over the guide wire and read off the length of the spiral blade on the scale. Remove the drill sleeve and depth gauge; the guide wire must remain in the bone.

Precaution: Guide Wires are single-use items, do not re-use.

- Pass the Cannulated Drill \varnothing 4.5 mm for Spiral Blades (358.691) over the guide wire and drill down to the stop under image intensifier control.
-

13b. Attach spiral blade to inserter

Insert the Connecting Screw (358.697) in the Inserter for Spiral Blade (358.696), mount the golden Spiral Blade (462.634–654) for 7.5/9.5 mm UHN and for PHN or the pink Spiral Blade (462.672–688) for 6.7 mm UHN of the determined length on the cams of the inserter and tighten the connecting screw. Check for a secure fit.



14b. Insert spiral blade

Introduce the spiral blade and inserter over the Kirschner wire, through the aiming arm and down to the lateral cortex.

Align the T-handle of the inserter parallel with the aiming arm. Applying gentle hammer blows to the connecting screw, advance the spiral blade to the desired position. This will cause the T-handle to rotate through 90°.

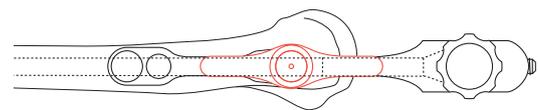
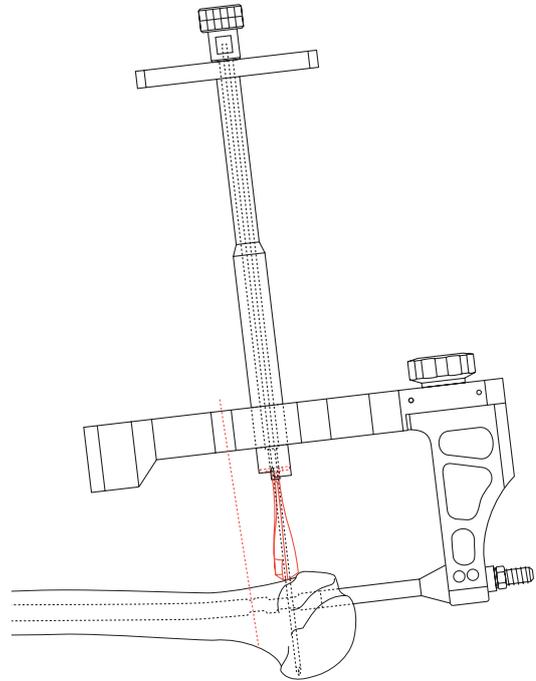
Check the position of the spiral blade under the image intensifier.

Unscrew the insertion instruments for the spiral blade and remove the Kirschner wire.

If necessary, a transverse locking bolt can still be inserted through the proximal hole (shown in red in the illustration).

Remove the insertion handle.

Note: For fractures with avulsion of the greater tuberosity (B fractures), the latter must always be reduced and fixed as well. This can be achieved either by means of a covered technique or by extending the cranial incision. The tuberosity can be fixed with a cannulated titanium screw B 4.0 mm or with tension-band wiring. In the latter technique, a suture or wire loop, for example, can be anchored in the specially provided holes on the spiral blade or on the most proximal locking bolt.



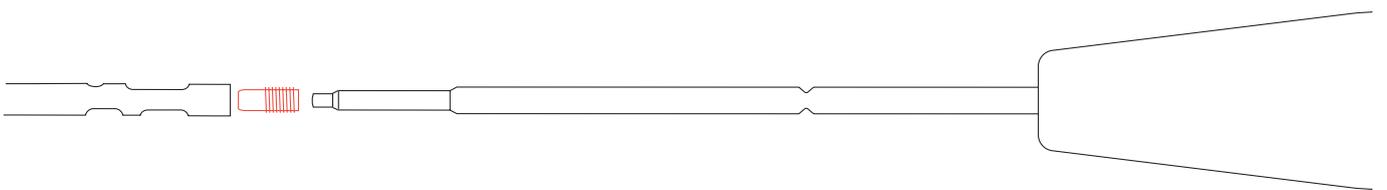
15b. Insert end cap into nail

The end cap protects the inner thread of the nail from tissue ingrowth and facilitates subsequent implant removal. A special gold-coloured End Cap (462.660/665/666/667) is used to lock the spiral blade. During insertion, increased resistance is encountered during the final few turns as a result of the notch on the thread, which is designed to prevent loosening of the screw. Tighten the end cap securely.

The end cap is available in four lengths (extension of 0, 5, 10 or 15 mm) and can, if necessary, be used to extend the nail and thus allow more flexible placement of the locking bolts in regions with better bone quality.

Ensure that the nail and the end cap are fully countersunk in the humeral head, so that shoulder function remains unhindered, including during abduction. For this reason, an end cap without extension should be used where possible.

Note: When locking with a spiral blade, an end cap must always be inserted into the nail, otherwise the spiral blade will not be properly secured.



16b. Postoperative management

Apply a sterile dressing with cotton wool padding post-operatively; additional splinting of the arm is not required. Check radial nerve function when the anaesthetic has worn off.

Remove the Redon drain on the second postoperative day.

Active and passive movements and muscle-tensing exercises in the shoulder and elbow area can begin immediately, although rotational movements against resistance should be avoided until the fracture has healed.

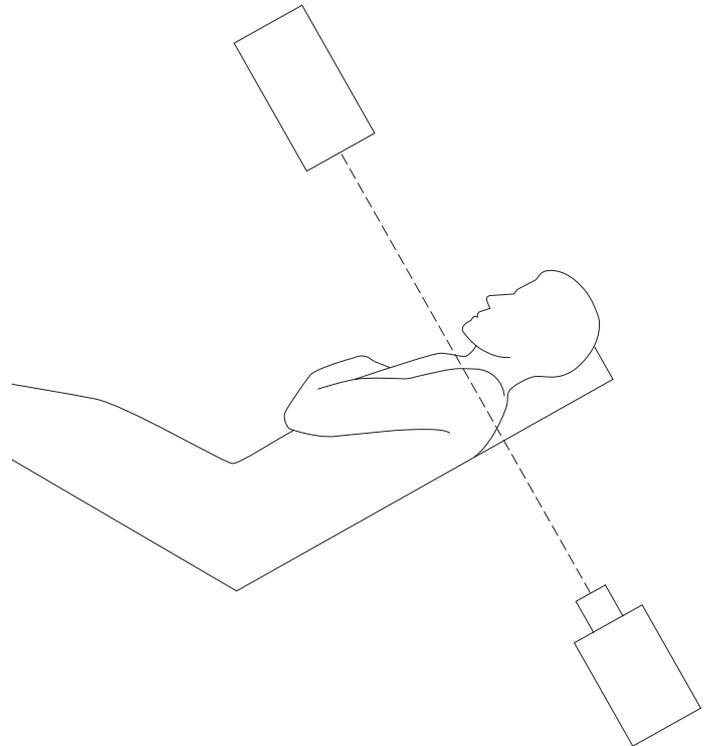
17b. X-ray follow-up

- X-rays are recorded immediately after the operation. X-rays are recorded after two, six and twelve weeks, and beyond, depending on the course of the healing process.

PHN – Antegrade insertion

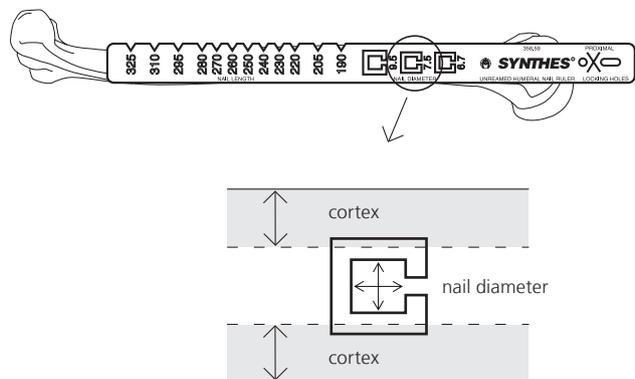
1. Position patient

Position the patient on his/her back with the upper body raised at an angle of 30°. Support the shoulder with pads. The operating table must be radiolucent in the shoulder area, or else it should be possible to remove the corresponding table section. It must be possible to view the humerus, including the humeral head, in two planes in the image intensifier. Support the fractured arm on a side rest.



2. Determine nail diameter

Due to its short length, the PHN usually occupies a relatively wide part of the medullary canal. The \varnothing 7.5 mm PHN is therefore used as the standard nail and the \varnothing 8.0 mm PHN for osteoporotic bone with a very wide medullary canal. In case of doubt, select the nail diameter according to the measuring procedure used for the UHN.



- Position the image intensifier for a lateromedial view of the proximal humerus. Hold the Radiographic Ruler for UHN (358.590) parallel or at right angles to the humerus so that the square "NAIL DIAMETER" marking (7.5 or 9.5 [corresponding to PHN \varnothing 8.0 mm]) is positioned over the medullary canal. The inner square of this marking corresponds to the nail diameter. Select the nail diameter shown when the medullary canal/cortex transition is still visible at the sides of the square in the image intensifier.

3. Open medullary canal

In certain cases after a closed reduction, the humeral head may need to be fixed temporarily with a raspatory or Kirschner wire. The correct head position is visible in the AP view by ensuring the maximum humeral head diameter.

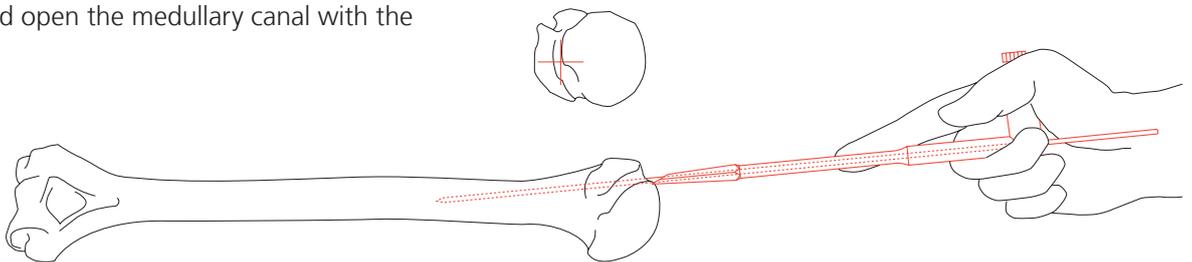


Perform an anterior incision in the region of the acromion process and split the deltoid muscle and rotator cuff.

Using the cannulated Awl with T-Handle (351.120), insert a Kirschner wire \varnothing 2.5 mm (292.260) at the appropriate insertion point in the proximal humerus and advance in the medullary canal. Check the position of the

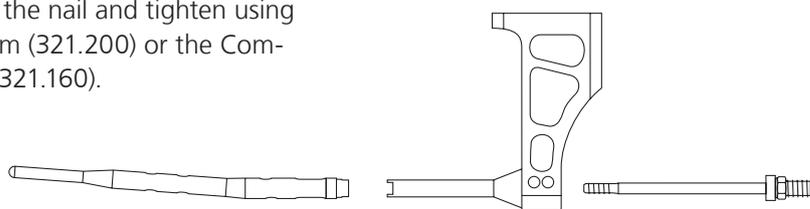


Kirschner wire under the image intensifier in both the frontal and sagittal planes. Unscrew the Kirschner wire retention nut and open the medullary canal with the awl.



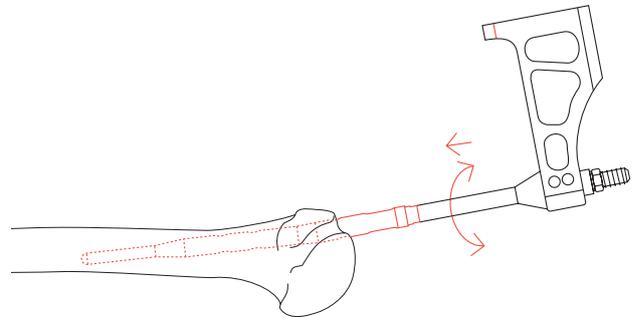
4. Mount nail on insertion handle

Mount the selected nail on the Insertion Handle (358.692), ensuring that the apex of the nail curvature points away from the insertion handle. Screw the Connecting Screw (358.540) into the nail and tighten using the Ratchet Wrench \varnothing 11.0 mm (321.200) or the Combination Wrench \varnothing 11.0 mm (321.160).



5. Insert nail

Insert the nail with slightly rotating movements of the insertion handle. Insert the nail up to the fracture site, reduce the fracture and continue beyond the fracture gap under the image intensifier.

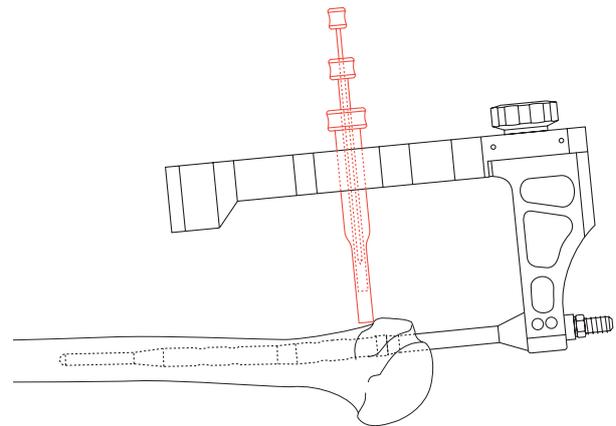


Proximal locking

After insertion, always lock the nail proximally first. To this end, the nail must be countersunk below the surface of the humeral head so that it does not project above the domed head even after the end cap is inserted and so that the spiral blade is not positioned too distally.

6. Mount aiming arm and insert trocar combination

Mount the Aiming Arm for Spiral Blade Locking (358.679) on the insertion handle. Check the insertion handle/nail connection and tighten the connecting screw if necessary. Likewise, check the reduction.



Swivel the insertion handle with aiming arm approx. 20° ventrally so as to respect the retrotorsion of the humeral head. Thus, the spiral blade will be positioned in the centre of the humeral head.

Make a skin incision and insert the three-piece trocar combination (Protection Sleeve 14.0/4.5 [358.688], Drill Sleeve 4.5/2.0 [358.694], Trocar Ø 2.0 mm [358.686]) through the hole in the aiming arm marked "Spiral Blade" and insert the trocar down to the bone.

Remove the trocar.

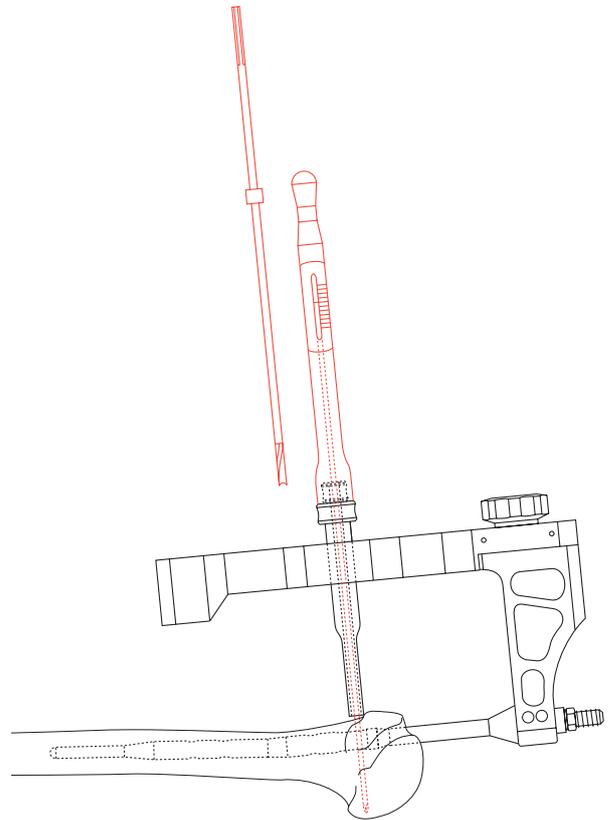
Precaution: Only incise the skin and then perform blunt dissection so as to avoid injury to the axillary nerve and its branches.

7. Determine length of spiral blade and drill

- Insert a Guide Wire \varnothing 2.0 mm (292.650) through the Drill Sleeve 4.5/2.0 (358.694) into the humeral head
- 1 and use the image intensifier to check the definitive position at the transition of the medial and lower third of the humeral head. The wire should extend almost to the cortex on the opposite side, but should not perforate it down to the subchondral space. Pass the Depth Gauge for Spiral Blades (358.698) over the guide wire and read off the length of the spiral blade on the scale. Remove the drill sleeve and depth gauge; the guide wire must remain in the bone.

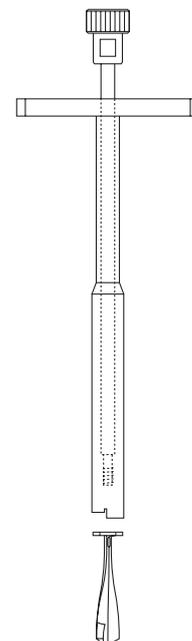
Precaution: Guide Wires are single-use items, do not re-use.

- Pass the Cannulated Drill \varnothing 4.5 mm for Spiral Blades (358.691) over the guide wire and drill down to the
- 1 stop under image intensifier control.



8. Attach spiral blade to inserter

Insert the Connecting Screw (358.697) in the Inserter for Spiral Blades (358.696), mount the selected Spiral Blade (462.634–654) on the cams of the inserter and tighten the connecting screw. Check for a secure fit.



9. Insert spiral blade

Introduce the spiral blade and inserter over the Kirschner wire, through the aiming arm and down to the lateral cortex.

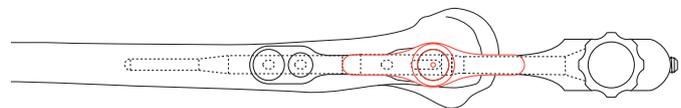
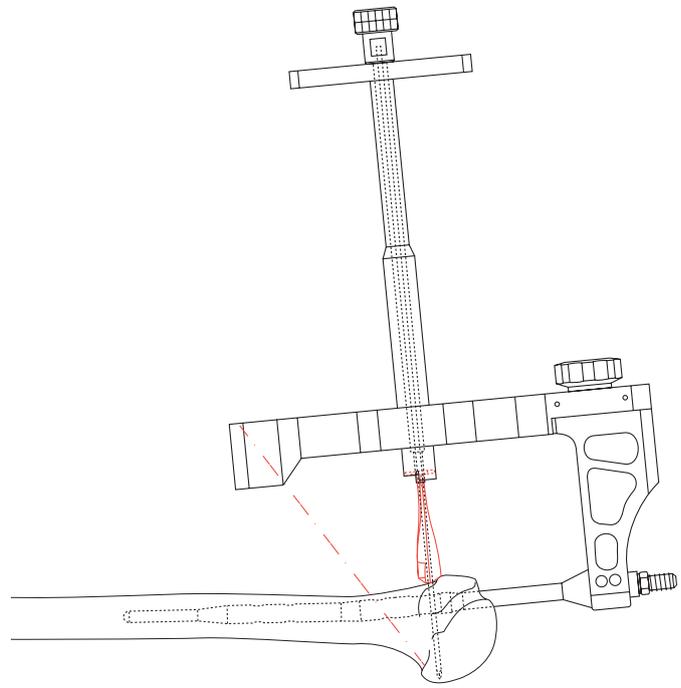
Align the T-handle of the inserter parallel with the aiming arm. Applying gentle hammer blows to the connecting screw, advance the spiral blade to the desired position. This will cause the T-handle to rotate clockwise through 90°. Check the position of the spiral blade under the image intensifier.

Unscrew the insertion instruments for the spiral blade and remove the Kirschner wire.

The lateral cortex fragment can be further secured with an oblique bolt (shown in red in the illustration). Insert the bolt as shown in steps 10, 11 and 12 on pages 39 and 40. Ensure that the drill bit does not come into contact with the spiral blade during drilling.

Precaution: The obliquely inserted bolt should not be longer than 50mm, otherwise it will come into contact with the spiral blade.

Note: For fractures with avulsion of the greater tuberosity (B fractures), the latter must always be reduced and fixed as well. This can be achieved either by means of a covered technique or by extending the cranial incision. The tuberosity can be fixed with a cannulated titanium screw \varnothing 4.0 mm or with tension-band wiring. In the latter technique, a suture or wire loop, for example, can be anchored in the specially provided holes on the spiral blade or on the most proximal locking bolt.

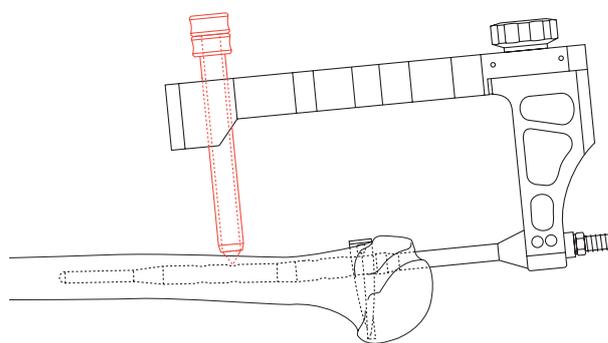


Distal locking

- ① Check the reduction and, if necessary, close the fracture gap by compression. Distal locking is performed using the Aiming Arm for Spiral Blade Locking (358.679).

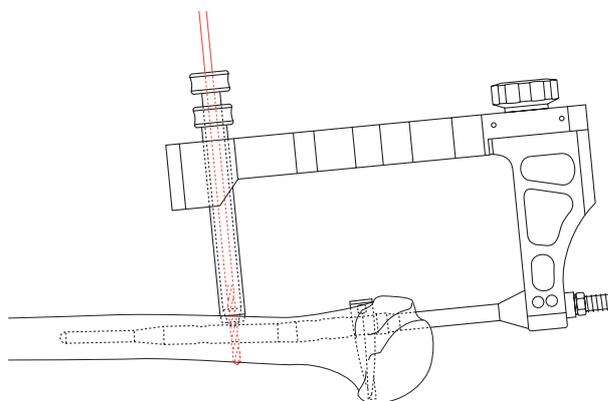
10. Insert trocar combination

Insert the two-piece trocar combination (Protection Sleeve 11.0/8.0 [355.700], Trocar \varnothing 8.0 mm [355.750]) through the desired hole in the aiming arm, make a stab incision and insert the trocar down to the bone. Remove the trocar and insert the Drill Sleeve 8.0/3.2 (355.722).



11. Drill and determine length of locking bolt

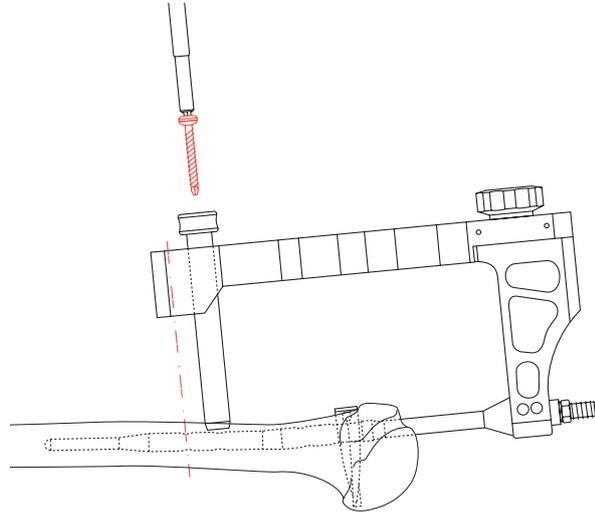
Using the Drill Bit \varnothing 3.2 mm (315.330) drill through both cortices until the tip of the bit just breaks through the medial cortex. The required length of the locking bolt can be determined either by reading it directly off the calibrated drill bit or by measuring with the Depth Gauge for Screws (319.010) or the Depth Gauge for Locking Bolts (355.790). If a depth gauge is used, add 2 mm to the measured length to ensure that the locking bolt can penetrate the medial cortex.



12. Insert locking bolts

Insert a locking bolt through the protection sleeve and tighten using the Large Hexagonal Screwdriver \varnothing 3.5 mm (314.270) until the bolt head rests against the lateral cortex. The tip of the locking bolt should project beyond the medial cortex by 1–2 mm.

Insert the second locking bolt in the same way.



13. Insert end cap into nail

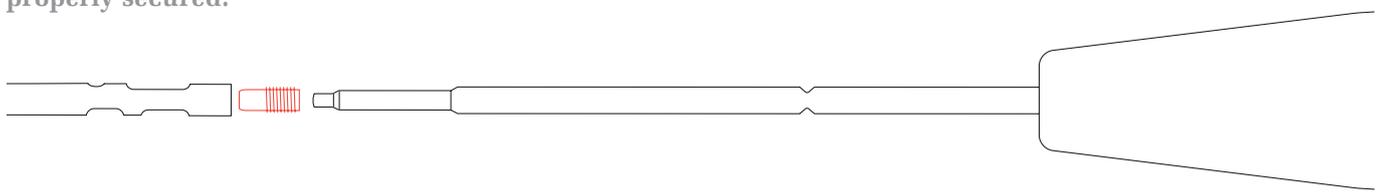
The end cap protects the inner thread of the nail from tissue ingrowth and facilitates subsequent implant removal. A special gold-coloured End Cap (462.660/665/666/667) is used to lock the spiral blade. During insertion, increased resistance is encountered during the final few turns as a result of the notch on the thread, which is designed to prevent loosening of the end cap. Tighten the end cap securely.

The end cap is available in four lengths (extension of 0, 5, 10 or 15 mm) and can, if necessary, be used to extend the nail and thus allow more flexible placement of the locking bolts in regions with better bone quality.

Ensure that the nail and the end cap are fully counter-sunk in the humeral head, so that shoulder function remains unhindered, including during abduction.

After removing the connecting screw, leave the insertion handle on the nail. Using the Small Hexagonal Screwdriver \varnothing 2.5 mm (314.240 or 314.570) place the End Cap 0 mm (462.660) in the proximal end of the nail through the insertion handle. If an end cap with extension is used, insert it directly using the Large Hexagonal Screwdriver \varnothing 3.5 mm (314.270).

Note: The end cap must always be inserted into the nail, otherwise the spiral blade will not be properly secured.



14. Postoperative management

Apply a sterile dressing with cotton wool padding post-operatively. No immobilisation is required if the situation is stable (A fractures). Physiotherapy can be started immediately. Rotational exercises should not be initiated until the end of the third week. Immobilisation for three weeks is indicated if the greater tuberosity has also been fixed or if the bone quality is poor.

15. X-ray follow-up

- X-rays are recorded immediately after the operation. Further X-rays are recorded after two, six and twelve weeks, and beyond, depending on the course of the healing process.

Implant removal

1. Remove end cap and locking bolts or spiral blade

Remove the ingrown tissue from the hexagonal recess of the end cap, the locking bolts and/or the inner thread of the spiral blade. Remove the end cap with extension 0 mm using the Small Hexagonal Screwdriver \varnothing 2.5 mm (314.240 or 314.570). Remove the end cap with extensions 5–15 mm using the Large Hexagonal Screwdriver \varnothing 3.5 mm (314.270). Unscrew all locking bolts except one using the large hexagonal screwdriver and the Holding Sleeve (314.280 or 314.060).

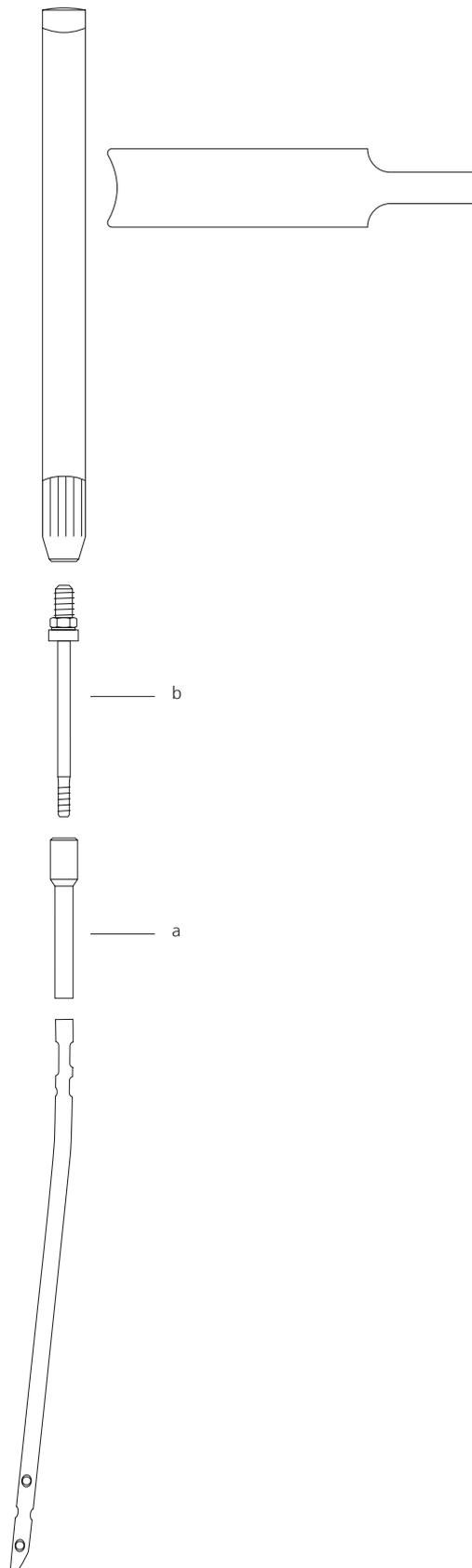
In case of spiral blade locking, screw the inserter onto the spiral blade using the connecting screw for spiral blades and knock the blade out using a hammer.

Before removing the remaining locking bolt, fasten the Connecting Piece for Extraction of UHN (359.021) (a) to the nail using the Connecting Screw (358.540) (b) in order to prevent the nail from rotating or sliding away.

Screw the Inserter/Extractor for UTN/CTN and UHN (356.490) onto the connecting screw.

2. Nail removal

Unscrew the remaining locking bolt and knock the nail out with gentle blows of the Slotted Hammer (332.200).



Case studies

1.

- a. Short oblique fracture of the humeral shaft, AP and lateral views
- b. Retrograde insertion of a \varnothing 7.5 mm UHN, interfragmental compression, static locking, postoperative, AP and lateral views
- c. Bony consolidation after 13 weeks, AP and lateral views



a



b



c

2.

- a. Spiral fracture of the humeral shaft after minor trauma in a patient after many years of cortisone therapy, conspicuously wide medullary canal, AP and lateral views
- b. Retrograde insertion of a \varnothing 9.5 mm UHN, static locking, postoperative, AP and lateral views
- c. Bony consolidation after 16 weeks, AP and lateral views



a



b



c

3.

- a. Pathological fracture of the humeral shaft with meta-static spread from a breast carcinoma, AP view
- b. Antegrade insertion of a \varnothing 7.5mm UHN, proximal oblique static locking, postoperative, AP and lateral views
- c. Situation after 6 months, AP and lateral views



a



b



c

4.

- a. Proximal humeral shaft spiral fracture with fracture extension to the greater tuberosity (accident views)
- b. Managed with a \varnothing 7.5 mm UHN and spiral blade (views recorded immediately after operation)
- c. Fracture united (5 months postoperatively)



a



b



c

5.

- a. Subcapital humeral fracture (accident views)
- b. Managed with PHN and spiral blade (views recorded immediately after operation)
- c. Fracture united (3 months postoperatively)



a



b

c

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MRI Information

Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-14 and ASTM F2119-07

Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a

Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils [whole body averaged specific absorption rate (SAR) of 2 W/kg for 6 minutes (1.5 T) and for 15 minutes (3 T)].

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.
- Patients with impaired thermo regulation or temperature sensation should be excluded from MR scanning procedures.
- 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.

