

Femoral Neck System

Surgical Technique

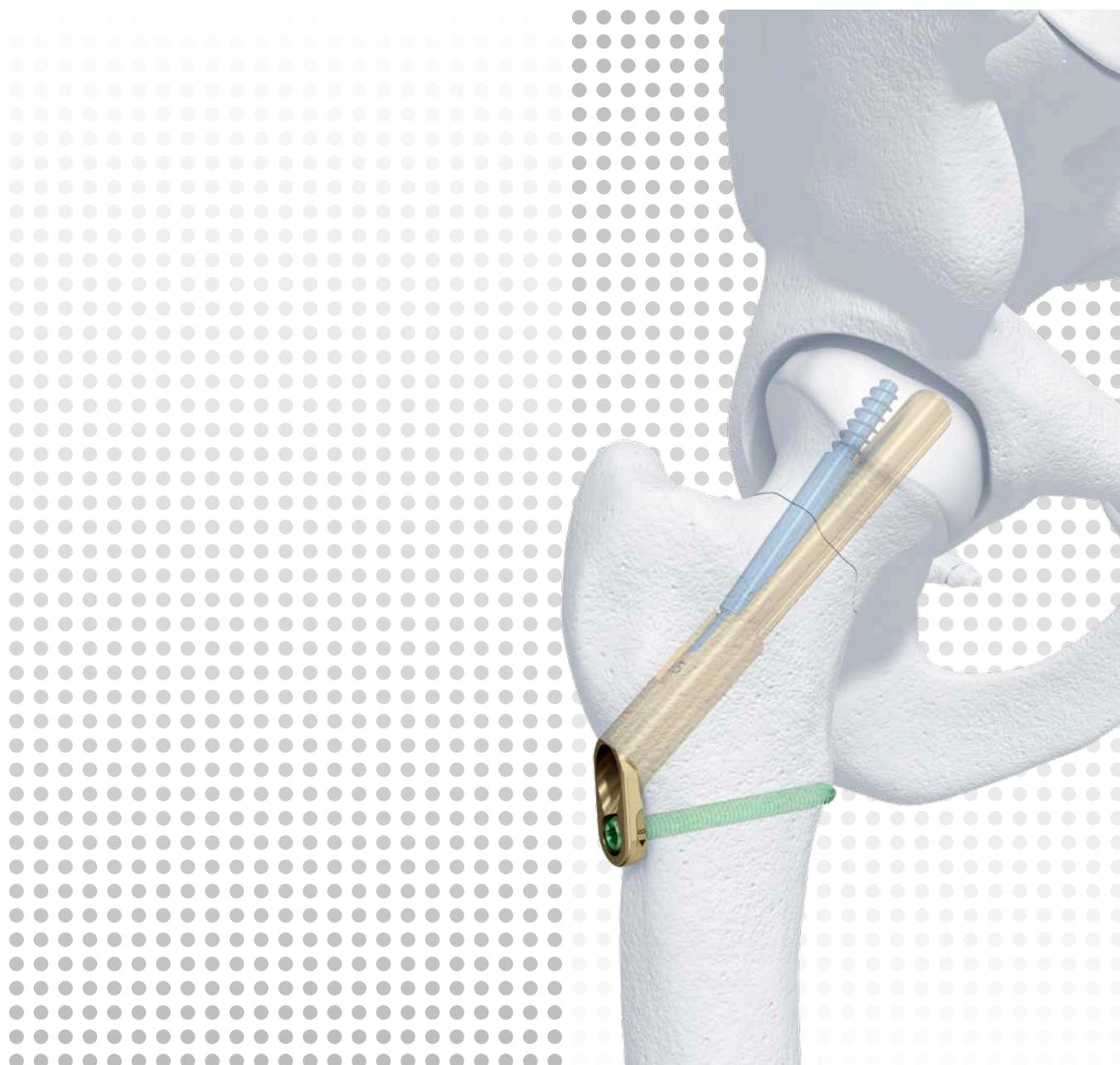


 Image intensifier control

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>

Table of Contents

Introduction	Femoral Neck System	2
	The AO Principles of Fracture Management	4

Surgical Technique	Preparation	5
	Implant Insertion	8
	Locking Screw and Antirotation-Screw Insertion	17
	Instrument Disassembly and Final Check	25
	Checking Fixation Sleeve Wear	27
	Option: Pre-Collapsed Insertion	28
	Option: Intra-Operative Compression	34
	Option: Implant Removal	37

Product Information	Implants	40
	Instruments	46
	MRI Information	49

Femoral Neck System

Overview

The Femoral Neck System (FNS) is a dedicated product for the fixation of femoral neck fractures and offers the following features:

Bolt

- Dynamic design with up to 20 mm of guided collapse, without lateral protrusion for the first 15 mm

Antirotation-Screw (ARScrew)

Product Offering

- Material: TAN (Ti-6Al-7Nb)
- Construct sizes: 75 mm to 130 mm (5 mm increments)
- 1-hole plate with 130° angle (2-hole plate optionally available)

Sterile Packaging

- Implant Kit packaging: Plate, Bolt and ARScrew packaged in one kit
- Also available in single packaging

Plate (with Locking Screw)

- Accommodates standard 5.0 mm Locking Screws



Surgical Step Etchings

- The main instruments are etched with letters and arrows to facilitate the surgical procedure
- Corresponding letters are highlighted in this surgical technique

Protection Sleeve

- Used to insert Locking Screws
- Helps to protect soft tissue from sharp edges

Insertion Handle

- Used to insert Plate and Bolt
- Guides additional wires

Insert for Insertion Handle

- Guides insertion of ARScrew

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

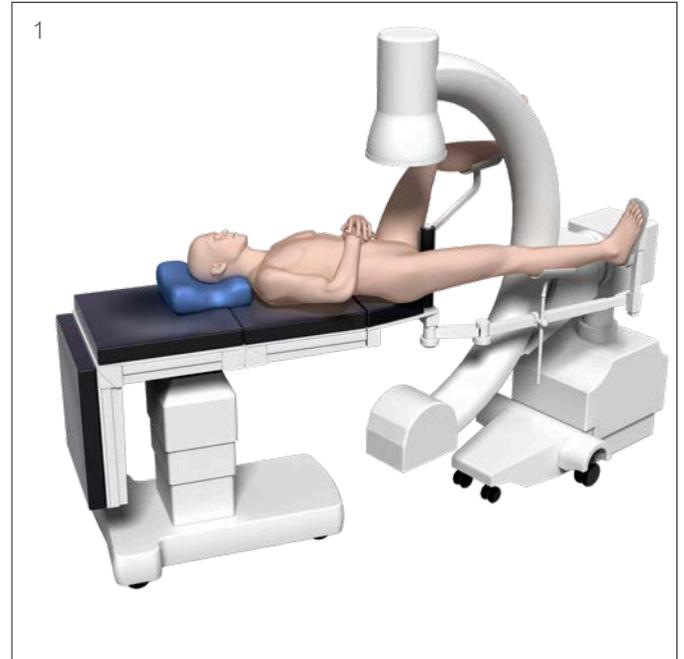
² Buckley RE, Moran CG, Apivatthakakul T. AO Principles of Fracture Management: 3rd ed. Vol. 1: Principles, Vol. 2: Specific fractures. Thieme; 2017.

Preparation

1. Position Patient

Place the patient in a supine position on the operating table.

- Position the image intensifier to enable visualization of the proximal femur in both the AP and lateral planes. (1)



2. Reduce Fracture

Instrument

357.399*	Guide Wire Ø 3.2 mm, length 400 mm or
356.830*	Guide Wire Ø 3.2 mm, for PFNA Blade

■ Note:

Proper reduction of the fracture is crucial for bone healing and function as well as reduction of complications.

Reduce the fracture by means of gentle traction/flexion, adduction/abduction and internal rotation (about 15°, so the femoral neck is parallel to the operating table).

- ⌚ Check the reduction in two planes under image intensifier control. If the reduction is insufficient consider open reduction.

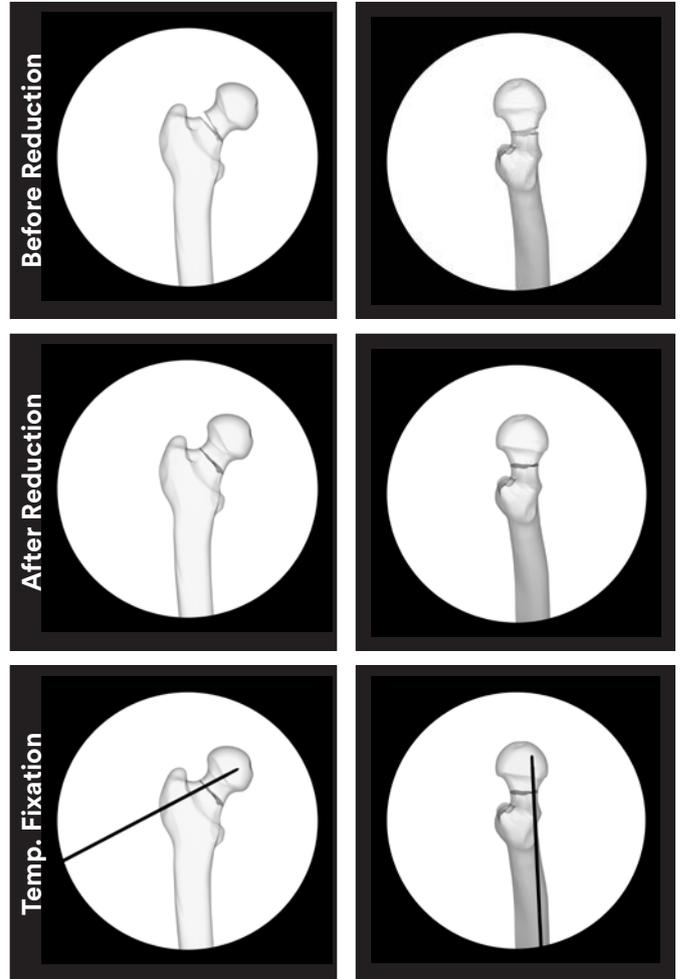
Insert an unused wire as an antirotation wire in the superior/anterior part of the femoral neck to prevent any inadvertent rotation of the femoral head.

■ Notes:

- An inappropriate position of the antirotation wire may interfere with the proper placement of the implant.
- The antirotation wire can be placed percutaneous or through the lateral incision.

▲ Precaution:

- ⌚ Monitor the position of the wire during insertion and confirm the final position using the image intensifier. Over inserting guide wires could lead to damage to vital organs.



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

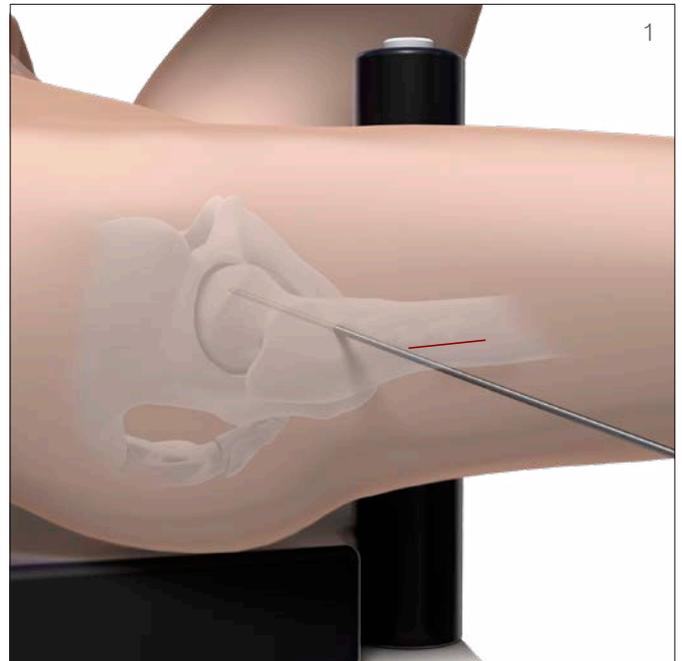
3. Approach

Make a straight lateral skin incision of approximately 6 cm in length, starting 2 to 3 cm proximal to the center of the femoral neck axis. (1)

Access and expose the lateral femoral surface accordingly for satisfactory hardware placement.

Option:

In obese patients, consider making a second incision during locking screw insertion. The second incision needs to be at the entry point of the protection sleeve, proximal to the main incision (see section “Locking Screw and Antirotation-Screw Insertion” for additional information on attaching the protection sleeve).



Implant Insertion

Irrigate and apply suction for removal of debris potentially generated during implant insertion.

1. Insert Guide Wire

Instruments

357.399*	Guide Wire Ø 3.2 mm, length 400 mm or
356.830*	Guide Wire Ø 3.2 mm, for PFNA Blade
03.168.001	Angled Guide 130°, for Guide Wires Ø 3.2 mm

Insert a second, unused guide wire as central guide wire, using the 130° angled guide. (1)

- Use image intensification to place the guide wire slightly inferior to the apex of the femoral head, extending into the subchondral bone on the AP view. (2)

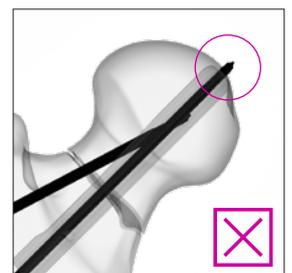
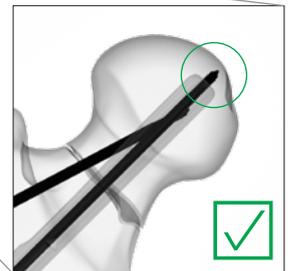
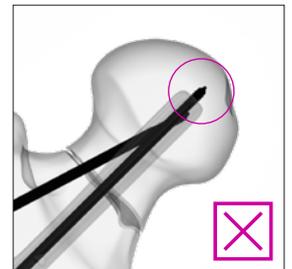
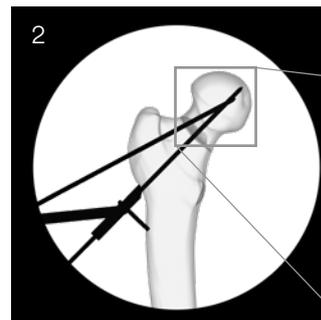
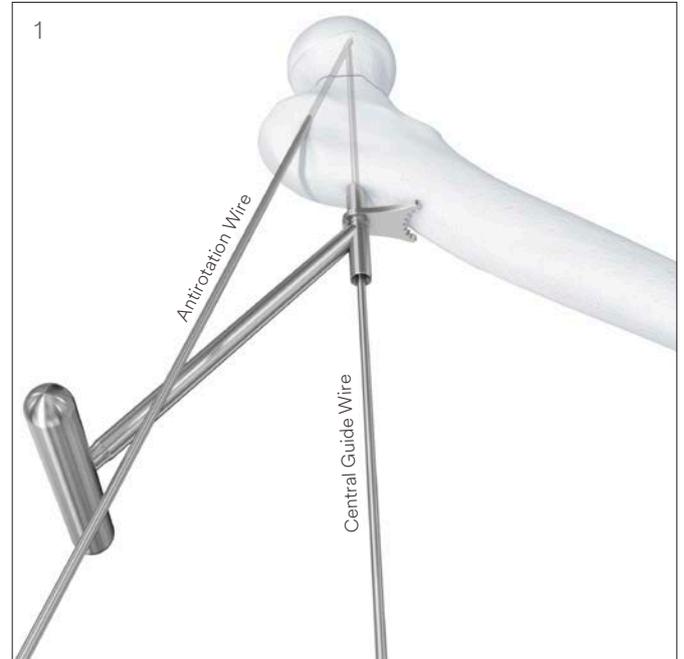
In the lateral view, the guide wire should be central in the femoral neck and head. (3)

Notes:

- The position of the guide wire within the femoral neck and head should be chosen according to the patient's anatomy before fracture. The implant plate allows a placement of about $\pm 5^\circ$ compared to the 130° angle.
- Depending on the calculated construct size (see step "3. Determine Length" under section "Implant Insertion"), the tip of the bolt will be 5 to 10 mm short compared to the tip of the guide wire.

Precautions:

- Monitor the position of the wire during insertion and confirm the final position using the image intensifier. Over inserting guide wires could lead to damage to vital organs.
- Replace wires if they are bent after insertion.



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

2. Adjust Guide Wire

Instruments

357.399*	Guide Wire Ø 3.2 mm, length 400 mm or
356.830*	Guide Wire Ø 3.2 mm, for PFNA Blade
03.168.002	Correction Guide, for Guide Wires Ø 3.2 mm (optional)

If required, use the correction guide and an unused guide wire to adjust the position of the central guide wire in reference to the initial central guide wire.

The following three types of adjustments are possible:

1. Parallel Correction (5 mm)

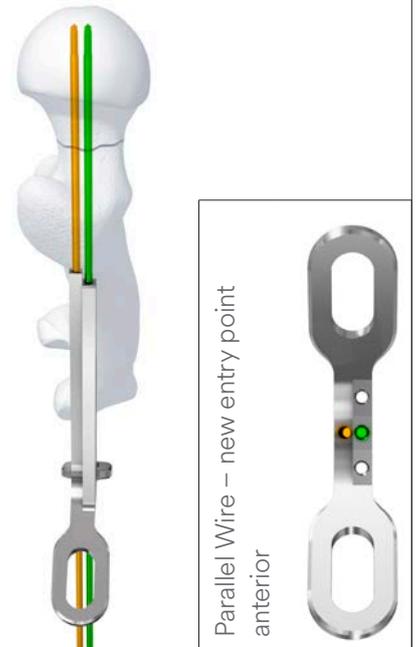
Insert the correction guide over the initial wire (orange) and turn the correction guide to define the new entry point (anterior/posterior or inferior/superior). Then use a new wire in the parallel hole (green) and remove the initial wire.

2. Angle Correction (5°) and Entry Point Correction (5 mm)

Insert the correction guide over the initial wire (orange) and turn the correction guide to define the new entry point. Then use a new wire in either the left or the right 5°-hole (green).

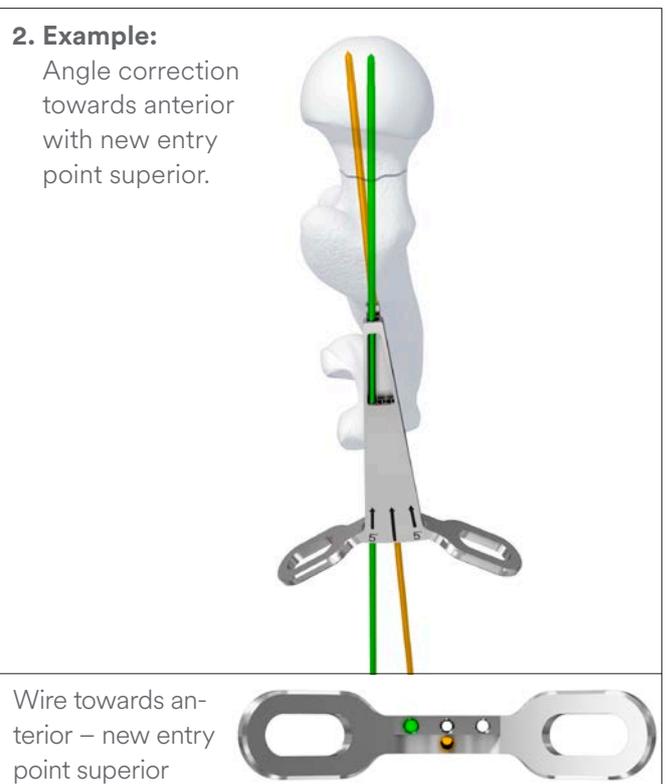
1. Example:

Parallel correction with new entry point anterior.



2. Example:

Angle correction towards anterior with new entry point superior.



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

1. Angle Correction (5°) and Same Entry Point

Insert the correction guide over the initial wire (orange hole in side-view), turn the correction guide to choose the new temporary entry point, insert a new wire in the parallel hole (blue) and remove the initial wire. Then use a new wire in either the left or the right 5°-hole (green) to correct the angle.

▲ Precautions:

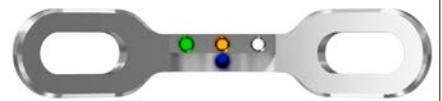
- Monitor the position of the wire during insertion and confirm the final position using the image intensifier. Over inserting guide wires could lead to damage to vital organs.
- Replace wires if they are bent after insertion.

3. Example:

Angle correction towards anterior with same entry point. Initial wire (orange) only shown in side-view).



Wire towards anterior – same entry point



3. Determine Length

Instruments

03.168.003 Direct Measuring Device, for Guide Wires \varnothing 3.2 mm

Slide the direct measuring device over the central guide wire. (1)

Read the depth of the guide wire on the direct measuring device. (2)

As the guide wire is inserted into the subchondral bone (in the AP view, see step “1. Insert Guide Wire” under section “Implant Insertion”), remove 5 mm from the measured depth and choose the next shorter construct size, resulting in the calculated construct size.

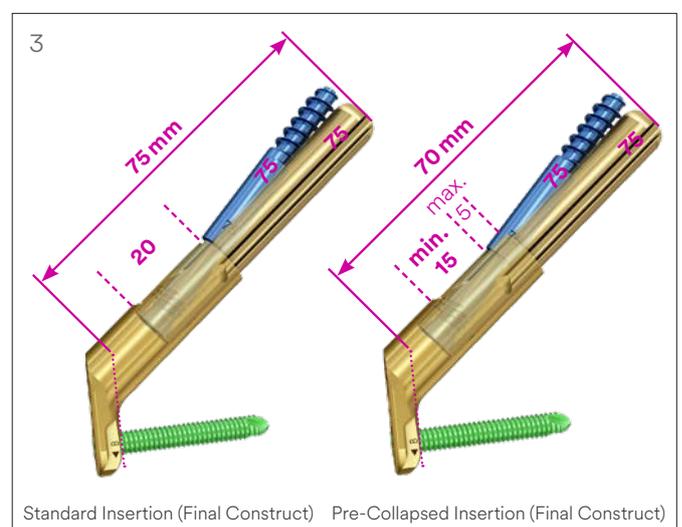
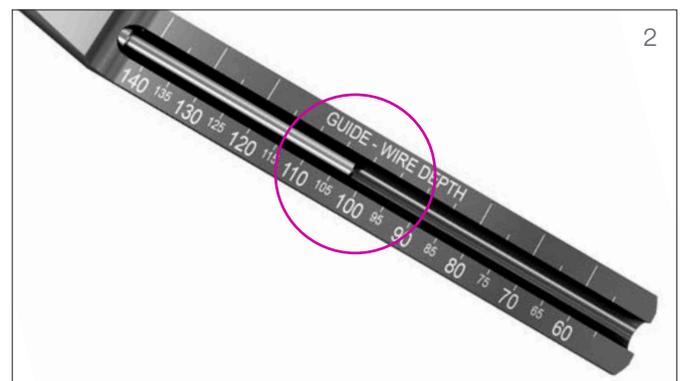
Example: If you read 102 mm on the direct measuring device, the calculated construct size should be 95 mm ($102 - 5 = 97 \rightarrow$ choose 95 mm).

Construct Sizes:

70 mm (see notes below)	95 mm	120 mm
75 mm	100 mm	125 mm
80 mm	105 mm	130 mm
85 mm	110 mm	
90 mm	115 mm	

Notes:

- If patient anatomy demands, a calculated construct size of 70 mm can be achieved by inserting a pre-collapsed 75 mm construct size (3).
- Proceed to section “Option: Pre-Collapsed Insertion” for pre-collapsed insertion before returning to section “Locking Screw and Antirotation-Screw Insertion” for locking screw and antirotation-screw insertion.
- This technique reduces the tolerated amount of collapse from 20 mm to a minimum of 15 mm and can be performed with other construct sizes as well (see example on step “4. Ream for Insertion of Plate and Bolt” under section “Option: Pre-Collapsed Insertion”).



4. Ream for Insertion of Plate and Bolt

Instruments

03.168.004 Reamer, complete

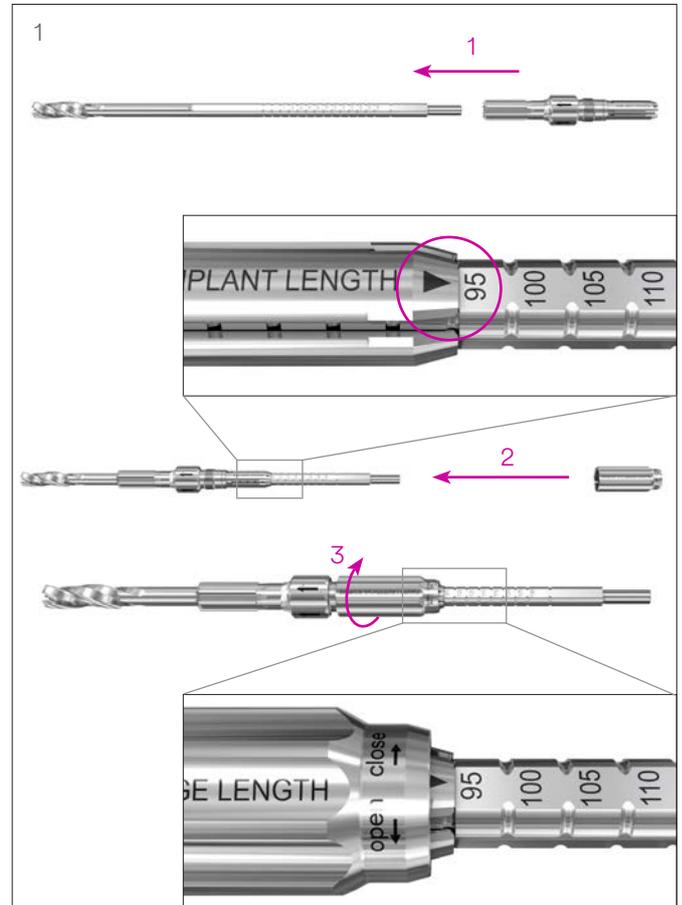
Consisting of:

03.168.005 Drill Bit Ø 10.2 mm, cannulated, length 251 mm

03.168.006 Reamer Ø 12.5 mm

03.168.007 Nut, for Reamer

Assemble the reamer by sliding the reamer-component over the drill bit until it clicks into place at the calculated construct size (95 mm in the example before). Lock the reamer by adding and fully tightening the nut. (1)



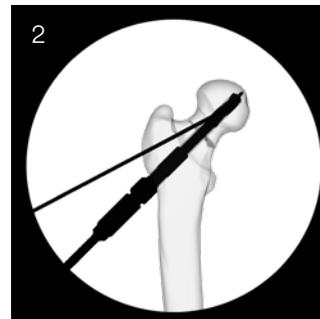
Ream down until the reamer stops on the bone. (2)

■ **Notes:**

- It is recommended that the femoral head is temporarily fixated with an antirotation wire prior to reaming.
- An inappropriate position of the antirotation wire may interfere with the proper placement of the implant.
- Control guide wire migration, check reaming depth during reaming and ensure complete reaming is achieved using the image intensifier.
- When reaming in dense bone, use of continuous irrigation is recommended.
- Avoid excessive reaming force during reaming.

Remove the reamer.

It is important to reinsert the guide wire if it is removed accidentally. To reinsert the wire push the reamer back into the reamed hole (without the use of a power tool) and use the cannulation to reinsert the guide wire into the original position.



5. Assemble Implant and Insertion Instruments

Instruments

03.168.008	Insertion Handle
03.168.009	Insert, for Insertion Handle

A Slide the insert into the insertion handle, without tightening the black screw. (1)

Fully insert the bolt with the calculated construct size (95 mm in the example before) into the plate. (2)

Option: A longer side plate with two locking holes (2-hole plate) is available as an option.

B Mount the implant onto the insertion handle. (3)

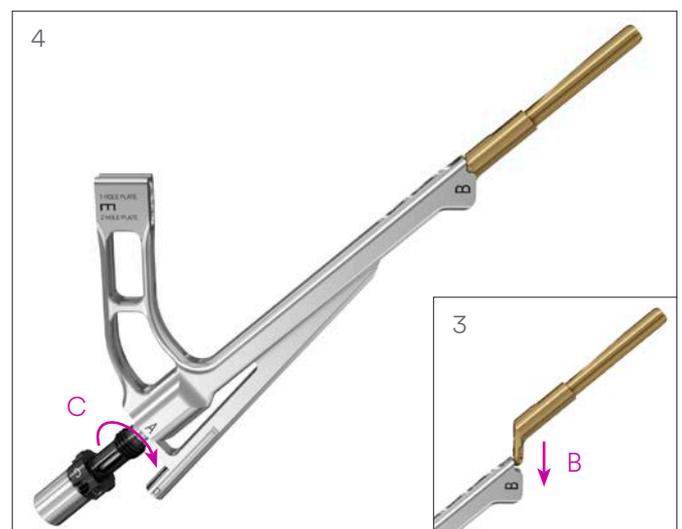
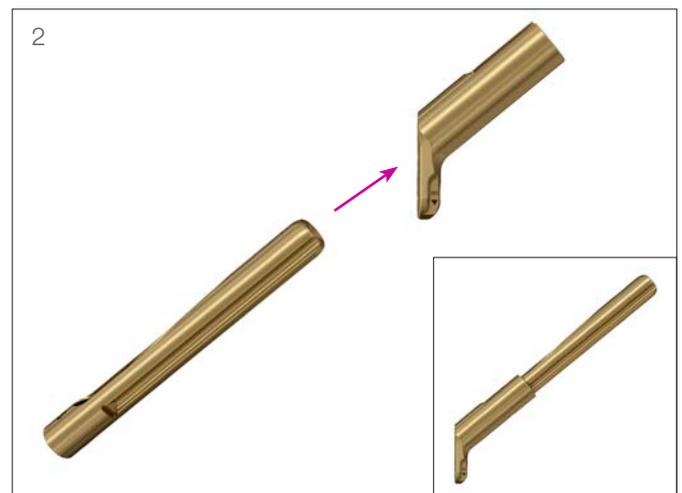
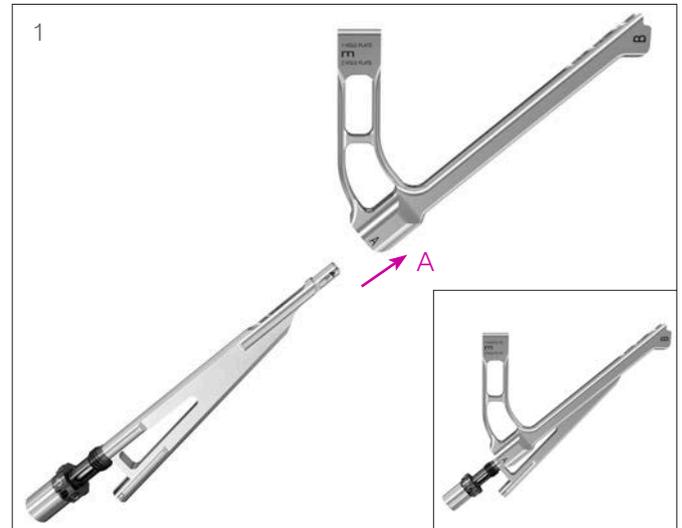
■ Note:

Ensure that the implant is correctly fixed to the insertion instrument and that the bolt is in the completely extended position.

C Manually tighten the black screw of the insert to attach the implant. (4)

▲ Precaution:

Hand-tightening the black screw is sufficient. Using additional tools might cause overtightening.



6. Insert Implant

Instrument

03.168.015 Cylinder, for Insertion Instruments (optional)

Insert the implant over the central guide wire into the pre-reamed hole. (1)

▲ Precaution:

When not using the cylinder, the guide wire will become visible on the outer side of the insert. Ensure not to move the guide wire. (2)

Option:

The cylinder can be used to manually tap the plate onto the bone. (3) If additional tapping is required, use a standard surgical hammer to slightly tap onto the cylinder.

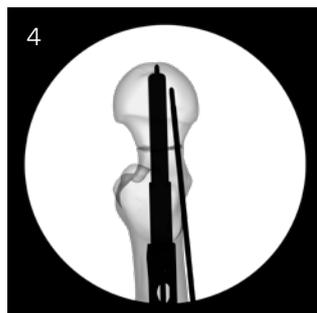
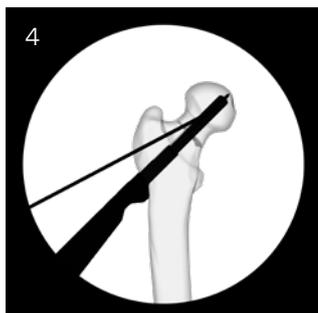
- Use image intensification to confirm the insertion depth and ensure that the plate is inserted down to the bone as well as aligned with the axis of the femoral shaft. (4)

■ Notes:

- It is recommended that the femoral head is temporarily fixated with an antirotation wire prior to implant insertion.
- Avoid excessive insertion force.

▲ Precaution:

Ensure that the black screw is not turning (e.g. by holding it), if tapping is required during insertion.



7. Remove Guide Wire

Remove the central guide wire. (1)

Keep the antirotation wire to prevent loss of reduction and rotation of the head.



Locking Screw and Antirotation-Screw Insertion

Irrigate and apply suction for removal of debris potentially generated during antirotation-screw and locking screw insertion.

1. Attach Protection Sleeve for Locking Screw Insertion*

Instrument

03.168.013	Protection Sleeve, for Insertion Instruments
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Note:

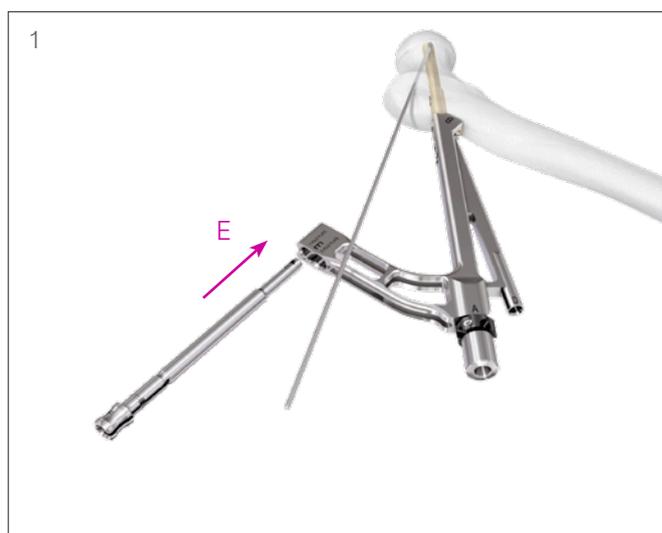
Ensure that the central guide wire is removed.

E Attach the protection sleeve to the insertion handle. (1)

Notes:

- In obese patients, the use of a second incision to insert the protection sleeve should be considered.
- Check that the protection sleeve is inserted in the correct position (1-hole plate or 2-hole plate) of the insertion handle.
- Insert the proximal locking screw first if using a 2-hole plate.

Check that the protection sleeve is fully inserted. (2)



* Alternative for standard insertion only: The system allows to insert the antirotation-screw before inserting the locking screw(s). Perform steps 5 to 8 first before completing steps 1 to 4.

2. Drill for Locking Screw

Instruments

03.168.011	Drill Bit Ø 4.3 mm, length 413 mm
03.168.017	Depth Gauge, measuring range up to 100 mm (optional)

▲ Precautions:

- Confirm that the insertion handle and plate are aligned with the femoral shaft axis.
- Push on the insertion handle to ensure that the plate is down to the bone.

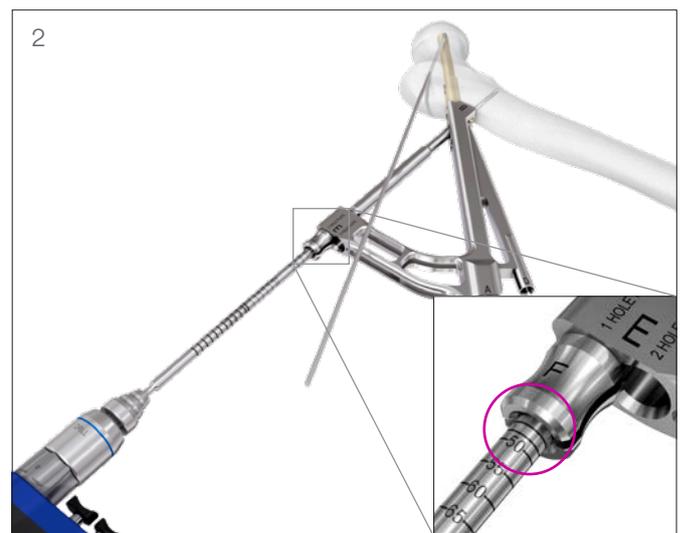
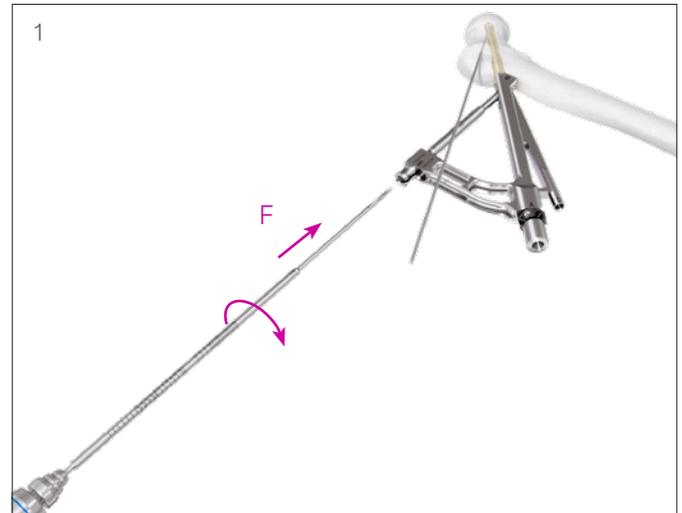
F Drill the hole for the bi-cortical locking screw through the protection sleeve. (1)

Read the screw length directly off the etching on the drill bit. (2)

Option: Use the depth gauge through the protection sleeve to determine the depth of the drilled hole. (3)

■ Note:

The screw length should be chosen at least 4 mm longer than the determined depth of the hole.



3. Insert Locking Screw

Instruments

03.168.014	Screwdriver Shaft Stardrive, T25, length 241 mm
or	
03.168.016	Screwdriver Shaft hexagonal, 3.5 mm, length 241 mm
511.774	Torque Limiter, 4 Nm, for AO/ASIF Quick Coupling for Reamers
03.140.027	Handle, large, cannulated, with Quick Coupling, Hex 12 mm

▲ Precautions:

- Confirm that the insertion handle and plate are still aligned with the femoral shaft.
- Push on the insertion handle to ensure that the plate is still down to the bone.

F Insert the locking screw with the determined length, as read from the drill bit or depth gauge. (1)

▲ Precaution:

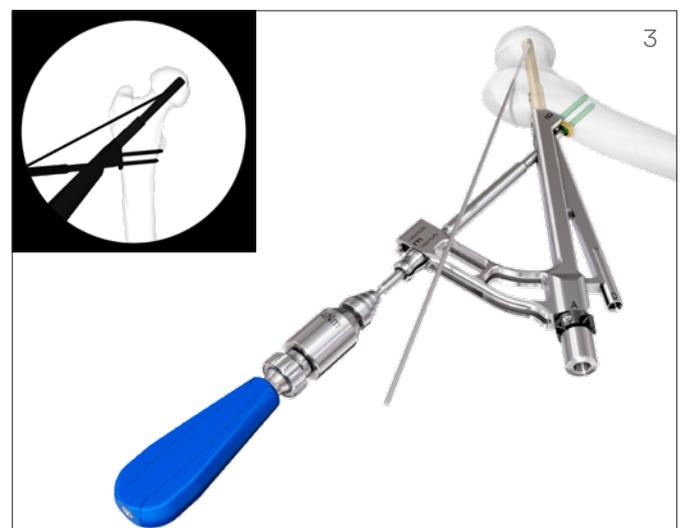
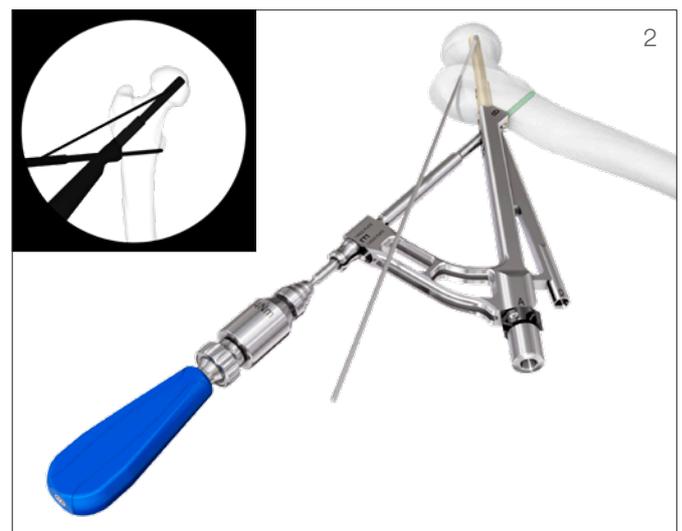
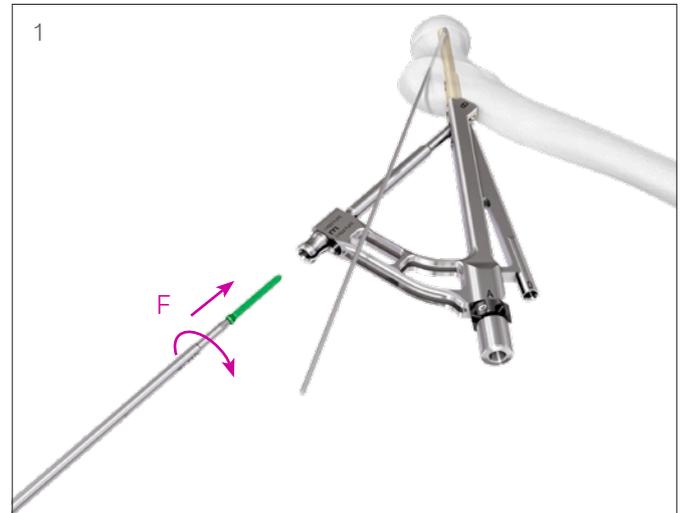
Use torque limiting attachment during final tightening of the locking screw. Failure to use the torque limiting attachment for final tightening may lead to difficulty in implant removal due to over-tightening of the locking screw.

The locking screw may be inserted using power equipment. Final tightening must be done slowly and by hand using the screwdriver shaft, together with the 4 Nm Torque Limiter and the appropriate handle. (2)

■ Note:

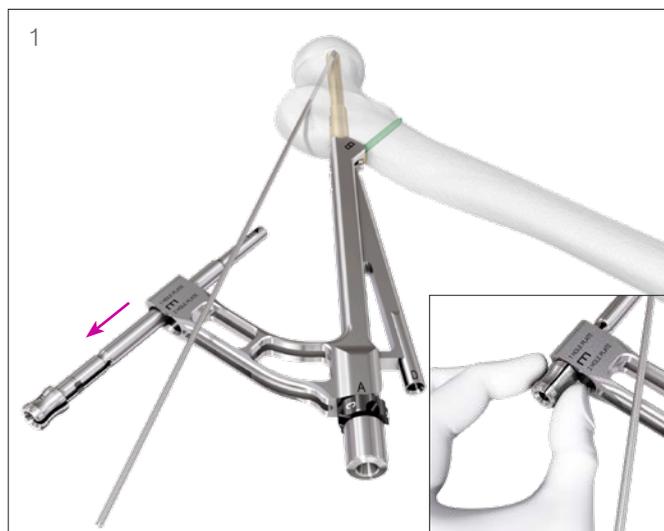
- ① Monitor locking screw insertion and confirm screw position as well as length using the image intensifier prior to final tightening.

Option: If using a 2-hole plate, repeat steps 1 to 3 to insert the distal screw. (3)



4. Remove Protection Sleeve

Remove the protection sleeve by pressing together the head of the sleeve while pulling. (1)



5. Check Insertion Instruments

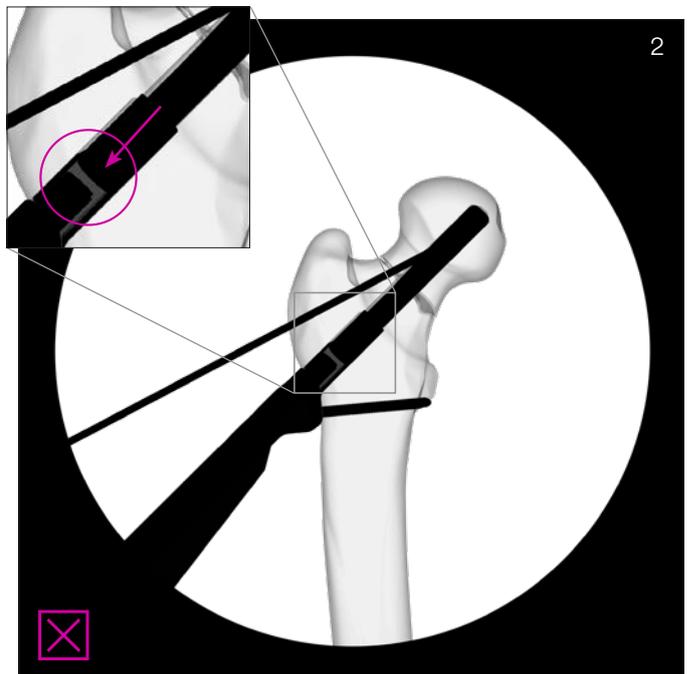
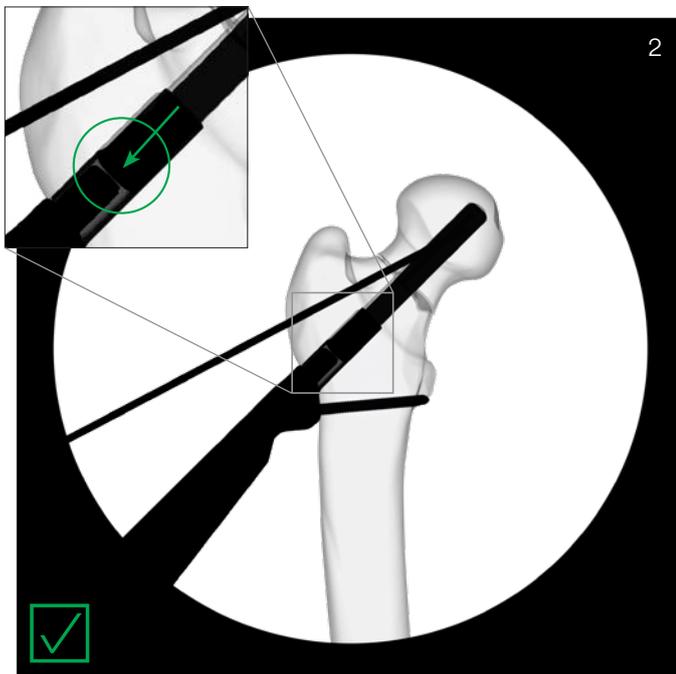
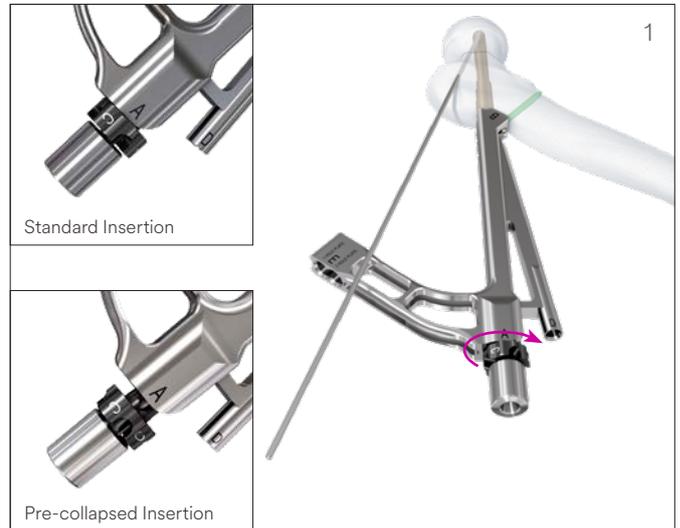
Ensure that the insert tip is in contact with the bolt by carefully turning the black screw clockwise. (1) If needed, this will close the gap between insert tip and bolt. (2)

■ Note:

If the implant is inserted pre-collapsed (see step “3. Determine Length” under section “Implant Insertion”), the black screw can have a distance from the handle of as much as 5 mm, even after tightening.

▲ Precautions:

- Use image intensification to reconfirm that the insert tip is in contact with the bolt. (2)
- Use image intensification to reconfirm the insertion depth of the bolt. (2)



6. Drill for Antirotation-Screw

Instruments

03.168.011	Drill Bit Ø 4.3 mm, length 413 mm
03.168.012	Fixation Sleeve, length 60 mm

Pass the fixation sleeve over the back end of the drill bit and check the fixation sleeve for wear per the instructions in step “1. Perform Fixation Sleeve Wear Test” under section “Checking Fixation Sleeve Wear”. (1) Adjust the setting to the same construct size as the bolt (95 mm in the example before, respectively 75 mm with pre-collapsed insertion as shown in table in step “4. Ream for Insertion of Plate and Bolt” under section “Option: Pre-Collapsed Insertion”). (2)

Note:

The length of the bolt and the antirotation-screw are pre-defined based on the calculated construct size.

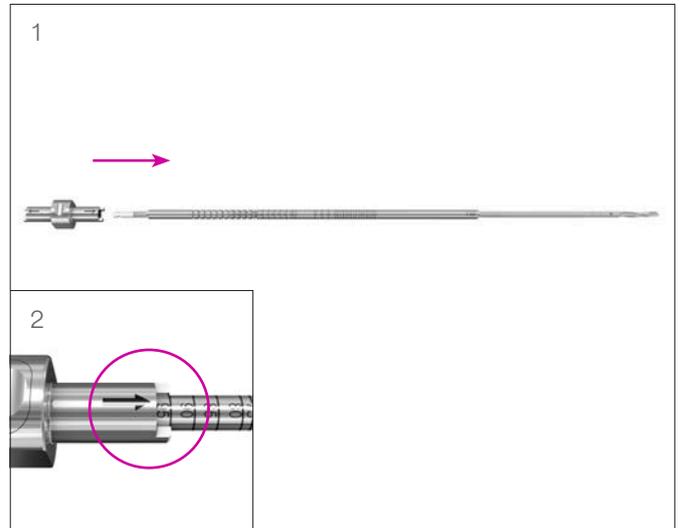
Precautions:

- Monitor depth during drilling using the image intensifier. Drilling too deep could lead to bone damage.
- Confirm that the insertion handle and plate are aligned with the femoral shaft, if using the alternative of inserting the antirotation-screw before inserting the locking screw.

D Use the guide of the insert to drill the hole for the antirotation-screw. (3)

Drill until the fixation sleeve stops on the guide of the insert. (4)

Remove the drill bit.



7. Insert Antirotation-Screw

Instruments

03.168.014	Screwdriver Shaft Stardrive, T25, length 241 mm
511.774	Torque Limiter, 4 Nm, for AO/ASIF Quick Coupling for Reamers
03.140.027	Handle, large, cannulated, with Quick Coupling, Hex 12 mm

▲ Precautions:

- Confirm that the femoral head is temporarily fixated with an antirotation wire and hold the position of the handle during final tightening to prevent any inadvertent rotation.
- Confirm that the insertion handle and plate are still aligned with the femoral shaft, if using the alternative of inserting the antirotation-screw before inserting the locking screw.

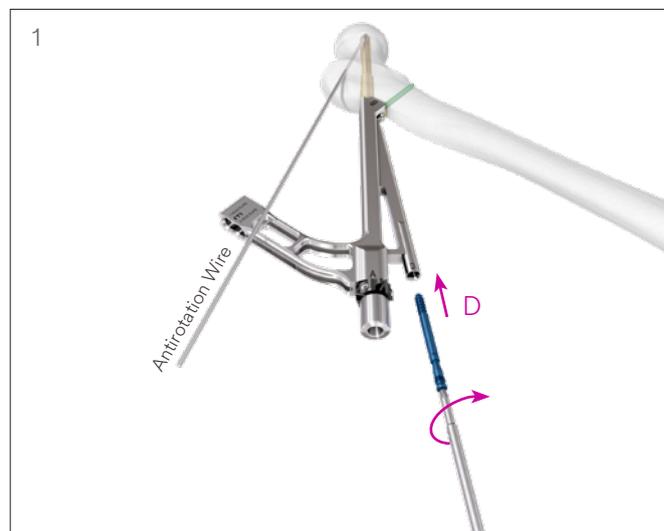
D Insert the antirotation-screw with the same construct size as the bolt (95 mm in the example before, respectively 75 mm with pre-collapsed insertion as shown in table in step “4. Ream for Insertion of Plate and Bolt” under section “Option: Pre-Collapsed Insertion”). (1)

Insertion as well as final tightening should be done slowly and by hand using the screwdriver shaft, together with the 4 Nm Torque Limiter and the appropriate handle. (2) If dense bone is preventing antirotation-screw insertion, then carefully use the handle without Torque Limiter for insertion.

▲ Precaution:

- ⌚ Monitor antirotation-screw insertion and confirm screw position using the image intensifier prior to final tightening.

Remove any antirotation wires.



8. Check Antirotation-Screw

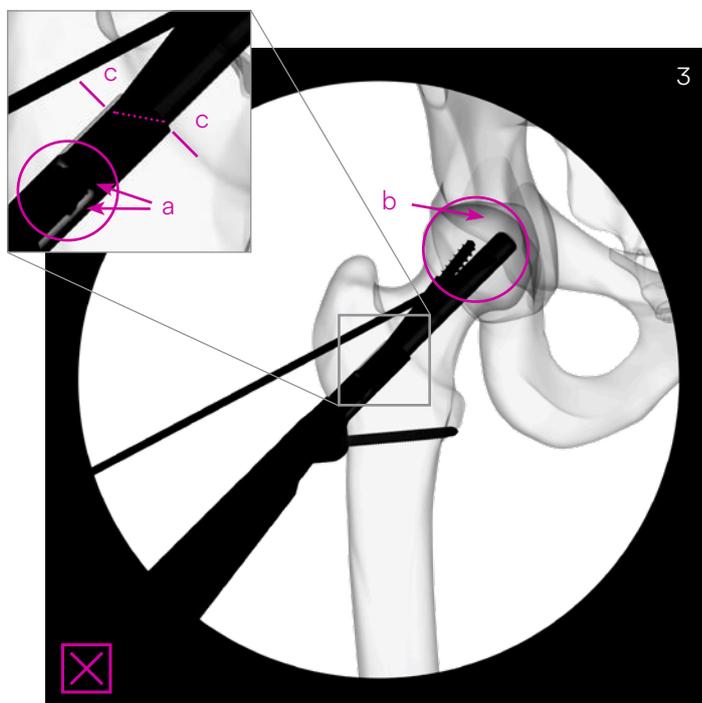
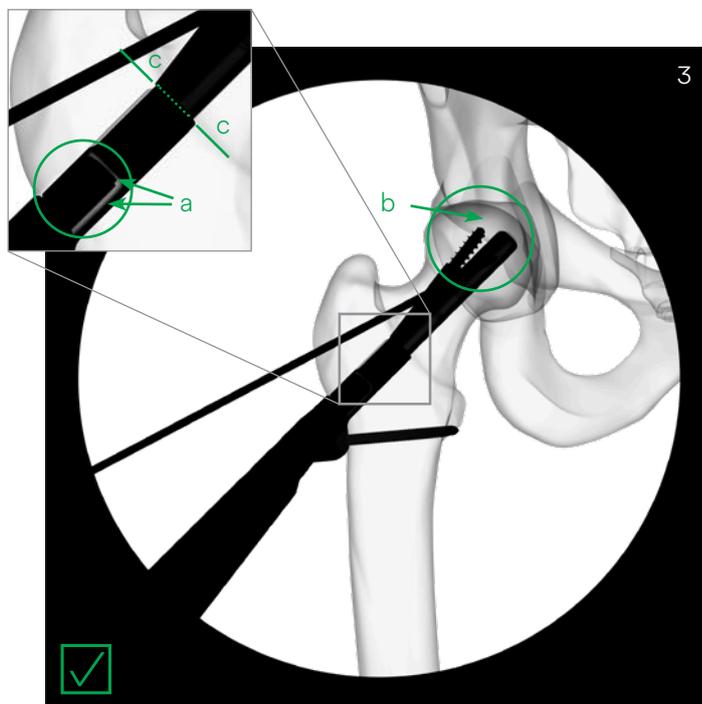
▲ Precaution:

- ⌚ After final tightening, use the image intensifier to check that the antirotation-screw is fully inserted. (3) If not, then loosen and reinsert the antirotation-screw. Use the 4 Nm torque limiter and the appropriate handle for final tightening.

- a** The head of the antirotation-screw should not appear outside of the bolt.
- b** The tip of the antirotation-screw should be in a similar insertion depth when compared to the tip of the bolt.

For Standard Insertion only (not applicable for Pre-Collapsed Insertion):

- c** The notch of the antirotation-screw should be at the same level as the notch of the plate barrel.



Instrument Disassembly and Final Check

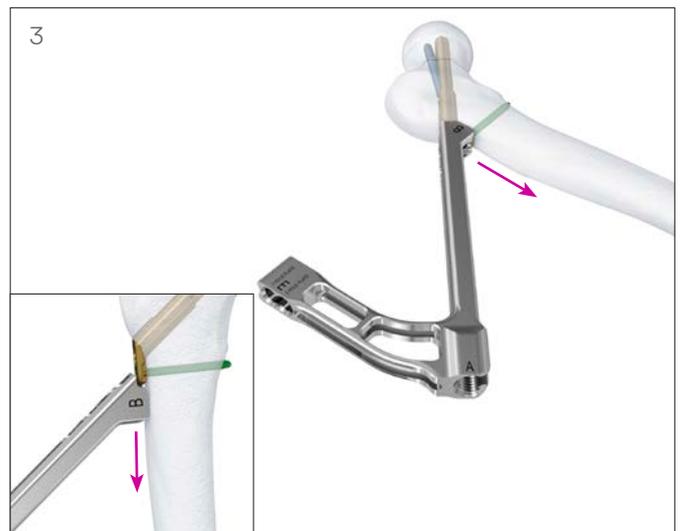
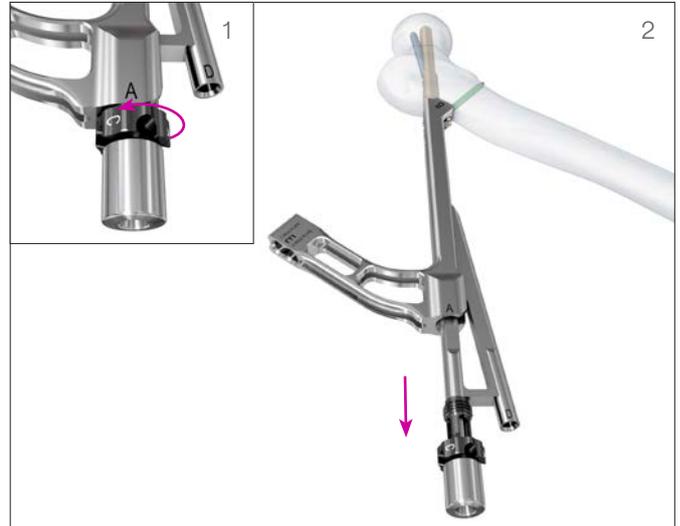
Option: The system allows to apply intra-operative compression. See section “Option: Intra-Operative Compression” to perform this option before instrument disassembly.

1. Remove Insertion Instruments

Unscrew (counter-clockwise) the insert from the insertion handle by completely loosening the screw of the insert. (1)

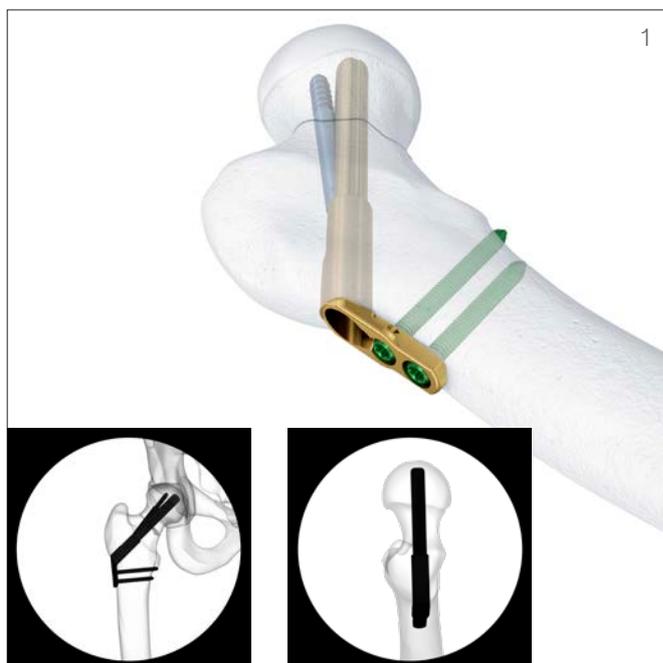
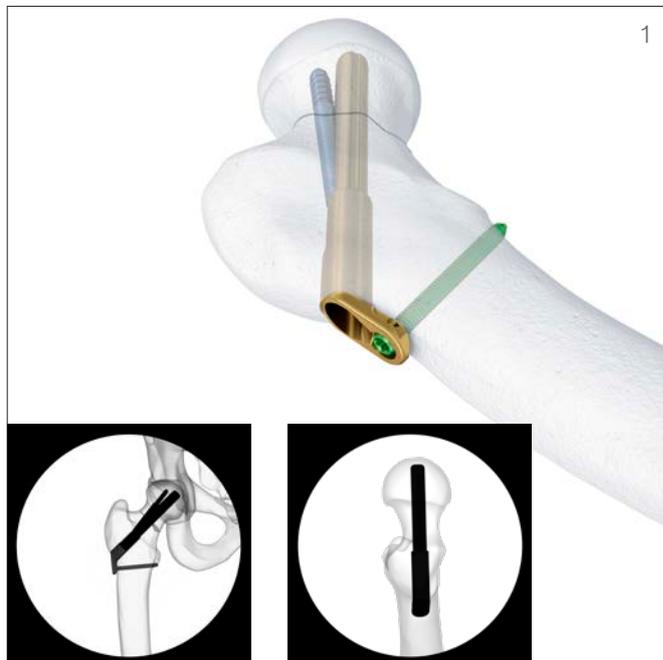
Remove the insert from the insertion handle. (2)

Remove the insertion handle by sliding it off the plate in a distal direction. (3)



2. Final Check

- ⌚ Before closing the wound, use the image intensifier to confirm implant size as well as positioning and re-confirm that the antirotation-screw and the locking screw are fully locked. (1)



Checking Fixation Sleeve Wear

1. Perform Fixation Sleeve Wear Test

Instruments

03.168.011	Drill Bit Ø 4.3 mm, length 413 mm
03.168.012	Fixation Sleeve, length 60 mm

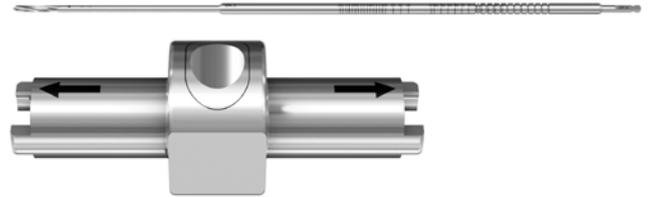
If excessive wear occurs, the fixation sleeve can slip, resulting in incorrect drilling depth.

Before use:

- Slide 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.

▲ Precautions:

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



Option: Pre-Collapsed Insertion

4. Ream for Insertion of Plate and Bolt

Instrument

03.168.004 Reamer, complete

Consisting of:

03.168.005 Drill Bit Ø 10.2 mm, cannulated, length 251 mm

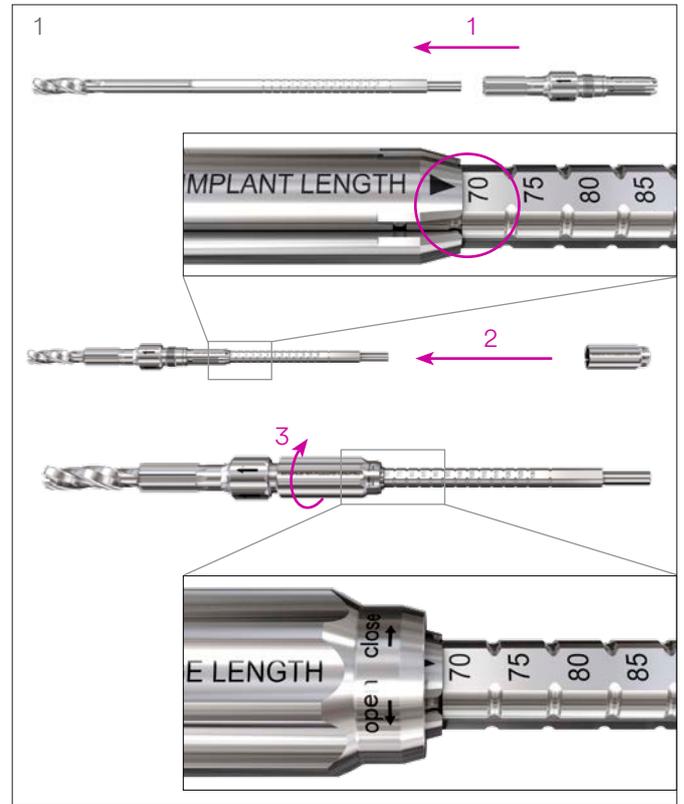
03.168.006 Reamer Ø 12.5 mm

03.168.007 Nut, for Reamer

Assemble the reamer by sliding the reamer-component over the drill bit until it clicks into place at the calculated construct size (70 mm in the example*). Lock the reamer by adding and fully tightening the nut. (1)

Note:

Set the reamer to the calculated construct size (therefore 5 mm shorter than the construct size to be used, see table below).



Pre-Collapsed Insertion – Reference Table:

Calculated Construct Size (refer to step “3. Determine Length” under section “Implant Insertion”)	Setting on Reamer (refer to above)	Construct Size to be Used (Bolt/ARscrew) (refer to step “7. Insert Antirotation-Screw” under section “Locking Screw and Antirotation-Screw Insertion” / step “5. Assemble Implant and Insertion Instruments” under section “Option: Pre-Collapsed Insertion”)	Setting on Drill for ARscrew (refer to step “6. Drill for Antirotation-Screw” under section “Locking Screw and Antirotation-Screw Insertion”)
70	70*	75	75

* If not etched, select the groove next to 75 mm towards the drill tip.

Note:

This technique can be performed with other construct sizes as well, for example using a 100 mm construct size when the calculated construct size is 95 mm (see table below).

Calculated Construct Size (refer to step “3. Determine Length” under section “Implant Insertion”)	Setting on Reamer (refer to above)	Construct Size to be Used (Bolt/ARscrew) (refer to step “7. Insert Antirotation-Screw” under section “Locking Screw and Antirotation-Screw Insertion” / step “5. Assemble Implant and Insertion Instruments” under section “Option: Pre-Collapsed Insertion”)	Setting on Drill for ARscrew (refer to step “6. Drill for Antirotation-Screw” under section “Locking Screw and Antirotation-Screw Insertion”)
95	95	100	100

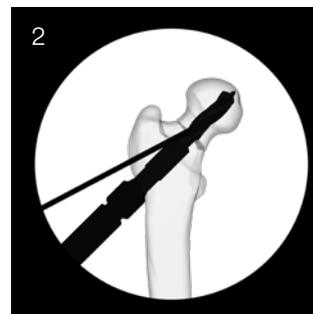
Ream down until the reamer stops on the bone. (2)

■ **Notes:**

- It is recommended that the femoral head is temporarily fixated with an antirotation wire prior to reaming.
- An inappropriate position of the antirotation wire may interfere with the proper placement of the implant.
- Control guide wire migration, check reaming depth during reaming and ensure complete reaming is achieved using the image intensifier.
- When reaming in dense bone, use of continuous irrigation is recommended.
- Avoid excessive reaming force during reaming.

Remove the reamer.

It is important to reinsert the guide wire if it is removed accidentally. To reinsert the wire push the reamer back into the reamed hole (without the use of a power tool) and use the cannulation to reinsert the guide wire into the original position.



5. Assemble Implant and Insertion Instruments

Instruments

03.168.008 Insertion Handle

03.168.009 Insert, for Insertion Handle

A Slide the insert into the insertion handle, without tightening the black screw. (1)

Fully insert the bolt with a 5 mm longer construct size than calculated and reamed (therefore 75 mm in the example, refer to table in step “4. Ream for insertion of Plate and Bolt” under section “Option: Pre-Collapsed Insertion”) into the plate. (2)

Option: A longer side plate with two locking holes (2-hole plate) is available as an option.

B Mount the implant onto the insertion handle. (3)

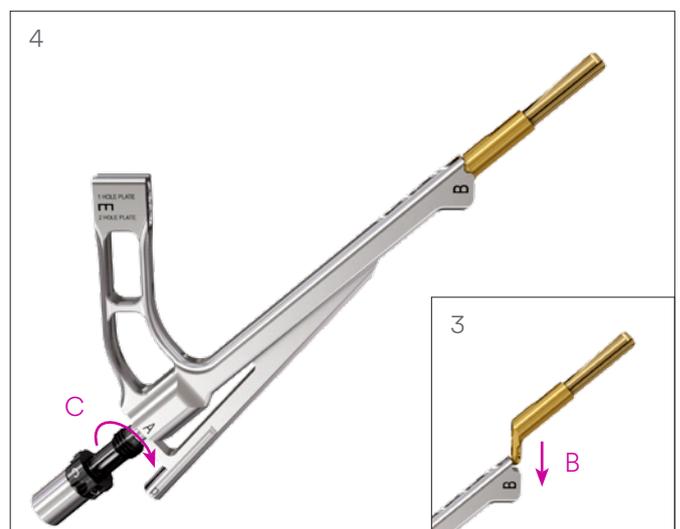
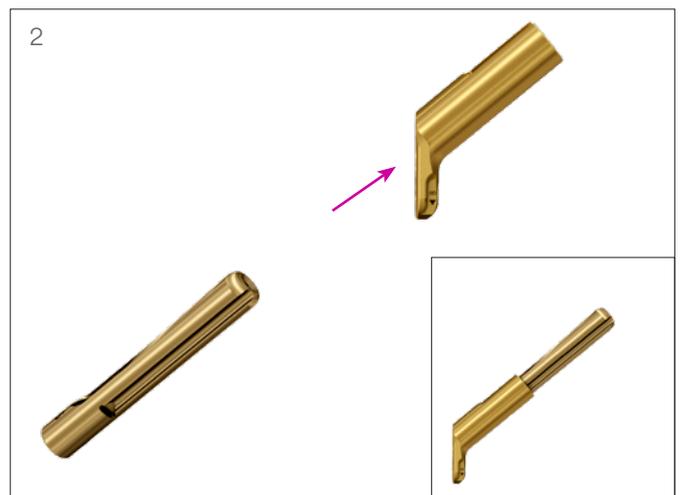
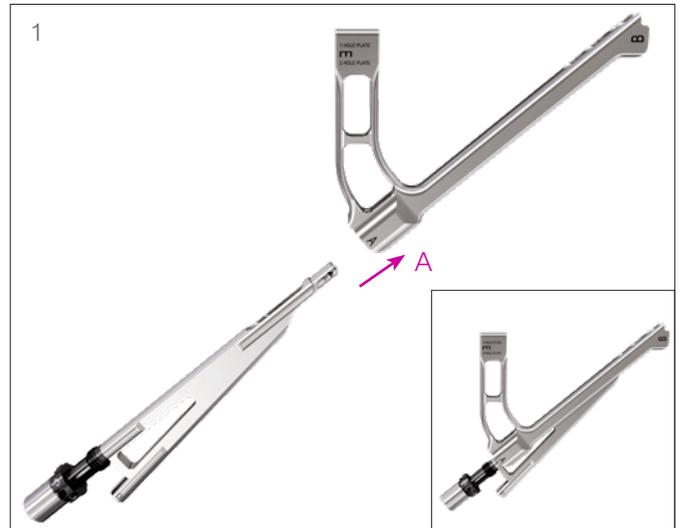
■ Note:

Ensure that the implant is correctly fixed to the insertion instrument and that the bolt is in the completely extended position.

C Manually tighten the black screw of the insert to attach the implant. (4)

▲ Precaution:

Hand-tightening the black screw is sufficient. Using additional tools might cause overtightening.



6. Pre-Collapse Insertion Instruments

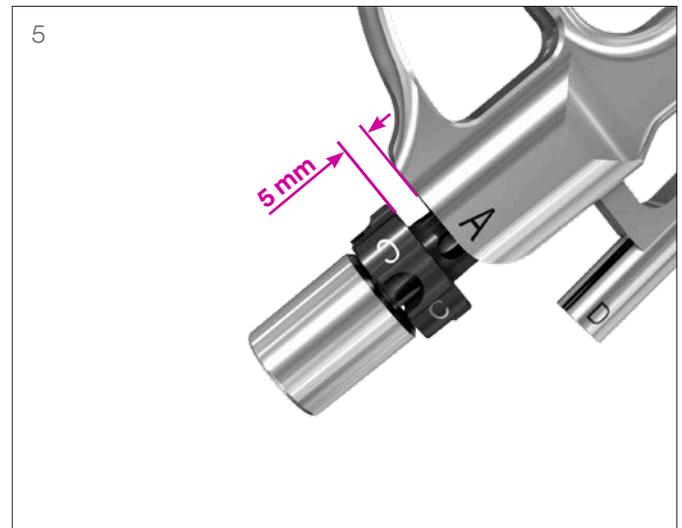
Instrument

03.168.003 Direct Measuring Device,
for Guide Wires \varnothing 3.2 mm

After tightening, untighten (counter-clockwise) the black screw by at least 5 mm (e.g. by 5 halfturns), allowing the implant construct to shorten for 5 mm. (5)

▲ Precaution:

Confirm that the distance is at least 5 mm, by loosely fitting the direct measuring device between the black screw and the insertion handle. (6)



7. Insert Implant

Instrument

03.168.015 Cylinder, for Insertion Instruments (optional)

Insert the implant over the central guide wire into the pre-reamed hole. (1)

▲ Precaution:

When not using the cylinder, the guide wire will become visible on the outer side of the insert. Ensure not to move the guide wire. (2)

Option:

The cylinder can be used to manually tap the plate onto the bone. (3) If additional tapping is required, use a standard surgical hammer to slightly tap onto the cylinder.

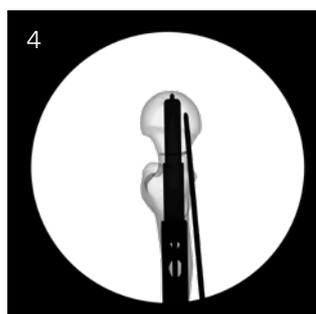
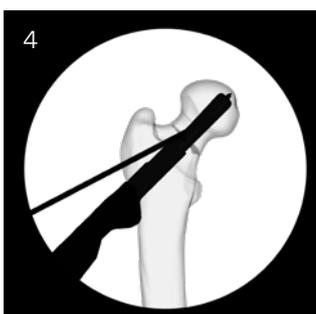
▲ Precaution:

Ensure that the black screw is not turning (e.g. by holding it), if tapping is required during insertion. (3)

- Use image intensification to confirm the insertion depth and ensure that the plate is inserted down to the bone as well as aligned with the axis of the femoral shaft. (4)

■ Notes:

- It is recommended that the femoral head is temporarily fixated with an antirotation wire prior to implant insertion.
- Avoid excessive insertion force.

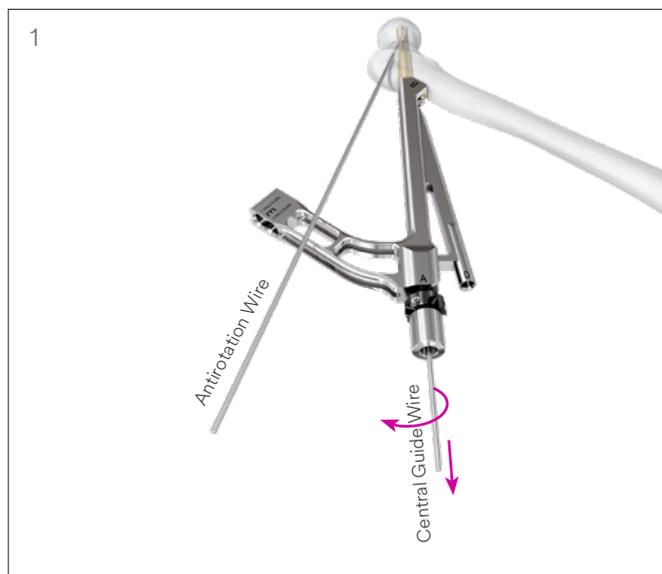


8. Remove Guide Wire

Remove the central guide wire. (1)

Keep the antirotation wire to prevent loss of reduction and rotation of the head.

Continue with Locking Screw and Antirotation-Screw Insertion.



Option: Intra-Operative Compression

Inter-fragmentary compression may be applied intra-operatively. The locking screw as well as the antirotation-screw need to be inserted prior to applying compression.

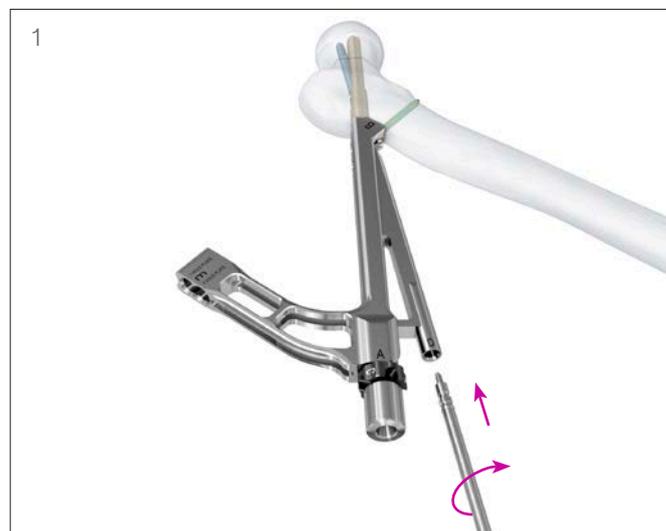
1. Attach Multifunction Rod for Compression

Instrument

03.168.010	Multifunction Rod for Insertion Instruments
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Insert the multifunction rod through the guide of the antirotation-screw. (1)

Hand-tighten the rod by turning it clockwise until the rod is fully inserted. (2)



2. Apply Compression

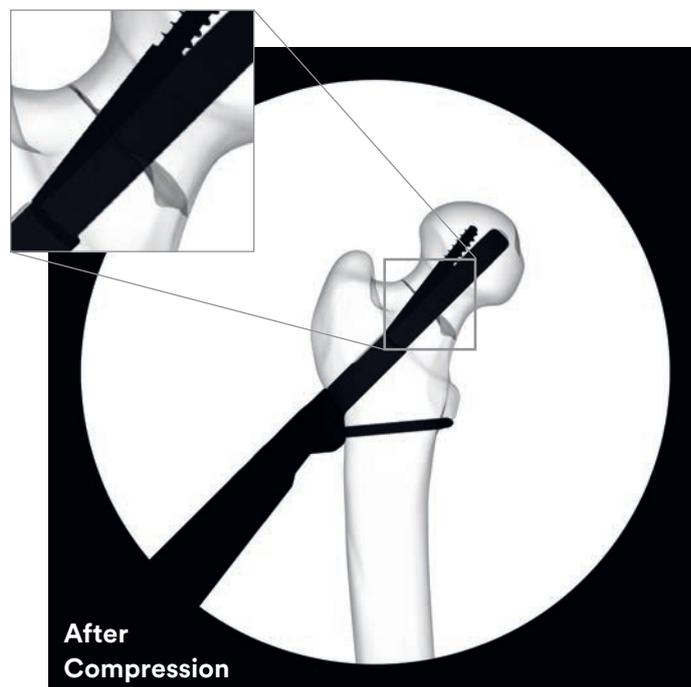
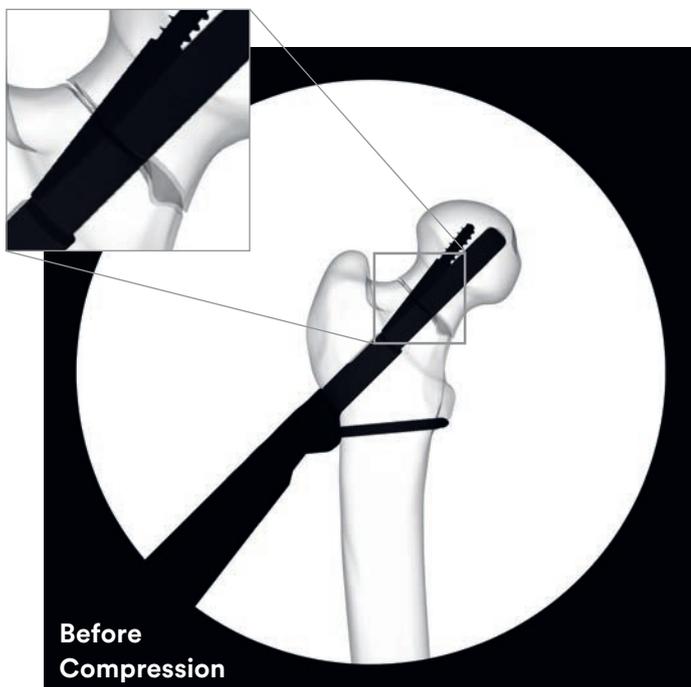
■ Note:

- If applicable (e.g. if using a traction table), consider to loosen traction before applying compression.
- Monitor the implant position during compression using the image intensifier.

Apply inter-fragmentary compression by turning the screw of the insert counter-clockwise. (1)

▲ Precaution:

Applying compression by hand is sufficient. Using additional tools for compression might cause excessive forces.



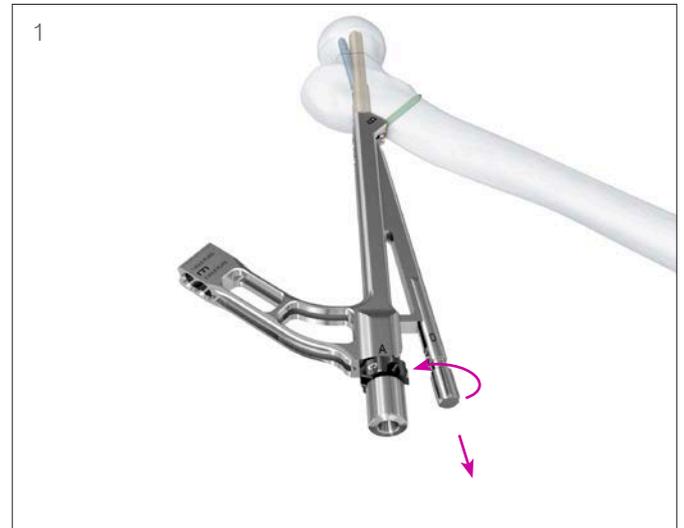
3. Remove Multifunction Rod

Remove the multifunction rod by turning it counter-clockwise. (1)

■ **Note:**

If loosening by hand is not possible, then use another instrument (e.g. a screwdriver shaft) through the hole in the multifunction rod to untighten it.

- ⓘ Use image intensification to confirm that the antirotation-screw remains locked in the implant.



Option: Implant Removal

Irrigate and apply suction for removal of debris potentially generated during implant removal.

1. Remove Locking Screw(s)

Instruments

03.168.014	Screwdriver Shaft Stardrive, T25, length 241 mm
or	
03.168.016	Screwdriver Shaft hexagonal, 3.5 mm, length 241 mm
03.010.516	Handle, large, with Quick Coupling

Alternative Instrument

03.900.042	Screwdriver Shaft, T25, length 100 mm
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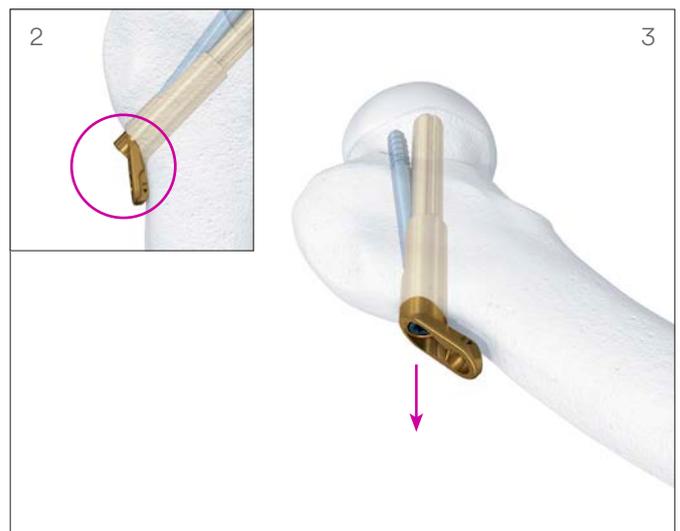
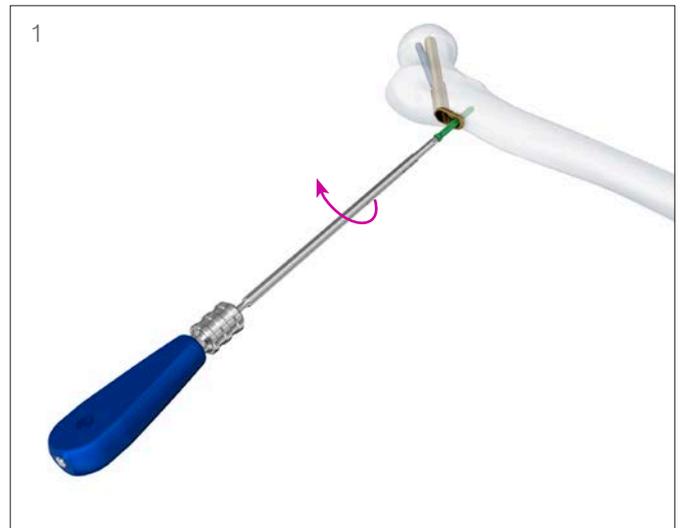
Remove the locking screw(s) by hand using the screwdriver shaft together with the appropriate handle and without torque limiter. (1)

■ Notes:

- Utilize the 03.900.042 T25 Straight Tip Screwdriver (can be ordered separately or found within the Screw Removal Set) for a straight tip driver design which increases the contact surface in the screw recess, if you are unsure if a Torque Limiting Attachment was used during locking screw insertion, or if the screw does not move easily using 03.168.014 T25 tapered tip driver.
- If the implant is fully telescoped, resulting in the bolt being more lateral than the plate (2), pull on the plate (e.g. with surgical pliers) to extend it from the bolt (to about 5 mm) before conducting the steps on the following pages. (3)

▲ Precaution:

Locking screw may strip if excessive force is applied and screw does not turn.



2. Remove Antirotation-Screw

Instruments

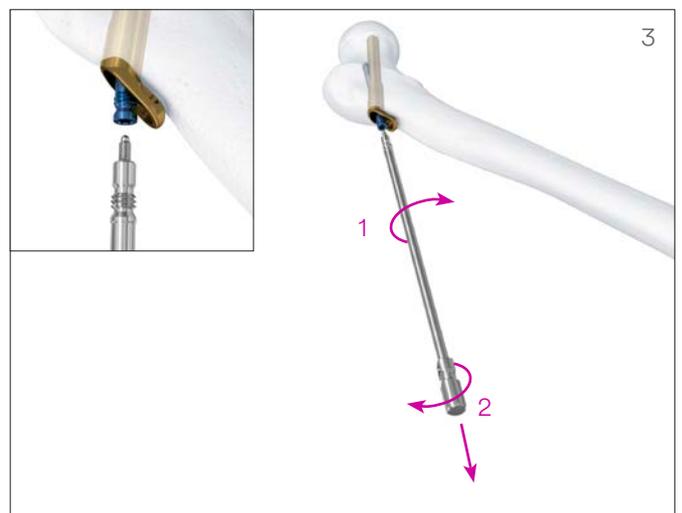
03.168.014	Screwdriver Shaft Stardrive, T25, length 241 mm
03.010.516	Handle, large, with Quick Coupling
03.168.009	Insert, for Insertion Handle (optional)
03.168.010	Multifunction Rod for Insertion Instruments (optional)

Remove the antirotation-screw by hand using the screwdriver shaft together with the appropriate handle and without torque limiter. (1)

Options:

- If it is difficult to find the recess of the antirotation-screw, then use the Insert (03.168.009) as a guide within the plate. (2)
- If the antirotation-screw gets detached from the screwdriver, then use the multifunction rod and turn it clockwise to catch the antirotation-screw. Pull on the multifunction rod and turn anti-clockwise to fully remove the antirotation-screw. (3)

If the antirotation-screw cannot be removed with the screwdriver or the multifunction rod, consult the separate publication "Screw Extraction Set" handling technique.



3. Remove Plate and Bolt

Instruments

03.168.010	Multifunction Rod for Insertion Instruments
03.168.015	Cylinder, for Insertion Instruments

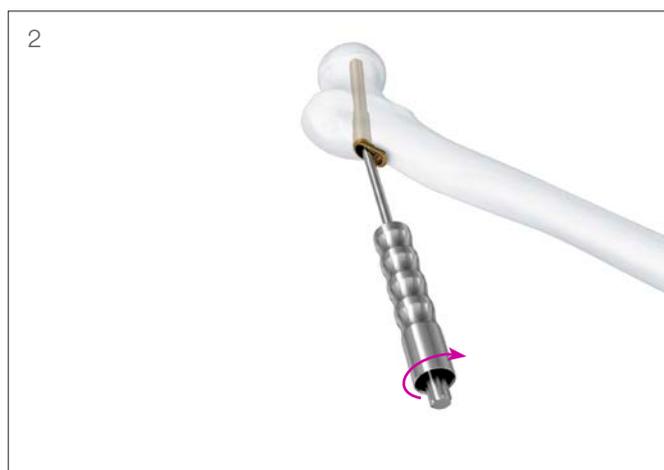
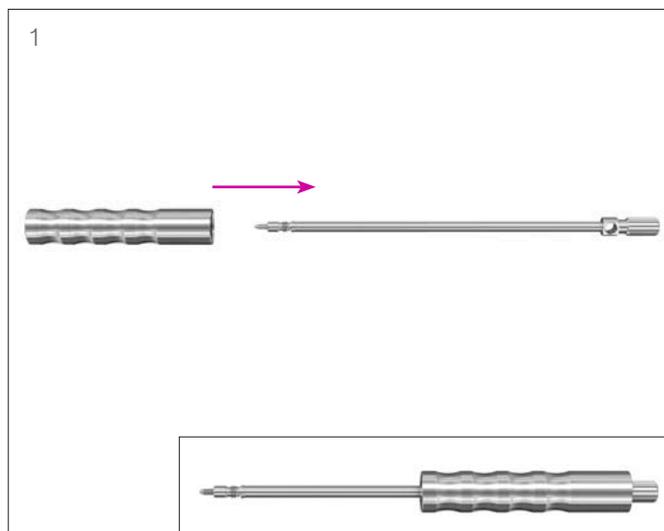
Slide the cylinder over the multifunction rod. (1)

Attach the multifunction rod by turning it clockwise. Use the direction of the previously removed antirotation-screw. (2)

Tap outward with the cylinder to remove the plate and bolt simultaneously. (3)

■ Note:

Avoid excessive forces during removal.



Implants

Features of the Femoral Neck System

Plate

- 130° CCD angle
- Material: Ti-6Al-7Nb (TAN)
- Color: Gold
- Lengths: 1-hole and 2-hole
- Sterile

Bolt

- Material: Ti-6Al-7Nb (TAN)
- Color: Gold
- Diameter: 10 mm
- Construct Lengths: 75 to 130 mm (5 mm increments)
- Sterile

Antirootation-Screw

- Material: Ti-6Al-7Nb (TAN)
- Color: Blue
- Diameter: 6.4 mm
- Recess: Stardrive T25
- Construct Lengths: 75 to 130 mm (5 mm increments)
- Sterile

Locking Screw

- Material: Ti-6Al-7Nb (TAN)
- Color: Green
- Diameter: 5.0 mm
- Recess: Stardrive T25 or Hexagonal
- Lengths: 30 to 60 mm – suggested range, other lengths available (30 to 50 mm with 2 mm increments, 50 to 60 mm with 5 mm increments)
- Sterile or non-sterile



Implants in Kit Packaging

Implant Kit

04.168.075S	Implant Kit, for Femoral Neck System, Construct Length 75 mm, Titanium Alloy (TAN), sterile
04.168.080S	Implant Kit, for Femoral Neck System, Construct Length 80 mm, Titanium Alloy (TAN), sterile
04.168.085S	Implant Kit, for Femoral Neck System, Construct Length 85 mm, Titanium Alloy (TAN), sterile
04.168.090S	Implant Kit, for Femoral Neck System, Construct Length 90 mm, Titanium Alloy (TAN), sterile
04.168.095S	Implant Kit, for Femoral Neck System, Construct Length 95 mm, Titanium Alloy (TAN), sterile
04.168.100S	Implant Kit, for Femoral Neck System, Construct Length 100 mm, Titanium Alloy (TAN), sterile
04.168.105S	Implant Kit, for Femoral Neck System, Construct Length 105 mm, Titanium Alloy (TAN), sterile
04.168.110S	Implant Kit, for Femoral Neck System, Construct Length 110 mm, Titanium Alloy (TAN), sterile
04.168.115S	Implant Kit, for Femoral Neck System, Construct Length 115 mm, Titanium Alloy (TAN), sterile
04.168.120S	Implant Kit, for Femoral Neck System, Construct Length 120 mm, Titanium Alloy (TAN), sterile
04.168.125S	Implant Kit, for Femoral Neck System, Construct Length 125 mm, Titanium Alloy (TAN), sterile
04.168.130S	Implant Kit, for Femoral Neck System, Construct Length 130 mm, Titanium Alloy (TAN), sterile



Implants in Single Packaging

Plate

04.168.000S Plate, 1 hole, for Femoral Neck System,
Titanium Alloy (TAN), sterile



04.268.000S Plate, 2 holes, for Femoral Neck System,
Titanium Alloy (TAN), sterile



Bolt

04.168.275S	Bolt, for Femoral Neck System, for Construct Length 75 mm, Titanium Alloy (TAN), sterile
04.168.280S	Bolt, for Femoral Neck System, for Construct Length 80 mm, Titanium Alloy (TAN), sterile
04.168.285S	Bolt, for Femoral Neck System, for Construct Length 85 mm, Titanium Alloy (TAN), sterile
04.168.290S	Bolt, for Femoral Neck System, for Construct Length 90 mm, Titanium Alloy (TAN), sterile
04.168.295S	Bolt, for Femoral Neck System, for Construct Length 95 mm, Titanium Alloy (TAN), sterile
04.168.300S	Bolt, for Femoral Neck System, for Construct Length 100 mm, Titanium Alloy (TAN), sterile
04.168.305S	Bolt, for Femoral Neck System, for Construct Length 105 mm, Titanium Alloy (TAN), sterile
04.168.310S	Bolt, for Femoral Neck System, for Construct Length 110 mm, Titanium Alloy (TAN), sterile
04.168.315S	Bolt, for Femoral Neck System, for Construct Length 115 mm, Titanium Alloy (TAN), sterile
04.168.320S	Bolt, for Femoral Neck System, for Construct Length 120 mm, Titanium Alloy (TAN), sterile
04.168.325S	Bolt, for Femoral Neck System, for Construct Length 125 mm, Titanium Alloy (TAN), sterile
04.168.330S	Bolt, for Femoral Neck System, for Construct Length 130 mm, Titanium Alloy (TAN), sterile



Antirotation-Screw

04.168.475S	Antirotation Screw, for Femoral Neck System, for Construct Length 75 mm, Titanium Alloy (TAN), sterile
04.168.480S	Antirotation Screw, for Femoral Neck System, for Construct Length 80 mm, Titanium Alloy (TAN), sterile
04.168.485S	Antirotation Screw, for Femoral Neck System, for Construct Length 85 mm, Titanium Alloy (TAN), sterile
04.168.490S	Antirotation Screw, for Femoral Neck System, for Construct Length 90 mm, Titanium Alloy (TAN), sterile
04.168.495S	Antirotation Screw, for Femoral Neck System, for Construct Length 95 mm, Titanium Alloy (TAN), sterile
04.168.500S	Antirotation Screw, for Femoral Neck System, for Construct Length 100 mm, Titanium Alloy (TAN), sterile
04.168.505S	Antirotation Screw, for Femoral Neck System, for Construct Length 105 mm, Titanium Alloy (TAN), sterile
04.168.510S	Antirotation Screw, for Femoral Neck System, for Construct Length 110 mm, Titanium Alloy (TAN), sterile
04.168.515S	Antirotation Screw, for Femoral Neck System, for Construct Length 115 mm, Titanium Alloy (TAN), sterile
04.168.520S	Antirotation Screw, for Femoral Neck System, for Construct Length 120 mm, Titanium Alloy (TAN), sterile
04.168.525S	Antirotation Screw, for Femoral Neck System, for Construct Length 125 mm, Titanium Alloy (TAN), sterile
04.168.530S	Antirotation Screw, for Femoral Neck System, for Construct Length 130 mm, Titanium Alloy (TAN), sterile



5.0 mm Locking Screws*



412.201 – Locking Screw Stardrive Ø 5.0 mm,
412.227 self-tapping, Titanium Alloy (TAN)



413.314 – Locking Screw Ø 5.0 mm,
413.390 self-tapping, Titanium Alloy (TAN)



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

Instruments

03.168.001 Angled Guide 130°, for Guide Wires
 Ø 3.2 mm



03.168.002 Correction Guide, for Guide Wires
 Ø 3.2 mm (optional)



357.399* Guide Wire Ø 3.2 mm, length 400 mm



356.830* Guide Wire Ø 3.2 mm, for PFNA Blade
 (alternative to 357.399)



03.168.003 Direct Measuring Device, for Guide Wires
 Ø 3.2 mm



03.168.004 Reamer, complete



Consisting of:

03.168.005 Drill Bit Ø 10.2 mm, cannulated,
 length 251 mm

03.168.006 Reamer Ø 12.5 mm

03.168.007 Nut, for Reamer

03.168.008 Insertion Handle



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

03.168.009	Insert, for Insertion Handle	
03.168.010	Multifunction Rod for Insertion Instruments	
03.168.011	Drill Bit Ø 4.3 mm, length 413 mm	
03.168.012	Fixation Sleeve, length 60 mm	
03.168.013	Protection Sleeve, for Insertion Instruments	
03.168.014	Screwdriver Shaft Stardrive, T25, length 241 mm	
03.168.015	Cylinder, for Insertion Instruments	
03.168.016	Screwdriver Shaft hexagonal, 3.5 mm, length 241 mm (alternative to 03.168.014 for Locking Screw insertion)	
Alternative Instrument		
03.900.042	Screwdriver Shaft, T25, length 100 mm	
03.168.017	Depth Gauge, measuring range up to 100 mm (optional)	

03.140.027 Handle, large, cannulated, with Quick Coupling, Hex 12 mm



511.774 Torque Limiter, 4 Nm, for AO/ASIF Quick Coupling for Reamers



03.010.516 Handle, large, with Quick Coupling



MRI Information

Torque, Displacement and Image Artifacts according to ASTM F 2213, ASTM F 2052 and ASTM F 2119

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 30 T/m. The largest image artifact extended approximately 25 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 F 2182

Non-clinical testing of worst case scenario lead to temperature rises of 6.6°C (1.5 T) and 9.2°C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 15 minutes).

▲ 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 specific absorption rate (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 thermoregulation 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.

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