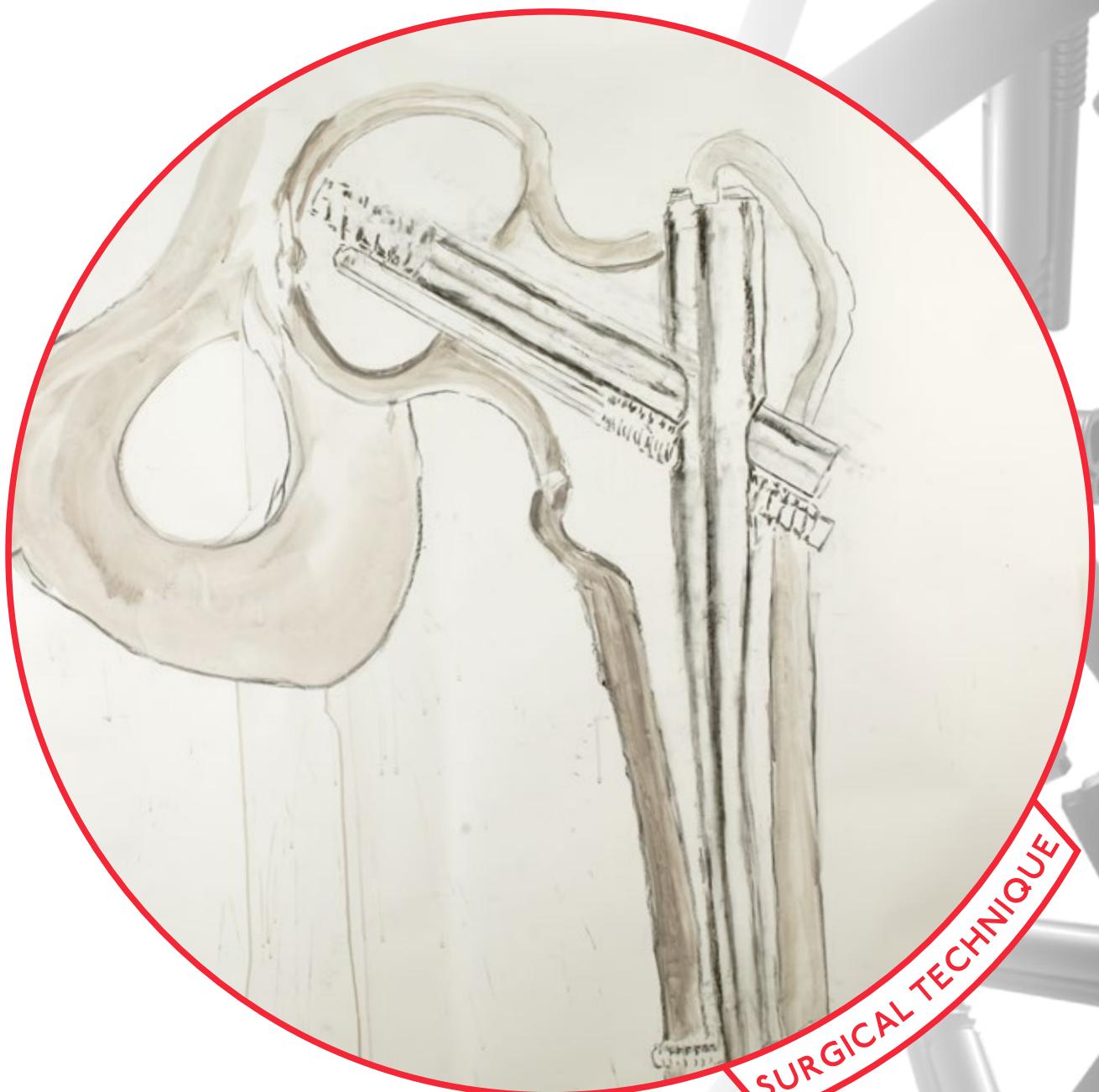


ITS.

Implants for Trauma Surgery



HIP-S

PROXIMAL FEMUR



THE ART of TRAUMA SURGERY

The Art of Trauma Surgery is a collaborative project between I.T.S. and Austrian artist Oskar Stocker that celebrates the skill, perseverance, and artistry of surgeons and engineers who work tirelessly to improve outcomes for trauma patients.

At I.T.S., we stand for long-term, trusting relationships with our customers, suppliers, and development partners. Through our devotion to innovation and development, we continuously seek to improve and optimize products and techniques in the field of traumatology.

We believe that the success of our mission lies in the combination of the technical expertise, compassion and dedication of surgeons and engineers to help patients regain their health and well-being. Join us in celebrating these remarkable individuals and *The Art of Trauma Surgery!*

About the Artist

The Austrian artist Oskar Stocker (b. 1956) lives and works in Graz, Austria. He has become known internationally through the exhibition *Facing Nations*, which consists of portraits of more than 120 people of various nationalities living in Graz; it was shown first in Graz itself, then in Vienna, and later culminated in 2010 with its display at the UN Headquarters in New York City.

In addition to the portraits of individual people, he devotes himself to the depiction of landscapes and objects, down to the smallest detail.





In memoriam

Prof. Dr. Volker Bühren

(*1952 †2023)

Our personal gratitude goes to Prof. Dr. Volker Bühren (Murnau / GER) for guiding this product development from the idea to serial production. His focus has been on reducing clinical problems while improving usability, with the patient and the best possible care always at the heart of his efforts.

His passionate support for all areas of our company were and remain very valuable and will continue to find their way into the product portfolio of I.T.S.

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Information



Introduction

WARNING: If there is no sufficient bone healing, wrong or incomplete postoperative care, the implant might break.



● Background

The I.T.S. G-series Intramedullary Nailing System is based on the proven concepts of intramedullary nail osteosynthesis, first introduced by Küntscher, and integrates the standards established in the following decades across the entire spectrum of intramedullary fracture management. These intramedullary nails and instruments are engineered with the clinical aspects of patient safety as a top priority for the planning, implementation, and follow-up phases.

The Hip-G Proximal Femur Nail is designed for the treatment of the full spectrum of fractures, revisions and tumor stabilizations in the area of the proximal femur and also combined forms of injury affecting the shaft area (*for a complete list of indications, see p. 19*). With the patented technology for Controlled Dynamization, built-in precision aides, and intuitive surgical procedure the Hip-G Proximal Femur Nail takes major steps in addressing the current shortcomings facing hip fracture nailing today.

The Hip-G Proximal Femur Nail features a two-portal concept, maintaining full rotational stability both intra- and post-operatively, with the DyCon® Screw pair forming a dynamically controlled force carrier system in the femoral neck and head. Three different neck angles (Centrum-Collum-Diaphyseal [CCD] angles) and a total of 14 nail lengths accommodate variations in patient anatomy. In addition to short and long nails, the system also includes an intermediate nail with distal locking via the targeting module and additional stabilization at the isthmus.

A special focus is placed on geriatric fractures with the goal of immediate postoperative weight-bearing and ensuring optimal biomechanics in the case of osteoporosis.

The top quality of the implants, manufactured in Austria, and the close collaboration with our international expert surgeon design team form the basis of a high-quality and comprehensive global nailing system.



● At a Glance



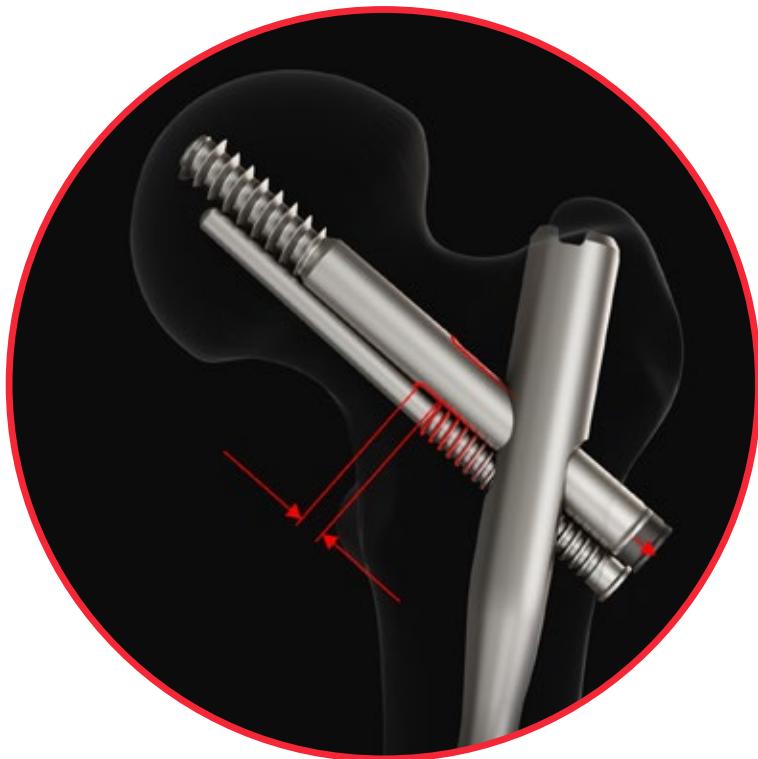
○ Proximal Features

- Easy-to-use, built-in targeting guides to reduce the risk of implant cut-out
- 2 portal approach providing rotational stability both intra- and post-operatively
- Inferior DyCon® Set screw allowing for controlled dynamization
- Built-in closing of the fracture gap and compression of fracture



○ Dynamization Control / DyCon®

The DyCon® Screw pair, consisting of the load-bearing Lag Screw with the inferiorly placed DyCon® Set Screw, forms a dynamically controlled force carrier system in the femoral neck and head.



The inferior DyCon® Set Screw anchors in the nail and runs at a slight angulation into the groove of the Lag Screw. This technology allows for controlled lateral dynamization of the Lag Screw, while inhibiting medial migration with the full contact area between the two screws.

The standard technique describes a recommended 5mm dynamization (*Dynamic* mode - shown above). However, with this design, the lateral movement of the Lag Screw can be controlled in a fully scalable manner, from 0mm (*Static*) to 10mm dynamization (*Dynamic +*).

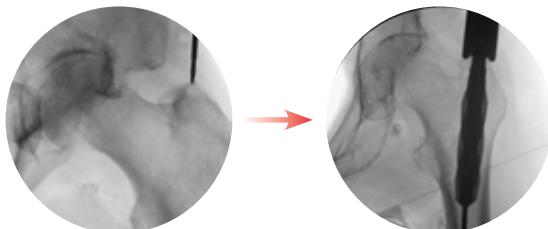


○ Surgical Technique Overview

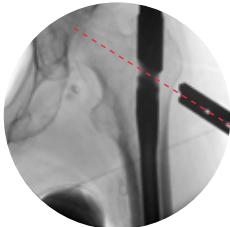
With the aim of optimizing the flow of surgery and minimizing the risk of user error, the surgical technique for the Hip-G proximal Femur Nail follows an intuitive step-by-step working pattern.

For detailed Surgical Technique, see p. 21

Operative Access to the Trochanter



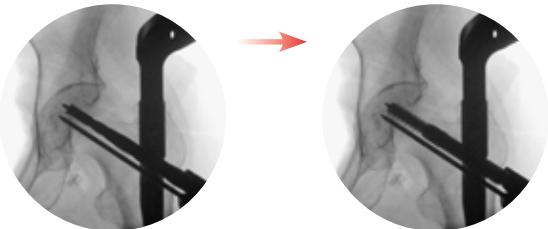
Insertion of the Intramedullary Nail



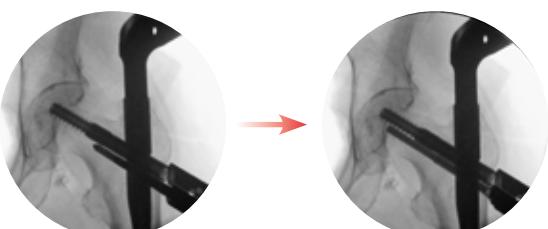
Drill-wire Placement



Lag Screw Insertion

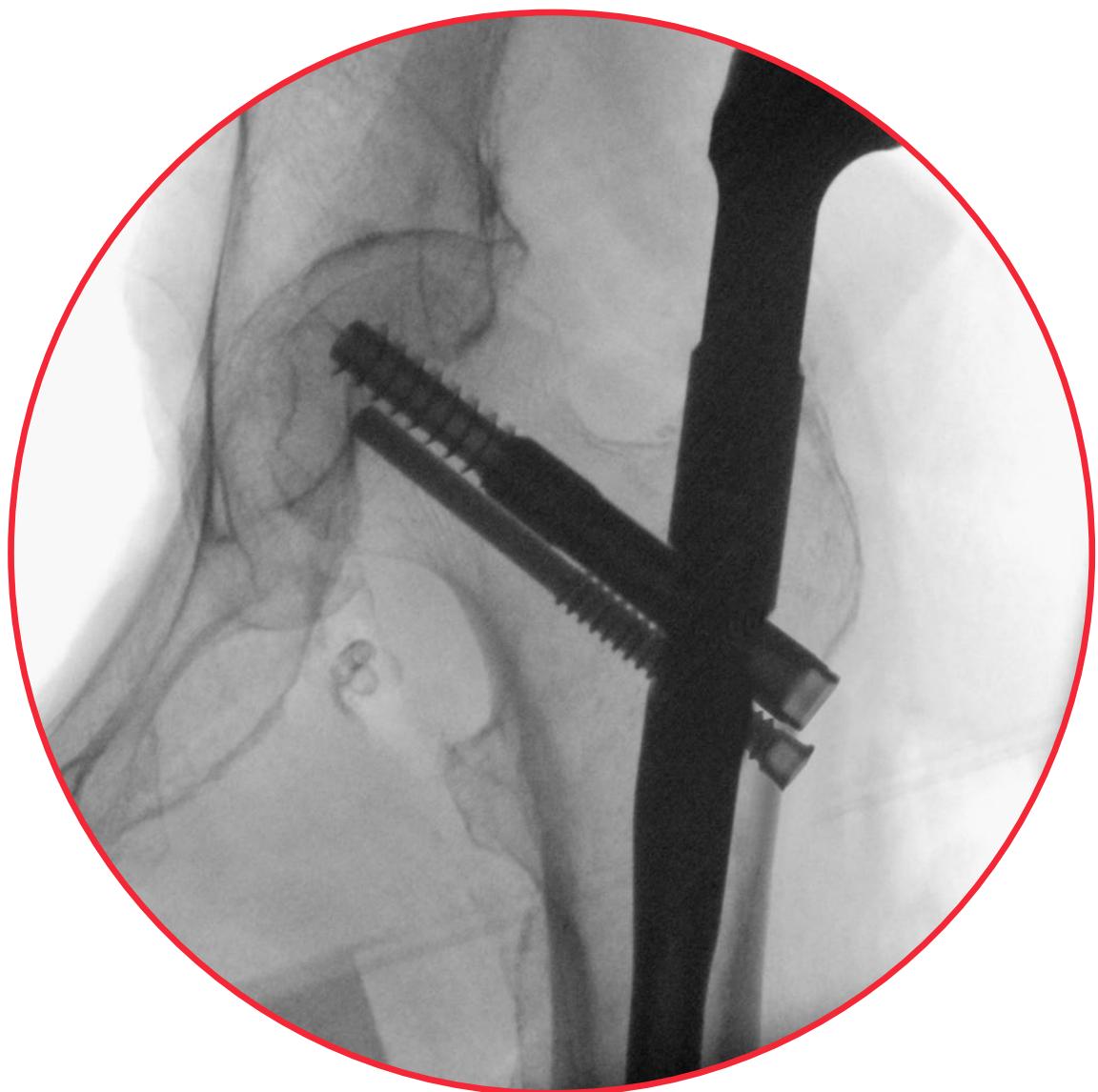


DyCon® Set Screw Insertion



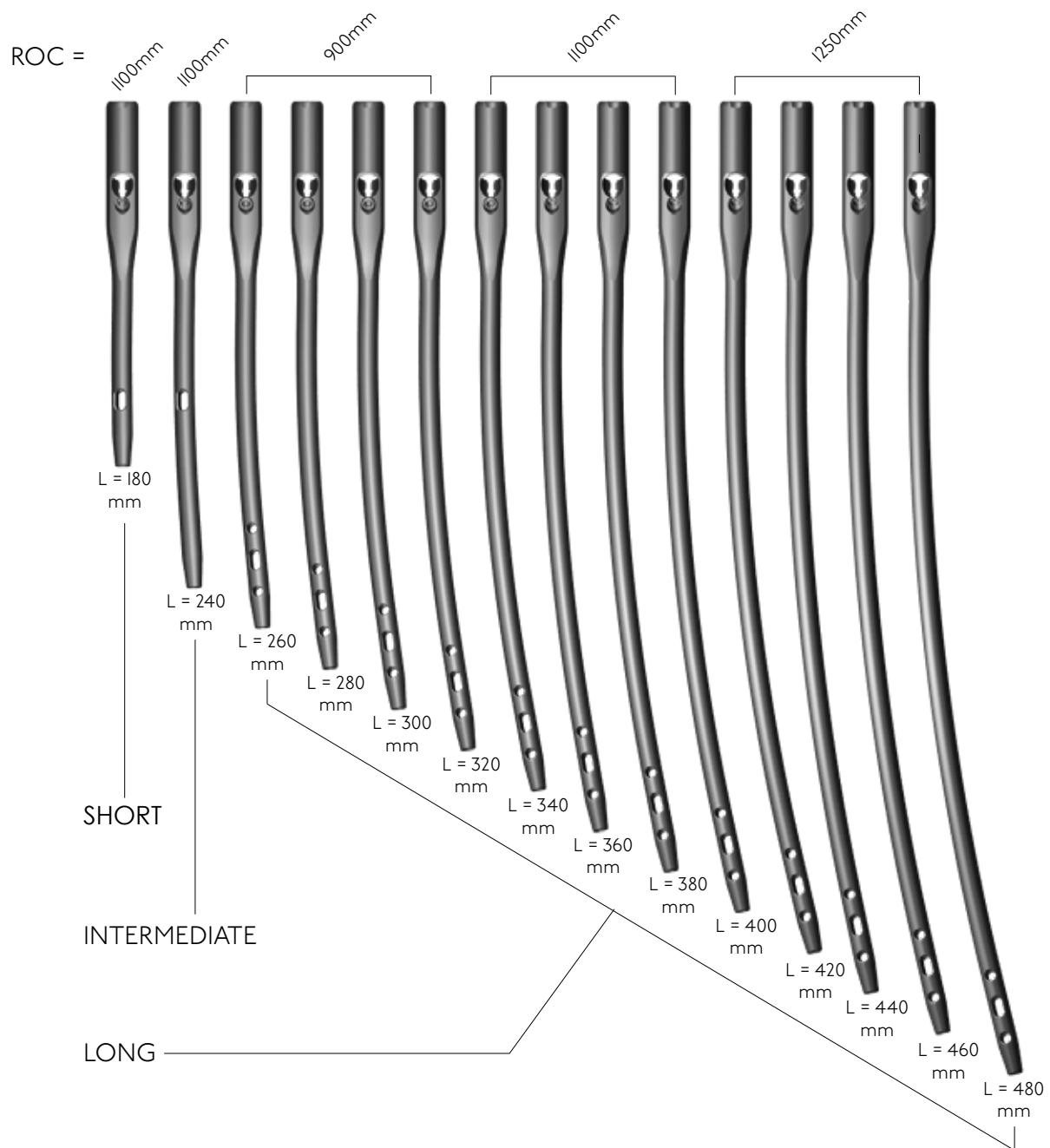
Guided Distal Locking



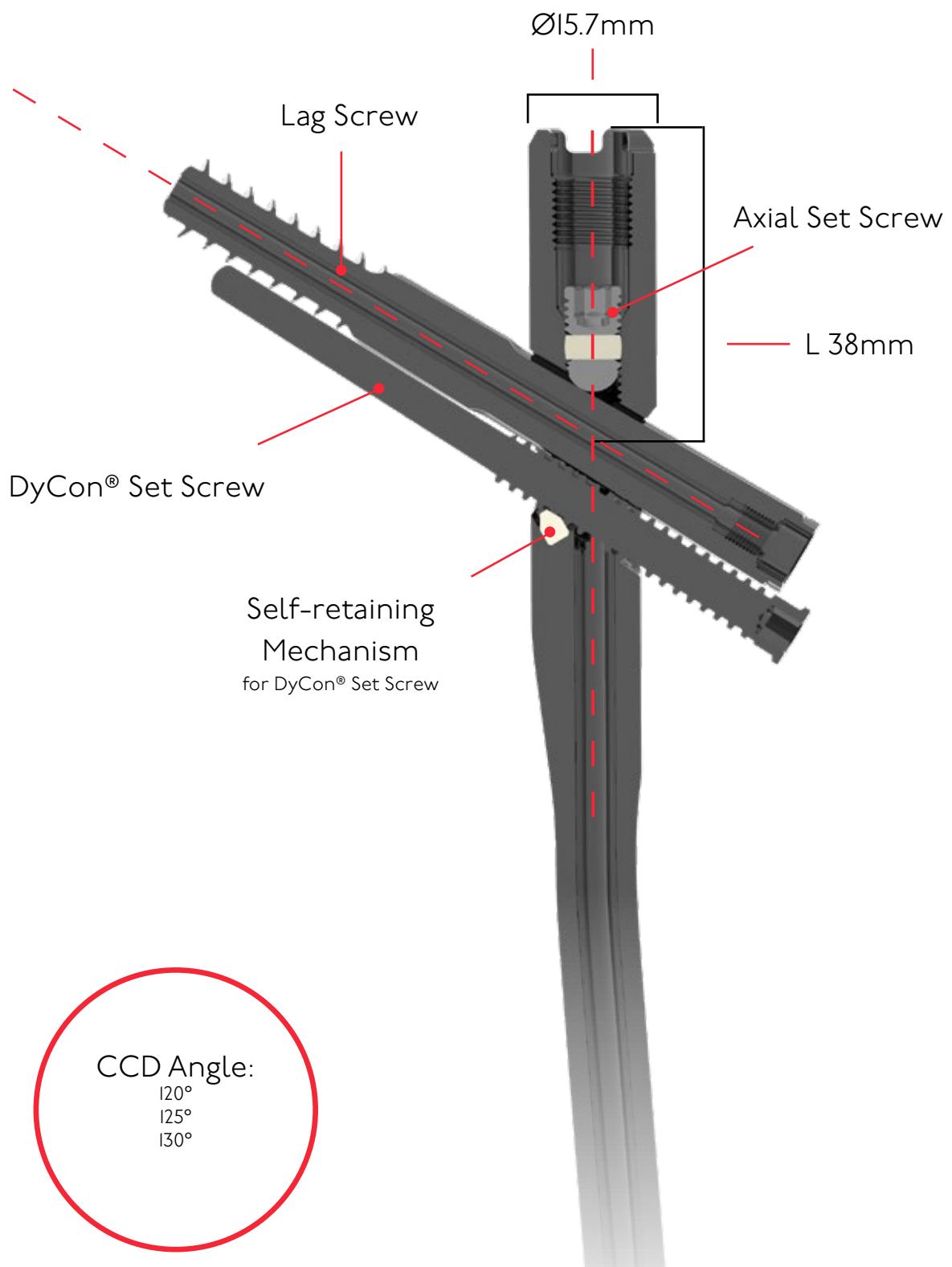


○ Nails

All nails come in left and right versions, with length-dependent antecurvatures to allow for a close anatomical fit to the patient. The short and intermediate nails are indicated for all lengths of femurs and as such use the average femoral antecurvature of 1100mm.



Decision making between the use of intermediate or long nails in highly unstable and more distal subtrochanteric fractures must be individualized. The short version of the nail is intended for stable and moderately unstable pertrochanteric fracture forms. The intermediate version can be used for highly unstable pertrochanteric as well as suitable subtrochanteric fracture forms due to a biomechanically improved support in the femoral shaft, while maintaining the possibility of rapid and easy locking via the target arm. Fractures extending into the shaft as well as combined forms of injury are addressed with the long nails. (For a complete list of indications, see p. 19)



○ DyCon® Screw Pair

The DyCon® Screw pair (Lag Screw and DyCon® Set Screw) relies on a 1:1 relationship between the two screws. The DyCon® Set Screw is thus chosen based on the measurement of the Lag Screw. No calculation or conversion is necessary as each DyCon® Set Screw is labeled with the corresponding Lag Screw length to ensure proper function in controlling the amount of dynamization.



Short DyCon® Set Screw

In cases where needed or preferred, a short version of the DyCon® Set Screw is available. The Short DyCon® Set Screw has the same dynamization control function as the standard versions and can be used universally for all lengths.

See technique p. 50



Axial Set Screw

The Axial Set Screw can be used alone or in combination with the DyCon® Set Screw. If used alone, the medial movement of the Lag Screw is blocked and the lateral movement is free depending on the remaining groove length of the Lag Screw.

See technique p. 51



Optional End Cap Screws with Axial Set Screw Function

The optional End Caps are available in lengths from 0-20mm. The End Caps can be used regardless of the selected locking mode of the Lag Screw.

See technique p. 72

Functions:

- keeps the thread free of scar tissue for a planned implant removal
- extends the proximal nail portion (5 - 20mm)



○ Correction Techniques

The G-series Hip-G Proximal Femur Nail includes a number of optional techniques to allow the surgeon to optimize the procedure as needed for each individual patient and surgery.

Rescue Sleeve for Correction of Trochanteric Entry Point

An optional rescue sleeve is available in case of a need to correct the original trochanteric entry point. The rescue sleeve is placed over the opening reamer sleeve and allows trochanteric opening to be adjusted either medially or laterally by a distance of 5, 10 or 15mm.

See technique p. 58



Correction of Lag Screw Drill-wire

The two-portal design allows for a simple, guided correction of the Lag Screw Drill-wire if needed. Thanks to the parallel trajectories of the two drill-wires, it is possible to adjust the drill-wire positioning superiorly or inferiorly, while retaining the correct central position in the lateral projection.

See technique p. 60

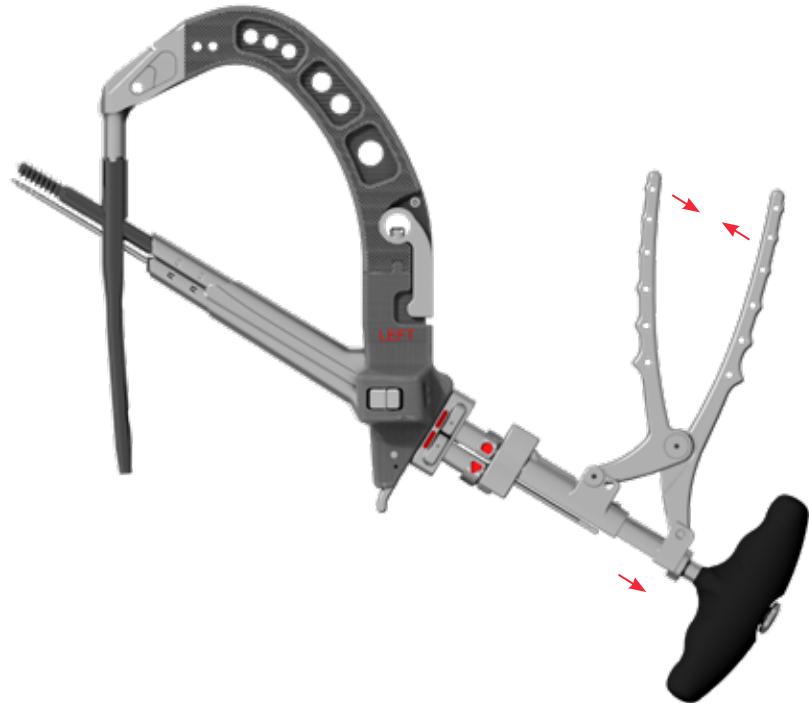


○ Closing of a Fracture Gap / Apposition

Closing of Fracture Gap

Optional instruments are available for closing of the fracture gap by using the Lag Screw. The appositioning instrument can be used to move the head fragment laterally.

See technique p. 63

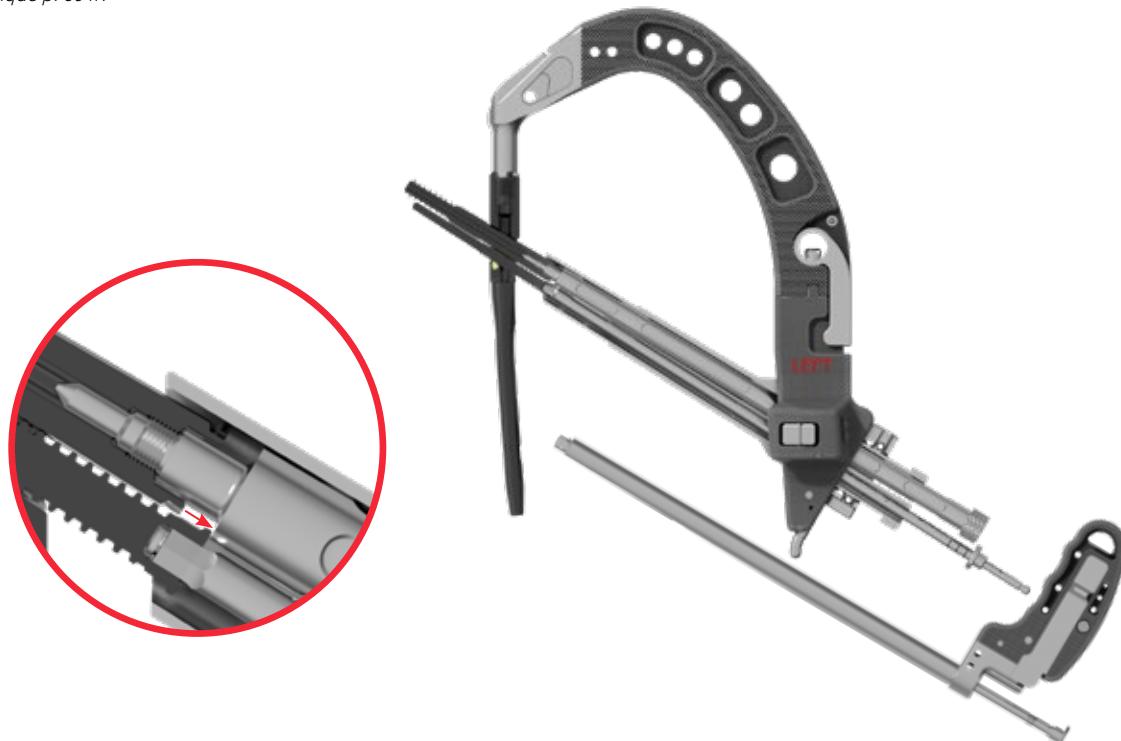


○ Advanced Compression

Advanced Compression

Compression to the fracture can be achieved by the Compression Rod together with the optional Set Screwdriver. Optionally, the compression can be performed using the L-Tool.

See technique p. 68 ff.



○ Indications

The indications for the I.T.S. G-series Hip-G Proximal Femur Nailing System include intramedullary treatment of fractures and stabilization after tumor resection in the area of the proximal femur, as well as combinations that additionally affect the shaft area using the long nails.

The indications for use of the Hip-G Proximal Femur Nail include:

All Nails:

- Stable and unstable pertrochanteric fractures
- Intertrochanteric fractures
- Combinations of fractures listed above

Additionally for Long Nails:

- Subtrochanteric fractures
- Proximal fractures as listed above associated with shaft fractures
- Pathological fractures in regions as listed above
- Nonunions and malunions in regions as listed above

○ Contraindications

Contraindications generally exist in the case of growth plates that have not yet been fused and in special circumstances such as infection or marked local inflammation.

Before choosing the implant certain precautions regarding preexisting and fracture related conditions have to be taken into account. As for most intramedullary implants, the I.T.S. Hip-G Proximal Femur Nail is designed to stabilize fractures temporarily until bony healing occurs and therefore depends on the patient's bone quality for adequate fixation. Conditions such as compromised vascularity, excessive stresses on bone and implant such as severe obesity or degenerative diseases have to be considered as well as every interfering systemic condition such as infection, demonstrated allergy or foreign body sensitivity to any of the implant materials. The decision whether to use the system in these conditions must be made by the physician taking into account risks versus benefits.



Surgical Technique

IMPORTANT: All instruments and implants in this surgical technique are calibrated to each other so that general instruments are not to be used unless specifically named.

2

● Diagnostics & Planning

Standardized fracture-related diagnostics for proximal femur fractures consist of a pelvic overview image and longitudinal images of the affected femur with the hip joint in the anteroposterior (a/p) direction and in a lateral projection if feasible due to pain. In the majority of cases, and especially in older patients, these images can be used to plan the procedure and select the appropriate implant. For complex and unclear fracture patterns, and especially for high-energy trauma in younger patients, additional clarification by means of computed tomography with reconstruction may be indicated.

Depending on the type of the fracture, the number of fragments, the dislocation, and other parameters, such as the integrity of the lateral femoral cortex, the fracture is classified as stable, unstable or highly unstable. Special cases are, for example, reverse oblique fractures that are difficult to reduce or fractures that have subtrochanteric extension. Accompanying pathologies beyond the actual fracture situation, such as hip joint arthrosis or tumorous destruction, must also be included in the planning.

For the planning of the implant position, the insertion depth of the Lag Screw, and the rotational locking of the Lag Screw with the alternatives of a long or short DyCon® Set Screw or an Axial Set Screw, the degree of pre-existing osteoporosis is an essential consideration. This should be evaluated both for the femoral head with the typical structural weakening, and for the shaft area with a typical thinning of the femoral cortex, e.g. indicating the use of the intermediate nail.

For prior planning of the implant configuration of the nail and Lag Screw, a mirror image of the opposite side is helpful. Essential factors are the femoral neck - diaphyseal angle and the width of the femoral medullary canal. The angle can be determined preoperatively analogously with a surgical goniometer or digitally in the X-ray PACS, whereby various software solutions also allow planning with projection of the implants. Essential for the selection of the nail diameter is the analysis of the femoral medullary canal width, especially in the isthmus region, under projection of the planned nail position.

Usually, an end position of the Lag Screw thread centrally in the femoral head is aimed for. For the application of the DyCon® Set Screw, it is necessary to maintain a sufficient distance between the Lag Screw and the cortex of the Adam's arch at the femoral neck for the passage of the DyCon® Set Screw. In case of an inferior implantation of the Lag Screw close to the Adam's arch, the use of a short DyCon® Set Screw or an Axial Set Screw should be considered.

● Patient Positioning

- The patient is placed in the supine position on an operating table with unobstructed fluoroscopy and freely adjustable extension device via a foot fixation.

ALTERNATIVE: It is also possible to treat the patient in the lateral position (e.g. in the case of shaft fractures), whereby a more difficult reduction of the proximal fracture must also be taken into account.

- The arm of the affected side is attached to a splint across the body.

TIP: If possible, the upper body is angled slightly by about 15° to the opposite side.

- The healthy leg is also rotated as far as possible to the opposite side with 90° flexion of hip and knee with the lower leg on a padded support.

TIP: To support reduction under traction, a padded post is positioned inguinally on the inner side of the affected thigh.

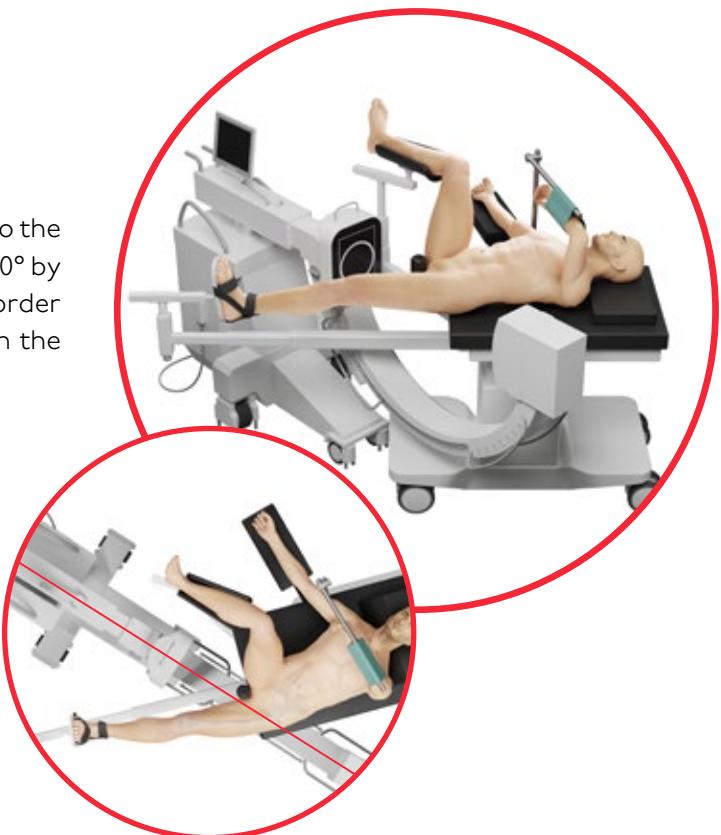
- The image intensifier is placed between the legs from the foot end. The aim is to obtain two standard projections of the hip joint with the adjacent femur by rotating the C-arm 90° under the leg to be operated on.

TIP: In the a/p position, the femoral head with acetabulum, the femoral neck and 10 to 15cm of the proximal femur with the trochanteric mass should ideally be imaged.

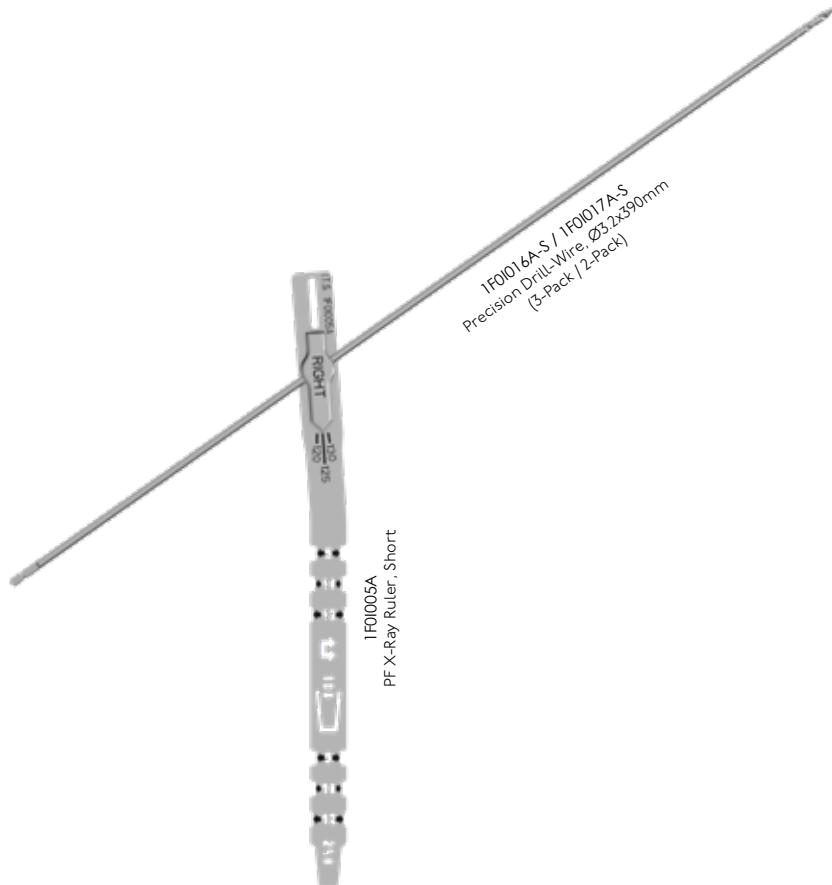


- The lateral projection is adjusted in relation to the femoral neck angle (e.g., at 120° by 30° or at 130° by 40°) rotated to the longitudinal body axis in order to obtain a projection of the femoral neck in the lateral plane.

CCD	Adjustment of lateral projection
120°	30°
125°	35°
130°	40°



○ Reduction & Verification of Implant Planning



The aim is to achieve a closed reduction of the main fragments, i.e. for the femoral shaft versus the proximal fracture portion with femoral neck and femoral head in terms of length, axis and rotation.

NOTE: Accurate reduction of the fracture before nail insertion is the first mandatory key point to achieving a satisfactory outcome.

TIP: If satisfactory reduction cannot be achieved closed, assisted percutaneous techniques can be used during surgery. If a complex fracture is irreducible closed, which is more often the case with e.g. displaced subtrochanteric fractures, an open reduction technique should be used.

IMPORTANT: Drill-wires are single use instruments and must not be reused.

- First, reduction is performed by increasing traction under image intensifier control in the a/p projection. The traction should bring the leg into a horizontal position corresponding to the condylar axis of the femur parallel to the body axis without distracting the fracture.

TIP: In highly unstable fracture patterns, it may be helpful to mount an additional support for the proximal femoral region from below the table.

- Next, the reduction is checked by pivoting the image intensifier to the lateral position.
- Readjustments are to be made first by rotating the leg usually inward or otherwise outward.

TIP: An initial check of correct rotation can be made visually by looking at the position of the patella compared to the position of the femoral neck using fluoroscopy. With the patella in a horizontal position corresponding to a neutral femoral condyle axis parallel to the floor, the neck of the femur should move upward 10-15° in the image intensifier image or anterior to the projection in the anatomic view. Alternatively, inward rotation of the patella by 10-15 deg can be performed and with the fracture satisfactorily reduced, a perfect lateral of the femoral neck should be seen.

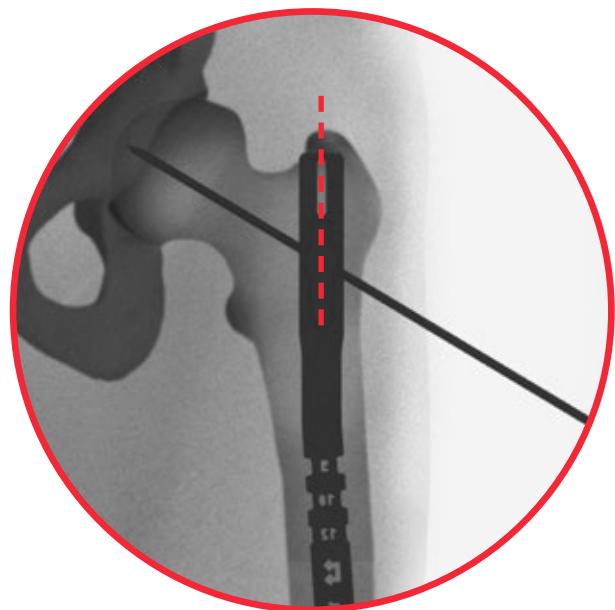
- The cover should leave a surgical field 20cm wide on the lateral thigh, with the center of the surgical field above the palpable greater trochanter. Cranially, the surgical field begins above the iliac spine; caudally, the area for the short and intermediate nails extends to the middle of the thigh; for the long nail, below the knee.

TIP: The surgical field should be taped off as fixation of the drapes with clamps may obscure fluoroscopic imagery.

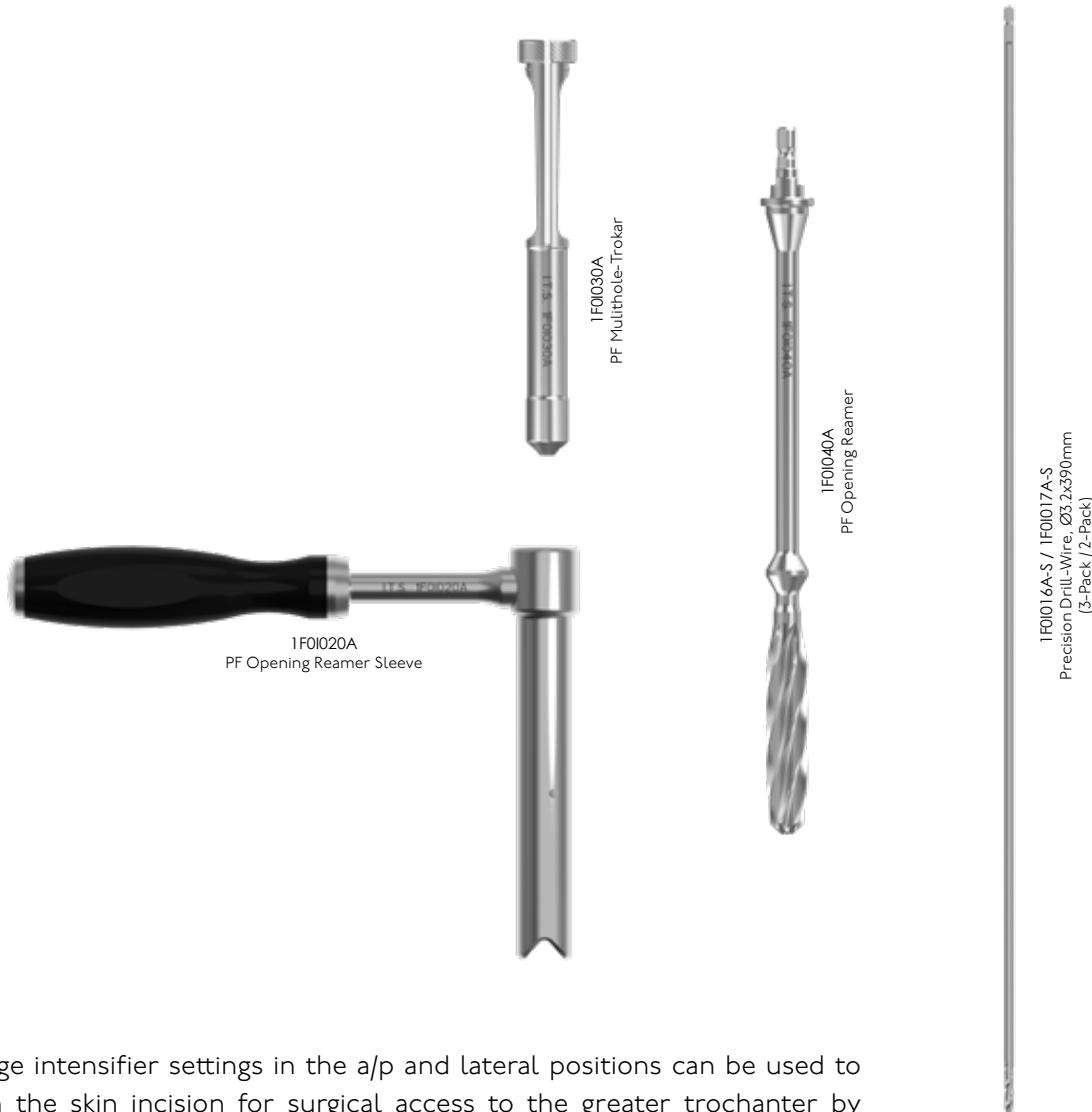
- Fluoroscopy in the a/p projection in the reduced state can now be used to check the planning of the implant selection and in particular the selection of the femoral neck-diaphyseal angle. The x-ray ruler (*PF X-Ray Ruler, Short or PF X-Ray Ruler, Long for the long nails*) allows measurement of the CCD angle together with an inserted drill-wire (*Precision Drill-Wire, Ø3.2x390mm*) as well as planning for the nail length, whereby the anticipated location of the distal locking can be estimated.

TIP: The indicator window at the proximal end of the x-ray ruler (*PF X-Ray Ruler, Short or PF X-Ray Ruler, Long for the long nails*) shows the path of the guiding drill wire during the proximal access to the trochanter.

NOTE/CAUTION: By placing the x-ray ruler in the a/p projection using the image intensifier, the medullary canal width and thus the required nail diameter can also be estimated. However, for the calculation, it must be taken into account that, depending on the distance between the x-ray ruler and the bony femur, a projection effect occurs due to the soft tissues in between. With a radiation source located at a distance of 5 to 10cm above the leg, this causes an increase in the reading of 2 to 3mm compared to the actual medullary diameter.



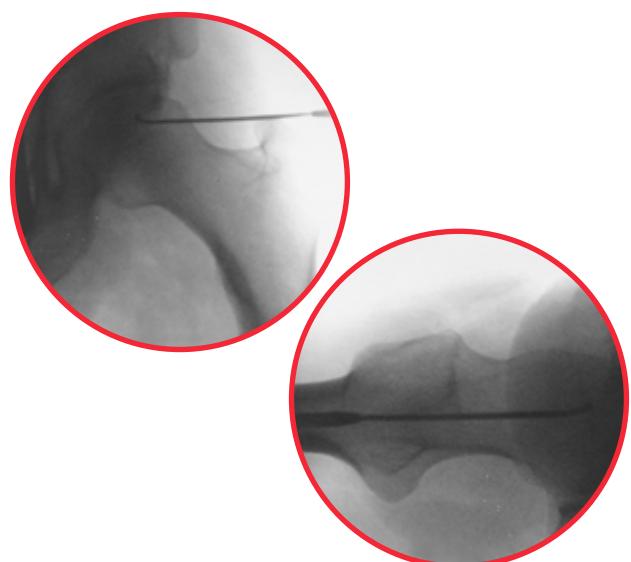
Operative Access to the Trochanter



The image intensifier settings in the a/p and lateral positions can be used to pre-plan the skin incision for surgical access to the greater trochanter by placing a drill-wire.

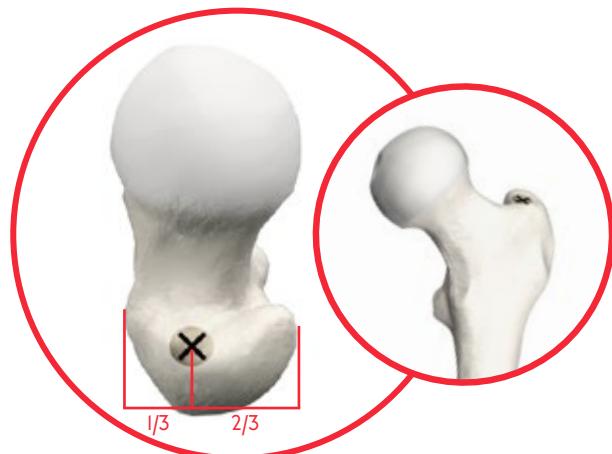
IMPORTANT: Drill-wires are single use instruments and must not be reused.

- In the a/p position, a drill-wire is placed transverse to the body axis so that it comes to rest on the tip of the trochanter in the projection. This height is marked transversely on the lateral thigh.
- In the lateral position of the image intensifier, the drill-wire is placed centrally in the axis of the femur and a mark is drawn longitudinally above the horizontal line.



- The skin incision (approx. 2 to 3cm) extends from 2 to 4cm (one to two transverse fingers) proximal to the palpated trochanteric apex or the trochanteric apex defined under radiological control, depending on the amount of the soft tissue.
- After transection of the subcutaneous tissue, the fascia is sharply cut longitudinally. The underlying musculature is elevated until the ridge of the trochanter running from anterior to posterior can be palpated.

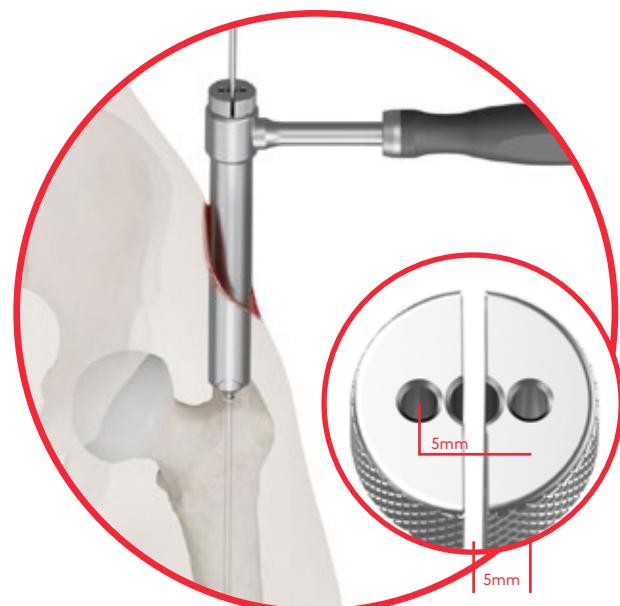
- The palpable bone ridge is divided visually into thirds, whereby the correct entry point for the guide wire is usually at the junction of the anterior third and the middle third.



- The guiding drill-wire (Precision Drill-Wire, Ø3.2x390mm) is drilled centrally in the longitudinal axis of the femoral shaft, if necessary with the aid of the conical drill sleeve (PF Multihole Trocar) with soft-tissue protective sleeve (PF Opening Reamer Sleeve) and under image intensifier control, whereby the valgus path must be observed in the a/p projection.

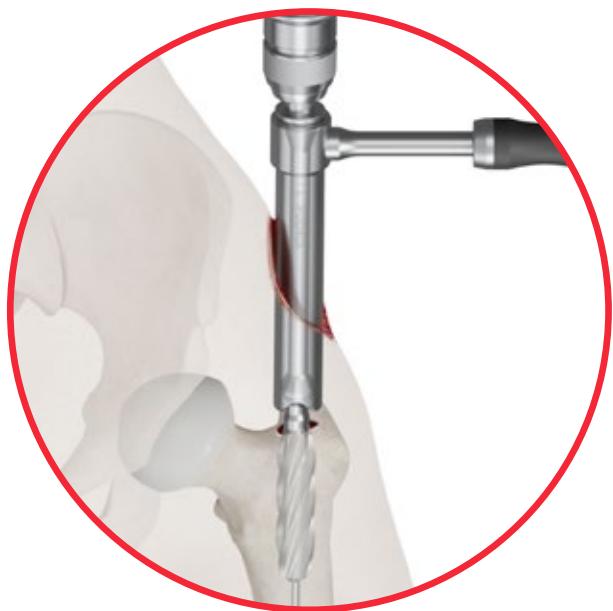
IMPORTANT: The correct position of the drill-wire is essential for the following surgical steps and should be implemented and checked with particular care.

TIP: If corrections are necessary, the first drill-wire can be left in place and a second parallel drill-wire can be inserted via the parallel holes of the conical drill sleeve or, alternatively, after appropriate repositioning within the specified hole selection.



- The conical drill sleeve is then removed, and the soft tissue protection sleeve is advanced so that the dovetail-like shape sits laterally and medially over the trochanteric ridge.
- The medullary canal is then opened over the drill-wire with the opening reamer through the soft tissue protection sleeve until the depth stop makes contact with the tissue protection sleeve.

IMPORTANT: All reaming steps should be performed under image intensifier control.



TIP: If the drilled opening is too medial or lateral, the rescue sleeve (*PF Opening Reamer Sleeve Rescue*) can be used, see p. 58.

For the short and intermediate nail, the opening procedure is thus completed and the instruments can be removed.

TIP: As an option if the medullary canal appears very narrow, the ball tip guide wire (*Ball Tip Guide Wire, Ø3x800mm*) is inserted through the soft tissue protective sleeve and the medullary canal is reamed over the wire.

The continued procedure when using the long intramedullary nails is described separately - see p. 73.

○ **OPTIONAL:** Opening of the Medullary Canal with the Awl



The optional awl can be used to open the medullary canal as an alternative to the opening reamer.

- Connect the awl (*Awl, Curved, Cannulated*) with the T-Handle (*T-Handle Zimmer-Hall, cannulated*), and insert the trocar (*Awl, Trocar*) into the cannulation of the awl.

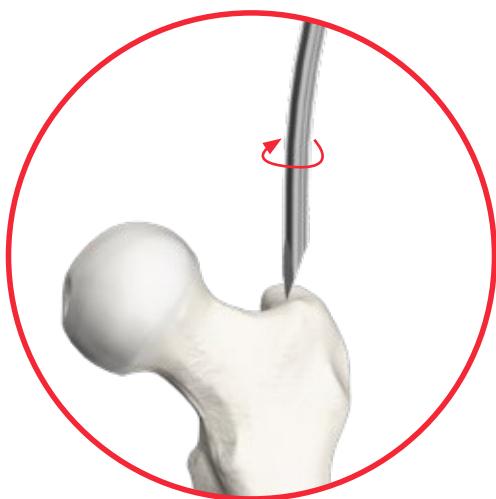
OPTIONAL: Opening of the Medullary Canal with the Awl

- Position the awl at the entry point localized under imaging and penetrate the cortex using controlled rotational movements to create access to the medullary canal.

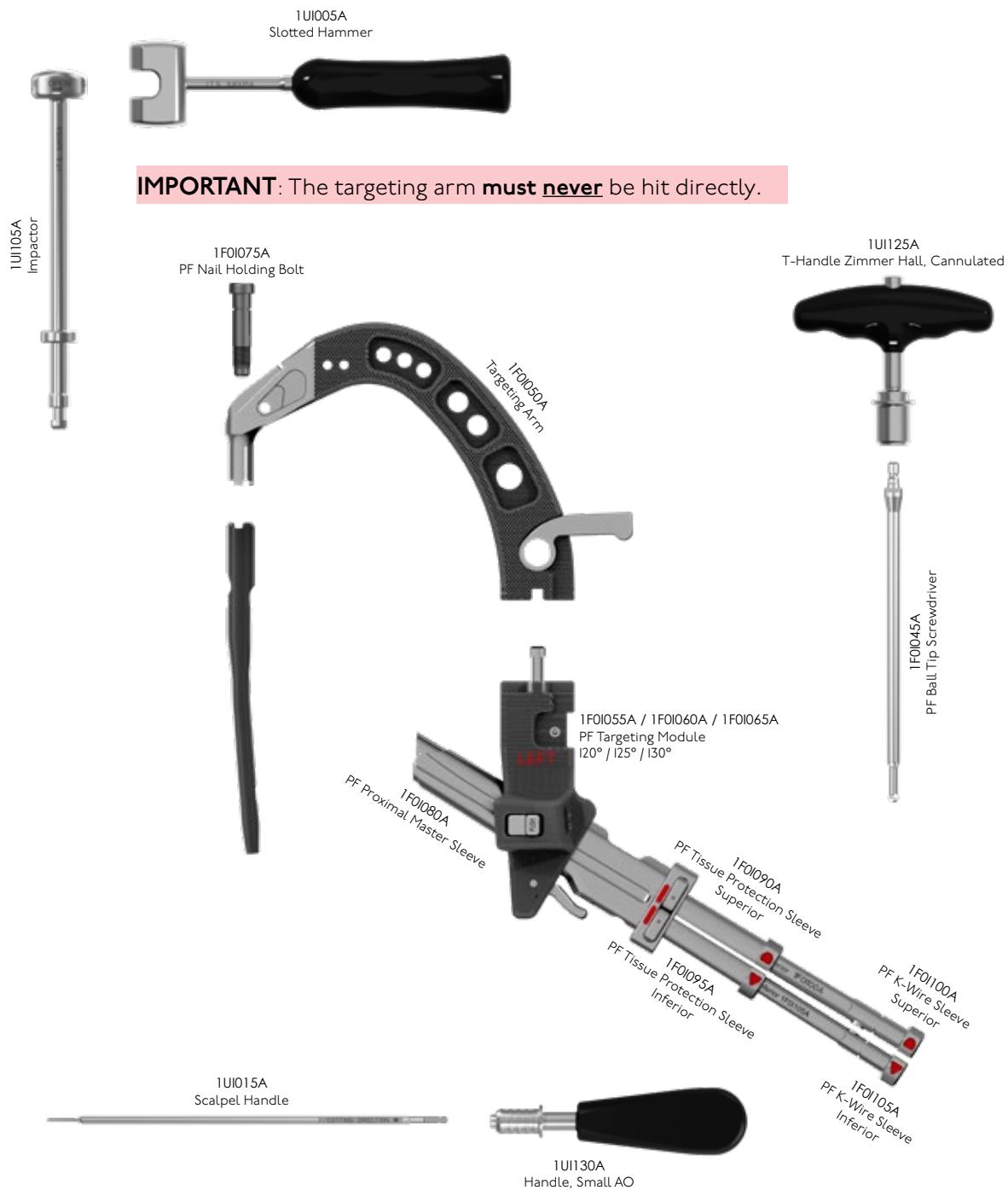
IMPORTANT: When creating the entry point, a dense cortex may block the tip of the awl. The inserted trocar prevents bone fragments from entering the cannulation of the awl.

TIP: Insertion of the awl should be performed under image guidance. Rotational movements should be controlled and applied with minimal force to avoid complications.

- After opening, the trocar is removed and a guide wire is inserted. The medullary canal is opened using the technique described on p. 30. If the PF opening reamer is not used, the proximal portion should be reamed to 16mm using the flexible medullary reamers.



○ Insertion of the Intramedullary Nail



COLOR CODING

Adhering to the navigation principles of Right/Starboard = **GREEN** and Left/Port = **RED**, the Hip-G Proximal Femur Nailing System is color coded for easy identification.

The targeting module as well as all sleeves are clearly marked indicating their correct orientation.



- The medullary nail is selected with regard to length, femoral neck angle and diameter.
- The nail is attached to the targeting arm by the nail holding bolt which is inserted using a ball-tip screwdriver (*Targeting Arm with Locking Lever, PF Nail Holding Bolt, PF Ball Tip Screwdriver incl. T-Handle Zimmer Hall Cannulated*).

IMPORTANT: The Targeting Module (*PF Targeting Module 120°, 125° or 130°*) must be double-checked for compatibility with the femoral neck angle of the mounted nail.

IMPORTANT: The Nail Holding Bolt (*PF Nail Holding Bolt*) securing the nail must be fully tightened to ensure that the nail does not loosen during insertion.

- The intramedullary nail is inserted into the entrance of the canal and advanced with a slightly rotating movement.

ALTERNATIVE: The intramedullary nail can be inserted over a ball-tip guide wire.

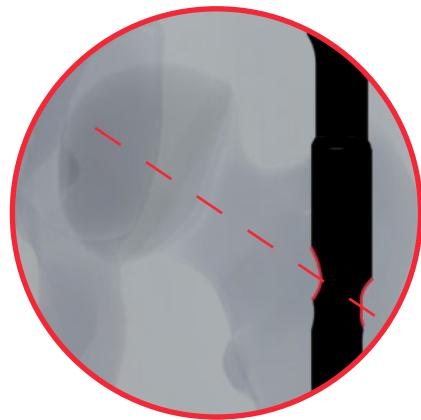
TIP: By lifting the insertion handle with resulting inward rotation, the antecurvature of the nail can be used to support the valgus entry path, if necessary, in contact with the medial cortex.

IMPORTANT: After the insertion of the nail, revalidate the attachment of the Nail Holding Bolt (*PF Nail Holding Bolt*) to the nail to ensure it is secure.

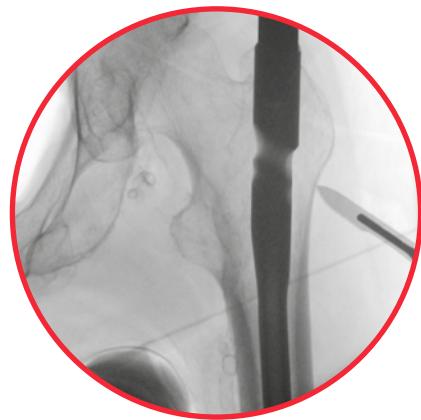


- The implantation depth is indicated by the hole configuration for the Lag Screw seen in the image intensifier.

TIP: When the leg has ideally been aligned horizontally with respect to the condylar axis, the insertion handle should be rotated towards the floor according to the anteversion of the femoral neck. If the leg has been turned inward - or more rarely outward - and fixed during reduction, the insertion handle must be adjusted accordingly.



- The soft tissue access (approx. 35mm incision) for positioning the femoral neck implants is started through the master sleeve opening in the targeting module using a scalpel (*Scalpel Handle*). It is then continued through the subcutaneous tissue and fascia until the bone is reached.



- The master sleeve (*PF Proximal Master Sleeve*) is then inserted into the corresponding hole in the targeting module and locked in place by turning the locking lever downwards.

TIP: The master sleeve can only be locked by inserting it completely up to the stop.



- The K-wire sleeves (*PF K-Wire Sleeve, Superior & Inferior*) are inserted into the corresponding soft tissue protection sleeves (*PF Tissue Protection Sleeve, Superior & Inferior*), and inserted fully into the master sleeve until contact with the lateral femoral cortex is made.

IMPORTANT: The tissue protection sleeves must make contact with the lateral femoral cortex. The sleeves are firmly fixed by a ratchet mechanism ensuring correct length measurement in the subsequent surgical steps.

- The nail position is then adjusted using the a/p projection with respect to the implantation height in the femoral medullary cavity.

IMPORTANT: The targeting arm **must never** be hit directly. The impactor must be used in these cases.

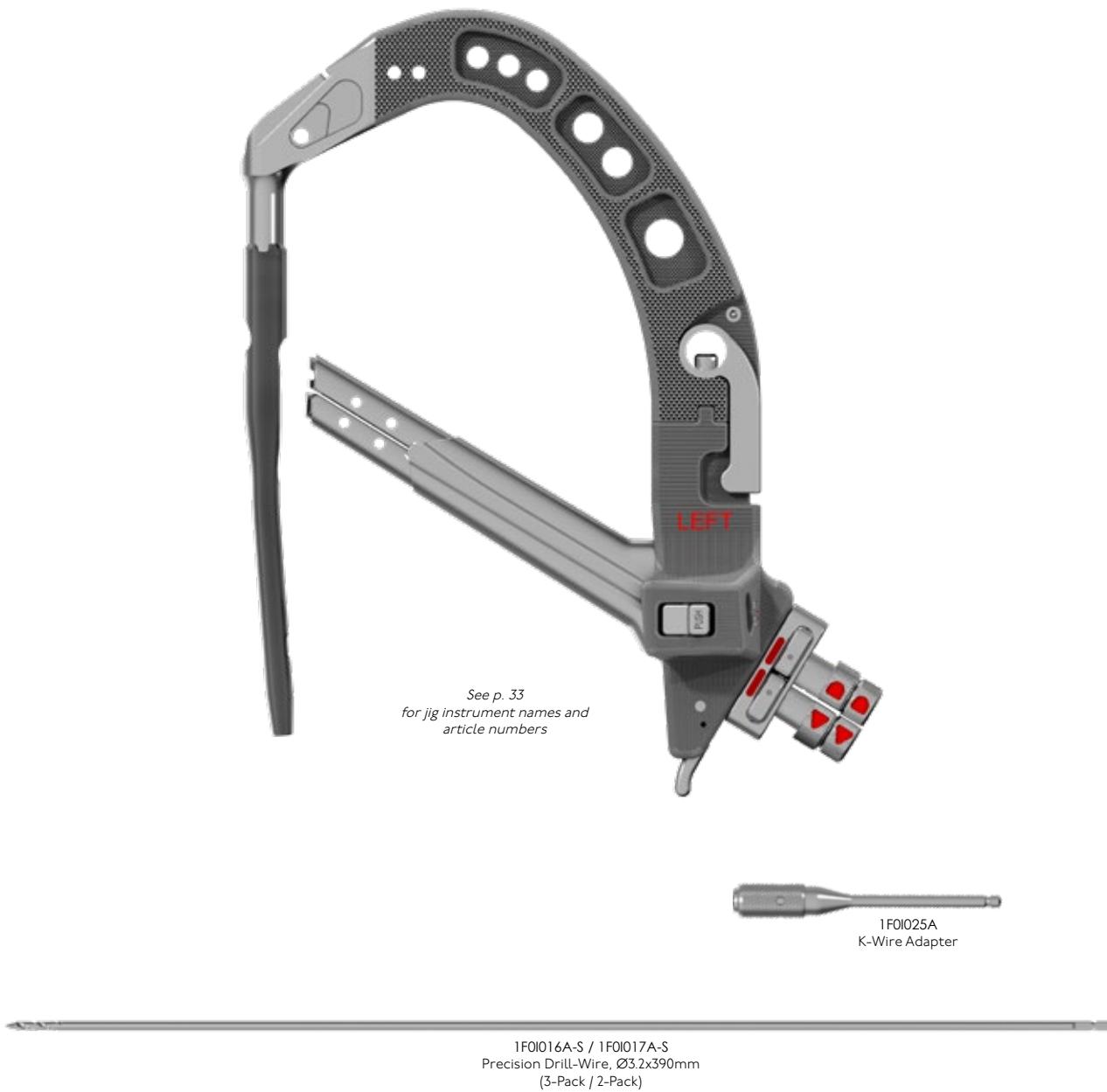
TIP: If the nail is firmly seated, fine positioning can be achieved by **light** hammer blows. For this purpose, the impactor (*Impactor*) must be mounted in advance, which then also permits recoil.

IMPORTANT: If rigid resistance is encountered during insertion, the nail must be retracted and the medullary canal reamed accordingly using the ball tip guide wire.

TIP: The soft tissue protection sleeves each contain a line of holes, which when seen in the a/p projection can be used as a guide to visualize the path of the drill-wires.



○ Drill-Wire Positioning



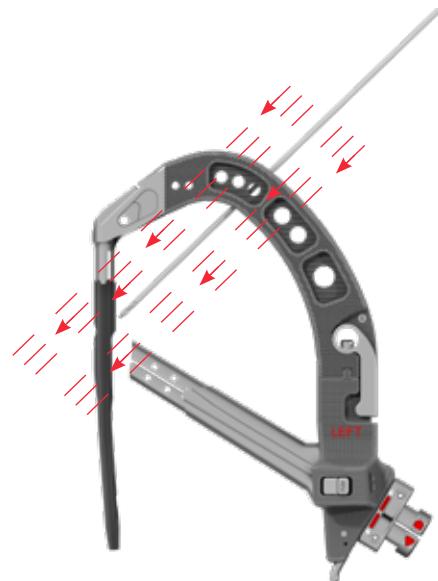
IMPORTANT: Drill-wires are single use instruments and must not be reused.

TIP: For all steps with the drill-wires, the K-Wire Adapter (*K-Wire Adapter*) should be used, which simplifies the connection to the drill and avoids interference between the wires and power tools with wire driver.

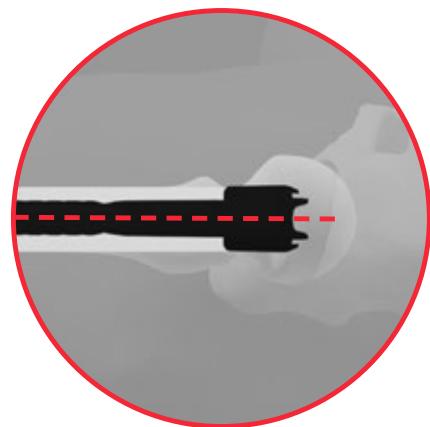
Positioning of Lag Screw Drill-wire:

- Once the desired nail position has been achieved, the image intensifier is rotated into the lateral projection of the femoral neck so that the femoral head appears in a central position.

TIP: The optimal position of the image intensifier is in the approximate lateral projection of the femoral neck. A reception hole in the targeting device allows for the placement of a drill-wire to indicate the direction of the image intensifier.



- By slightly rotating the nail, the integrated sighting device on the targeting arm can be centrally adjusted to the center of the femoral head.



IMPORTANT: Before proceeding, ensure that no drill-wire or guide wire used in earlier steps remains in the canal/nail.

- In this position, the drill-wire of the Lag Screw is drilled through the superior K-wire sleeve to a central position in the femoral head. This procedure initially fixes the nail and targeting device in a correct lateral position to the femoral neck and femoral head.



IMPORTANT: To avoid perforation into the joint, the drill-wire should never be predrilled too far medially in this initial placement step.

The image intensifier is then returned to the a/p position and the guide wire position is checked.

- If the position in the femoral head corresponds with the original plan, the drill wire for the Lag Screw can be definitively positioned in the a/p projection. The final position of the drill wire tip should be 5mm below the transition of the bony zone into the cartilage of the femoral head, depending on the bone quality and surgeon preference.

IMPORTANT: Make sure that drill-wires are straight and have an undamaged surface to guarantee the safe function with instruments and implants in subsequent steps.

TIP: If the drill-wire is not in the correct position in the femoral head, it can be corrected both in the cranial and in the caudal direction using the parallelity of the two drill-wire trajectories - see p. 60.



Positioning of DyCon® Set Screw Wire:

- The inferior drill-wire is placed through the corresponding K-wire sleeve.

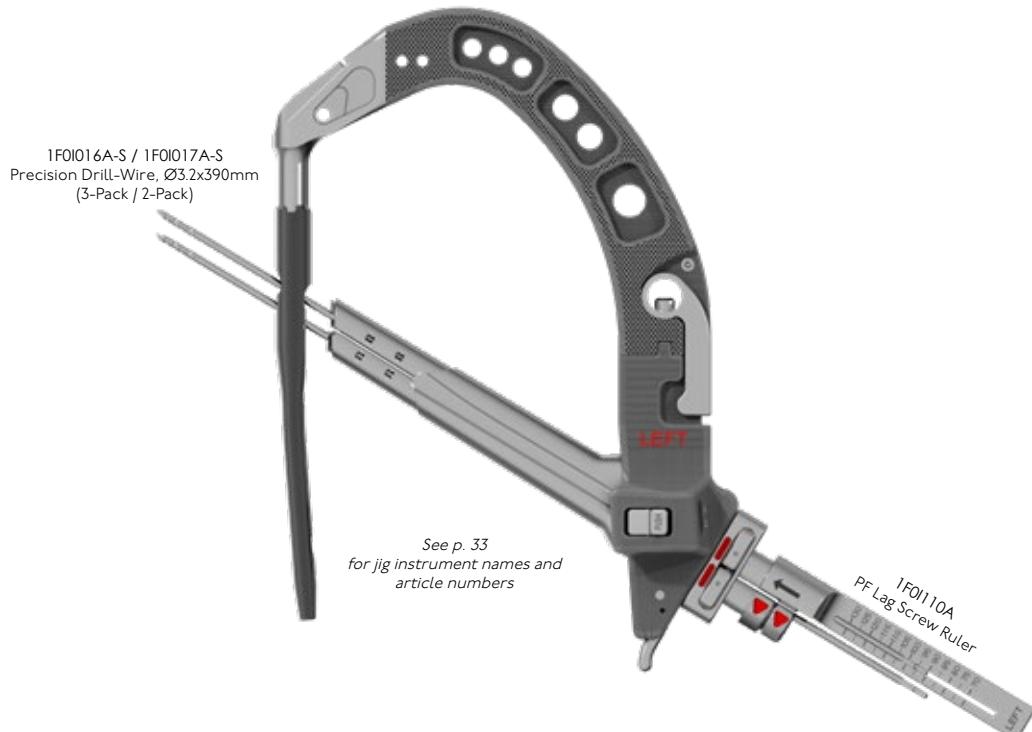
TIP: As a rule, this is anchored in the femoral head with a 5 to 10mm shorter length than the lag screw drill-wire.



IMPORTANT: The drill-wires are inserted in true parallel paths in order to provide clear visualization that the drill-wires have not been deflected, e.g. by the cortical bone in the Adam's Arc. Should a deflection be observed, the inferior drill-wire should be backed out to a point prior to the deflection. In such cases, only a short DyCon® Set Screw can be used.



○ Lag Screw Drilling & Insertion



1F01115A
PF Step Drill Lag Screw

1F01120A
Step Drill Depth Stop

1F01155A
PF Lag Screw Driver

1F01160A
PF Lag Screw Driver Retaining Rod

1F01130A
PF Lag Screw Tap

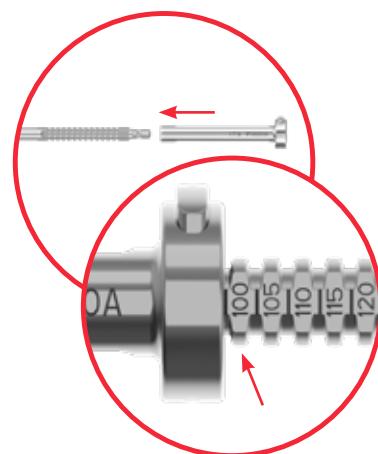
Lag Screw Drilling:

- The length for drilling and selecting the Lag Screw is determined using the lag screw ruler (*PF Lag Screw Ruler*).

IMPORTANT: The measured value is 5mm shorter than the drill-wire and provides the length for the correct depth of drilling and selection of the Lag Screw.



- The depth stop (*Step Drill Depth Stop*) is placed onto the step drill (*PF Step Drill Lag Screw*) prior to the drill being attached to the power tool, and is then adjusted to the intended drilling depth, engaging in 5mm increments.



- The superior K-wire sleeve is removed for the drilling process, while the inferior K-wire sleeve continues to fix the correct alignment of the insertion guide and nail.

IMPORTANT: During the drilling, the inferior drill-wire remains inserted in the inferior K-wire sleeve, in accordance with the consistent doubling technique securing the head fragment against rotation.

- Insert the drill over the drill-wire, through the superior tissue protection sleeve and drill until the depth stop is reached.

IMPORTANT: The pre-set depth stop on the step drill prevents drilling too deep unintentionally. Nevertheless, it is recommended to check this process using the image intensifier, also to verify the final selection for the length of the Lag Screw.

IMPORTANT: If passage of the drill through the nail is obstructed, check to make sure that the drill-wire is not deflected.

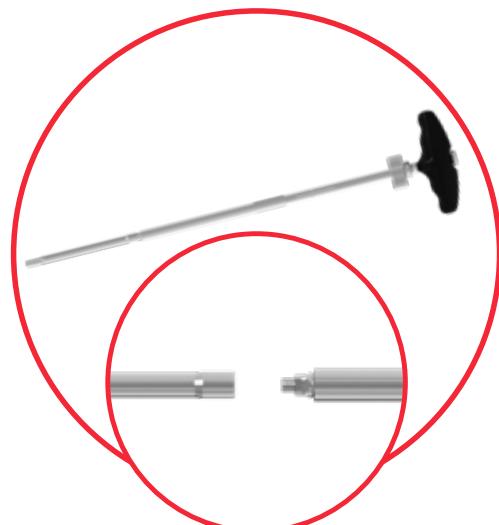


- After drilling for the Lag Screw, the step drill is withdrawn.

IMPORTANT: After completion of the superior drilling process, the position of the superior drill-wire should be checked. If the drill-wire has moved during the drilling process, it should be repositioned.

TIP: If pre-tapping of the Lag Screw thread is necessary in case of very firm bone quality, a tap (*PF Lag Screw Tap*) is available, which can be mounted on the Lag Screw driver.

IMPORTANT: Since the tap has no calibration and no end stop, the cutting process should be performed under image intensifier control.



Lag Screw Insertion:

- The selected Lag Screw is placed on the Lag Screwdriver (*PF Lag Screw Driver*) and secured with the thread-carrying inner rod (*PF Lag Screw Driver Retaining Rod*).

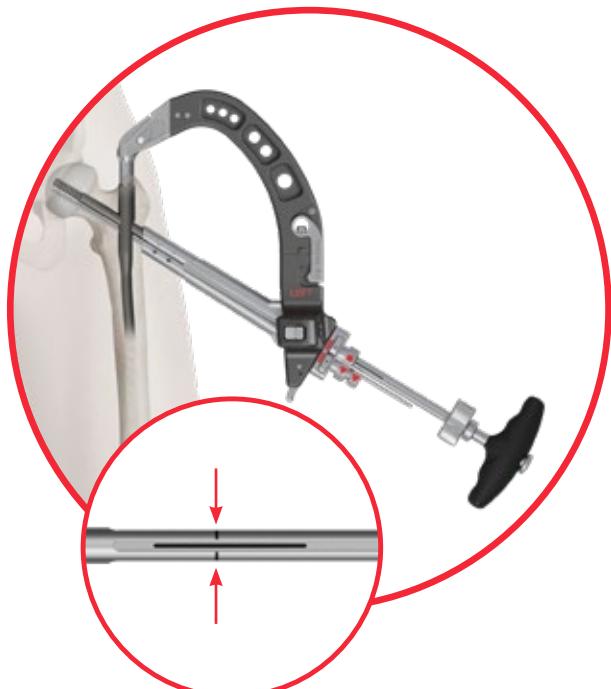


IMPORTANT: The correct positioning is ensured by the asymmetrically designed connection. The grooves of the Lag Screw are correspondingly imitated on the shaft of the screwdriver for reliable position control.

IMPORTANT: Prior to the insertion of the Lag Screw, revalidate the attachment of the Nail Holding Bolt (*PF Nail Holding Bolt*) to the nail to ensure it is secure.

- The cannulated Lag Screw is inserted into the soft tissue protection sleeve over the superior guide wire and screwed in maximally until to the end mark (black line on the lag screw driver) reaches the soft tissue protection sleeve.

TIP: This process is usually performed using the image intensifier.



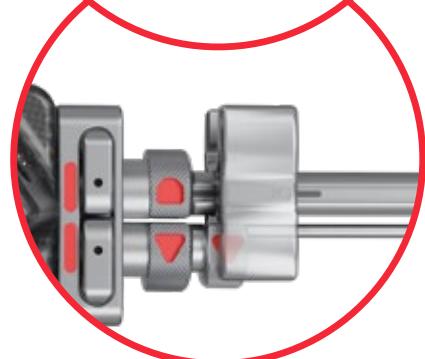
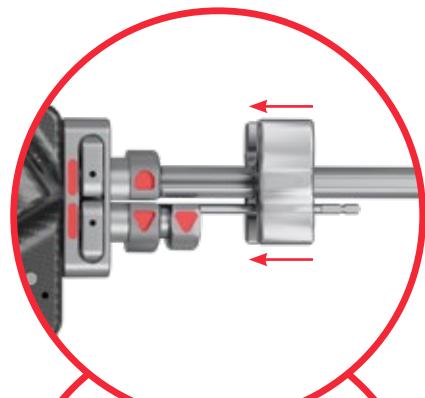
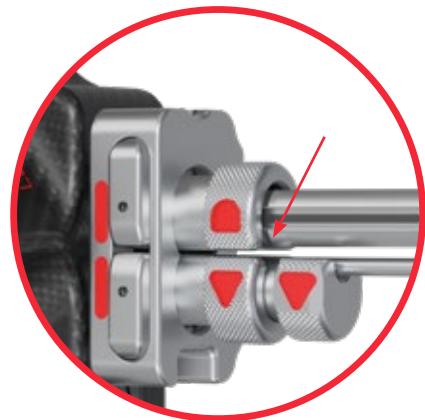
- The correct rotation of the Lag Screw is indicated by corresponding markings on the soft tissue protection sleeve and the screwdriver shaft.
- After each half turn (180°) of the Lag Screw, an end position can be reached that also ensures proper placement of the DyCon® Set Screw or Axial Set Screw.
- In addition, it is recommended to use the screwdriver (*PF Lag Screwdriver*) and its slider to verify rotational alignment. To do this, slide the slider medially over the inferior K-wire sleeve.

IMPORTANT: According to the pitch of the Lag Screw thread, this means a choice of final positioning in 1.6mm increments at a feed rate of 3.2mm per screw turn.

TIP: The rotational end position of the Lag Screw corresponds with a longitudinal orientation of the screwdriver handle in relation to the targeting device. This also references the orientation of the nail in the femoral shaft.

TIP: If reduction of a fracture gap by using the Lag Screw is desired, closing of the gap can be achieved using the appositioning instrument (*PF Appositioning Instrument*) - see p. 63.

- After final positioning of the Lag Screw, the lag screwdriver and lag screw drill-wire are removed.



● Set Screws - Implantation Overview

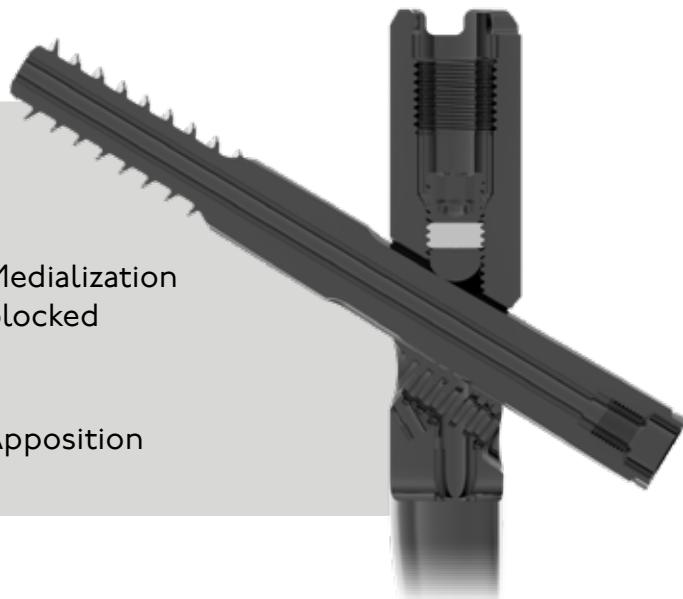
AXIAL SET SCREW

 Dynamization Control

 Medialization blocked

 Compression

 Apposition



DYCON SET SCREW

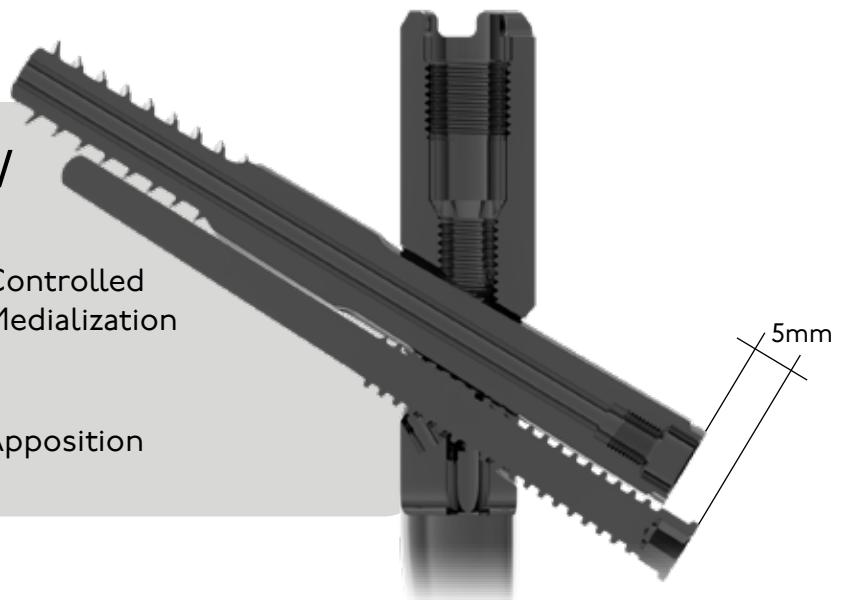
 Dynamization Control

 Controlled Medialization

 Compression

 Apposition

5mm



COMBINATION

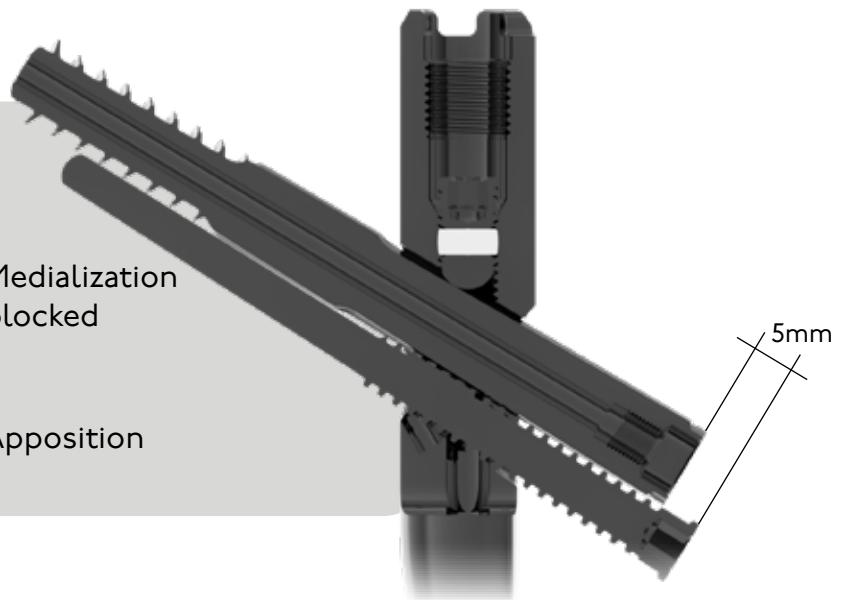
 Dynamization Control

 Medialization blocked

 Compression

 Apposition

5mm

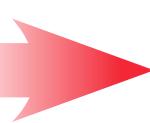


INTUITIVE



- Implantation of the Axial Set Screw - **P.51**
- Closure of a Fracture Gap - **P. 63**
- Closure of a Fracture Gap with the L-Tool - **P. 64**

TAILORED



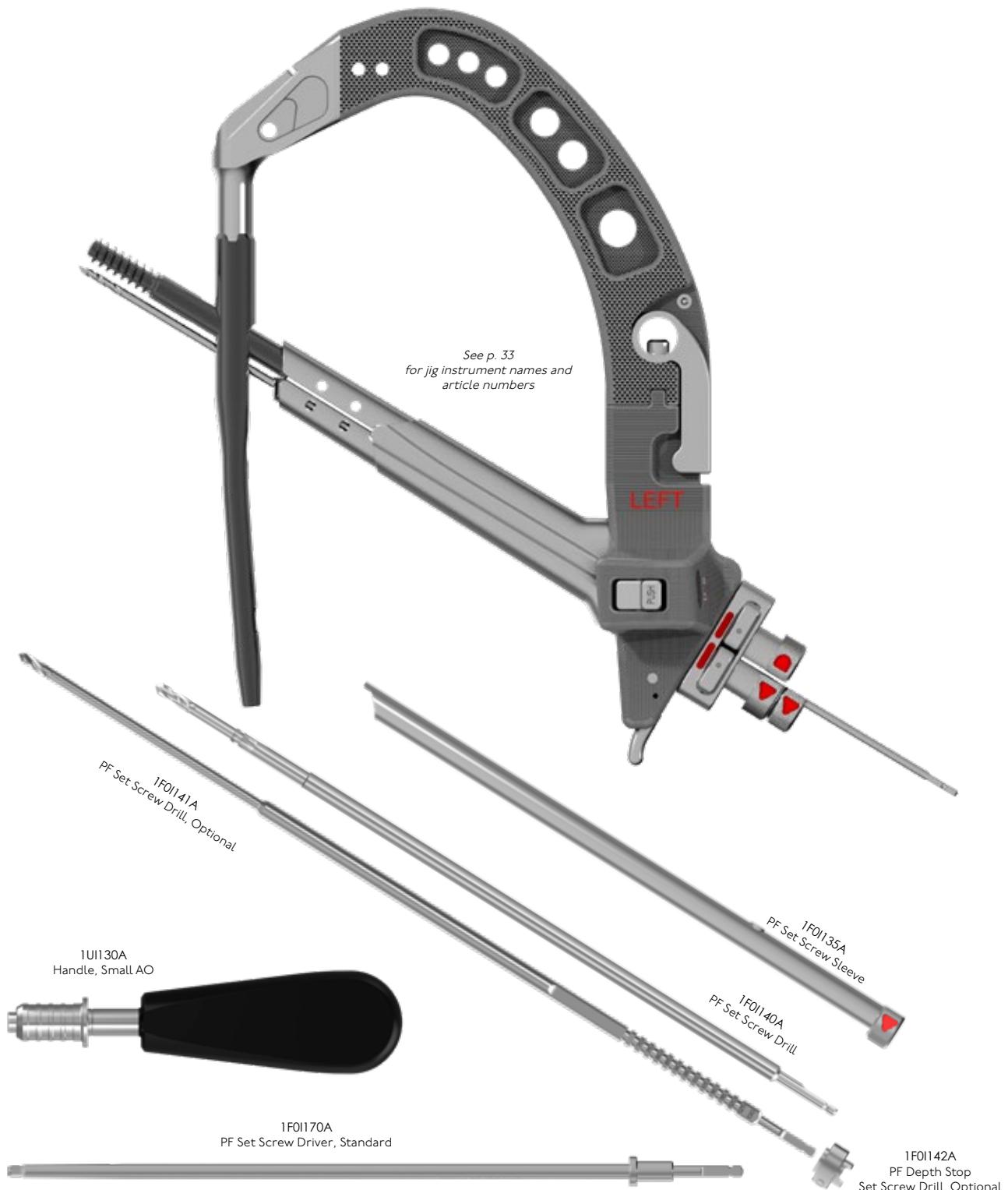
- Controlled Dynamization:
DyCon® Set Screw Drilling & Insertion - **P. 48**
- Closure of a Fracture Gap - **P. 63**
- Closure of a Fracture Gap with the L-Tool - **P. 64**
- Advanced Compression - **P. 68**
- Advanced Compression with the L-Tool - **P. 70**

SYNERGETIC



- Controlled Dynamization:
DyCon® Set Screw Drilling & Insertion - **P. 48**
- Implantation of the Axial Set Screw - **P.51**
- Closure of a Fracture Gap - **P. 63**
- Closure of a Fracture Gap with the L-Tool - **P. 64**
- Advanced Compression - **P. 68**
- Advanced Compression with the L-Tool - **P. 70**

○ Controlled Dynamization: DyCon® Set Screw Drilling & Insertion



IMPORTANT: The standard technique describes the recommended dynamization of 5mm built in on the DyCon® Set Screwdriver (*PF Set Screw Driver, Standard with Handle, Small AO*).

IMPORTANT: Insertion and setting of the controlled dynamization do not differ for the long and short versions of the DyCon® Set Screw.

DyCon® Set Screw Drilling:

- The inferior drill-wire and inferior K-wire sleeve are removed and replaced by the Set Screw Sleeve (*PF Set Screw Sleeve*).
- The length of the DyCon® Set Screw is selected corresponding to the Lag Screw inserted.

IMPORTANT: The long DyCon® Set Screw must be double-checked against the documentation or the packaging information for the inserted Lag Screw.

TIP: As an alternative to the rotation-locking standard DyCon® Set Screw, a short DyCon® Set Screw can also be selected (same design for all lengths of the Lag Screws).

- The Set Screw Drill (*PF Set Screw Drill*) is inserted through the set screw sleeve and used to drill until the stop is engaged.

TIP: Complete drilling can be checked using the image intensifier, upon which the indicator groove of the set screw drill should reach the lateral surface of the nail.



CAUTION: When using the DyCon® Set Screw, no instrument other than the L-tool must remain in or be inserted into the set screw sleeve.



DyCon® Set Screw Insertion:

- The selected DyCon® Set Screw is picked up with the standard DyCon® Set Screwdriver (*PF Set Screw Driver, Standard with Handle, Small AO*) and inserted through the set screw sleeve, coming to rest in the groove provided by the Lag Screw.

TIP: The DyCon® Set Screw is first guided through the lateral femoral cortex with a slight twisting motion and then through the nail until the thread in the rear part of the DyCon® Set Screw engages with the corresponding thread in the nail.

IMPORTANT: When the DyCon® Set Screw reaches the predetermined depth, corresponding to 5mm dynamization, it is automatically pushed off the screwdriver.



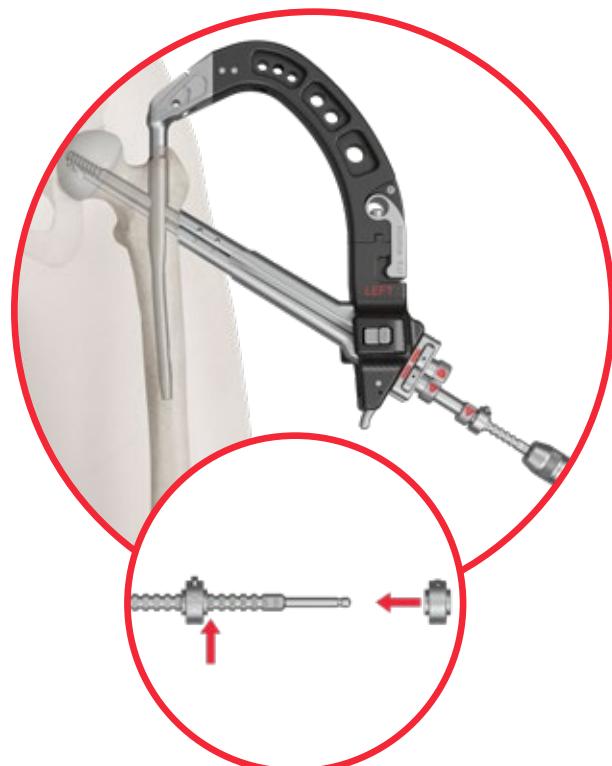
TIP: If preferred, the dynamization distance can also be freely selected according to surgeon preference, see p. 66

TIP: If additional compression of the fracture is needed, see p. 68

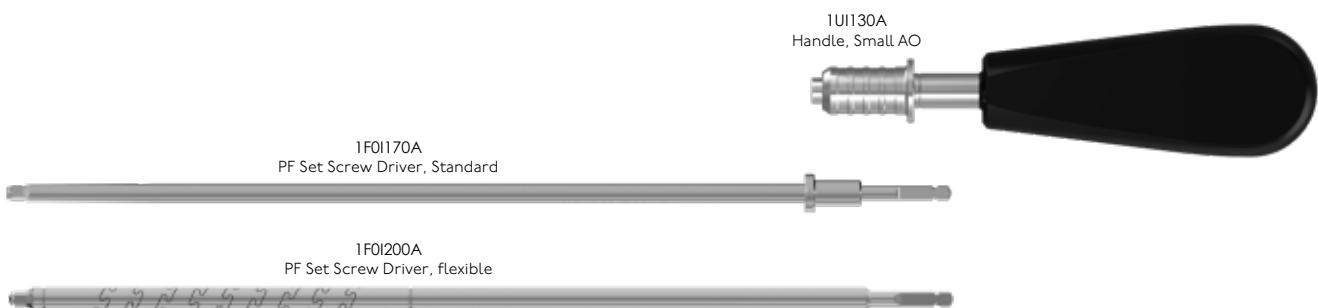
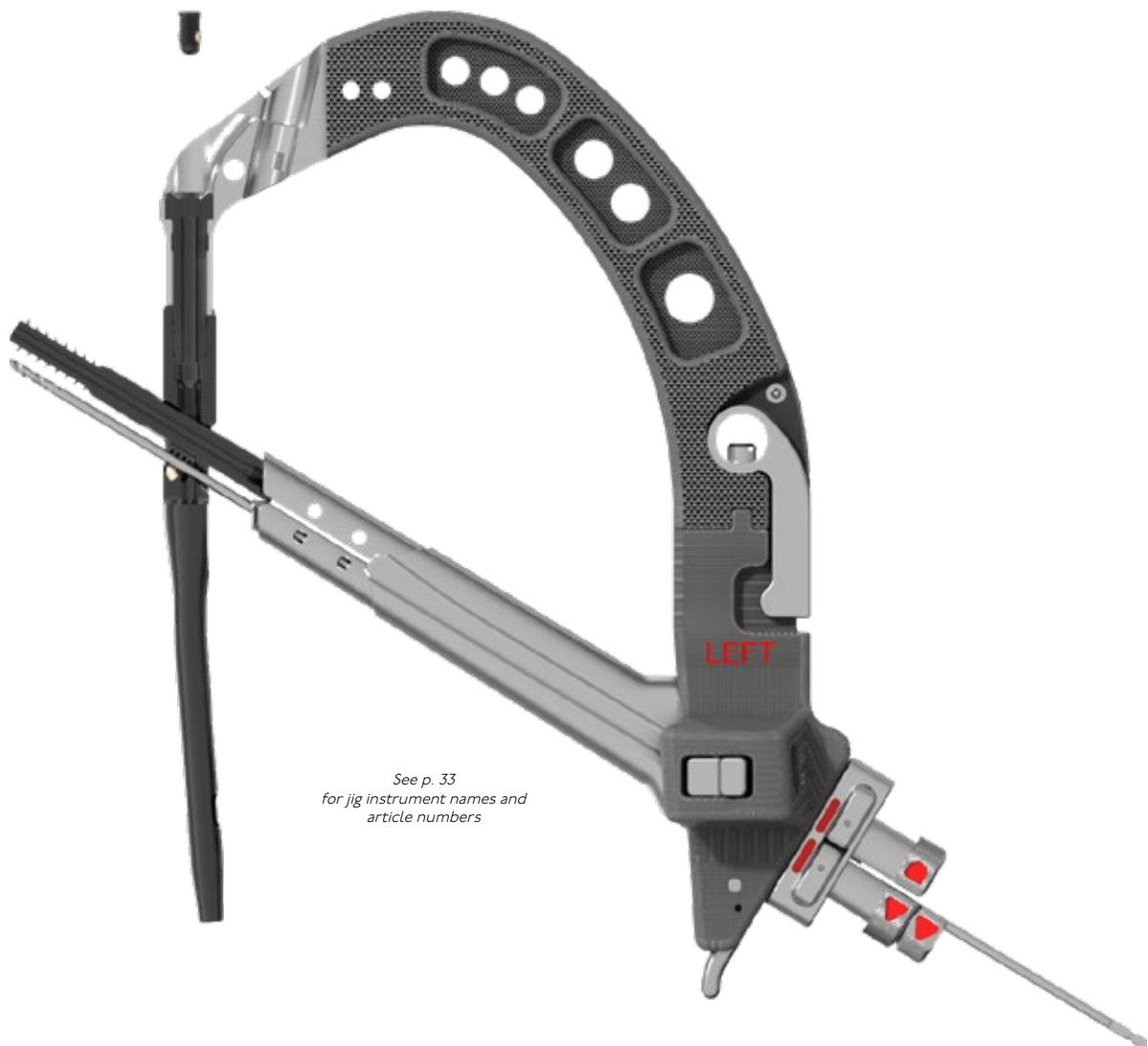
TIP: In cases of good bone quality and/or a close proximity to the Adam's arch the path of the set screw can be cleared out by a drill (*PF Set Screw Drill, optional*) with a corresponding depth stop (*PF Depth Stop Set Screw Drill, optional*).

Furthermore a possible distraction of the head/neck fragment can be avoided.

The drill depth must be chosen in accordance to the Lag Screw length.



Implantation of the Axial Set Screw



Implantation of the Axial Set Screw:

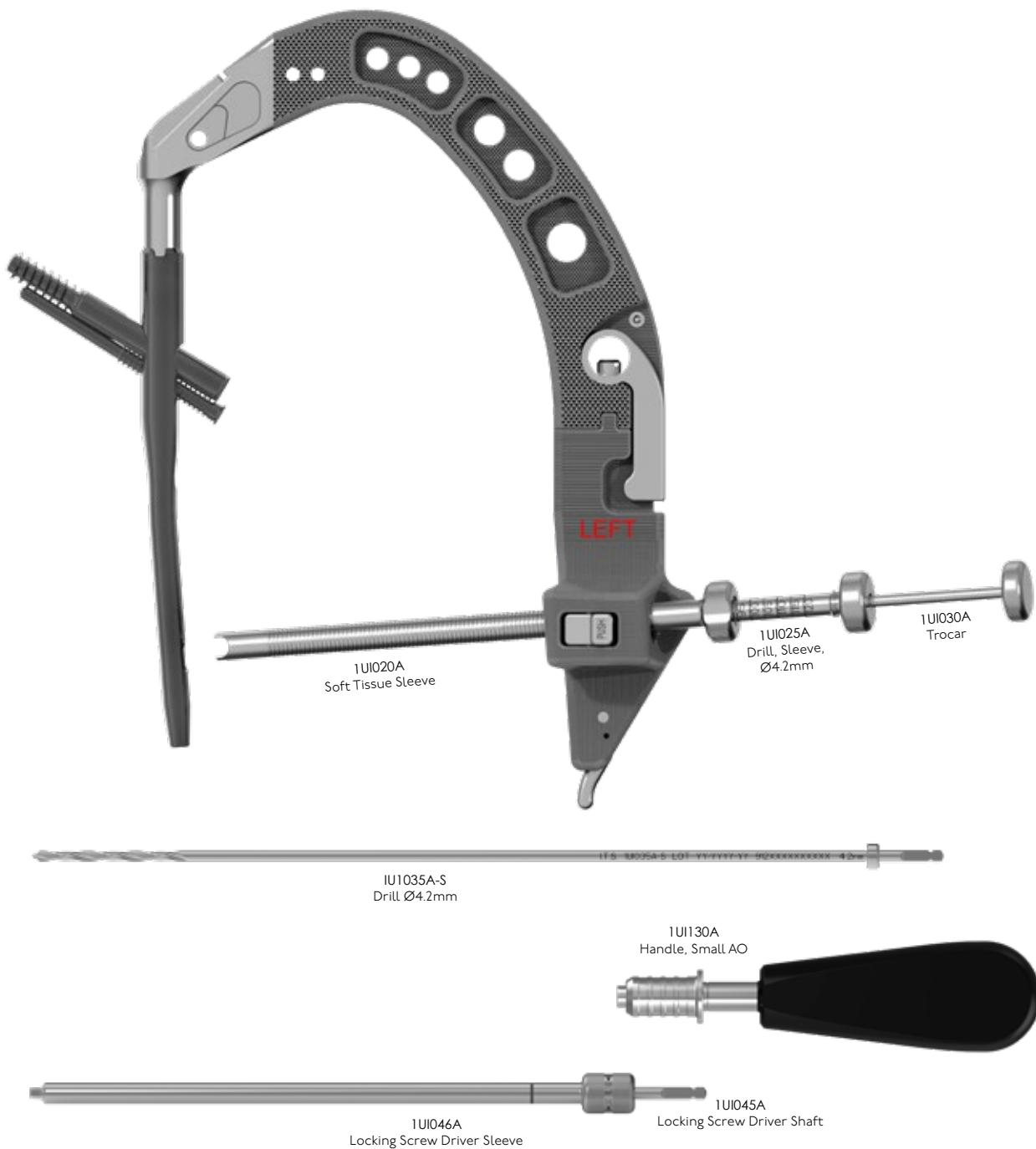
- The Nail Holding Bolt is inserted through the nail holding screw using the screwdriver (*PF Set Screw Driver, flexible*) or (*PF Set Screw Driver, Standard*).
- The Axial Set Screw is screwed in until the distal tip engages in the corresponding groove and is tightened to contact..

TIP: For a stable static locking of the screw, the DyCon® Set Screw must be additionally inserted in static mode.

IMPORTANT: The Axial Set Screw must rest in the groove of the Lag Screw and must not be backed out.



○ Guided Distal Locking



Distal locking is performed identically for the short (*PF Nail, short*) and intermediate (*PF Nail, intermediate*) nail via the holes located on the Targeting Module PF with the alternatives of an superior/cranial and thus static or inferior/caudal and thus dynamic screw position.

The freehand distal locking procedure for the long nails is described separately - see p. 76

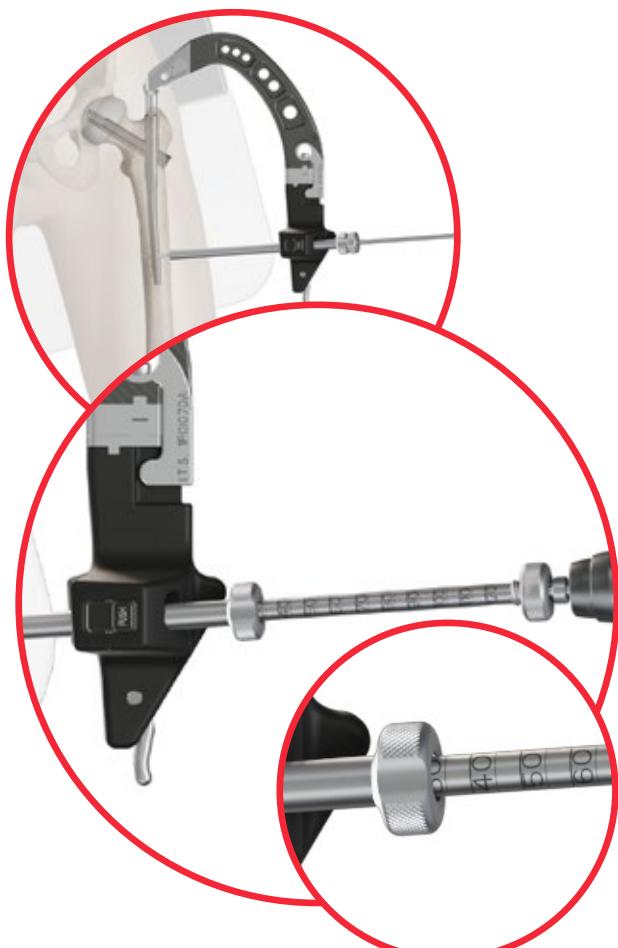
- The sleeve package for the distal 5mm locking screw is assembled (Soft Tissue Sleeve, Drill Sleeve, Ø4.2mm and Trocar).
- A separate stab incision is performed of the skin and fascia down to the bone.
- The sleeve package is then inserted through the selected static or dynamic position in the targeting module, and advanced through the soft tissue incision to the bone. The position is secured using an automatic ratchet mechanism.

IMPORTANT: To ensure correct measurement, make sure the sleeve package is seated close against the lateral cortex, causing the trocar to "pop off" the end of the drill sleeve.



- After removing the trocar, the calibrated drill (Drill, Ø4.2mm) for the 5mm locking screws (Locking Screw Ø5mm) is first predrilled through the lateral cortex of the nail and the medullary canal to the easily felt medial inner cortex.
- In this position, the drill sleeve is unlocked from the soft tissue protection sleeve and pulled back to the stop on the 4.2mm drill bit.
- The length of the screw up to the inner medial cortex can be read on the drill sleeve and then the necessary screw length calculated with an addition for the medial cortex.

IMPORTANT: For osteoporotic bone, an addition of 5mm may be sufficient. If the cortex is strong, a 7.5 or 10mm longer screw should be selected.



- Next, the medial cortex is overdrilled. The drill is then removed with the drill sleeve.

ALTERNATIVE: The Screw Gauge (Screw Gauge) can be used through the soft tissue sleeve after the drilling of both the lateral and medial cortices has been completed.

- The screwdriver shaft and sleeve are assembled (Locking Screw Driver Shaft and Locking Screw Driver Sleeve).
- The selected self-tapping locking screw is then picked using the Locking Screwdriver and screwed in.

TIP: In the case of strong cortical bone with a high insertion resistance, this process can be performed with the image intensifier, whereby the approach of the screw head in the final position to the lateral cortex can be easily observed via a recess in the soft tissue sleeve and a mark on the screwdriver.



- Once the screw reaches the final position, the screwdriver is released by turning the screwdriver sleeve in the “RELEASE” direction marked on the sleeve.



● Disassembly of Targeting Arm

- Once the DyCon® Screw pair and/or the Axial Set Screw has been placed as well as the distal locking screw, the Targeting Arm can be disassembled from the nail by removing any remaining sleeves and then unscrewing the Nail Holding Bolt.
- The final step is to decide whether an End Cap should be placed in the nail after removal of the Targeting Arm. For the placement of an optional End Cap - see p. 72.

● Rotation Control and Image Intensifier Documentation

- The rotation of the leg is 12° when the aiming sleeve for the distal locking is in line with the plane of the femoral condyles and the Lag Screw is in the center of the femoral head.

TIP: The position of the femoral condyles can be verified with the image intensifier and is ideally parallel to the floor at the beginning of surgery. The final clinical visual check can then be limited to establishing the parallel position of the drill sleeve inserted in the insertion handle (as an indicator for distal locking) in relation to the floor.

IMPORTANT: Before performing the final image intensifier check, all soft tissue protection sleeves, the master sleeve and the modular insertion handle portion are first removed.

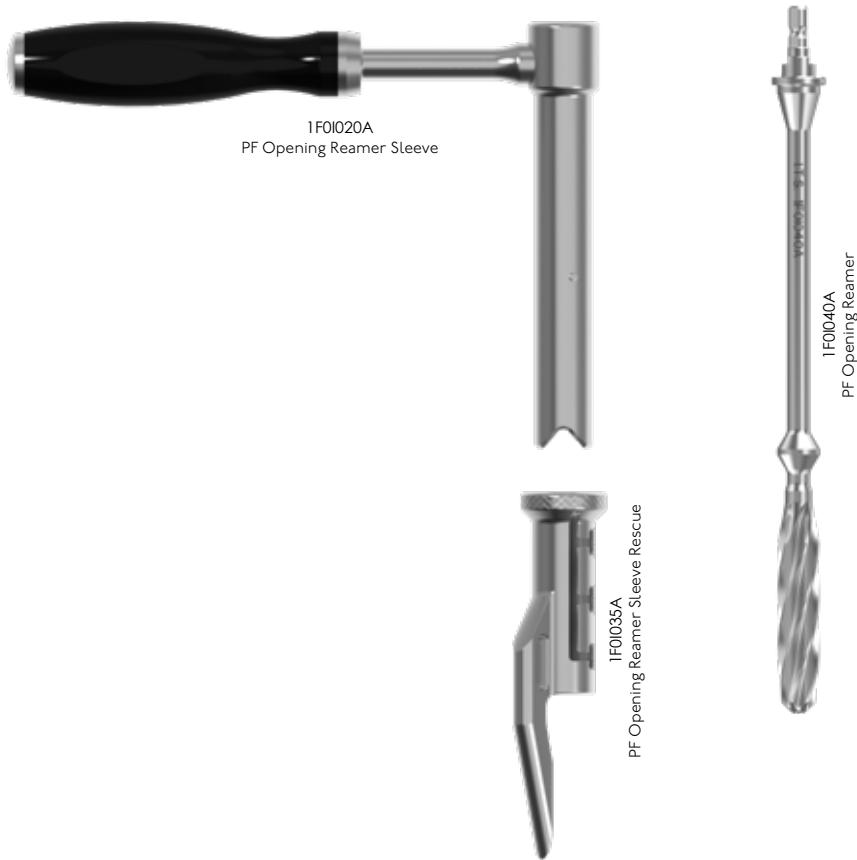
- The hip joint and the proximal femur with the full nail are adjusted in the a/p projections.
- The image intensifier is then rotated into the lateral projection of the femoral neck and the positions of the Lag Screw in the femoral head and the distal locking screw are checked.

IMPORTANT: The reduction, implant position and screw lengths are verified, with final documentation via paper printouts or integration into the hospital electronic documentation system.

● Wound Closure & Follow-up

- Wound closure is performed in the conventional manner in layers at the surgeon's discretion with or without suction drains.
- The postoperative weight-bearing capacity should be adapted to the fracture situation, where, especially for elderly patients, a full load bearing with walking aids is to be aimed for.
- With sufficient intraoperative image intensifier controls with corresponding documentation, standardized X-ray images in two planes should be performed before inpatient discharge, as well as at follow-up after 4-6 weeks and with documentation of fracture healing after 3-6 months.

OPTIONAL: Correction of Trochanteric Entry Point



If there is a deviation of the drilled trochanteric entry point, the hole can be repositioned using the rescue sleeve (*PF Opening Reamer Sleeve Rescue*).

The rescue sleeve allows for the opening to be adjusted either laterally or medially to three separate distances.

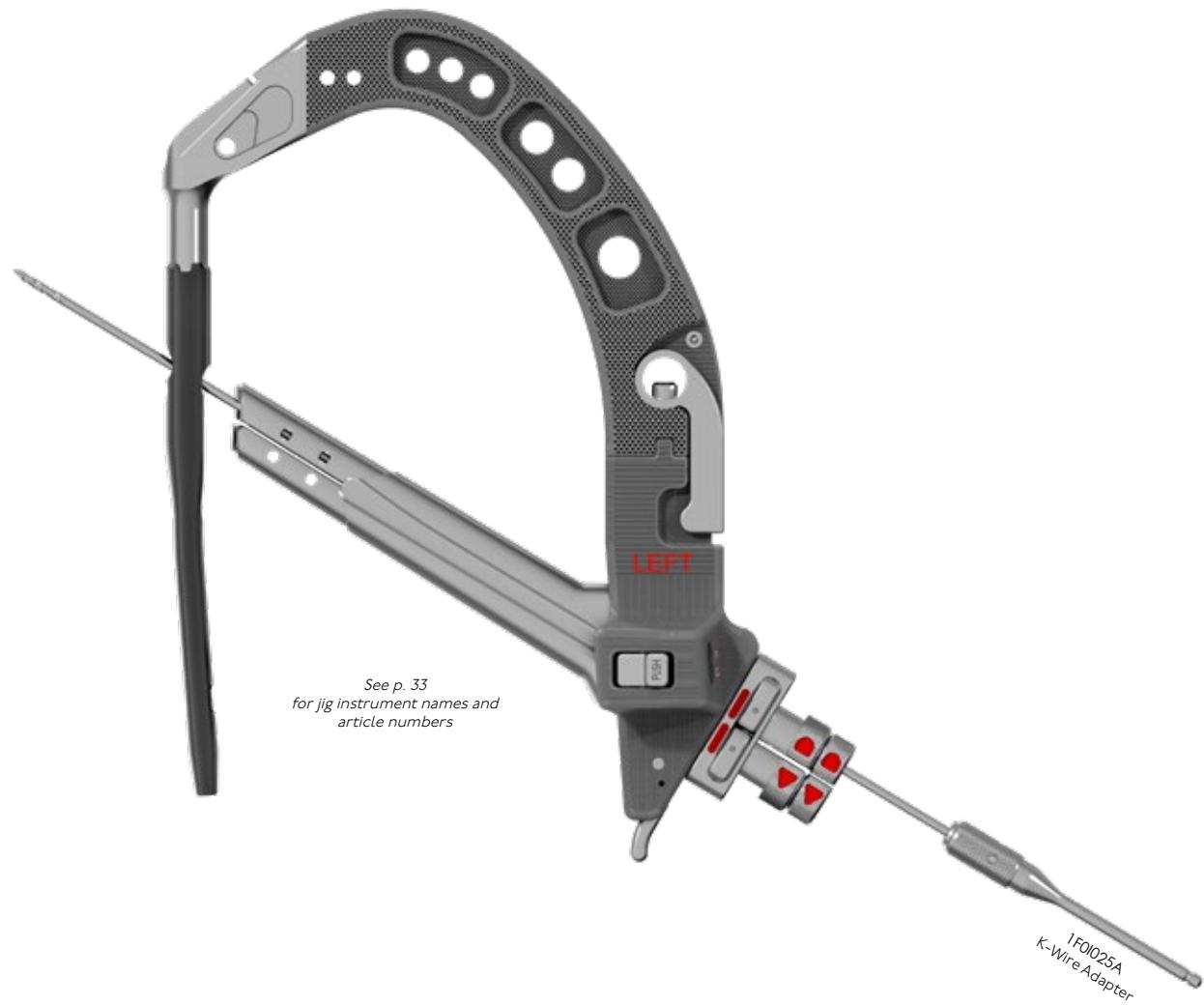
- The opening drill-wire, the multihole trocar and the opening reamer sleeve are removed.
- The rescue sleeve is assembled onto the opening reamer sleeve and one of the three possible adjustment distances (5mm, 10mm, 15mm) is selected.

- The opening reamer sleeve is reintroduced to the intramedullary canal such that the rescue sleeve protrudes into the medial side for a lateralization of the entry point and the lateral side for a medialization.
- The medullary canal opening is then re-drilled through the opening reamer sleeve using the opening reamer.



● OPTIONAL: Correction of Lag Screw Drill-Wire

OPTIONAL:
Correction of Lag Screw Drill-Wire

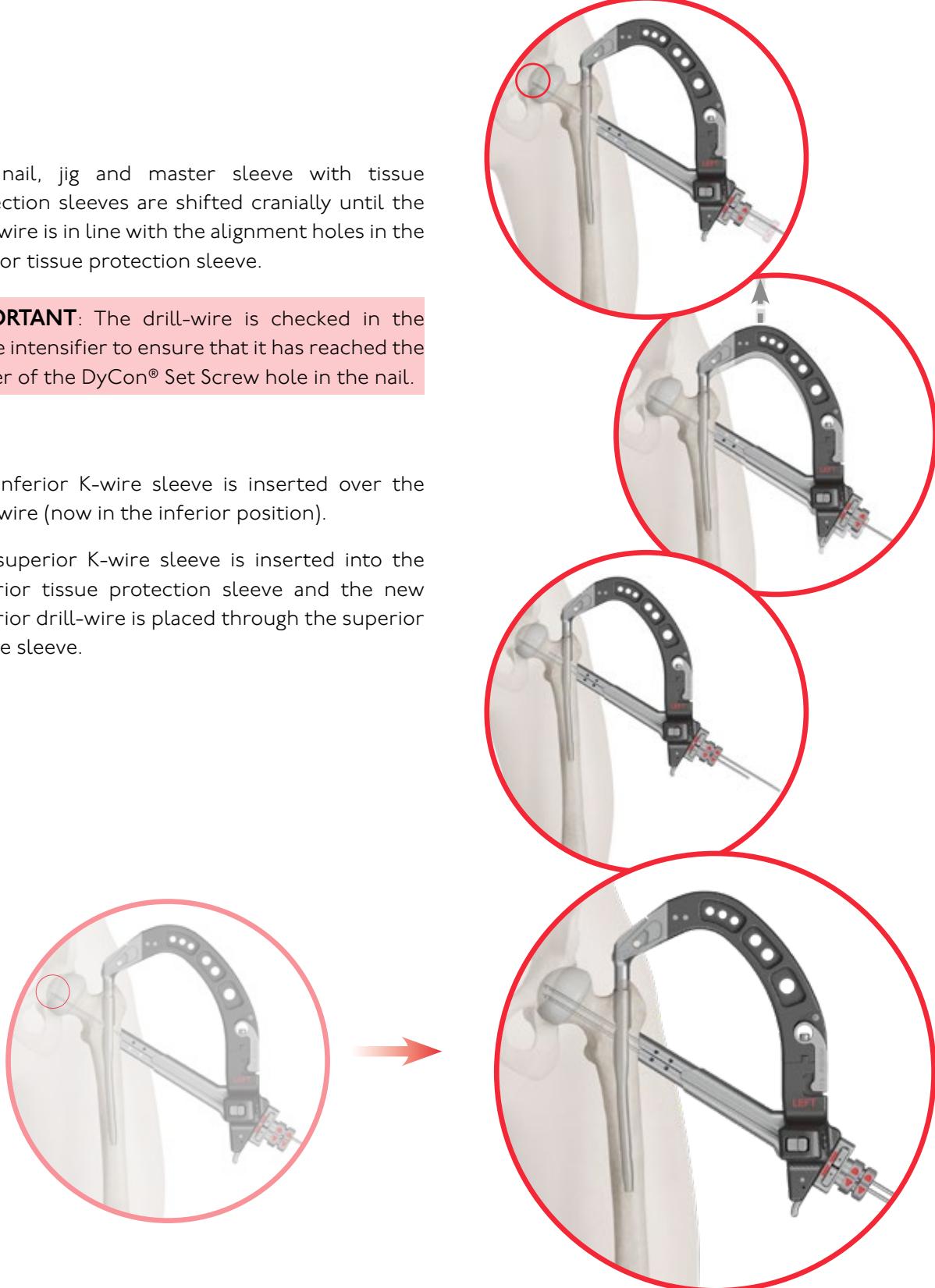


If a deviation of the superior drill-wire cranially or caudally is detected during the a/p image intensifier check, it is, thanks to the parallel trajectories of the two drill-wires, possible to adjust the drill-wire positioning, while retaining the correct central position in the lateral projection.

With the application of these described positioning steps, the superior drill-wire, which is decisive for the subsequent position of the Lag Screw, can be corrected by 8.5mm both caudally and cranially.

Correction to a superior position:

- Both K-wire sleeves are removed.



IMPORTANT: The drill-wire is checked in the image intensifier to ensure that it has reached the center of the DyCon® Set Screw hole in the nail.

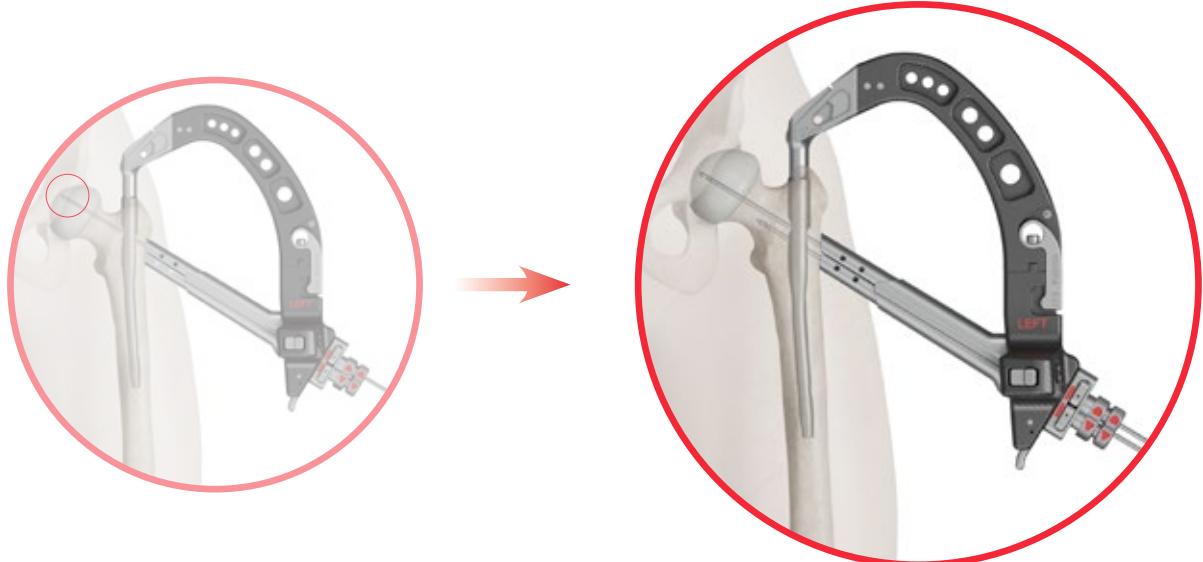
- The inferior K-wire sleeve is inserted over the drill-wire (now in the inferior position).
- The superior K-wire sleeve is inserted into the superior tissue protection sleeve and the new superior drill-wire is placed through the superior K-wire sleeve.

Correction to an inferior position:

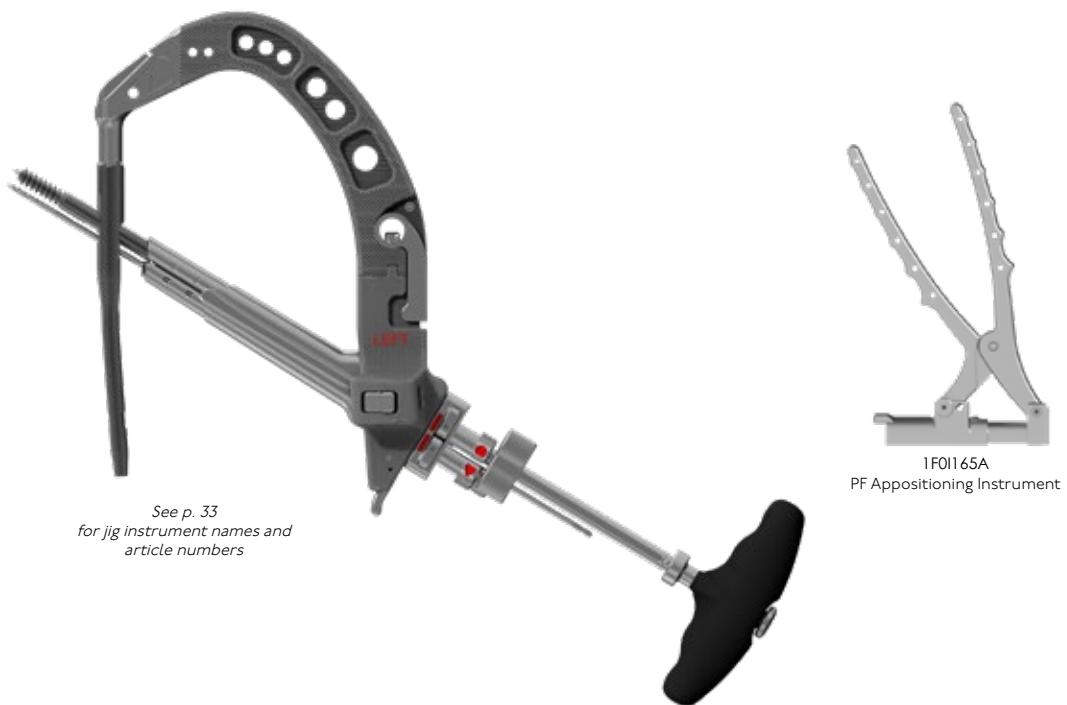
- A second drill-wire is placed through the inferior K-wire sleeve, becoming the central drill-wire for the Lag Screw.
- The superior drill-wire and both K-wire sleeves are removed.
- The nail, jig and master sleeve with tissue protection sleeves are shifted caudally until the remaining drill-wire is in line with the alignment holes in the superior tissue protection sleeve.

IMPORTANT: The drill-wire is checked with the image intensifier to ensure that it has reached the center of the Lag Screw hole in the nail.

- The superior K-wire sleeve is inserted over the corrected drill-wire (now in the superior position).
- The inferior K-wire sleeve is then inserted into the inferior tissue protection sleeve and the inferior drill-wire is placed through the inferior K-wire sleeve.



● OPTIONAL: Closure of a Fracture Gap



If closing of a fracture after insertion of the Lag Screw is desired, force can be applied between the tissue protection sleeve and the screwdriver by means of the appositioning instrument (PF Appositioning Instrument).

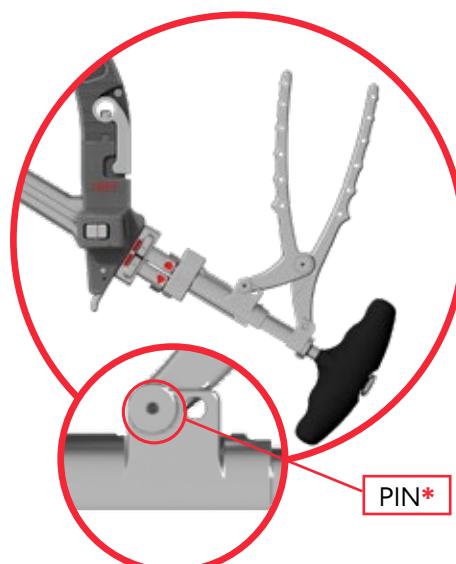
- The appositioning instrument (*PF Appositioning instrument*) is placed on the shaft of the screwdriver in such a way that the handles are directed cranially and are medially inclined. This creates a form-fitting connection with the screwdriver and Lag Screw.

TIP: The pin in the middle position represents the calibrated final position of the Lag Screw. If the Lag Screw is screwed in more or less than the indicated line, the appositioning instrument can be adjusted by moving the pin* to one of the external holes.

- Pressure is applied to the handle of the appositioning instrument, forcing the ends apart and thus closing the fracture gap.

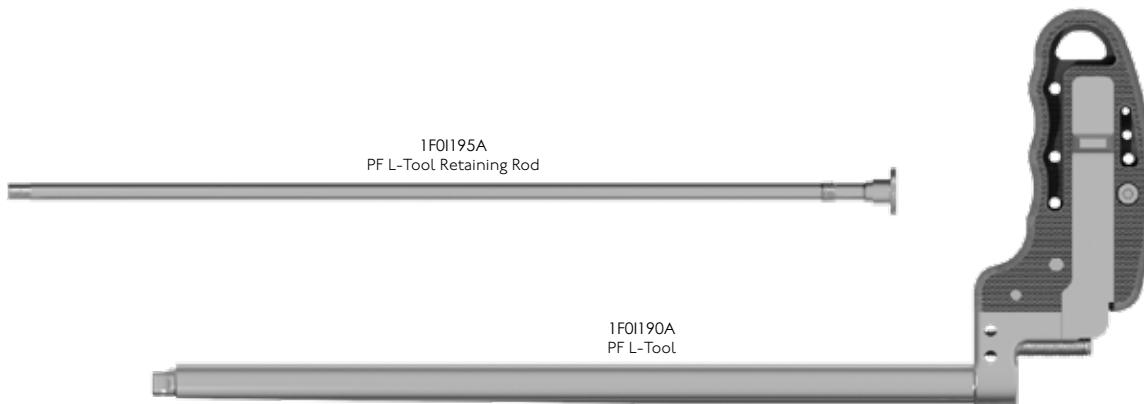
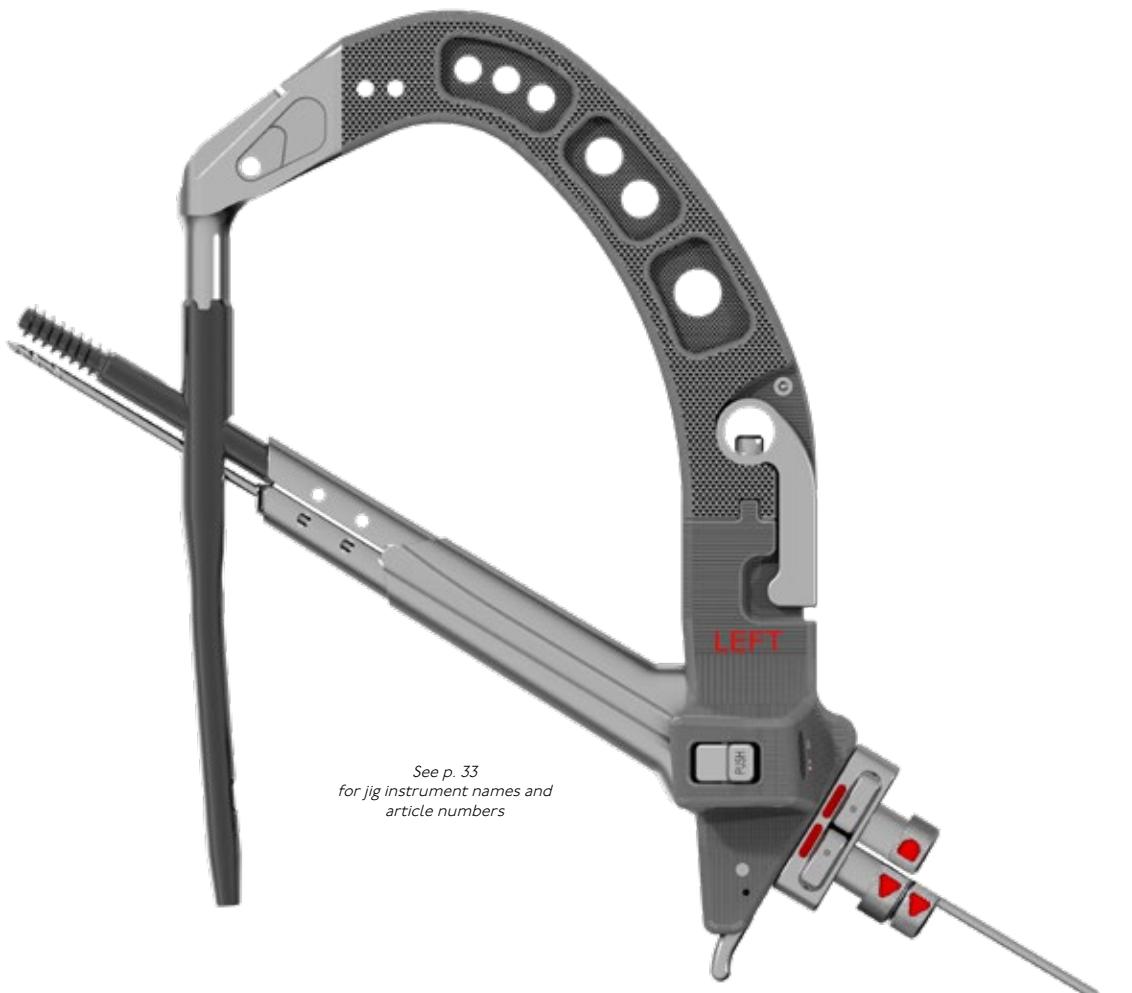
IMPORTANT: This step is usually performed with caution under image intensifier control.

TIP: If sufficient closure cannot be reached, the traction settings should be reduced.



● **OPTIONAL:**
Closure of a Fracture Gap with the L-Tool

OPTIONAL: Closure of a Fracture
Gap with the L-Tool



To close the fracture gap after implantation of the Lag Screw, controlled appositioning can be achieved by a distraction of the L-Tool vs. the Superior Soft Tissue Sleeve.

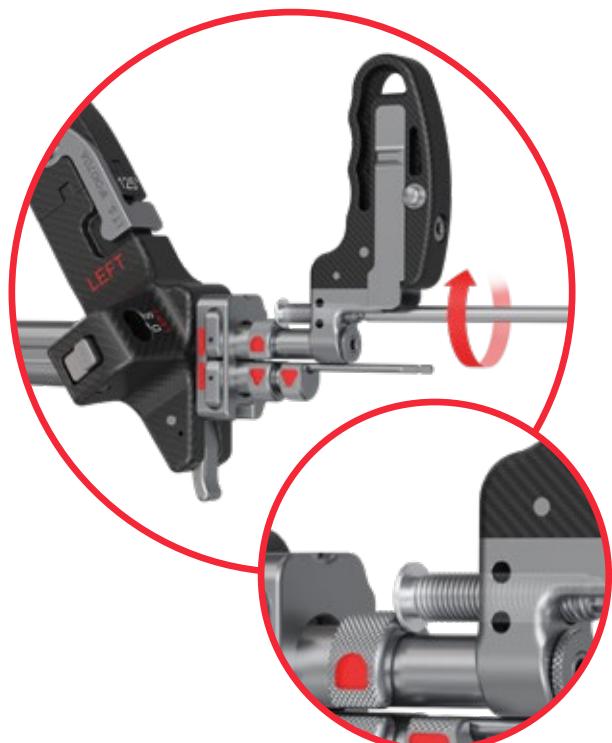
- After the Lag Screw has been correctly positioned, the holding rod (*PFL-Tool Holding rod*) is screwed into the L-Tool (*PF L-Tool*). The L-Tool is then introduced through the superior tissue protection sleeve and connected to the Lag Screw using the holding rod.

IMPORTANT: Make sure that the L-Tool is aligned correctly and stable.

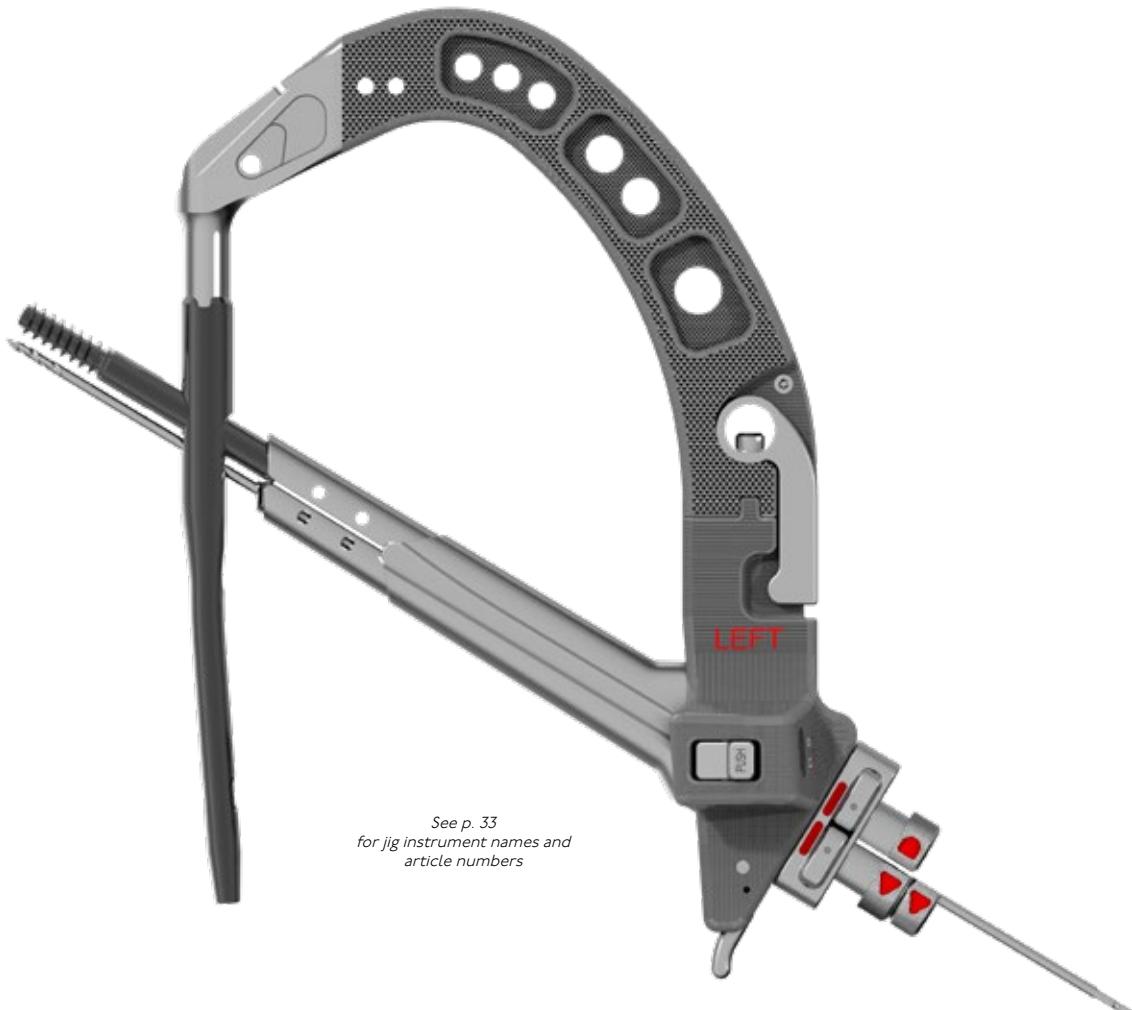


- The appositioning screw of the L-Tool is now screwed in with the screwdriver (*PF Screwdriver Set Screw, Optional*), causing the screw to press against the superior tissue protection sleeve and move the Lag Screw laterally, thereby closing the fracture gap.

IMPORTANT: This step is usually performed with caution under image intensifier control. Handle pointing in a cranial direction.



● **OPTIONAL:**
Free Selection of Dynamization Control

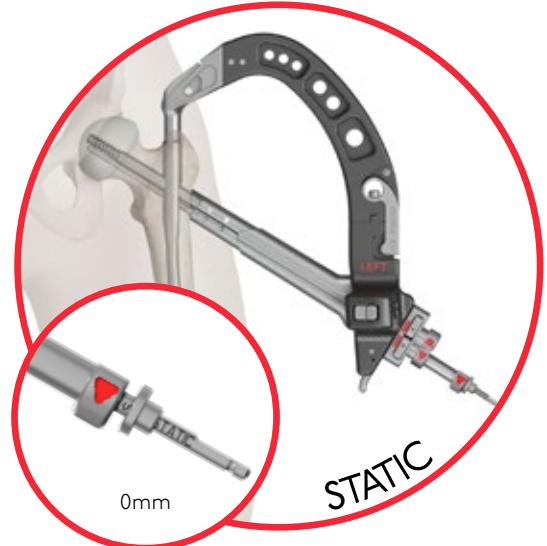
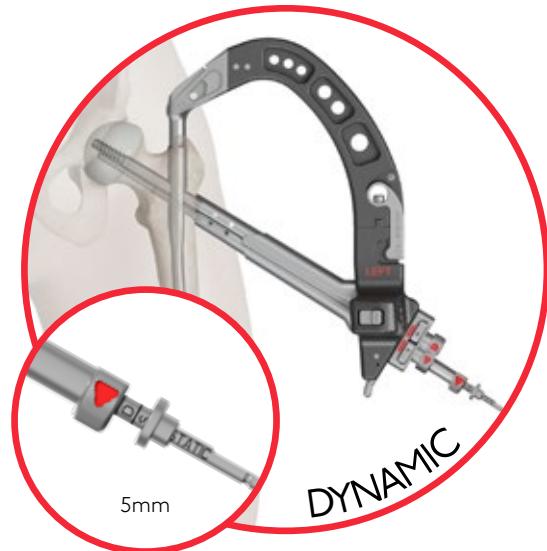
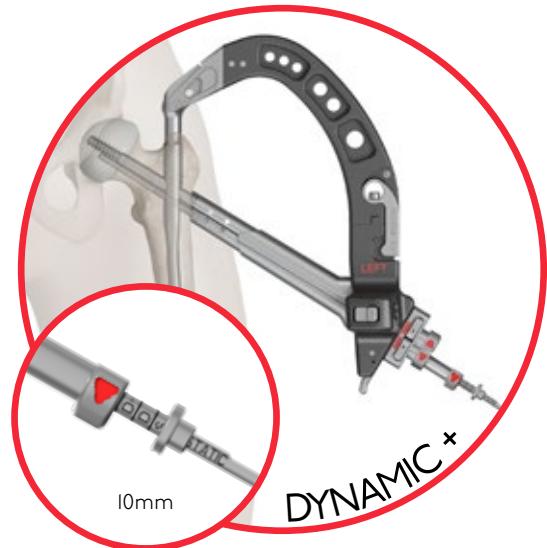


DyCon® Set Screw Insertion:

- For freely selectable dynamization, the selected DyCon® Set Screw is picked up with the optional DyCon® Set screwdriver (*PF Set Screw Driver, Optional with Handle, Small AO*) and inserted through the set screw sleeve, to the desired depth in the groove provided by the Lag Screw.

TIP: The DyCon® Set Screw is first guided through the lateral femoral cortex with a slight twisting motion and then through the nail until the thread in the rear part of the DyCon® Set Screw engages in the corresponding thread in the nail.

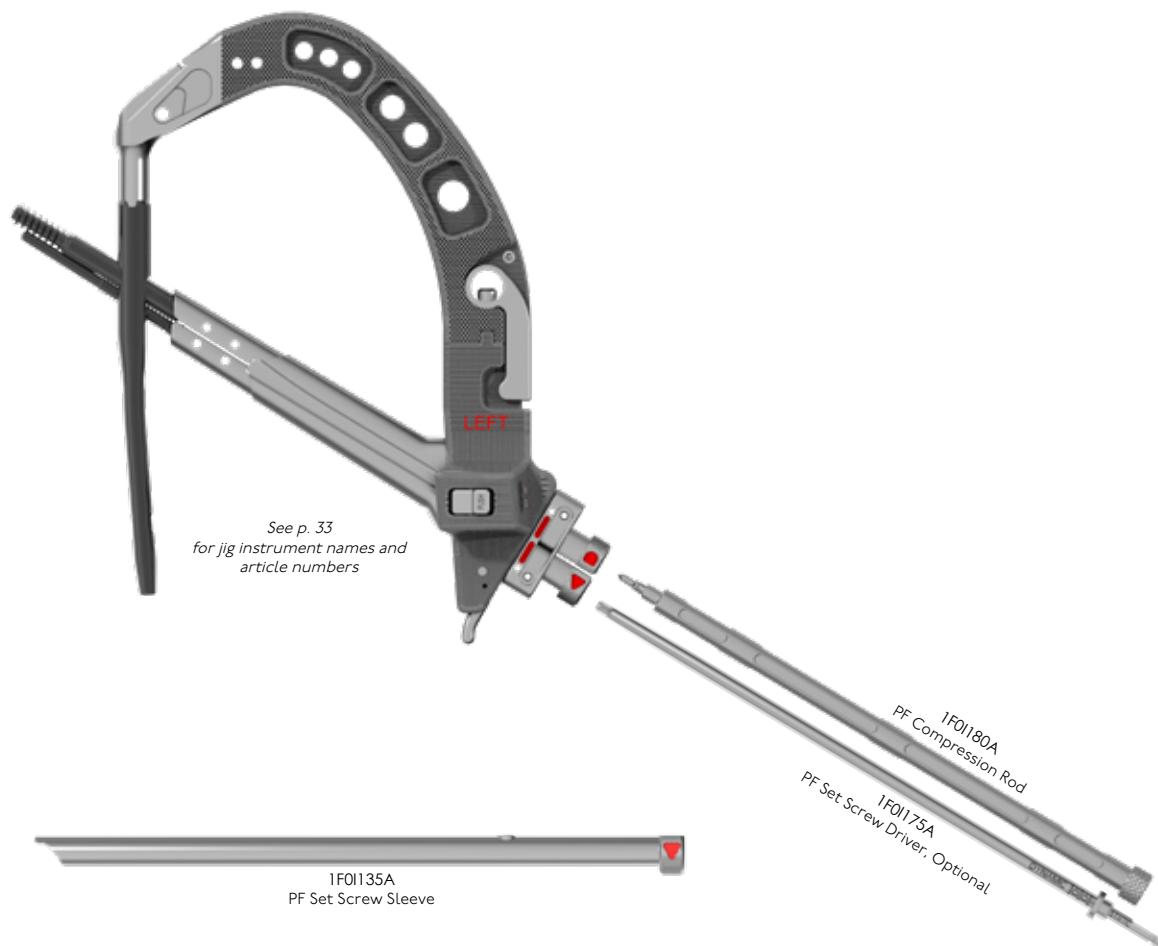
IMPORTANT: The depth to which the DyCon® Set Screw is screwed in determines the potential lateral dynamization distance for the Lag Screw. This is indicated by the laser markings on the screwdriver referenced against the set screw sleeve.



IMPORTANT: If inserted further than the markings the fracture may be distracted.

○ OPTIONAL: Advanced Compression

OPTIONAL:
Advanced Compression



The Compression Rod (PF Compression Rod) allows the DyCon® Screw pair to be pulled laterally by a slight unscrewing of the DyCon® Set Screw.

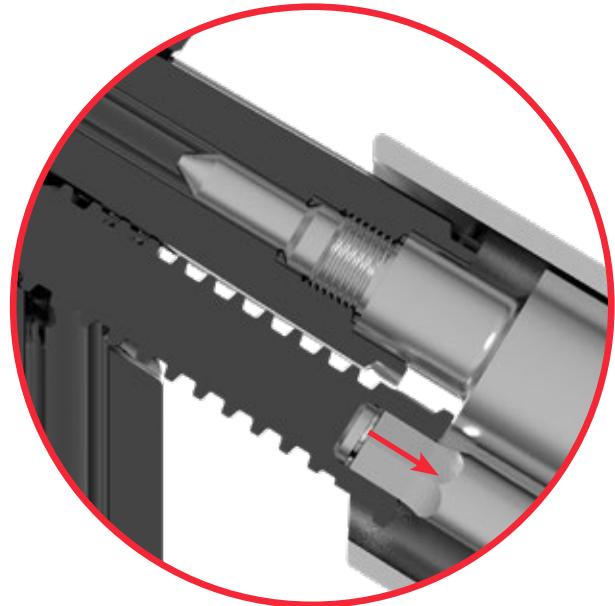
IMPORTANT: The Advanced Compression technique requires a selected dynamization mode of 5mm or less (Dynamic or Static modes). If a greater dynamization has been dialed in (Dynamic+), the DyCon® Set Screw must first be screwed further in to Dynamic Mode (indicated by the laser markings on the screwdriver opposite the set screw sleeve) in order to allow the Compression Rod to engage with the Lag Screw.

IMPORTANT: If the set screw sleeve was used to check the dynamic mode. It must be removed again.

- The compression rod is screwed into the Lag Screw.
- The optional DyCon® Set Screwdriver (*PF Set Screw Driver, Optional with Handle, Small AO*) is inserted into the set screw and turned anticlockwise to create compression.

IMPORTANT: Compression should be performed with caution under image intensifier control.

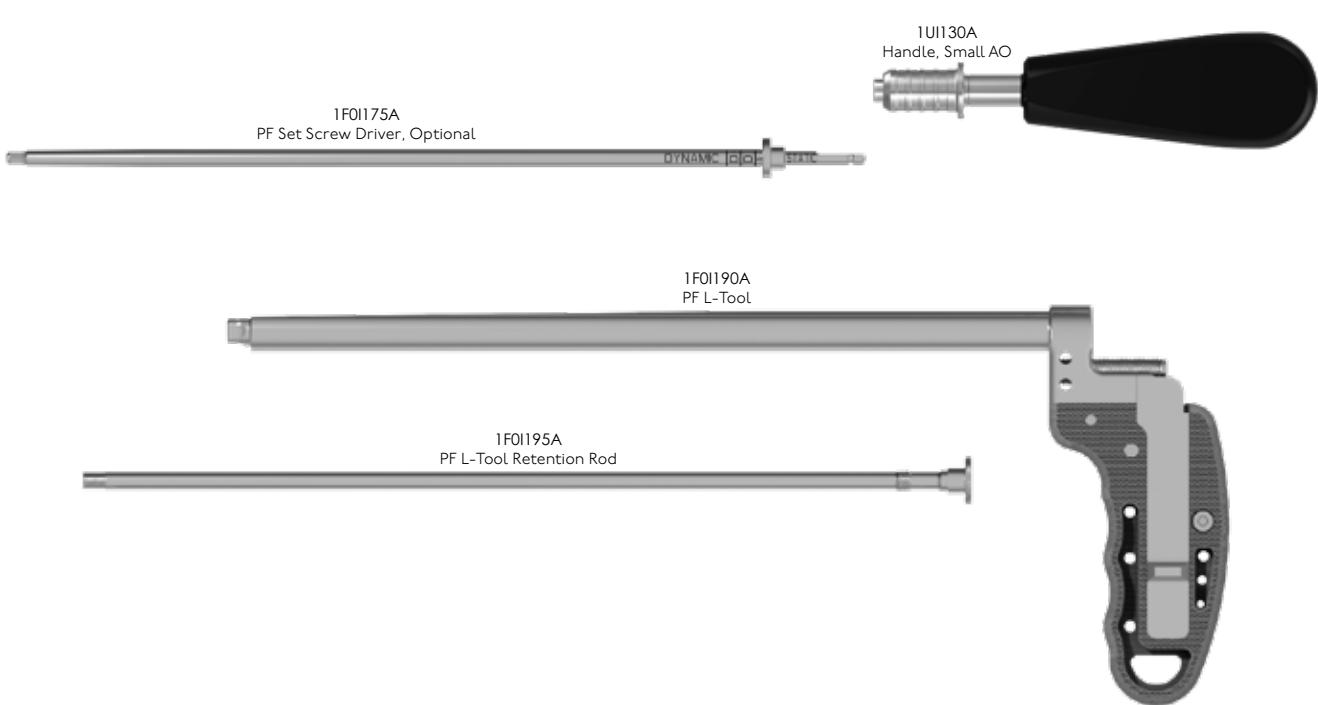
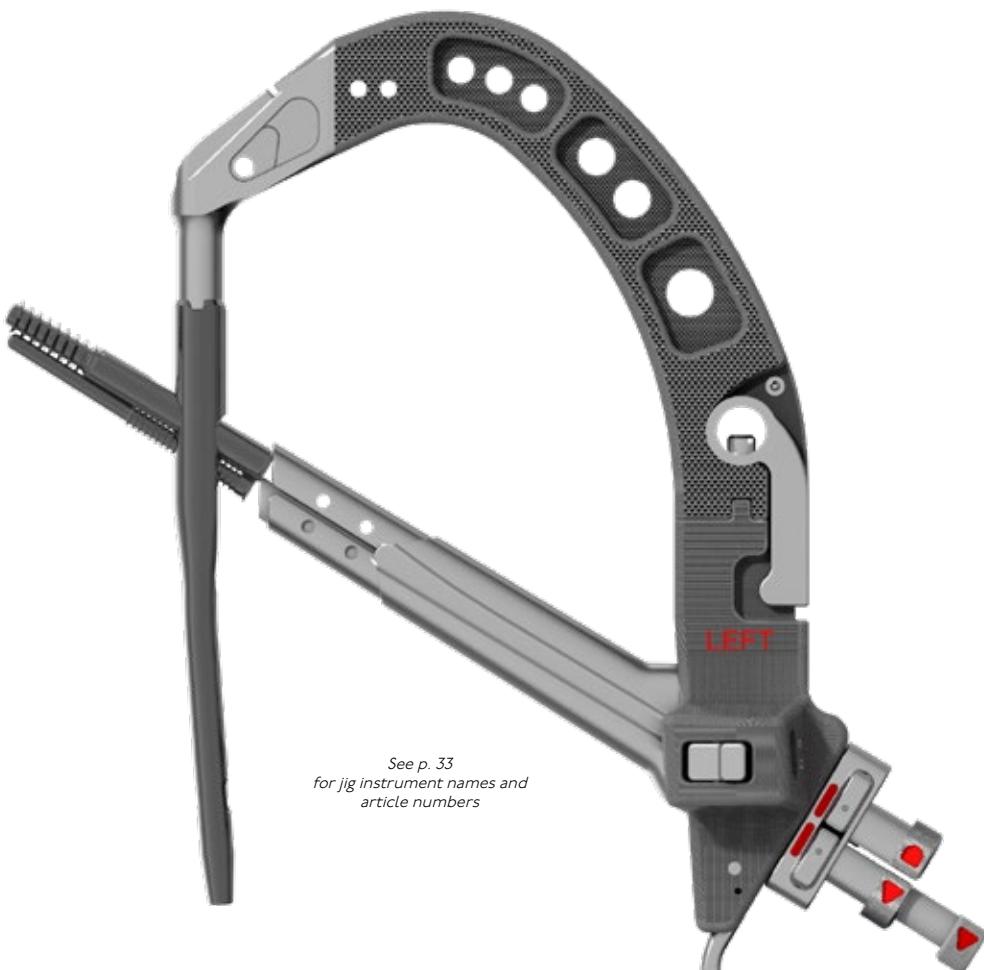
TIP: If the compression is to be additionally mechanically secured, an Axial Set Screw must be inserted - *see p. 50.*



- When the desired compression is achieved, the screwdriver and compression rod can be removed. The standard dynamisation of 5mm (Dynamic mode) is set.
- If a different dynamization mode is desired, the set screw sleeve is used in conjunction with the screwdriver. The orientation follows the laser marking - *see p. 67.*

● OPTIONAL: Advanced Compression with the L-Tool

OPTIONAL: Advanced Compression
with the L-Tool



To compress the fracture after the implantation of the DyCon® Screw pair, controlled compression can be applied using the L-Tool.

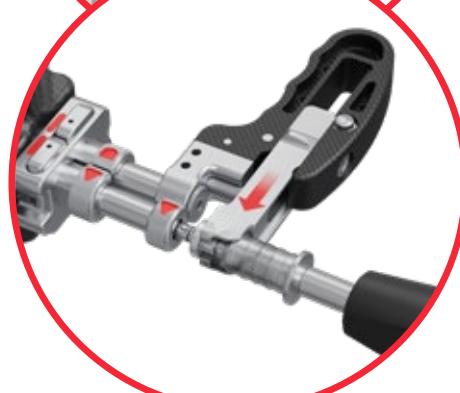
- After the DyCon® Screw pair has been correctly positioned, the holding rod (*PF L-Tool Retention Rod*) is screwed into the L-Tool (*PF L-Tool*). The L-Tool is then introduced through the superior tissue protection sleeve and fixed to the Lag Screw using the holding rod.

IMPORTANT: This step is usually performed with caution under image intensifier control. Handle pointing in a cranial direction.

- To enable compression, the optional screwdriver (*PF screwdriver set screw, optional with handle, small AO*) is introduced through the tissue protection sleeve up to the set screw. Then, the slider of the L-Tool is pushed towards the screwdriver.

- Subsequently, the fracture is compressed by turning the optional screwdriver counterclockwise.

TIP: If a mechanical block of the compression is desired an additional Axial Set Screw may be implanted. - see p. 51.



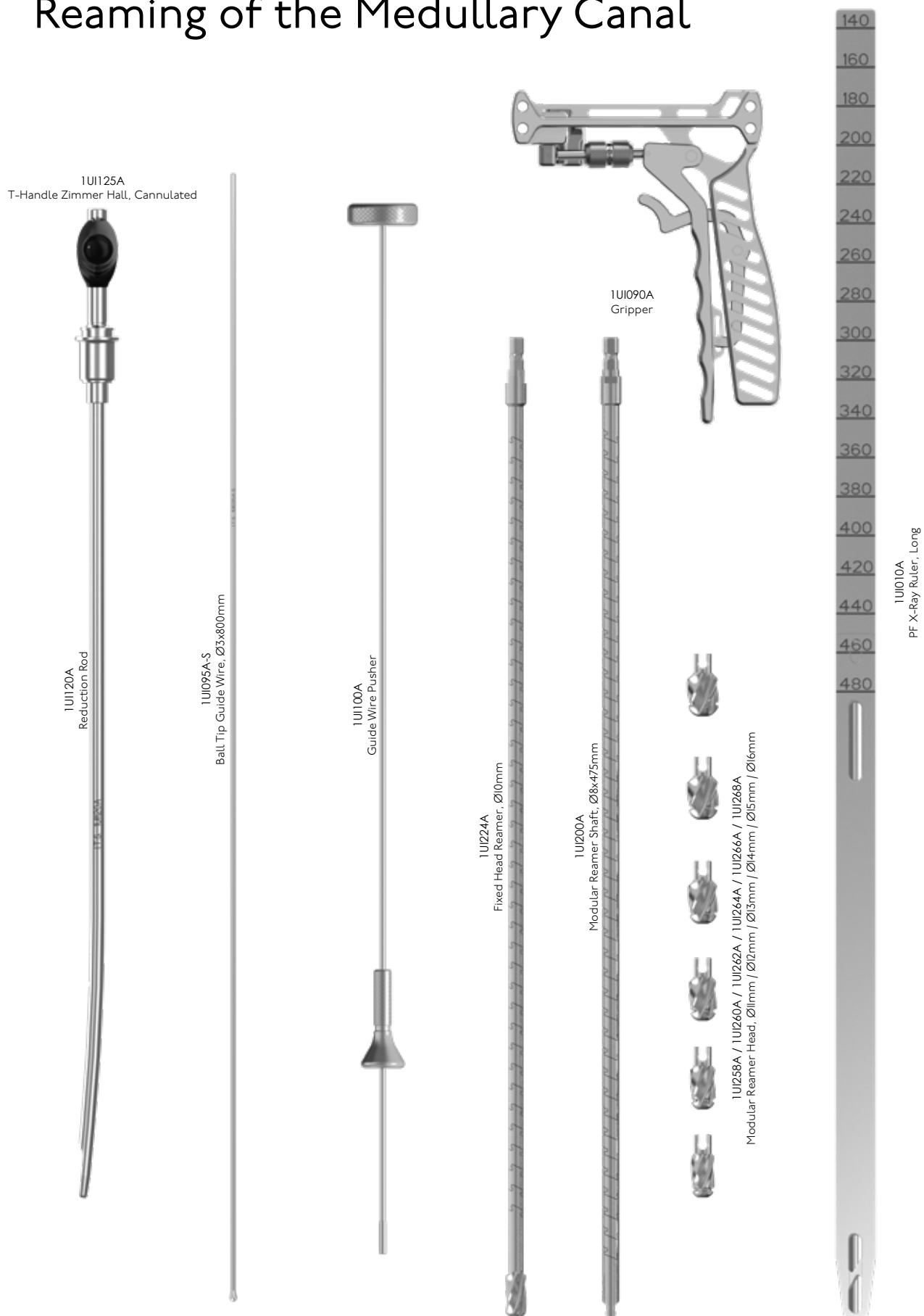
● OPTIONAL: End Cap Screws



IMPORTANT: In the majority of clinical situations, this surgical step is dispensable and can be saved in terms of time and material. Indications for End Caps exist if, for example, the thread is to be kept free of scar tissue for a planned implant removal, and/or an extension of the proximal nail end is desired.

- The End Cap Screws are available with a proximal extension of 0 to 20mm in 5mm increments.
- Secure the selected endcap to the ball-tip screwdriver (*PF Ball Tip Screwdriver, Self Retaining*) using the corresponding retaining rod (*PF Retaining Rod Ball Tip Screwdriver*).
- The End Cap is screwed in until it reaches the stop.

LONG NAILS: Reduction of the Shaft Fracture & Reaming of the Medullary Canal



LONG NAIL:
Reduction & Reaming

- The ball tip guide wire (*Ball Tip Guide Wire, Ø3x800mm*), which can be slightly bent at the end area. It is then inserted into the medullary canal using the wire holder (*Gripper*).
- The wire is inserted into the distal fragment under the control of the image intensifier.

TIP: A reduction instrument (*Reduction Rod*) can be inserted over the guide wire into the medullary canal, thus enabling manipulation to bring the fragments into a suitable position.

ALTERNATIVE: If the fractures are displaced and cannot be reduced on the fracture table, for example subtrochanteric fractures, a lateral position on a radiolucent table without traction can be used. In these cases, the reduction is carried out using an open technique with temporary fixation using reduction forceps. An additional fixation using wire cerclage has also proven successful. Nailing can then be carried out safely in the reduced and anatomically fixed position. In the case of shaft fractures, it is also possible to treat the patient in the lateral position.

- The medullary reaming wire is anchored precisely in the center of the cancellous bone in the distal femoral metaphysis.

IMPORTANT: The distal central placement of the medullary reaming wire is essential for the quality of the reduction by the nail itself with the alignment of the long axis of the femur.

- In this final position, the length measurement is checked by evaluating the protruding end of the ball tip guide wire with the guide wire ruler (*Guide Wire Ruler, Long*) as a subtraction measurement with direct length reading.



- Beginning with the front-cutting medullary reamer, reaming is carried out in 1mm and, if necessary, 0.5mm increments.

TIP: *3-step reaming guide*

Proximal: Opening Reamer

Isthmus: 2mm more than selected nail

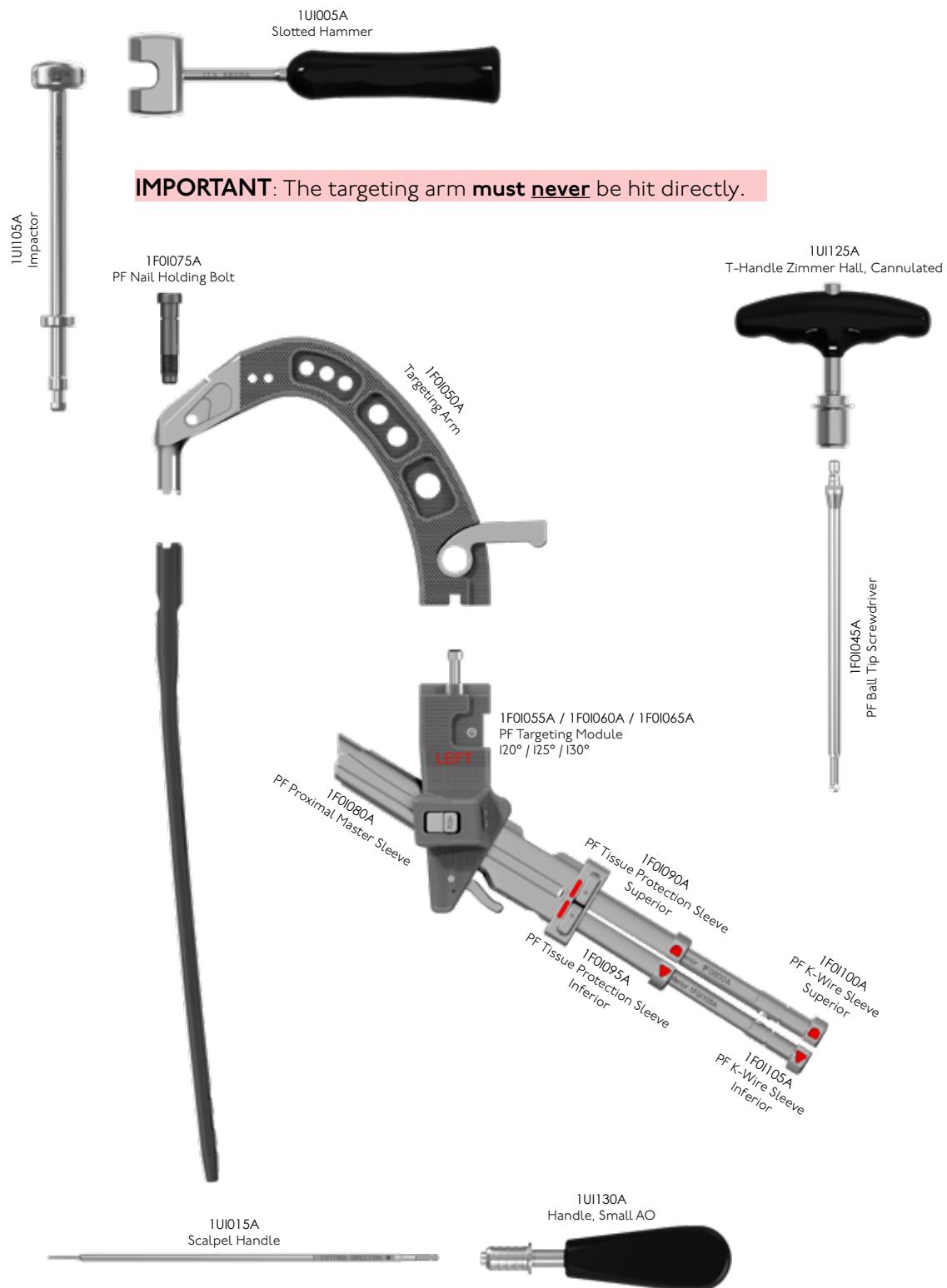
Distal: Same diameter as selected nail

IMPORTANT: If the medullary reamer comes into direct contact with the hard cortex in the isthmus, a 2mm larger reamer is then used to ensure safe passage of the intramedullary nail.

TIP: To ensure that the ball-tip guide wire remains in the correct position when the intramedullary reamer shafts are withdrawn, it should be held in position with the guide wire pusher (*Guide Wire Pusher*).

LONG NAILS:

Insertion of the Long Intramedullary Nail



- The long medullary nail is selected with regard to length, femoral neck angle and diameter.
- The nail is attached to the targeting arm by a ball-tip screwdriver (*Targeting Arm with Locking Lever, PF Nail Holding Bolt, PF Ball Tip Screwdriver incl. T-Handle Zimmer Hall Cannulated*).

IMPORTANT: The Targeting Module (*PF Targeting Module 120°, 125° or 130°*) must be double-checked for compatibility with the femoral neck angle of the mounted nail.

IMPORTANT: The Nail Holding Bolt (*PF Nail Holding Bolt*) securing the nail must be fully tightened to ensure that the nail does not loosen during insertion.

- The long intramedullary nail is inserted proximally over the ball-tip guide wire in such a way that the aiming arm is first turned anteriorly in order to use the antecurvature of the implant for passage through the entry route.
- When the isthmus is reached latest, the nail is turned back into the normal position, corresponding to a nearly horizontal position of the targeting arm.

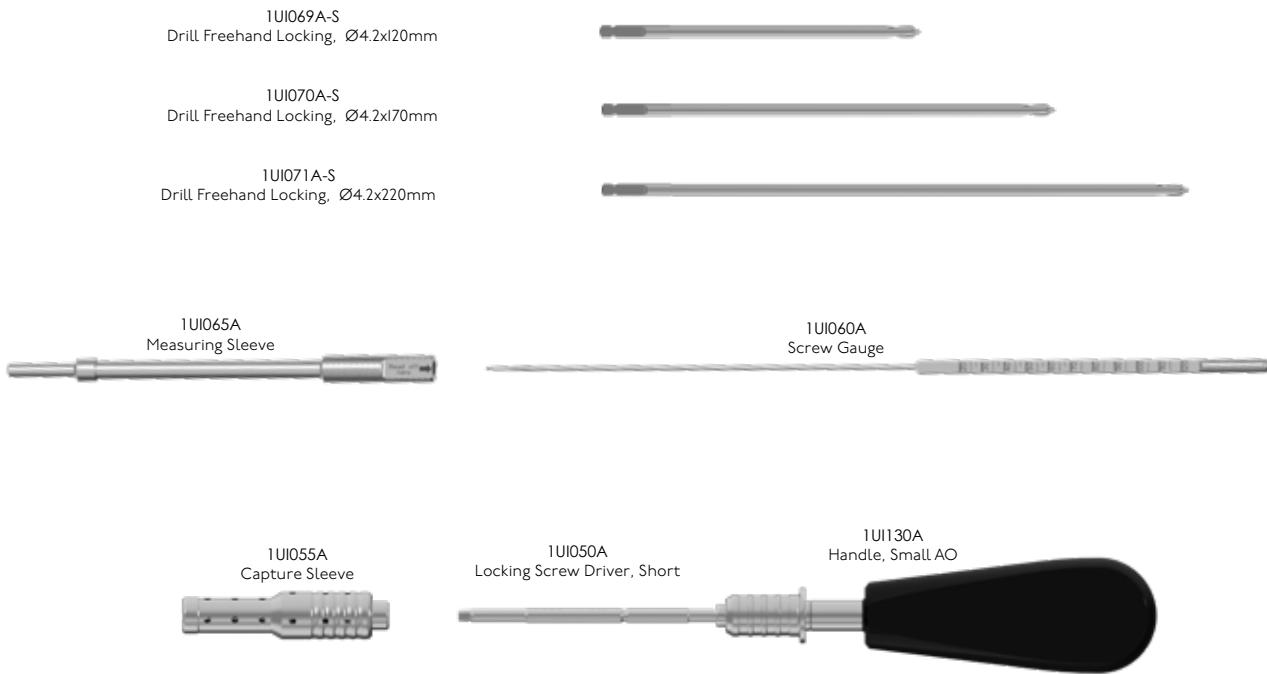
TIP: For the final positioning of the nail, the impactor can be used for the fine-adjustments, both to impact and retract. For this, the impactor must be mounted on the aiming arm.

IMPORTANT: The targeting arm **must never** be hit directly.



The next steps in the procedure for using the long intramedullary nails follows that of the standard technique from the section on the insertion of the Master Sleeve and checking implantation depth and onwards - see p. 33.

● LONG NAILS: Freehand Distal Locking



The distal locking when using the long nails can be carried out using one of the numerous freehand techniques, as chosen by the surgeon. The technique described here enables rotation control of the femoral axis using the image intensifier in the lateral projection of the distal femur.

A correct central position of the DyCon® Lag Screw with 12° anteversion of the femoral neck opens the possibility of rotation control via the distal freehand locking.

- After the final placement of the DyCon® Screw pair, the image intensifier is set in an exact lateral projection above the knee joint.

TIP: Assuming a normal anatomy, the exact lateral projection is achieved when both posterior femoral condyles (medial/lateral) are projected identically onto each other.

- In this image intensifier position, the distal end of the nail is moved into view and checked to determine whether the two round holes are projecting exactly circular. If this is not the case, the proximal femur part should be rotated using the aiming device until a circular projection results.

IMPORTANT: This position ensures that there is an anteversion of the femoral neck of 12° with a neutral femoral axis.

- Stab incisions are then placed over those holes that have been selected for locking.

TIP: Depending on the clinical situation, the two round holes are usually filled, which leads to a static locking. If a dynamic locking situation is desired, the elongated hole is filled in the lower position. This position is also selected if later dynamization is to be made possible by removing the two static screws.



- The drill (*Drill Freehand, Ø4.2 x 120mm*) is positioned under image intensifier control, through the stab incision in a slightly inclined position with its tip exactly above the center of the base hole.
- The tip of the drill is anchored in the cortex by gently engaging the drill.
- The power tool with the drill is then swiveled into the exact central position seen in the image intensifier.
- The first lateral cortex is drilled, and making sure the nail is passed, the second, medial cortex is drilled.
- The length is measured by a measuring gauge (*Screw Gauge*) with a measuring sleeve (*Measuring Sleeve*).
- The selected screw is then screwed in using the Locking Screwdriver for freehand locking (*Locking Screw Driver, Short*).



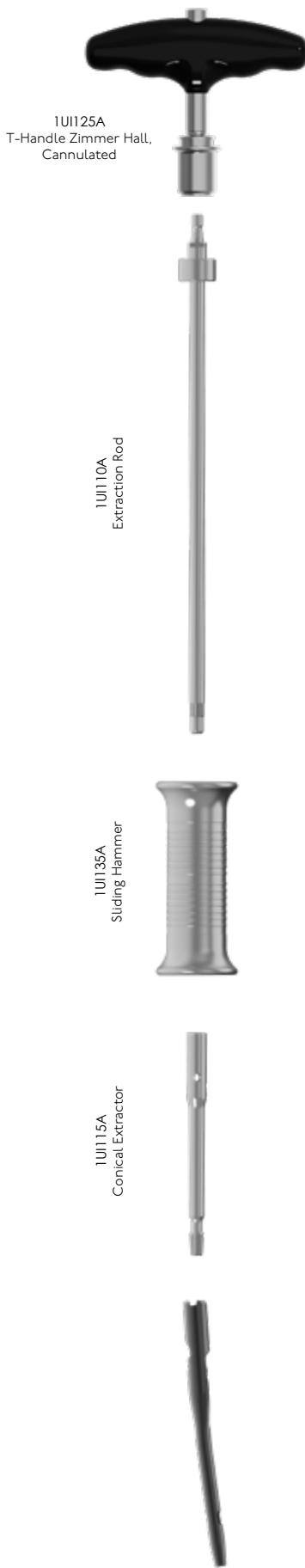
TIP: For screw insertion, the screwdriver can be used with an optionally available locking sleeve (*Capture Sleeve*).

- After inserting the screws, the position is documented with the image intensifier in two planes.

TIP: Ideally, both the screws and the posterior femoral condyles should be accurately visualized in the lateral projection.

The completion of the operation when using the long nails now corresponds to the procedure for the standard technique - see p. 56.

Implant Removal



Removal of implants usually is indicated only in younger patients. Exceptions are local irritation, for example in a thin patient with a limited soft tissue envelope and lateral migration of the Lag Screw.

To perform the implant removal, the identical instruments should be available as for insertion of the nail, with the exception of the targeting instruments and sleeves.

NOTE: After implant removal, especially in the case of osteoporosis, increased incidence of femoral neck fractures has been described in literature.

- After excision of the scars, the original surgical approaches are used and the nail, the DyCon® Screw pair and the distal locking screws are exposed.

NOTE: The Lag Screw can only be unscrewed after complete removal of the DyCon® and/or the Axial Set Screw as well as the End Caps.

IMPORTANT: The distal locking screw should not be unscrewed until the explantation instruments are securely connected to the nail.

- First, the conical nail connector (*Conical Extractor*) must be mounted to the extraction rod (*Extraction Rod*) by means of a screw connection. If the sliding hammer (*Sliding Hammer*) is to be used, it is first placed onto the extraction rod.
- Attach the T-Handle and screw this construct into the nail connection.
- Alternatively, the construct can be removed using the slotted hammer.

NOTE: Before striking the nail, it must always be ensured once again that all screws originally crossing the nail have been safely removed, especially the distal locking screws.



Information

3.

○ Type II Anodization

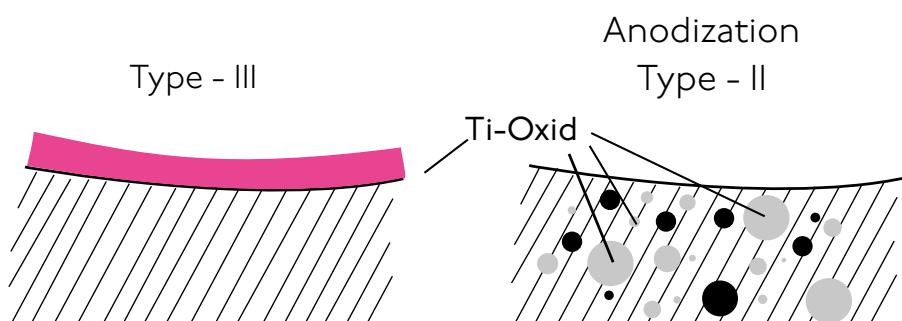
Chemical process - anodization in a strong alkaline solution*

Type III anodization

- Layer thickness 60-200nm
 - + Different colors
 - Implant surface remains sensitive to:
 - Chipping
 - Peeling
 - Discoloration

Type II anodization

- Layer thickness 1000-2000nm
 - + Film becomes an interstitial part of the titanium
 - No visible cosmetic effect

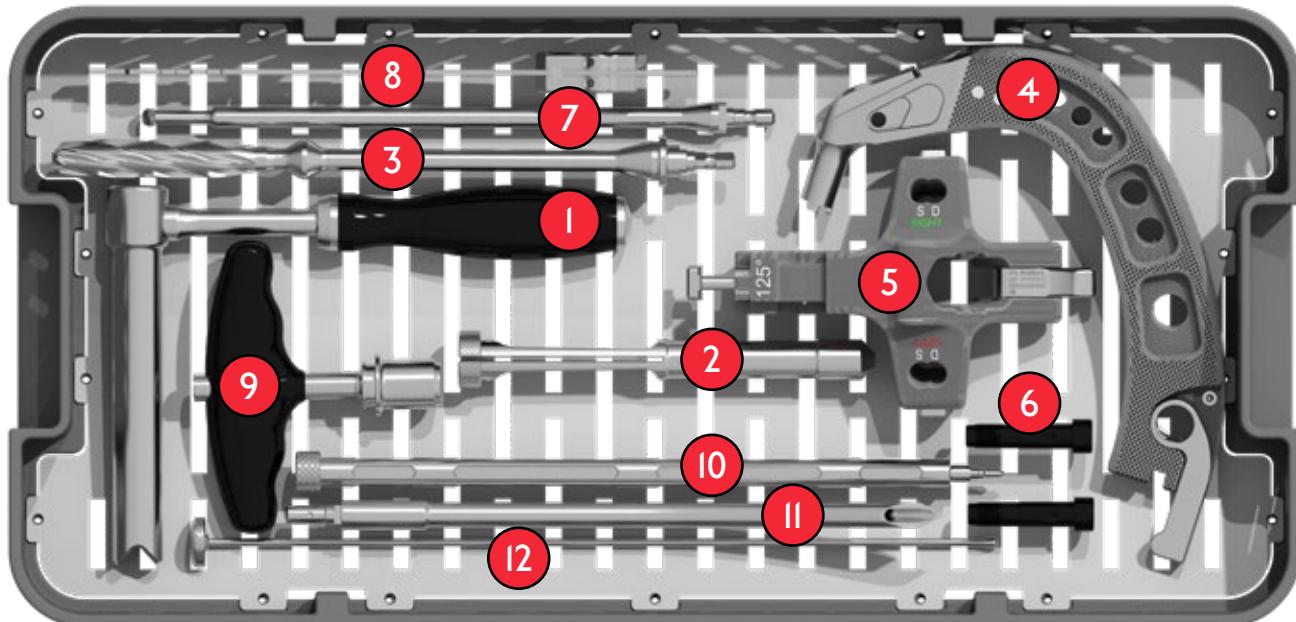


Anodization Type II leads to following benefits*

- Oxygen and silicon absorbing conversion layer
- Decrease in protein adsorption
- Closing of micro pores and micro cracks
- Reduced risk of inflammation and allergy
- Hardened titanium surface
- Reduced tendency of cold welding of titanium implants
- Increased fatigue resistance of implants
- Improved wear and friction characteristics

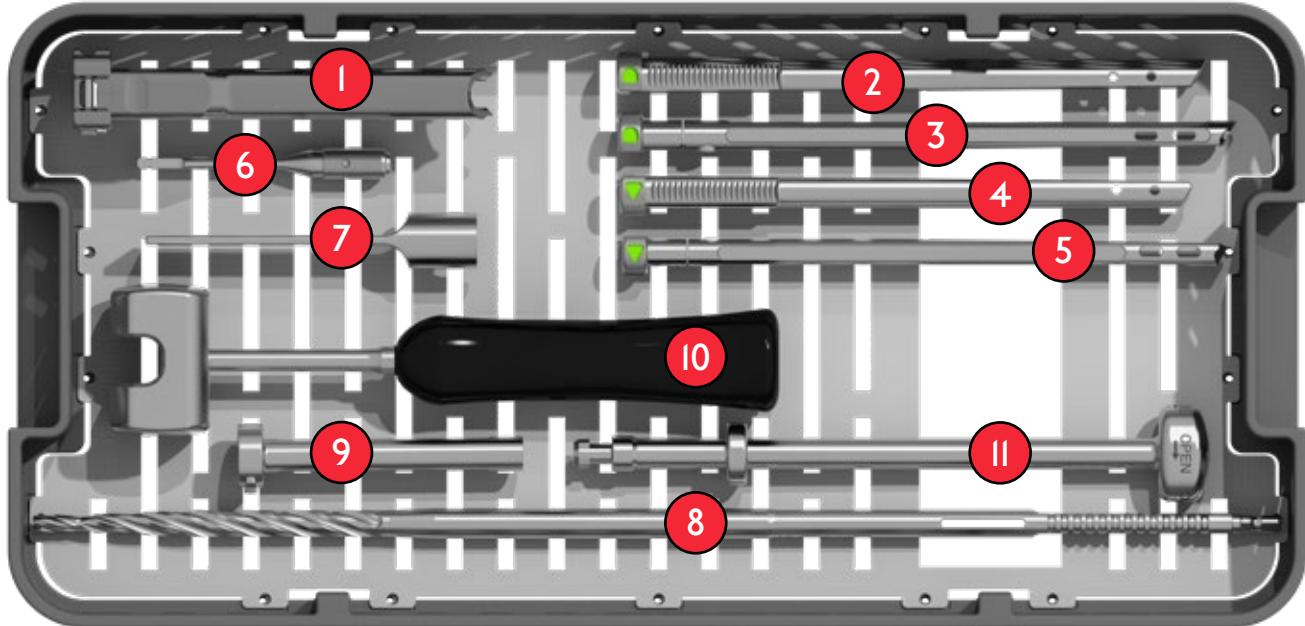
○ Article List

Basic Instruments



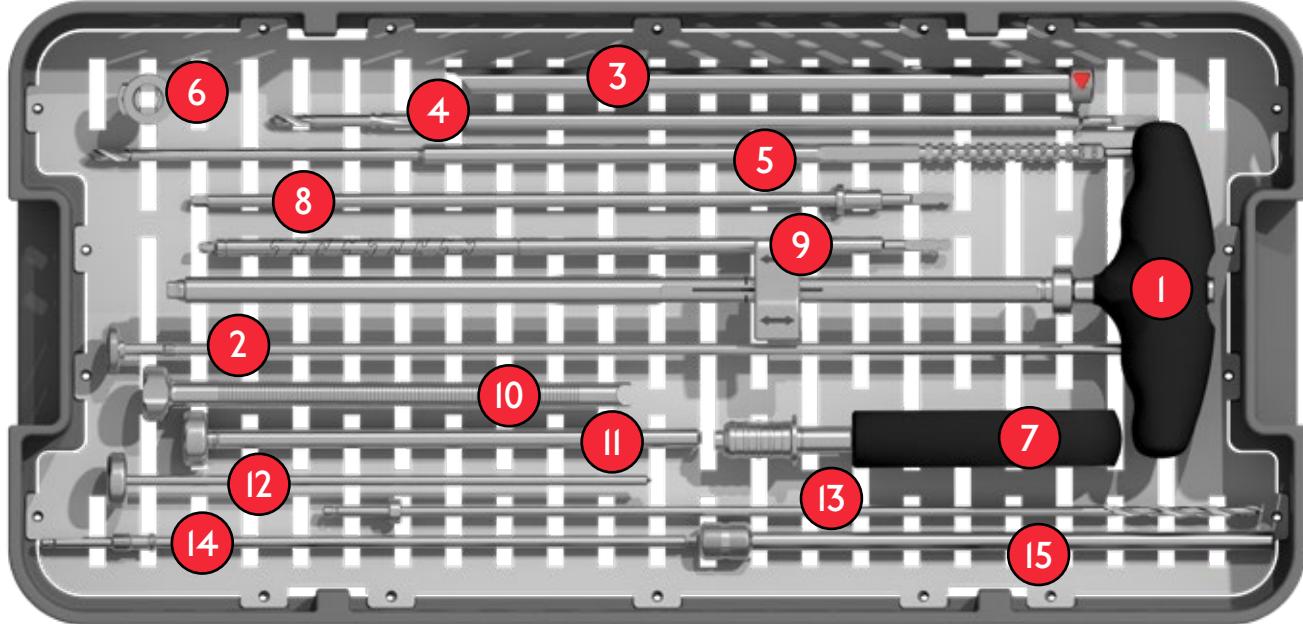
Opening & Nail Insertion

Description	Article number
1 PF Opening Reamer Sleeve	1F0I020A
2 PF Multihole Trocar	1F0I030A
3 PF Opening Reamer	1F0I040A
4 PF Targeting Arm	1F0I050A
5 PF Targeting Module I25°	1F0I060A
6 PF Nail Holding Bolt	1F0I075A
7 PF Ball Tip Screwdriver	1F0I045A
8 PF X-Ray Ruler, Short	1F0I005A
9 T-Handle Zimmer Hall, Cannulated	1UI125A
10 PF Compression Rod	1F0I180A
11 Awl, Curved, Cannulated	1F0I205A
12 Awl Trocar	1F0I210A



Proximal Targeting

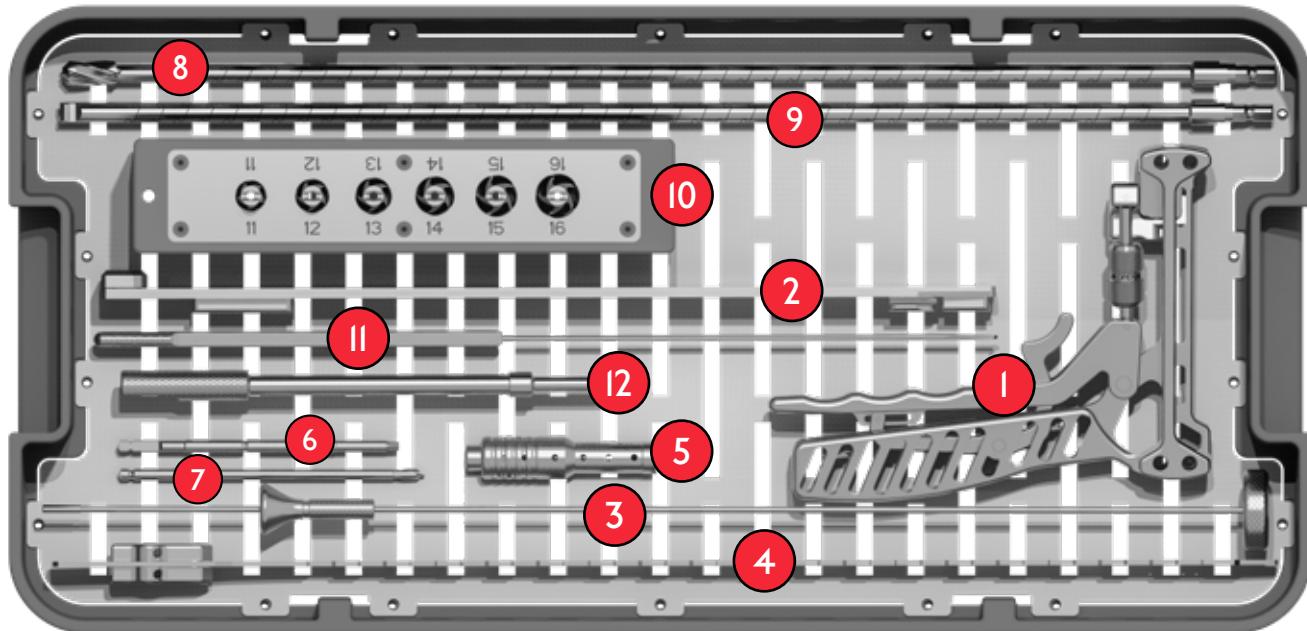
Description	Article number
1	PF Proximal Master Sleeve 1F0I080A
2	PF Tissue Protection Sleeve, Superior 1F0I090A
3	PF K-Wire Sleeve, Superior 1F0I100A
4	PF Tissue Protection Sleeve, Inferior 1F0I095A
5	PF K-Wire Sleeve, Inferior 1F0I105A
6	K-Wire Adapter 1F0I025A
7	PF Lag Screw Ruler 1F0I110A
8	PF Step Drill Lag Screw 1F0I115A
9	Step Drill Depth Stop 1F0I120A
10	Slotted Hammer 1UI005A
11	Impactor 1UI105A



Proximal & Distal Locking

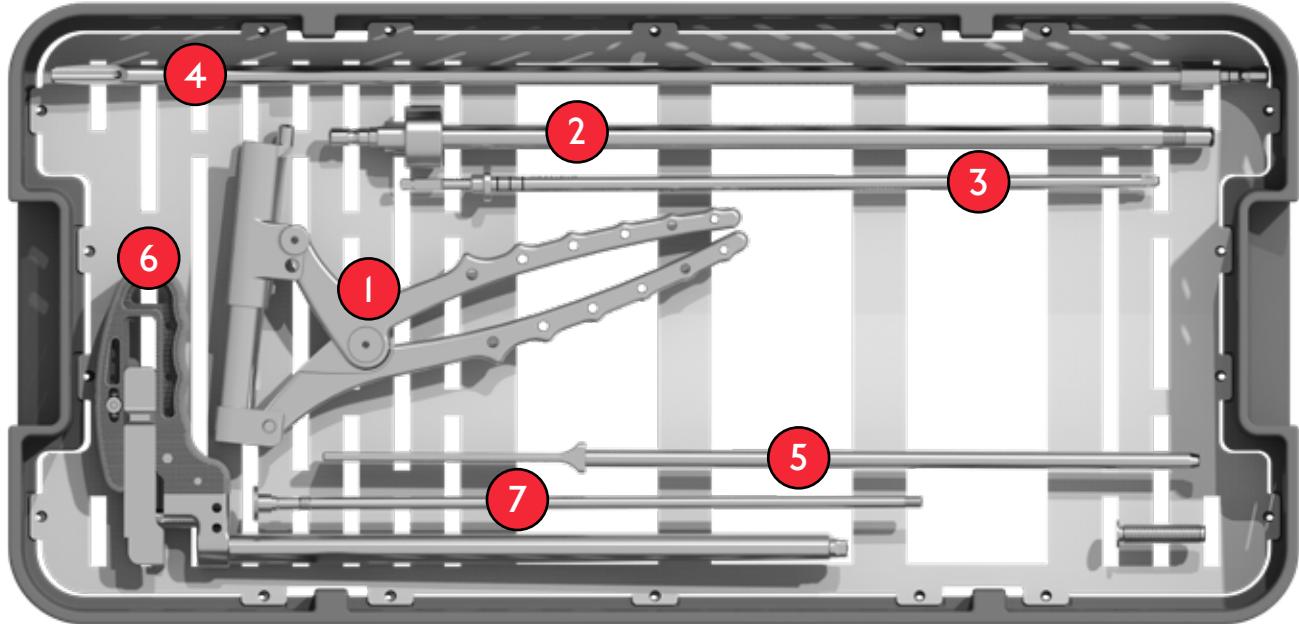
Description	Article number
1	PF Lag Screw Driver 1F0I155A
2	PF Lag Screw Driver Retaining Rod 1F0I160A
3	PF Set Screw Sleeve 1F0I135A
4	PF Set Screw Drill 1F0I140A
5	PF Set Screw Drill, Optional 1F0I141A
6	PF Depth Stop Set Screw Drill 1F0I142A
7	Handle, Small AO 1UI130A
8	PF Set Screw Driver, Standard 1F0I170A
9	PF Set Screw Driver, flexible 1F0I200A
10	Soft Tissue Sleeve 1UI020A
11	Drill Sleeve, Ø4.2mm 1UI025A
12	Trocar 1UI030A
13	Drill, Ø4.2mm 1UI035A-S
14	Locking Screw Driver Shaft 1UI045A
15	Locking Screw Driver Sleeve 1UI046A

Optional Instruments



Additional Instruments for Long Nail

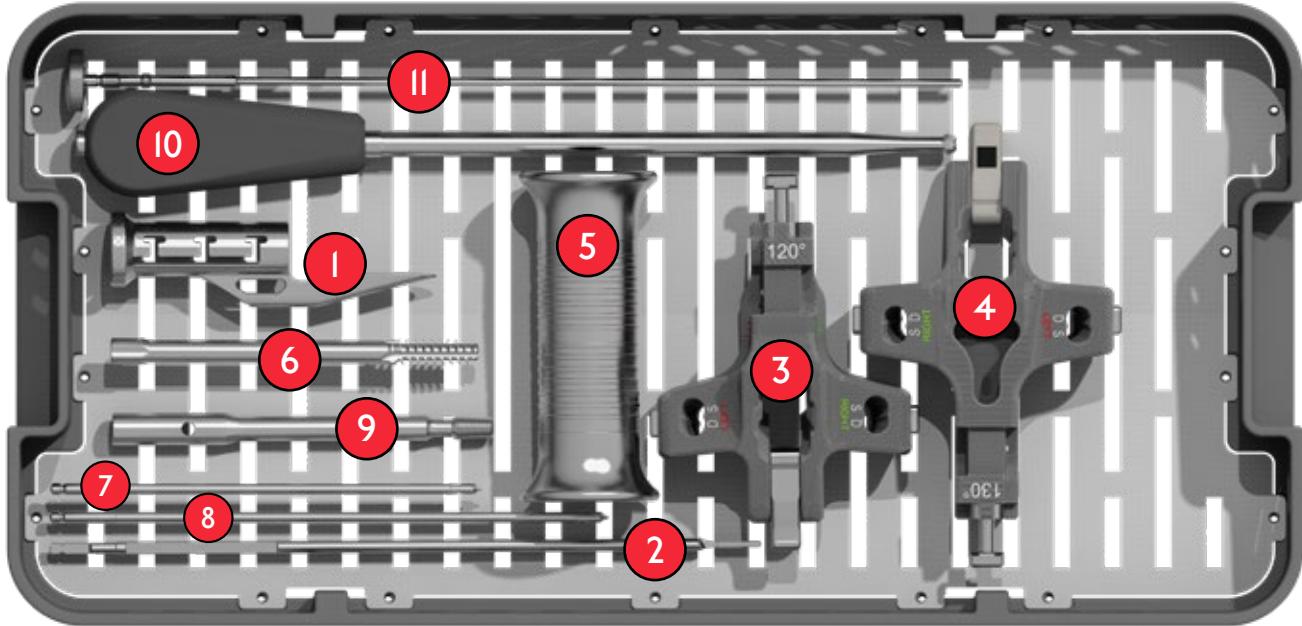
Description	Article number
1	Gripper 1UI090A
2	Guide Wire Ruler 1UI010A
3	Guide Wire Pusher 1UI100A
4	PF X-Ray Ruler, Long 1FO1010A
5	Capture Sleeve 1UI055A
6	Locking Screw Driver, Short 1UI050A
7	Drill Freehand Locking, Ø4.2x120mm 1UI069A-S
8	Fixed Head Reamer, Ø10mm 1UI224A
9	Modular Reamer Shaft, Ø8x475mm 1UI200A
10	Reamerbox 52350-23
	Modular Reamer Head, Ø11mm 1UI258A
	Modular Reamer Head, Ø12mm 1UI260A
	Modular Reamer Head, Ø13mm 1UI262A
	Modular Reamer Head, Ø14mm 1UI264A
	Modular Reamer Head, Ø15mm 1UI266A
	Modular Reamer Head, Ø16mm 1UI268A
11	Screw Gauge 1UI060A
12	Measuring Sleeve 1UI065A



Optional Instruments I

Description	Article number
1	PF Appositioning Instrument
2	Extraction Rod
3	PF Set Screw Driver, Optional
4	Reduction Rod
5	PF Lag Screw Ruler, Optional
6	PF L-Tool
7	PF L-Tool Compression Screw
	1F0I190A-05
	1F0I195A

IMPORTANT: For reprocessing, the L-Tool slider must be extended and the L-Tool compression screw removed.



Optional Instruments 2

	Description	Article number
1	PF Opening Reamer Sleeve Rescue	1F0I035A
2	Scalpel Handle	1UI015A
3	PF Targeting Module 120°	1F0I055A
4	PF Targeting Module 130°	1F0I065A
5	Sliding Hammer	1UI135A
6	PF Lag Screw Tap	1F0I130A
7	Drill Freehand Locking, Ø4.2x170mm	1UI070A-S
8	Drill Freehand Locking, Ø4.2x220mm	1UI071A-S
9	Conical Extractor	1UI115A
10	Ball Tip Screwdriver, Self Retaining	1F0I185A
11	Retaining Rod Ball Tip Screwdriver	1F0I150A

Nails - 120° CCD

SHORT

∅	Length (mm)	Left	Right
10mm	180	1FOL10-180-120A-S	1FOR10-180-120A-S

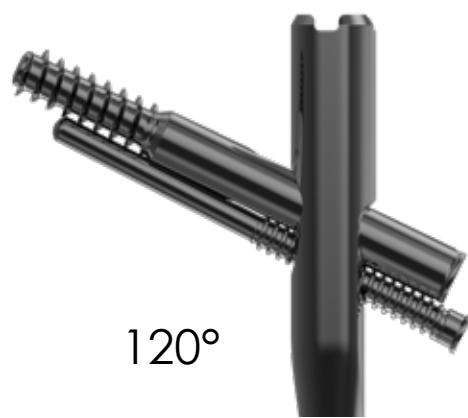
INTERMEDIATE

∅	Length (mm)	Left	Right
10mm	240	1FOL10-240-120A-S	1FOR10-240-120A-S

∅	Length (mm)	Left	Right
12mm	240	1FOL12-240-120A-S	1FOR12-240-120A-S

LANG

∅	Length (mm)	Left	Right
9mm	260	1FOL9-260-120A-S	1FOR9-260-120A-S
	280	1FOL9-280-120A-S	1FOR9-280-120A-S
	300	1FOL9-300-120A-S	1FOR9-300-120A-S
	320	1FOL9-320-120A-S	1FOR9-320-120A-S
	340	1FOL9-340-120A-S	1FOR9-340-120A-S
	360	1FOL9-360-120A-S	1FOR9-360-120A-S
	380	1FOL9-380-120A-S	1FOR9-380-120A-S
	400	1FOL9-400-120A-S	1FOR9-400-120A-S
	420	1FOL9-420-120A-S	1FOR9-420-120A-S
	440	1FOL9-440-120A-S	1FOR9-440-120A-S
	460	1FOL9-460-120A-S	1FOR9-460-120A-S
	480	1FOL9-480-120A-S	1FOR9-480-120A-S



120°

∅	Length (mm)	Left	Right
12mm	260	1FOL12-260-120A-S	1FOR12-260-120A-S
	280	1FOL12-280-120A-S	1FOR12-280-120A-S
	300	1FOL12-300-120A-S	1FOR12-300-120A-S
	320	1FOL12-320-120A-S	1FOR12-320-120A-S
	340	1FOL12-340-120A-S	1FOR12-340-120A-S
	360	1FOL12-360-120A-S	1FOR12-360-120A-S
	380	1FOL12-380-120A-S	1FOR12-380-120A-S
	400	1FOL12-400-120A-S	1FOR12-400-120A-S
	420	1FOL12-420-120A-S	1FOR12-420-120A-S
	440	1FOL12-440-120A-S	1FOR12-440-120A-S
	460	1FOL12-460-120A-S	1FOR12-460-120A-S
	480	1FOL12-480-120A-S	1FOR12-480-120A-S

∅	Length (mm)	Left	Right
10mm	260	1FOL10-260-120A-S	1FOR10-260-120A-S
	280	1FOL10-280-120A-S	1FOR10-280-120A-S
	300	1FOL10-300-120A-S	1FOR10-300-120A-S
	320	1FOL10-320-120A-S	1FOR10-320-120A-S
	340	1FOL10-340-120A-S	1FOR10-340-120A-S
	360	1FOL10-360-120A-S	1FOR10-360-120A-S
	380	1FOL10-380-120A-S	1FOR10-380-120A-S
	400	1FOL10-400-120A-S	1FOR10-400-120A-S
	420	1FOL10-420-120A-S	1FOR10-420-120A-S
	440	1FOL10-440-120A-S	1FOR10-440-120A-S
	460	1FOL10-460-120A-S	1FOR10-460-120A-S
	480	1FOL10-480-120A-S	1FOR10-480-120A-S

∅	Length (mm)	Left	Right
14mm	260	1FOL14-260-120A-S	1FOR14-260-120A-S
	280	1FOL14-280-120A-S	1FOR14-280-120A-S
	300	1FOL14-300-120A-S	1FOR14-300-120A-S
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	420	1FOL14-420-120A-S	1FOR14-420-120A-S
	440	1FOL14-440-120A-S	1FOR14-440-120A-S
	460	1FOL14-460-120A-S	1FOR14-460-120A-S
	480	1FOL14-480-120A-S	1FOR14-480-120A-S

Nails - 125° CCD

Short	Ø	Length (mm)	LEFT	Right
	10mm	180	1FOL10-180-125A-S	1FOR10-180-125A-S

INTERMEDIATE	Ø	Length (mm)	Left	Right
	10mm	240	1FOL10-240-125A-S	1FOR10-240-125A-S

INTERMEDIATE	Ø	Length (mm)	Left	Right
	12mm	240	1FOL12-240-125A-S	1FOR12-240-125A-S



125°

LANG	Ø	Length (mm)	Left	Right
	9mm	260	1FOL9-260-125A-S	1FOR9-260-125A-S
		280	1FOL9-280-125A-S	1FOR9-280-125A-S
		300	1FOL9-300-125A-S	1FOR9-300-125A-S
		320	1FOL9-320-125A-S	1FOR9-320-125A-S
		340	1FOL9-340-125A-S	1FOR9-340-125A-S
		360	1FOL9-360-125A-S	1FOR9-360-125A-S
		380	1FOL9-380-125A-S	1FOR9-380-125A-S
		400	1FOL9-400-125A-S	1FOR9-400-125A-S
		420	1FOL9-420-125A-S	1FOR9-420-125A-S
		440	1FOL9-440-125A-S	1FOR9-440-125A-S
		460	1FOL9-460-125A-S	1FOR9-460-125A-S
		480	1FOL9-480-125A-S	1FOR9-480-125A-S

Ø	Length (mm)	Left	Right
12mm	260	1FOL12-260-125A-S	1FOR12-260-125A-S
	280	1FOL12-280-125A-S	1FOR12-280-125A-S
	300	1FOL12-300-125A-S	1FOR12-300-125A-S
	320	1FOL12-320-125A-S	1FOR12-320-125A-S
	340	1FOL12-340-125A-S	1FOR12-340-125A-S
	360	1FOL12-360-125A-S	1FOR12-360-125A-S
	380	1FOL12-380-125A-S	1FOR12-380-125A-S
	400	1FOL12-400-125A-S	1FOR12-400-125A-S
	420	1FOL12-420-125A-S	1FOR12-420-125A-S
	440	1FOL12-440-125A-S	1FOR12-440-125A-S
	460	1FOL12-460-125A-S	1FOR12-460-125A-S
	480	1FOL12-480-125A-S	1FOR12-480-125A-S

LANG	Ø	Length (mm)	Left	Right
	10mm	260	1FOL10-260-125A-S	1FOR10-260-125A-S
		280	1FOL10-280-125A-S	1FOR10-280-125A-S
		300	1FOL10-300-125A-S	1FOR10-300-125A-S
		320	1FOL10-320-125A-S	1FOR10-320-125A-S
		340	1FOL10-340-125A-S	1FOR10-340-125A-S
		360	1FOL10-360-125A-S	1FOR10-360-125A-S
		380	1FOL10-380-125A-S	1FOR10-380-125A-S
		400	1FOL10-400-125A-S	1FOR10-400-125A-S
		420	1FOL10-420-125A-S	1FOR10-420-125A-S
		440	1FOL10-440-120A-S	1FOR10-440-125A-S
		460	1FOL10-460-125A-S	1FOR10-460-125A-S
		480	1FOL10-480-125A-S	1FOR10-480-125A-S

Ø	Length (mm)	Left	Right
14mm	260	1FOL14-260-125A-S	1FOR14-260-125A-S
	280	1FOL14-280-125A-S	1FOR14-280-125A-S
	300	1FOL14-300-125A-S	1FOR14-300-125A-S
	320	1FOL14-320-125A-S	1FOR14-320-125A-S
	340	1FOL14-340-125A-S	1FOR14-340-125A-S
	360	1FOL14-360-125A-S	1FOR14-360-125A-S
	380	1FOL14-380-125A-S	1FOR14-380-125A-S
	400	1FOL14-400-125A-S	1FOR14-400-125A-S
	420	1FOL14-420-125A-S	1FOR14-420-125A-S
	440	1FOL14-440-125A-S	1FOR14-440-125A-S
	460	1FOL14-460-125A-S	1FOR14-460-125A-S
	480	1FOL14-480-125A-S	1FOR14-480-125A-S

Nails - 130° CCD

SHORT

Ø	Length (mm)	LEFT	Right
10mm	180	1FOL10-180-130A-S	1FOR10-180-130A-S

INTERMEDIATE

Ø	Length (mm)	Left	Right
10mm	240	1FOL10-240-130A-S	1FOR10-240-130A-S

Ø	Length (mm)	Left	Right
12mm	240	1FOL12-240-130A-S	1FOR12-240-130A-S

LANG

Ø	Length (mm)	Left	Right
10mm	260	1FOL10-260-130A-S	1FOR10-260-130A-S
	280	1FOL10-280-130A-S	1FOR10-280-130A-S
	300	1FOL10-300-130A-S	1FOR10-300-130A-S
	320	1FOL10-320-130A-S	1FOR10-320-130A-S
	340	1FOL10-340-130A-S	1FOR10-340-130A-S
	360	1FOL10-360-130A-S	1FOR10-360-130A-S
	380	1FOL10-380-130A-S	1FOR10-380-130A-S
	400	1FOL10-400-130A-S	1FOR10-400-130A-S
	420	1FOL10-420-130A-S	1FOR10-420-130A-S
	440	1FOL10-440-130A-S	1FOR10-440-130A-S
	460	1FOL10-460-130A-S	1FOR10-460-130A-S
	480	1FOL10-480-130A-S	1FOR10-480-130A-S



130°

Ø	Length (mm)	LEFT	Right
12mm	260	1FOL12-260-130A-S	1FOR12-260-130A-S
	280	1FOL12-280-130A-S	1FOR12-280-130A-S
	300	1FOL12-300-130A-S	1FOR12-300-130A-S
	320	1FOL12-320-130A-S	1FOR12-320-130A-S
	340	1FOL12-340-130A-S	1FOR12-340-130A-S
	360	1FOL12-360-130A-S	1FOR12-360-130A-S
	380	1FOL12-380-130A-S	1FOR12-380-130A-S
	400	1FOL12-400-130A-S	1FOR12-400-130A-S
	420	1FOL12-420-130A-S	1FOR12-420-130A-S
	440	1FOL12-440-130A-S	1FOR12-440-130A-S
	460	1FOL12-460-130A-S	1FOR12-460-130A-S
	480	1FOL12-480-130A-S	1FOR12-480-130A-S

Ø	Length (mm)	LEFT	Right
14mm	260	1FOL14-260-130A-S	1FOR14-260-130A-S
	280	1FOL14-280-130A-S	1FOR14-280-130A-S
	300	1FOL14-300-130A-S	1FOR14-300-130A-S
	320	1FOL14-320-130A-S	1FOR14-320-130A-S
	340	1FOL14-340-130A-S	1FOR14-340-130A-S
	360	1FOL14-360-130A-S	1FOR14-360-130A-S
	380	1FOL14-380-130A-S	1FOR14-380-130A-S
	400	1FOL14-400-130A-S	1FOR14-400-130A-S
	420	1FOL14-420-130A-S	1FOR14-420-130A-S
	440	1FOL14-440-130A-S	1FOR14-440-130A-S
	460	1FOL14-460-130A-S	1FOR14-460-130A-S
	480	1FOL14-480-130A-S	1FOR14-480-130A-S

DyCon® Screw Pair

Lag Screw



DyCon® Set Screw



Lag Screw

Length	Article Number
70	1F0-10-70A-S
75	1F0-10-75A-S
80	1F0-10-80A-S
85	1F0-10-85A-S
90	1F0-10-90A-S
95	1F0-10-95A-S
100	1F0-10-100A-S
105	1F0-10-105A-S
110	1F0-10-110A-S
115	1F0-10-115A-S
120	1F0-10-120A-S
125	1F0-10-125A-S
130	1F0-10-130A-S

DyCon® Set Screw

Length	Article Number
70	1F0-7-70A-S
75	1F0-7-75A-S
80	1F0-7-80A-S
85	1F0-7-85A-S
90	1F0-7-90A-S
95	1F0-7-95A-S
100	1F0-7-100A-S
105	1F0-7-105A-S
110	1F0-7-110A-S
115	1F0-7-115A-S
120	1F0-7-120A-S
125	1F0-7-125A-S
130	1F0-7-130A-S

OPTIONAL Short DyCon® Set Screw

Article Number
1F0-7-45A-S

Axial Set Screw

Article Number
1F0-7-15A-S

5mm Locking Screw

Length	Article Number
25	1U1-5-25A-S
27.5	1U1-5-27A-S
30	1U1-5-30A-S
32.5	1U1-5-32A-S
35	1U1-5-35A-S
37.5	1U1-5-37A-S
40	1U1-5-40A-S
42.5	1U1-5-42A-S
45	1U1-5-45A-S
47.5	1U1-5-47A-S
50	1U1-5-50A-S
52.5	1U1-5-52A-S
55	1U1-5-55A-S
57.5	1U1-5-57A-S
60	1U1-5-60A-S
62.5	1U1-5-62A-S
65	1U1-5-65A-S
67.5	1U1-5-67A-S
70	1U1-5-70A-S
75	1U1-5-75A-S
80	1U1-5-80A-S
85	1U1-5-85A-S
90	1U1-5-90A-S
95	1U1-5-95A-S
100	1U1-5-100A-S
105	1U1-5-105A-S
110	1U1-5-110A-S
115	1U1-5-115A-S
120	1U1-5-120A-S



Accessories

Drill-Wires

Description	Article Number
 Precision Drill-Wire, Ø3.2x390mm (3-Pack)	1F0I016A-S
 Precision Drill-Wire, Ø3.2x390mm (2-Pack)	1F0I017A-S

Ball Tip Guide Wire

Description	Article Number
 Ball Tip Guide Wire, Ø3x800mm	1UI095A-S

Single Use Drills

Description	Article Number
 Drill, Ø4.2mm	1UI035A-S
 Drill Freehand Locking, Ø4.2x120mm	1UI069A-S
 Drill Freehand Locking, Ø4.2x170mm	1UI070A-S
 Drill Freehand Locking, Ø4.2x220mm	1UI071A-S

OPTIONAL Endcaps

Description	Article Number
 PF Endcap 0mm	1F0-10-30A-S
 PF Extension Endcap +5mm	1F0-15-05A-S
 PF Extension Endcap +10mm	1F0-15-10A-S
 PF Extension Endcap +15mm	1F0-15-15A-S
 PF Extension Endcap +20mm	1F0-15-20A-S

Notes

Notes

Disclaimer:

The intended users are limited to medical personnel with appropriate product training by the medical product consultants or knowledge of the surgical procedure to be applied. The medical staff must ensure that the use of I.T.S. GmbH medical devices is appropriate, taking into account the medical condition and medical history of the patient. Prior to product use, medical personnel must refer to complete information on product label and in IFU, including, but not limited to, indications, contraindications, warnings and preventative measures, and cleaning and sterilization instructions. Product availability is dependent on country registrations and clearances. For more information, please visit www.its-implant.com or contact us at office@its-implant.com. Unless otherwise noted, all information herein is the intellectual property of I.T.S. GmbH.



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