

OPERATIVE TECHNIQUE

Chimaera

Hip Fracture System™

Trochanteric Nailing System



Chimaera

Hip Fracture System™

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INTRODUCTION

More than 1.5 million patients suffer hip fractures worldwide each year⁽¹⁾. The majority of these fractures occur in an older population with an average age of around 80 years. Predominantly females over males suffer more frequently approximately four to one. The number of people sustaining a hip fracture continues to rise due to an increasingly aging population⁽²⁾. Approximately 50% of all hip fractures are extracapsular, which physicians can treat using a wide variety of possible internal fixation strategies⁽³⁾. Recently there has been an increase in the utilization of intramedullary nails: approximately two-thirds of newly trained orthopaedic surgeons now select them^(4,5). The new ORTHOFIX CHIMAERA Hip Fracture System - trochanteric nailing system (CHIMAERA trochanteric nail) was developed in conjunction with a team of Orthopaedic surgeons to be an efficient and intuitive solution for trochanteric fracture treatment. Its unique and distinguishing feature is the revolutionary locking mechanism of the lag screw that efficiently secures it to the nail without the need for a set screw.

References

1. Bhandari M, Sprague S, Schemitsch EH. International Hip Fracture Research Collaborative. Resolving controversies in hip fracture care: The need for large collaborative trials in hip fractures. *J Orthop Trauma*. 2009;23:479-484.
2. Parker MJ, Das A. Extramedullary fixation implants and external fixators for extracapsular hip fractures in adults (Review). *The Cochrane Collaboration*, JohnWiley & Sons, Ltd. 2013.
3. Evaniew N, Bhandari M. Cochrane in CORR: Intramedullary Nails for Extracapsular Hip Fractures in Adults (Review). *Clinical Orthopaedics and Related Research*. 2014; 473 (3): 767-774.
4. Anglen JO, Weinstein JN. American Board of Orthopaedic Surgery Research Committee. Nail or plate fixation of intertrochanteric hip fractures: Changing pattern of practice. A review of the American board of orthopaedic surgery database. *J Bone Joint Surg Am*. 2008;90:700-707.
5. Wood GW. Intramedullary nailing of femoral and tibial shaft fractures. *J Orthop Sci*. 2006; 11(6): 657-669.

SYSTEM DESCRIPTION

The proximal part of the nail features a threaded bore to connect the nail to the Targeting Handle by a cannulated bolt. The insertion is typically performed by a list of instruments including a guide wire, awl, reamer and impactor elements. The Targeting Handle is a radiolucent carbon fiber handle with steel connection elements. The handle features targeting holes to accommodate the use of targeting sleeves for the guide wire, trocar, reamer and the screwdriver. The targeting holes are designed to allow the placement of the cephalic screws, depending on the CCD angle of the nail (125° or 130°).

The proximal locking holes allow the placement of a lag screw and a second, supplementary screw, to provide additional rotational stability. The lag screw connects to the nail by a specifically designed wedging crown that is part of the screw. During insertion of the cephalic lag screw the crown is lodged between a tapered section of the screw barrel and the inner surface of the nail's locking hole. When the lag screw is fully seated it comes to a mechanical stop, which is provided by a feature on the nail and a reverse thread between the crown and the barrel.

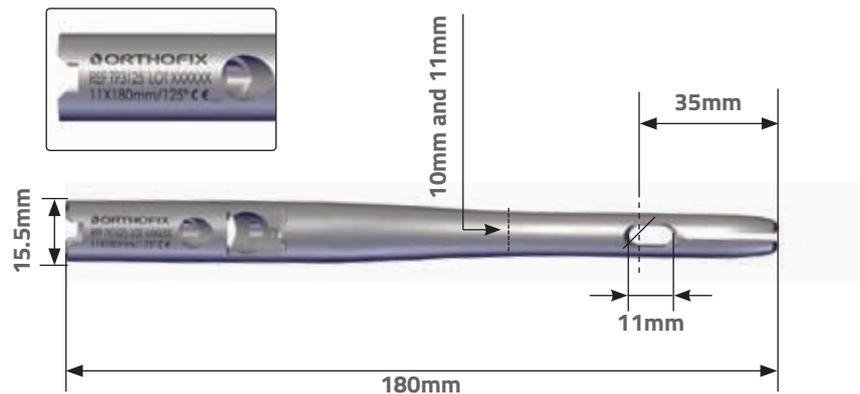
The lag screw is cannulated and provided in two versions, sliding or fixed. All screws come in a range of lengths that can be seen. The short nail comes in a 180mm length and it is universal for both left and right femur. The long nails are designed with a 10° anteversion therefore left and right nails are provided. Both the short and the long nails are available with 10mm and 11mm distal nail diameters. Please refer to the appropriate screws and nail sizes in the index provided in this document.

Appropriate surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience. Please refer to the 'Instructions for Use' supplied with the product for specific information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.

FEATURES AND BENEFITS

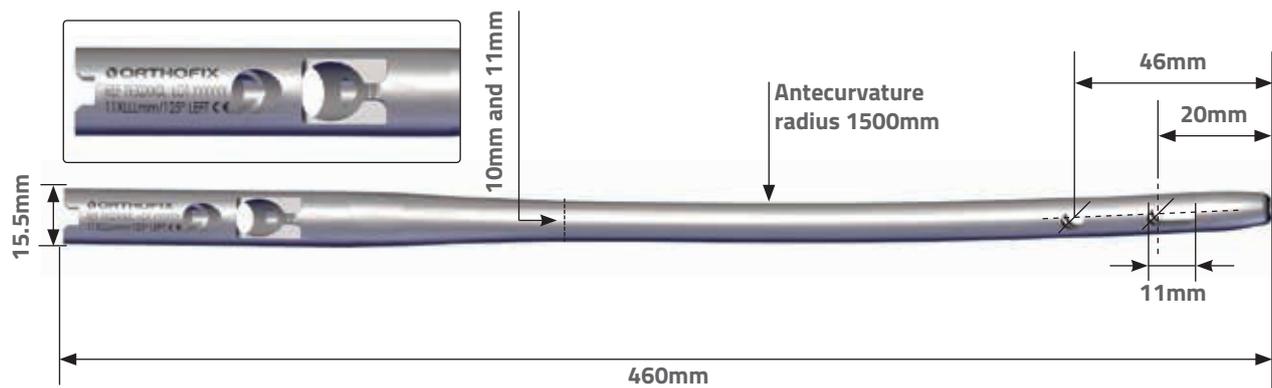
Short nail

- Material: Titanium alloy with anodized type II surface treatment
- Cannulation: the nail is cannulated for Guide-Wire-controlled insertion
- Nail length: 180mm
- Nail diameter: proximal 15.5mm, distal: 10mm and 11mm
- Proximal nail CCD angles: 125°, 130°
- M-L bend for valgus curvature: 5°
- Clothespin distal tip: it reduces nail stiffness and the risk of peri-implant fracture at the end of the nail



Long nail

- Material: Titanium alloy with anodized type II surface treatment.
- Cannulation: the nail is cannulated for Guide-Wire-controlled insertion.
- Nail length: 280mm to 460mm, in 20mm increments
- Nail diameter: proximal 15.5mm, distal: 10mm and 11mm
- Proximal nail CCD angles: 125°, 130°
- M-L bend for valgus curvature: 5°
- Proximal anteverision: 10 degrees in right and left options
- Antecurvature radius: 1500mm



End Caps

Cannulated, with a protruding length of 0mm, +5mm, +10mm and +15mm.

0mm

5mm

10mm

15mm



Lag screw - Sterile

- Diameter: 10.5mm
- Lengths: 70-130mm in 5mm increments
- Sliding version characterized by telescoping sliding movement without protrusion from lateral cortex
- Self retaining locking mechanism for a one-step-only insertion

Lag screw - fixed - Sterile



Lag screw - sliding - Sterile



Supplementary lag screw - Sterile

- Diameter: 6mm
- Lengths: 60-120mm in 5mm increments
- Telescoping sliding movement without protrusion from lateral cortex
- Threaded locking mechanism for a one-step-only insertion

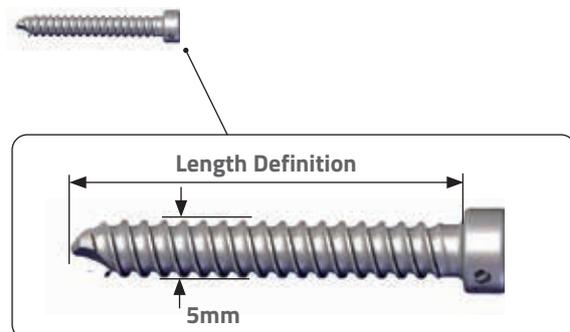
Supplementary lag screw - Sterile



Threaded Locking Screw (distal locking)-Sterile

- Thread diameter: 5mm
 - Fully threaded screw design
 - Lengths ranging from 25-90mm, in 5mm increments
- The Threaded Locking Screw is measured from underneath surface to tip.

Threaded Locking Screw



Proximal locking

Configurations - short nail:

- 125°
- 130°

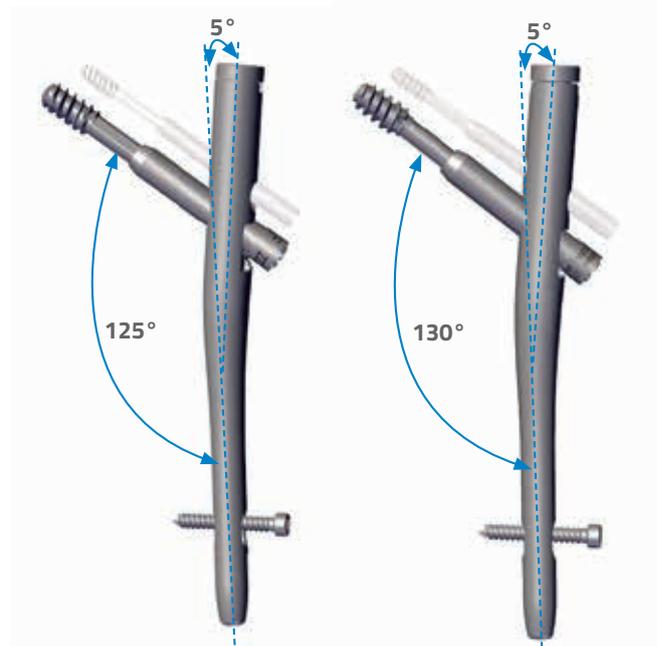
Configurations - long nail:

- 125° left
- 125° right
- 130° left
- 130° right

The use of the supplementary lag screw is at the surgeon's discretion.

Configuration 125°

Configuration 130°



Distal Locking

- Distal locking is done with a single screw that, depending on the type of fracture, may be static or dynamic, according to whether the screw is positioned in the upper or lower part of the oblong hole.

Short nail

- Locking in the distal part of the oblong hole creates a dynamic locking mechanism; up to 6mm dynamization is possible
- Locking in the proximal part of the oblong hole allows static locking of the nail.



Long nail

- Locking in the distal part of the oblong hole creates a dynamic locking mechanism. Up to 6mm dynamization is possible.
- Locking in the round hole and in the distal part of the oblong hole allow secondary dynamization. If dynamization is required after a period of time, the screw, placed in the round hole, has to be removed. Up to 6mm dynamization is possible.
- Locking in the round hole and the proximal part of the oblong hole allow static locking of the nail. One screw is placed in the round hole and the other is placed in the proximal part of the oblong hole.



INTENDED USE

The CHIMAERA Trochanteric Nail is intended for insertion into the medullary canal of a femur for the alignment, stabilization and fixation of various types of fractures or deformities.

INDICATIONS

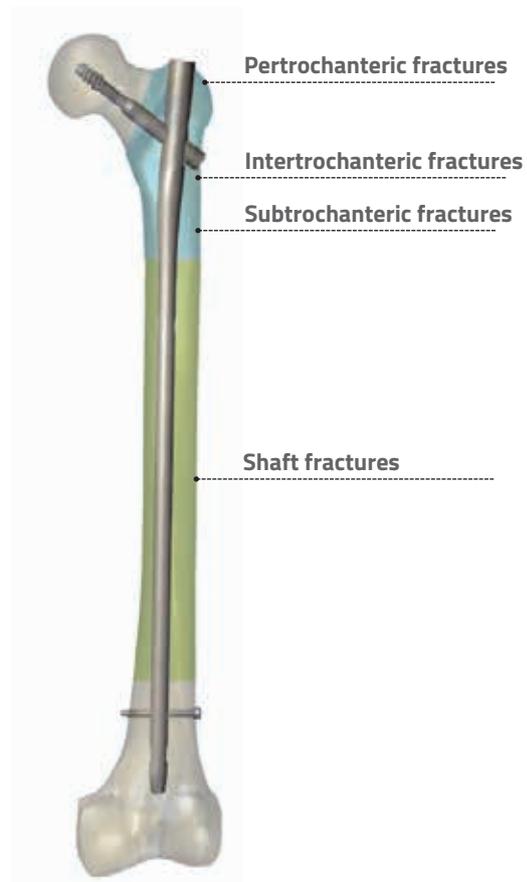
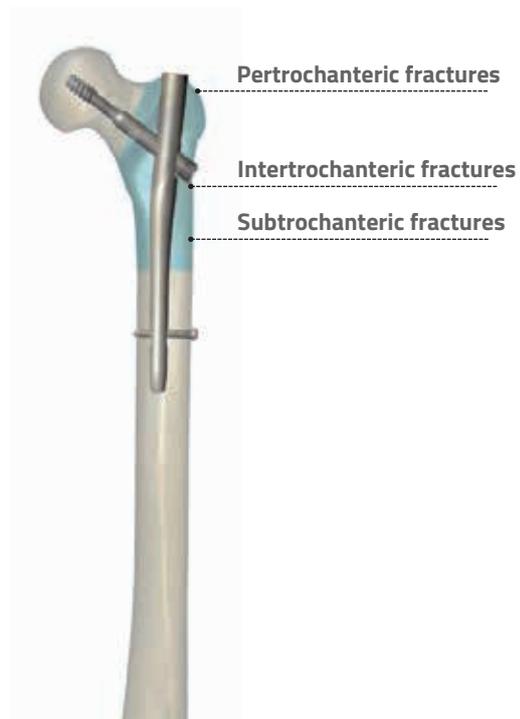
The CHIMAERA Trochanteric Nail is indicated for treatment of stable and unstable pertrochanteric, intertrochanteric and subtrochanteric fractures of the femur alone or when these fractures occur in combination with shaft fractures extending distally to a point approximately 10cm proximal to the intercondylar notch.

These include traumatic fractures, re-fractures, non-union, reconstruction, malunion, malalignment, pathological fractures and impending pathological fractures.

Stable or unstable pertrochanteric, intertrochanteric and subtrochanteric fractures can be treated either with a short or long nail. When these fractures occur in combination with femoral shaft fractures the use of a long nail is recommended.

NOTE: A sliding Lag Screw should be used when it crosses the fracture line. Otherwise, the use of a fixed Lag Screw is recommended.

Distal locking is available in static or dynamic configurations. In the case of transverse subtrochanteric fractures, dynamic distal locking is recommended.



End cap - Sterile

Code	Description
99-T930000	End cap - 0mm

End cap long - Sterile

Code	Description
99-T930005	End cap - 5mm
99-T930010	End cap - 10mm
99-T930015	End cap - 15mm

Screws

Lag screw - sliding - Sterile

Code	Description
99-T93770	Lag screw - sliding - 70mm
99-T93775	Lag screw - sliding - 75mm
99-T93780	Lag screw - sliding - 80mm
99-T93785	Lag screw - sliding - 85mm
99-T93790	Lag screw - sliding - 90mm
99-T93795	Lag screw - sliding - 95mm
99-T93700	Lag screw - sliding - 100mm
99-T93705	Lag screw - sliding - 105mm
99-T93710	Lag screw - sliding - 110mm
99-T93715	Lag screw - sliding - 115mm
99-T93720	Lag screw - sliding - 120mm
99-T93725	Lag screw - sliding - 125mm
99-T93730	Lag screw - sliding - 130mm

Lag screw - fixed - Sterile

Code	Description
99-T93670	Lag screw - fixed - 70mm
99-T93675	Lag screw - fixed - 75mm
99-T93680	Lag screw - fixed - 80mm
99-T93685	Lag screw - fixed - 85mm
99-T93690	Lag screw - fixed - 90mm
99-T93695	Lag screw - fixed - 95mm
99-T93600	Lag screw - fixed - 100mm
99-T93605	Lag screw - fixed - 105mm
99-T93610	Lag screw - fixed - 110mm
99-T93615	Lag screw - fixed - 115mm
99-T93620	Lag screw - fixed - 120mm
99-T93625	Lag screw - fixed - 125mm
99-T93630	Lag screw - fixed - 130mm

Threaded locking screw - Sterile

Code	Description
99-T931025	Threaded locking screw - 25mm
99-T931030	Threaded locking screw - 30mm
99-T931035	Threaded locking screw - 35mm
99-T931040	Threaded locking screw - 40mm
99-T931045	Threaded locking screw - 45mm
99-T931050	Threaded locking screw - 50mm
99-T931055	Threaded locking screw - 55mm
99-T931060	Threaded locking screw - 60mm
99-T931065	Threaded locking screw - 65mm
99-T931070	Threaded locking screw - 70mm
99-T931075	Threaded locking screw - 75mm
99-T931080	Threaded locking screw - 80mm
99-T931085	Threaded locking screw - 85mm
99-T931090	Threaded locking screw - 90mm

Supplementary lag screw - Sterile

Code	Description
99-T93560	Supplementary lag screw - 60mm
99-T93565	Supplementary lag screw - 65mm
99-T93570	Supplementary lag screw - 70mm
99-T93575	Supplementary lag screw - 75mm
99-T93580	Supplementary lag screw - 80mm
99-T93585	Supplementary lag screw - 85mm
99-T93590	Supplementary lag screw - 90mm
99-T93595	Supplementary lag screw - 95mm
99-T93500	Supplementary lag screw - 100mm
99-T93505	Supplementary lag screw - 105mm
99-T93510	Supplementary lag screw - 110mm
99-T93515	Supplementary lag screw - 115mm
99-T93520	Supplementary lag screw - 120mm

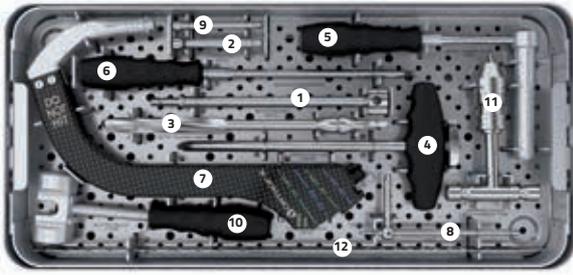
Cleaning, disinfection, sterilisation and maintenance of instrumentation

Please refer to the "Information for use" for cleaning, disinfection, sterilization and maintenance of instrumentation of the CHIMAERA Trochanteric Nail.

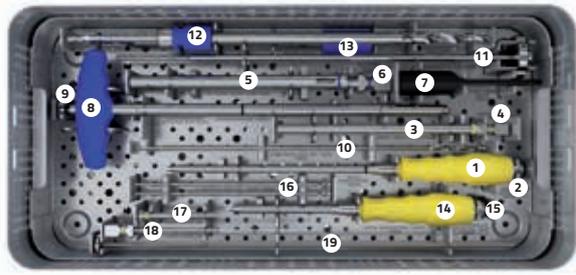
CHIMAERA - Hip Fracture System, Instrument Tray

The instruments are available in a specific sterilisation tray (193990) that comprises:

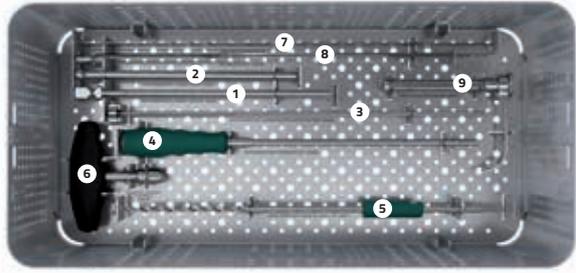
Top Tray



Mid Tray



Base Tray



Instrument Tray

Code	Description	Q.ty
TOP TRAY		
193115	1 Impaction Rod	1
193110	2 Locking Bolt	1
193270	3 Entry Reamer	1
193260	4 Cannulated Awl	1
193230	5 Entry Reamer Guide	1
193325	6 6mm Hex Screwdriver	1
193100	7 Targeting Handle	1
91017	8 Universal Allen Wrench	1
193271	9 6mm Hex Extension	1
177380	10 Slotted Mallet	1
17955	11 Universal Chuck With T-Handle	1
193275	12 Sizing Guide	1
MID TRAY		
193320	1 Distal Screwdriver	1
193319	2 Distal Screwdriver Retention Rod	1
193211	3 Distal Tissue Guide	1
193212	4 Distal Trocar	1
193231	5 Lag Screw Tissue Guide	1
193232	6 Lag Screw Trocar	1
193274	7 Screw Sizing Gauge	1
193283	8 Lag Screwdriver	1
193282	9 Lag Screwdriver Retention Rod	1
193286	10 4,2mm Distal Drill Bit - Long	1
193281	11 Lag Screw Compression Rod	1
193970	12 Lag Screw Gradual Reamer	1
193973	13 4mm Cortical Drill	1
193321	14 Distal Screwdriver - Short	1
193318	15 Distal Screwdriver Retention Rod - Short	1
193285	16 4,2mm Distal Drill Bit - Short	2
193213	17 Distal Tissue Guide - Short	1
193277	18 Distal Screw Sizing Gauge	1
193284	19 Wire Pusher	1

BASE TRAY

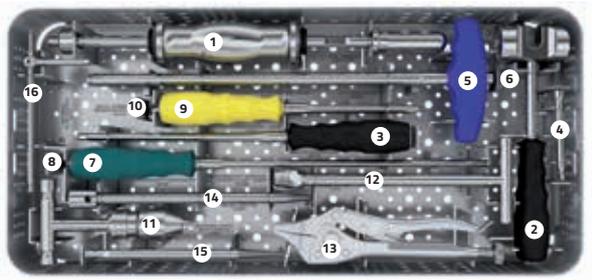
193222	1 Supplementary Screw Trocar	1
193221	2 Supplementary Tissue Guide	1
193292	3 Supplementary Screwdriver Retention Rod	1
193293	4 Supplementary Screwdriver	1
193971	5 Supplementary Gradual Drill Bit	1
193279	6 HJ Quick Connect T Handle	1
193276	7 Long Nail Ruler	1
173276	8 Ruler Support	1
193948	9 Multi Hole Wire Guide	1

Out of tray

Code	Description
99-193287	Threaded 3.2mm guide wire - 400mm - Sterile
172001	Flexible Reaming System Instruments Box, Complete
99-173281	Guide Wire with olive Ø 3x980mm
193265	Implant Template

CHIMAERA - Hip Fracture System, Extraction Instrument Tray

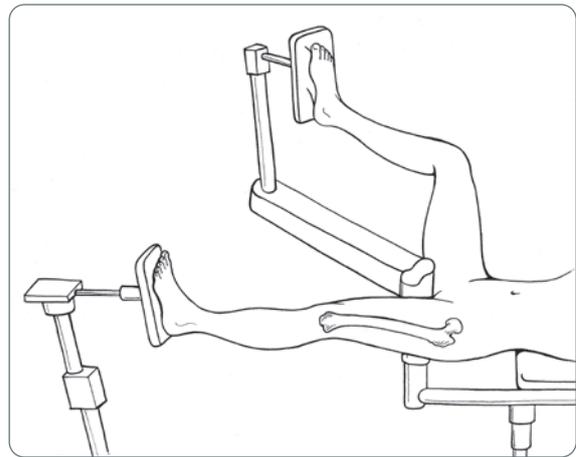
The instruments are available in a specific sterilisation tray (193991) that comprises:



Extraction Instrument Tray		
Code	Description	Q.ty
SMN173370	1 Slap Hammer	1
177380	2 Slotted Mallet	1
193325	3 6mm Hex Screwdriver	1
193271	4 6mm Hex Extension	1
193283	5 Lag Screwdriver	1
193280	6 Lag Screwdriver Retention Rod - Short	1
193293	7 Supplementary Screwdriver	1
193290	8 Supplementary Screwdriver Retention Rod - Short	1
193321	9 Distal Screwdriver - Short	1
193318	10 Distal Screwdriver Retention Rod - Short	1
17955	11 Universal Chuck With T-Handle	1
17978	12 Plier Cutter	1
177395	13 Needle Nose Vise Grips	1
193336	14 M8 Conical Mallet Adaptor	1
193337	15 Screw Extractor Size 4 - 9mm	1
91017	16 Universal Allen Wrench	1

FRACTURE REDUCTION IN THE FRONTAL PLANE

The patient is placed in a supine position on a fracture table. Initial reduction obtained by traction under image intensification. Traction and abduction are then adjusted if necessary, to achieve anatomic reduction.



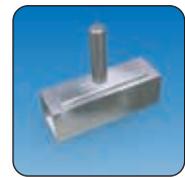
Fracture reduction in the sagittal plane with the "PORD™"

Any posterior sagging at the fracture site should now be corrected and maintained using the dedicated Posterior Reduction Device (PORD™). This device is easily attached to most fracture tables. (Please refer to PC PRD E0 for more information)

- 1 Slide the Clark Attachment on to the side rail of the fracture table. Insert the vertical post of the Box Bracket into the Clark Attachment from beneath and tighten the clamp on the post so that the bracket is held securely.
- 2 Assemble the PORD™ in the following way: Slide the Horizontal Bar through the Box Bracket with its curved portion facing the fracture table. This curved section is designed to allow for unobstructed multiple plane imaging using the C-arm of the Image Intensifier.
- 3 The Screw Jack of the Limb Support should be positioned in the housing at the end of the horizontal bar, with the nut under the radiolucent support. Turning the nut clockwise will then raise the support.



1



2

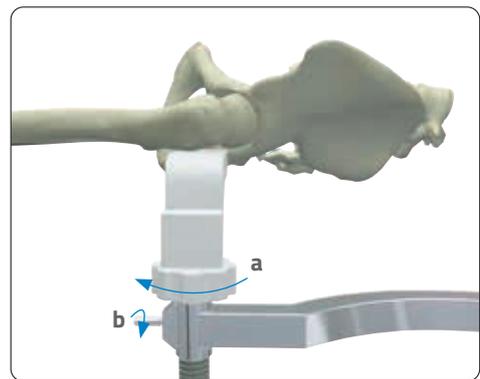
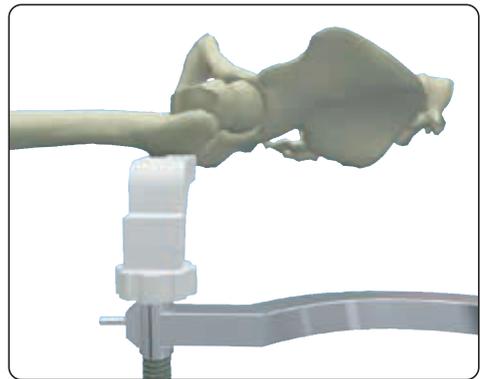
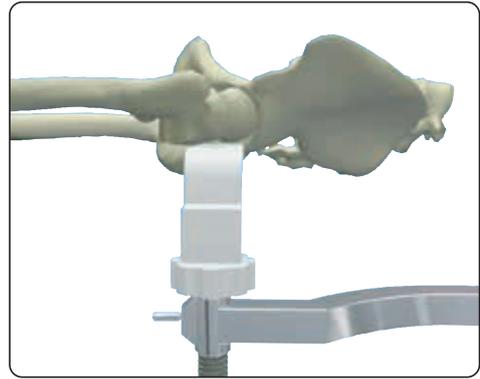
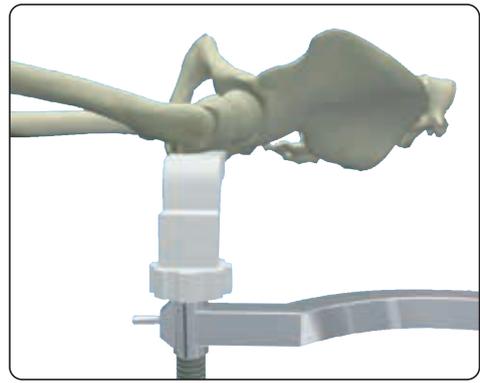


3



The Limb Support is positioned beneath that portion of the fracture that requires elevating. The correct position of the support is confirmed on the AP view (the shadow of the support can be seen). Using the lateral view, the limb support is raised by turning the nut **(a)** clockwise until exact posterior reduction has been achieved. The position of the Support is now maintained by tightening the Lug Screw on the housing **(b)**. There is tendency for the Limb Support to rotate when its position is being adjusted, due to the conical cross-section of the thigh. It should therefore be held firmly during this procedure, and while tightening the Lug Screw.

The PORD™ will now remain in position throughout surgery. Following use, the PORD™ should be washed thoroughly in a soapy solution and dried completely. It may be necessary to use forced air to dry out the housing of the Lug Screw. (Please refer to PC PRD E0 for more information).



PRE-OPERATIVE MANAGEMENT

X-Ray template

The X-Ray template can be used pre-operatively to select the optimal neck angle and the length of the lag and locking screws. This template shows the true size of the short nail, lag and locking screws at a magnification of 15% in anterior-posterior view.

The template must be positioned correctly on the pre-operative X-Ray. The measurements resulting from using the template must be verified intra-operatively to ensure appropriate implant selection.

ENTRY POINT OPENING

The patient is prepared and draped in the usual manner. A skin incision of about 2-3cm is made proximal to the tip of the greater trochanter, in line with the shaft of the proximal femur.

The exact entry point will vary with individual anatomy, and will generally be on the apex of the greater trochanter or slightly medial, halfway between its anterior and posterior extent.

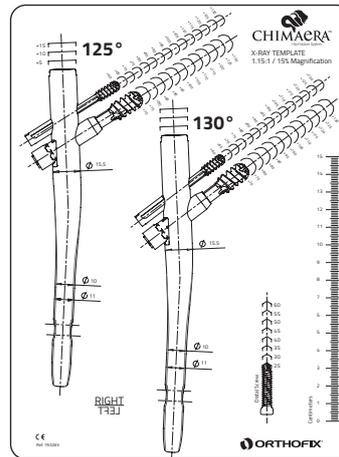
NOTE: The point of insertion should never be too medial in order to avoid injury to the Circumflex Femoral Artery. Using an Image Intensifier, on the AP view, the entry point should be the tip of the greater trochanter. On the lateral view, the entry point should be in the midpoint of the greater trochanter.

Option 1

Instrumentation	
Code	Description
193260	Canulated awl
193230	Entry reamer guide
193270	Entry Reamer
Out of tray	
99-173281	Guide Wire with olive \varnothing 3x980mm

The medullary canal can be opened by using the canulated awl (**Fig. 1**). The canulated awl is placed on the tip of the greater trochanter or slightly medial, and the entry point confirmed in both projections with Image Intensifier. The canulated awl is then advanced with rotational movements until its tip reaches the level of the lesser trochanter.

A 3x980mm guide wire with olive is inserted through the canulated awl into the medullary canal, and its position checked in both planes (**Fig. 2a-2b**). The canulated awl is removed leaving the guide wire in the desired position. Proceed with proximal reaming of the medullary canal (**Fig. 6, pag. 16**).



Code 193265

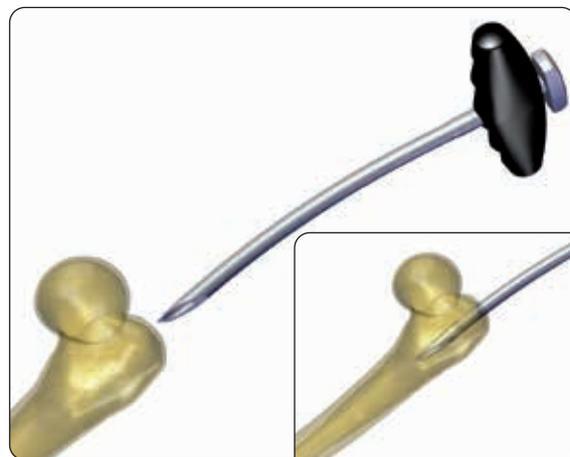


Fig. 1

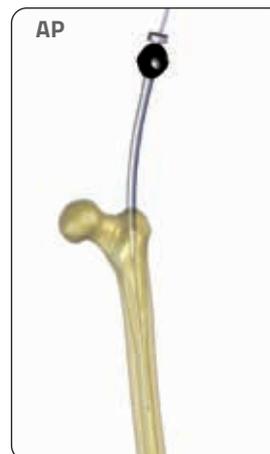


Fig. 2a

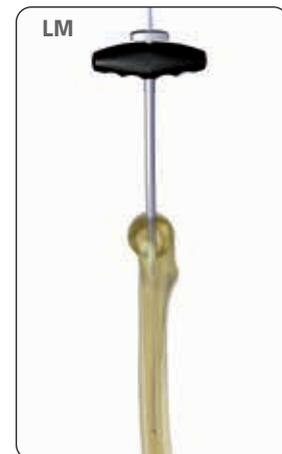


Fig. 2b

Option 2

Instrumentation

Code	Description
193230	Entry reamer guide
193948	Multi hole wire guide

Out of tray

193287	Threaded 3.2mm guide wire - 400mm
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A threaded 3.2mm guide is used to find the entry point. Its correct position is checked by Image Intensifier and the entry reamer guide inserted over the guide wire (**Fig. 3**).

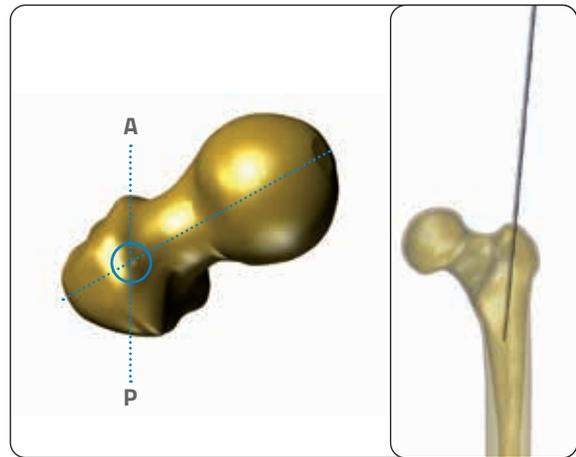


Fig. 3

If the threaded 3.2mm guide wire is not in the right position the use of the multihole wire guide is recommended (**Fig. 4**). This wire guide has 4 eccentric holes at different distances from the central hole and can help to insert a second guide wire in the optimal position. The multihole wire guide is inserted, through the central hole, on the incorrect guide wire.

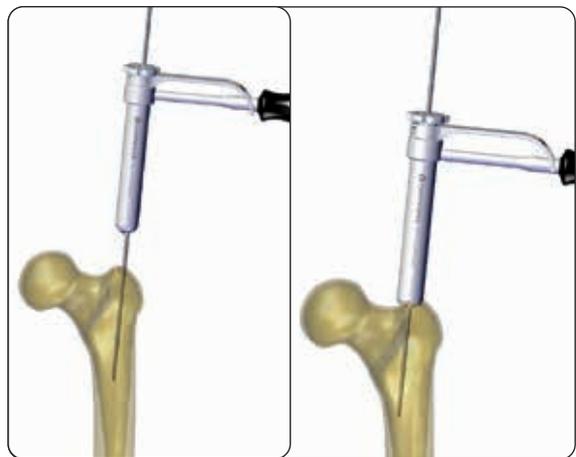


Fig. 4

Once the correct position of the second guide wire is selected by rotating the multihole wire guide crown, this is locked in place by pushing the handle over the entry reamer guide. The second guide wire is inserted and then the previous one removed (**Fig. 5**).

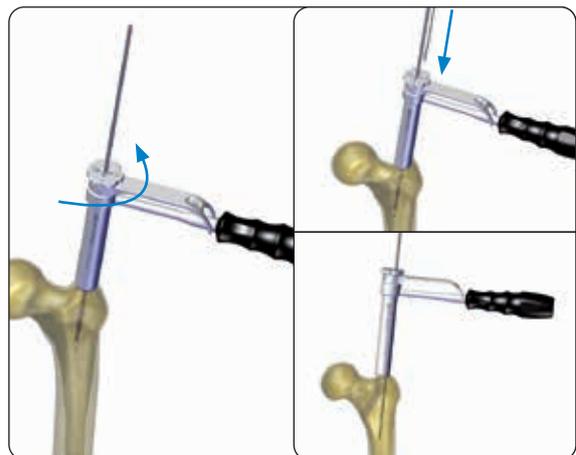


Fig. 5

Proximal Reaming of the medullary canal

With the entry reamer guide positioned at the level of the tip of the greater trochanter, the entry reamer is inserted over the guide wire and advanced under power using the Image Intensifier (**Fig. 6**).

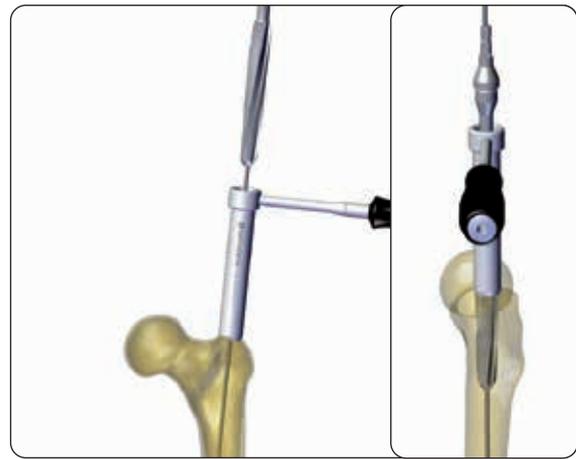


Fig. 6

The correct insertion amount for the entry reamer is reached when the entry reamer hits the entry reamer guide.

The correct insertion amount can be verified also by checking if the groove of the entry reamer is at the level of the greater trochanter (**Fig. 7**).

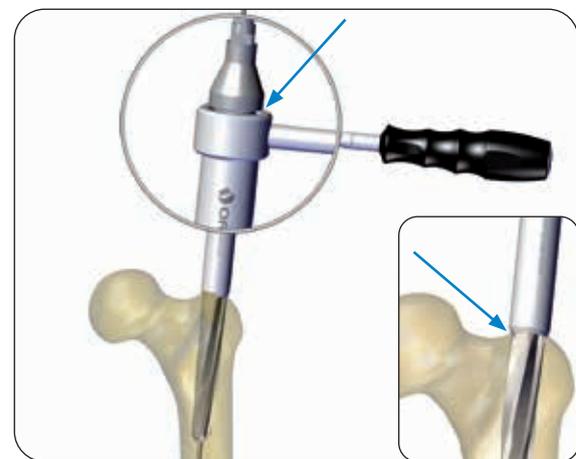


Fig. 7

Choose the optimum neck angle (Short and Long nail)

Instrumentation	
Code	Description
193275	Sizing guide
Out of tray	
193287	Threaded 3.2mm guide wire - 400mm

The sizing guide can be aligned over the femoral axis, starting from the tip of the greater trochanter, and used to determine the optimum proximal neck angle (125° or 130°), by positioning a guide wire over the corresponding marking on the sizing guide.

Choose the distal diameter of the nail.

The distal diameter of the nail can be chosen by using the template (**Fig. 8**).

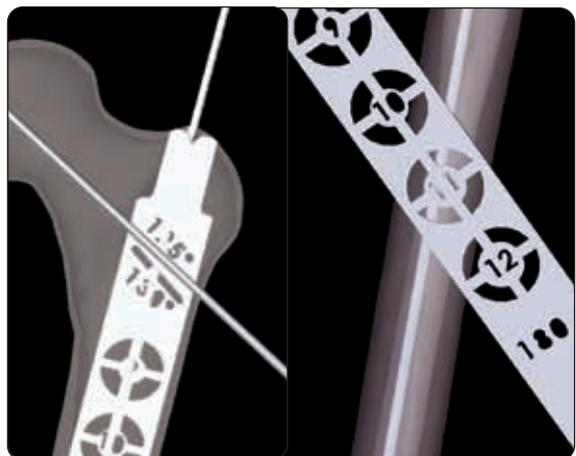


Fig. 8

LONG NAIL SELECTION

Instrumentation

Code	Description
193275	Sizing guide
193276	Long Nail Ruler
173276	Ruler Support

Out of tray

99-173281	Guide Wire with olive \varnothing 3x980mm
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The appropriate guide wire is inserted centrally in the medullary canal (**Fig. 9a**). This is ensured by driving it down until its tip sits in the subchondral bone exactly on the roof of the intercondylar notch, midway between the femoral condyles.

MEASUREMENT OF THE NAIL LENGTH

Option 1

With the ball tip of the guide wire at the level desired for the distal end of the nail, position the Ruler Support over the guide wire in the entry portal. The Nail Ruler is attached to the Ruler Support and the length of the nail read at the proximal tip of the guide wire (**Fig. 9b**).

NOTE: This only works with the standard 980mm guide wire.

Option 2

The sizing guide is positioned in line with the femoral axis (**Fig. 10**).

Position a guide wire over the sizing guide in correspondence with the optimum neck angle to obtain the correct position of the sizing guide. Correct position of the sizing guide can be checked with the Image Intensifier. The length of the required nail can be measured by reading the corresponding marking on the sizing guide, with the use of the Image Intensifier (**Fig. 11**).

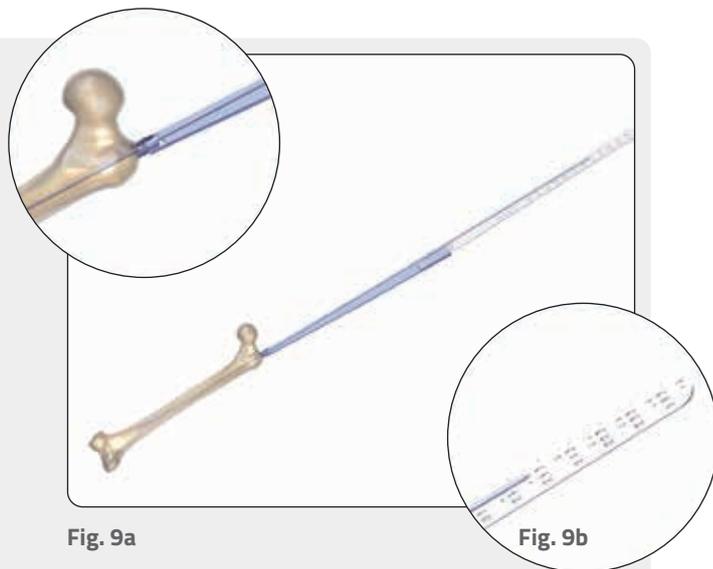


Fig. 9a

Fig. 9b



Fig. 10



Fig. 11

The diameter of the medullary canal can be checked directly from the sizing guide, determining the appropriate amount of reaming required (**Fig. 12**).



Fig. 12

Reaming

Instrumentation

Code	Description
193230	Entry reamer guide
193275	Sizing guide
Out of tray	
172001	Flexible Reaming System Instruments Box, Complete
99-173281	Guide Wire with olive \varnothing 3x980mm

The femoral canal has to be progressively reamed up to the diameter of 12.5-13mm (**Fig. 13**).

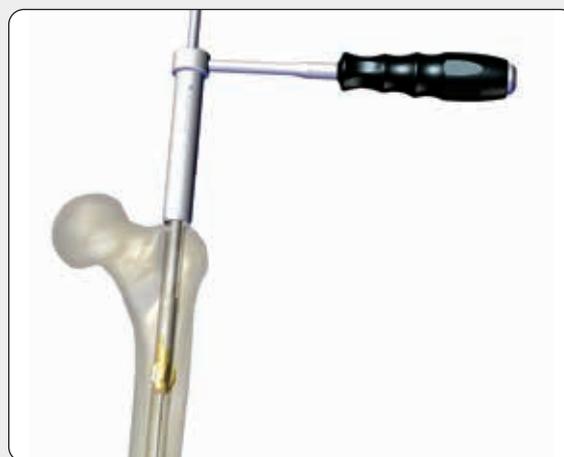


Fig. 13

A flexible reamer system should be used over the appropriate guide wire (**Fig. 14**).



Fig. 14

CHECKING THE PROXIMAL AND DISTAL LOCKING POSITIONING AND FUNCTION

Instrumentation

Code	Description
193100	Targeting Handle
193110	Locking Bolt
193325	6mm hex screwdriver
193231	Lag screw tissue guide
193970	La screw gradual reamer
193211	Distal tissue guide
193286	4.2mm distal drill bit - long
177380	Slotted Mallet



Fig. 15

Insert the locking mechanism into the handle, paying attention to the correct alignment (Fig. 16).



Fig. 16

The nail is attached to the Targeting Handle by aligning the tabs on the handle with the appropriate slots of the top on the nail (Fig. 17a).

The locking bolt is inserted on the top of the Targeting Handle and tightened firmly by using the 6mm hex screwdriver (black handle) (Fig. 17b).



Fig. 17a

The lag screw tissue guide is inserted over the appropriate hole of the Targeting Handle (125° or 130°). The lag screw gradual reamer should be advanced through the nail hole without impingement (**Fig. 18a**). In the same way the distal tissue guide must be inserted in the static hole of the Targeting Handle and the 4.2mm distal drill bit long advanced through the nail's oblong hole without impingement (**Fig. 18b**). This check is always recommended.



Fig. 18a

Fig. 18b

NAIL INSERTION

Instrumentation	
Code	Description
193115	Impaction rod
177380 1	Slotted Mallet
Out of tray	
SMN173370	Slap Hammer

The nail is inserted through the entry point to a desired depth (**Fig. 19a**). Attention should be paid to the position of the lag screw, which should be in the center of the femoral neck and head. If the supplementary lag screw is used, the lag screw could be below the center of the femoral neck and head. This is especially important in patients with a narrow femoral neck. If necessary, the impaction rod can be connected on top of the Targeting Handle and tightened by using the 6mm hex screwdriver for hammering with the slotted mallet (**Fig. 19b**). The condition of the medial/anterior cortex must be always checked prior to hammering.

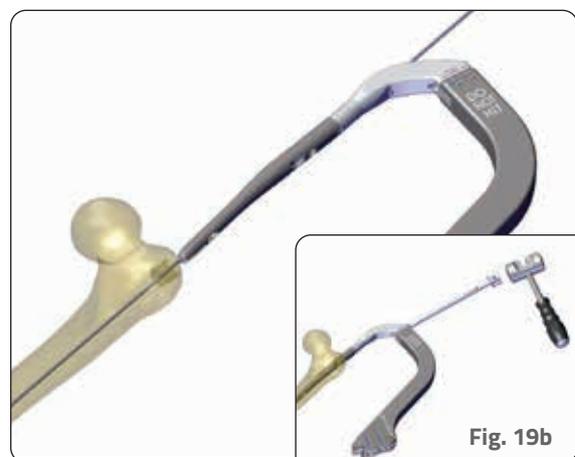


Fig. 19a

Fig. 19b

WARNING: Do not hammer on the Targeting Handle.

The correct position of the nail and its depth in the medullary canal must be checked with the Image Intensifier in both planes (AP, LM) (**Fig. 20**).



Fig. 20

If the nail is positioned too distal, connect the slap hammer to the impaction rod and gently hammer to position the nail more proximal (**Fig. 21**).



Fig. 21

Once the appropriate depth is reached, the nail position can be adjusted by carefully rotating the Targeting Handle of 5-10 degrees (anteversion of the femoral neck) in order to center the femoral neck with the lag screw hole (**Fig. 22**).

Remove the guide wire from the nail.

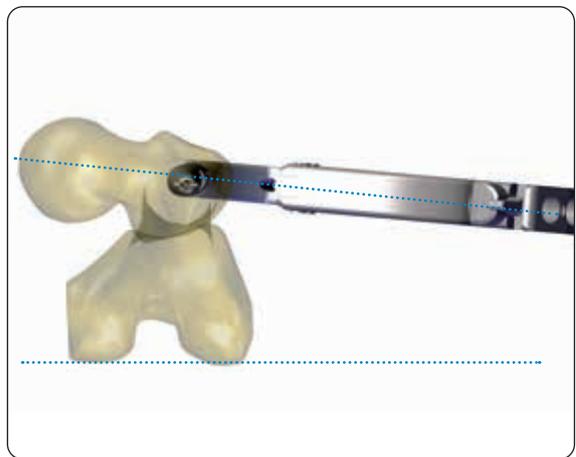


Fig. 22

PROXIMAL LOCKING

Instrumentation	
Code	Description
193231	Lag screw tissue guide
193232	Lag screw trocar
193973	4mm cortical drill
193287	Threaded 3.2mm guide wire - 400mm
193274	Screw sizing gauge
193970	Lag screw gradual reamer
193283	Lag screwdriver
193282	Lag screwdriver retention rod

The lag screw trocar is placed in the lag screw tissue guide, both inserted in the appropriate hole of the Targeting Handle (125° or 130°) and advanced to the skin. A 2cm incision is made at this point and the lag screw tissue guide is advanced down to the bone by rotating the trocar inside (**Fig. 23a**). The lag screw tissue guide is locked to the Targeting Handle by closing the locking knob (**Fig. 23b**).

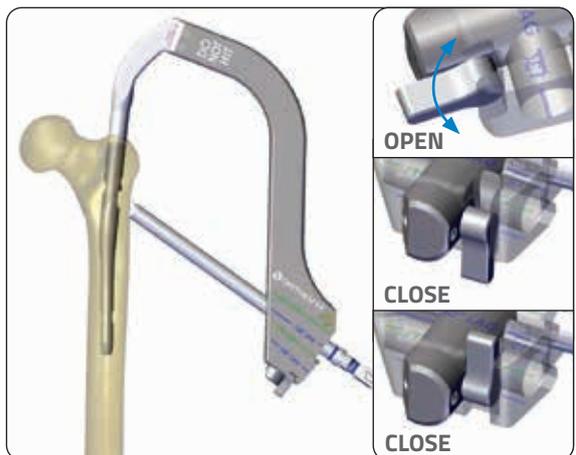


Fig. 23a

Fig. 23b

The lag screw trocar is removed (**Fig. 24a**) and the lateral cortex pre-drilled with the 4mm cortical drill until it is perfectly in contact with the Targeting Handle (**Fig. 24b**).

WARNING: Do not put pressure on drill when pre-drilling.

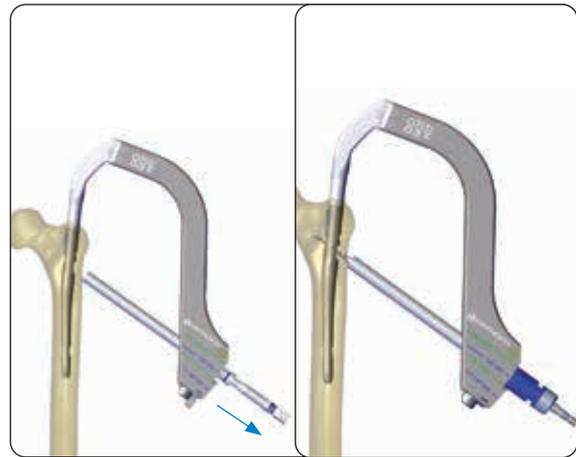


Fig. 24a

Fig. 24b

The 4mm cortical drill is removed and replaced by the lag screw trocar. To avoid incorrect insertion of the guide wire, the tip of the lag screw trocar must be correctly orientated to go flat against the bone. The marking on the lag screw trocar helps to confirm the correct position (**Fig. 25a**). A 3.2mm guide wire is inserted through the lag screw trocar with a power tool (**Fig. 25b**).

The position of the guide wire should be checked by Image Intensifier. **The tip of the wire should be at a distance of 5-10mm from the articular surface and it defines the final position of the screw (Fig. 26).**

NOTE: The use of a new 3.2mm guide wire is mandatory for this step; the 3.2mm guide wire used for the reaming of the medullary canal could be damaged or bent.



Fig. 25a



Fig. 25b

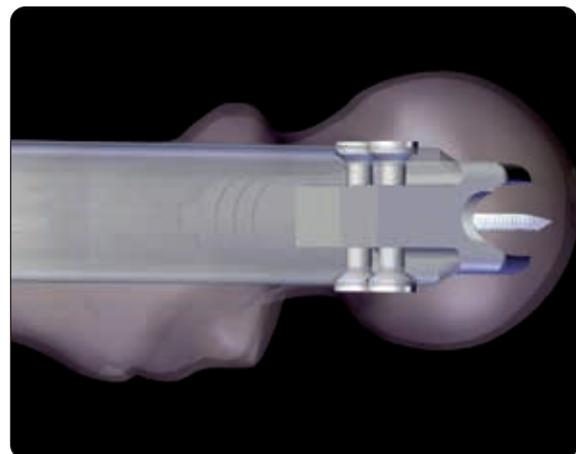


Fig. 26

The trocar is removed (**Fig. 27**).

WARNING: Attention must be paid to holding the Targeting Handle in position during removal of the cannulated trocar.



Fig. 27

To determine the length of the lag screw required, the sizing gauge is placed over the end of the guide wire (**Fig. 28a**).

The correct lag screw size is read on the scale of the sizing gauge at the level of the end of the guide wire (**Fig. 28b**). If the length measured is between two readings, the smaller reading should be selected.

NOTE: To determine correctly the Lag Screw length, the sizing gauge must be positioned perfectly in contact with the end of the Targeting Handle.



Fig. 28a

The lag screw gradual reamer should be set at the measured lag screw length (**Fig. 29**).

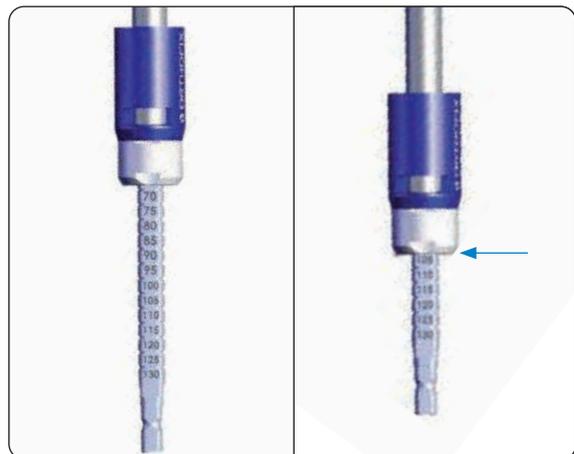


Fig. 29

The lag screw gradual reamer is drilled over the guide wire until it comes in contact with the Targeting Handle (**Fig. 30**).

WARNING: Check under Image Intensifier that the wire does not advance during drilling.

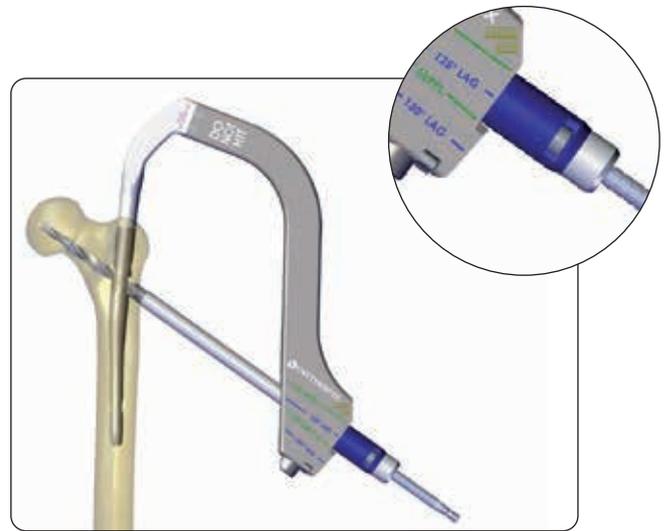


Fig. 30

Use the Guide Wire Pusher to keep the guide wire in place during the removal of the lag screw gradual reamer (**Fig. 31**).

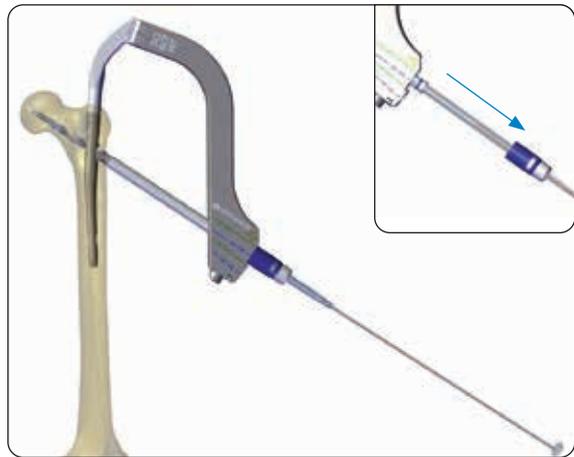


Fig. 31

PROCEDURE FOR INTRA-OPERATIVE ROTATIONAL STABILITY

Instrumentation

Code	Description
99-193287	Threaded 3.2mm guide wire - 400mm - Sterile
193221	Supplementary tissue guide
193222	Supplementary screw trocar

The supplementary tissue guide and supplementary trocar are inserted through the corresponding hole of the Targeting Handle (green mark) (**Fig. 32**). When the lag screw tissue guide is locked onto the Targeting Handle (by closing the locking knob), the supplementary screw tissue guide can still slide through the Targeting Handle and care must be taken that it does not fall out. For the correct insertion of the guide wire, the tip of the supplementary screw trocar must be correctly orientated to go flat against the bone. The marking on the supplementary screw trocar helps to confirm the correct position.



Fig. 32

The second guide wire is inserted through the supplementary trocar and drilled under Image Intensifier until it has passed the fracture line and stabilizes the fragments (**Fig. 33**).

WARNING: Make sure not to inadvertently advance the first guide wire when inserting the second guide wire.



Fig. 33

The supplementary trocar with its tissue guide and the lag screw trocar are then removed (**Fig. 34**).

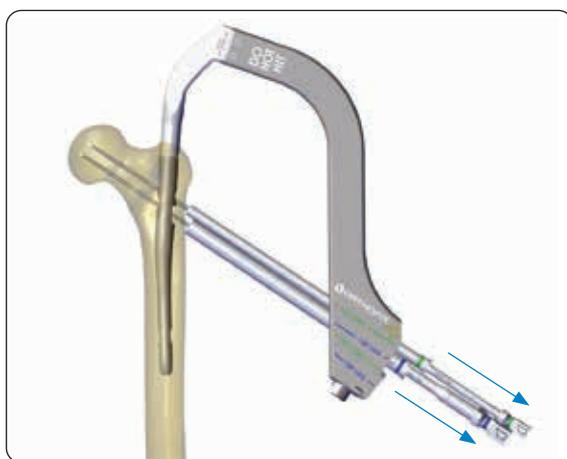


Fig. 34

If needed, remove the lag screw trocar and measure the length of the lag screw (**Fig. 35**), for additional details see **Fig. 28**, page 23.



Fig. 35

The lag screw gradual reamer should be set at the measured lag screw length (**Fig. 36**).

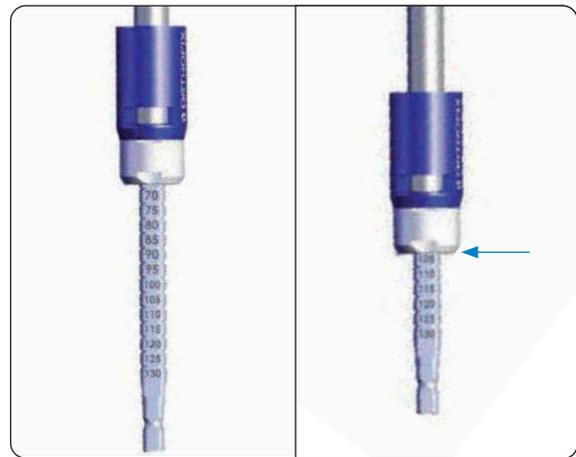


Fig. 36

WARNING: When drilling, the second guide wire must be kept away from the lag screw gradual reamer.

The lag screw gradual reamer is drilled until it comes in contact with the Targeting Handle (**Fig. 37**).

WARNING: Check under Image Intensifier that the wire does not advance during drilling.

Use the Guide Wire Pusher to keep the guide wire in place during the removal of the lag screw gradual reamer.



Fig. 37

LAG SCREW INSERTION

The lag screw must be removed from the packaging with the use of the lag screwdriver.

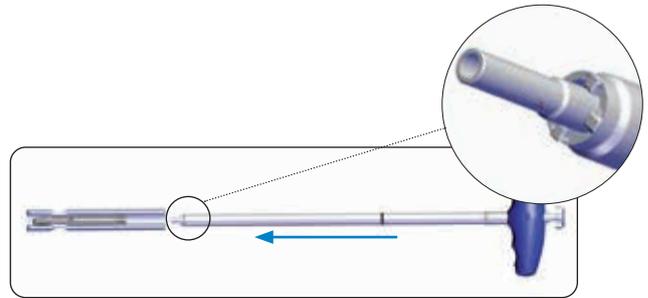


Fig. 38

Insert the tip of the lag screwdriver into the lag screw (**Fig. 38**), paying attention to the orientation of the teeth of both components (**Fig. 39**).



Fig. 39

The lag screw is secured to the lag screwdriver by rotating the blue internal screwdriver retention rod clockwise (**Fig. 40**).

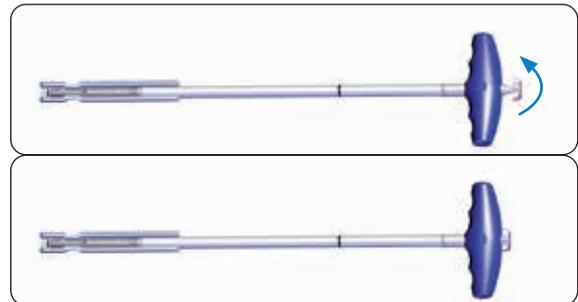


Fig. 40

The lag screw can now be removed from the packaging by tilting the screwdriver (**Fig. 41**).



Fig. 41

The lag screw is inserted into the bone by using the screwdriver through the tissue guide until the lag screw locks itself into the nail.

WARNING: Use the marking on the lag screwdriver as indication of advancement of the lag screw, but do not use it as a confirmation of full locking into the nail (**Fig. 42**). The lag screw is fully locked into the nail when further rotation of the lag screw is not possible.

NOTE: Fracture reduction must be confirmed prior to lag screw insertion.

If no compression is needed, remove the screwdriver by rotating counter-clockwise the blue internal screwdriver retention rod.

The locking knob is opened and the guide wire and the lag screw tissue guide are then removed.

WARNING: For the guide wire extraction the power drill must be reversed to avoid advancing the guide wire.

If needed, remove supplementary guide wire.

Compression of the sliding lag screw

Instrumentation	
Code	Description
193281	Lag screw compression rod

If additional compression is required the lag screwdriver and its retention rod are removed (**Fig. 43**), as well as the guide wire.

Remove the screwdriver retention rod from the screwdriver and insert the compression rod. Insert the lag screwdriver into the lag screw tissue guide and make sure the teeth of the screwdriver and the lag screw are aligned correctly. Secure the compression rod to the lag screw by rotating clockwise its small crown (**Fig. 44**).

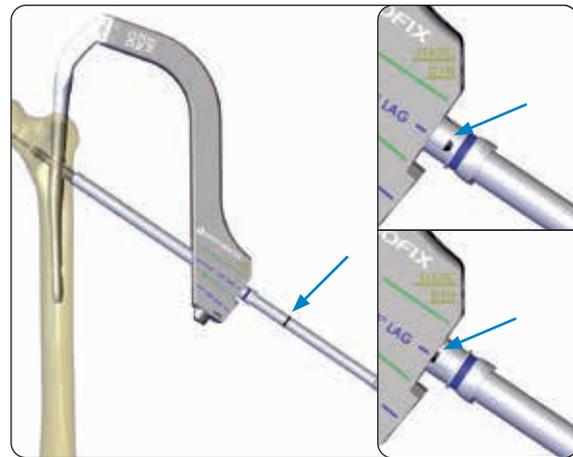


Fig. 42

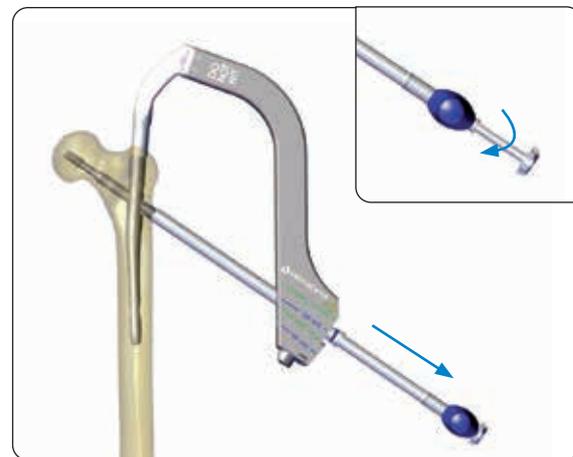


Fig. 43



Fig. 44

Compression can be achieved by rotating clockwise the big crown (**Fig. 45**). The compression amount should be checked by Image intensifier. A maximum compression of 17mm can be achieved.

NOTE: When using the universal Allen Wrench for rotating the knob clockwise, care must be taken in case of poor quality bone.

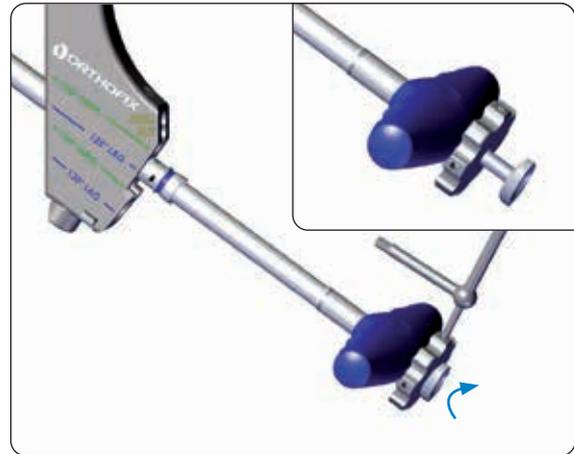


Fig. 45

INSERTION OF THE SUPPLEMENTARY LAG SCREW

Instrumentation

Code	Description
193221	Supplementary tissue guide
193222	Supplementary screw trocar
193287	Threaded 3.2mm guide wire - 400mm
193274	Screw sizing gauge
193971	Supplementary gradual drill bit
193293	Supplementary screwdriver
193292	Supplementary screwdriver retention rod

If additional rotational stability is needed, a supplementary screw can be used. The supplementary screw trocar is placed in the supplementary tissue guide, both inserted in the appropriate hole of the Targeting Handle (125° or 130°), and advanced to the skin. A 2cm incision is made at this point and the supplementary tissue guide is advanced down to the bone by rotating the trocar inside (**Fig. 46a**). The supplementary tissue guide is locked to the Targeting Handle by closing the locking knob (**Fig. 46b**).

The supplementary lag screw length can be determined according to the following two options:

Option 1. The supplementary lag screw length should be 10–15mm shorter than the lag screw used. If compression was performed, take the compression amount into consideration when choosing the supplementary screw or follow option 2.

Option 2. By using the sizing gauge:

- a 3.2mm guide wire is inserted through the supplementary trocar with a power tool. Its position should be checked by Image Intensifier (**Fig. 47a**).
- remove the trocar and place the sizing gauge over the end of the lag screw guide wire (**Fig. 47b**). The correct supplementary lag screw size is obtained by subtracting 5mm from the value read on the scale of the same sizing gauge used for measuring the main lag screw (**Fig. 47c**). If the length measured is between two readings, the smaller reading should be selected.

The supplementary gradual drill bit is set at the measured length (**Fig. 48**).

The supplementary screw trocar and the guide wire are removed and replaced with the supplementary gradual drill bit.

WARNING: Attention must be used to hold the Targeting Handle in position during removal of the cannulated trocar.

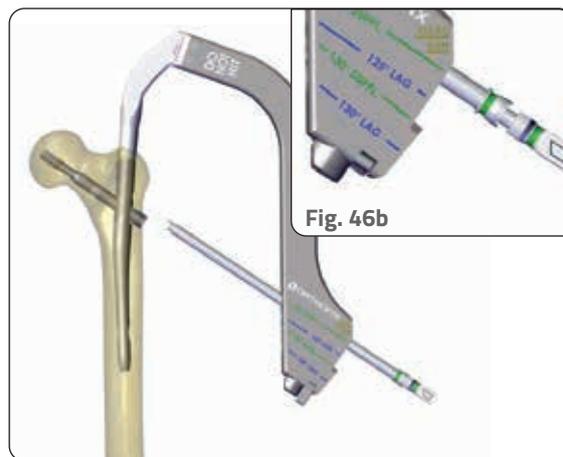


Fig. 46a



Fig. 47a

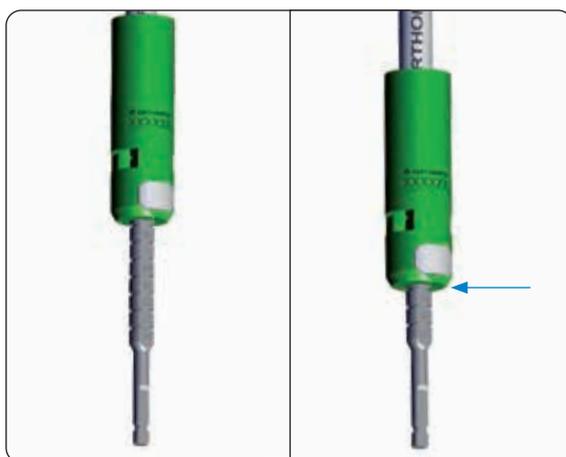


Fig. 48

The supplementary gradual drill bit is advanced, and its advancement is checked under Image Intensifier, through the supplementary tissue guide until it stops at the Targeting Handle (**Fig. 49**).

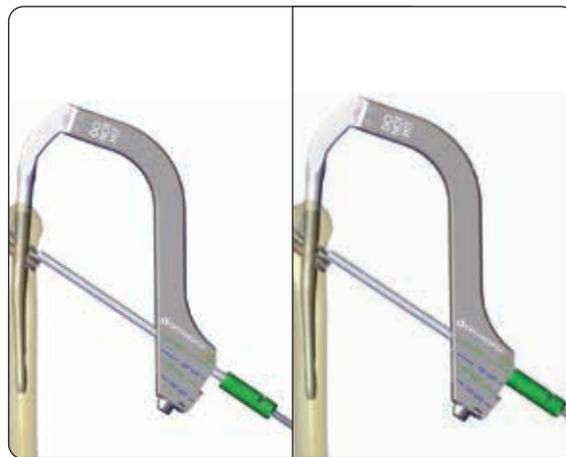


Fig. 49

The supplementary gradual drill bit is then removed. The supplementary lag screw is connected to the screwdriver (green handle) by rotating the retention rod and inserted into the bone (**Fig. 50**).

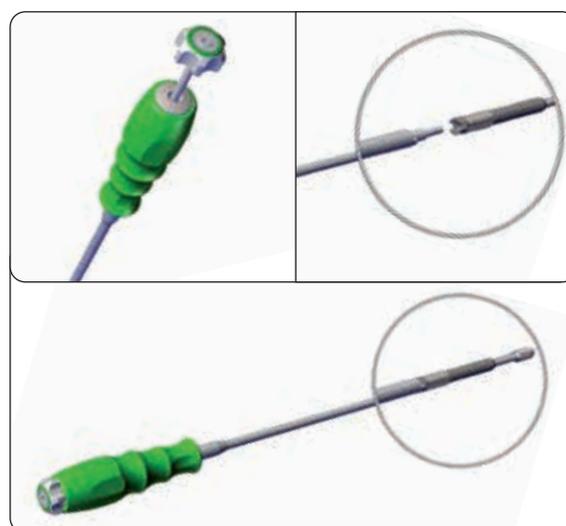


Fig. 50

The screw is fully locked into the nail when further rotation of the screwdriver is not possible. Please note that even if the supplementary screw is inserted correctly, some threads will remain out of the nail to grip the lateral cortex (**Fig. 51**).

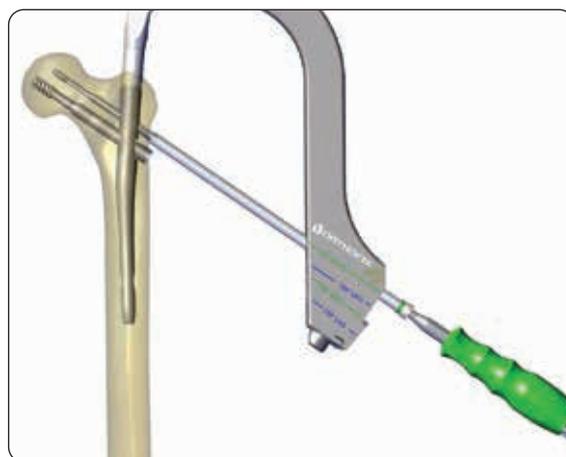


Fig. 51

DISTAL LOCKING (SHORT NAIL)

Instrumentation	
Code	Description
193320	Distal Screwdriver
193319	Distal Screwdriver Retention Rod
193211	Distal Tissue Guide
193212	Distal Trocar
193286	4,2mm Distal Drill Bit - Long

Two holes are provided on the Targeting Handle for distal locking. The proximal and distal holes correspond to static and dynamic locking respectively (**Fig. 52**). Dynamic locking should always be chosen in the presence of transverse subtrochanteric fractures.

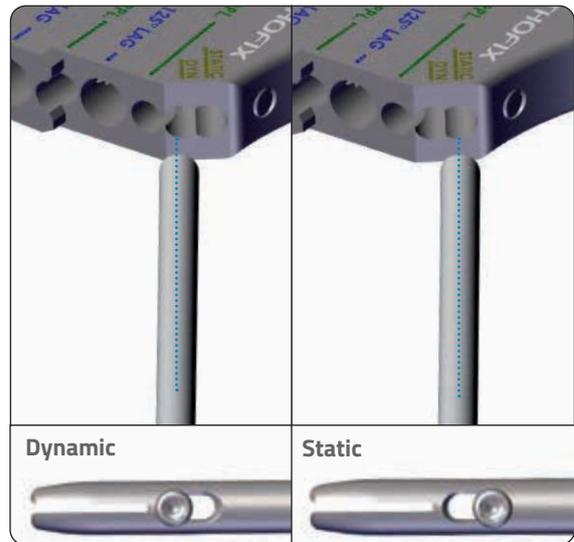


Fig. 52

The distal tissue guide is placed in the appropriate hole according to the fracture type, and used as a marker for the skin incision (**Fig. 53**).

Make sure to perform an adequate incision through the soft tissue to avoid deviation of the distal tissue guide.



Fig. 53

The distal tissue guide and the distal trocar are advanced down to the bone by rotating the trocar (**Fig. 54a**). The distal tissue guide is locked to the Targeting Handle by closing the locking knob (**Fig. 54b**).

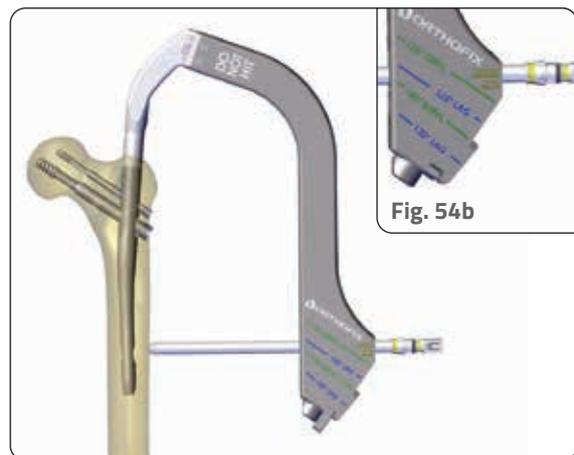


Fig. 54a

The 4.2mm distal drill bit-long is used to drill through the second cortex, under the Image Intensifier (**Fig. 55a**). The required screw size can be determined from the marking on the drill bit at the base of the distal trocar (**Fig. 55b**).

NOTE: It is important that the distal trocar is fully in contact with the bone for accurate measurement.

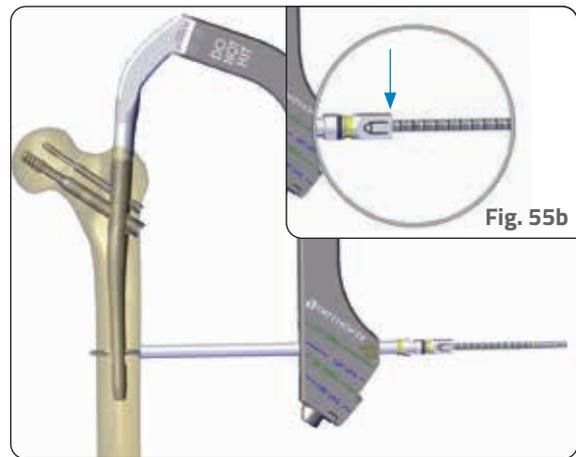


Fig. 55a

Remove the distal drill bit and the trocar prior to inserting the distal screw. The threaded locking screw is connected to the screwdriver (yellow handle) by rotating the retention rod and inserted into the bone (**Fig. 56**). Advance the distal screw in the bone until the lasermark on the screwdriver reaches the distal tissue guide (**Fig. 57**). The final position of the distal locking screw is checked with the Image Intensifier.

NOTE:

1. Any transverse force on the Targeting Handle, the Distal Tissue Guide and on the Distal Drill Bit may result in mismatching between the drill bit and the hole.
2. Overtightening of the screw should be avoided and the head of the screw should come just in contact with the cortex. Stop insertion when resistance is felt.

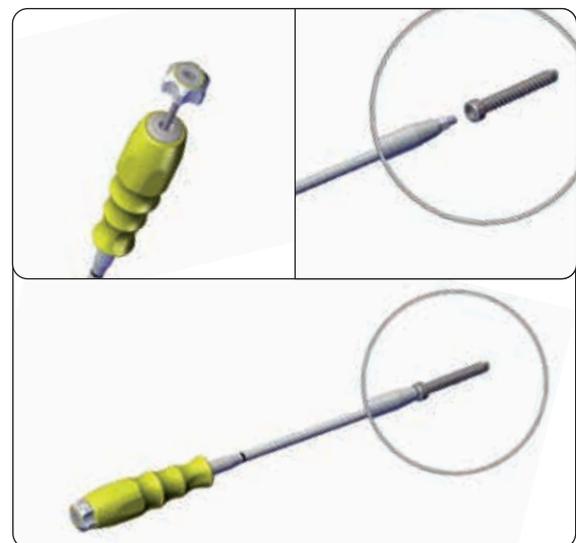


Fig. 56

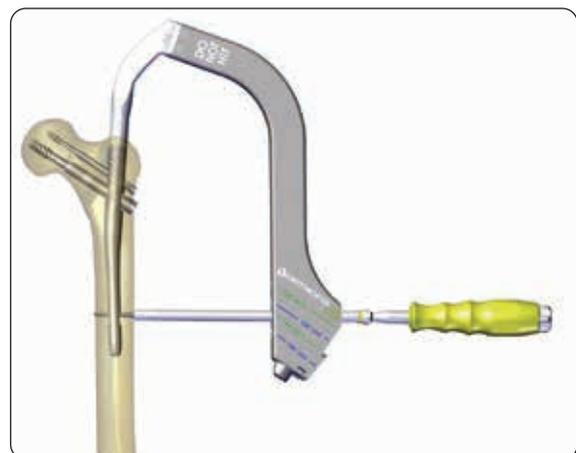


Fig. 57

DISTAL LOCKING (LONG NAIL)

Instrumentation

Code	Description
193321	Distal Screwdriver - Short
193318	Distal Screwdriver Retention Rod - Short
193285	4,2mm Distal Drill Bit - Short (2x)
193213	Distal Tissue Guide - Short
193277	Distal Screw Sizing Gauge

Distal locking configuration of long nails should be based on patient characteristics and fracture pattern, please see page 6 for more details.

Distal locking for long nails should be performed using the freehand technique with an Image Intensifier. The distal drill bit is advanced through the nail until it reaches the second cortex (**Fig. 58**). Bear in mind that the final screw position will be in correspondence with the tip of the distal drill bit short. The distal tissue guide is inserted over the distal drill bit until it is in contact with the bone (**Fig. 59a**). The correct size of the locking screw can be read on the scale of the distal drill bit protruding from the distal tissue guide (**Fig. 59b**).

NOTE: It is important that the distal tissue guide is fully in contact with the cortex for accurate measurement.

If two distal screws have to be inserted, the first distal drill bit short can be used as a reference for drilling the second hole (**Fig. 60**).

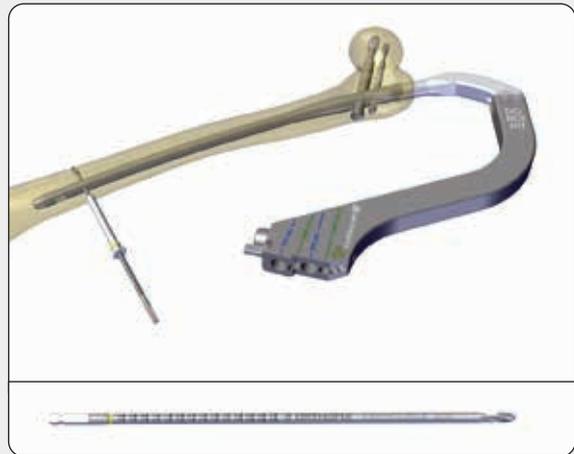


Fig. 58

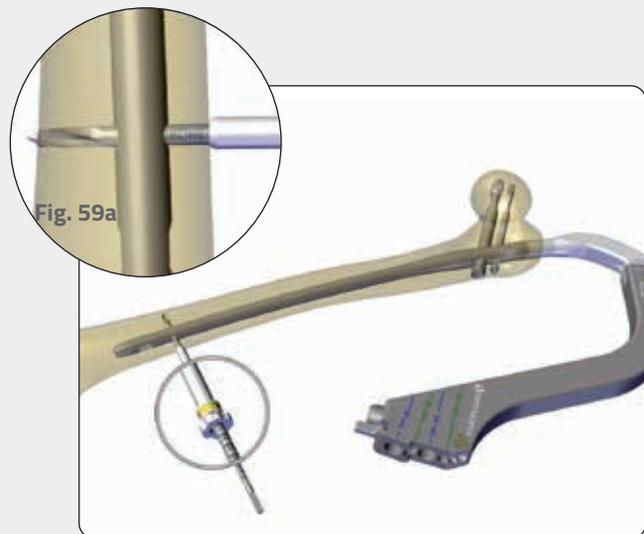


Fig. 59b



Fig. 60

ALTERNATIVE PROCEDURE

The Distal Screw Sizing Gauge is inserted into the Distal Tissue Guide Short. Once it has passed the second cortex, make sure the hook grasps the outside of the bone. The correct size of the locking screw can be read on the scale of the distal screw sizing gauge protruding from the distal tissue guide short (**Fig. 61**).

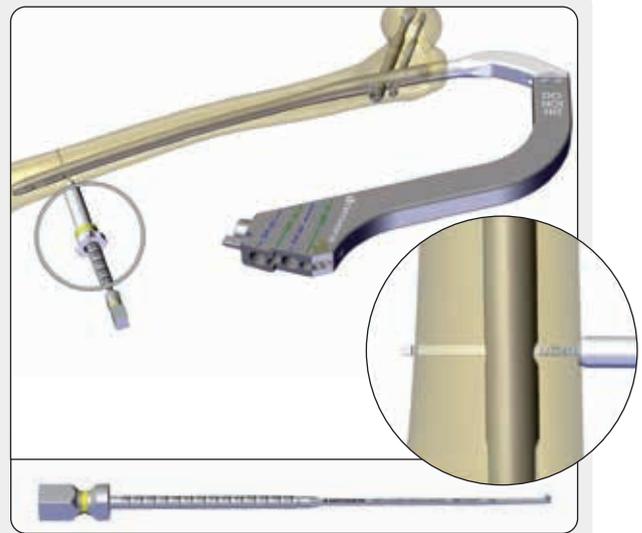


Fig. 61

The threaded locking screw is connected to the screwdriver (yellow handle) by rotating the retention rod and inserted into the bone (**Fig. 62**). Advance the distal screw in the bone (**Fig. 63a**). The final position of the distal locking screw is checked with the Image Intensifier.

NOTE: To avoid overtightening the screw, the screw head should come just into contact with the cortex; stop insertion when resistance is felt.

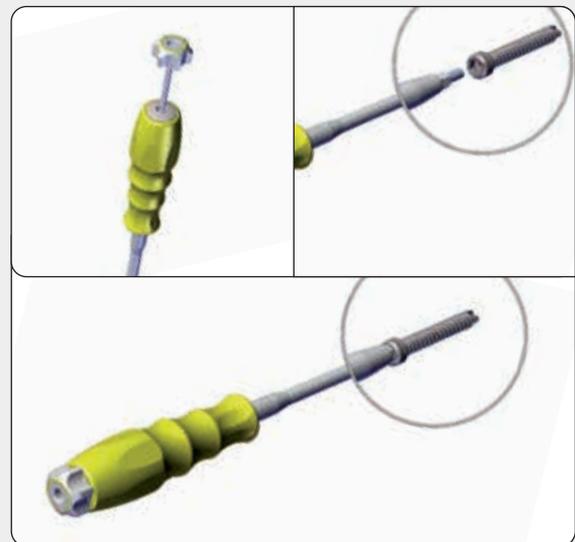


Fig. 62

Repeat steps described above also for the insertion of a second distal locking screw (**Fig. 63b**).



Fig. 63a

Fig. 63b

END CAP INSERTION

Instrumentation	
Code	Description
193325	6mm hex screwdriver
99-193287	Threaded 3.2mm guide wire - 400mm - Sterile
193271	6mm Hex extension

To avoid bone in-growth the use of end cap is advised.

The appropriate end cap can be selected by checking the marking lines at the top of the Targeting Handle (**Fig. 64**).

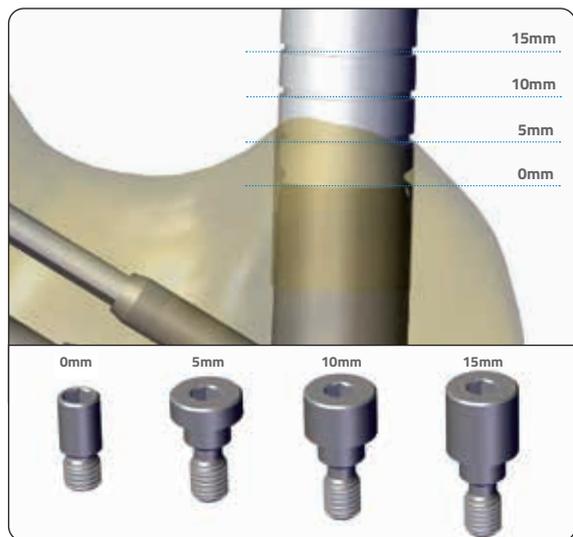


Fig. 64

Option 1.

Cap 0mm

The locking bolt is removed from the Targeting Handle by using the 6mm hex screwdriver (black handle) (**Fig. 65**).



Fig. 65

The end cap is inserted through the Targeting Handle and locked with the 6mm hex screwdriver (**Fig. 66**). The screwdriver and Targeting Handle are then removed.

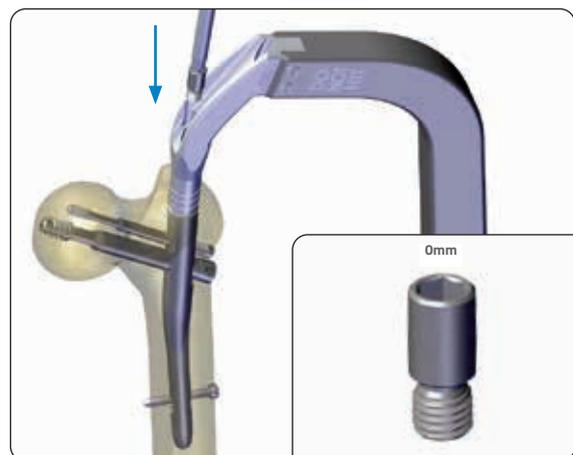


Fig. 66

Option 2.
Cap (0, 5, 10 and 15mm)

The locking bolt and Targeting Handle are removed, with the 6mm hex extension and a guide wire inserted through the top of the nail (Fig. 67).



Fig. 67

The end cap is passed over the guide wire and locked with the 6mm hex screwdriver (Fig. 68).



Fig. 68

POST-OPERATIVE MANAGEMENT

The patient may be allowed to sit up on the first post-operative day. In stable fractures with dynamic locking, full weight bearing should begin immediately. In less stable fractures, with static locking, the patient will generally regulate the amount of weight bearing, depending on the compaction and/or callus formation. In general, mobility and full weight bearing should be encouraged, under surgeon's discretion, as early as possible, within pain limits, according to the patient's specific local and general conditions.

NAIL EXTRACTION

Instrumentation	
Code	Description
SMN173370	Slap Hammer
177380	Slotted Mallet
193325	6Mm Hex Screwdriver
193271	6Mm Hex Extension
193283	Lag Screwdriver
193280	Lag Screwdriver Retention Rod - Short
193293	Supplementary Screwdriver
193290	Supplementary Screwdriver Retention Rod - Short
193321	Distal Screwdriver - Short
193318	Distal Screwdriver Retention Rod - Short
17955	Universal Chuck With T-Handle
17978	Plier Cutter
177395	Needle Nose Vise Grips
193336	M8 Conical Mallet Adaptor
193337	Screw Extractor Size 4 - 9mm
91017	Universal Allen Wrench

A 3.2mm guide wire is inserted into the nail end cap (**Fig. 69**) and the plier cutter (17978) is used to clean bone ingrowth on the proximal end of the nail (**Fig. 70**). If no nail end cap was placed, remove the bone ingrowth with standard instruments.



Fig. 69



Fig. 70

Option 1

Remove the guide wire after removal of the bone ingrowth. The 6mm hex extension is used to remove the nail end cap (**Fig. 71**).



Fig. 71

Option 2

With the guide wire still in place, the 6mm hex screwdriver is used to remove the nail end cap (**Fig. 72**).



Fig. 72

The M8 conical adaptor is inserted into the nail with a clockwise motion (**Fig. 73**). If needed, a guide wire can be used.

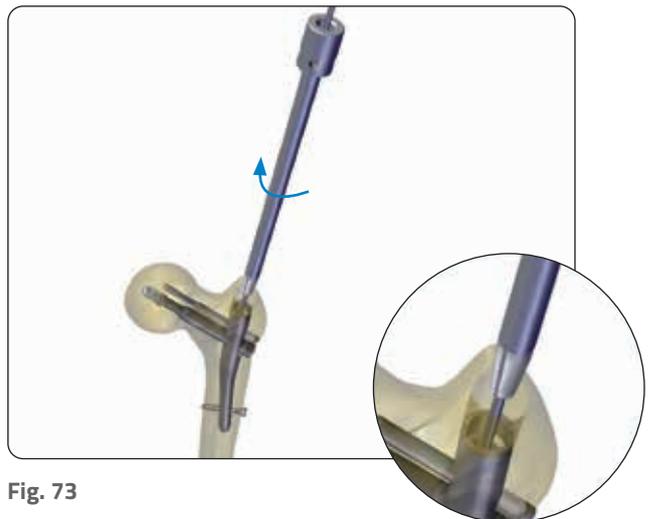


Fig. 73

To ensure a sufficient anchoring of the M8 conical mallet adaptor into the nail, remove the guide wire and tighten it with an Allen Wrench (**Fig. 74**). Do not hammer the M8 conical adaptor.



Fig. 74

DISTAL SCREW REMOVAL

Make a small incision at the position of the distal screw(s) and remove the bone ingrowth. Use the distal screwdriver short with the distal screwdriver short retention rod to extract the distal screw(s) (**Fig. 75**). If needed, use the needle nose vise grips to remove the distal screw(s).

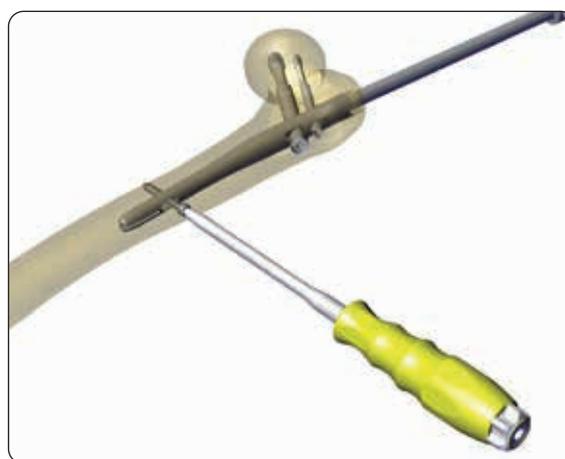


Fig. 75

If a long nail was implanted, make sure to remove all distal screws prior to nail extraction (**Fig. 76**).



Fig. 76

SUPPLEMENTARY LAG SCREW REMOVAL

Option 1

The supplementary retention rod short is inserted into the supplementary screwdriver (**Fig. 77**).



Fig. 77

An incision is made at the position of the lag screw and, if present, the supplementary lag screw. Remove the bone ingrowth and remove the supplementary lag screw with the supplementary lag screwdriver (**Fig. 78-79**).

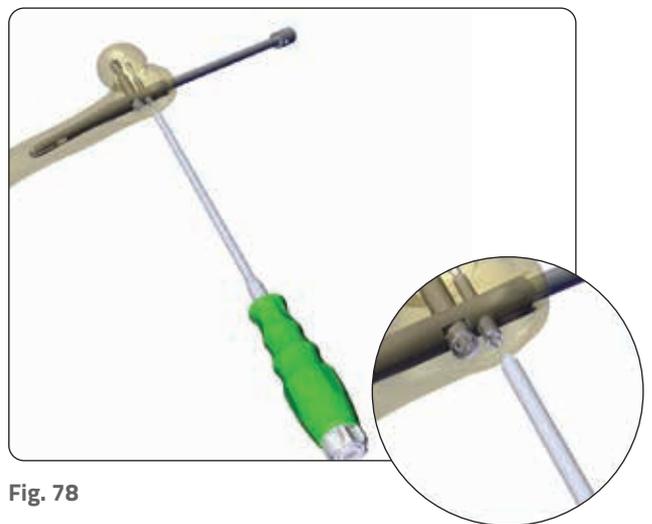


Fig. 78

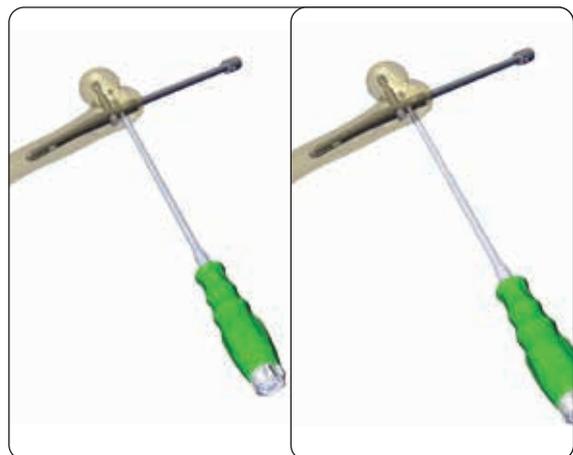


Fig. 79

Option 2

Alternatively, the screw extractor size 4-9mm can be used. Use it with the universal chuck with t-handle to connect to the supplementary lag screw with a counter-clockwise movement. Continue with the counter-clockwise movement until the supplementary lag screw is removed (**Fig. 80**).



Fig. 80

Option 3

If needed, a needle nose vise grip can be used to remove the supplementary lag screw (**Fig. 81**).

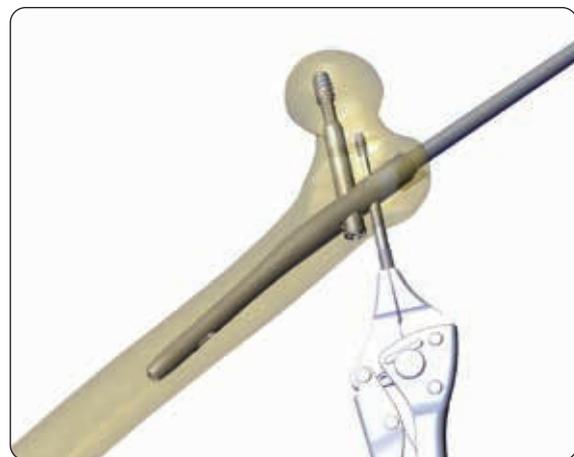


Fig. 81

LAG SCREW REMOVAL

Option 1

For the removal of the lag screw, the lag screwdriver retention rod short is inserted in the lag screwdriver (**Fig. 82**).



Fig. 82

Remove the lag screw with a counter-clockwise movement. A guide wire can aid in this (Fig. 83-84).

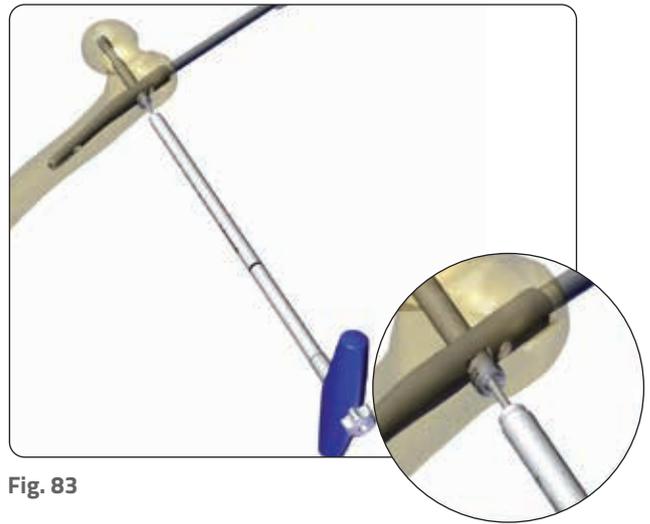


Fig. 83



Fig. 84

Option 2

Alternatively, the screw extractor size 4-9mm can be used. Use it with the universal chuck with t-handle to connect to the lag screw with a counter-clockwise movement. Continue with the counter-clockwise movement until the lag screw is removed (Fig. 85).

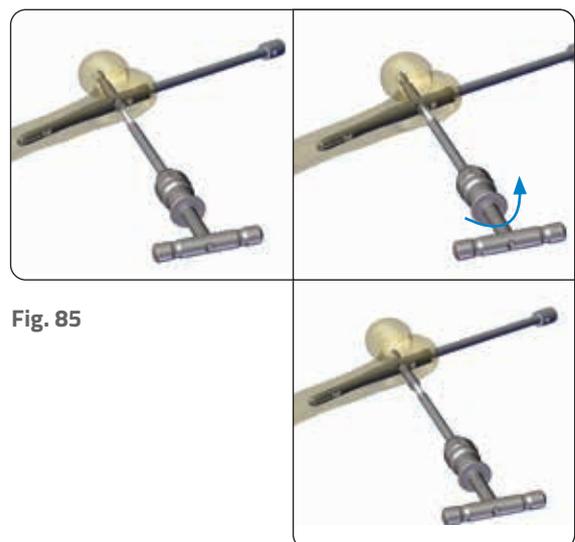


Fig. 85

NAIL REMOVAL

Option 1

Once all screws have been removed, the nail can be extracted. A slap hammer can be connected to the M8 conical adaptor (**Fig. 86**).



Fig. 86

Option 2

Alternatively, a slotted mallet can be used to extract the nail (**Fig. 87**).



Fig. 87

MRI SAFETY INFORMATION

The Orthofix Chimaera Hip Fracture System - Trochanteric Nailing System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Orthofix Chimaera Hip Fracture System - Trochanteric Nailing System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Please refer to the "Instructions for Use" supplied with the product for specific information on indications for use, contraindications, warnings, precautions, possible adverse events, MRI (Magnetic Resonance Imaging) safety information and sterilization.

Electronic Instructions for use available at the website <http://ifu.orthofix.it>

Electronic Instructions for use - Minimum requirements for consultation:

- Internet connection (56 Kbit/s)
- Device capable to visualize PDF (ISO/IEC 32000-1) files
- Disk space: 50 Mbytes

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e-mail: customerservice@orthofix.it

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