



Hip



Femur

stryker®

Distal Targeting System

Gamma3 Long Nail R1.5 /
T2 Recon Nail R1.5

Operative Technique



Hip, Femur Fractures

Distal Targeting Device

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This publication sets forth detailed recommended procedures for using Stryker Osteosynthesis devices and instruments.

It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when required. Stryker offers a comprehensive training program for the use of Distal Targeting System. Please contact your Stryker representatives and complete the "Distal Targeting Training Module" prior to first surgery.

All non-sterile devices must be cleaned and sterilized before use. Follow the instructions provided in our reprocessing guide (L24002000). Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions.

See package insert for a complete list of potential adverse effects, contraindications, warnings and precautions. The surgeon must discuss all relevant risks, including the finite lifetime of the implants, with the patient, when necessary.

Warning:

Fixation Screws:

Stryker Osteosynthesis bone screws are not approved or intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

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Introduction

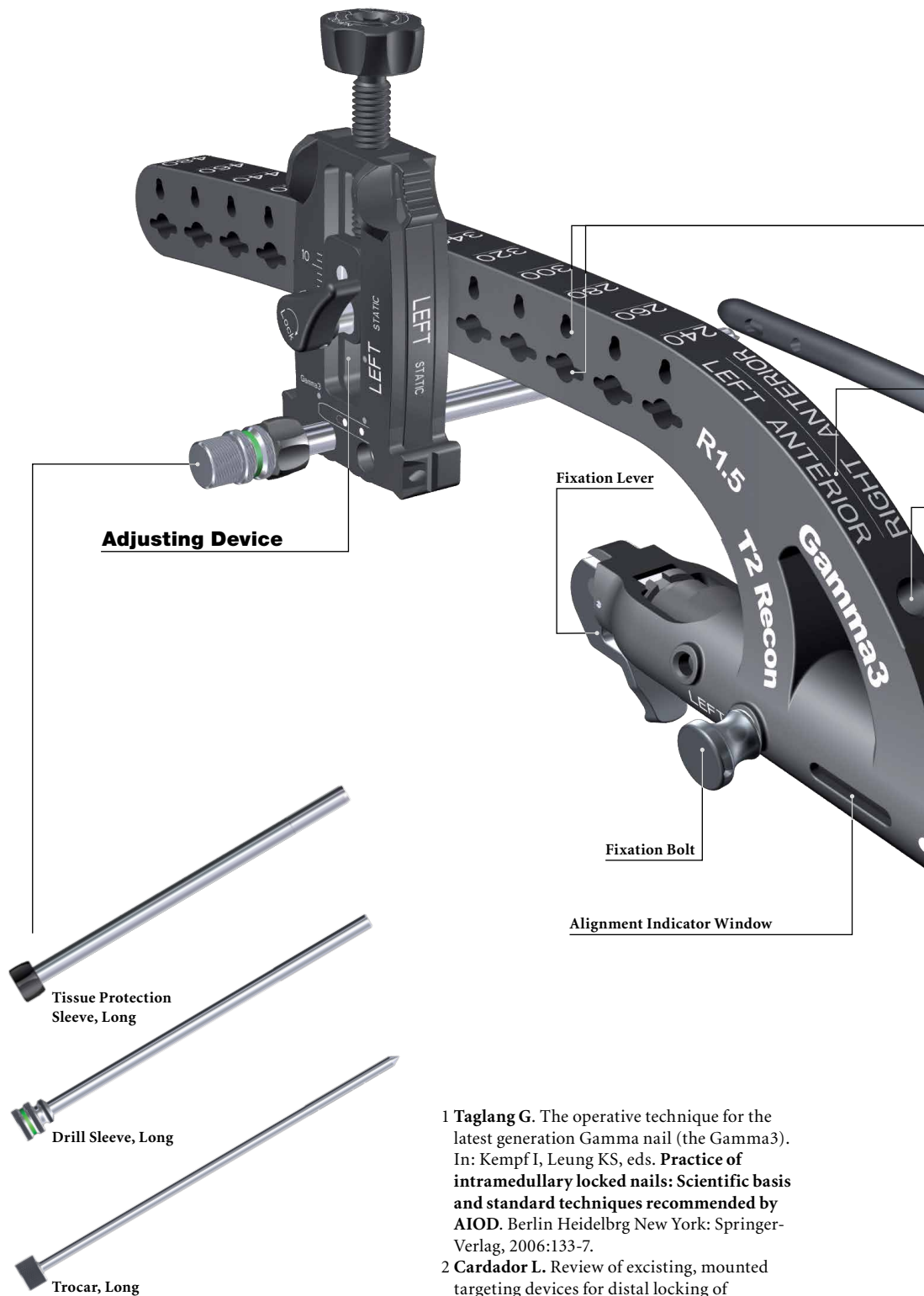
Distal Targeting System for Gamma3 Long Nails and T2 Recon Nails

In response to the request of surgeons around the world, Stryker Osteosynthesis has created a dedicated Distal Targeting System.

Without using the Distal Targeting System, the placement of the distal locking screws is done primarily by a variety of freehand techniques, using conventional or radiolucent drilling devices. These methods may result in repeated drilling, repeated X-Ray adjustment, which may require longer exposure as well as higher potential for mis-drilling².

Compatibility

Using the Distal Targeting System is recommended when distal locking screws are required for the Gamma3 Long Nail System and the T2 Recon Nail System.



1 Taglang G. The operative technique for the latest generation Gamma nail (the Gamma3). In: Kempf I, Leung KS, eds. **Practice of intramedullary locked nails: Scientific basis and standard techniques recommended by AIOD**. Berlin Heidelberg New York: Springer-Verlag, 2006:133-7.

2 Cardador L. Review of existing, mounted targeting devices for distal locking of intramedullary nails. In: Kempf I, Leung KS, eds. **Practice of intramedullary locked nails: Scientific basis and standard techniques recommended by AIOD**. Berlin Heidelberg New York: Springer-Verlag, 2006:265-70.

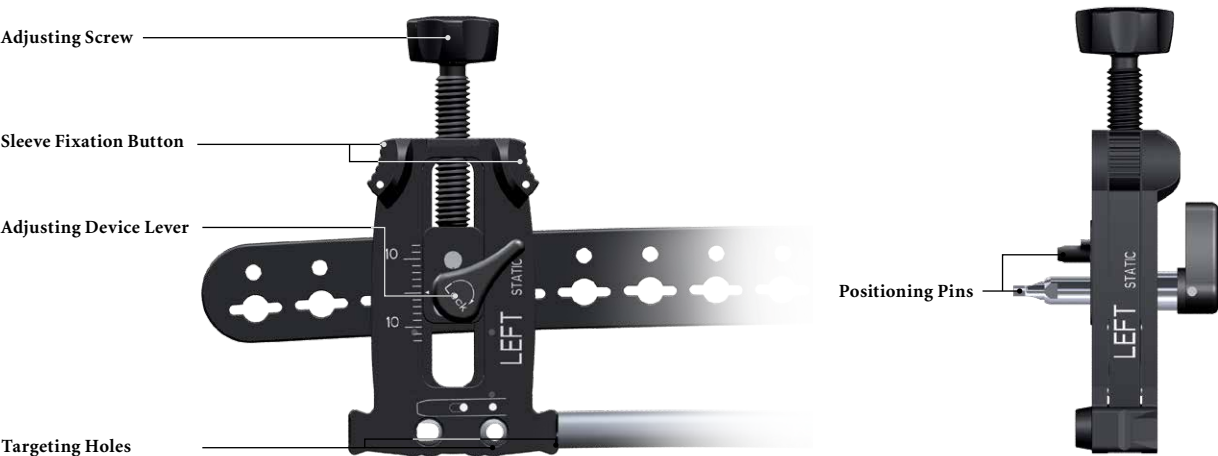
Introduction

Distal Targeting System Components

The major components of the device are made of carbon fiber material, providing radiolucency under the C-Arm imaging and stiffness for the distal locking procedure.



Adjusting Device



Operative Technique

Distal Targeting Device Calibration

This operative technique does not describe the entire surgical procedure. For full Gamma3 Long Nail R1.5 and for full T2 Recon Nail R1.5 surgical procedures, please refer to the dedicated operative techniques. It is important to perform Distal Targeting Device calibration prior to the nail insertion. Then, follow the operative technique until “Distal Screw Locking”.

The following description of the surgical technique is using a Gamma3 Long Nail R1.5 / LEFT and will describe distal locking in a static locking configuration.

Calibration

Calibration of the Distal Targeting Device with the selected Long Nail is an important step. Doing so ensures that the Drill Sleeve assembly in the Distal Targeting Device will align with the same axis as the distal locking holes.

A Calibration Stand has been designed into the instrument tray to stabilize the system. The Distal Targeting Device calibration must be performed prior to the nail insertion and requires the following 2 steps:

Step 1

Assembly and Length Adjustment

Step 2

Anterior/Posterior Adjustment



Fig. 1

Static Locking



Fig. 2

Dynamic Locking



Fig. 3

Secondary Dynamization

Distal Locking Options

The Gamma3 Long Nails and T2 Recon Nails offer the following three options for distal locking.

Static Locking (Fig. 1):

One screw is placed in the round hole and the other is placed in the proximal part of the oblong hole. This creates the configuration referred to as “Static Locking” – requires two screws.

Dynamic Locking (Fig. 2):

Locking in the distal part of the oblong hole creates a “Dynamic Locking” mechanism – requires only one screw.

Static/Dynamic Locking (Fig. 3):

One screw is placed in the distal part of the oblong hole and the other in the round hole. If dynamization is required after a period of time, the screw that was placed in the round hole has to be removed. This creates a configuration referred to as “Secondary Dynamization” and allows the fragments to dynamize 5mm in axial direction, while stabilizing against rotation – requires two screws initially.

Warning:

Distal Targeting System R1.5 version is designed for Gamma3 Long Nails R1.5 or T2 Recon Nails R1.5. Make sure to have the R1.5 nails prior to the surgery.

Note:

The calibration can be performed with and without the stand. In order to stabilize the T2 Recon Nails for calibration, the Adapter for DTS calibration is available as an option. Please check with your local representative regarding availability.

Operative Technique

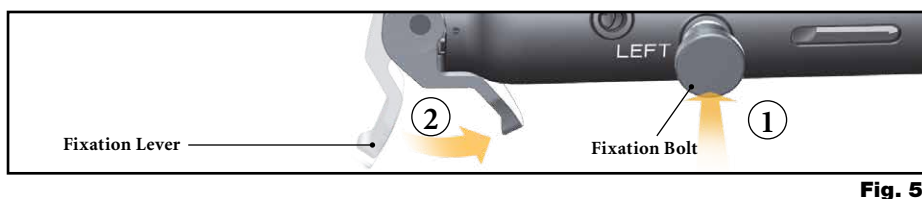
Distal Targeting Device Calibration

Assembly and Length Adjustment

Slide the Distal Targeting Arm R1.5 (REF 1320-5315) onto the Gamma3 Targeting Arm until a click is felt (Fig. 4). The white line must be seen through the Alignment Indicator Window for correct assembly (Fig. 4a).



Insert the Fixation Bolt completely (Fig. 5 ①) from the lateral opening until a click is felt. The Fixation Lever must then be securely locked (Fig. 5 ②).



Note:

Be sure that the Distal Targeting Arm is positioned anteriorly to the chosen nail (Fig. 5a).

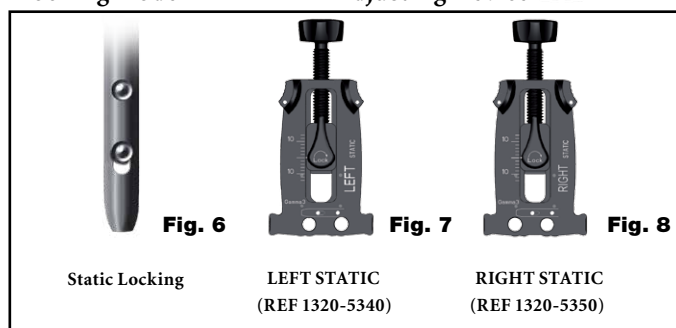


The appropriate Adjusting Device should then be selected according to the locking mode.

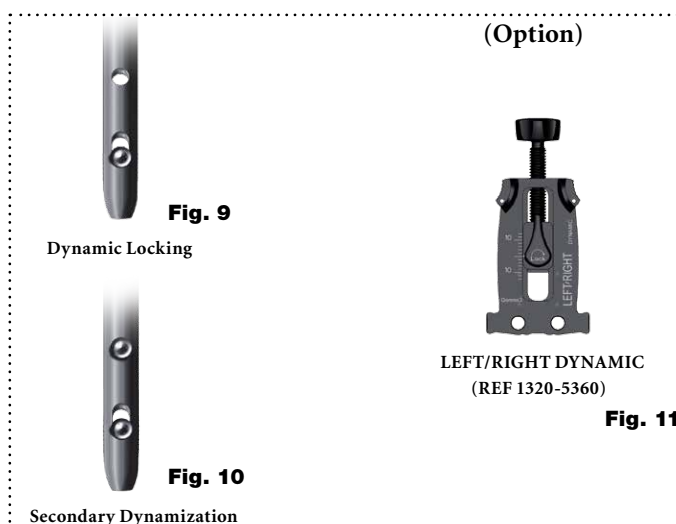
- If the locking configuration is static/static (Fig. 6) for the left side, select the Adjusting Device, LEFT STATIC (REF 1320-5340) (Fig. 7).
- If the locking configuration is static/static (Fig. 6) for right side, select the Adjusting Device, RIGHT STATIC (REF 1320-5350) (Fig. 8).

Locking mode

Adjusting Device



- For static/dynamic locking options for both left and right sides, the Adjusting Device, LEFT/RIGHT DYNAMIC (REF 1320-5360) (Fig. 11) is available as an option. The below two locking options are possible.
 - 1) "Dynamic Locking" mechanism – requires only one screw in the distal part of the oblong hole (Fig. 9).
 - 2) "Static/Dynamic" mechanism - one screw is placed in the distal part of the oblong hole and the other in the round hole. If dynamization is required after a period of time, the screw that was placed in the round hole has to be removed to allow "Secondary Dynamization" (Fig. 10).



Operative Technique

Distal Targeting Device Calibration

The length of the chosen nail determines where the Adjusting Device should be attached. The selected Adjusting Device (in this case we chose a left Gamma3 Long Nail R1.5 - 360mm to be locked in a static/static configuration) is placed into the Pin Positioning Holes that match the length of the selected nail. The corresponding nail lengths are marked on the Distal Targeting Arm (Fig. 12).

Insert the Positioning Pins into the Pin Positioning Holes, then lock the Adjusting Device Lever by turning it in a clockwise direction (Fig. 13).

Note:

Be certain that both Positioning Pins are placed into two Pin Positioning Holes and securely locked with the Adjusting Device Lever.

The following procedure describes **Gamma3 Long Nail R1.5, left with Static/Static Locking.**

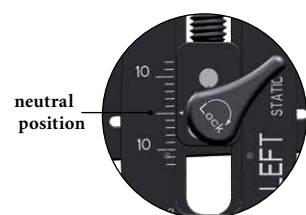


Fig. 14

Before continuing, make sure your Adjusting Device is positioned in neutral position as shown (Fig. 14). Position can be moved upwards (posteriorly) and downwards (anteriorly) by turning the Adjusting Screw. Take the Tissue Protection Sleeve and the Drill Sleeve, then mount the assembly into the proximal targeting hole of the Adjusting Device (Fig. 15 ②) by pressing the Sleeve Fixation Button on the Adjustment Device (Fig. 15 ①). The Adjusting Device has Sleeve Fixation Buttons providing friction lock of the sleeve assembly. The sleeve has a free movement when the Button is pressed and locks when the Button is released.

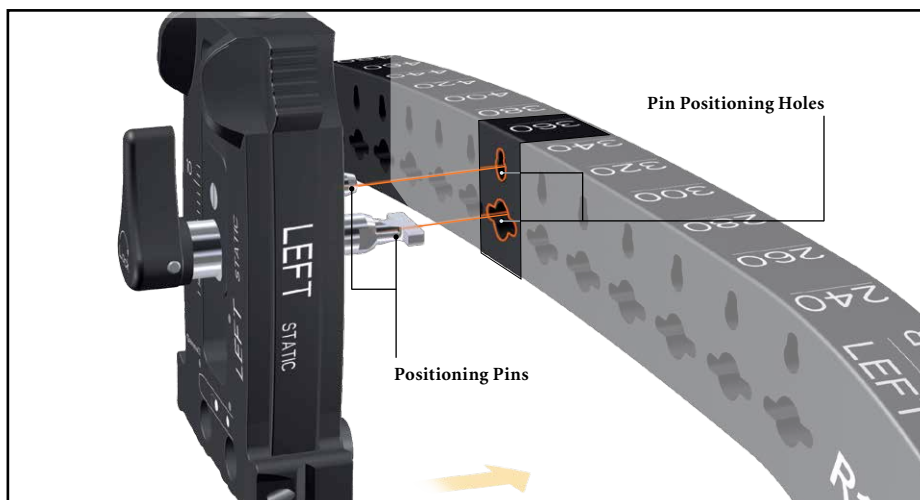


Fig. 12

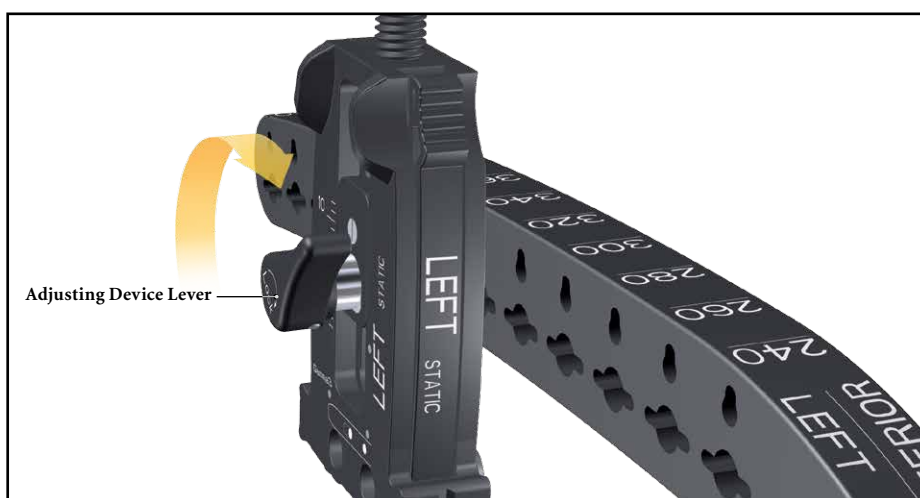


Fig. 13

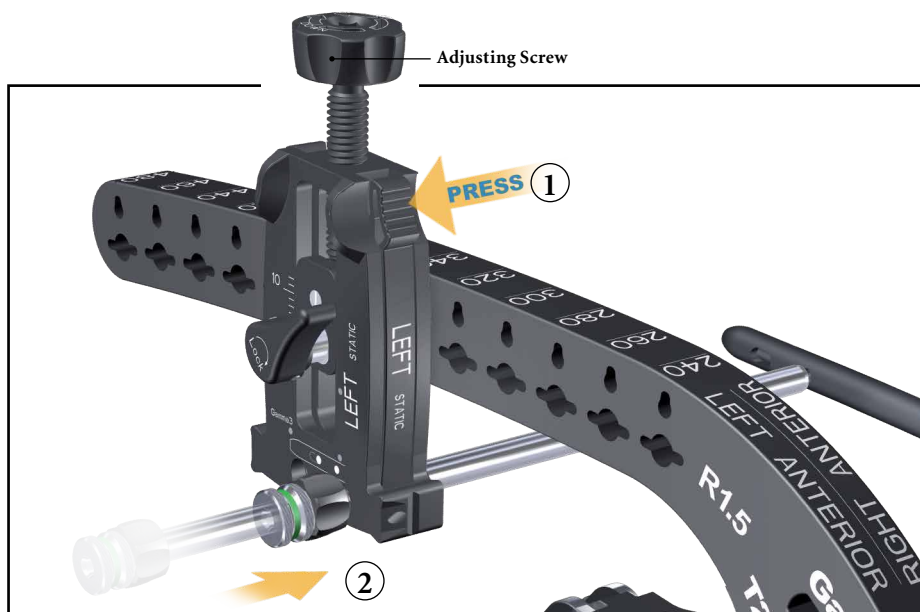


Fig. 15

Operative Technique

Distal Targeting Device Calibration

A/P Adjustment

The Instrument Tray has a dedicated Calibration Stand. Place the assembled device onto this by placing it onto the metal pin as shown (Fig. 16a).

Then, look through the Tissue Protection Sleeve and adjust the targeting position by turning the Adjusting Screw until the holes of the sleeve and the nail appear coaxial.

Now make final adjustments with the drill, passing it through the most proximal hole in the nail as shown. The drill must go through the nail hole smoothly and easily. If not, turn the Adjusting Screw until passage through the hole in the nail is easy and smooth (Fig. 16b).

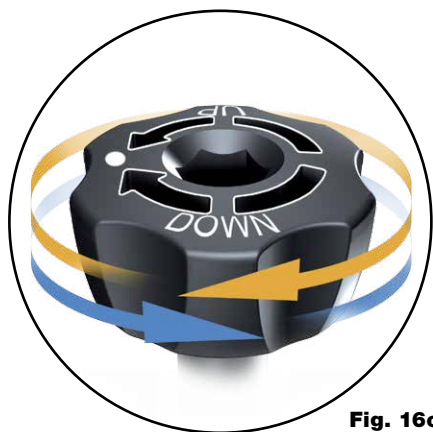


Fig. 16c

By turning the Adjusting Screw, the sleeve moves anteriorly or posteriorly (Fig. 16c).

- Clockwise = posterior direction (DOWN)
- Counterclockwise = anterior direction (UP)

Note:

The calibration can be performed with and without the stand. In order to stabilize the T2 Recon Nails for calibration, the Adapter for DTS calibration is available as an option. Please check with your local representative regarding availability.

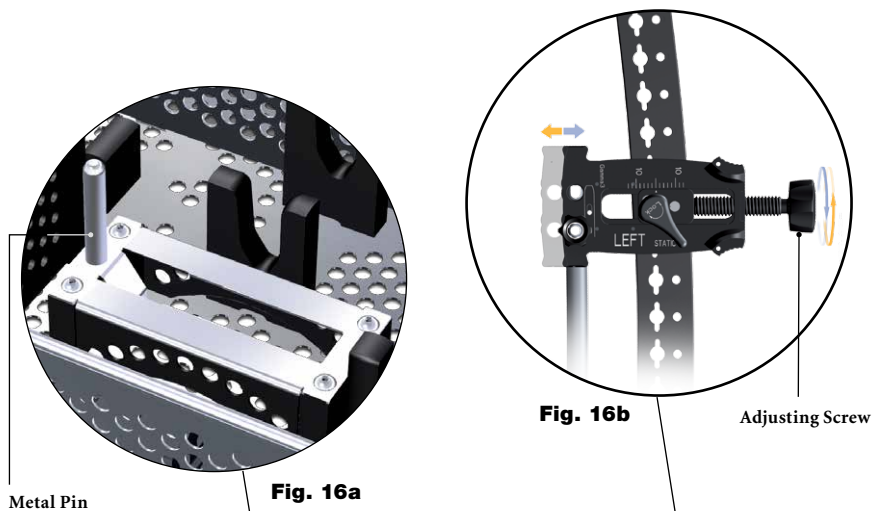


Fig. 16b

Adjusting Screw

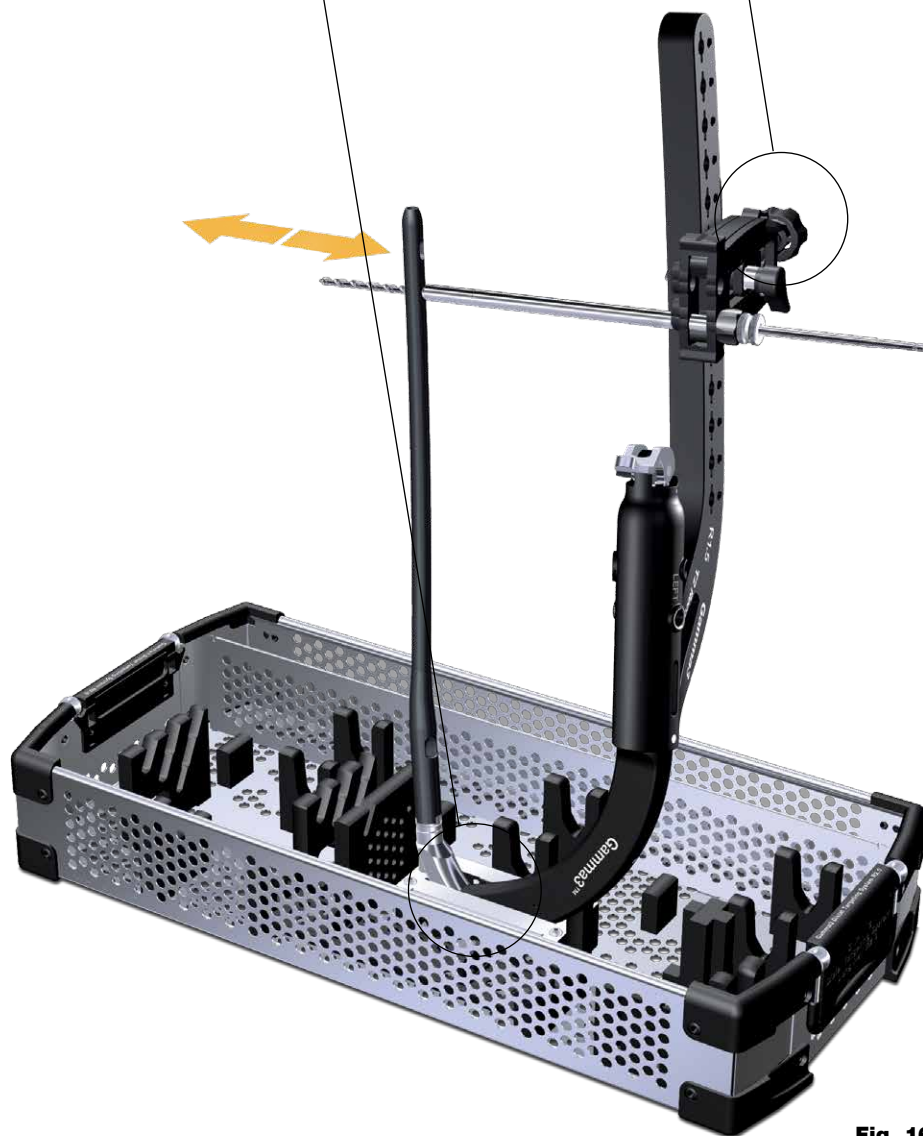


Fig. 16

Operative Technique – Distal Guided Locking

After the calibration steps have been completed, remove the Sleeve Assembly (Fig. 17 ②) by pressing the Sleeve Fixation Button (Fig. 17 ①) of the Adjusting Device.

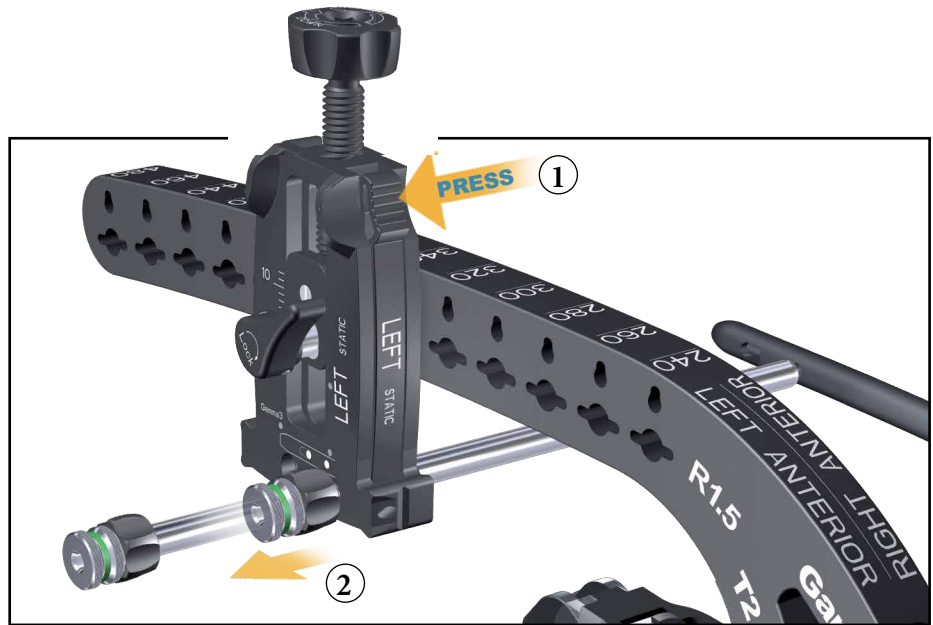


Fig. 17

Release the Fixation Lever (Fig. 18a ①), then remove the Fixation Bolt (Fig. 18a ②) and place it into the Fixation Bolt Storage Pocket (Fig. 18b ③).

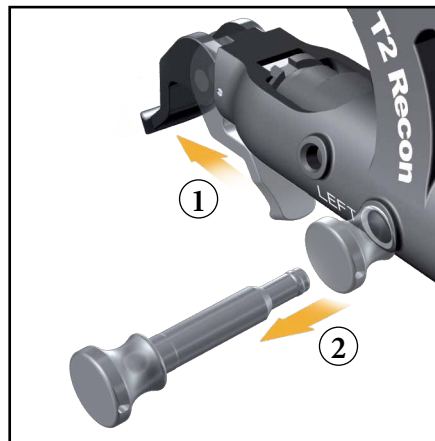


Fig. 18a



Fig. 18b

Detach the Distal Target Arm assembly and store it back onto the Tray (Fig. 19).

Warning:

Keep the Adjusting Device in its position as calibrated. Do NOT remove the Adjusting Device from the Distal Targeting Arm at this point.

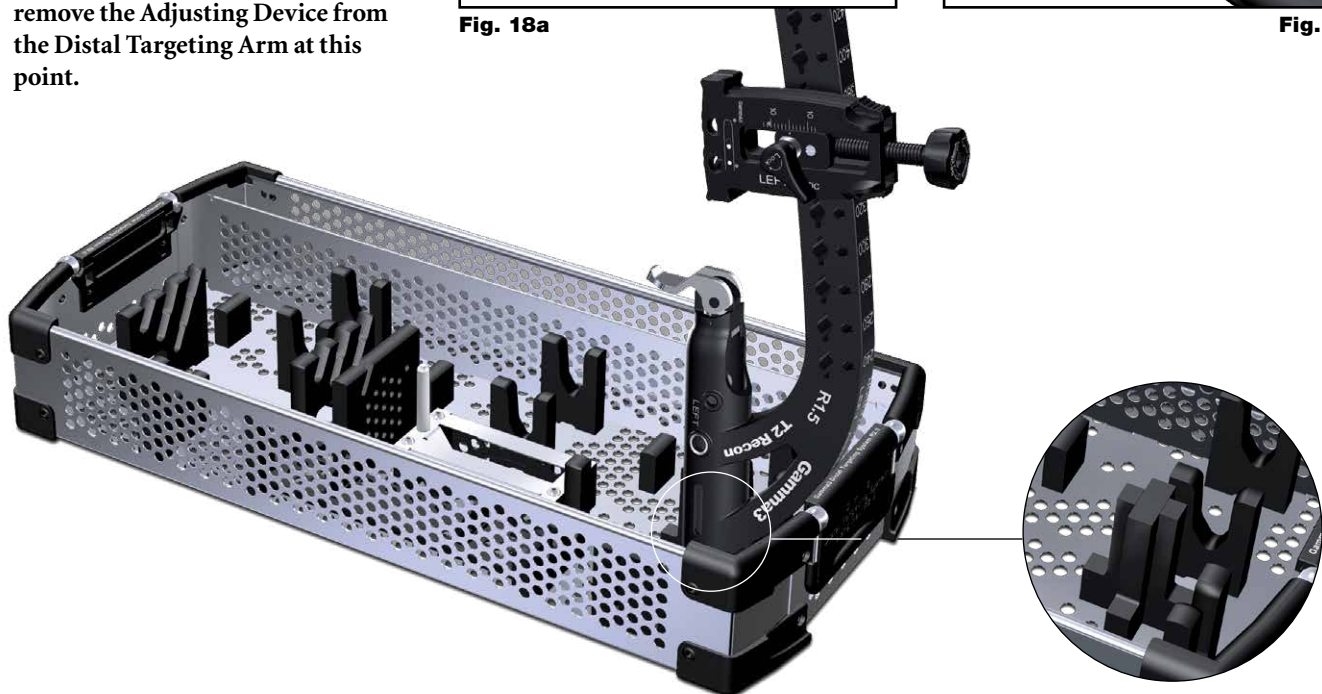


Fig. 19

Fig. 19a

Operative Technique – Distal Guided Locking

Prior to the Distal Locking Procedure

Reattach the proximal Gamma3 Targeting Sleeve Assembly to the Gamma3 Targeting Arm according to the Gamma3 Long Nail R 1.5 operative technique and select the chosen CCD angle on the device. Follow the Gamma3 Operative Technique, Long Nail R1.5, up to that part of the chapter entitled “Distal Screw Locking”. When this chapter is completed, the Set Screw has been properly positioned in a groove of the Lag Screw (Fig. 20) and a check has been done with the Lag Screwdriver T-handle to make sure that the Lag Screw can not be rotated.

The Closed Tube Clip (if used), Set Screwdriver, Lag Screwdriver, Tissue Protection Sleeve and K-Wire have to be removed, as well as the Targeting Sleeve, in order to allow the reassembly of the Distal Targeting Device. Continue with this operative technique for “Guided Distal Locking”. This manual describes the surgical technique using a 360mm Long Gamma3 Nail, left for Static/Static Locking.

Caution:

Prior to the insertion of the nail, make sure that reaming has been completed according to the Gamma3 operative technique Long Nail R1.5. With proper reaming, the nail should enter the canal with little resistance. This may help to avoid possible deformation of the nail.

Prior to the next step, it is recommended to adjust the operating table so that the proximal targeting device is placed parallel to the floor (Fig. 21a, b). This may allow easier visual guidance for the next coming steps.

Check that the Nail Holding Screw is still fully tightened.

Warning:

If the Nail Holding Screw is not securely tightened, the distal locking function may not work appropriately.

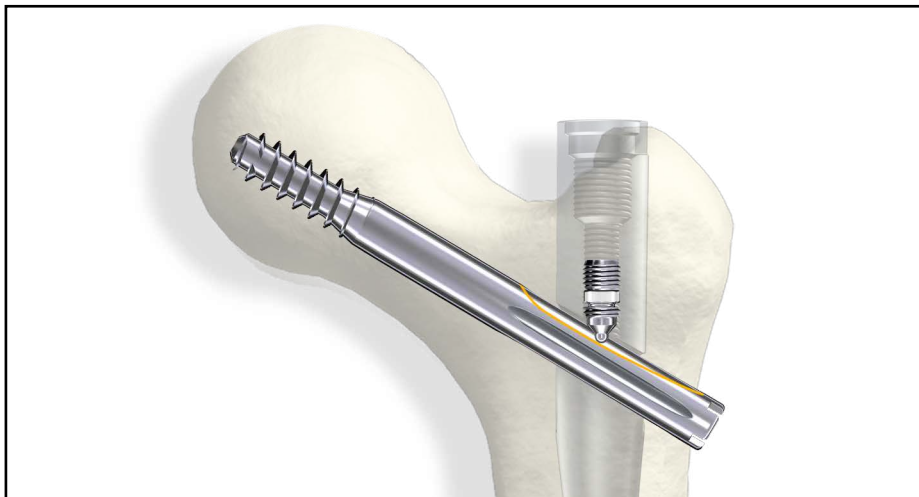


Fig. 20

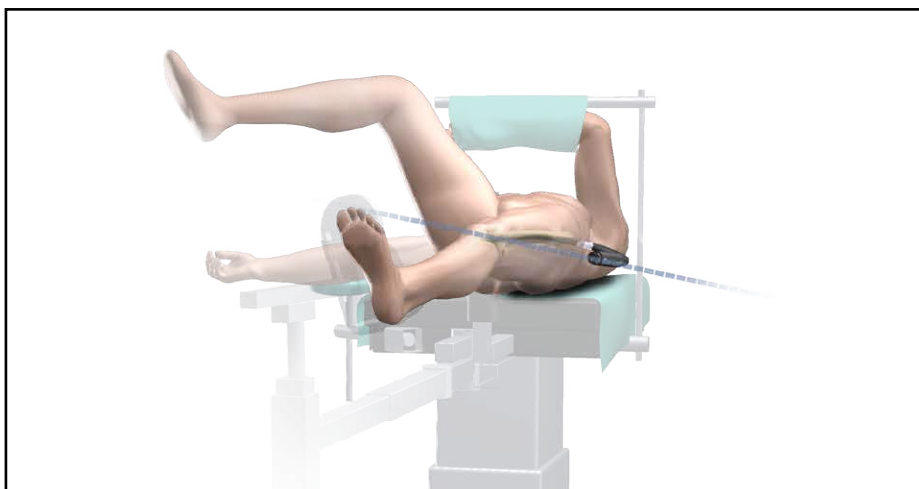


Fig. 21a

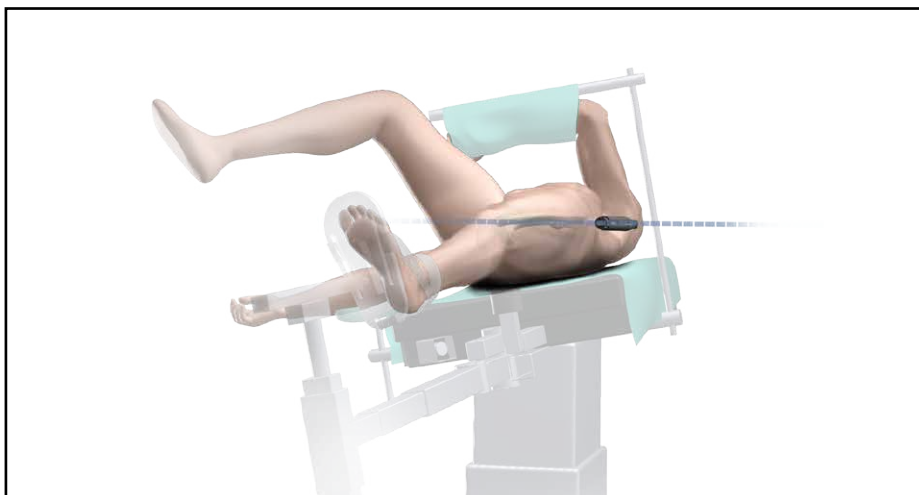


Fig. 21b

Operative Technique – Distal Guided Locking

Reassembly of the Calibrated Distal Targeting Arm

The calibrated Distal Targeting Arm is slid over the Gamma3 Targeting Arm (Fig. 22 ①).

The white line must be visible in the Alignment Indicator Window (Fig. 22a). The Fixation Bolt is removed from the Fixation Bolt Storage Pocket and reinserted into the hole (Fig. 23 ②), going completely through the Targeting Arm until a click is felt. Then, the Fixation Lever must be locked to ensure proper fixation. This is required to secure the arm to the targeter and stabilize the system. (Fig. 23 ③).

Note:

Make sure that the Distal Targeting Arm is positioned anteriorly to the nail.

Assemble the Tissue Protection Sleeve, Drill Sleeve and the Trocar. Press the Sleeve Fixation Button of the Adjusting Device (Fig. 24 ①) and insert the assembled sleeves through the distal targeting hole. Advance the assembly close to the skin; but make sure not to touch the skin with the tip of the Trocar so that free adjustment in anterior or posterior (UP or DOWN) directions is possible. By releasing the Sleeve Fixation Button, the sleeve assembly is fixed in the desired position (Fig. 24 ②).

Warning:

Do not make a skin incision before the final adjustment of the Adjusting Device to avoid soft tissue pressure to the Sleeve assembly.

In order to achieve the best result of the system, start the guided distal locking procedure from the most DISTAL hole. Once the image intensifier is properly positioned, relative to the nail hole geometry, the sleeves can be moved anteriorly (counter-clockwise) or posteriorly (clockwise) by turning the Adjusting Screw (Fig. 25). It may be turned by hand or by using the Ball Tip Screwdriver.



Fig. 22

Fig. 22a

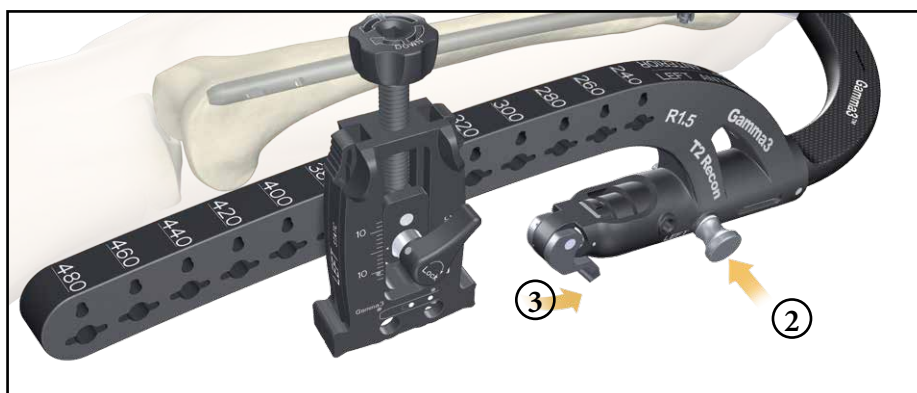


Fig. 23

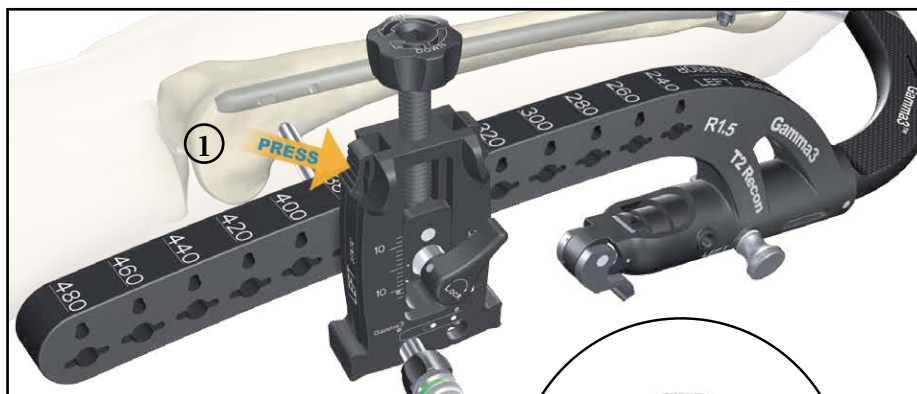


Fig. 24



Fig. 25

Operative Technique — Distal Guided Locking

Oblique Approach

In Gamma3 Distal Targeting System, the following operative procedure should be done by placing the C-Arm approximately 30 degrees oblique to the axis of the Drill Sleeve Assembly (Fig. 26).

As the image intensifier is not in the same axis as the power tool used, this offers the benefit that during the drilling, the tip of the drill can be seen under the fluoroscopic image. Additionally, the surgeon has more surgical working space during the distal locking procedure and can stay away from direct radiation to the hands.

On the fluoroscopic image, the goal is to achieve a projection showing the Drill Sleeve Assembly and the nail to be in line as shown on Fig. 26a.

The following three steps are taken prior to drilling

- **Oblique positioning of the C-Arm**
- **Height and orbital rotation**
- **Adjustment of the C-Arm**
- **Sleeve adjustment to the nail position**

Oblique Positioning of the C-Arm:

To perform the distal guided locking with the oblique approach, it is essential to place the X-Ray beam of a C-Arm approximately 30 degrees oblique to the axis of the Drill Sleeve Assembly, as shown. As an option, the Oblique Alignment Wire can be inserted from the lateral opening of the Adjusting Device. This wire indicates 30 degrees oblique to the axis of the Drill Sleeve Assembly and helps to adjust the C-Arm.

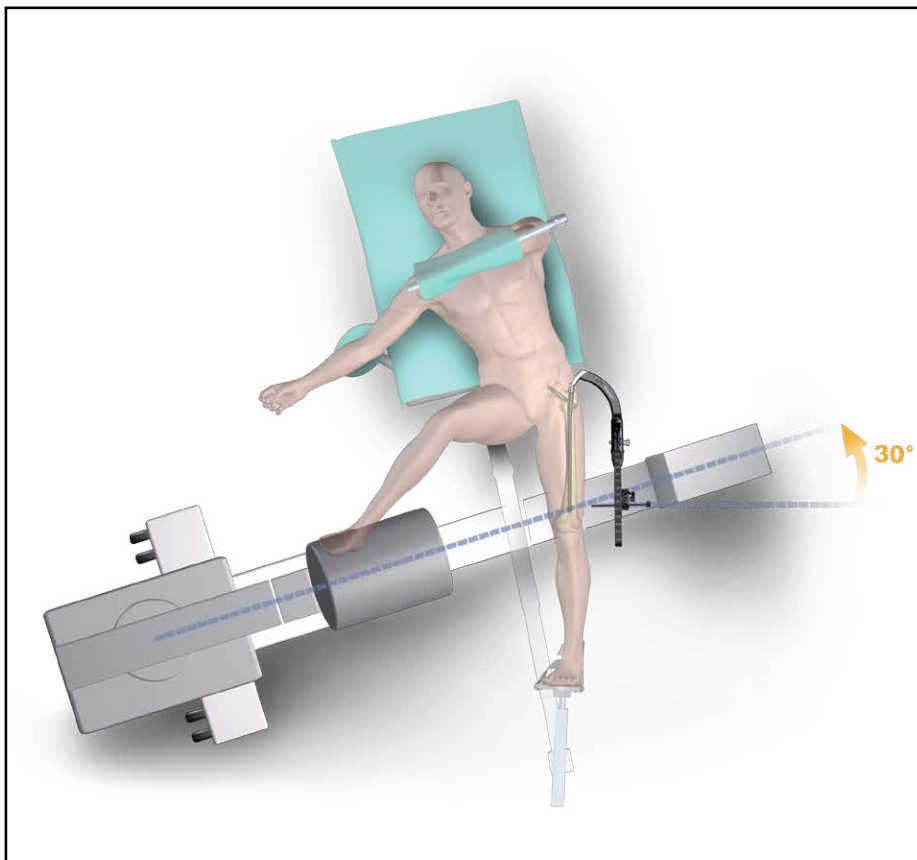


Fig. 26

Note:

30 degrees oblique positioning of the C-Arm is an average indication and may need to be readjusted according to the obtained fluoroscopic image. The goal is to achieve a projection showing the nail and the Drill Sleeve Assembly in the center of the fluoroscopic image (Fig. 26a).



Fig. 26a

Operative Technique

Oblique Approach

Height and Orbital Rotation Adjustment of the C-Arm

After the oblique C-Arm positioning is done, adjust the height (Fig. 27 ①) and orbital rotation (Fig. 27 ②) of the X-Ray beam at the same plane as the Drill Sleeve Assembly (Fig. 27).

Take an X-Ray shot. In this step, it is important to position the C-Arm so that the nail axis and the Drill Sleeve axis are seen parallel on the fluoroscopic image (Fig. 29a, b).

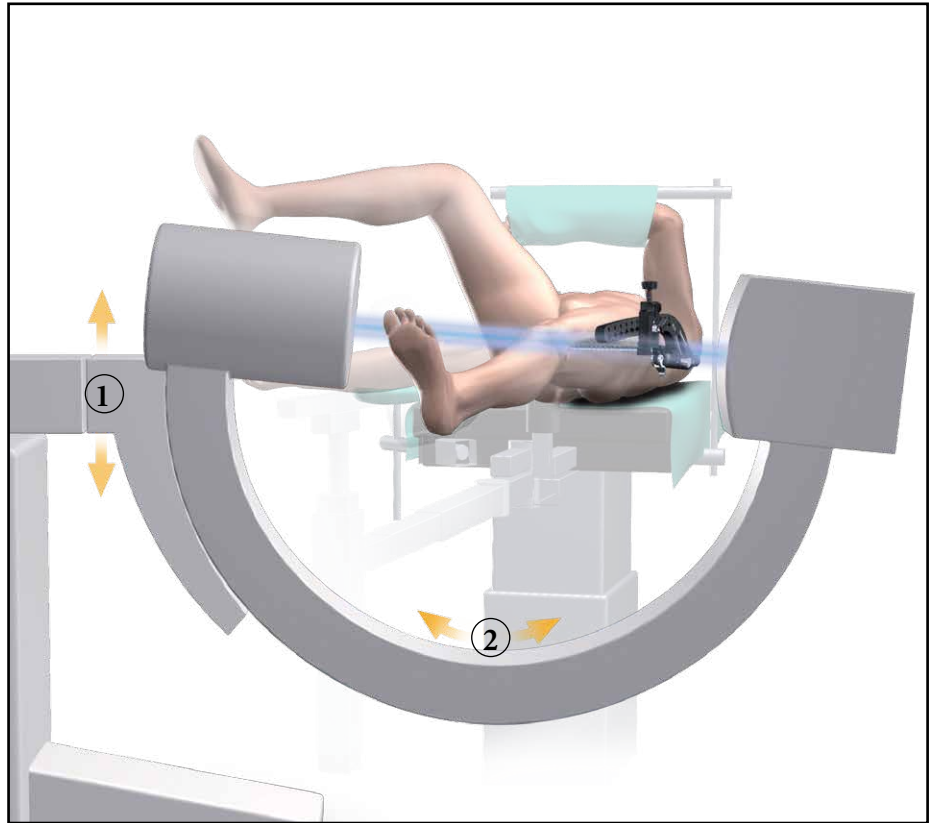


Fig. 27

When the C-Arm positioning is incorrect, you will see the nail and the sleeve NOT in parallel (Fig. 28a, b). Then readjust the C-Arm to achieve correct adjustment as shown (Fig. 29a, b).



Fig. 28a



Fig. 28b

Examples of incorrect C-Arm Positioning- The Nail and the Sleeve are NOT in parallel

When the C-Arm positioning is correct, you will see the nail and the sleeve parallel to each other as shown (Fig. 29a, b).

Note:

This step requires appropriate C-Arm positioning and no need to adjust the nail and the sleeve in the same height. Do not turn Adjusting Screw until the nail and the sleeve are parallel.



Fig. 29a



Fig. 29b

Examples of correct C-Arm Positioning - The Nail and the Sleeve are in parallel

Operative Technique

Oblique Approach

Examples for incorrect C-Arm Positioning

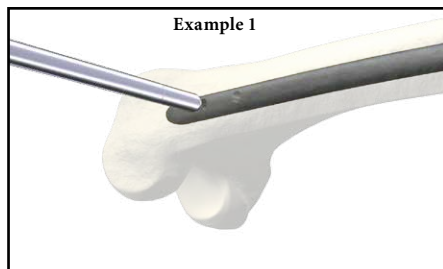


Fig. 30a

When you see the image shown in Fig. 30a on the image intensifier monitor, adjust the C-Arm position by making height and orbital rotation adjustment (Fig. 30) until sleeve and nail are seen parallel (Fig. 29a, b).

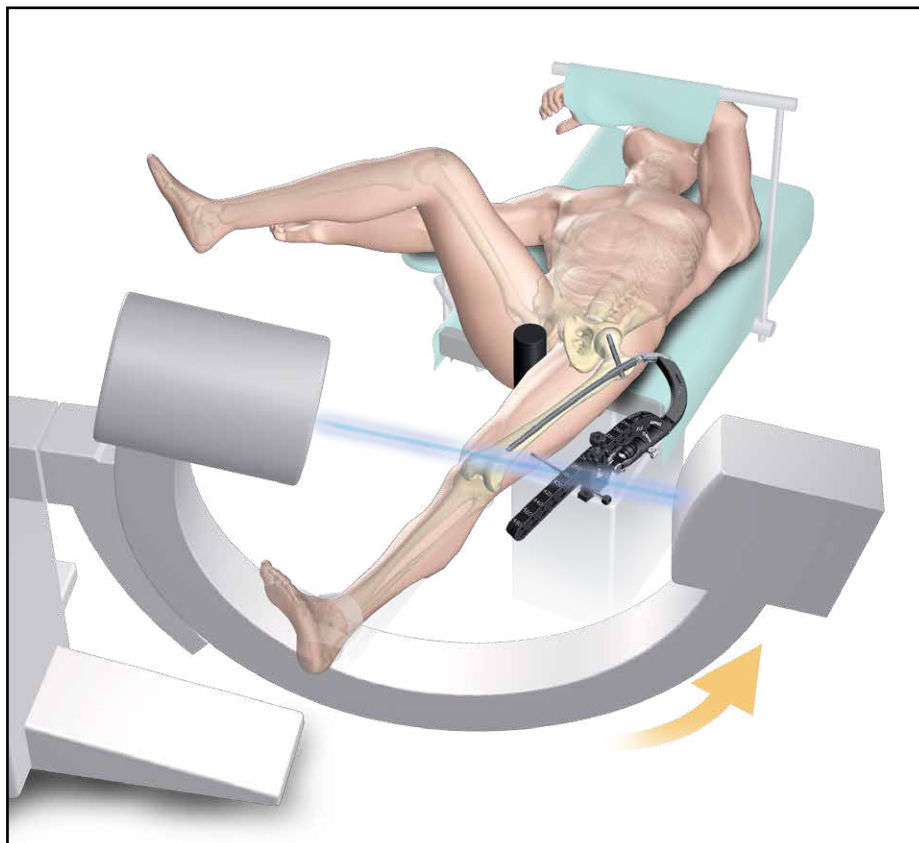


Fig. 30

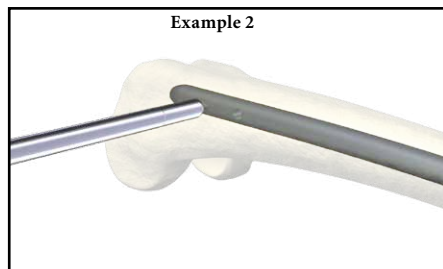


Fig. 31b

When you see the image shown in Fig. 31b on the image intensifier monitor, adjust the C-Arm position by making height and orbital rotation adjustment (Fig. 31) until sleeve and nail are seen parallel (Fig. 29a, b).

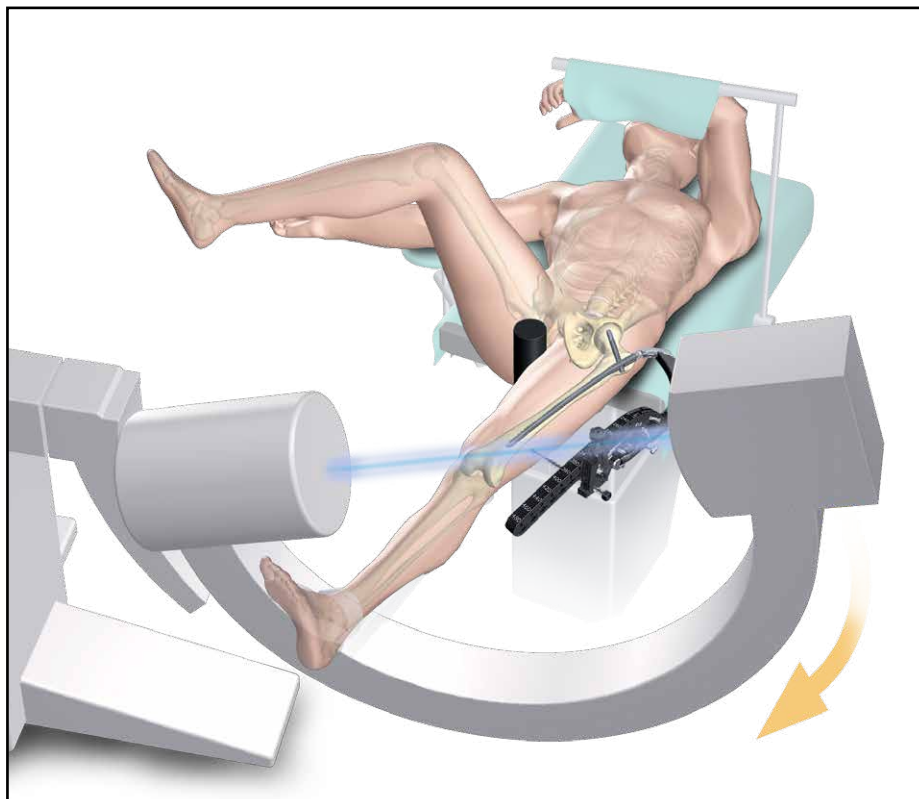


Fig. 31

Operative Technique

Oblique Approach



Fig. 32a

During insertion, if the nail has deviated posteriorly, move the Sleeve Assembly “DOWN”

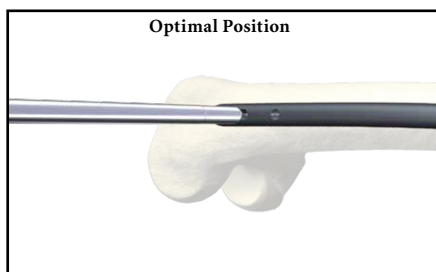


Fig. 32b

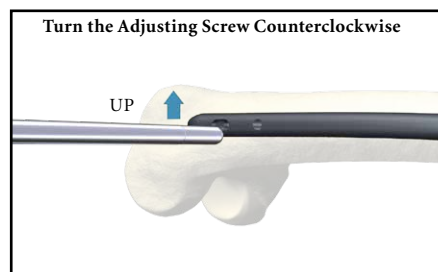


Fig. 32c

During insertion, if the nail has deviated anteriorly, move the Sleeve Assembly “UP”

Sleeve Adjustment to the Nail Position

Once the C-Arm has been adjusted, so that nail and sleeve are shown parallel (Fig. 32a, b, c), the deviated image will show the sleeve either above or below the nail (Fig. 32a, c). If the sleeve and the nail are shown parallel and in the same axis (Fig. 32b), no deflection of the nail shaft has occurred, and no further adjustment of the Adjusting Device is needed.

If the sleeve and nail are not seen on the same level (Fig. 32a, c), sleeve and nail adjustment is required by turning the Adjusting Screw counterclockwise or clockwise, i.e. anterior or posterior.

By turning, the sleeve moves anteriorly or posteriorly (Fig. 33).

- Clockwise=posterior direction (DOWN)
- Counterclockwise=anterior direction (UP)

Warning:

Maximum adjustments of ± 14 mm are possible from neutral position. As for the nail lengths 260 and 280mm, the adjustment amounts for posterior direction (DOWN) are limited mechanically. In rare cases when the required adjustment exceeds these limits, an alternative distal locking method should be considered.

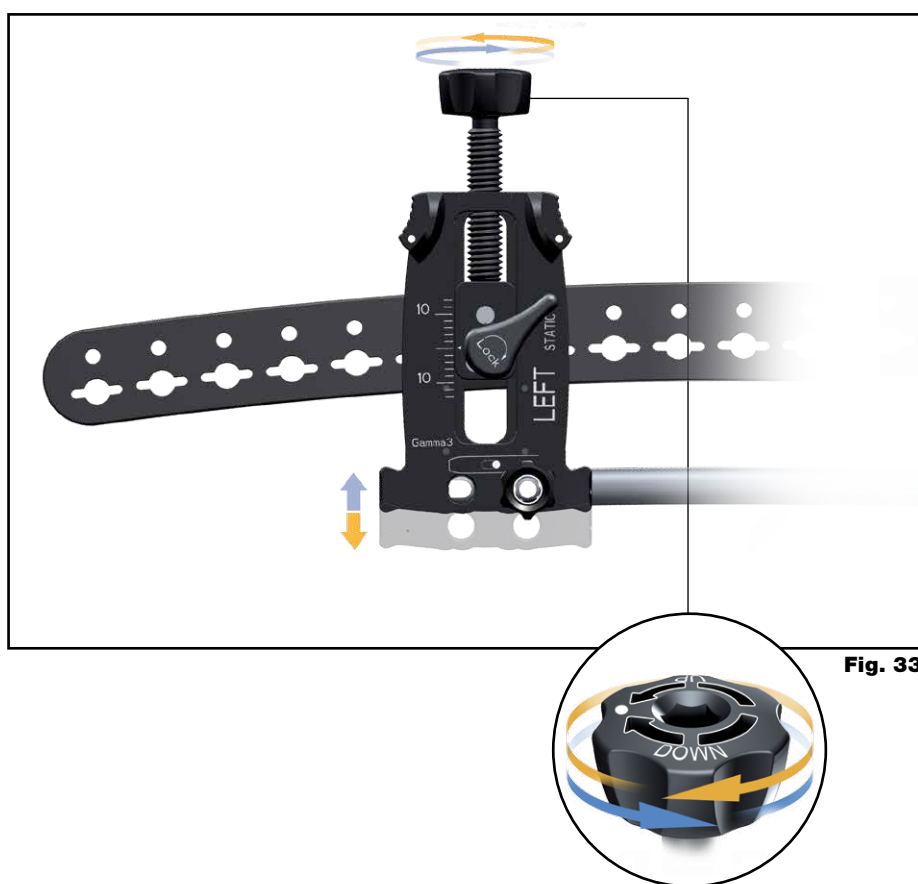


Fig. 33

Operative Technique

Distal Drilling and Locking

Locking the most distal hole

Once the correct nail and sleeve adjustment has been obtained (Fig. 32b), a small skin incision is made at the tip of the Trocar and then continued down to the lateral cortex in direction of the Sleeve. Press the Sleeve Fixation Button (Fig. 34 ①) so that the Tissue Protection Sleeve can advance freely. The head of the Trocar will rise a few millimeters above the sleeve, when the assembly has been pushed to its proper position against the lateral cortex. Always verify that the Tissue Protection Sleeve is in good contact to the bone (Fig. 34a).

Warning:

Make sure not to push the Sleeve Assembly too hard in order to avoid the possible slippage of the tip of the sleeve on the curved bone surface.

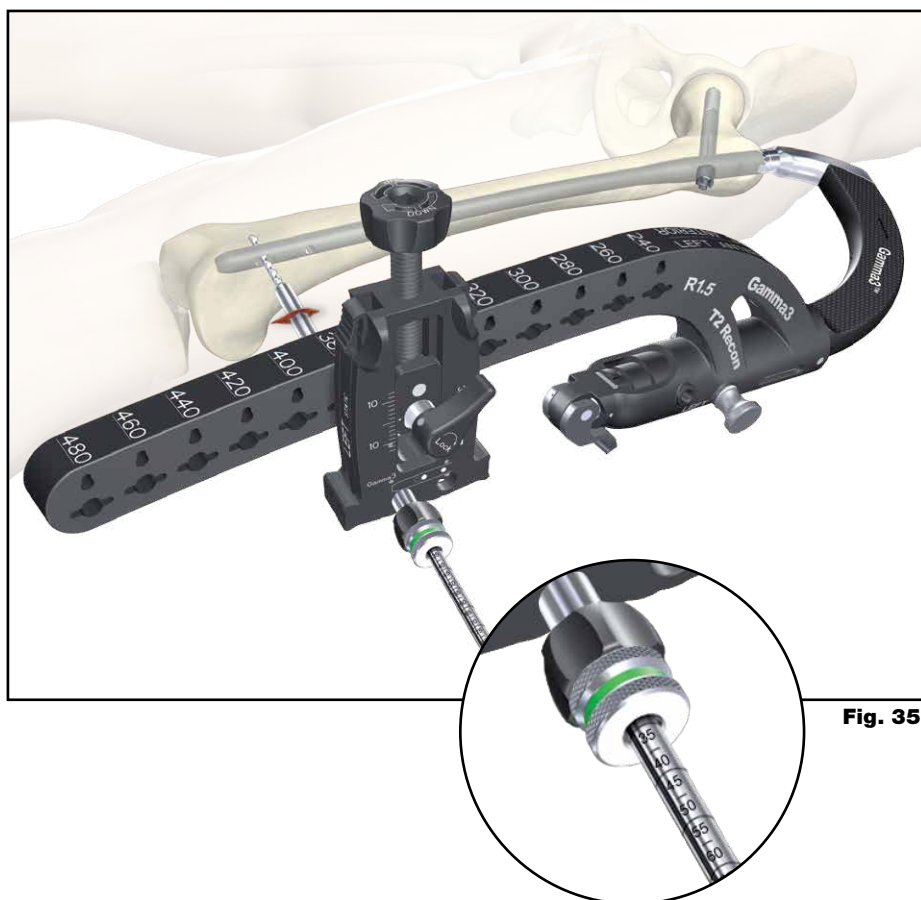
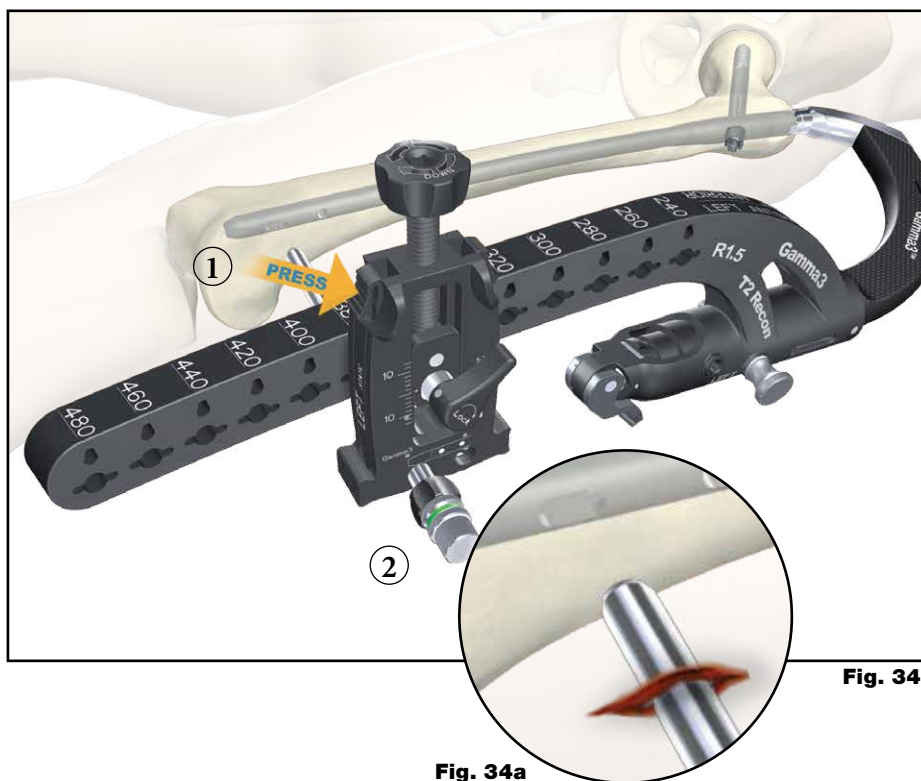
Another fluoroscopic shot has to be taken to confirm that the targeting position is still accurate. If not, readjust with the Adjusting Device, as described in the previous chapter.

Remove the Trocar and push the green coded 4.2mm × 300mm Drill through the Drill Sleeve. Start the drilling procedure keeping in mind the below notes.

Note:

- Check that the Fixation Bolt is still fully tightened
- Avoid soft tissue pressure on the distal locking sleeve assembly- therefore the skin incision was made in direction of the sleeve assembly
- Neutralize the power tool weight during drilling procedure and do not apply force to the Targeting Arm
- Start the power tool before having bone contact with the drill
- Use sharp and center tipped drills only

Two different drilling and length measurement procedures for the locking screws are described.



Operative Technique

Distal Drilling and Locking

Drill through the first cortex and as the second cortex is reached, stop drilling and read the depth measurement on the drill's calibrated scale (Fig. 36). Add the thickness of the cortex, approximately 5mm, to this measurement to select the correct screw length. Now continue by drilling through the second cortex. Remove the Drill.

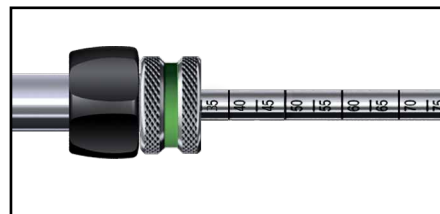
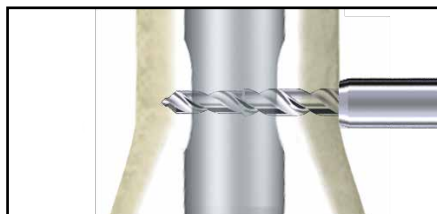


Fig. 36

Alternatively, the drilling can be performed by drilling the first cortex, passing the nail hole and then drilling the second cortex, monitored by the image intensifier. The screw length can then be **read directly** from the scale on the drill.

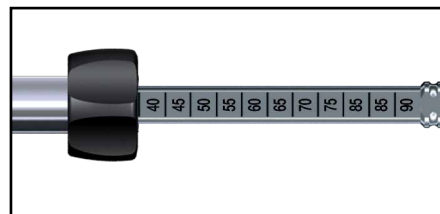
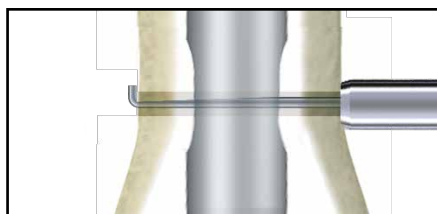


Fig. 37

Screw length measurement is also possible after drilling through the second cortex and using the Screw Depth Gauge. The Drill Sleeve must be removed and the Screw Depth Gauge may be used through the Tissue Protection Sleeve. Place the small hook on the medial cortex and read the required locking screw length from the scale (Fig. 37).

After removing the Drill/Screw Depth Gauge and the Drill Sleeve, attach the Screwdriver Bit 3.5mm to the Teardrop Handle. Insert the 5mm Distal Locking Screw through the Tissue Protection Sleeve by turning the Screwdriver clockwise until the mark on the Screwdriver shaft approaches the top of the Tissue Protection Sleeve. Advance the screw head carefully until it is slightly in contact with the cortex.

When the mark on the Screwdriver shaft reaches the Tissue Protection Sleeve, this indicates that the screw head is near the cortex (Fig. 38a). The screw head should come just into contact with the cortex and resistance should be felt.

Caution:

Care should be taken not to overtighten the screw.

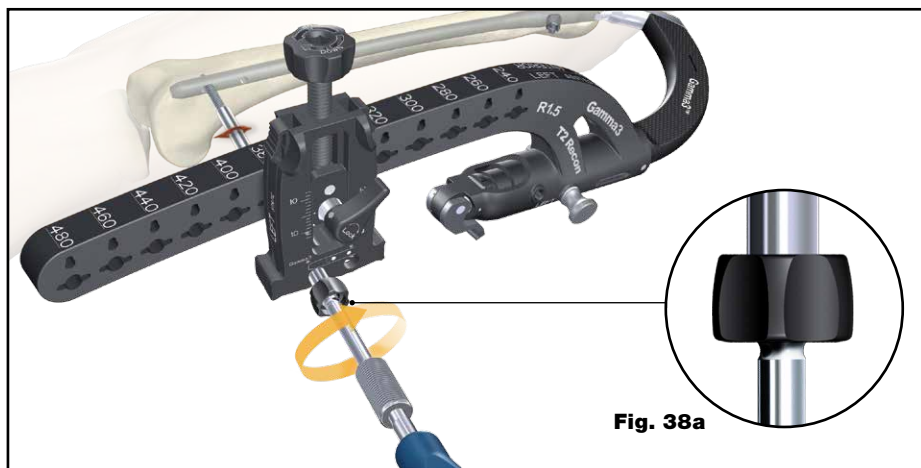


Fig. 38

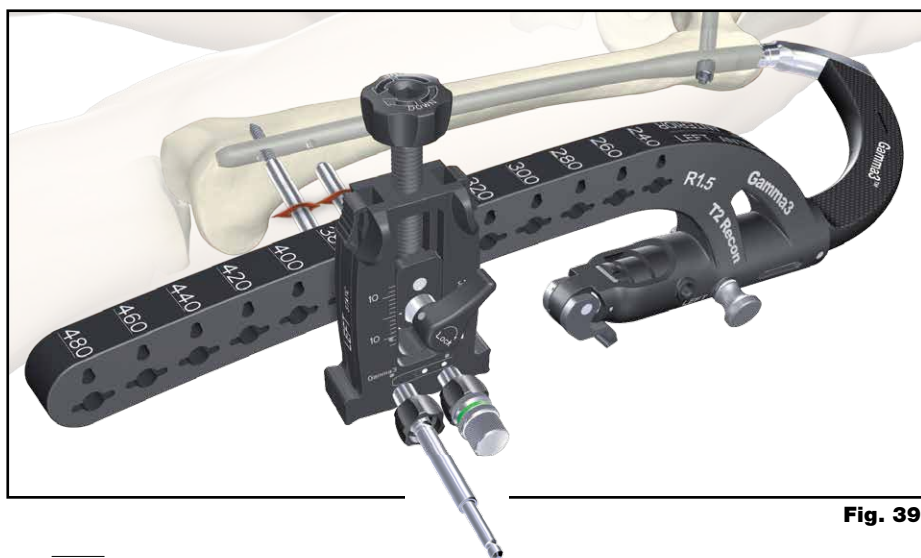


Fig. 39

Operative Technique

Distal Drilling and Locking

Note:

Leave the Screwdriver Shaft, still inserted into the screw head, inside the Tissue Protection Sleeve and just remove the Handle (Fig. 39). The Tissue Protection Sleeve should remain in contact with the lateral cortex. This will help stabilize the system when performing the second screw insertion procedure.

The Drill Sleeve and the Trocar are assembled with the second Tissue Protection Sleeve and then inserted through the most proximal Targeting Hole of the Adjusting Device and advanced to the skin.

Using the image intensifier, check that the target position is still accurate, i.e., that the sleeve and the nail are in-line. If not, readjust the Adjusting Device as described previously. Proceed with the skin incision, insert the Drill Sleeve, and use the green coded 4.2mm × 360mm Drill (Fig. 39).

Remove the Drill Sleeve and insert the selected 5mm Screw, using the Teardrop Handle and the Screwdriver Bit. Before the Targeting Device is disassembled a final check with the image intensifier should be made to confirm the correct position and the appropriate length of both Locking Screws.

Press the Sleeve Fixation Button and remove the Screwdrivers/Sleeves. Open the Fixation Lever of the Gamma3 Distal Targeting Arm (Fig. 42 ①).

Now withdraw the Fixation Bolt (Fig. 42 ②) and put the Fixation Bolt back in the Fixation Bolt Storage Pocket of the Distal Targeting Arm (Fig. 42 ③).

Remove the Distal Targeting Arm from the Gamma3 Targeting Arm. Complete the surgery with the chapter entitled “End Cap Insertion”, described in the Gamma3 Long Nail R1.5 operative technique.

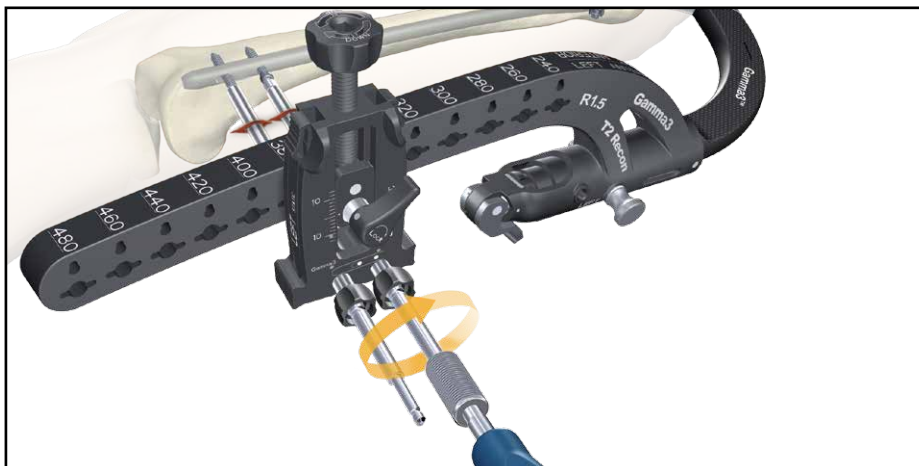


Fig. 40

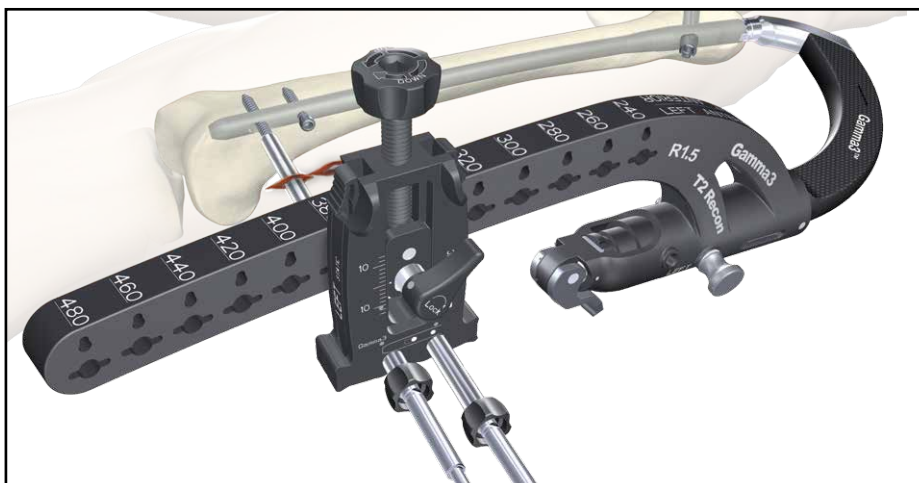


Fig. 41

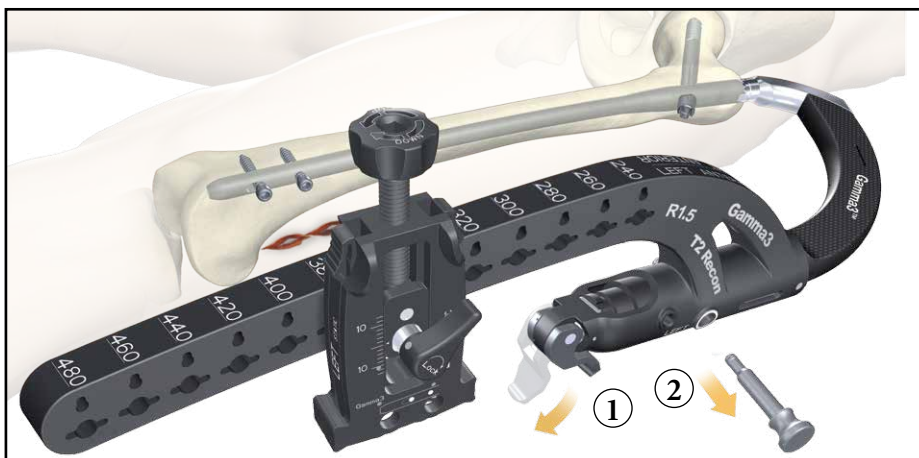

















Fig. 42



System Components – Instruments

	REF Number	Description
	1320-5316	Distal Targeting Arm, R1.5
	1320-5330	Fixation Bolt
	1320-5340	Adjusting Device, LEFT, STATIC
	1320-5350	Adjusting Device, RIGHT, STATIC
	1320-0315	Trocars, Long
	1320-0215	Drill Sleeve, Long
	1320-5380	Tissue Protection Sleeve, Long
	1320-3042S	Drill 4.2mm × 300mm, AO *
	1320-3642S	Drill 4.2 × 360mm, AO *
	1806-0227	Screwdriver Bit 3.5 Long
	702429	Teardrop Handle, AO coupling
	1320-5395	Oblique Alignment Wire
	1320-5385	5 Step Reference Chart
	1320-9515	Distal Targeting Instrument Tray, R1.5, Empty
	1320-5001	Distal Targeting Instrument Tray, R1.5, Complete

* For non-sterile, leave “S” off the REF number when ordering.

System Components – Instruments

REF Number	Description
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Optional Instruments



1320-5360 Adjusting Device, LEFT/RIGHT, DYNAMIC



1320-3045S 4.2 × 300mm, Tri-Flat *



1320-3645S 4.2 × 360mm, Tri-Flat *



1806-0229 Screwdriver Bit 3.5, Selfholding, Long

Spare parts

1320-5375 T2 Recon, adapter for DTS Calibration**

* For non-sterile, leave “S” off the REF number when ordering.
** Used with Instrument Tray DTD (REF 1320-9550)

Notes

Notes



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