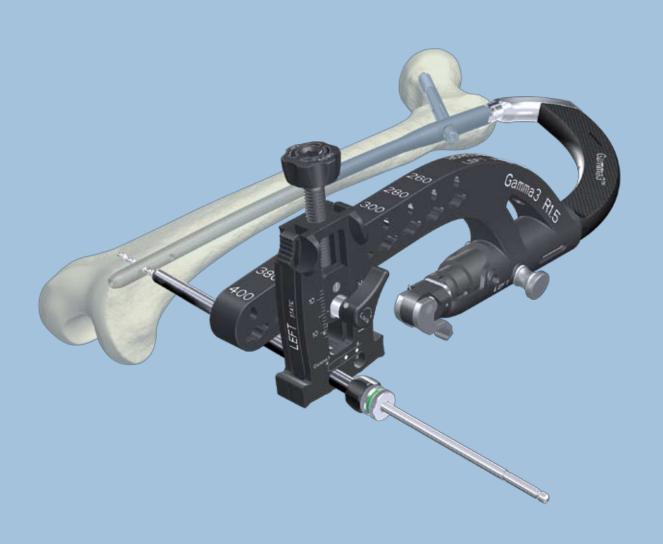


Trauma

Gamma3 Distal Targeting System

Operative Technique For Gamma3 Long Nails R1.5

Hip Fracture



Gamma3 Distal Targeting Device

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Acknowledgements

Thank you to the many Surgeons who participated during the worldwide Gamma3 System Panel Meetings. The valuable feedback, ideas and support we received helped make Gamma3 the leading product it is today.

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 Gamma3 Distal Targeting System. Please contact your Stryker representatives and complete the "Gamma3 Distal Targeting Training Module" prior to your first surgery.

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 device, with the patient, when necessary.

Warning:

All bone screws referenced in this document are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

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Introduction

Gamma3 Distal Targeting System

The Gamma3 Locking Nail System was developed based on more than 15 years of Gamma Nail experience. This is the third generation of Gamma intramedullary short and long fixation nails.

The evolution of the successful Trochanteric and Long Gamma Nails as well as the Asia Pacific and Japanese versions followed strict step-by-step improvements based on the clinical experience from surgeons all over the world.

The newest generation nail, Gamma3 System is designed to facilitate less invasive surgery and to potentially reduce OR time with the aid of percutaneous instrumentation and an optimized surgical technique.

A major advantage of the Gamma system is the state-of-the-art instrument platform.

In response to the request of surgeons around the world, Stryker Osteosynthesis has created a dedicated Distal Targeting System for the Gamma3 Long Nails. While still allowing a less invasive surgical technique, the Distal Targeting System may improve OR efficiency for a Gamma3 Long Nail surgery.

Without using the Gamma3 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.

The Gamma3 Distal Targeting System offers the following competitive advantages³:

- Using the Gamma3 Distal
 Targeting System may reduce
 X-Ray exposure and may improve
 OR efficiency due to the correct adjustment of the locking hole.
- Guided distal locking may allow the surgeon to find the correct entry point for the locking screw with the first approach.

Indication

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

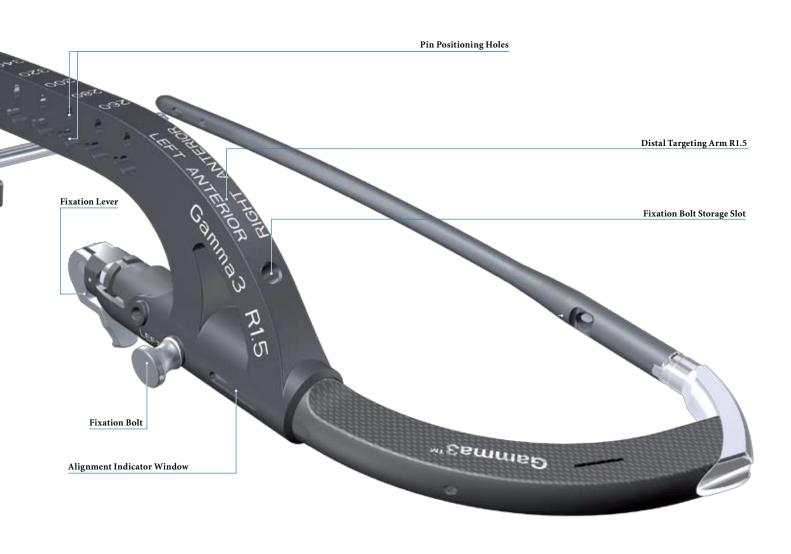


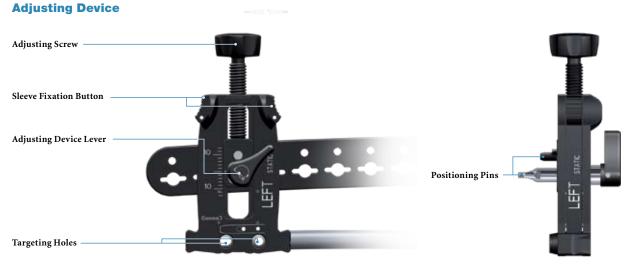
- 1 **Taglang G.** The operative technique for the latest generation Gamma nail (the Gamma3). In: Kempf I, Leung KS, eds. **Practice of intramedullary locked nails: Scientific basis and standard techniques recommended by AIOD**. Berlin, Heidelbrg, New York: Springer-Verlag, 2006:133-7.
- 2 Cardador L. 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.
- 3 Yokoyama M. The evolution of distal targeting device for femoral fractures. Abstract from JFSR 2007: S41.

Introduction

Gamma3 Distal Targeting System Components

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





Gamma3 Distal Targeting Device Calibration

It is important to calibrate the Gamma3 Distal Targeting Device prior to the Nail insertion. Then, follow the Gamma3 Operative Technique for Gamma3 Long Nails, through chapter entitled "Lag Screw Fixation" 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.

Distal Locking Options

Gamma3 Long Nails offer 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 as "Secondary Dynamization" and allows the fragments to dynamize 5mm in an axial direction, while stabilizing against rotation – requires two screws.

Calibration

Calibration of the Distal Targeting
Device with the selected Gamma3
Long Nail is an important step.
Doing so insures that the Drill Sleeve
Assembly in the Gamma3 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 Gamma3 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

Indications:

Fixation of stable and unstable femoral fractures occuring from the base of the femoral neck extending distally to a point approximately 10cm proximal to the intercondylar notch including fractures of the basilar neck, intertrochanteric fractures, peritrochanteric fractures, subtrochanteric fractures and femoral shaft fractures.

Warning:

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



Fig.1

Static Locking



Fig.2

Dynamic Locking



Fig.3

Secondary Dynamization

Gamma3 Distal Targeting Device Calibration



Adjustment Slide the Distal Targeting Arm R1.5

Assembly and Length

(REF 1320-5320) 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).

Alignment Indicator Window

LEF1 (1 **Fixation Lever Fixation Bolt**

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).

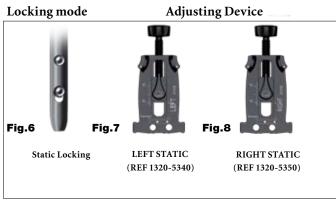
Fig.5



Note:

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

Fig.5a



(Option) Fig.9 **Dynamic Locking** LEFT/RIGHT DYNAMIC (REF 1320-5360)

Secondary Dynamization

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).
- 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 two locking options are:
- 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).

Gamma3 Distal Targeting Device Calibration

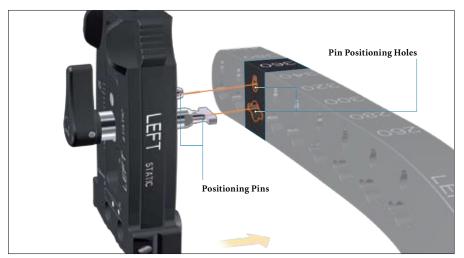


Fig.12





Fig.15

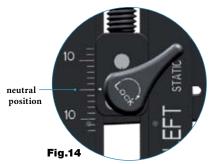
The length of the nail determines where the Adjusting Device should be attached. The selected Adjusting Device (in this case we chose a left Gamma3 Long Nail R1.5 - 360mm to be locked in a static/static configuration) is placed into the Pin Positioning Holes that match the length of the selected nail. 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 the two Pin Positioning Holes and securely locked with the Adjusting Device Lever.

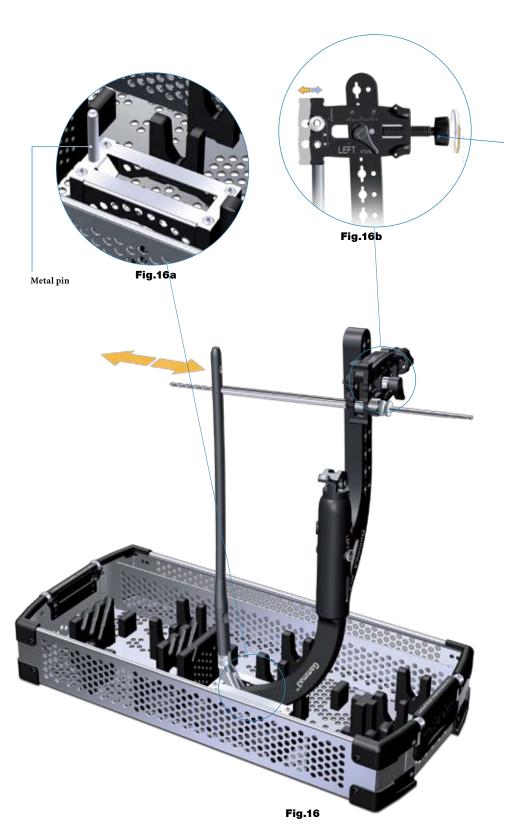
The following procedure describes Gamma3 Long Nail R1.5, left with Static/Static Locking.



Before continuing, make sure the Adjusting Device is positioned in the neutral position as shown (Fig.14). Position can be moved upwards (anteriorly) and downwards (posteriorly) 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 a friction lock of the sleeve assembly. The sleeve has a free movement when the Button is pressed and locks when the Button is released.

Gamma3 Distal Targeting Device Calibration



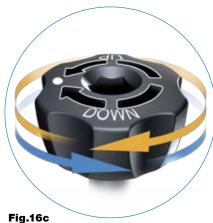
A/P Adjustment

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

Adjusting screw

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 the drill passes through the nail smoothly (Fig.16b).



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

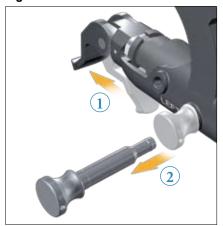
- · Clockwise = posterior direction (DOWN)
- Counter-clockwise = anterior direction (UP)

Gamma3 Distal Targeting Device Calibration



After the calibration steps have been completed, remove the Sleeve Assembly (Fig.17 ②) by pressing the Sleeve Fixation Button (Fig.18 ①) of the Adjusting Device.

Fig.17

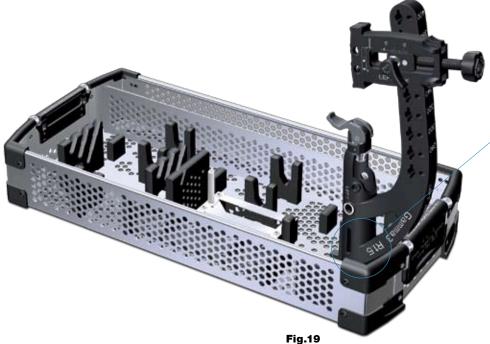




Release the Fixation Lever (Fig.18a ①), then remove the Fixation Bolt (Fig.18a ②) and place it into the Fixation Bolt Storage slot (Fig.18b ③).

Fig.18a

Fig.18b



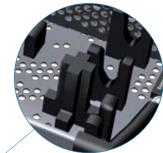


Fig.19a

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

Warning:

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

Prior to the Distal Locking Procedure



Fig.20

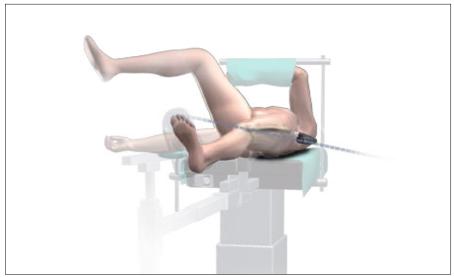


Fig.21a

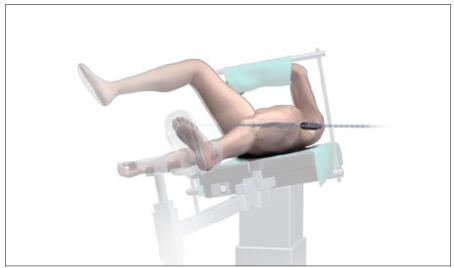


Fig.21b

Re-attach 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 are removed, as well as the Targeting Sleeve, in order to allow the re-assembly 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 steps.

Check that the Nail Holding Screw is fully tightened.

Warning:

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

Prior to the Distal Locking Procedure

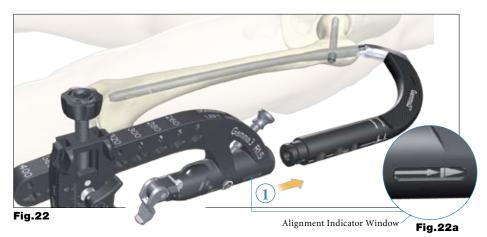




Fig.23



Re-assembly 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 seen through in the Alignment Indicator Window (Fig.22a). The Fixation Bolt is removed from the Fixation Bolt Storage Slot and re-inserted 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 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.25

Oblique Approach

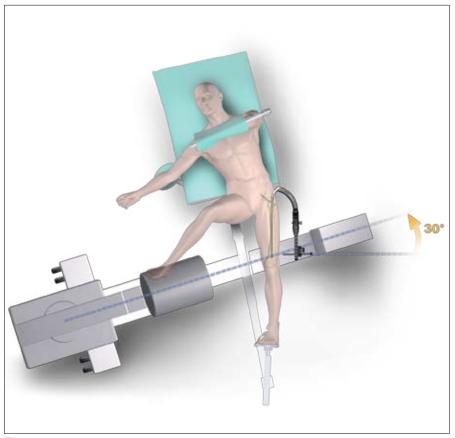


Fig.26

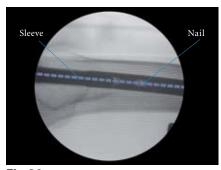


Fig.26a

In the 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 tip of the drill to remain viewable via fluoroscopic image while drilling. Additionally, the operator has more surgical working space during the distal locking procedure and is away from direct radiation.

Under 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

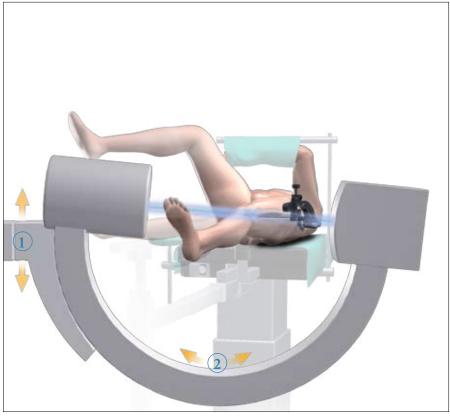
Oblique Positioning of the C-Arm:

To perform Distal Guided Locking with the Oblique Approach, it is essential to place the X-ray beam of the 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.

Note:

30 degrees Oblique Positioning of the C-Arm is an average indication and may need to be re-adjusted according to the 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).

Oblique Approach



Height and Orbital Rotation Adjustment of the C-Arm

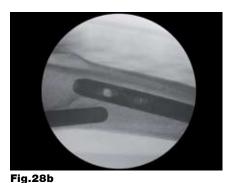
After the Oblique C-Arm positioning is done, adjust the height (Fig.27 ①) and orbital rotation (Fig.27 2) of the X-Ray beam at the same plane as the Drill Sleeve Assembly (Fig.27).

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



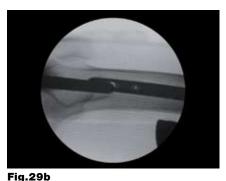
Examples of incorrect C-Arm Positioning - The Nail and the Sleeve are NOT in parallel



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



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

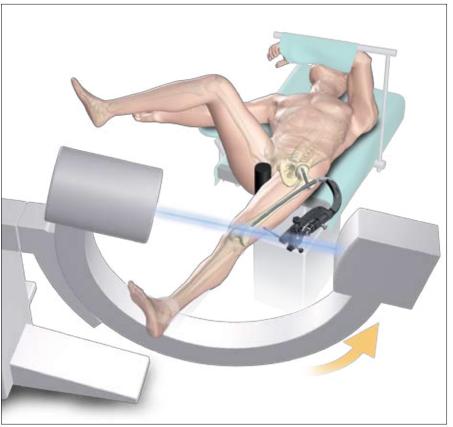


When the C-Arm positioning is correct, you will see the nail and the sleeve parallel to each other as shown (Fig.29a, b).

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.

Oblique Approach



Examples for incorrect C-Arm Positioning

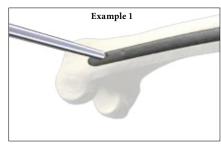


Fig.30a

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

Fig.30

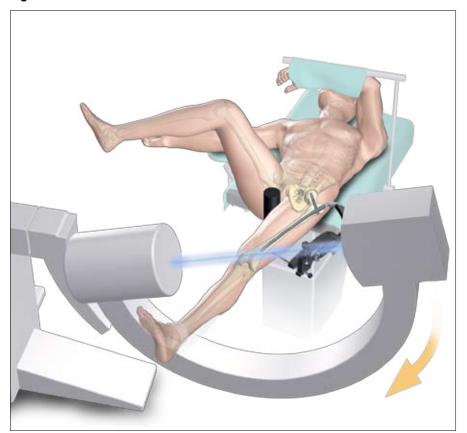
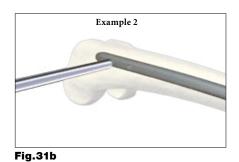


Fig.31



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

Oblique Approach



Fig.32a

During insertion, the nail has deviated posteriorly, requires to move the Sleeve Assembly "DOWN"

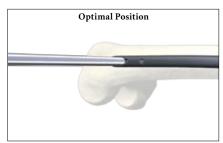


Fig.32b

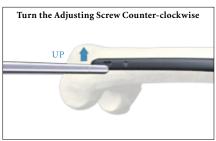


Fig.32c

During insertion, the nail has deviated anteriorly, requires to move the Sleeve Assembly "UP"

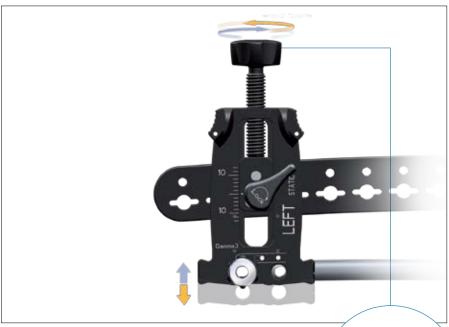


Fig.33

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 either the sleeve 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.

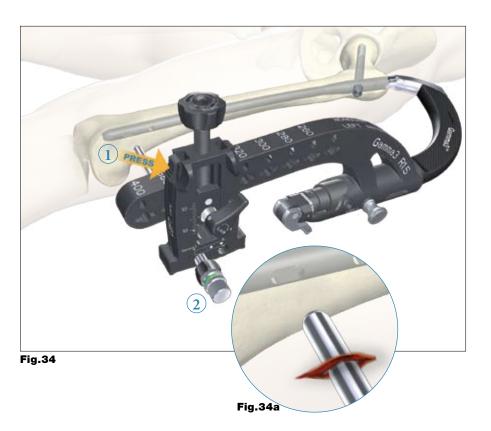
By turning, the sleeve moves anteriorly or posteriorly (Fig.33).

- Clockwise=posterior direction (DOWN)
- Counter-clockwise=anterior direction (UP)

Warning:

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

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 the 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 with the bone (Fig.34a).

Warning:

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

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

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

Note:

- Check that the Nail Holding Bolt is still fully tightened
- Avoid soft tissue pressure on the distal locking sleeve assemblytherefore the skin incision would be made in the 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.

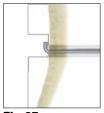
Distal Drilling and Locking







Fig.36





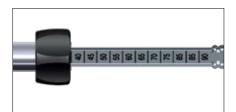
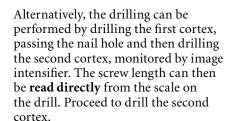


Fig.37



correct screw length. Now continue by drilling through the second cortex.

Remove the Drill.

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

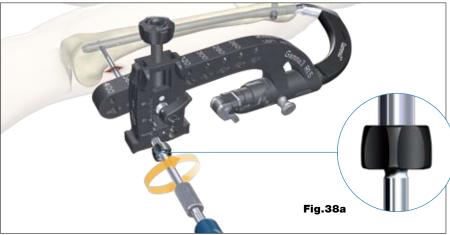
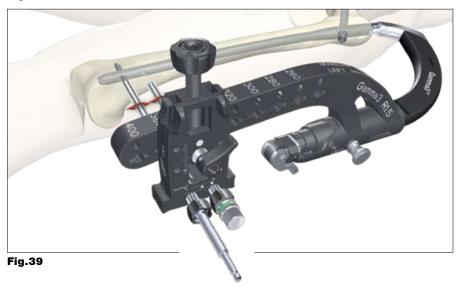


Fig.38



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 just come into contact with the cortex and resistance should be felt.

Caution:

Care should be taken not to overtighten the screw.

Distal Drilling and Locking



Fig.40



Fig.41



Fig.42



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, re-adjust the Adjusting Device as described previously. Proceed with the skin incision and with the green coded 4.2mm x 360mm Drill (Fig. 39).

Remove the Drill Sleeve and insert the selected 5mm Screw, using the Teardrop Handle and the Screwdriver Bit

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 Slot 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.

Notes

Notes

Ordering Information

	REF Number	Description
	1320-5315	Distal Targeting Arm, R1.5
	1320-5330	Fixation Bolt
##	1320-5340	Adjusting Device, LEFT, STATIC
	1320-5350	Adjusting Device, RIGHT, STATIC
	1320-0315	Trocar, Long
	1320-0215	Drill Sleeve, Long
	1320-5380	Tissue Protection Sleeve, Long
***************************************	1320-3042S	Drill 4.2mm x 300mm, AO *
4000000	1320-3642S	Drill 4.2 x 360mm, AO *
	1806-0227	Screwdriver Bit 3.5, Long
	702429	Teardrop Handle, AO coupling
	1320-9550	Instrument Tray, DTD, empty, R1.5
	1320-5015	Instrument Set, DTD, completely filled, R1.5
	1320-5395	Oblique Alignment Wire
THAIRITH	1320-5385	5-Step Reference Chart

 $^{^{\}star}$ For non-sterile, leave "S" off the REF number when ordering.

Ordering Information

REF Number	Description		

Optional Instruments



1320-5360 Adjusting Device, LEFT/RIGHT, DYNAMIC

1320-3045S 4.2 x 300mm, Tri-Flat *

1320-3645S 4.2 x 360mm, Tri-Flat *

 $^{^{\}star}$ For non-sterile, leave "S" off the REF number when ordering.



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