Gamma3 System

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All surgeons, who supported the idea of the U-Blade Lag Screw for the treatment of proximal femur fractures.

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Our thanks are due to the many surgeons who supported the development of the new Gamma3 System, with their feedback and ideas, during worldwide panel meetings and helped the Gamma3 System to be what 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 and as required. A workshop training is recommended 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 (L22000007) 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:

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.
## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gamma3 RC Lag Screw Set</td>
<td>4</td>
</tr>
<tr>
<td>Indications</td>
<td>5</td>
</tr>
<tr>
<td><strong>Operative Technique</strong></td>
<td>6</td>
</tr>
<tr>
<td>Gamma3 RC Lag Screw Placement</td>
<td>6</td>
</tr>
<tr>
<td>Lag Screw Fixation</td>
<td>9</td>
</tr>
<tr>
<td>Gamma3 RC U-Clip Insertion</td>
<td>10</td>
</tr>
<tr>
<td>Extraction</td>
<td>14</td>
</tr>
</tbody>
</table>
The Gamma3 RC Lag Screw Set

Gamma3 RC Lag Screw Set features a combination of a standard Gamma Lag Screw and a spreading U-Clip.

They are designed for use with the Gamma3 Trochanteric (Fig. 2) and Gamma3 Long Nails.

The insertion procedure of the Gamma3 RC Lag Screw is similar to the standard Gamma3 Lag Screw. Insertion of the Gamma3 RC U-Clip into the Gamma3 RC Lag Screw is done by sliding the U-Clip into the two grooves of the lag screw and inserted fully without any hammering.

Fig. 1: Gamma3 RC Lag Screw Set dis-assembled

Fig. 1a: Gamma3 RC Lag Screw Set assembled and spreaded

Fig. 2: Gamma3 RC Lag Screw Set in the Gamma3 Trochanteric Nail 180
Operative Technique

Indications

The Gamma3 U-Blade Lag Screw may be used with either the Gamma3 Trochanteric Nail or the Long Length Gamma3 Nail to treat patients with highly osteoporotic bone or metastatic disease in the femoral head, short femoral head/neck fragments, or unstable intertrochanteric fractures with missing medial-caudal bone support.

Precautions

Stryker Osteosynthesis systems have not been evaluated for safety and use in MR environment and have not been tested for heating or migration in the MR environment, unless specified otherwise in the product labeling or respective operative technique.

Contraindications

Contraindications are medial neck and sub-trochanteric fractures.

Caution:

The Gamma Nail is designed for temporary implantation until the bone consolidation occurs. Therefore, if no bone consolidation occurs or if consolidation is not sufficient, the system may fail. The aim of post-operative care must be to ensure the promotion of bone consolidation. The Gamma Nail is not intended for full weight bearing in patients with complex unstable fractures until sufficient bone consolidation is confirmed in the follow up X-rays.

This operative technique has been devised in consultation with leading surgeons in many countries to be a basic guide, particularly for less experienced users of the Gamma3 System. It is acknowledged that several alternative approaches to certain elements of the procedure are available, and may have advantages for particular situations or surgeons.

Note:

Follow the Gamma3 Operative Technique for Trochanteric or Long Nails, depending which nail you are using, up to the part of the chapter entitled Lag Screw Insertion where the K-Wire is in place, the Lag Screw length determination has been done and the value of the length measurement has been transferred to adjustable stop of the Lag Screw Step Drill. At this point, continue with this Operative Technique. The instructions for the Gamma3 RC Lag Screw Operative Technique should not interfere with or replace any chapters in the Gamma3 Operative Technique except for those detailing Lag Screw insertion and fixation. This manual is describing the surgical technique using a Gamma3 Trochanteric Nail 180.

For optimal positioning of the Gamma3 RC Lag Screw, use of the Gamma3 One Shot Device® is recommended.

The Gamma3 One Shot Device® is a radiolucent instrument that is used to find the ideal position for the Lag Screw before skin incision and opening the lateral cortex for K-Wire placement.
Operative Technique

Gamma3 RC Lag Screw Placement

If exceptional resistance is encountered, a power drill may be used with great care. Drilling should continue until the stop of the Step Drill comes into contact with the Lag Screw Guide Sleeve (Fig. 3a). Ensure that the Targeting Device is well supported to prevent it from slipping back or rotating. The drilling process, especially when the tip of the drill comes close to its final position in the femur head, should be controlled under an image intensifier to avoid hip joint penetration. The K-Wire also may be observed in the K-Wire Window of the Step Drill (Fig. 3b).

Note:
It is important to observe the K-Wire tip during drilling using the intensifier. The K-Wire window provides an additional possibility to double check the K-Wire end position. Ensure that under no circumstances the K-Wire is advanced into the pelvis.

The correct length of the Gamma3 RC Lag Screw is chosen by selecting a size that was measured previously with the Lag Screw Ruler. It is important that the assembled Gamma3 RC Lag Screw protrudes through the lateral femoral cortex. This will ensure rotational stability in the nail axis and allows the Gamma3 RC Lag Screw to slide laterally.

In case of using compression/apposition the chosen RC Lag Screw must be shorter depending on the expected amount of compression.

Note:
The disassembled Gamma3 RC Lag Screw (without Gamma3 RC U-Clip and Gamma3 End Cap) is 4 mm shorter than the regular Gamma3 Lag Screw. Because of this, the end of the Gamma3 RC Lag Screw itself will not protrude through the lateral cortical bone until the Gamma3 RC U-Clip and the End Cap have been completely assembled (Fig. 13, page 14).
Separate the selected Gamma3 RC Lag Screw Set from the End Cap and the Gamma3 RC U-Clip and attach the Gamma3 RC Lag Screw to the Gamma3 RC Lag Screwdriver (Fig. 4b) by turning the end thumbwheel clockwise (Fig. 4). Make sure that the pins of the RC Screwdriver are in the slot of the Gamma3 RC Lag Screw (Fig. 4b).

Tighten the thumbwheel. Make sure that the compression wheel of the Lag Screwdriver (Fig. 4a) is positioned closest to the handle.

**Note:**
The Gamma3 RC Lag Screw CAN NOT be connected to the regular Gamma3 Lag Screwdriver (1320-0200) because their designs differ.
Operative Technique

Gamma3 RC Lag Screw Insertion

The RC Lag Screw assembly is now passed over the K-Wire, through the Lag Screw Guide Sleeve, and threaded up to the end of the predrilled hole of the femur head. Check the end position of the RC Lag Screw on the image intensifier. A double check of the end position is also possible with the indicator ring on the RC Lag Screwdriver when it reached the end of the Lag Screw Guide Sleeve.

Compression / Apposition
If compression or apposition of the fracture gap is required, this can be achieved by gently turning the thumb-wheel of the Lag Screwdriver clockwise against the Guide Sleeve. Before starting compression, make sure that the Lag Screw Guide Sleeve is unlocked to allow free sliding. To unlock the Lag Screw Guide Sleeve, the Knob has to be turned counter clockwise.

In osteoporotic bone care must be taken to prevent Lag Screw pullout in the femoral head. The RC Lag Screw must be chosen shorter depending on the expected amount of compression.

Note:
The handle MUST be perpendicular to the Targeting Device, when the RC Lag Screw is in the final position.
Operative Technique

Gamma3 RC Lag Screw Fixation

Assemble the Set Screw to the Set Screw Driver. Insert the Set Screw as shown in Fig. 6 along the opening of the post of the Targeting Device and advance it through the Nail Holding Screw pushing the Set Screwdriver.

Push the Set Screw Driver down until you are sure, that the Set Screw engages the corresponding thread in the nail. While pushing down the assembly, you may feel a slight resistance.

Turn the Screwdriver handle clockwise under continuous pressure. You may notice a slight resistance when turning the Set Screw. This is because the Set Screw thread is equipped with the “Nylstop” system to prevent spontaneous loosening. Turn the Set Screw until you feel contact in one of the two grooves of the RC Lag Screw.

When slightly tightening the Set Screw, make sure that the handle of the Lag Screwdriver is at right angles (90°) to the target arm (Fig. 5a). The Set Screw alignment indicator will help to find the right position of the T-handle.

This ensures that the Set Screw will engage in one of the two Lag Screw sliding grooves (Fig. 6a). To verify the engagement the Set Screw in sliding groove of the Lag Screw, try to turn the RC Lag Screwdriver gently clockwise and counter-clockwise. If it is not possible to turn the RC Lag Screwdriver the Set Screw is engaged in one of the two sliding grooves. If the RC Lag Screw moves, recorrect the T-Handle position and tighten the Set Screw again until it engages in one of the two Lag Screw sliding grooves.

After slightly tightening the Set Screw, it should then be unscrewed by one quarter (¼) of a turn, until a small play can be felt at the RC Lag Screwdriver. This ensures a free sliding of the RC Lag Screw.

Make sure that the Set Screw is still engaged in the sliding groove by checking that it is still not possible to turn the RC Lag Screw with the RC Lag Screwdriver. Subsequently remove the Set Screw Driver.

**Note:**
Do not unscrew the Set Screw more than ¼ of a turn.

**Note:**
If the Gamma3 RC Lag Screw is not correctly secured with the Set Screw, rotational stability of the head fragment cannot be assured.

![Fig. 6: Set Screw insertion through the Targeting Device](image)

![Fig. 6a: Gamma3 RC Lag Screw; sliding possible after unscrewing the Set Screw by 1/4 turn](image)
Before inserting the Gamma3 RC U-Clip, disconnect the Gamma3 RC Lag Screwdriver from the Gamma3 RC Lag Screw by turning the thumbwheel counterclockwise. Remove the Gamma3 RC Lag Screwdriver and the K-Wire.

The Gamma3 RC Lag Screw Connector has to be pre-attached to the T-Handle first (Fig. 7).

Pass this assembly through the Lag Screw Guide Sleeve (Fig. 8) and turn it clockwise using the T-Handle (Fig. 8a). Turning stops when the Gamma3 RC Lag Screw Connector has reached its end position. Remove the T-Handle from the connector.
Operative Technique

Gamma3 RC U-Clip Insertion

Now connect the Gamma3 RC U-Clip to the Gamma3 RC U-Clip Connector by turning the Gamma3 RC U-Clip Connector clockwise (Fig. 9).

Push the Gamma3 RC U-Clip assembly gently over the Gamma3 RC Lag Screw Connector and into the flutes of the Gamma3 RC Lag Screw. If you do not hit the flutes directly turn your Gamma3 RC U-Clip Connector assembly by hand until the assembly glides in easily. The Gamma3 RC U-Clip should be inserted in the position shown in Fig. 10 & 10a so that it glides easily along the flutes of the Gamma3 RC Lag Screw. This is done by hand until the Gamma3 RC U-Clip stops when it reaches the bone. At this point, the Gamma3 RC U-Clip should be approximately 25 mm away from its final position.

Fig. 9: Gamma3 RC U-Clip and Gamma3 RC U-Clip Connector assembly

Fig. 10: Cranial-Caudal view. The Gamma3 RC U-Clip must be positioned perpendicular to the handle of the Target Device

Fig. 10a: Gamma3 RC U-Clip pushed up to RC Lag Screw thread
The Gamma3 RC U-Clip Inserter is required to move the Gamma3 RC U-Clip into its final position. The Gamma3 RC U-Clip will now start to spread to the anterior and posterior side. This procedure requires greater force and cannot be done by hand.

**Note:**
*Never use a hammer!*

The Gamma3 RC U-Clip Inserter is designed to provide the force that will bring the Gamma3 RC U-Clip in its final position, by spreading the U-Clip.

Position the Gamma3 RC U-Clip Inserter over the Gamma3 RC Lag Screw Connector until it contacts the Gamma3 RC U-Clip Connector (Fig. 11).
Operative Technique

Gamma3 RC U-Clip Insertion

Press the lever several times and the Gamma3 RC U-Clip Inserter will push the Gamma3 RC U-Clip forward (Fig. 11a). The Gamma3 RC U-Clip Inserter stops mechanically when the Gamma3 RC U-Clip has been inserted completely. The final position of the Gamma3 RC U-Clip is indicated when the peg of the Gamma3 RC U-Clip Inserter is in line with the indicator ring on the Gamma3 RC Lag Screw Connector (Fig. 11b).

A visual check with the intensifier in the axial view is recommended to affirm the Gamma3 RC U-Clip's final position.

Remove the Gamma3 RC U-Clip Inserter by moving it backwards away from the Gamma3 RC Lag Screw Connector.

The Gamma3 RC U-Clip Connector and the Gamma3 RC Lag Screw Connector are disassembled in the opposite order.
Operative Technique

Gamma3 RC U-Clip Insertion

Note:
Fixation of the Gamma3 RC U-Clip is always completed by securely fastening the End Cap into the Gamma3 RC Lag Screw.

Insert the End Cap through the Lag Screw Guide Sleeve using the Straight Screwdriver 4 mm and tighten firmly (Fig. 12). Gamma3 RC U-Clip insertion is now complete. Remove the Screwdriver and the Lag Screw Guide Sleeve (Fig. 13).

Follow the Gamma3 Operative Technique for Trochanteric or Long Nails, depending which nail is used. Beginning at the chapter entitled Distal Screw Locking, if distal locking is required. If no distal locking is required, continue with the chapter End Cap Insertion.
Operative Technique

Extraction of the Gamma3 Implants

Where implant extraction is indicated, please proceed as follows:

**Step I** (Fig. 14)
Remove the distal screw using the 3.5 mm Screwdriver through a short incision.

**Step II** (Fig. 15)
When the end of the Gamma3 RC Lag Screw Set is exposed in an incision, remove any bony ingrowth which may be obstructing the End Cap to enable the Screwdriver to engage fully. Remove the End Cap.

**Step III** (Fig. 16)
The K-Wire is then introduced via the Gamma3 RC Lag Screw into the head of the femur. The K-Wire provides an easy guide for the next instrument assemblies to be used.

**Step IV** (Fig. 17)
Mount the Gamma3 RC U-Clip Connector over the K-Wire to the Gamma3 RC U-Clip by turning it clockwise. Check that no ingrowth or soft tissue is between the connecting parts. If the thread of the Connector is engaged with the Gamma3 RC U-Clip, retract the Gamma3 RC U-Clip Connector. If the Gamma3 RC U-Clip is not loosened at this stage, a rod can be inserted through the holes of the Gamma3 RC U-Clip Connector assembly to provide a strong handle for pulling back the Gamma3 RC U-Clip.

**Step V**
The RC Lag Screwdriver is passed over the K-Wire and engaged with the distal end of the RC Lag Screw. Make sure that the two pegs of the Gamma3 RC Lag Screwdriver fit to the Gamma3 RC Lag Screw. Tighten the thumbwheel clockwise.

Check that tissue does not obstruct secure engagement of the Gamma3 RC Lag Screwdriver, otherwise the RC Lag Screw or Screwdriver may be damaged and extraction will be much more difficult.
Operative Technique

Extraction of the Gamma3 Implants

**Step VI** (Fig. 18a & 18b)
An incision is made over the proximal end of the nail, the proximal End Cap if used is removed using the Ball Tip Screwdriver or Strike Plate, and the Set Screwdriver is engaged with the Set Screw. The Set Screw is rotated anticlockwise until it is removed.

**Note:**
As the targeting device is not connected to the nail, we recommend using the Straight Set Screwdriver (1320-0210) for better guidance through the soft tissue to get access to the Set Screw.

**Step VII** (Fig. 19)
The Conical Extraction Rod is then threaded and tightened into the proximal end of the nail. The RC Lag Screw is extracted by counterclockwise rotation and pulling of the RC Lag Screwdriver. The K-Wire must then be removed.

**Note:**
It is useful to turn the RC Lag Screw Screwdriver clockwise slightly first to loosen any bony ingrowth into the screw threads before turning it counterclockwise.

**Step VIII** (Fig. 20)
After assembling the Universal Rod to the Conical Extraction Rod, an appropriate sliding hammer is attached to the assembly to extract the nail.
Operative Technique

Extraction of the Gamma3 Implants: Alternative

**Step I** (Fig. 21)

**Step II** (Fig. 22)

**Step III** (Fig. 23)

**Step IV** (Fig. 24)

Fig. 24: Nail extraction using Universal Rod