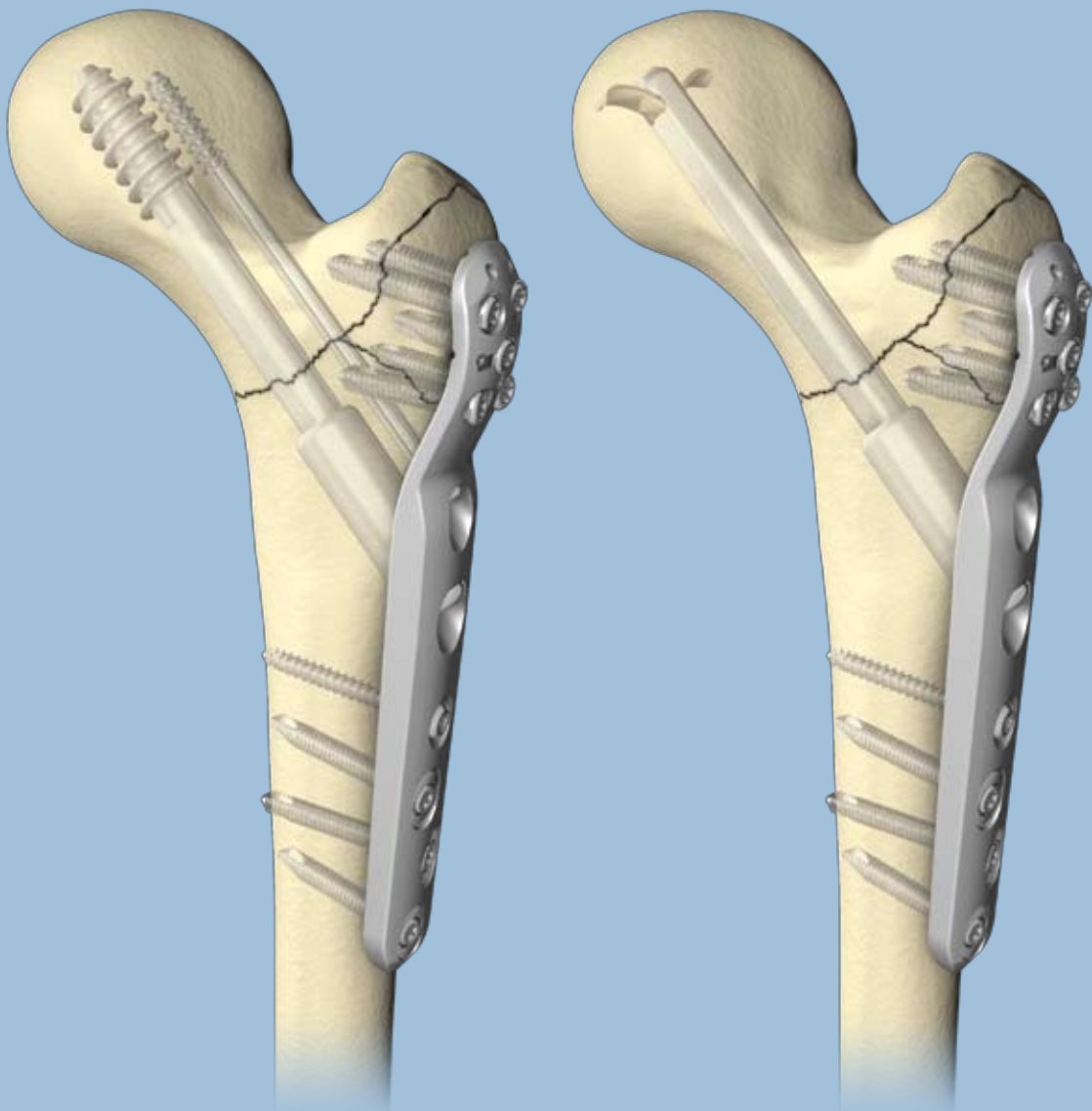


Omega3 System

Operative Technique

- Hip Fracture
- Trochanteric Stabilizing Plate



Introduction

The Omega3 Hip Fracture System

The Omega3 Hip Fracture System is reflecting the long experience of Stryker Osteosynthesis in the treatment of hip fractures. This modular system offers the surgeon a wide choice of slimlined hip plates combined with a unique option of cephalic implants (Hansson Twin Hook) and state of the art instrumentation.

The system provides a potentially simple and easy-to-use solution for surgeons facing hip fractures. The Omega3 Hip Fracture System denotes the new locking technique for the hip plate shaft holes.

Only the Omega3 Hip Plates offer the possibility to apply 5.0mm Locking Inserts and Locking Screws in the plate diaphysis as well as standard 4.5mm Cortical Screws, 6.5mm Cancellous Screws and Asnis III Cannulated Screws.



Potential Features & Benefits

Omega3 Trochanteric Stabilizing Plate

Trochanteric Stabilizing Plate design

- Slim Line Plate design in forged 316L stainless steel.
- Chamfered at the end for easy slide in when used in a minimal invasive approach.
- Corrosion resistant surface treatment.
- 135° degree CCD angle, standard barrel.
- Rotational stable keyed plate.

Anatomically contoured spoon section

- Little or no bending required.
- Reduced OR time.

Spoon section for increased lateral support

- The anatomically shaped spoon section enhances lateral support and prevents from over-lateralisation. Compared to other systems where the lateral support is offered by an additional plate which has to be mounted over the dynamic hip screw, the Omega3 Trochanteric Stabilizing Plate design is made out of one piece and therefore less fiddly and less time consuming for the procedure.

Shaft holes – Standard or Locking

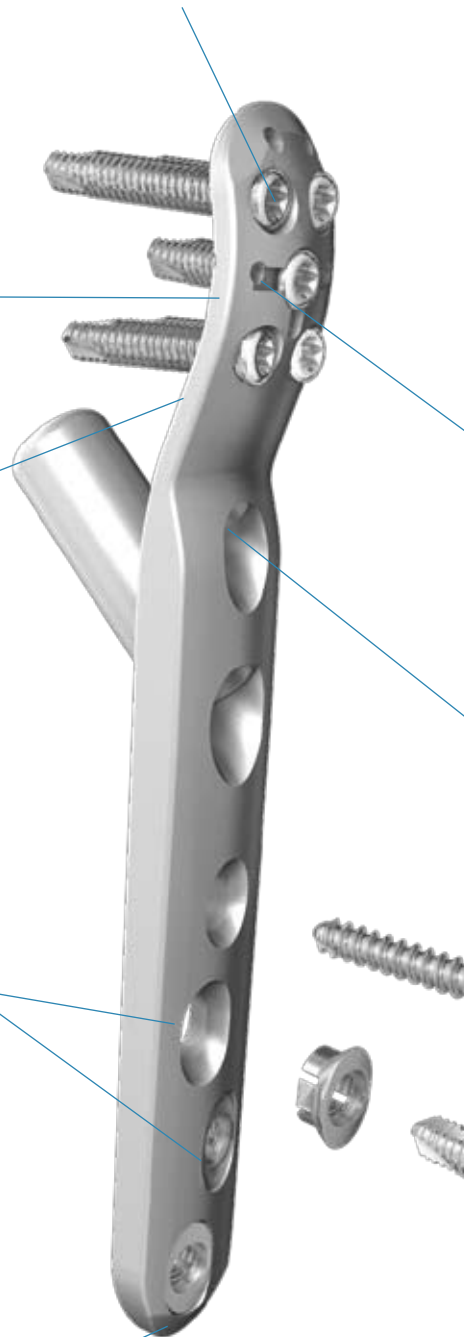
- Shaft holes allowing compression, neutral or buttress fixation with standard Cortical Screws.
- If desired accept Locking Inserts for axially stable fixation with 5.0mm Locking Screws.
- Diverging Locking of 14° when used in axially stable locking mode, thus allowing for increased stability. [1]

Monoaxial holes in the spoon section of the Trochanteric Stabilizing Plate

- Allow axially stable screw placement, enhancing stability of the construct.

Aiming Block

- Facilitates the placement of the Drill Sleeve.
- Handle allows easy removal of Aiming Block after locking.

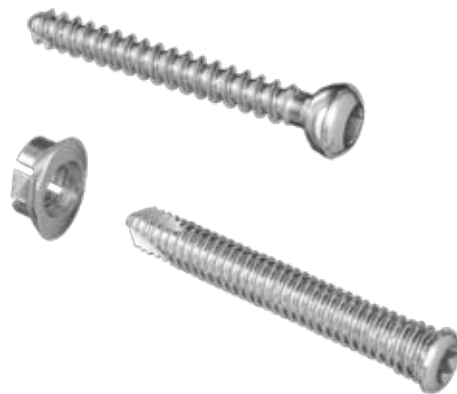


Ø2mm Wire or Suture Holes

- For primary or temporary fixation of fragments or re-attachment of tissue.
- Special undercuts on the reverse side of the plate correlating to the Suture Holes allow simple passing of sutures for tissue reattachment.

Hole for anti-rotation 6.5mm Asnis III Cannulated Screw

- To gain additional rotational stability – especially in indications with involvement of the basal neck or in neck fractures.



Rounded & Tapered Plate End

- Helps facilitate slide-in of plates sub-muscularly.

Note: For more detailed information about the features and benefits of the complete Omega3 Hip Fracture System please refer to the Omega3 Sales Brochure (REF 982309) or the comprehensive Operative Technique of the Omega3 with Twin Hook (REF 982307) or with Standard Lag Screws (REF 982306).

[1] Enhanced fixation with a locked Hip Plate'
 'Stryker Osteosynthesis
 Document & Data on File at Stryker

Relative Indications & Contraindications

Relative Indications

The Omega3 Trochanteric Stabilizing Plate is indicated for fractures of the proximal femur which may include:



- Trochanteric fractures, associated with fractures of the greater trochanter.



- Intracapsular Fractures, associated with fractures of the greater trochanter.

Note: When using the Omega3 System, if there is rotational instability, it is recommended that a 6.5mm Asnis III Cannulated Screw is added to stabilize the fracture.

Relative Contraindications

The physician's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment.

The following contraindications may be of a relative or absolute nature, and must be taken into account by the attending surgeon:

- Any active or suspected latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, infection or prior implantation that can not provide adequate support and/or fixation of the devices.
- Material sensitivity, documented or suspected.
- Obesity. An obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage over the operative site.
- Implant utilization that would interfere with anatomical structures or physiological performance.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

Detailed information is included in the instructions for use being attached to and shipped with every implant.

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

Caution: Bone Screws are not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Operative Technique

Preoperative Planning

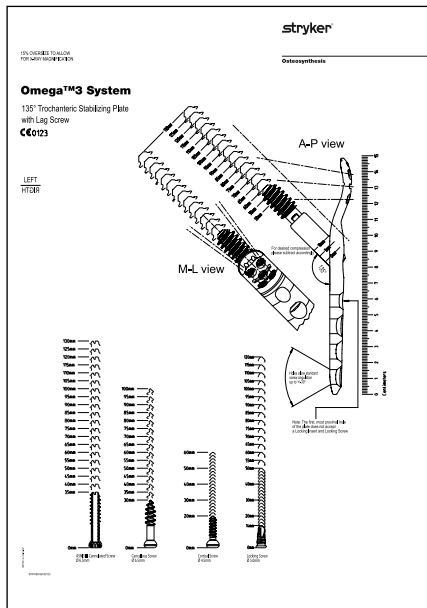


Fig. 1

Review the frontal and lateral X-Rays of the pelvis and injured femur prior to surgery to assess fracture stability, bone quality, as well as Lag Screw or Twin Hook length required.

Tip: Use templates (Fig. 1) preoperatively to plan plate position and Lag Screw or Twin Hook position and length. The template allows also to determine length or position of 5.0mm Locking Screws, 4.5mm Cortical Screws, 6.5mm Cancellous Screws or 6.5mm Asnis III Cannulated Screws.

The Lag Screw or Twin Hook should be centered in the head in medial - lateral (ML) view. In anterior - posterior (AP) view it should be positioned centrally or slightly inferior, this especially when an Asnis III anti-rotation screw is added proximally to the Lag Screw.

The tip of the Lag Screw or Twin Hook should be placed within 5 to 10 millimeters of subchondral bone.

Application of the template to an X-Ray of the uninjured hip may help simulate reduction of the fractured hip.

Preoperative X-Ray Templates for Omega3 Trochanteric Stabilizing Plate

REF	Description:
981132	Omega3 Trochanteric Stabilizing Plate X-Ray Template for Lag Screw technique
981133	Omega3 Trochanteric Stabilizing Plate X-Ray Template for Twin Hook technique



Operative Technique

Important note:

This operative technique only shows specific steps in the operative procedure of the Omega3 Trochanteric Stabilizing Plate (REF 597404S). For a successful operation with the Omega3 Trochanteric Stabilizing Plate the standard technique which is described in the comprehensive Operative Technique for the Omega3 with Twin Hook (REF 982307) or with Standard Lag Screws (REF 982306) has to be known and the surgeon must have had an appropriate training.

The steps of **preoperative planning, patient positioning and fracture reduction** are identical to the procedure of Omega3 with the Twin Hook or with a Standard Lag Screw.

The **skin incision** will most often have to be chosen slightly longer proximally compared to the standard Omega3 technique – this especially if the greater trochanter is fractured and visual access to this anatomic region is preferred for fracture reduction, implant placement and fixation with sutures, wires or 5.0mm Locking Screws.

For the **correct placement of the Guide Pin** follow the instructions in the comprehensive OP techniques mentioned above.

Note: Correct placement of the Guide Pin and with that placement of the Lag Screw or Twin Hook is very important for the outcome of the Omega3 operation. Therefore always make sure to check this position in anterior-posterior (AP) and medial-lateral (ML) view with the image intensifier.

The procedure is followed by Guide Pin measuring, and reaming with the appropriate depth adjusted Combination Reamer as described in the comprehensive OP-Technique. If desired, an anti-rotation 6.5mm Asnis III Cannulated Screw can be added to the Omega3 Trochanteric Stabilizing Plate. For this you will need the Asnis III instrument set in addition to the Omega3 instrumentation.

After reaming with the Combination Reamer, the appropriate length Lag Screw is inserted over the Guide Pin.

Note: If the standard Lag Screw technique is performed, insert a Lag Screw of appropriate length, then place the Omega3 Trochanteric Stabilizing Plate. If you chose the Twin Hook technique, the Omega3 Trochanteric Stabilizing Plate can be placed first, before the Twin Hook is inserted through the barrel of the plate into the prepared channel.

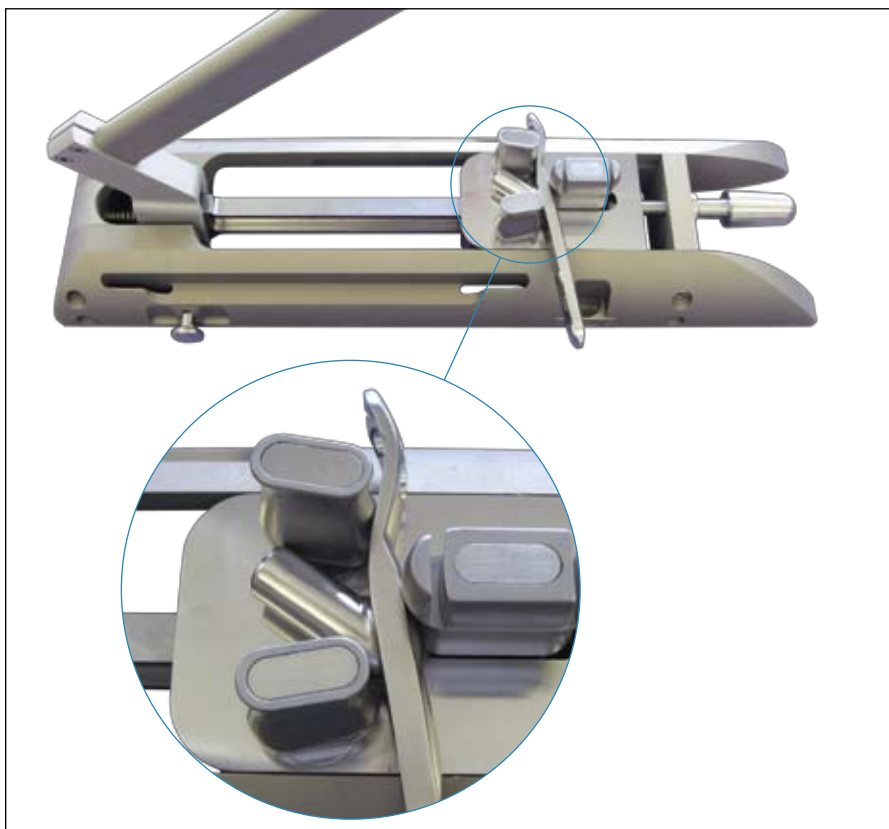


Fig. 2: Bending of the Omega3 Trochanteric Stabilizing Plate with the Table Plate Bender – please refer to the notes on this page.

Bending:

In most cases, the pre-contoured Omega3 Trochanteric Stabilizing Plate will fit without the need for further bending. Due to the functionality of the monoaxial 5.0mm Locking Screws as an internal fixator it is also possible to fix of the greater trochanter with a small gap between the spoon section of the plate and the bone.

However, should additional bending be required, the spoon section may be slightly contoured with the Table Plate Bender (REF 702900).

Note: Bending is only allowed in the region where no Locking Holes are affected (see Fig. 2). Never bend the area of the shaft of the plate or the barrel-to-shaft transition. Be careful not to overbend and never bend back because this might weaken the plate.

Operative Technique

Before the Omega3 Trochanteric Stabilizing Plate is implanted, the Aiming Block (REF 704050) has to be fixed to the spoon section at the proximal end of the plate.

Using the Screwdriver T20 (REF 702748) or the Screwdriver T20 Bit (REF 702754) which fits into a medium T-Handle, the fixation screw is threaded into the central Locking Hole of the spoon section of the plate (Fig. 3).

Note: The small fixation screw (Fig. 3) of the Aiming Block is not intended to be removed for cleaning and sterilization.

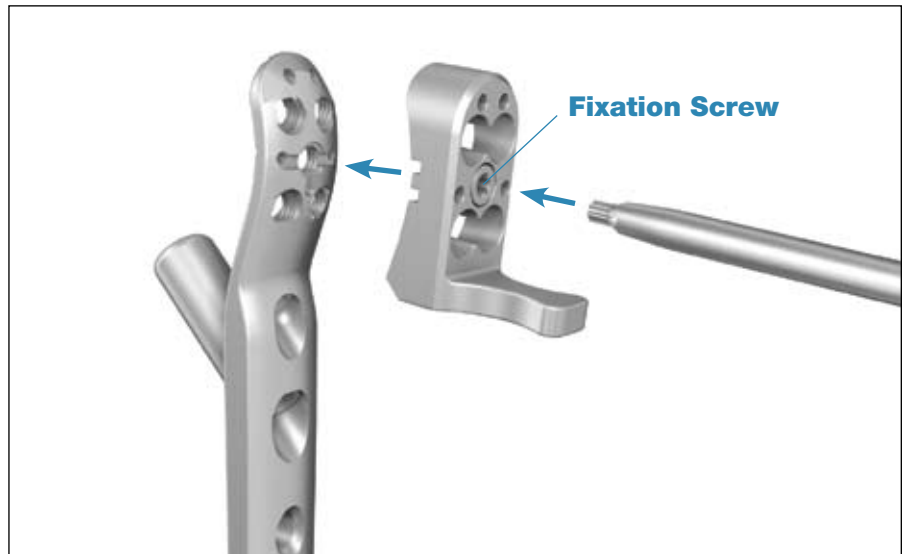


Fig. 3: Fixation of the Aiming Block to the Omega3 Trochanteric Stabilizing Plate.

Insert the Omega3 Trochanteric Stabilizing Plate and seat it if desired with the Plate Impactor (Fig. 4).

Note: Use gentle hammering only – otherwise the impactor may be destroyed.



Fig. 4: Implantation of the Omega3 Trochanteric Stabilizing Plate.

Operative Technique

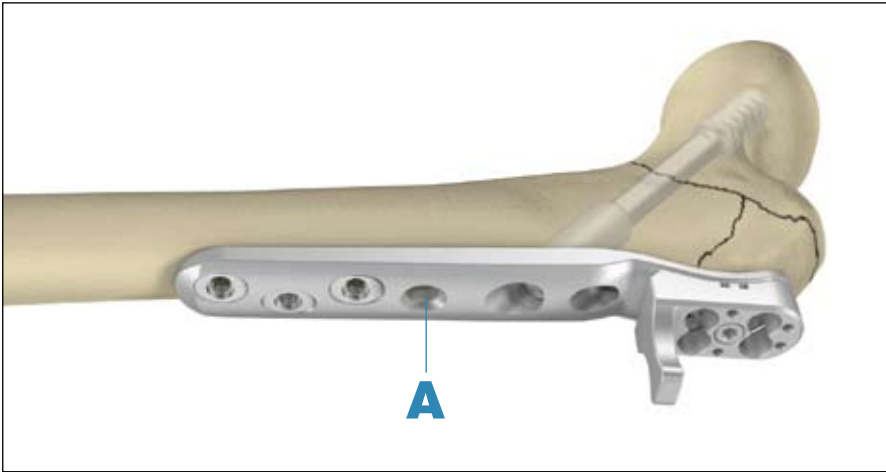


Fig. 5: Fixation of the Omega3 Trochanteric Stabilizing Plate to the femoral shaft. The hole (A) should be filled first with a standard 4.5 Cortical Screw.

Fixation of the Omega3 Trochanteric Stabilizing Plate to the femoral shaft is performed before any screw is inserted into the spoon section (proximal end of the plate). Use a Standard 4.5mm Cortical Screw in the first hole (A in Fig. 5) of the shaft of the plate.

Note: This first hole (A in Fig. 5) does not accept a Locking Insert and Locking Screw. Before drilling and inserting this first screw make sure that the plate is in line along the femoral shaft. If necessary check with the image intensifier from medial to lateral (ML).

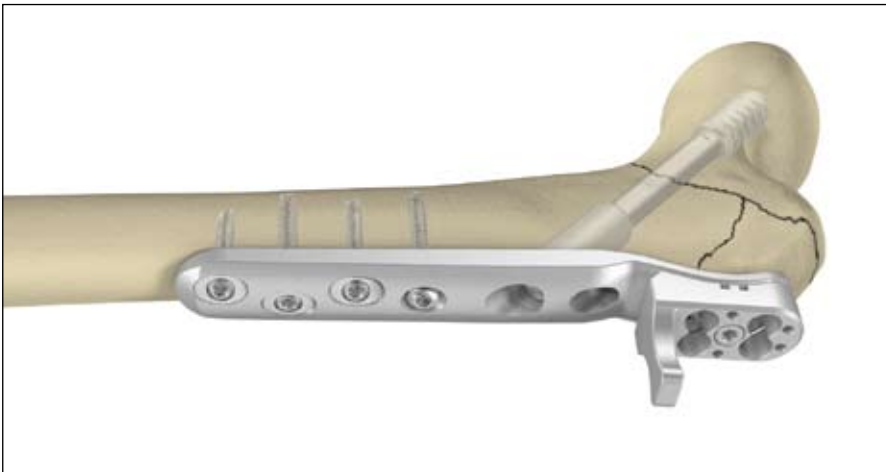


Fig. 6: Shaft holes with a 4.5mm Cortical Screw and locked with a maximum of three 5.0mm Locking Screws for optimal fixation along the femoral shaft.

Then all holes distal to the placed Cortical Screw (in hole A in Fig. 5) are filled either with standard Cortical Screws or Locking Inserts with 5.0mm Locking Screws for axial stable fixation in the shaft (Fig. 6).

For the placement of standard Cortical Screws or axial stable Locking Inserts with Locking Screws please refer to the detailed explanation in the comprehensive Operative Technique of the Omega3 with Twin Hook (REF 982307) or with Standard Lag Screw (REF 982306).

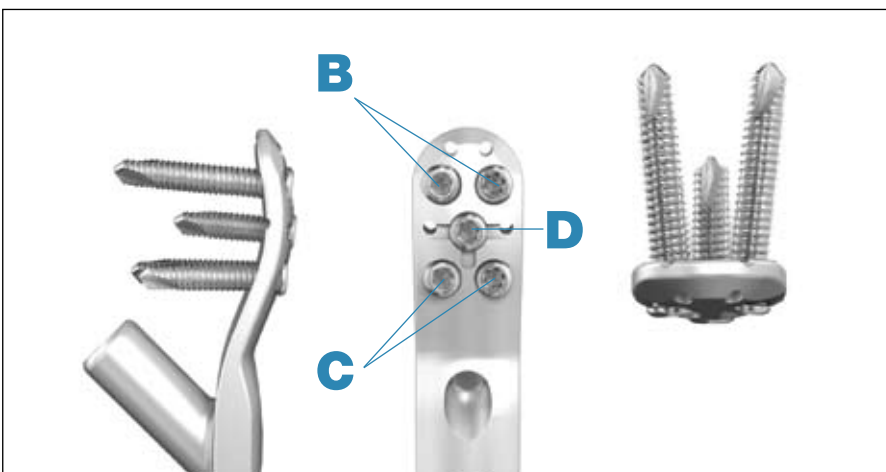


Fig. 7: Monoaxial locking configuration of the spoon section of the Omega3 Trochanteric Stabilizing Plate. The proximal (B) and distal (C) monoaxial locking holes are designed in diverging directions.

Then, if desired the greater trochanter or fragments of the greater trochanter may be fixed to the spoon section at the proximal end of the plate. The hole configuration allows to add five 5.0mm Locking Screws to create a monoaxial stable construct. Two diverging Locking Screws can be placed into the proximal area (B), two also diverging, in the distal portion (C) and one in the center (D) of the Trochanteric Stabilizing Plate (Fig. 7).

Note: For detailed preoperative planning to determine the position of the diverging Locking Screws please refer to page 5 where the preoperative X-Ray templates are described.

Operative Technique

Thread the Drill Sleeve (REF 702708) through the Aiming Block into the preferred hole (Fig. 8).

The Aiming Block guides the Drill Sleeve so that the direction and fixation is easy to be achieved. From there the procedure is the same as described in the comprehensive Operative Techniques.

Drilling is performed with the 4.3mm Drill Bit (REF 702743) under image intensifier control. Then either direct read off the Drill Bit or use the Direct Depth Gauge (REF 702884) to determine the appropriate 5.0mm Locking Screw length.

Then remove the Drill Sleeve. Choose the appropriate length 5.0mm Locking Screw and insert it with the Screwdriver T20 (REF 702748) or the Screwdriver T20 Bit (REF 702754) which fits into a power drill. This procedure is repeated with any desired locking hole.

Note: To avoid any unwanted forces or heat, screw insertion always has to be performed carefully. Always use the threaded drill sleeve when drilling for Locking Screws. Always start inserting the Locking Screw manually to ensure proper alignment. Final tightening always must be done with the Screwdriver T20 Bit (REF 702754) assembled to the Torque Limiter (REF 702751) and the T-Handle (REF 702430). The Locking Screw is adequately tightened when the Torque Limiter clicks at least once at the end of manual tightening.

Removal of the Aiming Block:

Holding the Aiming Block with two fingers on the designed handle, unscrew the central holding screw with the Screwdriver T20 and remove it.

For further steps like wound closure, post operative treatment and implant removal after healing, please refer to the above mentioned comprehensive Operative Techniques of the Omega3 System.

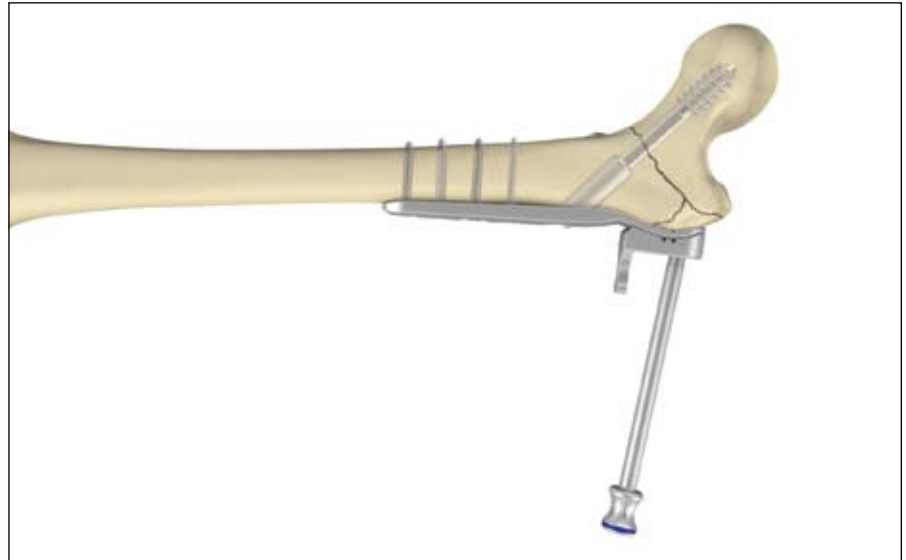


Fig. 8: Fixation of the spoon section of the Omega3 Trochanteric Stabilizing Plate to the greater trochanter.

Note: If desired a 5.0mm Locking Screw may be inserted into the central hole (D in Fig. 7) of the spoon section. For this, the Aiming Block has to be removed first and the Drill Sleeve has to be threaded into this hole free hand before drilling with the 4.3mm Drill Bit.

Note: Do not drill too deep or choose 5.0mm Locking Screws which are too long. As the central Locking Screw points directly towards the Lag Screw, Twin Hook or a anti-rotation Ansis III cannulated screw, be cautious not to allow these implants to make contact. Never allow a Locking Screw to touch these other implants. The proximal and distal screws (B and C in Fig. 7) are diverging and not touching the Lag Screw or Twin Hook. However they might penetrate the far cortex in the area of the femoral neck and hurt the patient.

If desired, tissue may be attached to the spoon section of the Trochanteric Stabilizing Plate. Special undercuts on the reverse side of the plate correlating to the 4 small Suture-Holes allow simple passing of sutures or wires of max. 2mm in diameter for tissue or fragment reattachment.

Note: For more detailed information about the features and benefits as well as the operative Technique of the complete Omega3 Hip Fracture System please refer to the Omega3 Sales Brochure (REF 982309) or the comprehensive Operative Technique of the Omega3 with Twin Hook (REF 982307) or with Standard Lag Screws (REF 982306).

Ordering Information

Omega3 Trochanteric Stabilizing Plate



Stainless Steel REF	Holes	Angle	Length in mm
597404S	4	135°	150

Note: Available Sterile Only

Aiming Block for Omega3 Trochanteric Stabilizing Plate



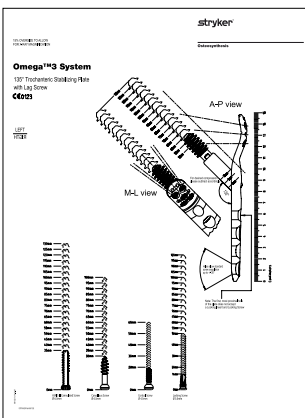
REF	Description
704050	Aiming Block for Omega3 Trochanteric Stabilizing Plate

Additional Instruments necessary to perform an Omega3 Trochanteric Stabilizing Plate procedure

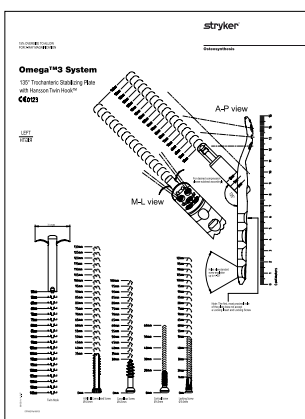
Please refer to the **Order Information** in the comprehensive Operative Technique Guides:

REF	Description
982306	Omega3 with Standard Lag Screw technique
982307	Omega3 with Twin Hook technique

X-Ray Template for Omega3 Trochanteric Stabilizing Plate



981132 Omega3 Trochanteric Stabilizing Plate X-Ray Template for Lag Screw technique



981133 Omega3 Trochanteric Stabilizing Plate X-Ray Template for Twin Hook technique

Notes

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