The Medoff Sliding Plate is a well-proven concept in the treatment of unstable trochanteric and subtrochanteric fractures of the hip. Unlike other devices, which allow dynamic compression only along the axis of the femoral neck, the Medoff Sliding Plate is designed to provide dynamic compression along the axis of the femoral shaft as well.

Product description

The Medoff Sliding Plate consists of a compression slide and a side plate. The implant is available in 4 or 6 holes with a plate barrel angle of 135°.

The Medoff Sliding Plate is used in combination with the Hansson Twin Hook or the Swemac Lag Screw. All plates can be used in combination with the Lateral Support Plate.

The implants are made from 316 LVM stainless steel and are delivered sterile for immediate use.

The problem – load-bearing

In “unstable” trochanteric fractures, subtrochanteric fractures or combined fractures, the sliding action of the Lag Screw is directed obliquely across a key region of the fracture. Thus, shear forces develop along the fracture line, which tend to cause sliding of the fracture fragments. This shear is directly responsible for medial displacement of the femoral shaft and may contribute to instability, increased pain, delayed union, non-union, screw penetration, varus settling of the femoral head and neck, or other complications caused by insufficient impaction of the fracture.

Patent No. EP1307152
Patent No. EP1492465
The solution – load-sharing

The Medoff Sliding Plate has the unique capability of providing dynamic compression along an axis parallel to the femoral shaft, as well as along the femoral neck, or a combination of both.

Axial impaction is achieved along the full length of the fracture line. Loading across the entire fracture site provides resistance to shear and prevents medialization of the femoral shaft keeping the relationship of the proximal and the distal fragments intact. Implant and bone interface stresses are lowered, and the risk of failure is reduced. (Ref. 1-12, 21-23, 26)
Prevents medial displacement

The Lateral Support Plate
– Biaxial dynamization

The Lateral Support Plate prevents medial displacement of the femoral shaft relative to the neck and head fragment, while allowing dynamic axial compression along an axis parallel to the femoral shaft, as well as along the femoral neck.

- **Adjustable and dynamic**
The position of the Lateral Support Plate can be adjusted depending on the distance between the plate barrel and the greater trochanter.

- **Low profile**
The Lateral Support Plate has been designed to minimize soft tissue irritation. The underside of the plate is curved to fit the anatomical curvature of the greater trochanter.

- **Fixation**
The holes in the Lateral Support Plate will accept either a self-drilling/self-tapping 4.5 mm Cortical Screw or a 6.5 mm Cancellous Screw. It is not necessary to introduce any screws through the Lateral Support Plate if the most proximal part of the plate, in its most distal position, is above the fracture line in the lateral cortex.

- **Allows compression**
Contrary to trochanter stabilizing plates, the Lateral Support Plate will allow compression between the fractured lateral cortex and the femoral shaft.

---

*Sevenfold increase in complications if medial displacement is more than 30%*

Parker MJ.

The Locking Set Screw – Uniaxial dynamization

If the fracture line is distal to the entry hole of the plate barrel (i.e. pure subtrochanteric fracture) a Locking Set Screw may be used as an alternative to the Lateral Support Plate to direct dynamic compression exclusively along the femoral shaft, thereby avoiding medial displacement of the femoral shaft.

The only advantage of using the Locking Set Screw in a pure subtrochanteric fracture, compared to a Lateral Support Plate, is a shorter skin incision.

Biplanar cortical bone screw fixation

The Medoff sliding plate has a unique arrangement of the Cortical Screws. The Cortical Screws secure the plate to the femoral shaft in two distinct planes. This biplanar screw fixation is significantly stronger than usual arrangement of other systems, in which the screws all lie in a single plane.

Note! A Proximal Compression Screw should always be inserted into the Hansson Twin Hook or Lag Screw prior to the insertion of a Locking Set Screw.
Biomechanics

Implant surface strains on unstable trochanteric and subtrochanteric fractures

The biomechanical differences between the Medoff Sliding Plate, standard compression screw systems and intramedullary nails are seen most notably in a comparison of the strains on the implant. Loading tests show that under a given load, the Medoff Sliding Plate is subjected to stresses that are two times less than those measured on standard compression screw systems and intramedullary nails. This is due to the fact that the Medoff Sliding Plate acts as a load-sharing device, whereas standard compression screw systems and intramedullary nails acts as load-bearing devices. (Ref. 21-23)

In contrast to the Richards Ambi Plate and the Gamma nail, the Medoff Sliding Plate device functioned as a load-sharing implant in all fracture types. Dynamic compression along the femoral neck and shaft permitted controlled collapse of the fracture along the axis of the femoral neck and the axis of the femur. Axial compression allowed the medial femoral cortex to be loaded under compression, simulating a more normal stress pattern.

Better load-sharing capacity with the Medoff sliding plate. This improves healing and reduces the stress on the implant, thus minimizing the risk of fixation failure.

Olsson O. Kummer FJ. Ceder L. Koval KJ. Larsson S. Zuckerman JD.

Kummer FJ. Olsson O. Pearlman CA. Ceder L. Larsson S. Koval KJ.
Case #1
Unstable trochanteric four part fracture

Preop.

1 week postop.: Some impaction of the fracture has occurred. The entry hole of the plate barrel has been enlarged.

4 months postop.: The fracture has impacted and found a stable configuration.

Case #2
Subtrochanteric fracture

Preop.

1 week postop.

4 months postop.: The fracture has impacted and found a stable configuration.
Results – Medoff Sliding Plate

Unstable trochanteric fractures – biaxial compression

<table>
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<tr>
<th>Author</th>
<th>Year</th>
<th>Reoperations / total patients</th>
<th>Reoperation rate</th>
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Subtrochanteric fractures – uniaxial compression or biaxial compression

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* Prospective randomized studies

Subtrochanteric fractures (Level II) The Medoff sliding plate has been associated with fewer failures of fixation when compared with other screw plates and is recommended for fixation of this fracture.

Chilov MN, Cameron ID, Lyn M March LM.
Evidence-based guidelines for fixing broken hips
References

Clinical articles


15. Lunsjö K, Ceder L, Hauggaard A, Stigsson L. The role of the greater trochanter in fracture stability in uni- or biaxial dynamization with the Medoff Sliding Plate. Hip International 2001; 11(2):71-79


Biomechanical articles

21. Medoff RJ. Implant surface strains 3.5 to 4.0 times lower than three standard compression screws tested. AAOS 1989


Theses


Surgical technique

Indications

- Unstable trochanteric hip fractures
- Subtrochanteric hip fractures
- Combined trochanteric and subtrochanteric hip fractures
- Revisions of intertrochanteric or subtrochanteric non-unions

This surgical technique will describe how to operate an unstable trochanteric fracture with a broken lateral wall. A Hansson Twin Hook will be used in combination with a 4 hole Medoff Sliding Plate and a Lateral Support Plate.

The instrument set of the Hansson Twin Hook together with the Medoff Reamer will be used.

Contraindications

The Medoff Sliding Plate is not recommended for use with pediatric hip fractures.

The physician’s education, training and professional judgement must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of implant failure include:

- 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.
- Patients who are unwilling or incapable of following postoperative care instructions are contraindicated for these devices.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

The surgeon must discuss all relevant risks, including the service life of the device and the need for postoperative protection of the implant with the patient, when necessary.
1. Patient positioning

Place the patient in supine position on the fracture operating table. Position the leg on the healthy side with the hip in flexion and adequate abduction so that the C-arm can be adjusted intraoperatively for both the anterior/posterior view, and the axial view which is necessary to obtain a true axial view of the femoral neck and head.

2. Reduction

The fracture is reduced by flexion, longitudinal traction, abduction and internal rotation on a fracture table. The fracture position should be anatomical or with a slight valgus tilt. The proximal femur should be positioned so that the head and neck are parallel to the floor.

The foot should be rotated inwards and fixed between 15° and 60° of internal rotation. The patella should have an either horizontal or slightly inward position. The patient should then be prepared and draped. In unstable fractures, Guide Wires can be placed, in order to stabilize the reduced fragments.
3. Locate the optimal point for skin incision

A Guide Wire, (1) is held under AP-view of the image intensifier, above the skin anterior to the hip joint and in line with the medial cortex of the femoral neck.

A second Guide Wire, (2), is held transversely to the femoral shaft and directed against the point where the first Guide Wire and the skin meet, (A).

The second Guide Wire is then rotated around the femur until it is in a vertical position. A third Guide Wire, (3) (the first Guide Wire can be used), is held under lateral view of the image intensifier. It is placed along the midline of the axis of the femoral shaft.

A second Guide Wire, (2), is held transversely to the femoral shaft and directed against the point where the first Guide Wire and the skin meet, (A).

The point where the second and the third Guide Wire cross, (B), is the optimal starting point for the incision.
4. Make incision

A longitudinal incision is made, distal from this point through the skin. The deep fascia is divided in the direction of the fibres. The lateral cortex of the femur may be approached either directly or posterior-laterally by lifting the vastus lateralis muscle. The area of the femur where the plate is to be positioned is cleared with a raspatorium.

The length of the incision is determined by the length of the chosen plate.
If a Lag Screw is used, the incision needs to be increased to allow the plate barrel to slide over the Lag Screw.

5. Introduce the Angle guide

Orientation and placement of the Guide Wire is the most critical step in the whole surgical procedure.
In the frontal view the Guide Wire should run centrally in the femoral head.

In the lateral view, the Guide Wire should be centered in relation to the femoral head and neck.

Note! Introduce the Guide Wire through the Angle Guide before starting to drill. The threaded tip of the Guide Wire may otherwise damage the Angle Guide.
6. Guide Wire insertion

The Angle Guide is placed on the lateral cortex and the 3.2 mm Guide Wire is inserted in the desired angle.

Using image intensification, once the alignment of the Guide Wire is satisfactory, it is advanced to subchondral bone of the femoral head.

The rigid 3.2 mm Guide Wire will allow the surgeon to adjust the position of the Guide Wire slightly while drilling.

**Note!** The Guide Wire is single use and shall not be re-used.
Enlargement of entry hole?

**Unstable trochanteric fracture**

If the fracture line extends into the trochanteric region, proximal to the entry hole of the sideplate barrel (unstable trochanteric fracture) it is necessary to enlarge the distal aspect of the sideplate barrel entry hole by approximately 20 mm to prevent the sideplate barrel from impinging on the lateral cortex of the distal fragment and obstructing dynamic axial compression.

A 4 hole plate is recommended for this indication.
If the lateral cortex is fractured, it is recommended to use a Lateral Support Plate.

**If in doubt ream it out!**
*(Enlargement of entry hole)*

---

**Subtrochanteric fracture**

If the fracture line is distal to the entry hole of the sideplate barrel (i.e., pure subtrochanteric fracture), no modification of the lateral cortex is required.

A Lateral Support Plate (1) or a Locking Set Screw (2) is recommended to prevent medial displacement.
A 6 hole plate is recommended for this indication.

**If in doubt leave it out!**
*(Locking Set Screw)*
7. Place a second Guide Wire through the Angle Guide

A second Guide Wire is placed through the most distal hole of the Angle Guide marked with a "M" and advanced through the lateral cortex until it reaches the medial side.

8. Length determination

Place the Measuring Sleeve over the most proximal of the two Guide Wires and read the length at the end of the Guide Wire.

Make sure that the Measuring Sleeve is in contact with the lateral cortex before reading the length. The measured value determines the length of the Hansson Twin Hook and the settings for the Step Reamer.

The correct depth for reaming and Hansson Twin Hook length will be 10 mm less than the measurement obtained from the Measuring Sleeve.
9. Assemble the Step Reamer

The locking nut is pushed forward onto the reamer and turned clockwise as far as it will go. The pre-assembled reamer and locking nut is now ready to be slid onto the back end of the drill.

For example
- Measuring Sleeve measurement: 115 mm
- Step Reamer depth setting: 105 mm
- Hansson Twin Hook length selected: 105 mm

10. Reaming

The Step Reamer is inserted over the Guide Wire and drilling is carried out to within 10 mm of the subchondral bone.

The hole which is made in one step has three different diameters: one for the Hansson Twin Hook, one for the plate barrel and one for the junction between the plate and the barrel.
11. Enlargement of the entry hole

The Medoff Reamer is inserted over the distal Guide Wire and advanced until the mechanical stop. The Guide Wire is then removed.

The Medoff Reamer is used to smooth out the connection between the holes into a slot. The Angle Guide can be used to push the Medoff Reamer from proximal to distal.

12. Plate insertion

The plate barrel is introduced through the distal end of the slot and pushed proximally. The Lateral Support Plate should always be used when the lateral cortex is fractured.

The Lateral Support Plate is introduced together with the Medoff Sliding Plate. A periost elevator is used in order to separate the soft tissue from the bone, creating a pocket proximal to the entrance hole of the plate barrel.
13. Assemble the Hansson Twin Hook and instruments

Select a Hansson Twin Hook of the appropriate length. The inner introducer is inserted into the outer introducer. The inner introducer is then firmly engaged into the base of the Hansson Twin Hook.

If preoperative compression of the fracture is needed, the Hansson Twin Hook must be positioned 5-15 mm within the end of the plate barrel. (A shorter Hansson Twin Hook must be selected.)

14. Hansson Twin Hook insertion

The Hansson Twin Hook is inserted through the plate barrel, and the assembly is pushed into the reamed channel. The insertion instruments can be used as a joystick.
15. Plate alignment

When the Hansson Twin Hook is in position, align the Medoff Sliding Plate with the femoral shaft.

16. Extrude the hooks

The Introducer Handle is rotated clockwise until it meets resistance, that is, the tip of the Introducer Handle touches the tip of the Hansson Twin Hook. It is important to push forward on the handle of the outer introducer, when activating the hooks.

The hooks are activated by turning the Introducer Handle clockwise as far as it will go. Both frontal and lateral image intensification is utilized to ensure accurate placement. The introducer assembly is then removed.
17. Drill for cortical bone screw

When starting to drill for 4.5 mm screw placement, always start with the most distal screw hole in order to get the correct alignment along the femoral shaft. Before any drilling is carried out, the surgeon may reduce traction from the fracture table to allow impaction of the fracture. Care should be taken to avoid losing the fracture reduction.

A pilot hole is drilled with a 3.2 mm Drill through the Drill Guide. The Medoff Sliding Plate is slightly curved to fit around the femoral shaft. The screw holes are designed to direct the Cortical Screws in two distinct planes.

18. Measure cortical screw length

The screw length is read against the projecting part of the Drill. In this case, the selected cortical screw length is 40 mm.

If the projecting part of the drill is positioned between two screw sizes, always choose the longer one. Always add 2 mm to the measured length when using self-cutting screws.
Measure with the Measuring Gauge (optional)

Measuring can also be done by using the traditional Measuring Gauge. The Drill is removed and the hook of the Measuring Gauge is introduced through the drill hole in the lateral cortex.

Capture the medial cortex with the hook and push the outer part of the Measuring Gauge forward against the lateral cortex. The length is read off the hook in the measurement window. Always add 2 mm to the measured length when using self-cutting screws.

19. Place cortical bone screw

The Plate is attached to the femoral shaft with 4.5 mm self-tapping Cortical Screws. All screws are inserted with a 3.5 mm Screw Driver Hex.

The cutting flutes of the cortical bone screw shall penetrate the medial cortex for maximal bone purchase.
Compression of the fracture (optional)

A Compression Screw can be used to compress the fracture. This is only possible if the surgeon left the end of the Hansson Twin Hook inside (5-15 mm) the end of the plate barrel.

Note! Too much compression might bend the hooks.

20. Removal of the Locking Set Screw

The Locking Set Screw is removed with a 3.5 mm Screw Driver Hex, making dynamic compression possible along the axis of the femoral shaft.
20. Check implant position

It is important to ensure that the Hansson Twin Hook is placed within the femoral head. This can be done by removing traction and rotating the hip under image intensification in both AP- and lateral-view.

21. Fixation of the Lateral Support Plate

The position of the Lateral Support Plate can be adjusted depending on the distance between the plate barrel and the greater trochanter.

The holes in the Lateral Support Plate will accept either a self-drilling/self-tapping 4.5 mm Cortical Screw or a 6.5 mm Cancellous Screw.

It is not necessary to introduce any screws through the Lateral Support Plate if the most proximal part of the plate, in its most distal position, is above the fracture line in the lateral wall.

When all Cortical Screws have been inserted, the wound is closed in layers, according to the normal procedures for wound closure.

Postoperative care

Full weight-bearing as tolerated by the patient may be allowed in elderly patients. In younger patients, partial weight-bearing is preferable.
Extraction

Should the need arise for implant removal, the Hansson Twin Hook is extracted with the Hansson Twin Hook Extractor.

The plate and the Lateral Support Plate is removed with a 3.5 mm Screw Driver Hex if needed.
## Implants

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Description</th>
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| Medoff Sliding Plate | Classic | 135° | 4 holes | 6011S  
|                                                  |                      | 6011N |
| Medoff Sliding Plate | DHS     | 135° | 4 holes | 6012S  
|                                                  |                      | 6012N |
| Medoff Sliding Plate | Classic | 135° | 6 holes | 6018S  
|                                                  |                      | 6018N |
| Medoff Sliding Plate | DHS     | 135° | 6 holes | 6019S  
|                                                  |                      | 6019N |
| Medoff Sliding Plate w. Locking Screw | Classic | 135° | 6 holes | 6022S  
|                                                  |                      | 6022N |
| Medoff Sliding Plate w. Locking Screw | DHS     | 135° | 6 holes | 6023S  
|                                                  |                      | 6023N |
| Lateral support plate short                      |                      | 250.01.005S  
|                                                  |                      | 250.01.005N |
| Lateral support plate                            |                      | 250.01.010S  
|                                                  |                      | 250.01.010N |

## Instruments

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Instruction For Use

– Medoff Sliding Plate

DESCRIPTION

The Medoff Sliding Plate consists of an anatomically shaped compression slide and a barred sliding plate, made of implantable stainless steel (ISO 5832-1). The device is a single use device intended for the temporary stabilization of bone segments or fragments until bone consolidation has been achieved. The Medoff Sliding Plate consists of sliding plates in different angulations and of several lengths. The Medoff Sliding Plate allows for placement of a lag screw or Triax Hook, for fixation in the femoral head.

Medoff Sliding Plate allows for axial compression across the fracture site. Rigid compression directed along the shaft of the femur at the fracture site is easily accomplished with this device. When the locking set screw is used, it will prevent sliding between the lag screw and the compression slide. The Medoff Sliding Plate is intended as a load sharing device; load bearing of the device without cortical contact across the fracture site should not be attempted. The Medoff Sliding Plate may be used in combination with a Swemac lag screw, Swemac Twin Hook, standard hip compression lag screw type CLASSIC or standard hip compression lag screw type DHS. The implants shall mate structurally with the type of lag screw system to be used. In order to ensure compatibility with Medoff Sliding Plate. Medoff Sliding Plate can be used in combination with a Swemac Lateral Support Plate.

The device is for professional use only.

COMPATIBILITY

The implants are safe for the patient undergoing an MR procedure, but depending on the implant materials, image artifacts may occur.

INDICATIONS

• Subtrochanteric hip fractures.
• Unstable trochanteric hip fractures.
• Commminuted intertrochanteric hip fractures
• Selected subtrochanteric non-unions

CONTRAINDICATIONS

The physician’s education, training and professional judgment must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

• Any active or suspected latent infection, sepsis or marked local inflammation in or around the surgical area.
• Severe osteoporosis, insufficient quantity or quality of bone/soft tissue.
• Material sensitivity, documented or suspected.
• Physical interference with other implants during implantation or use.
• Compromised vascularity, inadequate skin or neurovascular status.
• Compromised bone stock that cannot provide adequate support and/or fixation of the device due to disease, infection or prior implantation.
• Patients who are unwilling or incapable of following post-operative care instructions.
• Other physical, medical or surgical conditions that would preclude the potential benefit of surgery.
• Obesity. An obese patient can produce loads on the implant that can lead to device/implant failure.

The Medoff Sliding Plate is not recommended for use with pediatric hip fractures.

WARNINGS

• Do not use the device without reading the surgical manual, which has been provided to the clinic separately.
• The device must only be used by a professional surgeon who is thoroughly familiar with the implant, the methods of application, instruments, and the recommended surgical technique of the device.
• The implant can be available in different sizes and versions. It is important to select the appropriate combination of implant components and sizes taking into consideration the length, body weight, anatomy and functional demands of the patient. Implants which consist of several components must only be used in the prescribed combination (see surgical manual).
• Improper positioning of the device may lead to clinical failure.
• Do not re-use the implants, since previous stresses may have created imperfections, which can lead to a device failure.
• Do not touch sharp edges of instruments or implants.
• If either the product or package seems damaged, contaminated or if sterility is questioned for any reason, the product shall not be used.
• Do not re-use single use guide wires. Single use guide wires may be damaged or bent and their use for procedures. If a single use guide wire is re-used it may become lodged in a drill or reamer and unintentionally advanced into the body.
• Drills and reamers with measuring function must not be re-sharpened.
• The surgeon must be fully familiar with the biomechanical principles of the Medoff Sliding Plate.
• Re-sterilization of sterile components is prohibited due to complicated assembly. Incorrect re-assembly may lead to clinical failure.
• The device should not be used unless rigid medial contact of bone surfaces can be produced and maintained.

PRECAUTIONS

• Ensure that all components needed for the operation are available in the surgical theatre.
• Inspection is recommended prior to surgery to determine if implants have been contaminated or damaged during storage.

• Handle instruments with care. Instruments should be examined for wear or damage prior to surgery.
• Avoid surface damage to the implant and discard all damaged or mishandled implants.
• After the procedure check the proper positioning of all implants using an image intensifier. Correct positioning of the implant parts is extremely important for the outcome (see surgical manual).
• Do not use components from Swemac in combination with components from other manufacturer’s system.
• Prior to surgery, the surgeon should personally check that the type of lag screw to be used is compatible with the Medoff Sliding Plate.
• Prior to fitting the barred side plate to the femur, the location of the bone screws should be checked to assure that these screws will all transverse the canal of the femur when placed.
• To minimize the risk for medial displacement of the femoral shaft, Swemac Lateral Support Plate can be used in combination with the Medoff Sliding Plate.

ADVERSE EFFECTS

• Pain, discomfort, abnormal sensations, nerve damage, soft tissue damage, infections, necrosis of bone, bone resorption, necrosis of the tissue or inadequate healing may result from the presence of an implant or due to surgical trauma.
• Treatment failure such as fracture or loosening of the implant may occur due to excessive activity, prolonged loading upon the device, incomplete healing, delayed union, non-union or excessive force exerted on the implant during insertion.
• Implant migration and/or loosening may occur.
• Mal-union may occur.
• Shortening of the affected bone/fraction site.
• Metol sensitivity, histological or allergic reaction resulting from implantation of a foreign material may occur.
• Penetration of the femoral head may be associated with chondrolysis or improper placement of the implant.

POSTOPERATIVE CARE INSTRUCTIONS:

The patient must be cautioned about the use, limitations and possible adverse effects of this implant. The patient must also be warned that the implant and/or treatment might fail if he/she neglects the postoperative care instructions.

• The implantation affects the patient’s ability to carry loads and her/his mobility and general living circumstances. For this reason, each patient needs individual instructions on correct behaviour after implantation.
• The device is not designed to immediately withstand the stress of weight bearing, load bearing or excessive activity.
• Explain the need to report unusual changes in the implantation area as well as falls or accidents even if the device or the surgical area did not appear to be harmed at the time.
• The fixation of the subtrochanteric and unstable intertrochanteric femoral fractures carries an increased risk of complications for all types of fixation due to the nature of the high forces across this type of fracture. Postoperative rehabilitation should not permit full weight bearing of the injured extremity until union has occurred across the fracture site.

CLEANING AND DISINFECTION

The instruments should be disassembled before cleaning. Cleaning shall be performed in accordance with ISO 15883. Cannulated instruments must be visually inspected after cleaning.

STERILIZATION AND RE-STERILIZATION

Sterile devices have been exposed to a minimum dose of 25.0 kGy gamma irradiation. If either the implant or the package appears damaged, or if sterility is questioned for any reason, the implant shall not be used. The instruments shall be sterilized and re-sterilized by using a validated sterilization process in accordance with ISO 17065.

Re-sterilization of sterile components is prohibited due to complicated assembly. Incorrect re-assembly may lead to clinical failure.

The following sterilization parameters are recommended:

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</tbody>
</table>

* Holding time. These times do not include air removal or penetration times.

STORAGE INSTRUCTION

Store in a cool dry place and keep away from direct sunlight.

SYMBOLS USED ON THIS DEVICE

Symbol

- Sterile
- Non-sterile
- Do not re-use
- Re-sterilization is prohibited
- Do not use if product is damaged
- Consult instructions for use
- Do not use if package is damaged
- Caution

FURTHER INFORMATION

This Instruction For Use leaflet is only provided in English. Other languages of this leaflet and the recommended surgical technique as well as detailed instructions for cleaning, sterilization and re-sterilization can be downloaded in PDF format from the Swemac website www.swemac.com. Printed documentation can be provided free of charge upon request. Delivery time is max 7 days.
Swemac develops and promotes innovative solutions for fracture treatment and joint replacement. We create outstanding value for our clients and their patients by being a very competent and reliable partner.