**Medoff Sliding Plate System- Instructions For Use**

**English**

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**FURTHER INFORMATION:**
This Instruction For Use leaflet is only provided in English. Other languages of this leaflet and the recommended surgical techniques, as well as detailed instructions for cleaning, sterilization and re-sterilization can be downloaded in PDF format from the Swemac website:
http://www.swemac.com/ifu/IFU-0123/. Printed documentation can be provided free of charge upon request. Delivery time is max 7 days.

**DESCRIPTION:**
The Medoff Sliding Plate system consists of anatomically shaped compression slabs and barreled side plates, made of implantable stainless steel (ISO 5832-1). The system includes Medoff Sliding Plate (4 and 6 holes) and Medoff Locking Plate (4 holes, 2 holes are angle-stable) which are available in different angulations. The devices are single use and intended for temporary stabilization of bone segments or fragments until bone consolidation has been achieved. Both Medoff Sliding Plate and Medoff Locking Plate allows for placement of a Swemac Lag screw or Hansson Twin Hook, for fixation in the femoral head. Medoff Sliding Plate system allows for axial compression across the fracture site. When the locking set screw is used, it will prevent sliding between the lag screw and the compression slide. The Medoff Sliding Plate system is intended as a load sharing device; load bearing of the device without is achieved. Both Medoff Sliding Plate and Medoff Locking Plate can be used in combination with a Swemac Lateral Support Plate. Medoff Sliding Plate system is intended as a load sharing device; load bearing of the device without is achieved. Both Medoff Sliding Plate and Medoff Locking Plate can be used in combination with angle-stable cortical screws from Swemac.

**INDICATIONS:**
The correct selection of the fracture fixation application is extremely important. Failure to select the appropriate combination of implant components and sizes in accordance with the surgeon's needs and the needs of the patient may result in loosening, bending, cracking or fracture of the device and/or bone.

**CONTRAINdications:**

- 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 vascularly, 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.
- Previous implanted or extracted osteosynthesis implants of the diaphyseal or proximal femur increases the risk of secondary fracture.
- Obesity. An obese patient can produce loads on the implant that can lead to device/treatment failure.

**PRECAUTIONS:**

- The Medoff Sliding Plate system is not recommended for use with pediatric hip fractures.
- The Medoff Sliding Plate system is intended as a load sharing device; load bearing of the device without is achieved. Both Medoff Sliding Plate and Medoff Locking Plate can be used in combination with angle-stable cortical screws from Swemac.

**COMPATIBILITY:**
The Medoff Sliding Plate system may be used in combination with a Swemac Lag screw or a Hansson Twin Hook. Medoff Sliding Plate and Medoff Locking Plate can be used in combination with a Swemac Lateral Support Plate. Medoff Locking Plate can be only be used in combination with angle-stable cortical screws from Swemac.

**LIMITATIONS AND POSSIBLE ADVERSE EFFECTS:***

- Material sensitivity, histological or allergic reaction resulting from implantation of a metallic foreign body may occur.

**POSTOPERATIVE CARE INSTRUCTIONS:**
Postoperative care is extremely important. 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.
- 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 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.

**STERILITY:**
The implants are provided sterile. 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.

**CLEANING AND DISINFECTION:**
The instruments should be disassembled before cleaning. Cleaning shall be performed in accordance with ISO 11607. Cannulated instruments must be visually inspected after cleaning.

**STERILIZATION AND RE-STERILIZATION:**
The instruments should be sterilized and re-sterilized by using a validated sterilization process in accordance with ISO 17665. Sterile packaging shall be done in accordance to ISO 11607-1. Re-sterilization of sterile implant components is prohibited due to complicated assembly. Incorrect re-assembly may lead to clinical failure.

**SYMBOlS USED ON THIS PRODUCt:**

- Sterilized using irradiation
- Do not use if package is damaged
- Do not re-sterilize
- Caution
- Consult instruction for use
- Non-sterile

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**SAFETY:**

- 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 vascularly, 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.
  - Previous implanted or extracted osteosynthesis implants of the diaphyseal or proximal femur increases the risk of secondary fracture.
  - Obesity. An obese patient can produce loads on the implant that can lead to device/treatment failure.

**WARRNINGS:**

- Do not use the device without reading the surgical manual, which has been provided to the clinic separately.
- The correct selection of the fracture fixation application is extremely important. Failure to use the appropriate application for the fracture condition may accelerate clinical failure.
- Failure to use the proper component to maintain adequate blood supply and provide rigid fixation may result in loosening, bending, cracking or fracture of the device and/or bone.
- The implant may 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 insertion of the device during implantation can increase the possibility of loosening or migration.
- 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 contaminated or if sterility is questioned for any reason, the product shall not be used.
- Do not re-use single use guide wire. Single use guide wires may be bent or damaged through surgical procedures. If a single use 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 device is not designed to immediately withstand the stress of weight bearing, load bearing, or excessive activity.
- It is important to ensure that the guide wire does not penetrate the hip joint.
- The device must only be used by a professional surgeon who is thoroughly familiar with the implant, the methods of application, the biomechanical principles of the Medoff Sliding Plate system, instruments, and the recommeded surgical technique of the device.

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**THE FOLLOWING STERILIZATION PARAMETERS ARE RECOMMENDED:**

<table>
<thead>
<tr>
<th>Method</th>
<th>Temperature</th>
<th>Time</th>
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<tbody>
<tr>
<td>134°C for min. 3 minutes*</td>
<td>121°C for min. 15 minutes*</td>
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* Holding time. These times do not include air removal or penetration.

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**STRAIGHT**

- Sterilized using irradiation
- Do not use if package is damaged
- Do not re-sterilize
- Caution
- Consult instruction for use
- Non-sterile

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**BPOTENTIAL 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/fracture site
- Metal sensitivity, histological or allergic reaction resulting from implantation of a metallic foreign body may occur.