Swemac

Swemac Trochanteric Hip Fracture System - Instructions For Use

English
IFU-P110-EN-20200525

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CE 0413

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 http://download.swemac.com/Swemac-THF-System. Printed documentation can be provided free of charge upon request. Delivery time is maximum 7 days.

INTENDED USE:
The system is intended for stabilization of bone segments or fragments until bone consolidation has been achieved. The device is for professional use only.

Description:
The Swemac Trochanteric Hip Fracture System (THF) consists of anatomical hip plates (available in different lengths and angulations) for use in combination with either a Hansson Twin Hook or a lag screw. The THF System utilises cortical and cancellous screws for fixation of the hip plates to the femur and includes specialist instrumentation for the surgical procedure. The Swemac lateral support plate (which prevents medial displacement of the femoral shaft) is compatible with the system. All implants are manufactured in implantable stainless steel (ISO 5832-1).

Indications:
- Femoral neck fractures
- Basal neck fractures
- Stable trochanteric hip fractures
- Unstable trochanteric hip fractures
- Subtrochanteric fractures

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.
- 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.
- Previously 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.
- The THF System is not recommended for use with pediatric hip fractures.

COMPATIBILITY:
The components included in this system have not been tested for safety, heating, or migration in an MRI environment. Similar products have been tested and evaluated in terms of how they may be safely used using MRI equipment. Prior to an MRI scan, a patient with a Swemac implant must always disclose the specific implant information to their physician. For details see *Swemac MRI Statement*.
The Swemac Hip Plates can be used in combination with a Swemac Lateral Support Plate.
The Swemac Lag Screw can be used in combination with a Swemac Hip Plate or a Medoff Sliding Plate.
The Hansson Twin Hook can be used in combination with a Swemac Hip Plate or a Medoff Sliding Plate. The Twin Hook Locking Plate shall only be used in combination with a Hansson Twin Hook.

WARNINGS:
- **Do not use the device without reading the surgical manual, which has been provided to the user separately.**
- The device must only be used by a professional surgeon who is thoroughly familiar with the indications and contraindications, 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 described combination (see surgical manual).
- Improper insertion of the device during implantation can increase the risk of loosening or migration.
- Improper positioning of the device may lead to clinical failure.
- Do not reuse 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 during surgical 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.
- Insufficient quantity or quality of bone/soft tissue may increase the risk of loosening or migration.
- The implant is designed as a load sharing device and cannot withstand immediate weight bearing as a load bearing device.
- Selecting the most appropriate fracture fixation method is extremely important. Failure to do so may accelerate clinical failure. Failure to use the correct component to maintain blood supply and provide rigid fixation may result in loosening, bending, cracking or fracture of the device and/or the bone.
- It is important to ensure that neither the guide wire or drill penetrate the hip joint.
- Do not use the reamer or drill if the cutting edge has been damaged or shows evidence of wear.
- Applying too much torque during screw insertion may result in stripping of the bone.
- Twin Hook Locking Plate shall only be used in combination with a Hansson Twin Hook.
- Plate failure 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.
- Do not use the inner introducer as a repositioning tool.

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 transport or 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 clinical outcome (see surgical manual).
- Do not use components from Swemac in combination with components from other manufacturer's systems.
- The surgeon must be proficient in fracture reduction.

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

POSTOPERATIVE CARE INSTRUCTIONS:
Postoperative care is extremely important. The physician's education, training and professional judgment must be relied upon to choose the most appropriate postoperative care. 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 she/he 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 behavior after implantation.
- The implant is designed as a load sharing device and cannot withstand immediate weight bearing as a load bearing device.
- 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.
- Special precautions are necessary when a temporary internal fixation device is used to treat an unstable intertrochanteric fracture or a subtrochanteric fracture. These fractures are more difficult to reduce and can result in unusually strong (and unbalanced) muscle force transmission to the temporary internal fixation device (when compared to other types of femoral fractures). These bending forces increase the possibility of implant bending or breakage.

STERILITY:
The implants are provided sterile or non-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. Non-sterile implants must be sterilized by using a validated sterilization process following EN ISO 17665 prior to use.

CLEANING AND DISINFECTION:
The washer/disinfector used for the automated cleaning process should have proven effectiveness in accordance with ISO 15883. Multi-component instruments should be disassembled before cleaning. For details see *Swemac reprocessing instructions.*

STERILIZATION AND RE-STERILIZATION:
The instruments and non-sterile implants shall 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 Hansson Twin Hook implant components is prohibited due to complicated assembly. Incorrect re-assembly may lead to clinical failure.

The following sterilization parameters are recommended:	134°C for minimum 3 minutes*	132°C for minimum 4 minutes*
* Holding time. These times do not include air removal or penetration.		

STORAGE INSTRUCTIONS:
The package should not be exposed to direct sunlight, ionizing radiation, extreme temperatures or particulate contamination.

SYMBOLS USED ON THIS PRODUCT:

STERILE R	Sterilized using irradiation		Do not use if package is damaged
	Do not reuse	download.swemac.com	Consult instruction for use
	Caution		Do not re-sterilize
NON STERILE	Non-sterile	**RxOnly**	CAUTION: Federal law (USA) restricts this device to sale by or on order of a licensed physician or hospital.
	Keep away from sunlight		

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Swemac Trochanteric Hip Fracture System - Patient Implant Card

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You have received the implant/implants stated on this Patient Implant Card.

Warnings, Precautions, Postoperative care instructions and possible Adverse effects are stated on the back side of this document.

http://www.swemac.com/PIC
For instructions on how to find additional implant information visit the website. You will need the **REF** number and **UDI** number from the attached Patient Record Labels to access the information.

Alternatively, contact our customer service:

Phone: +46 13374030
E-mail: PIC@swemac.com

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Patient Record Labels

Attach Patient Record Label from the used implant package

Attach Patient Record Label from the used implant package

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