Swemac

Motec Wrist Arthrodesis System - Instructions For Use

English
IFU-P145-EN-20240129

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CE 0413

FURTHER INFORMATION:
This Instruction For Use leaflet is only provided in English. Other languages, any available updates, the recommended surgical techniques, information about wear and detailed instructions for cleaning, sterilisation and re-sterilisation can be downloaded from the Swemac website https://download.swemac.com. Printed documentation can be provided free of charge upon request and shall be delivered within 7 days.

INTENDED USE:
The Motec Wrist Arthrodesis implants are intended to be used as salvage procedures for the Motec Wrist Joint Prosthesis.

Description:
The Motec Wrist Arthrodesis System provides salvage options that limit unnecessary implant removal by taking advantage of pre-existing stable and osseointegrated implants from the Motec Wrist Joint Prosthesis. In cases where both the radius and metacarpal components from the Motec Wrist Joint Prosthesis are stable, a Double Taper can be used as a link between the osseointegrated implants. If the metacarpal component is loose, an intramedullary nail can be used together with the Radius Connector. The Metacarpal Nail is placed inside the metacarpal bone and fixed dorsally by cortical screws. Depending on which solution that is chosen, the wrist can be fused in 0°, 15° or 30° (in relation to the fixed radius component). All implant components are manufactured in blasted titanium alloy (Ti6Al4V). The device is for professional use only.

Indications:
Conversion from a failed Motec Wrist Joint Prosthesis.

Contraindications:
- Any active or suspected latent infection, sepsis or 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.
- Open fractures or infections in the joint.
- Other physical, mental, medical or surgical conditions that would preclude the potential benefit of surgery.

MRI SAFETY INFORMATION:
The implants in the Motec Wrist Arthrodesis System have not been evaluated for safety in the MRI environment. They have not been tested for heating or unwanted movement in the MRI environment. The safety of the Motec Wrist Arthrodesis System in the MRI environment is unknown. Performing an MRI examination on a person who has this medical device may result in an injury or device malfunction. For details see *Swemac MRI Statement*.

WARNINGS:
- **Do not use the device without reading the surgical technique brochure, which has been provided to the user separately.**
- The device must only be used by a professional surgeon who is thoroughly familiar with 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 height, body weight, anatomy and functional demands of the patient. Implants which consist of several components must only be used in the described combination (see the surgical technique brochure).
- Improper implantation and/or positioning of the device can increase the risk of loosening or migration and 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 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 must not be re-sharpened. This is especially important for instruments with a measuring function.
- Insufficient quantity or quality of bone/soft tissue may increase the risk of loosening or migration.
- Do not re-sterilize the sterile packed implants because this could lead to surface damages.
- Using the Motec Wrist Arthrodesis System for patients who are unwilling or incapable of following post-operative care instructions increases the risk of a failed wrist fusion.
- Failure to firmly engage the tapers of the Angled Double Taper into the Threaded Implants, or mobilising too early, can lead to unintentional rotation of the Angled Double Taper and fusion to occur in an undesirable wrist position.

PRECAUTIONS:
- Ensure that all components needed for the operation are available in the surgical theatre.
- Inspection of implants should be done prior to surgery to determine if implants have been contaminated or damaged during transport or storage, discard all damaged or mishandled implants.
- Handle instruments with care. Instruments should be examined for wear or damage prior to surgery. For details see *Swemac Inspection instructions*.
- The Motec Wrist Arthrodesis System is not compatible with implants from other manufacturer's systems.
- The device is compatible with Motec Wrist Joint Prosthesis System and the instruments from both the Arthrodesis- and the Prosthesis instrument tray are needed for surgery.

ADVERSE EFFECTS:
- Pain and swelling are expected after any wrist surgery. In addition, surgical or post-operative complications as well as non-compliance to the surgical technique might lead to wound infection, temporary or permanent nerve, tendon or soft tissue damage and/or an unsuccessful wrist fusion.
- Surgical intervention may be required to treat adverse effects. This may involve exchange of components, removal of the threaded implants and conversion to another arthrodesis technique.
- Material sensitivity, histological or allergic reactions resulting from implantation of a foreign material may occur.
- Breakage of the arthrodesis components may occur if the wrist is exposed to excessive force or trauma before complete fusion in between the bones have occurred. Breakage may also occur due to material fatigue if the fusion in between the bones do not occur or is delayed.

POSTOPERATIVE CARE INSTRUCTIONS:
Postoperative care is 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 the risk of clinical failure increases if exposed to load-bearing for a prolonged period of time.
- The patient must be informed about 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. Serious incidents shall be reported to Swemac and the Competent Authority.

STERILITY:
The implants are single-use devices and provided sterile or non-sterile (cortical screws). Sterile devices have been exposed to a minimum dose of 25.0 kGy gamma irradiation and shall not be re-sterilised. Re-sterilisation of sterile implant components is prohibited due to potential surface damage as implants might be scratched during handling which could have negative impact on the safety and performance of the device. If either the implant or the package appears damaged, or if sterility is questioned for any reason, the implant shall not be used. The non-sterile cortical screws must be sterilised by using a validated sterilisation process following ISO 17665 prior to use.

REPROCESSING:
Cleaning and sterilisation
The non-sterile re-usable instruments shall be cleaned and sterilised by using a validated sterilisation process in accordance with ISO 17665. Multi-component instruments should be disassembled before cleaning. The washer/disinfector used for the automated cleaning process should have proven effectiveness in accordance with ISO 15883. Do not re-use an instrument that is worn-out. For details see *Swemac reprocessing instructions*.

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

All devices in the Motec Wrist Arthrodesis System with a measuring scale have an accuracy of ±0.5 mm.

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Motec Wrist Arthrodesis 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

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