CUSTOM MADE PROSTHETIC REPLACEMENT INSTRUCTIONS FOR USE

PLEASE READ THIS IN CONJUNCTION WITH THE SUPPLIED OPERATION TECHNIQUE INSTRUCTION AND THE OPERATION DRAWING.

Implant description:

SIW “Custom made” implants are manufactured in accordance with an approved prescription for a named patient. It **MUST NOT** be used for any other patient.

Section 1

WARNINGS and PRECAUTIONS

SIW Custom made implants are manufactured in accordance with an approved prescription for a named patient. It must not be used for any other patient.

If the packaging of parts marked sterile has been compromised or is damaged do not use.

STERILE R

All plastic components are supplied sterile and must not be re-sterilised if the sterility of the component has been compromised an alternative sterile component must be used.

Stanmore Implants Worldwide custom implants must not be used with products from other manufacturers unless it is specifically authorised. Different manufacturers have different tolerances and therefore a mismatch could lead to failure of the implant. An operation instruction supplied with the implant contains any such authorisation.

The Stanmore Implants Worldwide custom implant are for Single Use Only.

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An operation instruction supplied with the implant contains patient specific information to aid the implantation.

The operation technique instruction must be read prior to carrying out any surgical procedure.

The patient should be cautioned to limit activities and protect the replaced joint from unreasonable stresses and follow the instructions of the physician with respect to follow-up care and treatment. The patient should be closely monitored if a change at the operative site has been detected. The possibility of deterioration of the joint should be evaluated and possible revision surgery considered.

The patient should be warned of surgical risks and made aware of possible adverse effects. The patient should be warned that the prosthesis does not replace normal healthy bone, that the prosthesis can break or become damaged as a result of certain activity or trauma, has a finite expected service life and may need to be replaced at some time in the future. The patient should also be advised of other risks that the surgeon believes should be disclosed.

Improper use or mishandling of the components can result in damage to one or more of the components reducing the in-service life of the implant.

Particular care and attention should be taken with respect to all bearing surfaces, tapers and ceramic coated surfaces.

If the HA coating is contaminated or damaged do not try to clean. Remove from use and contact Stanmore Implants Worldwide for advice.

The Surgical instruments are supplied not sterile. Clean and sterilise before use in accordance with the instructions provided

Surgical instruments must never be placed in physiological saline solution as contact leads to pitting and corrosion.

Improper cleaning tools (e.g. overlarge brushes, metal brushes) can cause damage. **DO NOT** use scouring agents or steel wool.

Ensure detergent solutions operate within a pH range of 6.0-8.0.

Any deviation from recommended sterilisation methods must be validated by the user.

The recommended sterilisation method is only valid with sterilisation equipment that is maintained, calibrated and operated in accordance with local regulatory guidelines.

Ensure steam quality meets acceptable standards to prevent damage and discolouration

For any items that are supplied sterile check to ensure that they are still within their shelf life prior to use.
If there is more than two months between supply custom implant and the implantation,

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further scans must be produced and reviewed against the design by Stanmore Implants Worldwide as this could result in a possible mis-match due to changes in bone geometry.
Specialised instruments are required to assemble and disassemble the components. Using other instruments may damage the components. Instruments can become damaged or may even fracture after repeated use or if used with excessive force. Instruments should be inspected prior to surgery and not used if damaged or worn excessively

Section 2

Indications:

- Primary bone tumours
- Secondary tumours arising in bone
- Non-neoplastic conditions affecting the shafts of long bone
- Failed joint replacements
- Failed massive replacements

Contraindications:

- Absolute contra-indications include
  - Infection and sepsis
- Relative contra-indications include
  - Long delay between manufacturing and insertion of a custom-made implant may result in significant mismatch due to possible changes in bone geometry
  - Inadequate or incomplete soft tissue coverage
  - Uncooperative or unwilling patient or patient unable to follow instruction
  - Foreign body sensitivity. Where materials sensitivity occurs seek advice with respect to testing
  - Obesity
  - Vascular disorder, neuromuscular disorders or muscular dystrophy

Patient Selection:

Factors that should be considered are

- Resection of neoplastic or diseased bone
- At risk from pathological fracture
- Pain relief and improved function
- Ability of patient to willingly follow instructions and under go rehabilitation

Possible adverse effects:

There are a range of potential adverse reactions these may include

- Patient sensitivity to implant materials which may ultimately require removal of the device
- Infection which may require temporary or permanent removal of the device
- Discolouration of the adjacent tissues may occur
- Fretting between metal parts is also possible under certain circumstances

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Intraoperative and early postoperative complications

These may include

- Temporary or permanent nerve damage
- Damage to blood vessels
- Haematoma
- Cardiovascular disorders
- Pulmonary embolism
- Myocardial infarction or venous thrombosis
- Delayed wound healing
- Infection
- Loosening
- Varus and valgus deformity
- Dislocation

Late postoperative complications

These may include

- Loosening
- Bone resorption
- Bone fracture
- Fatigue fracture of metal components
- Wear of components due to misalignment or excessive loading
- Inadequate range of movement
- Infection
- Metal sensitivity or allergic reaction

CUSTOM MADE PROSTHETIC REPLACEMENT INSTRUCTIONS FOR USE

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Cleaning and Sterilisation

All Instruments must be cleaned and sterilised prior to returning to Stanmore Implants Worldwide in accordance with the procedures defined in sections 3 and 4 and the form in appendix 1 must be completed and returned with any items being sent back to Stanmore Implants.

Section 3

INSTRUMENT STERILISATION

IMPORTANT

All instruments **MUST** be cleaned prior to sterilisation (see section 4).

Partially unthread the polymeric cap of the General Impactor (approximately 2mm) while still ensuring that it fits in its specified location within the tray, to improve steam penetration during sterilization.

If the implant is marked as STERILE on the packaging. It has been sterilised using 25 to 40KGy gamma irradiation **DO NOT** re-sterilise.

All components that are supplied sterile will be marked on the packaging as STERILE. They have been sterilised using 25 to 40KGy gamma irradiation **DO NOT** re-sterilise.

If the packaging of parts marked sterile has been compromised or is damaged **DO NOT** use.

All plastic components are supplied sterile and **MUST NOT** be re-sterilised. If the sterility of the component has been compromised, an alternative sterile component must be

For all items that are not marked sterile the following procedure should be followed:

The following sterilisation process should be used for instruments supplied non-sterile

The instruments are recommended to be sterilised using prevaccum or porous load, high temperature steam sterilisation

These devices must be placed in suitably wrapped porous membrane packaging for the sterilisation process (i.e. central supply wrap, autoclave bags, paper/plastic pouches etc.).

The suggested cycles, based on recommended industry standards and regulatory guidance consist of the following:

Method:	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Prevaccum	134-137m	3 minutes (minimum)	30 minutes (minimum)

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Method:	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Porous Load	134 +/-2°C	4 minutes (minimum)	30 minutes (minimum)

Stanmore Implants has validated the above recommended sterilisation cycles. Other sterilisation methods and cycles may also be suitable. Individuals or hospitals are advised, to validate whichever method is considered appropriate for their organisation. Ethylene Oxide (EtO) and cold sterilisation techniques are not recommended.

Ensure the polymeric cap is re-tightened on the General Impactor prior to use.

Ensure all components are dry prior to use.

Section 4

ORTHOPAEDIC INSTRUMENTS AND LOANER SETS

All instruments are supplied cleaned but are NON-STERILE and must be cleaned and sterilised before use and before being returned to Stanmore Implants in accordance with instructions in section 3 and 4 and the form in appendix 1 must be completed.

a. Information on methods

Listed here are validated methods for disinfection, cleaning and sterilisation for user reprocessing of Stanmore Implants Worldwide Limited, Orthopaedic Instruments and Loaner sets. As far as possible, it is recommend that decontamination is performed using an automatic washing-disinfector utilising thermal disinfection, followed by steam sterilisation.

b. Preparation for cleaning

At the point of use, remove all excess visible soil and keep the reusable medical devices moist until cleaning. Any device capable of disassembly must be disassembled before cleaning. Ensure that thorough cleaning and rinsing is performed as soon as possible. Manual cleaning may be undertaken either by immersion or non-immersion techniques dependent upon the device construction but these instructions relate solely to a validated automated cleaning cycle.

c. Cleaning Equipment and Agents

Water	Water quality is an important consideration in all cleaning steps. Demineralised or deionised water is recommended as this can help prevent discolouration and staining.
Detergents and Cleaning Agents	Only suitable detergents and cleaning agents within a range of pH 6.0-8.0 may be used.
Ultrasonic Cleaner	Ultrasonic cleaning is suitable for an especially thorough, mild cleaning of heavily soiled, and other difficult to access locations such as joints, crevices and channels.
Cleaning Equipment	Non-abrasive low linting clothe and general purpose cleaning brushes.

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d. **Product Cleaning Guidelines – Automatic**

The following validated cleaning instruction is based on general product features which present challenges to the cleaning process and not on specific products. The instructions presented are based on an automated method using a washer-disinfector and have been validated.
In the case of non-metals, unless otherwise instructed, reprocess following these guidelines.

Equipment and reagents:

Washer/disinfector (Medisafe SI Auto Workstation), Enzyme based detergent (3E-Zyme).

Procedure:

i. Load the instruments into washer/disinfector ensuring that the basket is not overloaded and that hinges are open and cannulation holes are able to drain.
ii. Run cycle (key stages):
- Cold pre-wash: 3 minutes, < 35°C
- Main wash: 13 minutes, 43°C
- Pre Rinse: 2 minutes, 20°C
- Disinfection fill
- Thermal disinfection: 2 minutes, 80-85°C
- Air purge dry: 2 minutes

iii. When the cycle is complete remove the contents from the washer for inspection.
iv. Inspect each instrument for cleanliness. If soiling is still evident repeat the cleaning cycle.

Section 5

RE- STERILISATION

Plastic parts **MUST NOT** be re-sterilised.

If an implant requires re-sterilisation please contact SIW for advice.
Re-sterilise using an autoclave as per section 3. Re-sterilisation and validation of the autoclave is the responsibility of the hospital and not SIW or its agent.

Orthopaedic Instruments and Loaner sets should be cleaned and re-sterilised in accordance with the instructions in section 3 and 4

	Company Information	Contact Information
	**Manufacturer** **Stanmore Implants Worldwide Ltd** **210 Centennial Avenue** **Centennial Park** **Elstree** **Hertfordshire** **WD6 3SJ** **United Kingdom** **Tel +44 (0) 208 2386500** **Fax +44 (0) 208 9537443**	**If further information is required on Stanmore Implants devices or instrumentation please contact the Design Office:** **Tel: (+44) 020 89541402** **Fax: (+44) 020 89530617** **E-mail: designgroup@stryker.com**

APPENDIX 1

Declaration of Contamination Status

This form is only to be used for the return of Instruments used with a custom implants for standard product please use appendix in form TF04-06.

Local forms can be supplied as an alternative as long as all the required information is supplied.

Product Description		Product Identification		
From				
Address				
Contact Name				
Emergency contact number		Contact e-mail		
Have any of the items been contaminated	Yes *	No	Don't Know	Please circle
* State type of contamination: Blood, Body fluids, or any other hazard				
Have the items been decontaminated	Yes †	No ‡	Don't Know	Please circle
† Was the process in accordance with the information given DM01/8-7 July 09 sections 3 and 4			Yes	No / Please circle
IF NO please provide details of what cleaning and sterilisation process was used				
‡ Please explain why the items have not been decontaminated				
Signature of person completing the form			Date	
Print Name		Job Title		
By signing this form you are confirming that all of the information is correct and accurate to the best of your knowledge at the time of approval.				

CONTAMINATED ITEMS MUST NOT BE RETURNED WITHOUT THE PRIOR AGREEMENT AND KNOWLEDGE OF STANMORE IMPLANTS WORLDWIDE.

THEY MUST BE RETURNED SUITABLY PACKAGED AND IDENTIFIED.