SURGICAL INSTRUMENTS AND TRIALS INSTRUCTIONS FOR USE

PLEASE READ THIS IN CONJUNCTION WITH SURGICAL PROCEDURE

Section 1

⚠ WARNINGS and PRECAUTIONS

⚠ **DO NOT** implant the trial implants

⚠ Stanmore Implants Worldwide trial implants must not be used with products from other manufacturers.

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

For instructions in the use of the trial instruments refer to the surgical planning guide provided.

⚠ Improper use or mishandling of the components can result in damage to one or more of the components, or improper selection of implants.

NON STERILE The surgical instruments and trials are supplied **NON-STERILE**. Clean and sterilise before use, in accordance with the instructions provided (see Section 2 and 3.)

⚠ 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.

SURGICAL INSTRUMENTS AND TRIALS INSTRUCTIONS FOR USE

PLEASE READ THIS IN CONJUNCTION WITH SURGICAL PROCEDURE

⚠ Ensure steam quality meets acceptable standards to prevent damage and discolouration

⚠ Do not sterilise using either Ethylene Oxide (EtO) or cold sterilisation techniques.

Cleaning and Sterilisation

All Instruments and trials must be cleaned and sterilised prior to returning to Stanmore Implants Worldwide in accordance with the procedures defined in Sections 2 and 3 and the form in Appendix 1 must be completed and returned with any items being sent back to Stanmore Implants.

Section 2

TRIALS and INSTRUMENTS CLEANING INSTRUCTIONS

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 the instructions in Sections 2 and 3 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 Trials 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 3

TRIALS and INSTRUMENT STERILISATION

IMPORTANT

⚠ All trials and instruments **MUST** be cleaned prior to sterilisation (see section 2)

⚠ 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 sterilisation.

The following sterilisation process should be used for trials and instrumentation.

The trials and instrumentation are recommended to be sterilised using prevacuum or porous load, high temperature steam sterilisation (air removal via pulsed pre-vacuum method)

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:

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Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Prevacuum	134-137°C	3 minutes (minimum)	30 minutes (minimum)

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Porous load	132°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, however 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

RE- STERILISATION

Orthopaedic instruments and trials should be cleaned and re-sterilised in accordance with the instructions in section 2 and 3.

Company Information

Manufacturer

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Contact Information

If further information is required on Stanmore Implants devices or instrumentation please contact the Design Office:

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APPENDIX 1

Declaration of Contamination Status

This form is only to be used for the return of Trials and Instruments used with a METS modular system product.

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 TF04-06 Issue 8 sections 2 and 3			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.				

ANY CONTAMINATED INSTRUMENTS OR TRIALS MUST NOT BE RETURNED WITHOUT THE PRIOR AGREEMENT AND KNOWLEDGE OF STANMORE IMPLANTS WORLDWIDE.

THE INSTRUMENTS OR TRIALS MUST BE RETURNED SUITABLY PACKAGED AND IDENTIFIED.

METs RELEASE NOTE

MODULAR SYSTEM

CRC Number: _____

SURGICAL INSTRUMENTS AND TRIALS: (Decontamination Certificate)

Special Instruments/ Trials included with the above system	Yes ☐ No ☐

These instruments/trials were previously used in a surgical invasive procedure and were exposed to blood, body fluids or pathological samples. These items were subsequently cleaned and sterilised prior to return to Stanmore Implants Worldwide By (Insert organisation name or leave blank)
In accordance with the validated process detailed in TF04-6 Issue 8.

After inspection all of the instruments and trails are cleaned and washed in accordance with the process defined in TF04-6 Issue 8.

I declare that I have taken all reasonable steps to ensure the accuracy of the above information

Signature	Date

Print Name

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