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Avis de sécurité sur le terrain PR 1457388

23 mai 2018

Avis de sécurité sur le terrain

Référence FSCA : Action corrective sur le terrain concernant un produit - **PR 1457388**

Type d'action : Action corrective de sécurité sur le terrain

Description : Mise à jour du mode d'emploi des instruments et des implants d'essai non stériles

Produit(s) concerné(s) : Instruments chirurgicaux et implants d'essai

Numéros de lot : Tous les instruments chirurgicaux et implants d'essai

Cher client,

Le 23 mai 2018, Stanmore Implants Worldwide Ltd. a lancé un avis de sécurité sur le terrain volontaire spécifique pour les modes d'emploi des instruments chirurgicaux et implants d'essai non stériles réutilisables. Le présent courrier vise à informer les utilisateurs des modifications apportées aux modes d'emploi des instruments chirurgicaux et implants d'essai, répertorier les risques potentiels associés à la stérilisation à la vapeur des dispositifs et à dresser la liste des facteurs d'atténuation des risques.

Problème

Il a été établi que les modes d'emploi envoyés avec les instruments et les implants d'essai non stériles indiquaient les paramètres de stérilisation à la vapeur britanniques (134 à 137 °C pendant 3 minutes - pré-vide), alors que les paramètres de stérilisation validés étaient ceux des États-Unis (132 °C pendant 4 minutes - charge poreuse).

Pour corriger l'écart des paramètres de stérilisation non validés et pour aligner les paramètres de stérilisation sur les exigences britanniques standard, Stanmore Implants Worldwide Ltd. a validé la stérilisation à la vapeur de tous les kits d'instruments et implants d'essai réutilisables en tenant compte des paramètres de stérilisation britanniques (au moins 3 minutes à 134-137 °C - pré-vide) de façon à obtenir un niveau d'assurance de stérilité (NAS) d'au moins 10^{-12} pour un cycle complet. Cette validation a également permis de déterminer que, pendant la stérilisation, la pénétration de la vapeur est améliorée si le filetage des capuchons en polymère de l'impacteur universel (référence imgenimp) et de sa variante, le long impacteur universel (référence imlgimp), est partiellement retiré (sur environ 2 mm), en vérifiant que le dispositif se place toujours à l'endroit prévu à cet effet dans le plateau.

Les modes d'emploi ont été mis à jour en conséquence (voir l'Annexe I pour les modes d'emploi des instruments chirurgicaux et implants d'essai mis à jour).

Les modifications apportées aux modes d'emploi sont les suivantes :

1. Les paramètres de stérilisation de la section 3 ont été modifiés :

Paramètres de stérilisation mentionnés dans les anciens modes d'emploi

Méthode	Type de cycle	Température	Durée d'exposition	Temps de séchage
Vapeur	Charge poreuse	132 ºC	4 minutes (minimum)	30 minutes (minimum)

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Paramètres de stérilisation mentionnés dans les modes d'emploi mis à jour

Méthode	*Type de cycle*	*Température*	*Durée d'exposition*	*Temps de séchage*
Vapeur	*Pré-vide*	*134 à 137 ºC*	*3 minutes (minimum)*	*30 minutes (minimum)*

2. Du texte supplémentaire a été ajouté à la section 3 :
   a. *Pour améliorer la pénétration de la vapeur pendant la stérilisation, retirez une partie du filetage du capuchon en polymère de l'impacteur universel et de sa variante (sur environ 2 mm) tout en vérifiant qu'il se place toujours à l'endroit prévu à cet effet dans le plateau.*
   b. *Avant toute utilisation, veillez à bien resserrer le capuchon en polymère de l'impacteur universel et de sa variante.*
   c. *Vérifiez que tous les composants sont secs avant de les utiliser.*

Dangers/dommages potentiels

Le ou les dangers potentiels associés à l'absence de retrait d'une partie du filetage de l'impacteur universel et de sa variante sont les suivants :

- Des agents infectieux demeurent sur le dispositif du fait du nettoyage, de la désinfection et d'une stérilisation inadéquate

Atténuation des risques :

1. Démontage du capuchon en polymère de l'impacteur universel et de sa variante pendant le nettoyage et la désinfection.
2. Retrait d'une partie du filetage du capuchon en polymère de l'impacteur universel et de sa variante pendant la stérilisation.

Actions requises

1. Veuillez informer les utilisateurs du présent FSCA et transmettre cet avis à toutes les personnes concernées au sein de votre établissement.
2. Hôpitaux : remplissez et signez le formulaire d'accusé de réception ci-joint, et envoyez-en un exemplaire par fax ou par e-mail au service clientèle au +44 (0) 20 8953 0617 ou à l'adresse Mets.requests@stammoreimplants.com.

Nos registres indiquent que vous avez reçu le dispositif susmentionné. Il nous incombe de nous assurer que les clients qui ont reçu le dispositif concerné reçoivent bien ce courrier important.

Merci de nous aider à respecter notre obligation réglementaire en nous retournant par fax le formulaire de réponse dans un délai de 5 jours.

Stanmore Implants Worldwide Limited confirme son engagement à développer, fabriquer et mettre sur le marché des produits de la plus haute qualité pour les chirurgiens et les patients. Nous nous excusons de la gêne que peut vous occasionner cette Action corrective de sécurité sur le terrain et vous remercions de votre coopération par rapport à cette demande.

Pour tout renseignement complémentaire, veuillez contacter votre représentant local.

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Cordialement,

[Signature]

Dervillia Murphy
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Pièces jointes :
1. Formulaire d'accusé de réception
2. Annexe I - Modes d'emploi des instruments chirurgicaux et implants d'essai mis à jour
   TF04-6 Numéro 11 : Mode d'emploi des instruments chirurgicaux et implants d'essai
   DM01-8 Numéro 10 : Mode d'emploi pour le remplacement d'une prothèse sur mesure
   QL041 Numéro 04 : Mode d'emploi de l'implant fémoral distal extensible JTS
   QL042 Numéro 05 : Mode d'emploi de l'implant tibial proximal extensible JTS

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STANMORE IMPLANTS WORLWIDE LIMITED
FORMULAIRE D'ACCUSÉ DE RÉCEPTION DE L'ACTION CORRECTIVE DE SÉCURITÉ SUR LE TERRAIN

23 mai 2018

NOM :

ADRESSE :

VILLE, PAYS,

CODE POSTAL :

Référence FSCA : Action corrective sur le terrain concernant un produit **PR 1457388**

Type d'action : Action corrective de sécurité sur le terrain

Description : Mise à jour du mode d'emploi des instruments et des implants d'essai non stériles

Produit(s) concerné(s) : Instruments chirurgicaux et implants d'essai

Informations sur les produits
Lot : Tous les instruments chirurgicaux et implants d'essai

Je confirme avoir reçu les modes d'emploi joints en Annexe I et avoir vérifié les paramètres de stérilisation britanniques de la section 3, ainsi que les consignes supplémentaires concernant la stérilisation de l'impacteur universel et de sa variante.

Client
(Signature)

Date

Nom du client
(EN LETTRES CAPITALES)

Appendix I - Updated Surgical Instruments and Trials IFUs

JTS EXTENDIBLE PROXIMAL TIBIA IMPLANT INSTRUCTIONS FOR USE

JTS® Non-Invasive Extendible Proximal Tibia Implant

IFU - Instructions for Use

Please Read in Conjunction with the Surgical Technique and the Operation Drawing Before Commencing Surgery

1. Implant description

The Stanmore Implants Worldwide JTS® Extendible Proximal Tibia Implant is manufactured in accordance with an approved prescription for a named patient. It **MUST NOT** be used for any other patient.

The patient name is detailed in the operation drawing supplied with the implant.

JTS® Extendible implant intended use/indications for use

The JTS® Extendible implant is indicated for cemented or cementless limb sparing procedures where radical resection and replacement of the proximal tibia is required with the following conditions:

Patients suffering from severe arthropathy of the knee that does not respond to any conservative therapy or better alternative surgical treatment;

Surgical intervention for severe trauma, revision arthroplasties, failed previous prostheses and/or oncology indications; and malignant diseases (e.g. osteogenic sarcoma).

The JTS® Extendible Proximal Tibia Implant and its components are for single use only.

2. Warnings and precautions:

Stanmore Implants Worldwide JTS® Extendible Proximal Tibial Implant is manufactured in accordance with an approved prescription for a named patient. It must not be used for any other patient.

The JTS® Extendible Proximal Tibial Implant is supplied sterilised and must not be steam sterilised. Contact Stanmore Implants for advice.

The JTS® Extendible Proximal Tibial Implant is MRI UNSAFE and neither the implant nor a patient with an implant in place must be taken into an MRI environment.

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

Do not steam sterilise the JTS® Extendible Proximal Tibial Implant as this will damage the internal magnet and it will not extend.

Once implant has been fully inserted and secured with axle and circlip or axle and axle-cap, remove retaining clip located on the femoral component. Failure to do so will result in malfunction of the device and may lead to future surgical intervention.

All polyethylene 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 JTS® Extendible Proximal Tibial Implant must not be used with products from other manufacturers. Different manufacturers have different tolerances and therefore a mismatch could lead to failure of the implant.

If cortical bone screws are to be used to fix the extra-cortical plate in place, these must be of a suitable size to fit through the plate (nominally ø4.5mm) and made from implant grade titanium.

The Stanmore Implants Worldwide JTS® Extendible Proximal Tibial Implant is for Single Use Only.

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

The surgical 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.

JTS EXTENDIBLE PROXIMAL TIBIA IMPLANT INSTRUCTIONS FOR USE

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.

Hitting or dropping the JTS® Extendible Proximal Tibial Implant can result in demagnetising the magnets in the growing section which will result in being unable to grow 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 HA coated components are not to be cemented in place.

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.

The surgical instruments are supplied not sterile. 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 six months between supply of the JTS® Extendible Proximal Tibial Implant and the implantation, 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.

If revision of the implant is required, this should be carried out by a suitably qualified person. There are no special techniques required for the revision of a JTS® Extendible Proximal Tibial Implant. The revision procedure would use the same surgical procedure and tooling required for implantation

Before any action is taken to grow the JTS® Extendible Proximal Tibial Implant, the JTS Drive Unit operations manual must be read and understood

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

Before any action is taken to grow the JTS® Extendible Proximal Tibial Implant, the operation Drawing must be consulted as this gives details of the direction of magnetic field rotation for each individual implant.

CT scans obtained with a metal implant inside the patient do produce artefacts and therefore tissue definition in the adjacent area is compromised and this must be taken into account when reviewing any results.

Indications and Complications

2.1. Indications:

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

The JTS® Extendible Proximal Tibial implant is indicated for cemented or cementless procedures where radical resection and replacement of the proximal tibia is required.

2.2. Contra-indications:

Absolute contra-indications include

- ☐ Infection and sepsis

Relative contra-indications include

- ☐ Long delay between manufacturing and insertion of a patient specific 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 instructions
- ☐ Foreign body sensitivity. Where materials sensitivity occurs seek advice with respect to testing
- ☐ Obesity
- ☐ Vascular disorder, neuromuscular disorders or muscular dystrophy

2.3. 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 undergo rehabilitation

2.4. Possible adverse effects:

There is 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 possible under certain circumstances

2.5. 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

2.6. 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

3. Cleaning and Sterilisation

3.1. Implant sterilisation:

IMPORTANT

THE JTS® EXTENDIBLE PROXIMAL TIBIAL IMPLANT IS SUPPLIED STERILE **DO NOT STEAM STERILISE THE IMPLANT AS THIS WILL AFFECT ITS FUNCTION**

STERILE R The implant has been sterilised using 25 to 40kGy gamma irradiation.

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

If the sterility of the component has been compromised, an alternative sterile component **MUST** be used.

For all items that are not marked sterile (this includes all surgical instruments) the procedure in Section 3.2 must be followed.

3.2. Orthopaedic Instruments and Loaner sets:

All instruments are supplied NON-STERILE and must be cleaned and sterilised before use and before being returned to Stanmore Implants in accordance with instructions in this section.

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 cloth and general purpose cleaning brushes.

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.

e. Steam Sterilisation

IMPORTANT

⚠ THE JTS® EXTENDIBLE IMPLANT IS SUPPLIED STERILE **DO NOT STEAM STERILISE THE IMPLANT AS THIS WILL AFFECT ITS FUNCTION**

⚠ 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 those items supplied non-sterile.

It is recommended that these items are sterilised using prevacuum 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/polyethylene 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	Prevacuum	134-137°C	3 minutes (minimum)	30 minutes (minimum)

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Porous load	132 +/- 2°C (266-273°F)	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 that the polymeric cap is re-tightened on the General Impactor prior to use.

Ensure all components are dry prior to use.

3.3. Re-Sterilisation

⚠ If the JTS® Extendible Proximal Tibial Implant or polyethylene components require re-sterilisation they must be returned to Stanmore Implants. They **MUST NOT** be steam sterilised.

⚠ Orthopaedic Instruments and loaner sets should be cleaned and re-sterilised in accordance with the instructions in Section 3.2

	**Company Information** **Manufacturer** **Stanmore Implants Worldwide Ltd** **210 Centennial Avenue** **Centennial Park** **Elstree** **Hertfordshire** **WD6 3SJ** **United Kingdom** **Tel: +44 (0) 20 8238 6500** **Fax: +44 (0) 20 8953 0617**	**Contact Information** **If further information is required on Stanmore Implants' devices or instrumentation please contact the Design Services Office:** **Tel: +44 (0) 20 8238 6500** **Fax: +44 (0) 20 8953 0617** **E-mail: designgroup@stryker.com**

JTS EXTENDIBLE DISTAL FEMORAL IMPLANT INSTRUCTIONS FOR USE

JTS® Non-Invasive Extendible Distal Femoral Implant

IFU - Instructions for Use

Please Read in Conjunction with the Surgical Technique and the Operation Drawing Before Commencing Surgery

1. Implant description

The Stanmore Implants Worldwide JTS® Extendible Distal Femoral implant is manufactured in accordance with an approved prescription for a named patient. It **MUST NOT** be used for any other patient.

The patient name is detailed in the operation drawing supplied with the implant.

JTS® Extendible implant intended use/indications for use

The JTS® Extendible implant is indicated for cemented and cementless limb sparing procedures where radical resection and replacement of the distal femur is required with the following conditions:

Patients suffering from severe arthropathy of the knee that does not respond to any conservative therapy or better alternative surgical treatment;

Surgical intervention for severe trauma, revision arthroplasties, failed previous prostheses and/or oncology indications; and malignant diseases (e.g. osteogenic sarcoma).

The JTS® Extendible Distal Femoral Implant and its components are for single use only.

2. Warnings and precautions:

Stanmore Implants Worldwide JTS® Extendible Distal Femoral Implant is manufactured in accordance with an approved prescription for a named patient. It must not be used for any other patient.

The JTS® Extendible Distal Femoral Implant is supplied sterilised and must not be steam sterilised. Contact Stanmore Implants for advice.

The JTS® Extendible Distal Femoral Implant is MRI UNSAFE and neither the implant nor a patient with an implant in place must be taken into an MRI environment.

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

Do not steam sterilise the JTS® Extendible Distal Femoral Implant as this will damage the internal magnet and it will not extend.

Once implant has been fully inserted and secured with axle and circlip or axle and axle-cap, remove retaining clip located on the femoral component. Failure to do so will result in malfunction of the device and may lead to future surgical intervention.

All polyethylene 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 JTS® Extendible Distal Femoral Implant must not be used with products from other manufacturers. Different manufacturers have different tolerances and therefore a mismatch could lead to failure of the implant.

If cortical bone screws are to be used to fix the extra-cortical plate in place, these must be of a suitable size to fit through the plate (nominally ø4.5mm) and made from implant grade titanium.

The Stanmore Implants Worldwide JTS® Extendible Distal Femoral Implant is for Single Use Only.

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.

JTS EXTENDIBLE DISTAL FEMORAL IMPLANT INSTRUCTIONS FOR USE

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.

Hitting or dropping the JTS® Extendible Distal Femoral Implant can result in demagnetising the magnets in the growing section which will result in being unable to grow 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 HA coated components are not to be cemented in place.

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.

The Surgical instruments are supplied not sterile. 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 six months between supply of the JTS® Extendible Distal Femoral Implant and the implantation, 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.

If revision of the implant is required, this should be carried out by a suitably qualified person. There are no special techniques required for the revision of a JTS® Extendible Distal Femoral Implant. The revision procedure would use the same surgical procedure and tooling required for implantation

Before any action is taken to grow the JTS® Extendible Distal Femoral Implant, the JTS Drive Unit operations manual must be read and understood

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

Before any action is taken to grow the JTS® Extendible Distal Femoral Implant, the operation Drawing must be consulted as this gives details of the direction of magnetic field rotation for each individual implant.

CT scans obtained with a metal implant inside the patient do produce artefacts and therefore tissue definition in the adjacent area is compromised and this must be taken into account when reviewing any results.

Indications and Complications

2.1. Indications:

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

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The JTS® Extendible Distal Femoral implant is indicated for cemented and cementless procedures where radical resection and replacement of the distal femur is required.

2.2. Contra-indications:

Absolute contra-indications include

- Infection and sepsis

Relative contra-indications include

- Long delay between manufacturing and insertion of a patient specific 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 instructions
- Foreign body sensitivity. Where materials sensitivity occurs seek advice with respect to testing
- Obesity
- Vascular disorder, neuromuscular disorders or muscular dystrophy

2.3. 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 undergo rehabilitation

2.4. Possible adverse effects:

There is 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 possible under certain circumstances

2.5. 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

2.6. 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

3. Cleaning and Sterilisation

3.1. Implant sterilisation:

IMPORTANT

THE JTS® EXTENDIBLE DISTAL FEMORAL IMPLANT IS SUPPLIED STERILE **DO NOT STEAM STERILISE THE IMPLANT AS THIS WILL AFFECT ITS FUNCTION**

STERILE R The implant has been sterilised using 25 to 40kGy gamma irradiation.

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

If the sterility of the component has been compromised, an alternative sterile component **MUST** be used.

For all items that are not marked sterile (this includes all surgical instruments) the procedure in Section 3.2 must be followed.

3.2. Orthopaedic Instruments and Loaner Sets:

All instruments are supplied NON-STERILE and must be cleaned and sterilised before use and before being returned to Stanmore Implants in accordance with instructions in this section.

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 cloth and general purpose cleaning brushes.

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.

e. Steam Sterilisation

IMPORTANT

⚠ THE JTS® EXTENDIBLE IMPLANT IS SUPPLIED STERILE **DO NOT STEAM STERILISE THE IMPLANT AS THIS WILL AFFECT ITS FUNCTION**

⚠ 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 those items supplied non-sterile.

It is recommended that these items are sterilised using prevacuum 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/polyethylene 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	Prevacuum	134-137°C	3 minutes (minimum)	30 minutes (minimum)

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Porous load	132 +/- 2°C (266-273°F)	4 minutes (minimum)	30 minutes (minimum)

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

Ensure all components are dry prior to use.

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.

3.3. Re-Sterilisation

⚠ If the JTS® Extendible Distal Femoral Implant or polyethylene components require re-sterilisation they must be returned to Stanmore Implants. They **MUST NOT** be steam sterilised.

⚠ Orthopaedic Instruments and loaner sets should be cleaned and re-sterilised in accordance with the instructions in Section 3.2

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	Manufacturer **Stanmore Implants Worldwide Ltd** **210 Centennial Avenue** **Centennial Park** **Elstree** **Hertfordshire** **WD6 3SJ** **United Kingdom** **Tel: +44 (0) 20 8238 6500** **Fax: +44 (0) 20 8953 0617**	**If further information is required on Stanmore Implants' devices or instrumentation please contact the Design Services Office:** **Tel: +44 (0) 20 8238 6500** **Fax: +44 (0) 20 8953 0617** **E-mail: designgroup@stryker.com**

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.

CUSTOM MADE PROSTHETIC REPLACEMENT INSTRUCTIONS FOR USE

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

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,

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

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

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

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

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

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)

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

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.

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

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

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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.

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.

PLEASE READ THIS IN CONJUNCTION WITH SURGICAL PROCEDURE

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:

PLEASE READ THIS IN CONJUNCTION WITH SURGICAL PROCEDURE

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:

Tel: (+44) 020 8954 1402
Fax: (+44) 020 8953 0167
E-mail: designgroup@stryker.com

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

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

Tel: (+44) 020 8954 1402
Fax: (+44) 020 8953 0167
E-mail: designgroup@stryker.com