# 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

.

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

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