CUSTOM-MADE / PATIENT-SPECIFIC PROSTHETIC REPLACEMENT INSTRUCTIONS FOR USE

TO BE USED IN CONJUNCTION WITH SUPPLIED OPERATION DRAWING AND SURGICAL PROTOCOL

℞ ONLY

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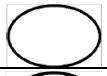
Contents

NOTE:

- Any serious incident that has occurred in relation to these custom-made or patient-specific devices should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Labelling Symbols Glossary

The following is a list of symbols that may be used on Onkos Surgical medical device labelling. Refer to individual product labels for applicable symbology for each product.

Symbol	Standard
Caution (See instructions for use for operator awareness) 	ISO 15223-1
Consult instructions for use or consult electronic instruction use 	ISO 15223-1
Do not re-use 	ISO 15223-1
Sterilized using irradiation 	ISO 15223-1
Sterilized using hydrogen peroxide 	N/A
Sterilized using ethylene oxide 	ISO 15223-1
Sterilized using Aseptic processing techniques (Aseptic fill) 	ISO 15223-1
Non-sterile 	ISO 15223-1
Do not re-sterilize 	ISO 15223-1
Single sterile barrier system 	ISO 15223-1
Double sterile barrier system 	ISO 15223-1
Use-by date 	ISO 15223-1
Date of manufacture 	ISO 15223-1
Legal manufacturer 	ISO 15223-1
UK Responsible Person 	N/A
Catalogue number 	ISO 15223-1
Batch code 	ISO 15223-1
Serial number 	ISO 15223-1

Symbol		Standard
MR Safe		ASTM F2503
MR Conditional		ASTM F2503
MR Unsafe		ASTM F2503
Do not use if package is damaged		ISO 15223-1
Medical device		ISO 15223-1
Quantity		N/A
"Caution: Federal Law (USA) restricts this device to sale by on the order of a physician"		N/A
Contains hazardous substances		ISO 15223-1
Temperature limit		ISO 15223-1
Keep dry		ISO 15223-1
Keep away from sunlight		ISO 15223-1
Patient identification		ISO 15223-1
Date (of Implantation)		ISO 15223-1
Health care center or doctor		ISO 15223-1
Patient information website		ISO 15223-1
Unique Device Identifier		ISO 15223-1

Description

Onkos Surgical (Onkos) single-use, custom-made or patient-specific devices (implants and instruments) are manufactured and supplied in accordance with an approved prescription for a specific patient. The prescribed device **MUST NOT** be used for any other patient.

Materials

Onkos Surgical custom-made or patient-specific devices are manufactured from biocompatible materials and coatings that meet internationally accepted standards. Refer to device label for applicable materials and coatings.

Contact Onkos Surgical for specific information when treating a patient with a material allergy or sensitivity.

Compatibility

The custom-made or patient-specific device is intended for compatibility with the devices that accompany it. For instruments that are not custom-made or patient-specific, refer to the Instructions for Use for those instruments

ADDITIONAL INFORMATION:

Unless otherwise specified on the instrument, markings on instruments with a measuring function have a linear accuracy of ±0.5mm.

Indications

This custom-made or patient-specific device is indicated solely for the use of the prescribing physician for the specific needs of an individual patient. For any additional indications specific to this device, please refer to the Design Proposal created specifically for this patient.

Contraindications

- Any active or suspected latent infection in or about the appropriate joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
- For any additional contraindications specific to this device, please refer to the operation drawing for this patient file.
- Obesity.

Warnings and Precautions - Implants

Onkos Surgical custom-made or Patient Specific Implants

- Onkos Surgical custom-made or patient specific implants are manufactured in accordance with an approved prescription for a specific patient and must not be used on any other patient.
- The operation drawing and surgical protocol supplied with the implant contains patient-specific information to aid the implantation. This must be read prior to carrying out any surgical procedure.
- Further evaluation for suitability of the supplied implant must be carried out prior to surgery. If any changes in the patient condition are suspected, further scans must be produced and reviewed against the design as this could result in a possible mis-match due to changes in bone geometry.
- Implants may not be suitable for patients with inadequate or incomplete soft tissue coverage.
- Implants may not be suitable for patients who are uncooperative or unwilling to follow instructions.
- 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 physician believes should be disclosed.
- 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.
- Onkos Surgical custom-made or patient specific implants must not be used with products from other manufacturers unless it is specifically authorized. Different manufacturers have different tolerances and therefore a mismatch could lead to implant failure. The operation drawing and surgical protocol supplied with the implant contains any such authorization.
- The Onkos Surgical custom-made or patient specific implant is for single-use only.
- If the packaging of parts marked sterile has been compromised or is damaged, do not use.
- All plastic custom-made or patient-specific devices are supplied sterile and must not be re-sterilized. If the sterility of the device has been compromised, the part must not be used.
- If the implant is marked as STERILE on the packaging, the device has been sterilized. DO NOT re-sterilize.
- Improper use or mishandling of the custom-made or patient-specific devices can result in damage, reducing the in-service life of the implant.
- Particular care and attention should be taken with respect to all bearing surfaces, tapers and coated surfaces.
- If the implant or HA coating is contaminated or damaged do not use. HA coated interfaces must not come into contact with cement.
- The custom-made or patient-specific device is intended for compatibility with the devices that accompany it. For instruments that are not custom-made or patient-specific, refer to the Instructions for Use for those instruments.

JTS Extendible Implants

- JTS implants are MR UNSAFE and neither the implant nor a patient with an implant in place must be taken into an MR environment.
- Do not steam sterilize the JTS 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 shaft. Failure to do so will result in malfunction of the device and may lead to future surgical intervention.
- Hitting or dropping the JTS Extendible Implant can result in demagnetizing the magnets in the growing section which will result in being unable to grow the implant.
- Before any action is taken to grow the JTS Extendible Implant, the JTS Drive Unit operations manual must be read and understood. In addition, the operation drawing, and surgical protocol 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 can produce artifacts and therefore tissue definition in the adjacent area may be compromised and this must be taken into account when reviewing any results.
- 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 (suitable size is advised in operation drawing) and made from implant grade titanium.
- HA coated interfaces must not come into contact with cement.

Warnings and Precautions - Instruments

- All non-sterile instruments **MUST** be cleaned prior to sterilization (see section 4).
- All instruments that are supplied sterile will be marked on the packaging as STERILE. **DO NOT** re-sterilize.
- If the packaging of parts marked sterile has been compromised or is damaged, **DO NOT** use.
- Surgical instruments must never be placed in physiological saline solution as contact leads to pitting and corrosion.
- Ensure detergent solutions operate within a pH range of 6.0-8.0.
- Any deviation from recommended sterilization methods must be validated by the user.
- The recommended sterilization method is only valid with sterilization equipment that is maintained, calibrated and operated in accordance with local regulatory guidelines.
- Ensure steam quality meets acceptable standards to prevent damage and discoloration.
- For any items that are supplied sterile check to ensure that they are still within their shelf life prior to use.
- Using other instruments may damage custom-made or patient-specific devices. Instruments can become damaged or may even fracture if misused.
- Improper cleaning tools can cause damage. **DO NOT** use scouring agents, steel wool, or metal brushes or other implements that are not specifically intended for cleaning medical devices.
- Instruments should be inspected prior to surgery and not used if damaged.
- U.S. ONLY: Any porous membrane packaging used for the sterilization process must be FDA approved.
- Instruments are not intended for use in magnetic resonance imaging (MR) environments.
- Prosthetic replacement implant procedures and the associated instruments are not intended for lay use. These devices are for use by trained medical professionals.

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.

MRI Environment

Onkos Surgical custom-made or patient-specific devices have not been evaluated for safety and compatibility in the MRI environment. These devices have not been tested for heating, migration, or image artifact in the MR environment. The safety of these devices in the MR environment is unknown and scanning a patient who has these parts may result in injury. Since potential hazards from exposure are unknown, these devices are required to be labeled as "MR Unsafe."

Onkos Surgical custom-made instruments are not intended to be used in or present within the MR environment. Since they are not intended to enter the MR environment, testing for safety in the MR environment has not been undertaken, and thus any potential hazards from exposure to such an environment is unknown.

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.
- Discoloration of the adjacent tissues may occur.
- Fretting between metal parts is also possible under certain circumstances.

Intraoperative and Post-operative Complications

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

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

Transport and Storage

The device is individually packed in protective packaging that is labelled according to its contents. Store and transport the device in the original protective packaging. Do not remove the device from the packaging until it is planned to be used. Store the device in standard hospital environmental conditions unless specific requirements are defined and described on the product label.

Declaration of Contamination Status

All devices must be cleaned and decontaminated prior to returning to Onkos Surgical in accordance with the cleaning and sterilization procedures defined in below. The form in Appendix 1 (Declaration of Contamination Status) must be completed and returned with any items being returned to Onkos Surgical.

Instrument Cleaning Instructions

Instruments that are supplied NON-STERILE must be cleaned and sterilized before use in accordance with the cleaning and sterilization procedures defined. The form in Appendix 1 (Declaration of Contamination Status) must be completed and returned with any items being returned to Onkos Surgical .

a. Information on methods

Listed here are validated methods for disinfection, cleaning and sterilization for Onkos Surgical instruments that are supplied non-sterile. Decontamination using an automatic washing-disinfector utilizing thermal disinfection, followed by steam sterilization is recommended.

b. Preparation for cleaning

At the point of use, remove all excess visible soil and keep the reusable medical devices moist until cleaning. Any reusable 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. If a tray is supplied, all instruments must be placed in the designated area in the tray.

c. Cleaning Equipment and Agents

Water	Water quality is an important consideration in all cleaning steps. Demineralized or deionized water is recommended as this can help prevent discoloration 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.

d. Product Cleaning Guidelines – Automatic

The following validated cleaning instruction is based on general product features which present challenges to the cleaning process. The instructions presented are based on an automated method using a washer- disinfector and have been validated.

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, < 35ºC (<95ºF)
- Main wash: 13 minutes, 43ºC (109ºF)
- Pre-Rinse: 2 minutes, 20ºC (68ºF)

- Disinfection fill
- Thermal disinfection: 2 minutes, 80-85ºC (176-185ºF)
- 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.

Instrument Sterilization Instructions

Instruments that are supplied NON-STERILE must be cleaned and sterilized before use in accordance with the cleaning and sterilization procedures defined. The form in Appendix 1 (Declaration of Contamination Status) must be completed and returned with any items being returned to Onkos Surgical.

- The instruments are recommended to be sterilized using pre-vacuum or porous load, high temperature steam sterilization (air removal via pulsed pre-vacuum method).
- These devices must be placed in suitably wrapped porous membrane packaging for the sterilization 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	Pre- vacuum	134-137ºC (273 - 278ºF)	3 minutes (minimum)	30 minutes (minimum)
Steam	Porous load	132ºC (270ºF)	4 minutes (minimum)	30minutes (minimum)

Individuals or hospitals are advised, however, to validate whichever method is considered appropriate for their organization. Ethylene Oxide (EtO) and cold sterilization techniques are not recommended.

Ensure all devices are dry prior to use.

Lifetime of the Device

Onkos Surgical does not define a lifetime for custom-made or patient specific devices. The useful life of these devices depends on many factors. Patient factors such as weight, bone quality, activity level and other medical conditions and comorbidities may increase or decrease the expected lifetime of this or any implantable orthopedic device.

Caution

Federal Law in the USA restricts this device to sale by or on the order of a physician.

List of abbreviations used in labelling

Acronym	Description	Acronym	Description	Acronym	Description
XSM	Extra Small	Ag	Agluna	TiN	Titanium nitride
SM	Small	CPTi	Commercially Pure Titanium	Ti-6Al-4V	Titanium alloy
STD	Standard	CoCrMo	Cobalt chrome molybdenum	UHMWPE	Ultra-High molecular weight polyethylene
L	Left	HA	Hydroxyapatite		
R	Right	PS	Plasma Spray		

Manufacturer:

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Parsippany, NJ USA 07054
+1-973-264-5400
www.onkossurgical.com

UK REP

UK Responsible Person:

IdealMed Ltd, Unit A2,
Beech House Oaklands
Office Park, Hooton
Cheshire, CH66 7NZ,
United Kingdom

Appendix 1: Declaration of Contamination Status

This form is only to be used for the return of Onkos Surgical custom-made / patient-specific devices.
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? Circle one

Yes * No Don't Know

* If Yes, state the type of contamination (blood, body fluids, or any other hazard):

Have the items been decontaminated? Circle one

Yes No ** Don't Know

** If No, explain why the items have not been decontaminated:

If the items have been decontaminated, were the cleaning and sterilization processes supplied in JTS IFU 06.01.23 v0 followed? Circle one

Yes No *** Don't Know

*** If No, provide details of what cleaning and decontaminating process was used:

Signature of person completing form:	Date:
Printed name of person completing form:	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 **Onkos Surgical**

RETURNED INSTRUMENTS

MUST BE SUITABLY PACKAGED AND IDENTIFIED.