SURGICAL INSTRUMENTS AND TRIALS
INSTRUCTIONS FOR USE

℞ ONLY

Printed in U.S.A.

PLEASE READ THIS IN CONJUNCTION WITH SURGICAL PROCEDURE

Onkos Surgical Instrumentation consists of manual surgical instruments intended for use in Orthopedic surgeries.

Utilization: Before clinical use, the surgeon must thoroughly understand all aspects of the surgical procedure and the limitations of the instrumentation. Surgical Protocols provide additional procedural information.

Labeling Symbols Glossary

The following is a list of symbols that may be used on Onkos Surgical medical device labeling. 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
MR Safe	ASTM F2503
MR Conditional	ASTM F2503
MR Unsafe	ASTM F2503
Do not use if package is damaged	ISO 15223-1

Symbol		Standard
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

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Section 1

WARNINGS and PRECAUTIONS

DO NOT implant the trial implants.

Onkos Surgical 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.

The surgical instruments and trials are supplied **NON-STERILE**. Clean and sterilize 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 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.

Do not sterilize using either Ethylene Oxide (EtO) or cold sterilization techniques.

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ADDITIONAL INFORMATION

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.

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

Cleaning and Sterilization

All loaner Instruments and trials must be cleaned and decontaminated prior to returning to Onkos Surgical in accordance with the procedures defined in Section 2 and the form in Appendix 1 must be completed and returned with any items being sent back to Onkos Surgical.

Section 2

TRIALS and INSTRUMENTS CLEANING INSTRUCTIONS

All loaner instruments are supplied washed but are NON-STERILE and must be cleaned and sterilized before use 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 sterilization for user reprocessing of Onkos Surgical, Orthopedic Instruments and Trials sets. As far as possible, it is recommend that decontamination is performed using an automatic washing-disinfector utilizing thermal disinfection, followed by steam sterilization.

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. 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 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, < 35ºC (<95ºF)
   - Main wash: 13 minutes, 43ºC (109ºF)
   - Pre-Rinse: 2 minutes, 20ºC (68ºF)
   - Disinfection fill
   - Thermal disinfection: 2 minutes, 80-85°C (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.

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Section 3

TRIALS and INSTRUMENT STERILISATION

IMPORTANT

All trials and instruments **MUST** be cleaned prior to sterilization (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 sterilization.

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

The trials and instrumentation 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)

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Porous load	132ºC (270ºF)	4 minutes (minimum)	30 minutes (minimum)

Onkos Surgical has validated the above recommended sterilization cycles. Other sterilization methods and cycles may also be suitable. 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 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

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

Manufacturer:

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UK REP

UK Responsible Person:

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United Kingdom

APPENDIX 1

DECLARATION OF CONTAMINATION STATUS

This form is only to be used for the return of Trials and Instruments.

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 supplied within section 2 of document JTS IFU06.02.23v0?	Yes	No	Please circle	
IF NO please provide details of what cleaning and decontaminating 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 <u>MUST NOT</u> BE RETURNED WITHOUT THE PRIOR AGREEMENT AND KNOWLEDGE OF ONKOS SURGICAL .

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

APPENDIX 2

RELEASE NOTE

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 decontaminated prior to return to Onkos Surgical By (Insert organization name or leave blank)
In accordance with the validated process detailed in JTS IFU06.02.23v0.

After inspection all of the instruments and trials are washed.

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 Onkos Surgical devices or instrumentation, please contact the Onkos Patient Solutions team:

Tel: +1-973-264-5400
Email: patientsolutions@onkossurgical.com