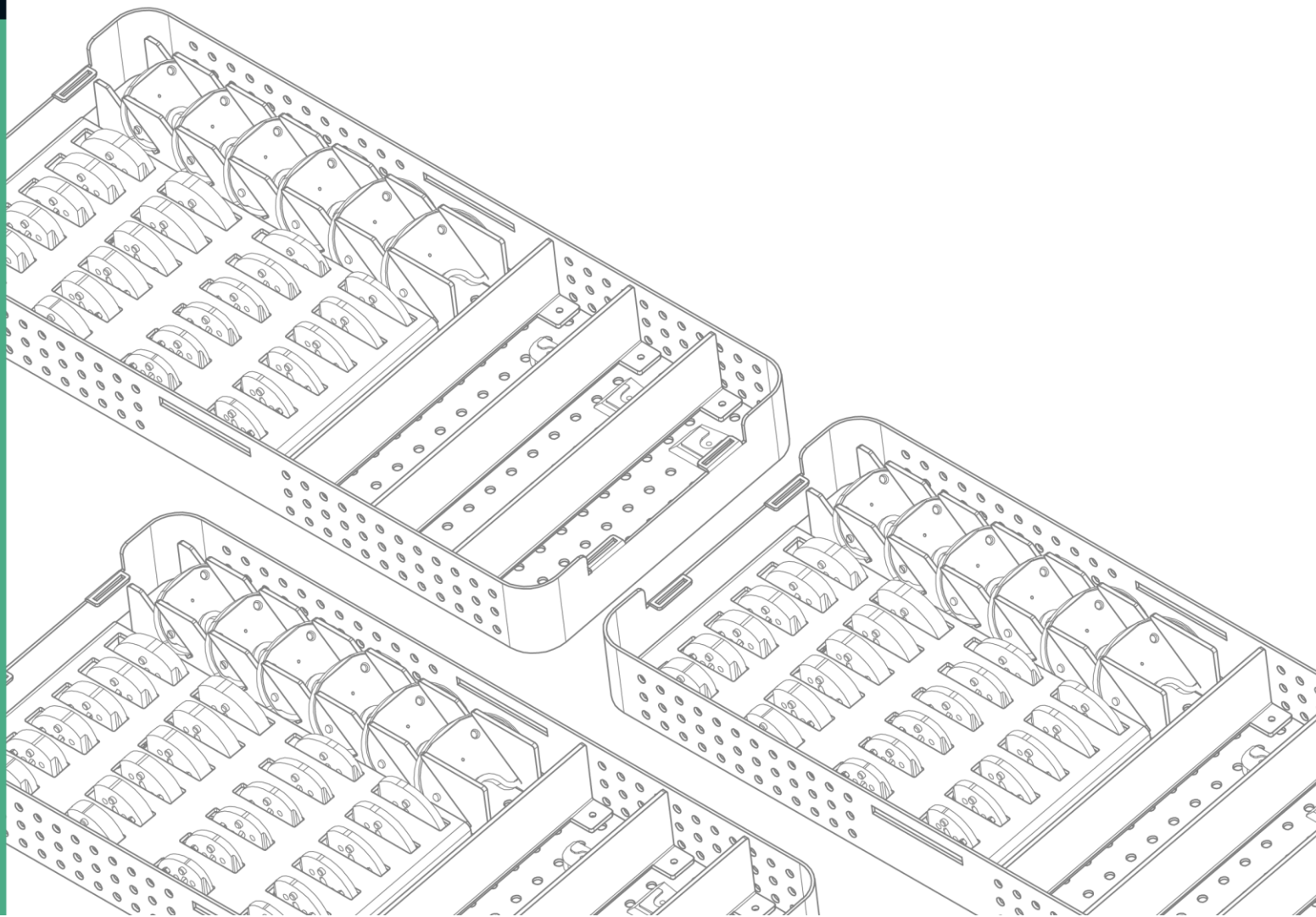
UNITED ORTHOPEDIC®

Reprocessing Instructions for Reusable Surgical Instruments

English



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DESCRIPTION

Reprocessing instructions is intended for health care professionals. This material is intended to assist hospital personnel in safe handling, and effective reprocessing **reusable surgical instruments**, instrument trays and cases supplied **Non-Sterile** by United Orthopedic Corporation (United). All hip, knee, trauma, and extremity of United reusable medical instruments must be cleaning, inspection, packing and sterilization prior to use.

United has validated the processes provided in reprocessing instructions to be capable of being effective. Equipment, operators, cleaning agents and procedures all contribute to the efficacy of the processing. The healthcare facility should ensure that the selected reprocessing steps are safe and effective. Alternative methods of reprocessing outside the scope of these instructions may be suitable for reprocessing; however, those must be validated by the end user. In the event of conflicting national cleaning and sterilization requirements, these shall prevail over United recommendations.

MATERIALS

Aluminum alloy
Cobalt/Chromium alloys
Stainless steels
Titanium
Titanium alloys
Titanium Nitride coatings
Polymers
Silicone rubber

INTENDED PURPOSE

United surgical instruments are designed for United implant systems and intended to be used by orthopedic surgeons to facilitate the implantation or explanation of specific implants described in the product-specific surgical technique.

The use of the identified instrumentation in accordance with its applicable surgical technique is essential to achieve the intended placement of the implant as described in the relevant surgical technique. The use of incompatible instruments (e.g. from another system) may lead to unpredictable short- and long- term clinical consequences. The incorrect use of the subject instrumentation may also lead to short- and long term clinical consequences.

Instrument trays and cases are intended to facilitate the organization, identification, storage, transportation, cleaning, and sterilization reprocessing of instruments.

General surgical instruments are available to facilitate surgical procedures to implant system.

INDICATIONS, CONTRAINDICATIONS AND PATIENT POPULATION

For information relating to indications, contraindications, patient population and clinical benefits can be found in the specific implant instructions for use.

CAUTIONS

1. **Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.**

   Following symbol: 

2. Reprocessing instructions apply to:
   - **Reusable surgical instruments** supplied **Non-Sterile** by United
   - Instruments intended for reprocessing in a health care facility setting
3. **Do not** apply to single-use devices.
4. **Personal Protective Equipment (PPE)** should be worn when handling or working with contaminated or potentially contaminated devices. PPE includes: gown, mask, goggles or face shield and shoe covers.
5. **Do not** place heavy instruments on top of delicate devices.
6. **Do not** use metal brush, scouring pads, abrasive cleaner during manual cleaning procedures. These materials will damage the surface and finish of instruments. Soft-bristled, nylon brushes and pipe cleaner brushes should be used.
7. Cleaning agents with a pH 7~9, low foaming surfactants, nonabrasive, free-rinsing, biodegradable and environmentally friendly, provides for rapid soil dispersion or suspension should be used during cleaning to ensure that instruments are visible in the cleaning solution. Cleaning agents must be easily and completely rinsed from device surfaces to prevent accumulation of detergent residue.
8. Manual scrubbing with brushes should always be performed with the instrument below the surface of the cleaning solution to prevent formation of aerosols and splashing which may spread contaminants.
9. **Do not** use saline and cleaning/disinfection agents containing aldehyde, mercury, active chlorine, bromine, or iodide. These are corrosive and should not be used.
10. **Do not** place or soak instruments in Ringers Solution.
11. **Do not** use oil-lubricants. Because these may: 1) coat microorganisms; 2) prevent direct contact of the surface with steam; and 3) be difficult to remove.
12. **Do not** apply that the devices are not manufactured and/or distributed by United. Only devices manufactured and/or distributed by United should be placed in United instrument trays and cases. These validated reprocessing instructions are not applicable

that the devices are not manufactured and/or distributed by United.

13. **Do not** use descaling agents that include morpholine in steam sterilizers. These agents leave residue which may damage polymer instruments over time.
14. **Do not** stack cases or trays during sterilization. Because it may limit steam penetration and prevent effective sterilization of the instruments.
15. Under certain classifications of risk, the World Health Organization (WHO), or local regulatory authorities recommend special Creutzfeldt-Jakob disease (CJD/TSE) inactivation processing procedures. Consult WHO and local regulations for further information.
16. **Do not** be equal to/or greater than **140°C/284°F** in washer/sterilizers. The most polymers will occur severe surface damage.
17. Flash (immediate-use) steam sterilization shall be used as an emergency procedure. Instruments shall be cleaned and disassembled without sterilization wrap or rigid container.
18. **Do not** use concentrated alcohol, and certain liquid chemical sterilants (LCSs)/high-level disinfectants (HLDs) (e.g. ortho-phthalaldehyde (OPA)). These can denature proteins.
19. May have sharp edges. Handle with care.
20. Contain and transport in a labeled, closed, puncture proof device per OSHA requirements.
21. To make sure the procedure properly and completely of cleaning and sterilization, if the procedure inappropriately or incompletely, and the contaminated device contact with patient, may cause patient infection and generate associated health problem.

LIMITATIONS ON REPROCESSING

The useful life of these devices depends on many factors including the method and duration of each use, and the handling between uses. Careful inspection and functional test of the device before use is the best method of determining the end of serviceable life of the medical device. Evidence of damage and wear on a device may include but is not limited to corrosion (i.e. rust, pitting), discoloration, excessive scratches, flaking, wear and cracks. Improperly functioning, unrecognizable markings, missing or removed part numbers, damaged, excessively worn and not repaired or reconditioned by United authorized personnel devices should not be used. If there is a need to return instruments to your sales or United, the devices must be cleaned, packaged and sterilized before returning.

CLEANING, INSPECTION, PACKAGING

A. Pre-treatment at the Point of Use	● Remove contamination: As soon as possible after use, remove excessive soiling with a disposable wipe, rinse and flush lumened devices with sterile or deionized water to prevent the drying of soil and/or debris to the inside. ● Ensure that no instruments or pieces of instruments are left in the surgical site prior to closure, as they may not be detectable using imaging techniques such as X-ray or MRI and patient injury may result.
B. Loading and Transportation	● Process instruments as soon as is reasonably possible after use. It is recommended not to delay cleaning for more than 2 hours. ● If transfer to the reprocessing area likely to be delayed, consider covering the medical devices with a damp cloth or store the medical devices in closed boxes to avoid drying of soil. ● If desired, place the instruments in its respective position within the instrument tray. The position of the instrument is labeled in its intended position within the tray.
C. Disassembly	● Disassembly multi-piece or complex instruments referred to their cleaning instructions. Care should be executed to avoid losing small screws and components. The cleaning instructions are available from your local sales representative or United.
D. Preparation of Cleaning (For All cleaning methods)	● Prepare a cleaning solution (Enzymatic/Detergent) proven efficacy and neutral pH 7~9 in accordance to the manufacturer's instructions provided information concerning specific materials, temperature, water quality, time, cleaning method. ● Tap water could be referred to the utility water of AAMI TIR34: Hardness <150ppm, Conductivity <500μS/cm, Chlorides <250ppm, Total organic carbon <1mg/mL. Used primarily for flushing, washing and rinsing. The cold tap water is at less 40°C. The warm tap water is at 30~ 44°C. ● **Deionized(DI) water** (ultra-filter (UF), reverse osmosis (RO), or equivalent) shall be referred to the critical water of AAMI TIR34[10], Hardness <1ppm, Conductivity <10μS/cm, Chlorides <1ppm, Bacteria <10CFU/mL, Endotoxin <10CFU/mL, Total

	organic carbon <1mg/mL. Used primarily for final rinses and steam generation. The warm deionized water is at 30~ 44°C. The Hot deionized water is at more than 44°C. ● Equipment: various sized soft-bristled brushes, lint-free cloths syringes, pipettes and/or water jet, ultrasonic cleaner, cleaning bath or vessel large enough to allow complete immersion of the instruments.
E. Cleaning-Manual Method with Ultrasonic	1) **Soak** soiled instruments and prevent air bubbles to ensure that all surfaces have contact with an enzyme solution for a minimum recommended time specified by the enzymatic cleaning solution manufacturer or 20 minutes, whichever is longer. 2) **Brush** the instruments with cleaned soft-bristled, nylon brush to clean and remove all traces of blood and debris. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush). For flexible shafts and springs, flex and relax the instrument under the cleaning solution while brushing. 3) **Flush** each difficult brush area thoroughly and aggressively in cold tap water for a minimum of 30 seconds. Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces. Repeat step 2~3 until all visible soil has been removed. 4) **Rinse** the instruments in cold top water for a minimum of 3 minutes. 5) **Ultrasonic cleaning**: Fully soak the opened instruments and prevent air bubbles to ensure that all surfaces have contact with an enzyme cleaning solution for 30 minutes at 45-50 kHz. 6) **Rinse** the instruments in cold tap water for a minimum of 3 minute. Repeat steps 2–6, until no visible debris, soil, enzyme cleaning solution remains on device. 7) **Final rinse** the instruments in **warm** deionized water for a minimum of 3 minutes to irrigate the challenging design features. 8) **Dry** the instruments after final rinse with a clean towel or clean compressed air until visibly dry.

F. Cleaning - Automated /Mechanical Method

1) Cleaning-Manual method with Ultrasonic step 1-6 should occur prior to this step. Mechanical washer with approved efficacy (e.g. Verified by ISO 15883) should be used.

2) Load the opened instruments in the washer such can drain (for example, hinges should be open and cannulations and holes can drain).

3) Process parameters follow "INSTRUMENT" cycle parameters validated by mechanical washer manufacturer and a pH neutral cleaning agent intended for use in automated cleaning using the **MINIMUM** cycle parameter set points below:

Cycle	Minimum Time	Temperature	Liquid
Pre-wash	2 minutes	<40°C	Tap water
Wash I	5 minutes	30~44°C	Enzymatic solution
Wash II	5 minutes	66°C	Neutral pH Detergent solution
Rinse	10 minutes	>44°C	Deionized water
Drying	30 minutes	100°C	None

G. Inspection, Functional Check

- **Visual inspect** all instruments, instrument trays, cases after processing prior to sterilization for: (Generally un-magnified visual inspection under good light conditions.)

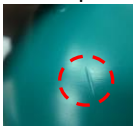
  Cleanliness: Ensure the complete removal of soil from surfaces, tubes and holes, moveable parts. If soil is still present, re-clean the instrument. Particular attention should be paid to: Soil “traps” such as mating surfaces, hinges, shafts of flexible reamers; recessed features (holes, cannulations) ; features where soil may be pressed into contact with the device, e.g. drill flutes adjacent to the cutting tip, sides of teeth on broaches and rasps.

Note: If contamination is noted repeat the cleaning process.

Completeness, damage and/or excessive wear: Visually inspect for no damage including but not limited to, malfunction, burrs, wear, tear, corrosion (rust, pitting), discoloration, creaked seals, excessive scratches and flaking.

Note: If damage or wear is noted that may compromise the function of the instrument, contact your sales or United.

- **Functional check** should be performed. Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and worn devices should not be used. The disassembled instruments should be **reassembled to check the function.**

Check Items	Suitable for Use	Not Suitable for Use
Assemblable	Reassembled successfully.	Can't be reassembled such as missing parts or can't be smooth moved.
Hinged instruments	Smooth operation throughout the intended range of motion.	Can't be operated as intended.
Locking mechanisms	Can be locked to the position as intended and not loosening.	Unable to lock.
Cutting features Reamer/Drill	Edges should be continuous without burrs. 	Edge distortion/large nicks. 
Trials	Smooth and free of cracks and deep nicks. (Minor crack don't affect the smooth operation is acceptable.) 	Cracks and deep nicks. 

	Hammering surfaces	Without burrs and large nicks.	Loose burrs or large nicks. 
	Flexible features	Flex and relax to inspect flexible feature like shafts, springs for any damage and major deformation 	Major deformation or can't operate smoothly. 
	Instrument tray/case	Inspect for burrs and locking from damage the wrap. (Minor burr is acceptable.) 	Burrs or locking mechanism loosening which may damage the wrap. 
	UDI Information 	Use DataMatrix barcode scanners to scan the UDI carrier to check is readable.	Can't read UDI carrier.
	Note: If any status above is noted, **do not** use the instrument and contact your sales or United. The instruments can be reused only if it is reconditioned by United.		

H. Packaging

- Use instrument cases to contain cleaned, checked, drying instruments that are provided in the instrument sets.
- For a sterilization wrap: United cases should be double wrapped according to AAMI/CSR technique. The packaging for terminally sterilized re-usable instruments should meet the following requirements: ISO 11607-1, CE Mark or FDA clearance, suitable for steam sterilization. **In the United States (US), only use an FDA-cleared Sterilization wrap.**
- For a rigid steam sterilization container system: Aesculap SterilContainer System -JN-400~JN-446 included with base vents use as packaging for the instrument sets. No more than one case can be placed directly into a rigid steam sterilization container.
- **The total weight of a wrapped instrument case should not exceed 11.4kg/25lbs.**

STERILIZATION

Using ANSI/AAMI ST79 *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care* is recommended to be steam sterilized by the health care facility using the process parameters below, which has been validated by United under laboratory conditions to provide a 10^{-6} sterility assurance level (SAL). A verified, properly maintained and calibrated steam sterilizer is recommended. The process parameters of sterilization should be followed explicitly. It is the responsibility of the medical facility to ensure that reprocessing is performed using the appropriate equipment and materials, and that personnel in the reprocessing facility have been adequately trained.

- **In the United States**

Cycle Type	Pulse Number	Exposure Temperature	Minimum Exposure time	Minimum Drying times
Dynamic-Air-Removal (Pre-vacuum)	4	132℃ (270℉)	4 minutes	30 minutes

- **Outside United States**

Cycle Type	Pulse Number	Exposure Temperature	Minimum Exposure time	Minimum Drying times
Dynamic-Air-Removal (Pre-vacuum)	4	132~135℃ (270~275℉)	4 minutes	30 minutes
Dynamic-Air-Removal (Pre-vacuum) For CJD/TSE contamination[1]		134℃[1] (273℉)	18 minutes[1]	

[1] Under certain classifications of risk, the World Health Organization (WHO), or local regulatory authorities recommend special Creutzfeldt-Jakob disease (CJD/TSE) inactivation processing procedures. Consult WHO and local regulations for further information.

STORAGE AND SHELF LIFE

After sterilization, re-usable instruments should be stored in the sterilization wrap or rigid steam sterilization container system in a dry and dust-free place. The shelf life is depending on the sterile barrier employed, storage manner, environmental conditions and handling. A maximum shelf life for sterilized re-usable instruments before use should be defined by each health care facility. Instruments must be examined for possible damage before use. Protective caps or other protective elements must be removed before cleaning.

VALIDATION INFORMATION

- **For Manual Cleaning/Automated Cleaning Validation:**

The reusable devices are exposed to the artificial test soil which is a mixture of Edinburgh test soil and bone meal to simulate the clinical soil, and be dried for 2 hours prior to clean. After manual cleaning/automated cleaning, visually inspect for any sign of remaining soil and test residual protein and total organic carbon (TOC) to an acceptable level.

- Following standards: AAMI TIR12, AAMI TIR30, AAMI TIR34, ANSI/AAMI ST79, ANSI/AAMI ST81, ISO 17664 and "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Food and Drug Administration Staff".
- Detergents: Prolystica 2X Concentrate Enzymatic Presoak And Cleaner (1C33), Prolystica 2X Concentrate Neutral Detergent(1C32)
- Automated washer – Miele PG 8535

- **For Moist Heat Sterilization Validation:**

The reusable devices in a maximum weight of loaded tray are placed biological indicators (BI) inoculated with more than one million (10^6) resistant spores (Geobacillus stearothermophilus) in the most challenging locations. The tray is packed with a sterilization wrap or rigid steam sterilization container system. The packed tray loaded in an empty chamber of steam sterilizer is validated a 10^{-6} sterility assurance level (SAL) by overkill method that half-cycle sterilization cycle result in total kill of all BIs demonstrating in

accordance with ISO 17665-1 Annex D. Recommended dry time is validated by demonstrating that pre-sterilization and post sterilization wrap/filter weight is no exceed ± 3 percent weight gain and no visible moisture on or within the sterilized packing, container, tray, instruments. Following standards: AAMI TIR12, ANSI/AAMI ST77, ANSI/AAMI ST79, ANSI/AAMI ST81, ISO 17664, BS EN ISO 17665-1, ISO/TS 17665-2, AAMI/ISO TIR17665-3 and "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Food and Drug Administration Staff".

- Sterilization wrap: Kimguard KC600 One-Step wrap
- Rigid steam sterilization container system: Aesculap SterilContainer Systems JN446(Bottom), JK486(Lid), MD344(Filter).
- Steam Sterilizer: AMSCO Eagle 3023-S Vacamatic Prevacuum Steam Sterilizer.

DISPOSAL INFORMATION

After use, an instrument is a potential biohazard, since it may be contaminated with blood or other body fluids, bone or other tissue. Handle and dispose of this product in accordance with accepted medical practice and with applicable local, state and national laws and regulations. In the event of an alleged product failure it is important to have the instrumentation returned to United for investigation.

Any sharp objects should be disposed of immediately after use into a sharps container conforming to national laws. The sharp object must not be bent, broken or resheathed prior to disposal.

ADVERSE INCIDENT REPORTING

For EU users, if any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

INFORMATION

For further information, please contact

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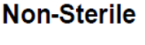
REFERENCES

1. AAMI TIR12: Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers.
2. AAMI TIR30: A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.
3. AAMI TIR34: Water for the reprocessing of medical devices
4. ANSI/AAMI ST77: Containment devices for reusable medical device sterilization.
5. ANSI/AAMI ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
6. ANSI/AAMI ST81: Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilizable medical devices.
7. ASTM F565: Standard Practice for Care and Handling of Orthopedic Implants and Instruments.
8. ISO 11607-1: Packaging for terminally sterilized re-usable instruments.
9. ISO 15223-1: Medical devices- Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements.
10. ISO 17664: Sterilization of re-usable instruments -Information to be provided by the manufacturer for the processing of resterilizable re-usable instruments.
11. ISO 17665-1: Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
12. ISO 17665-2: Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1.
13. ISO 17665-3: Sterilization of health care products - Moist heat - Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization.
14. Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Food and Drug Administration Staff, 2015.
15. European Commission, Council Directive 93/42/EEC.
16. Regulation (EU) 2017/745 of the European Parliament and of the Council.
17. ISO 16061: Instrumentation for use in association with non-active surgical implants-General Requirements.

SYMBOLS GLOSSARY

Symbol(s)	Title of symbol	Description of symbol	Standard / Ref. No.
	Medical Device	Indicates the item is a medical device. On the implant card, this symbol is used to indicate the device name (MDCG 2019-8 v2 Guidance document Implant Card relating to the application of Article 18 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices).	ISO 15223-1 / 5.7.7
	Catalogue number	Indicate the manufacturer's catalogue number.	ISO 15223-1 / 5.1.6
	Batch code	Indicate the manufacturer's batch code.	ISO 15223-1 / 5.1.5
	Manufacturer	Indicate the medical device manufacturer, as defined in EU Directives 93/42/EEC.	ISO 15223-1 / 5.1.1
	Caution	Indicate the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1 / 5.4.4
	Authorized representative in the European Community	Indicate the authorized representative in the European Community.	ISO 15223-1 / 5.1.2
	Rx only	Prescription Only. Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.	1. 21 CFR 801.15(c)(1)(i)F 2. 21 CFR 801.109
	Non-Sterile	Indicate the device is supplied non-sterile.	NA. United internal symbology.
	CE Marking	Indicate a presumption of conformity with the relevant EU Directives/REGULATION. Refer to label for CE mark and identification number of the notified body responsible for conformity assessment (if applicable).	1.Directive 93/42/EEC 2.Regulation (EU) 2017/745
	CE Marking	Indicate a presumption of conformity with the relevant EU Directives/REGULATION. Refer to label for CE mark and identification number of the notified body responsible for conformity assessment (if applicable).	1.Directive 93/42/EEC 2.Regulation (EU) 2017/745
QTY	Quantity	Indicate the quantity in a package of the medical device.	NA. United internal symbology.
	Unique Device Identifier (UDI)	Indicates a carrier that contains Unique Device Identifier information.	ISO 15223-1 / 5.7.10
	Importer	Indicates the entity importing the medical device into the locale.	ISO 15223-1 / 5.1.8

Please note that this Surgical Technique Guide has been authored in the English language. Any translations into other languages have not been reviewed or approved by United Orthopedic Corporation and their accuracy cannot be confirmed. Any translated guide should be reviewed carefully prior to use and questions regarding a Surgical Technique Guide should be directed to United Orthopedic Corporation at unitedorthopedic.com/contact

The CE mark is valid only if it is also printed on the product label.

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 UOC-UM-UN-00029 Rev.4 JAN. 2022