Corin

EN

CE 2797

INSTRUCTIONS FOR REPROCESSING OPS REUSABLE INSTRUMENTS

The following instructions are for all reusable instruments supplied by Corin as part of the OPS Acetabular and Femoral Delivery System unless stated otherwise with the packaging of the product.

1. WARNINGS

- Always follow instructions and warnings as issued by manufacturers of devices, materials and equipment.
- When reprocessing medical devices, handle with care, wearing protective clothing and face visors or goggles.
- These instructions are intended for use only by persons with the appropriate specialist knowledge and training.
- Incorrect cleaning, sterilisation, maintenance or handling may render the device unsuitable for its intended use and cause injury to the patient or user, such as infection.
- Device breakage or damage during use may cause post-operative complications such as osteolysis and adverse tissue reaction.
- Never modify the device.
- If there is a reason to believe that a serious incident has occurred in relation to the device, please report it to the national authority and to the manufacturer.
- Lasers are used with Corin instruments. The following instructions **DO NOT** apply to the lasers. The lasers are single use. **DO NOT** clean or sterilise the lasers. Refer to the laser pointer safety instructions provided with the laser pointer.

2. DESCRIPTION AND INTENDED USE

- The reusable instruments supplied by Corin are intended to be used with the OPS Acetabular Delivery System and the OPS Femoral Delivery System, refer to OPT-REC-RA-180 for the device description and intended use.

3. LIMITATIONS ON REPROCESSING

- Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage in use. Inspect devices for evidence of damage and wear prior to use, refer to Section 8 of this document (Inspection, Maintenance, Testing and Lubrication).

4. FROM POINT OF USE

- Soiled instruments should be placed into a holding solution (combined disinfectant / enzymatic solution) immediately after use and prior to cleaning. If a holding solution is not readily available, covering the soiled instruments in a moistened towel or moistened absorbent material is recommended. Dry, soiled surgical instruments are more difficult to clean. Do not allow contaminated devices to dry prior to reprocessing. All subsequent cleaning and sterilisation steps are facilitated by not allowing blood, body fluids, bone and tissue debris, saline, or disinfectants to dry on used instruments.
- Remove and dispose the laser pointer and batteries after use and prior to cleaning.

5. PREPARATION

- Reprocess all instruments as soon as it is reasonably practicable following use.
- If an instrument requires disassembly before cleaning and sterilisation, it must be dismantled in accordance with the instrument system instructions (Refer to **Appendix A**). After cleaning and prior to sterilisation, the instrument must be reassembled, unless otherwise indicated.

6. MANUAL PRECLEANING

- Automated cleaning using a washer/disinfector alone may not be effective for complex and significantly soiled orthopaedic instruments with lumens, cannulations, blind holes, mated surfaces and other features. These devices must be pre-cleaned if significantly soiled prior to the automated cleaning process. Some instruments require specific attention and additional cleaning instructions have been provided by Corin if required, and these should be followed first at the start of the precleaning process.
- The pre-clean should be carried out as follows:
    - Rinse device including hard to clean areas under running cold water for 1 minute.
    - Immerse device in enzymatic detergent solution and sonicate for 10 minutes at 45-50 kHz.
    - Remove device from solution and rinse with purified water for 1 minute, thoroughly flushing out any crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. If any visible soil remains, brush gently to remove from the device.

7. CLEANING: AUTOMATED

- The washer/disinfector manufacturer's instructions should be strictly adhered to. Use only cleaning agents recommended for the specific type of automated washer/disinfector. A washer/disinfector with approved efficacy (e.g., CE mark, FDA approval, and validation according to ISO 15883) should be used.
- Only agents with proven efficacy (FDA approved, VAH listed, or CE mark) should be used. As a large variety of cleaning agents and disinfectants exists around the globe, Corin does not recommend any specific brand.
- Alkaline enzymatic cleaning agents with low foaming surfactants are recommended.

Automated Washer/Disinfector Cycle for Surgical Instruments

Step	Description
1	2 minute prewash at ≥45°C with alkaline enzymatic detergent
2	5 minute cleaning cycle at ≥55°C with alkaline enzymatic detergent
3	2 minute rinse with purified water
4	Disinfection at 90°C with hot purified water for either (based on local requirements) a minimum of ≥1 minute until A_0 600 is reached, or up to ≥ 5 min until A_0 3000 is reached
5	≥22 minute hot air drying at ≥100°C

Note 1: *Unless stated otherwise, all Corin reusable instruments, other than aluminium trays, can withstand alkaline (pH≤12) detergents.*
Note 2: *Ensure instruments are dry before sterilisation.*
Note 3: *Refer to Appendix A for special instruments cleaning and sterilisation instruction.*

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8. INSPECTION, MAINTENANCE, TESTING AND LUBRICATION

- Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process.
- Visually inspect devices for completeness of parts/correct assembly, damage and/or excessive wear.
- Evidence of damage and wear on a device may include, but is not limited to, instruments with transparent window being scratched or cracked; instruments with a cutting edge may become dull; jaws and teeth do not align correctly; articulated instruments do not have a smooth movement; locking mechanisms (such as ratchets) do not fasten securely or close easily; distortion of long, slender instruments; component parts do not fit and assemble correctly with mating components; devices may suffer weld failures or thread damage, corrosion (i.e. rust/pitting); discoloration; excessive scratches; flaking, wear and cracks; unrecognisable/missing/removed (buffed off) part numbers or product marking.
- **Instruments which have experienced extensive use or excessive force, are susceptible to fracture. Damaged or excessively worn devices should not be used**. **If damage or wear is noted that may compromise the function of the instrument, contact your Corin representative for a replacement.**
- **Note 4:** *If an instrument is returned, the instrument **must** be decontaminated and sterilised and be accompanied with appropriate documented evidence.*
- Check the action of moving parts (e.g., hinges, connectors, sliding parts etc.) to ensure smooth operation throughout the intended range of motion.
- If necessary, apply surgical grade lubricants (specifically designed for compatibility with steam sterilization) to hinges, joints and moving parts as per the lubricant manufacturer's instructions.

9. INSTRUMENT TRAYS AND BOXES

- Do not stack instrument boxes during sterilisation.
- It is recommended that users thoroughly clean the instrument trays and boxes. Instrument trays and boxes should be visually clean prior to reinsertion of cleaned/decontaminated instruments into the boxes/trays.

10. STERILE PACKAGING

- Unless otherwise stated, the reusable device(s) should be placed into the dedicated sterilisation container or wrapped in two single layer wraps or one double bonded layer sterilisation wrap that is compatible with heavy instrument sets and steam sterilisation. This is required after cleaning and prior to sterilisation. The wrap should be compliant to the following standards: AAMI ST79, ISO 11607 and EN 868-2, have a CE mark or be FDA approved.
- All instruments to be packed following local protocol in accordance with applicable standards.
- Prior to sterilisation, if the Outer Box is identified with a '*Do Not Autoclave in the Outer Box'* label, the instruments should remain in the wire basket for autoclaving.

Note 5: *Instruments should not be autoclaved in a box identified with a 'Do Not Autoclave in the Outer Box' label.*

11. STERILISATION

- Ensure instruments are dry before sterilisation.
- When sterilising multiple instruments in one autoclave cycle, ensure that the steriliser manufacturer's stated maximum load is not exceeded.
- The following sterilisation parameters have been validated by Corin to provide a sterility assurance level of 10^{-6}.
- **Note 6.** *Sterilise in a steam autoclave conforming to BS EN 285 at a holding temperature of 134°C to 137°C for 3 minutes or 132°C for 4 minutes as per below table. Steam sterilisation is validated to recognised consensus standard EN 17665-1 and adheres to guidelines in AAMI TIR12, ISO 17664 and ISO 11138-3.*

Cycle Type	Temperature	Minimum Exposure Time	Minimum Dry Time	Minimum Cool Time
EU/UK Prevacuum / Pulsating Vacuum	134 - 137˚C / 273 - 279˚F	3 minutes	30 minutes	60 minutes
USA Prevacuum / Pulsating Vacuum	132˚C / 270˚F	4 minutes	30 minutes	60 minutes

12. STORAGE

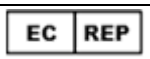
- Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.
  Sterile instrument packages should be carefully examined prior to opening to ensure that package integrity has not been compromised.

13. INTERPRETATION OF TERMS AND SYMBOLS

Refer to OPT-REC-RA-180 OPS Patient Specific Instruction For Use

KEY TO SYMBOLS USED ON PRODUCT LABELLING

Caution: The key for the following symbols is for reference only – some symbols listed may not apply. Please see product label for applicable symbols.

Symbol	Symbol title	Symbol description	Reference and Standard
	Manufacturer	Indicates the medical device manufacturer	ref. 5.1.1 in ISO 15223-1[1]
	Authorised Representative in the European Community/ European Union	Indicates the authorized representative in the European Community / European Union.	ref. 5.1.2 in ISO 15223-1[1]
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ref. 5.1.5 in ISO 15223-1[1]

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REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ref. 5.1.6 in ISO 15223-1[1]
	Importer	Indicates the entity importing the medical device into the locale	ref. 5.1.8 in ISO 15223-1[1]
NON STERILE	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	ref. 5.2.7 in ISO 15223-1[1]
	Do not use if package is damaged and consult instructions for use	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.	ref. 5.2.8 in ISO 15223-1[1]
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.	ref. 5.4.3 in ISO 15223-1[1]
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	ref. 5.4.4 in ISO 15223-1[1]
MD	Medical Device	Indicates the item is a medical device	ref. 5.7.7 in ISO 15223-1[1]
UDI	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information	ref. 5.7.10 in ISO 15223-1[1]
Rx	Prescription use only	Indicates that Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner	21 CFR 801.109
CE 2797	CE marking of conformity	Indicates that the device conforms to EU Medical Device Regulation	Regulation (EU) 2017/745
CH REP	Authorised Representative in Switzerland	Indicates the authorised representative in Switzerland.	ref. 5.1.2 in ISO 15223-1[1]

[1]: EN ISO 15223-1:2021 Medical Devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

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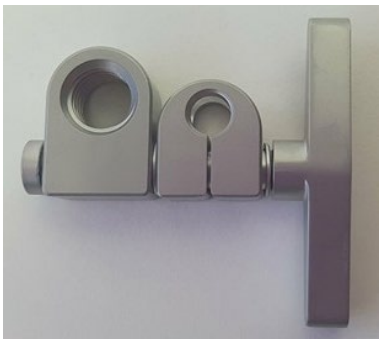
Appendix A - Special Instruments Cleaning and Sterilisation Instruction

	Ensure the Laser Canister Caps (Part# 1248-0037) is unscrewed from the Laser Canister (Part# 1248-0038), they must be cleaned and sterilised separately.
	The transparent window on the Laser Canister Caps (Part# 1248-0037) is subject to scratches. It should be protected from contact with other instruments during cleaning (e.g. by use of plastic baskets). An equivalent manual clean may be considered.
	Right Angle Clamp (Part# 1248-0041) has three (3) components. It must be disassembled by unscrewing both locking screws from the post completely. They must be cleaned and sterilised separately,
	Canister Clamp (Part# 1248-0064) must be completely loosened for clean and sterilisation. Turn counter-clockwise (left) to loosen.