Reprocessing Instructions

ABANZA

Index

1. INTRODUCTION

The purpose of this document is to provide detailed instructions for the reprocessing and maintenance of reusable instruments for orthopaedic surgery, sterilization trays and other accessories for orthopaedic surgical instruments to be reprocessed, which are manufactured by ABANZA (please see **APPENDIX I**).

Intended use: ABANZA reusable instruments for orthopaedic surgery are used in an operating theatre and come into contact with normally sterile tissues, blood or bodily fluids. In addition, surgical instruments, sterilization trays and other accessories may be subject to splashes of body fluids or blood although they are not in direct contact with the patient. In this context, there is a likelihood of microbial transmission and risk of infection if the device is not sterile. For this reason, such instruments are classified as critical, according to the Spaulding[1] classification, and should always be sterilized before use on each patient.

Taking into account the above information, ABANZA reusable instruments, sterilization trays, lids and other instrument accessories for orthopaedic surgery should be cleaned, inspected, packaged and sterilized before use by reprocessing staff.

In addition, this document **provides disassembly and assembly instructions** for those instruments consisting of several components that require disassembly/assembly for reprocessing (please see **APPENDIX II**).

This document was created based on the requirements of EN ISO 17664 (Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices) and ISO 17665/ANSI/AMMI ISO 17665. Furthermore, in accordance with EN ISO 17664, these instructions provide two methods for cleaning reusable surgical instruments manufactured by ABANZA: a manual method and an automatic method (using an automatic washing machine).

The reprocessing instructions described in this document have been validated by ABANZA as capable of being effective.

Equipment, operators, cleaning agents and procedures applied all contribute to the effectiveness of the reprocessing. Therefore, the end user is responsible for ensuring that reprocessing is performed correctly and efficiently so that the result is a safe and effective to use medical device.

Alternative processing methods may be also suitable for instruments; however, these should be validated by the end user prior to application. Clearly, in case of conflict, these will prevail over those recommended by ABANZA.

Following the recommendations in these instructions and performing regular maintenance will ensure that the instruments will last longer and function properly.

Note: These instructions do not apply to electrical active devices that may be used along with ABANZA non-electric reusable surgical instruments.

Note: Make sure that you use the most recent version of these instructions. The latest version is available at www.abanzamed.com

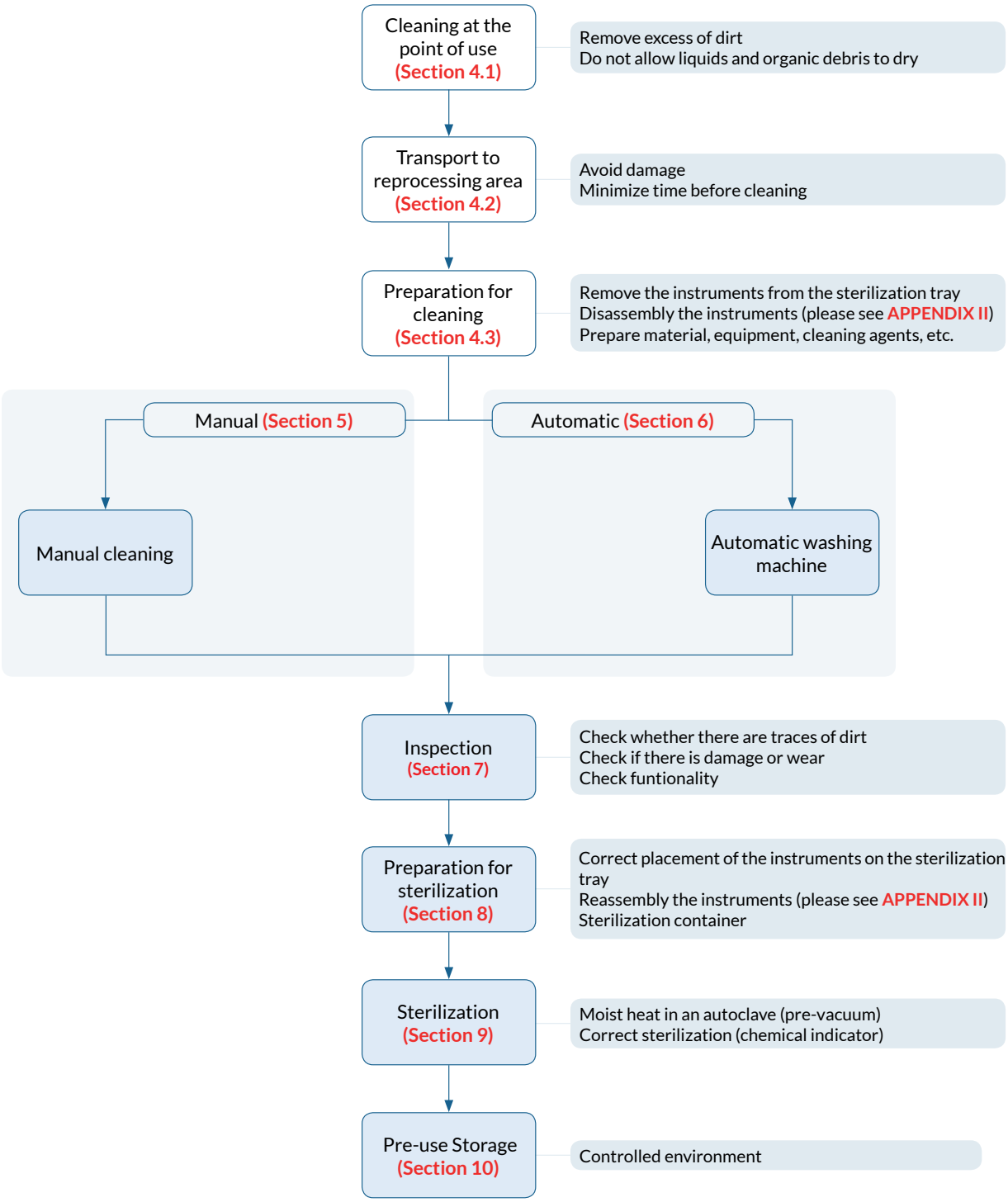
1 - Spaulding EH. Chemical disinfection of medical and surgical materials. In: Lawrence C, Block SS, eds. Disinfection, sterilization, and preservation. Philadelphia: Lea & Febiger, 1968:517-31.

2. WARNINGS AND PRECAUTIONS

- Federal law restricts this device to be sold to or on the order of a licensed health care professional.
- These reprocessing instructions **apply to:**
  - **Reusable instruments** for orthopaedic surgery manufactured as **Non-sterile** by ABANZA
  - **Sterilization trays, lids and other instrument accessories** for orthopaedic surgery to be reprocessed manufactured by ABANZA
- They do **not apply** to **single-use devices.**
- Perform a visual inspection and inventory upon receiving the reusable surgical instrument set to check that all parts of the set are present and that they have been received in proper condition. As well, to reduce the risk of infection, **surgical instruments, sterilization trays, lids and other instrument accessories should be cleaned and sterilized before their first use** following the procedures described in this document.
- It is recommended not to throw or hit the surgical instruments during surgery. If, during surgery, any of the reusable surgical instruments that makes up a set fells on the floor, it **should be removed and not used again during surgery** as it is likely to have lost its sterility.
- Accessories made of silicone or other polymeric materials, which are part of the sets (sterilization trays fasteners, handles, etc.), can be reprocessed following the same procedures as the instruments (cleaning and sterilization). However, if these parts show excessive surface deterioration or deformation, they should be replaced. If this occurs, please contact your ABANZA representative for replacement.
- Instruments may have sharp edges. **Handle with care.**
- Some ABANZA surgical instrument materials may develop changes in mechanical, physical or chemical characteristics (pitting, rusting, staining, etc.) due to repeated use, cleaning and re-sterilization, which may compromise the integrity of the design or material, potentially reducing safety, performance or compliance with relevant specifications. If this occurs, notify your ABANZA representative for replacement.
- Appropriate **personal protective equipment (PPE)** should be worn at all times when handling or working with contaminated or potentially contaminated devices. PPE includes (but is not limited to): gown, gloves, mask, goggles or face shield, shoe covers, etc.
- **Do not use metallic brushes, scouring pads, or abrasive cleaners during manual cleaning.** Their use can damage the surface and the refinishing of the instruments. **Soft bristle nylon brushes and tube cleaning brushes should be used.** For instruments with bone-cutting areas (drills, countersinks), brushes with firmer bristles should be used, but never use brushes with metal bristles for cleaning.
- Use **running/ tap water** (service water in accordance with AAMI TIR34: Hardness < 150 ppm, Conductivity < 500 µS/cm, Chloride < 250 ppm, Total organic carbon < 1 mg/mL), primarily for washing, cleaning and rinsing.
- Use ultrafiltration (UF) **deionized water,** reverse osmosis (RO), or equivalent (critical water in accordance with AAMI 5 TIR34: Hardness < 1 ppm, Conductivity < 10 µS/cm, Chloride < 1 ppm, Bacteria < 10 CFU/mL, Endotoxins < 10 CFU/mL, Total organic carbon < 1 mg/mL), primarily for final rinses and steam generation.
- Under certain risk classifications, the World Health Organization (WHO) or local regulatory authorities recommend special Creutzfeldt-Jakob Disease (CJD/TSE - Transmissible Spongiform Encephalopathy) inactivation procedures. ABANZA reusable instruments are not used in surgical procedures where they come into contact with CJD/TSE infectious tissue (according to WHO). Therefore, **excessively aggressive decontamination procedures** (using aggressive detergents such as sodium hydroxide or sodium hypochlorite, aldehydes, bromides, iodides) **are not required,** and are not recommended for normal reprocessing because material degradation may occur. Refer to the WHO and local regulations for more information.
- ABANZA reusable surgical instruments are not articulating, rotating or hinged, and therefore **do not require the use of lubricants** to reduce the friction commonly associated with metal-to-metal friction.
- These validated reprocessing instructions do not apply to ABANZA sterilization trays, which contain devices not manufactured or distributed by ABANZA.
- **Moist heat sterilization** is the recommended sterilization method of ABANZA reusable surgical instrument sets. The use of ethylene oxide, gas plasma or dry heat sterilization methods is not recommended.

3. PROCESSING SUMMARY

The sequence of steps necessary to perform the reprocessing of reusable instruments for re-use or preparation of devices for their first use is summarized in the following table:



4. PRE-CLEANING

4.1. POINT OF USE PROCESSING

1. **Remove gross soil** (liquids, tissue, bone fragments, organic debris) from the instruments, sterilization tray and lid with a disposable cloth **or** allowing water through the instruments, sterilization tray and lid, as soon as reasonably possible after use (a maximum of 2 hours after the intervention is recommended).

2. It is recommended to put the instruments, sterilization tray and lid into a bucket with water or cover them with wet cloths until they are processed.

IMPORTANT: Do not allow blood, body fluids or other organic debris to dry on the instruments.

4.2. TRANSPORT TO REPROCESSING AREA

1. **Take the** instruments, sterilization tray and lid **to the reprocessing area as soon as possible**—covered or closed—to avoid contamination risks and avoiding bumping against each other during transportation.

2. It is recommended to put the instruments inside the sterilization tray during transport, to prevent them from bumping against each other.

4.3. PREPARATION FOR CLEANING IN THE REPROCESSING AREA (for both cleaning methods)

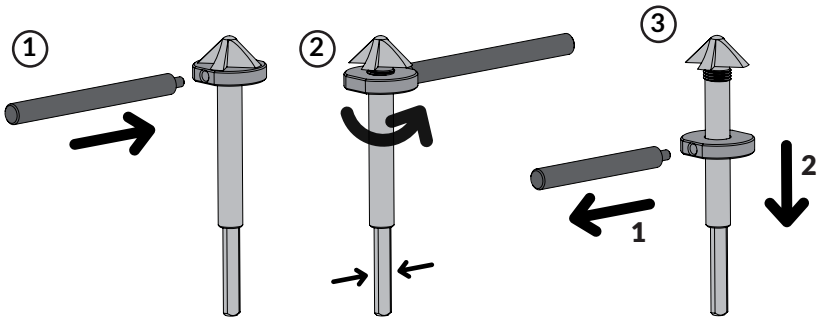
1. **Remove instruments from the sterilization tray** before performing the cleaning process.

⚠ **IMPORTANT: the cleaning process (both manual and automatic) should be carried out individually on each instrument, sterilization tray and lid and never jointly inside the sterilization tray.**

2. **Disassemble the instruments** consisting of several parts (according to **APPENDIX II**) in the reprocessing area for their proper cleaning.

⚠ **IMPORTANT: Please see "APPENDIX II: Instruments requiring disassembly and assembly for its reprocessing", search the set you are reprocessing and identify the instruments of this set that must be disassembled before cleaning.**

For example: WasherCap™ Countersink.



Note: Take special care with the small parts once instruments have been disassembled to avoid losses. In case of losing any item, immediately notify your ABANZA representative to replace it.

5. MANUAL CLEANING

IMPORTANT: If NOT previously performed at the point of use of the instruments, remove excess dirt from the instruments, sterilization tray and lid using a disposable cloth or allowing water through them.

Material and equipment required: brushes of various sizes, fiber-free cloths, syringes (pipettes, water jet, etc.), ultrasonic cleaner, bucket or container that allows complete immersion of the instruments.

STEPS:

1. **WASHING:**
   - **Prepare a cleaning solution** using an enzymatic or alkaline cleaning agent[2] (pH equal to or less than 12) in accordance with the manufacturer's instructions for the use of the cleaner in terms of recommended types of materials, concentrations, temperatures, water quality, exposure times and cleaning method.
   - **Completely immerse** the instruments, sterilization tray and lid separately (each individually and not inside the sterilization tray).
   - Make sure that the cleaning solution come into contact with all internal and external surfaces of the instrument parts.

     Note: If necessary, during this step, use a syringe to perform rinses in hard-to-reach areas.

2. **BRUSHING:**
   - **Remove any residue or traces of blood** found on instruments, sterilization tray and lid using a soft, smooth bristles brush.

     Note: Pay attention to hard-to-reach areas, such as threads, cracks, lumens/cannulas (using a special brush for cleaning lumens/cannulas), etc. For instruments with bone-cutting areas (drills, countersinks), brushes with firmer bristles should be used, but never use brushes with metal bristles for cleaning.

3. **RINSING 1:**
   - **Rinse the instruments and sterilization tray in running water**[3] until all visible traces of detergent have been removed.
   - It is recommended to rinse the instruments, sterilization tray and lid for at least 3 repetitions of 1 minute.

⚠ **Note**: Pay special attention to slits, cracks, lumens/cannulas, broken surfaces, etc. If necessary, during this step, use a syringe for rinsing hard-to-reach areas.

4. **ULTRASONIC BATH**[4]**:**
   - **Prepare a solution** with a cleaning agent suitable for the ultrasonic bath, according to the manufacturer's instructions for use of the cleaner in terms of recommended types of materials, concentrations, temperatures, water quality, exposure times and cleaning method.
   - **Completely immerse** the instruments, sterilization tray and lid separately (each individually and not inside the sterilization tray).
   - Make sure that the cleaning solution comes into contact with all internal and external surfaces of the instrumental parts.
   - **Ultrasonic cleaning** for a minimum of 10 minutes at a frequency of 40-50 kHz is recommended, provided that manufacturer's instructions advise so.

5. **RINSING 2 (after ultrasonic bath):**
   - **Rinse the instruments and sterilization tray in in running water**[5] until all visible traces of detergent have been removed.

2 - Manual cleaning of ABANZA reusable surgical instruments was validated using a 1% solution of Helizyme Enzymatic Cleaning in tap water for 5 minutes at room temperature.
3 - Service water in accordance with AAMI TIR34: Hardness < 150 ppm, Conductivity < 500 µS/cm, Chloride < 250 ppm, Total organic carbon < 1 mg/mL.
4 - Manual cleaning of ABANZA reusable surgical instruments was validated using a 1% solution of Helizyme Enzymatic Cleaning in tap water at a frequency of 40 kHz for 10 minutes.
5 - Service water in accordance with AAMI TIR34: Hardness < 150 ppm, Conductivity < 500 µS/cm, Chloride < 250 ppm, Total organic carbon < 1 mg/mL.

- It is recommended to rinse the instruments, sterilization tray and lid for at least 3 repetitions of 1 minute.

⚠ **Note**: Pay special attention to slits, cracks, lumens/cannulas, broken surfaces, etc. If necessary, during this step, use a syringe for rinsing hard-to-reach areas.

6. **FINAL RINSE:**
   - **Rinse the instruments, sterilization tray and lid with deionized water**[6].
   - It is recommended to rinse the instruments, sterilization tray and lid with deionized water for at least 1 minute.

     Note: Rinse water is not re-used.
7. **DRYING:**
   - **Dry the instruments, sterilization tray and lid with a clean cloth** made of fiber-free materials to ensure that the parts are completely dry.

     Note: Filtered pressurized air can be used to help with drying.

IMPORTANT: Visually inspect and repeat the manual cleaning process, if necessary.

Note: For the cleaning of reusable instruments, ABANZA does not recommend a specific cleaning agent for those instruments, as there is a wide variety of these types of agents and not all of them may be available on a given market. However, for instruments cleaning, cleaning agents developed specifically for that function, with proven effectiveness, should be used (enzymatic or alkaline cleaning solutions capable of breaking down blood, body fluids and tissues)

Note: Each time a wash cycle (manual, ultrasonic) is performed, the cleaning solution must be renewed.

6 - Critical water in accordance with AAMI 5 TIR34: Hardness < 1 ppm, Conductivity < 10 µS/cm, Chloride < 1 ppm, Bacteria < 10 CFU/mL, Endotoxins < 10 CFU/mL, < 1 mg/mL.

6. AUTOMATIC CLEANING

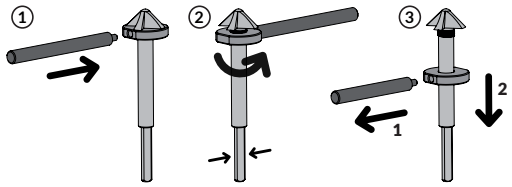
IMPORTANT: Cleaning at the point of use and, if necessary, manual cleaning (Section 5: steps 1-6) should be carried out before carrying out the automatic cleaning.

STEPS:

1. **LOADING INTO THE AUTOMATIC WASHING MACHINE**[7]**:**
   - **Introduce the instruments, sterilization tray and lid** separately (each individually and not inside the sterilization tray) into the washing machine, disassembled (please see **APPENDIX II**) and in an orderly manner.

⚠ **IMPORTANT: Please see "APPENDIX II: Instruments requiring disassembly and assembly for its reprocessing", search the set you are reprocessing and identify the instruments of this set that must be disassembled before cleaning.**

For example: WasherCap™ Countersink.



   - **Do not stack the instruments, sterilization tray and lid on top of each other.** Place the instruments, sterilization tray and lid in a way that the detergent solution can reach all exposed surfaces (avoid "shadow zones", e.g., hinges should be open and cannulations and holes can drain).

2. **CLEANING CYCLE:**
   - **Process instruments, sterilization tray and lid** with a standard cleaning cycle for surgical instruments[8] validated by the automatic washing machine manufacturer using a detergent suitable for automatic cleaning[9].

     Note: It is recommended to follow the manufacturer's instructions for detergent use in terms of recommended material types, concentrations, temperatures, water quality, exposure times and cleaning method.

3. **REMOVE THE INSTRUMENTS FROM THE AUTOMATIC WASHING MACHINE:**
   - **Remove the instruments, sterilization tray and lid from the automatic washing machine** and check if there is any remaining dirt; if so, repeat the process.

4. **DRYING:**
   - **Dry the instruments, sterilization tray and lid with a clean cloth** made of a fiber-free material to ensure that they are completely dry.

     Note: Filtered pressurized air can be used to help with drying.

IMPORTANT: Visually inspect and repeat the manual cleaning process, if necessary.

Note: To carry out automatic cleaning, automatic washing machines that are approved for their efficiency (FDA or CE marked according to ISO 15883), properly installed, qualified and subject to regular maintenance and testing should be used. The operating instructions of the automatic washing machine manufacturer should be followed. Use only cleaning agents recommended by the manufacturer specifically for their use in automatic washing machines.

7 - Automatic cleaning of ABANZA reusable surgical instruments was validated using Washer disinfector Miele Unit G 7836 CD.
8 - Automatic cleaning of ABANZA TECNOMED reusable surgical instruments was validated using washing cycle (Prewash I – 10°C/10 minutes; Washing– 55°C/5 minutes/0.3% detergent; Neutralization – 10°C/2 minutes; Rinsing II – 10°C/1 minute)
9 - Automatic cleaning of ABANZA reusable surgical instruments was validated using Neodisher MediClean Forte® at a concentration of 0.3%.

7. INSPECTION

After the cleaning process, instruments sterilization trays and lids **should be inspected before preparing them for sterilization.** For this purpose, each instrument, sterilization tray and lid should be **visually inspected and checked for signs of visible dirt and/or damage and wear.**

- In terms of **cleaning**, complete removal of dirt from all instruments, sterilization tray and lid surfaces should be ensured. If any trace of dirt is detected, repeat the manual cleaning process focusing on the areas that show dirt after the process. It is recommended to pay special attention to those areas where dirt can become embedded (cut areas or crannies).

- In terms of **damage and wear**,it is considered unacceptable and therefore as failure criteria when any damage to the instruments, sterilization tray and lid is identified visually, including but not limited to: burrs, breakage, corrosion (rust, pitting), discoloration, excessive scratches, flaking, wear, cracks, malfunction, etc. should be visually checked. Also check that the references marked on the instruments, sterilization tray and lid are legible in order to maintain their traceability.

I**n the event of damage or wear** that could affect the proper functioning of the instrument, sterilization tray and lid ask for a replacement to the ABANZA representative.

Note: If it is necessary to return the instruments to the ABANZA representative because they are damaged, the devices must be delivered clean and properly packaged and sterilized.

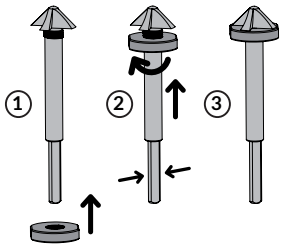
Note: ABANZA does not establish the maximum number of appropriate uses for reusable surgical instruments. The service life of these devices depends on many factors, including method of use, duration of each use, and handling of the devices between uses. Thorough visual inspection and function testing[10] of the instrument prior to use (before sterilization) is the best way to determine the end of service life.

10 - It is recommended to carry out a performance test to check functionality, before reusing the instruments. A sharpness test should be passed to check that the functionality on a simulation surface and to check that the cuts made by the instruments are clean and effective.

8. PREPARATION FOR STERILIZATION PROCESS

STEPS:

1. **Reassembly** the reusable surgical instruments that require disassembly (please see **APPENDIX II**) during the cleaning process before the sterilization process in the reprocessing area.



⚠ **IMPORTANT: Please see "APPENDIX II: Instruments requiring disassembly and assembly for its reprocessing", search the set you are reprocessing and identify the instruments of this set that must be reassembled before sterilization. For example: WasherCap™ Countersink.**

2. **Place the instruments in the sterilization tray** for sterilization.

   Note: The sterilization trays supplied with the ABANZA reusable surgical instrument sets have a defined design for the specific placement of each of the surgical instruments that composes each concerned set. In other words, only parts manufactured by ABANZA that are part of a given set can be included in the sterilization trays.

3. **Close the tray with its lid and check** that the latches are securely fastened to prevent them from opening.

4. **Place the closed sterilization tray in an authorized sterilization container**[11] (FDA approved or CE marked) with a tight lid and suitable for steam sterilization at the user's discretion.

Note: Follow the instructions of the sterilization container manufacturer for the insertion and replacement of sterilization container filters. Do not place more than one tray inside the sterilization container.

9. STERILIZATION PROCESS

IMPORTANT: Manual and/or automatic cleaning should be performed before beginning the sterilization process.

1. **Perform sterilization** of reusable surgical instruments by moist heat method in an autoclave (sterilizer)[12] with a pre-vacuum cycle (forced air removal).

   Note: The autoclave in which sterilization is performed must comply with the requirements of EN 285, EN 13060, EN ISO 17665 and AINSI/AAMI ST79, and be validated and maintained accordingly.

   It is recommended to follow the parameters described below:

US

Method	Moist heat sterilization according to ANSI/AAMI/ISO 17665
Cycle	Pre-vacuum
Temperature	132˚C (270˚F)
Exposure time[13]	4 minutes (minimum)
Drying time[14]	30 minutes (minimum in chamber)

Outside US

Method	Moist heat sterilization according to ISO 17665
Cycle	Pre-vacuum
Temperature	132-137 ˚C (270-277 ˚F)
Exposure time[13]	4 minutes (minimum)
Drying time[14]	30 minutes (minimum in chamber)

Note: Reduction of sterilant residual does not apply to the type of sterilization validated for ABANZA instruments.

11 - ABANZA has validated the sterilization of instruments by moist heat using a sterilization container with a multipurpose filter.
12 - The sterilization of ABANZA's reusable surgical instruments was validated using Selecta's moist heat sterilization autoclave (capacity 75 litres)
13 - Exposure time: Period during which the load and the entire chamber are maintained at the same sterilization temperature.
14 - Drying time: Period during which steam is removed from the chamber and chamber pressure is reduced to allow evaporation of condensate load by prolonged evacuation or by injection and extraction of hot air or other gases. Drying time varies depending on the load configuration, the method used for wrapping and the material.

10. PRE-USE STORAGE

1. **Place the sterilization container with the sterile instruments** in a specific area with limited access that is well ventilated and offers protection against dust, humidity, insects, temperature and humidity extremes[15].

Note: The set should be storage inside the sterilization container. If there is any indication or sign that the sterilization container has been opened or compromised (damaged lid seal, open filters, etc.) the instruments should be re-sterilized by changing the filters, if necessary.

Note: Storage period depends on several factors (storage form, environmental conditions, handling, etc.), so the maximum storage period for sterilized reusable instruments before use should be defined by each user.

11. CUSTOMER SERVICE INFORMATION

Address	**Contact**
ABANZA TECNOMED S.L. Calle Nueva 29 31192 Mutilva (Navarra) SPAIN	Tel.: (+34) 948 04 46 43 Email: contact@abanzamed.com
This instructions can be found at www.abanzamed.com	

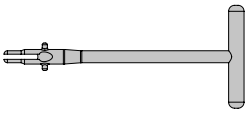
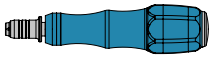
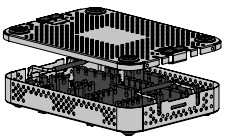
15 - ABANZA recommends storage conditions in accordance with USP, EP and JP for controlled ambient temperatures.

12. REFERENCES

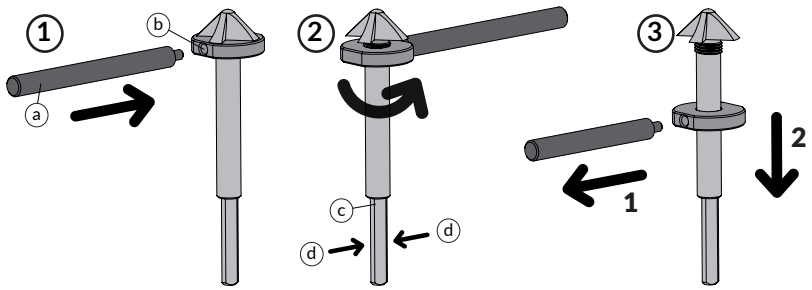
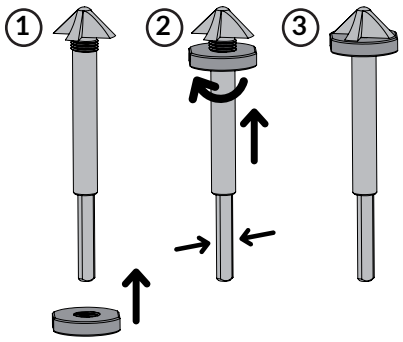
1. EN ISO 17664 (ANSI AAMI ST81): Processing of health care products. Information to be provided by the medical device manufacturer for the processing of medical devices.
2. EN ISO 17665-1 (ANSI AAMI ISO 17665): Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
3. AAMI TIR12: Designing, Testing and labeling medical devices intended for processing by health care facilities.
4. ASTM F565: Standard Practice of Care and Handling of Orthopedic Implants and Instruments.
5. AAMI TIR30: A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.
6. EN ISO 15883-1: Washer-disinfectors. Part 1: General requirements, terms and definitions and tests.
7. EN ISO 11607 (ANSI AAMI ISO 11607): Packaging for terminally sterilized medical devices.
8. AAMI TIR34: Water for the Reprocessing of Medical Devices.
9. ANSI/AAMI ST77: Containment devices for reusable medical device sterilization.
10. ANSI/AAMI ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
11. Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Food and Drug Administration Staff, 2015.

APPENDIX I: Abanza Surgical Instrument Set

Ref. ABWCIN00: Reusable surgical instrument set associated with the WasherCap™ Fixation System (for Reconstruction of the Anterior Cruciate Ligament of the knee)

Reference	Name	Description	Image
ATMWCIN80	WasherCap™ countersink positioner 7 mm	Instrument that is inserted into the tibial tunnel to perpendicularly position the "positioning guide" element in order to facilitate cortical shaping. Four appropriate positioners are supplied for each of the WasherCap™ Fixation System sizes (7 mm, 8 mm, 9 mm and 10 mm).	
ATMWCIN81	WasherCap™ countersink positioner 8 mm		
ATMWCIN82	WasherCap™ countersink positioner 9 mm		
ATMWCIN83	WasherCap™ countersink positioner 10 mm		
ATMWCIN79	Positioner guide	Cannulated instrument that is placed on the positioner (once it has been introduced into the tibial tunnel) to pass a Ø2.4 mm needle through it that will serve to guide the countersink of the cortex.	
ATMWCIN28	Kirschner wire	Blunt-tipped Kirschner wire (rounded tip) designed to guide the countersink phase without disturbing the cortex of the posterior part of the tibia.	
ATMWCIN06	WasherCap™ countersink, 7 mm	Cannulated instrumentation that is placed over the guide wire to shape the cortex of the bone so that the WasherCap™ Fixation System cap can be implanted correctly. 4 sizes of countersinks are supplied per set to use depending on the WasherCap ™ Fixation System to be implanted (7 mm, 8 mm, 9 mm or 10 mm). This instrument must be disassembled for cleaning and reassembled before sterilization during its reprocessing (see Appendix II).	
ATMWCIN07	WasherCap™ countersink, 8 mm		
ATMWCIN05	WasherCap™ countersink, 9 mm		
ATMWCIN08	WasherCap™ countersink, 10 mm		
ATMWCIN78	Countersink tool	Tool used to thread and unscrew the top of the countersink body for easy disassembly.	
ATMWCIN40	WasherCap™ inserter 7 mm & 8 mm	Instruments used to place the cap of the WasherCap™ Fixation System at the entrance of the tibial tunnel. 4 inserters sizes are supplied per set to use depending on the size of the WasherCap ™ Fixation System to be implanted (7 mm, 8 mm, 9 mm or 10 mm).	
ATMWCIN42	WasherCap™ inserter 9 mm & 10 mm		
ATMWCIN61	Inserter coupling screw 7 mm & 8 mm	The inserter screw is used to couple the sleeve to the inserter, threading it into the inserter until the "device-inserter" assembly is fully engaged. Two screw metrics are supplied depending on the WasherCap™ Fixation System to be implanted; one for sizes 7 mm and 8 mm, and one for sizes 9 mm and 10 mm.	
ATMWCIN62	Inserter coupling screw 9 mm & 10 mm		
ATMWCIN43	Awl, 7 mm & 8 mm	Used to insert the screw of the WasherCap™ Fixation System. Two awl sizes are supplied depending on the WasherCap™ Fixation System to be implanted; one for sizes 7 mm and 8 mm, and one for sizes 9 mm and 10 mm.	
ATMWCIN44	Awl, 9 mm & 10 mm		
ATMWCIN49	WasherCap™ Screwdriver	Instruments used to screw the "screw-washer" assembly to the cap, locking the tendon against the locking corridor of the cap.	
ATMWCIN45	Handle with AO connection system	Accessory handle used to insert instruments with AO connection.	
ATMWCIN52	Sterilization tray	Tray supplied with the set containing the above-mentioned instruments, fixed by silicon fasteners. The tray is used to transport, store and sterilize the set of surgical instruments.	

APPENDIX II: Instruments requiring disassembly and assembly for its reprocessing

Reusable surgical instrument set associated with the WasherCap™ Fixation System	
Reference	**Name**
ATMWCIN06	WasherCap™ countersink, 7 mm
ATMWCIN07	WasherCap™ countersink, 8 mm
ATMWCIN05	WasherCap™ countersink, 9 mm
ATMWCIN08	WasherCap™ countersink, 10 mm
Disassembly	
Follow the steps below to disassembly: 1) Insert the countersink tool (a) into the hole of the stop (b). 2) Holding the body of the countersink (c), using another instrument with a Chuck handle connection (d) if necessary, and turn the countersink tool counter-clockwise. 3) Once loosened, remove the countersink tool, and carefully remove the stop from the body.	
Assembly	
The set includes four (4) different countersink sizes, and each of them has a corresponding stop size. For this reason, after reprocessing, it is essential to mount the countersink with the stop that corresponds to its size. To do this: 1) Check that the numbering laser engraved on each of the two parts matches and insert the stop onto the body. 2) Screw the stop onto the body in a clockwise direction until it is tightened. Use a handle with Chuck connection, if necessary. 3) Check that it has been correctly tightened (when it is completely threaded), and, if necessary, tighten it using the countersink tool.	

Notes

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Information on products and/or procedures in this document is general in nature and does not represent medical advice. A surgeon should always rely on his/her own clinical and professional opinion when deciding whether to use a particular product to treat a patient.

ABANZA recommends surgeons to be trained in the use of any product before using it in surgery, being necessary an individual examination of each patient. Similarly, ABANZA strongly recommends that the staff in charge of reprocessing instruments reads carefully the involved processes.

Always consult the instructions for use and labeling accompanying the product before using any ABANZA product.

Not all ABANZA products may be available in all markets because availability is based on medical and/or regulatory practices in each market. Contact your ABANZA representative for availability in your area.

Reference of the document: CI-001
Version of the document: 04_EN - 10/2022