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EN Instructions for the care, cleaning, disinfection and sterilization of surgical instruments

1. INTRODUCTION

Permedica Spa surgical instruments consist of class I and class IIa reusable medical devices. They can be supplied individually or in sets, organized in trays. The exact identification of each individual instrument is given on the list provided together with the tray or, if the instrument is delivered individually, on the package identification label.
Before performing surgery, the surgeon must be familiar with the Surgical Technique, the use of surgical instruments and the devices to be implanted.
The purpose of this document is to provide detailed instructions for the treatment of reusable surgical instruments supplied by Permedica Spa. Permedica Spa has validated the processes illustrated in these instructions, verifying their effectiveness. The effectiveness of the procedures depends on the interaction between the systems used, detergents and operating procedures. Other treatment methods, not described in these instructions, may be suitable for reprocessing surgical instruments; it is the responsibility of the end user to validate the equipment and the cleaning, disinfection and sterilization processes of surgical instruments. In the event of a conflict with national regulations relating to cleaning, disinfection and sterilization, the latter will have priority over the recommendations provided by Permedica Spa.
The information below is not applicable to surgical instruments of other manufacturers. They are also not applicable to single use devices supplied by Permedica Spa.
Failure to comply with the instructions in this instruction sheet exonerates the manufacturer from any liability.
This instruction for use is drawn up in accordance with the ISO 17664 standard.

2. INTENDED USE, PERFORMANCE CHARACTERISTICS AND CLINICAL BENEFITS

The surgical instruments are intended to be used for the implantation and removal of orthopaedic implantable medical devices and osteosynthesis devices during surgery. Under no circumstances can a surgical instrument be implanted.
The surgical instruments are intended to facilitate the implantation of medical devices by the surgeon in order to obtain a correct positioning of the devices to be implanted or to allow for any explantation..

2.1 PATIENT TARGET GROUP

Adult patients with a mature skeleton undergoing total or partial arthroplasty or amputated and undergoing percutaneous invasive fixation treatment. Patients undergoing surgery for the treatment of traumatic injuries to the skeletal system or corrective surgery.

2.2 INTENDED USERS

The intended users of the surgical instruments are orthopaedic surgeons qualified in joint replacement and / or trauma specialists.

3. MATERIALS

Stainless steels, titanium alloys, chromium-cobalt alloys, polymeric materials

4. WARNINGS, PRECAUTIONS AND RESTRICTIONS

- Permedica Spa has developed a set of specific instruments for each type of implantable medical device. Instruments from other manufacturers should not be used unless specified in the surgical technique of the device.
- Permedica Spa surgical instruments are supplied in non-sterile conditions and must be properly cleaned, disinfected and sterilized before use. It is the responsibility of the health care facility to proceed with the control, cleaning, disinfection and sterilization of the instruments before use, according to validated methods. The recommendations contained in this document do not replace existing sanitary rules (standards, guidelines, etc.). Permedica Spa suggests the use of steam autoclave sterilization for the surgical instruments provided. The trays containing the surgical instruments are equipped with holes to allow the penetration of steam. They do not constitute a sterile barrier, therefore they must be properly packaged to maintain sterility.
- Wear personal protective equipment (i.e. gown, gloves, mask etc.) when using contaminated or potentially contaminated instruments.
- Start the reprocessing procedures immediately after use in order to facilitate cleaning, disinfection and sterilization activities and reduce the risk of infection (for the medical staff) and corrosion of the instruments.
- Surgical instruments and trays must be cleaned separately. Place the instruments in the trays only after having completed their cleaning and disinfection.
- Use softened or purified water. Softened water should be used for the initial rinse, purified water for the final one in order to avoid mineral deposits on the surface of the instruments. Purified water can be produced by one or more of the following processes: ultra-filtration, reverse osmosis, deionization or equivalent processes.
- Do not use wire brushes or abrasive sponges in manual cleaning activities as they could damage the surface of the surgical instruments.
- Use cleaning agents with a pH between 6.0 and 8.5. Cleaning agents with a pH outside the indicated range can damage surgical instruments. Do not use strong acids or alkaline agents, oxidizing agents or corrosive chemicals that can alter the surface of surgical instruments. Follow the instructions for use and the manufacturer's warnings for each cleaning agent, using the recommended concentrations.
- Follow the instructions for use and the manufacturer's warnings of the systems used for cleaning, disinfection and sterilization.
- Complex instruments (mating surfaces, hinges, retractable parts, sandblasted surfaces etc.) require special attention during cleaning. Manual cleaning, before automatic cleaning, is necessary for this type of instrument.
- Instruments made of polymeric materials must not be processed at temperatures above 140 ° C.
- For instruments that have come into contact with patients suffering from diseases for which the national authorities have provided for particular disinfection and / or sterilization procedures, it is recommended to follow them with extreme care.
- Before performing the surgical suture, check that any instruments or parts of them have not been left in the surgical site.

4.1 ADVERSE EVENTS

In accordance with the definition of incident / serious incident reported in EU regulation 2017/745, any serious incident occurring in relation to the devices must be reported to Permedica Spa and to the competent authority of the Member State in which the user and / or patient is established.

5. LIMITS FOR REPROCESSING

Surgical instruments, like all reusable instruments, are subject to unavoidable wear and aging due to repeated stresses deriving from contact with the bone, impact and positioning as well as cleaning, disinfection and sterilization processes, despite the latter have a minimal impact on the useful life of the devices.
The life cycle of surgical instruments is not unlimited. Permedica Spa recommends checking, before any intervention, that they are functioning properly, that no deformations or signs of breakage or wear are visible. If the wear conditions do not alter the properties and performances of the instruments, they can be reused. Otherwise, if the conditions of wear can deteriorate properties and performances, these must not be used but sent to Permedica Spa for repair or replacement. **Do not repair the instruments yourself.**
The list of controls that the user must carry out to evaluate the wear of surgical instruments is shown in the following section.

6. INSTRUCTIONS FOR CLEANING, DISINFECTION AND STERILIZATION

The activities listed below and suggested by Permedica Spa, must be carried out for the first use after delivery and following each use and before returning the surgical instruments to Permedica Spa. Different cleaning, disinfection and sterilization methods must be validated by the end user.

Initial treatment at the point of use

- Remove excess dirt (debris, fragments of tissue or bone) present on the surfaces with disposable wipe.
- Keep the devices moist during use to prevent the drying of organic and inorganic surgical residues on the surfaces of the instruments.
- Avoid prolonged exposure to saline solutions to minimize the probability of corrosion.

Preparation for cleaning

Disassemble instruments with articulated components (cannulated, threaded or interlocking). It is suggested to keep the components of the disassembled instruments grouped, to facilitate their reassembly.
To disassemble the instruments, follow the directions given in the surgical techniques.
After cleaning and before sterilization the instruments must be reassembled, unless otherwise specified.

Manual cleaning

Steps valid for all instruments.
1. Prepare the enzymatic cleaner solution for surgical instruments (eg Deconex® Power Zyme-Borer Chemie AG) according to the manufacturer's recommendations.
2. Completely immerse the devices in the prepared solution, leaving to act for the time indicated by the manufacturer (at least five (5) minutes).
3. Clean the instruments with a soft bristle brush, paying particular attention to the presence of cannulated parts, through or blind holes. Operate moving mechanisms such as articulated parts, hinges or retractable parts during cleaning. If the instrument has flexible areas, bend or flex the instrument while keeping it immersed in the prepared solution while brushing the flexible areas. Use a syringe to improve cleaning of hard-to-reach areas (e.g. through or blind holes, close surfaces).
4. Rinse the devices with deionized water at room temperature for at least two (2) minutes. Operate the moving mechanisms during rinsing and flush the internal parts that are difficult to access with a syringe.
5. Sonicate the instruments, in the fully open position, for at least ten (10) minutes in enzymatic detergent solution (eg Deconex® Power Zyme-Borer Chemie AG), prepared according to the manufacturer's recommendations.
6. Rinse according to what indicated in point 4.
7. Dry the instruments with a clean, soft, lint-free wipe.
8. Prepare the neutral pH alkaline detergent solution (eg Liquinox® Alconox inc.) according to the manufacturer's recommendations.
9. Carry out the operations indicated in points 2, 3 and 4.
10. Dry the instruments with a clean, soft, lint-free wipe.
11. Check that there is no visible dirt, if not, repeat the manual cleaning

Automatic cleaning and disinfection

Use a cleaning / disinfection system that has been adequately maintained, calibrated, checked and approved, preferably compliant with the EN ISO 15883 standard.
Perform automatic cleaning after having performed the manual cleaning described in the previous section "Manual Cleaning".
1. Load the instruments into the system by placing those with moving parts and those with cannulated parts, through or blind holes in the open position so that the water can drain.
2. Place the heavier instruments on the bottom, not overlapping the more delicate ones.
3. Select the instrument washing cycle by checking that the cycle parameters are properly set. The washing cycle must include the phases of: pre-washing, enzymatic washing, rinsing, thermal disinfection (90-95 ° C) and drying:

Phase	Duration	Water Temperature	Detergent
Pre-washing	03:00 min	Max. 30°C	n.a.
Enzymatic washing	08:00 min	55-65°C	Neutral enzymatic detergent in accordance with the manufacturer's instructions.
Rinse 1	02:00 min	40-45°C	n.a.
Rinse 2	01:00 min	Max. 30°C	n.a.
Thermal disinfection	07:00 min	90-95°C	n.a.
Drying	12:00 min	115°C - Filtered air	n.a.

4. Start the instruments washing cycle
5. Check that there is no visible dirt, if not, repeat the automatic cleaning. Note: for parts that are difficult to inspect, apply 3% hydrogen peroxide; the presence of bubbles is indicative of failure to eliminate blood residues.

Drying

There are no particular indications. If necessary, dry the instruments with a clean soft, lint-free wipe.

Maintenance, visual inspection and functional check

Maintenance:
Lubricate the moving parts of the instruments with lubricating oil intended for surgical instruments that must be sterilized. Some lubricants contain bacteriostatic agents; respect the expiry date indicated by the manufacturer.
Visual inspection and functional check:
- Check that there are no visible signs of wear such as cracks, breaks, bends or distortions / deformations.
- Check that the surface of the polymeric material instruments does not have "whitish" areas, surface damage such as cracks or delamination and that the device has no deformed / curved areas.

	• Check that the profile of the instruments with sharp edges has a continuous surface; the cutting edges must not show any nicks. • Check that any jaws and teeth are correctly aligned. • Check that the moving parts are free to move and do not have excessive play. • Verify that the locking mechanisms close firmly and the hooking / coupling mechanisms assemble easily. • Check that the adjustment mechanisms work correctly. • Check that on the instruments subjected to calibration, the expiration date has not passed. The calibration expiry date is marked on the instrument. Do not use instruments that are damaged, incomplete or show obvious signs of wear.
Packaging	After inspection place the instruments in the dedicated positions inside the original trays, washed and disinfected as described in the previous sections "Manual cleaning" and "Automatic cleaning and disinfection". All devices must be positioned to ensure steam penetration, avoiding stacking or placing them in close contact with each other. Instruments must be sterilized in an appropriate steam sterilization package.
Sterilization	Use a properly validated steam autoclave that has undergone maintenance, verification and calibration, preferably compliant with the EN 285 or EN 13060 standards. Each sterilization equipment has its own process parameters. The adequacy of these parameters must be validated by staff qualified for sterilization procedures. The responsibility for validation lies with the end user. Disinfection is only acceptable as a precursor to a complete sterilization cycle for surgical instruments. The instructions for use of the autoclave, the configuration and the maximum loads must be respected An effective steam sterilization can be obtained by adopting a sterilization cycle with the following parameters (to obtain a SAL of 10^{-5}): Autoclave Type: Pre-vacuum Minimum temperature: 135°C (275°F) Minimum exposure time: 3 minutes Minimum dry time: 40 minutes In case of choosing an alternative sterilization method, the user is responsible for evaluating the effectiveness of the sterilization and the possible damages caused to the instruments. The end user must establish an adequate shelf life of the sterile barrier in which the sterilized surgical instruments are packaged based on the type of packaging used and the manufacturer's instructions.

7. STORAGE USE AND MANAGEMENT CONDITIONS

Surgical instruments must be stored and transported inside the dedicated trays in order to ensure adequate protection from impact and damage and at the same time protect the user from the risk of being cut.
They must be stored at room temperature (avoid extreme temperature and humidity conditions) and in a dedicated area, adequately ventilated and clean.
Pay attention to the handling of instruments after sterilization. Check for damage to the sterile packaging before use. In case of damaged package, re-pack and repeat the sterilization procedure.
After each use and before returning to Permedica Spa the instruments (single or in sets) must be cleaned, disinfected and sterilized according to the recommendations reported in the previous section. Instruments that are damaged, not working or showing evident signs of wear must be returned to Permedica Spa for maintenance or replacement. Clear indication of the problem observed must be provided.

8. FURTHER INFORMATION

For any further information please contact Permedica Spa.

9. DECLARATION OF LIMITATION OF LIABILITY

The instructions provided have been approved by Permedica Spa for the preparation of reusable surgical instruments. It remains the responsibility of the end user to ensure that the reprocessing activities carried out using the systems, materials and dedicated staff are carried out in accordance with the instructions provided in order to achieve the desired result. This usually involves routine validation and monitoring of the process. Any deviation from the instructions provided must be evaluated and carried out by the end user at his own risk; Permedica Spa will not be able to address any requests for refund or exchange under warranty of instruments that have not been handled or reprocessed in accordance with the above instructions.

Catalogue Number

Batch Number

Medical Device


Consult Instructions for Use

Non-Sterile Product


Manufacturer