Instruction for use for Sterilization trays for Dental Implant System ROOTT

Application

Instruction for use for Sterilization trays for Dental Implant System ROOTT have been prepared in accordance with the recommendations of the tray manufacturers. The instructions apply to the following products: TRS, ESBIPRO, TRR, TRE, TRGF, TRSU.

Warning

Sterilization trays must be handled, packaged and used only by health professionals, hospital staff or persons trained, recognized and authorized to handle these medical devices.

General information

Device name

Sterilization tray.

Classification

Sterilization trays are Class I medical devices in accordance with Directive 93/42/EEC.

Materials

Sterilization trays accessories may contain: Stainless steel and / or Polypropylene and / or Silicone, these different materials are certified for medical use.

Utilization

Sterilization trays and accessories are designed to enable:

- Packaging, storage and transportation of surgical instruments and accessories,
- Cleaning and decontamination of surgical instruments and accessories after the pretreatment,
- Sterilization of surgical instruments or accessories after cleaning and drying.

Recommendations

- Detergents and compatible rinsing products can be used according to the recommendations of the washing-disinfection apparatus manufacturer.
- Do not exceed 140 ° C for all the operations.
- These detergents and/or compatible rinsing products must be pH neutral or close to.
- Check the water quality (including hardness) to reduce mineral deposits.
- Clean and decontaminate the tray as well as the instruments or accessories before starting the sterilization.
- Never use abrasive device for washing (wire brush or other abrasive).
- Be sure to remove any detergent residue prior packing for sterilization. Residues can be transferred from the packaging to the device and cause possible reactions to the patient.
- Place the tray in a sterilization bag before sterilization.
- Avoid contact / overlap between the instruments before the sterilization.
- Always check the integrity of the sterile wrap around the tray before any use in medical settings.
- Avoid handling sterilized trays to protect their sterile wrap.
- Make sure not to drop / scratch / sterilization trays and avoid shocks to protect the tray and its contents.
- Always check the absence of sharp edges that could appear during the life cycle of sterilization tray to minimize the risk of skin break-in of health professionals.
- Avoid prolonged contact between stainless steel tray and hypochlorite or saline substances to minimize any risk of corrosion.

Pretreatment

Pretreatment steps consist to the removal of contaminants from the medical practice which can be present on the sterilization tray and / or its contents. The effectiveness of this step is very important in order to continue the process of cleaning and decontamination. All traces of dried or coagulated proteins and / or other contaminants must be removed, even in the cavities by a mechanical cleaning process, with a stiff nylon brush for example, in a water bath with pretreatment products authorized. Avoid the risk of splashes and use of a too high-water temperature in order to

minimize aerosol production during this process. Health professionals operating the pretreatment step must wear individual protective equipment such as gloves, goggles and masks.

Cleaning and decontamination

Cleaning / Decontamination steps should always be performed before the first use and after breaking the sterile barrier protecting the tray and its contents sterilized. This step corresponds to the removal of most of the contaminants from the medical activity which can be present on the tray sterilization and / or its contents. It is recommended to decontaminate the tray and instruments separately (if possible) using a washer-disinfector (in accordance with ISO 15883) which may include a thermal disinfection (90 ° C for 5 minutes). A semi-automatic ultrasonic cleaning is also possible (15 minutes decontamination products). Detergents and compatible rinsing products can be used according to the manufacturer of the washer-disinfector. These detergents and / or compatible rinsing products should have a neutral pH or approaching. Too acidic or basic solutions can damage some materials of sterilization tray or its contents. As part of a step of cleaning / decontamination manual, using a solution of enzyme or alkaline cleaning for 10 minutes is required and use of a cleaning solution at neutral pH for 2 minutes minimum. For these two products, please follow the manufacturer's instructions, the concentration / dilution correct temperature, duration of exposure and the quality of the water. In addition to these two criteria, the cleaning step and hand decontamination must have many rinses with clear water (absolutely cold) and an active cleaning based on a mechanical action exerted by the operator by means of a soft brush.
After step cleaning / decontamination (manual or automatic), a visual inspection confirming the absence of residues must be carried out systematically. A final rinse with distilled water or purified water can be carried out, followed by a primary drying step using clean compressed air.

Packaging

Sterilization trays does not provide a sterile barrier and must be prepared before the sterilization. Using a wrap as a sterile barrier should be performed according to the instructions specified in ISO 11607. In this package, ensure the position of the instruments present in the tray so that no contact / overlap between them is possible. Any contact or poor positioning of the tray contents may cause a deficiency of the sterilization process. All packaging must be performed on dry parts. After conditioning, great attention must be paid to maintain the integrity of the sterile barrier, in order to guarantee the sterility of the tray and its contents after sterilization.

Sterilization

Unless manufacturers specifications of instruments to be sterilized, non-sterile products can be re-sterilized according to the steam sterilization method in accordance with ISO 17665 or other national standards. But whatever the method of sterilization used, users must ensure that the basic requirements for sterilization are met and the specific configuration of the tray and the content is acceptable to the sterilization procedure. Sterilization trays are not sterile when leaving the production site. The raw materials were selected in order to withstand steam sterilization operations.
The moist heat sterilization requires:

Cycle type	Exposition time	Temperature	Drying time
Satured steam	18 minutes	134 °C	20 minutes at least

The steam cycle, highly recommended, is the standard protocol Prion, which is designed to inactivate the NCTA. The drying time may vary from 20 to 60 minutes depending on the type of packaging material, the quality of steam, materials of instruments (including their surface, a porosity needing a greater drying time), the surface to be sterilized, the sterilization performance of the apparatus and differences in cooling time. The manufacturer disclaims any liability for sterilization procedure performed by the end user and to be conducted in non-compliance with the ISO 17665 standard.

Storage

Sterilization trays that have been reprocessed and packaged to maintain a sterile state must be stored so as to prevent excessive temperatures, humidity or breaking risk of the sterile barrier. When handling during transport, staff must take the utmost care to avoid damage to the sterile barrier. The health facility must establish a shelf life. The user must be aware that maintaining a sterile condition is circumstantial and that the likelihood of a contaminating event increases with time, with the number of handling and the type of sterile envelope used.

Further information

For the preparation and sterilization of instruments and accessories in these sterilization trays, see "*Instruction for cleaning, disinfection and sterilization of non sterile and reusable medical devices Dental Implant System ROOTT".*

Validity

Upon publication of these instructions for use (IFU), all previous versions are superseded.

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Signs explanation

	Catalogue number
	Sterilizable in steam sterilizer (autoclave) at the temperature specified
	CE compliance

Contact details

Manufacturer	**Supplier**
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01	2020-05-12	Printing date. Prepared according to the instruction of manufacturer 2020.05.05. RECOMMENDATION OF USE FOR STERILISATION TRAYS.	V. Shulezhko D. Karpavicius