

INSTRUMENTALS' CLEANING AND STERILIZATION INSTRUCTIONS

WARNING:

- THE NEW NON-STERILE INSTRUMENTS, MUST BE HANDLED IN THE SAME WAY AS USED ONES.
- IT IS RECOMMENDED TO PROCESS ALL THE INSTRUMENTS, AS SOON AS IT IS CONSIDERED TO BE REASONABLY PRACTICAL, AFTER THEY HAVE BEEN USED.
- ELIMINATE THE REMAINS OF: POVIDONE IODINE SOLUTION, PEROXYACETIC ACID, HYDROGEN PEROXYDE, OR ISOTONIC SOLUTION OF SODIUM CHLORIDE AT 0,9%, WHICH CAN TURN OUT TO BE THE CAUSE FOR CORROSION AND DETERIORATION.
- THE TEMPERATURE OF THE SOLUTIONS CANNOT BE OVER 45°C, SO TO AVOID BLOOD COAGULATION AND FACILITATES THE ELIMINATION OF PROTEIC SUBSTANCES.
- ML IMPLANT SYSTEM DRILLS ARE REUSABLE AND MUST BE REPLACED BY NEW SHARP DRILLS AFTER 20-30 USES OR WHEN EFFICIENCY DIMINISHES.

INSTRUCTIONS

PRE-CLEANING

Equipment: Rigid container, Enzymatic Solution.

Note: Do not use high level disinfectant such as glutaraldehyde. Before immersing **ML implant system** instruments the sharp, pointed elements must be separated and dismantled so as to promote the contact with the enzymatic solution. The user must use protection barriers to reduce the risk of exposition skin or the mucous membranes to the contaminated materials.

Steps to be followed:

- Immediately after being used, the instruments must be immersed in a rigid bucket with recently prepared enzymatic solution, according to the specifications of the manufacturer, respecting the temperature, concentration and immersion time, ensuring that all the instruments' surface is in contact with the solution. The drying of blood, secretions or other substances must not be allowed on any of them. The surgical instruments must be cleaned, having been used or not.
- Rinse the material with tap water, achieving the removal of any organic material and the diminishing of the bioburden through mechanical dragging.

MANUAL CLEANING

Equipment: Detergent of neutral PH, slightly alkaline (PH=7-8,5) prescribed for the cleaning of delicate surgical material, in case the instruments are very dirty, use a enzymatic detergent solution, alcohol at 96 v/v, demineralized water and non-abrasive, sterile soft bristle brush.

Steps to be followed:

- Immerse the ML Instruments in the chosen solution according to the degree of dirtiness, respecting the temperature, concentration and immersion time, according to the specifications of the solution manufacturer.
- Energetically brush the instruments under water, specially within the grooves.
- Rinse with plenty microbiologically and physicochemical apt water.
- Dry the instruments immediately after rinsing with sterile compressed filtrated air or with a microfiber cloth imbedded in alcohol solution, to avoid contamination afterwards.
- Check visually with the help of magnifying glass the non-existence of organic material.
- Prepare the instruments to be processed by the sterilization method by vapor.

MECHANICAL CLEANING

Equipment: Ultrasonic cleaner, neutral, slightly alkaline detergent (PH=7-8,5) prescribed for the cleaning of delicate surgical material, in case the instruments are very dirty, use solution of enzymatic detergent, always respecting in both cases the temperature, concentration and immersion time specified by the manufacturer of the solution and/or the equipment, alcohol at 96 v/v, demineralized water.

Steps to be followed:

- Degas the solution
- Choose the cleaning program and respect the times and temperatures established by the equipment manufacturer, bearing in mind that lengthening the cleaning can provoke a redeposit of dirt.
- Introduce the material in the corresponding baskets, without excessively overloading them, checking that no shadows that hinder the passing of ultrasound are produced and introduce the baskets, totally covering the material with the cleaning solution.
- Take out the material and rinse with microbiological and physiochemical demineralized apt water.
- Dry the instruments immediately after rinsing with sterile compressed filtered air or with a microfiber cloth, embedded in alcohol.
- Check visually with the help of a magnifying glass the non-existence of remaining organic material.
- Prepare the instruments to be processed by the sterilization method by vapor.



INSTRUMENTALS' CLEANING AND STERILIZATION INSTRUCTIONS

STERILIZATION

Equipment: Autoclave, medical grade paper bag (or crepe bag, peeling reels, polypropylene, non-woven cloth or tyvek) distilled water of biologically acceptable quality.

Note: The quality of the sterilizing agent can be affected by the contaminants present in the used water to generate vapor, this can be found suspended in the water, being the cause of toxic effects, corrosive effects and can also generate a barrier between the sterilizing agent and the microorganisms.

Steps to be followed:

- Load the material in the prepared autoclave in the medical grade paper bag or the chosen barrier system. Do not overload the equipment.
- Choose the sterilization program recommended by the manufacturer of the equipment, according to the material to be processed.

It's recommended to sterilize the instruments by autoclave following the guidelines established by the ISO 17665 with the following parameters: 121°C for 15 min.

Una vez finalizado el ciclo (Calentamiento - Esterilización - Secado) abrir la puerta del equipo, tener en cuenta de no descargar el material caliente como así también no colocarlo sobre una superficie más fría para prevenir la condensación de la humedad ambiente.

- Once the cycle is finished (Heating – Sterilization – Drying) open the equipment door, having in mind to not unload the hot material as well as not placing it over a colder surface to prevent the condensation of environmental humidity.
- Storage instrumentals in a clean environment at a controlled temperature and humidity.

