PROJECTOMETER

Cleaning Instructions

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Recommended Decontamination & Sterilization Procedure

As with the decontamination procedure, personnel should follow accepted guidelines for hand washing, the sue of protective attire, etc. as recommended by A.A.M.I. Standards and Recommended Practice., "Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and in Non-Clinical Settings", ANSI/AAMI ST35:2003.

A. **Manual Decontamination.** Is a process consisting of two steps:-

I. Thorough Cleaning.
II. Sterilization / disinfection.

PRE-CLEANING

To remove gross debris from the surgical instruments using a lap sponge and sterile water during the procedure to prevent drying out of the blood and bodily fluids over the instruments.

***Water Temperature**: >40°C*

***Time:** Minimum 5 minutes*

MANUAL CLEANING

To minimise the risk to personnel undertaking manual cleaning, splashing and the creation of spray must be avoided at all times. Staff carrying out manual cleaning should wear PPE at all times.

Devices should be:

1) Cleaned using a non-linting cloth, impregnated with the appropriate detergent solution, followed by a clean, damp, non-linting cloth; and then
2) Dried using another clean, non-linting cloth. Alcohol-impregnated wipes may be used following a manual cleaning process.

***Detergents:** Detergents used must be specifically designed to clean surgical instruments: washing-up liquid should not be used.*

Use of an enzymatic detergent and alkaline detergent to facilitate the cleaning of surgical instruments.

***Recommended Solution:** 0.8% Enzymatic Detergent/ 0.5% Alkaline Detergent*

***Recommended Detergent:** Cidezyme/Enzol (Enzymatic Detergent), Neodisher Mediclean/ Sekumatic® (Alkaline Detergent)*

DISINFECTION

Washer-disinfectors are used for processing a wide range of products used in clinical practice as per described in BS EN ISO 15883.

Disinfection can be achieved by washing or rinsing devices in water at between 73°C and 90°C.

A typical washer-disinfector cleans dental instruments using the following five stages.

Cold Rinse — removes both solid and fluid "gross" debris contamination. A temperature below 45°C is used preventing protein coagulation and fixing of contaminant to the instrument surface.

***Water Temperature**: <45°C*

***Time:** 5 minutes*

Warm Washing — removes any remaining debris contamination. Removes any remaining soil. Mechanical and chemical processes loosen and break up contamination adhering to the instrument surface.

***Water Temperature**: >55°C*

***Time:** 10 minutes*

Rinsing — removes the detergent used during cleaning. This stage can contain several sub-stages. The quality of water to be used for this stage is an important consideration in terms of ensuring a clean and unmarked product.

***Time:** 2 minutes*

Thermal disinfection — heat is used for a specified time to disinfect the instruments. The temperature of the load is raised and held at the pre-set disinfection temperature for the required disinfection holding time, for example 80ºC for ten minutes or 90ºC for one minute.

***Water Temperature**: 80ºC- 90ºC*

***Time:** Minimum 5 minutes*

Drying — hot air is used to dry the instruments. Purges the load and chamber with heated air to remove residual moisture.

***Time:** 15 minutes*

STERILIZATION

After following the above cleaning processes, reusable instruments are ready for sterilization. recommends Steam Sterilization as effective sterilization process for its reusable instruments. The wrapped instruments to be sterile at using following conditions;

Minimum Sterilization Temperature	Corresponding Steam Pressure	Maximum Permissible Temperature	Minimum Sterilization Hold Time
°C	Bar Gauge	°C	Minutes
121	1.03	124	15
134	2.30	137	3

This is recommended by *AAMI Standards and Recommended Practices, Volume 1, 1992.* Whereas, the sterilizer manufacturer's written instructions for cycle parameters should be followed.

Steam Sterilization of lumen instruments requires to be flushed thoroughly with sterile water just prior to wrapping and sterilization. The water generates steam within the lumen to move air out. Air is the greatest hurdle to steam sterilization, preventing steam to get into contact with the instrument. Therefore, it must be eliminated for proper steam sterilization.

Another important aspect is that the Medical Device Manufacturer's recommended exposure time to sterilization temperature may need to be longer than the minimum indicated by the sterilizer manufacturer but must never be shorter.

Tolerance of Instruments against Steam Sterilization:

Instruments provided by company can withstand in Steam temperature of 150°C and pressure of 3.61bar for up to an hour without showing any change in structure or chemical properties of instrument.

POINT OF USE HANDLING

All reusable surgical instruments supplied by company may only be used for the purpose of which they are designed, by adequately qualified personal only. The proper surgical technique for the use of the instrument is the responsibility of the surgeon. Moreover, the surgeon is responsible for an appropriate training and sufficient information for the operating theatre staff as well as for an adequate expertise with the handling of the instruments.

LIMITATIONS

Frequent reprocessing has little impact on the lifetime, which is generally determined by wear and damage incurred during the intended surgical use, or by misuse. If you reprocess and reutilize the instrument nevertheless, even according to the RKI2- guidelines, you bear all responsibility. Instruments containing aluminum get damaged by alkaline cleaner > pH7!

STORAGE & MAINTENANCE

The storage area should be appropriately designed to prevent damage to packs and to allow for the strict rotation of stocks. Shelving should be easily cleaned and allow the free movement of air around the stored product.

Products must be stored above floor level away from direct sunlight and water in a secure, dry and cool environment.

CONTAINMENT & TRANSPORTATION

To minimise this risk, the instruments must be placed in closed, secure containers and transported to the decontamination area as soon as possible following use.

Transport containers must protect both the product during transit and the handler from inadvertent contamination and therefore must be:

- leak-proof
- easy to clean
- rigid, to contain instruments, preventing them becoming a sharps hazard to anyone handling the goods and to protect them against accidental damage
- capable of being closed securely
- lockable, where appropriate, to prevent tampering
- clearly labelled to identify the user and the contents
- robust enough to prevent instruments being damaged in transit.

INSPECTION AND TESTING

Before being used, the sterile product should be checked to ensure that:

- the packaging is intact;
- the sterilization indicator confirms the pack has been subjected to an appropriate sterilization process; and
- the product is still within the expiry date.

WARNING:

Don't use the rusty instrument. Sterilize before use. Wash the hands with anti-bacterial soap or use approved hand sanitizer before use. Must only be used by the Surgeon or person authorized by the Surgeon. For any query regarding the intended use defined above contact " company " directly or its authorized EAR (European Authorized Representative), and follow the requirement of the directive MDR 2017/ 745. Ref to the risk analysis and safety requirements submitted with the shipment.

PRECAUTIONS:

Instruments must be handled by the trained personnel only. Only Surgeons or personnel authorized by the Surgeons must be allowed to use the instruments. Don't sterilize the instruments having the solution with Chloride ions. Sterilization solution must have the pH near to 6.0 - 7.0. For professional use only - disinfect before use.

RISK ASSESSMENT: EN 14971:2001

Estimation of Risk: The Risk related to rusting and breakage is minimal, as devices are tested for both the risks before shipping to the customer. A Boil tests are performed on 100% of lot to assess the effectiveness of the Passivation Process and resistance against oxidation / rust. Functional and hardness test are performed to test the strength and durability of the instruments.

ACCEPTABILITY OF RISK:

These Associated Risk are very low and therefore can be accepted without further Analysis or change in manufacturing.

CONCLUSION:

It is obvious that the risk to both the patient and the user are minimal if the instrument is used for its intended purpose by the qualified personnel. However, the sterilization and decontamination of the instruments must be performed before every use.