REV-03-2024 30004730 03.24

Processing of re-sterilisable medical devices (acc. to ISO 17664)

EN

Procedure:
Manual and mechanical procedure for processing re-sterilisable medical devices

Products:
VacuSoft Base (cannula tube)

Risk assessment/classification recommendation:
Due to contact with the mucosa, injured tissue and blood, classification of the medical device as semi-critical B is recommended. The following processing measures are recommended: mechanical cleaning in combination with thermal disinfection (WD) and steam sterilisation before use.

Warnings:
During reprocessing, there is a risk of transmitting pathogens via blood and tissue residues. Suitable protective equipment (gloves, face mask, goggles) is absolutely essential.

Instructions for use:
The cannula tube of the VacuSoft suction cannula must be reprocessed before the first application and subsequently after each application according to these reprocessing instructions. The cannula tube of the VacuSoft suction cannula must always be reprocessed without the cannula tip.

Processing limitations:
Due to the product design and the materials used, no definite limit to the maximum number of performable processing cycles can be specified. The service life of the medical devices is determined by their function and careful handling. If the products show visible changes in material or shape after reprocessing or if their functionality is restricted, the products may no longer be used. The number of times a product can be reused depends on its reprocessing and handling. The condition of the products should always be verified before and after every use.

Instructions for reprocessing

Pretreatment on site:
Remove general soiling from the products directly after application. Do not use fixating agents or hot water (>40°C), as this causes fixation of residues and can impair successful cleaning. In order to avoid contamination drying on, soak the used products in a disinfectant bath.

Transport:
Safe storage in a closed container and transport of the products to the processing location, in order to avoid damage to the products and environmental contamination.

Preparation before cleaning:
No particular requirements.

Mechanical cleaning and disinfection in the washer/disinfector
Machine: Use of a washer-disinfector (WD) in accordance with ISO 15883-1 and -2 (medical device according to Directive 93/42/EEC or REGULATION (EU) 2017/745).
Carrier for items to be washed: The cannulas are to be placed on injector nozzles for cleaning hollow instruments. The use of a cover net is recommended so that the cannulas do not fall off the injector nozzles during cleaning.
Process chemicals: Alkaline detergent (medical device according to Directive 93/42/EEC or REGULATION (EU) 2017/745).
Cycle: Cycle parameters as specified by the device manufacturer. A typical cycle consists of
- Rinsing stage (< 45 °C to avoid protein coagulation)
- Cleaning stage (e.g. 55 °C - according to instructions for the detergent)
- Rinsing stage (if required)
- Thermal disinfection
- Drying

Manual cleaning and disinfection in an ultrasonic apparatus:
For cleaning the products in the ultrasonic apparatus, put the products in a beaker filled with the cleaning liquid, place in the ultrasonic apparatus filled with a suitable contact liquid and start the ultrasonic cleaning process.
1. Main cleaning process at 25 °C with an alkaline disinfectant cleaner (medical device according to Directive 93/42/EEC or REGULATION (EU) 2017/745; concentration and application according to manufacturer's specifications)
2. Generous manual rinsing under running water (reverse osmosis water)

Manual disinfection:
If a disinfectant cleaner is not available for manual cleaning, separate disinfection must be performed after cleaning by placing in a suitable disinfectant (observe the instructions for use of the disinfectant with regard to effective concentration and exposure time). Then rinse thoroughly with reverse osmosis water and dry.

Manual drying:
Drying with low-germ / sterile filtered compressed air

Inspection and maintenance:
Cleaning inspection: Visual inspection for cleanliness. If necessary, repeat the reprocessing procedure until the product is visually clean.
Functional inspection: No particular requirements

Packaging:
Standardised packaging of products for sterilisation according to ISO 11607 and EN 868.

Sterilisation:
Equipment: Steam steriliser according to EN 285 or EN 13060; Cycle B (Declaration of conformity as a medical device according to Directive 93/42/EEC or REGULATION (EU) 2017/745).
Fractionated vacuum process; at least 3 minutes at 134 °C and subsequent drying.

Storage:
Store sterilised products in a dry, clean, and dust-free environment at temperatures of 5°C to 40°C (follow the instructions of the packaging supplier regarding storage temperature and duration).

The above instructions were validated by the manufacturer of the medical device as being suitable for the preparation of a medical device for its reprocessing. The reprocessor is responsible for ensuring that the actual reprocessing with the equipment, materials and personnel employed in the reprocessing plant delivers the desired results. This requires verification and/or validation and routine monitoring of the process.

Made in Germany

Glossary	
	Manufacturer
MD	**Medical Device**
CE 0483	**Notified body registration number**
Rx ONLY	**Rx only – restricted device for professional use only**
	Keep away from sun light
	Consult instructions for use

Coltène/Whaledent GmbH + Co. KG
Raiffeisenstraße 30
89129 Langenau / Germany
Tel +49 7345 805 0
Fax +49 7345 805 201
info.de@coltene.com
www.coltene.com