

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



<b>Procedure:</b>	<b>Manual and mechanical procedure for processing re-sterilisable medical devices</b>
<b>Products:</b>	Spreaders, pluggers and retraction cord packers
<b>Instructions:</b>	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. Faulty products must undergo complete reprocessing before being returned for repair.
<b>Instructions for reprocessing</b>	
<b>Preparation procedure at the site of application:</b>	Remove general soiling from the instruments directly after application. Do not use fixating agents or hot water (>40°C), as this causes fixation of residues and can impair successful cleaning.
<b>Transport:</b>	Safe storage in a closed container and transport of the instruments to the processing location, in order to avoid damage to instruments and environmental contamination.
<b>Preparation for decontamination:</b>	The instruments need to be disassembled or opened for processing.
<b>Manual cleaning and disinfection</b>	
<b>Storage:</b>	Prepare enzymatic cleaner in accordance with the manufacturer's instructions. Place the instruments in the solution for 30 minutes at room temperature.
<b>Pre-cleaning:</b>	Once the immersion time has been completed, visually check the instruments for caked blood and residual soiling. Clean the instruments using a nylon brush until all visible soiling has been removed. Rinse hollow spaces inside the instruments, threaded grooves and bore holes as required under running water for approx. 30 seconds. Place the instruments carefully in a container with 0.5% enzymatic cleaner for approx. 5-10 minutes.
<b>Primary cleaning:</b>	Visually check the instruments for residual soiling and clean again where appropriate with a suitable nylon brush. Rinse for at least 1 minute under running water. Visual check. Rinse off the instruments using deionised water.
<b>Disinfection:</b>	Place the instruments in a 2% disinfection solution for 30 minutes.
<b>Drying:</b>	Wipe the instruments carefully using a clean, absorbent, disposable lint-free cloth. Remove residual moisture in hard-to-reach areas using compressed air.
<b>Functional testing, maintenance:</b>	Visual inspection for cleanliness; if applicable, assembly of the instruments, maintenance and functional testing in accordance with the operating instructions. If necessary, repeat the reprocessing procedure until the instrument is visually clean.
<b>Mechanical cleaning and disinfection in the washer/disinfector (RDG)</b>	
<b>Pre-cleaning:</b>	No special requirements
<b>Cleaning:</b>	Place the instruments disassembled in a sterilisation tray on the slide-in trolley and start the cleaning process. 1. Pre-rinse for 1 minute with cold water 2. Drain 3. Pre-rinse for 3 minutes with cold water 4. Drain 5. Wash for 5 minutes at 55°C, 45°C with 0.5 % alkaline enzymatic cleaner (when using enzymatic cleaner, cleaning temperature of only 45°C) 6. Drain 7. 3 minutes: neutralisation with warm tap water (>40°C) and neutraliser 8. Drain 9. 2 minutes: intermediate rinsing with warm tap water (>40°C) 10. Drain
<b>Disinfection:</b>	Perform mechanical thermal disinfection observing national requirements with regard to the A0 value (see ISO 15883)
<b>Drying:</b>	Drying the outside of the instruments as part of the drying cycle of the washer/disinfector. If necessary, additional manual drying is also possible using a lint-free cloth. Dry hollow spaces inside instruments using sterile compressed air.
<b>Functional testing, maintenance:</b>	Visual inspection for cleanliness; if applicable, assembly of the instruments, care of instruments and functional testing in accordance with the operating instructions. If necessary, repeat the reprocessing procedure until the instrument is visually clean.
<b>Sterilisation</b>	
<b>Packaging:</b>	Standardized packaging of instruments for sterilisation according to ISO 11607 and EN 868
<b>Sterilisation:</b>	Product sterilisation using a fractionated pre-vacuum process (in accordance with ISO 13060 / ISO 17665), observing the respective national requirements. Three pre-vacuum phases with pressure of at least 60 millibar Heat up to a sterilisation temperature of at least 132°C; max. 137°C Shortest hold time: 4 min. Drying time: at least 10 min.
<b>Storage:</b>	Store sterilised instruments in a dry, clean, and dust-free environment at moderate temperatures of 5°C to 40°C.

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



Information on validation of reprocessing	
<b>Manual cleaning and disinfection process:</b>	The following test instructions, materials and machines were used during the validation: Enzymatic cleaner: ProZym, HIBOmed Medizinprodukte Disinfectant: Ventisept M Plus Neu, Heck Dental
<b>Mechanical cleaning and disinfection process:</b>	The following test instructions, materials and machines were used during the validation: Cleaning agent: Neodisher FA Dental; Dr. Weigert; Hamburg (alkaline) Endozime, Ruhof (enzymatic) Neutraliser: Neodisher Z; Dr. Weigert, Hamburg Washer/disinfectant: Miele G 7736 CD Slide-in trolley:: E 327-06 slide-in trolley MIS trolley E 450
<b>Additional instructions:</b>	If the above-mentioned chemicals and machines are not available, the user is obliged to validate his procedure accordingly.
We also refer to our general information with regard to the cleaning, sterilisation and care of instruments in our user instructions. It is the obligation of the user to ensure that the reprocessing procedure, including resources, materials and personnel, is suitable to achieve the required results. State-of-the-art technology and national laws require the compliance with validated processes.	

## Manufacturer contact details:

Coltene/Whaledent GmbH + Co. KG  
Raiffeisenstr. 30  
89129 Langenau/Germany  
Tel.: +49 (0)7345 8050  
Fax: +49 (0)7345 201  
E-mail: info.de@coltene.com  
Website: www.coltene.com