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

COLTENE

Procedure:	**Manual and mechanical procedure for processing re-sterilisable medical devices**
Products:	HyFlex™ root canal files
Instructions:	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.

Instructions for reprocessing	
Preparation procedure at the site of application:	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. In order to avoid contamination drying on, soak the used instruments in a disinfectant bath.
Transport:	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.
Preparation for decontamination:	No particular requirements.
Pre-cleaning:	No particular requirements.
Manual cleaning and disinfection in the ultrasound apparatus:	For cleaning the instruments in the ultrasound apparatus, put the instruments in a beaker filled with the cleaning liquid, place in the ultrasound apparatus sufficiently filled with water and 2% contact liquid and start the ultrasound cleaning process. 1. 30 min primary cleaning at 25°C, stage 5 with 2% cleaning agent concentration 2. Generous manual rinsing under running water (reverse osmosis water) 3. Dry using compressed air
Mechanical cleaning and disinfection in the washer/disinfector	Place the instruments in a sterilization tray on the slide-in trolley and start the cleaning process. 1. Pre-cleaning with 10 l cold water 2. 10 min primary cleaning at 55°C (10.5 l water and 62 ml cleaning agent (DOS 1)) 3. Rinse with 9.0 l cold water and 13 ml cleaning agent (DOS 3) 4. Rinse with 9.0 l cold reverse osmosis water 5. Thermal disinfection for 5 min at 90-93°C with 9.5 l reverse osmosis water 6. Dry for 35 min at 99°C
Functional testing, maintenance:	Optical inspection for cleanliness, care and functional testing according to the operating instructions. If necessary, repeat the reprocessing procedure until the instrument is visually clean.
Packaging:	Place instruments for sterilization on the Endo Procedure Block or HyFlex™ Organizer. Standardized packaging of instruments for sterilisation according to ISO 11607 and EN 868.
Sterilisation:	Steam sterilization of instruments, observing the respective national requirements. 3 pre-vacuum phases Heat up to a sterilization temperature of 134°C Shortest hold time: 3 min Drying time: at least 20 min
Storage:	Store sterilised instruments in a dry, clean, and dust-free environment at moderate temperatures of 5°C to 40°C.
Information on validation of reprocessing	The following test instructions, materials and machines were used during the validation: Cleaning agents: Tickopur TR 13 (contact fluid), Dr. H. Stamm GmbH Stammopur DR 8 (disinfectant cleaner), Dr. H. Stamm GmbH Neodisher Mediclean forte, Dr. Weigert Co. (dosing system DOS 1) Neodisher Z (neutralisation agent), Dr. Weigert Co. (dosing system DOS 3) SonoCheck (BAG Health Care) (indicator for ultrasound effectiveness) Cleaning/Sterilization devices: RDG: cleaning and disinfecting apparatus: Miele G7892 CD Powersonic® P 2600 D ultrasound cleaning apparatus (Martin Walter Ultraschalltechnik AG) Autoclave Systec VX-95 (Systec GmbH) Item carriers for washing: Upper basket/injector O177 / 1 Tray E 520 for 18 Root Canal Instruments Tray ½ E142 Covering net A 3 ¼ (if needed) Sieve with cover for small parts E473/1 HyFlex Endo Procedure Block
Additional instructions:	If the above-mentioned chemicals and machines are not available, the user is obliged to validate his procedure accordingly.

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.

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