

CLEANING, DISINFECTION AND STERILIZATION PROTOCOL



(Endodontic Instruments; H-Files, K-Files, Reamers)

INTRODUCTION	H-Files, K-Files and Reamers, are supplied NON STERILE. For this reason, they must be cleaned, disinfected and sterilized before first use or re-use, to prevent contamination.
SCOPE	Applicable to the following products: Endodontic instruments: H-Files, K-Files, Reamers
RE-TREATMENT LIMITATIONS	Sterilization has very little effect on the products. However, in accordance with regulatory requirements, the products' 3-year life span can vary depending on wear or damage to components from use or after 10 sterilization cycles. The appreciation of the quality of products and their use is the user's responsibility.
GENERAL RECOMMANDATIONS	<ul style="list-style-type: none"> - It is the user's responsibility to sterilize the products before first use and re-use. - For your safety, we recommend using EPIs (Individual Protective Equipment) - for example: Gloves, eye protection - Only use disinfectants with proven effectiveness (If you notice marks or stains, clean the instrument with a wipe first).
INSTRUCTIONS	
PLACE OF USE	Dental clinic
STORAGE AND TRANSPORT	No specific requirements for transport. We recommend to store devices in a clean, dry place protected from damp.
PREPARATION FOR CLEANING	No specific requirements Discard the instruments which are defective (broken, bent, not cutting any more, etc.)
CLEANING	<ul style="list-style-type: none"> - Do not use cleaning solution or disinfectant containing chloride or acid (caution with the running water too much chlorinated). - Avoid solution with aldehyde, owing to the ability of this product to keep the proteins. - Eliminate meticulously all the post-operative residues (blood, bone ...) on the devices. Use a nylon brush. - Remove the silicon stopper (applicable for root canal instruments) prior to immerge the devices in the cleaning solution. Cleaning must be carried out individually on the dismantled component. - Avoid, as much as possible, shocks and contacts with other instruments (damaging of the quality surface and / or cutting power). - Do not clean the devices with other instruments, which material is different, in the same ultrasonic box. - Use suitable cleaning solutions. Respect the manufacturer directions for use.
DISINFECTION	Immerse products in a disinfectant bath using ultrasound if required.
RINSING & DRYING	Rinse, and then dry the devices immediately after the cleaning process (preferably use distilled water to rinse). It is necessary to be meticulous during the drying.
OPERATIONAL CHECKS AND TESTS	Ensure that cleaning is done properly, if applicable, clean again.
PACKAGING	After disinfection, put instruments in sterilization sachets. (Check that sachets comply with EN ISO 11607-1 standard).
STERILISATION	Steam sterilize in an autoclave for 18 minutes at 134 °C. The autoclave must comply with current standard EN 13060, maintenance and upkeep conditions must be complied with in accordance with manufacturer's instructions.
ADDITIONAL INFORMATION	When several instruments are sterilized in a single autoclave cycle, ensure that the maximum load of the autoclave is not exceeded.
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: Coltène/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
 Webpage: www.coltene.com