

# Cleaning and Sterilisation for Burs, accessories and filling material

EN

FOR DENTAL USE ONLY

## **CLEANING AND STERILISATION PROCEDURE FOR BURS, ACCESSORIES AND FILLING MATERIAL**

### **1) FOREWORD**

Devices that are marked as “sterile” do not require any specific treatment before the first use. For all other devices not labelled “Sterile”, cleaning and sterilisation prior first use is required according to section 4) STEP-BY-STEP INSTRUCTIONS part 4 to 8 of this DFU.

For those devices that are not labelled “single use”, re-processing of the devices should be carried out as per this DFU. For hygiene and sanitary safety purposes, these devices must be cleaned and sterilised before each re-use to prevent any contamination.

### **2) AREA OF APPLICATION**

Cleaning, disinfection and sterilisation before each use (except for the first use of sterile devices) and reprocessing procedures concerning:

#### **CLEANING and STERILISATION**

##### **A. Device**

###### **A1. Burs:**

Tungsten carbide burs, carbon steel Burs and Diamond Burs.

###### **A2. Accessories:**

Supports, kits, device organisers and other accessories.

#### **DESINFECTION ONLY**

**B. Filling material:** Only chemical disinfection (no sterilisation) Gutta percha and Obturators.

### 3) GENERAL RECOMMENDATION

- 1) Use only a detergent solution, with disinfecting effect, which is approved for its efficacy (VAH/DGHM-listing, CE marking, FDA approval) and in accordance with the DFU of the detergent solution manufacturer. For all metal devices, it is recommended to use anticorrosion disinfecting and cleaning agents.
- 2) Always wear protective clothes for your own safety (gloves, glasses, mask and a waterproof gown).
- 3) The user is responsible for the cleaning and sterilisation of the product for the first cycle and each further usage as well as for the usage of not fully functional devices where applicable after sterilisation.
- 4) It is safest for the practitioner to use our devices only once. Should our devices be reused, we recommend that they should not be used more than 5 times. After each processing they should be carefully inspected before use: the appearance of defects such as cracks, deformations (bent, unwound), breakage, corrosion, loss of color coding or marking, indicate that the devices are not able to fulfil the intended use with the required safety level and must therefore be discarded.
- 5) Single use marked devices are not approved for re-use.
- 6) For the final rinsing step deionised water use is mandatory, whether using an automated washer-disinfector or a manual cleaning method. Tap water is permissible for the other rinsing steps.
- 7) Tungsten carbide burs and plastic supports are degraded by Hydrogen Peroxide (H<sub>2</sub>O<sub>2</sub>) solution.
- 8) The washer-disinfector is not recommended for devices made of aluminium, tungsten carbide or carbon steel.
- 9) Avoid device to dry out, prior to, or during pre-cleaning, or cleaning. Dried biological material can be difficult to remove.
- 10) Use only device appropriated support for reprocessing.
- 11) Do not use label systems or identification markers directly on the device.
- 12) Use only proper maintained equipment and materials approved according national laws and regulations.

## 4) STEP-BY-STEP INSTRUCTIONS

### A. Devices

	<b>Operation</b>	<b>Operating mode</b>	<b>A1. Burs</b>		<b>Following uses</b>	
			<b>A2. Accessories</b>		<b>First use</b>	
			<b>Warning</b>			
1.	Disassembling	- Disassemble the device, if required.	None.			X
2.	Pre-Cleaning	<ul style="list-style-type: none"> <li>- Soak all devices immediately after use in a pre-cleaning solution (we recommend the use of Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner at 0.4% for a minimum of 15 minutes). When applicable use a tray made from high density polyethylene or stainless steel.</li> </ul> <p><u>Instructions for Diamond Burs :</u></p> <ul style="list-style-type: none"> <li>- Abundant rinsing immediately after use (without exceeding 25 minutes after use) and for at least 1 minute under running water (ambient temperature +15°C/+25°C).</li> <li>- Soak all devices as soon as possible in a pre-cleaning solution, and in any case do not exceed 30 minutes after use before soaking (we recommend the use of Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner at 0.4% for a minimum of 15 minutes).</li> <li>- Brush the active part of the device (coated with diamonds) for a minimum of 10 seconds.</li> <li>- Visually inspect under appropriate lighting (min- 500 lux), if impurities are visible continue to brush until complete removal.</li> </ul>	<ul style="list-style-type: none"> <li>- For diamond burs take special care not to exceed the 25 minutes after use for rinsing and the 30 minutes after use for soaking in the pre-cleaning solution, if not the cleaning instructions below may be ineffective due to the combination of excessive drying of the soil and the roughness of the active part.</li> <li>- Follow instructions and observe concentrations and immersion times given by the manufacturer (an excessive concentration may cause corrosion or others defects on devices).</li> <li>- The pre-cleaning solution should be a specific solution targeted by the supplier for pre-cleaning. It should be used at the dilution specified by the supplier. It should contain, or be combined with a proteolytic enzyme.</li> <li>- The pre-cleaning solution should be aldehyde free (to avoid blood impurities fixation) and without di- or triethanolamines as corrosion inhibitor. Change the pre-cleaning solution regularly i.e. When it becomes soiled, or when efficacy is diminished due to exposure to microbial loads.</li> <li>- Do not use pre-cleaning solutions containing Phenol or any products, which are not compatible with the devices.</li> <li>- For visible impurities observed on devices a pre-cleaning is recommended with a soft brush. Manually brush the device until visible impurities are removed.</li> <li>- When needed the device must be manually brushed with a soft brush made from either nylon, polypropylene or acrylic.</li> </ul>			X
3.	Rinsing	- Abundant rinsing (at least 1 minute) under running water (ambient temperature).	<ul style="list-style-type: none"> <li>- Use tap water for rinsing.</li> <li>- If a pre-cleaning solution contains a corrosion inhibitor, it is recommended to do the rinsing step just before starting the cleaning step.</li> </ul>			X

4a.	Automated Cleaning with washer- disinfector	<ul style="list-style-type: none"> <li>- Place the devices in a kit, support or container to avoid any contact between devices.</li> <li>- Place the devices in the washer-disinfector and execute the defined cycle (Ao value &gt; 3000 or, at least 5 minutes at 90 °C (194°F)).</li> <li>- Use a detergent solution with cleaning properties (we recommend Neodisher Mediclean Forte at 0.4%).</li> </ul>	<ul style="list-style-type: none"> <li>- Discard any devices with defects (broken, bent).</li> <li>- Avoid any contact between devices when placing in the washer-disinfector use kits, supports or container. Pay particular attention to cutting edges, both to avoid injury and to avoid damage to the medical device</li> <li>- Follow instructions and concentrations given by the manufacturer of the detergent solution.</li> <li>- Follow the instructions of the washer-disinfector and verify the success criteria after each cycle have been met as stated by the manufacturer.</li> <li>- The final rinse step should be with deionised water. For other steps follow the water quality defined by the manufacturer.</li> <li>- Use only approved washer-disinfector according to EN ISO 15883 maintained and calibrated regularly.</li> <li>- It is recommended to use an alkaline detergent with tensides, which has grease removal, disinfection (against bacteria/fungi) and corrosion inhibition properties. The detergent should be approved for its efficacy (VAH/DGHM-listing, CE marking, FDA approval) and used in accordance with its DFU. The detergent should be aldehyde free and without di- or triethanolamines as corrosion inhibitor.</li> </ul>	X	X
OR					
4bi.	Manual Cleaning assisted by an ultrasonic device	<ul style="list-style-type: none"> <li>- Place the devices in a kit, support or container to avoid any contact between devices.</li> <li>- Immerse in the detergent solution with cleaning properties (we recommend Neodisher Mediclean Forte at 2%), assisted by an ultrasonic device if suitable for at least 15 minutes.</li> </ul>	<ul style="list-style-type: none"> <li>- No visible impurities should be observed on the devices.</li> <li>- If visible impurities are observed on the devices, the device must be manually brushed with a soft brush (made from either nylon, polypropylene, acrylic) until visible impurities are removed.</li> <li>- Discard any devices with defects (broken, bent, and twisted).</li> <li>- Follow instructions, observe water quality, concentrations and cleaning time stated by the manufacturer of the cleaning solution.</li> <li>- Follow the instructions of the ultrasonic device manufacturer.</li> <li>- It is recommended to use an alkaline detergent with tensides, which has grease removal, disinfection (against bacteria/ fungi) and corrosion inhibition properties. The detergent should be approved for its efficacy (VAH/DGHM-listing, CE marking, FDA approval) and used in accordance with the DFU of the detergent solution manufacturer.</li> <li>- The detergent should be aldehyde free and without di- or triethanolamines as corrosion inhibitor.</li> </ul>	X	X
4bii.	Rinsing	<ul style="list-style-type: none"> <li>- Abundant rinsing (at least 1 minute) under running water (ambient temperature).</li> </ul>	<ul style="list-style-type: none"> <li>- Use deionised water for rinsing.</li> <li>- If the previous used cleaning solution contains a corrosion inhibitor, it is recommended to do the rinsing step just before starting the autoclaving.</li> </ul>	X	X
4biii.	Drying	<ul style="list-style-type: none"> <li>- Devices should be thoroughly dried before inspection and packaging.</li> </ul>	<ul style="list-style-type: none"> <li>- Dry with a single use lint free cloth.</li> <li>- Devices should be dried until visual traces of moisture are eliminated.</li> <li>- Particular attention has to be paid to effectively dry joints or cavities within a device.</li> </ul>	X	X
5.	Inspection	<ul style="list-style-type: none"> <li>- If applicable assemble the devices (including the placement of new silicon stops).</li> <li>- Inspect the devices functionality (check the sharpness of cutting parts).</li> <li>- Visually inspect devices with naked eye under appropriate lighting (min 500 lux) and sort out those with defects.</li> </ul>	<ul style="list-style-type: none"> <li>- Dirty devices must be cleaned again.</li> <li>- Discard devices which show any defect as described in the General Recommendation above (chapter 3).</li> <li>- Protect carbon steel bur with corrosion inhibitor before packaging (we recommend RS-Spray from Meisinger).</li> <li>- Follow the instructions of the corrosion inhibitor manufacturer.</li> <li>- These reprocessing instructions together with the use of the corrosion inhibitor may make the carbon steel burs become darker, this color change is different from the corrosion observed when no corrosion inhibitor is used and should not be considered as a defect.</li> </ul>	X	X

6.	Packaging	<ul style="list-style-type: none"> <li>- Place the devices in a kit, support or container to avoid any contact between devices and pack the devices in "Sterilisation pouches".</li> </ul>	<ul style="list-style-type: none"> <li>- Device must be double-packaged using paper-plastic pouches for steam sterilisation prior sterilisation. Ensure that the pouches are suitable for steam sterilisation and were validated and manufactured as per ISO 11607 and EN 868-5.</li> <li>- Use an appropriate packaging, moist-heat resistant (141°C, 286°F) and compliant with ISO 11607.</li> <li>- Avoid any contact between devices during sterilisation. Use kits, supports or containers.</li> <li>- For sharp devices that are not contained within a box, silicon tubes should be placed around the devices to prevent packaging piercing.</li> <li>- Seal the pouches according to the recommendation of the pouch manufacturer. If a thermo-sealer is used, the process must be validated and the thermosealer must be calibrated and qualified.</li> <li>- Check the validity period of the pouch given by the manufacturer to determine the shelf life.</li> </ul>	X	X
7.	Sterilisation	<ul style="list-style-type: none"> <li>- The following sterilisation cycles can be used : <ul style="list-style-type: none"> <li>• 132°C (269.6°F), 4 minutes;</li> <li>• 134°C (273.2°F), 3 minutes;</li> <li>• 134°C (273.2°F), 18 minutes.</li> </ul> </li> <li>- We recommend a steam sterilisation at 134°C / 273.2°F during 18 minutes for the purpose of de-activating potential prions.</li> </ul>	<ul style="list-style-type: none"> <li>- The devices must be sterilised according to the packaging labelling.</li> <li>- Always observe the operating instructions of the steriliser manufacturer, especially about the loading weight, the operating time and functional testing.</li> <li>- When sterilising multiple devices in one autoclave cycle ensure that the steriliser's maximum load is not exceeded.</li> <li>- Place the pouches in the steam steriliser according to the recommendation given by the steriliser manufacturer.</li> <li>- Use only Pre-Vacuum air Removal steam steriliser that are matching the requirements of EN 13060 (class B, small steriliser) and EN 285 (full size steriliser), with saturated steam.</li> <li>- Use a validated sterilisation procedure according ISO 17665 with a minimum drying time of 20 minutes.</li> <li>- Respecting the maintenance procedure of the steriliser is under the responsibility of the owner and should be performed following the requirements for medical devices sterilisation (examples: planning of maintenance, qualification, acceptance criteria of condensate and water as per EN 285, annex 2).</li> <li>- Control the efficiency and acceptance criteria of the sterilisation procedure (packaging integrity, no humidity, no colour change of packaging, positive physico-chemical indicators, conformity of actual cycle parameters, to reference cycle parameters). A special attention should be paid to the packaging integrity if the sterilisation cycle 134°C (273.2°F), 18 minutes is used.</li> <li>- If visible signs of moisture are present (damp spots on sterile packaging, pooled water in the load) at the end of the sterilisation cycle, repackage and re-sterilise using a longer drying time.</li> <li>- Store traceability records and define shelf-life according to packaging manufacturer guidelines.</li> <li>- The shorter sterilisation cycles can be used according to local regulations but are not guaranteed to de-activate prions.</li> </ul>	X	X
8.	Storage	<ul style="list-style-type: none"> <li>- <i>Keep devices in sterilisation packaging in a clean environment, away from sources of moisture and direct sunlight. Store at ambient temperature (typically 15 - 25°C (59 - 77°F)).</i></li> </ul>	<ul style="list-style-type: none"> <li>- <i>After sterilisation, the product should be manipulated with care in order to keep the integrity of the packaging (sterile barrier).</i></li> <li>- <i>Sterility cannot be guaranteed if packaging is open, damaged or wet.</i></li> <li>- <i>Check the packaging and the medical devices before using them (packaging integrity, no humidity and use by date).</i></li> <li>- <i>In case of damage, a complete rework should be performed.</i></li> <li>- <i>Check the Instructions For Use given by the pouch manufacturer to determine the shelf life of the sterile packaging.</i></li> </ul>	X	X

## **B. Filling material**

	<b>Operation</b>	<b>Operating mode</b>	<b>Warning</b>
1.	Disinfection	<ul style="list-style-type: none"> <li>- Immerse the obturation devices in NaOCl (2,5 % at least) during 5 minutes at ambient temperature.</li> </ul>	<ul style="list-style-type: none"> <li>- Do not use disinfecting solutions containing Phenol or any products which are not compatible with the treated filling material. (See General Recommendation chapter 3).</li> </ul>

Symbols	EN
	Sterilised product, electromagnetic or ionic radiation sterilisation process
	Autoclavable at the specified temperature
	Do not reuse
	Aluminium
	Carbon steel
	Diamond
	Gel
	Fiberglass
	Gutta-Percha
	Nickel titanium
	Plastic
	Root-canal sealer
	Paper
	Platinum
	Silicone
	Stainless steel
	Titanium
	Tungstene carbide

### Manufacturer



Maillefer Instruments Holding Sàrl  
 Chemin du Verger, 3  
 CH-1338 Ballaigues  
 Switzerland  
[dentsplysirona.com](http://dentsplysirona.com)