

# Cleaning, Disinfection and Sterilisation instructions

## Reprocessing of Produits Dentaires reusable Products.

### 1. Basic Principles

- All reusable Produits Dentaires Products are supplied non-sterile and are to be appropriately cleaned, disinfected and sterilized before the first use.
- All reusable Produits Dentaires Products are to be cleaned, disinfected and sterilized before every use.
- Failure to process medical devices correctly and effectively can risk transmission of infectious agents.
- Effective cleaning and disinfection are mandatory requirements for efficient sterilization.
- Materials may alter over time. Sterilization or exposure to chemicals can accelerate this deterioration. Always check your Produits Dentaires Products for wear and damage before use or replace them when they become distorted, worn or cracked. Specifically for reprocessing of the Produits Dentaires forceps, refer to section “Tips and tricks”.
- Avoid contact of dissimilar metals at any point during the cleaning, disinfection and sterilization process.
- Instructions contained in this guide have been validated using representative Produits Dentaires devices.
- The user is responsible for the sterility of reusable Produits Dentaires Products and to ensure the following as well:
  - Only procedures that are sufficiently validated specifically for devices are used for cleaning, disinfection and sterilization.
  - The equipment used (disinfector, sterilizer) is regularly maintained, checked and calibrated.
  - The instructions regarding the equipment, disinfectant and cleaning agents must be respected at all time.
  - The user has to be trained adequately.
  - In addition to these instructions, please observe the legal regulations valid in your country as well as the hygiene regulations of the dental practice.

### 2. Protection of Staff Members

All used and contaminated reusable Produits Dentaires Products must be handled with appropriate Personal Protective Equipment.

### 3. Reprocessing steps

#### 3.1 Recommendations

All assembled Produits Dentaires Products must be disassembled before reprocessing. Specifically, for Produits Dentaires forceps, refer to section “Tips and tricks”.

An automatic method (disinfector) should be used for the cleaning and the disinfection. Manual methods alone are not recommended because of their clearly lower effectiveness and reproducibility, also when using an ultrasonic bath.

A manual procedure should only be used if an automatic procedure is not available.

The pre-treatment step should be performed in case of both procedures.

### 3.2 Pre-treatment

Coarse impurities shall be removed from the products.

Rinse the products with cold running water to remove gross soiling.

Disassemble multi-piece components into their single parts (e.g. rings and extremities). Never place products made of different materials together.

Clean immediately following the procedures.

If products cannot be cleaned immediately, soak instruments in a solution of Dürr Dental ID 215.

Use a stiff nylon / soft cleaning brush to carefully scrub instruments for gross debris removal.

Use of a stainless steel wire brush or steel wool could damage the instruments.

Note that too strong concentration of the disinfectant or too long exposure time may damage instruments.

For further details refer to section "Tips and Tricks".

### 3.3 Cleaning and disinfection

Always clean instruments! Disinfection and rinsing are not sufficient.

#### Cleaning alternatives: Ultrasonic cleaning (A) or Automated cleaning (B)

If possible, an automatic procedure should be always used for cleaning of Produits Dentaires Products.

A manual procedure, even in case of application of an ultrasonic bath, should only be used if an automatic procedure is not available; in this case, the significantly lower efficiency of a manual procedure must be considered.

#### A. Ultrasonic cleaning

- **Please assure that Produits Dentaires Products have the relevant symbol on the packaging.**
- Completely disassemble Produits Dentaires Products if applicable.
- Follow carefully the instructions for use of the ultrasonic bath device. Service and clean the ultrasonic bath device frequently, according to the instructions for use. Ensure that maximum load is not exceeded.
- We recommended to use a cleaning solution such as, but not limited to Dürr Dental ID215 or cleaning solutions based on Quaternary Ammonium compounds.
- Prepare the cleaning solution according to manufacturer's instructions (Dürr Dental ID 215 2% solution was validated) and fill into an ultrasonic bath.
- Completely immerse products in the solution.
- Make sure that the parts do not touch one another. Separate the components according to the material.
- Expose the products for 1 minute to the ultrasonic bath.
- Remove the instruments from the ultrasonic bath immediately after cleaning and post rinse them each thoroughly (at least 1 minute) under running water. Use, preferably, deionized water.
- Check for cleanliness. If debris are still visible, repeat the procedure.
- Prepare the disinfectant solution according to manufacturer's instructions (Dürr Dental ID 212 Forte 2% solution was validated) and fill into a disinfection bath.
- Place the disassembled, cleaned and inspected components for the specified action time in the disinfection bath. Ensure that the components are sufficiently covered by the disinfection solution and that the instruments do not touch one another.
- Remove the components after 5 minutes from the disinfection bath and rinse them thoroughly with water (deionized) according to manufacturer's instructions for use.





B. Automated cleaning in an automated washer disinfectant



- **Please assure that Produits Dentaires Products have the relevant symbol on the packaging.**
- Completely disassemble Produits Dentaires Products if applicable.
- Use a washer-disinfectant conforming with the ISO 15883 series.
- Inspect the thermal disinfectant regularly according to the instructions for use.
- Follow carefully the instructions for use given by the manufacturer of the thermal disinfectant and cleaning detergents; and prefer cleaning agents with corrosion protector. Use deionized water.
- For the optimum loading of products, insert them into a mesh tray equipped with lid. The procedure has been validated with Miele E 363 mesh insert.
- The procedure has been validated according to P7 (TD90°C x 5 min (A0 = 6000)) in SMEG WD2145D using Smeg Deterliquid C2 4ml/l (Alkaline detergent) and Smeg Acidglass C2 2ml/l (Neutralizer).
- Remove the instruments from the automated washer disinfectant after end of the program.
- Check for cleanliness. If debris are still visible, clean products manually then repeat the procedure.

### 3.4 Drying

Check the dryness of the devices and if necessary use a disposable lint-free cloth to remove any water/moisture residue.

To prevent staining, refer to section “Tips and tricks”.

### 3.5 Checking

Inspect all instruments, after the cleaning and rinsing steps, for cleanliness, integrity and functionality. All products are to be checked for damage, wear and corrosion. For further details, refer to section “Surface defects and Troubleshooting”.

During the checking phase, particular care should be taken to the friction areas of forceps. Local lubrication is recommended. See section “Tips and tricks”.

If instruments are still visibly soiled, clean again.

Damaged medical devices may no longer be used and must be discarded.

**Warning!** It is extremely important to check that the products are truly clean and dry before the sterilization.

### 3.6 Packaging

Packaging can influence the attainment of sterilization conditions. We recommend the use of sterilization pouches/ reels compliant with ISO 11607-1 and suitable for steam sterilization. For further details, refer to section “Tips and tricks”.

Before packaging, make sure the instruments are completely dry.

The packaging shall be large enough to avoid stressing the sealing seam.

**Warning!** After the heat sealing process, the sealing seam shall be checked visually for any defects.

In case of defects, the packaging must be opened and the product repacked and sealed.



### 3.7 Sterilization

Sterilize Produits Dentaires Products **only** in a steam autoclave using distilled water and at the temperature specified on the relevant symbol. **Do not use chemical or cold or dry heat sterilization.** Steam sterilization shall be validated according to ISO 17665 series. The autoclave shall be preferably compliant with EN 13060.



- **Please assure that Produits Dentaires Products have the relevant symbol on the packaging.**
- The products shall be disassembled.
- Follow carefully the instructions for use of the autoclave.
- Inspect the autoclave regularly according to the instructions for use. Service and clean the device frequently, according to the instructions for use.
- Ensure that maximum load is not exceeded.
- Place all components in a sterilization disposable pouch (refer to 3.6 Packaging).
- Plastic parts must not touch the autoclave walls, since the temperature there might be higher.
- We recommended to use always the following cycle (Prion Cycle):  
Temperature of sterilisation: 134°C  
Time of sterilisation: 20 min  
Drying time: 20 min
- Remove Produits Dentaires Products from the autoclave immediately after sterilisation.
- Check the integrity of packaging and instruments.

### 3.8 Storage

- Store sterilized product in a dry and clean conditions at ambient temperature.
- Keep product sealed in the sterilization pouch until ready to use.

## Tips and tricks

Produits Dentaires forceps are manufactured from medical grade stainless steel which is naturally protected from rust by a passive oxide layer. Under certain circumstances, the integrity of this passive layer can be compromised, eventually leading to corrosion of the underlying bulk material. In order to prevent this, it is important to follow the instruction reported below. **Produits Dentaires cannot be held responsible for damage to instruments if the customer fails to follow these guidelines.** They reflect the current state of the art for reconditioning of medical instruments, as published for example in: "Reprocessing of instruments to retain value." 11th Edition – 2017 issued by the Instrument Reprocessing Working Group (AKI).

- **The use of distilled or de-mineralized water is highly recommended in all phases of cleaning, especially in the final rinsing. Use always distilled or de-mineralized water in the autoclave.**

The quality of water used for instrument reprocessing has a considerable influence on the appearance of instruments and materials after autoclaving. Tap water contains naturally dissolved substances, that may lead to staining after autoclave. In most cases, such discoloration is a harmless, thin residual layer that does not cause or promote corrosion. However, there may be dissolved substances that can contribute to corrosion:

Water constituents	Effect after autoclaving
calcium and magnesium salts	Hard deposits of lime or scale, potential corrosion underneath such deposits
Heavy and nonferrous metals (e.g. iron, manganese, copper)	Brown-red deposits. In case of iron dissolved, secondary rust spots that can evolve to corrosion of the instrument
Rust (flushed from corroded pipework)	Rust spots (extraneous rust) that can evolve to corrosion of the instrument near to the rust spots
Chlorides	Pitting corrosion

- **Avoid long intervals between use and reprocessing.**

Field experience has shown that in the case of dry disposal, intervals of up to 2 hours do not pose any problem, whereas longer intervals (e.g. overnight or over the weekend) may let drying blood or other biological residues, making the cleaning phase more difficult. Protein residues may leave yellow/brown stains after autoclaving.

- **Use cold water (<30°C) during pre-treatment.**

The use of warmer water may lead to fixing proteins with the consequence of making the cleaning phase more difficult. Such protein residues may leave yellow/brown stains after autoclaving.

- **Use preferably neutral-pH detergents.**

Acidic detergents (pH<7) may cause surface pitting or black staining if not rinsed off properly. Alkaline detergents (pH>7) can cause orange to brown phosphates deposits which could be mistaken for rust. Most of these stains are more evident on instruments with a matt finish. Thoroughly rinse instruments after cleaning in order to prevent staining due to detergent residuals. For automated cleaning in a washer-disinfector, the use of an acidic neutralizer facilitates the removal of residual alkaline cleaning agents. Do not exceed concentrations recommended by the manufacturers of the cleaning or neutralizing substances.

- **Avoid contact between different metals during all phases of the reprocessing cycle.**

The contact of dissimilar metals inside an aqueous solution will cause an electrolytical reaction that may lead to staining. In most cases, these stains do not alter the metal material except for the discoloration. In extreme cases, these electrolytical reaction can cause pitting corrosion.



- **Instruments should be carefully dried immediately after final rinsing.**

Slow evaporation of water droplets with a mineral content may lead to spotting and scaling after autoclaving. Drying using oil-free compressed air is preferred over other drying methods, however the use of disposable lint-free cloths is possible. The use of linen or towels for drying should be avoided, as any laundry detergent residue could be transferred to the instrument surface, resulting in visible stains after autoclaving.

- **During steam sterilization, use preferably sterilization pouches/ reels compliant with ISO 11607-1.**

The use of reusable sterilization trays is possible, however damp or wet containers pose a risk of instrument corrosion. The use of linen or towels to wrap instruments should be avoided, as any laundry detergent residue may be transferred to the instrument surface, resulting in visible stains after autoclaving.

- **Never expose Produits Dentaires Forceps to bleach or other corrosive chemicals for the purpose of disinfection.**

Exposure to bleach will result in severe pitting of instruments. Produits Dentaires cannot be held responsible for corrosion of instruments exposed to bleach.

- **Open all hinged instruments before processing.**

Residuals of biological matters or detergents may lead to localized staining if not removed properly from the hinge surfaces.

- **Lubricate all instruments, which have any “metal to metal” action**

Targeted application of instrument lubricant to the friction surfaces prevents friction corrosion. Apply lubricants just before autoclaving, in accordance with the lubricant manufacturer's instructions. Instruments should not be treated with lubricants containing silicone oil. Use only non-silicone, water-soluble surgical lubricants. Don't use industrial lubricants. Steam can penetrate only water-based surgical lubricants, the use of other lubricants would interfere with the sterilization process.

- **How to perform the “eraser test”**

Phosphate stains are a common result of improper processing. Due to their brown/orange appearance, phosphates can be mistaken for rust. A quick test to verify if a discoloration is rust or just a phosphate deposit, is to take a standard pencil eraser and try to rub the stain off. If the exposed metal is clean and smooth, the discoloration is a phosphate deposit. If the exposed metal has pit marks, this is corrosion.

## Surface defects and troubleshooting

“Stainless” means “without stains”. However, in some cases, this may not be true. When stains appear after autoclaving, the cause is always related to substances left on the instrument surface rather than the material composition. It is important to distinguish between the different stains, as in most cases discolorations are harmless residual layers that do not cause or facilitate corrosion. Diversely, corroded instruments should be immediately withdrawn from service. Further details on the identification and treatment of stains can be found in the guidelines for the reprocessing of surgical instruments such as, for example: “Reprocessing of instruments to retain value.” 11th Edition – 2017 issued by the Instrument Reprocessing Working Group (AKI).

Appearance	Caused by	How to treat	How to prevent occurrence
Brown/orange stains	<ul style="list-style-type: none"> <li>alkaline detergents residuals</li> <li>trace minerals in tap water (heavy and nonferrous metals).</li> <li>detergents residuals on instrument wraps and towels.</li> <li>blood or other organic residues.</li> </ul>	<ul style="list-style-type: none"> <li>Perform the eraser test (see directions in the “Tips and tricks”) in order to distinguish phosphate staining from corrosion.</li> <li>Ultrasonic and/or targeted manual recleaning.</li> </ul>	<ul style="list-style-type: none"> <li>Reduce the time between use and reprocessing.</li> <li>Use only cold water for pre-treatment.</li> <li>To remove organic residuals, use a suitable enzymatic cleaner as, but not limited to Dürr Dental ID 215.</li> <li>Use only pH-neutral detergents for washing or a well dosed neutralizing agent for rinsing.</li> <li>Use only distilled or de-mineralized water for rinsing and steam vapour sterilization.</li> <li>Avoid using towels for drying or wrapping instruments.</li> </ul>
Microscopically small spot surrounded by brown/orange or multicolored halos	<ul style="list-style-type: none"> <li>Chlorides residuals in tap water.</li> <li>Blood or other organic residuals.</li> <li>Excess of iron ions in tap water.</li> <li>Rust particles carried over from the pipework.</li> </ul>	<ul style="list-style-type: none"> <li>Perform the eraser test (see directions in the “Tips and tricks”) in order to distinguish phosphate staining from corrosion.</li> <li>Corroded instruments should be immediately withdrawn from service.</li> </ul>	<ul style="list-style-type: none"> <li>To remove organic residuals, use a suitable enzymatic cleaner as, but not limited to Dürr Dental ID 215.</li> <li>Use only distilled or de-mineralized water for rinsing and steam vapour sterilization.</li> </ul>
Brown staining on friction surfaces, e.g. hinge area	<ul style="list-style-type: none"> <li>Insufficient cleaning or rinsing – organic residuals, detergents or other residuals.</li> <li>Insufficient lubrication.</li> </ul>	<ul style="list-style-type: none"> <li>Perform the eraser test (see directions in the “Tips and tricks”) in order to distinguish phosphate staining from corrosion.</li> <li>Corroded instruments should be immediately withdrawn from service.</li> </ul>	<ul style="list-style-type: none"> <li>Open all hinged instruments before processing in order to ensure a complete cleaning/drying.</li> <li>To remove organic residuals, use a suitable enzymatic cleaner as, but not limited to Dürr Dental ID 215</li> <li>Lubricate all friction surfaces according to the lubricant manufacturer’s instructions.</li> <li>Use only non-silicone, water-soluble surgical lubricants.</li> </ul>
Brownish/blue stains in crevice areas e.g. in the joint gaps	<ul style="list-style-type: none"> <li>Presence of humidity in conjunction with higher salt concentrations</li> </ul>	<ul style="list-style-type: none"> <li>Corroded instruments should be immediately withdrawn from service.</li> </ul>	<ul style="list-style-type: none"> <li>Use only distilled or de-mineralized water for rinsing and steam vapour sterilization.</li> </ul>

Appearance	Caused by	How to treat	How to prevent occurrence
No staining - visible cracks and fractures in high stress components	<ul style="list-style-type: none"> <li>Instruments reprocessed under high stress (e.g. with ratchet fully closed)</li> </ul>	<ul style="list-style-type: none"> <li>Crevice corrosion may occur inside the cracks, thus accelerating the mechanical decay of the instrument. Immediately withdrawn from service.</li> </ul>	<ul style="list-style-type: none"> <li>Open all hinged instruments before processing.</li> <li>Use only distilled or de-mineralized water for rinsing and steam vapour sterilization.</li> <li>Avoid improper handling that could lead to oversteering.</li> <li>Always inspect instruments before each use.</li> </ul>
Milky /grey discolorations	<ul style="list-style-type: none"> <li>Excessive lime in the water used for the cleaning stage or at the final rinse.</li> </ul>	<ul style="list-style-type: none"> <li>Wipe off with a clean, low-lint cloth.</li> <li>Reprocess the instrument.</li> </ul>	<ul style="list-style-type: none"> <li>Use only distilled or de-mineralized water for rinsing and steam vapour sterilization.</li> </ul>
Yellow/brown to blue/violet discolorations	<ul style="list-style-type: none"> <li>Trace minerals in tap water (silicate/ silicic acid).</li> </ul>	<ul style="list-style-type: none"> <li>Wipe off with a clean, disposable lint-free cloths.</li> <li>Reprocess the instrument.</li> </ul>	<ul style="list-style-type: none"> <li>Use only distilled or de-mineralized water for rinsing and steam vapour sterilization.</li> </ul>
Grey spots	<ul style="list-style-type: none"> <li>Water droplets drying on surface.</li> <li>Slow evaporation of water drops with mineral content.</li> </ul>	<ul style="list-style-type: none"> <li>Wipe off with a clean, low-lint cloth.</li> <li>Reprocess the instrument.</li> </ul>	<ul style="list-style-type: none"> <li>Dry instruments completely upon washing/rinsing.</li> <li>Follow autoclave manufacturer's operating instructions in order to avoid water droplets and moisture.</li> <li>Use only distilled or de-mineralized water for rinsing and steam vapour sterilization.</li> </ul>
Blue/black	<ul style="list-style-type: none"> <li>Reverse plating due to contact of dissimilar metals during cleaning process.</li> </ul>	<ul style="list-style-type: none"> <li>Corroded instruments should be immediately withdrawn from service.</li> </ul>	<ul style="list-style-type: none"> <li>Separate instruments by type when cleaning or autoclaving.</li> </ul>