



## FOREWORD

For hygiene and sanitary safety purposes, dental instruments marketed by Produits Dentaires SA (see list below) must be cleaned, disinfected and/or sterilized before each usage to prevent any contamination. This applies to the first use as well as to the subsequent ones.

## SCOPE

Product name	Disinfection	Sterilization
Copper band	✓	
Preformed Aluminium crowns	✓	
Toffemire matrix bands	✓	
Plastic pipettes	✓	
Steel abrasive strips	✓	
Glass fiber posts	✓	
Gold plated / Titanium screw posts	✓	
Acrylic / silver points	✓	
Cotton pellets / solution dispenser	✓	
Dappen dish	✓	
Plastic / ball chain napkin holders	✓	
Bur cleaning brush	✓	
Rubber polishing cups	✓	✓
Root canal barbed broaches	✓	✓
Toffemire matrix retainer	✓	✓
Root needles	✓	✓
Adjustable enamel stripper	✓	✓
Gates / Peeso / Spiral bladed tapered reamers	✓	✓
Special drills and reamers for screw posts	✓	✓
MAP system	✓	✓
Paste fillers	✓	✓
Steel / tungsten carbide burs	✓	✓

## STANDARDS AND REGULATORY REFERENCES

- EN ISO 17664 : Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices
- EN ISO 17665-1 : Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- EN 13060 : Small steam sterilizers
- EN 285 : Sterilization – Steam sterilizers – Large sterilizers
- EN ISO 15883 : Washers-disinfectors
- EN ISO 11607-1 : Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems

## GENERAL RECOMMENDATIONS

- Equipment used for disinfection, cleaning and sterilization processes shall be validated with a maintenance program and routine controls. Validated parameters shall be followed for each cycle.
- Do not exceed 200°C (392°F)
- The sterilization of the product before first use and reuse is the responsibility of the user. Similarly, if the latter should use dirty and/or damaged instruments, they will assume full responsibility herewith.
- The appearance of defects such as cracks, deformations (bent, twisted), corrosion, loss of color coding or marking, are indications that the devices are not able to fulfill the intended use with the required safety level
- Do not reuse medical devices marked “single use”
- For your own safety, please wear the required personal protective equipment (gloves, mask, glasses)
- Use only disinfectant solutions of proven efficiency (VAH/DGHM listing, CE marked, FDA approval)



- Tungsten carbide burs, plastic supports, hand instruments and nickel-titanium instruments are degraded by hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) solution.
- Nickel-Titanium devices are degraded if immersed more than 5 minutes in a solution of NaOCl at more than 5%
- Aluminum devices are degraded in presence of caustic soda solution with mercury salt. Do not use acid (pH < 6) or alkaline (pH > 8) solutions.
- For metallic devices, it is recommended to use disinfection and cleaning solutions with a corrosion inhibitor.
- The washer-disinfector is not recommended for instruments made of aluminum, tungsten carbide or carbon steel.
- The water quality has to comply with the local regulations especially for the last rinsing step and the water used by the washer-disinfector



			Following uses	
#	Step	Operating mode	Warning	First use
1.	Disassembling	Disassemble the device if required	Silicon stops have to be removed Discard instruments which show any default (see general recommendations)	✓
2.	Pre-disinfection	Soak all instruments immediately after use in a detergent and disinfecting solution with proteolytic enzyme if possible	Follow concentrations and immersion times given by the manufacturer, because a excessive concentration may cause corrosion or others defects on instruments. The disinfecting solution should be aldehyde free to avoid blood impurities fixation and without di or triethanolamine as corrosion inhibitor. Do not use disinfecting solutions containing phenol or any products which are not compatible with the instruments (see general recommendations) For visible impurities observed on instruments, a pre-cleaning is recommended by brushing them manually with soft material	✓
3.	Rinsing	Abundant rinsing (at least 1 min)	If pre-disinfectant solution contains a corrosion inhibitor, it is recommended to rinse instruments just before the cleaning	✓
<b>OR</b>				
4.	Automated cleaning with washer-disinfector	Place the devices in a kit, support or container to avoid any contact between instruments Put them in the washer-disinfector at least 5 min at 90°C (or Ao value > 3000)	Discard any instruments with large defects. (see general recommendations) Follow instructions and observe concentrations and working time given by the manufacturer Use only approved washer-disinfector according to EN ISO 15883, maintain and calibrate it regularly	✓ ✓
5.	Manual cleaning with or without an ultrasonic device	Place the devices in a kit, support or container to avoid any contact between instruments Immerse in the disinfecting solution with cleaning properties, assisted by an ultrasonic device if suitable	Discard any instruments with large defects. (see general recommendations) No visible impurities should be observed on the instruments (pre-clean with brush, swab or soft material) Follow instructions and observe concentrations and working time given by the manufacturer The disinfecting solution should be aldehyde-free and without di-or triethanolamines as corrosion inhibitor	✓ ✓
6.	Rinsing	Abundant rinsing (at least 1 min)	If pre-disinfectant solution contains a corrosion inhibitor, it is recommended to rinse instruments just before the autoclaving Dry on a single use non-waved cloth, or with a drying machine or filtered compressed air	✓ ✓



#	Step	Operating mode	Warning	Following uses	
				First use	
7.	Inspection	Inspect devices and sort out those with defects Assemble the devices (stops)	Dirty instruments must be cleaned again Discard instruments which show any defects affecting the resistance, the safety or the performance of the instrument (see general recommendations)	✓	✓
8.	Packaging	Place the devices in a kit, support or container to avoid any contact between instruments and pack the devices in "sterilization pouches"	Check validity period of the pouch given by the manufacturer Use packaging which are resistant up to a temperature of 141°C (286°F) and in accordance with EN ISO 11607	✓	✓
9.	Sterilization	Steam sterilization at 134°C (273°F) at 2.1 bar during 18 min Check the success of the sterilization cycle (cycle parameters consistent with the validated data) Use physicochemical indicator for each performed cycle	This sterilization protocol have been validated by Produits Dentaires SA according to EN ISO 17665 Sterilize instruments and plastic holders following the instructions that appear on the packaging Use only autoclaves that are matching the requirements of EN 13060 or EN 285 Respect the maintenance procedure of the autoclave device given by the manufacturer Control the efficiency : packaging integrity, no humidity, colour change of sterilization indicators, physicochemical integrators, digital records of cycles parameters Traceability of procedure records	✓	✓
10.	Storage	Keep devices in sterilization packaging in a dry and clean environment	Sterility cannot be guaranteed if packaging is open, damaged or wet Check the packaging and the devices before using them (packaging integrity, no humidity and validity period)	✓	✓