

Manual Pre-disinfection/Cleaning and Sterilization Instructions for SATELEC Tips and Files

Cautions

Do not use steel wool or abrasive cleaners.
Avoid solutions containing iodine or with a high chlorine content.
The pH of detergents/disinfectants must be between 7 and 11.

The cleaning method for tips and files recommended by Satelec is manual or automated.

All devices must be carefully cleaned and must be sterilized after cleaning prior to use.

The sterilization parameters are only valid for correctly cleaned devices.

Tips and files must be cleaned with extreme care.

During automated cleaning, tips or files must be placed on suitable instrument holders or in small baskets to prevent them from damage during washing.

It is the responsibility of the end user to ensure that all equipment used to treat Satelec devices is properly installed, validated, maintained and calibrated.

Whenever possible, a washer/disinfector should be used for tips. Prevent the overloading of wash baskets for ultrasonic cleaning or cleaning in a washer/disinfector.

Cleaning/sterilization cycle limits

Repeated treatment cycles that include ultrasonic cleaning, manual washing and sterilization have minimal effects on tips and files.

End of service life is normally determined by wear and damage due to use.

Important

If the irrigation tubing is external or if configuring the device with tank, press the cleaning button on the device after each use and

- Remove the perforator from the irrigation solution, and then immerse it in an enzymatic or alkaline cleaning solution. By pressing the flush button on the device, rinse the irrigation tubing, the handpiece and the tip (or the file) for 1 minute to prevent the drying of soil and debris inside the device.
- Immerse the perforator in a distilled or purified water solution, rinse for 1 minute in order to eliminate the enzymatic or alkaline cleaning solution.
- Remove the perforator from the distilled or purified water solution and purge the irrigation tubing to remove the liquid from the inside.
- If the case of irrigation coming from the dental practice water network, clean and rinse the cord, the handpiece and the tip (or file) for 1 minute after each use.

- Soiled devices should be separated from non-contaminated devices to avoid contamination of personnel or surroundings.
- Wipe blood and/or debris from the tips or files to prevent it from drying onto the surfaces. Cover the tip or the file with a soft lint-free wipe dampened with purified water to prevent blood and/or debris from drying.

Containment and transportation

Soiled devices must be transported separately from non-contaminated devices to avoid contamination.

Preparation for pre-disinfection/cleaning

It is advisable to treat devices immediately or as soon as possible after use. Satelec devices must be treated within two hours of use.

Before cleaning, unscrew the tip or the file at the front of the ultrasonic handpiece after each use.

Pre-disinfection/Cleaning - Manual method

Equipment: soft-bristled brush, soft and lint-free swab, lint-free cloth, syringe, pipette and/or water jet, enzymatic or alkaline cleaning solution, ultrasonic cleaner.

	Step duration (minimum)	Cleaning instructions
	1 minute	Rinse soiled device under cold running water. Use a soft-bristled brush or a soft and lint-free clean cloth to remove most of the contamination and debris. Use a syringe, a pipette or a water jet with an enzymatic or alkaline cleaning solution to rinse the tip cannulation.
	10 minutes	In an ultrasonic cleaner, immerse the device in a freshly prepared enzymatic or alkaline cleaning solution.
	1 minute	Rinse device under cold running water. Use a syringe, a pipette or a water jet to rinse the tip cannulation.
	4 minutes	Manually wash device in a freshly prepared enzymatic or alkaline cleaning solution. Use a soft-bristled brush to remove soil and debris. Wash device under water to prevent aerosolization of contaminants.
	1 minute	Thoroughly rinse device with distilled or purified water. Use a syringe, a pipette or a water jet to rinse the tip cannulation. Repeat rinsing.
		Repeat the pre-cleaning procedure until no visible contamination remains on device.

	Perform a final rinse of device using distilled or purified water.
	Dry the device with a soft, lint-free cloth or with clean compressed air.

Inspection

- Devices must be inspected to check that no contamination remains, that they are not corroded, dulled, discoloured or damaged.
- Before packaging and sterilizing the cleaned devices, check they are clean, undamaged and function properly.
- Damaged devices must be discarded. Tips must not be lubricated.

Packaging

Use suitable packaging for sterilization, such as a Sterile Barrier System in compliance with ISO 11607. Care should be taken to protect tips (or files) from contact with other objects that may damage their surface or the Sterile Barrier System.

Sterilization

Unless otherwise specified, non-sterile products can be re-sterilized using validated steam sterilization methods (ISO 17665 or national standards).

Satelec recommendations for packed tips are as follows:

Cycle type	Sterilization exposure time	Sterilization exposure temperature	Drying time
Saturated steam - forced air removal (pre-vacuum)	4 minutes	132°C	Minimum 20 minutes

Dry times generally range from 20 to 60 minutes due to the difference in packaging materials, steam quality, device materials, total mass, sterilizer performance, and varying cool-down time.

The distributor and manufacturer accept no responsibility for sterilization procedures performed by the customer that are not performed according to these Satelec recommendations.

Storage

Storage conditions for products labelled "STERILE" are printed on the packaging label. Packaged products should be stored in a dry, clean environment, protected from direct sunlight, pests, and extremes of temperature and humidity. Use products in the order in which they are received ("first in, first out" principle), taking into account the expiry date indicated on the label.

Automated Pre-disinfection/Cleaning and Sterilization Instructions for SATELEC Tips and Files

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During automated cleaning, tips or files must be placed on suitable instrument holders or in small baskets to prevent them from damage during washing.

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Whenever possible, a washer/disinfector should be used for tips. Prevent the overloading of wash baskets for ultrasonic cleaning or cleaning in a washer/disinfector.

Cleaning/sterilization cycle limits

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Before cleaning, unscrew the tip or the file at the front of the ultrasonic handpiece after each use.

Pre-disinfection/Cleaning - Automated method

Pre-disinfection/pre-cleaning method

Note: The manual pre-disinfection/pre-cleaning method has to be performed for the tips prior to automated cleaning.

Equipment: soft-bristled brush, soft and lint-free swab, lint-free cloth, syringe, pipette and/or water jet, ultrasonic cleaner, washer/disinfector, enzymatic or alkaline cleaning solution.

	Step duration (minimum)	Cleaning instructions
	1 minute	Rinse soiled device under cold running water. Use a soft-bristled brush or a soft and lint-free clean cloth to remove most of the contamination and debris. Use a syringe, a pipette or a water jet with an enzymatic or alkaline cleaning solution to rinse the tip cannulation.
	1 minute 30 seconds	Manually wash device in a freshly prepared enzymatic or alkaline cleaning solution. Use a soft-bristled brush to remove soil and debris. Wash device under water to prevent aerosolization of contaminants.
	1 minute	Rinse device under cold running water. Use a syringe, a pipette or a water jet to rinse the tip cannulation.
	10 minutes	In an ultrasonic cleaner, immerse the device in a freshly prepared enzymatic or alkaline cleaning solution.
	1 minute	Thoroughly rinse device with distilled or purified water. Use a syringe, a pipette or a water jet to rinse the tip cannulation. Repeat rinsing.
		Repeat the pre-cleaning procedure until no visible contamination remains on device.

Automated cleaning method

Step	Duration	Cleaning instructions
Pre-washing	2 minutes	Cold tap water
Washing	10 minutes	Warm tap water (> 40°C); use alkaline or enzymatic cleaning solution
Neutralization	2 minutes	Warm tap water with neutralizer, if necessary
Rinsing	2 minutes	Rinse with warm distilled or purified water (>40°C)
Drying	40 minutes	90°C

Thermal disinfection

For automated cleaning: thermal disinfection at 90°C for a minimum of 5 minutes.

Inspection

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