

Manual Pre-disinfection/Cleaning and Sterilization Instructions for SATELEC Scaler Handpieces

These instructions only apply to Suprasson, Newtron and Newtron LED Handpieces.

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 scaler handpieces recommended by Satelec is manual or automated.

Scaler handpieces and their accessories (nosepiece, LED ring, optical guide, cord pass-through depending on model) must be cleaned with extreme care.

Do not immerse or place scaler handpieces in an ultrasonic cleaner.

Only the Nosepiece disassembled from Newtron or Newtron LED handpieces can be immersed and treated using the ultrasonic procedure.

If the surface of the devices is damaged, ultrasonic cleaning may cause further damage.

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

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

Cleaning/sterilization cycle limits

Repeated treatment cycles including manual washing and sterilization have minimal effects on Newtron LED handpiece scaler handpieces, LED ring and Optical guide.

Repeated treatment cycles that include ultrasonic cleaning, manual washing and sterilization have minimal effects on scaler Handpiece Nosepieces.

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

Important

- Throughout the procedure, wipe blood and/or debris from the Handpiece to prevent it drying on the surfaces.
- In case of external irrigation tubing or configuration of the device with tank, after each use, rinse the irrigation tubing, Handpiece and tip for 1 minute with an enzymatic or alkaline cleaning solution to prevent debris and contamination from drying on the device.
Rinse with distilled or purified water for 1 minute to remove the enzymatic or alkaline cleaner.
Flush the irrigation tubing to remove liquid from the inside.
- In the case of irrigation coming from the dental practice water network, clean and rinse the cord, the handpiece and the tip for 1 minute after each use.

- Soiled devices should be separated from non-contaminated devices to avoid contamination of personnel or surroundings.
- The Handpiece must be covered with a cloth dampened with purified water to prevent blood and/or debris from drying on the surface.

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).

After each use and prior to cleaning the device:

- o Unscrew the tip at the front of the Handpiece-cord assembly and place it in the appropriate container. The cleaning of the tip is subject to a separate protocol.
- o Remove the single-use or autoclavable irrigation tubing and autoclavable clips from the handpiece-cord assembly, if applicable. Their cleaning is subject to a separate protocol. Always discard the single-use perforator and/or single-use irrigation tubing.
- o Disconnect the Handpiece from the cord.
 - o With regards to Newtron and Newtron LED Handpieces: Unscrew the Nosepiece.
 - o With regards to the Newtron LED handpiece: remove the optical guide
 - o With regards to the Newtron LED handpiece: disconnect the LED ring from the Handpiece, pulling it gently.

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.

Step duration (minimum)	Cleaning instructions
1 minute	Rinse soiled device under cold running water for at least 1 minute. Use a soft-bristled brush and a lint-free swab 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 handpiece cannulation.
15 minutes	Only the Nosepiece disassembled from Newtron or Newtron LED handpieces can be treated using the ultrasonic procedure. Wash the Nosepiece using an ultrasound process for 15 minutes in an enzymatic or alkaline cleaning solution.
4 minutes	Clean and disinfect each element separately: the handpiece body, in particular the screw threading, the nosepiece for Newtron handpieces, the LED ring and optical guide for the Newtron LED handpiece, with an enzymatic or alkaline cleaning solution for a minimum of 4 minutes.

1 minute	Rinse each component separately with deionized or purified water. Use a syringe, a pipette or a water jet to flush the handpiece cannulation with deionized or purified water.
	Visually inspect device. Repeat the cleaning procedure until no visible contamination remains on the device.
	Dry components using a soft, lint-free cloth or clean compressed air.

Inspection

- Handpieces and Nosepieces must be inspected to check that no contamination remains, that they are not corroded, dulled, discoloured or damaged.
- Before packaging and sterilizing the cleaned products, check they are clean, undamaged and function properly. Repeat cleaning steps until no visible contamination remains on the device.
- Damaged devices must be discarded. Handpieces 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 handpieces 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 Handpieces and their accessories 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 Scaler Handpieces

These instructions only apply to Suprasson, Newtron and Newtron LED Handpieces.

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 scaler handpieces recommended by Satelec is manual or automated.

Scaler handpieces and their accessories (nosepiece, LED ring, optical guide, cord pass-through depending on model) must be cleaned with extreme care.

Do not immerse or place scaler handpieces in an ultrasonic cleaner.

Only the Nosepiece disassembled from Newtron or Newtron LED handpieces can be immersed and treated using the ultrasonic procedure.

If the surface of the devices is damaged, ultrasonic cleaning may cause further damage.

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

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

Cleaning/sterilization cycle limits

Repeated treatment cycles including manual washing and sterilization have minimal effects on Newtron LED handpiece scaler handpieces, LED ring and Optical guide.

Repeated treatment cycles that include ultrasonic cleaning, manual washing and sterilization have minimal effects on scaler Handpiece Nosepieces.

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

Important

- Throughout the procedure, wipe blood and/or debris from the Handpiece to prevent it drying on the surfaces.
- In case of external irrigation tubing or configuration of the device with tank, after each use, rinse the irrigation tubing, Handpiece and tip for 1 minute with an enzymatic or alkaline cleaning solution to prevent debris and contamination from drying on the device. Rinse with distilled or purified water for 1 minute to remove the enzymatic or alkaline cleaner. Flush the irrigation tubing to remove liquid from the inside.
- In the case of irrigation coming from the dental practice water network, clean and rinse the cord, the handpiece and the tip for 1 minute after each use.
- Soiled devices should be separated from non-contaminated devices to avoid contamination of personnel or surroundings.

- The Handpiece must be covered with a cloth dampened with purified water to prevent blood and/or debris from drying on the surface.

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.

After each use and prior to cleaning the device:

- o Unscrew the tip at the front of the Handpiece-cord assembly and place it in the appropriate container. The cleaning of the tip is subject to a separate protocol.
- o Remove the single-use or autoclavable irrigation tubing and autoclavable clips from the handpiece-cord assembly, if applicable. Their cleaning is subject to a separate protocol. Always discard the single-use perforator and/or single-use irrigation tubing.
- o Disconnect the Handpiece from the cord.
 - o With regards to Newtron and Newtron LED Handpieces: Unscrew the Nosepiece.
 - o With regards to the Newtron LED handpiece: remove the optical guide
 - o With regards to the Newtron LED handpiece: disconnect the LED ring from the Handpiece, pulling it gently.

Pre-disinfection/Cleaning - Automated method

Pre-disinfection/pre-cleaning method

Note: The pre-disinfection/pre-cleaning method must be performed on the Handpiece and accessories prior to automated cleaning.

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

	Step duration (minimum)	Cleaning instructions
	1 minute	Rinse the soiled device under cold running tap water for at least 1 minute. Remove most of the contamination and debris using a soft brush, a lint-free swab or a lint-free cloth. Use a syringe, a pipette or a water jet with an enzymatic or alkaline cleaning solution to rinse the handpiece cannulation.
	2 minutes	Only the Nosepiece disassembled from Newtron or Newtron LED handpieces can be treated using the ultrasonic procedure. Wash the Nosepiece using an ultrasound process for 2 minutes in an enzymatic or alkaline cleaning solution.
	2 minutes	Clean and disinfect each element separately: the handpiece body, in particular the screw threading, the nosepiece for Newtron handpieces, the LED ring and optical guide for the Newtron LED handpiece, with an enzymatic or alkaline cleaning solution for a minimum of 2 minutes.

	1 minute	Rinse the components separately under cold running tap water for at least 1 minute. Use a syringe, a pipette or a water jet with an enzymatic or alkaline cleaning solution to rinse the handpiece cannulation.
		Visually inspect device. Repeat the cleaning procedure until no visible contamination remains on the device.

Pre-disinfection/Cleaning - Automated method

<i>Step</i>	<i>Duration (minimum)</i>	<i>Cleaning/decontamination instructions</i>
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

- Handpieces and Nosepieces must be inspected to check that no contamination remains, that they are not corroded, dulled, discoloured or damaged.
- Before packaging and sterilizing the cleaned products, check they are clean, undamaged and function properly. Repeat cleaning steps until no visible contamination remains on the device.
- Damaged devices must be discarded. Handpieces 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 handpieces 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 handpieces and their accessories are as follows:

Cycle type	Sterilization exposure time	Sterilization exposure temperature	Drying time
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