

Manual Pre-disinfection/Cleaning and Sterilization Instructions for SATELEC® Piezotome Handpiece-Cord assembly

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.

Contaminated or used parts cannot be loaded into a sterilization box or cleaned in a machine.

The cleaning method for the Piezotome handpiece-cord assembly 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.

Handpiece components (depending on model: nosepiece, LED ring, light guide, cord pass-through) must be cleaned with extreme care.

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

Note: The ultrasonic process is for the Nosepiece only. The Handpiece-cord assembly, LED ring and Optical guide must not be exposed to ultrasonic cleaning.

It is the responsibility of the end user to ensure that all equipment used to recondition 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 conditioning cycles including manual washing and sterilization have minimal effects on the Piezotome Handpiece-cord assembly, depending on the model the LED ring and Optical guide.

Repeated conditioning cycles that include ultrasonic cleaning, manual washing and sterilization have minimal effects on the Piezotome Nosepiece.

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.
- Remove the perforator from the irrigation solution.
- Immerse the perforator in an enzymatic or alkaline cleaning solution.
- Using the device's flush button, clean the irrigation tubing, the Handpiece and the tip for 1 minute after each use to prevent pollutants and debris from drying in the device.
 - Immerse the perforator in a distilled or purified water solution and, using the cleaning button, rinse for 1 minute to remove the enzymatic or alkaline cleaning solution.
 - Remove the perforator from the distilled or purified water solution and flush the irrigation tubing to remove the liquid from the inside.

- Soiled devices should be separated from non-contaminated devices to avoid contamination of personnel or surroundings.
- After use, the Handpiece must be covered with a cloth soaked in 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 recondition devices as soon as possible after use. SATELEC® devices must be reconditioned within two hours of use.

- After each use and prior to cleaning the device:
 - 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.
 - Remove the single-use or autoclavable irrigation tubing and autoclavable clips from the handpiece-cord assembly. Their cleaning is subject to a separate protocol. Always discard the single-use perforator and/or single-use irrigation tubing.
 - Unscrew the Nosepiece.
 - Depending on the model, remove the optical guide.
 - Depending on the model, 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, washer-disinfector, enzymatic or alkaline cleaning solution.

| | Minimum step duration | Cleaning instructions |
|---|-----------------------|--|
| 1 | 2 minutes | Rinse soiled device under running water for at least 2 minutes. 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 spray with an enzymatic or alkaline cleaning solution to rinse the handpiece cannulation. |
| 2 | 10 minutes | Soak the device in an enzymatic or alkaline cleaning solution for a minimum of 10 minutes. Follow the enzymatic or alkaline cleaning solution manufacturer's instructions for use for correct concentration/dilution, temperature, exposure time and water quality (e.g. pH, hardness, etc.). |
| 3 | 2 minutes | Rinse device under cold running water for a minimum of 2 minutes. Use a syringe, a pipette or a water jet to flush the handpiece cannulation with running water. |

| | Minimum step duration | Cleaning instructions |
|----|-------------------------|---|
| 4 | 5 minutes | Manually wash the device for at least 5 minutes in a freshly prepared enzymatic or alkaline cleaning solution. Use a soft-bristled brush to remove soil and debris on the Nosepiece, Optical guide, LED ring depending on the model, the handpiece-cord assembly and the threaded fitting. Use a lint-free swab to remove soil and debris on the Nosepiece, Optical guide and LED ring. Wash device under water to prevent aerosolization of contaminants. |
| 5 | 2 minutes | Rinse device thoroughly with distilled or purified water for 2 minutes. |
| 6 | 2 minutes | Manually wash device in a neutral pH cleaning solution for a minimum of 2 minutes. Use a soft-bristled brush for the Nosepiece, Optical guide, LED ring depending on the model, the handpiece-cord assembly and threaded fitting. Use a lint-free swab to remove soil and debris on the Nosepiece, Optical guide and ring. Wash device under water to prevent aerosolization of contaminants. |
| 7 | 2 minutes | Use a syringe, a pipette or a water jet to flush the handpiece cannulation with distilled or purified water. Rinse device thoroughly with distilled or purified water for 2 minutes. |
| 8 | Visually inspect device | Use a syringe, a pipette or a water jet to flush the handpiece cannulation with distilled or purified water. Rinse device thoroughly with distilled or purified water for 2 minutes. |
| 9 | Rinsing | Perform a final rinse of device using distilled or purified water. |
| 10 | Drying | Dry components using a soft, lint-free cloth or clean compressed air. |

Inspection

- Handpieces and the Nosepiece 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

The Handpiece and its accessories must be placed in a purpose-provided sterilization box. Use suitable packaging or a re-usable rigid container 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 | Minimum drying time |
|---|-----------------------------|------------------------------------|---------------------|
| Saturated steam - forced air removal (pre-vacuum) | 4 minutes | 132°C | 20 minutes |
| | 4 minutes | 134°C | 20 minutes |
| | 3 minutes | 134°C | 20 minutes |
| | 18 minutes | 134°C | 20 minutes |

Dry times generally range from 20 to 60 minutes due to the difference in packaging materials (Sterile Barrier System, e.g. reusable rigid containers or wraps), 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® Piezotome Handpiece-Cord assembly

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.

Contaminated or used parts cannot be loaded into a sterilization box or cleaned in a machine.

The cleaning method for the Piezotome handpiece-cord assembly 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.

Piezotome Handpiece components, depending on the model, nosepiece, LED ring, light guide, cord pass-through, must be cleaned with extreme care.

Do not place the handpiece-cord assembly in an ultrasonic cleaner.

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

Note: The ultrasonic process is for the Nosepiece only. The Handpiece-cord assembly, LED ring and Optical guide must not be exposed to ultrasonic cleaning.

It is the responsibility of the end user to ensure that all equipment used to recondition 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 conditioning cycles including manual washing and sterilization have minimal effects on the Piezotome Handpiece-cord assembly, LED ring and Optical guide.

Repeated conditioning cycles that include ultrasonic cleaning, manual washing and sterilization have minimal effects on the Piezotome Nosepiece.

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.
- Remove the perforator from the irrigation solution.
- Immerse the perforator in an enzymatic or alkaline cleaning solution.
- Using the device's flush button, clean the irrigation tubing, the Handpiece and the tip for 1 minute after each use to prevent pollutants and debris from drying in the device.

- Immerse the perforator in a distilled or purified water solution and, using the cleaning button, rinse for 1 minute to remove the enzymatic or alkaline cleaning solution.
- Remove the perforator from the distilled or purified water solution and flush the irrigation tubing to remove the liquid from the inside.
- Soiled devices should be separated from non-contaminated devices to avoid contamination of personnel or surroundings.
- After use, the Handpiece must be covered with a cloth soaked in 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 recondition devices as soon as possible after use (SATELEC® devices must be reconditioned within two hours of use).

- After each use and prior to cleaning the device:
 - 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.
 - Remove the single-use or autoclavable irrigation tubing and autoclavable clips from the handpiece-cord assembly. Their cleaning is subject to a separate protocol. Always discard the single-use perforator and/or single-use irrigation tubing.
 - Unscrew the Nosepiece.
 - Depending on the model, remove the optical light guide.
 - 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, ultrasonic cleaner, washer-disinfector, enzymatic or alkaline cleaning solution.

Note: Only the Nosepiece of the handpiece can be treated using an ultrasound process.

| | Step duration (minimum) | Cleaning instructions |
|--|-------------------------|---|
| | 1 minute | Rinse the contaminated device under cold running 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 spray with an enzymatic or alkaline cleaning solution to rinse the handpiece cannulation. |

| | Step duration (minimum) | Cleaning instructions |
|--|-------------------------|---|
| | 2 minutes | Manually wash the device for at least 2 minutes in a freshly prepared enzymatic or alkaline cleaning solution. Follow the enzymatic or alkaline cleaning solution manufacturer's instructions for use for correct concentration/dilution, temperature, exposure time and water quality (e.g. pH, hardness, etc.). Use a lint-free swab to remove contamination and debris from the Nosepiece, and depending on the model from the Optical guide, LED ring, Handpiece-cord assembly and Threaded fitting. Wash device under water to prevent aerosolization of contaminants. |
| | 1 minute | Rinse device under cold to warm running water for at least 1 minute. Use a syringe, a pipette or a water jet to flush the handpiece cannulation with running water. |
| | 15 minutes | The ultrasonic process is for the Nosepiece only. Wash the tip using an ultrasound process for 15 minutes in an enzymatic or alkaline cleaning solution. |
| | 2 minutes | Rinse Nosepiece under cold to warm running water for a minimum of 2 minutes. |
| | | Visually inspect device. Repeat the cleaning procedure until no visible contamination remains on the device. |

Automated cleaning method

| Step | Duration (minimum) | Cleaning/decontamination instructions |
|----------------|--------------------|--|
| Pre-washing | 2 minutes | Cold tap water |
| Washing | 2 minutes | Warm tap water (> 40°C); use alkaline or enzymatic cleaning solution |
| Neutralization | 5 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 the Nosepiece 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.
- Damaged devices must be discarded. Handpieces must not be lubricated.

Packaging

The Handpiece and its accessories must be placed in a purpose-provided sterilization box. Use suitable packaging or a re-usable rigid container 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 |
| | 4 minutes | 134°C | Minimum 20 minutes |
| | 3 minutes | 134°C | Minimum 20 minutes |
| | 18 minutes | 134°C | Minimum 20 minutes |

Dry times generally range from 20 to 60 minutes due to the difference in packaging materials (Sterile Barrier System, e.g. reusable rigid containers or wraps), 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.