Pre-disinfection, cleaning and sterilisation instructions

Tips and files

This document is an English translation of the original French version.
Reference J02000 version V4 and drawing number RB01FR010D

Contents

1 Applicability

These instructions do not apply to tips and files for veterinary use.

Tips and files IRR 25-45, SPR 30, SPR 60, SPR 80, PLU 60, PLU 90 and PLU 110 are not dealt with in this document.

2 Documentation

This document contains the following information:

- preparation for cleaning;
- medical device disinfection;
- medical device sterilisation.

2.1 Associated documentation

Document title	References
Consulting electronic user instructions	J00007
Cleaning, disinfection and sterilisation instructions for handpieces	J12911

2.2 Electronic documentation

The user instructions for your device are available in electronic format on the specified website and not in printed format. If the website is unavailable, try again later. You can also request a free printed copy of the user instructions within seven days via our website, by telephone or in writing.
The electronic user instructions are available in PDF format (Portable Document Format). You will need to have a PDF file reader installed to read the electronic user instructions. It is important for you to have read and understood the content of the user instructions relating to the use of your device and its accessories.

> Never use your device without first reading the user instructions.

The device user instructions can be consulted at the following addresses:www.ultradent.com and www.satelec.com.
When you receive your device, you are asked to print and/or to download all documents or sections of documents that you may need to refer to in the event of an emergency, if you are unable to connect to the internet or if your electronic display tool is not working (computer, tablet, etc.). We recommend that you visit the website regularly to consult and to download the latest version of your device's user instructions. Users are asked to keep documentation close at hand for reference when necessary.

2.3 Latest document update

09/2017

3 Warnings

Do not clean the medical device with steel wool or abrasive cleaning products.
Do not use solutions containing iodine or with a high chlorine content.
The pH of the detergents and disinfectants must be between 7 and 11.
Contaminated or used devices cannot be placed in sterilisation box or cleaned in a machine.
The cleaning method for tips and files recommended by SATELEC, a company of Acteon group is manual or automatic.
All devices must be carefully cleaned and then undergo a final sterilisation before use.
The sterilization parameters are only valid for correctly cleaned devices.
Tips and files require special attention during cleaning.
During automatic cleaning, tips or files must be placed on suitable instrument holders or in small baskets to prevent them from being damaged during washing.
It is the responsibility of the end user to ensure that all equipment used to recondition SATELEC, a company of Acteon group products is properly installed, validated, maintained and calibrated.
When possible, use a washer-disinfector. Prevent the overloading of wash baskets during ultrasonic cleaning or in a washer-disinfector.

> Throughout the procedure, wipe away blood and debris to prevent it from drying on the surfaces.

> After the procedure, soiled devices must be covered with a damp cloth to prevent residue from drying. Soiled devices must also be separated from non-contaminated devices to avoid contamination of personnel or surroundings.

3.1 Precautions to be taken

At the end of the procedure, rinse, clean and disinfect the irrigation line.

- remove the perforator from the irrigation solution;
- immerse it in a container filled with an enzymatic or alkaline liquid;
- run the purge cycle on your medical device and allow the liquid to pass through the irrigation line for at least one minute;
- stop the purge cycle, then immerse the perforator in distilled or purified water;
- run the purge cycle for at least one minute to rinse the irrigation line;
- remove the perforator from the liquid and purge the line until all liquid has been removed ;
- wipe blood and debris from the tips or files to prevent them from drying on the surfaces;
- cover the tip or the file with a soft lint-free cloth dampened with purified water to prevent blood and debris from drying.

3.2 Cleaning cycle limits

Repeated packaging cycles involving manual washing have little effect on tips and files. End of service life is normally determined by wear and damage due to use.

3.3 Containment and transportation

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

3.4 Preparation for pre-disinfection

It is advisable to recondition devices as soon as possible after use. SATELEC, a company of Acteon group devices must be reconditioned within two hours of use.

Prior to cleaning and after each use, remove the tip or the file from the handpiece.

Prior to cleaning and after each use, remove the tip from the front of the handpiece and place it in the appropriate container. Its cleaning is subject to a different set of instructions.

- Remove the single-use or autoclavable irrigation line and the clips from the handpiece-cord assembly, if applicable. Their cleaning is subject to a different set of instructions. Always dispose of the single-use perforator and/or irrigation line.
- Disconnect the handpiece from the cord.
- Unscrew the nosepiece.
- Depending on the model, remove the optical light guide.
- Depending on the model, disconnect the LED ring from the handpiece by pulling on it gently.

4 Manual instructions

4.1 Pre-disinfection and cleaning – Manual method

> Equipment: soft brush, soft lint-free swab, lint-free cloth, syringe, pipette or water spray, alkaline cleaner, ultrasonic cleaner.

Minimum duration of step	Cleaning instructions
1 minute	Rinse the soiled device under cold running water. Use a soft-bristled brush, a swab or a lint-free cloth to remove most of the contamination. Use a syringe, a pipette or a water spray with an alkaline or enzymatic cleaning solution to rinse the tip cannulation.
10 minutes	Immerse the medical device in a freshly prepared alkaline cleaning solution in an ultrasonic cleaner for at least ten minutes. Adhere to the manufacturer's exposure time, concentration, water quality and temperature recommendations.
1 minute	Rinse the device under cold running water. Use a syringe, a pipette or a water spray to rinse the tip cannulation.
4 minutes	Wash and disinfect the medical device using an alkaline cleaning solution. Remove surface contamination using a soft brush or a swab. Wash the medical device in water to prevent contaminants from spreading into the air
1 minute 30 seconds	Rinse the medical device in deionised or purified water. Use a syringe, a pipette or a water spray to rinse the tip cannulation.
	Visually inspect the medical device. Repeat this procedure until the medical device is visibly clean. Perform a final rinse of the device using distilled or purified water. Dry the medical device using a soft lint-free cloth or medical grade clean compressed air

4.2 Sterilisation

Unless otherwise specified, non-sterile products can be resterilised using validated steam sterilisation methods (ISO 17665 or national standards). SATELEC, a company of Acteon group recommends the following:

Sterilisation exposure time	Sterilisation exposure temperature	Drying time
4 minutes	132 °C	15 minutes minimum and 20 minutes
18 minutes	134 °C	15 minutes minimum and 20 minutes
4 minutes	134 °C	15 minutes minimum and 20 minutes
3 minutes	134 °C	15 minutes minimum and 20 minutes

> Saturated steam sterilisation with pre-vacuum

The drying times vary from 15 to 60 minutes according to the following criteria:

- the type of packaging material, such as a sterile barrier system or rigid reusable containers;
- steam quality;
- device materials;
- total mass;
- steriliser performance;
- usual practices for the geographical area;
- varying cool-down times.

> The manufacturer accepts no responsibility for sterilisation procedures performed by the end user or the customer that are not performed according to the manufacturer’s recommendations.

4.3 Inspection

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

4.4 Packaging

Use suitable packaging or a rigid reusable container for sterilisation; the sterile barrier system must comply with ISO standard 11607. Prevent any contact between devices and other objects that could damage their surface or the sterile barrier system.

4.5 Storage

Storage conditions are printed on the packaging label. Packaged products should be stored in a clean, dry environment, protected from direct sunlight, pests, humidity and extreme temperatures. Use products in the order in which they are received First in, First out, taking into account the expiry date indicated on the label.

5 Automatic Instructions

5.1 Pre-disinfection and cleaning – Manual method

> The manual pre-disinfection/pre-cleaning method must be performed prior to the automatic cleaning.

> Equipment: soft brush, soft lint-free swab, lint-free cloth, syringe, pipette or water spray, alkaline cleaner, ultrasonic cleaner.

Minimum duration of step	Cleaning instructions
1 minute	Rinse the soiled device under cold running water. Use a soft-bristled brush, a swab or a lint-free cloth to remove most of the contamination. Use a syringe, a pipette or a water spray with an alkaline or enzymatic cleaning solution to rinse the tip cannulation.
1 minute 30 seconds	Wash and disinfect the medical device using an alkaline cleaning solution. Remove surface contamination using a soft brush or a swab. Wash the medical device in water to prevent contaminants from spreading into the air
1 minute	Rinse the device under cold running water. Use a syringe, a pipette or a water spray to rinse the tip cannulation.
10 minutes	Immerse the medical device in a freshly prepared alkaline cleaning solution in an ultrasonic cleaner for at least ten minutes. Adhere to the manufacturer's exposure time, concentration, water quality and temperature recommendations.
1 minute 30 seconds	Rinse the medical device in deionised or purified water. Use a syringe, a pipette or a water spray to rinse the tip cannulation.
	Visually inspect the medical device. Repeat this procedure until the medical device is visibly clean. Perform a final rinse of the device using distilled or purified water. Dry the medical device using a soft lint-free cloth or medical grade clean compressed air

5.2 Cleaning, automated method

Step	Minimum duration	Cleaning instructions
Pre-washing	2 minutes	Cold tap water
Washing	10 minutes	Warm tap water, hotter than 40°C. Use an alkaline cleaning solution
Neutralisation	2 minutes	Warm tap water (40°C), with neutraliser if necessary.
Rinsing	2 minutes	Distilled or purified water, hotter than 40°C
Drying	40 minutes	At a temperature of 90°C.

5.3 Thermal disinfection

Thermal disinfection at 90°C for at least five minutes.

5.4 Sterilisation

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> Saturated steam sterilisation with pre-vacuum

The drying times vary from 15 to 60 minutes according to the following criteria:

- the type of packaging material, such as a sterile barrier system or rigid reusable containers;
- steam quality;
- device materials;
- total mass;
- steriliser performance;
- usual practices for the geographical area;
- varying cool-down times.

> The manufacturer accepts no responsibility for sterilisation procedures performed by the end user or the customer that are not performed according to the manufacturer's recommendations.

5.5 Inspection

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

5.6 Packaging

Use suitable packaging or a rigid reusable container for sterilisation; the sterile barrier system must comply with ISO standard 11607. Prevent any contact between devices and other objects that could damage their surface or the sterile barrier system.

5.7 Storage

Storage conditions are printed on the packaging label. Packaged products should be stored in a clean, dry environment, protected from direct sunlight, pests, humidity and extreme temperatures. Use products in the order in which they are received First in, First out, taking into account the expiry date indicated on the label.

6 Regulations and standards

6.1 Manufacturer identification

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CE 0459
CE Marking

7 Index

8 Glossary

A

Active implantable device

Active implantable medical devices are devices which are designed to be wholly or partially implanted in the human body or located in a natural orifice, and that require the supply of electricity or another energy source to operate correctly other than energy that is directly generated by the human body or gravity. (Public Health Code L.5211-1)

alcohol wipe

disposable wipe soaked in an alcoholic solution designed to disinfect medical devices

autoclave

container with thick walls and hermetic seal designed to steam sterilise under a pressure of several bars. For an item to be considered sterile, the theoretical probability of isolating a germ must be less than 1 in a million. This is the sterility assurance level (SAL) stipulated in standard EN 556.

C

cleaning

essential pre-conditioning step to remove contamination through the physical-chemical action of a suitable product such as a detergent, combined with a mechanical action to ensure that the medical device is fully operational and clean. After cleaning, the cleanliness of the medical device components should be checked in addition to the cleanliness of the reassembled medical device. It is also important to make sure there is no damage likely to impact the safety, integrity or correct operation of the device

D

disinfection

voluntary and momentary removal of some germs to stop or prevent an infection, risk of infection or secondary infection by unwanted or pathogenic viruses or micro-organisms.

E

expiry date

date up to which the medical device can be used. After this date, the medical device will need to be resterilised

I

Implantable device

Any device designed to be completely implanted in the human body or to replace an epithelial surface or the surface of the eye, during a surgical procedure and to remain in place after surgery. An implantable device also incorporates any device designed to be partially implanted in the human body during surgery and that is intended to remain in place after the surgical procedure for a period of at least thirty days. (directive 93/42/EEC)

M

Medical device

A medical device is any instrument, device, item of equipment, material or product, excluding products of human origin, or any other item used alone or with another item, including accessories and software required to ensure correct operation of the medical device, designed by the manufacturer to be used on humans for medical purposes and of which the main desired action is not obtained using pharmacological or immunological means or metabolism, but whose

function may be aided by such means. Software designed by the manufacturer to be specifically used for diagnostic or therapeutic purposes also constitutes a medical device. (Public Health Code L.5211-1)

O

operator
practitioner using the medical device during a treatment

P

practitioner
medically qualified person responsible for buying and operating the medical device

pre-disinfection
initial treatment to be performed on contaminated objects and equipment in order to reduce the number of micro-organisms and to facilitate subsequent cleaning. It is important to prevent residue from drying on the equipment. The other purpose of pre-disinfection is to protect personnel during the handling of instruments and to protect the environment. It is performed as soon as possible after use of the medical device within the vicinity of the place of use, prior to cleaning and in accordance with a procedure validated by the quality assurance system manager. The bactericidal, fungicidal and virucidal activities of the products used are determined in accordance with standards in force. These products are compatible with the medical devices to be handled and do not contain any substance known to be able to bind proteins

pre-vacuum
forced extraction of air from inside the autoclave sterilisation chamber

S

sterilisation
process used to kill potentially infectious viable or revivable germs in medicines or on medical devices. By definition, the sterility of a medical device is determined by a 1 in 1,000,000 probability of finding a viable or revivable germ on (or in) a product

U

ultrasonic tank
or ultrasonic cleaning. Rapid part cleaning or product dissolution procedure using the mechanical effect of ultrasonic waves

user
practitioner using the medical device to perform a clinical procedure. Also called operator

W

washer-disinfector
device designed to clean and disinfect batches of surgical instruments, anaesthetic accessories, earthenware, utensils, glassware and similar items. Generally works by washing with a detergent, thermally disinfecting and drying, sometimes by means of vacuum

CE Marking 0459 Instructions | tips and files | J02001 | V4 | (13) | 09/2017 | RB01EN010D

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