Cleaning and sterilisation protocol

Handpiece-piezotome cord assembly

ACTEON

This document is an English translation of the original French version.
Reference J12800 version V9 and drawing number RO42FR010I

Contents

1 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 bar. 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 temporary 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

2 Required information

2.1 Applicability

This protocol applies to the Piezotome M+ handpiece and Cube LED, Piezotome LED, Piezotome I handpieces.

2.2 Inspection

- 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.

2.3 Latest document update

03/2022

3 Documentation

This document contains the following information:

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

3.1 Associated documentation

This document must be used in association with the following documents:

Document title	References
Consulting electronic user instructions	J00007
Cleaning, disinfection and sterilisation instructions for keys	J81001
Cleaning, disinfection and sterilisation instructions for tips	J02001
Cleaning, disinfection and sterilisation instructions for the Handpiece-piezotome cord assembly	J12801
Piezotome Cube User Manual	J50101

3.2 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 `www.satelec.com/documents`

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.

4 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 the Piezotome handpiece-cord assembly 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.
Handpiece parts (depending on model: nosepiece, LED ring, light guide, cord grommet) require special attention during cleaning.
If the surface of the devices is damaged, ultrasonic cleaning may compound this damage.

> Only the handpiece nosepiece can be ultrasonically treated. The handpiece-cord assembly, the LED ring and the 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, 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.

4.1 Precautions to be taken

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

- remove the perforator from the irrigation solution;
- immerse it in a container filled with an enzymatic cleaner;
- 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;
- take the perforator out of the liquid and purge the line until all the liquid has been removed;
- wipe any blood and debris from the handpiece and cord to prevent them from drying on the surfaces;
- cover the handpiece with a soft lint-free cloth dampened with purified water to prevent blood and debris from drying.

4.2 Cleaning cycle limits

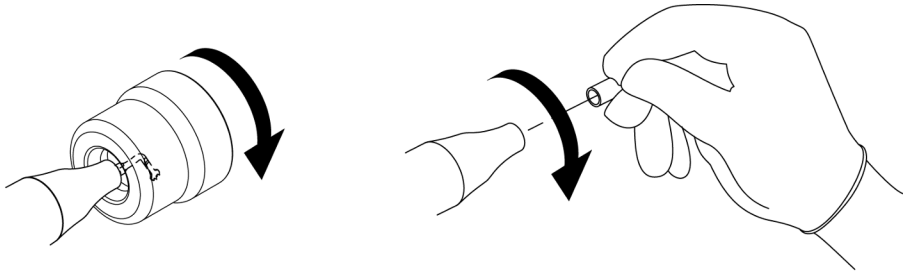
Repeated packaging cycles involving manual washing and sterilisation have little effect on the handpiece-cord assembly, the LED ring and the Piezotome light guide.
Repeated packaging cycles involving ultrasonic cleaning, manual washing and sterilisation have little effect on the nosepiece of the Piezotome handpiece.
End of service life is normally determined by wear and damage due to use.

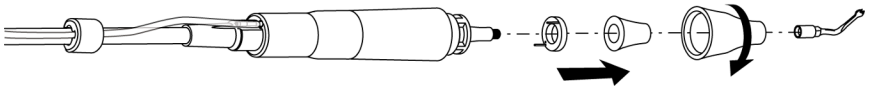
4.3 Containment and transportation

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

5 Preparation

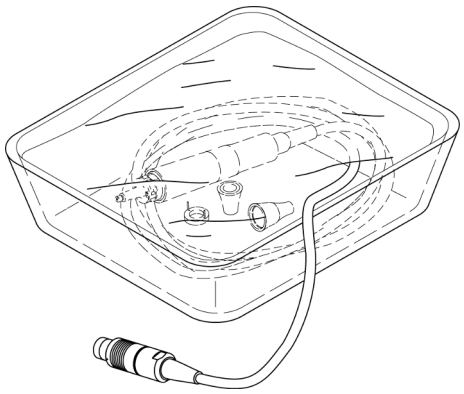
After use and before cleaning, unscrew the tip from the front of the handpiece and place it in the appropriate container. Its cleaning is subject to a different set of instructions.



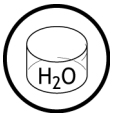
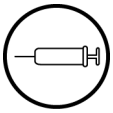


1. Remove the single-use irrigation line and the clips from the handpiece-cord assembly.
2. Dispose of the single-use irrigation line in a biomedical waste container.
3. Unscrew the nosepiece.
4. Remove the light guide.
5. Disconnect the LED ring from the handpiece by pulling on it gently.

Arrange the medical device as follows in the dipping stages.



6 Equipment

a tap on the osmosis-purified water circuit	 
a soft-bristled brush used to clean the exterior of the medical devices	
a single-use bottle brush, measuring 1.2 mm to 1.5 mm in diameter	
a single-use bottle brush, measuring 7 mm to 9 mm in diameter	
a single-use bottle brush, measuring 12 mm to 16 mm in diameter	
a syringe	
a dipping tank	
a pipette or water spray	
an enzymatic cleaner	

7 Manual instructions

Equipment	Minimum duration of step	Cleaning instructions
 	1 minute	Rinse the soiled device under cold running water. Remove most of the contamination with the soft-bristled brush and bottle brushes of a suitable diameter.
	1 minute	Rinse the handpiece lumen with a syringe filled with an enzymatic cleaner.
	10 minutes	Dip in a tank of enzymatic cleaner. - handpiece body - handpiece nosepiece - LED ring - optical guide
	1 minute	Rinse the device under cold running water.
		Rinse the handpiece lumen with a syringe filled with an enzymatic cleaner.
	3 minutes	In a fresh tank of enzymatic cleaner use the soft brush and bottle brushes to clean: - the handpiece body, and the screw thread in particular, - the handpiece nosepiece, and the screw thread in particular, - the LED ring, paying attention to the fragile connectors, - optical guide
		Visually inspect the medical device.
		Repeat this procedure until the medical device is visibly clean.
 	1 minute	Rinse the medical device in osmosis-purified, deionised or purified water.
		Visually inspect the medical device.
		Dry the medical device with a soft, lint-free cloth

8 Automatic Instructions

8.1 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, washer-disinfector, alkaline 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 handpiece cannulation.
2 minutes	Manually wash the device for at least 2 minutes in a freshly prepared enzymatic or alkaline cleaning solution. 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 handpiece cannulation. Adhere to the manufacturer's exposure time, concentration, water quality and temperature recommendations. Wash the medical device in water to prevent contaminants from spreading into the air.
1 minute	Rinse the device under cold to tepid running water for a least 1 minute. Use a syringe, a pipette or a water spray to rinse the tip cannulation.
15 minutes	Only the detachable handpiece nosepiece can be ultrasonically treated. Ultrasonically wash the nosepiece for 15 minutes in an enzymatic or alkaline cleaning solution.
2 minutes	Rinse the nosepiece under cold to tepid running water for a least 2 minutes.
1 minute 30 seconds	Rinse the medical device in deionised or purified water
	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

8.2 Cleaning, automated method

Step	Minimum duration	Cleaning instructions
Pre-washing	2 minutes	Cold tap water
Washing	5 minutes	Warm tap water, hotter than 40°C. Use an alkaline cleaning solution
Neutralisation	2 minutes	Warm tap water, hotter than 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.

9 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	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.

9.1 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.

9.2 Inspection

The devices must be inspected to check that they are not corroded, dulled, discoloured or damaged.
Inspect the sterile packaging. It must not show any signs of humidity. If humidity or water is present on or in the devices, clean and sterilise them again, leaving the devices to dry for longer.

9.3 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.

10 Regulations and standards

10.1 Manufacturer identification

SATELEC
A Company of the ACTEON Group
17, avenue Gustave Eiffel
ZI du Phare
33700 MERIGNAC
France
Tel. +33 (0) 556.34.06.07
Fax. +33 (0) 556.34.92.92
E-mail: satelec@acteongroup.com
www.acteongroup.com

CE 0459
CE Marking

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SATELEC | A Company of the ACTEON Group
17 av. Gustave Eiffel | ZI du Phare
33700 MERIGNAC | FRANCE
Tel. +33 (0) 556 34 06 07 | Fax. +33 (0) 556 34 92 92
satelec@acteongroup.com | www.acteongroup.com