Pre-disinfection, cleaning and sterilisation instructions

Optical guide

This document is an English translation of the original French version.
Reference J02940 version V5 and drawing number RG39FR060E

Contents

1 Documentation

This document contains the following information:

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

1.1 Associated documentation

Document title	References
Cleaning, disinfection and sterilisation instructions for the MINILED optical guide	J02941
Cleaning and disinfection instructions for the MINILED rigid protection shield	J05541
General instructions relating to the complete range of table curing lamps	J05102EN
Consulting electronic user instructions	J00007
MINILED ACTIVE User manual	J05271
MINILED STANDARD User Manual	J02541
MINILED SUPERCHARGED User manual	J02261EN
Cleaning and disinfection instructions for the MINILED flexible protection shield	J05551
MINILED ORTHO 2 User manual	J05221

1.2 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.

1.3 Latest document update

08/2018

2 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.

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.

2.1 Cleaning cycle limits

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

2.2 Containment and transportation

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

3 Manual instructions

3.1 Pre-disinfection and cleaning – Manual method

> Equipment: soft brush, soft lint-free swab, lint-free cloth, 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.
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
1 minute 30 seconds	Clean and disinfect the medical device for a least one minute 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
	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

3.2 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.

3.3 Inspection

Before being packaged, sterilised MINILED optical guides must be examined to ensure they are perfectly clean and to ensure they are not scratched or damaged. Damaged devices must be disposed of.

3.4 Packaging

Use suitable packaging. Acteon recommends packaging that is compliant with ISO standard 11607. Prevent any contact between optical guides and other objects that could damage their surface or the packaging.

3.5 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.

4 Automatic Instructions

4.1 Pre-disinfection and cleaning – Manual method

Equipment: soft brush, soft lint-free swab, lint-free cloth, 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.
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
1 minute 30 seconds	Clean and disinfect the medical device for a least one minute 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
	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 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, 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.

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- 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.

4.4 Thermal disinfection

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

4.5 Inspection

Before being packaged, sterilised MINILED optical guides must be examined to ensure they are perfectly clean and to ensure they are not scratched or damaged. Damaged devices must be disposed of.

4.6 Packaging

Use suitable packaging. Acteon recommends packaging that is compliant with ISO standard 11607. Prevent any contact between optical guides and other objects that could damage their surface or the packaging.

4.7 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.

5 Regulations and standards

5.1 Manufacturer identification

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CE

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7 Glossary

A

Active diameter
area of the effective optical cross-section of the LED light beam at the optical guide tip

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

F

Ferrule
metal ring placed on the end of the optical guide. Makes it easier to insert the optical guide into the handpiece nozzle and prevents the optical guide from rotating.

Flexible protection shield
available in 5.5 mm-diameter and 7.5 mm-diameter sizes. In contact with the patient, it must be sterilised by autoclave before and after each use. Previously called the cup

I

Irradiance
term used in radiometry to quantify the power of an electromagnetic radiation per unit area. It is expressed in watts per square metre. Often confused with the power of a light source

L

LED
electroluminescent diode, more commonly known as Led (light-emitting diode). Designates an optoelectronic component that allows the emission of monochromatic light

O

operator
practitioner using the medical device during a treatment

Optical guide
light conductor fitted to the handpiece nosepiece and transmitting light to the cure site. Is cleaned, disinfected and sterilised in an autoclave.

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

Protection plug
two plastic plugs used to protect the handpiece connectors and electronics during cleaning. One fits to the nosepiece and the other fits to the handpiece's electrical connectors

R

Rigid protection shield
removable oval shield forming an integral part of the handpiece once in place. Is cleaned with wipes. Not suitable for autoclaving

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

Wavelength peak
maximum amplitude of a wavelength spectrum

CE Instructions | optical guide | J02941 | V5 | (14) | 08/2018 | RG39EN060E

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