

General guidelines for machine reprocessing of Bausch & Lomb ophthalmologic instruments

Revision: 08.09.2005

1. General

All reusable instruments that are not marked as sterile, must be cleaned and sterilised before first-time use as well as after each use.

Note: Bausch & Lomb recommends **sterile single-use tubing systems as well as sterile single-use instruments** for all applications involving hard to clean medical devices.

In case additional instructions (e.g. referring to disassembling of instruments or use of cleaning adapters) for specific products are given in the instructions for use provided with the respective product, these are to be considered supplementary to these instructions.

2. Basics

The adherence to validated and consistent procedures in conformance with the applicable standards and regulations represent the basis for effective cleaning and sterilisation.

3. Cleaning/Disinfection

For effective processing, there must not be any delay between the end of the surgery, precleaning and processing in order to avoid that biological debris dry and bake on the instrument which would strongly reduce the cleaning effectiveness, especially for lumen instruments.

3.1. Pretreatment

Instruments with unobstructed lumen need to be flushed with potable water for 20 seconds with the aid of a water gun.

Verify that all lumina are unobstructed, otherwise repeat the process!

Optional:

Place instruments in an ultrasonic bath containing 1% enzyme cleaning solution at 35°-40°C for 15 minutes. Please note: due to the energy created in the ultrasonic bath, the temperature of the solution may rise. The temperature of the solution must not exceed 40°C, as this may result in a decreased cleaning effect of the enzymatic cleaning agent as well as denaturation of protein residues in the instruments. After this cleaning step, thoroughly flush all instruments with unobstructed lumina with de-ionised water. Make sure that no cleaning agents remain in the lumen in order to avoid causticisation of the eye.

* When using ultrasonic cleaning, ensure that the ultrasonic bath is not overloaded. Instruments should not be piled on top of one another. A silicone mat in the instrument tray may diminish the cleaning effect significantly. It must be ensured that the perforated instrument tray is placed in the area of maximum cleaning effectiveness. In most ultrasonic baths, this area is located approx. 35mm above the bottom of the sink. For medical instruments a bath with a frequency of approx. 31 kHz should be used. Please inquire with your ultrasonic bath manufacturer for further information. The quality of water should be at least equivalent to potable water. (refer to EN285).

The cleaning solution of the ultrasonic bath must be renewed at least once a day. As a high contamination level reduces the cleaning effect and promotes corrosion, a more frequent replacement of the cleansing solution may be necessary.

3.2. Machine Cleaning/Disinfection (Disinfector)

Equipment:

The disinfector should fulfill the requirements outlined in HTM2030 and EN ISO 15883 for general surgical and critical instruments.

It must have the adequate hubs and connectors for the instruments to be cleaned. We recommend a thermal disinfection in order to avoid residues which may occur with chemical disinfection.

The equipment must have a programme which is suitable for the instruments to be cleaned.

Only use distilled or de-ionised, sterile or low-germ (max. 10 germs/ml) water.

If air is used to dry the instrument, it should fulfill the requirements of hospital compressed air.

The equipment should be subject to regular maintenance and validation according to the regulation of operation and the instructions provided by the manufacturer.

Cleaning agent:

The cleaning agent must be approved for use with your equipment and for instruments. (Operator's manual of the equipment).

Usage and dosage instructions of the cleaning agent must comply with the instructions provided by the manufacturer.

Machine cleaning process:

- 1) Place the products in the disinfector basket or the perforated sterilisation tray according to the equipment manufacturer's instructions and fixate them, if necessary (ensure that they do not touch each other).

- 2) Connect any lumen instruments to the flushing adaptors of the disinfectant. Otherwise they will not be cleaned sufficiently.
- 3) Place the disinfectant basket or the perforated sterilisation tray correctly (refer to manufacturer's instructions) in the disinfectant. Do not exceed the maximum number of disinfectant baskets or perforated sterilisation trays.
- 4) Start the programme.
- 5) Remove the disinfectant basket or the perforated sterilisation tray with the products only after the programme has finished. In case the programme has not finished (malfunction), repeat the cleaning process. Make sure that no cleaning agents remain in the lumen in order to avoid causticisation of the eye. Lumen instruments (e.g. cannulas, handpieces) may have to be dried using compressed air.
- 6) Package the product or the perforated sterilisation tray immediately.

4. Sterilisation

Standardised steam sterilisation: 18 minutes at 134°C (fractionated vacuum evaporation).
Sterilisation periods of more than 18 minutes do not increase effectiveness.