

INSTRUCTIONS FOR USE
Reusable Irrigation/Aspiration Systems

INTENDED USE

Reusable irrigation/aspiration systems are used to administer solutions into the eye, and to extract/aspirate solutions and tissue debris in the anterior chamber from the eye during cataract surgery. Instruments are connected to the aspiration/irrigation system via standard Luer cones.

Reusable irrigation/aspiration systems must only be used by suitable qualified surgeons.

IMPORTANT USER INFORMATION

Insufficient flow behaviour can cause a fluid imbalance. We strongly recommend that you observe pressure ratios closely and adjust as necessary. This is essential to prevent a collapse of the anterior chamber. Bürki inno med AG refuses any liability whatsoever for the improper or incorrect handling of reusable irrigation/aspiration instruments.

MONOMANUAL (SL) / BIMANUAL SYSTEM

The **monomanual system** both irrigates solutions for the eye and extracts solutions and tissue residues from the eye in a **single instrument**. It can be operated with one hand. The instrument uses a standard flush Luer (female) and a standard aspiration Luer (male). It is connected to the aspiration/irrigation system via two standard Luer cones.

The **bimanual system** irrigates with solutions for the eye and extracts solutions and tissue residues from the eye via two independent handpieces. These are operated simultaneously with two hands. Each handpiece is colour-coded:

- Irrigation handpiece (female Luer) **BLUE**
- Aspiration handpiece (male Luer) **PURPLE**

They are connected to the aspiration/irrigation system via standard Luer cones.

WARNINGS/PRECAUTIONS (Observe packaging symbols with care.)

- Instruments must only be used by qualified, specialist personnel
- Instruments are not sterile when delivered. Before use, they must be cleaned, disinfected and sterilized.
- The cleaning and disinfection method must follow the **CLEANING AND MAINTENANCE** instructions exactly
- The use of reusable instruments that have not been cleaned and sterilized is strictly prohibited. This can cause dangerous postoperative eye infections.
- Never use instruments if their packaging is damaged.
- Inspect tips before use. Never use a product if the tip or any other part is damaged.
- The manufacturer bears no liability for any injury or damage suffered by a patient due to use of the product.
- **BIO 128/T**: this elliptical system features greater leak tightness at the edge of the cannula, resulting in far less outflow. The custom TWIN PORT design means that **irrigation** has the potential to significantly increase intraocular pressure. To prevent damage, e.g. any form of eye collapse, we strongly recommend lowering the height of the irrigation fluid bottle.
- The pressure ratio must be constantly monitored and adjusted (reduced) if necessary.

TECHNICAL SPECIFICATIONS

Settings	Specifications
Connectors	Standard Luer cone
Sterilization	Steam sterilization
Delivery condition	Not sterile
Quality Management System at Bürki inno med AG	EN ISO 13485

DISPOSAL

Devices must be disposed of according to local regulations. For further information, please contact your local environmental/public authority, or a qualified waste disposal company. Waste must therefore be recycled or disposed of:

- Without harming human health
- Without using any processes or methods that are harmful to the environment, specifically water, air, soil, flora or fauna
- Without generating noise or smells

LABELLING AND SYMBOLS ON DEVICES

	Item number		Product is not sterile
	Batch/lot number		See instructions for use
	ID number, number of notified body Representative/Importer		Manufacturer
	Bürki inno med GmbH, Im Schaffner 47/1, 69123 Heidelberg-Pfaffengrund, Germany		Flow direction

Reprocessing instructions, according to EN ISO 17664-1

Cleaning, disinfecting and sterilizing reusable devices by Bürki inno med AG

PRODUCTS

These processing instructions only apply to reusable products by Bürki inno med AG. To ensure that products can be cleaned in an autoclave, please read the Instructions for use.

INTRODUCTION:

All products must be cleaned, disinfected and sterilised before every use. This also applies the first time non-sterile products are used after delivery. Proper cleaning and disinfection is an essential prerequisite to sterilizing products effectively.

WARNING BEFORE REPROCESSING:

The user is responsible for product sterility and must ensure that:

- Only devices with the proper, validated methods are used for cleaning, disinfection and sterilization
 - All equipment used (washer-disinfector, sterilizer) is maintained and checked regularly
 - Validated settings are used for each cycle
 - Local legal provisions and the hygiene instructions for the hospital or institution are followed
- The original device packaging cannot be cleaned, disinfected or sterilized. Never use it to process the device.

1. CLEANING AND DISINFECTION

If possible, use an automated cleaning and disinfection method to clean and disinfect the products. Using a manual method is not recommended by the manufacturer and has not been validated. Only use a manual method if no automated method is available. In this case, please take into account the significantly lower performance and reproducibility of a manual method. If a manual cleaning and disinfection method is used, product- and process-specific validation is required, and is the responsibility of the user.

I. Pretreatment

Remove any visible contamination from the products directly after use on a patient using potable water and a soft brush (with 15 minutes of the surgical procedure ending at most).

WARNING

- Never use ultrasound treatment as a pretreatment
 - Never use fixing agents or hot potable water (temperature <40°C) during pretreatment
 - Check that the disinfectant/cleaning agent generally has been approved as effective. We recommend using e.g. Bomix Plus (an aldehyde-free disinfectant with cleaning properties) as a pretreatment.
- The disinfectant/cleaning agent must be suitable for instruments made of metal or plastic, and be compatible with the products (see "Material resistance"). Please note that any disinfectant/cleaning agent used during pretreatment is only for the safety of personnel. In no way can it replace the disinfection carried out after cleaning.

Method

1. Disconnect the product from the system.
2. Place the instrument in the soaking bath according to the manufacturer's instructions (**Bomix Plus**: the manufacturer recommends a solution of 2% for 5 minutes at maximum room temperature). Ensure the instrument is fully immersed in the disinfectant/cleaning agent and that there is no contact between instruments.
3. Remove the instrument from the pre-cleaning solution, flush the product under running potable water (at a temperature of <40°C) for at least 1 minute, then brush off any residue on the instrument with a soft brush.
4. Rinse the lumen from the aspiration/irrigation system at least three times with a syringe (minimum volume 50 ml) in the direction of flow. During this process, check the patency (flow) on the instrument.

WARNING

Any cleaning agent used must be:

- Suitable for cleaning metal or plastic instruments
- Compatible with the products (see "Material resistance")

Please refer to the instructions for any disinfecting/cleaning agents for information on concentration, temperature, soaking time and rinsing.

II Automated cleaning/disinfecting

The washer-disinfector must:

- Be certified for meeting performance requirements (e.g. CE marking according to EN ISO 15883 or DGHM approval)
 - Feature approved programs for thermal disinfection (A0 value ≥ 3000 or, for older devices, at least 5 min. at 90°C).
 - Have a suitable program for the products and include a sufficient number of flushing/rinsing steps
 - Only rinse with demineralized/deionized water
 - Only use filtered air for drying (oil-free, minimal contamination with micro-organisms and particles)
 - Be regularly maintained, inspected and calibrated
 - The washer-disinfector must be fitted with flush connectors for instruments with lumen (e.g. cannulae, handpieces).
- Adequate, reproducible flushing pressure must be confirmed through specific validation.

WARNING

When choosing a cleaning agent, please ensure it is:

- Suitable for cleaning metal or plastic instruments
- Compatible with the product (see the section "Materials resistance")

You must follow the manufacturer's instructions for the cleaning agent on concentration, temperature, soaking time and rinsing. Chemical disinfection should only be used when thermal disinfection is not available. Chemical disinfection may leave dangerous residues on the product. When using chemical disinfection, product- and process-specific validation is required, under the responsibility of the user.

Method

- 1a. Connect the instruments to the appropriate connectors on the washer-disinfector cart. (SL model: with tips installed). Make sure that the instruments do not come into contact with each other and, if possible, close any unused flush connectors.
- 1b. Connect the lumen instruments (e.g. handpieces) to the appropriate connectors on the washer-disinfector cart and, if possible, close any unused flush connectors. Use the adapter provided to properly connect the instruments to the washer-disinfector.
2. Start the program. The program sequence must include the following program steps:
 - Rinse for 1 minute with cold water at <40°C
 - Flush for 2 minutes with cold water
 - Wash for 10 minutes with 0.5% Neodisher MediZym at 45°C +/- 5°C
 - Flush for 1 minute with deionised water at <40°C
 - Flush for 1 minute with deionised water at <40°C
 - Thermal disinfection for 5 minutes at 92°C +/- 2°C
 - Dry for 30 minutes at 100°C (program settings)

3 After the program ends, disconnect and remove the instrument from the washer-disinfector. Instruments with lumen (e.g. cannulae, handpieces) may have to be dried further using filtered compressed air.

4. After cleaning/disinfection, all products must be checked for corrosion, damage, changes in colour and impurities for subsequent sterilization. The basic suitability of the products for effective automated cleaning and disinfection has been proven by an independent, state-accredited, recognized testing laboratory, using a Miele PG 8535 washer/disinfector, and using *Neodisher medizym* detergent and cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg), in accordance with the stated method.

5. Please package the cleaned, disinfected instruments in disposable sterilization packaging (individual packaging) that meets the following requirements (material/process):

- EN ISO 11607
- Can be steam sterilized (resistant to temperatures of at least 138°C (273°F), sufficient steam permeability)
- Offer sufficient protection to the products and the sterilization packaging from mechanical damage

WARNING

Never reuse damaged products (for the maximum number of reuse cycles, see "Reusability"). Visibly contaminated products must be cleaned and disinfected again.

No maintenance is required. Instrument oils must not be used.

III Sterilization

Only the following sterilization methods have been validated. Other sterilization methods must not be used.

Steam sterilization

- Method using 20 minutes of product drying and at least 3 pre-vacuum cycles.
- Steam sterilizer according to EN 13060/EN 285
- Validated according to EN ISO 17665-1
- Maximum sterilization temperature of 134°C (273°F); plus tolerance according to EN ISO 17665-1)
- Sterilization time (exposure time at sterilization temperature):

Area	Fractionated vacuum/dynamic air removal	Gravity displacement ¹
Germany	At least ² 5 minutes at 134°C (273°F)	Not recommended
Switzerland	At least ² 18 minutes at 134°C (273°F)	Not recommended
Other countries	At least ² 3 minutes at 132°C (270°F) / 134°C (273°F)	Not recommended

Sterilizer EHS 3870 Tuttnauer. The fundamental suitability of the products for effective steam sterilization using the fractional vacuum/dynamic air removal method has been proven by an independent/state-accredited testing laboratory. This took into account standard conditions in clinics and doctors' surgeries, and the specified method.

¹ The use of methods involving gravity displacement is not recommended: These require significantly longer sterilization times, and specific validation of the device, method, program, settings and products used. Any such validation is the responsibility of the user.

² Drying time required depends directly on a range of factors determined by the user (load configuration and density, sterilization conditions). Effective drying times must be determined by the user. Drying times of less than 20 minutes should not be used.

IV. Storage

After sterilization, store the products in the sterilization packaging, at room temperature and in a dry and dust-free location.

V. Materials resistance

You must ensure that the detergent/cleaning agent is an enzymatic cleaner, and that the detergent/cleaning agent or disinfectant does not contain any of the substances listed below:

- Organic, mineral and oxidizing acids (minimum pH value 5.5)
- Alkalis (maximum permissible pH value is 8.5, a neutral/enzymatic cleaner is recommended)
- Organic solvents (e.g. acetone, ether, benzene)
- Oxidants (e.g. peroxide)
- Halogens (chlorine, iodine, bromine)
- Halogenated aromatic hydrocarbons

WARNING

The product does not require corrosion inhibitors, which may leave potentially dangerous residues on the product.

Never use acid neutralizing agents or rinse aids, as these can leave potentially dangerous residues on the product. Never clean products with metal brushes, sharp instruments or steel wool. Never expose products to temperatures in excess of 138°C.

VI. Reusability

The products can be reused up to 51 times, if appropriate care is taken during processing and if they are undamaged and clean. The user is responsible for ensuring that the products are clean and working properly after processing. The manufacturer accepts no liability for the cleanliness or functionality of the product after processing. Monomanual system: Replace the silicone rings on all reusable systems that can be dismantled after approximately 10 cleaning/sterilization cycles.

Manufacturer

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