INSTRUCTION FOR USE
Reusable Irrigation /Aspiration Systems

INTENDED USE
The reusable irrigation / aspiration systems are intended to be used to deliver solutions to the eye and to extract solutions and residuals of tissue from the eye during cataract operations in the anterior chamber. The instruments are connected to the aspiration / irrigation system by standard Luer-cones.
The reusable irrigation / aspiration systems are intended to be used only by appropriately specialist surgeon.

IMPORTANT USER INFORMATIONEN
Insufficient flow conditions can cause an imbalance of the fluidics. It is strongly recommended to observe the pressure conditions and, if necessary, to adjust them. It is very important to prevent any collapse of the anterior chamber. Bürki inno med AG disclaims any liability for any inappropriate and incorrect handling of the reusable irrigation / aspiration instruments.

MONOMANUAL (SL) / BIMANUAL SYSTEM
Monomanual System combine the irrigation of solutions to the eye and the extraction of solutions and residuals of tissue from the eye **in one instrument**, which is operated with one hand.
The instrument has a standard irrigation luer (female) and a standard aspiration luer (male). It is connected to the aspiration / irrigation system by two standard Luer-cones.

Bimanual system separates the irrigation of solutions to the eye and the extraction of solutions and residuals of tissue from the eye into two independent handpieces which are operated simultaneously by two hands.
The different handpieces are colour coded:
- Irrigations-handpiece (female Luer) **BLUE**
- Aspirations-handpiece (male Luer) **VIOLET**

They are connected to the aspiration / irrigation system by two standard Luer-cones.

WARNINGS/ PRECAUTIONS (Regard packaging symbols, too.)
- The instruments are only to be used by qualified professionals
- The instruments are delivered unsterile. They need to be cleaned, disinfected and steriled prior to every use
- The cleaning and disinfection procedure has to be done according the **CLEANING AND MAINTENANCE instructions**
- The use of uncleaned and unsterile reusable instruments is strictly forbidden. This can lead **to dangerous post-operative infections of the eye.**
- Don't use the instruments if the packaging is damaged
- Prior the use, inspect the tips. Don't use the product, if the tips or other parts are damaged
- The manufacturer shall not be liable for any injury or damage suffered by a patient due the use of the product
- **BIO 128/T**; as elliptic system it has a higher impermeability on the edge of the cannula. This leads to substantial less efflux. In consequence, the **irrigation** has the potential of a substantially increase of the inner eye pressure due to the specific TWIN PORT design. To prevent any damage, e.g. any form of collapse of the eye, a reduced height of the irrigation liquid bottle is strongly recommended. Keep the pressure conditions in permanent observation and, if necessary, adjust (decrease).

TECHNICAL SPECIFICATION

Parameter	Specification
Connectors	Stanard Luer-cones
Sterilisation type	Steam sterilization
State of delivery	Non-sterile
Quality Management System of Bürki inno med AG	EN ISO 13485

DISPOSAL
The devices must be disposed according to local regulations. For further information, contact your local environmental or public office and appropriate waste disposal companies. In this regard, waste is to be recycled or disposed of:
- without danger to human health
- without using procedures or methods harmful to the environment, particularly to the water, air, soil, flora and fauna
- without creating noise or smell

DEVICE LABEL AND SYMBOLS

REF	Article number	NON STERILE	Product not sterile
LOT	Batch- / Lot Number		See instruction for use
CE 0297	ID number of notified body		Manufacturer
EC REP	Authorised representative Bürki inno med GmbH, Im Schaffner 47/1, 69123 Heidelberg-Pfaffengrund, Germany		Flow direction row

Processing instruction according to EN ISO 17664
Cleaning, disinfection and sterilization of Bürki inno med AG reusable devices

PRODUCTS
This processing instructions is valid only for reusable products of Bürki inno med AG. To ensure if the products are autoclavable, consult instructions for use.

INTRODUCTION:
All products shall be cleaned, disinfected and sterilized prior to each application. This is required as well for the first use after delivery of the unsterile products. Correct cleaning and disinfection is an indispensable requirement for an effective sterilization of the products.

WARNING BEFORE REPROCESSING:
The user is responsible for the sterility of the products and shall ensure that:
• only devices with appropriately validated procedures shall be used for cleaning, disinfection and sterilization
• the used equipment cleaning desinfaction device, sterilizer) must be maintained and checked regularly
• the validated parameters must be applied for each cycle
• attention is paid to the local legal provisions and the hygienic instructions of the hospital or institution
The original packaging of the device isn't compatible for cleaning, disinfection and sterilisation. Don't use this for processing of the device.

1. CLEANING AND DISINFECTION (WD)
If possible, an automated procedure cleaning desinfaction device should be used for cleaning and disinfection of the products. A manual procedure should only be used if an automated procedure is not available; In this case, the significantly lower efficiency and reproducibility of a manual procedure has to be considered. In case of application of a manual cleaning and disinfection procedure a product and procedure specific validation under responsibility of the user is required. The pre-treatment step is to be performed in both cases.

1.1. Pre-treatment
Visible contamination shall be removed in a distilled water from the products directly after on-patient use (latest 15min after end of operation).

WARNING
- Ultrasonic treatment must not be applied for pre-treatment!
- Don't use fixating detergent or hot water (temperature >40°C) during pre-treatment

Consider, that the cleaning detergents must be aldehyde-free, possess a fundamentally approved efficiency (for example VAH/DGHM approval or CE marking), be suitable for the disinfection of instruments made of metallic or plastic material and be compatible with the products (see chapter „material resistance„). Consider, that a disinfectant used in the pre-treatment step serves only the safety of the personnel, but cannot replace the disinfection step performed after cleaning.

Procedure
1. Disconnect the product from the system.
2. Attach the aspiration adapter for cleaning (included in delivery) to a syringe. Rinse the product for at least 1 min under running water (temperature < 35°C / 95°F).
3. Rinse the lumen of Aspiration and Irrigation system at least five times with a syringe (minimum volume 10ml) in flow direction.
4. Soak the product for the given soaking time in the pre-cleaning solution until the product is sufficiently covered. Pay attention that there is no contact between the products.
5. Assist cleaning by careful brushing of the outer surfaces of the products with a soft brush,
6. Remove the product of the pre-cleaning solution and post-rinse them at least three times intensively (at least 1min) with water.

WARNING
Select the cleaning detergent depending on following points:
• fundamental suitability for the cleaning of instruments made of metallic or plastic material
• compatibility of the cleaning detergent with the products (see chapter „material resistance„)
Refer to the instructions of the detergent manufacturer regarding concentration, temperature, soaking time and post-rinsing.
Only use:
• freshly prepared solutions
• sterile, low contaminated (max. 10 germs/ml) or low endotoxin contaminated water (max. 0.25 endotoxin units/ml), for example purified or highly purified water
• soft, clean and lint-free cloths and/or filtered air for drying

1.2. Automated cleaning/disinfection (WD)
Requirements regarding the WD:
• approved efficiency (for example CE marking according to EN ISO 15883 or DGHM approval)
• approved programs for thermal disinfection (A0 value ≥ 3000 or – in case of older devices – at least 5 min at 90°C / 194°F).
• suitability of the program for products as well as sufficient rinsing steps in the program
• post-rinsing only with sterile or low contaminated water (max. 10 germs/ml, max. 0.25 endotoxin units/ml), for example purified/highly purified water
• only use of filtered air (oil-free, low contamination with microorganisms and particles) for drying
• regularly maintenance, check and calibration
• The WD must be equipped with flush port connectors for instruments with lumen (e.g., cannulas, hand pieces). Their adequate and reproducible flush pressure must be confirmed by specific validation.

WARNING
Pay attention to following points during selection of the cleaning detergent:
• suitability for the cleaning of instruments made of metallic or plastic material
• compatibility of the used detergents with the product (see chapter „material resistance„)
The instructions of the detergent manufacturers regarding concentration, temperature, soaking time and post-rinsing must be followed. A chemical disinfection should only be used if a thermal disinfection is not available; in this case, dangerous residues may remain on the product. In case of application of a chemical disinfection procedure a product and procedure specific validation under responsibility of the user is required.

Procedure
1. First, check that instruments are not clogged.
2. Put the products in the cleaning desinfaction device (SL models: with tips mounted). Pay attention that the products have no contact to each other.
3. Connect the lumen instruments (such as cannulas, hand pieces) to the rising connectors provided on the disinfector and, where possible, close rinsing connectors not in use. Use the supplied adapter to connect to the rising connectors.
4. The products must be placed in exact horizontal position.
5. Start the program.
6. Disconnect and remove the product from the cleaning desinfaction device after end of the program. Instruments with lumen (such as cannulas, handpieces) may require additional drying with filtered compressed air.
7. Check and pack the product immediately after removal (see chapters „check„, „maintenance„, and "packaging„, if necessary after additional post-drying at a clean place).
The fundamental suitability of the products for an effective automated cleaning and disinfection was demonstrated by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory by application of the WD G 7836 CD, Miele & Cie. GmbH & Co., Gütersloh, (thermal disinfection) and the pre-cleaning and cleaning detergent Neodisher medizym (Dr. Weigert GmbH & Co. KG, Hamburg) considering to the specified procedure.

1.3. Check
After cleaning/disinfection, all products shall be checked for corrosion, damaged surfaces, colour changes and impurities.
WARNING
Do not re-use damaged products (for limitation of the number of reuse cycles see chapter „reusability„). Visibly contaminated products shall be cleaned, disinfected and steriled again.

1.4. Maintenance
No maintenance is required. Instrument oils must not be applied.

1.5. Packaging
Please pack the cleaned and disinfected products in single-use sterilization packaging (single packaging), which fulfil the following requirements (material/process):
• EN ISO 11607
• suitable for steam sterilization (temperature resistance up to at least 138°C (273°F), sufficient steam permeability)
• sufficient protection of the products and the sterilization packaging from mechanical damage

2. Sterilization
Only the following sterilization procedures have been validated; other sterilization procedures shall not be used.
Steam sterilization
• fractionated vacuum/dynamic air removal procedure, at least three vacuum steps; [1] (with sufficient product drying[2])
• steam sterilizer according to EN 13060/EN 285
• validated according to EN ISO 17665
• maximum sterilization temperature 134°C (273°F; plus tolerance according to EN ISO 17665)
• sterilization time (exposure time at the sterilization temperature):

Area	fractionated vacuum/dynamic air removal	gravity displacement
Germany	at least 5 min[2] at 134°C (273F)	not recommended
Switzerland	at least 18 min[2] at 134°C (273F)	not recommended
other countries	at least 3 min[2] at 132°C (270°F) / 134°C (273°F)	not recommended

[1] Use of a gravity displacement procedure is not recommended: these require significantly longer sterilization times, as well as a specific validation of the device, procedure, program, parameter and products used. Such validation is the responsibility of the user.
[2] The required drying time depends directly on a number of factors under control of the user (load configuration and density, sterilizer conditions). Effective drying times are to be determined by the user. Drying times less than 20 min should not be used.

The fundamental suitability of the products for an effective steam sterilization was demonstrated by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory by application of the steam sterilizer HST 6 × 6 × 6 (Zirbus technology GmbH, Bad Grund) and the fractionated vacuum/dynamic air removal procedure. For this, typical conditions in clinic and doctor´s practice as well as the specified procedure were considered.

WARNING
Do not use any flash/immediate use sterilization. Do not use dry heat, radiation, formaldehyde, ethylene oxide and plasma sterilization.

3. Storage
After sterilization, store the products in the sterilization packaging at a dry and dust free place at room temperature.

4. Material resistance
Ensure that the below listed substances are not ingredients of the cleaning or disinfection detergent:
• organic, mineral, and oxidizing acids (minimum admitted pH-value 5.5)
• lyes (maximum admitted pH-value 8.5, neutral/enzymatic cleaner recommended)
• organic solvents (for example: acetone, ether, alcohol, benzine)
• oxidizing agents (for example: peroxide)
• halogens (chlorine, iodine, bromine)
• phenol
• aromatic, halogenated hydrocarbons

WARNING
Corrosion inhibitors are not necessary for the product and may leave potentially dangerous residues on the product.
Do not apply acid neutralizing agents or rinse aids as these may leave potentially dangerous residues on the product. Do not clean any products by the use of metal brushes, pointed instruments or steel wool. Do not expose any products to temperatures higher than 138 °C (280 °F)!

5. Reusability
The products may be re-used up to 51 times if appropriate care is given to their processing and if they are undamaged and clean. It is the user's responsibility to ensure that the products are clean and functioning correctly following processing. The manufacturer has no liability for the cleanliness and functionality of the product following processing.
Monomanual System: Change the silicon rings on all dismountable reusable systems after about 10 cleaning / re-sterilisation cycles

Manufacturer
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