INTENDED USE
The reusable irrigation / aspiration systems are intended to be used to deliver solutions to the eye and to extract solutions and residues 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 trained specialist operators.

IMPORTANT USER INFORMATION
Insufficient flow conditions can cause an irritation of the lacrimalics. 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 innomed AG disclaims any liability for any inappropriate and incorrect handling of the reusable irrigation / aspiration instruments.

MONOMONAL (SL) / BIMANUAL SYSTEM
Monomunal System
It contains the irrigation of solutions to the eye and the extraction of solutions and residues of tissue from the eye in one instrument, which is operated with one hand.

Bimanual System
It has a standard irrigation aspiration (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 residues of tissue from the eye into two independent handpieces which are operated simultaneously by two hands.

The different handpieces are colour coded:
- Irrigation-handpiece (female Luer) BLUE
- Aspiration-handpiece (male Luer) VIOLET

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

WARNINGS / PRECAUTIONS
(Regarding packaging symbols, too.)

The instruments are only to be used by qualified professionals.

The instruments are delivered sterile. They need to be cleaned, disinfected and sterilized 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-infective operations 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.

ISO 1287, as electrical system it has a higher impermeability on the edge of the cannula. This leads to substantial less reflux. In consequence, the irrigation has the potential of a substantially lower 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 is strongly recommended. Keep the pressure conditions in permanent observation and, if necessary, adjust (decrease).

TECHNICAL SPECIFICATION
Parameter

<table>
<thead>
<tr>
<th>Article number</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOT</td>
<td>See instruction for use</td>
</tr>
<tr>
<td>C027</td>
<td>ID number of notified body</td>
</tr>
<tr>
<td>EC REP</td>
<td>Manufacturer</td>
</tr>
</tbody>
</table>

Quality Management System of Bürki innomed AG .

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 way, waste may be recyled or disposed of:

- without danger to human health
- without using procedures or harmful to the environment, particularly to the water, air, soil, flora and fauna
- without creating noise or smell

DEVICE LABEL AND SYMBOLS

Processing instruction according to EN ISO 17664

Cleaning, disinfection and sterilization of Bürki innomed AG reusable devices

PRODUCTS
This processing instructions is valid only for reusable products of Bürki innomed AG. To ensure that the products are acceptable, 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 unpacked sterile instruments. Correct cleaning and disinfection is an indispensable requirement for an effective sterilization of the product.

WARNING BEFORE REPROCESSING:
The user is responsible for the sterility of the products and shall ensure that:
- only devices with appropriate instructions for use shall be used for cleaning, disinfection and sterilization
- only devices with appropriate disinfection 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 of the hygiene instructions of the hospital or institution.
The original packaging of the device isn’t compatible for cleaning, disinfecting and sterilization. Don’t use this for processing of the device.

1. CLEANING AND DISINFECTATION (W/D)
If possible, an automated procedure cleaning disinfection device should be used for cleaning and disinfection of the products. A manual procedure should 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.

1.1. Pre-treatment
Visible contamination may be removed in a distilled water from the products directly after patient-on-patient use (latest 15min after end of use). The products are to be stored at a dry and dust free place at room temperature.

WARNING
- Ultrasound treatment must not be applied for pre-treatment
- Irritation or burning sensation with or without discomfort is not to be expected 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.

Consider, that the cleaning detergents must be alkaline-free, possess a fundamentally approved efficacy (for example VAHD/GMPA 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 disinfector used in the pre-treatment step serves only the safety of the personnel, but cannot replace the disinfection step performed after cleaning.

2. WATER DISINFECTING
2.1. Automated cleaning/disinfection (WD)
2.2. Automated cleaning/disinfection (W/D)
2.3. Manual cleaning/disinfection (M/D)
2.4. Automated cleaning/disinfection (W/D) + sterilization
2.5. Automated cleaning/disinfection (W/D) + sterilization + packaging

WARNING
- Do not use chemicals or heat and other methods to disinfect a product that is not designed or approved for disinfection.
- Do not use heat or other methods to disinfect a product that is not designed or approved for sterilization.
- Do not use steam sterilization to sterilize a product that is not designed or approved for steam sterilization.
- Do not use chemical disinfection to disinfect a product that is not designed or approved for chemical disinfection.
- Do not use radiation sterilization to sterilize a product that is not designed or approved for radiation sterilization.

WARNING
- Do not use the products for treatment of the anterior chamber.
- Do not use the products for treatment of the posterior segment.
- Do not use the products for treatment of the cornea.
- Do not use the products for treatment of the conjunctiva.
- Do not use the products for treatment of the sclera.
- Do not use the products for treatment of the orbital tissues.
- Do not use the products for treatment of the eyelids.
- Do not use the products for treatment of the lacrimal sac.
- Do not use the products for treatment of the lacrimal ducts.
- Do not use the products for treatment of the lacrimal puncta.
- Do not use the products for treatment of the lacrimal fossa.
- Do not use the products for treatment of the lacrimal sac organs.
- Do not use the products for treatment of the lacrimal duct organs.
- Do not use the products for treatment of the lacrimal puncta organs.
- Do not use the products for treatment of the lacrimal fossa organs.
- Do not use the products for treatment of the lacrimal sac system.
- Do not use the products for treatment of the lacrimal duct system.
- Do not use the products for treatment of the lacrimal puncta system.
- Do not use the products for treatment of the lacrimal fossa system.
- Do not use the products for treatment of the lacrimal sac system.
- Do not use the products for treatment of the lacrimal duct system.
- Do not use the products for treatment of the lacrimal puncta system.
- Do not use the products for treatment of the lacrimal fossa system.