Instructions For Use

002
Accessory for bladder irrigation kits

TF-15.02-002

Lettix bv
medical supplies

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1 Contents

2 Manufacturer information

Manufacturer name: Lettix b.v.
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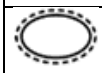
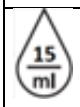
CE 0344

Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

3 Explanation of Symbols

	Indicates a medical device that has been sterilized using ethylene oxide
	Indicates a single sterile barrier system
	Indicates a single sterile barrier system with protective packaging outside
	Indicates that the fluid path is non-pyrogenic, ISO 7000-2723
	Indicated product is not in a sterile states
	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	Indicates a medical device that is intended for one single use only. Do not re-use
	Indicates a medical device that is not to be re-sterilized, this device is for Single Use Only.
	Indicates the manufacturer's catalogue number so that the medical device can be identified
	Indicates the manufacturer's batch code so that the batch or lot can be identified

	Indicates the item is a medical device
	Indicates a carrier that contains unique device identifier information
	Indicates the medical device manufacturer
	Indicates the date when the medical device was manufactured
	Indicates the entity distributing the medical device into the locale
	Indicates the date after which the medical device is not to be used
	Product contains or presence of DEHP
	CE mark including the number of the notified body
	Consult instructions for use
	Indicates a medical device that needs to be protected from moisture
	Keep away from sunlight, ISO 7000-0624

	Indicates the temperature limits to which the medical device can be safely exposed. Temperature limit, ISO 7000-0632
	Indicates the range of humidity to which the medical device can be safely exposed. Humidity limitation, ISO 7000-2620
	Indicates the number of drops per milliliter
	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences

4 General description

"Accessory for bladder irrigation kits" are non-active non-implantable devices for channeling liquids in and out of the body. This medical device has a risk classification **Is** and is a CE-marked device.

Bladder irrigation sets are Well Established Technology without a specific medical benefit.

Performance of the device is defined by its ability to serve as a fluid conduit. **Safety** of the device relates to the ability to maintain a closed system (no leak or ingress).

The following **technical** claims have been stated:

- Products are sold in packaging that maintains a Sterility Assurance Level (SAL) of 10-6.
- Fluid lines meet leakage and tensile strength requirements of the EN ISO 8536-4
- Products are manufactured using high-quality materials
- Products do not contain natural rubber latex

4.1 General warnings and cautions

Guideline on phthalates: As phthalates being marked as substances of concern, it is advised to limit exposure of products marked containing phthalates, to patient groups considered particularly vulnerable or exposed to high levels of phthalates such as, and including; paediatric population, peripubertal males, pregnant women, breast-feeding women.

In the event of the packaging being: 1) damaged; 2) unintentionally opened before use; and 3) if the packaging is exposed to environmental conditions outside of those specified, the device is not to be used and disposed of.

Re-use of single use devices can lead to the risk of cross contamination between patients.

Re-sterilization of single use devices can lead to a damaged devices.

4.2 Variants covered

This instruction for use is applicable to the following product variants:

Variant number	Variant name
9503152	Verlenglijn met spike, S
9512102	Blaasspoelsysteem 5L, S
9619142	Blaasspoelsysteem enkel, S
9641142	Blaasspoelsysteem enkel, S
9655142	Y Blaasspoelsysteem, S
9708152	Blaasspoelsysteem enkel, S
9768150	Curapharm systeem L=225cm
9797142	Y Blaasspoelsysteem, S

5 Intended use

5.1 Intended purpose

- Accessory for bladder irrigation kits.
- May not be connected to an active device of class IIa and higher.
- Not intended to be used for administering bodily fluids into the body.

5.2 Intended conditions of use

Non-measuring. This product family contains non-sterilized and sterilized products by the manufacturer.

5.3 Intended use environment

Hospital use.

5.4 Intended part of the body or type of tissue applied to or interacted with

Non-invasive use.

5.5 Intended user profile

The product is intended to be used by trained healthcare practitioners, such as doctors or nurses. This means the user has a high level of education and professional competence. No disabilities are expected.

5.6 Intended medical indication

Patients who need a bladder irrigation.

5.7 Intended patient population

It is advised to limit exposure of products marked containing phthalates to patient groups considered particularly vulnerable or exposed to high levels of phthalates such as, and including: paediatric population, peripubertal males, pregnant women, breast-feeding women.

6 Principles of operation and compatibility

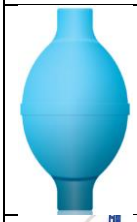
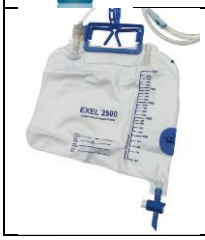
This is an accessory to perform a bladder irrigation with a non-active medical device. Liquids are transported via tubing by gravity. Luer locks are used to connect the tubing to an irrigation tool like a Cystoscope (female luer lock) or a catheter (silicon tube) and on the other side of the tubing to a liquid bag (spike) pump (female luer lock) or

Urine collection bag (included). Transfer can be controlled by a clamp or balloon. Y-connector allows the user to connect multiple irrigation liquid bags to the system, to ensure quick replacement of bags.

7 Identification of parts

Note: depending on the configuration of the accessory, different parts below are included. Not all accessories contain all parts identified below.

	Spike
	Clamp: roller
	Clamp: multistep
	Clamp: open/close
	Connector: luer locks
	Connector: barbed
	Connector: catheter

	Connector: Y
	Connector: Y + septum
	Flexible drip chamber
	Check valve
	Caps/protector
	Balloon
	Urine collection bag

8 Operating Instructions

Note: depending on the configuration of the accessory, different parts below are included. Not all accessories contain all parts.

8.1 Priming

Follow hygiene policy, safety practices and identification policy of the hospital. Do not allow the free end of the giving set to touch any non-sterile surface.

8.2 Spike

- Use protective gloves to prevent irritation from the leakage onto the hand of the operator.
- Take the liquid bag into non-dominant hand
- Remove the stopper from the spiking port of the liquid bag.
- Remove the cap from the spike, do not touch the sterile sections or allow them to come into contact with any non-sterile areas.
- Penetrate the spike into the spiking port while twisting back and forwards the spike.
- Make sure the spike is inserted as far as it will go, up to the raised ridge.

8.3 Roller Clamps

The primary function of a roller clamp is to control the flow rate of the fluid. The roller has two directions:

- Fully rolled up, flow rate is at its maximum.
- Roller halfway, the flow rate increased when the rolled up, and when it is rolled down, the flow rate goes down.
- Fully rolled down, the tubing is compressed, and the flow stops.

8.4 Multistep clamps

The primary function of a multistep clamp is to control the flow rate of the fluid. This clamp can be squeeze multiple times to narrow the tube, flow rate is compressed. The clamp can be released to set the flow rate at its maximum.

8.5 Open/Close clamps

The primary function of an open/close clamps is to control the flow rate of the fluid. Push the tube into the clamp to open or stop the flowrate.

8.6 Luer locks

The primary function of the luer locks is to make a leak-free connecting between tubing systems and medical- and Laboratory devices or other tubing systems. Luer locks has male- and female-taper fittings. Carefully connect the luer locks by pushing the female luer lock straight into the male luer lock using a clockwise, twisting motion. Tug gently to ensure the connection is secure. Visually inspect for damage before use. Do not try to insert at an angle or try to pry open the slit in the male luer lock.

Do not over tighten- may cause cracking of the luer and make removal difficult.

8.7 Catheter connection

The tube connector is used to connect leads in non-invasive applications.

8.8 Flexible drip chamber

During priming the system, filling the drip chamber prevents air from entering the tubing, the drip chamber allows gas to rise out from a fluid so that the air is not passed downstream.

Fill the drip chamber one-third to one-half full by gently squeezing the chamber.

The drip chamber also helps estimate the rate at which fluid is administered.

8.9 Y-connector (including septum)

Clean the access port with disinfectant swab before injecting prepared drug into the Y-connector including septum.

8.10 Balloon

Squeeze the balloon to help the fluid flow.

8.11 Urine collection bag

Waste bag with anti-reflux valve, Pasteur drip-chamber, antibacterial filter for internal pressure compensation, handle for patient ambulation and hooks for bed fixing.

8.12 Caps

Caps protect Luer locks connectors and spikes for contamination. Remove caps only according hospital procedures.

9 Cleaning / Disinfection / Disposal

Always dispose of blood contaminated products in a manner consistent with established biohazard procedures. Dispose according to applicable legislation and/or infection prevention standards for healthcare waste, to minimize potential risk of contamination, infection or pollution.

9.1 Sterilization instructions

Articles marked as non-sterile require sterilization before use. Ethylene Oxide (EO) sterilization must be conducted by trained personnel and shall comply with EN-ISO 11135 using the overkill approach (Annex B) with a sterility assurance level (SAL) of 10^{-6} (EN 556-1).

Devices must be packaged within a sterile barrier system (SBS) suitable with EO sterilization and compatible with the respective process parameters. The packaging system must meet the requirements of ISO 11607-1/2, allowing sterility to be achieved during the sterilization process and maintained throughout the product's shelf life. The processor is responsible for selecting and validating an appropriate SBS for the EO sterilization method. The packaging must be carried out under controlled environmental conditions to maintain product integrity. During handling of the article, the processor shall maintain environmental control to prevent contamination. The sterilization process parameters for EO, outlined below, have been validated in accordance with ISO 11135. However, the customer is responsible for validating their own sterilization process to ensure compliance with regulatory and operational requirements, as well as achieving a SAL of 10^{-6} considering their chosen SBS and the packaging levels.

CYCLE PARAMETERS	SPECIFICATION	DURATION
PRECONDITIONING		
Min. load temperature	5,8°C	-
Temperature	43-53°C	22-72h
Relative Humidity	45-75%RH	
STERILIZATION		
EO injection pressure increment	280-300 mbar	12-25 min
N2 injection pressure increment	200-220 mbar	6-12 min
Calculated concentration	478 mg/L	4:10-4:10h
Chamber temperature	45-51°C	
AERATION		
Transfer time to post-conditioning	-	0-300 min
Temperature	40-50°C	72-96h

Post-sterilization, the device's shelf life is determined by the shorter duration between the product intrinsic shelf life and the shelf life of the selected sterile barrier system.

Additionally, the processor is responsible for ensuring compliance with the residual levels defined for the article, as specified in ISO 10993-7.