Instructions For Use

003

Accessory for urologic procedures

TF-15.02-003

Lettix bv
medical supplies

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1 Contents

2 Manufacturer information

Manufacturer name: Lettix b.v.
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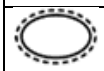
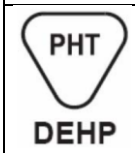
Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the Member State; (Inspectie Gezondheidszorg en Jeugd - FSCA)

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 state
	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

4 General description

"Accessory for urologic procedures" are non-active non-implantable devices channeling liquids into the body. This medical device has a risk classification **Is.**

Connecting tubing sets for urology are Well Established Technologies 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:

- Sterile products are sold in packaging that maintains a Sterility Assurance Level (SAL) of 10-6
- Product meets tensile strength and leakage requirements of EN ISO 8536-4.
- Products are manufactured using high-quality materials (e.g., biocompatible)
- 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
9037182	T.U.R. systeem, (275cm), S
9045152	Blaasspoelsysteem, S
9119152	Cystoscopiesysteem, S

9292142	Cystoscopiesysteem 011, S
9325152	Cystoscopiesysteem 012, S
9371152	T.U.R. systeem, S
9372152	Spoelsysteem urologie, S
9388152	Cystoscopiesysteem, S
9389132	TUR-systeem, S
9404152	Cystoscopiesysteem, S
9524142	Cystoscopiesysteem, S
9571192	Urologisch systeem voor ps, S
9604152	Cystoscopiesysteem enkel, S
9614142	Cystoscopieset LL 250cm, S
9615842	Cystometrieset LL 150cm, S
9616142	Spoelset, S
9617162	Terugslagklep met spike, S
9623142	Cystoscopiesysteem dr. kamer, S
9657152	Cystoscopie systeem enkel 160cm, S
9693152	Cystoscopie systeem enkel, S
9701142	TUR systeem enkel, 225cm, S
9747152	Urologisch spoelsysteem, S
9748132	T.U.R. Systeem, S
9781142	Cystoscopiesysteem L=260cm, S
9782152	Cystoscopiesysteem L=160cm, S
9792362	T.U.R. systeem dubbel, S
9799152	Cystoscopie systeem enkel, S
9804152	Cystoscopie systeem enkel, S

5 Intended use

5.1 Intended purpose

- Accessory for urologic procedures.
- May not be connected to an active device of class IIa and higher.
- Not intended to be used with bodily fluids.

5.2 Intended conditions of use

Sterile, non-measuring.

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 urologic procedure.

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.

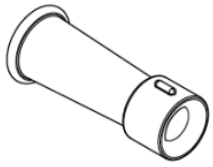
6 Principles of operation and compatibility

This is an accessory used during a urologic procedure with a non-active medical device. Liquids are transported via tubing by gravity. Adaptors are used to connect the tubing to a urologic tool like a Cystoscope (female luer lock) or Catheter (catheter connection or silicon tube connection) and on the other side of the tubing to a liquid bag (spike) or pump (female luer lock). Transfer can be controlled by a clamp or tap. 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: rotating
	Connector: catheter
	Connector: Y
	Connector: Y + septum
	Flexible drip chamber
	Check valve
	Funnel
	Two way tap/stopcock

	Caps/protector

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, whilst you are running fluids through the line.

8.2 Spike

- Use protective gloves to prevent irritation from the leakage onto the hand of the operator.
- Take the IV bag into non-dominant hand
- Remove the stopper from the spiking port of the IV 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 IV 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 IV tubing is compressed and the flow stops.

8.4 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 over tighten- may cause cracking of the luer and make removal difficult.

8.5 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.

8.6 Check valve

Prevents backflow into infusion line. This valve is not operatable.

8.7 Four-way tap / Stopcock

The valve is used to control the flow of the liquid and stops the flow when closed fully.

A 4-way stopcock allows for 360 degrees of rotation and has the states (shown below) for each of the four available positions. A 3-way stopcock has only three positions and has the first three states shown below.

- In the first state, liquid flows between points A and B.
- In the second, it flows between points A and C.
- In the third, it flows between points B and C.
- In the fourth state (4-way only), it flows between all three points.

8.8 Caps

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

9 Cleaning / Disinfection / Disposal

This medical device is single use only, when the product has been used or is contaminated it has to be disposed according to the hospital policy.

Always dispose of blood contaminated products in a manner consistent with established biohazard procedures.

9.1 Sterilization instructions

Articles marked as non-sterile require sterilization before use. Ethylene Oxide (EO) sterilization is to be performed conform EN-ISO 11135 using the overkill approach (Annex B) with a sterility assurance level (SAL) of 10^{-6} (EN 556-1).