Instructions For Use

001
Accessory for liquids infusion

TF-15.02-001

Lettix bv
medical supplies

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1 Contents

2 Manufacturer information

Manufacturer name: Lettix b.v.
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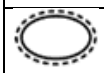
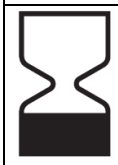
CE 0344

Note: 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
	Indicated product is not in a sterile state
	Indicates that the fluid path is non-pyrogenic, ISO 7000-2723
	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
	Gravity-feed infusion apparatus
	Pressurized infusion apparatus
	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
	Storage volume, ISO 8536-8
	Indicates the number of drops per milliliter

4 General description

"Accessory for liquids Infusion" are non-active non-implantable devices for administration and channeling of substances, including devices for dialysis. This medical device has a risk classification **IIa**.

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).

There is no direct **clinical benefit** for Infusion Sets. Clinical benefits related to the IV therapy/fluids are out of scope. However, infusion sets are a prerequisite for intravenous therapy. Therefore, infusion sets have an indirect clinical benefit by making intravenous therapy possible. Infusion sets allow the patient to benefit from the intravenous therapy benefits.

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 applicable parts of the ISO8536 standard.
- Products are manufactured using medical-grade 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. Please refer to chapter 4.2 for the product variants containing phthalates (DEHP).

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 is to be 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.

If articles marked as non-sterile are not sterilized prior to use it can lead to the risk of infection.

4.2 Variants covered

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

Variant number	Variant name	Sterile / non-sterile	Containing phthalates (DEHP)
9760182	Monitorlijn 1x3mm L=30cm,S	sterile	No
9761222	Monitorlijn 1x3mm L=180cm,S	Sterile	No
9762242	Monitorlijn 1x3mm L=200cm,S	Sterile	No
9763160	OS IV-set 240cm	Non-sterile	Yes
9764150	OS Contraset met bel	Non-sterile	Yes
9765150	OS IV-set met onbel.	Non-sterile	Yes
9766150	OS IV-set met bel spike	Non-sterile	Yes
9767100	OS Curapharm systeem MMB	Non-sterile	Yes
9769150	IV set met bel spike en	Non-sterile	Yes
9793102	Verlengslang 350cm,S	Sterile	No

5 Intended use

5.1 Intended purpose

- Accessory for the administration of liquids by gravity or with Infusion pumps.
- May 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-sterile variants must be sterilized prior use), 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 to receive liquid from an infusion system.

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 liquid infusion with a non-active or active medical device. Liquids are transported by means of a tubing. Luer locks are used to connect the tubing to an infusion needle (female luer lock) and on the other side of the tubing to an IV bag (spike) or pump (female luer lock). Transfer can be controlled by a clamp and or stopcock.

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
	Connector: luer locks

	Connector: rotating
	Connector: barbed
	Flexible drip chamber
	Check valve
	Four way tap/stopcock
	Caps/protector
	Filter

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 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.

Note: Spikes without an accompanying air inlet can only be used with collapsible plastic containers (e.g. IV bag) and not with rigid containers.

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

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.