Instructions For Use

005

Accessory for delivering radioactive pharmaceutical

TF-15.02-005

Lettix bv
medical supplies

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2 Manufacturer information

Manufacturer name: Lettix b.v.
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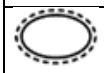
Website: www.lettixbv.com

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
	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

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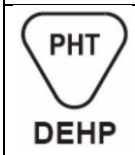
	Indicates the item is a medical device
	Indicates a carrier that contains unique device identifier information
	Indicates the medical device manufacturer
	Indicates the date when the medical device was manufactured
	Indicates the entity distributing the medical device into the locale
	Indicates the date 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

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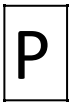
	Indicates the temperature limits to which the medical device can be safely exposed. Temperature limit, ISO 7000-0632
	Indicates the range of humidity to which the medical device can be safely exposed. Humidity limitation, ISO 7000-2620
	Cardiac floating (CF) applied part
	Pressurized infusion apparatus
	Storage volume, ISO 8536-8
	Not made with natural rubber latex
	Caution: Federal law (USA) restricts this device to sale by or on the order of a health care professional

4 General description

"Accessory for delivering radioactive pharmaceutical" are non-active non-implantable devices, tubing for channeling liquids or gases in the body. This medical device has a risk classification **IIa** and is a CE-marked device.

The product that is basically a Transfer Set and Infusion Sets without needle 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).

There is no direct **clinical benefit** for Accessory for delivering radiopharmaceuticals. Clinical benefits related to the IV therapy/fluids are out of scope. However, the disposable infusion sets for radiopharmaceuticals are a prerequisite for the IRIS injector (a closed drug reconstruction and transfer system) functioning. Therefore, the disposable infusion sets for radiopharmaceuticals have an indirect clinical benefit by making the use of the IRIS injector possible (providing fluid pathway).

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

- Products are sold in packaging that maintains a Sterility Assurance Level (SAL) of 10^{-6}
- Products meet the Comecer specifications for the IRIS injector disposables.

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- Products meet applicable parts of the ISO 8536-8 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.

In the event of the packaging being: 1) damaged; 2) unintentionally opened before use; or 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.

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)
9705172	Batch KIT IRIS, S	Sterile	Yes
9706152	Patient KIT IRIS, S	Sterile	No

5 Intended use

5.1 Intended purpose

- Accessory for delivering a prepared dose of radioactive pharmaceutical to the patient with IRIS
- 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-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.

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5.6 Intended medical indication

Patients who need to receive radioactive pharmaceutical.

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 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

	Spike
	Connector: luer locks
	Connector: barbed
	Connector: Y
	Check valve

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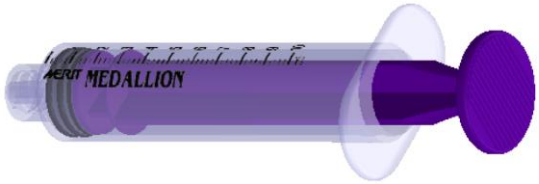
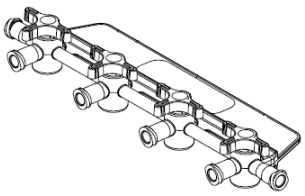
	Caps/protector
	Filter
	Injection syringe
	Needleless luer lock adaptor
	Chemfort syringe adaptor + Chemfort luer lock adaptor
	Manifold

8 Operating Instructions

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.

Check all luer connections and tighten if needed.

Check if double needles are parallel to each other before use.

Check for bubbles. The filter/flow needs to be checked before use by flushing the line with fluid.

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8.2 Spike

- Use protective gloves to prevent irritation from the leakage onto the hand of the operator.
- Close the roller clamp
- 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- this may cause cracking of the luer lock and make removal difficult.

8.5 Check valve

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

8.6 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.

8.7 Caps

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

8.8 Injection syringe

The injection syringe is controlled by the IRIS system.

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8.9 Barbed connector

To connect spike to fluid line and manifold.

8.10 Chemfort syringe adaptor + Chemfort luer lock adaptor

To connect Batch KIT IRIS and Patient KIT IRIS.

8.11 Double needle

The double needle is used to penetrate the septum and access the pots.

8.12 Manifold

The manifold is used for directional control of fluid flow and for providing one or more access ports for administration of solutions.

8.13 Needle-free connector

Swabable luer activated. For IV applications, mates with standard luerlock syringes and luel lock connectors

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

Not applicable. Products are sold sterile already and are for single use only.

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