

Instructions For Use

006

Accessory for aspiration

TF-15.02-006

Lettix bv
medical supplies

1 Contents

2	Manufacturer information	3
3	Explanation of Symbols	3
4	General description.....	5
4.1	General warnings and cautions.....	5
4.2	Variants covered	6
5	Intended use.....	6
5.1	Intended purpose.....	6
5.2	Intended conditions of use	6
5.3	Intended use environment	6
5.4	Intended part of the body or type of tissue applied to or interacted with	6
5.5	Intended user profile	6
5.6	Intended medical indication	7
5.7	Intended patient population.....	7
6	Principles of operation and compatibility	7
7	Identification of parts	7
8	Operating Instructions	8
8.1	Funnel.....	8
8.2	Luer locks	8
8.3	Big bore connector.....	8
8.4	Stopcock.....	8
8.5	Patient port adapter	8
8.6	Vacuum control adapter	9
8.7	Caps.....	9
9	Cleaning / Disinfection / Disposal	9
9.1	Sterilization instructions	9

2 Manufacturer information

Manufacturer name: Lettix b.v.

Telephone: +31 (0)55 522 46 65

Email: info@lettix.nl

Address: Prinsenweide 66, 7317 BC Apeldoorn, The Netherlands

Website: www.lettixbv.com



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 state
	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
	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 pressure, ISO 7000-1701

4 General description

“Accessory for aspiration” are non-active non-implantable devices, tubing for draining liquids and gases out of the body. This medical device has a risk classification **Is**.

Performance of the device is defined by its ability to serve as a fluid and gas 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 aspiration. However, the device provides an indirect clinical benefit by acting as a conduit for negative pressure (the tubing is a passive component that facilitates the action of the suction source), compliant with EN ISO 10079-4:2021. It enables the effective evacuation of bodily fluids, tissue debris, and gases across a wide variety of clinical applications. By meeting stringent requirements for collapse resistance under vacuum, kink resistance, biocompatibility, leakage and sterility the tubing set ensures an uninterrupted flow, which is a fundamental prerequisite for the safe and effective delivery of suction therapy, thereby contributing to positive procedural outcomes of suction.

The following **technical** claims have been stated in accordance to MDR article 7:

- Products are sold in packaging that maintains a Sterility Assurance Level (SAL) of 10^{-6} .
- Products are manufactured using medical-grade materials
- Products do not contain natural rubber latex
- Products meet applicable parts of EN ISO 10079-4 standard:
 - Products withstand a certain level of vacuum
 - Products are kink resistant
 - Products have leak proof seals
- Products use standards connector assuring connection to aspiration catheters/cannulas.

4.1 General warnings and cautions

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)
9365152	Zuigverbindingsslang, S	Sterile	No
9508122	Silicone slang 6x10mm L=2,77m	Sterile	No
9609142	ROVAC-Systeem 2m, S	Sterile	No
9637112	ROVAC-Systeem 3m, S	Sterile	No
9660142	Smoke evac. Verlengslang 1,5m incl. conn., S	Sterile	No
9703152	Extension cable 1,5m, S	Sterile	Yes
9722152	Verlengslang Big bore conn. MLL, S	Sterile	No
9753162	Afzuigslang Haemoband 7x10mm L=1,5m, S	Sterile	No
9783152	Zuigverbindingslang 6x9mm L=3m, S	Sterile	No
9784152	Zuigverbindingslang 5x8mm L=3m, S	Sterile	No
9811182	Vinyl Connecting tube, S	Sterile	No
9819242	Afzuigslang 12x15mm L=3m, S	Sterile	No
9826100	Con,tub,30cm drainbag-con, S	Sterile	No

5 Intended use

5.1 Intended purpose

Accessory for aspiration of fluids, bodily fluids and tissue, and gases.

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 drainage of body liquids, cells or tissues.

5.7 Intended patient population

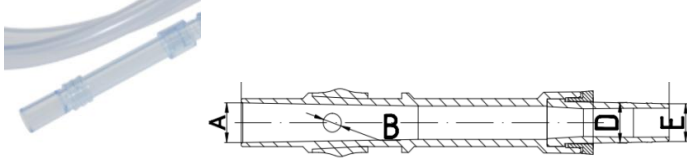
Non-specific identified. All age groups, weight ranges, types of health indications and conditions. No contra-indications and warnings are specified.

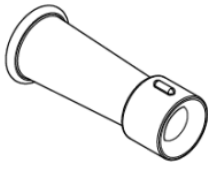
6 Principles of operation and compatibility

This is an accessory for aspiration device. Liquids, Body liquids, cells or tissues, or gases are transported by means of a tubing. Adaptors are used to connect the tubing to an aspiration device and on the other side of the tubing to a suction tool. Transfer can be controlled by a control adaptor.

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.

	Connector: luer locks
	Connector: patient port adapter
	Vacuum control adapter
	Connector: Y
	Connector: big bore

		2 way tap/stopcock
		Check valve
		Funnel
		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 Funnel

For temporary connection with medical instruments or devices

8.2 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.

8.3 Big bore connector

To connect a female big bore luer lock

8.4 Stopcock

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

8.5 Patient port adapter

Push the patient port adapter onto PATIENT port of VacSax liner. Should the adapter become blocked, replace connector and tubing.

8.6 Vacuum control adapter

The vacuum control adapter is used to control the suction force and flow.

8.7 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

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