Instructions For Use

006

Accessory for aspiration

TF-15.02-006

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

STERILE EO	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
NON STERILE	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
2 STERILIZE	Indicates a medical device that is not to be re-sterilized, this device is for Single Use Only.
REF	Indicates the manufacturer's catalogue number so that the medical device can be identified

LOT	Indicates the manufacturer's batch code so that the batch or lot can be identified
MD	Indicates the item is a medical device
UDI	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
PHT DEHP	Product contains or presence of DEHP
CE 0344	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.**

Suction tubing are Well Established Technologies without a specific medical benefit.

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).

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

- Products sold sterile are sold in packaging that maintains a Sterility Assurance Level (SAL) of 10-6.
- Products are manufactured using high-quality materials (e.g., biocompatible)
- Products do not contain natural rubber latex
- Products withstand a certain level of vacuum
- Products are kink resistant
- Products have leak proof seals
- Products use standard connectors 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
9365152	Zuigverbindingsslang, S
9508122	Silicone slang 6x10mm L=2,77m
9609142	ROVAC-Systeem 2m, S
9637112	ROVAC-Systeem 3m, S
9722152	Verlengslang Big bore conn. MLL, S
9783152	Zuigverbindingslang 6x9mm L=3m, S
9784152	Zuigverbindingslang 5x8mm L=3m, S
9811182	Vinyl Connecting tube, S
9819242	Afzuigslang 12x15mm L=3m, S
9660142	Smoke evac. Verlengslang 1,5m incl. conn., S
9703152	Extension cable 1,5m, S
9753162	Afzuigslang Haemoband 7x10mm L=1,5m, S
9826100	Con,tub,30cm drainbag-con, S

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

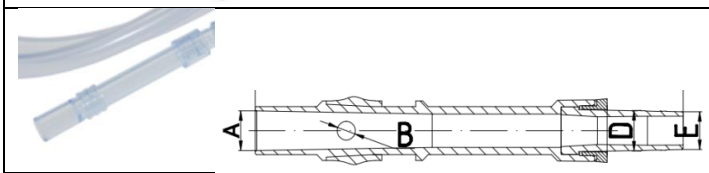
Non-specific identified. All age groups, weight ranges, types of health indications and conditions. No contra-indications and warnings are specified.

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

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.