

Puncture- and Drainage Kit (Veress Needle and Accessories)



Product description:

The Veress needle used in the Puncture- and Drainage Kit consists of:

- an external cannula with a sharp tip;
- an internal, retractable cannula with an open or rounded end;
- a Luer-Lock connection (female).

Syringes, taps, suction tubes and collection bags, for example, can be connected to this Luer-Lock connection (female), which may be included in the Puncture- and Drainage Kit depending on the design of the set.

The functional feature of the Veress needle is that the inner, atraumatic cannula retracts during puncture thanks to a damping device. After penetration during puncture and reaching the target area, the inner cannula returns to its original position. The inner cannula is also equipped with different opening typologies so that optimal suction and infusion can be achieved. In the rest position, the atraumatic part of the needle extends beyond the sharp tip, which provides more security against accidental punctures or injuries. The rear part of the needle has a transparent connector that allows the user to see the positioning of the tip at all stages of the operation and to reach the thoracic or abdominal cavity by means of a red indicator. Depth indicators are provided on the needle's external cannula at 1 cm intervals. The 5 and 10 cm indicators are marked in an even clearer way. To adjust the penetration depth, you can adjust the slide stopper on the external needle before inserting the device.

Content:

The Puncture- and Drainage Kit can consist of the following components:

- One Veress needle
- One syringe LL 50-60 ml
- One collection bag 2.0 ltr.
- One infusion line with 4-way stopcock
- One three-way stopcock
- One suction hose
- Possibly further components

Intended purpose:

The Puncture- and Drainage Kits are suitable for short-term (< 30 days) use during the aspiration of fluids from the thoracic cavity (pleural puncture) or from the abdominal cavity (paracentesis) and also

Technical Data Sheet

during the infusion of gas during laparoscopy. The Veress needle used in the Puncture- and Drainage Kit prevents perforation of the internal organs.

Indications:

- Aspiration of fluids from the thoracic cavity (pleural puncture)
- Aspiration of fluids from the abdominal cavity (paracentesis)
- Infusion of gas during an abdominal endoscopy

Contraindications:

- The Veress needle cannot be used in an MRI (magnetic resonance imaging) environment.

Intended user and patient target group:

Of particular importance are the processes in anaesthesia, intensive care and internal medicine, surgery and emergency medicine and for all other patients with the listed indications and where the user with the required qualifications considers this necessary.

Specifications

<i>REF</i>	<i>Catheter OD / Length</i>	<i>Catheter ID</i>	<i>Needle Length</i>	<i>Needle OD / ID</i>
Veress-Needle-Kit				
503 060	/	/	120 mm	2,0 mm
503 061	/	/	120 mm	1,8 mm
010 050	/	/	120 mm	2,0 mm

Also valid for kits with the addition E in the article number (the kits differ only in aspects of sterility)

Classification

Veress Needle: Class IIa

Rule 7

Kit: Sterile Procedure Pack according to article 12 of the Council Directive 93/42/EEC

UMDNS: 10-817

Packaging / Sterilization

The products are packed in peel away sachet.

The sterilization of the kits is done with ethylene oxide according to a method validated on the physical and microbiological level. The period of validity is 5 years starting from the date of sterilization.

Kits with the addition E in the article number are **non-sterile** and must be sterilized according to manufacturer's specifications for use.

Technical Data Sheet

Materials

a) veress needle:	
- stopper:	PEHD
- handle and red depth indicator:	ABS
- LLF connector:	PVC
- Protection tube:	PELD
- cannula (ext – int):	steel AISI 304
- spring:	steel AISI 302
b1) suction bag:	
- bag:	PVC
- tube:	PVC
- Connector:	PVC
- Cap:	LDPE, HDPE
- Push/Pull valve:	PVC, LDPE
b2) suction bag	medical PVC, DEHP
c1) syringe	
- barrel:	PP
- three-piece plungers:	pp (homopolymer)
- piston:	TPE
c2) syringe	PP
d) infusion tube with 4-way stopcock:	
- LL-adapter:	ABS
- protection cap:	HDPE
- tube:	PVC
- 4-way stopcock:	PC, PS, HDPE
e) stopcock	
- body:	PC
- core handle:	PC
f) connecting line for suction bag	PVC
- connectors:	PC, ABS

Applicable standards

DIN EN 20697:2018	DIN EN ISO 13485:2016
ISO 15223-1	DIN EN ISO 14971:2013
DIN EN 1041	DIN EN ISO 868-5:2019-03
DIN EN ISO 10993-1	DIN EN ISO 80369-7
DIN EN ISO 11135-1	DIN EN 556-1
DIN EN ISO 11737-1	

Technical Data Sheet

General

The quality of the products is guaranteed by inspections on all the levels of manufacturing. All our products are manufactured and packed in zone with controlled atmosphere.

Final control is made on the level packaging.

intra special catheters conforms to the requirements of the European Directive 93/42/EEC and maintains a Quality System in accordance with ISO 13485:2016 (CE 0044).