Spiegelberg:
Technology for brains

External Ventricular Drainage Kit	**EVD 30.001.01/FV800**
External ventricular drainage kit with plate and clamp	**EVD 30.004.01**
External ventricular drainage bag	**EVD 30.106.01**

Instructions for use

Content

Symbols used

REF	Article number		Do not use if package is damaged.
SN	Serial number		Upper temperature limit
STERILE EO	Sterilized using ethylene oxide		Attention!
	Do not re-use		Refer to instructions for use
	Do not re-sterilize		Use by
	Store in a dry place		Date of manufacture
	Keep away from sunlight		Manufacturer
CE 0297	Product complies with the requirements of European Directive 93/42/EEC		Information note

General information

The instructions for use must be read carefully before use. The product may only be used according to the described intended use. The manufacturer shall not assume liability or warranty for damage due to inappropriate use or noncompliance with the instructions for use.

The product is to be transported and stored dry. The following temperatures are to be maintained in order not to affect the product properties:

- Transport temperature: -25°C to +50°C
- Storage temperature; room temperature
- Ambient temperature during use: room temperature to 50°C

The product is intended exclusively for single use. Reprocessing can lead to destruction of the product or a change in product properties. Safe use is then no longer given.
The product is to be cleaned only with a cloth wetted with water and without cleaning additives.

If a pressure transducer is to be used, this must be connectable to a BF/CF input and remain connected over the entire period of application.

The EVD kit with plate and clamp (EVD 30.004.01) and the EVD bag (EVD 30.106.01) can be suspended via a cord (18). The stand clamp for EVD 30.004.01 is also intended for for fixation to an infusion stand with a maximum diameter of 31 mm.
Attention should be paid to adequate stability of the suspension device for fixation. The increasing weight due to drained cerebrospinal fluid is to be taken into account.

In the following, all three products are described as the EVD kit. If there are additions or exclusions for a product, then this is characterized by quoting the reference number. The addition of numbers

in brackets refers to illustrations of the products in these instructions for use. The term "proximal" means close to the patient for the EVD kits, and "distal" means removed from the patient.

Technical data

The values given reflect nominal values and may, if applicable, deviate.

REF / Order number	EVD 30.001.01/ FV800	EVD 30.004.01	EVD 30.106.01
Tube length	1900 mm	1900 mm	1675 mm
Volume drip chamber	100 ml	100 ml	-
Volume drainage bag	700 ml	700 ml	700 ml
Duration of use	short-term up to 30 days	short-term up to 30 days	short-term up to 30 days
Mounting option	Velcro fastener	Cord clamp	Cord
Cord length	-	1300 mm	350 mm
Measuring accuracy of the drip chamber	± 10 ml	± 10 ml	-

Original package contents

1 External ventricular drainage kit (except for EVD 30.106.01)
1 Drainage bag

Double packed
EO-sterilized
For single use

Tested accessories

EVD 30.101.02	Bag for external ventricular drainage kit
EVD 30.102.01	Filter for external ventricular drainage kit
	Pressure transducers designed according to PB22 and which are connected via a male Luer-Lock connector.

User group and environment

The EVD kit should only be used by persons with a completed medical qualification as well as having experience with neurological traumas (intensive care nurse).
The products are intended exclusively for use in professional healthcare institutions.

Indication and intended use

The EVD kit serves for the drainage and collection of cerebrospinal fluid (CSF) as well as other fluids with similar physical properties for the temporary reduction and control of cerebral pressure. Among other things, CSF drainage is indicated in traumatic brain injury, acute hydrocephalus, subarachnoid hemorrhage, a tumor or inflammation of the cerebrospinal space. It is intended for connection to a ventricle catheter with Luer-Lock connector.

The EVD kit EVD 30.001.01/FV800 consists of a male Luer-Lock connector for connection to the ventricular catheter (1), a tube connection to the drip chamber, a drip chamber (9) and a replaceable drainage bag (15). The tubing connection contains a puncture chamber (2) for withdrawing cerebrospinal fluid, two three-way stopcocks (3, 5), a pump chamber (6) and a check valve. The drip chamber is aerated with a replaceable microbe filter (7). Pressure transducers can be connected to the three-way stopcocks.

The EVD kit with plate and clamp (EVD 30.004.01) is designed similar to the EVD kit EVD 30.001.01/FV800, whereby the drip chamber (9) is mounted on the plate which is marked with a scale in mmHg (blue) and in cmH_2O (green). Dual coloring prevents confusing the scales. Furthermore, the plate is fitted with a clamp for fixation to an infusion stand and a suspension cord (18) with cord stopper (19).

The external ventricular drainage bag (EVD 30.106.01) consists of a male Luer-Lock connector for connection to the ventricular catheter (1), a tubing connection to the drainage bag and the drainage bag (15). The tubing connection contains a puncture chamber (2) for withdrawing cerebrospinal fluid, one three-way stopcock (10) for locking and a check valve. The EVD bag is fitted with a suspension cord (18) with cord stopper (19).

All tube connectors are permanently glued in place with exception of the filters (7, 13) for all products and the drainage bag (15) for EVD 30.001.01/FV800 and EVD 30.004.01.

Contraindication

The EVD kit may not be used for purposes other than those indicated. Use is always contraindicated in infections of the scalp, in patients receiving anticoagulant treatment as well in tendencies to bleeding. It is also contraindicated if continuous monitoring of the patient by trained personnel is not possible.

Warnings


Handling of the EVD kit is to be performed with care and caution.


Do not pull on the tubes!


Prior to first use, the EVD kit must be checked for leakage, loosened components and closed valves. If one of these criteria applies, the EVD kit must not be used.


Before changing a replaceable component, the corresponding stopcock or corresponding clamp is to be closed. Once the component has been replaced, the connection must be reopened.


Keep the EVD kit away from magnetic fields. It may not be used in the immediate vicinity of a magnetic resonance tomography scanner (MRT).


The EVD kit is to be protected from sunlight and to be kept away from radiation sources. Irradiation can lead to a deterioration of material properties and thus lead to functional failure.


An open, leaking or damaged system may not continue to be used and must be replaced. Otherwise there is a risk of overdrainage or an infection.


Pay attention to suspended tubes and cords. Tripping hazard! Clear suspended tubes and cords from the work field and make sure that the tube system is not pinched!


When transporting patients, care should be exercised to fixate the EVD kit such, that it cannot change its position even due to swinging. Should the EVD kit be transported in a supine position, the valve below the filter (8 or 20 for EVD 30.106.01) is to be closed to avoid contact of the cerebrospinal fluid with the filter membrane. If the product lies below the foramen of Monro of the patient during transport, the valve before the drip chamber (5) and before the drainage bag (10) is to be closed, otherwise there is a risk of overdrainage.


The filter (7, 13) must always be kept dry and replaced if necessary. After replacing the component, the stopcock (8 or 20 resp. for EVD 30.106.01) or the clamp (14) are to be opened again.


The intracranial pressure (ICP) is regulated via the height of the drip chamber (for EVD 30.106.01 via the drainage bag (15) with regard to the patient's foramen of Monro. The height of the product or the position of the patient's head should therefore only be changed by trained personnel and on instructions of a physician. In addition, the EVD kit should not be lifted above or below a given level to avoid over or underdrainage.


Regular checking of the correct height adjustment and secure fixation of the EVD kit is recommended. Accidental or intentional adjustment can lead to over or underdrainage. After every transport or move of the patient, the alignment and fixation should be checked and readjusted if necessary.

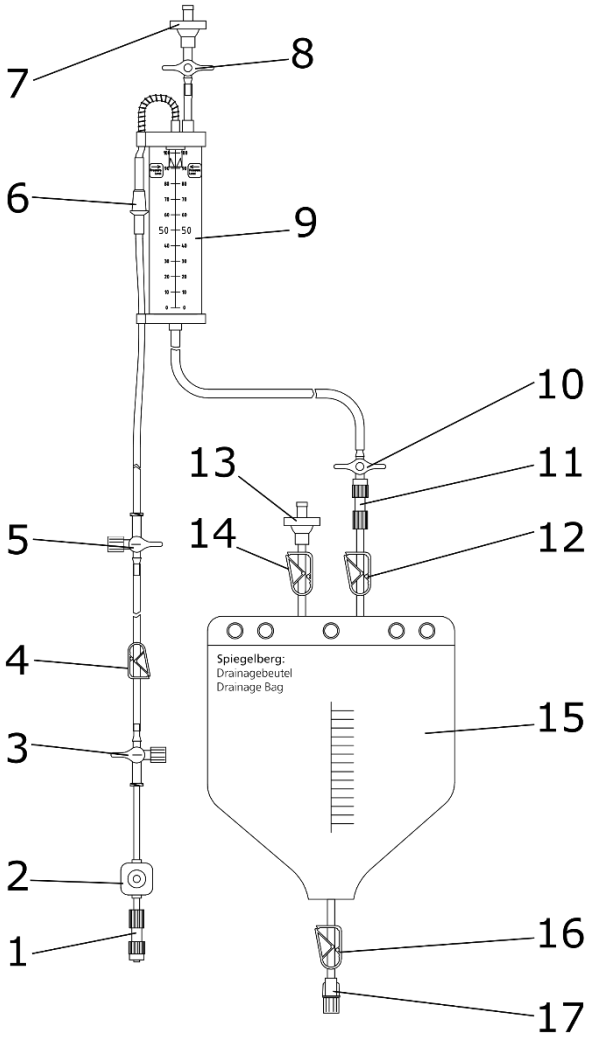
⚠ When using EVD 30.001.01/FV800 and EVD 30.106.01 attention should be paid to having a scale on the EVD holder or stand for graduating the cerebral pressure.

⚠ The EVD kit may not be tilted. If an inclined position cannot be avoided, then all stopcocks and clamps must be closed beforehand.

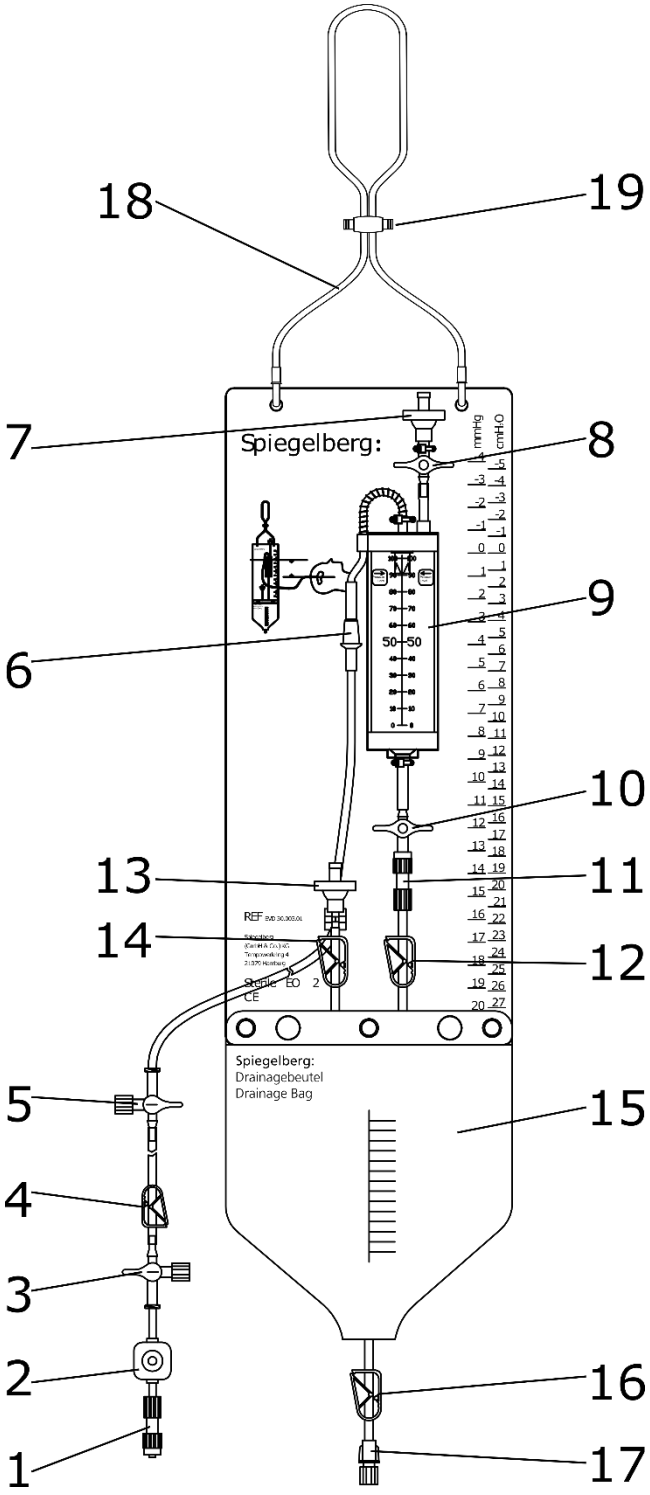
⚠ The ports (2, 3, 5) exclusively serve the purpose of initial rinsing and the withdrawal of cerebrospinal fluid. Any administration of medication or anesthetics is impermissible.

⚠ Check the connections regularly for leaks. In case of a leaking connection, there is a risk of overdrainage.

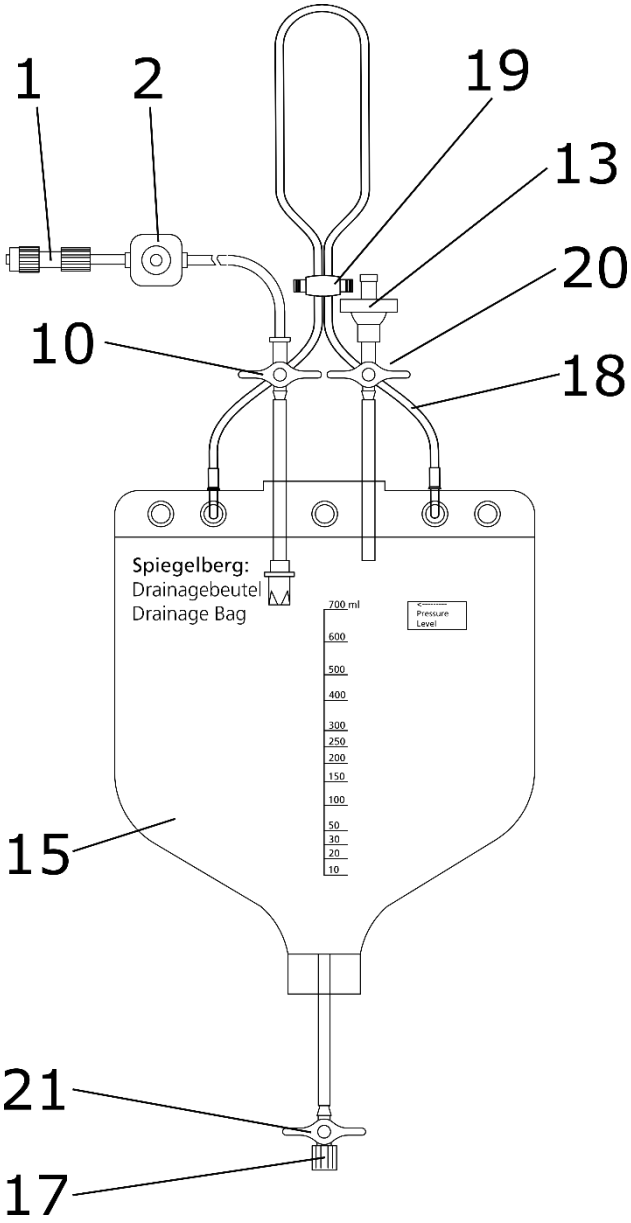
⚠ The filling height of the drip chamber (9) is to be checked regularly and the cerebrospinal fluid is to be drained regularly.



EVD 30.001.01/FV800



EVD 30.004.01



EVD 30.106.01

Application & handling

Attaching the EVD kit

The EVD kits EVD 30.001.01/FV800 and EVD 30.106.01 must be attached to a stand with a graduation scale to be able to use them in accordance with their intended use. Once the stand has been securely fixated as instructed by the manufacturer, the EVD kit can be attached via the Velcro fasteners (EVD 30.001.01/FV800) or the cord (18) to the drip chamber (9). In the case of the EVD 30.001.01/FV800, the drip chamber (9) can also be clamped into an existing drip chamber holder for fixation purposes. When attaching the EVD kit with the cord (18), the length of the cord can be adjusted via the cord stopper (19).
The EVD kit with plate and clamp can either be suspended via the cord (18) or attached to an infusion stand with the clamp provided on the rear.
Attention should be paid to using the loop which results between the cord stopper (19) and the product for attaching the EVD kit.

Setting the reference pressure

NOTE! Prior to first use, the valve below the drip chamber (10) or before the drainage bag (10) for EVD 30.106.01 is to be closed.

WARNING! If the EVD kit is placed too low, there is a risk of overdrainage. If the EVD kit is placed too high, there is a risk of underdrainage. One should therefore pay attention to a precise as possible setting of the reference pressure.

The intracranial pressure (ICP) is regulated via the height of the drip chamber (9 for EVD 30.106.01 via the drainage bag 15) with regard to the patient's foramen of Monro. The reference pressure stands for the desired maximum ICP and is adjusted via the "pressure level" markings on the drip chamber (9) and the drainage bag (15) respectively. To this purpose, the zero mark of the used EVD stand for the EVD 30.001.01/FV800 and EVD 30.106.01 is aligned to the height of the foramen of Monro and the reference pressure is set via the "pressure level" marking. In the case of the EVD 30.004.01, the relevant value for the reference pressure must be set to the height of the foramen of Monro.

NOTE! Pay attention to appropriate strain relief and safe suspension of the drainage bag (15) to prevent a change in height due to the increasing weight of the bag during drainage. This could otherwise led to overdrainage.

Preparing the tubing system

This section does not apply to the EVD bag EVD 30.106.01.

WARNING! Filling of the tubing system may only be done manually using a syringe to avoid injection at too high a pressure.

1. Fill a 20ml syringe with sterile isotonic saline solution.
2. Close the inlet to the drip chamber at the proximal stopcock (3).
3. Remove the cover cap at the proximal stopcock (3) and connect the syringe.
4. Rinse the short connecting piece up to the connection to the catheter (1).
5. Close the inlet to the catheter connection (1) at the proximal stopcock (3).

6. Rinse the tubing system up to the drip chamber (9). Check for leaks.
7. Ensure that the fluid flows from the drip chamber into the drainage bag (15).
8. Close the connection to the syringe at the proximal stopcock (3) and remove the syringe.
9. Close the proximal stopcock (3) with the cover cap.

NOTE! The puncture chamber (2) and the stopcocks (3, 5) may not be used for administering medication or anesthetics.

Connecting a pressure transducer

If a pressure transducer is to be used, this must be connected to the provided stopcocks (3, 5) according to the manufacturer's instructions.

Connecting to the catheter

Prior to connecting the catheter, the proximal stopcock (3 or 10 resp. in case of the EVD 30.106.01) must be closed.
After placing the catheter according to the manufacturer's instructions, the prepared EVD kit is connected to the catheter by joining the connectors with each other and closing the closure tightly.

Drainage of cerebrospinal fluid

WARNING! Prior to commencing drainage, pay attention to the correct setting of the reference pressure. Incorrect setting can lead to over or underdrainage of the patient.

To start drainage, the proximal stopcock (3) is opened. The correct placement of the catheter and the function of the EVD kit can be checked by the flow of the cerebrospinal fluid.
To collect the cerebrospinal fluid in the drip chamber (9), (not for the EVD 30.106.01), the stopcock below the drip chamber (10) must be closed.

WARNING! After withdrawal of the cerebrospinal fluid from the puncture chamber (2), check whether the system has remained leakproof. If the chamber (2) is not leakproof, the EVD kit is to be replaced as quickly as possible.

NOTE! If the patient's condition or the ICP do not change during application, then the flow of cerebrospinal fluid is to be checked.

WARNING! If there is no flow of cerebrospinal fluid during drainage, the correct alignment of the EVD kit and the setting of the stopcocks are to be checked. If necessary, the presence of cerebrospinal fluid in the patient must be checked.

Emptying the drip chamber

The EVD-Set EVD 30.106.01 is not fitted with a drip chamber, therefore this step is dispensed with.

WARNING! If cerebrospinal fluid has been withdrawn from the drip chamber (9), the proximal stopcock (3) must be opened again. Otherwise there is a risk of underdrainage.

WARNING! If the proximal stopcock (3) is not closed when withdrawing cerebrospinal fluid, this causes underpressure in the patient for a certain period (EVD 30.001.01: 18 mmHg for approx. 90 s; EVD 30.004.01: 12 mmHg for approx. 180 s), which leads to overdrainage.

1. Close the tubing system via the proximal stopcock (3).
2. Ensure that the stopcock of the filter above the drip chamber (8) and the clamp above the drainage bag (12) are opened.
3. Open the stopcock below the drip chamber (10).
4. Close the stopcock below the drip chamber (10) when the drip chamber has been emptied.
5. The proximal stopcock (3) may only be opened again 90 s (EVD 30.001.01) or 180 s (EVD30.004.01) after starting withdrawal.
6. Visual inspection of the system for leaks and function.

Changing the drainage bag

The bag of the EVD bag EVD 30.106.01 (6) cannot be changed. If this needs to be changed, a new product is required.

1. Close the stopcock below the drip chamber (10).
2. Close the clamps above the drainage bag (12) and before the filter (14).
3. Remove the old drainage bag (15) and connect the new drainage bag.
4. If applicable, open the stopcock below the drip chamber (10).
5. Visual inspection of the system for leaks and function.

Emptying the drainage bag

NOTE! A suitable collection device for the cerebrospinal fluid must be available for emptying the drainage bag (15).

1. Close the stopcock below the drip chamber (10) and the distal end of the tubing system (10) respectively. The stopcock (14) and the clamp below the filter (20) respectively must be open.
2. Opening the cover cap at the lower end of the drainage bag (17) and draining of cerebrospinal fluid.
3. Close the clamp (16) and the stopcock (21) below the drainage bag respectively.
4. Close the cover cap (17) and open the stopcock below the drip chamber (10) and the distal end of the tubing system (10) respectively.
5. Visual inspection of the system for leaks and function.

Transport or moving of the patient.

NOTE! Secure attachment of the EVD kit is to be ensured to avoid movement of the product (e.g. swinging).

WARNING! Prior to transporting the patient, the stopcock to the filter at the drip chamber (8) and the drainage bag (14) and the clamp respectively in case of the EVD 30.106.01 (20) must be closed, to prevent clogging of the filter through contact with the cerebrospinal fluid. This could lead to a loss of function and, depending on the next application step, to over or underdrainage.

NOTE! After transport or moving of the patient, the correct setting of the reference pressure must be checked and corrected if necessary. Especially after changing the position of the head, the EVD kit needs to be aligned again with regard to the foramen of Monro.

Transport:

The EVD kit can be transported both suspended upright as well as lying. However, it is recommended not to lay the EVD kit.

1. Close the proximal stopcock (3 or 10 resp. for EVD 30.106.01) as well as stopcock (8 or14 resp. for EVD 30.106.01) and the clamp (14) to the filters.
2. Check for secure attachment of the EVD kit.
3. Transport of the patient.
4. Check the fixation as well as the correct setting of the reference pressure, realignment of the EVD kit if necessary.
5. Open the stopcock (8 or 14 resp. for the EVD 30.106.01) and the clamp (14) to the filters.
6. Open the proximal stopcock (3 or 10 resp. for the EVD 30.106.01).
7. Visual inspection of the system for leaks and function.

⚠ **WARNING! After transport, the proximal stopcock (3 or 10 resp. for the EVD 30.106.01) must be opened again, otherwise there is a risk of underdrainage.**

Moving:

1. Close the proximal stopcock (3 or 10 resp. for the EVD 30.106.01).
2. Moving the patient.
3. Check the correct setting of the reference pressure, realignment of the EVD kit if necessary.
4. Open the proximal stopcock (3 or 10 resp. for the EVD 30.106.01).
5. Visual inspection of the system for leaks and function.

Replacing a filter

1. Close the proximal stopcock (3 or 10 resp. for the EVD 30.106.01).
2. Close the stopcock (8 or 14 resp. for the EVD 30.106.01) and the clamp (14) to the filters.
3. Replacing the filter (7, 13).
4. Open the stopcock (8 or 14 resp. for the EVD 30.106.01) and the clamp (14) to the filters.
5. Open the proximal stopcock (3 or 10 resp. for the EVD 30.106.01).
6. Visual inspection of the system for leaks and function.

Removing blockages in the tubing system

In case of clogging in the tubing system, the EVD kit should be replaced as a matter of principle. If this is not possible, the EVD 30.001.01/FV800 and EVD 30.004.01 have the option of removing blockages.

1. Identify the position of the blockage in the tubing system.
2. Close the connection to the patient via the proximal stopcock (3).
3. Inject sterile isotonic saline solution via the proximal (3) and distal stopcock (5) respectively.
4. If blockage persists: careful peristaltic pressing of the pump chamber (6). Then rinse the tubing section again up to the drip chamber with sterile isotonic saline solution.
5. Open the proximal stopcock (3).
6. Visual inspection of the system for leaks and function.

Disposal

After use, the product is disposed of in compliance with the regulations on infectious waste and according to the national or regional regulations.

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