EN - INSTRUCTIONS FOR USE

CSF Drainage

General information:

These instructions for use contain important information on the correct and safe application of the medical product. By means of these instructions for use, application faults as well as risks for the patient can be prevented. For this reason, these instructions for use shall have to be read carefully prior to application.
The product may be operated for the intended use only. However, the techniques described in these instructions for use are only a choice of the procedures which are medically possible. It shall remain left to the doctor and his own responsibility to carry out the individual application steps according to a technique he prefers.
The manufacturer shall assume no liability and/or guarantee for any damage caused by incorrect application and/or non-observation of the instructions for use.
If and when system faults occur, the manufacturer and/or the competent sales organisation shall have to be informed.
Do not use a product when the individual package is broken or dirty or if the product itself looks abnormal in any way. Use the product prior to the expiry date rendered on the packaging. Do not resterilise. This medical product is intended for single use only. If it is reused there is a danger that prions are transmitted (Creutzfeld-Jacob disease). The reprocessing methods described in the specialist literature destroy the medical product or cause significant changes in the characteristics of the product and a safe application can no longer be guaranteed. RAUMEDIC AG shall not assume any guarantee for expired or resterilised products.

Technical data:

For technical data, please refer to the label of the individual packaging.

Indication and medical purpose:

The external drainage and monitoring system can be used for temporal drainage of cerebrospinal fluids (CSF) in order to reduce and to control the intracranial volume and pressure, if the implantation of a permanent internal drainage is not indicated.

Contra-indications:

In case of scalp infections, the use of the drainage is not recommended, which also applies for patients who have been given anticoagulants or in whom a blood coagulation deficiency has been detected.

Caution notes:

- Caution. The measuring chamber may be fitted and applied vertically only.
- The product may be used only, if a 24-hour surveillance of the patient by trained medical experts is ensured.
- Prior to the first use of the system, all Luer lock connections have to be checked. The connections – injecting plug (1), bacteria filter (7), drainage bag (11) – may have come loose during sterilisation or transport.
- The intracranial pressure is controlled by the height of the measuring chamber (8) relative to the *foramen monroi*. **For this reason, it is extremely important that this height difference is retained even after a partial change of the head position.** The height of the drip chamber or the head position of the patient may be changed only by trained staff and upon instruction of the doctor.
- After activation of the drainage, changes of the position and level of the patient's head may have an influence on the intracranial pressure.
- When the measuring chamber is emptied, the patient line (3) always has to be closed by the injection three-port directional cock (2) (marked "CSF").
- When the patient is transported, the shut-off clip (6) below the bacteria filter (7) has to be closed in order to prevent a contact of the filter membrane with the liquor.
- The clear plastic components used in our products offer the advantage of visual flow channel monitoring. However, please note that with plastics such as e.g. polycarbonate (PC) or acrylonitrile butadiene styrene (ABS), contact with alcohol-containing disinfectants or lipids-containing solutions may under certain circumstances lead to stress cracks and ultimately to fluid leakage. All connections should therefore be regularly checked for leakage.
- Contact of parts made of PC or ABS with specific drugs like cytostatics and those containing alcohol or phenol may also under certain circumstances weaken materials. All connections should therefore be regularly checked for any leakage.

Indwelling time:

It is recommended to change the liquor drainage system after about four to five days as the ventriculitis risk increases distinctly in case of a longer period of indwelling (cf. Aschoff / Annecke, Neurochirurgie Heidelberg, 1996).

Notes on handling / initial operation:

(1) Attaching the measuring chamber

The measuring chamber has to be attached vertically to a bed-side infusion stand by means of the Velcro strips. If no non-slip attachment of the measuring chamber can be achieved on the stand, the measuring chamber has to be secured by suitable additional measures. Close the clip or stopcock below the measuring chamber before the first start-up!

Caution

When attaching the measuring chamber, the user has to ensure a suitable strain relief and/or safe suspension of the drainage bag so that the measuring chamber does not change the overflow position on account of the permanent weight increase of the drainage bag. As a consequence, life-threatening cranial pressure reductions may occur.

(2) Adjustment of the reference pressure level

The reference pressure (requested maximum ICP) is adjusted by moving the measuring chamber (8) on the infusion stand. The "Pressure Level" marking on the measuring chamber (8) is the highest point of the drainage system and determines the maximum ICP; for this reason, it has to be set to the requested distance to the *foramen monroi* (relative zero point of the drainage).

(3) Preparation of the drainage

Before the drainage system is connected up to the ventricle catheter, it can be filled with a sterile isotonic NaCl solution. By means of a 10 ml syringe the system is filled through the injecting plug (1) until no air bubbles can be seen in the patient line (3) between the catheter connection and the measuring chamber (8).
NOTE: In order to prevent artefacts, the system has to be free from air bubbles.
The drainage bag of the drainage system should be attached to the intensive-care bed by means of an attachment strap below the measuring chamber (8).

3.1 Catheter connection

After the catheter has been placed, the previously prepared drainage system is connected to the catheter observing the strictest sterile measures.
Caution: Before the measuring chamber (8) has not been set to the reference pressure, the injection three-port directional cock (2) (marked "CSF") must not be opened for drainage.

(4) Liquor drainage

After the correct height adjustment of the liquor drainage system, the drainage is activated by opening the injection three-port directional cock (2) (marked "CSF").

4.1 Emptying the measuring chamber

- Close the patient line (3) by means of the injection three-port directional cock (2) (marked "CSF").
- Observe the chamber contents with respect to liquor consistency and quantity.
- Open the tube clip (9) below the measuring chamber (8).

After emptying

- Close the tube clip (9) below the measuring chamber (8).
- Open the patient line (3) by means of the injection three-port directional cock (2) (marked "CSF").
- Visual inspection of the system.

4.2 Changing the drainage bag

- Close the tube clip (9) below the measuring chamber (8).
- Close the filled drainage bag by means of the clip (10).
- Fit a replacement bag (095424-001) observing the strictest sterile measures.
- Open tube clip (9) below the measuring chamber (8).
- Visual inspection of the system.

4.3 Head adjustment

- The patient line (3) has to be closed by the injection three-port directional cock (2) (marked "CSF").
- Readjust the reference pressure level (cf. section (2)).

- Open the patient line (3) by means of the injection three-port directional cock (2) (marked “CSF”).

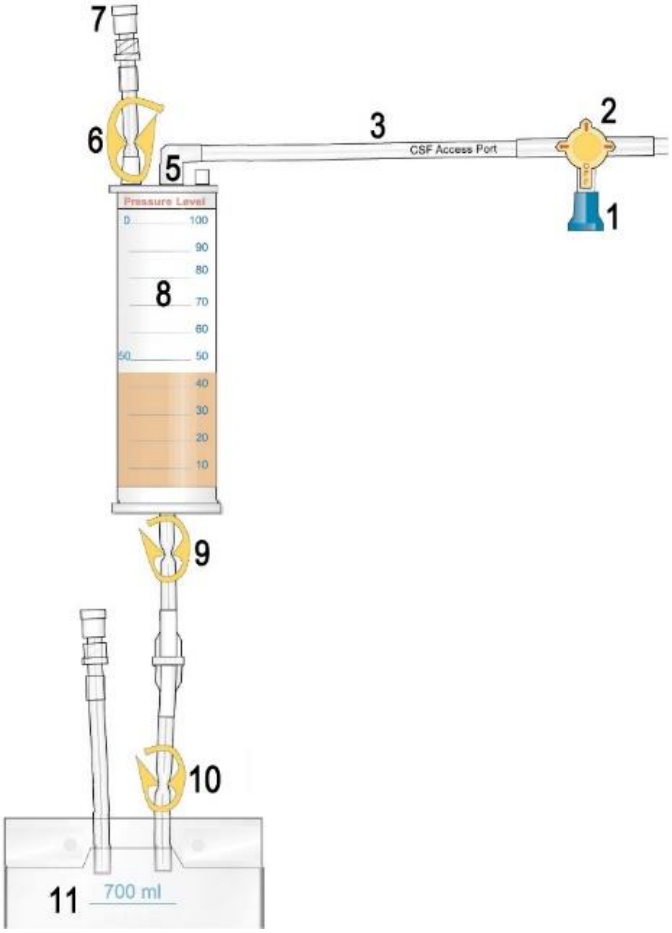
Disposal:

After use, the product has to be disposed of in keeping with the regulations on contagious waste and/or in keeping with the national / regional regulations.

Disclaimer of warranty:

RAUMEDIC® products are handled with extreme care during development, product parts selection, manufacturing and final testing prior to delivery. The responsibility for the suitability of the product used and for the correct employment shall be borne by the customer or user. Incorrect handling may lead to functional impairment which in turn could lead to damage and injury. RAUMEDIC® will not be responsible for any injuries of any type nor for any losses or damages, whether these be direct, indirect or consequential losses resulting from use of the product outside its intended medical use as described in the instruction manual. But other medical complications can also generally not be ruled out. Therefore no guarantee can be provided, nor can it be warranted or guaranteed that no functional faults or failures of the products will occur, that the body will not display an immune reaction.
The customer or user, respectively, shall be obligated to check the suitability for the intended purpose of application by suitable performance tests in particular. RAUMEDIC shall not assume any explicit or implicit warranty, guarantee or liability for the suitability for any purpose which exceeds the description of the article in these operating instructions. This shall also apply for the further processing of this article and for its use for the manufacture of other products. RAUMEDIC warranty terms shall apply exclusively.

CSF drainage



(1) Injecting plug
(2) Three-port directional injection cock
(3) Patient line
(5) Ball valve
(6) Transport lock (tube clip)
(7) Bacteria filter 0.2 µm
(8) Measuring chamber
(9) Tube clip
(10) Clip to close the drainage bag
(11) Drainage bag

Possible faults

Problem:	Potential cause:	Measures:
Insufficient liquor drainage.	Ventricle catheter is kinked or blocked.	▪ Remove kink. ▪ Use bacteria filter (0.2 µm) to carefully rinse the catheter, if and when necessary. ▪ Replace the catheter, if and when necessary.
	Drainage tube or ball valve (5) is blocked.	1. Close the three-port directional injection cock (2) to the patient. 2. Use sterile isotonic NaCl solution to rinse the system through the three-port directional injection cock (2) via the bacteria filter (0.2 µm). 3. Set the three-port directional injection cock (2) to the initial position.
	Bacteria filter (7) is closed.	▪ Open the transport lock (6) in front of the bacteria filter (7).
	Liquor in bacteria filter (7).	1. Close the patient line (3). 2. Empty the measuring chamber (8). 3. (If the filter has not emptied within two minutes, replace the filter using a replacement filter (095568-001).) 4. Set the cock to the initial position.
	Bacteria filter (7) is clumped up.	▪ Replace the filter using a replacement filter (095568-001).
Content of the measuring chamber does not run off.	Drainage tube is clogged below the chamber.	1. Close the patient line (3). 2. Close the transport lock (6) on the filter. 3. Open the tube clip (9) below the chamber. 4. Apply slight manual pressure on the measuring chamber (8) to remove the clogging. 5. Reset the tube clip (9) and the transport lock (6) to the initial position.
	Drainage tube is closed below the measuring chamber (8).	▪ Open the tube clip (9) below the measuring chamber (8).
	Bacteria filter (7) is clumped up or closed.	▪ Cf. “Insufficient liquor drainage”. ▪ Bacteria filter (7) is closed. ▪ Liquor in bacteria filter (7). ▪ Bacteria filter (7) is clumped up.