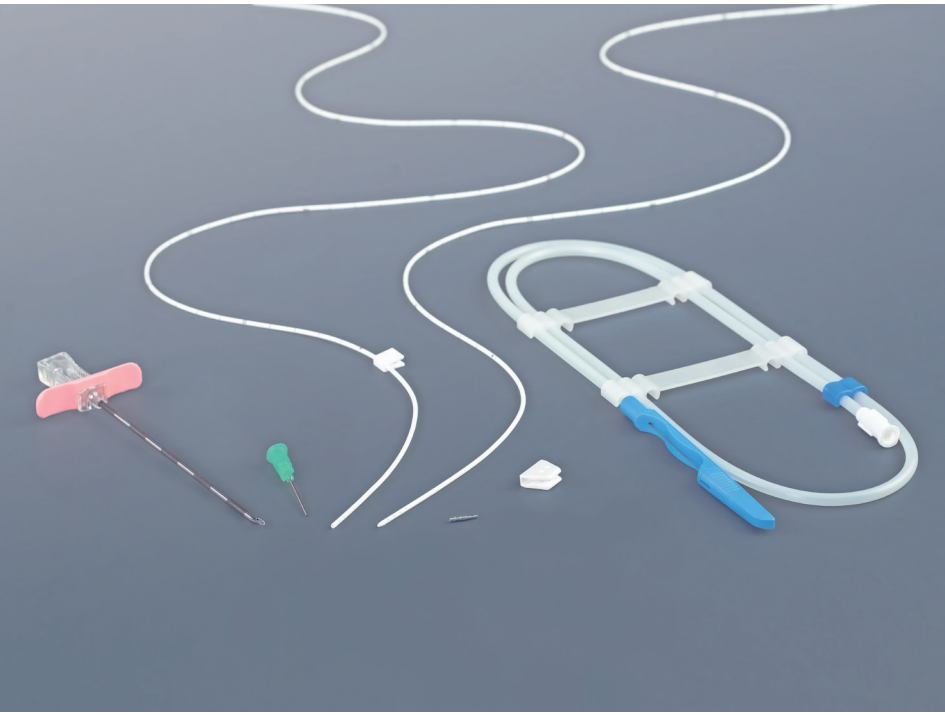
MIETHKE



Lumbar Catheter Set

EN Instructions for use |

www.miethke.com

US This Instructions for Use is NOT intended for United State users. Please discard.

The Instructions for Use for United States users can be obtained by visiting our website at www.aesculapusa.com. If you wish to obtain a paper copy of the Instructions for Use, you may request one by contacting your local Aesculap representative or Aesculap's customer service at 1-800-282-9000. A paper copy will be provided to you upon request at no additional cost.

TABLE OF CONTENTS

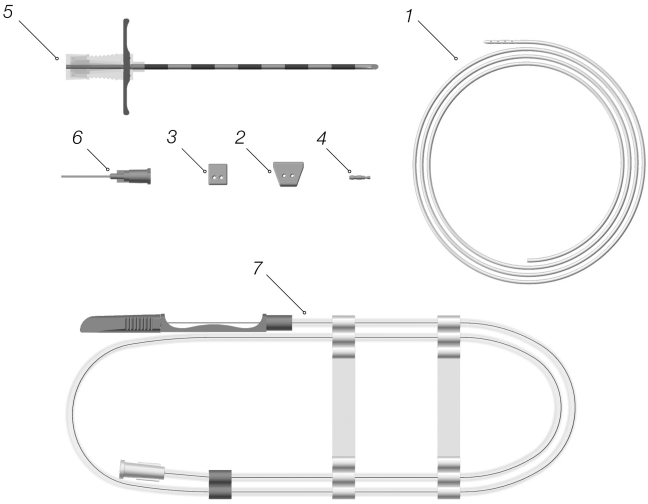


Fig. 1: Lumbar Catheter Set

1 *Lumbar catheter (with open or closed tip)*

2 *Peritoneal catheter suture wings*

3 *Lumbar catheter suture wings*

4 *Titanium connector, step down*

5 *Tuohy cannula, including wing*

6 *Flushing cannula lumbar catheter*

7 *Guide wire in dispenser (only in the set with a closed lumbar catheter)*

GENERAL INFORMATION

NOTE

Before use:

- **Read the instructions for use carefully**
- **Check expiry date**
- **Check packaging for integrity**
- **Check product for intactness**

The product and the accompanying instructions for use are intended only for medical personnel who are qualified to use the product based on their training and experience.

The product may be used only in accordance with the defined indication and may only be adapted within the scope of the possibilities mentioned. Products with damaged packaging or products that are defective or expired must not be used.

INDICATION

The *lumbar catheter set* is used to drain cerebrospinal fluid (CSF).

TECHNICAL DESCRIPTION

Lumbar catheter

NOTE

The catheter is available in different versions. Please note the relevant information for each variant.

- **Lumbar catheter with open tip**
- **Lumbar catheter with closed tip**

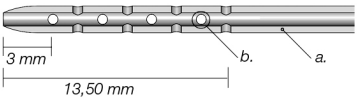


Fig. 2: Lumbar catheter, open tip
a. Silicone catheter
b. Drainage hole

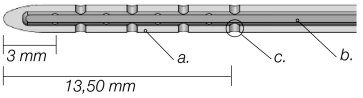


Fig. 3: Lumbar catheter, closed tip
a. Silicone catheter
b. Guide wire
c. Drainage hole

CAUTION

The lumbar catheter marking is adapted to the length of the Tuohy cannula. The lumbar catheter may be combined only with the Tuohy cannula of the individual set.

Lumbar catheters from Christoph Miethke GmbH & Co. KG have an inner diameter of 0.8 mm and an outer diameter of 1.6 mm. At these dimensions, the pressure characteristics of a shunt system are only slightly affected. The lumbar catheters are silicone catheters and contain barium sulphate. This ensures that the X-ray image is clearly visible.

To ensure safe placement of the lumbar catheter, it has numerical markings after every 5 cm up to a length of 65 cm from the exit of the tip of the Tuohy cannula. The line markings are at a distance of 1 cm. As delivered, the lumbar catheters are 80 cm in length.

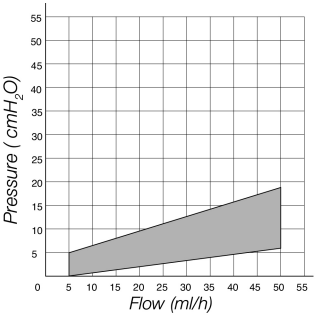


Fig. 4: Pressure-flow characteristics for the lumbar catheter
The flow resistance is influenced by the length of the lumbar catheter, the shorter the lumbar catheter, the less the influence.

NOTE

The number markings indicate the length of the lumbar catheter that has emerged from the Tuohy cannula. The dot mark indicates the zero point of the lumbar catheter exit from the Tuohy cannula.

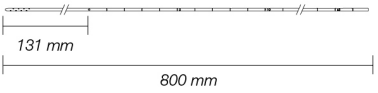


Fig. 5: Lumbar catheter marked from 131 mm

Suture wings catheter

The catheter suture wings from Christoph Miethke GmbH & Co. KG are made of silicone and contain barium sulphate. This ensures that X-ray images are clearly visible. Catheter suture wings allow the catheter to be fixed to subcutaneous tissue. The catheter suture wings are included in the set in two versions (cf. Fig. 6):

1 Lumbar catheter suture wings
2 Peritoneal catheter suture wings

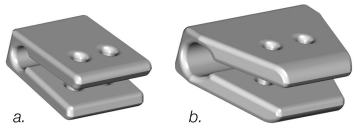


Fig. 6: Catheter suture wings
a. Lumbar catheter suture wings
b. Peritoneal catheter suture wings

Titanium connector (step down)

Titanium connectors are used to connect the catheters in the shunt system. The titanium connector step-down enables the lumbar catheter to connect to the continuing catheter with an inner diameter of 1.2 mm to 1.5 mm; the outer diameter should be approximately twice the inner diameter.

NOTE

The catheters must be carefully attached to the titanium connector step-down by a ligature. Kinks in the catheters must be avoided.

Fig. 7: Titanium connector, step-down

Tuohy cannula

The Tuohy cannula from Christoph Miethke GmbH & Co. KG with stylet and wings enables the puncture of the subarachnoid space in the spinal canal for placement of the lumbar catheter. The Tuohy cannula has an inner diameter of 1.85 mm and an outer diameter of 2.2 mm. The Tuohy cannula has a length of 131 mm. The Tuohy cannula has an NRFit connector. The wing of the Tuohy cannula is firmly inserted into the groove of the Tuohy cannula.

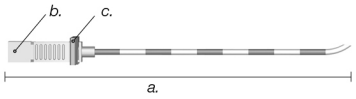


Fig. 8: Tuohy cannula
a. Tuohy cannula
b. Stylet Tuohy cannula
c. Wing Tuohy cannula

Flushing cannula lumbar catheter

The flushing cannula from Christoph Miethke GmbH & Co. KG is used to flush the lumbar catheter. The flushing cannula has an outer diameter of 0.80 mm, a length of 22 mm and a Luer Lock connector.

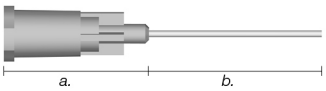


Fig. 9: Flushing cannula lumbar catheter
a. Cannula set with Luer Lock connector
b. Cannula tube

Guide wire

The guide wire from Christoph Miethke GmbH & Co. KG assists the introduction of the closed lumbar catheter and thus enables better manoeuvring of the catheter. The guide wire has an outer diameter of 0.46 mm and a length of 90 cm. The tip at the proximal end of the guide wire is flexible. The guide wire dispenser has a Luer Lock connector at the distal end of the guide wire, so that the guide wire can be flushed before use.

The dispenser is equipped with an insertion guide at the proximal end of the guide wire.

WARNING

The guide wire may be used only in combination with the closed lumbar catheter from Christoph Miethke GmbH & Co. KG.

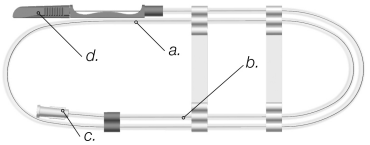


Fig. 10: Guide wire
a. Guide wire, b. Dispenser, c. Luer Lock connector, d. Insertion guide

POSSIBLE SHUNT COMPONENTS

The long-term implants in the *lumbar catheter set* can be combined in the shunt system with all Christoph Miethke GmbH & Co. KG valves that are suitable for lumboperitoneal CSF drainage. Please refer to the instructions for use for the relevant valve.

IMPLANTATION

Preparing the lumbar catheter

The lumbar catheter must be carefully checked for permeability before implantation. This is done by inserting the flushing cannula into the distal end of the lumbar catheter and flushing the catheter with a sterile physiological saline solution at low injection pressure.

WARNING

Contaminants in the solution used for testing can impair the product's performance.

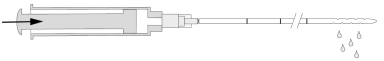


Fig. 11: Patency test / Flushing of the lumbar catheter

NOTE

The lumbar catheter must be cut off and not pulled off of the flushing cannula after use. The lumbar catheter must not be stretched when doing so.

Preparing the guide wire

The guide wire dispenser must also be flushed with a sterile physiological saline solution before use, so that the guide wire can be inserted into and removed from the lumbar catheter with easy sliding. To do this, attach a sterile syringe to the Luer Lock connector of the dispenser and flush the guide wire with a sterile physiological saline solution. Then insert the end of the guide wire with the flexible tip into the open end of the closed lumbar catheter up to the tip of the lumbar catheter.

WARNING

Contaminants in the solution used for testing can impair the product's performance.

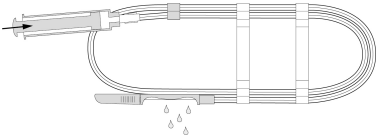


Fig. 12: Flushing the guide wire

Placement of the lumbar catheter

Various surgical techniques are possible for placing the lumbar catheter. It is up to the surgeon to choose them according to his experience and the patient's clinical condition.

- Before introducing the Tuohy cannula, making a skin incision is at the surgeon's discretion.
- Introduce the Tuohy cannula with the inserted stylet and puncture the subarachnoid space in the spinal canal using a suitable technique. The puncture technique is left to the surgeon. One possible procedure would be to insert the bevelled cannula tip (cannula bevel) parallel to the longitudinal dural fibres when puncturing the dura.
- Check the correct insertion of the Tuohy cannula by carefully pulling back the stylet. If CSF does not drip out, reinsert the stylet into the Tuohy cannula and correct the placement of the Tuohy cannula.
- If CSF drips out of the Tuohy cannula, remove the stylet from the Tuohy cannula and advance the lumbar catheter, with or without a guide wire depending on the variant, through the cannula to the desired lumbar area.

WARNING

When using the guide wire, make sure that it does not penetrate the drainage holes or another location on the lumbar catheter, as this can damage the catheter and / or tissue.

NOTE

When introducing a lumbar catheter with an open tip, this can be blocked with an atraumatic clamp at the distal end in order to avoid the loss of CSF. Trim a damaged catheter after removing the clamp.

- After correct placement of the proximal lumbar catheter, leave the Tuohy cannula in place and expose a sufficiently large subcutaneous area on the Tuohy cannula to fix the catheter in the subcutaneous tissue at a later stage. The Tuohy cannula prevents damage to the catheter during the exposure of subcutaneous tissue. Create a smooth transition to the attachment point so that the catheter is bent only slightly.
- Then carefully remove the Tuohy cannula via the free end of the lumbar catheter. Meanwhile, hold the lumbar catheter at the exit point so that it remains at the implantation site. If used, only remove the guide wire afterwards.

WARNING

To avoid damaging the lumbar catheter, it must never be withdrawn individually but only simultaneously with the Tuohy cannula. When using the guide wire, first remove the Tuohy cannula and then the guide wire.

WARNING

Remove the guide wire slowly from the lumbar catheter to avoid damaging the lumbar catheter.

- Remove air from the catheter using CSF, then block it.

CAUTION

Catheters should only be blocked with a atraumatic clamp, as they might be damaged otherwise.

- Fix the lumbar catheter in the subcutaneous tissue using the lumbar catheter suture wings.

WARNING

Fixation of the lumbar catheter is particularly important to counteract possible migration.

- Then advance the distal end of the lumbar catheter to the selected valve implantation site.
- Shorten the lumbar catheter to the appropriate length and attach it to the valve or connector using ligature. The valve should not be located directly under the skin incision.
- The peritoneal catheter can be fixed in the subcutaneous tissue using the peritoneal catheter suture wings.

CAUTION

Do not mismatch the catheter suture wings, as the suture wings are adapted to the respective catheters. If the two are mixed up, the lumbar catheter might not be fixed and the peritoneal catheter might be blocked.

WARNING

Catheters should not be fixed with the catheter suture wings in the immediate vicinity of the valve, otherwise the catheters can be damaged.

Products that have already been implanted must not be reimplanted in the same patient or in another patient, as valid cleaning without loss of function cannot be achieved.

PRECAUTIONS AND CONTRAINDICATIONS

When using sharp instruments, care should be taken to avoid cuts and scratches in the silicone elastomer. Also make sure that the ligature is not tightened too much or too little. Damage may result in a loss of integrity of the shunt and therefore may require a revision.

Silicone is very electrostatic. Please ensure that the catheter does not come into contact with dry cloths, talcum powder or rough surfaces. Clinging particles can lead to tissue reactions.

Patients must be carefully monitored after implantation. Reddening of skin or tightness in the area of the drained tissue may be indications of infections at the shunt system.

Symptoms such as headache, dizziness, mental confusion or vomiting often occur in conjunction with shunt dysfunction. These symptoms and a leakage within the shunt system require the immediate replacement of the affected shunt component or the entire shunt system.

The implantation of medical devices is contraindicated if the patient has an infection or suspected infection (e.g. meningitis, ventriculitis, peritonitis, bacteriaemia, septicaemia) in the region affected by the implantation.

FUNCTIONAL SAFETY AND COMPATIBILITY WITH DIAGNOSTIC PROCEDURES

These medical devices are constructed in such a way as to ensure their precise and reliable operation over long periods of time. However, no guarantee can be assumed that these medical devices will not require replacement for medical or technical reasons. These medical devices are able to resist positive and negative pressures up to 200 cm H_2O during and after implantation. These medical devices must always be stored clean and dry. Magnetic resonance examinations up to a field strength of 3 Tesla or computer tomography examinations can be carried out with the lumbar catheter, catheter suture wings and the titanium connector without impairing the function. The lumbar catheter and catheter suture wings are MR Safe, the titanium connector step-down is MR Conditional. The guide wire, Tuohy cannula and flushing cannula are MR Unsafe.

⚠ **WARNING**

The guide wire, Tuohy cannula and flushing cannula must not be used in MRI!

INTERACTIONS WITH PRODUCTS BY OTHER MANUFACTURERS

A secure connection must always be ensured when using accessory products of Christoph Miethke GmbH & Co. KG in conjunction with valves from other manufacturers. As a rule, we do not recommend combining products from different manufacturers in one shunt system.

ADVERSE REACTIONS AND INTERACTIONS

The following complications can arise in the treatment of hydrocephalus with shunts (as described in the literature): Infections, blockages caused by protein and/or blood in the CSF and/or over-/underdrainage. Violent external shocks (accident, fall, etc.) can put the integrity of the shunt system at risk.

Disconnecting the shunt can lead to a migration of the catheter in the subarachnoid or peritoneal space. Complications such as scoliosis, hyperlordosis and back pain can also occur.

PATIENT EDUCATION

The attending doctor is responsible for informing the patient and/or his/her proxy in advance. This includes a comprehensive description of the course of the operation, the surgical technique, the medical devices to be implanted and the instruments to be used. The patient must be informed about complications associated with the operation and possible alternative treatment methods.

STERILISATION

Christoph Miethke GmbH & Co. KG products are sterilised under strict control. The lumbar catheter, catheter suture wings and titanium connector step-down are sterilised by steam. The Tuohy cannula, Tuohy cannula wing, flushing cannula and guide wire are sterilised by ethylene oxide (ETO). The expiry date is printed on the label of each individual product. If the packaging is damaged, the product must not be used under any circumstances.

No guarantee can be assumed for the functional safety and reliability of resterilised products.

DISPOSAL

The products of the *lumbar catheter set* are disposed of after use as contaminated hospital waste in accordance with the relevant regional regulations.

REQUIREMENTS OF THE MEDICAL DEVICE DIRECTIVE (DIRECTIVE 93/42/EEC)

The Medical Device Directive requires comprehensive documentation of the fate of medical devices used in humans, especially for implants. The individual implant identification number should therefore be recorded in the patient's medical records and patient card to ensure complete traceability. Translations of these instructions for use into additional languages can be found on our website (https://www.miethke.com/en/products/downloads/).

GUARANTEE

Christoph Miethke GmbH & Co. KG guarantees a faultless product for single use, which is free of material and manufacturing defects upon delivery. No liability, guarantee or warranty for safety and functionality can be assumed if the product is modified in any way other than described in the "Implantation" chapter, if it is combined with products by another manufacturer or if it is used in any way other than for the intended purpose.

MEDICAL DEVICES CONSULTANTS

In compliance with the European Directive concerning medical devices (Directive 93/42/EEC), Christoph Miethke GmbH & Co. KG has nominated medical devices consultants as contacts for all product-related questions.

You can contact our medical devices consultants via:
Tel. +49 331 62083-0
info@miethke.com

DIMENSIONS

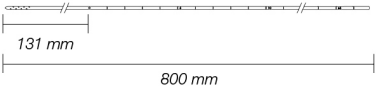


Fig. 13: Lumbar catheter, open tip, marked from 131 mm
- Inner diameter: 0.8 mm
- Outer diameter: 1.6 mm

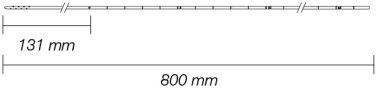


Fig. 14: Lumbar catheter, closed tip, marked from 131 mm
- Inner diameter: 0.8 mm
- Outer diameter: 1.6 mm

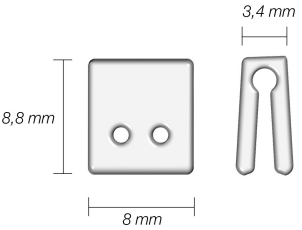


Fig. 15: Lumbar catheter suture wing

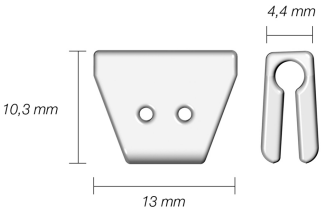


Fig. 16: Peritoneal catheter suture wing

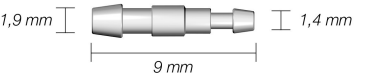


Fig. 17: Titanium connector, step down

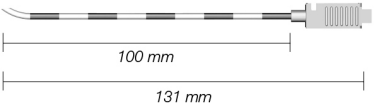


Fig. 18: Tuohy cannula, long

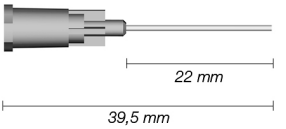


Fig. 19: Flushing cannula lumbar catheter

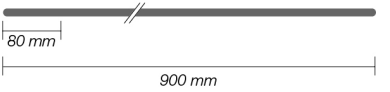


Fig. 20: Guide wire

CE 0297

EN CE marking according to directive 93/42/EEC

EN Technical alterations reserved

Manufacturer:

MIETHKE

Christoph Miethke GmbH & Co KG | Ulanenweg 2 | 14469 Potsdam | Germany
Phone +49 331 62 083-0 | Fax +49 331 62 083-40 | www.miethke.com

注册人: Christoph Miethke GmbH & Co. KG 克里斯托福弥提柯股份有限公司
住所: Ulanenweg 2, 14469 Potsdam, Germany
联系方式: www.miethke.com, info@miethke.com

Distributor:

B BRAUN
SHARING EXPERTISE

Aesculap AG | Am Aesculap-Platz | 78532 Tuttlingen | Germany
Phone +49 7461 95-0 | Fax +49 74 61 95-26 00 | www.bbraun.com

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