Ventricular Catheter
Peritoneal Catheter

Instructions for use
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CAUTION

Federal law restricts this device to sale by or on the order of a physician.

INDICATION

One possible treatment in cases of hydrocephalus is the implantation of a shunt system. The catheter is used for draining cerebrospinal fluid (CSF) from the ventricles into an appropriate cavity.

TECHNICAL DESCRIPTION

The catheters of the Christoph Miethke GmbH & Co. KG have a inner diameter of 1.2 mm and an outer diameter of 2.5 mm. The pressure-flow-characteristic of the shunt system is insignificantly influenced due to these inner and outer dimensions.

Ventricular Catheter

The ventricular catheters are silicone catheters added with 9-20 % BaSO₄. Therefore a good identification on X-ray image is warranted. For a safe placement the ventricular catheter has got markings of 3, 5, 7, 10 and 13 cm seen from the catheter tip. By using the ventricular catheter the introducing stylet can be pushed into the tip of the catheter (Fig. 1). Therefore kinking of the catheter tip is avoided. The holes start at 3 mm from the tip and end after 14 mm. In treatment of slitlike ventricles drainage from the ventricles into the brain is therefore avoided.

Peritoneal Catheter

The peritoneal catheter are silicone catheters added with 9-20 % BaSO₄. Therefore a good identification on X-ray image is warranted.

Peritoneal Catheter, barium striped

The peritoneal catheter, barium striped is a silicone catheter with a stripe of BaSO₄ which is completely enclosed by silicone (Fig. 3).

IMPLANTATION

When implanting a catheter, the physician have to ensure that the catheter is secured with ligatures. The ventricular catheter can be implanted with the aid of an introducing stylet. The length of the catheter that extends into the cranium can be predetermined with the help of the deflector, after which it can be brought through the 90° angle. (The deflector can be ordered separately). Under no circumstances should products that have had previously been implanted in a patient be subsequently reimplanted in another, because a successful decontamination of the device cannot be reached without functional degradation.

Warning notice: Do not implant if an infection (f.e. meningitis, ventriculitis, peritonitis, bacteremia, septicemia) or the suspicion of an infection is diagnosed in a region of the patient's body where the shunt system will be implanted.
INTERACTION WITH PRODUCTS FROM OTHER MANUFACTURERS

When using accessory products of the Christoph Miethke GmbH & Co. KG in combination with valves from other manufacturers it should be ensured that the connection between products is secure. The combination of products from different manufacturers in a shunt system is generally not recommended.

SAFETY MEASURES

To avoid cuts and scratches in the silicone elastomer, close attention should be paid while using sharp instruments. Likewise attention should be paid not to tighten the ligature too firmly. Damage may result in a loss of integrity of the shunt and therefore may require a revision.

Silicone is extremely electrostatic. You shall ensure that the catheter does not come into contact with dry towels, talcum or rough surfaces. Adherent particles may lead to tissue reactions.

Following implantation of a shunt system, the patient's condition should be carefully and thoroughly monitored. Inflamed skin and tension in the area of the drainage tissues could possibly be a sign of infection in the shunt system. Symptoms such as headache, dizziness, 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, bacteriemia, septicemia) in the region affected by the implantation.

FUNCTIONAL SAFETY

The medical products have been designed for long-term reliable and precise operation. Still, it cannot be excluded that the medical products need to be replaced for technical or medical reasons. The medical products are able to resist positive and negative pressure up to 200 cmH₂O during and after implantation. The medical products should be stored dry and clean.

ADVERSE REACTION

In the treatment of hydrocephalus with shunts, the following complications may arise (as described in the literature): infections, blockages caused by protein and/or blood in the cerebrospinal fluid, over/under drainage as well as intercranial and interabdominal injuries.

Due to violent shocks from the outside (accident, fall, etc.) the integrity of the shunt may be endangered.

STERILISATION

All products are carefully and thoroughly steam sterilized. Owing to the fact that the product is packaged in two layers of sterile packaging, five years of sterility are guaranteed. The expiration date for each item is indicated on the package. If the packaging is damaged in any way, the product should not be used under any circumstances.

The functional safety and reliability of resterilized products cannot be guaranteed.

MEDICAL PRODUCTS CONSULTANTS

In compliance with the requirements of the European law MDD 93/42/EEC, Christoph Miethke GmbH & Co. KG names medical products consultants as the individuals to be addressed with all queries concerning the products:

Dipl.-Ing. Christoph Miethke
Dipl.-Ing. Roland Schulz
Michaela Funk-Neubarth
Dipl.-Ing. Thoralf Knitter
Dr. Andreas Bunge
Jan Mügel

Our contact details are written on the back page of this instructions for use.

REQUIREMENTS OF THE MDD 93/42/EEC

The MDD calls for the comprehensive documentation of the whereabouts of medical products that are applied in human beings, especially the whereabouts of implants. For this reason, the individual identification numbers of any implanted valves are to be noted in patients' records, so that in the event of any inquiries, the implant can be traced without any difficulties. Each valve is outfitted with a sticker for this purpose.
CE marking according to directive 93/42/EEC

Technical alterations reserved

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<td>Pg 2</td>
<td>Added information about barium striped peritoneal catheter</td>
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