M.scio

DE Gebrauchsanweisung | GB Instructions for use | FR Mode d'emploi
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CHRISTOPH MIETHKE GMBH CO. KG

CE 0086

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VARIANTS

The *M.scio* is available in four variants with and without a preconnected distal catheter (fig. 1).

INDICATION

The *M.scio* can be used for the pressure-based functional control of the shunt system for the treatment of hydrocephalus. The “domed” variants (fig. 1a and 1b) offer the additional option of withdrawing CSF and drug application.

INTENDED PURPOSE

The *M.scio* is used for the pressure-based functional control of shunt systems.

TECHNICAL DESCRIPTION

One option in the treatment of hydrocephalus is the implantation of a shunt system, which facilitates the drainage of the cerebrospinal fluid from the ventricles into a suitable part of the body (typically the abdominal area). Such a shunt system consists of multiple catheters and a valve. Integrating the *M.scio* into the shunt system offers the option of performing a non-invasive functional control of the shunt system. The basis for this is the measurement of the pressure and pressure changes by a measuring cell, which is localised inside the *M.scio*. The recording of the determined relative pressure values allows conclusions to be drawn in relation to the proper functioning of the shunt system. The use of the *M.scio* does not increase the opening pressure of the shunt system.

The “domed” variants also perform the functions of a conventional reservoir: The silicone membrane means that they can measure intraventricular pressure, inject drugs and control the functioning of the valve. Any tapping of the silicone membrane should be performed perpendicular to the reservoir surface with a cannula of max. Ø 0.9 mm. 30 taps are possible without any restrictions. The biocompatible titanium housing of the measuring cell hermetically protects the electronics. The robust titanium housing prevents any accidental puncturing of the base of the measuring cell. The volume per pump procedure is approx. 0.062 ml.

The flexible silicone membrane and the higher overall height means that the domed variants look and feel different to the flat variants.

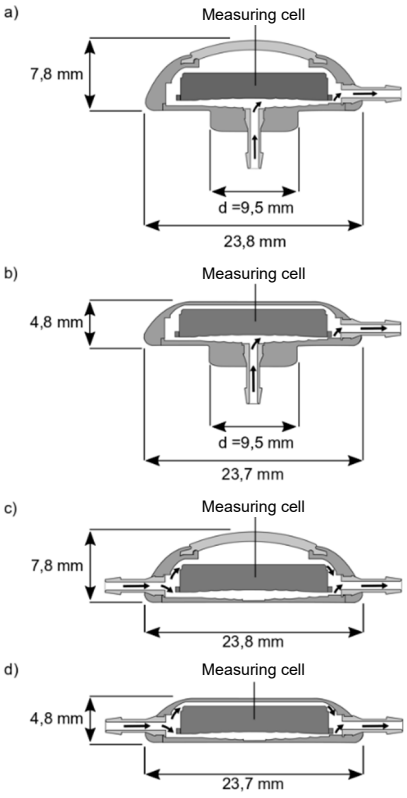

Fig. 1: M.scio with integrated measuring cell in the following variants
a) domed, angled
b) flat, angled
c) domed, inline
d) flat, inline

MODE OF OPERATION

The *reader unit* is used to read and display the measured data of the measuring cell in the *M.scio (fig. 2)*. The measured data may only be read out using the *reader unit* (FV905X). Measured data are automatically stored on the associated SD card for later evaluation. The relative behaviour of the CSF pressure in the shunt system can provide information about its function. This permits the non-invasive detection, localisation and evaluation of an occlusion within the shunt system as well as a mechanical loss of function.

Caution: Looking at these relative pressure readings in isolation cannot be taken as reliable data for absolute brain pressure. Even though the pressure measurement in the *reader unit* is monitored regularly, thus complying with all criteria of a calibrated assessment, the same is not possible for the implanted cell.

If the shunt system is to be revised on the basis of data gained from the implant with integrated measuring cell, the diagnosis must be confirmed through combination with other non-invasive, but also interventional and radiological diagnostic methods (CT, MRI, tap or another method).

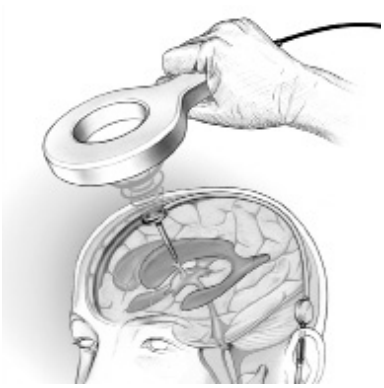

Fig. 2: Pressure measurement with the M.scio and reader unit

FUNCTIONAL TESTS

Functional test prior to implantation

Note: The functionality of the implant must be tested prior to implantation.

The *reader unit* and the SD card associated with the implant are used to test whether the measuring cell can be addressed correctly (see instructions for use for the *reader unit*). If the sensor ID (individual sensor cell number) is recognised by the *reader unit*, measured data can be read correctly. The *M.scio* should be checked for patency prior to implantation. Permeability can be checked by aspiration of a sterile fluid from the distal end and this also allows air to be removed from the implant.

Post-implantation functional test

After implantation, the functionality of the implant should be checked once again with the aid of the *reader unit* and the associated SD card (see instructions for use for the *reader unit*). Once communication is established between the measuring cell and the *reader unit* and the implant is correctly integrated into the shunt system, a plausibility test can be performed. The “Fast measurement” mode is used to observe pulses (pulse waves) and ventilatory fluctuations in the pressure signal *(fig. 3)*.

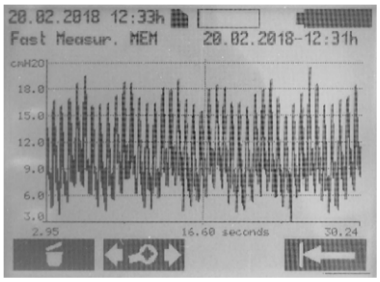

Fig. 3: Typical measurement curves on the display of the reader unit sets with pulses and ventilatory fluctuations in “Fast measurement” mode after implantation

After implantation, the “domed” variants provide the additional option, when the patient is in a stable position, of applying gentle pressure to the silicone membrane of this implant to observe a pressure change in the measurement curves.
The measuring cell is calibrated. Its correct functioning is guaranteed under the following conditions:

Temperature range	20 … 39 °C
Pressure measuring range (relative)	-66.66 hPa … +133.32 hPa (-50 … +100 mmHg)
Pressure measuring range (absolute)	800 …1100 hPa

Warning notices

Caution: excessive pumping of the "domed" variant can result in excessive drainage and thus lead to pressure conditions outside the normal physiological range. The patient should be properly informed about this risk.

Caution: Conclusion about absolute pressure - in patients with acute or chronic brain disorders or injuries (e.g. craniocerebral trauma, cerebral haemorrhage, hydrocephalus, brain tumours, etc.), please note that the measuring cell can only be used to obtain differential intracranial pressure measurements (relative, time-dependent changes in CSF values) when taking cerebral pressure readings. The readings taken by the measuring cell do not permit conclusions as to the absolute pressure within the cranial cavity. To determine such absolute pressure values, reference pressure has to be assessed transcutaneously.

Note: Increased temperature - if the patient has a raised temperature, functional impairment of the reader unit may occur (see instructions for use for the *reader unit*). In readout mode, the temperature in the *M.scio* may rise. An integrated temperature safety device stops the measurement at 39 °C as well as in the event of temperature increases by 2 Kelvin in the implant.

Note: Metal parts - the telemetric link between the *reader unit* antenna and the implant may be disrupted by metal components within the vicinity of the implant. In this case, increase the distance to the metal parts!

IMPLANTATION

The *M.scio* must always be placed outside of the skullcap. A burr hole with a diameter of 10 mm is recommended for the implantation of the "angled" variants. The *M.scio* is designed for use with catheters with an inner diameter of approx. 1.2 mm and an outer diameter of approx. 2.5 mm. The ventricular catheter is implanted with the help of a mandrel. The implantation of the "inline" variants also requires a burr hole deflector to orient the ventricular catheter at a 90° angle. The *M.scio* is connected to the shunt system. The individual connections must be secured by a ligature. We recommend using Miethke products in combination with the *M.scio*. The position of the ventricular catheter should be checked after the procedure by CRT or MRI. It is recommended to check the entire shunt system for patency.

Products that have previously been implanted must not subsequently be reimplanted into the same or another patient.

PRECAUTIONS AND CONTRAINDICATIONS

Patients must be carefully monitored after implantation. Reddening of skin or tightness in the area of the implant may be indications of infections at 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, bacteriaemia, septicaemia) in the region affected by the implantation.

Violent shocks for the outside (accident, fall) may put the integrity of the shunt system and *M.scio* at risk. If high pressure or physical shocks are likely from patient activities (diving, boxing, football, etc.), an *M.scio* should not be used in shunt systems.

FUNCTIONAL SAFETY

The 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 given that these medical devices may not require replacement for

medical or technical reasons. The *M.scio* as well as the entire shunt system are safely able to resist positive and negative pressures up to 100 mmHg during and after the procedure.
These medical devices have to be stored in a clean and dry environment at all times.

If the *measuring cell* fails, the "domed" variants continue to function as a conventional burr hole reservoir or a conventional prechamber without any limitations, while the "inline" variants function as a connector or deflector. The integrated measuring cell poses no additional risk.

COMPATIBILITY WITH DIAGNOSTIC AND THERAPEUTIC PROCEDURES

The *M.scio* consists of the non-magnetic materials PEEK and titanium, while the "domed" variant also contains silicone. The optional distal catheters are made of silicone. MRI or CT scans can be performed without impairment up to a field strength of 3 teslas. Artefacts can occur in MRI scans. The *M.scio* is MR compatible. Supplied catheters are MR safe.

Warning notices:
Caution: During therapeutic ultrasound procedures, there is a risk of the concentration of the ultrasound field being unintentionally increased and thus injuring the patient.

Note: The use of energy-emitting devices such as defibrillators and HF devices can cause the measuring cell to fail!

Note: In cases where an electrical current from an external source comes into contact with the body, the measuring cell can sustain damage.

Note: The use of radiation therapy and radionuclide patient imaging procedures can cause the measuring cell to fail.

SIDE EFFECTS

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 or in very rare cases noise development.

STERILISATION

The products are sterilised with ethylene oxide under strictly controlled conditions. The double wrapping in sterile bags ensures sterility for a five-year period. If the packaging is damaged, the product must not be used in any circumstances. No guarantee can be given for the functional safety and reliability of resterilised products.

SHELF LIFE and STORAGE

The expiry date is printed on the package. The function of the "domed" variants as pure burr hole reservoirs and prechambers as well as that of the "inline" variants as connectors and deflectors is not influenced by the measuring cell.

Temperature range for storage	0 °C … 50 °C
Pressure range for storage	800 hPa … 1100 hPa

PATIENT PASSPORT AND SD CARD

The treating physician is encouraged to fill in the complete patient passport. In addition to the patient passport, the patient is given an SD card on which all individual data about the implant are stored. If the SD card is lost, it can be reordered by specifying the serial number of the *M.scio* or the sensor ID.

PRODUCT TRAINING

Appropriate product training prior to using the product is recommended. Please contact Christoph Miethke GmbH & Co. KG for information about product training.

Use the product only as specified in these instructions for use.

REQUIREMENTS OF THE AIMDD DIRECTIVE (90/385/EEC) I CE MARK

The Medical Device Directive requires the comprehensive documentation of the whereabouts of medical devices used in humans. The individual ID of the implants should therefore be recorded in the patient's medical records and patient passport to ensure complete traceability. Approval for marking with the CE mark for active implantable medical devices (in accordance with Directive 90/385/EEC) was initially granted in 2011.

MEDICAL DEVICES CONSULTANT

In compliance with the AIMDD directive (Directive 90/385/EEC), Christoph Miethke GmbH & Co. KG has nominated medical device consultants as contacts for all product-related questions:

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

Contact details can be found on the reverse of these instructions for use.

CE 0086

(DE) CE-Kennzeichnung gemäß Richtlinie 90/385/EWG
(GB) CE mark in accordance with Directive 90/385/EEC
(FR) Label CE conforme à la directive 90/385/CEE
(ES) Identificatión CE en conformidad con la directriz 90/385/CEE
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