miniNAV

Instructions for use
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</table>
Warning note:
Federal law restricts this device to sale by or on order of a physician!

Indication

The miniNAV is used for draining cerebrospinal fluid from the ventricles into the peritoneum in hydrocephalus patients.

The miniNAV is composed of a robust titanium casing (1) whose proximal end contains a ball-cone valve. A spiral spring (2) maintains the opening pressure of the ball-cone valve and the sapphire ball (3) ensures the precise closure of the valve. The inlet connector (4) and the outlet connector (5) are also made of titanium.

Technical description

The miniNAV was developed to offer a small-sized valve for the treatment of hydrocephalus. Our recommendation to use the miniNAV in a shunt system is to drain to the abdominal cavity in accordance to the indication of use.

Fig. 1 Schematic cross-section of the miniNAV
Instructions for use

Physics background

The intraventricular pressure is positive in a healthy human in a horizontal position. To maintain this pressure through shunt drainage, one has to choose the appropriate pressure range, taking into account the abdominal cavity pressure. The resulting IVP is the sum of the shunt opening pressure and the abdominal cavity pressure (fig. 6).

In a healthy human, the ventricular pressure in the vertical position becomes slightly negative. To maintain this pressure by means of shunt drainage, the shunt opening pressure has to be significantly higher so that the shunt can compensate for the hydrostatic pressure minus the sum of the abdominal cavity pressure and the slightly negative intraventricular pressure. Conventional shunts open immediately as soon as the patient stands up, which can lead to critical overdrainage.

<table>
<thead>
<tr>
<th>IVP</th>
<th>Intraventricular pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>PVII</td>
<td>Opening pressure (horizontal)</td>
</tr>
<tr>
<td>PVst</td>
<td>Opening pressure (vertical)</td>
</tr>
<tr>
<td>PB</td>
<td>Pressure in the abdominal cavity</td>
</tr>
<tr>
<td>PHyd</td>
<td>Hydrostatic pressure</td>
</tr>
</tbody>
</table>

horizontal: $IVP = PVII + PB$
vertical: $IVP = PHyd - PVst - PB$

Fig. 2: The pressure conditions for the valve in the horizontal and vertical positions
**Function of the miniNAV**

The operating principle of the miniNAV is illustrated in fig. 3 and fig. 4. Fig. 3a shows the miniNAV in the horizontal position. The ball-cone valve is closed and drainage is prevented. If the patient's IVP increases and continues to rise, the spring pressure of the ball-cone unit will be overcome. The sealing ball will move away from the cone and a gap opens for fluid drainage.

The coding of the miniNAV can be identified according to the shape of the valve's housing. For example the miniNAV with an opening pressure of 5 cmH₂O has a concave proximal part (curved inwards) and a convex distal part (curved outwards). Each miniNAV is calibrated in accordance with strict quality control standards. The following pressure levels are available:

<table>
<thead>
<tr>
<th>Pressure rating (cmH₂O)</th>
<th>Coding</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td><img src="image1" alt="0 cmH₂O" /></td>
</tr>
<tr>
<td>5</td>
<td><img src="image2" alt="5 cmH₂O" /></td>
</tr>
<tr>
<td>10</td>
<td><img src="image3" alt="10 cmH₂O" /></td>
</tr>
<tr>
<td>15</td>
<td><img src="image4" alt="15 cmH₂O" /></td>
</tr>
</tbody>
</table>

**Selecting the appropriate miniNAV-SHUNTSYSTEM**

The miniNAV is available in 4 different pressure pressure levels (0, 5, 10 and 15 cmH₂O). The pressure setting should be chosen according to the clinical picture (normal-pressure hydrocephalus, hypertonic hydrocephalus).

In case the patient suffers from symptoms associated with overdrainage, or complications with overdrainage are expected, we recommend implantation of the SHUNTASSISTANT in addition to the miniNAV. The SHUNTASSISTANT is a hydrostatic, supplementary valve specially designed for preventing problems with overdrainage. It is made by Christoph Miethke GmbH & Co. KG.

**Fig. 4 Radiographic image of the miniNAV (pressure rating 5 cmH₂O)**
Possible shunt components

The miniNAV is available with different shunt accessories. These variants are comprised of a variety of components, which are described briefly introduced below:

The borehole reservoir is positioned in the cranial borehole. It allows flushing and extraction of CSF. Its solid titanium base is highly puncture-resistant. All reservoirs are available with integrated catheters or connectors. A special borehole reservoir is the SPRUNG RESERVOIR. An additional new feature of this reservoir is that CSF can be flushed towards the miniNAV because of a one-way valve in the bottom of the reservoir. By this mechanism, flow in the direction of the ventricular catheter is avoided during the pumping procedure. The opening pressure of the shunt system is not increased by the implantation of the SPRUNG RESERVOIR.

The prechamber is positioned on the cranium. It allows flushing, extraction of CSF and palpatory ventricle inspection. Its solid titanium base is highly puncture-resistant. A puncture of the prechamber or the CONTROL RESERVOIR should be performed as perpendicular to the reservoir surface as possible with a cannula of maximum diameter 0.9 mm. 30 punctures are possible without any restrictions. A special prechamber is the CONTROL RESERVOIR. As an additional new feature of this reservoir, CSF can be flushed towards the miniNAV because of a one-way valve in the proximal inlet of the reservoir. By this mechanism, flow in the direction of the ventricular catheter is avoided during the pumping procedure. The opening pressure of the shunt system is not increased by the implantation of the CONTROL RESERVOIR.

Warning note: Frequent pumping can lead to overdrainage and thus to pressure conditions outside the normal physiological range. The patient should discuss the risks (involved) with their surgeon.

Tight tolerancing of the deflector ensures a good fit with the ventricular catheter. By adjusting the deflector (prior to implantation) the length of catheter penetrating into the skull can be optimised. The ventricular catheter is “deflected” at a right angle in the borehole (see chapter “Variants”).

Tube systems

The miniNAV has been designed to ensure the optimal ventricular pressure. It is available as a shunt system or as individual valve units with or without an integrated distal catheter (internal diameter 1.2 mm, external diameter 2.5 mm). Individual valve units should be used with catheters of approx. 1.2 mm internal diameter and approx. 2.5 mm external diameter. The connector on the valve allows using catheters of 1.0 mm to 1.5 mm internal diameter. The external diameter of the catheter should be about double the internal diameter. Regardless, the catheters must be carefully fixed, with a ligature, to the valve connectors. It is essential that kinks in the catheter are avoided. The included catheters have virtually no effect on the Pressure-flow characteristics.
Surgical procedure

Positioning the ventricular catheter
Several surgical techniques are available for positioning the ventricular catheter. The necessary skin incision should be carried out, preferably, in the shape of a lobule pedicled towards the draining catheter or as a straight skin incision. To avoid CSF leakage, care should be taken that the dura opening is kept as small as possible after applying the borehole. The ventricular catheter is stiffened by the introducing stylet supplied with the product. The miniNAV is available in different shunt variants:

When using a miniNAV-SHUNTSYSTEM with borehole reservoir or SPRUNG RESERVOIR, the ventricular catheter is implanted first. Once the introducing stylet has been removed, the patency of the ventricular catheter can be tested by checking if CSF is dripping out. The catheter is shortened and the borehole reservoir is connected, with the connection secured with a ligature. The skin incision should not be located directly above the reservoir.

The miniNAV-SHUNTSYSTEM with prechamber or CONTROL RESERVOIR comes with a deflector. This deflector is used for adjusting the position of deflection before implantation of the ventricular catheter. The catheter is deflected; the prechamber is put into place. The position of the ventricular catheter should be inspected again by postoperative CT or MR imaging.

Positioning the miniNAV
The miniNAV should be implanted in the head of the patient. The valve is marked with an arrow pointing to distal (downwards) to indicate the flow direction. Whether the label faces towards the skin or the brain is of no importance in terms of the valve’s performance.

Following subcutaneous tunneling, the catheter is either pushed from the borehole, possibly through a reservoir, to the selected valve implantation site; or it is pushed through from the valve and connected to the reservoir, if there is any.

Positioning the peritoneal catheter
The access site for the peritoneal catheter is left to the surgeon’s discretion. It can be applied e.g. para-umbilically in a horizontal direction or transrectally at the height of the epigastrum.

Likewise, various surgical techniques are available for positioning the peritoneal catheter.

We recommend pulling through the peritoneal catheter, using a subcutaneous tunneling tool and perhaps with an auxiliary incision, from the shunt to the intended position of the catheter. The peritoneal catheter, which is usually securely attached to the miniNAV, has an open distal end, but no wall slits. Following the exposure of, and the entry into, the peritoneum by means of a trocar, the peritoneal catheter (shortened, if necessary) is pushed forward into the open space in the abdominal cavity.

Warning note: Frequent pumping can lead to overdrainage and thus pressure conditions outside of the normal physiological range. Patients should discuss the risks (involved) with their surgeon.
Testing the valve patency

Fig. 7: Patency test

The miniNAV can be filled by aspiration through a sterile, single-use syringe attached to the distal end of the catheter. The proximal end of the valve is immersed in a sterile physiological saline solution. The valve is patent if fluid can be extracted in this way (see Fig. 7).

Caution: Pressure admission through the single-use syringe should be avoided, both at the proximal and the distal end. Contaminations in the solution used for the test can impair the product’s performance.

Valve test prior to implantation

Each miniNAV valve has been tested to ensure that the performance specifications given on the label are always met. The dynamic performance characteristics of the shunt cannot be tested in a static test performed in the operating room.

If the surgeon wishes to verify, prior to implantation, that the shunt meets the specifications given by the manufacturer, the test described in the following can be carried out in the operating room:

Caution: Always take care that sterility is maintained and particle contamination is avoided.

Test method
Equipment required for this test:
  a) sterile fluid reservoir or water bath
  b) sterile fluid 60-cm water manometer with millimeter grading and three-branch faucet at the base
  c) sterile syringe, 30 cc to 50 cc
  d) sterile 5-μ tip filter
  e) sterile tube adapter
  f) sterile silicone tube

Setting up the equipment
  a) Position the manometer and the water bath in such a way that the zero point of the manometer and the fluid level of the water bath are at the same height (see Fig. 8).
  b) Fill the syringe, with the 5-μ tip filter attached, with sterile water (Always use the 5-μ tip filter when topping up the syringe). Remove the tip filter when the syringe is full.
  c) Connect the syringe, the manometer and the silicone tube with each other. Use the tube adapter if necessary. (see Fig. 8)
  d) To release all air from the test assembly, turn the three-way faucet (see Fig. 9).
  e) Immerse the silicone tube in the sterile water bath and rinse it with the sterile water from the syringe.

Fig. 8: Test setup

1 miniNAV a horizontal, b vertical; 2 water bath; 3 constant water level; 4 silicone tube; 5 three-way tap; 6 single-use syringe with syringe filter; 7 manometer
Calibrating the equipment

a) Turn the three-way faucet (see Fig. 10) and fill the manometer to minimum 5 cmH₂O.
b) With the silicone tube immersed in the water bath, turn the three-way faucet so that the syringe is isolated from the manometer (see Fig. 11).
c) Allow the water column in the manometer to drop.
d) The water column should stop dropping at the zero point. Adjust the zero point of the manometer to fluid level of the water bath, if necessary.
e) The manometer has now been calibrated to the zero-level of the water bath. Fixate the manometer to maintain its position in relation to the water bath.

Test procedure

Please note: During the test the shunt must be submerged in the water bath. The zero point of the manometer has to be aligned with the water level of the water bath in order to obtain correct results.

a) Connect the sterile shunt to be tested to the ready assembled, sterile test equipment.
b) Turn the three-way faucet as shown in Fig. 10 and fill the manometer to 10 cmH₂O above the expected opening pressure. (Example: For testing a miniNAV with an opening pressure setting of 5 cmH₂O, the manometer is filled to 15 cmH₂O.)
c) Turn the three-way faucet as shown in Fig. 9 so that the manometer is isolated.
d) Remove all air from the shunt and the test setup by carefully rinsing it through with sterile water from the syringe.
e) Immerse the sterile shunt in the sterile water bath. The distal part of the shunt must be under water to obtain valid test results.
f) Carefully maintain a flow through the shunt and turn the three-way faucet as shown in Fig. 11 to isolate the syringe. As soon as the three-way faucet is in the correct position, the water column should begin to drop. The syringe is now isolated from the valve and it is not necessary anymore to maintain its flow. Repeat steps b to f if the water column fails to drop.

g) Allow the water level in the manometer to drop for 2 to 2.5 minutes. Read the resulting pressure at the manometer.

Test results – pre-implantation test

The pressure readings obtained by this method should yield the following results:

<table>
<thead>
<tr>
<th>Pressure rating cmH₂O</th>
<th>Acceptable pressure ranges</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0-5 cmH₂O</td>
</tr>
<tr>
<td>5</td>
<td>2-9 cmH₂O</td>
</tr>
<tr>
<td>10</td>
<td>7-15 cmH₂O</td>
</tr>
<tr>
<td>15</td>
<td>12-20 cmH₂O</td>
</tr>
</tbody>
</table>
Pressure-flow characteristics

The diagrams below show the pressure-flow characteristics for the pressure ratings in which the miniNAV is available.

The total opening pressure refers to a reference flow of 5 ml/h. When the flowrates reach 20 ml/h, the opening pressures are approximately 1-2 cmH2O higher.
Test on reflow safety

This test is carried out with the same equipment as the pre-implantation test. The shunt is carefully filled with sterile saline solution from the syringe before the air is removed from it (Fig. 11). The shunt is connected against the direction of flow (see arrow on the shunt). The outlet of the shunt has to be at the zero level of the manometer. The manometer is filled up to 14 cmH₂O (Fig. 12). The three-way faucet is used for unblocking the flow to the shunt and blocking the flow to syringe. In this setup, no more than 2 drops (0.1 cc) per minute should emerge from the proximal part of the shunt (Fig. 13).

Caution: Be careful to maintain sterility and to avoid particle contamination.

Re-implantation

Under no circumstances should products that have had previously been implanted in a patient be subsequently reimplanted in another, as a validated decontamination process will compromise the functionality of the valve.

Safety measures

The patients must be carefully monitored after the implantation. Reddened skin and tension in the area of the drainage tissue could indicate infections at the shunt system. Symptoms such as headache, dizzy spells, mental confusion or vomiting are common occurrences in cases of shunt dysfunction. Such symptoms, as well as shunt system leakage, necessitate the immediate replacement of the shunt component responsible, or of the entire shunt system.

Compatibility with diagnostic procedures

MRI examinations with field strengths of up to 3.0 tesla and CT examinations can be carried without endangering or impairing the functionality of the shunt. The miniNAV is MR Conditional (ASTM-F2503-08). All components are visible via X-ray. The provided catheters are MR Safe. Reservoirs, deflectors and connectors are MR Conditional.
MRI information

The miniNAV valve was determined to be MR Conditional (ASTM F2503-08). Non-clinical testing has demonstrated the miniNAV differential pressure valve is MR Conditional. It can be scanned safely under the following conditions:

- static magnetic field of 3.0 Tesla and 1.5 Tesla, with
- spatial gradient field of 54.5 T/m (5,450 Gauss/cm) and less
- scanning can be safely performed in the normal operating mode only with a maximum whole body specific absorption rate of 2 W/kg or a maximum head averaged specific absorption rate of 3.2 W/kg.

In non-clinical testing the miniNAV differential pressure valve produced a temperature rise of less than 3.0°C (with a background temperature increase of ≈ 2.4°C) at a maximum whole body (body coil used) averaged specific absorption rate (SAR) of 2 W/kg assessed by calorimetry for 15 min. of continuous MR scanning in a 1.5 Tesla Intera Philips Medical Systems (Software: Release 12.6.1.3, 2010-12-02) MR Scanner.

In non-clinical testing the miniNAV differential pressure valve produced a temperature rise of less than 3.0°C (with a background temperature increase of ≈ 5.1°C) at a maximum whole body (body coil used) averaged specific absorption rate (SAR) of 2 W/kg assessed by calorimetry for 15 min. of continuous MR scanning in a 3 Tesla Magnetom Trio Siemens Medical Solutions (Software: Numaris/4, syngo MR A30) MR Scanner.

General notice: the whole body or head averaged SAR is inappropriate to scale exact local temperature increases. Local SAR can deviate and result in much higher values than the WBA-SAR software displayed.

The image artifact extends approximately 7 mm from the device, both inside and outside the device lumen when scanned in nonclinical testing using the sequence:

<table>
<thead>
<tr>
<th>Valve orientation</th>
<th>coronal</th>
<th>transverse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imaging plane and phase encoding direction</td>
<td>sagittal ap</td>
<td>sagittal hf</td>
</tr>
<tr>
<td>TSE artifact in [cm²]</td>
<td>3,38</td>
<td>3,78</td>
</tr>
<tr>
<td>Imaging plane</td>
<td>sagittal</td>
<td>coronal</td>
</tr>
<tr>
<td>GRE artifact in [cm²]</td>
<td>5,58</td>
<td>5,58</td>
</tr>
</tbody>
</table>

Artifact size for the miniNAV associated with MR imaging at 3.0 tesla. The lumen is not obscured by the artefact.
GRE in a 3.0 tesla MR scanner Magnetom Trio of Siemens at the section on Experimental Radiology in Tübingen, Germany. (Software Numaris/4, Version: MRB15) with a body coil. As such, the \textit{miniNAV} should not be placed in close proximity to a location, which may require an MR image.

Patients should register the conditions under which the implant can be scanned safely with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

\textbf{Warning note:} The \textit{miniNAV} will produce signal-intensity voids in MR images that extends 7 mm beyond the physical size of the device.

It may be necessary to optimize MR imaging parameters for the presence of this implant. On page 12 is a chart containing the signal void associated with the \textit{miniNAV} as tested to ASTM F2119-07.

\textbf{Warning: No local RF transmit coils should be placed over the implant.}

\textbf{Postoperative valve test}

The \textit{miniNAV} has been designed as a safe and reliable unit even without the implantation of a pumping device. However, the inclusion of a prechamber or a \textit{borehole reservoir} allows the shunt system to be tested by flushing or pressure measurements.

\textbf{Functional safety}

The valves have been designed for long-term reliable and precise operation. Still, the possibility that the shunt system will need to be replaced for technical or medical reasons cannot be excluded. The valve and the valve system are able to resist positive and negative pressure up to 200 cmH\textsubscript{2}O during and after implantation.

\textbf{Sterilization}

The products are sterilized with steam under closely monitored conditions. Double wrapping in sterile bags ensures sterility for a period of five years. The expiry date is printed on the wrapping of each individual product. Products taken from a damaged wrapping must not be used under any circumstances.

\textbf{Rестерилізація}

The functional safety and reliability of resterilized products cannot be guaranteed, therefore resterilisation is not recommended.
Note on the instructions for use

The descriptions and explanations given in this document are based on the clinical experience available to date. It is for the surgeon to decide if surgical procedures should be changed according to his or her experience and to surgical practice.

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.

Medical products consultant

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

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General information

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Christoph Miethke GmbH &amp; Co. KG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product name</td>
<td>miniNAV</td>
</tr>
<tr>
<td>Intended use</td>
<td>Treatment of Hydrocephalus</td>
</tr>
<tr>
<td>Intended for one-time use (disposable)</td>
<td></td>
</tr>
<tr>
<td>Store in a clean, dry place</td>
<td></td>
</tr>
</tbody>
</table>

Schematic representation of the shunt with its external dimensions:

Scale: 1:1

2.8 mm

14.7 mm
Variants

The miniNAV is available as a single valve or as a shunt system comprising various components.

miniNAV

miniNAV-SHUNTSYSTEM

miniNAV-SHUNTSYSTEM with borehole reservoir or SPRUNG RESERVOIR (adult and pediatric)

or

miniNAV-SHUNTSYSTEM with prechamber or CONTROL RESERVOIR (adult and pediatric)

or

Scale 1:1
CE-Kennzeichnung gemäß Richtlinie 93/42/EWG
CE marking according to directive 93/42/EEC
Label CE conforme à la directive 93/42/CEE
Identificación CE en conformidad con la directriz 93/42/CEE
Marchio CE conforme alla direttiva 93/42/CEE
CE 标志，符合 93/42/EEC 指令

Technische Änderungen vorbehalten
Technical alterations reserved
Sous réserve de modifications techniques
Sujeto a modificaciones técnicas
Con riserva di modifiche tecniche
保留技术更改的权利

Manufacturer acc. MDD 93/42/EEC

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