proGAV 2.0®

USA Instructions for Use

CHRISTOPH MIETHKE GMBH & CO. KG
## CONTENT

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>INDICATION</td>
<td>4</td>
</tr>
<tr>
<td>TECHNICAL DESCRIPTION</td>
<td>4</td>
</tr>
<tr>
<td>FUNCTION OF THE VALVE</td>
<td>5</td>
</tr>
<tr>
<td>PHYSICS BACKGROUND</td>
<td>6</td>
</tr>
<tr>
<td>SELECTING THE APPROPRIATE SHUNT</td>
<td>7</td>
</tr>
<tr>
<td>USING THE INSTRUMENTS</td>
<td>7</td>
</tr>
<tr>
<td>proGAV Check-mate</td>
<td>10</td>
</tr>
<tr>
<td>ADJUSTING THE ADJUSTABLE DP-UNIT</td>
<td>10</td>
</tr>
<tr>
<td>READING THE PRESSURE SETTING FROM AN X-RAY IMAGE</td>
<td>11</td>
</tr>
<tr>
<td>POSSIBLE SHUNT COMPONENTS</td>
<td>12</td>
</tr>
<tr>
<td>TUBE SYSTEMS</td>
<td>12</td>
</tr>
<tr>
<td>SURGICAL PROCEDURE</td>
<td>12</td>
</tr>
<tr>
<td>PREOPERATIVE VALVE TEST</td>
<td>13</td>
</tr>
<tr>
<td>VALVE TEST PRIOR TO IMPLANTATION</td>
<td>14</td>
</tr>
<tr>
<td>TEST RESULTS OF PREIMPLANTATION TEST</td>
<td>15</td>
</tr>
<tr>
<td>PRESSURE-FLOW CHARACTERISTICS</td>
<td>15</td>
</tr>
<tr>
<td>CONTRAINDICATIONS</td>
<td>16</td>
</tr>
<tr>
<td>INTERACTIONS WITH PRODUCTS FROM OTHER MANUFACTURERS</td>
<td>16</td>
</tr>
<tr>
<td>RE-IMPLANTATION</td>
<td>16</td>
</tr>
<tr>
<td>SAFETY MEASURES</td>
<td>16</td>
</tr>
<tr>
<td>COMPATIBILITY WITH DIAGNOSTIC PROCEDURES</td>
<td>16</td>
</tr>
<tr>
<td>MRI SAFETY INFORMATION</td>
<td>17</td>
</tr>
<tr>
<td>ARTIFACT INFORMATION</td>
<td>17</td>
</tr>
<tr>
<td>POSTOPERATIVE VALVE TEST</td>
<td>17</td>
</tr>
<tr>
<td>FUNCTIONAL SAFETY</td>
<td>17</td>
</tr>
<tr>
<td>ADVERSE REACTION</td>
<td>17</td>
</tr>
<tr>
<td>STERILIZATION</td>
<td>17</td>
</tr>
<tr>
<td>RESTERILIZATION</td>
<td>18</td>
</tr>
<tr>
<td>NOTE ON THE INSTRUCTIONS FOR USE</td>
<td>18</td>
</tr>
<tr>
<td>REQUIREMENTS OF THE MDD 93/42/EEC</td>
<td>18</td>
</tr>
<tr>
<td>MEDICAL PRODUCTS CONSULTANT</td>
<td>18</td>
</tr>
<tr>
<td>GENERAL INFORMATION</td>
<td>19</td>
</tr>
<tr>
<td>proGAV 2.0 ADJUSTMENT TROUBLE SHOOTING</td>
<td>20</td>
</tr>
<tr>
<td>VARIATIONS</td>
<td>21</td>
</tr>
</tbody>
</table>
The adjustable DP-unit is composed of a solid titanium body with a well-tried ball-cone valve (1) integrated in its proximal part. A bow spring (2) defines the opening pressure of the ball-cone valve. The pretensioning of the spring, and thus the valve opening pressure, can be adjusted by turning a rotor (3), with the valve implanted under the patient’s skin. The gravitational unit contains a tantalum ball (4), which defines the opening pressure of this valve, and a sapphire ball (5), which ensures the precise closure of the valve. Underneath the silicone catheters (6), a connector is provided.

**FUNCTION OF THE VALVE**

The opening pressure of the proGAV 2.0 is defined by the opening pressure of the adjustable DP-unit and the opening pressure of the gravitational unit.

**Horizontal position**

When the patient is lying down, the gravitational unit is always open and therefore does not present any resistance to the fluid flow. (fig. 3).

**Vertical position**

When the patient moves into an upright position, in that moment the gravitational unit closes (fig. 5a). Now, additionally to the opening pressure of the adjustable DP-unit, the weight of the tantalum ball has to be exceeded (opening pressure of the gravitational unit), thus the opening pressure of the proGAV 2.0 is significantly increased. Only when the sum of the IVP and the hydrostatic pressure exceeds the opening pressure of the proGAV 2.0, drainage will be possible again (fig. 5b).

Note: During physical activity which is associated with shocks (e.g.: running), laboratory results have shown that the proGAV 2.0’s opening pressure can decrease temporarily around 25% to 35%

This concerns the single valve as well as the combination with the gravitational unit. Principally, the reliability of the proGAV 2.0 is preserved. Once physical activity is stopped the original opening pressure will be re-established.
PHYSICS BACKGROUND

The intraventricular pressure is positive in a healthy human in a horizontal position. To adjust 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).

The ventricular pressure in a healthy human in a 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 the hydrostatic pressure minus the sum of the abdominal cavity pressure and the slightly negative intraventricular pressure.

SELECTING THE APPROPRIATE SHUNT

The proGAV 2.0 is a position-dependent shunt, meaning the opening pressure changes depending on the position of the patient. To choose the suitable proGAV 2.0 for an individual patient, one opening pressure is set for the horizontal position (patient lying down), and one for the vertical position (patient standing upright).

Horizontal position

The opening pressure for the horizontal position is defined by the adjustable DP-unit. The pressure level should be chosen according to the clinical situation and indication. The unit can be adjusted to a pressure setting between 0 cmH\(_2\)O and 20 cmH\(_2\)O. The valve is preset to 5 cmH\(_2\)O.

Vertical position

The opening pressure of the proGAV 2.0 for the vertical position is calculated by the sum of the opening pressure of both the adjustable unit and of the gravitational unit. The selection of the gravitational unit depends on the activity and the abdominal pressure (adiposity).

USING THE INSTRUMENTS

Caution: Do not use the proGAV 2.0 Tools nearby pacemakers due to magnets inside the proGAV 2.0 Tools.

Note: DO NOT use in or around strong magnetic fields such as MR imaging equipment.

With the proGAV 2.0 Tool Set the selected opening pressure of the proGAV 2.0 can be determined, varied and controlled.

The proGAV 2.0 Compass is used to locate and verify the DP adjustable unit.

The proGAV 2.0 Adjustment Tool is used for adjusting the valve opening pressure of the proGAV 2.0 from 0 to 20 cmH\(_2\)O.

Each proGAV 2.0 is calibrated under strict quality control procedures. The presetting of the adjustable DP-unit is 5 cmH\(_2\)O, but it must be checked before implantation. The setting is changed in the following steps:
1. Locating the valve
If the instrument is opened a template is visible (fig. 9). Then the valve can be located on the patient’s head with the forefinger.

Fig. 9 Locating the valve with the proGAV 2.0 Compass

The proGAV 2.0 Compass must be positioned centrally on the valve. The markings on the instrument “proximal” and “distal” shows the flow direction.

2. Verifying the opening pressure
When the compass is closed, the pressure setting is indicated automatically. (fig. 10)

Fig. 10: Verifying the pressure setting with the proGAV 2.0 Compass

**Caution:** Placing the proGAV 2.0 Compass in a non-central position on the valve can lead to erroneous readings!

The proGAV 2.0 Compass is sensitive to external magnetic fields. To exclude undesirable interactions the proGAV 2.0 Adjustment Tool should not be in the immediate vicinity of the proGAV 2.0 Compass while determining the opening pressure. We recommend a distance of about 30 cm to the 2.0 proGAV Compass.

3. Adjusting the opening pressure
The proGAV 2.0 Adjustment Tool must be positioned centrally on the valve. For a correct placement the valve should be palpated with the forefinger through the opening in the middle of the instrument. The desired pressure setting must point on the scale in direction of the inlet connector and the ventricular catheter. By applying light pressure the rotorbrake will be released and the pressure of the proGAV 2.0 can be changed.

**NOTE:** Fig. 12 depicts the function of the inner components and should not be used to determine the orientation of the valve radiographically.

From proGAV 2.0 Adjustment Tool a magnetic field emanates. Metallic objects and magnetic media storages should have a sufficient safety margin.

4. Verifying the adjustment
After adjusting the valve by using the proGAV 2.0 Adjustment Tool, it can be verified using the proGAV 2.0 Compass as described in step 2 and may be confirmed by radiograph (X-ray). If the measured pressure now differs from the intended pressure level, the adjustment procedure has to be repeated from step 3.

**Caution:** Due to postoperative swelling of the skin the adjustment of the valve setting may be difficult within the first few days.

**Caution:** If the pressure configuration of the valve cannot be determined with complete certainty by the proGAV 2.0 Compass, the use of imaging techniques is recommended (excluding MRI: danger of artifacts).

**Caution:** X-ray confirmation may still be necessary for patients with scalp thicknesses greater than or equal to 5 mm thick.

The following table shows the quantitative information regarding the overall agreement rates between the X-ray and the respective verification tool for the proGAV 2.0 valve. The maximum deviation from the actual valve readings used were 0, ≤ 1, ≤ 2, > 2 cmH2O. For example at ≤ 2 cmH2O 98.7% of the measurements made by the proGAV VERIFICATION TOOL with the proGAV 2.0 valve deviate not more than ± 2 cmH2O from the actual value of the valve. The agreement rates are based on non-clinical testing with readings of 15 valves by 15 clinical users under simulated use conditions, yielding a total of 225 readings with each valve and verification tool or compass.

<table>
<thead>
<tr>
<th></th>
<th>≤ 0 cmH2O</th>
<th>≤ 1 cmH2O</th>
<th>≤ 2 cmH2O</th>
<th>&gt; 2 cmH2O</th>
</tr>
</thead>
<tbody>
<tr>
<td>proGAV VERIFICATION TOOL</td>
<td>44.4 %</td>
<td>90.2 %</td>
<td>98.7 %</td>
<td>1.3 %</td>
</tr>
<tr>
<td>proGAV VERIFICATION COMPASS</td>
<td>65.3 %</td>
<td>97.8 %</td>
<td>100 %</td>
<td>0 %</td>
</tr>
<tr>
<td>proGAV 2.0 Valve</td>
<td>56.0 %</td>
<td>97.8 %</td>
<td>99.6 %</td>
<td>0.4 %</td>
</tr>
</tbody>
</table>

MRI examinations must be performed at field strengths no greater than 3.0 tesla.

**Note:** Please refer to the MRI Safety Information section of this Instructions for Use for MR-related safety information.
The proGAV Check-mate is delivered sterile and is intended to be re-sterilised. It is possible to change and to verify an applied pressure setting on the valve directly. To verify the actual pressure setting the proGAV Check-mate has to be put centrally over the valve. The proGAV Check-mate will immediately start to move. If it remains stable, the pressure setting can be read in alignment to the inlet connector.

To adjust a new pressure setting, the proGAV Check-mate has to be placed centrally over the valve. The new pressure setting has to point towards the proximal catheter (leading to the ventricle). By pressing down slightly the proGAV Check-mate, the brake of the valve is decoupled, the rotor turns and the opening pressure of the proGAV 2.0 is changed.

Please be aware that the steps for changing the pressure setting should not be more than 8 cmH₂O per step.

ADJUSTING THE ADJUSTABLE DP-UNIT

Please verify specifically before using any tool for verifying or adjusting the opening pressure:

For the adjustable DP-unit use either the proGAV 2.0 Tools or the first generation proGAV Tools.

The first generation proGAV Tool Instructions for Use can be obtained by visiting our website at www.aesculapusa.com and clicking the „Products“ menu. 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.

For a combination of proGAV 2.0 with an adjustable gravitational-unit, use only proSA Tools. The proSA Tools are only to be used to locate, verify and adjust the opening pressure of the proSA valve.

Caution: Due to magnets inside the proGAV 2.0 Tools, do not use the proGAV 2.0 Tools nearby pacemakers. Further more do not use the proGAV 2.0 Tools nearby MRI scanner, since there is a danger of damaging the MRI-scanner.

READING THE PRESSURE SETTING FROM AN X-RAY IMAGE

Adjustments of the proGAV 2.0 shunt can be verified by using the proGAV 2.0 Compass and may be confirmed by radiograph (X-ray). The position of the rotor determines and indicates the pressure setting in the X-ray. The rotor includes four magnets, arranged in pairs and face to face on top of the rotor, which are recognizable in the X-ray as four white dots. Two additional drill holes on one side of the rotor, arranged on the left respectively right side of the magnets, serve as an additional support for orientation: the two drill holes are recognizable as black dots in the X-ray.

The rotor side with the two drill holes can be described as the back side of the rotor. The gap of the two magnets opposite to those on the back side of the rotor is regarded as the triangle tip. A triangle is formed by visually connecting the magnets and the drill holes. The sharp corner of the triangle indicates the position of the triangle tip. The direction of the triangle tip indicates the pressure setting of the valve (see fig. 16).

The tringle tip can occupy any position outside the region „range not adjustable“ (fig. 16). Thus, the opening pressure of the proGAV 2.0 can be adjusted in increments of 1 cmH₂O between 0 and 20 cmH₂O.

In order to avoid misidentification of the adjusted opening pressure in the X-ray image, the valve is marked with a orientation indicator on one side (recognizable as a black cut-out in the X-ray see fig. 17). On the schematic top view as in fig. 16 the valve indication is visible on the right hand side of the valve’s housing.

<table>
<thead>
<tr>
<th>Opening pressure for vertical posture</th>
<th>Coding of gravitational unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 cmH₂O</td>
<td>small, no ring</td>
</tr>
<tr>
<td>15 cmH₂O</td>
<td>large, no ring</td>
</tr>
<tr>
<td>20 cmH₂O</td>
<td>large, 1 ring</td>
</tr>
<tr>
<td>25 cmH₂O</td>
<td>large, 2 rings</td>
</tr>
<tr>
<td>30 cmH₂O</td>
<td>large, 3 rings</td>
</tr>
<tr>
<td>35 cmH₂O</td>
<td>large, 4 rings</td>
</tr>
</tbody>
</table>

The following opening pressure ranges for the gravitational unit are possible, the pressure range selected can be checked postoperatively on X-ray image:
POSSIBLE SHUNT COMPONENTS

The proGAV 2.0 is available in different configurations. These shunt variations (for pediatric hydrocephalus and adult hydrocephalus) comprise a variety of components, which are briefly described below.

The borehole reservoir, the SPRUNG RESERVOIR or the McLANAHAH RESERVOIR are positioned in the cranial borehole. They allow flushing and extraction of CSF. Their solid titanium base is highly puncture-resistant.

With the SPRUNG RESERVOIR it is possible to flush CSF one-way in the direction of the valve, this is achieved due to a non-return valve in the bottom of the reservoir. With the aid of this mechanism a flow in direction of the ventricular catheter is avoided during the pumping procedure. A control of the distal part of the shunt system (the reservoir is hard to pump) and whether the ventricular catheter is occluded (the reservoir does not refill after pumping) can be carried out.

The CONTROL RESERVOIR or the (pediatric) prechamber are positioned on the cranium. They allow flushing and extraction of CSF, as well as palpatory inspection of the ventricle.

Similarly to the SPRUNG RESERVOIR the CONTROL RESERVOIR contains a non-return valve. Its solid titanium base is highly puncture-resistant. A puncture of the prechamber or the CONTROL RESERVOIR should be performed with a cannula with a maximum diameter of 0.9 mm as perpendicular to the reservoir surface as possible. 30 punctures are possible without any restrictions.

The opening pressure of the shunt system is not increased by the implantation of the SPRUNG RESERVOIR or 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 “Variations”).

TUBE SYSTEMS

The proGAV 2.0 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 no fundamental 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 proGAV 2.0 is available in different shunt variations:

When using a proGAV 2.0 SHUNTSYSTEM with borehole reservoir, SPRUNG RESERVOIR or McLANAHAH 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 proGAV 2.0 SHUNTSYSTEM with (pediatric) prechamber or CONTROL RESERVOIR comes with a Ventricular Catheter with 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 valve

The adjustable DP-unit of the proGAV 2.0 is supplied with a factory setting of 5 cmH₂O. This opening pressure can be set to a different value prior to implantation (see chapter “Adjusting the proGAV 2.0”). The gravitational unit of the proGAV 2.0 is a posture-dependent valve. Therefore, care must be taken that the unit is implanted parallel to the body axis. A suitable implantation site is behind the ear.

After the skin incision and tunneling under the skin, the catheter is pushed forward, from the borehole to the intended shunt implantation site. The catheter is shortened, if necessary, and secured at the proGAV 2.0 with a ligature. The shunt should not be located directly under the skin incision. The valve is marked with arrows pointing in the direction of flow (arrows pointing to distal or downward).

Warning note: The adjustable DP-unit must be placed over a hard boney surface and should not be implanted within an area, which makes finding and feeling the valve more difficult (e.g. under a scar).

Frequent pumping can lead to overdrainage and thus to unphysiological pressure conditions. The patient should be informed about the risk.

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 epigastrium. 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 secured attached to the proGAV 2.0, 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.
VALVE TEST PRIOR TO IMPLANTATION

Each proGAV 2.0 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 syringes, 30 cc to 50 cc
d) sterile 5 µ tip filter
(e) sterile tube adapter
f) sterile silicone tube

test.

Setting up the equipment

a) Position the manometer and the water bath in such a way that the zero point of the manometer has to be aligned with the water level of the water bath in order to obtain correct results.

b) Turn the three-way faucet as shown in fig. 22 and fill the manometer to at least 5 cmH₂O above the expected opening pressure. (Example: For testing a proGAV 2.0 with an opening pressure setting of 5 cmH₂O horizontal and 25 cmH₂O vertical, the manometer is filled to 15 cmH₂O with the shunt in a horizontal position and to 40 cmH₂O with the shunt in a vertical position.)

c) Turn the three-way faucet as shown in fig. 21 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 upper part of the shunt must be under water to obtain valid test results.

Calibrating the equipment

a) Turn the three-way faucet as shown as fig. 22 and fill the manometer to at least 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. 23).

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 RESULTS OF PREIMPLANTATION TEST

The following table shows results, which should be achieved by this method, for some selected pressure levels:

<table>
<thead>
<tr>
<th>Pressure rating (cmH₂O)</th>
<th>Acceptable pressure ranges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adjustable unit</td>
<td>Gravitational unit</td>
</tr>
<tr>
<td>Horizontal</td>
<td>Vertical</td>
</tr>
<tr>
<td>0</td>
<td>10 cmH₂O</td>
</tr>
<tr>
<td>0</td>
<td>10-25 cmH₂O</td>
</tr>
<tr>
<td>10</td>
<td>5-25 cmH₂O</td>
</tr>
<tr>
<td>10</td>
<td>15-35 cmH₂O</td>
</tr>
<tr>
<td>20</td>
<td>10-25 cmH₂O</td>
</tr>
<tr>
<td>20</td>
<td>20-45 cmH₂O</td>
</tr>
<tr>
<td>30</td>
<td>10-25 cmH₂O</td>
</tr>
<tr>
<td>30</td>
<td>25-55 cmH₂O</td>
</tr>
<tr>
<td>35</td>
<td>10-25 cmH₂O</td>
</tr>
<tr>
<td>35</td>
<td>25-60 cmH₂O</td>
</tr>
</tbody>
</table>

PRESSURE-FLOW CHARACTERISTICS

Horizontal position

The following diagrams show the pressure-flow-characteristics for some pressure settings of the adjustable DP-unit of the proGAV 2.0.

Vertical position

The opening pressure of the proGAV 2.0 in the vertical position is the sum of the opening pressure of the adjustable DP-unit and the gravitational unit.
The total opening pressure refers to a reference flow of 5 ml/h. When the flow rates reach 20 ml/h, the opening pressures are approximately 1-2 cmH₂O higher.

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 proGAV 2.0 is MR Conditional (ASTM F2503-13). The setting of the proGAV 2.0 will not change when subjected to an MRI of 1.5 T or 3.0 T. All components are visible via X-ray. The provided catheters are MRI Safe. Reservoirs, deflectors and connectors are MR Conditional.

Note: Please refer to the MRI Safety Information section of this Instructions for Use for MR-related safety information.

Warning note: When using a magnetic field and simultaneous pressing on the valve an adjustment of the valve cannot be excluded. The proGAV 2.0 will produce artifacts or signal-intensity voids in MR images larger than the physical size of the device.

MATERIALS

The materials used are suitable in terms of biocompatibility. The valves have been designed for long-term functionality and reliable use. The setting of the adjustable unit can be checked with the proGAV 2.0 Compass. In non-clinical testing, the image artifact caused by the device extends approximately 20mm from the proGAV 2.0 valve when imaged with a gradient echo pulse sequence and a 3-Tesla MR system.

Under the scan conditions defined above, the proGAV 2.0 valve is expected to produce a maximum temperature rise of +3°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 20mm from the proGAV 2.0 valve when imaged with a gradient echo pulse sequence and a 3-Tesla MR system.

To confirm that the valve setting has not been altered by exposure to the MRI scanner, the pressure setting of the adjustable unit can be checked with the proGAV 2.0 Compass.

The proGAV 2.0 valve is MR Conditional. Non-clinical testing demonstrated that the proGAV 2.0 valve is MR Conditional. A patient with this device can be safely scanned immediately after implantation in an MR system meeting the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 1,400-Gauss/cm (14.0 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg (First Level Controlled Operating Mode)
- Do not take the proGAV 2.0 tools into the MR environment. They are MR Unsafe.

Under the scan conditions defined above, the proGAV 2.0 valve is expected to produce a maximum temperature rise of +3°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 20mm from the proGAV 2.0 valve when imaged with a gradient echo pulse sequence and a 3-Tesla MR system.

Under the scan conditions defined above, the proGAV 2.0 valve is expected to produce a maximum temperature rise of +3°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 20mm from the proGAV 2.0 valve when imaged with a gradient echo pulse sequence and a 3-Tesla MR system.

To confirm that the valve setting has not been altered by exposure to the MRI scanner, the pressure setting of the adjustable unit can be checked with the proGAV 2.0 Compass.

Postoperative Valve Test

The proGAV 2.0 has been designed as a safe and reliable unit even without the provision of a pumping device. However, there are ways of testing the unit if a shunt system with a prechamber or a borehole reservoir is used. Valve tests can be carried out by flushing or pressure measurements.

Contraindications

The adjustable DP-unit should not be implanted within an area which makes locating and sensing the valve more difficult (e. g. under a scar). The valve should lie on the periost or the bone to make an adjustment after implantation possible.

Interactions with Products from Other Manufacturers

The proGAV 2.0 with gravitational unit should not be used under any circumstances in conjunction with any additional hydrostatic valves, as this can bring about abnormally high ventricular pressure outside of the normal physiological range. Hydrostatic valves allow for changes in hydrostatic pressure in the drainage system caused by changes in position. If in doubt, please contact the medical product consultants at Christoph Miethke GmbH & CO. KG.

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.

Warning note: When using a magnetic field and simultaneous pressing on the valve an adjustment of the valve cannot be excluded. The proGAV 2.0 will produce artifacts or signal-intensity voids in MR images larger than the physical size of the device.

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

The products are sterilized with steam under closely monitored conditions. The 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.

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 or in very rare cases, noise development. Due to violent shocks from the outside (accident, fall, etc.) the integrity of the shunt may be endangered. Due to violent shocks from the outside (accident, fall, etc.) the integrity of the shunt may be endangered. Due to violent shocks from the outside (accident, fall, etc.) the integrity of the shunt may be endangered.
RESTERILIZATION

The functional safety and reliability of resterilized products cannot be guaranteed, therefore re-sterilisation 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:

Dipl.-Ing. Christoph Miethke
Dipl.-Ing. Roland Schulz
Michaela Funk-Neubarth

Christoph Miethke GmbH & Co. KG
Ulanenweg 2
D-14469 Potsdam · Germany
Phone: +49(0) 7000 6438453 or +49(0) 331 620 83 0
Fax: +49(0) 331 620 83 40 e-mail: info@miethke.com

Please address any enquiries to:
AESCULAP AG
Am Aesculap Platz
D-78532 Tuttlingen · Germany
Phone: +49 (0) 7461 95-0
Fax: +49 (0) 7461 95-26 00
e-mail: information@aesculap.de

Service address in the US
AESCULAP Inc.
Attn. AESCULAP Technical Services
615 Lambert Pointe Road
Hazelwood, MO, 63042

AESCULAP Repair Hotline
Phone: +1 (800) 214-3392
Fax: +1 (314) 895-4420

Distributor in the US/ Contact in Canada
AESCULAP Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Phone: +1-800-282-9000
www.aesculapusa.com

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>proGAV 2.0</td>
</tr>
<tr>
<td>Intended use</td>
<td>Treatment of Hydrocephalus</td>
</tr>
</tbody>
</table>

Schematic representation of the valve with its external dimensions:

Height 4,4 mm

Height 4,6 mm

17 mm

15 mm
**proGAV 2.0 ADJUSTMENT TROUBLE SHOOTING**

<table>
<thead>
<tr>
<th>Issue</th>
<th>The proGAV 2.0 does not adjust to the pressure setting desired</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resolution Steps</td>
<td>Insure that the markings and scale windows on either the Adjustment Tool or the Verification Tool are aligned with the proGAV 2.0 valve’s proximal connector (the one pointing towards the ventricle) when used. Approximately ±15 degrees of misalignment will result in a ±1 cmH₂O measurement discrepancy. Note: When adjusting the proGAV 2.0 in its sterile packaging the arrow on the proGAV 2.0 points distally towards the peritoneal catheter and distal connector, the proximal connector is opposite the direction pointed by the arrow.</td>
</tr>
<tr>
<td></td>
<td>Insure that the desired tool is centered over the proGAV 2.0. The Adjustment Tool will not be able to adjust the proGAV 2.0 unless it is located over the center of the proGAV 2.0. The Verification Tool will not provide accurate readings unless it is also centered over the proGAV 2.0. Note: For thick skin where the proGAV 2.0 can not be palpated, use the Verification Compass to locate the center of the proGAV 2.0 valve.</td>
</tr>
<tr>
<td></td>
<td>The proGAV 2.0 can be adjusted without completely pushing down on the Adjustment Tool's button for patients with thin skin covering the proGAV 2.0 or while the proGAV 2.0 is still in its sterile packaging. However, this is NOT the case for patients with thick skin or scar tissue covering the proGAV 2.0. For these patients, insure that the tool is pressed firmly against the proGAV 2.0 valve and that the button on the tool is pressed down completely. If the patient moves their head away when pressing the button on the tool, you may need to steady the patient’s head by supplying support with your hand on the opposite side of their head.</td>
</tr>
<tr>
<td></td>
<td>Check the accuracy of the Verification Tool against the Masterdisc. If the measurements of the Verification Tool do not match with the Masterdisc, use a different Verification Tool, the Verification Compass, or an X-ray scan to obtain the setting confirmation. If the Verification Tool is accurate, try using an alternate Adjustment Tool.</td>
</tr>
<tr>
<td></td>
<td>Multiple attempts to adjust the proGAV 2.0 may be required in some cases. Typically and experienced user will be able to complete an adjustment procedure with 3 attempts or less. However, for patients with thick skin and/or scar tissue covering the valve studies have shown that up to 10 attempts may be required to complete the proGAV 2.0 adjustment. The clinical condition of the skin above the valve is the only limiting factor with regard to the number of adjustment attempts. The maximum distance possible for readjusting the valve is approximately 10 mm from the base of the Adjustment Tool to the top surface of the proGAV 2.0.</td>
</tr>
<tr>
<td></td>
<td>Was the desired change in pressure settings greater than 8 cmH₂O? See note on page 11. Repeat reprogramming, but use a smaller increment of change. Thus, it may require more than one adjustment to reach the desired pressure setting.</td>
</tr>
</tbody>
</table>

---

**VARIATIONS**

The proGAV 2.0 is available as a single valve or as a shunt system comprising various components.

- proGAV 2.0
- proGAV 2.0 SHUNTSYSTEM
- proGAV 2.0 SHUNTSYSTEM with SPRUNG RESERVOIR or McLANAHAN RESERVOIR or (pediatric) borehole reservoir
- proGAV 2.0 SHUNTSYSTEM with CONTROL RESERVOIR or with (pediatric) prechamber

Scale: 1:1
CE marking according to directive 93/42/EEC
Technical alterations reserved

Manufacturer acc. MDD 93/42/EEC:

**CHRISTOPH MIETHKE GMBH & CO. KG**

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

Distributed by:

**BRAUN**

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

Aesculap - a B. Braun company

TA013871