proGAV 2.0 Tool Set®

USA Instructions for Use
INDICATION

The Miethke proGAV 2.0 Adjustable Shunt System is intended to shunt cerebrospinal fluid (CSF) from the lateral ventricles of the brain into the peritoneum.

The proGAV 2.0 is a posture dependent hydrocephalus valve. It comprises an adjustable differential pressure unit and a fixed gravitational unit.

Fig. 2: proGAV 2.0 Compass
a) open b) closed

proGAV Compass

Alongside the proGAV 2.0 Compass there is an additional device for measuring the adjusted opening pressure. The proGAV Compass can be used to locate the valve when palpation is not possible. The proGAV Compass is set on the skin over the implanted valve and moved in a circeling motion until the internal disc is fixed over the valve. The opening pressure corresponds to the value indicated towards the direction of the ventricular catheter.

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

Fig. 3: proGAV Compass

Airbubbles inside the proGAV Compass do not affect its functionality!

CAUTION

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

DESCRIPTION OF THE INSTRUMENTS

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

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

proGAV 2.0 Compass

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

If the instrument is opened a template is visible (fig. 2a). Then the valve can be located on the patient’s head with the forefinger. Align the template of the proGAV 2.0 Compass in the direction of cerebral spinal fluid flow and place on the valve. After the compass is closed (fig. 2b), the pressure setting is indicated automatically.
**proGAV 2.0 Adjustment Tool**

The proGAV 2.0 Adjustment Tool is used for adjusting the valve opening pressure of the proGAV 2.0 from 0 to 20 cmH₂O.

**Fig. 4: proGAV 2.0 Adjustment Tool**

**proGAV Adjustment Disc**

The proGAV Adjustment Disc offers an other option to adjust the pressure setting. The proGAV Adjustment Disc is placed centrally over the valve. The desired pressure setting should be aligned with the proximal catheter (leading to the ventricle).

By pressing down the proGAV Adjustment Disc on the valve, the brake is decoupled and the opening pressure of the valve is changed.

Ensure that the pressure setting is changed no more than 8 cmH₂O. (see Chapter “Adjusting the opening pressure”)

**Fig. 5: proGAV Adjustment Disc**

Each proGAV 2.0 is calibrated under strict quality control procedures. The presetting of the adjustable DP-unit is 5 cmH₂O, but it must be checked before implantation. The setting is changed in the following steps:

1. **Locating the valve**
   The valve is located under the skin.

   **Fig. 6 Locating the valve**

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

2. **Verifying the opening pressure**
   When the compass is closed, the pressure setting is indicated automatically. (fig. 7)

   **Fig. 7: Verifying the pressure setting**

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

3. **Adjusting the opening pressure**

   **Adjustment with the proGAV 2.0 Adjustment Tool**

   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.

   **Fig. 8 a) and b): Adjustment with the proGAV 2.0 Adjustment Tool**

   **Adjustment with the proGAV Adjustment Disc**

   Center the proGAV Adjustment Disc over the adjustable DP-unit of the valve and align the desired pressure setting (b) on top of the proGAV Adjustment Disc in direction of the ventricular catheter (c), see fig. 9a.

   **Fig. 9a: Adjustment with the proGAV Adjustment Disc**

   For changing the opening pressure, press down the proGAV Adjustment Disc and release (fig. 9b). Do not press and turn. Finally, remove the proGAV Adjustment Disc. After adjusting the valve, it can be verified using the proGAV Compass and may be confirmed by radiograph (X-ray).

   **Fig. 9b: Positioning the proGAV Adjustment Disc**

   Caution: The new opening pressure setting of the valve must not differ from the measured opening pressure by more than 8 cmH₂O in any one setting (see chapter 4 “verifying the adjustment”)

   **Fig. 9c: proGAV 2.0 Adjustment Disc**
Example: Opening pressure is to be changed from 3 to 18 cmH₂O. With only one adjustment procedure the rotor would turn in the wrong direction (short way) and would stop at the position 0 cmH₂O. The correct adjustment is in 2 steps: Adjustment from 3 to 11, and from 11 to 18 cmH₂O. The rotor turns correctly.

When adjusting the proGAV 2.0 pro-operatively through the packaging, only moderate force with the proGAV 2.0 Adjustment Tool should be applied till the valve produces the clicking sound.

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

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

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>proGAV VERIFICATION TOOL</th>
<th>≤ 0 cmH₂O</th>
<th>≤ 1 cmH₂O</th>
<th>≤ 2 cmH₂O</th>
<th>&gt; 2 cmH₂O</th>
</tr>
</thead>
<tbody>
<tr>
<td>proGAV 2.0 Valve</td>
<td>44.4%</td>
<td>90.2%</td>
<td>98.7%</td>
<td>1.3%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>proGAV VERIFICATION COMPASS</th>
<th>proGAV 2.0 Valve</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>65.3%</td>
</tr>
<tr>
<td>proGAV 2.0 Valve</td>
<td>97.8%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>proGAV 2.0 COMPASS</th>
<th>proGAV 2.0 Valve</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>99.6%</td>
</tr>
<tr>
<td>proGAV Check-mate</td>
<td>0.4%</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Adjustable DP-unit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard (children and NPH patients)</td>
<td>5 cmH₂O</td>
</tr>
<tr>
<td>Defensive (e.g. patients with extremely wide ventricles and highly elevated ICP or aqueductal stenosis)</td>
<td>10 cmH₂O</td>
</tr>
<tr>
<td>Special (e.g. patients with pseudotumor cerebri)</td>
<td>15 cmH₂O</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gravitational unit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Children up to 5 years</td>
<td>20 cmH₂O</td>
</tr>
<tr>
<td>Children over 5 years and Adults up to 60 years</td>
<td>25 cmH₂O</td>
</tr>
<tr>
<td>Adults over 60 years</td>
<td>20 cmH₂O</td>
</tr>
</tbody>
</table>

The recommendations are based on common patient treatments, but can vary depending on the individual patient’s condition, see also www.miethke.com.

**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.

**CLEANING AND DISINFECTING THE proGAV Check-mate**

Avoid damage to the product due to inappropriate cleaning/disinfecting agents and/or excessive temperatures!
- Use cleaning and disinfecting agents approved for surgical steels according to the manufacturer’s instructions.
- Observe specifications regarding concentration, temperature and exposure time.
- Do not exceed the maximum allowable cleaning temperature of 55°C.
- Carry out ultrasound cleaning:
  - as an effective mechanical supplement to manual cleaning/disinfecting.
  - as a pre-cleaning procedure for products with encrusted residues, in preparation for mechanical cleaning/disinfecting.
  - as an integrated mechanical support measure for mechanical cleaning/disinfecting.
  - for additional cleaning for products with residues left after mechanical cleaning/disinfecting.
- Machine type: Single-chamber cleaning/disinfecting machine without ultrasound
- Place the product on a tray that is suitable for cleaning (avoid rinsing blind spots)

**Manual cleaning/disinfecting**
- Check visible surfaces for residues after manual cleaning/disinfecting.
- Repeat the cleaning process if necessary.

**Mechanical cleaning/disinfecting**
- Place the product on a tray that is suitable for cleaning (avoid rinsing blind spots).

**Mechanical cleaning/disinfecting with manual pre-cleaning**

<table>
<thead>
<tr>
<th>Phase</th>
<th>I</th>
<th>II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step</td>
<td>Desinfecting ultrasound cleaning</td>
<td>Intermediate rinse</td>
</tr>
<tr>
<td>T (°C/°F)</td>
<td>RT (cold)</td>
<td>RT (cold)</td>
</tr>
<tr>
<td>t (min)</td>
<td>15</td>
<td>1</td>
</tr>
<tr>
<td>Conc. (%)</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td>Water quality</td>
<td>D-W</td>
<td>D-W</td>
</tr>
<tr>
<td>Chemie</td>
<td>BBraun Stabimed; aldehyd-phenol- und QAV-frei; pH = 9</td>
<td></td>
</tr>
</tbody>
</table>

*D-W: Drinking water, RT: Room temperature*

**Mechanical alkaline cleaning and thermal disinfecting**

- Machine type: Single-chamber cleaning/disinfecting machine without ultrasound
- Place the product on a tray that is suitable for cleaning (avoid rinsing blind spots)

**Manual pre-cleaning with ultrasound**

**Mechanical cleaning/disinfecting with manual pre-cleaning**

**Manual cleaning/disinfecting**
- Check visible surfaces for residues after manual cleaning/disinfecting.
- Repeat the cleaning process if necessary.

**Mechanical cleaning/disinfecting**
- Place the product on a tray that is suitable for cleaning (avoid rinsing blind spots).
**Stage** | I | II | III | IV | V | VI
---|---|---|---|---|---|---
Step | Prewash | Cleaning | Neutralization | Intermediate rinse | Thermal disinfecting | Drying

| T (°C/°F) | <25/77 | 55/131 | 20/68 | 70/158 | 94/201 | 90/194
| t (min) | 3 | 10 | 2 | 1 | 10 | 40
| Water-quality | D-W | FD-W | FD-W | FD-W | - | -

**Chemical:** - Concentrate, alkaline: pH = 10.9 <5% anionic tensides - 1% solution: pH = 10.5 - Concentrate, acid: pH = 2.6 Basis: Citric acid - 1% solution: pH = 3.0

**D-W:** Drinking water, **FD-W:** Fully desalinated water (demineralized)

### RECOMMENDATION FOR STERILIZATION

Except for the proGAV Check-mate, proGAV 2.0 Tools and proGAV Tools can not be sterilised.

### RECOMMENDATION FOR STERILIZATION OF THE proGAV Check-mate.

The proGAV Check-mate should be sterilised by steam sterilization (fractionated vacuum process) at 132°C and 4 minutes cycle time.

### CLEANING RECOMMENDATION FOR proGAV 2.0 Tools and proGAV Tools WHICH ARE NOT STERILIZABLE

**Caution:** proGAV 2.0 Tools and proGAV Tools are made from heat unstable components which are affectable by heat or humidity or chemical aggressive substances.

Do not steep proGAV 2.0 Tools or proGAV Tools in liquids and keep the inside of the instruments dry!

Remove surface pollution of the proGAV 2.0 Tools or proGAV Tools after the use immediately with alcohol based cleaners (more than 75% alc.) by a wiping procedure.

The time of impact should be more than 60 sec. and should be depending on the level of pollution. For final cleaning use a dry wipe.

The following cleaning methods are not allowed for the cleaning of the proGAV 2.0 Tools or proGAV Tools (except proGAV Check-mate):

- Irradiation
- Ultrasonic
- Sterilization
- Machine preparation
- Inserting into liquids.

### 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

**Control, care and inspection**
- Allow the product to cool down to room temperature.
- Inspect the product after each cleaning and disinfecting cycle to be sure it is clean, functioning properly, not damaged, has intact insulation and does not have any loose, bent, broken, cracked, worn, or fractured components.
- Set aside the product if it is damaged.

After cleaning the proGAV Check-mate it should be placed in a double sterile bag. The double sterile bag is to be used during the steam sterilization cycle.

**Sterilization for proGAV Check-mate in the USA**

| Validated Cycle: | Prevacuum
| Minimum Temperature: | 132 °C
| Full Cycle Time: | 4 minutes
| Minimum Dry Time: | 20 minutes
| Sample Configuration: | Sterilization Container (Aesculap SterilContainer)

**Manufacturers**

<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 Tool Set</td>
</tr>
<tr>
<td>Intended use</td>
<td>Treatment of Hydrocephalus</td>
</tr>
<tr>
<td>Store in a clean, dry place</td>
<td>---</td>
</tr>
</tbody>
</table>
CE marking according to directive 93/42/EEC

Technical alterations reserved

Manufacturer acc. MDD 93/42/EEC:

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