proGAV® 2.0

Rx Only
proGAV® 2.0


MIETHKE Gravitational Valves provide a new solution for drainage control in offering the latest advancement in the treatment of Hydrocephalus. proGAV 2.0 provides the reliability of our existing valves with new features to ensure simplicity for the surgeon, with comfort and protection for the patient.

Simplicity.

- 3-Step Reprogramming offers an easy solution if adjustment to the pressure setting is necessary
- Tactile “feedback mechanism” provides confidence that the adjustment has been made

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

*See Indications for Use on back cover.
Comfort.
- “Soft Touch” technology provides protection against painful readjustments
- 0 – 20 cm H₂O Pressure settings allow for a custom approach and a wide range of treatment options

Protection.
- Gravitational technology provides the latest advancement in Hydrocephalus drainage control
- “Active Lock” mechanism provides security against inadvertent readjustment caused by MRI 3 Tesla or less


**Reprogramming Instruments**

**Compass**

The *proGAV 2.0 Compass* can be used to locate and verify the current setting of the valve.

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**3-Step Reprogramming**

1. **Verify**
   
   Place the *Compass* over the *valve*. Open the lid and align the valve with the internal template. Close the lid and the current setting will be reflected in the window.

2. **Adjust**
   
   Remove the compass and position the *Adjustment Tool* over the *valve* so that the desired setting is in line with the reservoir or proximal catheter. Press gently in the center of the *valve* until a tactile click occurs.
Adjustment tool

The proGAV® 2.0 Adjustment Tool allows for an adjustment to the opening pressure (0 to 20 cm H₂O).

Verify

Place the Compass over the valve. Open the lid and align the valve with the internal template. Close the lid and the new setting will be reflected in the window. Verification may be confirmed by radiograph (x-ray).
How the valve works

The proGAV 2.0 is a position-dependent valve, meaning the opening pressure changes gradually corresponding to the patient’s body position. proGAV 2.0 allows for complete customization of the patient’s needs in allowing for a specific opening pressure when the patient is lying down, and a specific opening pressure for when the patient is upright.

Adjustable unit

The adjustable unit can be set in increments of 1 cm H2O between 0 and 20 cm H2O.

Gravitational unit

The gravitational unit is available in various pressure settings.

Low profile design

Optimized rotor design

Protective titanium housing

“Active Lock” MR brake 3T or less
Horizontal position

When the patient is in the supine position, only the adjustable unit is active and preset to 5 cm H₂O*. The gravitational unit is not active in this body position.

Vertical position

In the upright position, the gravitational and adjustable units work together. As the patient sits up, the tantalum ball (green) is activated within the gravitational unit and causes an increase in the opening pressure.

The gradual increase in opening pressure in the upright position effectively protects against excessive drainage.

In the example shown, a gravitational unit with 25 cm H₂O has been selected. Therefore the total opening pressure equals 30 cm H₂O** when in the upright position.

*The free Miethke app for Apple and Android simply explains the functionality of all Miethke gravitational valves.*
Pressure Selection

Some considerations for proGAV 2.0 pressure selection include patient height, weight, activity level, medical condition and age. The opening pressure of the adjustable valve can be set to a value between 0 and 20 cm H₂O depending on the patient’s clinical presentation and indication. Please refer to the product Instructions for Use for more information.

- The gravitational unit is available in 6 pressures, from 10-35 cm H₂O in increments of 5 cm H₂O.
- The taller the patient, the higher the pressure level of the gravitational unit.
- The shorter the patient or more overweight, the lower the pressure level of the gravitational unit.
- The more immobile the patient, the lower the pressure level of the gravitational unit.

The pressure of the shunt system in the supine position is maintained by the setting of the adjustable valve only. In the upright position, the pressure is the total of the adjustable valve pressure and the pressure of the gravitational unit.

Recommended settings only; may vary according to patient and medical history.

See the Pressure Recommendation Chart available as a download from www.aesculapusa.com

### ADJUSTABLE VALVE

<table>
<thead>
<tr>
<th>Patient Type</th>
<th>Recommended Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard (children, NPH patients)</td>
<td>5 cm H₂O</td>
</tr>
<tr>
<td>Defensive (patients with extremely wide ventricles and highly elevated ICP or aqueductal stenosis)</td>
<td>10 cm H₂O</td>
</tr>
<tr>
<td>Special (patients with pseudotumor cerebri)</td>
<td>15 cm H₂O</td>
</tr>
</tbody>
</table>
**X-ray Verification**

The setting of the proGAV® 2.0 valve can be easily identified on post-operative x-rays by placing an x-ray template (supplied) over the radiographic image.

**NOTE:** The orientation indicator should face three o’clock to maintain the correct position. In the event the image is reversed, simply flip the template over.

A triangle is formed by visually connecting the magnets and drill holes. The sharp corner of the triangle indicates the position of the rotor tip. The direction of the rotor tip indicates the pressure setting of the valve.

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**GRAVITATIONAL UNIT**

<table>
<thead>
<tr>
<th>Patient Type</th>
<th>Recommended Valve</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children up to 5 years</td>
<td>20 cm H₂O</td>
</tr>
<tr>
<td>Children over 5 years Adults up to 60 years</td>
<td>25 cm H₂O</td>
</tr>
<tr>
<td>Adults over 60 years</td>
<td>20 cm H₂O</td>
</tr>
</tbody>
</table>

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**Instruments**

<table>
<thead>
<tr>
<th>Article No.</th>
<th>Tools</th>
</tr>
</thead>
<tbody>
<tr>
<td>FX400T</td>
<td>proGAV® 2.0 adjustment tool</td>
</tr>
<tr>
<td>FX401T</td>
<td>proGAV® 2.0 compass</td>
</tr>
<tr>
<td>FV403T</td>
<td>proGAV® compass</td>
</tr>
<tr>
<td>FV407T</td>
<td>proGAV® adjustment disc</td>
</tr>
<tr>
<td>FV409T</td>
<td>proGAV® checkmate*</td>
</tr>
</tbody>
</table>

*Ordered separately*
Notes
INDICATIONS FOR USE: The Miethke proGAV® 2.0 Adjustable Shunt System is intended to shunt cerebrospinal fluid (CSF) from the lateral ventricles of the brain to the peritoneum. See Instructions for Use for additional information including Warnings and Precautions. Rx only.