proGAV 2.0®

USA Instructions for Use

CHRISTOPH MIETHKE GMBH & CO. KG

CE 0297

CONTENT

INDICATION	4
TECHNICAL DESCRIPTION	4
FUNCTION OF THE VALVE	5
PHYSICS BACKGROUND	6
SELECTING THE APPROPRIATE SHUNT	7
USING THE INSTRUMENTS	7
proGAV Check-mate CE 0297	10
ADJUSTING THE ADJUSTABLE DP-UNIT	10
READING THE PRESSURE SETTING FROM AN X-RAY IMAGE	11
POSSIBLE SHUNT COMPONENTS	12
TUBE SYSTEMS	12
SURGICAL PROCEDURE	12
PREOPERATIVE VALVE TEST	13
VALVE TEST PRIOR TO IMPLANTATION	14
TEST RESULTS OF PREIMPLANTATION TEST	15
PRESSURE-FLOW CHARACTERISTICS	15
CONTRAINDICATIONS	16
INTERACTIONS WITH PRODUCTS FROM OTHER MANUFACTURERS	16
RE-IMPLANTATION	16
SAFETY MEASURES	16
COMPATIBILITY WITH DIAGNOSTIC PROCEDURES	16
MRI SAFETY INFORMATION	17
ARTIFACT INFORMATION	17
POSTOPERATIVE VALVE TEST	17
FUNCTIONAL SAFETY	17
ADVERSE REACTION	17
STERILIZATION	17
RESTERILIZATION	18
NOTE ON THE INSTRUCTIONS FOR USE	18
REQUIREMENTS OF THE MDD 93/42/EEC	18
MEDICAL PRODUCTS CONSULTANT	18
GENERAL INFORMATION	19
proGAV 2.0 ADJUSTMENT TROUBLE SHOOTING	20
VARIATIONS	21

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

INDICATION

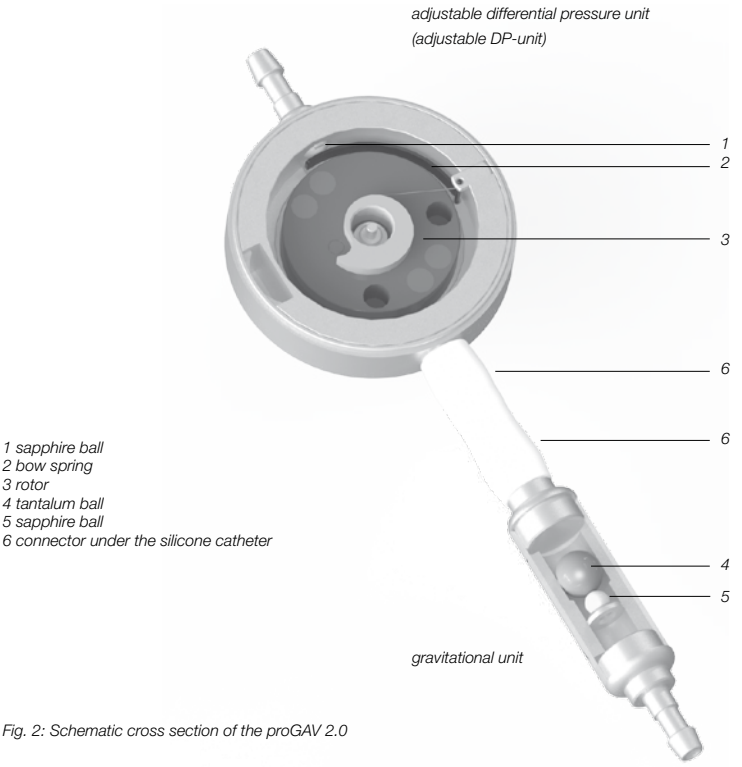
The *proGAV 2.0* Adjustable Shunt System is intended to shunt cerebrospinal fluid (CSF) from the lateral ventricles of the brain into the peritoneum.

TECHNICAL DESCRIPTION

The *proGAV 2.0* is a posture dependent hydrocephalus valve. It comprises an adjustable differential pressure unit and a fixed gravitational unit (fig. 1 and 2).

Fig. 1: proGAV 2.0 - side view

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.



1 sapphire ball
2 bow spring
3 rotor
4 tantalum ball
5 sapphire ball
6 connector under the silicone catheter

Fig. 2: Schematic cross section of the proGAV 2.0

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).

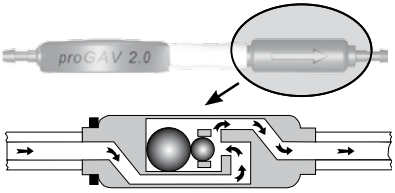


Fig. 3: Gravitational unit in horizontal position

Hence, the opening pressure of the *proGAV 2.0* is defined by the adjustable DP-unit. The operational principle of the adjustable DP-unit is illustrated in figures 3 and 4.
In fig. 4a, the ball-cone valve is closed. The drainage is blocked. In fig. 4b, the adjustable DP-unit is shown in the open condition. The patient's IVP is increased and the spring force, which otherwise keeps closed the ball-cone valve, is overcome. The closing ball moves out of the cone and a gap opens to allow drainage.

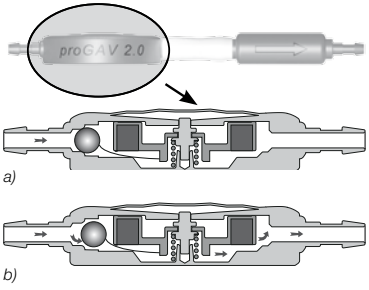


Fig. 4: Adjustable DP-unit
a) closed b) open

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).

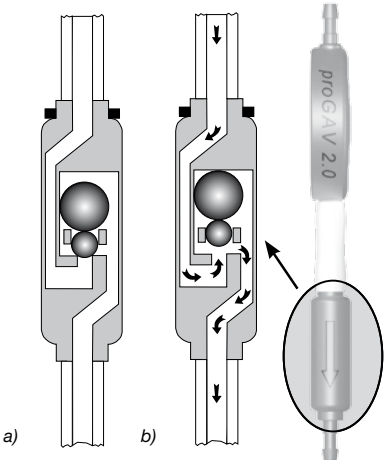


Fig. 5: Gravitational unit in vertical position
a) closed, b) open

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 aswell as the combination with the gravitational unit. Principallly, 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.

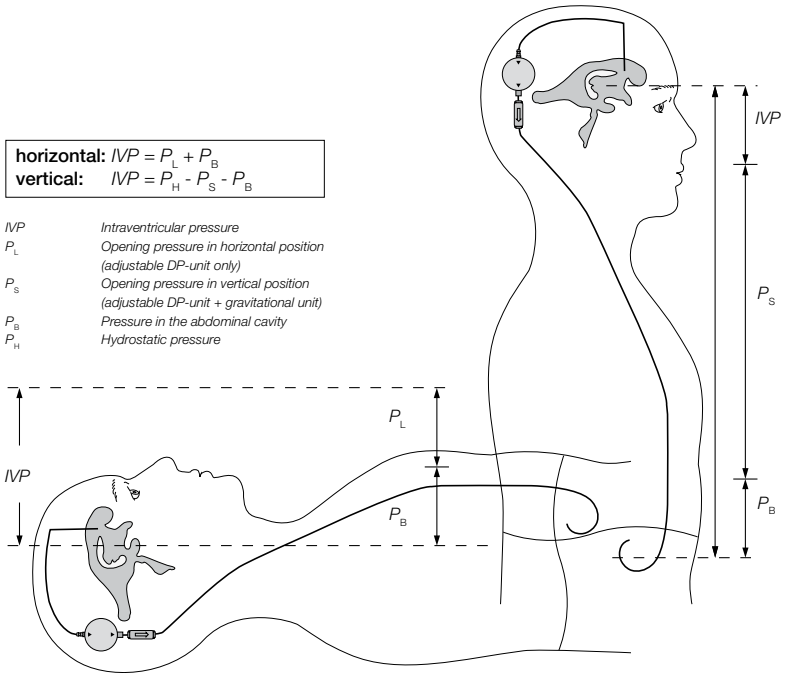


Fig. 6: Calculating the intraventricular pressure for horizontal and vertical body position

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 choosen according to the clinical situation and indication. The unit can be adjusted to a pressure setting between 0 cmH_2O and 20 cmH_2O. The valve is preset to 5 cmH_2O.

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.

a) *b)*

Fig. 7: proGAV 2.0 Compass
a) open b) closed

The *proGAV 2.0 Adjustment Tool* is used for adjusting the valve opening pressure of the *proGAV 2.0* from 0 to 20 cmH_2O.

Fig. 8: proGAV 2.0 Adjustment Tool

Each *proGAV 2.0* is calibrated under strict quality control procedures. The presetting of the adjustable DP-unit is 5 cmH_2O, 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.

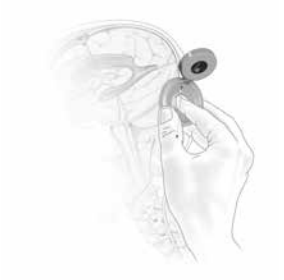


Fig. 9 Locating the valve with the proGAV 2.0 Compass

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)

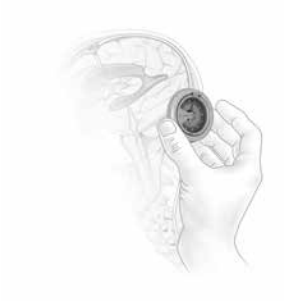
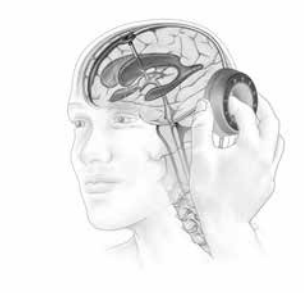


Fig. 10: Verifying the pressure setting with the proGAV 2.0 Compass

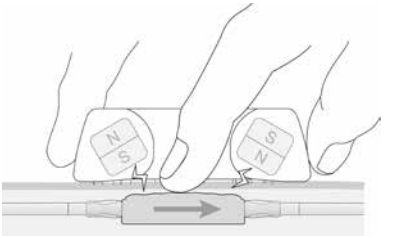
Caution: Placing the *proGAV 2.0 Compass* in a non-central position on the valve can lead to erroneous readings!

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.



a)



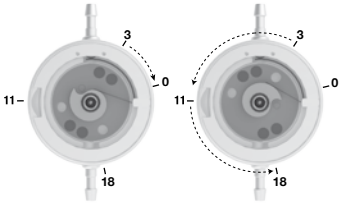
b)
Fig. 11: a) and b)
Adjustment with the proGAV 2.0 Adjustment Tool

The *proGAV 2.0* is equipped with a feedback-mechanism. When using the *proGAV 2.0 Adjustment Tool*, pressure on the housing of the valve is created and a resulting acoustic signal (a clicking sound) is produced due to the unique construction of the valve housing. This clicking sound indicates that the rotorbrake is released. Now the rotor can rotate freely. Once the pressure on the valve is released, a clicking sound is heard and the rotorbrake is again locked safely so that the valve is safe against spontaneous re-adjustments.

The clicking sound is well recognizable before implantation. However after implantation, once the valve is filled up, depending on place and texture of the surrounding area of the implant, the acoustic signal could be considerably muted. The clicking sound should generally be audible by the patient itself or via a stethoscope.

Caution: The new opening pressure setting of the valve must not differ from the measured opening pressure by more than 8 cmH_2O in any one setting (see chapter 4 "verifying the adjustment").

Example: Opening pressure is to be changed from 3 to 18 cmH_2O. With only one adjustment procedure the rotor would turn in the wrong direction (short way) and would stop at the position 0 cmH_2O. The correct adjustment is in 2 steps: Adjustment from 3 to 11, and from 11 to 18 cmH_2O. The rotor turns correctly.



a) *b)*

Fig. 12: Rotor rotation during adjustment
a) false b) correct

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

Caution: Ensure that the instrument remains close to the valve during the adjustment procedure.

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. 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 certainly by the *proGAV 2.0 Compass,* the use of imaging techniques is recommended (excluding MRI: danger of artifacts).

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.

proGAV Check-mate CE 0297

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 cmH_2O per step.

Fig. 13: proGAV Check-mate

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 ther is a danger of damaging the MRI-scanner.**

ADJUSTING THE ADJUSTABLE DP-UNIT

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

a) *b)*

Fig. 14 a): proGAV 2.0 Compass
b) proGAV 2.0 Adjustment Tool

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.**

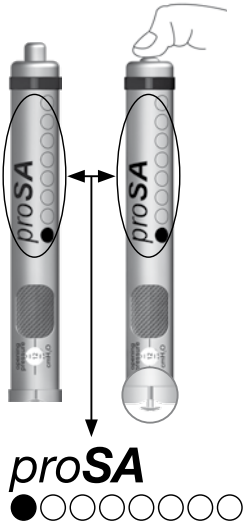


Fig. 15: proSA Adjustment Tool

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*.
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).

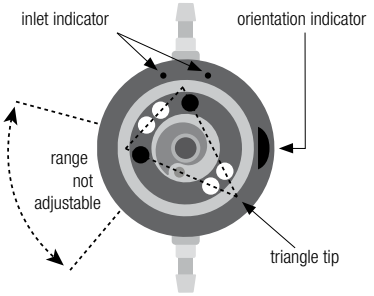


Fig. 16: Schematic X-ray image

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 cmH_2O between 0 and 20 cmH_2O.
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.

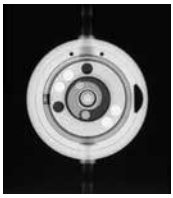


Fig. 17: Radiograph pressure setting 13 cmH_2O

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

Opening pressure for vertical posture	Coding of gravitational unit
10 cmH_2O	small, no ring
15 cmH_2O	large, no ring
20 cmH_2O	large, 1 ring
25 cmH_2O	large, 2 rings
30 cmH_2O	large, 3 rings
35 cmH_2O	large, 4 rings

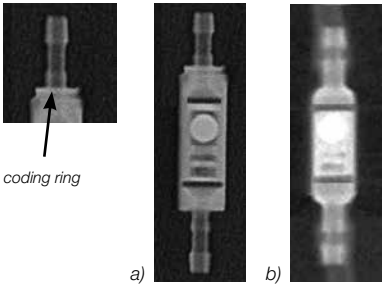


Fig. 18: X-ray image of the gravitational unit
a) large, 1 ring = 20 cmH_2O,
b) small, no ring = 10 cmH_2O

POSSIBLE SHUNT COMPONENTS

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

The *borehole reservoir, the SPRUNG RESERVOIR* ore the *McLANAHAN 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 (pedriatic) *prechamber* are positioned on the cranium. They allow flushing and extraction of CSF, as well as palpatory inspection of the ventricle.
Similarily 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 *McLANAHAN 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 (pedriatic) prechamber* or *CONTROL RESERVOIR* comes with a V*entricular 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 cmH_2O. 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 securely 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.

PREOPERATIVE VALVE TEST

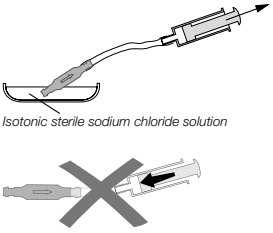


Fig. 19: Patency test

The *proGAV 2.0* 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. 19).

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 *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 syringe, 30 cc to 50 cc
d) sterile 5-µ tip filter
e) sterile tube adapter
f) sterile silicone tube

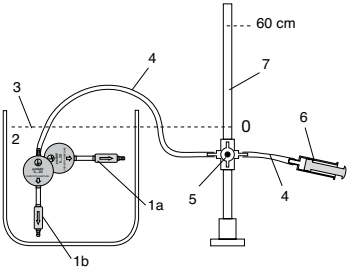


Fig. 20: Test setup
1 proGAV 2.0 a) horizontal, b) vertical;
2 water bath; 3 constant water level; 4 silicone tube; 5 three-way tap; 6 single-use syringe with syringe filter; 7 manometer

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. 20).
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. 20)
d) To release all air from the test assembly, turn the three-way faucet as shown in fig. 21.
e) Immerse the silicone tube in the sterile water bath and rinse it with the sterile water from the syringe.

Calibrating the equipment

a) Turn the three-way faucet as shown in fig. 22 and fill the manometer to at least 5 cmH_2O.
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.

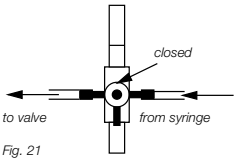


Fig. 21

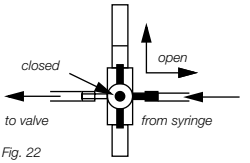


Fig. 22

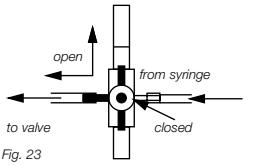


Fig. 23

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. 22 and fill the manometer to 10 cmH_2O above the expected opening pressure. (Example: For testing a *proGAV 2.0* with an opening pressure setting of 5 cmH_2O horizontal and 25 cmH_2O vertical, the manometer is filled to 15 cmH_2O with the shunt in a horizontal position and to 40 cmH_2O 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 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. 23 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 OF PREIMPLANTATION TEST

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

Pressure rating (cmH_2O)		Acceptable pressure ranges	
adjustable unit	gravitational unit	horizontal	vertical
0	10	0-5 cmH_2O	5-15 cmH_2O
0	20	0-5 cmH_2O	10-25 cmH_2O
10	10	5-15 cmH_2O	10-25 cmH_2O
10	20	5-15 cmH_2O	15-35 cmH_2O
20	20	10-25 cmH_2O	20-45 cmH_2O
20	30	10-25 cmH_2O	25-55 cmH_2O
20	35	10-25 cmH_2O	27-60 cmH_2O

Table 1: Selected pressure ranges

PRESSURE-FLOW CHARACTERISTICS

Horizontal position

The following diagrams show the pressure-flow characteristics of the adjustable DP-unit of the *proGAV 2.0* for the pressure settings 0, 10 and 20 cmH_2O.

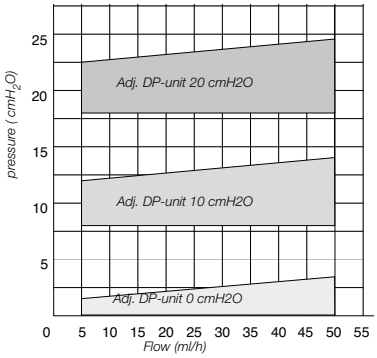
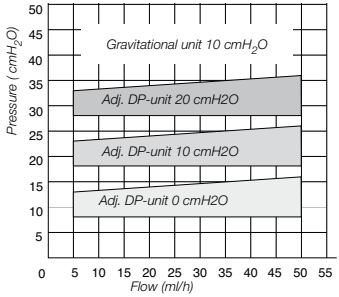


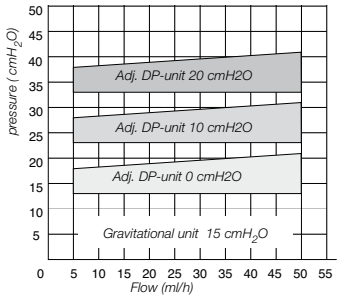
Fig. 24: Pressure-flow characteristics for some pressure settings of the adjustable DP-unit

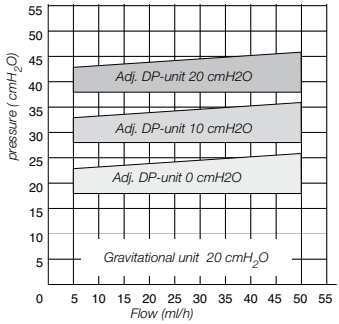
Vertical position

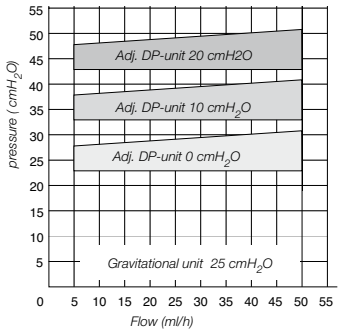
The opening pressure of the *proGAV 2.0* in the vertical position is the sum of the opening pressure of the adjustable DP-unit and the gravitational unit.

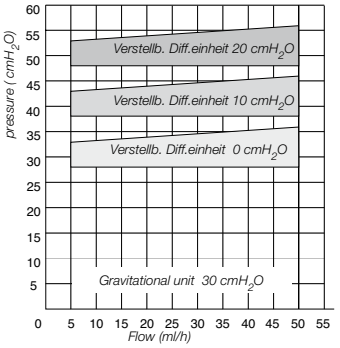
The following diagrams show the pressure-flow-characteristics for some pressure settings in the vertical body position.

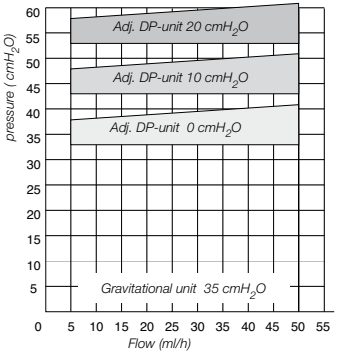












The total opening pressure refers to a reference flow of 5 ml/h. When the flowrates reach 20 ml/h, the opening pressures are approximately 1-2 cmH$_2$O higher.

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.

RE-IMPLANTATION

Under no circumstances should products that have had previously been implanted in a patient be subsequently reimplanted in another, because a successfull decontamination of the device cannot be reached without functional degradation.

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 *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.

MRI SAFETY INFORMATION

MR Conditional

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.

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.*

ARTIFACT INFORMATION

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal void size	2,274 mm^2	2,246 mm^2	5,418 mm^2	4,768 mm^2
Plane orientation	parallel	perpendicular	parallel	perpendicular

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.

FUNCTIONAL SAFETY

The valves have been designed for long-term reliable and precise operation. Still, it cannot be excluded that the shunt system needs to be replaced for technical or medical reasons. The valve and the valve system are able to resist positive and negative pressure up to 200 cmH_2O during and after implantation.

Warning note for carriers of pacemakers:Due to the implantation of a *proGAV 2.0* the function of a pacemaker can be affected.

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.

STERILIZATION

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.

RESTERILIZATION

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:

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
Phone: +49(0) 331 620 83 0
Fax: +49(0) 331 620 83 40 e-mail: info@miethke.com

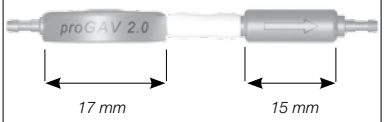
Please address any enquiries to:
AESCULAP AG
Am Aesculap Platz
D-78532 Tuttlingen · Germany
Phone: +49 (0) 7461 95-0
Fax: +49 (0) 7461 95-26 00
e-mail: information@aesculap.de

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

Manufacturer	**Christoph Miethke GmbH & Co. KG**
Product name	*proGAV 2.0*
Intended use	Treatment of Hydrocephalus
Intended for single use (disposable)	
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**

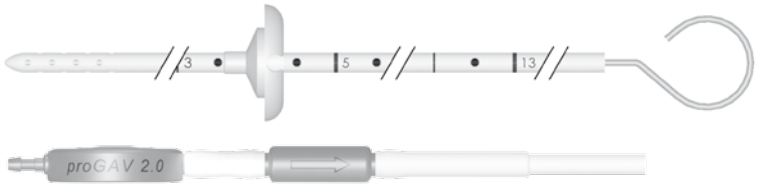
Issue	**The *proGAV 2.0* does not adjust to the pressure setting desired**
Resolution Steps	Insure that the markings and scale windows on either the Adjustment Tool or the Verification Tool are aligned with the *proGAV 2.0* valve's proximal connector (the one pointing towards the ventricle) when used. Approximately ±15 degrees of misalignment will result in a ±1 cmH_2O 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.
	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.
	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.
	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.
	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*.
	Was the desired change in pressure settings greater than 8 cmH_2O? 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.

VARIATIONS

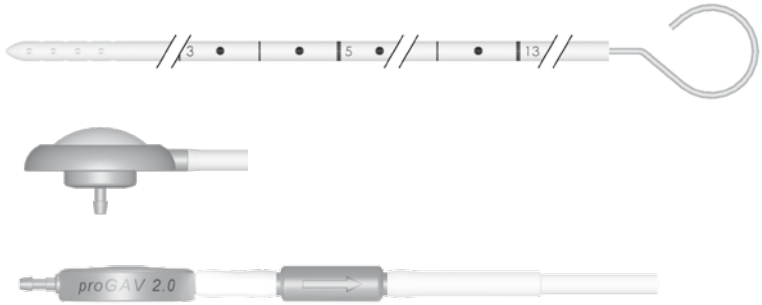
The *proGAV 2.0* is available as a single valve or as a shunt system comprising various components.

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 0297

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:

B BRAUN
SHARING EXPERTISE

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 GBA_81_06_0816_USA