MIETHKE proGAV 2.0 In Touch With You Christoph Instruction Manual

Contents

MIETHKE proGAV 2.0 In Touch With You Christoph

Product Information

Specifications

- **Product Name:** proGAV 2.0
- **Manufacturer:** Miethke
- **Website:** www.miethke.com

Indication

The proGAV 2.0 is designed for cerebrospinal fluid drainage in the treatment of hydrocephalus.

FAQ

- **Q:** Where can I obtain the Instructions for Use for United States users?
  - **A:** The Instructions for Use for United States users can be obtained by visiting the website www.aesculapusa.com. You can also request a paper copy by contacting your local Aesculap representative or Aesculap's customer service at 1-800-282-9000.
- **Q:** How much does a paper copy of the Instructions for Use cost?
  - **A:** A paper copy of the Instructions for Use will be provided to you upon request at no additional cost.

Technical Description

The proGAV 2.0 consists of the following components:

1. Adjustable differential pressure unit
2. Spring rod

3. Sapphire ball
4. Rotor
5. Gravitational unit (SHUNTASSISTANT 2.0)
6. Tantalum ball

Function of the Valve

- The proGAV 2.0 valve can be adjusted to two positions: closed and open.

Selection of the Appropriate Pressure Level

The proGAV 2.0 offers different pressure levels that can be selected by adjusting the valve. The pressure levels and their corresponding codings are:

Pressure Level	Coding
10 cmH_2O	Code 1
15 cmH_2O	Code 2
20 cmH_2O	Code 3
25 cmH_2O	Code 4
30 cmH_2O	Code 5
35 cmH_2O	Code 6

Product Usage Instructions

Localization of the Valve

To locate the valve on the patient's head, follow these steps:

1. Open the instrument to reveal a template.
2. Use your index finger to locate the valve through the template.

Adjustment of the Valve

To adjust the proGAV 2.0 valve, follow these steps:

1. Use the proGAV 2.0 adjustment instrument.
2. Ensure that the feedback mechanism is activated.
3. Rotate the instrument in the correct direction to adjust the valve.
4. Check the rotor rotation to ensure it is correct.

Tube Systems and Implantation

When implanting the proGAV 2.0, consider the following:

- The adjustable differential pressure unit should not be implanted in an area that makes it difficult to locate or palpate the valve.
- Avoid applying pressure with a syringe at both the proximal and distal ends of the tube system.

Sterilization

- The proGAV 2.0 should be sterilized according to the manufacturer's instructions.

Product Overview

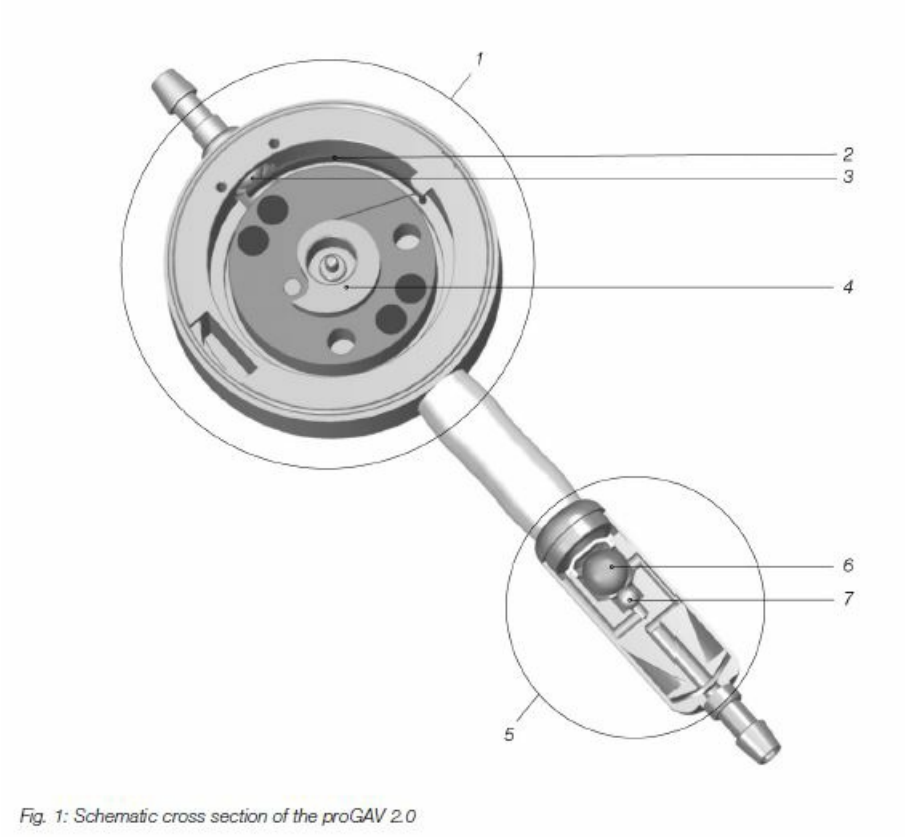


Fig. 1: Schematic cross section of the proGAV 2.0

1. Adjustable differential pressure unit (adjustable DP-unit)
2. Bow spring
3. Sapphire ball
4. Rotor
5. Gravitational unit (SHUNTASSISTANT 2.0)
6. Tantalum ball
7. Sapphire ball

INDICATION AND TECHNICAL DESCRIPTION

INDICATION

- The proGAV 2.0 is used for cerebrospinal fluid (CSF) drainage in the treatment of hydrocephalus.

TECHNICAL DESCRIPTION

The proGAV 2.0 is a valve made from titanium. It consists of an adjustable differential pressure unit and a gravitational unit. The adjustable differential pressure unit consists of a stable titanium housing in which a tried and tested ball cone valve (1) is integrated in the proximal section. A bow spring (2) determines the opening pressure of this unit. The pretension of the spring, and therefore the valve opening pressure, can be adjusted through the skin using a revolving rotor on a bearing (3). Major components in the gravitational unit are a tantalum ball (4), which defines the opening pressure for this valve depending on the body position and a sapphire ball (5), which ensures precise closure.

FUNCTION OF THE VALVE

- The proGAV 2.0 is a posture dependent hydrocephalus valve.
- The opening pressure for the proGAV 2.0 is composed of the opening pressures for the adjustable differential pressure unit and the gravitational unit.

Horizontal position

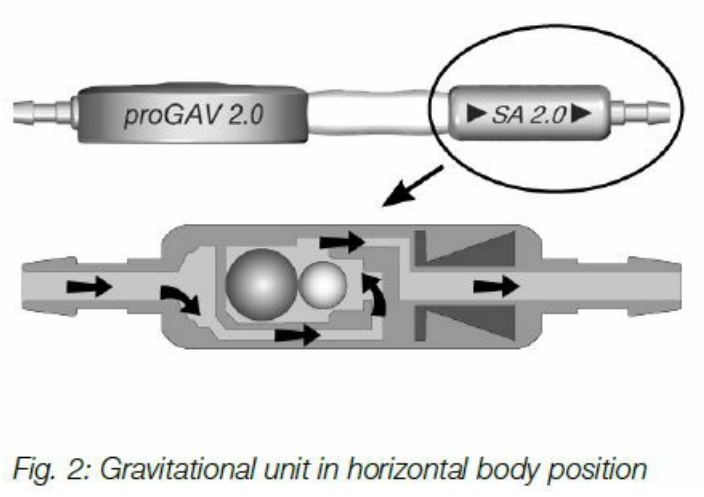


Fig. 2: Gravitational unit in horizontal body position

- In the horizontal position, the gravitational unit is always open and does not present any resistance.

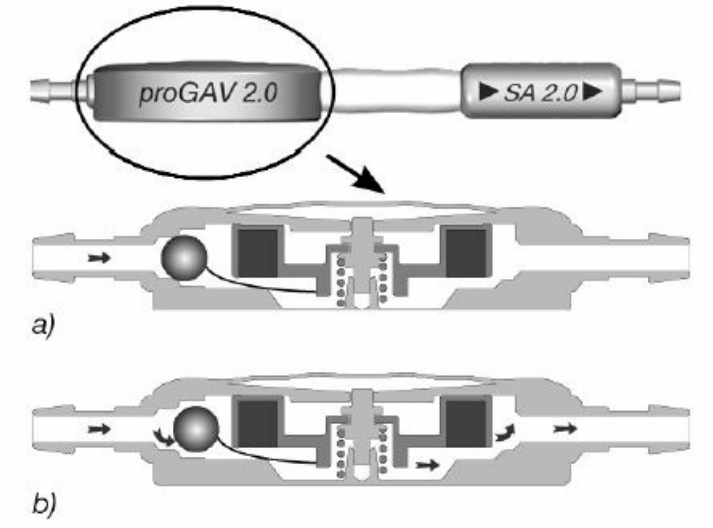


Fig. 3: Adjustable differential pressure unit in horizontal body position
a) closed b) open

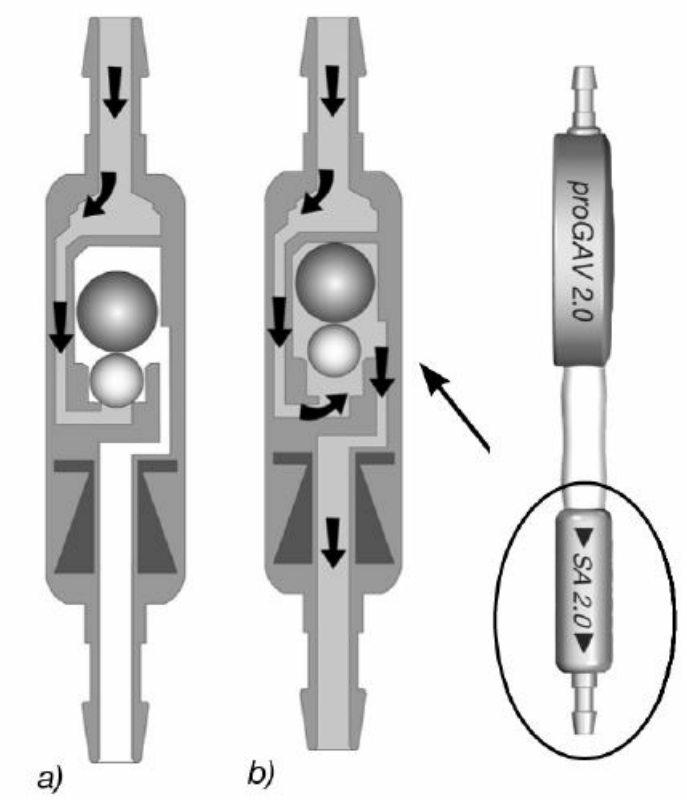
- Consequently, the opening pressure of the pro GAV 2.0 in the horizontal body position is characterised by the adjustable differential pressure unit. The principal working method used by the adjustable differential pressure

unit is shown in fig. 3a and b.

- In fig. 3a it is closed so that no drainage is possible.
- In fig. 3b, the adjustable differential pressure unit is shown in the open state.

The intraventricular pressure (IVP) of the patient is increased and the spring force which would otherwise keep the differential pressure unit closed is overcome. Now, the sealing ball moves out of the cone and a gap is sealing for liquor drainage.

Vertical position



When the patient moves into an upright position, in that moment the gravitational unit closes (fig. 4a). 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. 4b).

During physical activity which is associated with vibrations (for example jogging) the opening pressure of the proGAV 2.0 can decrease temporarily by 25 % to 35 % according to laboratory results. This aKects both the individual valve and the combination with a gravitational unit. As a basic principle, functionality is retained. At the end of physical activity, the opening pressure returns to its original level and remains stable.

SELECTION OF THE APPROPRIATE PRESSURE LEVEL

Horizontal position

The opening pressure for the horizontal body position is achieved using the adjustable differential pressure unit. Here, the pressure stage should be set in accordance with the clinical picture and indications. Depending on the clinical picture and age of the patient, the opening pressure for this position can be selected between pressure levels 0 and 20 cmHRO.

Vertical position

The proGAV 2.0 opening pressure for the vertical body position is calculated from the sum of the opening pressure of the adjustable differential pressure unit and the gravitational unit. Patient size, activity level and potentially increased abdominal pressure (obesity) should be taken into account in selecting the opening pressure for this position (see pressure level recommendations at **https://www.miethke.com/downloads/**).

READING THE PRESSURE SETTING FROM AN X-RAY IMAGE

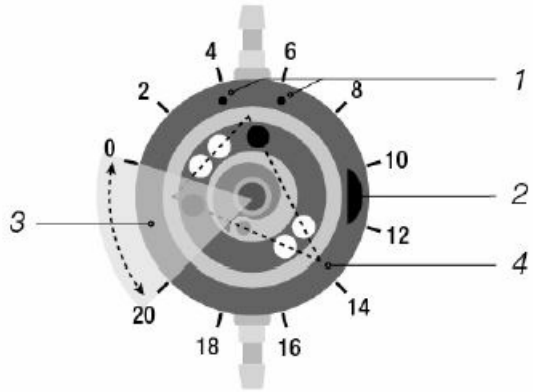


Fig. 5: Schematic representation of rotor in X-ray image
1) Admittance markings 2) Valve marking
3) Non-adjustable range 4) Triangle apex

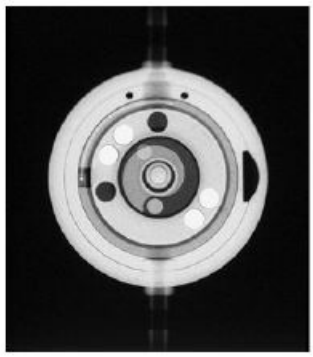


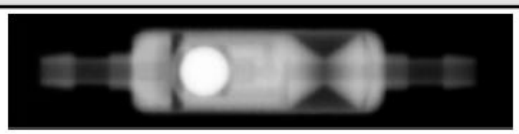
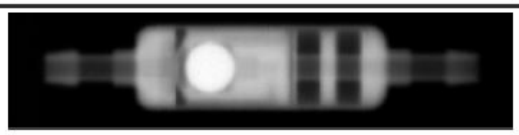
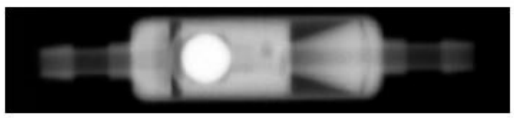
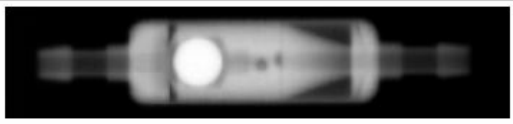
Fig. 6: X-ray image of an adjustable differential pressure unit, setting 14 cmH_2O

The set pressure level of the proGAV 2.0 should always be checked using the proGAV 2.0 Compass, but it can also be checked using an x-ray image. The rotor setting is decisive in this case. The four magnets in the rotor can be seen on the x-ray image as white points and are located opposite each other in pairs. Two additional burrholes (right and left next to the magnet pairs) on one side of the rotor can be used as orientation. They can be seen as black points on the X-ray image. This side can be designated as the rotor rear side. The two front magnets are opposite. The space between these two magnets can be considered as the triangle apex.

The pressure level can be read oK using the orientation of this intermediate space. The triangle apex can take up any position except the space labelled as a non-adjustable area in fig. 5. This means that the opening pressure of the proGAV 2.0 can be infi nitely variably adjusted from 0 up to 20 cmH2O. To ensure that the pressure stage is not read oK as a mirror image, the valve is provided with a valve marking on one side which is visible as black in the X-ray image – on a plan view of the implanted valve as in fig. 6 the recess on the right-hand side is visible.

The pressure levels can be identified by coding in the X-ray image. The following pressure levels are

possible for the gravitational unit:

Opening Pressure	Coding
10 cmH_2O	
15 cmH_2O	
20 cmH_2O	
25 cmH_2O	
30 cmH_2O	
35 cmH_2O	

USING THE INSTRUMENTS

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

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

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

Fig. 8: proGAV 2.0 Adjustment Tool

- The proGAV 2.0 Adjustment Tool is used for adjusting the valve opening pressure of the pro- GAV 2.0 from 0 to 20 cmHRO.
- Each proGAV 2.0 is calibrated under strict quality control procedures. The presetting of the adjustable DP-unit is 5 cmHRO, but it must be checked before implantation. The setting is changed in the following steps:

Locating the valve

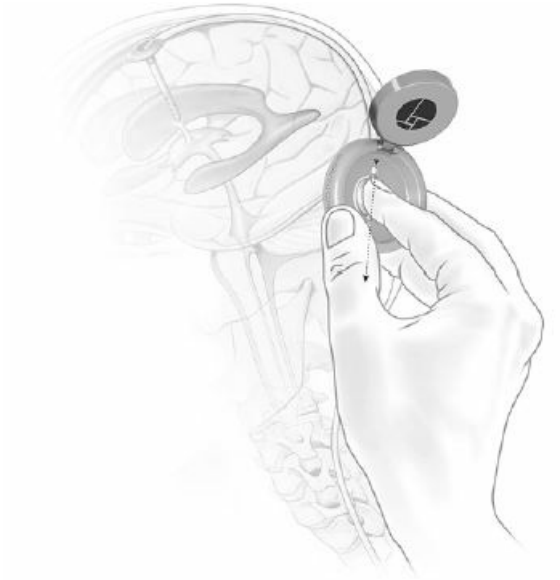


Fig. 9: Locating the valve with the proGAV 2.0 Compass

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

Verifying the opening pressure

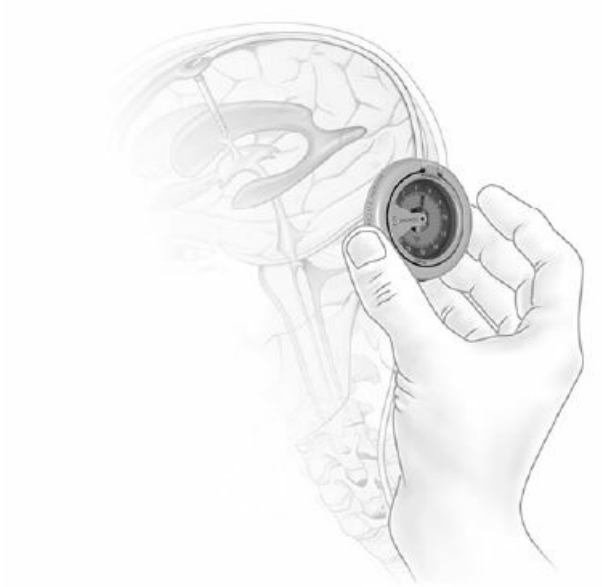


Fig. 10: Verifying the pressure setting with the proGAV 2.0 Compass

- When the compass is closed, the pressure setting is indicated automatically (fig. 10).

CAUTION: Placing the proGAV 2.0 Compass in a noncentral 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.

Adjusting the opening pressure

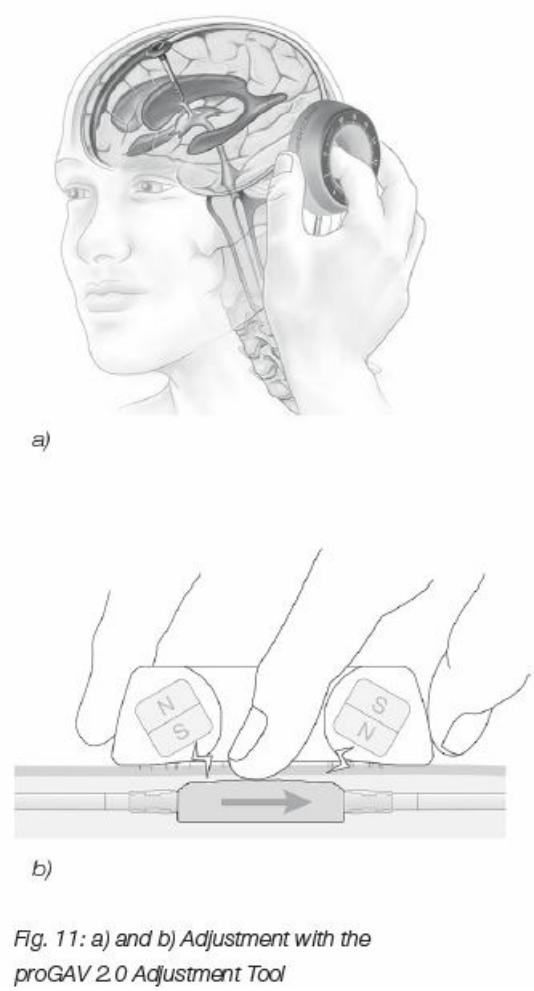


Fig. 11: a) and b) Adjustment with the proGAV 2.0 Adjustment Tool

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.

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 rotor brake is released.

Now the rotor can rotate freely. Once the pressure on the valve is released, a clicking sound is heard and the rotor brake 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 cmH2O in any one setting.

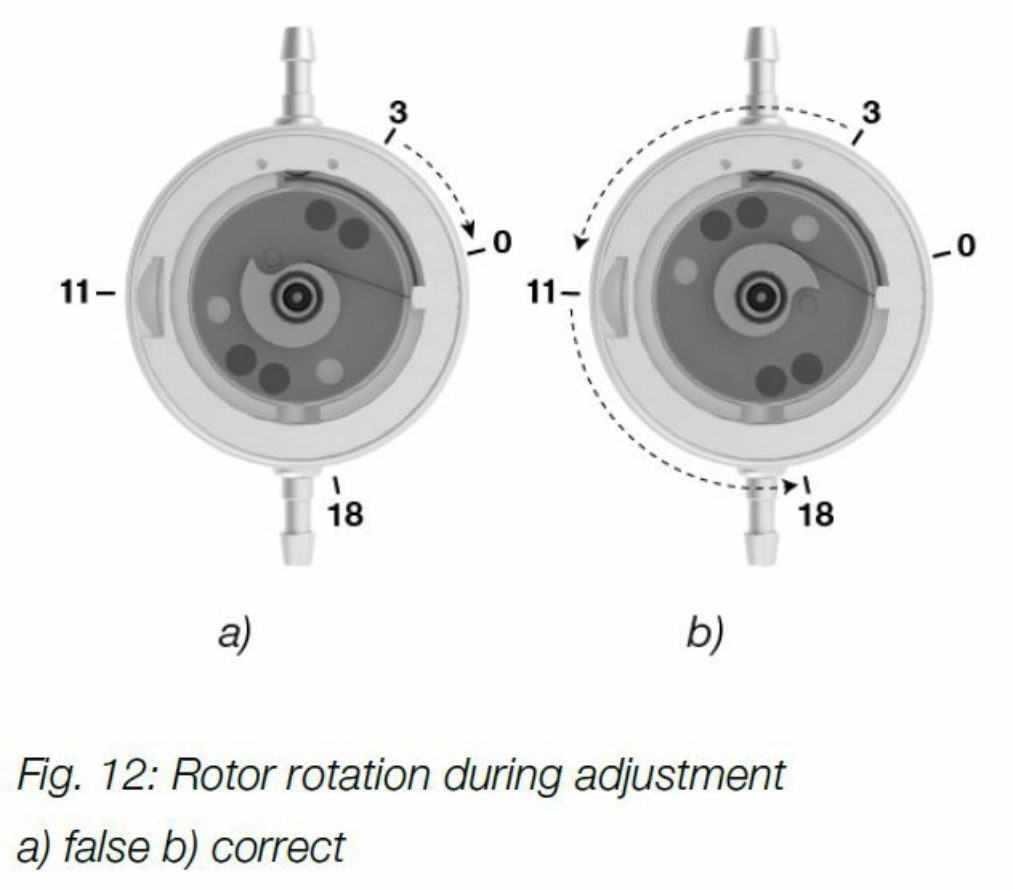


Fig. 12: Rotor rotation during adjustment
a) false b) correct

Example: Opening pressure is to be changed from 3 to 18 cmHRO. With only one adjustment procedure the rotor would turn in the wrong direction (short way) and would stop at the position 0 cmHRO (fig. 12a). The correct adjustment is in 2 steps: Adjustment from 3 to 11 cmHRO, and from 11 to 18 cmHRO. The rotor turns correctly (fig. 12b).

CAUTION

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

Verifying the adjustment

After adjusting the valve by using the proGAV 2.0 Adjustment Tool, it must 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. Due to postoperative swelling of the skin the adjustment of the valve setting may be difficult within the first few days. 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.

proGAV Checkmate

Fig. 13: proGAV Checkmate

The proGAV Checkmate 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 Checkmate has to be put centrally over the valve. The proGAV Checkmate 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 Checkmate 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 Checkmate, 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 cmHRO per step.

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.

M.blue plus Instruments

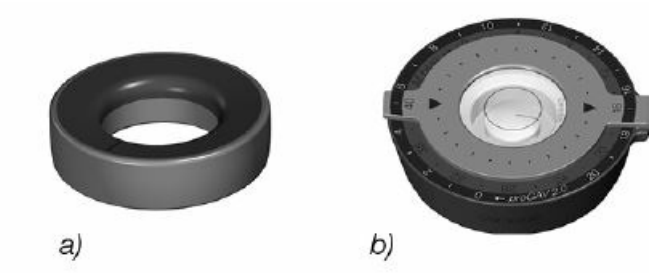


Fig. 14: a) M.blue plus Adjustment ring
b) M.blue plus Compass

- In addition to the described proGAV 2.0 Tools, the M.blue plus Instruments can also be used for locating, reading and adjusting the adjustable differential pressure unit of the pro- GAV 2.0.
- When combining proGAV 2.0 with M.blue (adjustable gravitational unit), the M.blue plus Instruments can also be used to locate, read and adjust the pressure level of the M.blue (adjustable gravitational unit).

POSSIBLE SHUNT COMPONENTS

The proGAV 2.0 can be ordered as a shunt system in a range of configurations. The configurations can be combined with the accessories presented in brief below. In each case, versions for paediatric hydrocephalus and for normal pressure hydrocephalus (NPH) in adults are available.

Reservoirs

The use of a reservoir in combination with shunt systems provides options for the withdrawal of cerebrospinal fluid, administration of drugs and pressure control. Due to the non-return valve of the SPRUNG RESERVOIR and the CONTROL RESERVOIR, cerebrospinal fluid can be pumped towards the valve, thus making it possible to check the distal part of the drainage system as well as (proximal) ventricular catheter.

During the pump action, access to the ventricular catheter is closed. The use of reservoirs does not increase the opening pressure of the shunt system. A puncture should be performed as perpendicular as possible to the reservoir surface with a maximum cannula diameter of 0.9 mm. 30 punctures are possible without any restrictions.

WARNING

- Frequent pumping can result in excessive drainage and thus lead to pressure conditions outside the normal physiological range.
- The patient should be properly informed about this risk.

Burrhole Deflector

Because of the tight fit on the ventricular catheter, the Burrhole Deflector makes it possible to choose the length of catheter penetrating into the skull prior to implantation. The ventricular catheter is deflected at a right angle in the burrhole (see chapter “Implantation”).

TUBE SYSTEMS

The proGAV 2.0 can be ordered as an individual valve unit or as a shunt system with integrated catheters (interior diameter 1.2 mm, exterior diameter 2.5 mm). The supplied catheters do not fundamentally change the pressure-flow characteristics. If catheters by other manufacturers are used, a tight fit must be ensured. In any case, catheters have to be carefully fixed with a ligature to the valve’s titanium connectors.

IMPLANTATION

Positioning the ventricular catheter

Several surgical techniques are available for positioning the ventricular catheter. The required skin incision should be made in form of a lobule pedicled towards the draining catheter. If a burrhole deflector is used, the skin incision should not be located right above the reservoir.

To avoid CSF leakage, care should be taken that the dura opening is kept as small as possible after applying the burrhole. The proGAV 2.0 is available in a range of different configurations:

If a burrhole reservoir is used, 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 cerebrospinal fluid is dripping out. The catheter is shortened and connected the burrhole reservoir connected, with the connection secured with a ligature. A shunt system with prechamber comes with a burrhole deflector. The deflector is used for adjusting the length of catheter to be implanted and for its positioning inside the ventricle. The ventricular catheter is deflected and the prechamber is put into place. The position of the ventricular catheter should be checked after implantation by imaging (such as CT or MRI).

Positioning the valve

The proGAV 2.0 operates depending on its position. You must therefore ensure that the gravitational unit is implanted parallel to the body axis. Therefore, if a Shunt System in which the valve has been pre-fitted with a burrhole reservoir, only the occipital access should be used. A location behind the ear is suitable as an implantation position, whereby the implantation height has no influence on the valve function. The adjustable differential pressure unit should be contacting the bone or the periosteum since pressure must be exerted on the valve during any later adjustment. A large arch-shaped or a smaller straight skin incision should be made, which is then provided with two pockets (proximal from the incision for the adjustable differential pressure unit and distal from the incision for the gravitational unit).

The catheter is then pushed forward from the burrhole to the selected valve implantation location, shortened if necessary, and secured to the proGAV 2.0 with a ligature. Neither the adjustable differential pressure unit nor the gravitational unit should be located directly under the skin incision. Both valve units have been provided with an arrow in the flow direction (arrow towards distal or downwards).

WARNING

- The adjustable differential pressure unit should not be implanted in an area which makes the detection or palpation of the valve difficult (e.g. underneath heavily scarred tissue).
- The catheters should only be blocked with a sheathed clamp and not directly behind the valve as they might be damaged otherwise.

Positioning the peritoneal catheter

The place of 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.

VALVE TEST

Preoperative valve test

- The most careful way of filling the valve is by aspiration through a sterile single-use syringe attached to the distal end of the catheter.
- The distal end of the valve is connected and immersed in a sterile physiological saline solution.

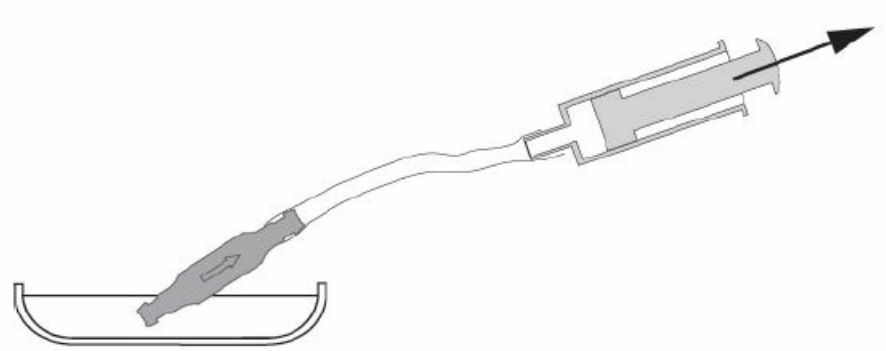


Fig. 15: Patency test

- The valve is patent if saline solution can be extracted (fig. 15).

CAUTION: Contamination in the solution used for testing can impair the product‘s performance.

WARNING

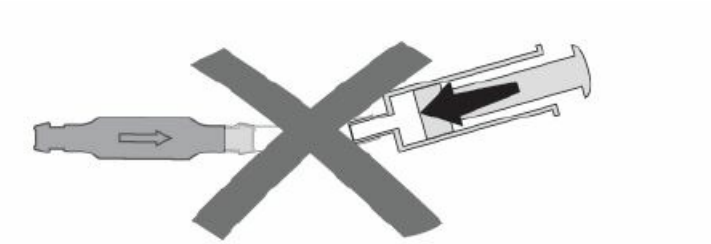


Fig. 16: Avoidance of pressurisation

- Pressurisation by the single-use syringe should be avoided both at the proximal and the distal end (fig. 16).

Postoperative valve test

- The proGAV 2.0 has been constructed as a reliably functioning unit without pump or test function.
- The valve test can be performed by flushing, pressure measurement or pumping.

RE-IMPLANTATION

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

PRESSURE-FLOW-CHARACTERISTICS

Horizontal valve position

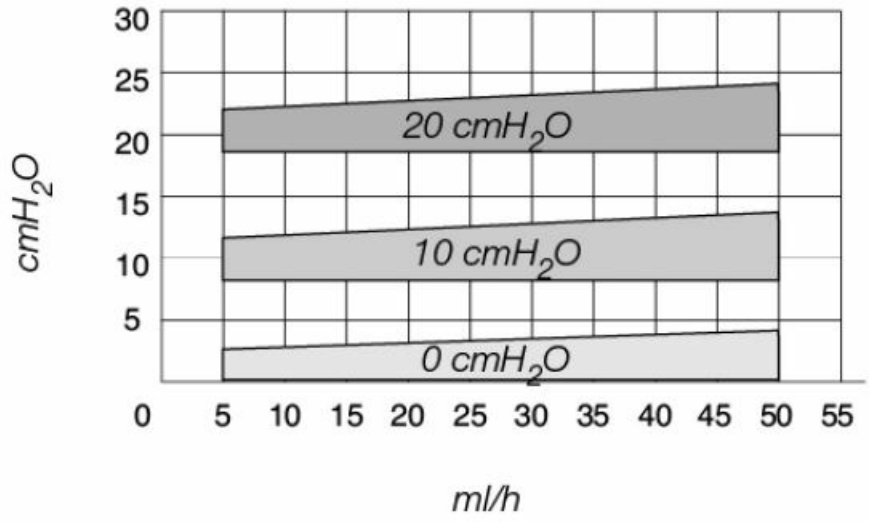
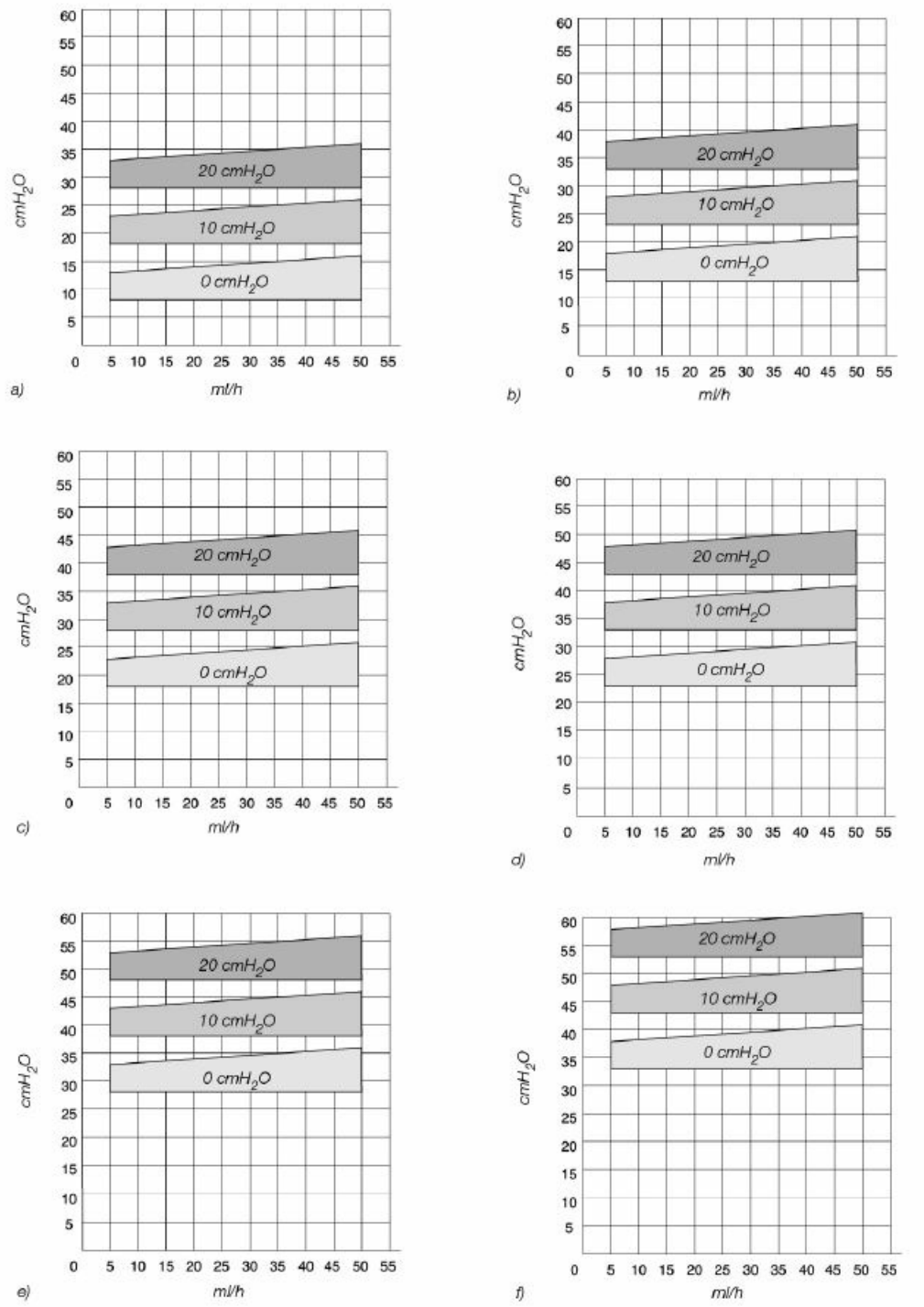


Fig. 17: Pressure flow characteristics for selected pressure levels of the adjustable differential pressure unit

The pressure flow characteristics of the adjustable differential pressure unit in the pro- GAV 2.0 are shown as an example for pressure levels 0, 10 and 20 cmHRO in the horizontal valve position below.

Vertical valve position



The pressure flow characteristics of the available proGAV 2.0 pressure settings:
a) 10 cmH_2O, b) 15 cmH_2O, c) 20 cmH_2O, d) 25 cmH_2O, e) 30 cmH_2O, f) 35 cmH_2O

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 flow rates reach 20 ml/h, the opening pressures are approximately 1-2 cmHRO higher.

PRECAUTIONS AND CONTRAINDICATIONS

Patients must be carefully monitored after implantation. Reddening of skin or tightness in the area of the drained tissue may be indications of infections at the shunt system. Symptoms such as headache, dizziness, confusion or vomiting often occur in conjunction with shunt dysfunction. These symptoms and a leakage within the shunt system require the immediate replacement of the aKected shunt component or the entire shunt system. The implantation of medical devices is contraindicated if the patient has an infection or suspected infection (e.g.

meningitis, ventriculitis, peritonitis, bacteriaemia, septicaemia) in the region aKected by the implantation.

FUNCTIONAL SAFETY

FUNCTIONAL SAFETY AND COMPATIBILITY WITH DIAGNOSTIC PROCEDURES

These medical devices are constructed in such a way as to ensure their precise and reliable operation over long periods of time. However, we cannot guarantee that these medical devices will require replacement for medical or technical reasons. These medical devices are able to resist positive and negative pressures up to 200 cmHRO during and after implantation.

These medical devices have to be stored in a clean and dry environment at all times. Nuclear magnetic resonance examinations up to a field strength of 3 Tesla or computed tomography examinations can be performed without risk or impairment to the valve function. The valve is MR Conditional. Supplied catheters are MR Safe. Reservoirs, deflectors and connectors are MR Conditional.

The conditions for MR compatibility of the products can be found on our website:
https://www.miethke.com/downloads/

WARNING

- If a magnetic field is being applied and pressure is applied to the valve at the same time, it is not possible to rule out valve adjustment.
- In MRI the proGAV 2.0 creates artefacts which are larger than the valve itself.
- For people using cardiac pacemakers: it is possible that the function of the heart pacemaker is influenced by the implementation of a proGAV 2.0.

ADVERSE REACTIONS AND INTERACTIONS

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. Violent shocks from the outside (accident, fall) may put the integrity of the shunt system at risk. The proGAV 2.0 must not be used in conjunction with hydrostatic valves as this may result in increased ventricular pressure outside of the physiological range. In case of doubt, please contact the medical products consultants at Christoph Miethke GmbH & Co. KG.

STERILISATION

The products are sterilised with steam under strictly controlled conditions. The expiry date is printed on the wrapping of each individual product. If the packaging is damaged, the product must not be used in any circumstances. No guarantee can be given for the functional safety and reliability of resterilised products.

REQUIREMENTS OF THE MDD

REQUIREMENTS OF THE MDD (DIRECTIVE 93/42/EEC)

The Medical Device Directive requires comprehensive documentation of the fate of medical devices used in humans, especially for implants. The individual implant identification number should therefore be recorded in the patient’s medical records and patient card to ensure complete traceability. Translations of these instructions for use into additional languages can be found on our website: **https://www.miethke.com/downloads/**

MEDICAL DEVICES CONSULTANTS

In compliance with the European Directive concerning medical devices (Directive 93/42/EEC), Christoph Miethke GmbH & Co. KG has nominated medical devices consultants as contacts for all product-related questions.

You can contact our medical devices consultants via:

- **Tel.** +49 331 62083-0
- **info@miethke.com**

VARIATIONS

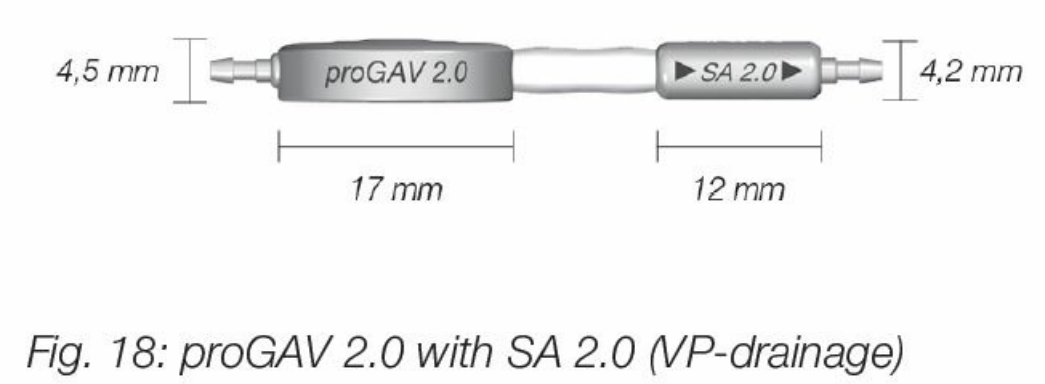


Fig. 18: proGAV 2.0 with SA 2.0 (VP-drainage)

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

Contact

Manufacturer

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Documents / Resources

	MIETHKE proGAV 2.0 In Touch With You Christoph [pdf] Instruction Manual proGAV 2.0 In Touch With You Christoph, proGAV 2.0, In Touch With You Christoph, Touch With You Christoph, You Christoph, Christoph

References

- Aesculap, Inc.
- B. Braun: A leading medical technology company
- Medizintechnik aus Potsdam – Neurochirurgische Implantate zur Therapie des Hydrocephalus :: Christoph Miethke GmbH & Co. KG
- Hier finden Sie alle Gebrauchsanweisungen und Produktinformationen :: Christoph Miethke GmbH & Co. KG
- Hier finden Sie alle Gebrauchsanweisungen und Produktinformationen :: Christoph Miethke GmbH & Co. KG
- User Manual