proSA®

Ⓓ Gebrauchsanweisung | ⒼⒷ Instructions for use | Ⓕ Mode d´emploi
Ⓔ Instrucciones de manejo

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CHRISTOPH MIETHKE GMBH & CO. KG

CE 0297

CONTENT

INDICATION

The *proSA* is intended to divert cerebrospinal fluid (CSF) from the lateral ventricles of the brain into the peritoneum. It is the first hydrocephalus valve that is adjustable for the vertical body position, respectively for inclined body position.

TECHNICAL DESCRIPTION

The *proSA* combines a fixed DP-unit or an adjustable DP-unit and an adjustable gravitational unit (Fig. 1). Each valve unit consists of a robust titanium housing and uses the reliable ball-cone principle.

A spiral spring (1) defines the fixed opening pressure of the fixed DP-unit. The sapphire ball (2) ensures the precise closure of the valve.

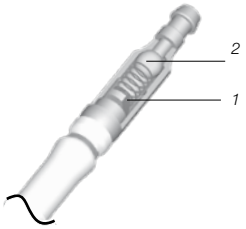


Fig. 1a: Schematic cross section of the proSA with DP-unit

A bow spring (3) defines the opening pressure of the adjustable DP-unit . The pretensioning of the spring and thus the opening pressure can be adjusted by turning the rotor (4), with the valve implanted under the patient's skin.

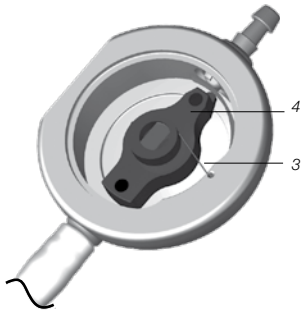


Fig. 1b: Schematic cross section of the adjustable DP-unit

The adjustable gravitational unit contains a tantalum weight (5), which is connected to the bow spring (3). The weight keeps the sapphire ball in its position. Depending on the body position, the influence of the tantalum weight changes and therefore the opening pressure. By turning the rotor (4) the pretension of the bow spring can be adjusted and the opening pressure can be changed with the valve implanted under the patient's skin.

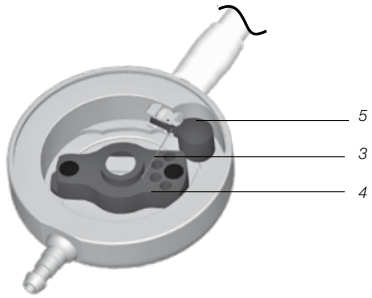


Fig. 1c: Schematic cross section of the adjustable gravitational unit

PHYSICS BACKGROUND

The intraventricular pressure is positive in a healthy human in the horizontal position. To adjust this pressure through shunt drainage, the appropriate pressure range must be chosen, taking into account the abdominal cavity pressure. The resulting IVP is the sum of the shunt opening pressure and the abdominal cavity pressure (Fig. 2).
The ventricular pressure in a healthy human when moving to the 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 for the change in pressure differential. This is equal to the hydrostatic pressure minus the sum of the abdominal cavity pressure and the slightly negative intraventricular pressure.

Conventional shunts open immediately as soon as the patient stands up, which can lead to critical overdrainage.

IVP	*Intraventricular pressure*
PVli	*Opening pressure in horizontal position (DP-unit only)*
PVst	*Opening pressure in vertical position (DP-unit + gravitational unit)*
PB	*Pressure in the abdominal cavity*
PHyd	*Hydrostatic pressure*

horizontal: $IVP = PVli + PB$
vertical: $IVP = PHyd - PVst - PB$

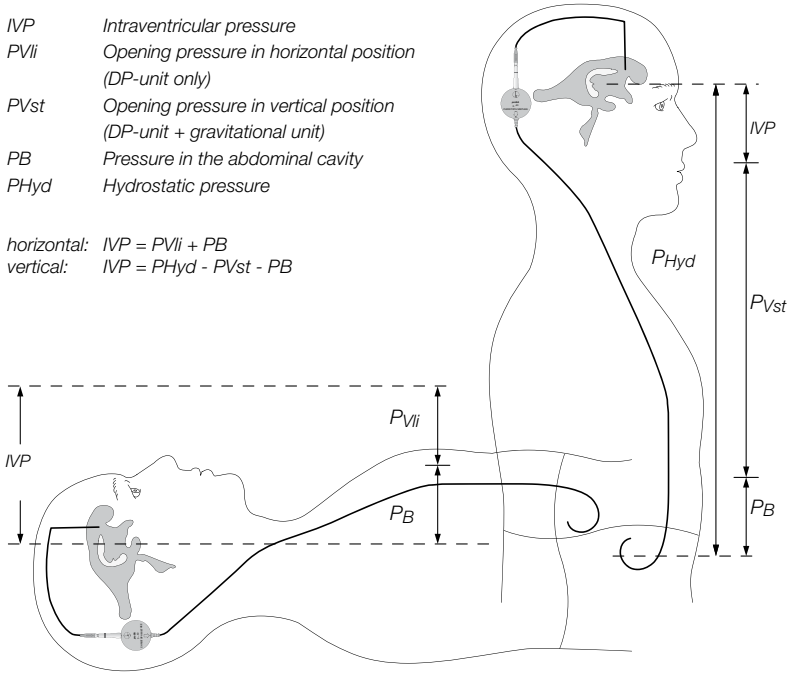


Fig. 2: Calculating the intraventricular pressure

FUNCTION OF THE VALVE

Horizontal body position

proSA with DP-unit

The operating principle of the DP-unit is illustrated in Fig. 3. a) and b). Fig. 3 a shows the fixed DP-unit in the horizontal position. The ball-cone valve is closed and drainage is prevented. If the patient's IVP increases and continues to rise, the spring pressure of the ball-cone unit will be overcome. The sapphire ball will move away from the cone and a gap will open for fluid drainage.

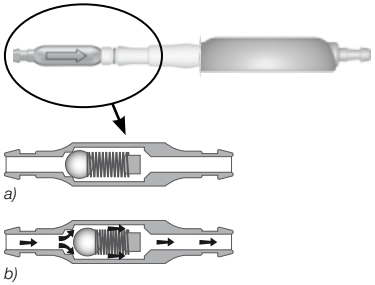


Fig. 3: DP-unit
a) closed and b) open

proSA with adjustable DP-unit

In Fig. 4a the ball-cone unit of the adjustable DP-unit is closed, hence the drainage is blocked. Fig. 4b shows the adjustable DP-unit in an open condition. The patient's IVP is increased and the spring force, which otherwise keeps the ball-cone unit closed, is overcome. The sapphire ball moves out of the cone and a gap opens up to allow drainage.

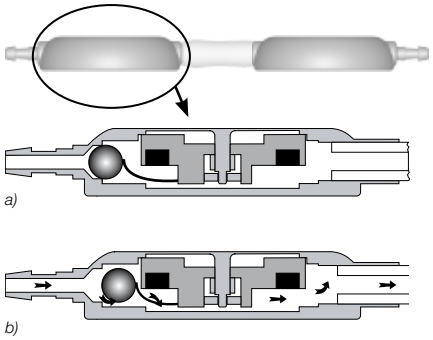


Fig. 4: adjustable DP-unit
a) closed, b) open

With the *proSA* in the horizontal position (Fig. 5), the weight (1) does not affect the sapphire ball (2). Hence, in this configuration the *proSA* is open, and the force brought to bear by the weight does not counteract the fluid pressure. The ventricular pressure is now controlled solely by the differential-pressure valve installed.

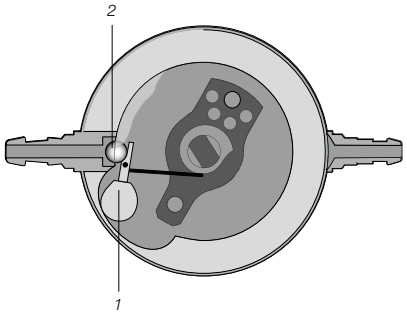


Fig. 5: adjustable gravitational unit in horizontal position

Vertical body position

In the vertical position, the DP-unit and the adjustable gravitational unit of the *proSA* work together. The total opening pressure is the sum of the opening pressures of the DP-unit and the adjustable gravitational unit. If the IVP (intraventricular pressure) of the patient and the hydrostatic pressure exceed this opening pressure, the closing ball of the gravitational unit is pushed away from the cone seal and a gap opens for fluid drainage (Fig. 6).

The valve system prevents increases in intraventricular pressure above the physiological range.

To ensure optimal CSF drainage for each individual patient in any body position, the opening pressure of the adjustable gravitational unit can be adjusted from 0 to 40 cmH_2O.

The adjustment can be achieved non-invasively using the *proSA Tool Set*, preventing the need for further surgery.

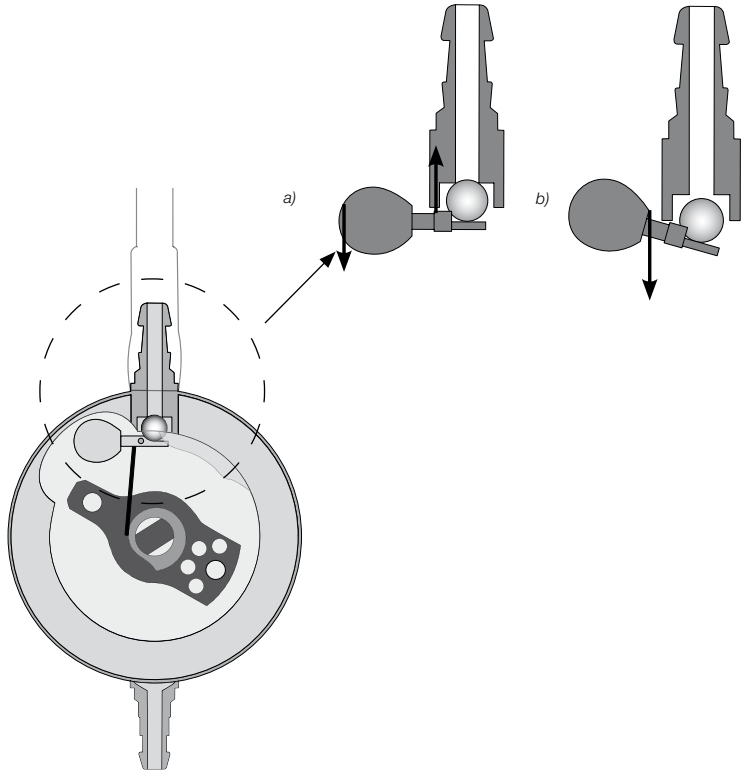
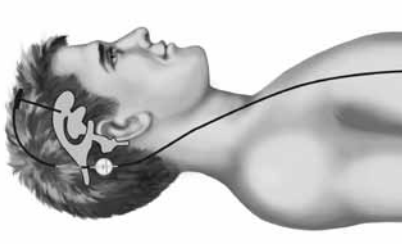


Fig. 6: gravitational unit in vertical body position a) closed b) open

SELECTING THE APPROPRIATE OPENING PRESSURE OF THE VALVE

The *proSA* is a position-dependent valve, that means the opening pressure changes depending on the body position of the patient. Hence, one opening pressure for the horizontal position and one for the vertical position is set to fit the *proSA* individually to the patient.
(see recommendation for pressure levels: www.miethke.com)

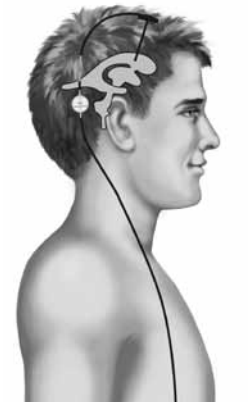


Horizontal position
In the horizontal position the gravitational unit doesn't have any resistance. Only the differential pressure unit determines the opening pressure of the whole shunt system.
As standard configuration we recommend a differential pressure unit with opening pressure of 5 cmH_2O.

		opening pressure differential pressure unit		opening pressure gravitational unit
opening pressure of the whole shunt system	=	standard 5 cmH_2O defensive* 10 cmH_2O special** 15 cmH_2O	+	0 cmH_2O

**e.g. patients with extremely wide ventricles and highly elevated ICP or aqueductal stenosis*
***e.g. patients with pseudotumor cerebri*

Vertical position
In the vertical position the opening pressure of the complete shunt system is the sum of the opening pressure of the differential unit and the opening pressure of the gravitational unit.
The opening pressure of the gravitational unit should be chosen depending on height, weight and age of the patient.



		opening pressure differential pressure unit		recommendation opening pressure gravitational unit
opening pressure of the whole shunt system	=	opening pressure of the differential unit	+	children up to 5 years 20 cmH_2O adults up to 60 years 25 cmH_2O adults over 60 years 20 cmH_2O

The recommendations are based on common patient treatments, but can vary depending on the individual patient´s condition.

ASSESSORIES

Warning note for carriers of pacemakers: The magnets inside the *proGAV* and *proSA Tools* can alter the function of a pacemaker.

Caution: Do not use the *proGAV* and *proSA Tools* nearby MRI scanner, since there is a danger of damaging the MRI scanner due to the magnets inside *proGAV* and *proSA* Tools.

Note: In order to locate, to verifiy and to adjust either the adjustable DP-unit or the adjustable gravitational unit, different *Verification* and *Adjustment Tools* are used:

Tools used for the adjustable DP-unit:
proGAV Verification Tool
proGAV Masterdisc
proGAV Compass
proGAV Adjustment Tool
proGAV Adjustment Tool
proGAV Check-mate

Tools used for the adjustable gravitational unit:
proSA Verification Tool
proSA Masterdisc
proSA Compass
proSA Adjustment Tool
proSA Adjustment Tool
proSA Check-mate

Please verify specifically before using any tool for verifying or adjusting the opening pressure:
for the adjustable DP-unit, use only *proGAV Tools*

*pro**GAV***
■□□□□□□□

and

for the adjustable gravitational unit, use only *proSA Tools*

*pro**SA***
●○○○○○○○

The mode of operation of *proGAV* und *proSA Tools* are identical.
Hence, the instructions on the following pages are classified for both *proGAV Tools* and *proSA Tools.*

VERIFICATION TOOL

The *Verification Tool* is used for reading the valve opening pressure setting (Fig. 7). Firstly, it is essential that the *Verification Tool* is placed centrally over the valve. The notch (3) on the *Verification Tool* must be in line with the proximal (ventricular) catheter. The tool contains two magnets. As soon as the button (2) on the instrument is pushed the magnets in the tool align with the magnets in the valve. The opening pressure is shown on the scale (1). The arrow on the underside of the *Verification Tool* should be aligned with the direction of flow.

Fig. 7: proSA Verification Tool

MASTERDISC

The *Verification Tool* can be easily checked by using the *Masterdisc* before measuring the opening pressure of the valve. On the *proGAV Masterdisc* the positions 0, 5, 10, 15, 20 cmH_2O (Fig. 8a) and on the *proSA Masterdisc* the positions 0, 10, 20, 30 and 40 cmH_2O (Fig. 8b) are indicated. If the *Verification Tool* is placed on the disc the opening pressure shown by the instrument should be aligned to the value of the *Masterdisc*.

Example: The *Verification Tool* is put on the *Masterdisc* so that the marking on the instrument is in line with the value 10 cmH_2O on the *Masterdisc*. The *Verification Tool* should indicate the value of 10 cmH_2O.

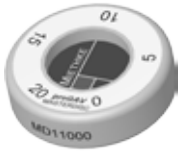


Fig. 8a: proGAV Masterdisc

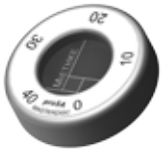


Fig. 8b: proSA Masterdisc

COMPASS

Alongside the *Verification Tool* there is an additional device for checking the adjusted opening pressure. The *Compass* can be used to locate the valve when palpation is not possible. The *Compass* is set to the skin above the implanted valve. The opening pressure corresponds to the value indicated towards the direction of the ventricular catheter.

Fig. 9a: proGAV Compass

Fig. 9b: proSA Compass

Caution: Airbubbles inside the compass do not affect its functionality.

ADJUSTMENT TOOL

The *Adjustment Tool* is used for adjusting the valve opening pressure. First the intended pressure setting is selected at the knurled dial (1), the opening pressure is shown on a scale (2). Then the *Adjustment Tool* is placed centrally on the valve. By pushing the button (3), the adjustment tip (4) appears, the brake is decoupled, the rotor turns and the adjusted pressure is set.
The marking (5) on the *Adjustment Tool* has to point towards the proximal catheter (leading to the ventricle).

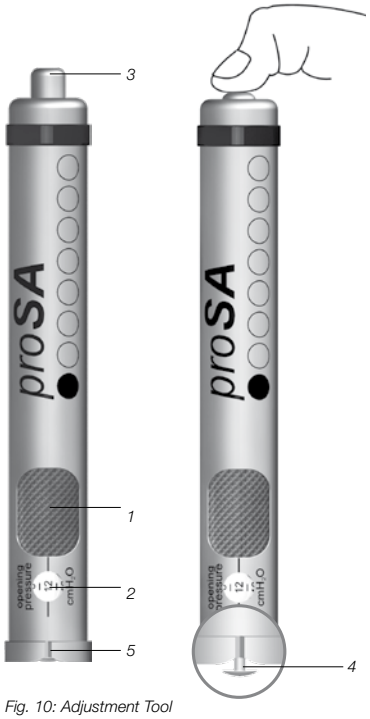


Fig. 10: Adjustment Tool

ADJUSTMENT DISC

The *Adjustment Disc* offers another option to adjust the pressure setting (Fig. 11a, 11b). The *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 *Adjustment Disc* on the valve, the brake is decoupled and the opening pressure of the valve is changed.

colour: blue

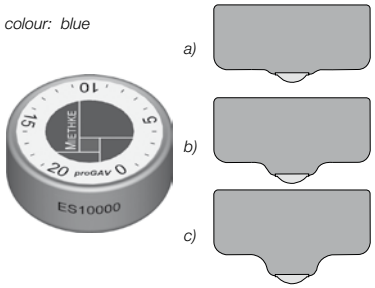


Fig. 11a: proGAV Adjustment Disc
a) size S b) size M c) size L

colour: red

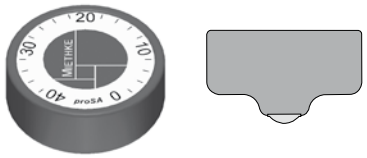


Fig. 11b: proSA Adjustment Disc
one size only

CHECK-MATE CE 0297

The *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 adjustable DP-unit and on the adjustable gravitational unit directly in the OR.

To verify the actual pressure setting the *Check-mate* has to be put centrally over the adjustable DP-unit or the adjustable gravitational unit. The *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 *Check-mate* has to be placed centrally over the adjustable DP-unit or the adjustable gravitational unit. The new pressure setting has to point towards the proximal catheter (leading to the ventricle). By pressing down slightly the *Check-mate*, the brake of the adjustable DP-unit or adjustable gravitational unit is decoupled, the rotor turns and the opening pressure of the valve is changed.

colour: titanium

Fig. 12a: proGAV Check-mate,
pressure range 0-20 cmH_2O

colour: gold

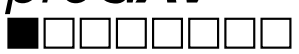
Fig. 12b: proSA Check-mate
pressure range 0-40 cmH_2O

ADJUSTING THE VALVE

The pressure setting of the adjustable DP-unit and the adjustable gravitational unit can be adjusted pre- and postoperatively.
Each *proSA* is calibrated under strict quality control procedures. The adjustable DP-unit is preset to 5 cmH_2O and the adjustable gravitational unit is preset to 20 cmH_2O. Each unit must be checked before implantation.

Note: The mode of operation of *proGAV* und *proSA Tools* are identical. Hence, the instructions on the following pages are shown using the example of *proSA Tools* but the instructions are classified for both: *proGAV* and *proSA Tools* .

Please verify specifically before using any tool for verifying or adjusting the opening pressure:
for the adjustable DP-unit, use only *proGAV Tools*



and for the adjustable gravitational unit, use only *proSA Tools*

The adjustment procedure for the adjustable DP-unit and the adjustable gravitational unit (in the following named adjustable unit) is outlined in the steps below:

1. Localisation
The adjustable unit is located under the skin (Fig. 13).

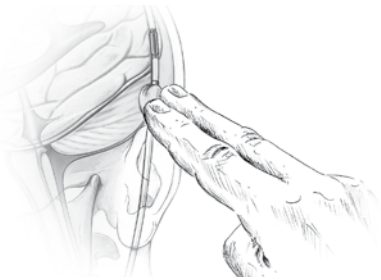


Fig. 13: Locating the adjustable unit

2. Verifying:
The *Verification Tool* is positioned centrally over the valve. (Fig. 14a). The notch on the instrument must point towards the proximal catheter (leading to the ventricle).

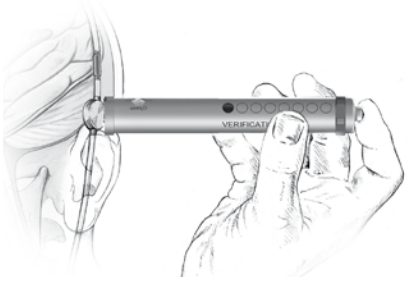


Fig. 14a: Place centrally over the valve

The arrow on the bottom side of the *Verification Tool* indicates the direction of CSF-flow.
The button is pushed and the pressure setting is read (Fig. 14b).

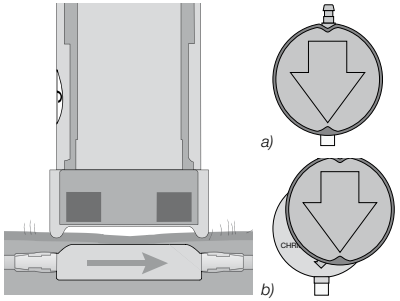


Fig. 14b: Measuring the pressure setting a) correctly, b) incorrectly

Caution: Failing to centre the *Verification Tool* over the valve can lead to erroneous readings!

3. Adjustment of the opening pressure
When adjusting the *proSA* preoperatively through the packaging, moderate force with the *Adjustment Tool* is sufficient. DO NOT USE THE BUTTON. Strong pressure can cause damage to the housing, which might affect valve function.

Caution: Due to postoperative swelling of the skin the adjustment of the valve may be difficult within the first few days!
Please ensure that the opening pressure is changed by no more

- **than 8 cmH_2O per each adjustment for the adjustable DP-unit.**
- **than 16 cmH_2O per each adjustment for the adjustable gravitational unit.**

Example: Opening pressure is to be changed from 6 to 36 cmH_2O. With only one adjustment step the rotor would turn in a counter clockwise direction (shortest path) and would stop at the position 0 cmH_2O (Fig. 15a).

A correct adjustment is performed in two steps: Adjustment from 6 to 22 cmH_2O, and then from 22 to 36 cmH_2O. The rotor turns now in a clockwise direction (Fig. 15b).

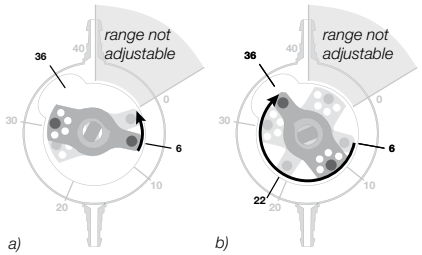


Fig. 15: Rotor rotation during adjustment a) false b) correct

3a. Adjustment with the *Adjustment Tool*
The *Adjustment Tool* is set to the required opening pressure by turning the knurled dial of the unit (Fig. 16).

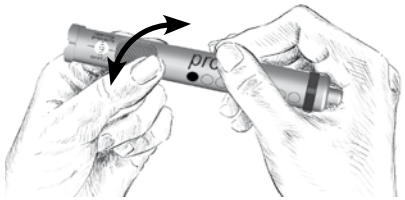


Fig. 16: Setting the Adjustment Tool

The *Adjustment Tool* is positioned centrally on the valve. The notch on the instrument and the scale (a) must point towards the proximal catheter (b) (leading to the ventricle), see Fig. 17.

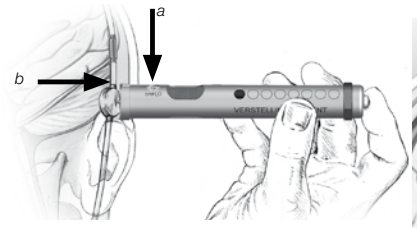


Fig. 17: Positioning the Adjustment Tool

As soon as the *Adjustment Tool* has been positioned centrally over the valve, the button is pushed and the adjustment tip appears to apply pressure to the valve. This triggers the mechanical decoupling of the rotor and the valve setting is adjusted to the required opening pressure setting (Fig. 18).

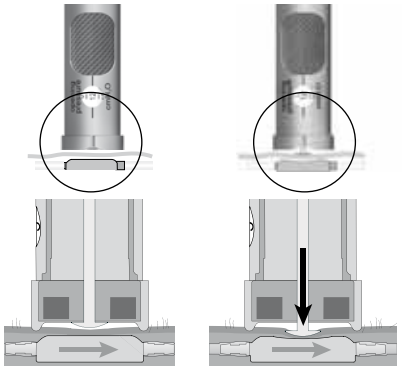


Fig. 18: Adjusting the pressure setting

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

When treating patients who have a low tolerance to pain, local anaesthesia (e.g. applied through a plaster) should be considered, in cases where contraindication can be excluded.

3b. Adjustment with the *Adjustment Disc*
Center the *Adjustment Disc* over the gravitational unit of the and align the desired pressure setting (b) on top of the disc in direction of the ventricular catheter (c), see Fig. 18a.

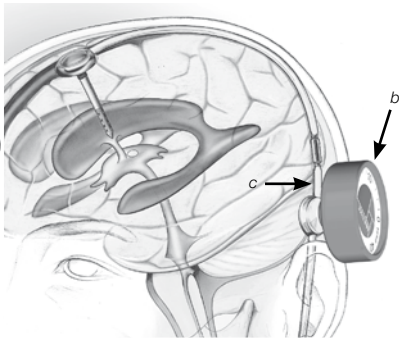


Fig. 18a: Adjustment with the Adjustment Disc

For changing the opening pressure, press down the adjustment disc and release (Fig. 18b). Do not press and turn.

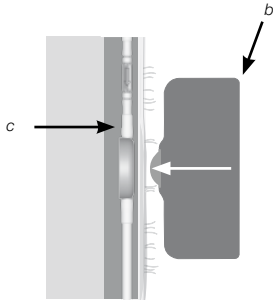


Fig. 18b: Press down slightly the Adjustment Disc and release

Finally, remove the *Adjustment Disc* and confirm the setting with the *Verification Tool*.

4. Verifying after adjustment
After the adjustment, the valve opening pressure has to be measured again, as described in step 2. If the pressure measured now differs from the intended pressure level, the adjustment procedure has to be repeated from step 3.

If the pressure configuration of the valve cannot be determined with complete certainly by the *Verification Tool*, the use of imaging techniques is recommended (excluding MRI: danger of artefacts).

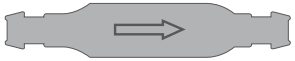
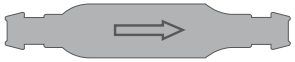
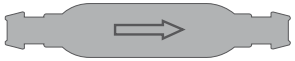
MRI examinations must be performed at field strengths no greater than 3.0 tesla.

Caution: If the site of implantation is poorly selected or if the skin over the valve is too thick, an adjustment of the adjustable unit can be difficult or sometimes impossible. The adjustable gravitational unit then behaves like a gravitational unit with a fixed opening pressure for a given position.

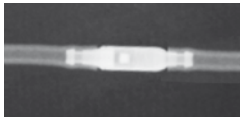
READING THE PRESSURE SETTING FROM AN X-RAY IMAGE

A DP-unit or an adjustable DP-unit is available for the lying position.

The coding of the DP-unit can be identified according to the shape of the valve's housing.

pressure setting (cmH_2O)	Coding
0	
5	
10	
15	

Example: the DP-unit with an opening pressure of 5 cmH_2O has a concave proximal part (curved inwards) and a convex distal part (curved outwards).



Radiographic image of the fixed DP-unit (pressure rating 5 cmH_2O)

The pressure setting of the adjustable DP-unit should be checked with the *proGAV Verification Tool*. If there is any discrepancy between the desired adjustment setting and the setting that is read by the *proGAV Verification Tool*, then a radiographic confirmation can be performed in addition to confirm the actual valve setting. The postition of the rotor tip indicates the opening pressure. The rotor can take any position outside the region indicated shown below, see Fig. 19a.

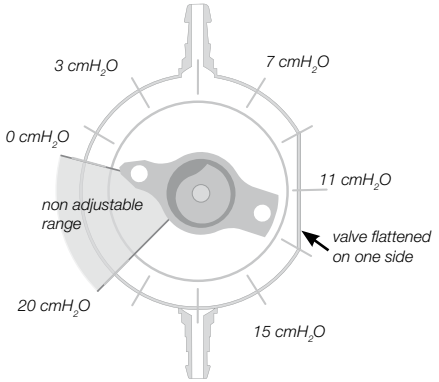


Fig. 19a: Schematic X-ray image of adjustable DP-unit

The opening pressure of the adjustable DP-unit can be adjusted from 0 to 20 cmH_2O, in increments of 1 cmH_2O. To further assist correct identification of the adjusted opening pressure, the housing of the valve has a flat profile on one side (Fig. 19b).

valve flattened on one side

Fig. 19b: X-ray image adjustable DP-unit: setting 0 cmH_2O

Pressure settings for the adjustable gravitational unit

The pressure setting of the adjustable DP-unit should be checked with the *proSA Verification Tool*. If there is any discrepancy between the desired adjustment setting and the setting that is read by the *proSA Verification Tool*, then a radiographic confirmation can be performed in addition to confirm the actual valve setting. The postition of the rotor tip indicates the opening pressure. The rotor can take any position outside the region indicated shown below, see Fig. 20a.

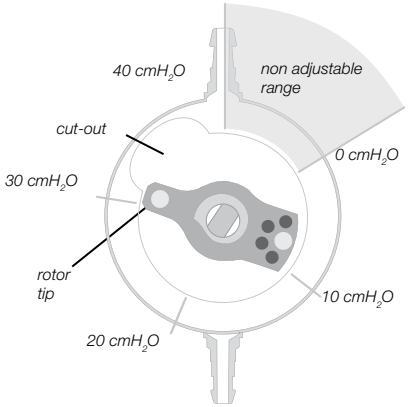


Fig. 20a: Schematic X-ray image of adjustable gravitational unit

The opening pressure of the adjustable gravitational unit can be adjusted from 0 to 40 cmH_2O, in increments of 1 cmH_2O.
To further assist correct identification of the adjusted opening pressure, a cut-out in the casing ring is visible under X-ray imaging (Fig. 20b).

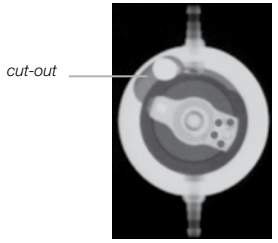


Fig. 20b: X-ray image adjustable gravitational unit: setting 31 cmH_2O

POSSIBLE SHUNT COMPONENTS

The *proSA* is available in combination with different accessory components for the treatment of adult and pediatric hydrocephalus which are briefly described below:

The DP-unit is available in pressure configurations of 0, 5, 10 and 15 cmH_2O.
The adjustable differential pressure unit is adjustable from 0 to 20 cmH_2O, in increments of 1 cmH_2O.

The *borehole reservoir* is positioned in the cranial borehole. It allows measurement of the intraventricular pressure and a site for the injection of drugs and extraction of CSF. Its solid titanium base is highly puncture-resistant. All reservoirs are available with integrated catheters or connectors. A special *borehole reservoir* is the *SPRUNG RESERVOIR*. As an additional new feature of this reservoir CSF can be flushed towards the valve because of a one-way valve in the bottom of the reservoir. By this mechanism a flow in the direction of the ventricular catheter is avoided during the pumping procedure. The opening pressure of the shunt system is not increased by the implantation of the *SPRUNG RESERVOIR*.

The *prechamber* and the *CONTROL RESERVOIR* are positioned on the cranium. It allows measurement of the intraventricular pressure and a site for the injection of drugs and extraction of CSF, as well as palpatory inspection of the ventricle. Its solid titanium base is highly puncture-resistant. If required, a puncture of the *prechamber* or the *CONTROL RESERVOIR* should be performed as perpendicular to the reservoir surface as possible with a cannula of max. diameter 0,9 mm. Up to 30 punctures are possible without any restrictions.

A special *prechamber* is the *CONTROL RESERVOIR*. As an additional new feature of this reservoir, CSF can be flushed towards the valve because of a one-way valve in the proximal inlet of the reservoir.
By this mechanism, flow in the direction of the ventricular catheter is prevented during the pumping procedure. The opening pressure of the shunt system is not increased by the implantation of the *CONTROL RESERVOIR*.

Caution: Frequent pumping can lead to overdrainage and thus pressure conditions outside of the normal physiological range. Patients 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.

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.

Positioning the valve

The *proSA* is supplied with a factory setting of
- 5 cmH_2O for the adjustable DP- unit
- 20 cmH_2O for the adjustable gravitational unit.

This opening pressure can be set to a different value prior to implantation (see chapter "Adjusting the *proSA*").
The *proSA* 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 *proSA* with a ligature. The shunt should not be located directly under the skin incision. The valve is marked with an arrow pointing in the direction of flow (arrow pointing to distal or downward).

Caution: The adjustable gravitational unit must be placed over a hard bony surface and should not be implanted within an area that makes locating the valve more difficult (e. g. under a scar).
To prevent damage to the catheter, clamps with protective coverslips should be used. The catheter should not be tied off directly behind the valve.

The *proSA* is available in different shunt variants:
When using a *proSA SHUNTSYSTEM with borehole reservoir* or *SPRUNG 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 by a ligature. The skin incision should not be located directly above the reservoir.

The *proSA SHUNTSYSTEM* with prechamber or *CONTROL RESERVOIR* comes with a *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.

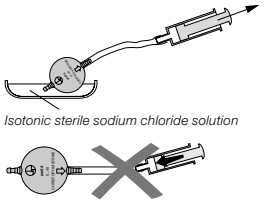
Positioning the peritoneal catheter

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 *proSA*, 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.

TUBE SYSTEMS

The *proSA* has been designed to ensure the optimal ventricular pressure. It is available as a shunt system or as an 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 the use of 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 virtually no effect on the pressure-flow characteristics.

TESTING THE VALVE PATENCY



Isotonic sterile sodium chloride solution

Fig. 21: Patency test

The *proSA* 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. 21).

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 *proSA* 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

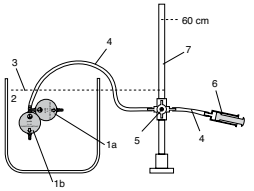


Fig. 22: Test setup
1 *proSA* a horizontal, b vertical; 2 water bath; 3 constant water level; 4 silicone tube; 5 three-way tap; 6 single-use syringe with syringe filter; 7 manometer

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. 22).
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. 24)
d) To release all air from the test assembly, turn the three-way faucet as shown in Fig. 23.
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. 23 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. 24).
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.

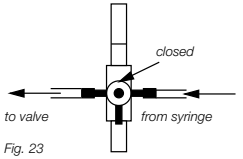


Fig. 23

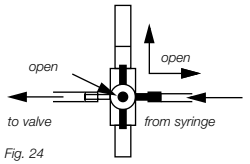


Fig. 24

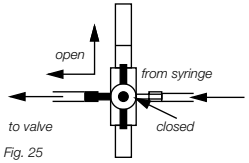


Fig. 25

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. 23 and fill the manometer to 10 cmH_2O above the expected opening pressure. (Example: For testing a *proSA* with an opening pressure setting of 5 cmH_2O, the manometer is filled to 15 cmH_2O.)
c) Turn the three-way faucet as shown in Fig. 24 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. 24 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:

DP-unit (*proSA* adjusted to „0“)

opening pressure (cmH_2O)	acceptable pressure range
0 cmH_2O	0-5 cmH_2O
5 cmH_2O	2-9 cmH_2O
10 cmH_2O	7-15 cmH_2O
15 cmH_2O	12-20 cmH_2O

Adjustable DP-unit (*proSA* adjusted to „0“)

opening pressure (cmH_2O)	acceptable pressure range
0 cmH_2O	0-5 cmH_2O
10 cmH_2O	5-15 cmH_2O
20 cmH_2O	10-25 cmH_2O

proSA (without DP-unit)

opening pressure (cmH20)	acceptable pressure range
0 cmH_2O	0-5 cmH_2O
10 cmH_2O	2-14 cmH_2O
20 cmH_2O	8-24 cmH_2O
30 cmH_2O	13-34 cmH_2O
40 cmH_2O	20-44 cmH_2O

PRESSURE-FLOW CHARACTERISTICS

Horizontal position

DP-unit

The following diagram shows the pressure-flow characteristics of the DP-unit for the opening pressure of 0, 5, 10 and 15 cmH_2O.

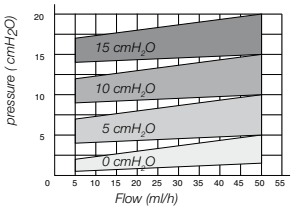


Fig. 26:Pressure-flow characteristics for the pressure settings of the fixed DP-unit

Adjustable DP-unit

The following diagrams show the pressure-flow characteristics of the adjustable DP-unit for the pressure settings 0, 5, 10 and 15 cmH_2O.

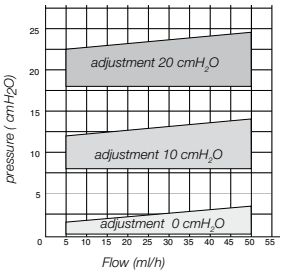


Fig. 27: Pressure-flow characteristics for the pressure settings of the adjustable DP-unit

Vertical position

Adjustable gravitational unit

The total opening pressure in the vertical position is the sum of the opening pressure of the DP-unit and the adjustable gravitational unit. The following diagram shows the pressure-flow characteristics of the adjustable gravitational unit as an example for the pressure settings 0, 20 and 40 cmH_2O.

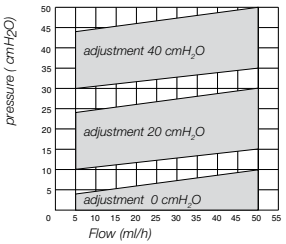


Fig. 28: Pressure-flow characteristics for selected pressure settings of the adjustable gravitational unit

The total opening pressure refers to a reference flow of 5 ml/h. When the flowrate reaches 20 ml/h, the opening pressures are approximately 1-2 cmH_2O higher.

TEST ON REFLOW SAFETY

This test is carried out with the same equipment as the pre-implantation test. The shunt is carefully filled with sterile saline solution from the syringe before the air is removed from it (Fig. 29). The shunt is connected against the direction of flow (see arrow on the shunt). The outlet of the shunt has to be at the zero level of the manometer. The manometer is filled up to 14 cmH_2O (Fig. 30).
The three-way faucet is used for unblocking the flow to the shunt and blocking the flow to syringe. In this setup, no more than 2 drops (0.1 cc) per minute should emerge from the proximal part of the shunt (Fig. 31).
Caution: Be careful to maintain sterility and to avoid particle contamination.

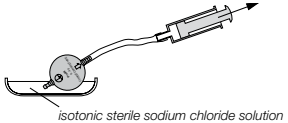


Fig. 29

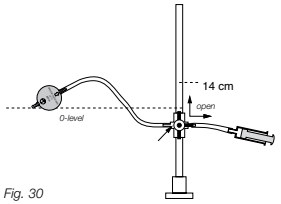


Fig. 30

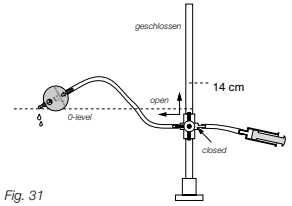


Fig. 31

CONTRAINDICATIONS

The adjustable DP-unit and the adjustable gravitational 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 *proSA* should not be used under any circumstances in conjunction with 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 *proSA* is MR Conditional (ASTM F2503-08). All components are visible via X-ray. The provided catheters are MRI Safe. Reservoirs, *deflector*s and connectors are MR Conditional.

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

POSTOPERATIVE VALVE TEST

The *proSA* 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 *proSA* the function of a pacemaker can be affected.

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.

RESTERILISATION

The functional safety and reliability of resterilized products cannot be guaranteed, therefore resterilisation is not recommended.

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

Christoph Miethke GmbH & Co. KG
Ulanenweg 2
D-14469 Potsdam
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
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

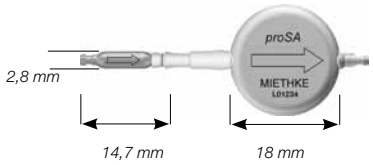
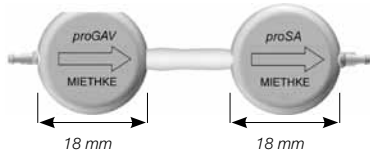
NOTE ON THE INSTRUCTIONS FOR USE

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.

GENERAL INFORMATION

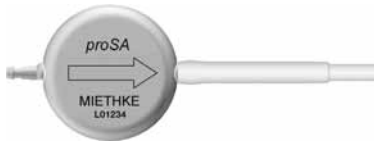
Manufacturer	**Christoph Miethke GmbH & Co. KG**
Product name	*proSA*
Intended use	Treatment of Hydrocephalus
Intended for one-time use (disposable)	
Store in a clean, dry place	
Schematic representation of the *proSA* with its external dimensions: *proSA*  *proSA with adjustable DP-unit*  	

VARIANTS

The *proSA* is available as a single valve or as a *proSA SHUNTSYSTEM* with DP-unit or adjustable DP-unit.

proSA

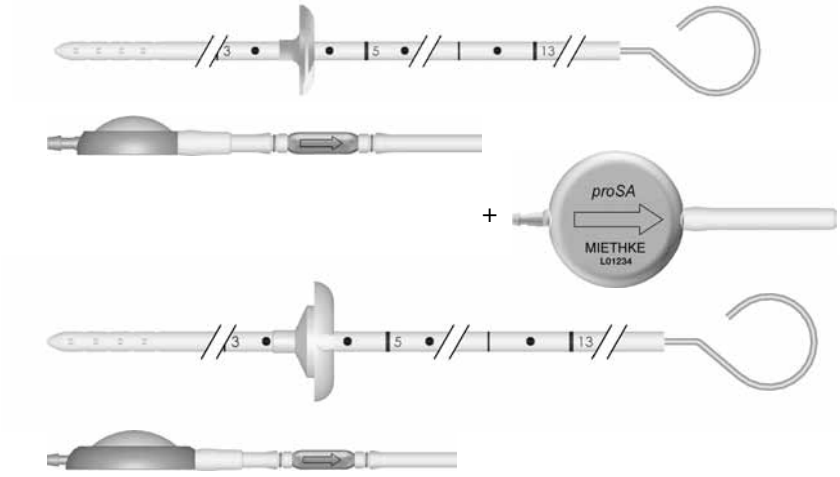
proSA with distal catheter



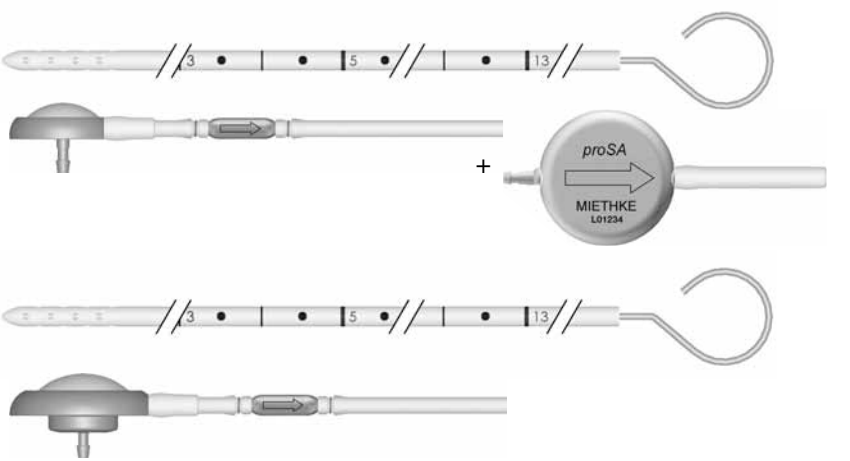
proSA

proSA with adjustable differential pressure unit

proSA SHUNTSYSTEM with (pediatric) prechamber



proSA SHUNTSYSTEM with (pediatric) borehole reservoir



Scale 1:1

CE 0297

CE-Kennzeichnung gemäß Richtlinie 93/42/EWG
CE marking according to directive 93/42/EEC
Label CE conforme à la directive 93/42/CEE
Identificatión CE en conformidad con la directriz 93/42/CEE
Marchio CE conforme alla direttiva 93/42/CEE

Technische Änderungen vorbehalten
Technical alterations reserved
Sous réserve de modifications techniques
Sujeto a modificationes técnicas
Con riserva di modifiche tecniche

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

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Aesculap AG | Am Aesculap-Platz | 78532 Tuttlingen | Germany
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