MIETHKE

# *paediGAV VALVE*

US Instructions for Use

www.aesculapusa.com

**TABLE OF CONTENTS**

## CAUTION

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

## INDICATION

The *paediGAV* is intended to shunt cerebrospinal fluid (CSF) from the lateral ventricles of the brain into the peritoneum.

## TECHNICAL DESCRIPTION

The *paediGAV* is a site-specific shunt valve for the treatment of pediatric hydrocephalus. It consists of a ball-cone valve and a gravity valve. This configuration ensures physiological drainage in all body positions.

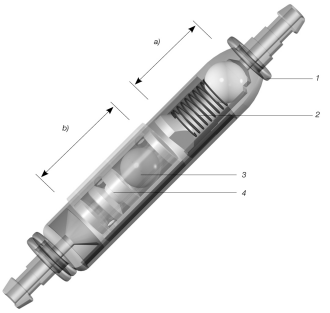



*Fig. 1: Schematic cross-section of the paediGAV*

| **a) ball-cone unit** | **b) gravitational unit** |
|---|---|
| 1 coding ring | 3 tantalum ball |
| 2 spiral spring | 4 sapphire ball |

The *paediGAV* is composed of a robust titanium casing whose proximal end contains a ball-cone valve. A spiral spring (2) controls the opening pressure of the ball-cone valve. The gravity valve at the distal end consists of a tantalum ball (3) that controls the opening pressure of the gravity valve and a sapphire ball (4) that ensures reliable sealing and seating of the gravity valve. As an option, a connector or a silicone catheter is installed at the distal end of the valve.

## OPERATING MODES OF THE *paediGAV*

The principal operating modes of the *paediGAV* are shown in fig. 2 and fig. 3. Fig. 2a shows the *paediGAV* in horizontal position.

The ball-cone valve is closed, thereby preventing any drainage from taking place. Fig. 2b shows the *paediGAV* in open position. The patient's intraventricular pressure is elevated, and the spring pressure that would ordinarily keep the ball-cone valve closed is suppressed. The sealing ball moves away from the cone, thereby creating a gap that allows fluid drainage to occur. When the patient is in a horizontal position, the gravity valve remains open and exerts no countervailing force.

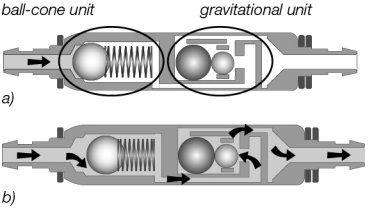



*Fig. 2: paediGAV in horizontal body position*

As soon as the patient stands up, the gravity valve closes and fluid drainage is interrupted (fig. 3a). Fluid drainage can resume only if the sum total of intraventricular pressure and hydrostatic pressure exceeds the opening pressure of the ball-cone valve and the force exerted by the weight of the tantalum ball in the gravity valve (fig. 3b).

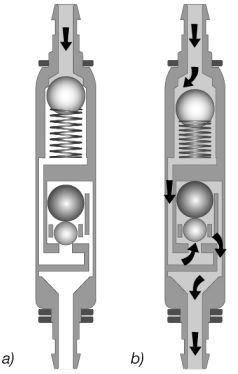



*Fig. 3: paediGAV in vertical body position*

## PHYSICS BACKGROUND

With the body in a horizontal position, the intraventricular pressure in healthy individuals is positive. To regulate intraventricular pressure using valve drainage, only the pressure in the abdominal cavity needs to be taken into account.

**horizontal:** $IVP = P_L + P_B$
**vertical:** $IVP = P_H - P_S - P_B$

| | |
|---|---|
| *IVP* | *Intraventricular pressure* |
| $P_L$ | *Opening pressure in horizontal position (ball-cone unit)* |
| $P_S$ | *Opening pressure in vertical position (ball-cone unit + gravitational unit)* |
| $P_B$ | *Pressure in the abdominal cavity* |
| $P_H$ | *Hydrostatic pressure* |

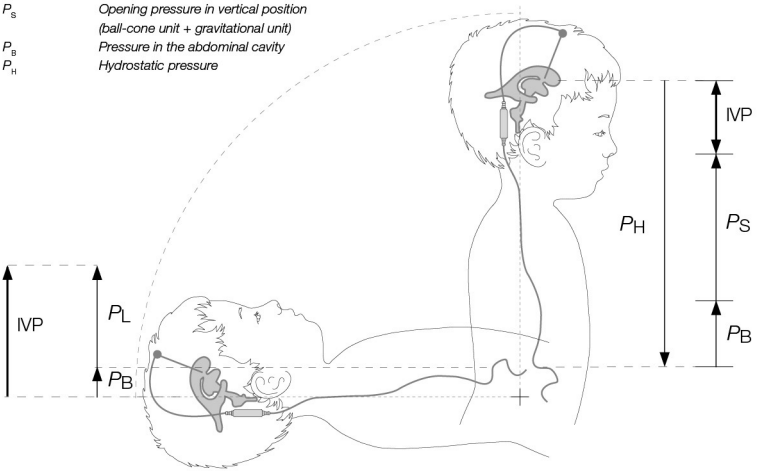



*Fig. 4: Calculation of intraventricular pressure for the horizontal and standing body positions*

In standing position, the ventricular pressure should be slightly negative. To regulate ventricular pressure using shunt valve drainage, valve opening pressure in standing position must be set considerably higher. Only in this way can the shunt valve compensate for the hydrostatic pressure reduced by the pressure in the abdominal cavity. Conventional valves open instantly, as soon as the patient rises to a standing position, and a critical overdrainage may occur.

### Selecting a suitable *paediGAV*

The *paediGAV* is a site-dependent valve. It features two different opening pressures, one is suitable for the patient's horizontal body position, while the other is used for the vertical position. This obviates the necessity of performing percutaneous modification of valve opening pressure in as much as increased opening pressure in vertical body position counteracts an unfavorably high level of drainage. In horizontal position, on the other hand, the requisite low opening pressure prevents underdrainige.

- **Horizontal body position:**
  For the horizontal position, two different opening pressure settings are available (4 and 9 $cmH_20$). Selection of the appropriate pressure rating should be made in accordance with indication (age of the patient).
- **Vertical body position:**
  The opening pressure for the vertical body position depends upon the size of the patient (hydrostatic parameter). If an infant is being treated, a low pressure rating should be selected. If, on the other hand, a larger child is being treated, a *paediGAV* with a higher pressure rating should be applied.

## PRESSURE RATING

Every *paediGAV* is calibrated according to strict quality control standards. The following pressure combinations are available:

| Opening pressure ($cmH_2O$) | | Coding |
|---|---|---|
| **horizontal** | **vertical** | |
| 4 | 14 | |
| 4 | 19 | |
| 4 | 24 | |
| 9 | 19 | |
| 9 | 24 | |
| 9 | 29 | |

The pressure ratings given above represent the pressure drop in the valve at a drainage rate of 5 ml/h.

Postoperatively, the pressure ratings selected can be identified radiographically according to their codes.

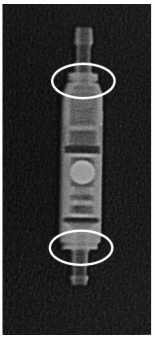


*Fig. 5: Radiograph of a paediGAV (9/24 $cmH_2O$)*

## SHUNT VARIANTS AVAILABLE

The *paediGAV* is available in several different variants. These variants are comprised of a variety of components, which are described briefly below:

- The *Burrhole Reservoir* is positioned in the cranial burrhole, thereby allowing for measurement of intraventricular pressure, injection of medication, and siphoning off of fluid. A robust titanium floor protects against puncture or perforation. The *Burrhole Reservoir* is available with integrated catheters or connectors.
- The *Prechamber* is positioned on the cranium, thereby allowing for measurement of intraventricular pressure, injection of medication, siphoning off of liquid, and palpatory checking of shunt valve status. A robust titanium floor protects against puncture or perforation. The *Prechamber* is available with integrated catheters or with connectors.
- Owing to the fact that the *Burrhole Deflector* is very firmly seated on the ventricular catheter, the length of the catheter to be inserted into the skull can be adjusted prior to implantation. The ventricular catheter is positioned inside the burrhole at a 90 degree angle, see "Operating procedure".

## TUBE SYSTEMS

The *paediGAV* is constructed in such a way that it ensures optimal ventricular pressure. It is available either as a shunt system or as an individual shunt valve with or without an integrated distal catheter (inner diameter 1.2 mm, outer diameter 2.5 mm). Individual shunt valves should be used in conjunction with a catheter with an inner diameter of approximately 1.2 mm and an outer diameter of approximately 25 mm. The shunt valve connector allows for the use of catheters with an inner diameter ranging from 1.0 mm to 15 mm. The outer diameter of the catheter should be approximately twice that of the inner diameter. In any case, the catheter must be carefully fixed to the valve connector by means of a ligature. Kinks in the catheter must be avoided.

### Testing the patency of the valve

The safest way to drain the *paediGAV* is to aspirate it using a sterile disposable syringe attached to the distal end of a catheter. The proximal end of the valve is submerged in a sterile, physiological saline solution in this process. If fluid can be removed, the valve is patent.

**CAUTION**

**Any pressure charge through a single-use syringe should be avoided, both at the proximal and the distal end. Contaminations in the solution used for the patency test can adversely affect the performance of the product. Make certain that sterility is maintained and particle contamination is avoided.**

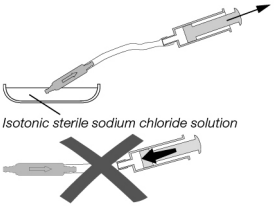



*Fig. 6: Patency test*

## TESTING THE VALVE PRIOR TO IMPLANTATION

Each *paediGAV* is tested to ensure that the performance characteristics indicated on the label have been met. The dynamic performance characteristics of the valve can not be checked in a static test performed in an operation room. If the surgeon wishes to convince him-/herself of the valve meeting the specifications given by Miethke, the test described in the following can be carried out in the operation room:

**CAUTION**

**Special care has to be taken that sterility is maintained and particle contamination does not occur.**

Equipment required for this test

- Sterile fluid reservoir or water bath
- Sterile 60-cm hydrostatic pressure gauge with millimeter grading and three-way faucet at its base
- Sterile syringe (30 cc - 50 cc)
- Sterile 5-µ syringe filter
- Sterile tube adapter
- Sterile silicone tube

Equipment set-up

- Set up the manometer and water bath in such a way that the zero point on the manometer lines up with the water level in the water bath, see fig. 7.
- Fill the syringe with sterile water, using the 5-µ syringe filter (when topping up the syringe, always use the 5-µ syringe filter). Having filled up the syringe, remove the syringe filter.
- Connect the syringe to the pressure gauge and the silicone tube, see fig. 7; use a tube adapter if necessary.
- To remove all air from the complete, sterile test equipment, turn the three-way faucet, see fig. 8.
- Dip the silicone tube into the sterile water bath and rinse it with sterile water from the syringe.

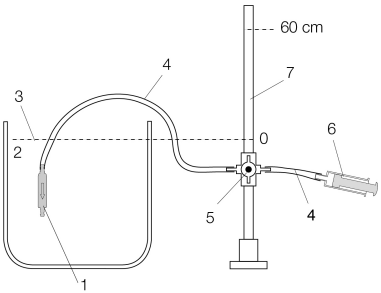



*Fig. 7: Test set-up*
*1 Product*
*2 Water bath*
*3 Constant water level*
*4 Silicone tube*
*5 Three-way faucet*
*6 Single-use syringe with syringe filter*
*7 Pressure gauge*

Calibrating the test set-up

- Turn the three-way faucet and fill up the pressure gauge to at least 5 $cmH_20$, see fig. 9.
- To isolate the syringe from the pressure gauge, rotate the three-way faucet with the silicone tube submerged in the water bath, see fig. 10.

- Allow the water column in the pressure gauge to drop.
- The water column should come to rest at zero. If necessary, align the zero point of the pressure gauge with the water level in the water bath.
- The pressure gauge has now been calibrat-ed to the zero level of the water bath. Fixate in order to maintain its position relative to the water bath.

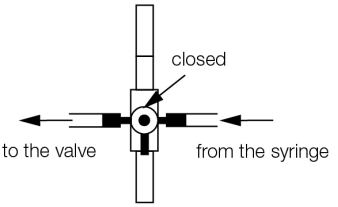



*Fig. 8: Calibrating the test set-up (1)*

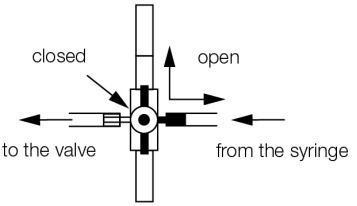



*Fig. 9: Calibrating the test set-up (2)*

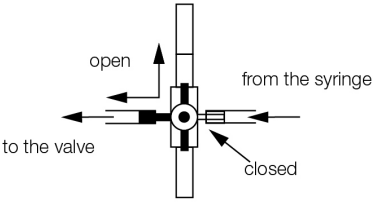



*Fig. 10: Calibrating the test set-up (3)*

## TEST PROCEDURE

**NOTE**

**During the tests, the valve must be submerged in the water bath. In order to obtain correct readings, the zero point of the pressure gauge must be in alignment with the fluid level of the water bath.**

- Connect the sterile valve to be tested to the complete sterile test set-up.
- Rotate the three-way faucet, see fig. 9, and fill the pressure gauge to 10 $cmH_2O$ higher than the envisaged valve opening pressure (e.g., with the *paediGAV*, 9/29, the pressure gauge for the low pressure side is filled to19 $cmH_2O$, while the high pressure side is filled to 39 $cmH_2O$).
- Rotate the three-way faucet, see fig. 8, in order to isolate the pressure gauge.
- Remove all air from the valve and the complete test set-up by carefully rinsing with sterile water from the syringe.
- Dip the sterile valve into the sterile water bath. In order to obtain valid test results, the distal end of the shunt valve must be under water.
- To isolate the syringe, maintain some flow through the shunt valve, while at the same time rotating the three-way faucet, see fig. 10. With the three-way faucet in the correct position, the water column in the pressure gauge should start dropping. The syringe is isolated from the valve now and it is not necessary anymore to maintain the flow from the syringe. If the water column fails to drop, repeat steps 2 to 6.
- Allow the water level in the pressure gauge to drop for 2 to 2.5 minutes. Read the resulting pressure at the pressure gauge.

**Test results - pre-implantation test**

The pressure readings obtained by this method should yield the following results:

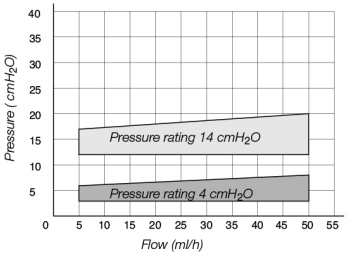
| **Prone/horizontal valve position** | |
|---|---|
| Pressure rating | Acceptable pressure ranges |
| 400 $mmH_2O$ | 100 to 600 $mmH_2O$ |
| 900 $mmH_2O$ | 400 to 1200 $mmH_2O$ |

| **Upright/vertical valve position** | |
|---|---|
| Pressure rating | Acceptable pressure ranges |
| 1400 $mmH_2O$ | 500 to 1400 $mmH_2O$ |
| 1900 $mmH_2O$ | 900 to 1900 $mmH_2O$ |
| 2400 $mmH_2O$ | 1200 to 2400 $mmH_2O$ |
| 2900 $mmH_2O$ | 1500 to 2900 $mmH_2O$ |

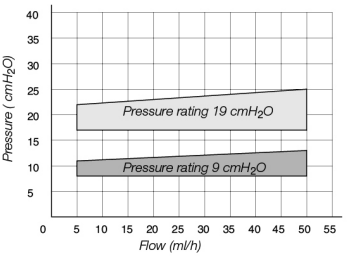
## PRESSURE-FLOW CHARACTERISTICS

The pressure-flow characteristics of the pressure ratings available for the *paediGAV* are shown in the following graphs:

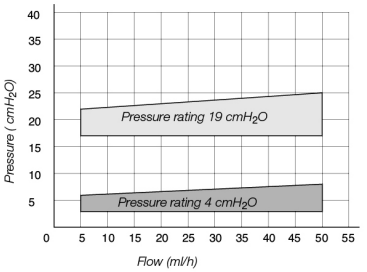
*paediGAV 4/14 cmH$_2$O*



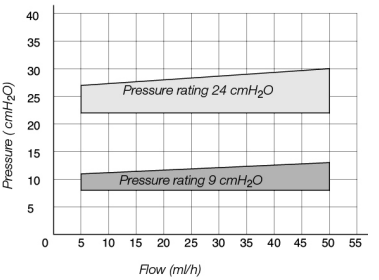

*paediGAV 9/19 cmH$_2$O*



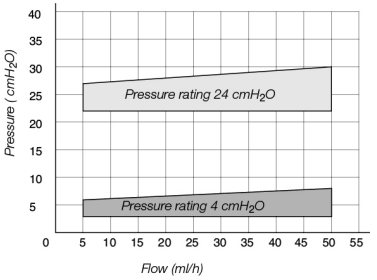

*paediGAV 4/19 cmH$_2$O*



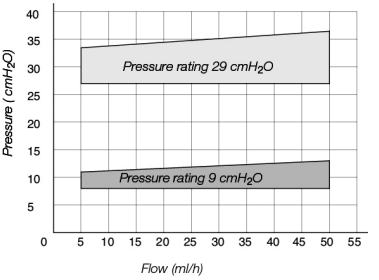

*paediGAV 9/24 cmH$_2$O*




*paediGAV 4/24 cmH$_2$O*




*paediGAV 9/29 cmH$_2$O*




## BACKFLOW PROTECTION TEST

Use the pre-implantation test set-up for this test. Using a single-use syringe, fill the shunt valve carefully with sterile saline and bleed the air out of it, see fig. 11. Connect the shunt valve against the direction of flow (see the arrow on the valve). The valve outlet port must be at the height of the zero level of the pressure gauge. The pressure gauge is filled to 14 cmH$_2$O, see fig. 12.

The flow to the valve is opened, and the flow to the syringe closed, by means of the three-way faucet. At this point, no more than two drops per minute (0.1 ccm) should be expelled from the distal end of the shunt valve, see fig. 13.

**CAUTION**

**Take care to maintain sterility and to avoid particle contamination.**

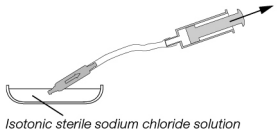



*Fig. 11: Backflow protection test (1)*

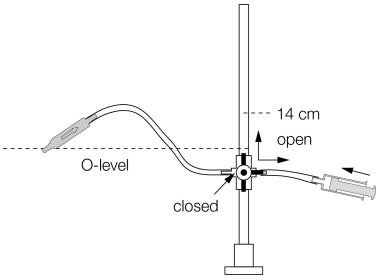



*Fig. 12: Backflow protection test (2)*

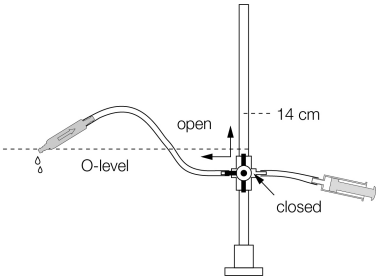



*Fig. 13: Backflow protection test (3)*

## OPERATING PROCEDURE

### Positioning the ventricular catheter

A number of different operative techniques can be used to position the ventricular catheter. Preferably, the required skin incision should be carried out either in form of a skin lobule pedicled towards the draining catheter or as a straight skin incision. In order to prevent cerebrospinal fluid from leaking, it should be taken care that the opening of the dura is as small as possible after drilling the burrhole. The ventricular catheter is stiffened by the mandrin supplied with the product.

The *paediGAV* is available in various shunt configurations.

- When the *paediGAV* shunt system is used with a *Burrhole Reservoir*, the ventricular catheter is implanted first. Then the mandrin is removed and the patency of the valve can be checked by letting CSF drip out. The catheter is shortened and the *Burrhole Reservoir* is connected, securing the connection with a ligature. The skin incision should not be situated directly above the reservoir.
- When a *paediGAV* sunt system with a *Prechamber* is used, an included *Burrhole Deflector* is used to adjust the catheter that is to be implanted to the required length. The ventricular catheter is inserted in the ventricle and placed at a 90 degree angle, and the *Prechamber* is then set in place.

The position of the ventricular catheter should be verified postoperatively by means of CT or MRI.

### Positioning the *paediGAV*

The *paediGAV* is a site-dependent valve. Consequently, care must be taken to ensure that the shunt valve is implanted parallel to the body axis. A suitable implant site is behind the ear. After the skin incision and subcutaneous tunnelling have been performed, the catheter is pushed from the *Burrhole Reservoir* to the selected shunt valve implantation site. The catheter is shortened (if necessary), and is then attached to the *paediGAV* with a ligature. In doing this, care must be taken to ensure that the shunt valve is not localized directly beneath the skin incision.

The shunt valve is equipped with an arrow pointing distally and downwards, indicating flow direction.

### Positioning the peritoneal catheter

The access site for the peritoneal catheter is left to the surgeon's discretion. For example, it can be created as a horizontal access, paraumbilical or transrectal, adjacent to the epigastrium.

Concerning the operative technique for positioning of the peritoneal catheter, there are various options, too.

The peritoneal catheter should be guided from the shunt valve to the selected position with the aid of a subcutaneous tunneler, and if necessary, an auxiliary incision. The peritoneal catheter - which as a rule is fastened to the *paediGAV* - is equipped with an open distal end, but has no wall aperture. Having exposed and entered the peritoneum, or by means of a trocar, the peritoneal catheter (shortened if necessary) is pushed forward into the intestinal cavity.

### Reimplantation

Shunt components that have already been implanted in one patient should under no circumstances be implanted in another.

## SAFETY MEASURES

After the implantation, the patients must be monitored carefully. Inflamed skin and tension in the area of the drainage tissues could possibly be a sign of infection in the shunt system. Symptoms like headaches, dizzy spells, mental confusion or vomiting, are a common occurrence in cases of shunt disfunction. In the event such symptoms occur, or if there is any leackage in the shunt system, either individual shunt system components or the entire shunt system must be replaced without delay.

## COMPATIBILITY WITH DIAGNOSTIC PROCEDURES

The *paediGAV*, like all other shunt components, contains only non-magnetic materials (titanium, sapphire, stainless steel and tantalum). Therefore, nuclear magnetic resonance imaging or computerized tomography can be carried out without any risk to the patient or to the performance of the valve.

## POSTOPERATIVE VALVE TESTS

The *paediGAV* is designed to function safely and reliably without a pump or testing component. However, testing can be performed when shunt systems containing a *Prechamber* or a *Burrhole Reservoir* are used. For such systems, a valve test can be performed by rinsing, pressure measurements or pumping.

## SAFE FUNCTIONING

The shunt valves are designed and manufactured to perform precisely and reliably over a long period of time. Still, it cannot be excluded that a valve system needs to be replaced for technical or medical reasons.

## STERILIZIATION

All products are carefully and thoroughly steam-sterilized. The double-layer packaging in sterile bags ensures sterility for five years. The expiration date for each item is indicated on the package. If the packaging is damaged in any way, the product should not be used under any circumstances.

## RESTERILIZATION

The functional safety and reliability of resterilized products cannot be guaranteed.

## MEDICAL PRODUCTS CONSULTANTS

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:

- Eng. Roland Schulz
- Michaela Funk-Neubarth
- Josefine Kehl
- Eng. Thoralf Knitter
- Dr. Andreas Bunge
- Jan Mugel
- Thammo Weise
- August von Hardenberg

**Manufacturer:**

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

## 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.

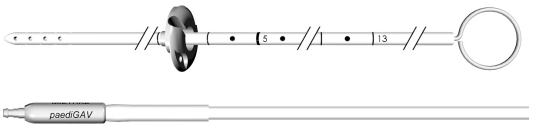
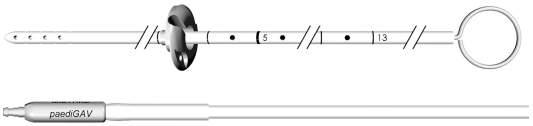
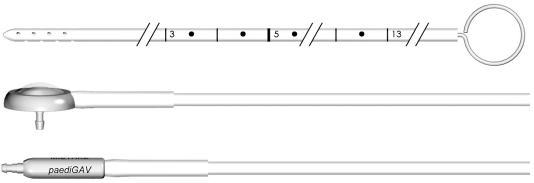
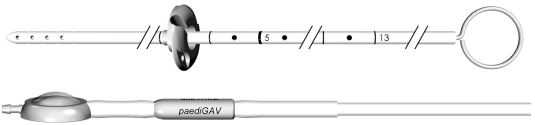
## NOTE ON THE INSTRUCTIONS FOR USE

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.

## GENERAL INFORMATION

| | |
|---|---|
| Manufactured by | Christoph Miethke GmbH & Co. KG |
| Product name | *paediGAV* |
| Intended use | Treatment of pediatric hydrocephalus |
| Side-effects | None known |
| Intended for single use only (disposable) | |
| Store in a clean, dry place | |
| Package contains | 1 Gravity valve |

## PRODUCT CONFIGURATIONS

| Illustration | Designation |
|---|---|
|  | *paediGAV* |
|  Catheter: 900 mm ; inner diameter: 1.2 mm outer diameter: 2.5 mm | *paediGAV* with distal catheter |
|  | *paediGAV* shunt system |
|  | *paediGAV* shunt system with *Burrhole Reservoir* |
|  | *paediGAV* shunt system with *Prechamber* |

CE 0297

US CE marking according to directive 93/42/EEC

US Technical alterations reserved

Manufacturer:

MIETHKE

Christoph Miethke GmbH & Co. KG | Ulanenweg 2 | 14469 Potsdam | Germany
Phone +49 331 62 083-0 | Fax +49 331 62 083-40 | www.miethke.com

Distributor:

B BRAUN
SHARING EXPERTISE

Aesculap AG | Am Aesculap-Platz | 78532 Tuttlingen | Germany
Phone +49 7461 95-0 | Fax +49 74 61 95-26 00 | www.bbraun.com

AESCULAP® – a B. Braun brand

TA011137
SOP-AIC-500556 V2.0 0 121
GBA_40_02_0820_USA