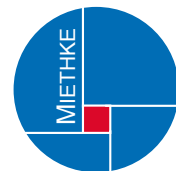


Aesculap Neurosurgery

paediGAV[®]



Gravitational valve for the treatment of
paediatric hydrocephalus



paediGAV[®]



Alliance for Innovation

When two strong partners combine their expertise, innovative and ground-breaking solutions frequently arise that would scarcely have been possible working alone.

Aesculap and Miethke have followed this path and have been cooperating since 1999. The goal was and is to develop better solutions for the difficult treatment of hydrocephalus and to make them available all over the world.

This vision has inspired and motivated everyone involved. An intensive dialogue was initiated with customers, doctors and patients about the problems associated with this complex medical condition. New solutions were developed and discussed in small circles of experts and scientific symposia.

The eventual outcome of this fruitful process was the market introduction of the first gravitational unit for pediatric patients - which can effectively prevent the overdrainage of cerebrospinal fluid. A unique product worldwide, and a milestone in modern hydrocephalus therapy.

What has already been achieved is only the beginning. For us, it is a duty and a necessity to continue along the path we have begun. In the patients' interest we will carry on our extensive investment into research and development and will not tire of learning more, collecting new insights and remaining open for future developments.



Aesculap, Tuttlingen



Miethke, Potsdam

*We will continue to venture in new directions
and cross every frontier to provide help for cases where
a solution has not been found yet.*



paediGAV®

paediGAV®

The Valve

The Miethke *paediGAV*® is the world's first and only gravitational valve for the treatment of hydrocephalus in children.

The conventional differential pressure valves that were used previously, including the programmable varieties, were passive systems which only permitted one opening pressure, irrespective of the body position. As a result, many hydrocephalus patients suffered from side effects ranging from chronic headaches to slit ventricles.

The choice of the correct shunt system with active pressure adjustment is of enormous importance in treating hydrocephalus in children, and has a major influence on their subsequent development.

It is precisely here that the great improvement and strength of the Miethke *paediGAV*® lies, a valve that has been specially developed for paediatric use. Through the combination of a tried and tested ball-in-cone unit with an innovative gravitational unit, the *paediGAV*® can actively vary its opening pressure. Different pressure situations arising from variations in the patient's body position can be automatically compensated for, whether the child is lying, sitting, standing, running or playing ...

***P**hysiological drainage is made possible*

in all body positions and overdrainage is effectively

prevented. The natural growth of the child's

head is thus optimally guaranteed.



Another advantage of the *paediGAV*[®] valve is its very slim, streamlined design. This facilitates extremely easy and quick implantation in the retroauricular area, decreasing the risk of infection. The valve is made from titanium, a material that guarantees outstanding precision, reliability and biocompatibility. It is MRI compatible and offers effective protection against subcutaneous pressure.

*“The paediGAV[®] prevents
overdrainage very effectively.*

*Despite the small outer dimensions, CSF pathway
within the device are comparatively large,
what is reflected by the absence
of shunt failure due to valve occlusion.”**

*Eymann R., Kiefer M. "6 Years Experience With the First Gravitational Shunt for Children: The paediGAV"
(Poster presented at: AANS/CNS Section on Pediatric Neurological Surgery, December 8-11, 2004, San Francisco)





paediGAV®

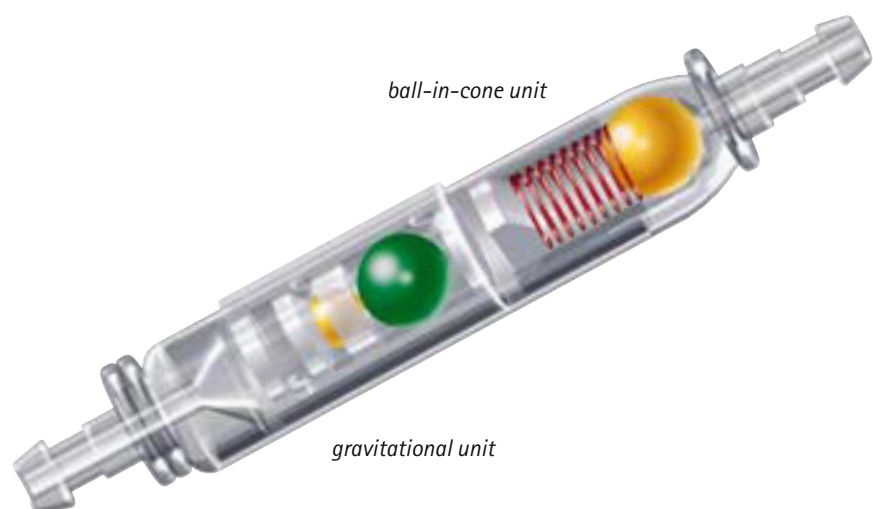
paediGAV®

The Valve

*“The gravitational ball valves...showed the closest relation to physiological flow requirements.”**

*Oikonomou J., Aschoff A., Hashemi B., Kunze S., New valves – new dangers? 22 valves designed in the nineties in ultralong-term tests (365 days). Eur J Pediatr Surg 1999; 9 Suppl 1:23-6

- Combined ball-in-cone and gravitational unit
- Active adaptation of opening pressure to the body position maintains physiological drainage of CSF
- Effective protection against overdrainage avoids the formation of slit ventricles
- Timesaving and easy implantation of the streamlined valve lowers the infection risk
- The use of titanium as the housing material permits the maximum possible flow volume with the smallest possible valve dimensions, reducing the risk of obstruction





Our Recommendation:**



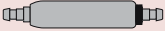

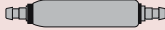

Age	Standard valve
up to 6 months	4 / 24 cmH ₂ O
6 months – 5 years	9 / 24 cmH ₂ O
over 5 years	9 / 29 cmH ₂ O

** These guide values are not binding. Other specifications may be preferable for the individual patient and anamnesis.

paediGAV®
Our Recommendation
Your Choice

Your Choice:

The *paediGAV®* is available in different pressure level settings. Each pressure level is specially coded, enabling the valve to be identified on post-operative X-rays.

Opening pressure horizontal/vertical (cmH ₂ O)	Coding on X-ray
4 / 14	
4 / 19	
4 / 24	
9 / 19	
9 / 24	
9 / 29	



paediGAV®

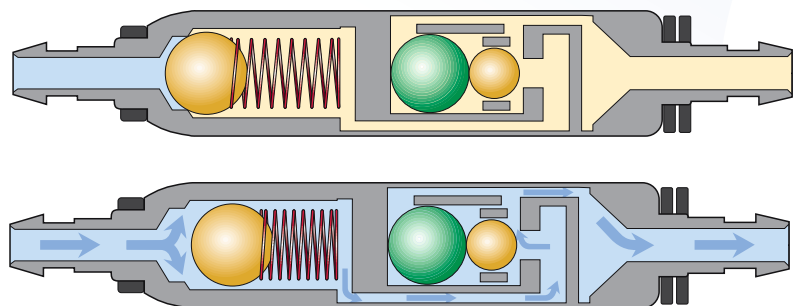
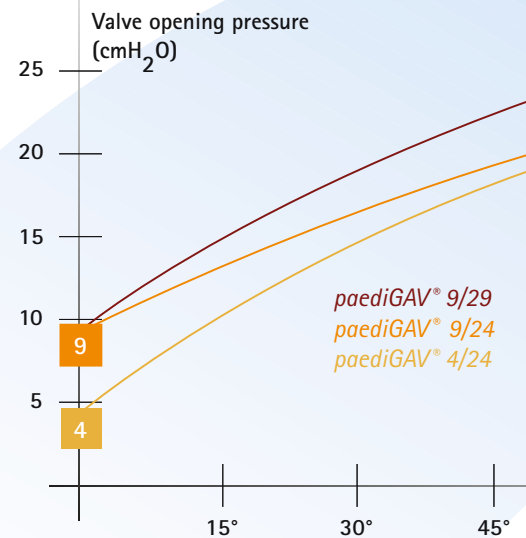
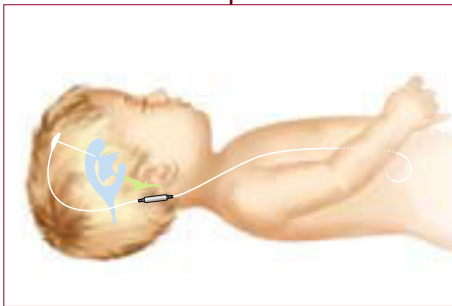
paediGAV®

The Function

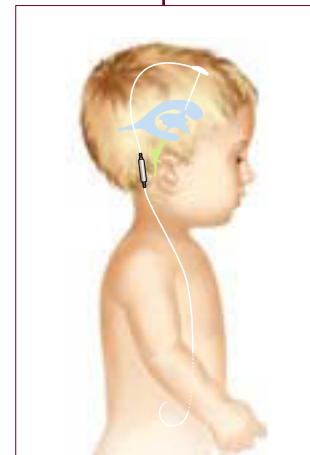
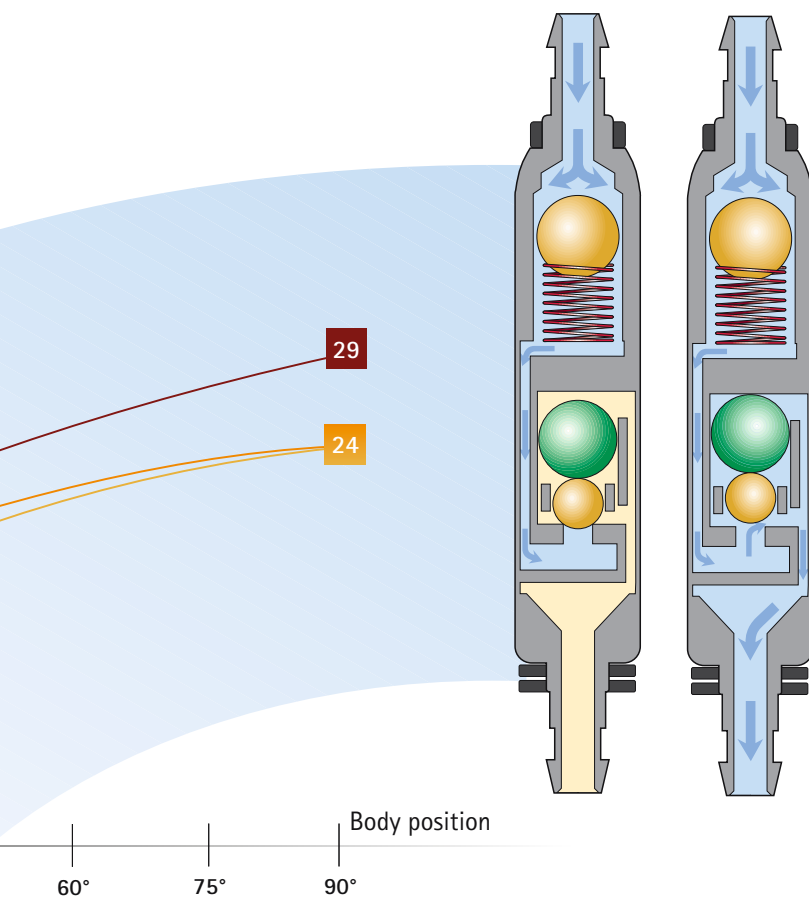
Supine Function

Implantation parallel to the child's body axis guarantees precise and reliable functionality of the paediGAV®.

- When the child is supine, the paediGAV® is in a horizontal position.
- The low pressure setting of the ball-in-cone unit keeps the child's intraventricular pressure within physiological limits.
- The freely moving balls in the gravitational unit do not create any additional resistance when the child is supine, and automatically keep the flow channel open in this position.



paediGAV®
The Function



Upright Function

When the child becomes upright, the gravitational unit is activated:

- A higher valve opening pressure is produced, since the opening pressures of both valve mechanisms (ball-in-cone and gravitational unit) must now be overcome.
- This higher valve opening pressure in the upright position effectively prevents overdrainage and guarantees physiological intracranial pressure in this body position too.





Single valve with two connections



Connector: $d_o = 1.9$ mm
 Valve: $d_o = 4$ mm
 Catheter: $d_i = 1.2$ mm, $d_o = 2.5$ mm

Scale 1:1

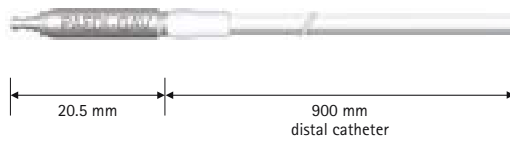
Cat. no.	Valve pressure level (cmH ₂ O*)	
		
FV290T	4	14
FV291T	4	19
FV292T	up to 6 months**	4
FV293T	9	19
FV294T	6 months – 5 years**	9
FV295T	over 5 years**	9

**Standard pressure levels recommended levels only; may vary according to patient and medical history

* 1 cmH₂O = 0,74 mmHg





paediGAV® with distal catheter



Single valve with preattached distal catheter

Connector: $d_o = 1.9$ mm
 Valve: $d_o = 4$ mm
 Catheter: $d_i = 1.2$ mm, $d_o = 2.5$ mm

Scale 1:1

Cat. no.	Valve pressure level (cmH ₂ O*)	
		
FV270T	4	14
FV271T	4	19
FV272T	up to 6 months**	4
FV273T		9
FV274T	6 months – 5 years**	9
FV275T	over 5 years**	9

**Standard pressure levels recommended levels only; may vary according to patient and medical history

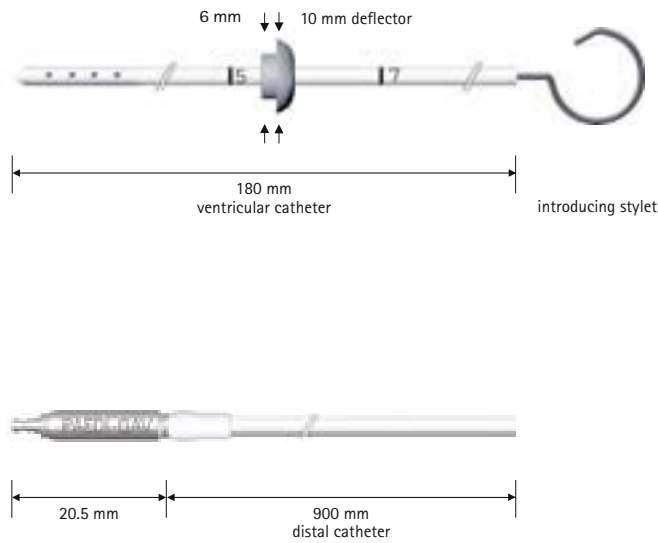
* 1 cmH₂O = 0,74 mmHg



paediGAV® SHUNTSYSTEM

Valve system with one connection

- Ventricular catheter with introducing stylet and deflector
- Valve with preattached distal catheter



Connector: $d_o = 1.9$ mm
 Valve: $d_o = 4$ mm
 Catheter: $d_i = 1.2$ mm, $d_o = 2.5$ mm

Scale 1:1

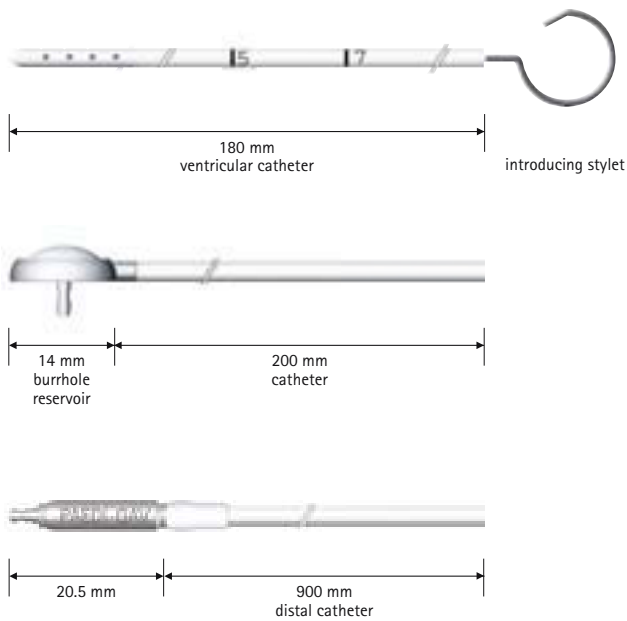
Cat. no.	Valve pressure level (cmH ₂ O*)	
FV276T	4	14
FV277T	4	19
FV278T	up to 6 months**	24
FV279T	9	19
FV280T	6 months – 5 years**	24
FV281T	over 5 years**	29

**Standard pressure levels recommended levels only; may vary according to patient and medical history

* 1 cmH₂O = 0,74 mmHg



paediGAV® SHUNTSYSTEM with BURRHOLE RESERVOIR





Scale 1:1

Valve system with two connections

- Ventricular catheter with introducing stylet
- Burrhole reservoir with integrated catheter
- Valve with preattached distal catheter

Connector: $d_o = 1.9 \text{ mm}$
 Valve: $d_o = 4 \text{ mm}$
 Catheter: $d_i = 1.2 \text{ mm}, d_o = 2.5 \text{ mm}$

Cat. no.	Valve pressure level (cmH ₂ O*)		
			
FV296T	4	14	
FV297T	4	19	
FV298T	up to 6 months**	4	24
FV299T		9	19
FV300T	6 months – 5 years**	9	24
FV301T	over 5 years**	9	29

**Standard pressure levels recommended levels only; may vary according to patient and medical history

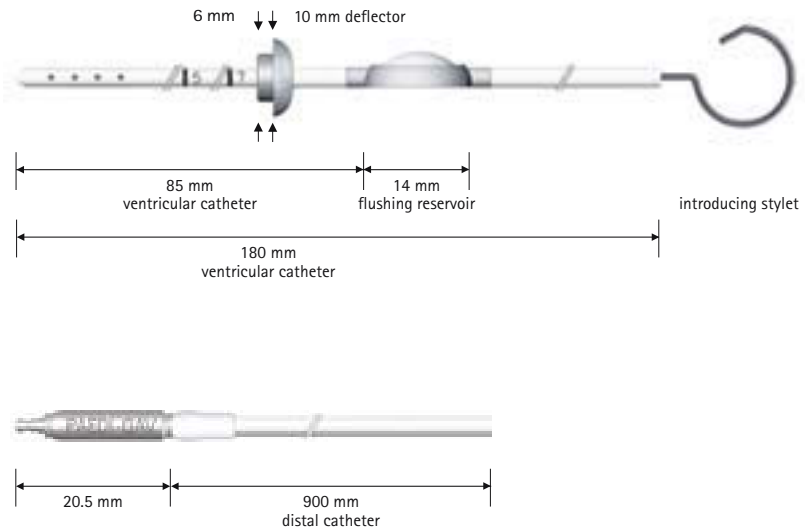
* 1 cmH₂O = 0,74 mmHg



paediGAV® SHUNTSYSTEM with FLUSHING RESERVOIR

Valve system with one connection

- Ventricular catheter with introducing stylet, integrated Flushing reservoir and deflector
- Valve with preattached distal catheter



Connector: $d_o = 1.9$ mm
 Valve: $d_o = 4$ mm
 Catheter: $d_i = 1.2$ mm, $d_o = 2.5$ mm

Scale 1:1

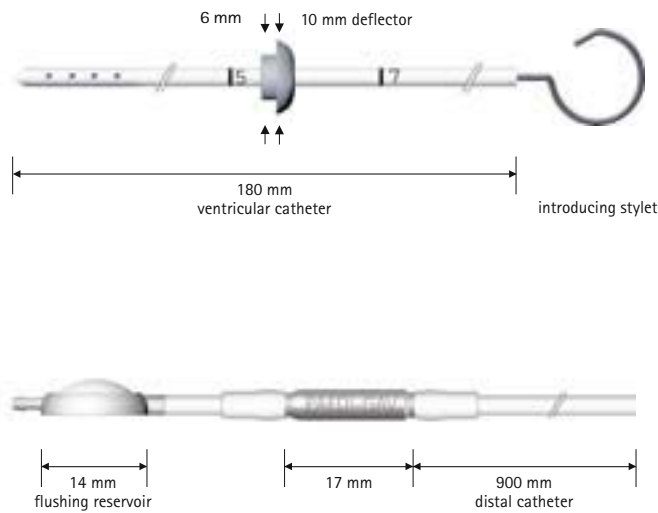
Cat. no.	Valve pressure level (cmH ₂ O*)	
FV282T	4	14
FV283T	4	19
FV284T	up to 6 months**	24
FV285T	9	19
FV286T	6 months – 5 years**	24
FV287T	over 5 years**	29

**Standard pressure levels recommended levels only; may vary according to patient and medical history

* 1 cmH₂O = 0,74 mmHg



paediGAV® SHUNTSYSTEM with FLUSHING RESERVOIR





Valve system with one connection

- Ventricular catheter with introducing stylet and deflector
- Valve with preattached distal catheter and Flushing reservoir

Connector: $d_o = 1.9 \text{ mm}$
 Valve: $d_o = 4 \text{ mm}$
 Catheter: $d_i = 1.2 \text{ mm}, d_o = 2.5 \text{ mm}$

Scale 1:1

Cat. no.	Valve pressure level (cmH ₂ O*)	
		
FV302T	4	14
FV303T	4	19
FV304T	up to 6 months**	24
FV305T	9	19
FV306T	6 months – 5 years**	24
FV307T	over 5 years**	29

**Standard pressure levels recommended levels only; may vary according to patient and medical history

* 1 cmH₂O = 0,74 mmHg



AESCULAP®

Manufacturer acc. MDD 93/42/EEC

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