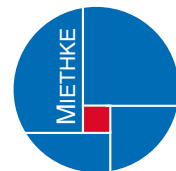
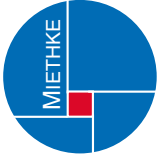


Aesculap Neurosurgery

SHUNTASSISTANT®
PAEDI-SHUNTASSISTANT®



For integration in shunt systems: siphon control and prevention of overdrainage with hydrocephalus



SHUNTASSISTANT[®]
PAEDI-SHUNTASSISTANT[®]



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 frontiers in order to be able to help
where no solutions have yet been found.*



SHUNTASSISTANT® PAEDI-SHUNTASSISTANT®

SHUNTASSISTANT®/ PAEDI- SHUNTASSISTANT®

The valve

The *SHUNTASSISTANT*® is a gravitational valve made of titanium. It is implanted in combination with an adjustable or non-adjustable differential pressure valve.

Its purpose is to prevent overdrainage in shunted hydrocephalus patients, independent of the patient's body position. As an auxiliary valve, it can be implanted either secondarily to support drainage in problem patients, or initially in combination with non-adjustable or adjustable differential pressure valves.

For pediatric hydrocephalus treatment we offer the *PAEDI-SHUNTASSISTANT*®, which is developed specifically to meet the requirements of patients in early childhood.

The *SHUNTASSISTANT*® and the *PAEDI-SHUNTASSISTANT*® are configured with extremely small, streamlined valve bodies, only slightly bigger than the catheter. Thanks to this sleek design, the valve slips smoothly through the incision and under the skin, for a quick and easy subcutaneous implantation.

Because titanium is used as the shell material, the valve configuration could be kept small while maintaining relative large flow channels for the cerebrospinal fluid. In this way the valves do not present any additional risk of blockage.

The *SHUNTASSISTANT*[®] or *PAEDI-SHUNTASSISTANT*[®] can be integrated anywhere in the tube system. The implantation height does not influence the functionality of the valve.

*“The analysis of our material demonstrates that gravitational shunt systems for treatment of adult chronic hydrocephalus minimise the risk of overdrainage.”**

*Source: "Five Years Experience with Gravitational Shunts in Chronic Hydrocephalus of Adults"
M. Kiefer, R. Eymann and U. Meier
Acta Neurochir (2002) 144: 755–767





SHUNTASSISTANT® PAEDI-SHUNTASSISTANT®

SHUNTASSISTANT®/ PAEDI- SHUNTASSISTANT®

The valve

*“Adding a gravitational unit to a pre-existing or newly inserted shunt system is able to reduce the occurrence or severity of an overdrainage syndrome in shunted hydrocephalic children.”**

**Treatment of Overdrainage Syndrome in Shunted Pediatric Patients with Additional Gravitational Unit"
A.M. Messing-Jünger M.D., Luisa Wilms, Poster Presented at AANS/CNS Section on Pediatric Neurological Surgery
December 8-11, 2004 San Francisco, CA

- Separate gravitational device for combination with a non-adjustable or an adjustable differential pressure valve
- Physiological CSF drainage through active adaptation of the opening pressure to the patient's physical position
- Effective protection against CSF overdrainage, thus prevention of slit ventricle syndrome
- Lower risk of infection thanks to simple and time-saving implantation of the streamlined valve
- Reduced risk of blockages thanks to the use of titanium as shell material, maximizing the flow volume while minimizing the valve dimensions

SHUNTASSISTANT®



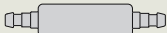


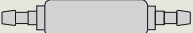

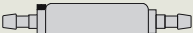
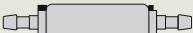
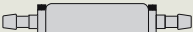
Your choice:

The *SHUNTASSISTANT*[®] is available with various pressure levels. Each pressure level is identified by a special marker code, which can be read through post-operative radiography. The *PAEDI-SHUNTASSISTANT*[®] is easily discerned from the *SHUNTASSISTANT*[®] by its different design.

SHUNTASSISTANT[®]/
PAEDI-SHUNTASSISTANT[®]

Your choice

| Opening pressure (cmH ₂ O) | X-ray marker code <i>PAEDI-SHUNTASSISTANT</i> [®] |
|--|---|
| 10 |  |

| Opening pressure (cmH ₂ O) | X-ray marker code <i>SHUNTASSISTANT</i> [®] |
|--|---|
| 15 |  |
| 20 |  |
| 25 |  |
| 30 |  |
| 35 |  |



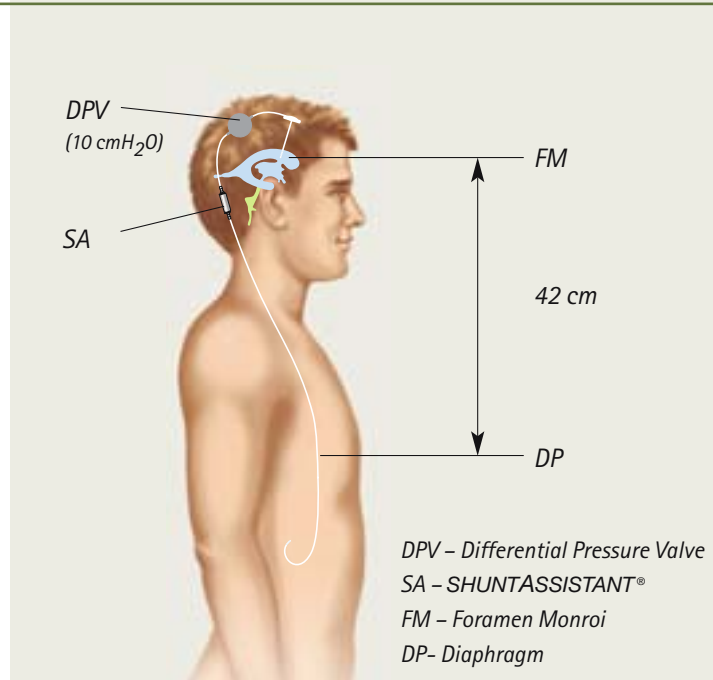
SHUNTASSISTANT® PAEDI-SHUNTASSISTANT®

SHUNTASSISTANT®/
PAEDI-
SHUNTASSISTANT®
Our recommendation

Recommended procedure for selecting the standard pressure levels: **

- Measure the distance between the Foramen Monroi and the diaphragm
(e.g. 42 cm)
- Subtract from this value the opening pressure value of the differential pressure valve
(e.g. 10 cmH₂O) 42 cm - 10 cmH₂O = 32 cmH₂O
- From that result subtract another 5 cmH₂O
(assuming that the intraventricular pressure in upright position is slightly negative)
32 cmH₂O - 5 cmH₂O = 27 cmH₂O
- Select the SHUNTASSISTANT® whose pressure level comes closest to the calculated value
(25 cmH₂O in this example)

Measuring the distance between the Foramen Monroi and the diaphragm





Recommended pressure levels: **

| Distance between Foramen Monroi and diaphragm in cm | Opening pressure of the differential pressure valve in cmH ₂ O | | | | |
|---|---|----|----|----|----|
| | 5 | 7 | 10 | 13 | 16 |
| < 28 | 15 | 15 | 10 | 10 | 10 |
| 28 - 32 | 20 | 15 | 15 | 15 | 10 |
| 33 - 37 | 25 | 20 | 20 | 20 | 15 |
| 38 - 42 | 30 | 25 | 25 | 25 | 20 |
| 43 - 47 | 35 | 30 | 30 | 30 | 25 |
| 48 - 52 | 35 | 35 | 35 | 35 | 30 |
| > 53 | 35 | 35 | 35 | 35 | 35 |

SHUNTASSISTANT®/
PAEDI-
SHUNTASSISTANT®
Our recommendation

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



SHUNTASSISTANT® PAEDI-SHUNTASSISTANT®

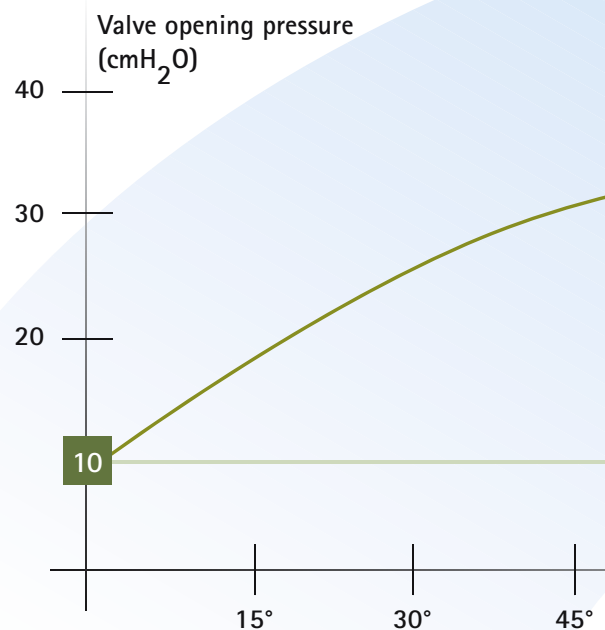
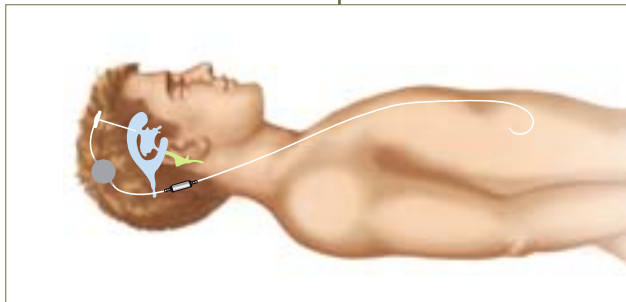
SHUNTASSISTANT®/ PAEDI- SHUNTASSISTANT®

The Functions

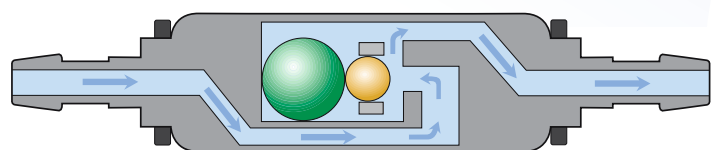
Supine Function

Precise and safe functioning of the SHUNTASSISTANT® or PAEDI-SHUNTASSISTANT® is ensured by implanting the valve parallel to the body axis.

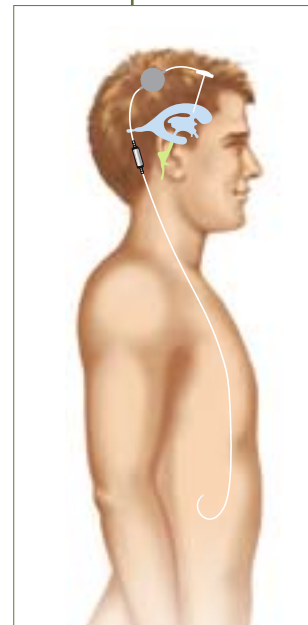
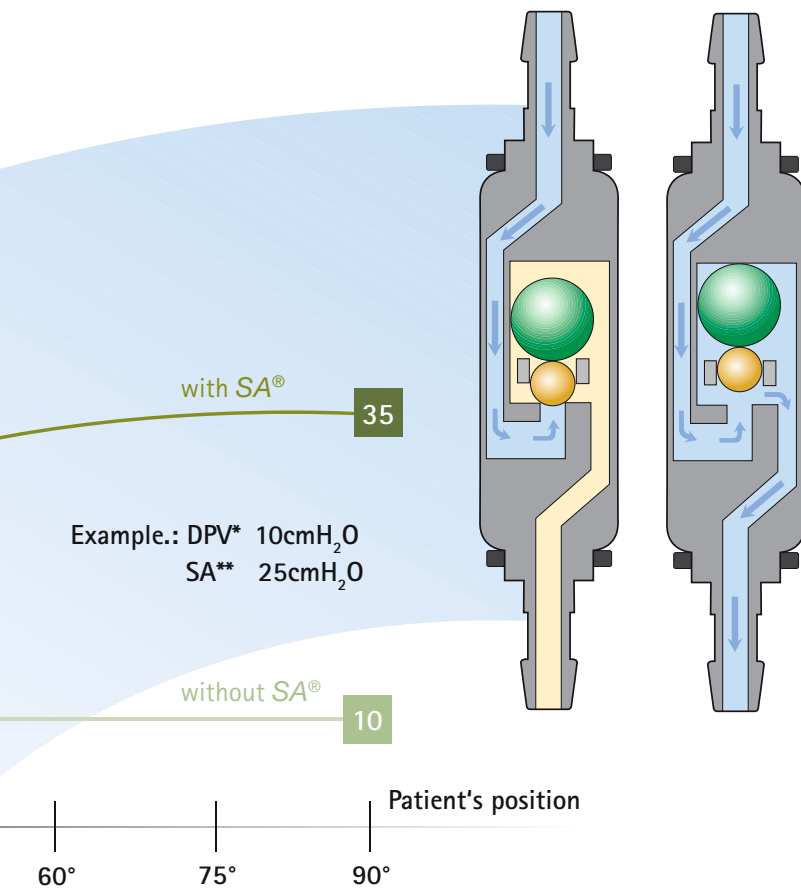
- The balls of the SHUNTASSISTANT® and PAEDI-SHUNTASSISTANT® can move freely and do not present an additional flow resistance while the patient is supine, because the flow channel at this point is kept open automatically.
- The differential pressure valve keeps the patient's intraventricular pressure within physiological limits.



* Differential Pressure Valve
** SHUNTASSISTANT®



*SHUNTASSISTANT®/
PAEDI-
SHUNTASSISTANT®
The Functions*



Upright Function

Whenever the patient moves to an upright position, the valve balls move down and the *SHUNTASSISTANT®/PAEDI-SHUNTASSISTANT®* is activated automatically.

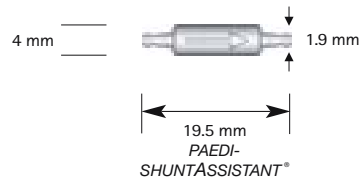
- Since the opening pressure both of the differential pressure valve and of the *SHUNTASSISTANT®/PAEDI-SHUNTASSISTANT®* must be overcome now, the overall opening pressure of the shunt system is set to a higher level.
- This higher shunt opening pressure in the upright position effectively prevents increased drainage, which can result e.g. from the suction effect at the distal catheter.




SHUNTASSISTANT® PAEDI-SHUNTASSISTANT®

PAEDI-SHUNTASSISTANT®

Single valve with two connections



Scale 1:1

| | Opening pressure (cmH ₂ O*) |
|----------|---|
| Art. no. |  |
| FV288T | 10 |

* 1 cmH₂O = 0.74 mmHg



SHUNTA ASSISTANT®



Single valve with two connections

Scale 1:1

| Art. no. | Opening pressure (cmH ₂ O*) |
|----------|--|
| | |
| FV250T | 15 |
| FV251T | 20 |
| FV252T | 25 |
| FV253T | 30 |
| FV254T | 35 |

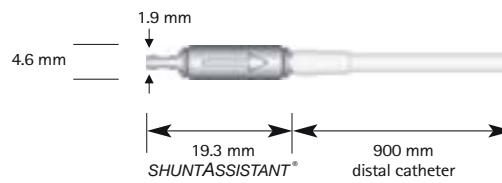
* 1 cmH₂O = 0.74 mmHg



SHUNTASSISTANT® PAEDI-SHUNTASSISTANT®


SHUNTASSISTANT® with distal catheter

Single valve with
preattached distal catheter



all catheters: $d_i = 1.2 \text{ mm}$, $d_o = 2.5 \text{ mm}$

Scale 1:1

| Art. no. | Opening pressure (cmH ₂ O*) |
|----------|---|
| |  |
| FV260T | 15 |
| FV261T | 20 |
| FV262T | 25 |
| FV263T | 30 |
| FV264T | 35 |

* 1 cmH₂O = 0.74 mmHg



proGAV[®] – the adjustable MIETHKE gravitational valve

3 Tesla
MRI safe



Aesculap Neurosurgery

- Adjustable ball-in-cone valve, 0–200 mmH₂O
- Integrated *SHUNTASSISTANT*[®] for effective protection against overdrainage
- "Active-Lock" mechanism to prevent unintended readjustment in MRI fields up to 3 Tesla
- Set pressure level can be read without use of X-ray imaging
- Handy instruments for easy readjustment and reading of the pressure level
- High-precision titanium valve technology



AESCULAP®

Manufacturer acc. MDD 93/42/EEC

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