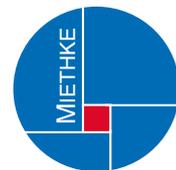


Aesculap Neurosurgery

proGAV[®]



The adjustable MIETHKE gravitational valve



proGAV[®]



Alliance for innovation

When two strong partners combine their know-how, this often leads to innovative and groundbreaking solutions, which could not be achieved independently by any of the partners.

Following this philosophy, Aesculap and Miethke have been cooperating since 1999. Our aim was and still is to develop and make available worldwide better solutions for the complex treatment of hydrocephalus.

This vision inspired and motivated everybody in our cooperation. It started with an intensive exchange with customers, doctors and patients about the difficult issues involved in hydrocephalus therapy. New solutions were conceived and discussed in small circles of experts and at scientific meetings.

This process finally resulted in the market launch of the first gravitational system, which effectively prevents overdrainage of cerebrospinal fluid (CSF). – a world first and milestone in modern hydrocephalus therapy.

So we already achieved a lot, but this is only the beginning. We are determined to continue on the route we embarked on. For the good of the patient, we will continue with our considerable investments in research and development and will not tire to learn more, create further expertise and remain 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.*



proGAV[®]

proGAV[®]

The valve

The *proGAV*[®] is the first adjustable gravitational valve for the treatment of pediatric and adult hydrocephalus. In its design it combines the advantages of an adjustable valve with those of a gravitational unit. It also is MR safe up to 3 tesla.

In combination with the tried and tested *MIETHKE SHUNTASSISTANT*[®], gravitational unit, the *proGAV*[®] offers effective protection against overdrainage. The gravitational unit assists the adjustable valve in maintaining physiological ventricular pressure independent of the patient's body position.

The patented adjustment and verification instruments allow easy, fast and uncomplicated treatment at any location, without having to expose the patient to X-ray.

The unique "Active-Lock" mechanism protects the *proGAV*[®] against inadvertent readjustments caused by external magnetic fields.



The unequalled opening pressure adjustment range of the *proGAV*[®], 0-20 cmH₂O, opens up more treatment options for the neurosurgeon, while the large adjustment radius of 300° ensures excellent adjusting precision.

*“The **proGAV**[®] shunt is an adjustable, low resistance valve that is able to limit posture-related overdrainage. Unlike other adjustable valves, the **proGAV**[®] cannot be accidentally re-adjusted by external magnetic field such as a 3T MR scanner.” **

*Source: Cerebrospinal Fluid Research 2006, 3:9 doi:10.1186/1743-8454-3-9
"In vitro hydrodynamic properties of the Miethke *proGAV* hydrocephalus shunt"
David M Allin, Zofia H Czosnyka*, Marek Czosnyka, Hugh K Richards and John D Pickard
Academic Neurosurgical Unit, Addenbrooke's Hospital, Cambridge CB2 2QQ, UK





proGAV®

proGAV®
The valve

“From the clinical point of view, the programmable gravity-assisted valve (proGAV® Aesculap) is an indispensable development in the valve manufactory technique, offering a new standard in the management of INPH.”

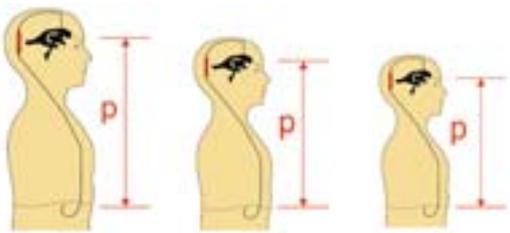
*Source: Neurosurg Q 2007; 17(1): 52-55
„Clinical experiences in the treatment of idiopathic normal-pressure hydrocephalus using the programmable gravity assisted valve proGAV® Aesculap”
Meier U, Lemcke J, Al-Zain F

- Wide range of pressure levels for continuous adjustment between 0 and 20 cmH₂O
- Integrated gravitational unit for effective protection against overdrainage
- “Active-lock” mechanism to prevent inadvertent pressure level readjustments caused by external magnetic fields
- 3-tesla MR compatible
- X-ray-free verification of the pressure level setting
- Patented instruments for easy and quick adjustment of the pressure level
- Titanium shell ensuring reliable operation independent of external or subcutaneous pressures



Our recommendation:

- The gravitational unit should be selected according to the body height and immobility of the patient.



Example: FV414T

Gravitational unit = 25 cmH₂O

Adjustable valve = 10 cmH₂O (setting)

Opening pressure:

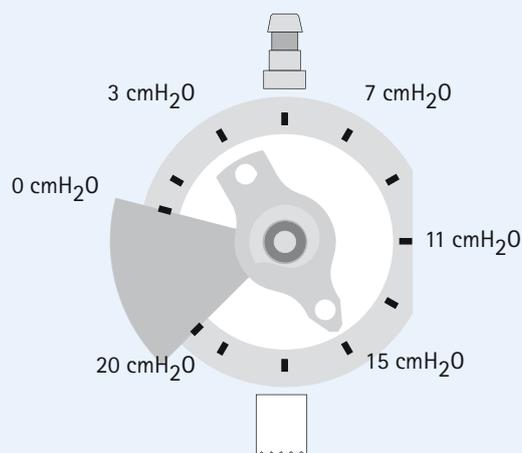
Patient supine = 10 cmH₂O (adjustable valve only)

Patient upright = 35 cmH₂O (adjustable valve + gravitational unit)

- The taller the patient, the higher the pressure level of the gravitational unit to be selected. The shorter or more adipose the patient, the lower the required pressure level.
- The more immobile the patient, the lower the pressure level of the gravitational unit to be selected.

proGAV®
Our recommendation

proGAV®
in X-ray view





proGAV[®]

proGAV[®]

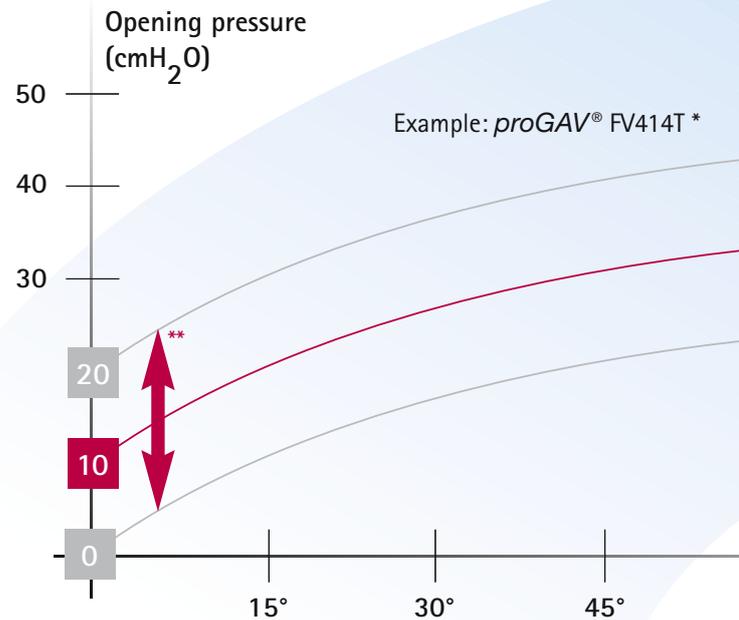
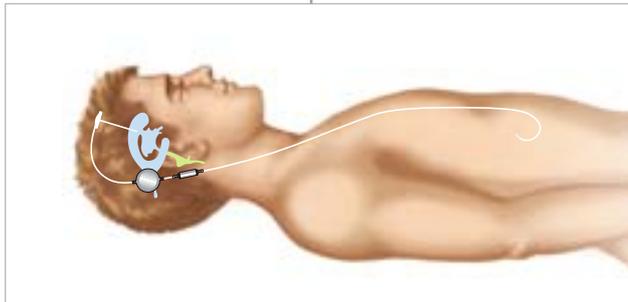
The Functions

Supine Function

The proGAV[®] is a position-dependent valve. The opening pressure of the valve varies continuously with the patient's body position.

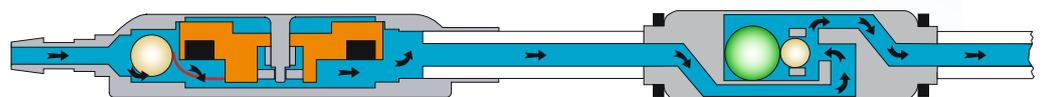
To adapt the proGAV[®] to the individual patient, one opening pressure is selected for the supine position and one for the upright position.

- The opening pressure for the supine position is defined exclusively by the adjustable valve. The gravitational unit does not influence the opening pressure in this body position.
- The opening pressure can be set to a value between 0 and 20 cmH₂O, depending on clinical presentation and indication.



* Adjustable valve set to 10 cmH₂O / gravitational unit 25 cmH₂O

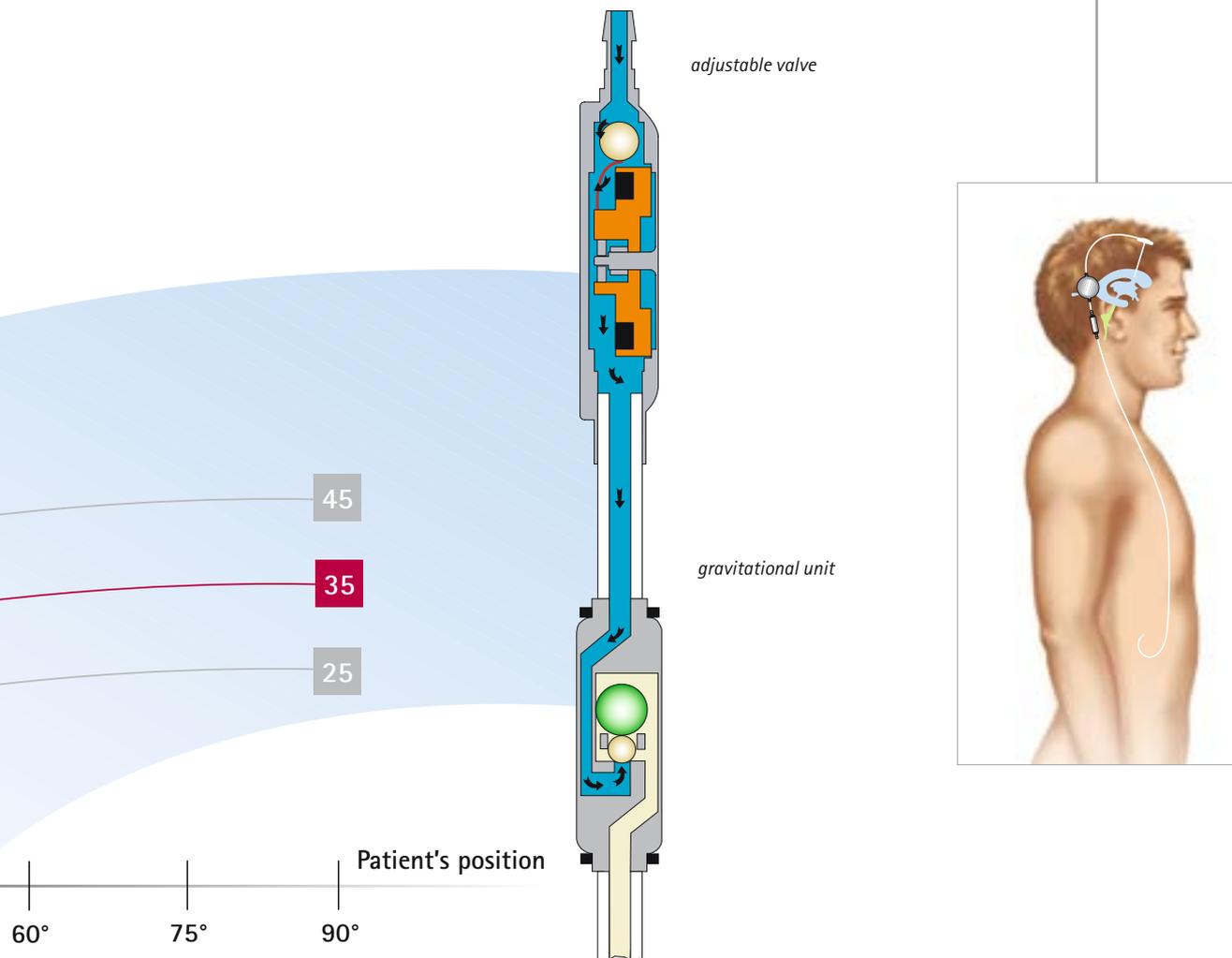
** proGAV[®] adjustment range 0-20 cmH₂O



adjustable valve

gravitational unit

proGAV®
The Functions



Upright Function

The gravitational unit is activated whenever the patient moves to an upright position.

- As the patient moves to an upright position, the tantalum weight ball is activated and provides a gradually increasing opening pressure of the shunt system.
- In this mode the shunt opening pressure is the sum of the pressure level set at the adjustable valve and the increasing opening pressure of the gravitational unit.
- The continuous increase of the opening pressure, up to the maximum when the patient is fully upright, offers effective protection against overdrainage.



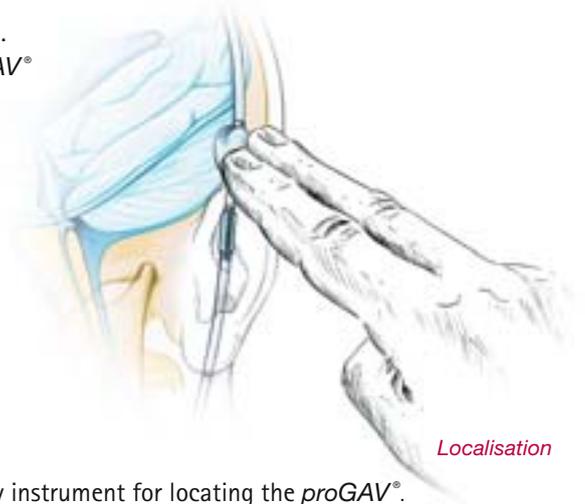
proGAV®

proGAV®

Instruments for valve adjustment

Localisation

The proGAV® is located by palpation. This procedure is aided by the proGAV® compass, which can also be used for reading the actual opening pressure setting.



Localisation

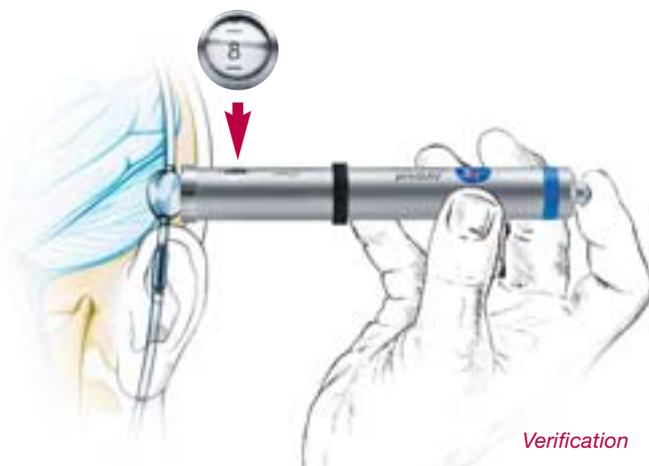


■ proGAV® compass:

The compass is an auxiliary instrument for locating the proGAV®. As the compass is held above the valve implant site, the floating compass aligns over the adjustable proGAV® valve. The set present opening pressure setting can be read from the compass scale.

Verification

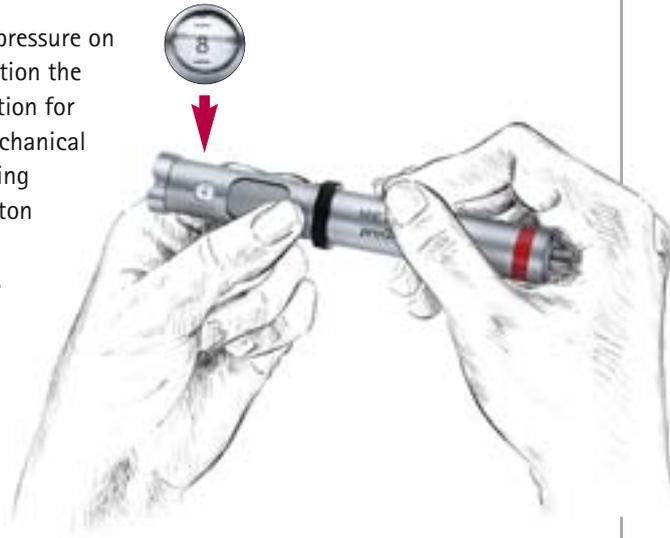
Position the verification instrument according to instruction for use on the valve. Press the trigger button to see the actual opening pressure setting displayed in the display window.



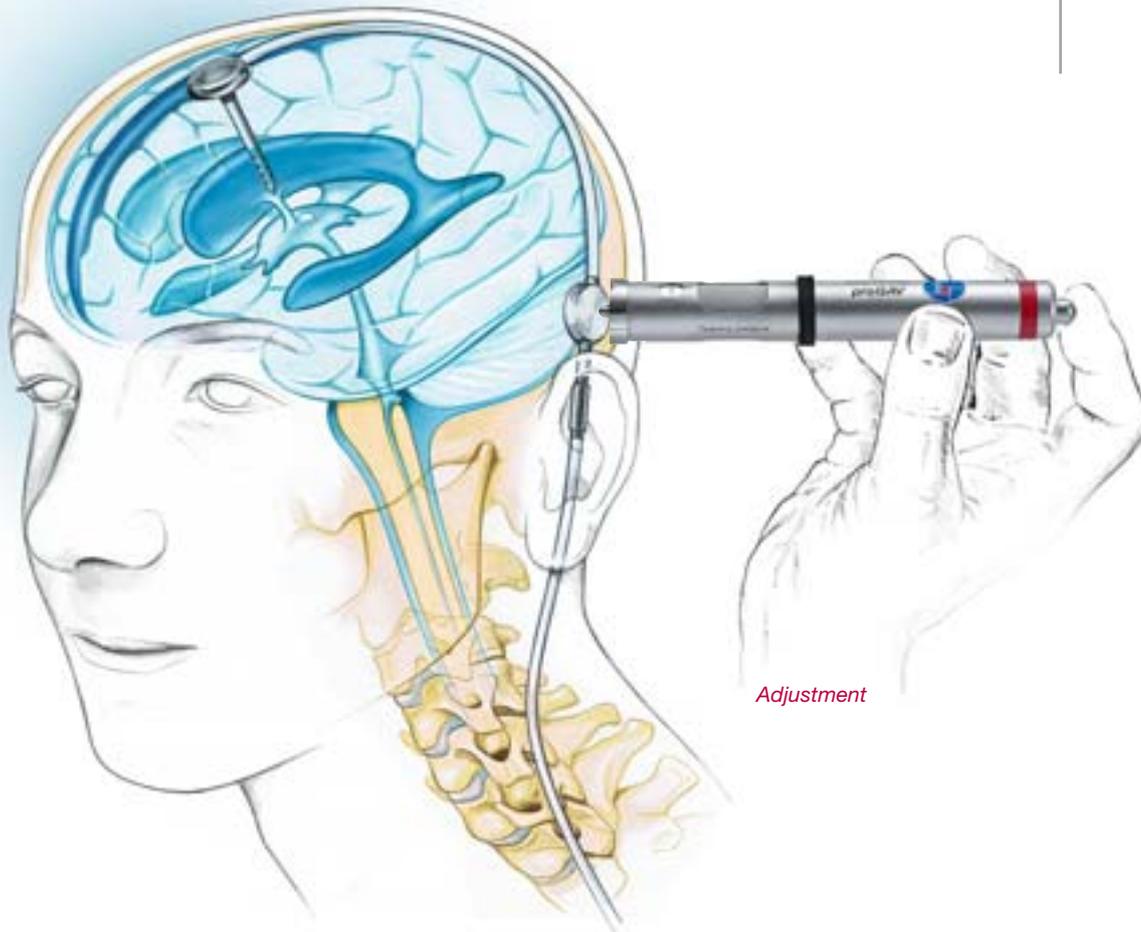
Verification

Adjustment

Select the appropriate opening pressure on the adjustment instrument. Position the instrument according to instruction for use on the valve. Unlock the mechanical coupling "Active-Lock" by applying mild pressure on the trigger button and set the intended opening pressure of the adjustable valve.



*proGAV®
Instruments for
valve adjustment*

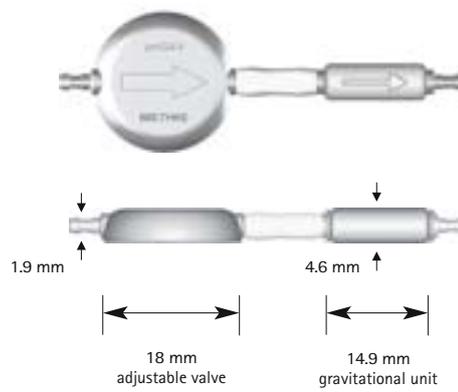




proGAV®

Valve

- Available as adjustable valve only or in combination with gravitational unit



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

Scale 1:1

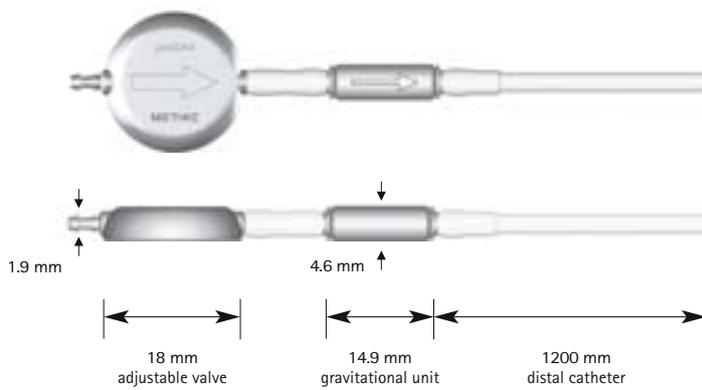
Art. no.	Adjustable valve (cmH ₂ O*)	Gravitational unit (cmH ₂ O*)
FV410T	0 to 20	-
FV411T	0 to 20	10
FV412T	0 to 20	15
FV413T	0 to 20	20
FV414T **	0 to 20	25
FV415T	0 to 20	30
FV416T	0 to 20	35

**Standard pressure levels. These guide values are not binding. Other specifications may be preferable depending on the individual patient and anamnesis.

* 1 cmH₂O = 0.74 mmHg



proGAV® with distal catheter



Scale 1:1

Valve with integrated distal catheter

- Available as adjustable valve only or in combination with gravitational unit

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

Art. no.	Adjustable valve (cmH ₂ O*)	Gravitational unit (cmH ₂ O*)
FV417T	0 to 20	-
FV418T	0 to 20	10
FV419T	0 to 20	15
FV420T	0 to 20	20
FV421T **	0 to 20	25
FV422T	0 to 20	30
FV423T	0 to 20	35

**Standard pressure levels. These guide values are not binding. Other specifications may be preferable depending on the individual patient and anamnesis.

* 1 cmH₂O = 0.74 mmHg



proGAV[®]

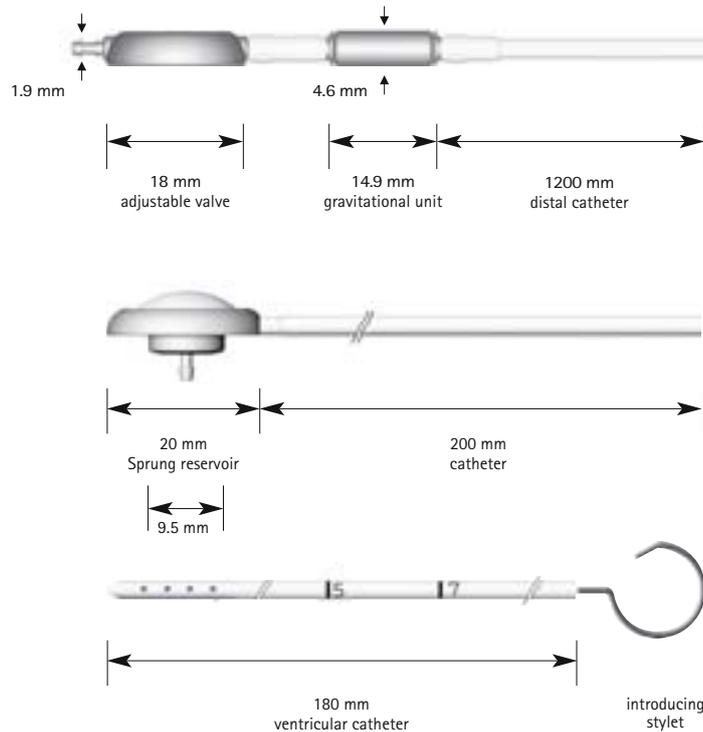
proGAV[®] SHUNT SYSTEM with SPRUNG RESERVOIR*

Shunt system with two connections

- Available as adjustable valve only or in combination with gravitational unit
- Sprung reservoir* with integrated distal catheter; design acc. to Dr. Sprung
- Ventricular catheter with introducing stylet

*Flushing reservoir for control of the ventricular catheter's patency and the distal share of drainage

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



Scale 1:1

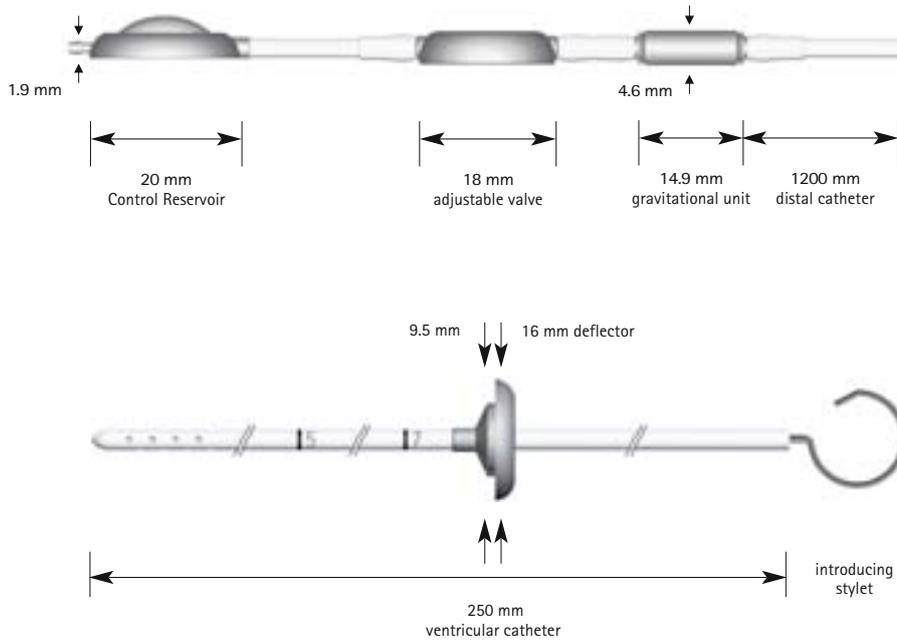
Art. no.	Adjustable valve (cmH ₂ O*)	Gravitational unit (cmH ₂ O*)
FV424T	0 to 20	-
FV425T	0 to 20	10
FV426T	0 to 20	15
FV427T	0 to 20	20
FV428T **	0 to 20	25
FV429T	0 to 20	30
FV430T	0 to 20	35

**Standard pressure levels. These guide values are not binding. Other specifications may be preferable depending on the individual patient and anamnesis.

* 1 cmH₂O = 0.74 mmHg



proGAV® SHUNT SYSTEM with CONTROL RESERVOIR*



Scale 1:1

Shunt system with one connection

- Available as adjustable valve only or in combination with gravitational unit
- with integrated catheter and integrated Control Reservoir*
- Ventricular catheter with introducing stylet and deflector

*Flushing reservoir for control of the ventricular catheter's patency and the distal share of drainage

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

Art. no.	Adjustable valve (cmH ₂ O*)	Gravitational unit (cmH ₂ O*)
FV431T	0 to 20	-
FV432T	0 to 20	10
FV433T	0 to 20	15
FV434T	0 to 20	20
FV435T **	0 to 20	25
FV436T	0 to 20	30
FV437T	0 to 20	35

**Standard pressure levels. These guide values are not binding. Other specifications may be preferable depending on the individual patient and anamnesis.

* 1 cmH₂O = 0.74 mmHg



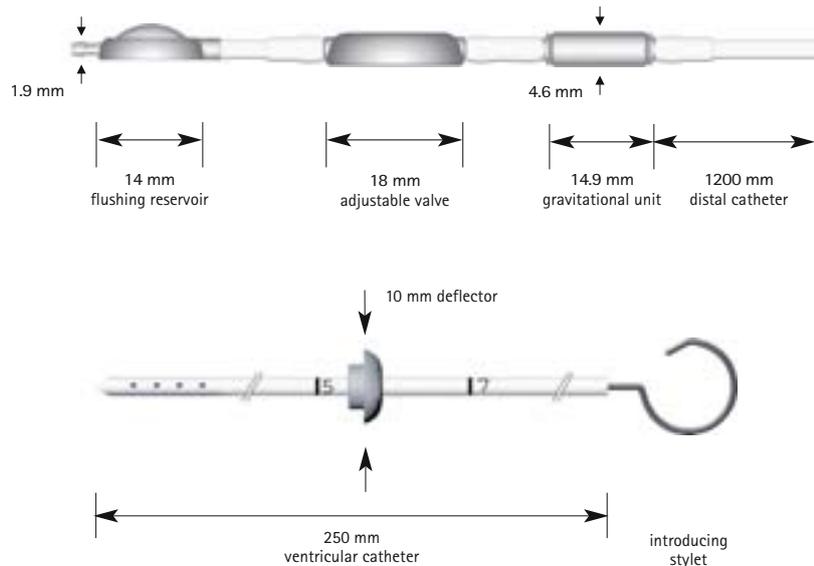
proGAV®

proGAV® SHUNT SYSTEM with FLUSHING RESERVOIR
for pediatric application

Shunt system with one connection

- Available as adjustable valve only or in combination with gravitational unit
- with integrated distal catheter and integrated pediatric flushing reservoir
- Ventricular catheter with introducing stylet and deflector

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



Scale 1:1

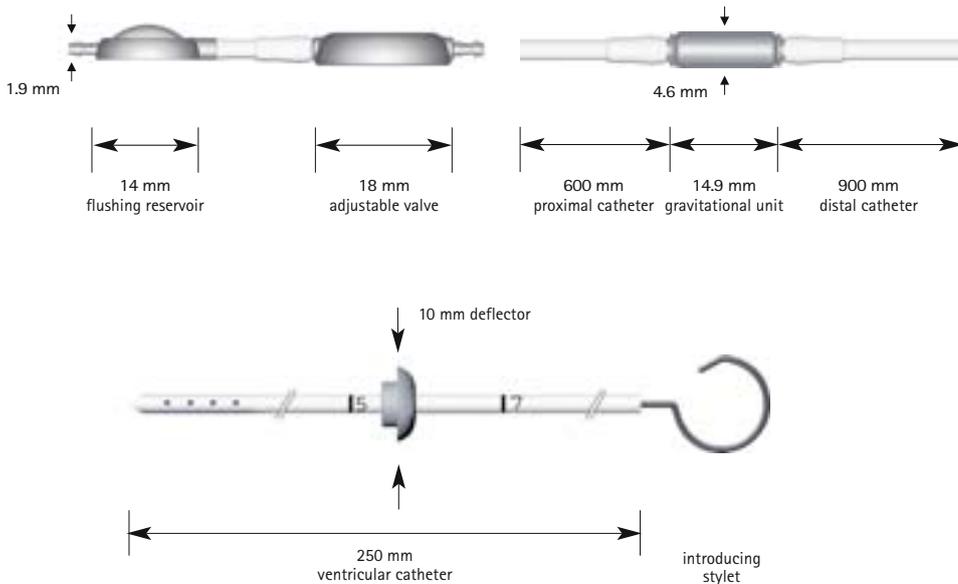
Art. no.	Adjustable valve (cmH ₂ O*)	Gravitational unit (cmH ₂ O*)
FV438T	0 to 20	-
FV439T	0 to 20	10
FV440T	0 to 20	15
FV441T **	0 to 20	20
FV442T	0 to 20	25
FV443T	0 to 20	30
FV444T	0 to 20	35

**Standard pressure levels. These guide values are not binding. Other specifications may be preferable depending on the individual patient and anamnesis.

* 1 cmH₂O = 0.74 mmHg



proGAV® SHUNT SYSTEM with FLUSHING RESERVOIR
for pediatric application



Scale 1:1

Shunt system with two connections

- Available as adjustable valve only or in combination with gravitational unit
- Valve with integrated pediatric flushing reservoir
- Distal catheter with integrated gravitational unit
- Ventricular catheter with introducing stylet and deflector

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

Art. no.	Adjustable valve (cmH ₂ O*)	Gravitational unit (cmH ₂ O*)
FV452T	0 to 20	-
FV453T	0 to 20	10
FV454T	0 to 20	15
FV455T **	0 to 20	20
FV456T	0 to 20	25
FV457T	0 to 20	30
FV458T	0 to 20	35

**Standard pressure levels. These guide values are not binding. Other specifications may be preferable depending on the individual patient and anamnesis.

* 1 cmH₂O = 0.74 mmHg



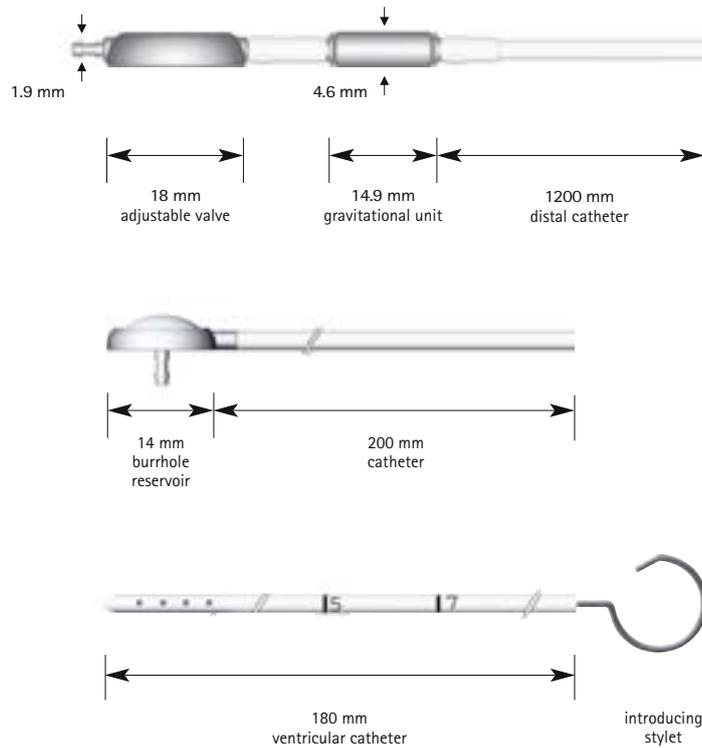
proGAV®

proGAV® SHUNT SYSTEM with BURRHOLE RESERVOIR
for pediatric application

Shunt system with two connections

- Available as adjustable valve only or in combination with gravitational unit
- Pediatric burrhole reservoir with integrated distal catheter
- Ventricular catheter with introducing stylet

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



Scale 1:1

Art. no.	Adjustable valve (cmH ₂ O*)	Gravitational unit (cmH ₂ O*)
FV445T	0 to 20	-
FV446T	0 to 20	10
FV447T	0 to 20	15
FV448T **	0 to 20	20
FV449T	0 to 20	25
FV450T	0 to 20	30
FV451T	0 to 20	35

**Standard pressure levels. These guide values are not binding. Other specifications may be preferable depending on the individual patient and anamnesis.

* 1 cmH₂O = 0.74 mmHg

Adjustment instrument:



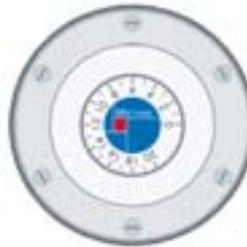
Verification instrument:



Masterdisc:



Compass :



Instruments for valve adjustment

- proGAV® adjustment instrument for setting the required opening pressure
- proGAV® verification instrument for reading the actual opening pressure setting
- proGAV® masterdisc for calibrating the verification instrument
- Compass for locating the proGAV®

Art. no.	Instruments
FV400T	proGAV® adjustment instrument
FV401T	proGAV® verification instrument
FV402T	proGAV® masterdisc
FV403T	proGAV® compass
FV404T	proGAV® instrument set (comprising FV400T-FV403T)



AESCULAP®

Manufacturer acc. MDD 93/42/EEC

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