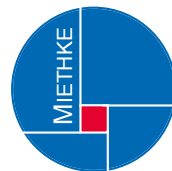


proSA®

Adjustable MIETHKE Shunt Systems
Your Simple Choice for Precise Patient Care



Aesculap Neurosurgery



Enhanced Patient Care

Active people spend about 2/3 of the day walking, standing or sitting upright. Consequently, hydrocephalus patients with a shunt often risk overdrainage.

The introduction of the gravitational technology for hydrocephalus treatment brought new options to avoid the symptoms and long-term complications caused by overdrainage.

The new *proSA* is the result of continuous evolution of the proven and accepted gravitational technology. The *proSA* allows individual adjustment, which can be necessitated by body growth or increased peritoneal pressure.

"The analysis of our material demonstrates that gravitational shunt systems for treatment of adult chronic hydrocephalus minimise the risk of overdrainage." ^[10]



■ Gravity approved

The Miethke valves *proGAV*, *GAV* and *paediGAV* based on this technology offer effective solutions for pediatric and adult hydrocephalus [1,2,3,4,5].

■ Approved instruments

The patented adjustment and verification instruments allow easy, fast and uncomplicated treatment at any location, without having to expose the patient to X-ray [1,9].

■ MRI approved

Like the *proGAV*, the *proSA* features an "Active Lock" mechanism. This mechanism protects the valve against inadvertent adjustment by external magnetic fields and is MR-conditional* up to 3 Tesla [6,7,8,9].

* According to the new ASTM (American Society for Testing and Materials) standards.



- 1 The Adjustable *proGAV* Shunt: A Prospective Safety and Reliability Multicenter Study
Sprung C, Schlosser HG, Lemcke J, Meier U, Messing-Jünger M, Trost HA, Weber F, Schul C, Rohde V, Ludwig HC, Höpfner J, Sepehrnia A, Mirzayan MJ, Krauss JK - *Neurosurgery*. 2010 Mar;66(3):465-74.
- 2 Experiences with a gravity-assisted valve in hydrocephalic children
Haberl EJ, Messing-Juenger M, Schuhmann M, Eymann R, Cedzich R, Fritsch MJ, Kiefer M, van Lindert EJ, Söller C, Lehner M, Rohde V, Stroux A, von Behrenberg P - *Journal of Neurosurgery Pediatrics* 4:000-000, 2009.
- 3 First experiences with an adjustable gravitational valve in child hood hydrocephalus
Rohde V, Haberl EJ, Ludwig H, Thomale UW - *Journal of Neurosurgery Pediatrics* 2009; 3(2):90-93.
- 4 Clinical experience in the treatment of idiopathic Normalpressure Hydrocephalus using the programmable gravity-assisted valve (*proGAV* Aesculap)
Meier U, Lemcke J, Al-Zain F - *Neurosurgery Quarterly* 2007;17(1):52-55.
- 5 Gravitational Shunts in Longstanding Overt Ventriculomegaly in Adults
Kiefer M, Eymann R, Strowitzki M, Steudel WI - *Neurosurgery* 57:109-119, 2005.
- 6 Programmable CSF shunt valve: in vitro assessment of MR imaging safety at 3T
Shellock FG, Habibi R, Knebel J - *AJNR American Journal of Neuroradiology* 2006; 27(3):661-665.
- 7 Effect of 3T MRI on the function of shunt valves-evaluation of *paediGAV*, *DualSwitch* and *proGAV*
Lindner D, Preul C, Trantakis C, Moeller H, Meixensberger - *J European Journal of Radiology* 2005; 56(1):56-59.
- 8 Magnetic field interactions in adjust able hydrocephalus shunts
Lavinio A, Harding S, Van Der Boogaard F, Czosnyka M, Smielewski P, Richards HK, Pickard JD, Czosnyka ZH. et al - *Journal of Neurosurgery Pediatrics* 2008;2(3):222-228.
- 9 Programmable Shunt Assistant tested in Cambridge Shunt Evaluation Laboratory
Czosnyka M, Czosnyka Z. - *Acta Neurochirurgica Suppl.* 2010 (in press)
- 10 Five Years Experience with Gravitational Shunts in Chronic Hydrocephalus of Adults
Kiefer M, Eymann R, Meier U - *Acta Neurochir* 2002, 144: 755-767
- 11 Treatment of Overdrainage Syndrome in Shunted Pediatric Patients with Additional Gravitational Uni
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

Enhanced Treatment Options

proSA offers extended options and possibilities for all fields of hydrocephalus treatment, beyond the limitations of conventional adjustable shunt systems.

The pressure setting range of 0 to 40 cmH₂O allows individual adjustment for each patient.

The *proSA* valve can be combined with any differential pressure valve.

- One valve fits all patients
- Wide range of pressure levels for adjustment between 0 to 40 cmH₂O
- Automatic adaption of pressure depending on bodyposition within adjusted pressure range
- Titanium shell ensures reliable function, independent of external and subcutaneous pressures

"Adding a gravitational unit to a preexisting or newly inserted shunt system is able to reduce the occurrence or severity of an overdrainage syndrome in shunted hydrocephalic children." ^[11]



Our Recommendation

| Patient Age | Initial Valve Adjustment [cmH ₂ O] |
|-------------|--------------------------------------------------|
| < 5 years | 20 |
| 5-60 years | 25 |
| > 60 years | 20 |

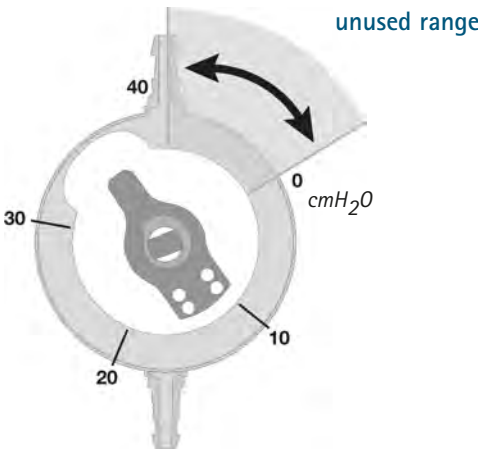
■ The *proSA* valve should be implanted in combination with a differential pressure unit.

■ The less mobile the patient, the lower the opening pressure to be set.

■ Individual characteristics of the patient, e.g. the Body Mass Index, adiposity, pregnancy, growth of pediatric patients, etc. can be easily adapted for, by adjusting the gravitational unit in the course of the therapy.

** These guide values are not binding. Other settings may be preferable depending on the individual patient and anamnesis*

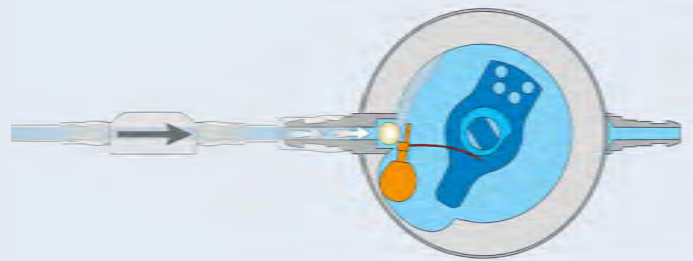
proSA
in X-ray view



The Function – Supine Function

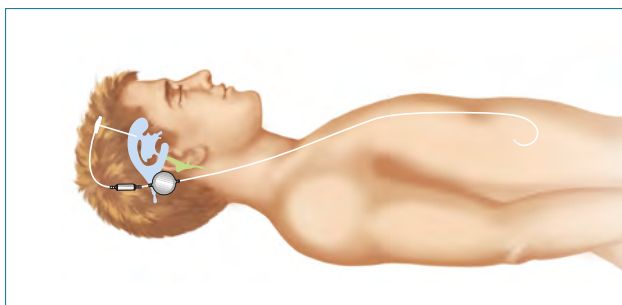
The *proSA* is an adjustable gravitational valve whose opening pressure automatically adapts to the patient's body position.

- In the supine position, the opening pressure of the *proSA* is 0 cmH₂O.
- In this mode, the shunt opening pressure is completely defined by the differential pressure unit.

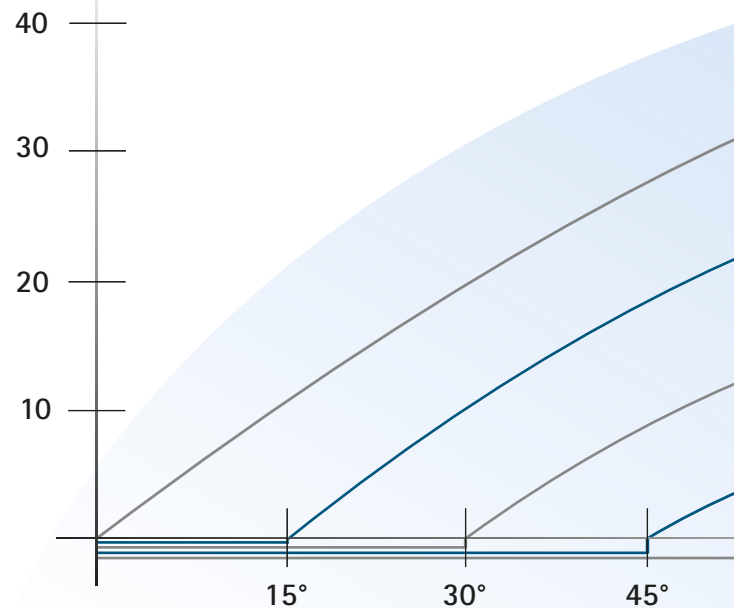


Optional differential pressure unit

Adjustable gravitational unit



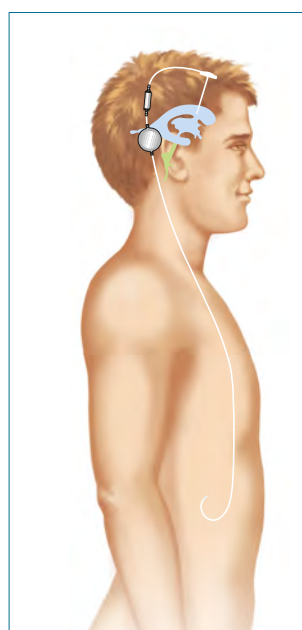
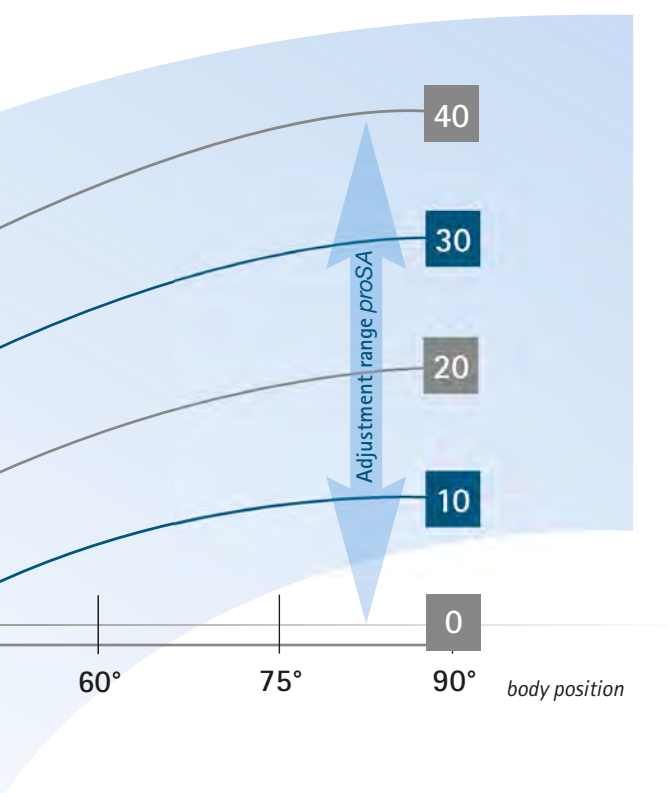
Valve opening pressure*
(cmH₂O)



* The graph only represents the opening pressure of the *proSA*. For the opening pressure of the shunt system as a whole, the opening pressure of the differential pressure unit has to be added in.

The Function – Upright Function

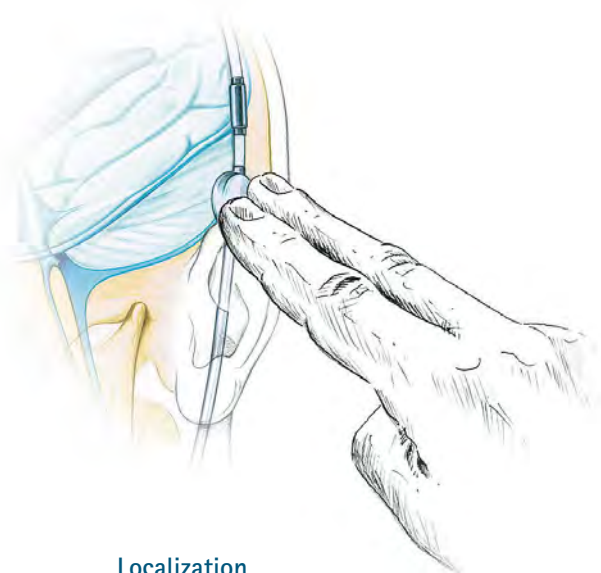
- When the patient is in an upright body position, the gravitational unit and the differential pressure unit work together, i.e. the opening pressure of the shunt system as a whole is the sum of the differential pressure level and the pressure level set at the gravitational unit.



Instruments for Valve Adjustment

■ Localization

The *proSA* is located by palpation.

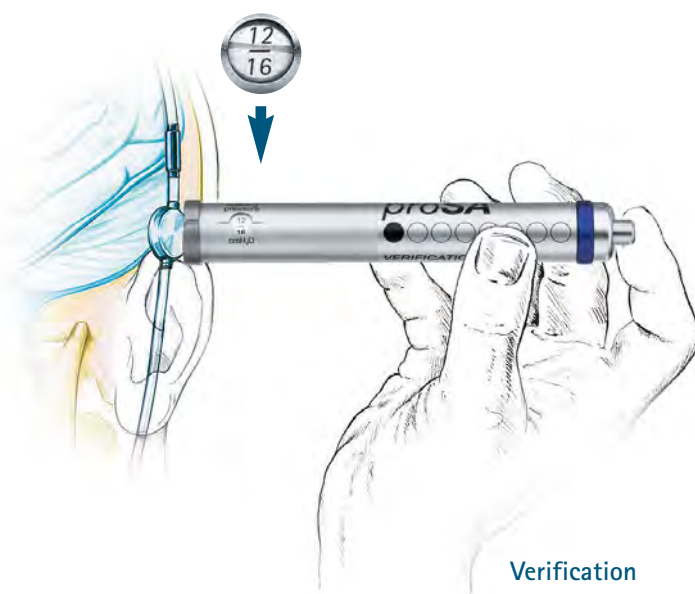


Localization

■ 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.



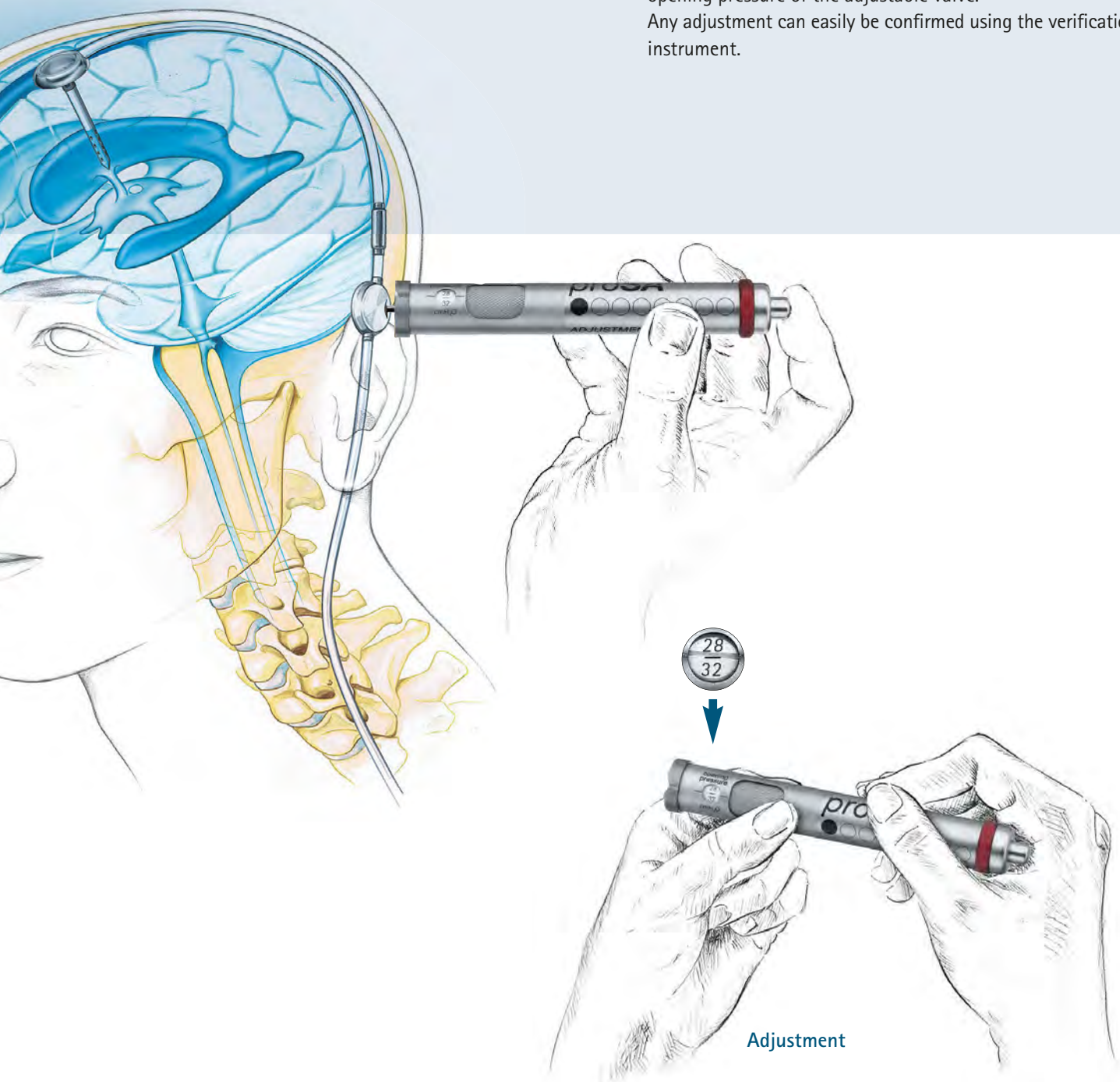
Verification

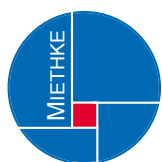
Adjustment

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.

Any adjustment can easily be confirmed using the verification instrument.





proSA®

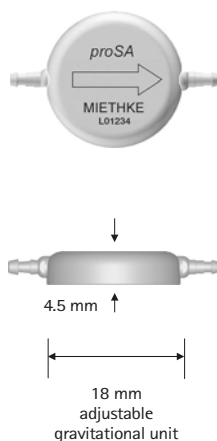
Optional with differential pressure unit

proSA®

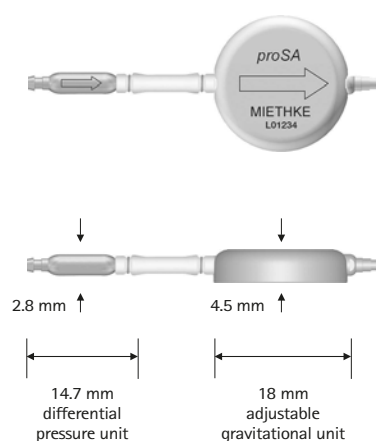
- Available as adjustable gravitational unit only or in combination with differential pressure unit
- Adjustable between 0 - 40 cmH₂O

Connector: $d_o = 1.9 \text{ mm}$
 Diff. press. Unit: $d_o = 2.8 \text{ mm}$
 Catheter: $d_i = 1.2 \text{ mm}$,
 $d_o = 2.5 \text{ mm}$

no differential pressure unit:



with differential pressure unit:



Scale 1:1

| Art. no. | Differential pressure unit (not adjustable / cmH ₂ O) |
|--------------------------------------------------------|---------------------------------------------------------------------|
| FV701T | — |
| ■ optional combination with differential pressure unit | |
| FV702T | 0* |
| FV703T | 5 |
| FV704T | 10 |
| FV705T | 15 |

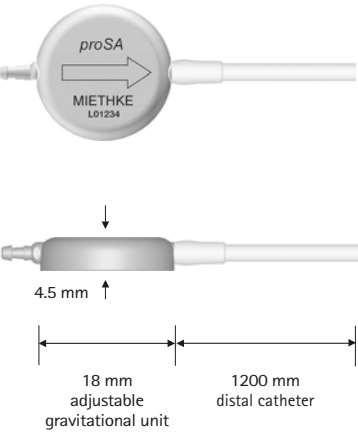
* for prevention of reflux only

proSA® with distal catheter

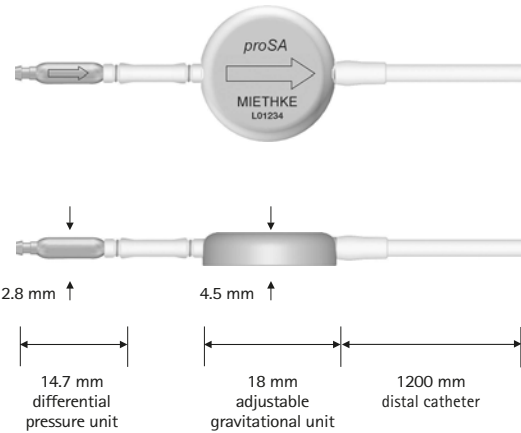
- Available as adjustable gravitational unit with integrated distal catheter only or in combination with differential pressure unit
- Adjustable between 0 – 40 cmH₂O

Connector: d₀ = 1.9 mm
Diff. press. Unit: d₀ = 2.8 mm
Catheter: d_i = 1.2 mm, d_o = 2.5 mm

no differential pressure unit:



with differential pressure unit:



Scale 1:1

| Art. no. | Differential pressure unit (not adjustable / cmH ₂ O) |
|----------|---------------------------------------------------------------------|
| FV706T | — |

optional combination with differential pressure unit

| | |
|--------|----|
| FV707T | 0* |
| FV708T | 5 |
| FV709T | 10 |
| FV710T | 15 |

* for prevention of reflux only

proSA® SHUNT SYSTEM with SPRUNG RESERVOIR

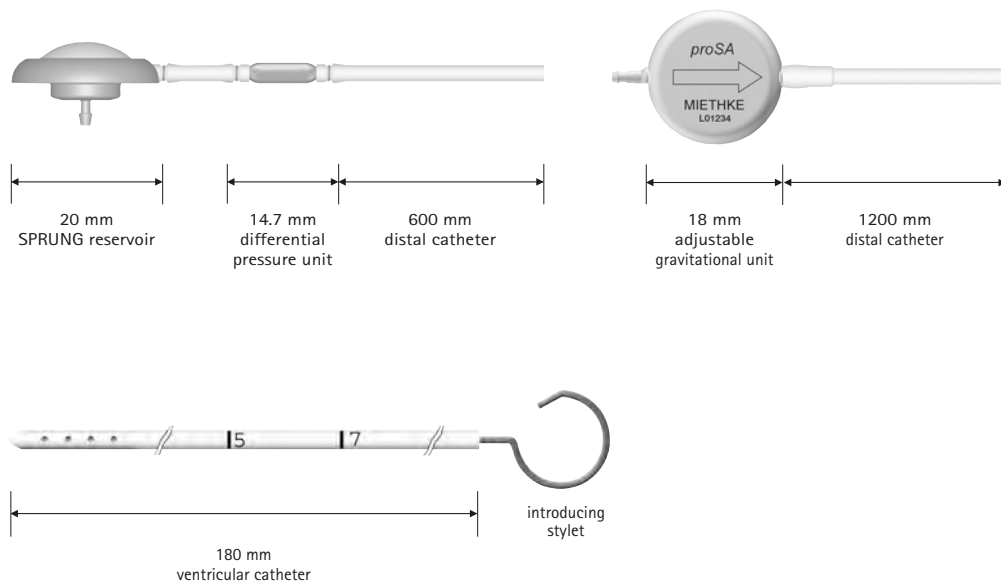
■ Adjustable gravitational unit with integrated distal catheter

■ Adjustable between 0 – 40 cmH₂O

■ SPRUNG reservoir* with integrated distal catheter

**Flushing reservoir allows for the checking of the ventricular catheter's patency and ensures only distal drainage.*

■ Ventricular catheter with introducing stylet



Connector: $d_o = 1.9$ mm
Diff. press. Unit: $d_o = 2.8$ mm
Catheter: $d_i = 1.2$ mm,
 $d_o = 2.5$ mm

Scale 1:1

| Art. no. | Differential pressure unit (not adjustable / cmH ₂ O) |
|----------|---------------------------------------------------------------------|
| FV711T | — |

■ optional combination with differential pressure unit

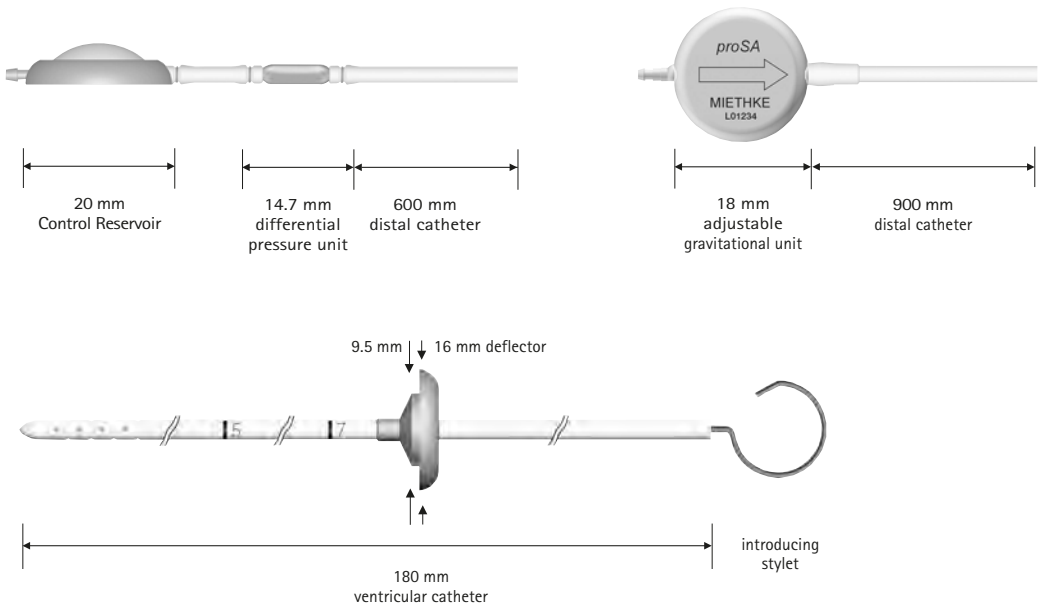
| | |
|--------|----|
| FV712T | 0* |
| FV713T | 5 |
| FV714T | 10 |
| FV715T | 15 |

*for prevention of reflux only

proSA® SHUNT SYSTEM with CONTROL RESERVOIR

- Adjustable gravitational unit with integrated distal catheter
- Adjustable between 0 - 40 cmH₂O
- Control Reservoir* with integrated distal catheter
**Flushing reservoir allows for the checking of the ventricular catheter's patency and ensures only distal drainage.*
- Ventricular catheter with introducing stylet and deflector

Connector: d_o = 1.9 mm
Diff. press. Unit: d_o = 2.8 mm
Catheter: d_i = 1.2 mm, d_o = 2.5 mm



Scale 1:1

| Art. no. | Differential pressure unit (not adjustable / cmH ₂ O) |
|----------|---------------------------------------------------------------------|
| FV716T | — |

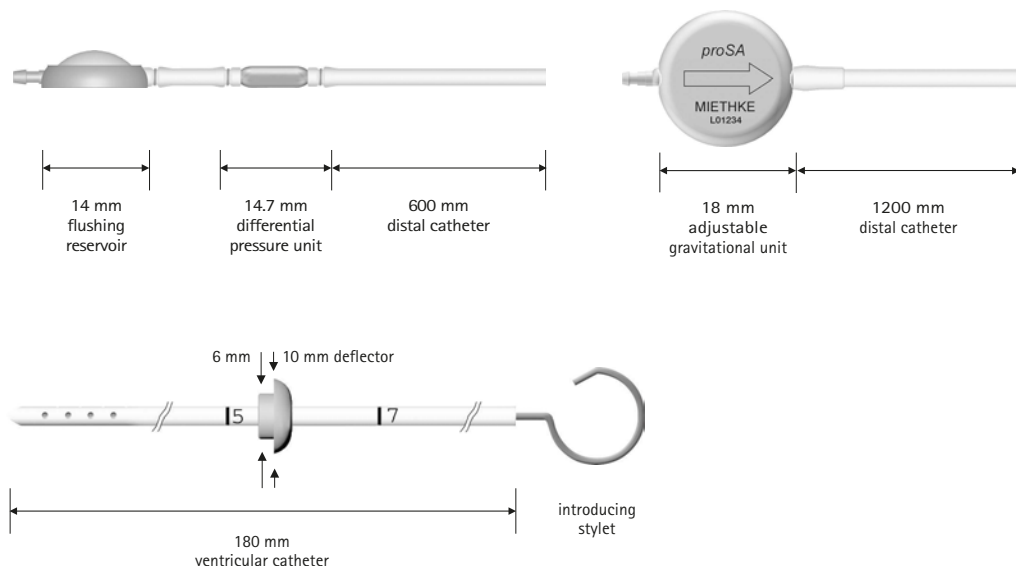
■ optional combination with differential pressure unit

| | |
|--------|----|
| FV717T | 0* |
| FV718T | 5 |
| FV719T | 10 |
| FV720T | 15 |

*for prevention of reflux only

proSA® SHUNT SYSTEM with FLUSHING RESERVOIR for pediatric application

- Adjustable gravitational unit with integrated distal catheter
- Adjustable between 0 – 40 cmH₂O
- Pediatric flushing reservoir with integrated distal catheter; optional combination with differential pressure unit
- Ventricular catheter with introducing stylet and pediatric deflector



Connector: $d_o = 1.9$ mm
 Diff. press. Unit: $d_o = 2.8$ mm
 Catheter: $d_i = 1.2$ mm,
 $d_o = 2.5$ mm

Scale 1:1

| Art. no. | Differential pressure unit (not adjustable / cmH ₂ O) |
|----------|---------------------------------------------------------------------|
| FV721T | — |

■ optional combination with differential pressure unit

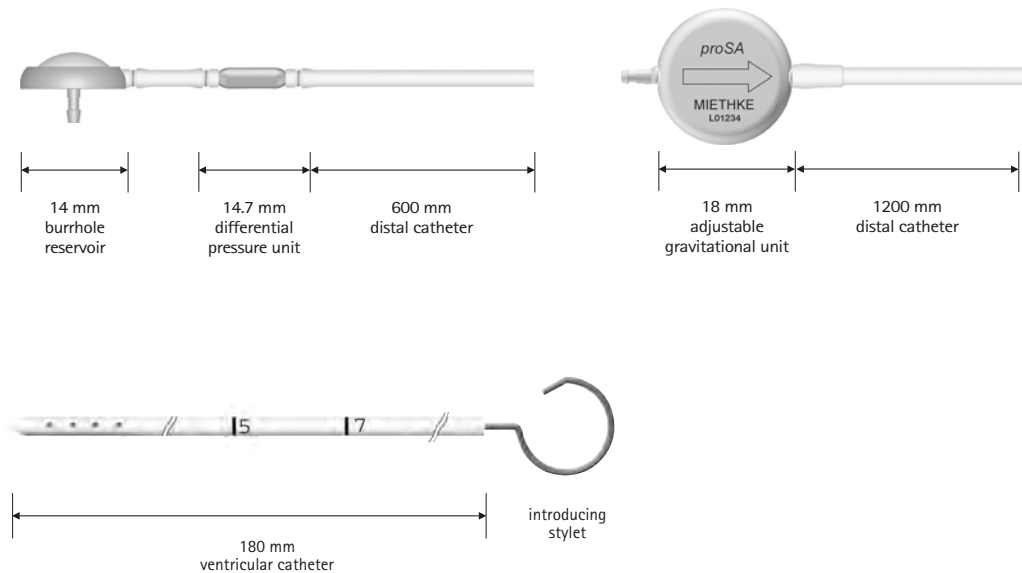
| | |
|--------|----|
| FV722T | 0* |
| FV723T | 5 |
| FV724T | 10 |
| FV725T | 15 |

*for prevention of reflux only

proSA® SHUNT SYSTEM with BURRHOLE RESERVOIR for pediatric application

- Adjustable gravitational unit with integrated distal catheter
- Adjustable between 0 - 40 cmH₂O
- Pediatric burrhole reservoir with integrated distal catheter; optional combination with differential pressure unit
- Ventricular catheter with introducing stylet

Connector: d₀ = 1.9 mm
Diff. press. Unit: d₀ = 2.8 mm
Catheter: d_i = 1.2 mm, d₀ = 2.5 mm



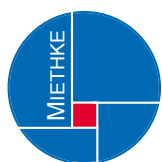
Scale 1:1

| Art. no. | Differential pressure unit (not adjustable / cmH ₂ O) |
|----------|---------------------------------------------------------------------|
| FV726T | — |

■ optional combination with differential pressure unit

| | |
|--------|----|
| FV727T | 0* |
| FV728T | 5 |
| FV729T | 10 |
| FV730T | 15 |

*for prevention of reflux only

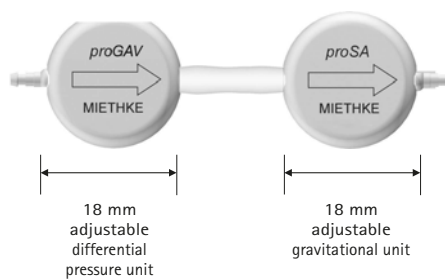


proSA®

With adjustable differential pressure unit

proSA® with adjustable differential pressure unit proGAV®

- Adjustable gravitational unit with adjustable differential pressure unit
- Gravitational valve adjustable between 0 – 40 cmH₂O



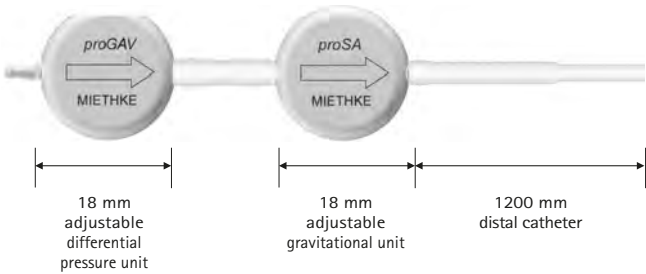
Connector: $d_o = 1.9 \text{ mm}$
 Catheter: $d_i = 1.2 \text{ mm}$,
 $d_o = 2.5 \text{ mm}$

Scale 1:1

| Art. no. | Differential pressure unit (adjustable / cmH ₂ O) |
|----------|-----------------------------------------------------------------|
| FV782T | 0 – 20 |

proSA® with adjustable differential pressure unit proGAV® and distal catheter

- Adjustable gravitational unit with adjustable differential pressure unit
- Gravitational valve adjustable between 0 – 40 cmH₂O
- Integrated distal catheter



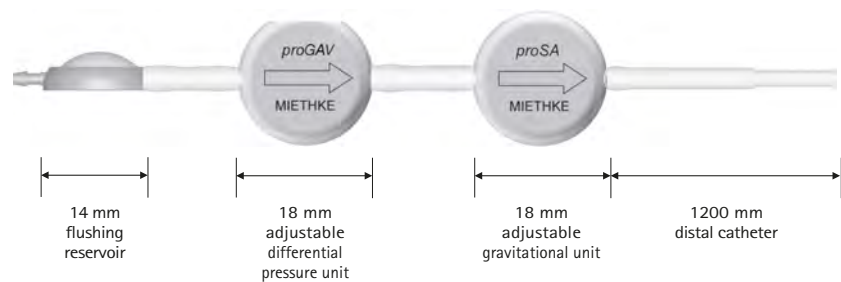
Connector: $d_o = 1.9 \text{ mm}$
Catheter: $d_i = 1.2 \text{ mm}$,
 $d_o = 2.5 \text{ mm}$

Scale 1:1

| Art. no. | Differential pressure unit (adjustable / cmH ₂ O) |
|----------|-----------------------------------------------------------------|
| FV783T | 0 – 20 |

proSA® with adjustable differential pressure unit proGAV® and FLUSHING RESERVOIR for pediatric application

- Adjustable gravitational unit with adjustable differential pressure unit
- Gravitational valve adjustable between 0 – 40 cmH₂O
- Integrated pediatric flushing reservoir
- Integrated distal catheter



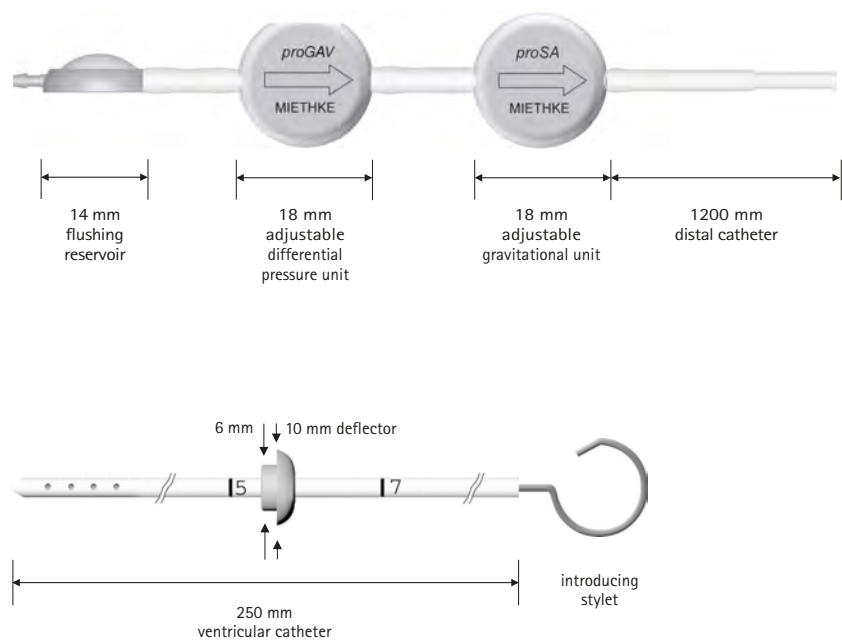
Connector: $d_o = 1.9\text{ mm}$
Catheter: $d_i = 1.2\text{ mm}$,
 $d_o = 2.5\text{ mm}$

Scale 1:1

| Art. no. | Differential pressure unit (adjustable / cmH ₂ O) |
|----------|-----------------------------------------------------------------|
| FV785T | 0 – 20 |

proSA® with adjustable differential pressure unit proGAV® and FLUSHING RESERVOIR for pediatric application

- Adjustable gravitational unit with adjustable differential pressure unit
- Gravitational valve adjustable between 0 – 40 cmH₂O
- Integrated pediatric flushing reservoir
- Integrated distal catheter
- Ventricular catheter with introducing stylet and deflector



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

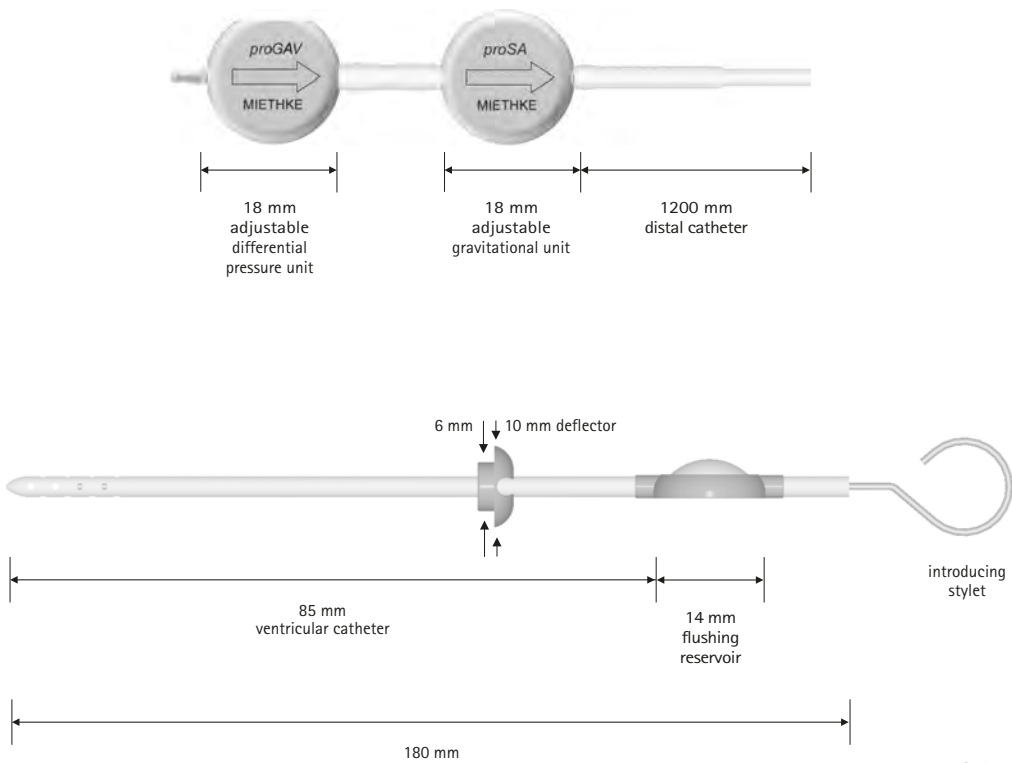
Scale 1:1

| Art. no. | Differential pressure unit (adjustable / cmH ₂ O) |
|----------|-----------------------------------------------------------------|
| FV788T | 0 – 20 |

proSA® with adjustable differential pressure unit proGAV® and FLUSHING RESERVOIR for pediatric application

- Adjustable gravitational unit with adjustable differential pressure unit
- Gravitational valve adjustable between 0 – 40 cmH₂O
- Integrated distal catheter
- Ventricular catheter with integrated pediatric flushing reservoir, introducing stylet and pediatric deflector

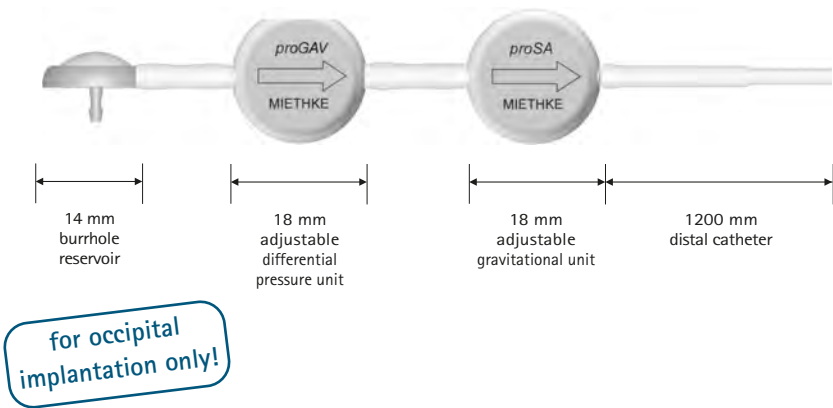
Connector: d₀ = 1.9 mm
Catheter: d_i = 1.2 mm,
d₀ = 2.5 mm



| Art. no. | Differential pressure unit (adjustable / cmH ₂ O) |
|----------|-----------------------------------------------------------------|
| FV789T | 0 – 20 |

proSA® with adjustable differential pressure unit proGAV® and BURRHOLE RESERVOIR for pediatric application

- Adjustable gravitational unit with adjustable differential pressure unit
- Gravitational valve adjustable between 0 – 40 cmH₂O
- Integrated pediatric burrhole reservoir
- Integrated distal catheter



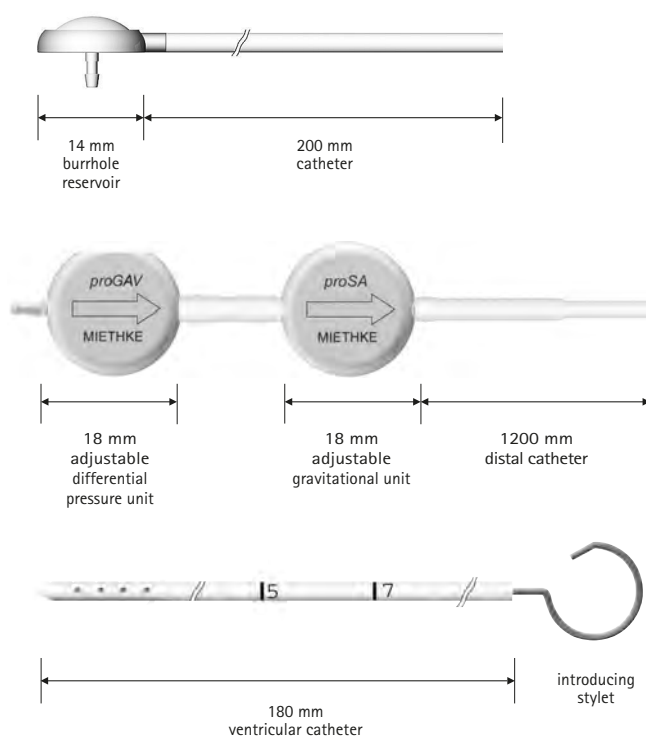
Connector: $d_o = 1.9\text{ mm}$
Catheter: $d_i = 1.2\text{ mm}$,
 $d_o = 2.5\text{ mm}$

Scale 1:1

| Art. no. | Differential pressure unit (adjustable / cmH ₂ O) |
|----------|-----------------------------------------------------------------|
| FV784T | 0 – 20 |

proSA® with adjustable differential pressure unit proGAV® and BURRHOLE RESERVOIR for pediatric application

- Adjustable gravitational unit with adjustable differential pressure unit
- Gravitational valve adjustable between 0 – 40 cmH₂O
- Pediatric burrhole reservoir with integrated distal catheter
- Ventricular catheter with introducing stylet



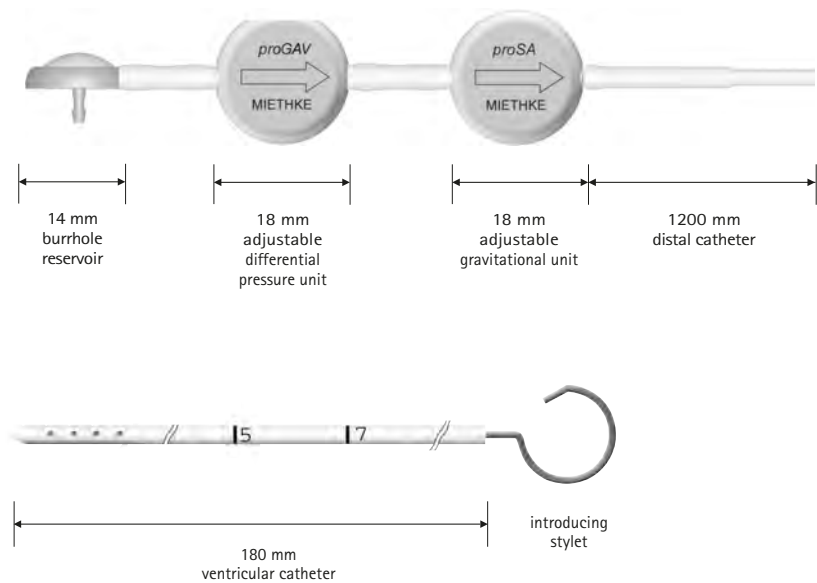
Connector: $d_o = 1.9 \text{ mm}$
 Catheter: $d_i = 1.2 \text{ mm}$,
 $d_o = 2.5 \text{ mm}$

Scale 1:1

| Art. no. | Differential pressure unit (adjustable / cmH ₂ O) |
|----------|-----------------------------------------------------------------|
| FV786T | 0 – 20 |

proSA® with adjustable differential pressure unit proGAV® and BURRHOLE RESERVOIR for pediatric application

- Adjustable gravitational unit with adjustable differential pressure unit
- Gravitational valve adjustable between 0 – 40 cmH₂O
- Integrated pediatric burrhole reservoir
- Integrated distal catheter
- Ventricular catheter with introducing stylet



for occipital
implantation only!

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

Scale 1:1

| Art. no. | Differential pressure unit (adjustable / cmH ₂ O) |
|----------|-----------------------------------------------------------------|
| FV787T | 0 – 20 |

proSA[®] Instruments

Instruments for valve adjustment

- **proSA Adjustment**
instrument for setting the
required opening pressure
- **proSA Verification**
instrument for reading the
actual opening pressure
setting

Adjustment instrument:



Verification instrument:



| Art. no. | Instruments |
|----------|-------------------------------|
| FV790T | proSA Adjustment instrument |
| FV791T | proSA Verification instrument |

Instruments for valve adjustment

- *proSA* Masterdisc for calibrating the verification instrument
- *proSA* Compass for locating the *proSA*
- *proSA* Adjustment disc for setting the required opening pressure in patients with thicker skin
- *proSA* Checkmate for sterile reading and setting the opening pressure of a *proSA* prior to the implantation (resterilizable)

Masterdisc:



Compass:



Adjustment disc:



Checkmate:



| Art. no. | Instruments |
|----------|--------------------------------------------------------------|
| FV792T | <i>proSA</i> Instrument set (comprising of FV790T-FV795T) |
| FV793T | <i>proSA</i> Masterdisc |
| FV794T | <i>proSA</i> Compass |
| FV795T | <i>proSA</i> Adjustment disc |
| FV796T | <i>proSA</i> Checkmate |

proGAV[®] Instruments

Instruments for valve adjustment

- *proGAV* Adjustment instrument for setting the required opening pressure
- *proGAV* Verification instrument for reading the actual opening pressure setting

Adjustment instrument:



Verification instrument:



| Art. no. | Instruments |
|----------|---------------------------------------|
| FV400T | <i>proGAV</i> Adjustment instrument |
| FV401T | <i>proGAV</i> Verification instrument |

proGAV® Instruments

Instruments for valve adjustment

- *proGAV* Masterdisc for calibrating the verification instrument
- Compass for locating the *proGAV*
- *proGAV* Adjustment disc for setting the required opening pressure in patients with thicker skin
- *proGAV* Checkmate for sterile reading and setting the opening pressure of a *proGAV* prior to the implantation (resterilizable)

Masterdisc:



Compass:



Adjustment disc:











Checkmate:



| Art. no. | Instruments |
|----------|-----------------------------------------------------------|
| FV402T | <i>proGAV</i> Masterdisc |
| FV403T | <i>proGAV</i> Compass |
| FV404T | <i>proSA</i> Instrument set (comprising FV400T-FV403T) |
| FV407T | <i>proGAV</i> Adjustment disc |
| FV409T | <i>proGAV</i> Checkmate |

Our Shunt Systems – Your Choice

| Shunt System | | Description | Indication | | | | Patient | | Grav.-assist. | MRT comp. 3 Tesla |
|-------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|------------|---------|-----|----|---------|-----------|---------------|-------------------|
| | | | adult HC | ped. HC | NPH | LP | active | recumbent | | |
| <i>proSA</i> |  | Adjustable gravitational unit for combination with differential pressure valve | X | X | X | | X | X | X | X |
| <i>proGAV</i> |  | Adjustable differential pressure valve with gravitational unit | X | X | X | | X | X | X | X |
| <i>GAV</i> |  | Gravitational valve for adult Hydrocephalus | X | | X | | X | | X | X |
| <i>paediGAV</i> |  | Gravitational valve for pediatric Hydrocephalus | | X | | | X | | X | X |
| <i>SHUNTASSISTANT</i> |  | Gravitational unit for combination with differential pressure valve | X | X | X | | X | | X | X |
| <i>DUALSWITCH-VALVE</i> |  | Gravitational valve system with extra large flow path for CSF | X | | X | X | X | | X | X |
| <i>miniNAV</i> |  | Smallest differential pressure valve | X | X | | | | X | | X |
| <i>Accessories</i> |  | | | | | | | | | |



Aesculap, Tuttlingen



Miethke, Potsdam

Alliance for Innovation

When two strong partners combine their expertise, innovative and groundbreaking 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.

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

Manufacturer acc. MDD 93/42/EEC

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