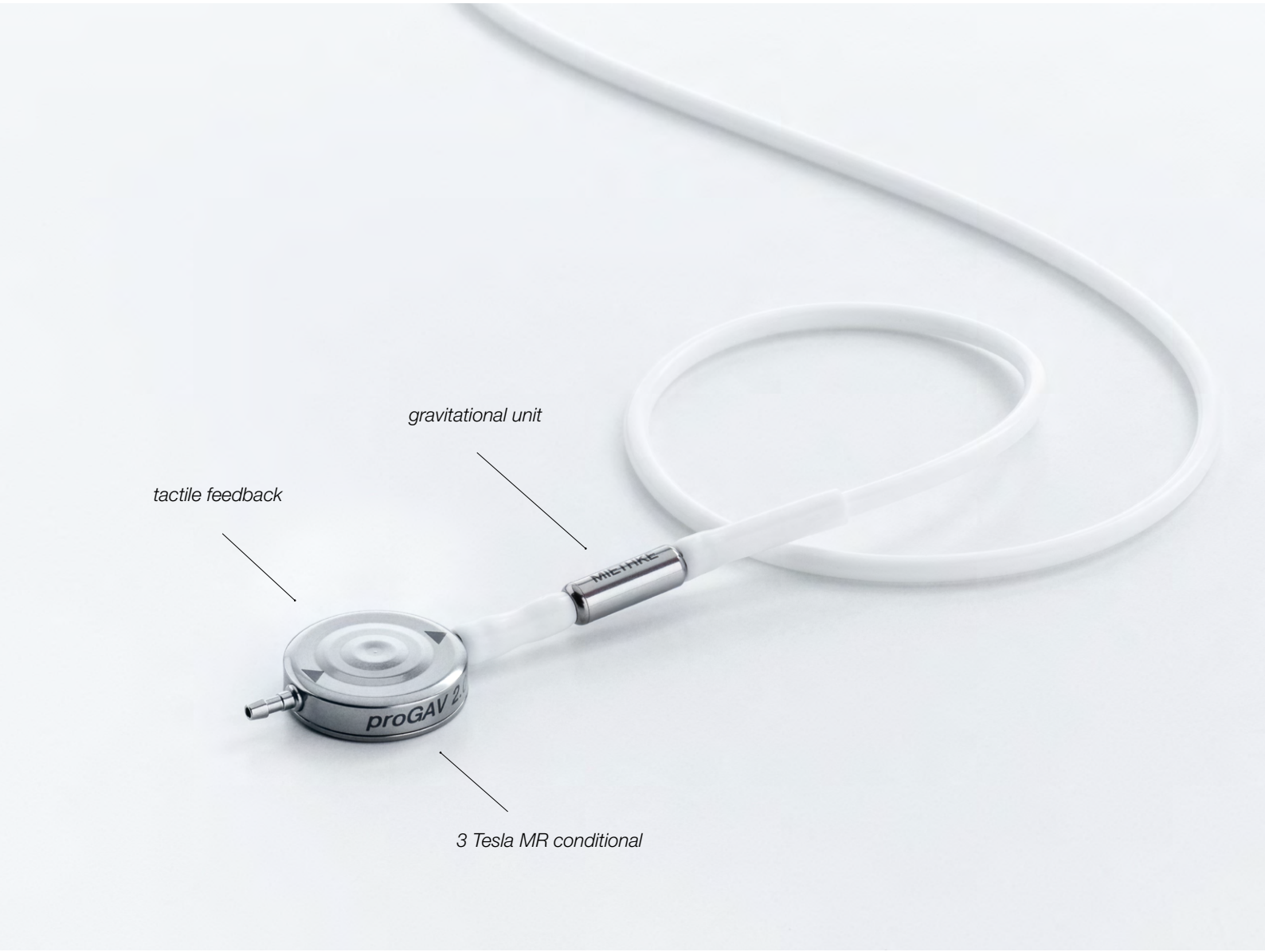
MIETHKE

proGAV®2.0

IN TOUCH WITH YOU

miethke.com

proGAV® 2.0
VALVE AND SOFT TOUCH TOOLS



MIETHKE gravitational valves provide a reliable solution in prevention of overdrainage complications[1,2] associated with the management of hydrocephalus.

proGAV 2.0 represents the latest development in refining our existing *proGAV* technology to better meet the needs of our customers and their patients.

proGAV 2.0 offers the reliability of our existing technology with a new tactile feedback mechanism and soft-touch tools.

The adjustable differential pressure unit is equipped with a new valve surface: By using slight pressure with your finger, the active lock mechanism of the valve is released and a tactile feedback is received.

The combination of the refined *proGAV 2.0* technology and soft-touch tools provides comfort for patients and security against inadvertent readjustment caused by magnet fields up to 3 Tesla.[3]

With the new *proGAV 2.0 Compass* the opening pressure of the valve can be identified quickly, without having to expose the patient to X-ray.

1 Thomale U.W., Gebert A.F., Haberl H., Schulz M. Shunt survival rates by using the adjustable differential pressure valve combined with a gravitational unit (*proGAV*) in pediatric neurosurgery. Childs Nerv Syst. 2013 Mar; 29(3):425-31.

2 Lemcke J., Meier U., Müller C., Fritsch M.J., Kehler U., Langer N., Kiefer M., Eymann R., Schuhmann M.U., Speil A., Weber F., Remenez V., Rohde V., Ludwig H.C., Stengel D. Safety and effi cacy of gravitational shunt valves in patients with idiopathic normal pressure hydrocephalus: a pragmatic, randomised, open label, multicentre trial (SVASONA). J Neurol Neurosurg Psychiatry. 2013 Aug; 84(8):850-57.

3 Allin D.M., Czosnyka Z.H., Czosnyka M., Richards H.K., Pickard J.D. In vitro hydrodynamic properties of the Miethke *proGAV* hydrocephalus shunt. Cerebrospinal Fluid Res. 2006 Jun; 3:9. doi:10.1186/1743-8454-3-9.

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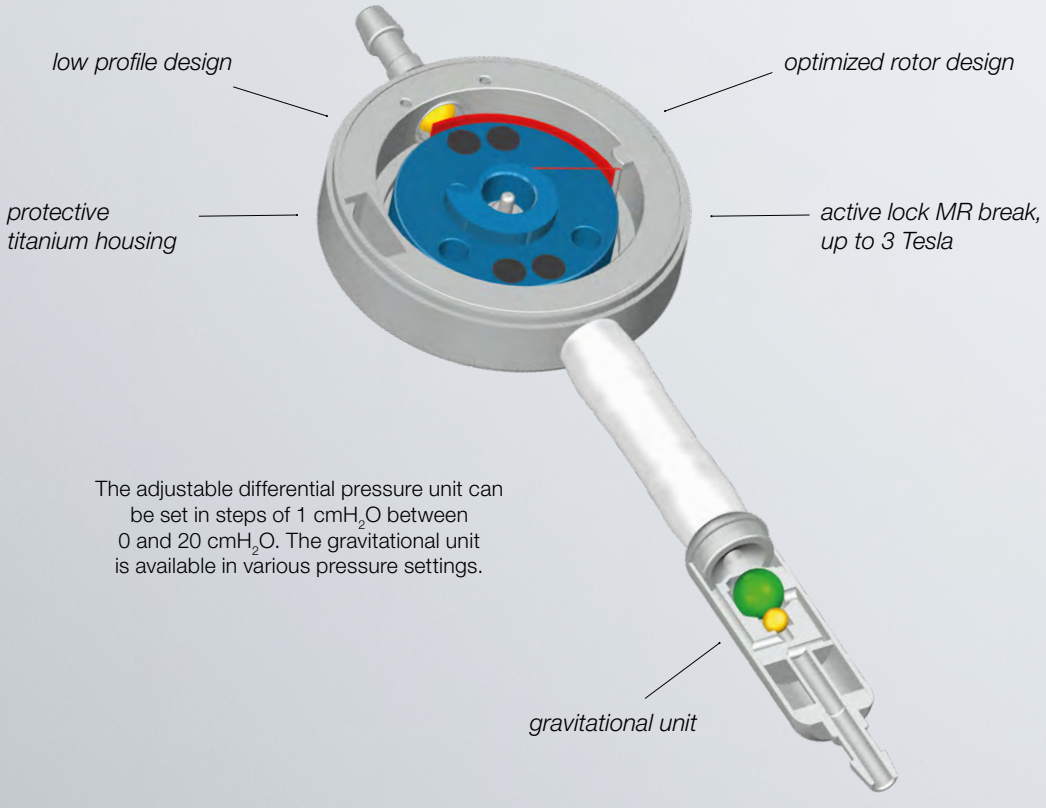
FUNCTIONALITY OF VALVE AND BODY POSITION



FUNCTIONALITY

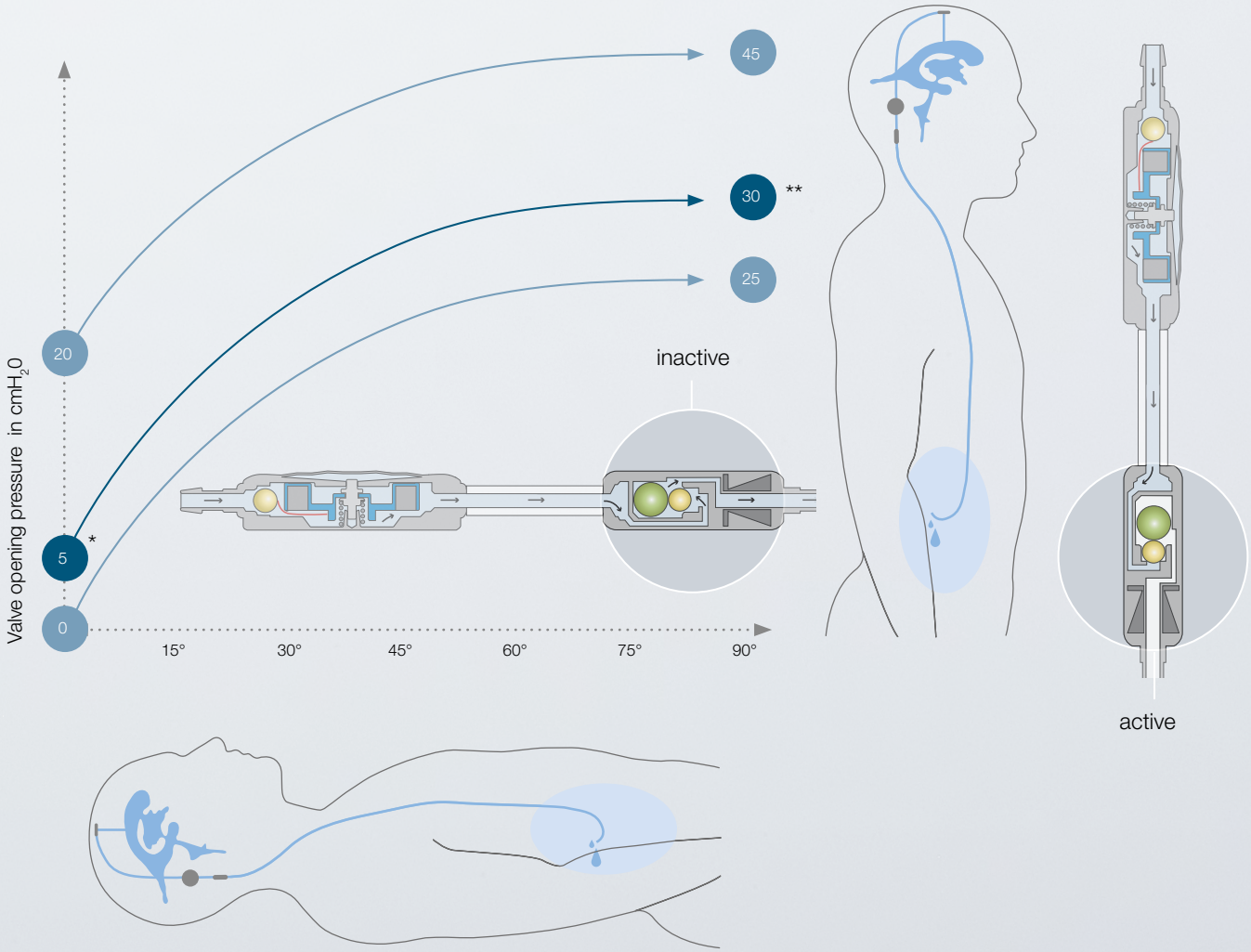
The *proGAV 2.0* is a posture-dependent valve, i.e. its opening pressure changes gradually to correspond with the patients body position. For complete customization of the patients needs, the *proGAV 2.0* allows a specific opening pressure when the patient is lying down, and an opening pressure for when the patient is upright.

SUPINE POSITION

When the patient is in the supine position, only the adjustable differential pressure unit is active, which is preset to 5 cmH_2O*.

The gravitational unit is not active in this body position.

The functionality of the *proGAV 2.0* is illustrated interactively in the MIETHKE App.



UPRIGHT POSITION

In the upright position, the gravitational and adjustable differential pessure unit work together. As the patient gets in upright position, the tantalum ball (green) is activated within the gravitational unit and causes an increase in the valve opening pressure, due to its gravitational force.

The gradual increase in opening pressure in the upright position effectively protects against excess drainage.[4,5]

In the example shown, a gravitational unit with 25 cmH_2O has been selected. The total opening pressure therefore amounts to 30 cmH_2O** while standing.

4 Lemcke J., Meier U., Müller C., Fritsch M., Kiefer M., Eymann R., Kehler U., Langer N., Schuhmann M.U., Speil A., Weber F., Remenez V., Rohde V., Ludwig H.C., Stengel D. On the method of a randomised comparison of programmable valves with and without gravitational units: the SVASONA study. Acta Neurochir Suppl. 2012; 114:243-46.

5 Freimann F.B., Sprung C. Shunting with gravitational valves - can adjustments end the era of revisions for overdrainage-related events?. J. Neurosurg. 2012 Dec; 117(6):1197-204.

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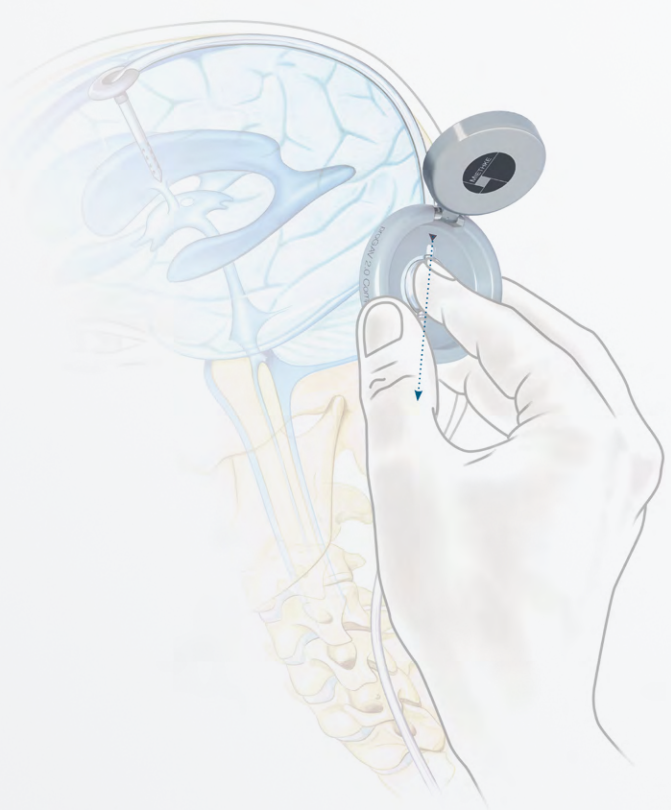
SOFT TOUCH TOOLS FOR VALVE ADJUSTMENT



After the adjustable differential pessure unit has been localized with the finger, the *proGAV 2.0 Compass* is applied over the valve in the direction of flow.

The closed *proGAV 2.0 Compass* indicates the opening pressure setting.

LOCALIZATION AND PRESSURE SETTING IDENTIFICATION

The *proGAV 2.0 Compass* is used to localize the adjustable differential pressure unit and identify current setting of the valve.

The Compass should be aligned over the valve with the aid of the integrated template – For this purpose, the compass lid is opened.

The compass needle reflects the current opening pressure on the scale – Compass lid is closed.

The *proGAV 2.0 Adjustment Tool* centered over the valve.

By pressing lightly with the finger on the adjustable differential pessure unit, the mechanical “active lock” mechanism is deactivated and the opening pressure is set.

Releasing the finger pressure automatically locks the valve.

ADJUSTING THE VALVE

With the *proGAV 2.0 Adjustment Tool*, the opening pressure of the adjustable differential pressure unit can be set from 0 to 20 cmH_2O.

The *proGAV 2.0 Adjustment Tool* has to be placed above the valve, so that the value of the desired opening pressure points towards the valve inlet connector.

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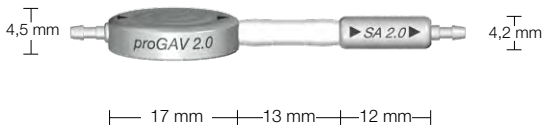
\+ *proGAV 2.0* valve with *SA 2.0*



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

Standard configurations

Art. no.	Adjustable unit	Gravitational unit	Recommendation**
FX642T	0 - 20 cmH_20 (preset to 5 cmH_20)	20 cmH_20	Children up to 5 and adults over 65 years old
FX643T	0 - 20 cmH_20 (preset to 5 cmH_20)	25 cmH_20	Individuals between 5 and 65 years old

Alternative configurations available

Art. no.	Adjustable unit	Gravitational unit
FX410T	0 - 20 cmH_20 (preset to 5 cmH_20)	without
FX640T	0 - 20 cmH_20 (preset to 5 cmH_20)	10 cmH_20
FX641T	0 - 20 cmH_20 (preset to 5 cmH_20)	15 cmH_20
FX644T	0 - 20 cmH_20 (preset to 5 cmH_20)	30 cmH_20
FX645T	0 - 20 cmH_20 (preset to 5 cmH_20)	35 cmH_20

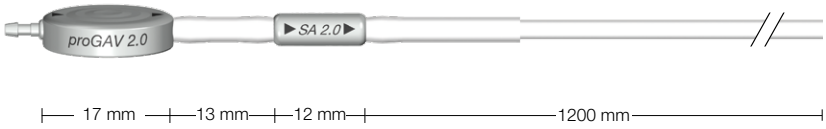
*** Recommendations should only be used as guideline as other settings may also be necessary depending on the patient and anatomy.*

proGAV® 2.0

with Distal Catheter

MIETHKE

\+ *proGAV 2.0* valve with *Distal Catheter*, 1200 mm



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

Standard configurations

Art. no.	Adjustable unit	Gravitational unit	Recommendation**
FX648T	0 - 20 cmH_20 (preset to 5 cmH_20)	20 cmH_20	Children up to 5 and adults over 65 years old
FX649T	0 - 20 cmH_20 (preset to 5 cmH_20)	25 cmH_20	Individuals between 5 and 65 years old

Alternative configurations available

Art. no.	Adjustable unit	Gravitational unit
FX417T	0 - 20 cmH_20 (preset to 5 cmH_20)	without
FX646T	0 - 20 cmH_20 (preset to 5 cmH_20)	10 cmH_20
FX647T	0 - 20 cmH_20 (preset to 5 cmH_20)	15 cmH_20
FX650T	0 - 20 cmH_20 (preset to 5 cmH_20)	30 cmH_20
FX651T	0 - 20 cmH_20 (preset to 5 cmH_20)	35 cmH_20

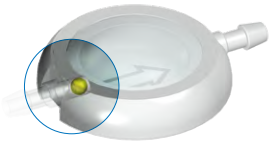
*** Recommendations should only be used as guideline as other settings may also be necessary depending on the patient and anatomy.*

proGAV® 2.0

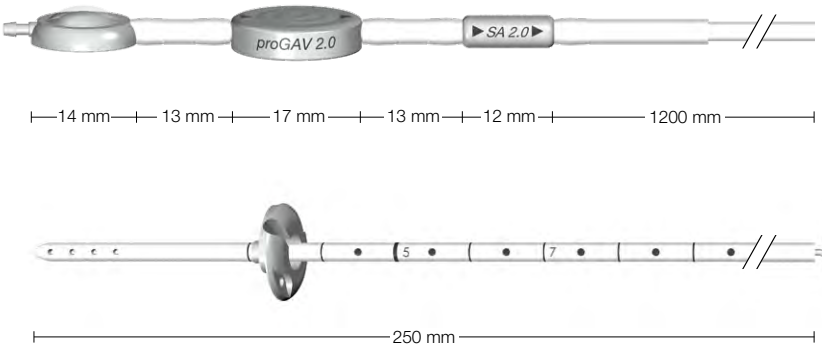
Shunt System with Pediatric CONTROL RESERVOIR

+ *proGAV 2.0* valve with *Pediatric CONTROL RESERVOIR** and *Distal Catheter*, 1200 mm
+ *Ventricular Catheter* with *Pediatric Burrhole Deflector* and introducing stylet, 250 mm

* An additional valve in the base of the *Pediatric CONTROL RESERVOIR* makes it possible to flush the fluid only in the distal direction. This feature allows for controlling the patency of the *Ventricular Catheter* and the distal drainage.



Pediatric CONTROL RESERVOIR



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

Standard configurations

Art. no.	Adjustable unit	Gravitational unit	Recommendation**
FX609T	0 - 20 cmH_20 (preset to 5 cmH_20)	20 cmH_20	Children up to 5 and adults over 65 years old
FX610T	0 - 20 cmH_20 (preset to 5 cmH_20)	25 cmH_20	Individuals between 5 and 65 years old

Alternative configurations available

Art. no.	Adjustable unit	Gravitational unit
FX606T	0 - 20 cmH_20 (preset to 5 cmH_20)	without
FX607T	0 - 20 cmH_20 (preset to 5 cmH_20)	10 cmH_20
FX608T	0 - 20 cmH_20 (preset to 5 cmH_20)	15 cmH_20
FX611T	0 - 20 cmH_20 (preset to 5 cmH_20)	30 cmH_20
FX612T	0 - 20 cmH_20 (preset to 5 cmH_20)	35 cmH_20

*** Recommendations should only be used as guideline as other settings may also be necessary depending on the patient and anatomy.*

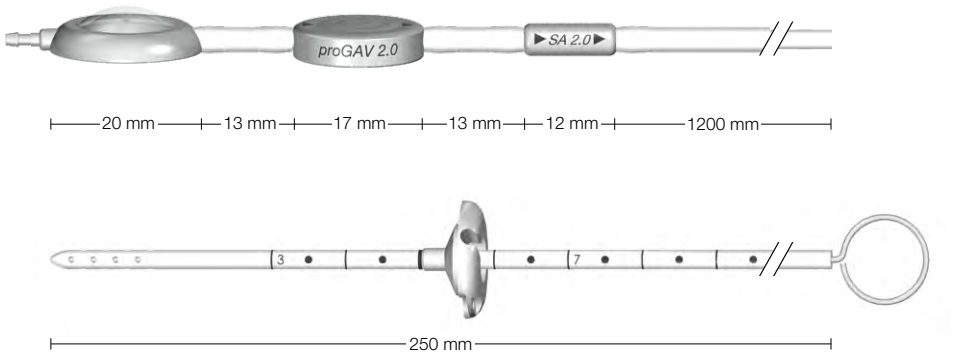
proGAV® 2.0

Shunt System with CONTROL RESERVOIR

+ *proGAV 2.0* valve with *CONTROL RESERVOIR** and *Distal Catheter*, 1200 mm
+ *Ventricular Catheter* with *Burrhole Deflector* and introducing stylet, 250 mm

* An additional valve in the base of the *CONTROL RESERVOIR* makes it possible to flush the fluid only in the distal direction. This feature allows for controlling the patency of the *Ventricular Catheter* and the distal drainage.

CONTROL RESERVOIR



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

Standard configurations

Art. no.	Adjustable unit	Gravitational unit	Recommendation**
FX602T	0 - 20 cmH_20 (preset to 5 cmH_20)	20 cmH_20	Children up to 5 and adults over 65 years old
FX603T	0 - 20 cmH_20 (preset to 5 cmH_20)	25 cmH_20	Individuals between 5 and 65 years old

Alternative configurations available

Art. no.	Adjustable unit	Gravitational unit
FX431T	0 - 20 cmH_20 (preset to 5 cmH_20)	without
FX600T	0 - 20 cmH_20 (preset to 5 cmH_20)	10 cmH_20
FX601T	0 - 20 cmH_20 (preset to 5 cmH_20)	15 cmH_20
FX604T	0 - 20 cmH_20 (preset to 5 cmH_20)	30 cmH_20
FX605T	0 - 20 cmH_20 (preset to 5 cmH_20)	35 cmH_20

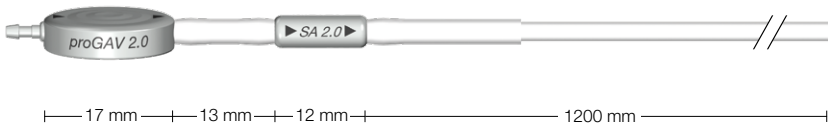
*** Recommendations should only be used as guideline as other settings may also be necessary depending on the patient and anatomy.*

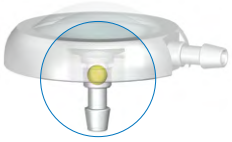
proGAV® 2.0

Shunt System with Pediatric SPRUNG RESERVOIR

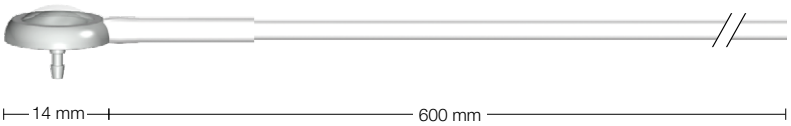
+ *proGAV 2.0* valve with *Distal Catheter*, 1200 mm
+ *Pediatric SPRUNG RESERVOIR** with *Distal Catheter*, 600 mm
+ *Ventricular Catheter* with introducing stylet, 180 mm

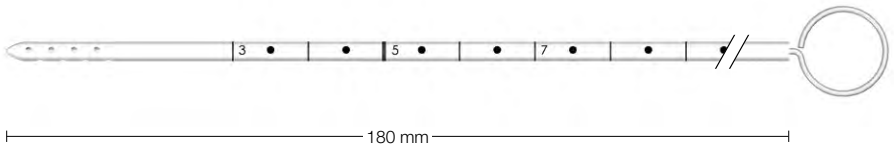
* An additional valve in the base of the *Pediatric SPRUNG RESERVOIR* makes it possible to flush the fluid only in the distal direction. This feature allows for controlling the patency of the *Ventricular Catheter* and the distal drainage.





Pediatric SPRUNG RESERVOIR





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

Standard configurations

Art. no.	Adjustable unit	Gravitational unit	Recommendation**
FX583T	0 - 20 cmH_20 (preset to 5 cmH_20)	20 cmH_20	Children up to 5 and adults over 65 years old
FX584T	0 - 20 cmH_20 (preset to 5 cmH_20)	25 cmH_20	Individuals between 5 and 65 years old

Alternative configurations available

Art. no.	Adjustable unit	Gravitational unit
FX580T	0 - 20 cmH_20 (preset to 5 cmH_20)	without
FX581T	0 - 20 cmH_20 (preset to 5 cmH_20)	10 cmH_20
FX582T	0 - 20 cmH_20 (preset to 5 cmH_20)	15 cmH_20
FX585T	0 - 20 cmH_20 (preset to 5 cmH_20)	30 cmH_20
FX586T	0 - 20 cmH_20 (preset to 5 cmH_20)	35 cmH_20

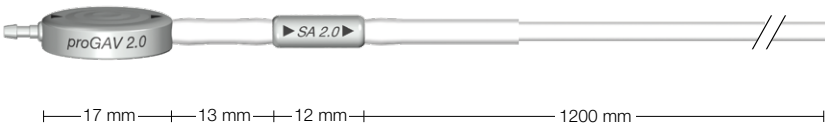
*** Recommendations should only be used as guideline as other settings may also be necessary depending on the patient and anatomy.*

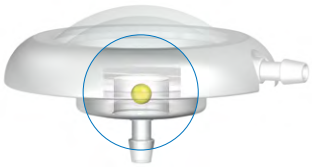
proGAV® 2.0

Shunt System with SPRUNG RESERVOIR

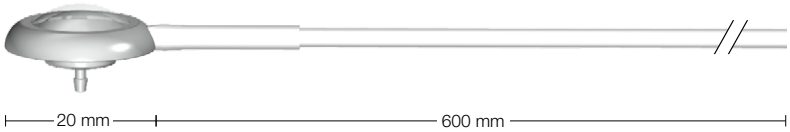
+ *proGAV 2.0* valve with *Distal Catheter*, 1200 mm
+ *SPRUNG RESERVOIR** with *Distal Catheter*, 600 mm
+ *Ventricular Catheter* with introducing stylet, 180 mm

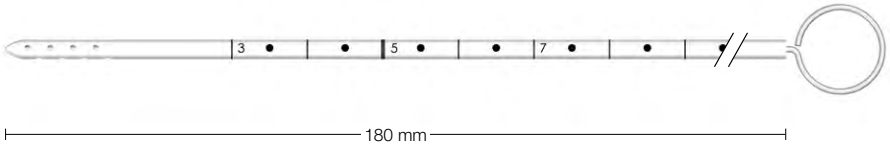
* An additional valve in the base of the *SPRUNG RESERVOIR* makes it possible to flush the fluid only in the distal direction. This feature allows for controlling the patency of the *Ventricular Catheter* and the distal drainage.





SPRUNG RESERVOIR





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

Standard configurations

Art. no.	Adjustable unit	Gravitational unit	Recommendation**
FX576T	0 - 20 cmH_20 (preset to 5 cmH_20)	20 cmH_20	Children up to 5 and adults over 65 years old
FX577T	0 - 20 cmH_20 (preset to 5 cmH_20)	25 cmH_20	Individuals between 5 and 65 years old

Alternative configurations available

Art. no.	Adjustable unit	Gravitational unit
FX424T	0 - 20 cmH_20 (preset to 5 cmH_20)	without
FX574T	0 - 20 cmH_20 (preset to 5 cmH_20)	10 cmH_20
FX575T	0 - 20 cmH_20 (preset to 5 cmH_20)	15 cmH_20
FX578T	0 - 20 cmH_20 (preset to 5 cmH_20)	30 cmH_20
FX579T	0 - 20 cmH_20 (preset to 5 cmH_20)	35 cmH_20

*** Recommendations should only be used as guideline as other settings may also be necessary depending on the patient and anatomy.*

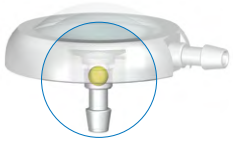
proGAV® 2.0

Shunt System with Pediatric SPRUNG RESERVOIR

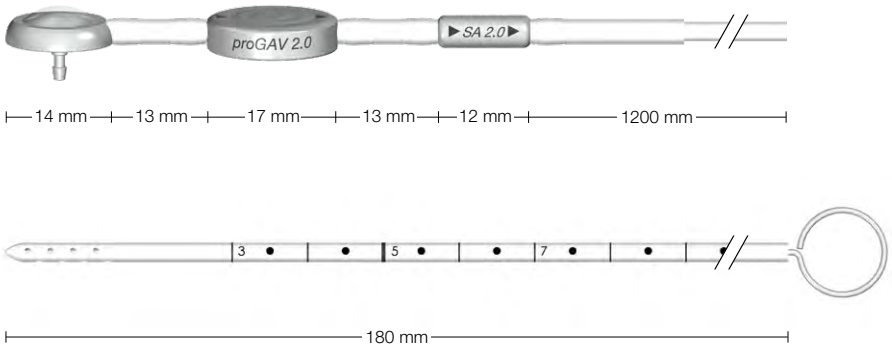
+ *proGAV 2.0* valve with integrated *Pediatric SPRUNG RESERVOIR** and *Distal Catheter*, 1200 mm
+ *Ventricular Catheter* with introducing stylet, 180 mm

* An additional valve in the base of the *Pediatric SPRUNG RESERVOIR* makes it possible to flush the fluid only in the distal direction. This feature allows for controlling the patency of the ventricular catheter and the distal drainage.

OCCIPITAL
ONLY



Pediatric
SPRUNG RESERVOIR



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

Standard configurations

Art. no.	Adjustable unit	Gravitational unit	Recommendation**
FX636T	0 - 20 cmH_20 (preset to 5 cmH_20)	20 cmH_20	Children up to 5 and adults over 65 years old
FX637T	0 - 20 cmH_20 (preset to 5 cmH_20)	25 cmH_20	Individuals between 5 and 65 years old

Alternative configurations available

Art. no.	Adjustable unit	Gravitational unit
FX633T	0 - 20 cmH_20 (preset to 5 cmH_20)	without
FX634T	0 - 20 cmH_20 (preset to 5 cmH_20)	10 cmH_20
FX635T	0 - 20 cmH_20 (preset to 5 cmH_20)	15 cmH_20
FX638T	0 - 20 cmH_20 (preset to 5 cmH_20)	30 cmH_20
FX639T	0 - 20 cmH_20 (preset to 5 cmH_20)	35 cmH_20

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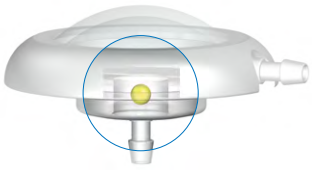
proGAV® 2.0

Shunt System with SPRUNG RESERVOIR

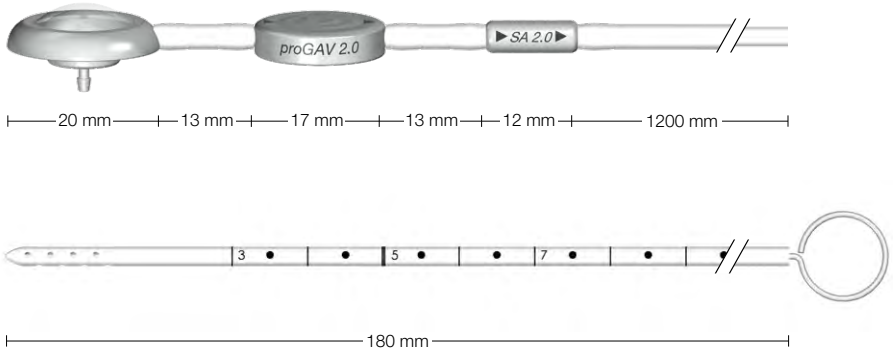
+ *proGAV 2.0* valve with integrated *SPRUNG RESERVOIR** and *Distal Catheter*, 1200 mm
+ *Ventricular Catheter* with introducing stylet, 180 mm

* An additional valve in the base of the *SPRUNG RESERVOIR* makes it possible to flush the fluid only in the distal direction. This feature allows for controlling the patency of the ventricular catheter and the distal drainage.

OCCIPITAL
ONLY



SPRUNG RESERVOIR



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

Standard configurations

Art. no.	Adjustable unit	Gravitational unit	Recommendation**
FX629T	0 - 20 cmH_20 (preset to 5 cmH_20)	20 cmH_20	Children up to 5 and adults over 65 years old
FX630T	0 - 20 cmH_20 (preset to 5 cmH_20)	25 cmH_20	Individuals between 5 and 65 years old

Alternative configurations available

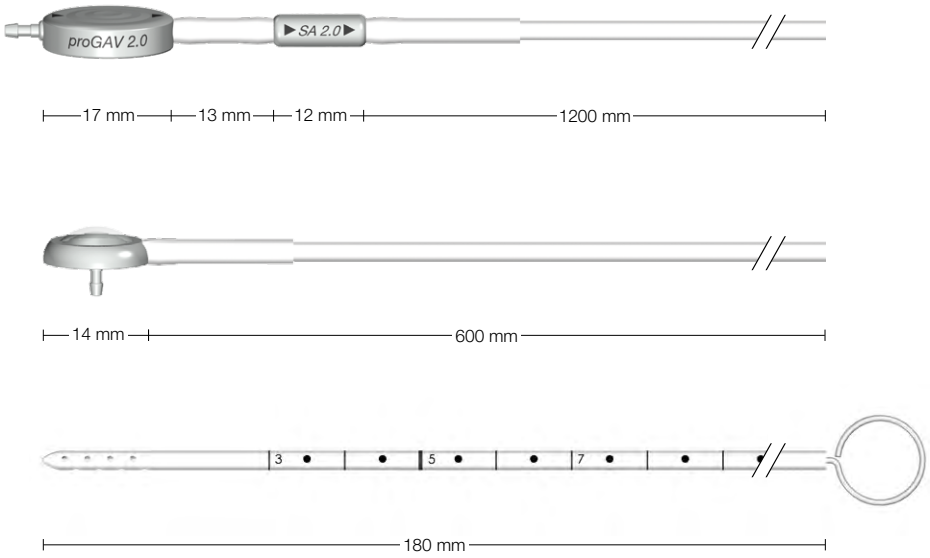
Art. no.	Adjustable unit	Gravitational unit
FX626T	0 - 20 cmH_20 (preset to 5 cmH_20)	without
FX627T	0 - 20 cmH_20 (preset to 5 cmH_20)	10 cmH_20
FX628T	0 - 20 cmH_20 (preset to 5 cmH_20)	15 cmH_20
FX631T	0 - 20 cmH_20 (preset to 5 cmH_20)	30 cmH_20
FX632T	0 - 20 cmH_20 (preset to 5 cmH_20)	35 cmH_20

*** Recommendations should only be used as guideline as other settings may also be necessary depending on the patient and anatomy.*

proGAV® 2.0

Shunt System with Pediatric Burrhole Reservoir

+ *proGAV 2.0* valve with *Distal Catheter*, 1200 mm
+ *Pediatric Burrhole Reservoir* with *Distal Catheter*, 600 mm
+ *Ventricular Catheter* with introducing stylet, 180 mm



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

Standard configurations

Art. no.	Adjustable unit	Gravitational unit	Recommendation**
FX570T	0 - 20 cmH_20 (preset to 5 cmH_20)	20 cmH_20	Children up to 5 and adults over 65 years old
FX571T	0 - 20 cmH_20 (preset to 5 cmH_20)	25 cmH_20	Individuals between 5 and 65 years old

Alternative configurations available

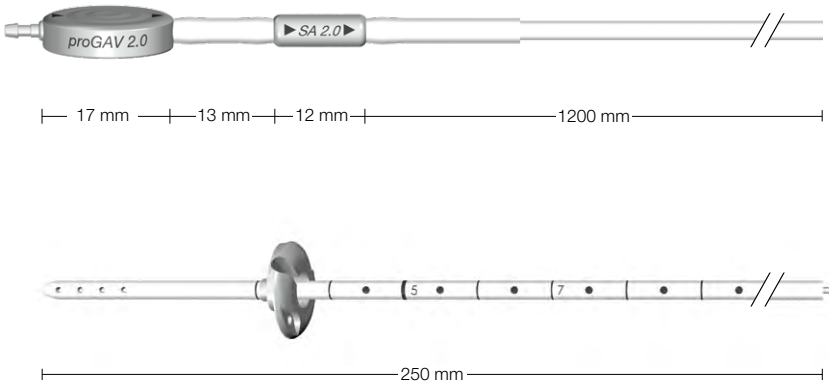
Art. no.	Adjustable unit	Gravitational unit
FX445T	0 - 20 cmH_20 (preset to 5 cmH_20)	without
FX568T	0 - 20 cmH_20 (preset to 5 cmH_20)	10 cmH_20
FX569T	0 - 20 cmH_20 (preset to 5 cmH_20)	15 cmH_20
FX572T	0 - 20 cmH_20 (preset to 5 cmH_20)	30 cmH_20
FX573T	0 - 20 cmH_20 (preset to 5 cmH_20)	35 cmH_20

*** Recommendations should only be used as guideline as other settings may also be necessary depending on the patient and anatomy.*

proGAV® 2.0

Shunt System

+ *proGAV 2.0* valve with *Distal Catheter*, 1200 mm
+ *Ventricular Catheter* with *Pediatric Burrhole Deflector* and introducing stylet



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

Standard configurations

Art. no.	Adjustable unit	Gravitational unit	Recommendation**
8220 2020	0 - 20 cmH_20 (preset to 5 cmH_20)	20 cmH_20	Children up to 5 and adults over 65 years old
8220 2025	0 - 20 cmH_20 (preset to 5 cmH_20)	25 cmH_20	Individuals between 5 and 65 years old

Alternative configurations available

Art. no.	Adjustable unit	Gravitational unit
8220 2000	0 - 20 cmH_20 (preset to 5 cmH_20)	without
8220 2010	0 - 20 cmH_20 (preset to 5 cmH_20)	10 cmH_20
8220 2015	0 - 20 cmH_20 (preset to 5 cmH_20)	15 cmH_20
8220 2030	0 - 20 cmH_20 (preset to 5 cmH_20)	30 cmH_20
8220 2035	0 - 20 cmH_20 (preset to 5 cmH_20)	35 cmH_20

*** Recommendations should only be used as guideline as other settings may also be necessary depending on the patient and anatomy.*

proGAV® 2.0 Tools

\+ *proGAV 2.0 Adjustment Tool, proGAV 2.0 Compass, proGAV 2.0 Tool Set and proGAV 2.0 Checkmate*

proGAV 2.0 Adjustment Tool

proGAV 2.0 Compass

proGAV 2.0 Tool Set

proGAV 2.0 Checkmate

Art. no.	Tools
FX400T	*proGAV 2.0 Adjustment Tool*
FX401T	*proGAV 2.0 Compass*
FX404T	*proGAV 2.0 Tool Set* (contains FX400T and FX401T)
FX409T	*proGAV 2.0 Checkmate*
on request	*proGAV 2.0* X-ray template and pressure recommendation card

CE/CE 0297

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