GAV® 2.0

MIETHKE

Take the headaches out of treating hydrocephalus

Rx Only

INDICATIONS FOR USE: The MIETHKE Shunt System *GAV 2.0* is used for cerebrospinal fluid (CSF) shunting.

Aesculap Neurosurgery

AESCULAP®

GAV® 2.0

Take the headaches out of treating hydrocephalus

When treating hydrocephalus the choice of the valve pressure frequently results in a compromise. Low pressure level settings are avoided to prevent complications due to excess drainage. However, studies show that low pressure valves could lead to better clinical result for the patient.[1, 2]

Conventional valve technology provides inadequate protection against overdrainage complications such as hygroma, hematoma or slit ventricles.

Excessive drainage induced by the hydrostatic suction of the vertical shunt system is considered to be one of the major causes of shunt dysfunction in the treatment of pediatric hydrocephalus.[3]

Many hydrocephalus patients suffering from chronic headaches due to excessive drainage, frequently develop an irreversible slit ventricle syndrome.[4, 5]

1 Lemcke J, Meier U, Müller C, Fritsch MJ, Kehler U, Langer N, Kiefer M, Eymann R, Schuhmann MU, Speil A, Weber F, Remenez V, Rohde V, Ludwig HC, Stengel D. Safety and efficacy 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):850-7.

2 Suchorska B, Kunz M, Schniepp R, Jahn K, Goetz C, Tonn JC, Peraud A. Optimized surgical treatment for normal pressure hydrocephalus: comparison between gravitational and differential pressure valves. Acta Neurochir (Wien). 2015 Apr;157(4):703-9.

3 Gruber RW, Roehrig B. Prevention of ventricular catheter obstruction and slit ventricle syndrome by the prophylactic use of the Integra antisiphon device in shunt therapy for pediatric hypertensive hydrocephalus: a 25-year follow-up study. J Neurosurg Pediatr. 2010 Jan;5(1):4-16.

4 Rekate HL. Shunt-related headaches: the slit ventricle syndromes. Childs Nerv Syst. 2008 Apr;24(4):423-30.

5 Buxton N, Punt J. Subtemporal decompression: the treatment of noncompliant ventricle syndrome. Neurosurgery. 1999 Mar;44(3): 513-8.

GAV® 2.0

The Valve

Gravitational Technology

The combination of a differential pressure unit and gravitational unit allows for an automatic opening pressure adjustment to a patient's body position and in that way counteracts complications due to excess drainage.

Design

The slender cylindrical design allows for quick and easy implantation and is suitable for the treatment of hydrocephalus in adults, as well as pediatric patients.

Two Additional LP-Variants

GAV® 2.0 is also suitable for lumbar drainage due to two special variants.

Titanium

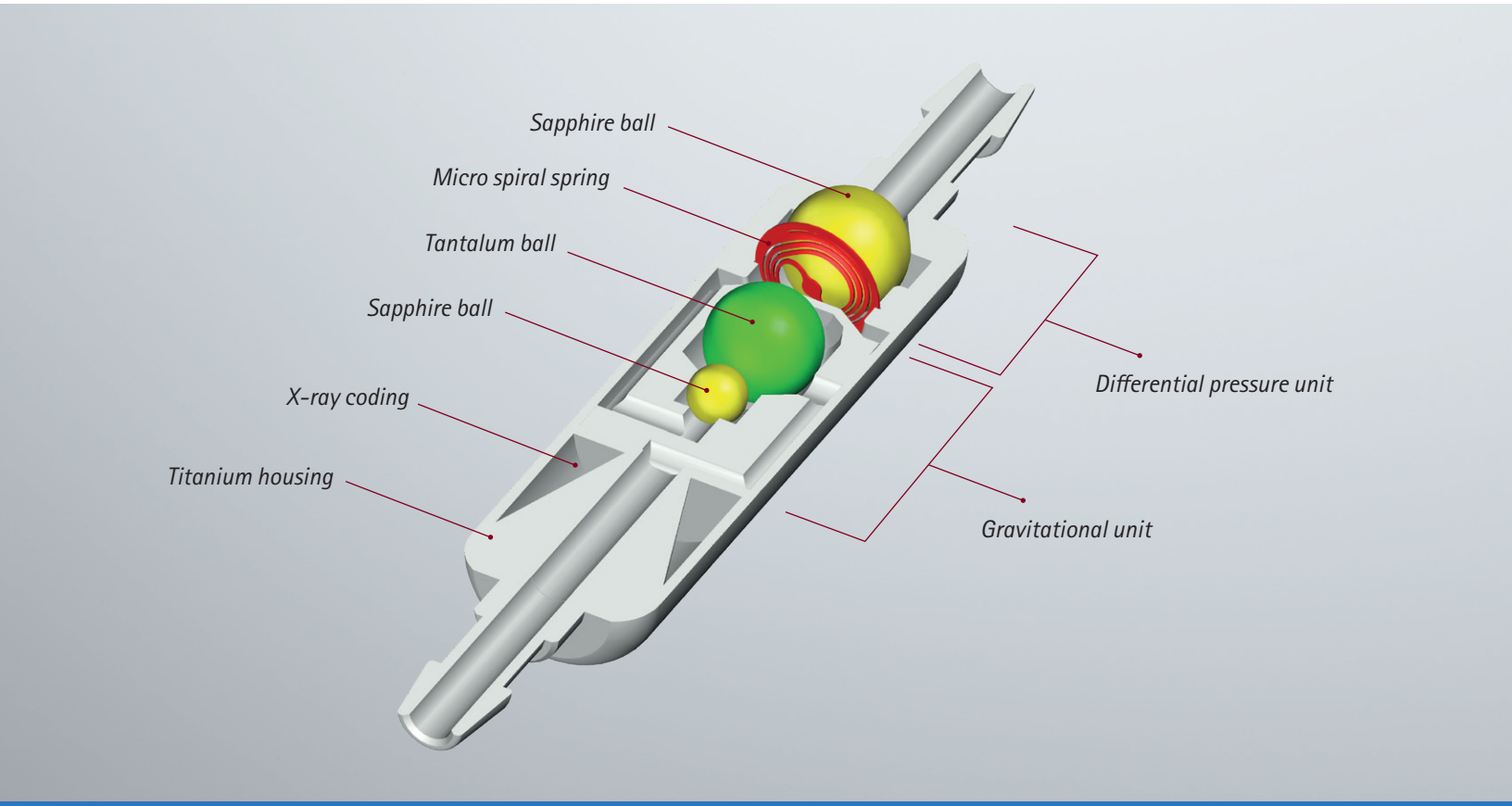
The valve material titanium assures high precision, durable reliability and biocompatibility. It prevents effectively external and subcutaneous pressure influences and is MR Conditional.

GAV® 2.0 LP

GAV® 2.0 LP
with deflection

GAV® 2.0

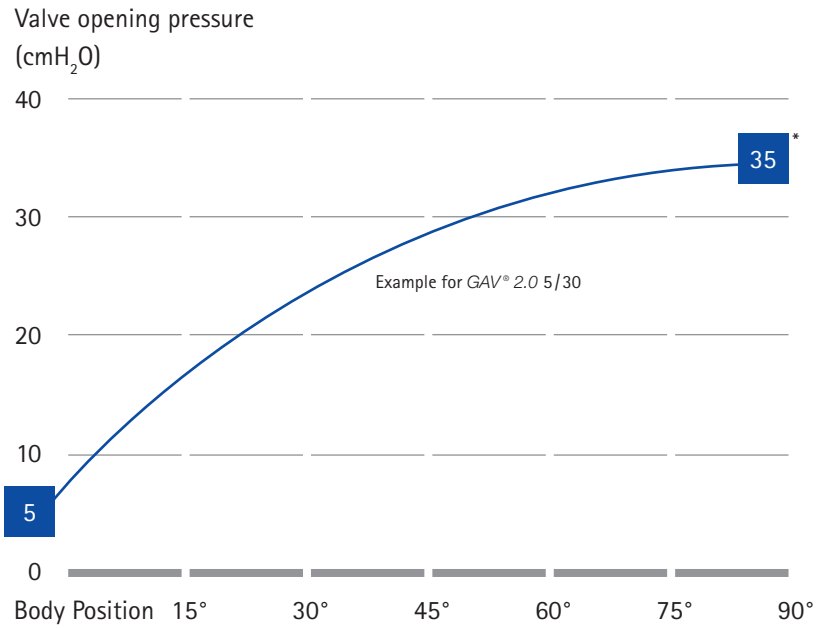
Function and Body Position

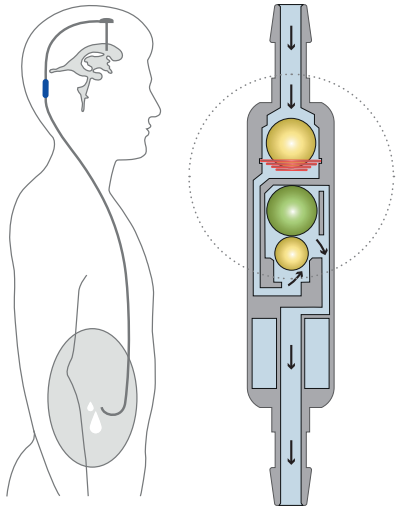


The functionality of *GAV® 2.0* is illustrated in the MIETHKE® App.

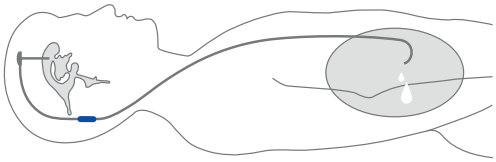
for Apple

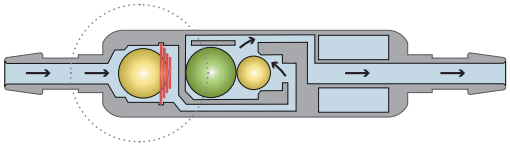
for Android





Differential pressure unit and gravitational unit interact in the upright position.





In the supine position, only the differential pressure unit is active.

* Gravitational unit 30 cmH_2O plus differential pressure unit of 5 cmH_2O has a total opening pressure of 35 cmH_2O in the vertical position.

Horizontal Body Position

The opening pressure of *GAV® 2.0* in the lying position is determined by the micro spiral spring of the differential pressure unit. The gravitational unit is inactive in this body position and is open. If the patient's intraventricular pressure (IVP) exceeds the opening pressure of the micro spiral spring, the ball moves out of the cone, opening a gap to allow drainage.

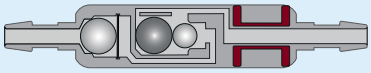
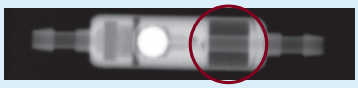
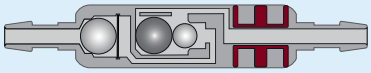
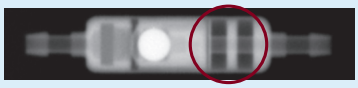
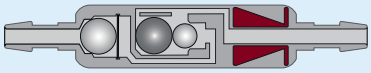
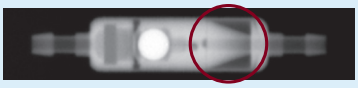
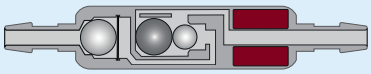
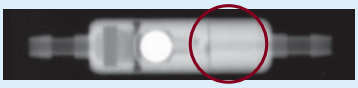
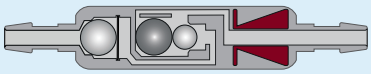
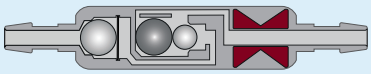
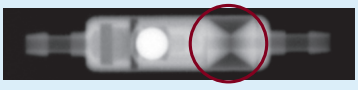
Vertical Body Position

In the vertical position of the body, the gravitational and differential pressure units act in conjunction. When the patient stands up, the tantalum ball (green) in the gravitational unit is activated, causing gravity to increase the valve opening pressure. The weight of the tantalum ball (opening pressure of the gravitational unit) must be overcome in addition to the opening pressure of the differential pressure unit. Only when the sum of intraventricular pressure (IVP) and hydrostatic pressure exceeds the opening pressure of both units, drainage can take place again. The opening pressure in the upright position of the patient is the sum of the differential pressure and gravitational pressure.

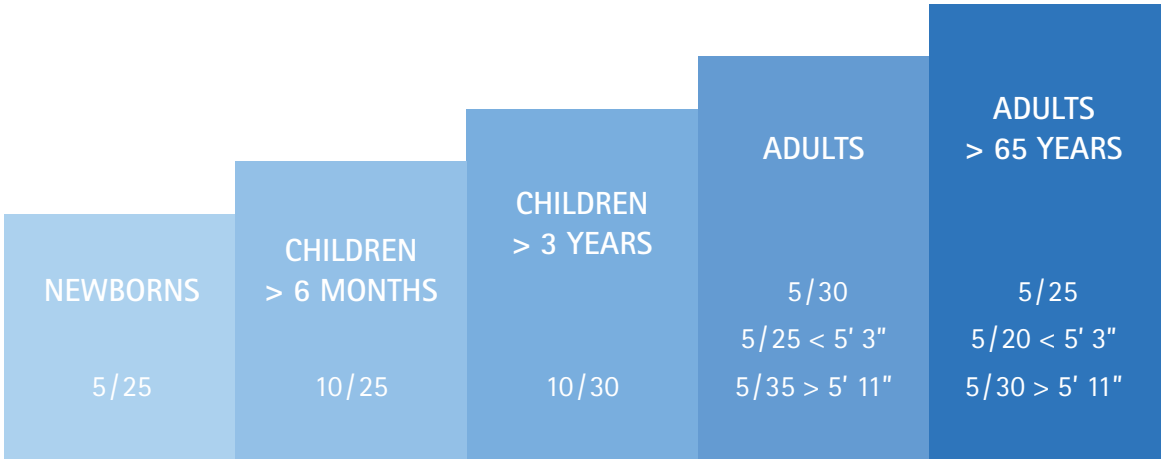
GAV® 2.0

X-ray Recognition and Pressure Level Recommendation

Pressure Level Variants

Supine	Upright	X-ray coding	Radiograph
5 cmH_2O	20 cmH_2O		
5 cmH_2O	25 cmH_2O		
5 cmH_2O	30 cmH_2O		
5 cmH_2O	35 cmH_2O		
10 cmH_2O	25 cmH_2O		
10 cmH_2O	30 cmH_2O		

Pressure Level Recommendation*



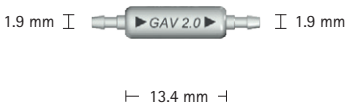
* Recommended pressure level in cmH_2O.
This is a non-binding recommendation. The treating physician will decide each case individually.

The choice of the appropriate pressure level of *GAV® 2.0* depends on several other factors, including age, degree of activity, size and height of the patient.

The values given apply to mobile patients. For patients with little mobility or a high BMI, a lower pressure level should be chosen for the gravitational unit.

Ordering Information

GAV® 2.0
valve

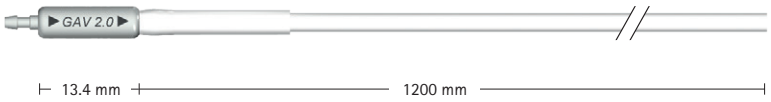


Order	Supine	Upright
FX210T	5 cmH_2O	20 cmH_2O
FX211T	5 cmH_2O	25 cmH_2O
FX212T	5 cmH_2O	30 cmH_2O
FX213T	5 cmH_2O	35 cmH_2O
FX214T	10 cmH_2O	25 cmH_2O
FX215T	10 cmH_2O	30 cmH_2O

Valve: d_o = 4.2 mm
Connector: d_o = 1.9 mm
preferably used with
Catheter: d_i = 1.2 mm, d_o = 2.5 mm

For pressure level recommendation see page 9.

GAV® 2.0
valve with distal catheter
(1200 mm)



Order	Supine	Upright
FX216T	5 cmH_2O	20 cmH_2O
FX217T	5 cmH_2O	25 cmH_2O
FX218T	5 cmH_2O	30 cmH_2O
FX219T	5 cmH_2O	35 cmH_2O
FX220T	10 cmH_2O	25 cmH_2O
FX221T	10 cmH_2O	30 cmH_2O

Valve: d_o = 4.2 mm
Connector: d_o = 1.9 mm
Catheter: d_i = 1.2 mm, d_o = 2.5 mm

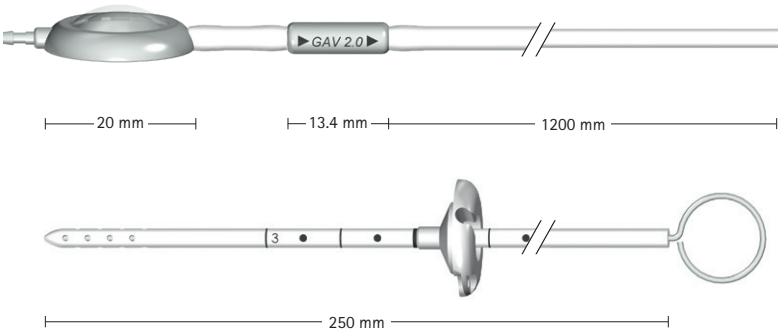
For pressure level recommendation see page 9.

GAV® 2.0
valve with integrated
*CONTROL RESERVOIR**
and distal catheter (1200 mm)

Ventricular catheter (250 mm)
with pediatric deflector and
introducing stylet

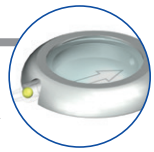
* An additional valve in the base of the CONTROL RESERVOIR makes it possible to flush the fluid only in the distal direction. This feature allows for the patency check.

Valve: d_o = 4.2 mm
Connector: d_o = 1.9 mm
Catheter: d_i = 1.2 mm, d_o = 2.5 mm



Order	Supine	Upright
FX146T	5 cmH_2O	20 cmH_2O
FX147T	5 cmH_2O	25 cmH_2O
FX148T	5 cmH_2O	30 cmH_2O
FX149T	5 cmH_2O	35 cmH_2O
FX150T	10 cmH_2O	25 cmH_2O
FX151T	10 cmH_2O	30 cmH_2O

For pressure level recommendation see page 9.



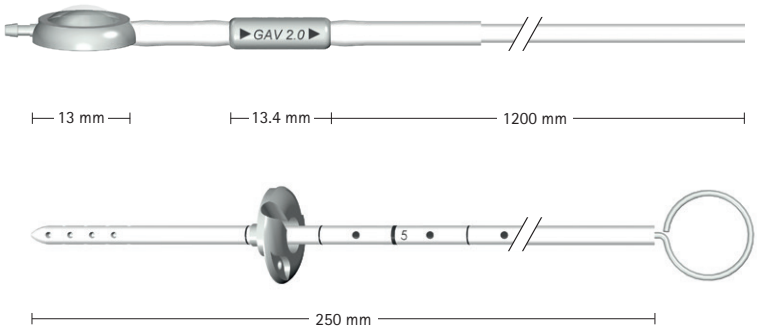
*CONTROL RESERVOIR**

GAV® 2.0
valve with integrated pediatric
*CONTROL RESERVOIR**
and distal catheter (1200 mm)

Ventricular catheter (250 mm)
with pediatric deflector and
introducing stylet

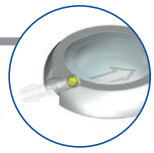
* An additional valve in the base of the pediatric CONTROL RESERVOIR makes it possible to flush the fluid only in the distal direction. This feature allows for the patency check.

Valve: d_o = 4.2 mm
Connector: d_o = 1.9 mm
Catheter: d_i = 1.2 mm, d_o = 2.5 mm



Order	Supine	Upright
FX152T	5 cmH_2O	20 cmH_2O
FX153T	5 cmH_2O	25 cmH_2O
FX154T	5 cmH_2O	30 cmH_2O
FX155T	5 cmH_2O	35 cmH_2O
FX156T	10 cmH_2O	25 cmH_2O
FX157T	10 cmH_2O	30 cmH_2O

For pressure level recommendation see page 9.



*pediatric CONTROL RESERVOIR**

Ordering Information

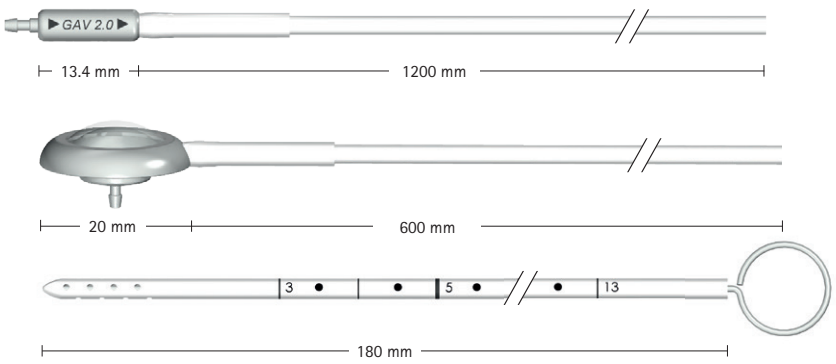
GAV® 2.0
valve with distal catheter
(1200 mm)

SPRUNG RESERVOIR®
with distal catheter (600 mm)

Ventricular catheter (180 mm)
with introducing stylet

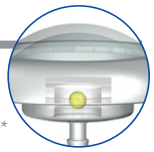
* An additional valve in the base of the SPRUNG RESERVOIR makes it possible to flush the fluid only in the distal direction. This feature allows for the patency check.

Valve: d_o = 4.2 mm
Connector: d_o = 1.9 mm
Catheter: d_i = 1.2 mm, d_o = 2.5 mm



Order	Supine	Upright
FX270T	5 cmH_2O	20 cmH_2O
FX271T	5 cmH_2O	25 cmH_2O
FX272T	5 cmH_2O	30 cmH_2O
FX273T	5 cmH_2O	35 cmH_2O
FX274T	10 cmH_2O	25 cmH_2O
FX275T	10 cmH_2O	30 cmH_2O

For pressure level recommendation see page 9.



*SPRUNG RESERVOIR**

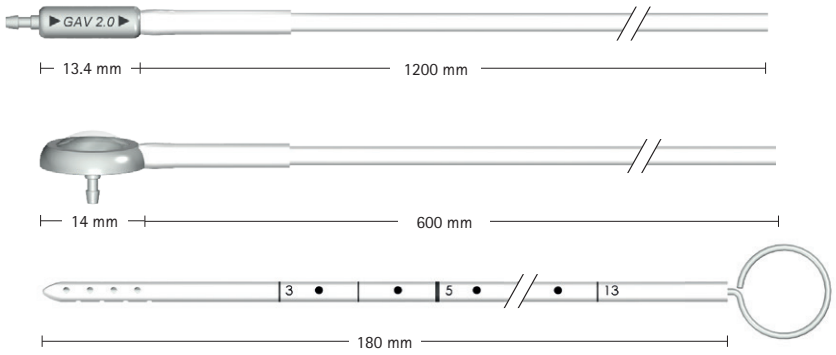
GAV® 2.0
valve with distal catheter
(1200 mm)

Pediatric
SPRUNG RESERVOIR®
with distal catheter (600 mm)

Ventricular catheter (180 mm)
with introducing stylet

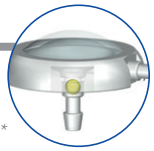
* An additional valve in the base of the pediatric CONTROL RESERVOIR makes it possible to flush the fluid only in the distal direction. This feature allows for the patency check.

Valve: d_o = 4.2 mm
Connector: d_o = 1.9 mm
Catheter: d_i = 1.2 mm, d_o = 2.5 mm



Order	Supine	Upright
FX276T	5 cmH_2O	20 cmH_2O
FX277T	5 cmH_2O	25 cmH_2O
FX278T	5 cmH_2O	30 cmH_2O
FX279T	5 cmH_2O	35 cmH_2O
FX280T	10 cmH_2O	25 cmH_2O
FX281T	10 cmH_2O	30 cmH_2O

For pressure level recommendation see page 9.



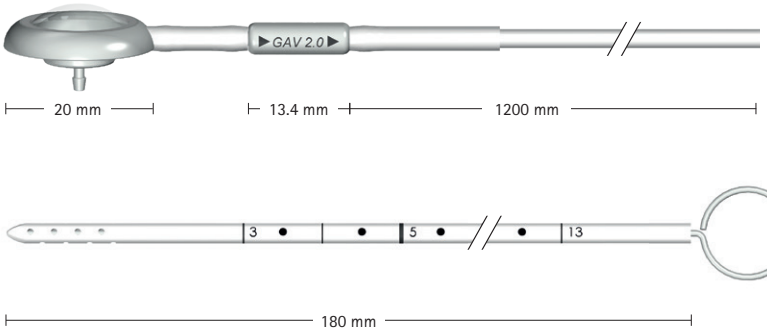
*pediatric SPRUNG RESERVOIR**

GAV® 2.0
valve with integrated
SPRUNG RESERVOIR®
and distal catheter (1200 mm)

Ventricular catheter (180 mm)
with introducing stylet

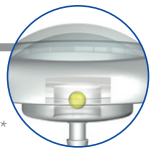
* An additional valve in the base of the SPRUNG RESERVOIR makes it possible to flush the fluid only in the distal direction. This feature allows for the patency check..

Valve: d_o = 4.2 mm
Connector: d_o = 1.9 mm
Catheter: d_i = 1.2 mm, d_o = 2.5 mm



Order	Supine	Upright
FX170T	5 cmH_2O	20 cmH_2O
FX171T	5 cmH_2O	25 cmH_2O
FX172T	5 cmH_2O	30 cmH_2O
FX173T	5 cmH_2O	35 cmH_2O
FX174T	10 cmH_2O	25 cmH_2O
FX175T	10 cmH_2O	30 cmH_2O

For pressure level recommendation see page 9.



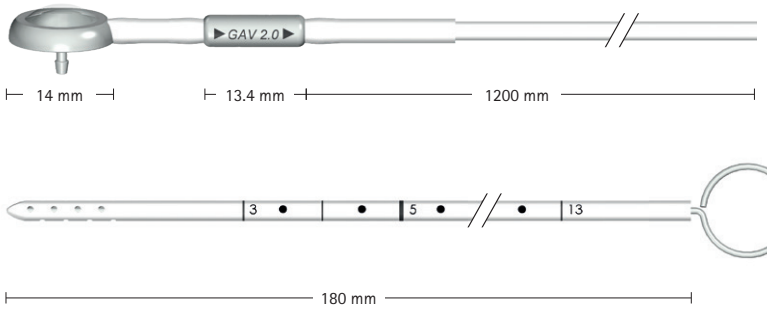
*SPRUNG RESERVOIR**

GAV® 2.0
valve with integrated pediatric
*SPRUNG RESERVOIR**
and distal catheter (1200 mm)

Ventricular catheter (180 mm)
introducing stylet

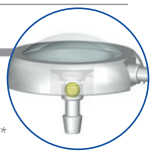
* An additional valve in the base of the pediatric SPRUNG RESERVOIR makes it possible to flush the fluid only in the distal direction. This feature allows for the patency check.

Valve: d_o = 4.2 mm
Connector: d_o = 1.9 mm
Catheter: d_i = 1.2 mm, d_o = 2.5 mm



Order	Supinr	Upright
FX176T	5 cmH_2O	20 cmH_2O
FX177T	5 cmH_2O	25 cmH_2O
FX178T	5 cmH_2O	30 cmH_2O
FX179T	5 cmH_2O	35 cmH_2O
FX180T	10 cmH_2O	25 cmH_2O
FX181T	10 cmH_2O	30 cmH_2O

For pressure level recommendation see page 9.



*pediatric SPRUNG RESERVOIR**

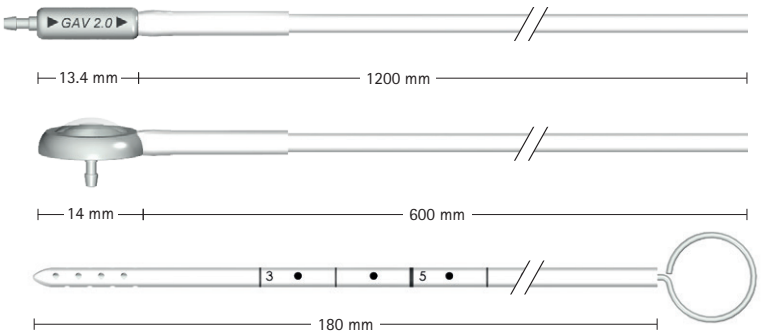
Ordering Information

GAV® 2.0
valve with distal catheter
(1200 mm)

Pediatric burrhole reservoir
with distal catherter (600)

Ventricular catheter (180 mm)
with introducing stylet

Valve: d_o = 4.2 mm
Connector: d_o = 1.9 mm
Catheter: d_i = 1.2 mm, d_o = 2.5 mm



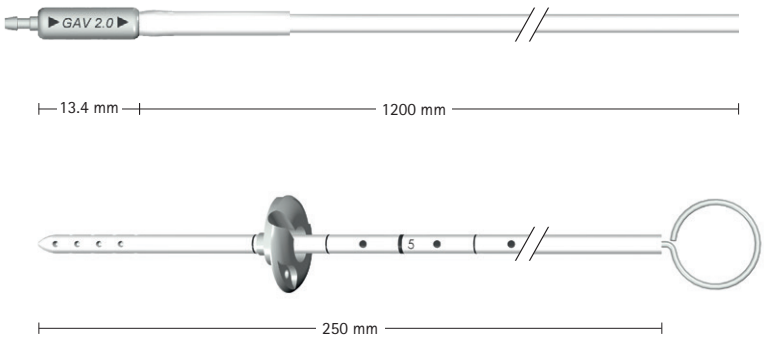
Order	Supine	Upright
FX264T	5 cmH_2O	20 cmH_2O
FX265T	5 cmH_2O	25 cmH_2O
FX266T	5 cmH_2O	30 cmH_2O
FX267T	5 cmH_2O	35 cmH_2O
FX268T	10 cmH_2O	25 cmH_2O
FX269T	10 cmH_2O	30 cmH_2O

For pressure level recommendation see page 9.

GAV® 2.0
valve with distal catheter
(1200 mm)

Ventricular catheter (250 mm)
with pediatric deflector and
introducing stylet

Valve: d_o = 4.2 mm
Connector: d_o = 1.9 mm
Catheter: d_i = 1.2 mm, d_o = 2.5 mm



Order	Supine	Upright
FX204T	5 cmH_2O	20 cmH_2O
FX205T	5 cmH_2O	25 cmH_2O
FX206T	5 cmH_2O	30 cmH_2O
FX207T	5 cmH_2O	35 cmH_2O
FX208T	10 cmH_2O	25 cmH_2O
FX209T	10 cmH_2O	30 cmH_2O

For pressure level recommendation see page 9.

GAV® 2.0 LP
valve (straight) with distal catheter (1200 mm)

Valve: d_o = 4.2 mm
Connector: d_o = 1.4 mm
for connection with lumbar catheter
Connector: d_o = 1.9 mm
Catheter: d_i = 1.2 mm, d_o = 2.5 mm

Order	Supine	Upright
FX222T	5 cmH_2O	20 cmH_2O
FX223T	5 cmH_2O	25 cmH_2O
FX224T	5 cmH_2O	30 cmH_2O
FX225T	5 cmH_2O	35 cmH_2O
FX226T	10 cmH_2O	25 cmH_2O
FX227T	10 cmH_2O	30 cmH_2O

For pressure level recommendation see page 9.

GAV® 2.0 LP
valve (U-form) with distal catheter (1200 mm)

Valve: d_o = 4.2 mm
Connector: d_o = 1.4 mm
for connection with lumbar catheter
Connector: d_o = 1.9 mm
Catheter: d_i = 1.2 mm, d_o = 2.5 mm

Order	Supine	Upright
FX228T	5 cmH_2O	20 cmH_2O
FX229T	5 cmH_2O	25 cmH_2O
FX230T	5 cmH_2O	30 cmH_2O
FX231T	5 cmH_2O	35 cmH_2O
FX232T	10 cmH_2O	25 cmH_2O
FX233T	10 cmH_2O	30 cmH_2O

For pressure level recommendation see page 9.

See Instructions for Use for additional information including Contraindications, Warnings and Precautions.

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