

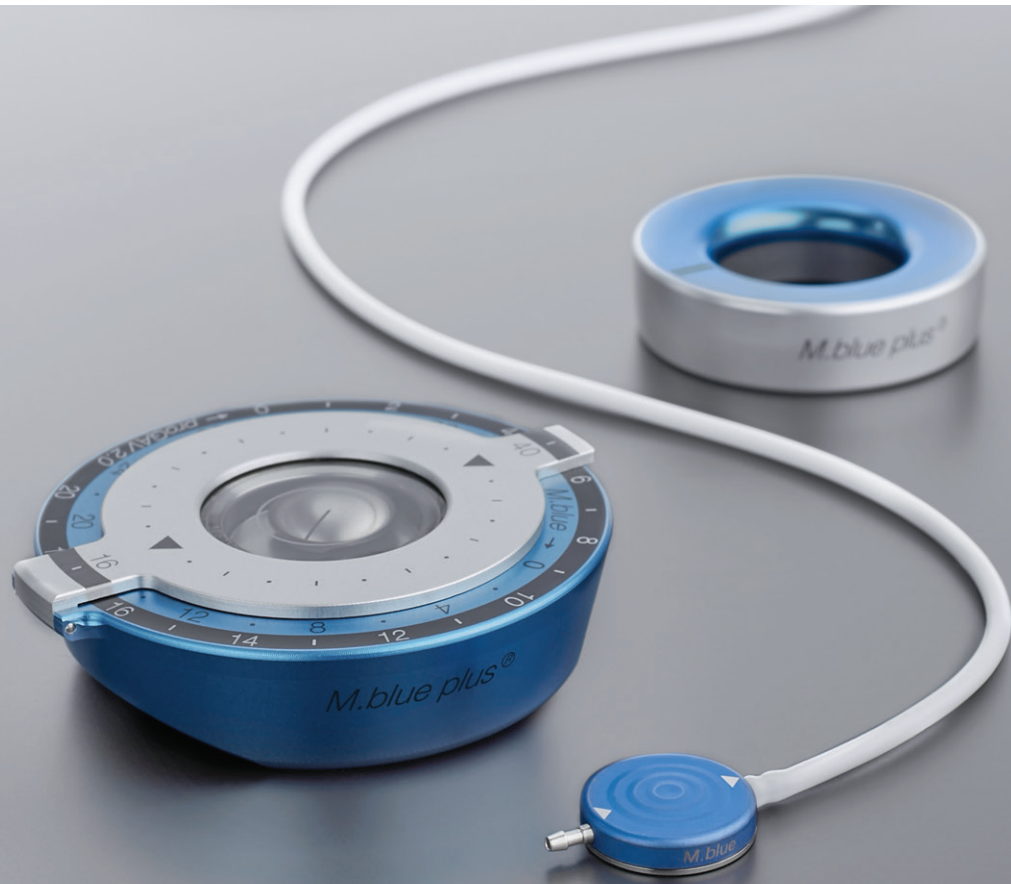
M.blue™



Take the headaches out of treating hydrocephalus

Rx Only

INDICATIONS FOR USE: The *M.blue* Adjustable Shunt System is used for cerebrospinal fluid (CSF) shunting.



Aesculap Neurosurgery

AESCLAP®

Hydrocephalus Treatment

Take the headaches out of treating hydrocephalus

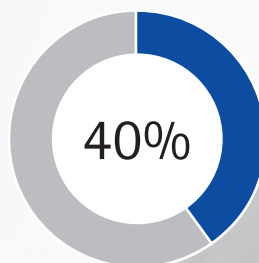
Hydrocephalus treatment and the need for better solutions.

The most common surgical strategy in managing hydrocephalus is the placement of shunts. However, conventional shunts have very high failure rates, and nearly every fourth patient is affected by complication.^{1,2} Complications occur without distinction of valve usage.^{4,5}

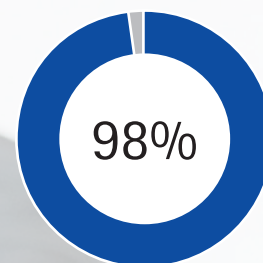
Overdrainage-related complications can necessitate a variety of different revisions, which are burdensome for patients as well as their healthcare teams and are accompanied by unavoidable perioperative risks.² In addition, a healthcare system's responsibility not only includes better patient outcomes, but also an expectation to focus on sustainability from a business and operations perspective.

We believe that the current treatment situation for hydrocephalus can be better.

High Failure Rates



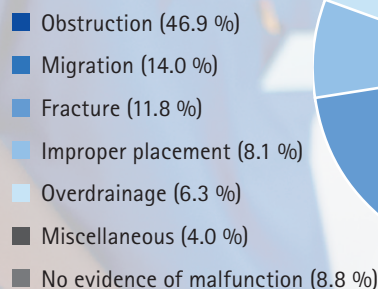
Proportion of shunts failing within 2 years



Proportion of shunts failing within 10 years

» High failure rates overshadow the effectiveness of shunts.¹

Complications³



» About one in four patients experiences at least one complication.²



Mechanical Failure

Mechanical failure is the most common cause of multiple shunt revisions⁶, with catheter or valve obstruction being the predominant reason.³ Failure of individual shunt components may also occur, e.g., at stress points or due to poor design.⁷



Catheter breakage



Catheter fracture



Obstruction



Catheter separation



Damaged housing



Valve migration

Accidental Reprogramming

As the optimal pressure setting of adjustable valves is of great importance for the patient, the accidental reprogramming of adjustable valves by external magnetic fields, e.g., from smart-phones, is a cause of concern and leads to great uncertainty among patients and doctors.^{8-12, 26}



Mobile devices



MRI



Headphones
Hearing devices



Toy magnets

Hydrocephalus Treatment

Need for Action

There is a better way.

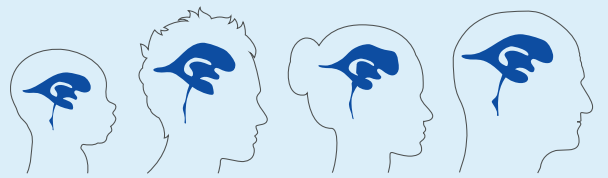
Active patients are exposed to gravity every day. Posture-dependent gravitational effects increase the potential for overdrainage. Overcoming these gravitational effects can help improve patient outcomes.





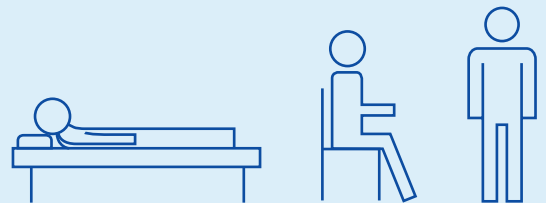
Each patient is unique.

Every patient with hydrocephalus is unique and requires customized setting of the valve opening pressure.



Are patients getting optimal individual treatment?

Determining the patient-individual valve opening pressure can be complex. Non-ideal pressure settings can lead to follow-up examinations and revisions, which are burdensome for patients and their families and put an additional strain on physicians and surgeons.^{13,14}



Are conventional adjustable valves the best available therapy?

The pressure setting of a conventional adjustable valve is a compromise between the pressure requirements of the upright position and the supine position. Therefore, patients can never benefit from optimal opening pressures for both positions.

Gravitational Valves by MIETHKE®

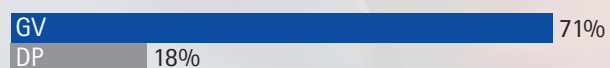


Better design.

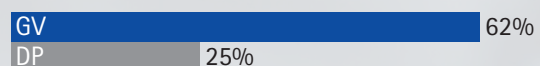
Gravitational shunts provide neurosurgeons with a possibility to address the posture-dependent effects of gravity, with positive clinical outcomes for the patient and a significant reduction of overdrainage events.¹⁵

Gravitational valves (GV) improve patient outcomes compared to differential pressure valves (DP).¹⁶

Symptom improvement >2 points on Kiefer-Scale.



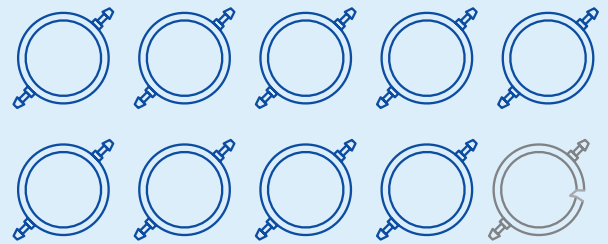
Daily improvement rated good/very good on Black-Scale.



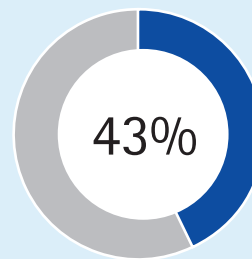


Better protection. Better outcomes.

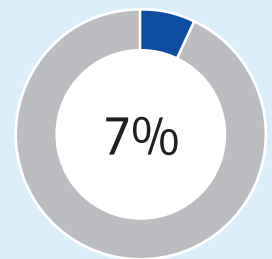
Clinical studies have shown that MIETHKE gravitational devices reduce the risk of revisions¹⁷⁻²¹ and overdrainage complications.¹⁸



» Valve survival rates up to 90% at 12 months.¹⁹



Overdrainage rate
with **conventional**
valves



Overdrainage rate
with **gravitational**
valves

- » Implanting a gravitational valve avoids one additional overdrainage complication in about every third patient.¹⁸
- » Gravitational devices may have the potential to reduce revision costs; 52.6% for pediatrics and 69.5% for the general population.²⁵

Gravitational Valves by MIETHKE®

Reduce mechanical failure.

All MIETHKE valves are manufactured with high precision from titanium. The extremely small valves have optimized flow paths, rigid housing unsusceptible to subcutaneous pressure and high MRI and biocompatibility.

Don't let magnetic fields bother you.

The Active-Lock mechanism protects programmable MIETHKE valves against reprogramming by magnetic fields of up to 3 Tesla.²²

Miethke Gravitational Valves



Made from Titanium
for high MRI and
biocompatibility



Protected against
reprogramming
up to 3 Tesla



Low profile



Rigid housing
unsusceptible to
subcutaneous pressure





Benefit from primary implantation.²³



22%

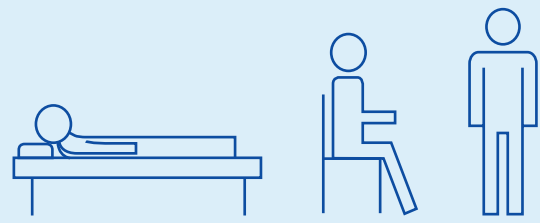
higher survival of gravitational valves after **primary** vs secondary implantation

Get it right the first time.

Early treatment with the optimal treatment option is important for patients with hydrocephalus^{23, 24} and can also help to avoid shunt replacements and associated perioperative risks.

Optimize – don't compromise.

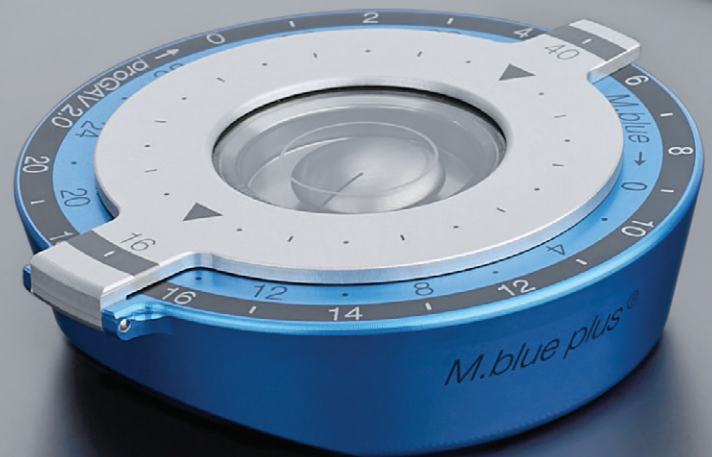
MIETHKE gravitational shunts allow for the prevention of overdrainage in the standing position without compromising the pressure setting for the supine position. The optimal opening pressure for each patient can be set both for the upright and the supine position - without needing to compromise.



» With gravitational valves the optimal pressure for both supine and upright position can be set.

The latest generation of valve technology

- ONE valve for the special requirements of a life with hydrocephalus: mobility, growth, changes in the course of condition
- 2 in 1 technology: adjustable gravitational unit combined with fixed differential pressure unit in one valve
- Unique, uncompromising pressure adaption to optimize individual patient needs
- Smallest adjustable gravitational valve
- Allows for efficient protection against overdrainage. Adjustable opening pressure from 0-40 cmH₂O
- MR Conditional up to 3 Tesla - no X-ray verification after MRI necessary, no additional radiation exposure for the patient
- Safe from unintentional adjustment by everyday magnets such as smartphones, toys, hearing devices, induction cookers and safety barriers at airports
- Innovative *M.blue plus* Instruments for *M.blue* and *proGAV® 2.0*
- Intuitive, secure and comfortable adjustment
- Precision engineering
- Robust and durable: made of titanium





M.blue™ and M.blue plus™

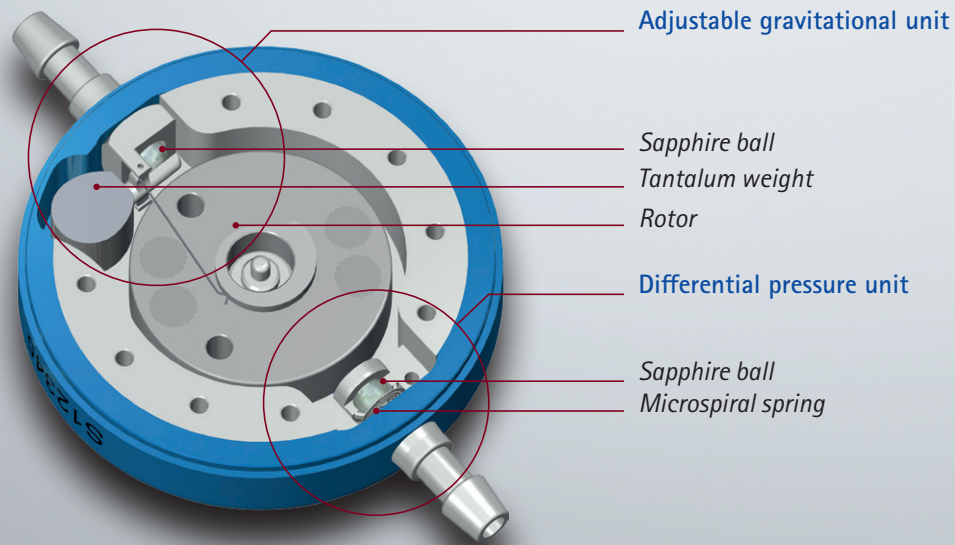
The *M.blue* is the result of 26 years of expert experience with hydrocephalus and valve technology including the feedback of numerous doctors and patients worldwide.

When developing a hydrocephalus valve, it is important to focus on a custom fit during the active time of the day to achieve an optimal and individual treatment.

The *M.blue* is a valve for all forms of hydrocephalus and is highly customizable.

M.blue™

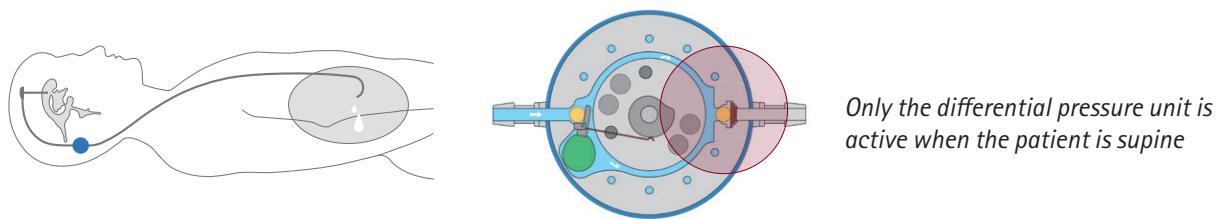
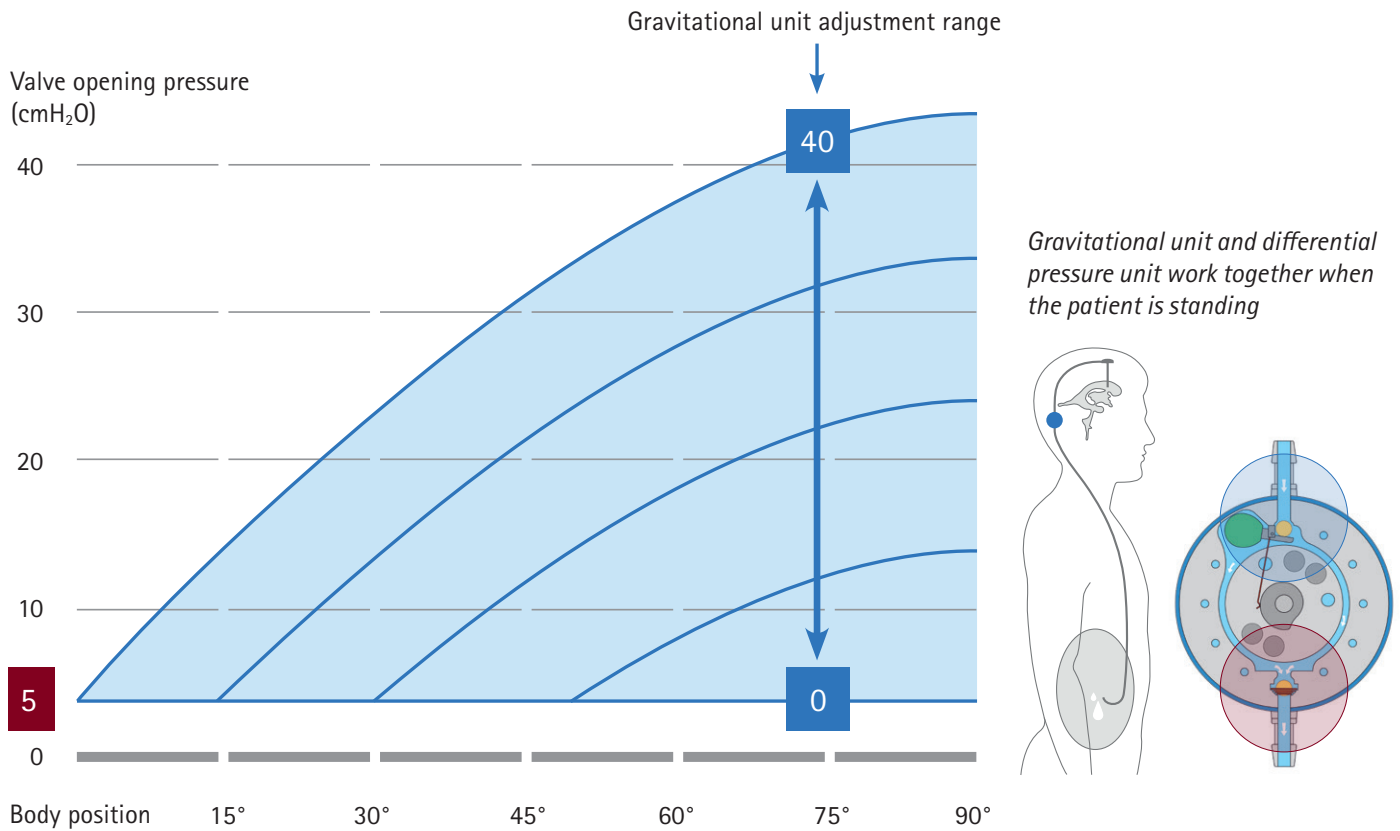
Valve functionality and position of the body



The functionality of *M.blue* is illustrated interactively in the MIETHKE® app.



Example of the adjustable graduated pressure range of an *M.blue*TM with a differential pressure unit of 5 cmH₂O



M.blue is a hydrocephalus valve operating in a position-dependent manner. It consists of an adjustable gravitational unit and a fixed differential pressure unit. The combination of these two units adjusts the opening pressure automatically depending on what position the patient is in, thus countering the risk of possible overdrainage complications, particularly when the patient is in an upright and active position.

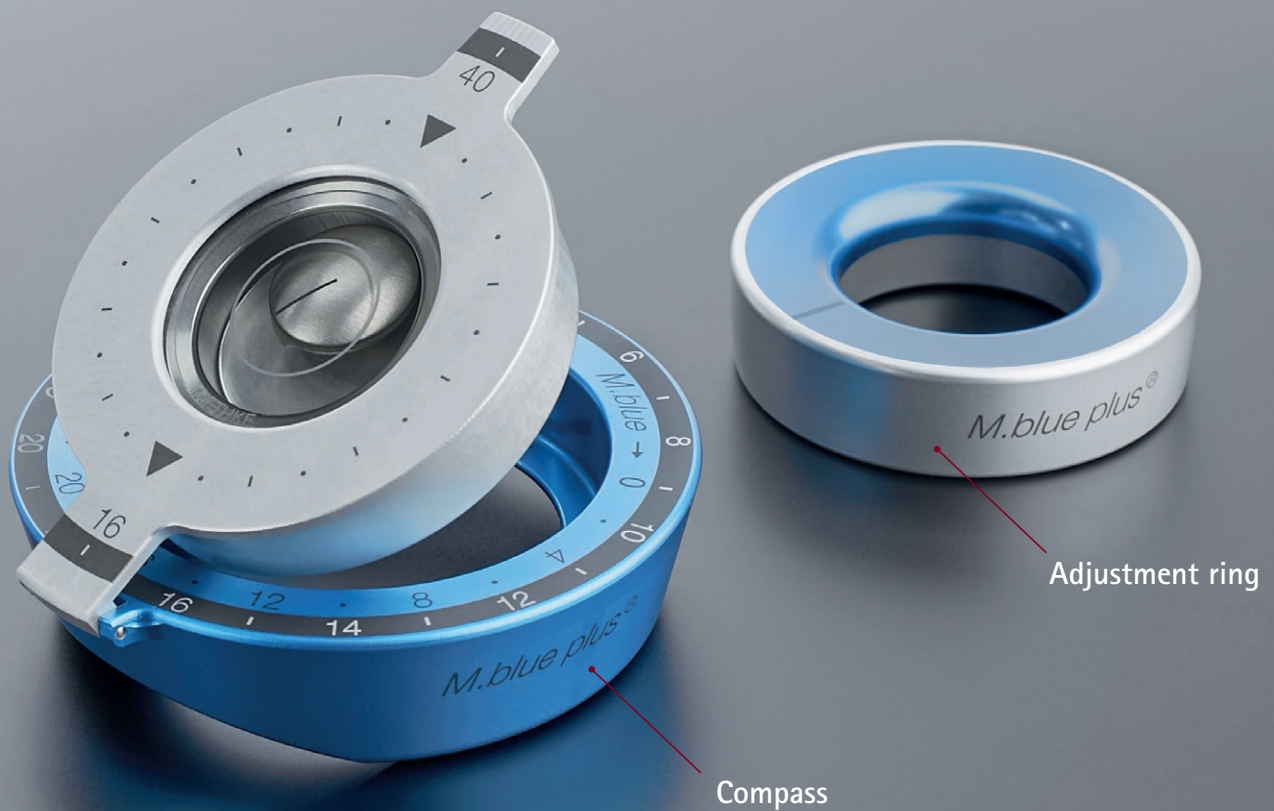
M.blue plus™ Instruments

Soft touch instrument

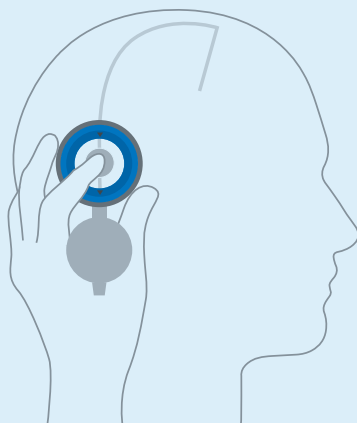
User-friendly adjustment and verification

M.blue plus instruments allow users to measure, verify and adjust the pressure level on the *M.blue*'s adjustable gravitational unit (0-40 cmH₂O) as well as the pressure level on the adjustable differential pressure unit (*proGAV*® 2.0) of the *M.blue plus*.

The instruments offer simple steps for the physician and make the adjustment process comfortable for patients.

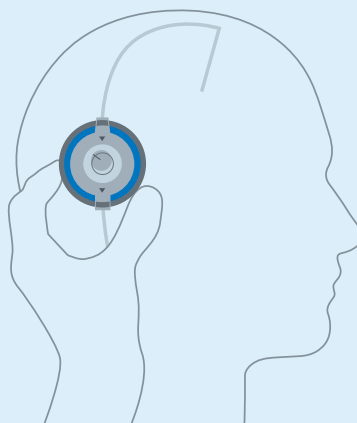


3 Step Reprogramming



Locate

Locate valve by palpating the area with your finger through the open *M.blue plus*[™] compass.



Verify

Close the *M.blue* compass and use the floater to lock location and read current valve opening pressure setting.



Adjust

With the help of the inserted adjustment ring the valve opening pressure can easily be set to the desired level. After setting the valve opening pressure, it is advisable to double-check the pressure level settings.

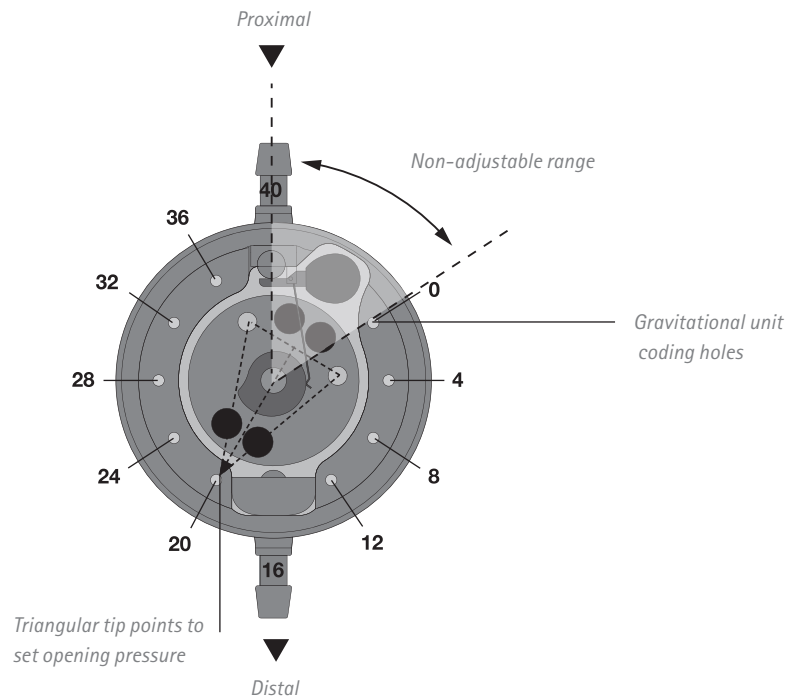
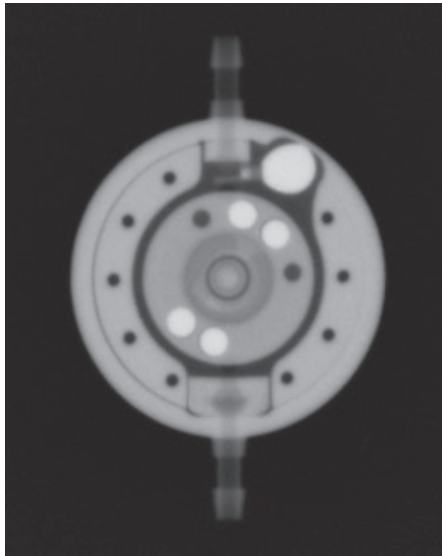
Pressure level recommendations and radiographic identification

Patient	Selection of pressure levels		Combined opening pressure	
	Differential pressure unit	Adjustable gravitational unit		
Newborns and children under 5	5	20	5	25
Children ages 5 and up		25		30
Adults < 5' 3"		25		30
Adults > 5' 9"		30		35
Adults > 65 years		20		25
Adults < 5' 3"	15	20		
Adults > 5' 9"	25	25		

All of the pressure levels shown here are given in cmH₂O. These recommendations are non-binding. The treating physician will need to decide each case individually.

Pressure level recommendation

The choice of the appropriate pressure level of *M.blue* depends on many other factors, including age, degree of activity, size and stature of the patient. The values given apply to mobile patients. For patients with little mobility or a high BMI, the pressure of the gravitational unit should be chosen lower than recommended above.



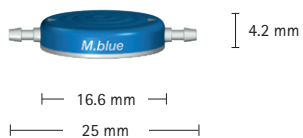
Using radiographic imaging to determine pressure levels

Pressure settings on the *M.blue*™ should always be checked using the *M.blue plus*™ compass, but radiographic imaging can be used for verification as well.

Ordering Information

M.blue[™] single valve

Diameter connector: 1.9 mm
Recommended catheter diameters:
Inner diameter: 1.2 mm
Outer diameter 2.5 mm

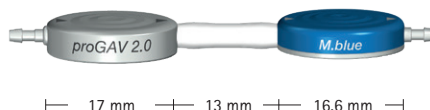


M.blue

Order	Differential pressure unit	Adjustable gravitational unit
FX800T	0 cmH ₂ O	0 - 40 cmH ₂ O
FX801T	5 cmH ₂ O	0 - 40 cmH ₂ O
FX802T	10 cmH ₂ O	0 - 40 cmH ₂ O
FX803T	15 cmH ₂ O	0 - 40 cmH ₂ O

M.blue plus[™] valve combination

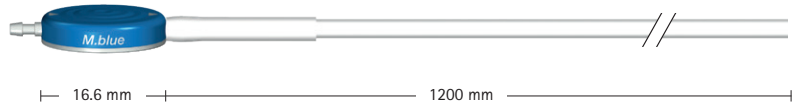
Diameter connector: 1.9 mm
Recommended catheter diameters:
Internal diameter: 1.2 mm
Outer diameter 2.5 mm



M.blue plus

Order	Adj. differential pressure unit	Adjustable gravitational unit
FX804T	0 - 20 cmH ₂ O	0 - 40 cmH ₂ O

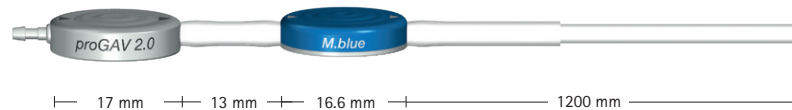
M.blue[™]
individual valve with
distal catheter (1200 mm)



M.blue[®]

Order	Differential pressure unit	Adjustable gravitational unit
FX805T	0 cmH ₂ O	0 - 40 cmH ₂ O
FX806T	5 cmH ₂ O	0 - 40 cmH ₂ O
FX807T	10 cmH ₂ O	0 - 40 cmH ₂ O
FX808T	15 cmH ₂ O	0 - 40 cmH ₂ O

M.blue plus[™]
valve combination with
distal catheter (1200 mm)



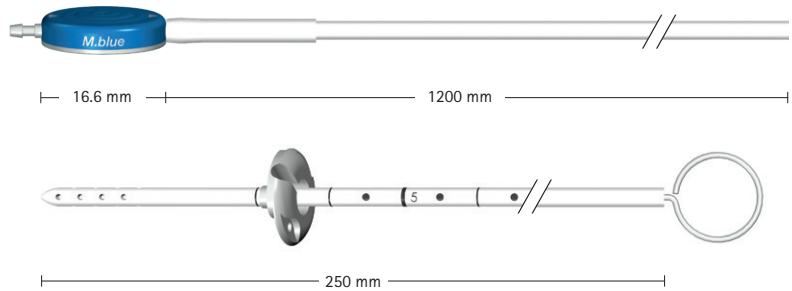
M.blue plus

Art. no.	Adj. differential pressure unit	Adjustable gravitational unit
FX809T	0 - 20 cmH ₂ O	0 - 40 cmH ₂ O

Ordering Information

M.blue™ SHUNT SYSTEM
valve with distal catheter
(1200 mm)

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

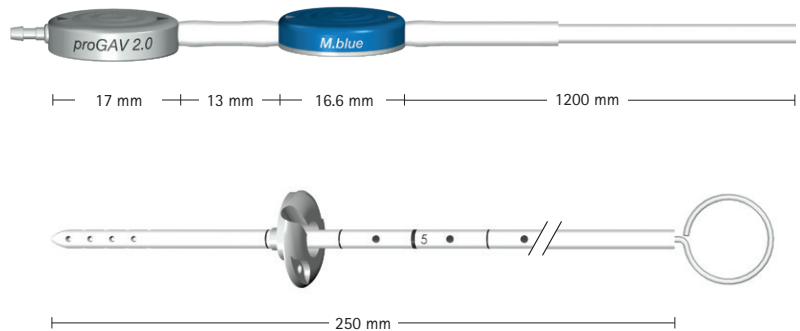


M.blue

Order	Differential pressure unit	Adjustable gravitational unit
FX810T	0 cmH ₂ O	0 - 40 cmH ₂ O
FX811T	5 cmH ₂ O	0 - 40 cmH ₂ O
FX812T	10 cmH ₂ O	0 - 40 cmH ₂ O
FX813T	15 cmH ₂ O	0 - 40 cmH ₂ O

M.blue plus™ SHUNT SYSTEM
valve with distal catheter
(1200 mm)

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



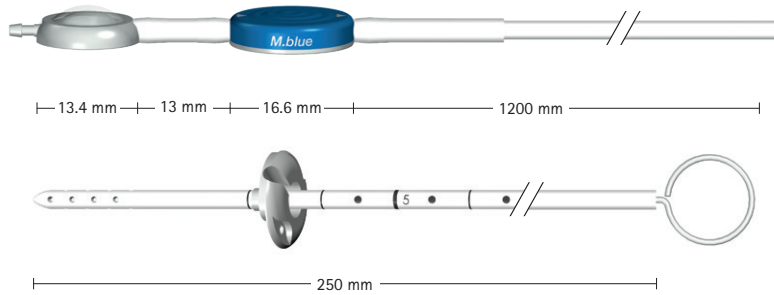
M.blue plus

Order	Adj. differential pressure unit	Adjustable gravitational unit
FX814T	0 - 20 cmH ₂ O	0 - 40 cmH ₂ O

M.blue™ SHUNT SYSTEM
valve with integrated pediatric
CONTROL RESERVOIR
and distal catheter (1200 mm)

** An additional valve in the inlet of the pediatric *CONTROL RESERVOIR* makes it possible to pump cerebrospinal fluid in the direction of drainage only, allowing inspection of both the distal drainage section as well as the ventricular catheter.

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



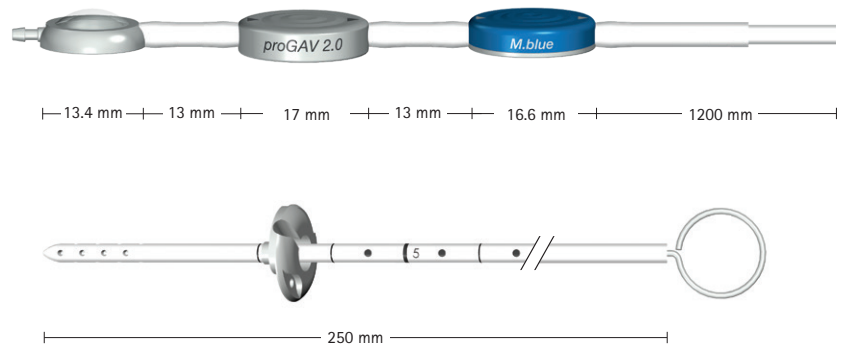
M.blue

Order	Differential pressure unit	Adjustable gravitational unit
FX815T	0 cmH ₂ O	0 - 40 cmH ₂ O
FX816T	5 cmH ₂ O	0 - 40 cmH ₂ O
FX817T	10 cmH ₂ O	0 - 40 cmH ₂ O
FX818T	15 cmH ₂ O	0 - 40 cmH ₂ O

M.blue plus™ SHUNT SYSTEM
valve with integrated pediatric
CONTROL RESERVOIR
and distal catheter (1200 mm)

** An additional valve in the inlet of the pediatric *CONTROL RESERVOIR* makes it possible to pump cerebrospinal fluid in the direction of drainage only, allowing inspection of both the distal drainage section as well as the ventricular catheter.

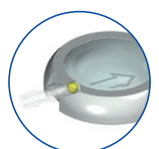
Ventricular catheter (250 mm)
with introducing stylet and
pediatric burrhole deflector
(14 mm)



M.blue plus

Order	Adj. differential pressure unit	Adjustable gravitational unit
FX819T	0 - 20 cmH ₂ O	0 - 40 cmH ₂ O

pediatric *CONTROL RESERVOIR***

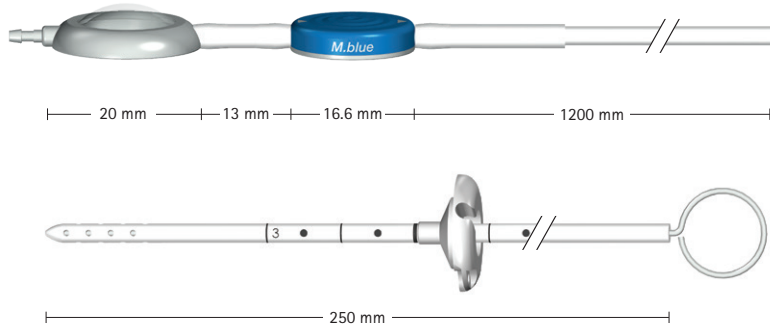


Ordering Information

M.blue™ SHUNT SYSTEM valve with integrated CONTROL RESERVOIR and distal catheter (1200 mm)

** An additional valve in the inlet of the CONTROL RESERVOIR makes it possible to pump cerebrospinal fluid in the direction of drainage only, allowing inspection of both the distal drainage section as well as the ventricular catheter.

Ventricular catheter (250 mm) with introducing stylet and pediatric burrhole deflector (20 mm)



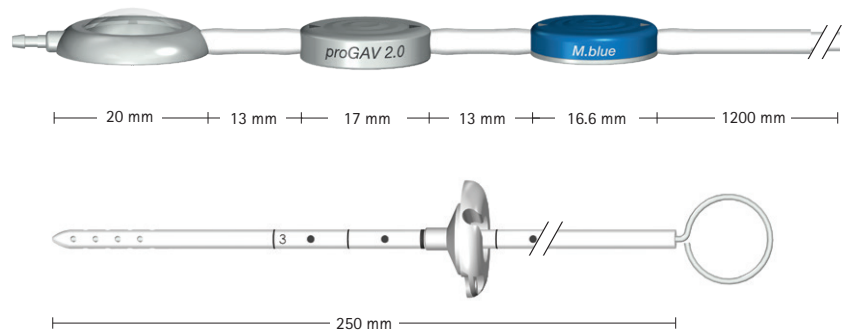
M.blue

Order	Differential pressure unit	Adjustable gravitational unit
FX820T	0 cmH ₂ O	0 - 40 cmH ₂ O
FX821T	5 cmH ₂ O	0 - 40 cmH ₂ O
FX822T	10 cmH ₂ O	0 - 40 cmH ₂ O
FX823T	15 cmH ₂ O	0 - 40 cmH ₂ O

M.blue plus™ SHUNT SYSTEM valve with integrated CONTROL RESERVOIR and distal catheter (1200 mm)

** An additional valve in the inlet of the CONTROL RESERVOIR makes it possible to pump cerebrospinal fluid in the direction of drainage only, allowing inspection of both the distal drainage section as well as the ventricular catheter.

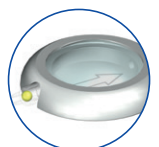
Ventricular catheter (250 mm) with introducing stylet and pediatric burrhole deflector (20 mm)



M.blue plus

Order	Adj. differential pressure unit	Adjustable gravitational unit
FX824T	0 - 20 cmH ₂ O	0 - 40 cmH ₂ O

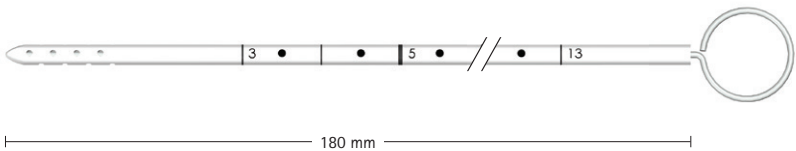
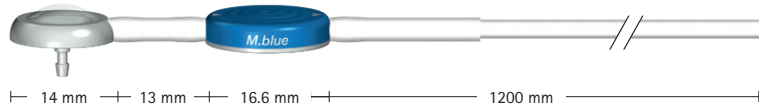
CONTROL RESERVOIR**



M.blue™ SHUNT SYSTEM
valve with integrated pediatric
SPRUNG RESERVOIR
and distal catheter (1200 mm)

** An additional valve in the inlet of the pediatric *SPRUNG RESERVOIR* makes it possible to pump cerebrospinal fluid in the direction of drainage only, allowing inspection of both the distal drainage section as well as the ventricular catheter.

Ventricular catheter with
introducing stilet (180 mm)



M.blue

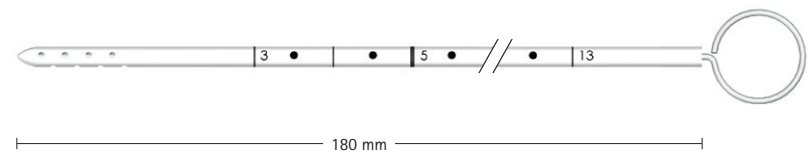
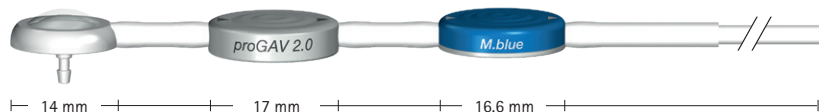
Order	Differential pressure unit	Adjustable gravitational unit
FX825T	0 cmH ₂ O	0 - 40 cmH ₂ O
FX826T	5 cmH ₂ O	0 - 40 cmH ₂ O
FX827T	10 cmH ₂ O	0 - 40 cmH ₂ O
FX828T	15 cmH ₂ O	0 - 40 cmH ₂ O

OCCIPITAL ONLY

M.blue plus™ SHUNT SYSTEM
valve with integrated pediatric
SPRUNG RESERVOIR
and distal catheter (1200 mm)

** An additional valve in the inlet of the pediatric *SPRUNG RESERVOIR* makes it possible to pump cerebrospinal fluid in the direction of drainage only, allowing inspection of both the distal drainage section as well as the ventricular catheter.

Ventricular catheter with
introducing stilet (180 mm)



M.blue plus

Order	Adj. differential pressure unit	Adjustable gravitational unit
FX829T	0 - 20 cmH ₂ O	0 - 40 cmH ₂ O

OCCIPITAL ONLY

pediatric *SPRUNG RESERVOIR***

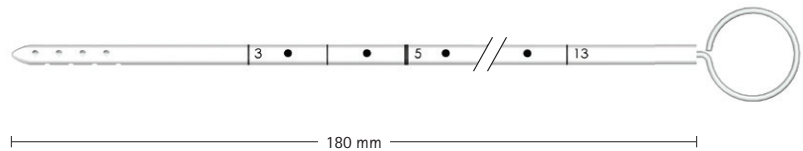
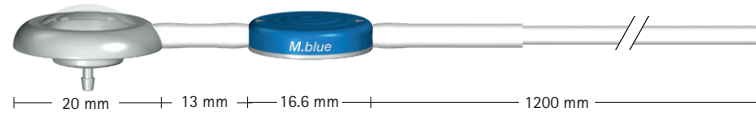


Ordering Information

M.blue™ SHUNT SYSTEM valve with integrated *SPRUNG RESERVOIR* and distal catheter (1200 mm)

** An additional valve in the inlet of the *SPRUNG RESERVOIR* makes it possible to pump cerebrospinal fluid in the direction of drainage only, allowing inspection of both the distal drainage section as well as the ventricular catheter.

Ventricular catheter with introducing stylet (180 mm)



M.blue

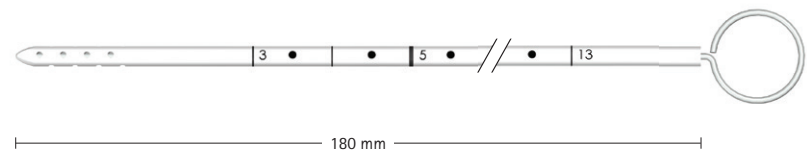
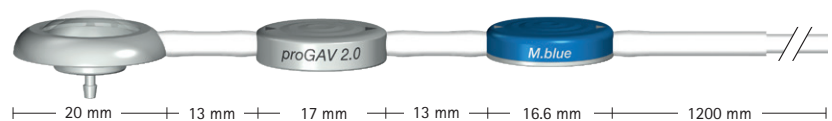
Order	Differential pressure unit	Adjustable gravitational unit
FX830T	0 cmH ₂ O	0 - 40 cmH ₂ O
FX831T	5 cmH ₂ O	0 - 40 cmH ₂ O
FX832T	10 cmH ₂ O	0 - 40 cmH ₂ O
FX833T	15 cmH ₂ O	0 - 40 cmH ₂ O

OCCIPITAL ONLY

M.blue plus™ SHUNT SYSTEM valve with integrated *SPRUNG RESERVOIR* and distal catheter (1200 mm)

** An additional valve in the inlet of the *SPRUNG RESERVOIR* makes it possible to pump cerebrospinal fluid in the direction of drainage only, allowing inspection of both the distal drainage section as well as the ventricular catheter.

Ventricular catheter with introducing stylet (180 mm)

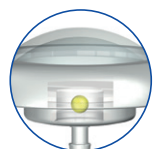


M.blue plus

Order	Adj. differential pressure unit	Adjustable gravitational unit
FX834T	0 - 20 cmH ₂ O	0 - 40 cmH ₂ O

OCCIPITAL ONLY

*SPRUNG RESERVOIR***

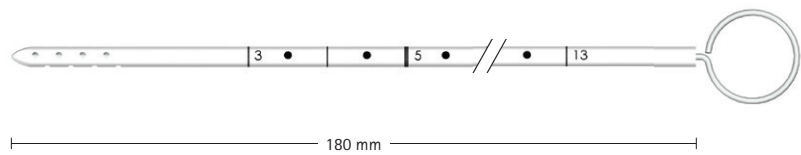
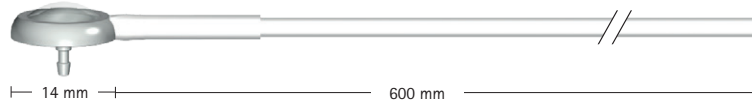
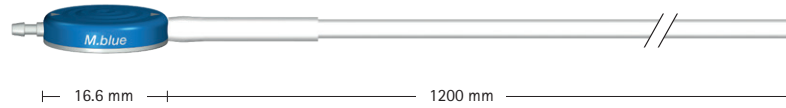


M.blue™ SHUNT SYSTEM
valve with distal catheter
(1200 mm)

pediatric
SPRUNG RESERVOIR
with distal catheter (600 mm)

** An additional valve in the inlet of the pediatric *SPRUNG RESERVOIR* makes it possible to pump cerebrospinal fluid in the direction of drainage only, allowing inspection of both the distal drainage section as well as the ventricular catheter.

Ventricular catheter with
introducing stilet (180 mm)



M.blue

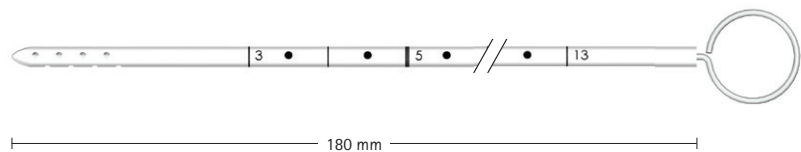
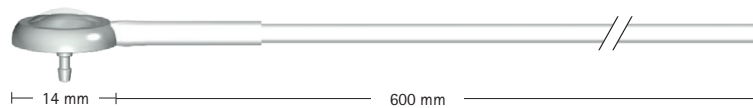
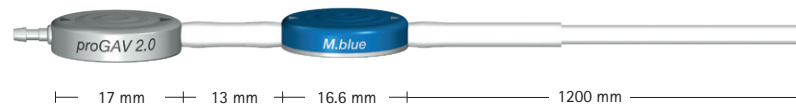
Order	Differential pressure unit	Adjustable gravitational unit
FX835T	0 cmH ₂ O	0 - 40 cmH ₂ O
FX836T	5 cmH ₂ O	0 - 40 cmH ₂ O
FX837T	10 cmH ₂ O	0 - 40 cmH ₂ O
FX838T	15 cmH ₂ O	0 - 40 cmH ₂ O

M.blue plus™ SHUNT SYSTEM
valve with distal catheter
(1200 mm)

pediatric
SPRUNG RESERVOIR
with distal catheter (600 mm)

** An additional valve in the inlet of the pediatric *SPRUNG RESERVOIR* makes it possible to pump cerebrospinal fluid in the direction of drainage only, allowing inspection of both the distal drainage section as well as the ventricular catheter.

Ventricular catheter with
introducing stilet (180 mm)



M.blue plus

Order	Adj. differential pressure unit	Adjustable gravitational unit
FX839T	0 - 20 cmH ₂ O	0 - 40 cmH ₂ O

pediatric *SPRUNG RESERVOIR***



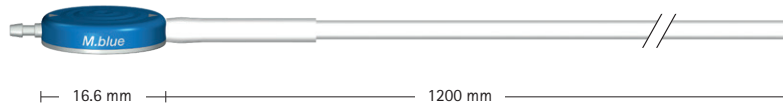
Ordering Information

M.blue™ SHUNT SYSTEM
valve with distal catheter
(1200 mm)

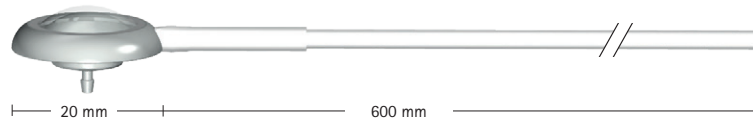
SPRUNG RESERVOIR
with distal catheter (600 mm)

** An additional valve in the inlet of the *SPRUNG RESERVOIR* makes it possible to pump cerebrospinal fluid in the direction of drainage only, allowing inspection of both the distal drainage section as well as the ventricular catheter.

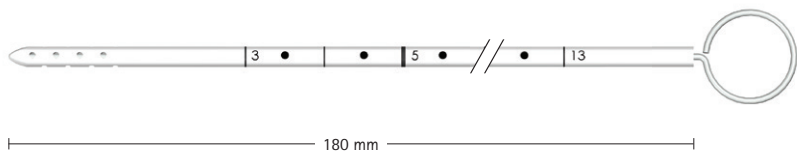
Ventricular catheter with
introducing stylet (180 mm)



16.6 mm 1200 mm



20 mm 600 mm



180 mm

M.blue

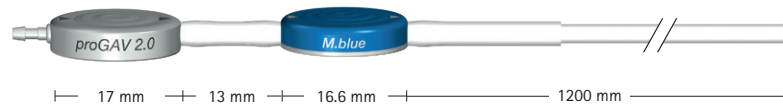
Order	Differential pressure unit	Adjustable gravitational unit
FX840T	0 cmH ₂ O	0 - 40 cmH ₂ O
FX841T	5 cmH ₂ O	0 - 40 cmH ₂ O
FX842T	10 cmH ₂ O	0 - 40 cmH ₂ O
FX843T	15 cmH ₂ O	0 - 40 cmH ₂ O

M.blue plus™ SHUNT SYSTEM
valve with distal catheter
(1200 mm)

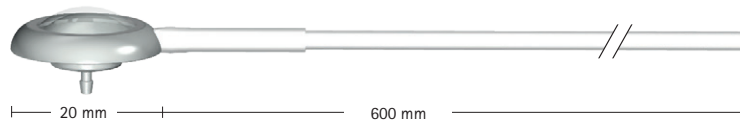
SPRUNG RESERVOIR
with distal catheter (600 mm)

** An additional valve in the inlet of the *SPRUNG RESERVOIR* makes it possible to pump cerebrospinal fluid in the direction of drainage only, allowing inspection of both the distal drainage section as well as the ventricular catheter.

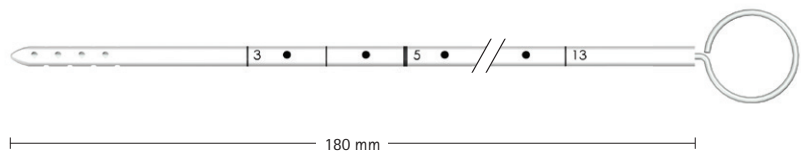
Ventricular catheter with
introducing stylet (180 mm)



17 mm 13 mm 16.6 mm 1200 mm



20 mm 600 mm

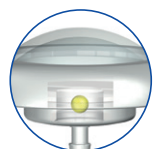


180 mm

M.blue plus

Order	Adj. differential pressure unit	Adjustable gravitational unit
FX844T	0 - 20 cmH ₂ O	0 - 40 cmH ₂ O

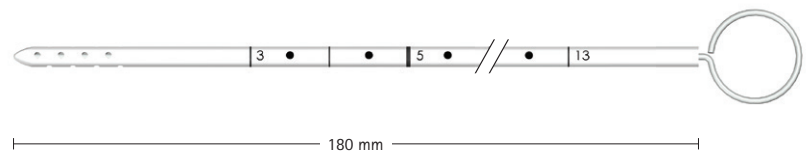
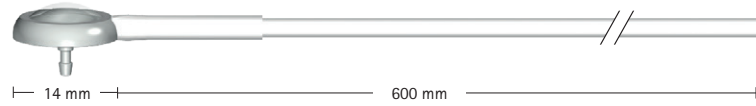
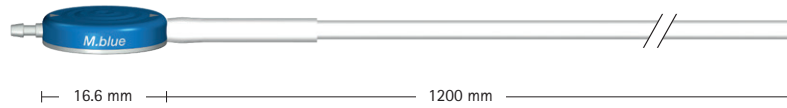
*SPRUNG RESERVOIR***



M.blue™ SHUNT SYSTEM
valve with burrhole reservoir
and distal catheter (1200 mm)

pediatric
burrhole reservoir
with distal catheter (600 mm)

Ventricular catheter with
introducing stylet (180 mm)



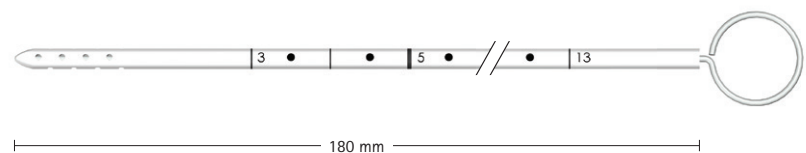
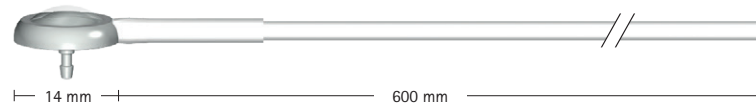
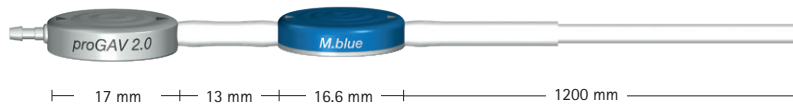
M.blue

Order	Differential pressure unit	Adjustable gravitational unit
FX845T	0 cmH ₂ O	0 - 40 cmH ₂ O
FX846T	5 cmH ₂ O	0 - 40 cmH ₂ O
FX847T	10 cmH ₂ O	0 - 40 cmH ₂ O
FX848T	15 cmH ₂ O	0 - 40 cmH ₂ O

M.blue plus™ SHUNT SYSTEM
valve with burrhole reservoir
and distal catheter (1200 mm)

pediatric
burrhole reservoir
with distal catheter (600 mm)

Ventricular catheter with
introducing stylet (180 mm)



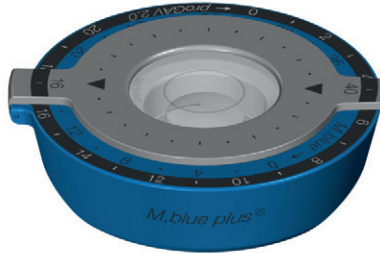
M.blue plus

Order	Adj. differential pressure unit	Adjustable gravitational unit
FX849T	0 - 20 cmH ₂ O	0 - 40 cmH ₂ O

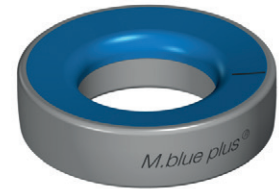
Ordering Information

M.blue™ *Soft Touch Instruments*

- *M.blue plus™* compass
- *M.blue plus* adjustment ring
- *M.blue plus* adjustment assistant
- *M.blue* check-mate



M.blue plus compass



M.blue plus adjustment ring



M.blue plus adjustment assistant



M.blue check-mate

Order	Instruments
FX890T	<i>M.blue plus</i> instrument set (includes FX891T and FX892T)
FX891T	<i>M.blue plus</i> compass
FX892T	<i>M.blue plus</i> adjustment ring
FX893T	<i>M.blue plus</i> adjustment assistant
FX894T	<i>M.blue</i> adjustment check-mate

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Notes

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