



M.blue[®]

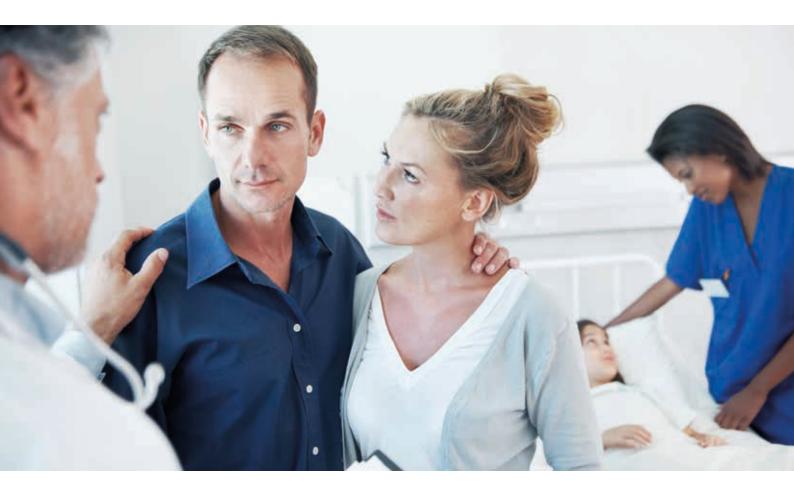
THE BALANCED WAY OF LIFE. INSPIRED BY YOU.



M.blue[®]

The balanced way of life. Inspired by you.

TREATMENT OF HYDROCEPHALUS NEED FOR ACTION

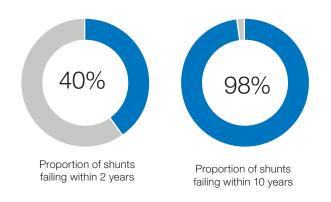


WHY DOES IT NEED BETTER SOLUTIONS FOR THE TREATMENT OF HYDROCEPHALUS?

Since the 1960s, the main 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 complications (1, 2) with no difference between different conventional valves and programmable valves (4, 5). Overdrainage-related complications can necessitate a variety of different revisions, which are burdensome for patients and are accompanied by unavoidable perioperative risks.

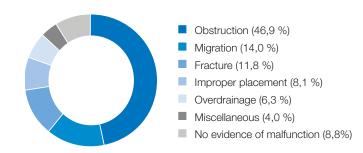
We believe that the current treatment situation for hydrocephalus is not acceptable and better solutions have to be found.

HIGH FAILURE RATES



» High failure rates overshadow the effectiveness of shunts (3). «

COMPLICATIONS (3)



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

MECHANICAL FAILURE

Mechanical failure is the most common cause of multiple shunt revisions (6), with catheter or valve obstruction being the predominant reason (3). However, failure of individual shunt components may also occur, e.g., at stress points or due to poor design (7).







Obstruction

Catheter breakage

Catheter fracture





Catheter separation

Damaged housing

Valve migration

WHAT COULD BE BETTER?

Active patients are exposed to gravity for up to 16 hours, every day. Posture-dependent gravitational effects increase the potential for overdrainage. Overcoming these gravitational effects can help to improve patient outcomes.

NO TWO PATIENTS ARE ALIKE!

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



ARE PATIENTS GETTING OPTIMAL INDIVIDUAL TREATMENT?

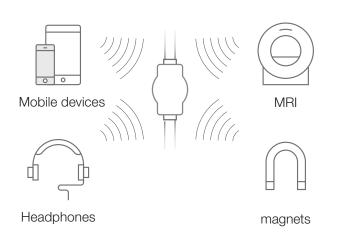
Determining the patient-individual setting of the valve opening pressure can be complex. Non-ideal pressure settings can lead to follow-up examinations and revisions, which are burdensome for patients and put an additional strain on physicians and surgeons with limited time and high workload (13, 14).

ARE ADJUSTABLE DIFFERENTIAL PRESSURE VALVES THE BEST AVAILABLE THERAPIE?

The pressure setting of conventional adjustable valves is always 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.

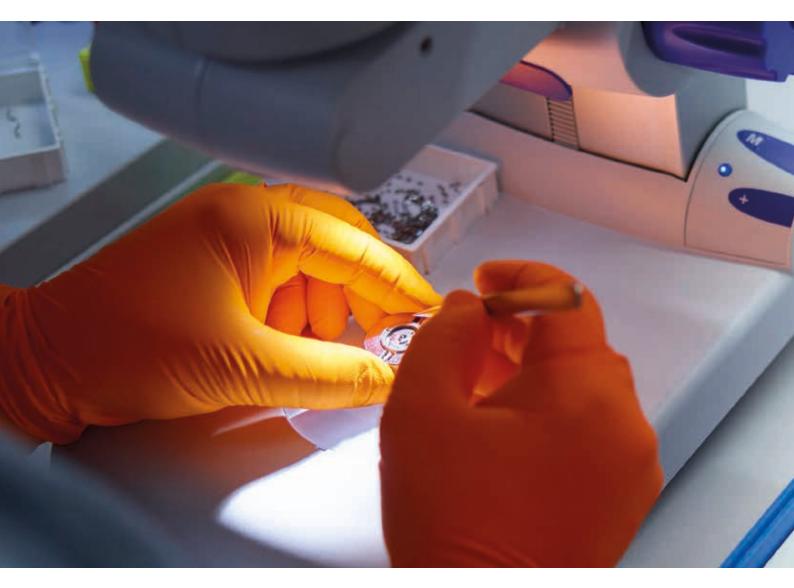
ACCIDENTAL REPROGRAMMING

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 smartphones, is a cause of concern and leads to great uncertainty among patients and doctors (8-12).



GRAVITATIONAL VALVES BY MIETHKE

DEVELOPED TO ENSURE SAFETY



BE CONFIDENT!

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.

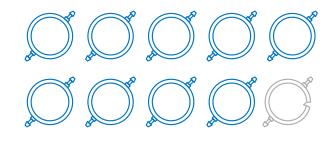
GV		62%
DP	25%	



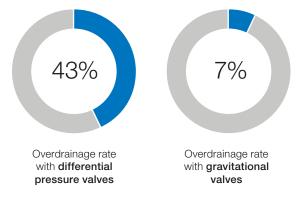


REDUCE COMPLICATIONS! REDUCE REVISIONS!

Clinical studies have shown that MIETHKE gravitational devices reduce the risk of revisions (17-21) and overdrainage complications (18).



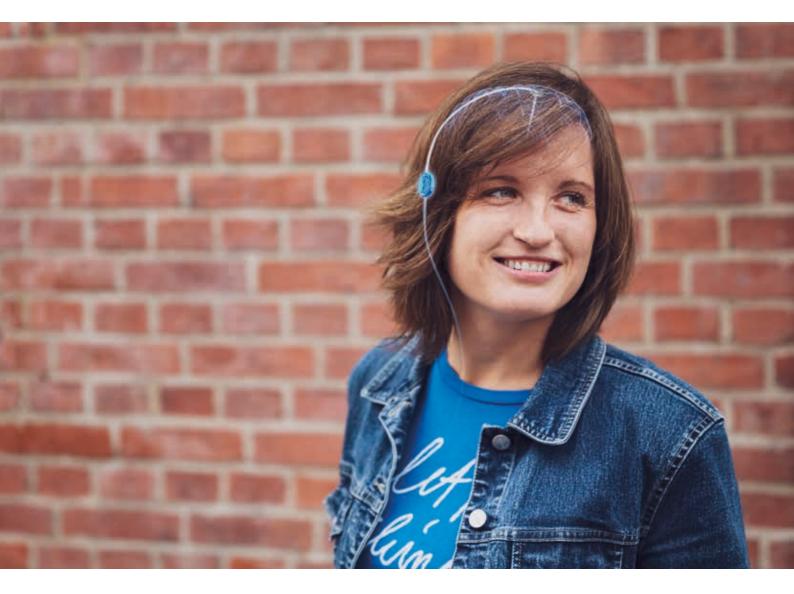
» Valve survival rates up to 90 % at 12 months (19). «



» Implanting a gravitational valve avoids one additional overdrainage complication in about every third patient (18). «

GRAVITATIONAL VALVES BY MIETHKE

DEVELOPED TO ENSURE SAFETY

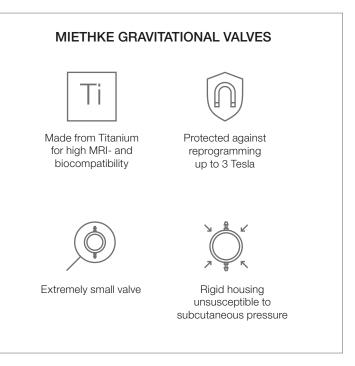


AVOID MECHANICAL FAILURE!

All MIETHKE valves are manufactured with high precision from titanium. The extremely small valves have aligned 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).



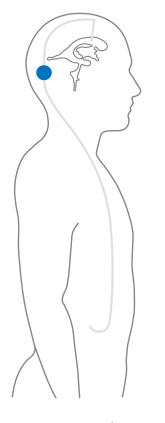
BENEFIT FROM PRIMARY IMPLANTATION (23)!

GET IT RIGHT THE FIRST TIME!

Early treatment with the optimal therapy is important for patients with hydrocephalus (23, 24) and can also help to avoid shunt replacements and associated perioperative risks.

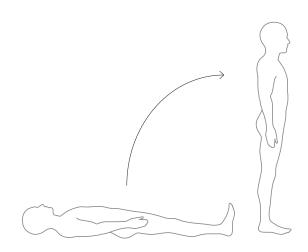
OPTIMIZE – DON'T COMPROMISE!

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.



22 %

higher survival of gravitational valves after primary vs secondary implantation



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

$M.blue^{\circ}$ our latest generation of valve technology

M.blue[®] is the essence of 26 years of experience with hydrocephalus and valve technology and the feedback of numerous physicians and patients worldwide. *M.blue*[®] is a valve for all forms of hydrocephalus with a particularly high flexibility in therapy. Particularly challenging and difficult characteristics of hydrocephalus require a much higher flexibility in the treatment. This is what *M.blue plus*[®] stands for: a combination of an adjustable gravitational unit and adjustable differential pressure unit *proGAV* [®]2.0.

- + ONE valve for the special requirements of a life with hydrocephalus: mobility, growth, changes in the course of disease
- + 2 in 1 technology: adjustable gravitational unit combined with fixed differential pressure unit in one valve
- + Unique uncompromising pressure adaption to fulfill individual patient needs
- + Smallest adjustable gravitational valve worldwide
- Efficient protection against overdrainage through individually and continuously adjustable opening pressure from 0-40 cmH₂O
- MRI-compatible 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, induction cookers and safety barriers at the 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 plus®

$M.blue^{\rm B}$ functionality of valve and position of the body



ADJUSTABLE GRAVITATIONAL UNIT

Sapphire ball Tantalum weight Rotor

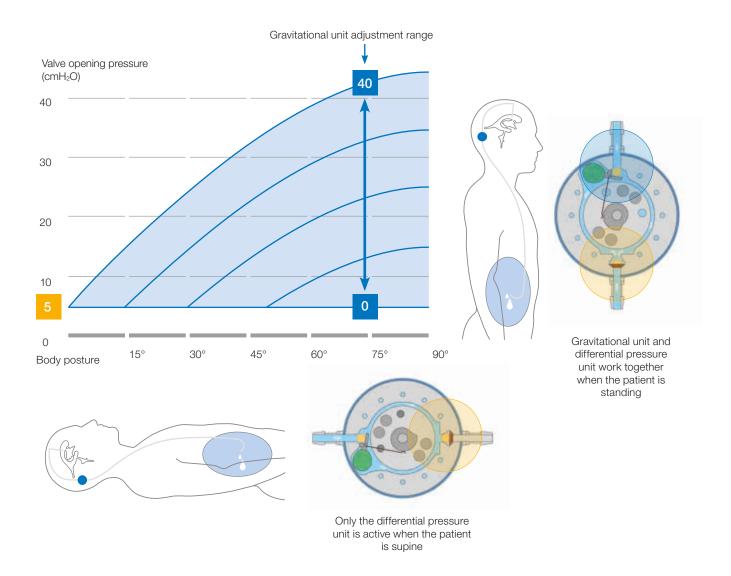
DIFFERENTIAL PRESSURE UNIT

Sapphire ball Microspiral spring



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

EXAMPLE OF THE ADJUSTABLE GRAVITATIONAL PRESSURE RANGE OF A $\it M.blue^{\circledast}$ WITH A DIFFERENTIAL PRESSURE UNIT OF 5 CMH_2O



M.blue[®] is a hydrocephalus valve operating in a positiondependent 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[®] soft touch instrument functionality

USER-FRIENDLY ADJUSTMENT AND VERIFICATION

M.blue plus[®] instruments allow users to measure, verify, and adjust the pressure level on *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 *M.blue plus*[®]. The instruments offer simple steps for the physician and make the adjustment process comfortable for patients.





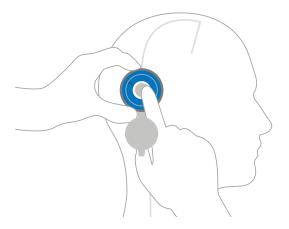
LOCATE

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



VERIFY

Close *M.blue plus®* 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.

$M.blue^{\circ}$ pressure level recommendations and radiographic identification

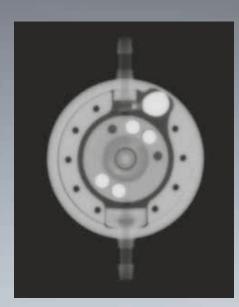
Patient	Selection of press	ure levels	Combined opening	ng pressure
	Differential pressure unit	Adjustable gravitational unit		
lewborns and O hildren under 5		20		25
hildren ages		25		30
dults		25		30
1,60 m	5*	20	5*	25
1,80 m		30		35
dults		20	-	25
65 years		15		20
> 1,80 m		25		30

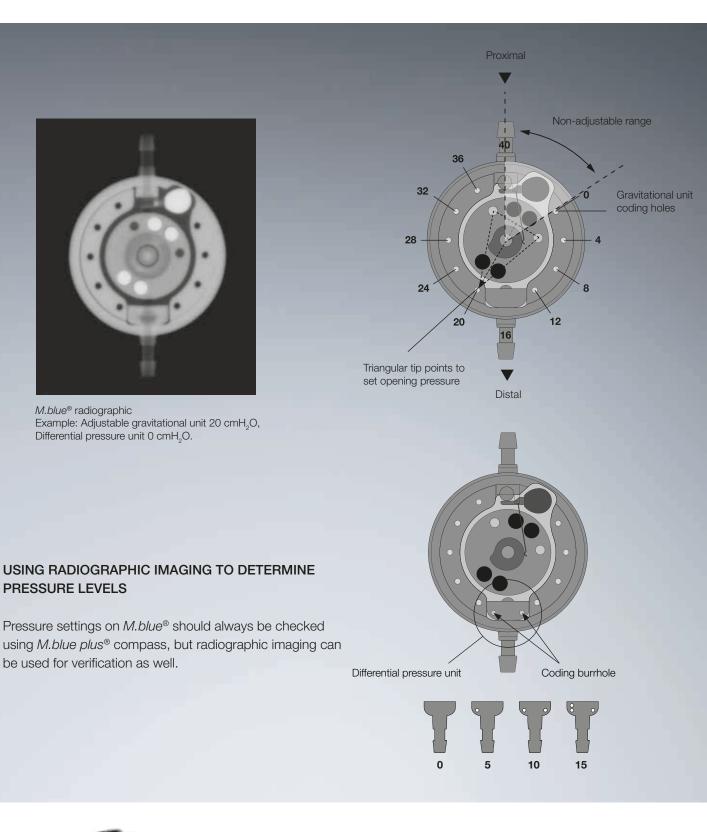
All of the pressure levels shown here are given in cmH_20 . These recommendations are non-binding. The treating physician will need to decide each case individually.

* As special configurations in addition to the standard configuration the *M.blue*[®] is also available with differential pressure units with pressure levels 0, 10, 15 cmH₂0. In case of *M.blue plus*[®] the opening pressure of the differential pressure unit (*proGAV 2.0*[®]) is adjustable from 0-20 cmH₂0.

PRESSURE LEVEL RECOMMENDATION

The choice of the appropriate pressure level of *M.blue*[®] depends on several 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.



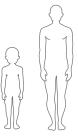


M.blue[®] radiographic Example: Adjustable gravitational unit 20 cmH $_2$ O, Differential pressure unit 0 cmH $_2$ O.

PRESSURE LEVELS

be used for verification as well.

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



+ M.blue[®] valve

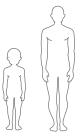


Diameter connector: 1.9 mm Recommended cather diameters: Inner diameter: 1.2 mm Outer diameter: 2.5 mm

M.blue®		
Art. no	Differential pressure unit	Adjustable gravitational unit*
FX800T	0 cmH₂O	0 - 40 cmH ₂ O
FX801T	5 cmH₂O	0 - 40 cmH ₂ O
FX802T	10 cmH ₂ O	0 - 40 cmH ₂ O
FX803T	15 cmH₂O	0 - 40 cmH ₂ O

 $^{\star}\,$ preset to 20 cmH_2O

M.blue plus®



+ M.blue plus® valve



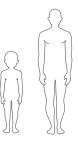
⊢ 17 mm → 13 mm → 16,6 mm →

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

M.blue plus®		
Art. no	Adj. differential pressure unit*	Adjustable gravitational unit**
FX804T	0 - 20 cmH ₂ O	0 - 40 cmH₂O

* preset to 5 cmH₂O ** preset to 20 cmH₂O

M.blue® with catheter



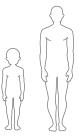
+ *M.blue*[®] valve with distal catheter



M.blue [®]		
Art. no	Differential pressure unit	Adjustable gravitational unit*
FX805T	0 cmH₂O	0 - 40 cmH ₂ O
FX806T	5 cmH₂O	0 - 40 cmH ₂ O
FX807T	10 cmH₂O	0 - 40 cmH ₂ O
FX808T	15 cmH₂O	0 - 40 cmH ₂ O

 $^{\star}\,$ preset to 20 cmH_2O

M.blue plus® WITH CATHETER



+ *M.blue plus*[®] valve with distal catheter

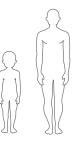


⊢ 17 mm → 13 mm → 16,6 mm → — 1200 mm —

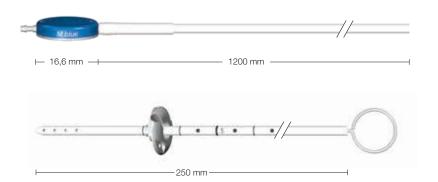
Adj. differential pressure unit*	Adjustable gravitational unit**
0 - 20 cmH ₂ O	0 - 40 cmH ₂ O
	pressure unit*

* preset to 5 cmH₂O ** preset to 20 cmH₂O

M.blue® shunt system



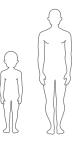
- + *M.blue*[®] valve with distal catheter
- + Ventricular catheter with introducing stylet and pediatric deflector (13 mm)



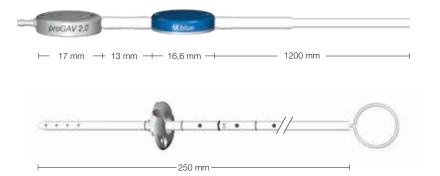
M.blue [®]		
Art. no	Differential pressure unit	Adjustable gravitational unit*
FX810T	0 cmH₂O	0 - 40 cmH ₂ O
FX811T	5 cmH₂O	0 - 40 cmH ₂ O
FX812T	10 cmH ₂ O	0 - 40 cmH ₂ O
FX813T	15 cmH ₂ O	0 - 40 cmH ₂ O

 * preset to 20 cmH₂O

M.blue plus® SHUNT SYSTEM



- + *M.blue plus*[®] valve with distal catheter
- + Ventricular catheter with introducing stylet and pediatric deflector (13 mm)

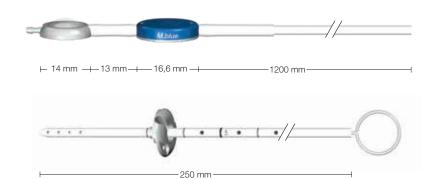


M.blue plus®		
Art. no	Adj. differential pressure unit*	Adjustable gravitational unit**
FX814T	0 - 20 cmH₂O	0 - 40 cmH₂O

* preset to 5 cmH₂O ** preset to 20 cmH₂O

M.blue[®] shunt system with pediatric control reservoir

- *M.blue*[®] valve with integrated pediatric CONTROL RESERVOIR and distal catheter
- + Ventricular catheter with introducing stylet and pediatric deflector (13 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.





pediatric CONTROL RESERVOIR*

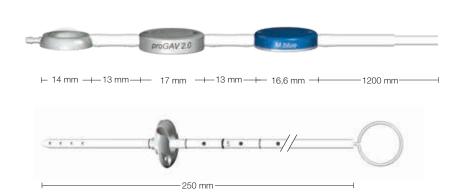
M.blue®	
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Art. no	Differential pressure unit	Adjustable gravitational unit**
FX815T	0 cmH₂O	0 - 40 cmH ₂ O
FX816T	5 cmH₂O	0 - 40 cmH ₂ O
FX817T	10 cmH₂O	0 - 40 cmH ₂ O
FX818T	15 cmH ₂ O	0 - 40 cmH ₂ O

** preset to 20 cmH2O

M.blue plus® SHUNT SYSTEM WITH PEDIATRIC CONTROL RESERVOIR

- + *M.blue plus*[®] valve with integrated pediatric CONTROL RESERVOIR and distal catheter
- + Ventricular catheter with introducing stylet and pediatric deflector (13 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.





pediatric CONTROL RESERVOIR*

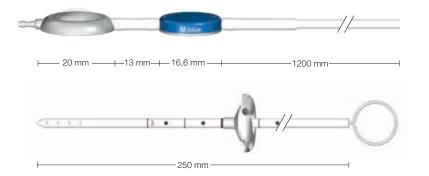
M.blue plus®		
Art. no	Adj. differential pressure unit**	Adjustable gravitational unit***
FX819T	0 - 20 cmH₂O	0 - 40 cmH ₂ O

** preset to 5 cmH₂O *** preset to 20 cmH₂O

M.blue[®] **SHUNT SYSTEM WITH** CONTROL RESERVOIR



- + *M.blue*[®] valve with integrated *CONTROL RESERVOIR* and distal catheter
- Ventricular catheter with introducing stylet and deflector (16 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.





CONTROL RESERVOIR*

M.blue®

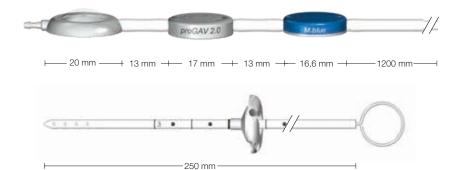
Art. no	Differential pressure unit	Adjustable gravitational unit**
FX820T	0 cmH₂O	0 - 40 cmH ₂ O
FX821T	5 cmH₂O	0 - 40 cmH ₂ O
FX822T	10 cmH₂O	0 - 40 cmH ₂ O
FX823T	15 cmH₂O	0 - 40 cmH ₂ O

** preset to 20 cmH₂O

M.blue plus® SHUNT SYSTEM WITH CONTROL RESERVOIR



- + M.blue plus® valve with integrated CONTROL RESERVOIR and distal catheter
- Ventricular catheter with + introducing stylet and deflector (16 mm)
- An additional valve in the inlet of the CONTROL RESERVOIR makes it possible to pump cere-brospinal fluid in the direction of drainage only, * allowing inspection of both the distal drainage section as well as the ventricular catheter.





CONTROL RESERVOIR*

M.blue plus®		
Art. no	Adj. differential pressure unit**	Adjustable gravitational unit***
FX824T	0 - 20 cmH ₂ O	0 - 40 cmH₂O

 ** preset to 5 cmH_2O *** preset to 20 cmH_2O

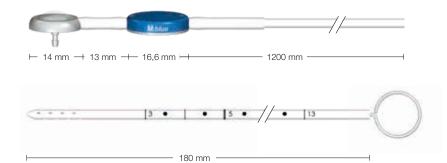
M.blue[®] shunt system with pediatric *sprung reservoir*

OCCIPITAL ONLY

- *M.blue*[®] valve with integrated pediatric SPRUNG RESERVOIR* and distal catheter
- + Ventricular catheter with introducing stylet
- * 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.



pediatric SPRUNG RESERVOIR*

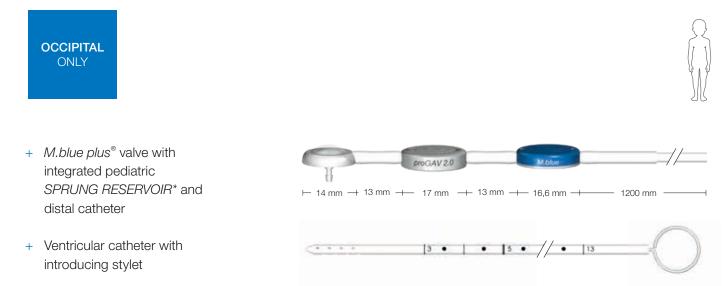


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Art. no	Differential pressure unit	Adjustable gravitational unit**
FX825T	0 cmH₂O	0 - 40 cmH ₂ O
FX826T	5 cmH₂O	0 - 40 cmH ₂ O
FX827T	10 cmH₂O	0 - 40 cmH ₂ O
FX828T	15 cmH₂O	0 - 40 cmH ₂ O

** preset to 20 cmH₂O

M.blue plus® SHUNT SYSTEM WITH PEDIATRIC SPRUNG RESERVOIR



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.



pediatric SPRUNG RESERVOIR*

M.blue plus®		
Art. no	Adj. differential pressure unit**	Adjustable gravitational unit***
FX829T	0 - 20 cmH ₂ O	0 - 40 cmH ₂ O

180 mm

** preset to 5 cmH₂O *** preset to 20 cmH₂O

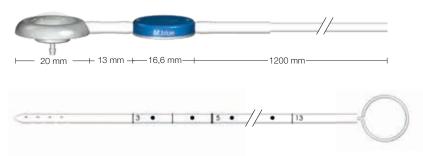
M.blue[®] **SHUNT SYSTEM WITH** SPRUNG RESERVOIR



- *M.blue*[®] valve with integrated SPRUNG
 RESERVOIR and distal catheter
- + Ventricular catheter with introducing stylet
- * 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.



SPRUNG RESERVOIR*



------ 180 mm -

M.blue®	

miniae		
Art. no	Differential pressure unit	Adjustable gravitational unit**
FX830T	0 cmH₂O	0 - 40 cmH ₂ O
FX831T	5 cmH₂O	0 - 40 cmH ₂ O
FX832T	10 cmH₂O	0 - 40 cmH₂O
FX833T	15 cmH₂O	0 - 40 cmH₂O

** preset to 20 cmH₂O

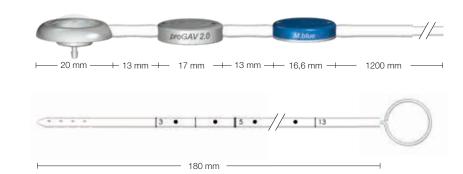
M.blue plus® SHUNT SYSTEM WITH SPRUNG RESERVOIR



- + M.blue plus[®] valve with integrated SPRUNG RESERVOIR and distal catheter
- + Ventricular catheter with introducing stylet
- 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.



SPRUNG RESERVOIR*



M.blue plus®		
Art. no	Adj. differential pressure unit**	Adjustable gravitational unit***
FX834T	0 - 20 cmH₂O	0 - 40 cmH ₂ O

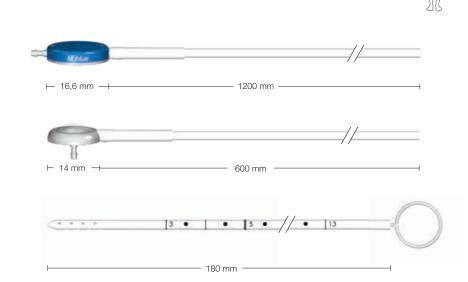
** preset to 5 cmH₂O *** preset to 20 cmH₂O

M.blue[®] shunt system with pediatric *sprung reservoir*

- + *M.blue*[®] valve with distal catheter
- + Pediatric SPRUNG RESERVOIR* with distal catheter
- + Ventricular catheter with introducing stylet
- * 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.



pediatric SPRUNG RESERVOIR*



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Art. no	Differential pressure unit	Adjustable gravitational unit**
FX835T	0 cmH₂O	0 - 40 cmH ₂ O
FX836T	5 cmH₂O	0 - 40 cmH ₂ O
FX837T	10 cmH₂O	0 - 40 cmH ₂ O
FX838T	15 cmH₂O	0 - 40 cmH ₂ O

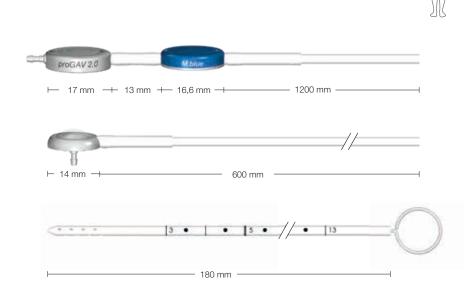
** preset to 20 cmH₂O

M.blue plus® SHUNT SYSTEM WITH PEDIATRIC SPRUNG RESERVOIR

- + *M.blue plus*[®] valve with distal catheter
- Pediatric SPRUNG RESERVOIR* + with distal catheter
- Ventricular catheter with + introducing stylet
- 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.



pediatric SPRUNG RESERVOIR*



M.blue plus®		
Art. no	Adj. differential pressure unit**	Adjustable gravitational unit***
FX839T	0 - 20 cmH₂O	0 - 40 cmH₂O

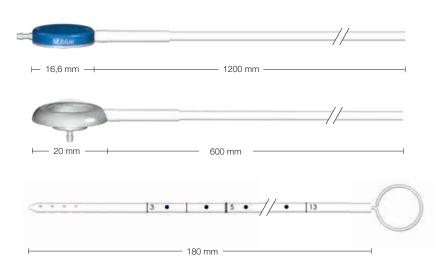
** preset to 5 cmH₂O *** preset to 20 cmH₂O

M.blue[®] **SHUNT SYSTEM WITH** SPRUNG RESERVOIR

- + *M.blue*[®] valve with distal catheter
- + SPRUNG RESERVOIR* with distal catheter
- + Ventricular catheter with introducing stylet
- * 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.



SPRUNG RESERVOIR*



M.blue [®]		
Art. no	Differential pressure unit	Adjustable gravitational unit**
FX840T	0 cmH₂O	0 - 40 cmH ₂ O
FX841T	5 cmH₂O	0 - 40 cmH ₂ O
FX842T	10 cmH ₂ O	0 - 40 cmH ₂ O
FX843T	15 cmH₂O	0 - 40 cmH ₂ O

** preset to 20 cmH₂O

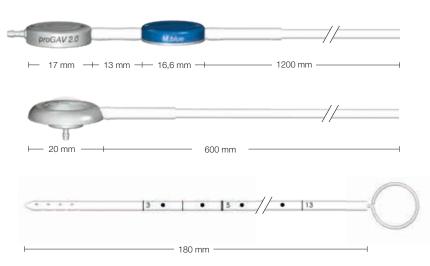
M.blue plus® SHUNT SYSTEM WITH SPRUNG RESERVOIR



- + *M.blue plus*[®] valve with distal catheter
- SPRUNG RESERVOIR* with + distal catheter
- + Ventricular catheter with introducing stylet
- An additional valve in the inlet of the *SPRUNG RESERVOIR* makes it possible to pump cere-brospinal fluid in the direction of drainage only, * allowing inspection of both the distal drainage section as well as the ventricular catheter.



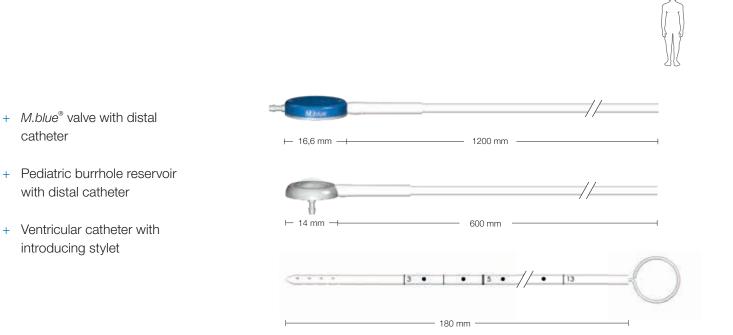
SPRUNG RESERVOIR*



M.blue plus®		
Art. no	Adj. differential pressure unit**	Adjustable gravitational unit***
FX844T	0 - 20 cmH₂O	0 - 40 cmH₂O

** preset to 5 cmH₂O *** preset to 20 cmH₂O

$M.blue^{\circ}$ shunt system with pediatric burrhole reservoir



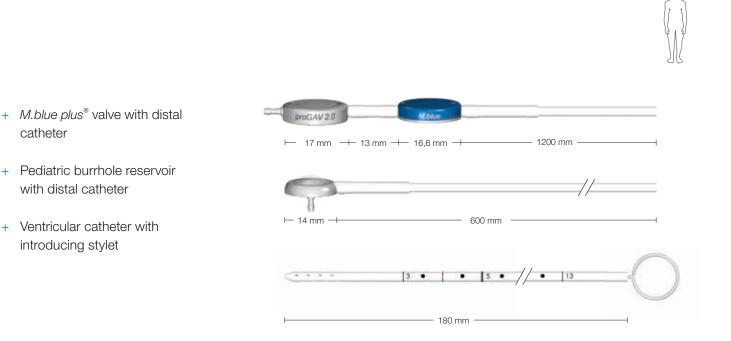
M.blue®		
Art. no	Differential pressure unit	Adjustable gravitational unit*
FX845T	0 cmH₂O	0 - 40 cmH ₂ O
FX846T	5 cmH₂O	0 - 40 cmH ₂ O
FX847T	10 cmH ₂ O	0 - 40 cmH ₂ O
FX848T	15 cmH ₂ O	0 - 40 cmH ₂ O

* preset to 20 cmH₂O

M.blue plus® SHUNT SYSTEM WITH PEDIATRIC BURRHOLE RESERVOIR

catheter

+

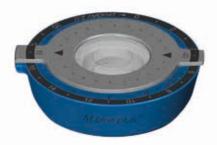


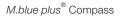
M.blue plus®		
Art. no	Adj. differential pressure unit*	Adjustable gravitational unit**
FX849T	0 - 20 cmH ₂ O	0 - 40 cmH₂O

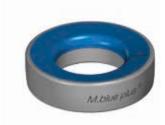
* preset to 5 cmH₂O ** preset to 20 cmH₂O

M.blue plus® Instruments

- + M.blue plus[®] Instruments Set
- + M.blue plus[®] Compass
- + M.blue plus® Adjustment Ring
- + M.blue plus® Adjustment Assistant
- + M.blue® Checkmate







M.blue plus® Adjustment Ring



M.blue plus[®] Adjustment Assistant



M.blue[®] Checkmate

M.blue [®]	
Art. no.	Instruments
FX890T	<i>M.blue plus</i> [®] Instruments Set (contains FX891T and FX892T)
FX891T	M.blue plus® Compass
FX892T	M.blue plus® Adjustment Ring
FX893T	M.blue plus® Adjustment Assistant
FX894T	M.blue [®] Checkmate

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Manufacturer: Christoph Miethke GmbH & Co. KG | Ulanenweg 2 | 14469 Potsdam | Germany Tel. +49 331 62 083-0 | Fax +49 331 62 083-40 | www.miethke.com

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