





WE UNDERSTAND.

**NEUROSURGERY** 

M.blue®

THE BALANCED WAY OF LIFE. INSPIRED BY YOU.

# TREATMENT OF HYDROCEPHALUS

### **NEED FOR ACTION**

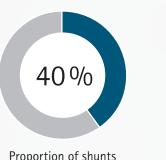
# WHY DOES IT NEED BETTER SOLUTIONS FOR THE TREATMENT OF HYDROCEPHALUS?

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

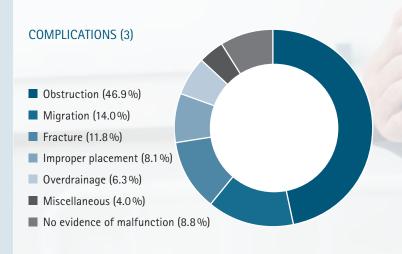




Proportion of shunts failing within 2 years

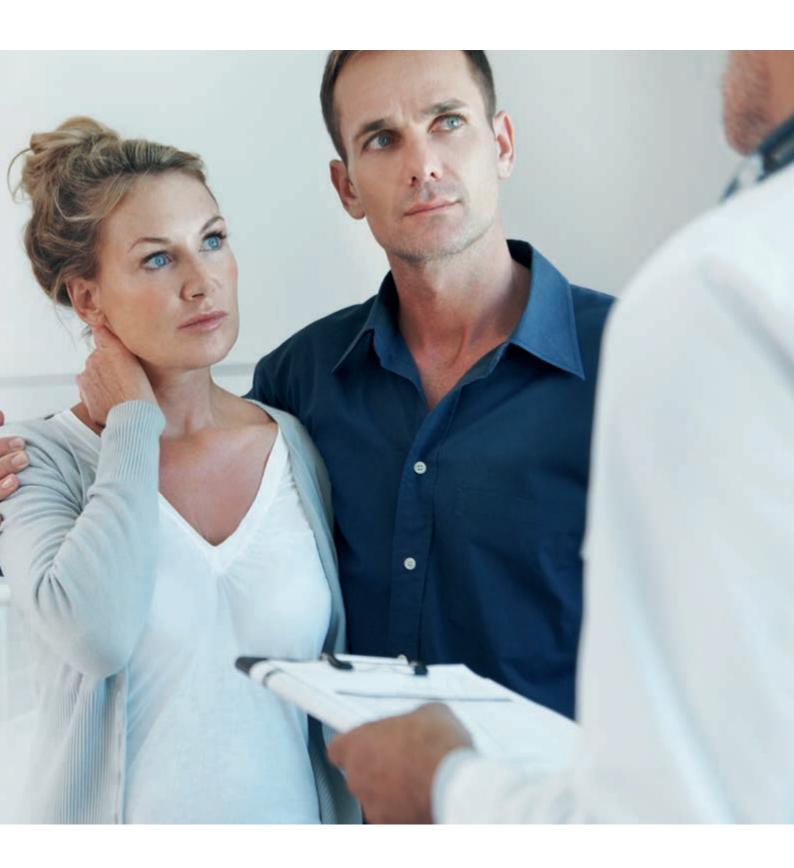
.

) High failure rates overshadow the effectiveness of shunts (1).



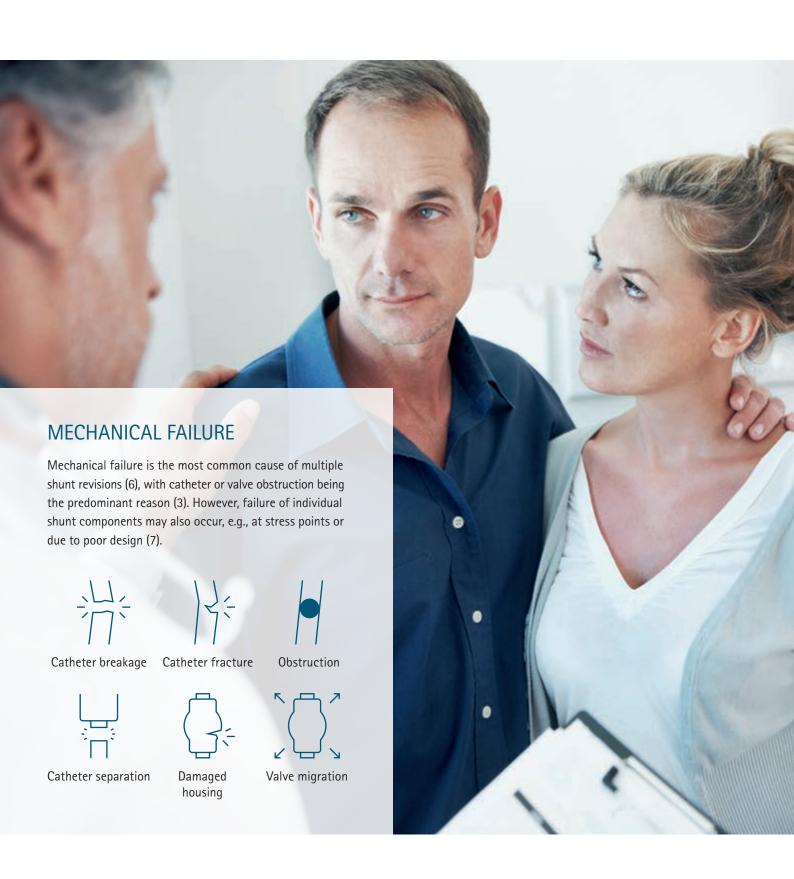
**»** About one in four patients experiences at least one complication (2).





# TREATMENT OF HYDROCEPHALUS

**NEED FOR ACTION** 



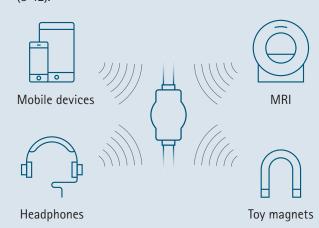






# ACCIDENTAL REPROGRAMMING

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).



# TREATMENT OF HYDROCEPHALUS

**NEED FOR ACTION** 

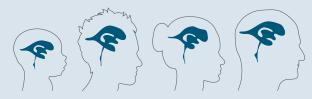






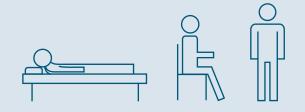
## NO TWO PATIENTS ARE ALIKE!

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.

# GRAVITATIONAL VALVES BY MIETHKE

**DEVELOPED TO ENSURE SAFETY** 

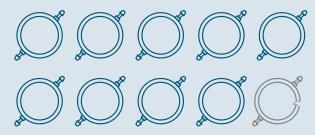




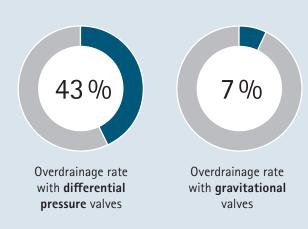


# REDUCE COMPLICATIONS! REDUCE REVISIONS!

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



Walve 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)!



22%

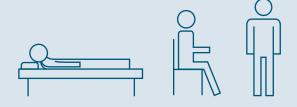
higher survival of gravitational valves after **primary** vs secondary implantation

### 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.

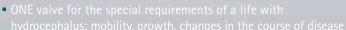
### OPTIMIZE - DON'T COMPROMISE!

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.



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

### OUR LATEST GENERATION OF VALVE TECHNOLOGY



- 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 cmH<sub>2</sub>C
- 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





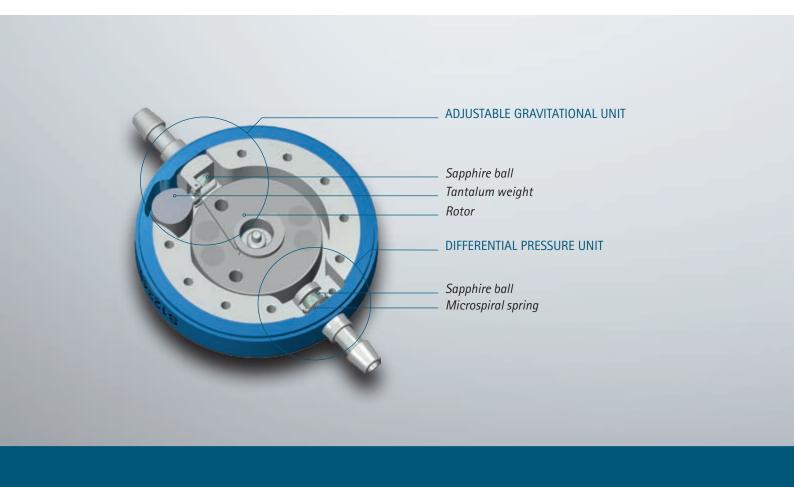




*M.blue*° is the essence of 26 years of experience with hydrocephalus and valve technology and the feedback of numerous physicians and patients worldwide.

*M.blue*° is a valve for all forms of hydrocephalus with a particularly high flexibility in therapy.

# FUNCTIONALITY OF VALVE AND POSITION OF THE BODY



The functionality of  $\textit{M.blue}^{\circ}$  is illustrated interactively in the MIETHKE app.

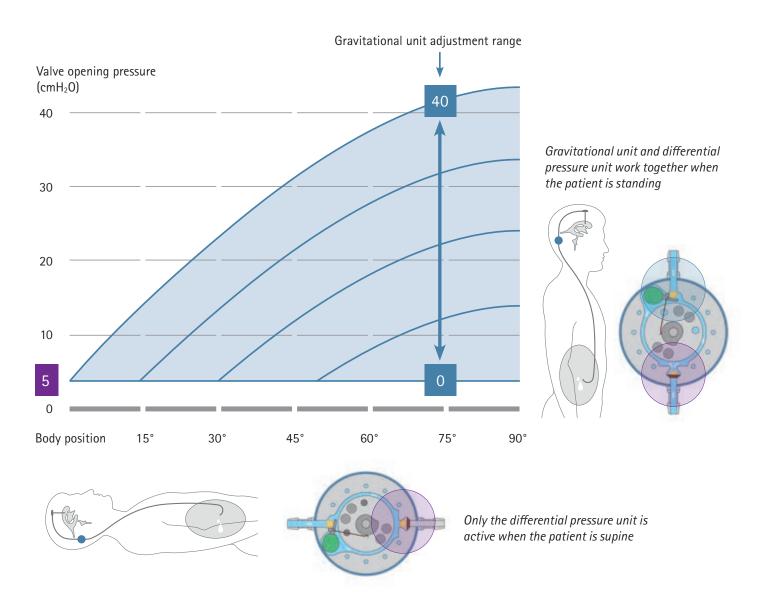
APP DOWNLOAD

https://apps.apple.com/de/app/miethke/id450290015 https://play.google.com/store/apps/details?id=com.miethke.graviton





# EXAMPLE OF THE ADJUSTABLE GRADUATED PRESSURE RANGE OF A M.blue® WITH A DIFFERENTIAL PRESSURE UNIT OF 5 CMH<sub>2</sub>O



*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

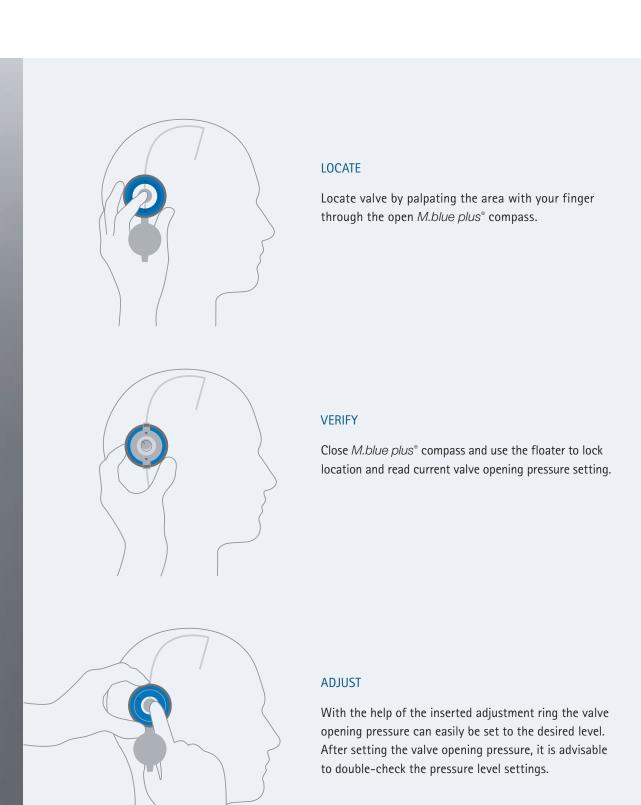
## SOFT TOUCH INSTRUMENT FUNCTIONALITY

### LISER-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 cm $\rm H_2O$ ) 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.









# PRESSURE LEVEL RECOMMENDATIONS AND RADIOGRAPHIC IDENTIFICATION

Patient	Selection of pressure	levels	Combined opening pro	essure
	1)—	-2		
	1 Differential pressure unit	2 Adjustable gravitational unit		
Newborns and Children under 5		20		25
Children ages 5 and up		25		30
Adults (1.60 m	5	25 20	5	30 25
> 1.80 m	5	30	J	35
Adults > 65 years < 1.60 m		20 15		25 20
> 1.80 m		25		30

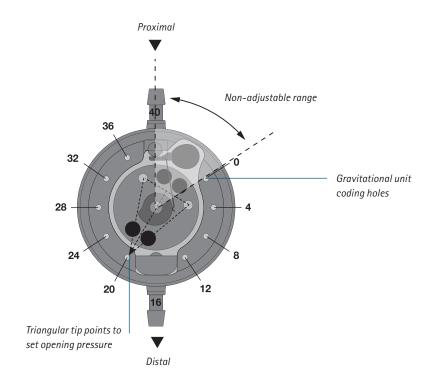
All of the pressure levels shown here are given in cmH<sub>2</sub>0. These recommendations are non-binding. The treating physician will need to decide each case individually.

### PRESSURE LEVEL RECOMMENDATION

The choice of the appropriate pressure level of *M.blue*° depends on 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.





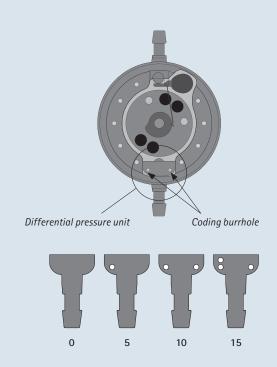


# USING RADIOGRAPHIC IMAGING TO DETERMINE PRESSURE LEVELS

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

All of the pressure levels shown here are given in cmH<sub>2</sub>0.

X-ray recognition and product information can be found in the free MIETHKE App.



# M.blue® SINGLE VALVE

■ *M.blue*® valve

☐ 4.2 mm ☐ 4.2 mm

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

Art. no.	Differential pressure unit	Adjustable gravitational unit
FX800T	$0 \text{ cmH}_2\text{O}$	$0 - 40 \text{ cmH}_2\text{O}$
FX801T	5 cmH <sub>2</sub> O	0 - 40 cmH <sub>2</sub> 0
FX802T	10 cmH₂0	0 - 40 cmH <sub>2</sub> 0
FX803T	15 cmH₂0	0 - 40 cmH <sub>2</sub> 0

# M.blue plus® VALVE COMBINATION



■ M.blue plus® valve



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

Art. no.	Adj. differential pressure unit	Adjustable gravitational unit
FX804T	0 - 20 cmH₂O	0 - 40 cmH <sub>2</sub> 0

# INDIVIDUAL VALVE WITH CATHETER

 M.blue® valve with distal catheter



Art. no.	Differential pressure unit	Adjustable gravitational unit
FX805T	0 cmH <sub>2</sub> 0	0 - 40 cmH <sub>2</sub> 0
FX806T	5 cmH <sub>2</sub> O	0 - 40 cmH <sub>2</sub> 0
FX807T	10 cmH <sub>2</sub> 0	0 - 40 cmH <sub>2</sub> 0
FX808T	15 cmH₂0	0 - 40 cmH <sub>2</sub> 0

# M.blue plus® VALVE COMBINATION



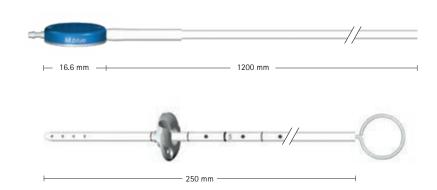
 M.blue plus® valve with distal catheter



Art. no.	Adj. differential pressure unit	Adjustable gravitational unit
FX809T	0 - 20 cmH <sub>2</sub> 0	0 - 40 cmH <sub>2</sub> 0

# M.blue® SHUNT SYSTEM

- M.blue® valve with distal catheter
- Ventricular catheter with introducing stylet and pediatric burrhole deflector (14 mm)

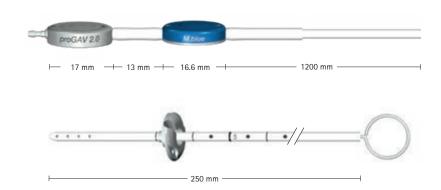


Art. no.	Differential pressure unit	Adjustable gravitational unit
FX810T	$0 \text{ cmH}_2\text{O}$	$0 - 40 \text{ cmH}_2\text{O}$
FX811T	5 cmH <sub>2</sub> O	0 - 40 cmH <sub>2</sub> 0
FX812T	10 cmH₂0	0 - 40 cmH <sub>2</sub> 0
FX813T	15 cmH₂0	0 - 40 cmH <sub>2</sub> 0

# M.blue plus® SHUNT SYSTEM



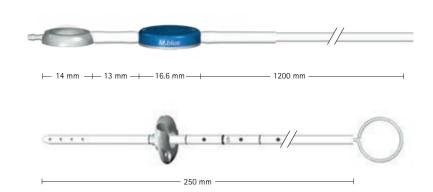
- M.blue plus® valve with distal catheter
- Ventricular catheter with introducing stylet and pediatric burrhole deflector (14 mm)



Art. no.	Adj. differential pressure unit	Adjustable gravitational unit
FX814T	0 - 20 cmH₂O	0 - 40 cmH <sub>2</sub> 0

# SHUNT SYSTEM WITH PEDIATRIC CONTROL RESERVOIR

- M.blue® valve with integrated pediatric CONTROL RESERVOIR and distal catheter
- \* 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 with introducing stylet and pediatric burrhole deflector (14 mm)





 $pediatric\,CONTROL\,RESERVOIR^*$ 

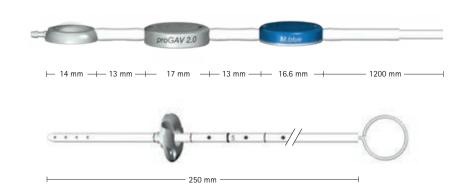
Art. no.	Differential pressure unit	Adjustable gravitational unit
FX815T	$0 \text{ cmH}_2\text{O}$	$0 - 40 \text{ cmH}_2 \text{O}$
FX816T	5 cmH <sub>2</sub> O	0 - 40 cmH <sub>2</sub> 0
FX817T	10 cmH₂0	0 - 40 cmH <sub>2</sub> 0
FX818T	15 cmH₂0	0 - 40 cmH <sub>2</sub> 0

# M.blue plus®



# SHUNT SYSTEM WITH PEDIATRIC CONTROL RESERVOIR

- M.blue plus® valve with integrated pediatric CONTROL RESERVOIR and distal catheter
- \* 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 with introducing stylet and pediatric burrhole deflector (14 mm)





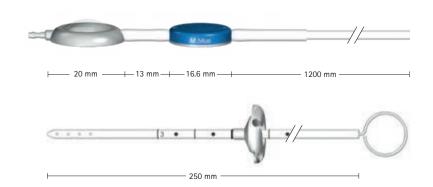
 $pediatric\,CONTROL\,RESERVOIR^*$ 

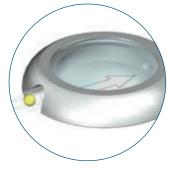
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Art. no.	Adj. differential pressure unit	Adjustable gravitational unit
FX819T	0 - 20 cmH₂0	0 - 40 cmH <sub>2</sub> 0

# SHUNT SYSTEM WITH CONTROL RESERVOIR

- M.blue® valve with integrated CONTROL RESERVOIR and distal catheter
- \* 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 with introducing stylet and burrhole deflector (20 mm)





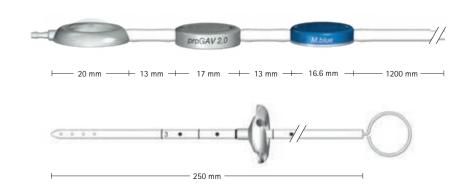
Art. no.	Differential pressure unit	Adjustable gravitational unit
FX820T	$0 \text{ cmH}_2 0$	0 - 40 cmH <sub>2</sub> 0
FX821T	5 cmH₂O	0 - 40 cmH <sub>2</sub> 0
FX822T	10 cmH₂0	0 - 40 cmH <sub>2</sub> 0
FX823T	15 cmH₂O	0 - 40 cmH <sub>2</sub> 0

# M.blue plus®



# SHUNT SYSTEM WITH CONTROL RESERVOIR

- M.blue plus® valve with integrated CONTROL RESERVOIR and distal catheter
- \* 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 with introducing stylet and burrhole deflector (20 mm)



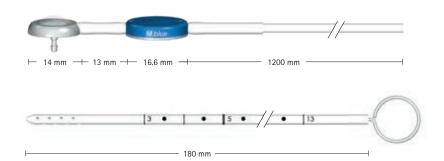


CONTROL RESERVOIR\*

Art. no.	Adj. differential pressure unit	Adjustable gravitational unit
FX824T	0 - 20 cmH <sub>2</sub> 0	0 - 40 cmH <sub>2</sub> 0

# SHUNT SYSTEM WITH PEDIATRIC SPRUNG RESERVOIR

- M.blue® valve
   with integrated pediatric
   SPRUNG RESERVOIR
   and distal catheter
- \* An additional valve in the inlet of the pediatric SPRUNG RESERVOIR makes it possible to pump cerebrospinal fluid in the direction of drainage, allowing inspection of both the distal drainage section as well as the ventricular catheter.
- Ventricular catheter with introducing stylet



# **OCCIPITAL ONLY**



pediatric SPRUNG RESERVOIR\*

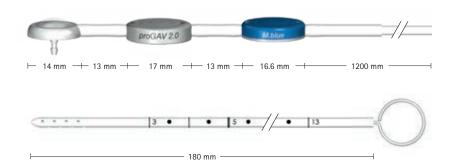
Art. no.	Differential pressure unit	Adjustable gravitational unit
FX825T	$0 \text{ cmH}_2\text{O}$	0 - 40 cmH <sub>2</sub> 0
FX826T	5 cmH <sub>2</sub> 0	0 - 40 cmH <sub>2</sub> 0
FX827T	10 cmH₂0	0 - 40 cmH <sub>2</sub> 0
FX828T	15 cmH₂0	0 - 40 cmH <sub>2</sub> 0

# M.blue plus®



# SHUNT SYSTEM WITH PEDIATRIC SPRUNG RESERVOIR

- M.blue plus® valve with integrated pediatric SPRUNG RESERVOIR and distal catheter
- \* 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 stylet



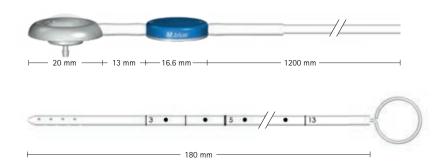
# OCCIPITAL ONLY



Art. no.	Adj. differential pressure unit	Adjustable gravitational unit
FX829T	0 - 20 cmH <sub>2</sub> 0	0 - 40 cmH <sub>2</sub> 0

# SHUNT SYSTEM WITH SPRUNG RESERVOIR

- M.blue® valve with integrated SPRUNG RESERVOIR and distal catheter
- \* 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



# OCCIPITAL ONLY



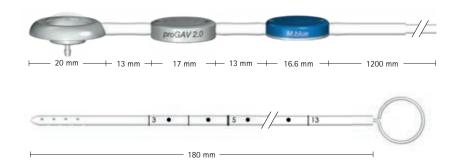
Art. no.	Differential pressure unit	Adjustable gravitational unit
FX830T	$0 \text{ cmH}_2\text{O}$	0 - 40 cmH <sub>2</sub> 0
FX831T	5 cmH <sub>2</sub> O	0 - 40 cmH <sub>2</sub> 0
FX832T	10 cmH₂0	0 - 40 cmH <sub>2</sub> 0
FX833T	15 cmH₂0	0 - 40 cmH <sub>2</sub> 0

# M.blue plus®



# SHUNT SYSTEM WITH SPRUNG RESERVOIR

- M.blue plus® valve with integrated SPRUNG RESERVOIR and distal catheter
- \* An additional valve in the inlet of the drainage only, allowing inspection of both the distal drainage section as well as the ventricular catheter.
- Ventricular catheter with introducing stylet



# **OCCIPITAL ONLY**

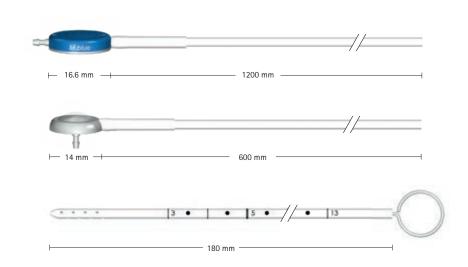


SPRUNG RESERVOIR\*

Art. no.	Adj. differential pressure unit	Adjustable gravitational unit
FX834T	0 - 20 cmH <sub>2</sub> 0	0 - 40 cmH <sub>2</sub> 0

# SHUNT SYSTEM WITH PEDIATRIC SPRUNG RESERVOIR

- M.blue® valve with distal catheter
- Pediatric SPRUNG RESERVOIR with distal catheter
- \* 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 stylet





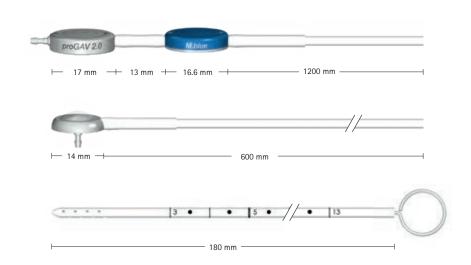
Art. no.	Differential pressure unit	Adjustable gravitational unit
FX835T	0 cmH₂0	0 - 40 cmH <sub>2</sub> 0
FX836T	5 cmH₂0	0 - 40 cmH <sub>2</sub> 0
FX837T	10 cmH₂0	0 - 40 cmH <sub>2</sub> 0
FX838T	15 cmH₂0	0 - 40 cmH <sub>2</sub> 0

# M.blue plus®



# SHUNT SYSTEM WITH PEDIATRIC SPRUNG RESERVOIR

- M.blue plus<sup>®</sup> valve with distal catheter
- Pediatric SPRUNG RESERVOIR with distal catheter
- \* 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 stylet



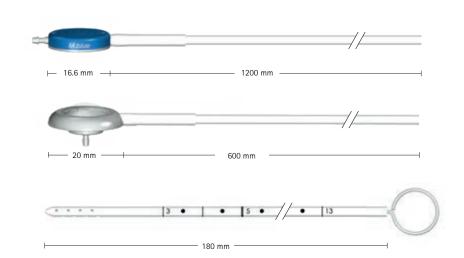


pediatric SPRUNG RESERVOIR\*

Art. no.	Adj. differential pressure unit	Adjustable gravitational unit
FX839T	0 - 20 cmH <sub>2</sub> 0	0 - 40 cmH <sub>2</sub> 0

# SHUNT SYSTEM WITH SPRUNG RESERVOIR

- M.blue® valve with distal catheter
- SPRUNG RESERVOIR with distal catheter
- \* 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





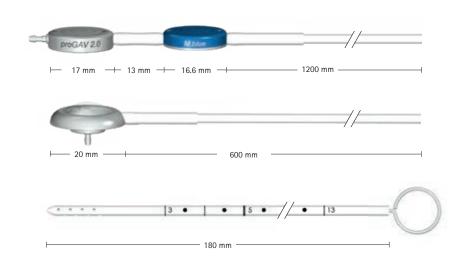
Art. no.	Differential pressure unit	Adjustable gravitational unit
FX840T	$0 \text{ cmH}_2 0$	0 - 40 cmH <sub>2</sub> 0
FX841T	5 cmH₂O	0 - 40 cmH <sub>2</sub> 0
FX842T	10 cmH <sub>2</sub> 0	0 - 40 cmH <sub>2</sub> 0
FX843T	15 cmH₂O	0 - 40 cmH <sub>2</sub> 0

# M.blue plus®



# SHUNT SYSTEM WITH SPRUNG RESERVOIR

- M.blue plus® valve with distal catheter
- SPRUNG RESERVOIR with distal catheter
- \* 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

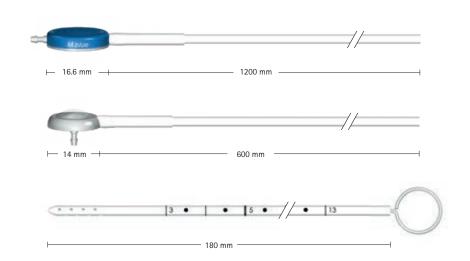




Art. no.	Adj. differential pressure unit	Adjustable gravitational unit
FX844T	0 - 20 cmH <sub>2</sub> 0	0 - 40 cmH <sub>2</sub> 0

# SHUNT SYSTEM WITH PEDIATRIC BURRHOLE RESERVOIR

- M.blue® valve with distal catheter
- Pediatric burrhole reservoir with distal catheter
- Ventricular catheter with introducing stylet



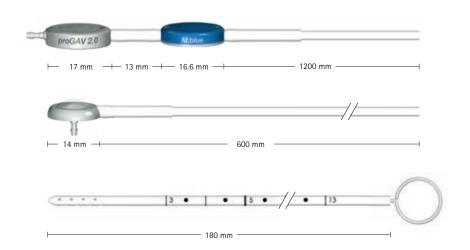
Art. no.	Differential pressure unit	Adjustable gravitational unit
FX845T	0 cmH <sub>2</sub> 0	0 - 40 cmH <sub>2</sub> 0
FX846T	5 cmH <sub>2</sub> 0	0 - 40 cmH <sub>2</sub> 0
FX847T	10 cmH <sub>2</sub> 0	0 - 40 cmH <sub>2</sub> 0
FX848T	15 cmH₂0	0 - 40 cmH <sub>2</sub> 0

# M.blue plus®



# SHUNT SYSTEM WITH PEDIATRIC BURRHOLE RESERVOIR

- M.blue plus® valve with distal catheter
- Pediatric burrhole reservoir with distal catheter
- Ventricular catheter with introducing stylet

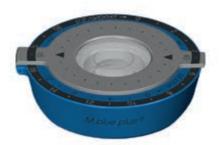


Art. no.	Adj. differential pressure unit	Adjustable gravitational unit
FX849T	0 - 20 cmH₂0	0 - 40 cmH <sub>2</sub> 0

# M.blue plus® INSTRUMENTS

# **SOFT TOUCH INSTRUMENTS**

- M.blue plus® instrument set
- M.blue plus<sup>®</sup> compass
- M.blue plus® adjustment ring
- *M.blue plus*® adjustment assistant
- M.blue® adjustment check-mate



M.blue plus® compass



M.blue plus® adjustment ring



M.blue plus® adjustment assistant



M.blue® adjustment check-mate

Art. no.	Instruments
FX890T	M.blue plus <sup>®</sup> instrument set (includes FX891T and FX892T)
FX891T	M.blue plus <sup>®</sup> compass
FX892T	M.blue plus® adjustment ring
FX893T	M.blue plus® adjustment assistant
FX894T	M.blue® adjustment check-mate



# OUR PRODUCTS – YOUR SELECTION

	M.blue®	proGAV® 2.0	GAV® 2.0	SHUNT- DUALS ASSISTANT® 2.0 VALVE	DUALSWITCH VALVE	miniNAV® Accessories	ies
					Ď		1/0
Description							
	Adjustable gravitational unit with integrated differential presure valve unit	Adjustable differential pres- sure valve with gravitational unit	Gravitational valve for treating hydrocephalus	"Add-on" gravita- tional valve for preventing com- plications due to excess drainage	Gravitational valve with large flow volumes for CSF	Differential pressure valve, specifically for premature babies and newborns or bedridden, non-	
Indication							
LP			>	>	>		
NPH	>	>	>	>	>		
Ped. HC	>	>	>	>		>	
Adult HC	>	>	>	>	>	>	
Patient							
Bed ridden	>					>	
Active	>	>	>	>	>	*	
Characteristic							
3-Tesla MR Conditional	>	>	>	>	>	>	
Gravitational unit	>	>	>	>	>		
Adjustable	>	>					

in conjunction with SHUNTASSISTANT® 2.0 or proS/

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