MIETHKE

XABO®

ANTIBIOTIC-IMPREGNATED CATHETERS

XTRA PROTECTION AGAINST INFECTION

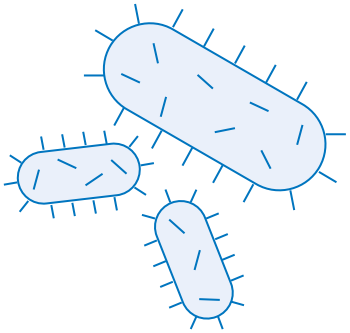
www.miethke.com

INFECTION AS A SERIOUS SHUNT COMPLICATION

INFECTIONS ARE A SERIOUS COMPLICATION OF SHUNT IMPLANTATION

The implantation of a ventriculoperitoneal shunt is the main treatment option for hydrocephalus patients but complications occur quite often and are burdensome for patients, their relatives as well as the neurosurgeons. Surgery on the brain is perceived as a very demanding procedure by the patient and family members. When such a surgery is followed by severe and potentially life-threatening complications, fears may arise. One of the most common and potentially serious complications of hydrocephalus treatment is an infection of the shunt [1]. This complication affects pediatric as well as adult patients and impairs their quality of life, cognitive function, and shunt survival [2].

Shunt infections mostly require removal of the shunt, antibiotic treatment and reimplantation [2].



» Bacterial shunt infection is one of the most common complications of shunt surgery, affecting 7-15% of hydrocephalus patients [3]. «

CONSEQUENCES OF SHUNT INFECTIONS

Shunt infections can have severe consequences for the patient: They are associated with a higher risk for further complications, such as seizures, psychomotor retardation, and shunt failure, which increase morbidity and mortality [6–9]. The removal of the infected shunt, antibiotic treatment and shunt re-implantation means two additional surgeries, which is an enormous burden both for the patient and the patient's family.

For the neurosurgeon, shunt infections drastically increase the workload and in the worst-case scenario require additional unplanned surgeries.

For the hospital, repeated shunt infections are associated with high economic losses and may affect the hospitals reputation. The costs for one adult patient amount to approximately $50,000 per infection, with even higher costs for pediatric patients [10].

High associated costs

Lower shunt survival

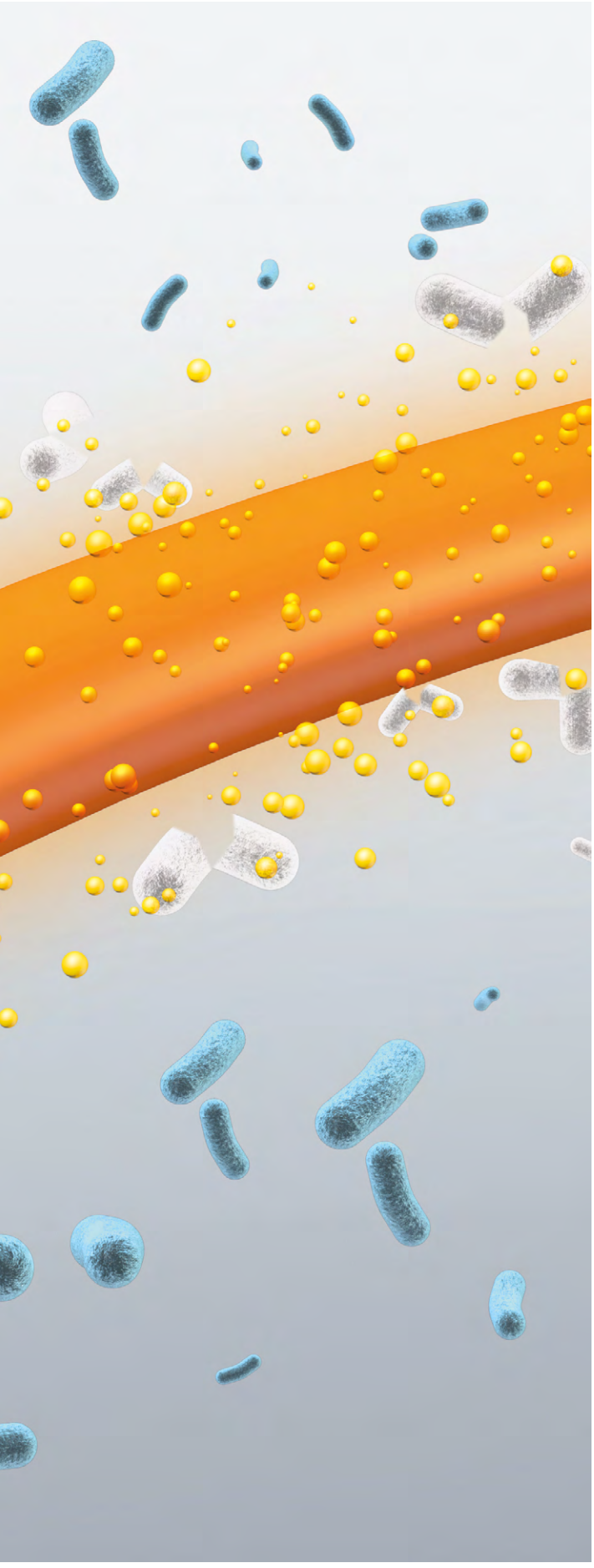
Prolonged treatment

Emotional burden

» *Removal of the infected shunt and re-implantation is an enormous burden for patients and their families and means high economic losses for the hospital [10].* «

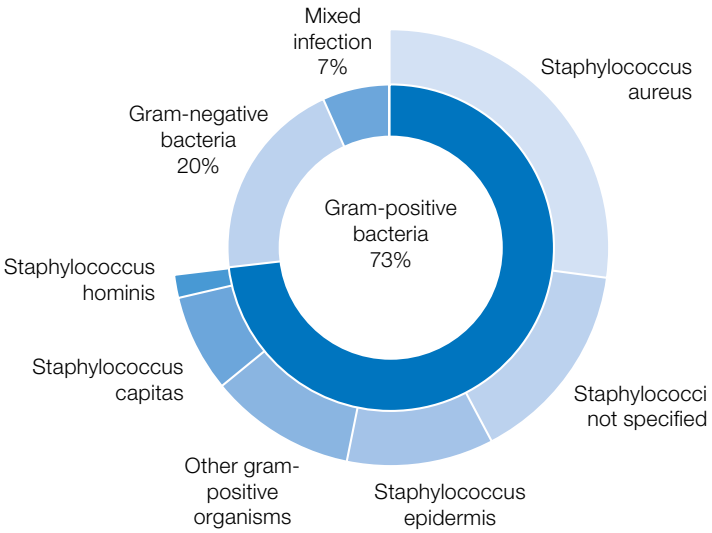
XABO®

XTRA PROTECTION AGAINST INFECTION



CAUSES OF BACTERIAL SHUNT INFECTIONS

Shunt infections are mainly caused by gram-positive bacteria, e.g. Staphylococcus species [4], and often occur within the first month after surgery [5].



» *73% of all bacterial infections are caused by gram-positive pathogens [11].* «

PREVENTION OF SHUNT INFECTIONS

Use of antibiotic-impregnated catheters can prevent two-thirds of shunt infections [11], thus helping to reduce patient burden and improve patient outcome. By avoiding additional hospital stays and surgeries the patient's wellbeing and the acceptance for the treatment can be increased. Moreover, as time-consuming complications are reduced, neurosurgeons can focus on their further work and thus help a greater number of patients. Prevention of infections also has a financial impact as it can save $42,125 and $230,390 per 100 first-time shunt placements in adult and pediatric patients, respectively [10].

Prevention of shunt infection can therefore help to reduce costs for hospitals and the health care system. In addition, follow-up operations can be avoided, thus easing the hospital staff's workload. The time saved and the reduced stress allow neurosurgeons to focus more on the individual patient, thus improving the treatment of hydrocephalus for every patient.

MIETHKE's new antibiotic-impregnated catheter *XABO* uses a balanced ratio of clindamycin hydrochloride and rifampicin to effectively fight gram-positive bacteria [12].

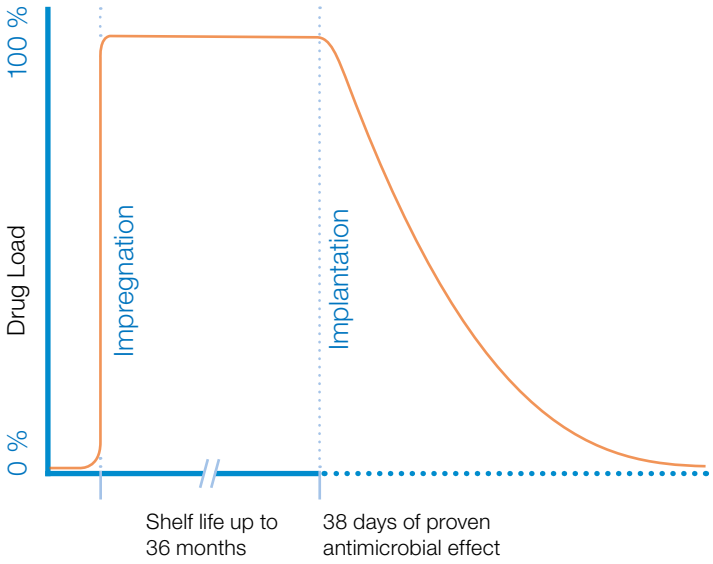
XABO®

LASTING EFFECTS AND CONVENIENT HANDLING

XABO - GENTLE STERILIZATION, OPTIMIZED RELEASE KINETICS

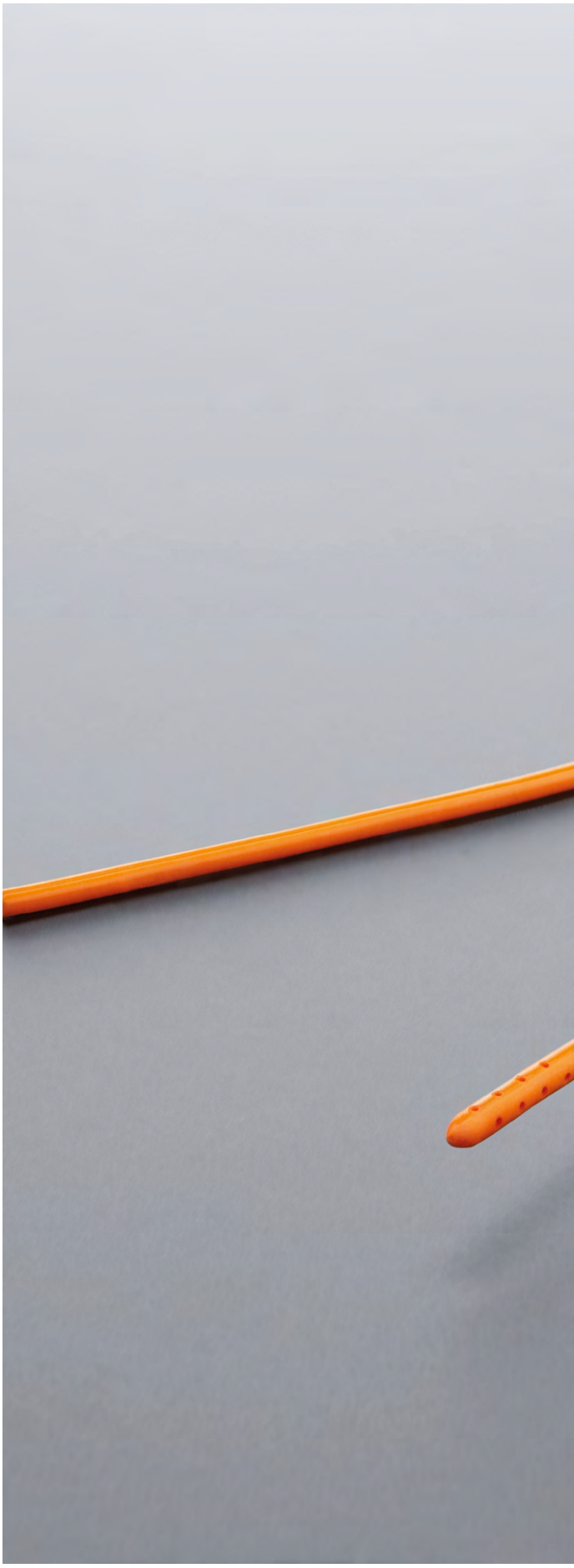
XABO's initial antibiotic loading is retained thanks to the gentle sterilization process. In addition, *XABO* comes wrapped in a specifically designed complete package combination that minimizes degradation products [13], ensuring the antibiotic-impregnated catheter is kept in prime condition for longer. Patients can benefit from *XABO*'s optimized release kinetics: the antibiotics are released continuously over at least 38 days after implantation [14], ensuring that *XABO*'s antimicrobial activity covers the time window when the patient is most susceptible to infection [1,15-17]. The high potency of the clindamycin hydrochloride and rifampicin impregnation allows for the release of low antibiotic doses, which prevents allergic reactions and minimizes the risk of resistance development.

RELATION BETWEEN DRUG LOAD AND TIME



XABO - EASY HANDLING, CONVENIENT STORAGE

XABO is designed to simplify transport and storage: Thanks to the gentle sterilization process and safe packaging it is storable for up to 36 months and withstands temperatures up to 30°C without losing its effectiveness [18].



36 MONTHS

» XABO catheters are the only antibiotic-impregnated catheters for hydrocephalus therapy with a shelf life of up to 36 months. This simplifies the clinical routine and the handling for the physician.«

XABO®

HOLISTIC TREATMENT FOR HYDROCEPHALUS

» *XABO offers long-lasting antimicrobial effects, easy handling, convenient storage and perfectly fits all our innovative MIETHKE valves.* «

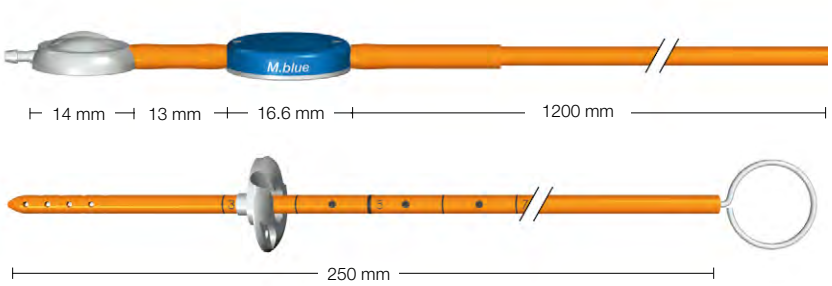

GAV 2.0 LP
MIETHKE
GAV 2.0

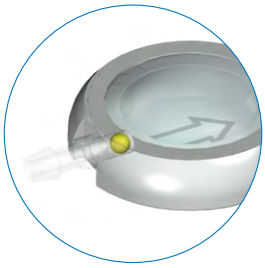
M.blue® / *M.blue plus*® Shunt System XABO®

with Pediatric CONTROL RESERVOIR

* 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

+ *M.blue* valve with integrated *Pediatric CONTROL RESERVOIR* and *XABO Distal Catheter*
+ *XABO Ventricular Catheter* with introducing stylet and *Pediatric Burrhole Deflector* (13 mm)



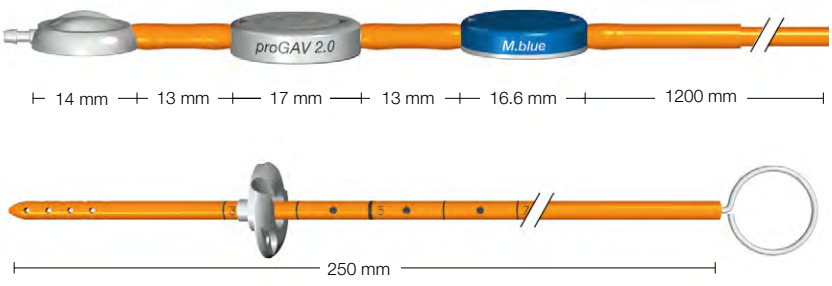


* *Pediatric CONTROL RESERVOIR*

M.blue configurations

Art. No.	Differential pressure unit	Gravitational unit **
FX815A	0 cmH_2O	0 - 40 cmH_2O
FX816A	5 cmH_2O	0 - 40 cmH_2O
FX817A	10 cmH_2O	0 - 40 cmH_2O
FX818A	15 cmH_2O	0 - 40 cmH_2O

+ *M.blue plus* valve with integrated *Pediatric CONTROL RESERVOIR* and *XABO Distal Catheter*
+ *XABO Ventricular Catheter* with introducing stylet and *Pediatric Burrhole Deflector* (13 mm)



Connector: d_o = 1.9 mm
M.blue: h = 4.2 mm
proGAV 2.0: h = 4.5 mm
Catheters: d_i = 1.2 mm
d_o = 2.5 mm

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

M.blue plus configuration

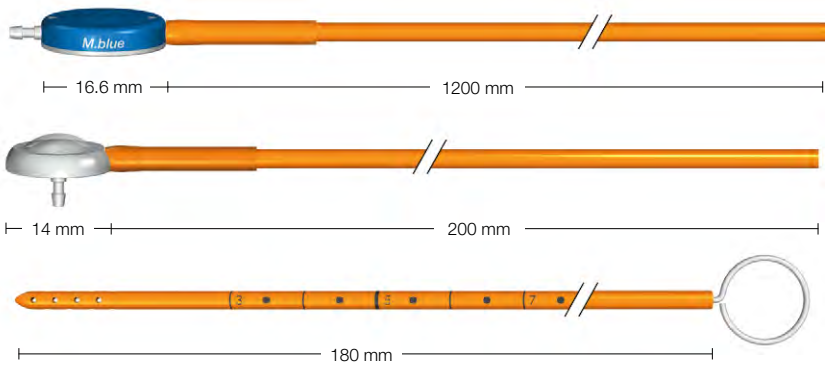
Art. No.	Differential pressure unit ***	Gravitational unit **
FX819A	0 - 20 cmH_2O	0 - 40 cmH_2O

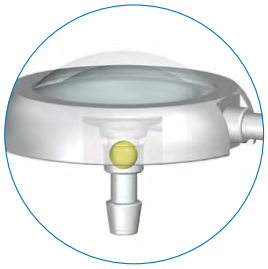
M.blue® / *M.blue plus*® Shunt System XABO®

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

+ *M.blue* valve
  with *XABO Distal Catheter*
+ *Pediatric SPRUNG RESERVOIR*
  with *XABO Distal Catheter*
+ *XABO Ventricular Catheter*
  with introducing stylet



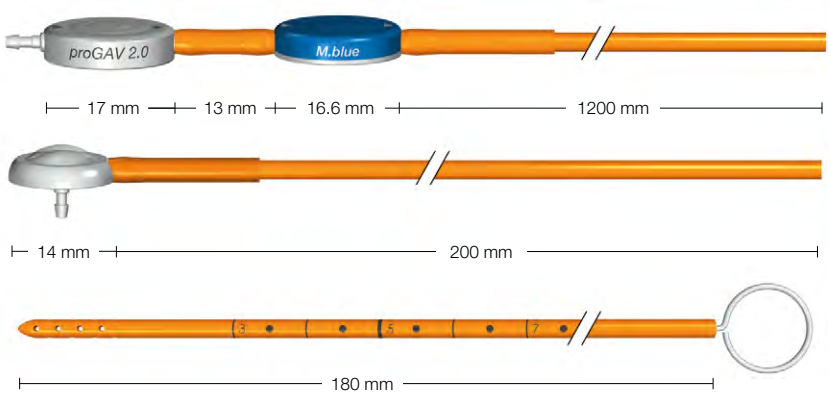


* Pediatric SPRUNG RESERVOIR

M.blue configurations

Art. No.	Differential pressure unit	Gravitational unit **
FX835A	0 cmH_2O	0 - 40 cmH_2O
FX836A	5 cmH_2O	0 - 40 cmH_2O
FX837A	10 cmH_2O	0 - 40 cmH_2O
FX838A	15 cmH_2O	0 - 40 cmH_2O

+ *M.blue plus* valve
  with *XABO Distal Catheter*
+ *Pediatric SPRUNG RESERVOIR*
  with *XABO Distal Catheter*
+ *XABO Ventricular Catheter*
  with introducing stylet



Connector: d_o = 1.9 mm
M.blue: h = 4.2 mm
proGAV 2.0: h = 4.5 mm
Catheters: d_i = 1.2 mm
d_o = 2.5 mm

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

M.blue plus configuration

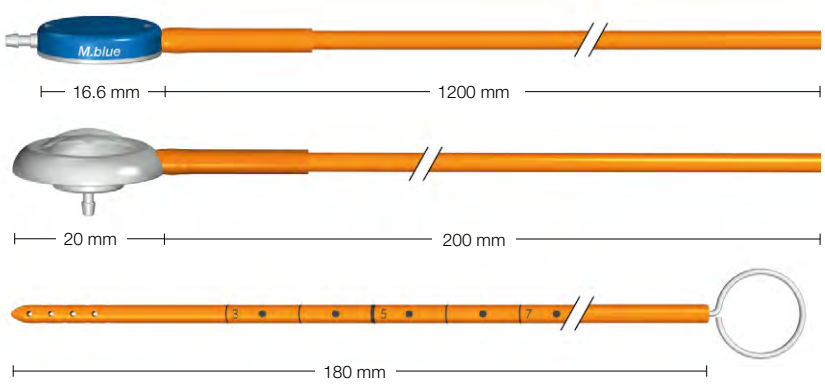
Art. No.	Differential pressure unit ***	Gravitational unit **
FX839A	0 - 20 cmH2O	0 - 40 cmH2O

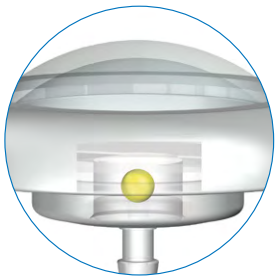
M.blue® / *M.blue plus*® Shunt System XABO®

with SPRUNG RESERVOIR

* 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

+ *M.blue* valve with *XABO Distal Catheter*
+ *SPRUNG RESERVOIR* with *XABO Distal Catheter*
+ *XABO Ventricular Catheter* with introducing stylet



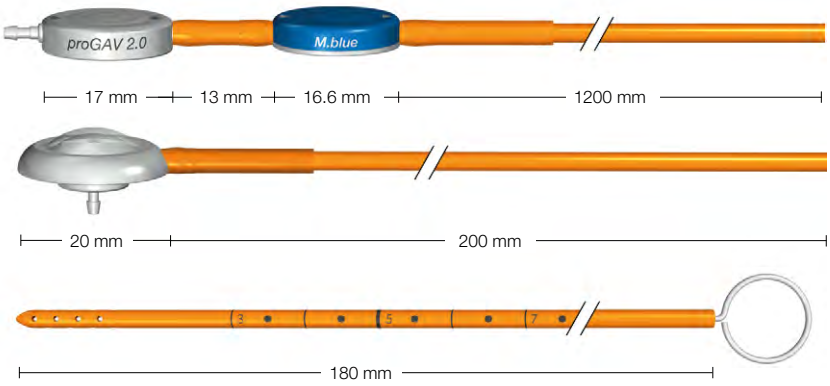


*SPRUNG RESERVOIR

M.blue configurations

Art. No.	Differential pressure unit	Gravitational unit **
FX840A	0 cmH_2O	0 - 40 cmH_2O
FX841A	5 cmH_2O	0 - 40 cmH_2O
FX842A	10 cmH_2O	0 - 40 cmH_2O
FX843A	15 cmH_2O	0 - 40 cmH_2O

+ *M.blue plus* valve with *XABO Distal Catheter*
+ *SPRUNG RESERVOIR* with *XABO Distal Catheter*
+ *XABO Ventricular Catheter* with introducing stylet



M.blue plus configuration

Art. No.	Differential pressure unit ***	Gravitational unit **
FX844A	0 - 20 cmH_2O	0 - 40 cmH_2O

Connector: d_o = 1.9 mm
M.blue: h = 4.2 mm
proGAV 2.0: h = 4.5 mm
Catheters: d_i = 1.2 mm
d_o = 2.5 mm

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

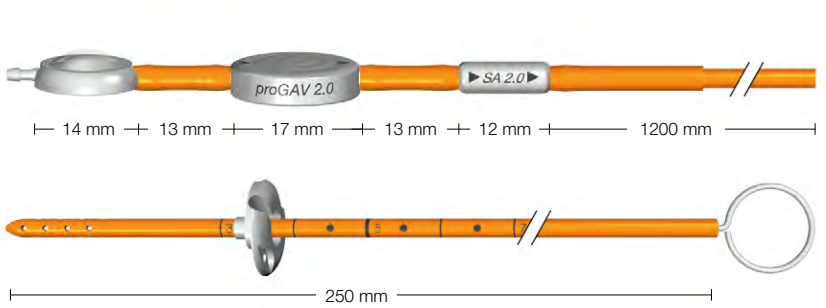
proGAV® 2.0 Shunt System XABO®

with Pediatric CONTROL RESERVOIR

* 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

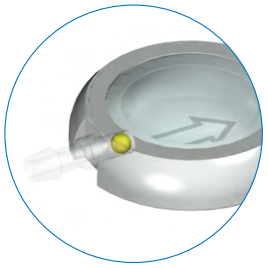
+ *proGAV 2.0* valve with integrated *Pediatric CONTROL RESERVOIR* and *XABO Distal Catheter*

+ *XABO Ventricular Catheter* with introducing stylet and *Pediatric Burrhole Deflector* (13 mm)



Connector: d_o = 1.9 mm
proGAV 2.0: h = 4.5 mm
SA 2.0: d_o = 4.2 mm
Catheters: d_i = 1.2 mm
d_o = 2.5 mm

** preset to 5 cmH_2O



** Pediatric CONTROL RESERVOIR*

Standard configurations

Art. No.	Differential pressure unit **	Gravitational unit
FX609A	0 - 20 cmH_2O	20 cmH_2O
FX610A	0 - 20 cmH_2O	25 cmH_2O

Alternative configurations

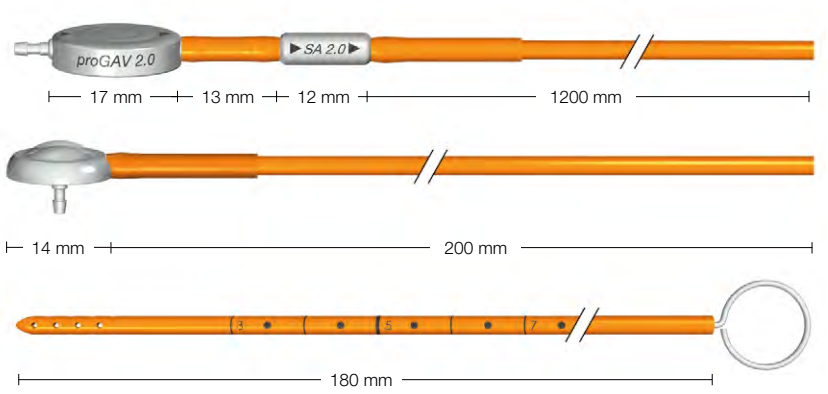
Art. No.	Differential pressure unit **	Gravitational unit
FX607A	0 - 20 cmH_2O	10 cmH_2O
FX608A	0 - 20 cmH_2O	15 cmH_2O
FX611A	0 - 20 cmH_2O	30 cmH_2O
FX612A	0 - 20 cmH_2O	35 cmH_2O

proGAV® 2.0 Shunt System XABO®

with Pediatric SPRUNG RESERVOIR

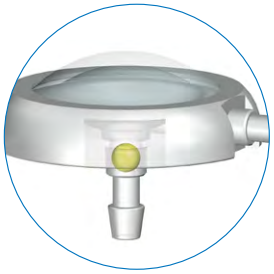
* An additional valve in the inlet of the *Pediatric SPRUNG RESERVOIR* makes it possible to pump cerebrospinal fluid in the direction of drainage only, allowing inspection of both the distal drainage section as well as the ventricular catheter

+ *proGAV 2.0* valve with *XABO Distal Catheter*
+ *Pediatric SPRUNG RESERVOIR* with *XABO Distal Catheter*
+ *XABO Ventricular Catheter* with introducing stylet



Connector: d_o = 1.9 mm
proGAV 2.0: h = 4.5 mm
SA 2.0: d_o = 4.2 mm
Catheters: d_i = 1.2 mm
d_o = 2.5 mm

** preset to 5 cmH_2O



** Pediatric SPRUNG RESERVOIR*

Standard configurations

Art. No.	Differential pressure unit **	Gravitational unit
FX583A	0 - 20 cmH_2O	20 cmH_2O
FX584A	0 - 20 cmH_2O	25 cmH_2O

Alternative configurations

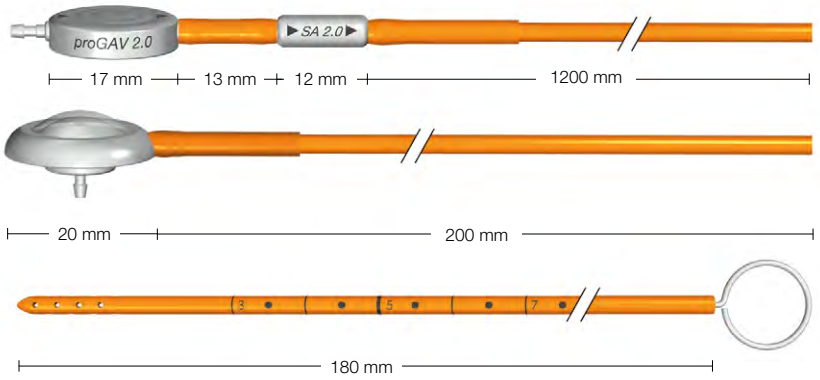
Art. No.	Differential pressure unit **	Gravitational unit
FX581A	0 - 20 cmH_2O	10 cmH_2O
FX582A	0 - 20 cmH_2O	15 cmH_2O
FX585A	0 - 20 cmH_2O	30 cmH_2O
FX586A	0 - 20 cmH_2O	35 cmH_2O

proGAV® 2.0 Shunt System XABO®

with SPRUNG RESERVOIR

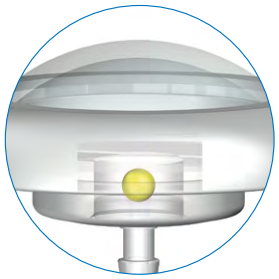
* An additional valve in the inlet of the *SPRUNG RESERVOIR* makes it possible to pump cerebrospinal fluid in the direction of drainage only, allowing inspection of both the distal drainage section as well as the ventricular catheter

+ *proGAV 2.0* valve with *XABO Distal Catheter*
+ *SPRUNG RESERVOIR* with *XABO Distal Catheter*
+ *XABO Ventricular Catheter* with introducing stylet



Connector: d_o = 1.9 mm
proGAV 2.0: h = 4.5 mm
SA 2.0: d_o = 4.2 mm
Catheters: d_i = 1.2 mm
d_o = 2.5 mm

** preset to 5 cmH_2O



**SPRUNG RESERVOIR*

Standard configurations

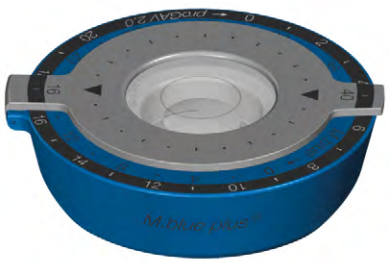
Art. No.	Differential pressure unit **	Gravitational unit
FX576A	0 - 20 cmH_2O	20 cmH_2O
FX577A	0 - 20 cmH_2O	25 cmH_2O

Alternative configurations

Art. No.	Differential pressure unit **	Gravitational unit
FX574A	0 - 20 cmH_2O	10 cmH_2O
FX575A	0 - 20 cmH_2O	15 cmH_2O
FX578A	0 - 20 cmH_2O	30 cmH_2O
FX579A	0 - 20 cmH_2O	35 cmH_2O

M.blue plus® Instruments

+ Soft Touch Instruments
+ *M.blue plus Instruments Set*
+ *M.blue plus Compass*
+ *M.blue plus Adjustment Ring*
+ *M.blue plus Adjustment Assistant*



M.blue plus Compass

M.blue plus Adjustment Ring

M.blue plus Adjustment Assistant

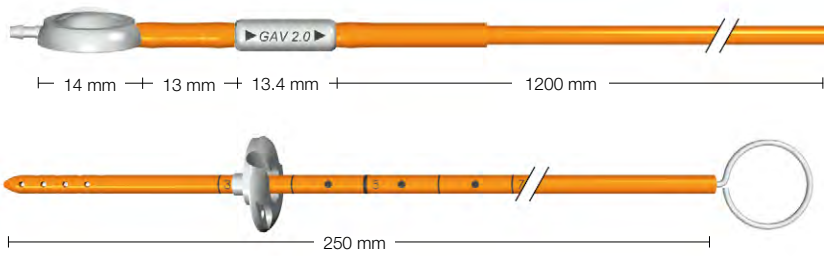
Art. Nr.	Instruments
FX890T	*M.blue plus Instrument Set (includes FX891T and FX892T)*
FX891T	*M.blue plus Compass*
FX892T	*M.blue plus Adjustment Ring*
FX893T	*M.blue plus Adjustment Assistant*

GAV® 2.0 Shunt System XABO®

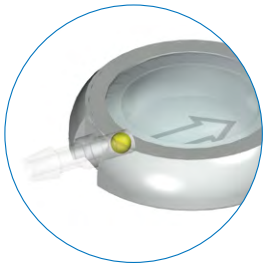
with Pediatric CONTROL RESERVOIR

* 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

+ *GAV 2.0* valve with integrated *Pediatric CONTROL RESERVOIR* and *XABO Distal Catheter*
+ *XABO Ventricular Catheter* with introducing stylet and *Pediatric Burrhole Deflector* (13 mm)



Connector: d_o = 1.9 mm
Valve: d_o = 4.2 mm
Catheters: d_i = 1.2 mm
d_o = 2.5 mm



* *Pediatric CONTROL RESERVOIR*

GAV 2.0 configurations

Art. No.	lying	upright
FX152A	5 cmH_2O	20 cmH_2O
FX153A	5 cmH_2O	25 cmH_2O
FX154A	5 cmH_2O	30 cmH_2O
FX155A	5 cmH_2O	35 cmH_2O
FX156A	10 cmH_2O	25 cmH_2O
FX157A	10 cmH_2O	30 cmH_2O

GAV® 2.0 Shunt System XABO®

with Pediatric SPRUNG RESERVOIR

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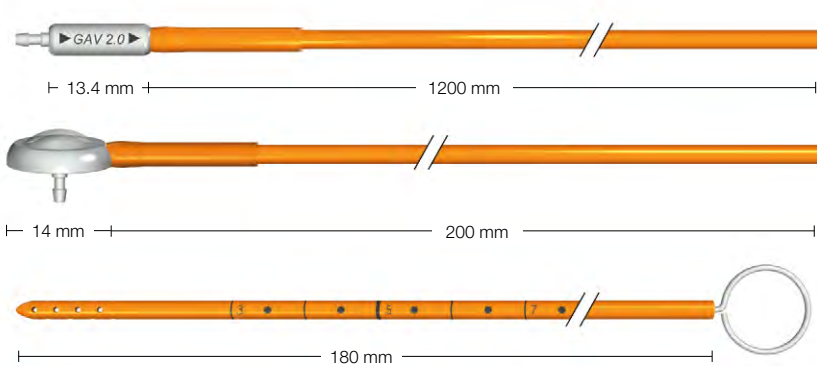
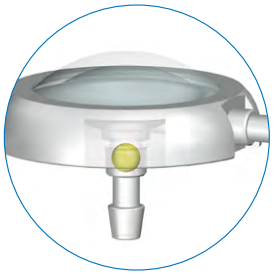
+ *GAV 2.0* valve
  with *XABO Distal Catheter*
+ *Pediatric SPRUNG RESERVOIR*
  with *XABO Distal Catheter*
+ *XABO Ventricular Catheter*
  with introducing stylet



Connector: d_o = 1.9 mm
Valve: d_o = 4.2 mm
Catheters: d_i = 1.2 mm
d_o = 2.5 mm



* *Pediatric SPRUNG RESERVOIR*

GAV 2.0 configurations

Art. No.	lying	upright
FX276A	5 cmH_2O	20 cmH_2O
FX277A	5 cmH_2O	25 cmH_2O
FX278A	5 cmH_2O	30 cmH_2O
FX279A	5 cmH_2O	35 cmH_2O
FX280A	10 cmH_2O	25 cmH_2O
FX281A	10 cmH_2O	30 cmH_2O

GAV® 2.0 Shunt System XABO®

with SPRUNG RESERVOIR

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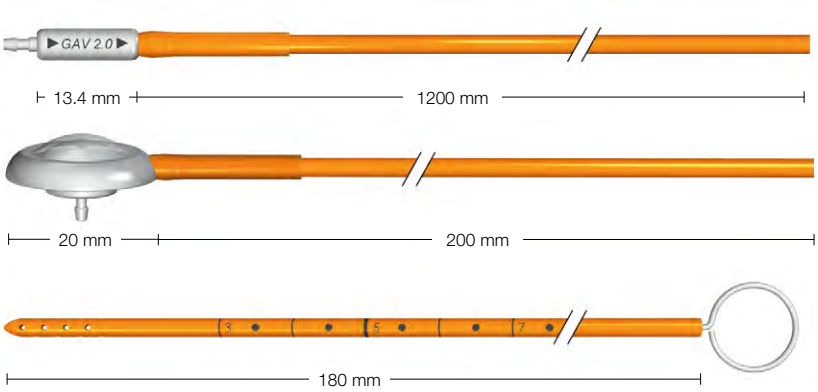
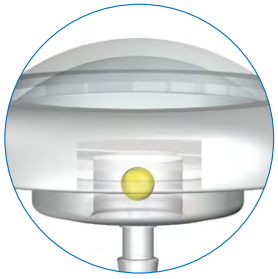
+ *GAV 2.0* valve
  with *XABO Distal Catheter*
+ *SPRUNG RESERVOIR*
  with *XABO Distal Catheter*
+ *XABO Ventricular Catheter*
  with introducing stylet



Connector: d_o = 1.9 mm
Valve: d_o = 4.2 mm
Catheters: d_i = 1.2 mm
d_o = 2.5 mm



**SPRUNG RESERVOIR*

GAV 2.0 configurations

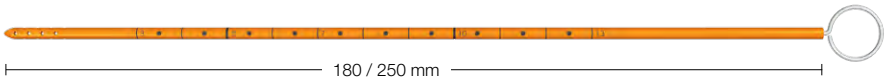
Art. No.	lying	upright
FX270A	5 cmH_2O	20 cmH_2O
FX271A	5 cmH_2O	25 cmH_2O
FX272A	5 cmH_2O	30 cmH_2O
FX274A	5 cmH_2O	35 cmH_2O
FX274A	10 cmH_2O	25 cmH_2O
FX275A	10 cmH_2O	30 cmH_2O

XABO® Catheters

+ Impregnated with Clindamycin hydrochloride (0.15 weight %) and Rifampicin (0.054 weight %)
+ Catheters are made of radiopaque silicone
+ Inner diameter 1.2 mm
+ Outer diameter 2.5 mm

XABO Peritoneal Catheter

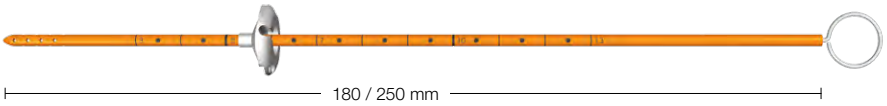
Art. No.	Length
FY010A	600 mm
FY011A	900 mm
FY012A	1200 mm



XABO Ventricular Catheter

Art. No.	Length
FY020A	180 mm
FY021A	250 mm

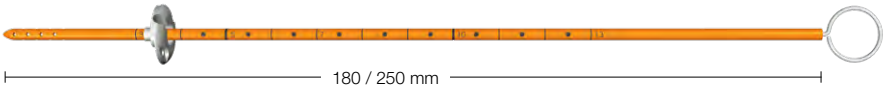
Burrhole Deflector



XABO Ventricular Catheter with Burrhole Deflector

Art. No.	Length	Deflector diameter
FY022A	180 mm	16 mm
FY023A	250 mm	16 mm

Pediatric Burrhole Deflector

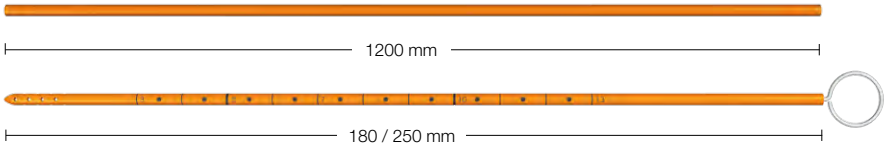


XABO Ventricular Catheter with Pediatric Burrhole Deflector

Art. No.	Length	Deflector diameter
FY024A	180 mm	13 mm
FY025A	250 mm	13 mm

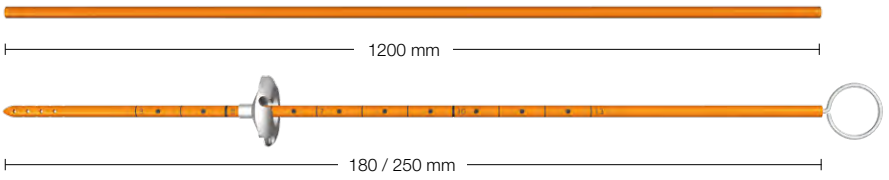
XABO® Catheter Sets

+ Set contains one *Ventricular Catheter* and one *Peritoneal Catheter*



XABO Catheter Set

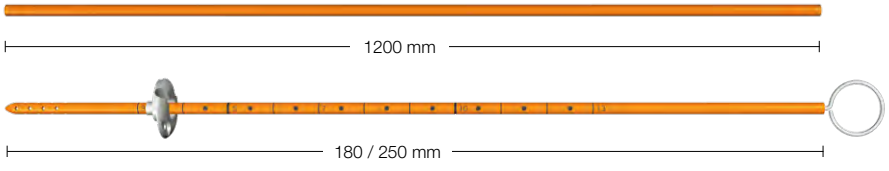
Art. No.	Ventricular Catheter	Peritoneal Catheter
FY040A	180 mm	1200 mm
FY041A	250 mm	1200 mm



Burrhole Deflector

XABO Catheter Set with Burrhole Deflector

Art. No.	Ventricular Catheter	Peritoneal Catheter
FY042A	180 mm	1200 mm
FY043A	250 mm	1200 mm



Pediatric Burrhole Deflector

XABO Catheter Set with Pediatric Burrhole Deflector

Art. No.	Ventricular Catheter	Peritoneal Catheter
FY044A	180 mm	1200 mm
FY045A	250 mm	1200 mm

	M.blue®	*M.blue plus®*	*proGAV® 2.0*	*GAV® 2.0*	*SHUNT-ASSISTANT® 2.0*	*miniNAV ®*	*Shunt Components*
							
Description							
	Adjustable gravitational valve with integrated differential pressure unit	Adjustable differential pressure valve with adjustable gravitational unit	Adjustable differential pressure valve with gravitational unit	Gravitational valve for the treatment of hydrocephalus	Gravitational unit for integration into shunt systems in order to avoid excess drainage	Differential pressure valve, specifically for premature babies and newborns or bedridden or non-mobile patients	
Indication							
NPH	✓	✓	✓	✓	✓		
Pediatric HC	✓	✓	✓	✓	✓	✓	
Adult HC	✓	✓	✓	✓	✓	✓	
Patient							
Bedridden	✓	✓				✓	
Active	✓	✓	✓	✓	✓	*	
Feature							
3-Tesla MR Conditional	✓	✓	✓	✓	✓	✓	
Gravitational unit	✓	✓	✓	✓	✓		
Adjustable	✓	✓	✓				
LP				✓	✓		
XABO®	✓	✓	✓	✓			✓

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