



## WE UNDERSTAND.

NEUROSURGERY

## LUMBOPERITONEAL SHUNTS

GAV

GRAVITATIONAL VALVE TECHNOLOGY FOR LUMBOPERITONEAL SHUNTING

# TREATMENT OF HYDROCEPHALUS

NEED FOR IMPROVEMENT

## TREATMENT OF HYDROCEPHALUS

Since the 1960s, the main surgical strategy in managing hydrocephalus is the placement of shunts. Ventriculoperitoneal (VP) shunts are still the surgical standard, but lumboperitoneal (LP) shunts are an increasingly important alternative. However, these conventional shunt types have specific high failure rates, each with its own typical causes. Almost every fourth patient is affected by complications (1, 2) with no difference between conventional and programmable valves (3, 4).

Mechanical failure, such as obstruction and valve malfunction, followed immediately by overdrainage, remain the most common causes of multiple shunt revisions (5). Revisions are burdensome for patients and are accompanied by unavoidable perioperative risks.

We believe that the current treatment options for hydrocephalus are not definitive and improvement is required.

HIGH FAILURE RATES (1)



**»** High failure rates overshadow the effectiveness of shunts (1)





#### COMPLICATIONS LP-SHUNTING (5)



- Overdrainage
- Spinal Deformities
- Infection
- Others



About one in four patients experience at least one complication (2)

## 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 (6-10).



# 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 (11-13).

#### GRAVITATIONAL VALVES (GV) IMPROVE PATIENT OUTCOMES COMPARED TO DIFFERENTIAL PRESSURE VALVES (DP) (14).

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 (15–19) and overdrainage complications (8, 13).



**W** Valve survival rates up to 90 % at 12 months (17).



 Implanting a gravitational valve avoids one additional overdrainage complication in about every third patient (16).

# **GRAVITATIONAL VALVES BY MIETHKE**

DEVELOPED TO ENSURE SAFETY

## AVOID MECHANICAL FAILURE!

All MIETHKE valves are manufactured with high precision from titanium. The 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 magneticfields of up to 3 Tesla (20).







## BENEFIT FROM PRIMARY IMPLANTATION (21)!



>> 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 (21, 22) 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.

# HYDROCEPHALUS THERAPY

LUMBOPERITONEAL SHUNT AS AN ALTERNATIVE

MIETHKE develops innovative gravitational valves with low opening pressures in supine position and simultaneous high overdrainage protection in upright position, that improve patient outcome compared to conventional differential pressure valves (14, 16). This reflects our philosophy to provide the best possible treatment of hydrocephalus.

VP-shunt placement is the most common treatment, whereas LP-shunts are less commonly used due to initial reports of high rates of complications (23).

Recent international studies provide evidence that LP-shunting is equally as effective as VP-shunting for normal pressure hydrocephalus (NPH) and is associated with comparable complication rates (24-27); without statistically significant difference between the two groups (25, 26, 28). As a matter of fact LP-shunting has become an increasingly popular treatment option (24, 26-31).

Early treatment with the optimal therapy is essential (32). Hydrostatic pressure is created in every patient in an upright position driven by gravity. VP- and LP-shunts are in principle equally at risk of overdrainage in standing position, if no resistance compensation is considered, such as gravitational valves. Thus, avoiding overdrainage is just as important for LP- as it is for VP-shunts (27).

Modern gravitational valve technology from MIETHKE, which has proven its superiority in overdrainage prevention for VP-shunts, can now also be used for LP-shunts using the MIETHKE Valve Board (15, 20).





# ADJUSTABLE GRAVITATIONAL VALVES AND ACCESSORIES

#### MEETING IMPORTANT REQUIREMENTS OF NEUROSURGEONS AND PATIENTS

- Valve technology for the special requirements of a life with hydrocephalus: mobility, growth, changes in the course of disease
- Superior clinical outcome of gravitational valves: survival rates, improvement in patient symptoms
- Reliable overdrainage protection
- MRI conditional up to 3 Tesla
- Safe from unintentional adjustment by everyday magnets such as smartphones, toys, induction cookers and safety barriers at the airports

## MIETHKE VALVE BOARD: FLEXIBILITY AND SAFETY IN APPLICATION

- Various treatment options: *M.blue, proGAV 2.0, GAV 2.0* and *SHUNTASSISTANT 2.0*
- Different configurations available: with and without CONTROL RESERVOIR
- Various placement options: e.g. dorsal, paramedian; ventral, anterolateral; thoracic
- Firm and reliable fixation for axial alignment of gravitational valves
- Integrated kinking protection of catheters
- Intuitive, secure and comfortable instruments

#### POTENTIAL BENEFITS FROM LP-SHUNTS (29, 33)

No cranial surgery, minimally invasive



No head shaving

# HYDROCEPHALUS THERAPY

#### FUNCTIONALITY OF GRAVITATIONAL VALVES AND PRESSURE LEVEL RECOMMENDATION

EXAMPLE OF THE ADJUSTABLE GRAVITATIONAL PRESSURE RANGE OF AN *M.blue* LUMBAR WITH A DIFFERENTIAL PRESSURE UNIT OF 5 CMH<sub>2</sub>O

MIETHKE GVs are hydrocephalus valves operating in a position-dependent manner. GVs consist of a gravitational unit and a 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.



## STANDARD PRESSURE LEVELS\*

stature of the patient.

Patient	Selection of pressure levels		Combined opening pressure	
	differential pressure unit	gravitational unit	horizontal potition	upright position
Adults	5	25	5	30
Adults < 1.60 m	5	20	5	25
Adults > 1.80 m	5	30	5	35
Adults from 65 years	5	20	5	25
Adults from 65 years < 1.60 m	5	15	5	20
Adults from 65 years > 1.80 m	5	25	5	30

All indicated pressure levels are in  $cmH_2O$ . \* This is a non-binding recommendation for the attending physician. According to his diagnosis, the physician decides each case independently, without instructions and individually. The stated values consider the current scientific knowledge up to 02/2021





Gravitational unit and differential pressure unit work together when the patient is standing





Only the differential pressure unit is active when the patient is supine



X-ray image of Valve Board with proGAV 2.0 with prechamber, lumbar right (pressure rating of proGAV 2.0 - 20 cmH<sub>2</sub>O pressure rating of SHUNTASSISTANT 2.0 - 25 cmH<sub>2</sub>0)



#### The choice of the appropriate pressure level depends on several factors, including age, degree of activity, size and

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





# HYDROCEPHALUS THERAPY

VALVE ADJUSTMENT IN LUMBOPERITONEAL SHUNTS

#### SOFT TOUCH INSTRUMENT FUNCTIONALITY

#### USER-FRIENDLY ADJUSTMENT AND VERIFICATION

Innovative *M.blue plus* instruments allow users to measure, verify and adjust the pressure level on *M.blue*'s adjustable gravitational unit (0-40 cmH<sub>2</sub>O) as well as the pressure level on the adjustable differential pressure unit *proGAV 2.0*. The instruments offer simple steps for the physician and make the adjustment process comfortable for patients.













#### ADJUSTMENT OF MIETHKE LP-SHUNTS

Patient after LP-shunting in a sitting and slightly bent downward position for shunt valve adjustment.

#### LOCATE

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

#### CHECK

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

#### 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® LUMBAR

M.blue



M.blue <sup>®</sup>		
Art. No.	Differential pressure unit	Adjustable gravitational unit (preset to 20 cmH <sub>2</sub> 0)
FX850T	0 cmH <sub>2</sub> 0	0 - 40 cmH <sub>2</sub> 0
FX851T	5 cmH <sub>2</sub> 0	0 - 40 cmH <sub>2</sub> 0
FX852T	10 cmH <sub>2</sub> 0	0 - 40 cmH <sub>2</sub> 0
FX853T	15 cmH <sub>2</sub> 0	0 - 40 cmH <sub>2</sub> 0



# M.blue®

## WITH CONTROL RESERVOIR, LUMBAR LEFT

## COMING SOON

- Valve board premounted with:
- *M.blue* with *CONTROL RESERVOIR,* proximal catheter 600 mm and peritoneal catheter 900 mm
- Step-down connector
- 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 lumbar catheter.



Catheter:  $d_i = 1.2 \text{ mm}$ ,  $d_o = 2.5 \text{ mm}$ 



M.blue <sup>®</sup>		
Art. No.	Differential pressure unit	Adjustable gravitational unit (preset to 20 cmH <sub>2</sub> 0)
FX854T	0 cmH <sub>2</sub> 0	0 - 40 cmH <sub>2</sub> 0
FX855T	5 cmH₂O	0 - 40 cmH <sub>2</sub> 0
FX856T	10 cmH₂0	0 - 40 cmH <sub>2</sub> 0
FX857T	15 cmH <sub>2</sub> 0	0 - 40 cmH <sub>2</sub> 0



M.blue<sup>®</sup>

COMING SOON

Valve board premounted with:

with CONTROL RESERVOIR,

and peritoneal catheter 900 mm

RESERVOIR makes it possible

to pump cerebrospinal fluid in

the direction of drainage only,

allowing inspection of both the

distal drainage section as well

Catheter:  $d_i = 1.2 \text{ mm}$ ,  $d_o = 2.5 \text{ mm}$ 

proximal catheter 600 mm

- An additional valve in the

inlet of the CONTROL

as the lumbar catheter.

Step-down connector

M.blue

WITH CONTROL RESERVOIR, LUMBAR RIGHT

# M.blue® Art. No. FX858T FX859T FX860T

FX861T

CONTROL RESERVOIR





Differential pressure unit	Adjustable gravitational unit (preset to 20 cmH <sub>2</sub> 0)
0 cmH <sub>2</sub> 0	0 - 40 cmH <sub>2</sub> 0
5 cmH <sub>2</sub> 0	0 - 40 cmH <sub>2</sub> 0
10 cmH <sub>2</sub> 0	0 - 40 cmH <sub>2</sub> 0
15 cmH₂0	0 - 40 cmH <sub>2</sub> 0

proGAV® 2.0 LUMBAR LEFT



- Valve board premounted with:
- proGAV 2.0 with proximal catheter 600 mm and peritoneal catheter 900 mm
- Step-down connector

Catheter:  $d_i = 1.2 \text{ mm}$ ,  $d_o = 2.5 \text{ mm}$ 







proGAV® 2.0

Art. No.	Graviational unit	Differential pressure unit (preset to 5 cmH <sub>2</sub> O)
FX700T	-	0 - 20 cmH <sub>2</sub> 0
FX701T	10 cmH <sub>2</sub> 0	0 - 20 cmH <sub>2</sub> 0
FX702T	15 cmH <sub>2</sub> 0	0 - 20 cmH <sub>2</sub> 0
FX703T	20 cmH <sub>2</sub> 0	0 - 20 cmH <sub>2</sub> 0
FX704T	25 cmH <sub>2</sub> 0	0 - 20 cmH <sub>2</sub> 0
FX705T	30 cmH <sub>2</sub> 0	0 - 20 cmH <sub>2</sub> 0
FX706T	35 cmH₂0	0 - 20 cmH <sub>2</sub> 0



	proGAV® 2.0
	Art. No.
_	FX700T
	FX707T
	FX708T
	FX709T
	FX710T
	FX711T
	FX712T

0

0





Graviational unit	Differential pressure unit (preset to 5 cmH <sub>2</sub> O)
-	0 - 20 cmH <sub>2</sub> 0
10 cmH₂0	0 - 20 cmH <sub>2</sub> 0
$15 \text{ cmH}_2\text{O}$	0 - 20 cmH <sub>2</sub> 0
$20 \text{ cmH}_20$	0 - 20 cmH <sub>2</sub> 0
25 cmH <sub>2</sub> 0	0 - 20 cmH <sub>2</sub> 0
30 cmH₂0	0 - 20 cmH <sub>2</sub> 0
35 cmH₂0	0 - 20 cmH <sub>2</sub> 0

## proGAV® 2.0 WITH CONTROL RESERVOIR, LUMBAR LEFT

## proGAV® 2.0 WITH CONTROL RESERVOIR, LUMBAR RIGHT

- Valve board premounted with:
- proGAV 2.0 with CONTROL RESERVOIR, proximal catheter 600 mm and peritoneal catheter 900 mm
- Step-down connector
- 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 lumbar catheter.





#### proGAV® 2.0

572
0
CONTROL RESERVOIR

Art. No.	Graviational unit	Differential pressure unit (preset to 5 cmH <sub>2</sub> 0)
FX713T	-	0 - 20 cmH <sub>2</sub> 0
FX714T	10 cmH <sub>2</sub> 0	0 - 20 cmH <sub>2</sub> 0
FX715T	15 cmH₂0	0 - 20 cmH <sub>2</sub> 0
FX716T	20 cmH₂0	0 - 20 cmH <sub>2</sub> 0
FX717T	25 cmH₂0	0 - 20 cmH <sub>2</sub> 0
FX718T	30 cmH₂0	0 - 20 cmH <sub>2</sub> 0
FX719T	35 cmH <sub>2</sub> 0	0 - 20 cmH <sub>2</sub> 0

#### Valve board premounted with:

- proGAV 2.0 with CONTROL RESERVOIR, proximal catheter 600 mm and peritoneal catheter 900 mm
- Step-down connector
- 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 lumbar catheter.

Catheter:  $d_i = 1.2 \text{ mm}$ ,  $d_o = 2.5 \text{ mm}$ 



#### proGAV® 2.0

0

	Art. No.
-	FX720T
	FX721T
	FX722T
	FX723T
	FX724T
	FX725T
	FX726T

CONTROL RESERVOIR





Graviational unit	Differential pressure unit (preset to 5 cmH <sub>2</sub> 0)
-	0 - 20 cmH <sub>2</sub> 0
10 cmH <sub>2</sub> 0	0 - 20 cmH <sub>2</sub> 0
15 cmH <sub>2</sub> 0	0 - 20 cmH <sub>2</sub> 0
20 cmH <sub>2</sub> 0	0 - 20 cmH <sub>2</sub> 0
25 cmH <sub>2</sub> 0	0 - 20 cmH <sub>2</sub> 0
30 cmH <sub>2</sub> 0	0 - 20 cmH <sub>2</sub> 0
35 cmH <sub>2</sub> 0	0 - 20 cmH <sub>2</sub> 0



- Valve board premounted with:
- GAV 2.0 with proximal catheter 600 mm and peritoneal catheter 900 mm
- Step-down connector



Catheter:  $d_i = 1.2 \text{ mm}$ ,  $d_o = 2.5 \text{ mm}$ 

#### GAV® 2.0

Art. No.	Lying	Upright	
FX182T	5 cmH₂0	20 cmH <sub>2</sub> 0	
FX183T	5 cmH <sub>2</sub> 0	25 cmH <sub>2</sub> 0	
FX184T	5 cmH <sub>2</sub> O	30 cmH₂0	
FX185T	5 cmH <sub>2</sub> 0	35 cmH₂0	
FX186T	10 cmH <sub>2</sub> 0	25 cmH <sub>2</sub> 0	
FX187T	10 cmH <sub>2</sub> 0	30 cmH <sub>2</sub> 0	





#### WITH CONTROL RESERVOIR, LUMBAR LEFT

## COMING SOON

- Valve board premounted with:
- GAV 2.0 with CONTROL RESERVOIR, proximal catheter 600 mm and peritoneal catheter 900 mm
- Step-down connector
- 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 lumbar catheter.



Catheter:  $d_i = 1.2 \text{ mm}$ ,  $d_o = 2.5 \text{ mm}$ 



CONTROL RESERVOIR

#### GAV® 2.0

Art. No.	Lying	Upright
FX188T	5 cmH₂0	20 cmH <sub>2</sub> 0
FX189T	5 cmH₂0	25 cmH <sub>2</sub> 0
FX190T	5 cmH₂0	30 cmH <sub>2</sub> 0
FX191T	5 cmH <sub>2</sub> 0	35 cmH <sub>2</sub> 0
FX192T	10 cmH <sub>2</sub> 0	25 cmH <sub>2</sub> 0
FX193T	10 cmH <sub>2</sub> 0	30 cmH <sub>2</sub> 0

# COMING SOON

WITH CONTROL RESERVOIR, LUMBAR RIGHT

• Valve board premounted with:

GAV<sup>®</sup> 2.0

- GAV 2.0 with CONTROL RESERVOIR, proximal catheter 600 mm and peritoneal catheter 900 mm
- Step-down connector
- 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 lumbar catheter.

Catheter:  $d_i = 1.2 \text{ mm}$ ,  $d_o = 2.5 \text{ mm}$ 



GAV® 2.0

Art. No.
FX194T
FX195T
FX196T
FX197T
FX198T
FX199T

24





Lying	Upright
5 cmH <sub>2</sub> 0	20 cmH <sub>2</sub> 0
5 cmH <sub>2</sub> 0	25 cmH <sub>2</sub> 0
5 cmH₂0	30 cmH <sub>2</sub> 0
5 cmH₂0	35 cmH₂0
10 cmH₂0	25 cmH <sub>2</sub> 0
10 cmH₂0	30 cmH <sub>2</sub> 0

# Valve Board

## VALVE BOARD FOR M.blue® OR proGAV® 2.0

• Valve board for *M.blue* or *proGAV 2.0* 





VALVE BOARD

Art. No.	Description	
FV087P	Valve board for M.blue® or proGAV® 2.0	

## COMING SOON

## VALVE BOARD FOR CONTROL RESERVOIR



## VALVE BOARD FOR SHUNTASSISTANT® 2.0 OR GAV® 2.0

• Valve board for SHUNTASSISTANT 2.0 or GAV 2.0



#### VALVE BOARD

Art. No.	Description
FV088P	Valve board for SHUNTASSISTANT® 2.0 or GAV® 2.0





• GAV 2.0 LP Valve (U-Form) • GAV 2.0 LP Valve (straight) 1.4 mm I == ►GAV 2.0 LP ► with distal catheter (1200 mm) with distal catheter (1200 mm) ⊢ 13.2 mm +--1200 mm

> Valve: d = 4.2 mm Connector:  $d_0 = 1.4 \text{ mm}$ Connector:  $d_0 = 1.9 \text{ mm}$

for connection with lumbar catheter Catheter:  $d_i = 1.2 \text{ mm}$ ,  $d_o = 2.5 \text{ mm}$ 

GAV® 2.0 LP, STRAIGHT

Art. No.	Lying	Upright
FX222T	5 cmH <sub>2</sub> 0	20 cmH <sub>2</sub> 0
FX223T	5 cmH <sub>2</sub> 0	25 cmH <sub>2</sub> 0
FX224T	5 cmH <sub>2</sub> 0	30 cmH <sub>2</sub> 0
FX225T	5 cmH <sub>2</sub> 0	35 cmH <sub>2</sub> 0
FX226T	10 cmH <sub>2</sub> 0	25 cmH <sub>2</sub> 0
FX227T	10 cmH <sub>2</sub> 0	30 cmH <sub>2</sub> 0

Art. No.	
FX228T	
FX229T	
FX230T	
FX231T	
FX232T	
FX233T	

Valve: d = 4.2 mm Connector:  $d_0 = 1.4 \text{ mm}$ for connection with lumbar catheter Connector:  $d_0 = 1.9 \text{ mm}$ Catheter:  $d_i = 1.2 \text{ mm}$ ,  $d_o = 2.5 \text{ mm}$ 





Lying	Upright
5 cmH <sub>2</sub> 0	20 cmH <sub>2</sub> 0
5 cmH <sub>2</sub> 0	25 cmH <sub>2</sub> 0
5 cmH <sub>2</sub> 0	30 cmH <sub>2</sub> 0
5 cmH <sub>2</sub> 0	35 cmH <sub>2</sub> 0
10 cmH <sub>2</sub> 0	25 cmH <sub>2</sub> 0
10 cmH <sub>2</sub> 0	30 cmH <sub>2</sub> 0

# SHUNTASSISTANT® 2.0 LP

## SHUNTASSISTANT<sup>®</sup> 2.0 LP, STRAIGHT

Valve LP, s<sup>-</sup>

Valve: d<sub>o</sub> = Connector

for connector

preverably Catheter:

## SHUNTASSISTANT® 2.0 LP, U-FORM

traight 1.4 mm I CARDOLP		፲ 1.9 mm	<ul> <li>Valve LP, U-Form</li> </ul>
	1 12 100		
	Art. No.	Opening pressure	
	FX106T	10 cmH <sub>2</sub> 0	
4.0 mm	FX107T	15 cmH <sub>2</sub> 0	Valve: $d_0 = 4.2 \text{ mm}$ Connector: $d_0 = 1.4 \text{ mm}$ for connection with lumbar cather Connector: $d_0 = 1.9 \text{ mm}$ preverably used with Catheter: $d_1 = 1.2 \text{ mm}$ , $d_0 = 2.5 \text{ m}$
4.2 mm d <sub>o</sub> = 1.4 mm tion with lumbar catheter d <sub>o</sub> = 1.9 mm used with t <sub>i</sub> = 1.2 mm, d <sub>o</sub> = 2.5 mm	FX108T	20 cmH <sub>2</sub> 0	
	FX109T	25 cmH <sub>2</sub> 0	
	FX110T	30 cmH <sub>2</sub> 0	
	FX111T	35 cmH <sub>2</sub> 0	

## SHUNTASSISTANT<sup>®</sup> 2.0 LP, STRAIGHT WITH DISTAL CATHETER

Valve LP, straight with distal catheter (900 mm)	► 12 mm +	→ 12 mm → 900 mm →	
	Art. No.	Opening pressure	
	FX124T	10 cmH <sub>2</sub> 0	
	FX125T	15 cmH <sub>2</sub> 0	
Valve: $d_o = 4.2 \text{ mm}$	FX126T	20 cmH <sub>2</sub> 0	
for connection with lumbar catheter Connector: d <sub>o</sub> = 1.9 mm	FX127T	25 cmH <sub>2</sub> 0	
Catheter: $d_i = 1.2 \text{ mm}$ , $d_o = 2.5 \text{ mm}$	FX128T	30 cmH₂0	
	FX129T	35 cmH <sub>2</sub> 0	

## SHUNTASSISTANT<sup>®</sup> 2.0 LP, U-FORM WITH DISTAL CATHETER

<ul> <li>Valve LP, U-Form with distal catheter (900 mm)</li> </ul>	/	900 mm
	Art. No.	Opening pressure
	FX130T	10 cmH <sub>2</sub> 0
	FX131T	15 cmH <sub>2</sub> 0
Valve: $d_o = 4.2 \text{ mm}$ Connector: $d = 1.4 \text{ mm}$	FX132T	20 cmH <sub>2</sub> 0
for connection with lumbar catheter Connector: $d_o = 1.9 \text{ mm}$	FX133T	25 cmH <sub>2</sub> 0
Catheter: d <sub>i</sub> = 1.2 mm, d <sub>o</sub> = 2.5 mm	FX134T	30 cmH₂0
	FX135T	35 cmH <sub>2</sub> 0





1.9 mm T

1.4 mm

Art. No.

FX112T

FX113T

FX114T

FX115T

FX116T

FX117T

Opening pressure
10 cmH <sub>2</sub> 0
15 cmH <sub>2</sub> 0
20 cmH <sub>2</sub> 0
25 cmH <sub>2</sub> 0
30 cmH₂0
35 cmH <sub>2</sub> 0

# DUALSWITCH® VALVE

DUALSWITCH® VALVE FOR LP DRAINAGE

# DUALSWITCH® VALVE

### DUALSWITCH® SHUNT SYSTEM FOR LP DRAINAGE

Single valve with two connections





Valve system with one connection

Valve only, with integrated



distal catheter

flushing reservoir and integrated

Connector: d = 1.4 mm for connection with lumbar catheter Connector: d = 1.9 mm Catheter:  $d_i = 1.2 \text{ mm}$ , do = 2.5 mm

> Art. No. FV382T FV383T FV163T FV164T

Connector:  $d_{a} = 1.4 \text{ mm}$ for connection with lumbar catheter Connector: d = 1.9 mm

Art. No.	Lying	Upright
FV373T	5 cmH <sub>2</sub> 0	30 cmH <sub>2</sub> 0
FV374T	5 cmH <sub>2</sub> 0	40 cmH <sub>2</sub> 0
FV127T	10 cmH <sub>2</sub> 0	30 cmH <sub>2</sub> 0
FV128T	10 cmH <sub>2</sub> 0	40 cmH <sub>2</sub> 0
FV129T	10 cmH <sub>2</sub> 0	50 cmH <sub>2</sub> 0





Lying	Upright
5 cmH <sub>2</sub> 0	30 cmH <sub>2</sub> 0
5 cmH <sub>2</sub> 0	40 cmH <sub>2</sub> 0
10 cmH <sub>2</sub> 0	30 cmH <sub>2</sub> 0
10 cmH <sub>2</sub> 0	50 cmH <sub>2</sub> 0

# LUMBAR CATHETER SET

#### LUMBAR CATHETER WITH OPEN TIP

# LUMBAR CATHETER SET

#### LUMBAR CATHETER WITH CLOSED TIP

- Barium impregnated silicone catheter for X-ray visibility
- Catheter with 16 drainage holes, in four opposite rows
- Length markings on both sides of the catheter
- Length markings aligned to the Tuohy cannula
- Barium impregnated silicone suture wings for X-ray visibility
- Step-down connector for connecting standard catheter to lumbar catheter

Catheter:  $d_1 = 0.80 \text{ mm}$ ,  $d_2 = 1.60 \text{ mm}$ Connector:  $d_{a} = 1.9 \text{ mm}$  to 1.4 mm

15	65
800 mm	
100 mm	d <sub>i</sub> = 1.85 mm d <sub>o</sub> = 2.20 mm
Flushing cannula	
4.40 mm ⊢—i	
10.30 mm	
Peritoneal catheter suture wings	
	$\frac{10.30 \text{ mm}}{10.30 \text{ mm}} \qquad \frac{4.40 \text{ mm}}{13 \text{ mm}}$ Peritoneal catheter suture wings

- Barium impregnated silicone catheter for X-ray visibility
- Catheter with 16 drainage holes, in four opposite rows
- Length markings on both sides of the catheter
- Length markings aligned to the Tuohy cannula
- Barium impregnated silicone suture wings for X-ray visibility
- Step-down connector for connecting standard catheter to lumbar catheter

Catheter:  $d_1 = 0.80 \text{ mm}$ ,  $d_2 = 1.60 \text{ mm}$ Connector:  $d_{a} = 1.9 \text{ mm}$  to 1.4 mm Guide wire: d<sub>o</sub> = 0.46 mm



		3.40 r ⊢⊣
T 3.80 mm		R
$\perp$	00	UU
	8 mm	
mbar cath	eter su	ture win



Art. No.	Description	Art. No.	Descri
FV083P	Lumbar Catheter Set, open tip, long Tuohy cannula	FV084P	Lumba
	· Lumbar catheter with open tip, 800 mm long		· Lumt
	· Tuohy cannula 14G, insertion length 100 mm		· Tuoh
	· Lumbar catheter suture wings, peritoneal catheter		· Lumt
	suture wings		sutur
	· Titanium connector, step-down		· Titan
	· Flushing cannula lumbar catheter		<ul> <li>Flush</li> </ul>
			· Guide



#### ription

- ar Catheter Set, closed tip, long Tuohy cannula
- bar catheter with closed tip, 800 mm long
- ny cannula 14G, insertion length 100 mm
- bar catheter suture wings, peritoneal catheter
- ire wings
- nium connector, step-down
- hing cannula lumbar catheter
- de wire

## M.blue plus<sup>®</sup> INSTRUMENTS SOFT TOUCH INSTRUMENTS



- *M.blue plus* instrument set
- M.blue plus compass
- M.blue plus adjustment ring
- *M.blue plus* adjustment assistant



*M.blue plus*<sup>®</sup> compass



M.blue plus® adjustment ring



M.blue plus® adjustment assistant

rigid version	
■ S - 300 mm	
■ M - 450 mm	
<b>L</b> – 600 mm	
= XL - 700 mm	

4 lengths available in standard or

Art. No.	Instruments
FX890T	<i>M.blue plus®</i> 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

300	I

S

Μ

XL

	300 mm	450 mm	600 mm	700 mm
STANDARD VERSION (with ring marking)	FX005SU	FX006SU	FX007SU	FX008SU
RIGID VERSION (no ring marking)	FX001SU	FX002SU	FX003SU	FX004SU



ه 450 mm	
600 mm	
	0

## REFERENCES

(1) Lutz BR, Venkataraman P, Browd SR. New and improved ways to treat hydrocephalus: Pursuit of a smart shunt. Surg Neurol Int. 2013;4(Suppl 1):S38-S50. 2013.

(2) Merkler AE, Ch'ang J, Parker WE, Murthy SB, Kamel H. The Rate of Complications after Ventriculoperitoneal Shunt Surgery. World Neurosurg. 2017;98:654-658

(3) Drake JM, Kestle JR, Milner R, et al. Randomized trial of cerebrospinal fluid shunt valve design in pediatric hydrocephalus. Neurosurgery. 1998;43(2):294-305.

(4) Pollack IF, Albright AL, Adelson PD. A randomized, controlled study of a programmable shunt valve versus a conventional valve for patients with hydrocephalus. Hakim-Medos Investigator Group. Neurosurgery. 1999;45(6):1399-1411.

(5) Browd SR, Ragel BT, Gottfried ON, Kestle JR. Failure of cerebrospinal fluid shunts: part I: Obstruction and mechanical failure. Pediatr Neurol. 2006;34(2):83-92.

(6) Anderson RC, Walker ML, Viner JM, Kestle JR. Adjustment and malfunction of a programmable valve after exposure to toy magnets. Case report. J Neurosurg. 2004;101(2 Suppl):222-225.

(7) Ozturk S, Cakin H, Kurtuldu H, Kocak O, Erol FS, Kaplan M. Smartphones and Programmable Shunts: Are These Indispensable Phones Safe and Smart?. World Neurosurg. 2017;102:518-525.

(8) Spader HS, Ratanaprasatporn L, Morrison JF, Grossberg JA, Cosgrove GR. Programmable shunts and headphones: Are they safe together?. J Neurosurg Pediatr. 2015;16(4):402-405.

(9) Strahle J, Selzer BJ, Muraszko KM, Garton HJ, Maher CO. Programmable shunt valve affected by exposure to a tablet computer. J Neurosurg Pediatr. 2012;10(2):118-120.

(10) Zuzak TJ, Balmer B, Schmidig D, Boltshauser E, Grotzer MA. Magnetic toys: forbidden for pediatric patients with certain programmable shunt valves?. Childs Nerv Syst. 2009;25(2):161-164.

(11) Tschan CA, Antes S, Huthmann A, Vulcu S, Oertel J, Wagner W. Overcoming CSF overdrainage with the adjustable gravitational valve proSA. Acta Neurochir (Wien). 2014;156(4):767-776.

(12) Nakajima M, Miyajima M, Akiba C, et al. Lumboperitoneal Shunts for the Treatment of Idiopathic Normal Pressure Hydrocephalus: A Comparison of Small-Lumen Abdominal Catheters to Gravitational Add-On Valves in a Single Center. Oper Neurosurg (Hagerstown). 2018;15(6):634-642. (13) Udayakumaran S, Roth J, Kesler A, Constantini S. Miethke DualSwitch Valve in lumboperitoneal shunts. Acta Neurochir (Wien). 2010;152(10):1793-1800.

(14) Suchorska B, Kunz M, Schniepp R, et al. Optimized surgical treatment for normal pressure hydrocephalus: comparison between gravitational and differential pressure valves. Acta Neurochir (Wien). 2015;157(4):703-709.

(15) Gölz L, Lemcke J, Meier U. Indications for valve-pressure adjustments of gravitational assisted valves in patients with idiopathic normal pressure hydrocephalus. Surg Neurol Int. 2013;4:140. 2013.

(16) Lemcke J, Meier U, Müller C, et al. Safety and efficacy of gravitational shunt valves in patients with idiopathic normal pressure hydrocephalus: a pragmatic, randomised, open label, multicentre trial (SVASONA). J Neurol Neurosurg Psychiatry. 2013;84(8):850-857.

(17) Sprung C, Schlosser HG, Lemcke J, et al. The adjustable proGAV shunt: a prospective safety and reliability multicenter study. Neurosurgery. 2010;66(3):465-474.

(18) Thomale UW, Gebert AF, Haberl H, Schulz M. Shunt survival rates by using the adjustable differential pressure valve combined with a gravitational unit (proGAV) in pediatric neurosurgery. Childs Nerv Syst. 2013;29(3):425-431.

(19) Xinxing L, Hongyu D, Yunhui L. Using individualized opening pressure to determine the optimal setting of an adjustable proGAV shunt in treatment of hydrocephalus in infants. Childs Nerv Syst. 2015;31(8):1267-1271.

(20) Chari A, Czosnyka M, Richards HK, Pickard JD, Czosnyka ZH. Hydrocephalus shunt technology: 20 years of experience from the Cambridge Shunt Evaluation Laboratory. J Neurosurg. 2014;120(3):697-707.

(21) Gebert AF, Schulz M, Schwarz K, Thomale UW. Longterm survival rates of gravity-assisted, adjustable differential pressure valves in infants with hydrocephalus. J Neurosurg Pediatr. 2016;17(5):544-551.

(22) Toma AK, Watkins LD. Surgical management of idiopathic normal pressure hydrocephalus: a trial of a trial. Br J Neurosurg. 2016;30(6):605.

(23) Yang TH, Chang CS, Sung WW, Liu JT. Lumboperitoneal Shunt: A New Modified Surgical Technique and a Comparison of the Complications with Ventriculoperitoneal Shunt in a Single Center. Medicina (Kaunas). 2019;55(10):643. 2019. (24) Wang Z, Wang K, Qian Z, Zeng L, Gao L. Lumboperitoneal and Ventriculoperitoneal Shunt Surgery for Posthemorrhagic Communicating Hydrocephalus: A Comparison. World Neurosurg. 2019;127:e638-e643.

(25) Nakajima M, Miyajima M, Ogino I, et al. Shunt Intervention for Possible Idiopathic Normal Pressure Hydrocephalus Improves Patient Outcomes: A Nationwide Hospital-Based Survey in Japan. Front Neurol. 2018;9:421. 2018.

(26) Azad TD, Zhang Y, Varshneya K, Veeravagu A, Ratliff JK, Li G. Lumboperitoneal and Ventriculoperitoneal Shunting for Idiopathic Intracranial Hypertension Demonstrate Comparable Failure and Complication Rates. Neurosurgery. 2020;86(2):272-280.

(27) Giordan E, Palandri G, Lanzino G, Murad MH, Elder BD. Outcomes and complications of different surgical treatments for idiopathic normal pressure hydrocephalus: a systematic review and meta-analysis. J Neurosurg. 2019;131:1024-1036.

(28) Nakajima M, Yamada S, Miyajima M, et al. Guidelines for Management of Idiopathic Normal Pressure Hydrocephalus (Third Edition): Endorsed by the Japanese Society of Normal Pressure Hydrocephalus. Neurol Med Chir (Tokyo). 2021;61(2):63-97.

(29) Miyajima M, Kazui H, Mori E, Ishikawa M; , on behalf of the SINPHONI-2 Investigators. One-year outcome in patients with idiopathic normal-pressure hydrocephalus: comparison of lumboperitoneal shunt to ventriculoperitoneal shunt. J Neurosurg. 2016;125(6):1483-1492.

(30) Hussain MA, Strachan RD. Gravity-assisted valve (GAV) systems to prevent low-pressure headaches in patients with lumboperitoneal shunts. Br J Neurosurg. 2017;31(4):426-429.

(31) Kazui H, Miyajima M, Mori E, Ishikawa M; SINPHONI-2 Investigators. Lumboperitoneal shunt surgery for idiopathic normal pressure hydrocephalus (SINPHONI-2): an open-label randomised trial. Lancet Neurol. 2015;14(6):585-594.

(32) Todisco M, Picascia M, Pisano P, et al. Lumboperitoneal shunt in idiopathic normal pressure hydrocephalus: a prospective controlled study. J Neurol. 2020;267(9):2556-2566.

(33) Prof. Nakajima, M. Lecture in Global Webinar series 2020-2021 - Lumboperitoneal Shunt for ideopathic Normal Pressure Hydrocephalus (Japan). 2021.

(34) Gutowski P, Gölz L, Rot S, Lemcke J, Thomale UW. Gravitational shunt valves in hydrocephalus to challenge the sequelae of over-drainage. Expert Rev Med Devices. 2020;17(11):1155-1168.



# HC&ME APP

My Hydrocephalus Diary





Document wellbeing, symptoms & activities



Simple overview of all diary entries

Digital patient pass: All shunts & pressure settings



Support of HC research: voluntary & anonymous\*

Download now for free for iOS and Android. More information: www.HCandME.com

MIETHKE



Our Strong Partner in Neurosurgery:





Manufacturer acc. to RL 93/42/EWG

#### MIETHKE

Christoph Miethke GmbH & Co. KG | Ulanenweg 2 | 14469 Potsdam | Germany Tel. +49 331 62083-0 | Fax +49 331 62083-40 | www.miethke.com

## AESCULAP<sup>®</sup> – a B. Braun brand

Aesculap AG | Am Aesculap-Platz | 78532 Tuttlingen | Germany Phone +49 7461 95-0 | Fax +49 7461 95-2600 | www.aesculap.com

The product trademarks "*GAV*", "*M.blue*", "*M.blue plus*", "*miniNAV*", "*proGAV*", "*proSA*" and "*SHUNTASSISTANT*" are registered trademarks of Christoph Miethke GmbH & Co. KG in the majority of the world. For more detailed information please contact us: info@miethke.com. The main product trademark "Aesculap" is a registered trademark of Aesculap AG.

Subject to technical changes. All rights reserved. This brochure may only be used for the exclusive purpose of obtaining information about our products. Reproduction in any form partial or otherwise is not permitted.