MIETHKE

M.blue®
M.blue plus®

THE BALANCED WAY OF LIFE
INSPIRED BY YOU

Patient Manual

CAUTION: US Federal law restricts this device to sale by or on order of a physician!

"Everyone has a cross to bear - some more than others. The most important thing is not to give up and to live your life to its fullest."

Sarah, nurse and hydrocephalus patient

Foreword

Hydrocephalus is a disease that is frequently connected to the widest range of other existing problems. Some say that hydrocephalus is not a disease but the symptom of another underlying disorder.

Successful treatment of hydrocephalus only became possible in the 1950s. In a dramatic race for the life of his son Casey who had hydrocephalus, Philadelphia technician John D. Holter took only a few weeks to develop a silicone valve. The implantation of this valve in March 1956 marked a great step forward in the clinical treatment of this disease.

Christoph Miethke GmbH & Co. KG has built on the insights of over 50 years of valve treatment, and with the development of gravitation technology pioneered the development of valves that consistently consider the physical framework conditions in the drainage of cerebrospinal fluid, thus ensuring an intraventricular pressure in all body positions that matches that of a healthy person as closely as possible. These days, the primary aim of hydrocephalus therapy is no longer to prevent death or severe impairment as the result of the condition, but to enable patients to lead a life that is as normal as possible.

Your *M.blue / M.blue plus* serves as a gravitational valve. The purpose of this handbook is to provide you and your family with a small insight into the treatment of hydrocephalus with the *M.blue / M.blue plus* implant. *The M.blue plus* is the combination of the valve *M.blue* with a *proGAV 2.0* valve.

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Basics

The human brain is surrounded by a special fluid (scientific term: cerebrospinal fluid - CSF). Inside the head are several chambers (scientific term: ventricles) where CSF is produced. These ventricles are interconnected with channels and constitute a complex drainage system.

CSF has the task of protecting the brain from mechanical damage, regulating intracranial pressure, maintaining moisture levels of the brain tissue and transporting metabolic products.

Fresh CSF is produced in the ventricles each day which is absorbed by the venous blood system. A healthy balance between the production and absorption of CSF is thus very important.

Hydrocephalus

Hydrocephalus means that the balance between production and absorption of CSF is impaired. If more CSF is being produced than can be drained, the cerebral ventricles expand and a hydrocephalus develops ("hydro": Greek for water; "cephale": Greek for head). The ventricles exert pressure on the surrounding brain tissue and can cause neurological damage, some of which is irreversible.

Symptoms

Symptoms depend on the level of impairment and may include: headache, nausea, vomiting, coordination disorders, sleepiness up to the loss of consciousness. For children under the age of two, head circumference can increase significantly, because the bones in their skulls have not yet fused.

The causes of hydrocephalus are very varied and occur at any stage in life.

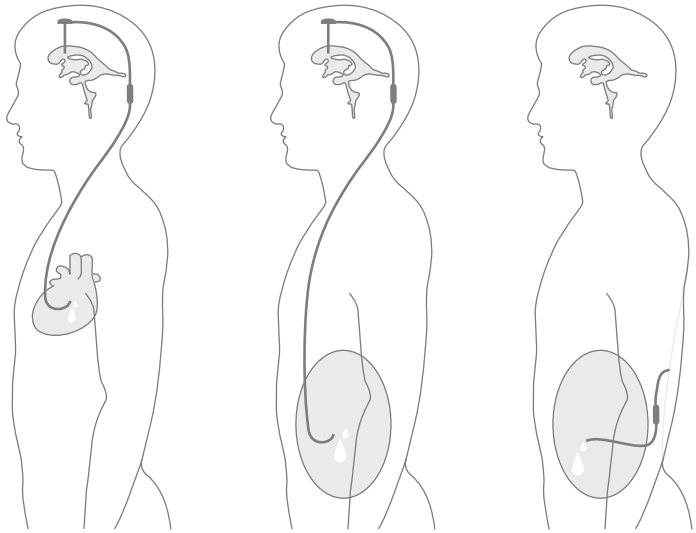
Treatment methods

Even though there have been consistent efforts to find alternative treatment options to the implantation of a valve, e.g. by drug-based treatment or recently by minimally invasive surgical procedures, to this day there is not really an alternative in many cases to the implantation of a drainage system, known as a shunt.

In a hydrocephalus, intracranial pressure has to be reduced to within normal limits. To this end, in most cases a shunt system is implanted, creating a link between the cerebral ventricles and another bodily cavity, generally the abdomen, in order to drain excess CSF from the ventricles.

There are three types of shunt implantation:

1. Ventriculo-atrial (from the cerebral ventricle to the right atrium of the heart)
2. Ventriculo-peritoneal (from the cerebral ventricle to the abdominal cavity)
3. Lumbo-peritoneal (from the spinal canal to the abdominal cavity)



1. *2.* *3.*

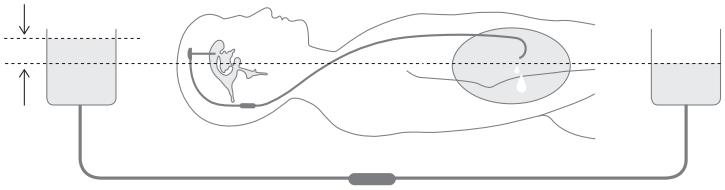
Operating principle of *M.blue*

A proper understanding of the operating principle of *M.blue* requires a brief look at the physics that are involved in this type of drainage. Creating a link between the cerebral ventricle and the abdominal cavity using a tube system might allow the CSF to drain without control, particularly when the patient stands upright, thus transporting too much of the fluid from the ventricles to the abdominal cavity. This is called overdrainage and must be prevented by all means, using what ever means necessary. However, it is entirely normal for a mobile human being to change position frequently: to stand up, walk, sit down or lie down. All this results in continuous physical changes in the drainage system.

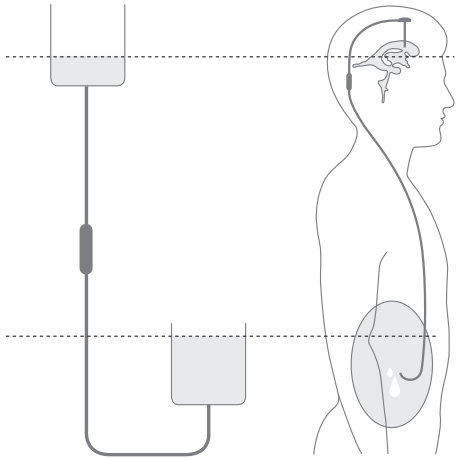
In order to achieve controlled drainage of the cerebrospinal fluid, a valve such as *M.blue* is implanted together with the tube system. This combination of a tube system and a valve is known as a shunt system. Ideally, a valve such as *M.blue* ensures that CSF is only drained when the pressure inside the cerebral ventricles becomes too high. To that end, the valves have preset or adjustable opening pressures, i.e. a valve opens once a predefined intraventricular pressure has been reached, thus preventing over or underdrainage. However, the optimum opening pressure in a prone position is not the same as in an upright one. This is the result of the physical laws of gravity (gravitation).

Physical background

The cerebral ventricle and abdominal cavity connected by the shunt system can be exemplary compared with two connected fluid vessels. When these vessels are level with each other (as in a lying human being), the liquid contained in them tends to equalise. A low opening pressure setting in the shunt system ensures sufficient control in the lying position.

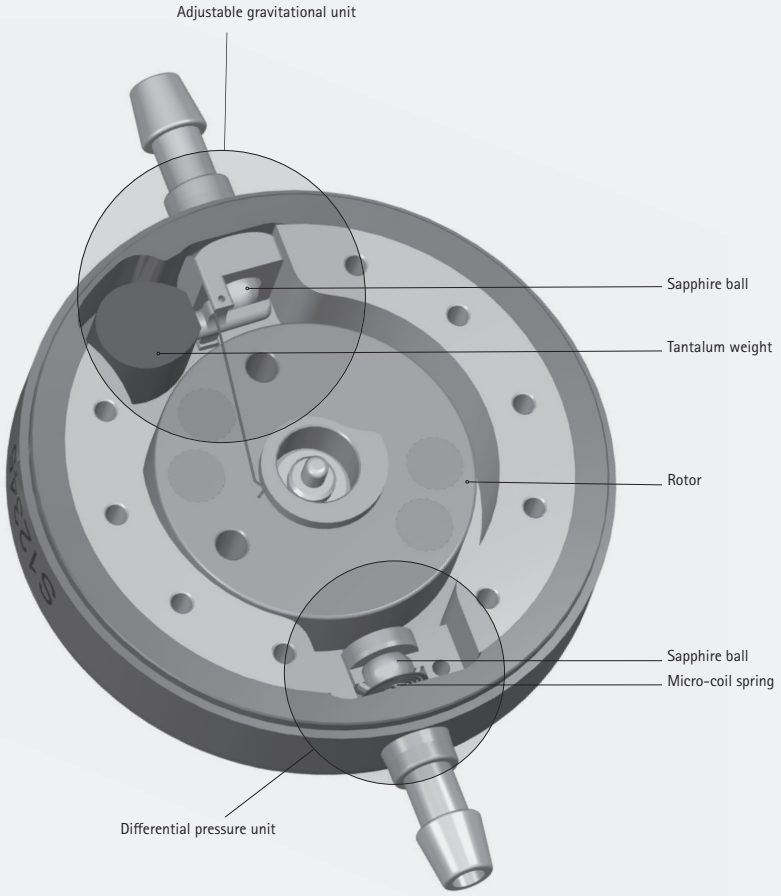


However, when there is a difference in height between the connected fluid vessels (as in a person in upright body position), the fluid contained in the vessels tends to follow gravity and run downwards. The height of a patient has a significant impact on the suction effect being created in the catheter in the upright position. The valve previously set to a low pressure now also opens at a low opening pressure in the upright position, thus ensuring that excessive cerebrospinal fluid drains while the patient is upright.



A single opening pressure would be a constant compromise between the prone and the upright body position. and would constitute a serious restriction to the quality of life.

This means that different opening pressures are required for the various body positions.



Mode of action of M.blue

The *M.blue* is a position-dependent valve. It consists of an adjustable gravitational unit and a fixed differential pressure unit. The *M.blue plus* is the combination of the valves *M.blue* and *proGAV 2.0* and thus consists of an adjustable gravitational unit (*M.blue*) and an adjustable differential pressure unit (*proGAV 2.0*).

Horizontal position

In the horizontal position, the gravitational unit is always open and does not present any resistance. The opening pressure of *M.blue* in the horizontal position is characterised by the adjustable differential pressure unit. The differential pressure unit operates the same in all body positions and usually has a low opening pressure set to ensure that in case of increasing intraventricular pressure the valve facilitates the timely drainage of cerebrospinal fluid, particularly in the prone position.

Vertical position

The gravitational unit makes use of the principle of gravity. As soon as the patient stands up, a tantalum weight is activated which additionally increases the valve opening pressure due to its gravitational force. The more upright the upper body of the patient is, the greater the opening pressure of the whole *M.blue*. This allows the valve to respond with an automatic opening pressure adjustment depending on the body position. Furthermore, the opening pressure of the gravitational unit can also be adjusted to individual patient needs after implantation through the skin, without requiring new surgery.
When using *M.blue plus* (*M.blue* with *proGAV 2.0*), the opening pressure of the differential pressure unit can also be adjusted after implantation through the skin, if necessary.

Adjustment mechanism

M.blue is an adjustable valve. The integrated rotor brake ensures that an unintentional adjustment by externally acting magnetic fields is excluded. The adjustable gravitational unit of *M.blue* is equipped with a feedback mechanism. If external pressure is exerted on the valve an acoustic signal (a click sound) is audible, or a resistance can be felt, as soon as the rotor brake has been released due to the valve housing construction. In other words the valve shows both acoustically and haptically when the pressure is sufficient for uncoupling. Once this pressure has been released the rotor is adjustment-proof again. Although the click caused by releasing the rotor brake is easily audible before implantation, this can be considerably reduced after implantation and filling of the valve depending on its position and the condition of the implant surroundings. Normally, however, it should be audible to the patients themselves or through the use of a stethoscope.

Warning: Pressing the valve should be reserved for the attending physician.

Warning: The shunt system may be fitted with a pumpable reservoir. As too frequent pumping can result in excessive drainage

(overdrainage) and thus unfavourable pressure conditions, this process should exclusively be performed by a doctor.

Materials of *M.blue*

M.blue consists of high-quality materials that have been proven and standardised for use in implants; the main component is titanium. The stable housing ensures reduction of outside influences that could affect the valve function (such as external pressure). This results in a high level of functional assurance and thus a long operating life. The catheters are made from silicone and are not made with natural rubber latex.

Patient pass

Each *M.blue* is accompanied by a patient pass. This is completed by the treating physician and thus contains all of the important information for follow-up examinations.

We recommend that you always carry your patient pass with you in order to identify yourself as an implant holder and to have the most important information available to the treating doctor on site in an emergency.

Treatment complications

The treatment of hydrocephalus with a shunt system is not always free from complications. As with every surgical intervention, there is a risk of infection. Unfortunately, problems can develop occasionally that could be directly or indirectly linked to the implanted valve. Such complications include blockages of the shunt system or undesired excessive or insufficient drainage of cerebrospinal fluid (over- or underdrainage). Violent shocks for the outside (accident, fall) may put the integrity of the shunt system at risk.

Suspected Infection

Reddening of skin or tightness in the area of the drained tissue may be indications of infections at the shunt system. Symptoms such as headache, dizziness, confusion or vomiting often occur in conjunction with shunt dysfunction. These symptoms and a leakage within the shunt system require the immediate replacement of the affected shunt component or the entire shunt system. The implantation of medical devices is contraindicated if the patient has an infection or suspected infection (e.g. meningitis, ventriculitis, peritonitis, bacteriaemia, septicaemia) in the region affected by the implantation.

These medical devices are constructed in such a way as to ensure their precise and reliable operation over long periods of time. However, no guarantee can be given that these medical devices may not require replacement for medical or technical reasons. These medical devices are able to resist positive and negative pressures up to 200 cmH20 during and after implantation.

Conduct after the operation

Patients supplied with a shunt system are normally not restricted in their daily lives. You can safely travel by plane, do sports or go to work with *M.blue*. Only for the period immediately after the surgery, you should discuss with your doctor to what extent you should avoid physical exertion and for how long that would be advisable in your specific case.

MRI

The following applies for potential MRI follow-up examinations: Both the *M.blue* and the *M.blue plus* (combination of *M.blue* and *proGAV 2.0*) are MR Conditional up to 3 Tesla.

Cardiac Pacemakers

For people using cardiac pacemakers: It is possible that the function of the pacemaker is influenced by the implantation of *M.blue*.

Sound from the Valve

Some patients hear their valve, others do not. Simply put, it can be assumed that the valve works when you hear it. On the other hand, the same does not apply. Just because you do not hear the valve does not mean that it does not work. Most patients who hear their valve describe this phenomenon when they change their body position - for example when they get up in the morning. What they hear is a vibration of the ball that closes the valve or is responsible for opening it. When changing the body position, it is in a constant state of alternation between opening and closing to ensure that the pressure is equalised.

About the company

Christoph Miethke GmbH & Co. KG, based in Potsdam, has from 1992 concentrated on the development, production and distribution of innovative neurosurgical implants for the treatment of hydrocephalus.

Our daily aim is through the innovative development and production of high-quality reliable products to improve the life of hydrocephalus patients. One of our foremost tasks hereby in cooperation with hospitals, physicians and patients is primarily this, to understand. Again and again, we change perspectives and meet with our colleagues, partners and patients on an equal footing.

For detailed information about our company, please visit our website:
www.miethke.com.
More about the *M.blue* is available on our *M.blue* website:
www.thenewblue.com.

More about the operating principle of our valves is available here:
www.miethke.com/produkte

Or use our app:
Apple: https://itunes.apple.com/de/app/miethke/id450290015?mt=8
Android: https://play.google.com/store/apps/details?id=com.miethke.graviton

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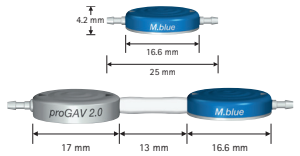
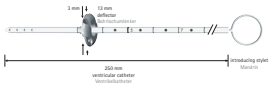
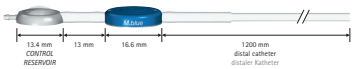
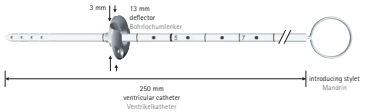
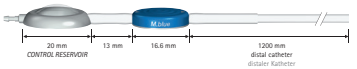
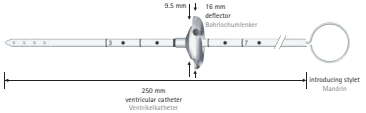
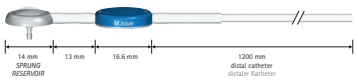
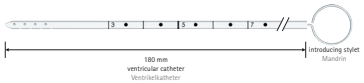
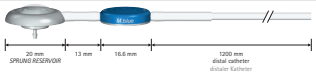
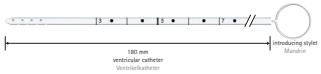
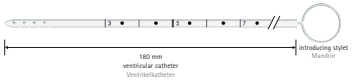
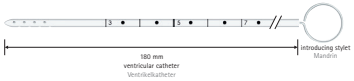
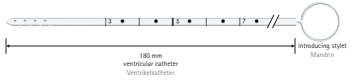
For up-to-date information, visit our social media channels:
facebook.com/MiethkeDeutschland youtube.com/Miethke_International

M.BLUE Shunt Portfolio

B BRAUN
SHARING EXPERTISE

Component	Material	Product Code
M.blue 0 valve		FX800T
M.blue 5 valve		FX801T
M.blue 10 valve		FX802T
M.blue 15 valve		FX803T
M.blue plus valve		FX804T
M.blue 0 Valve with peritoneal Catheter		FX805T
M.blue 5 Valve with peritoneal Catheter		FX806T
M.blue 10 Valve with peritoneal Catheter		FX807T
M.blue 15 Valve with peritoneal Catheter		FX808T
M.blue plus Valve with peritoneal Catheter		FX809T
M.blue 0 Shunt System		FX810T
M.blue 5 Shunt System		FX811T
M.blue 10 Shunt System		FX812T
M.blue 15 Shunt System		FX813T
M.blue plus Shunt System		FX814T
M.blue 0 System with pediatric CONTROL RESERVOIR		FX815T
M.blue 5 System with pediatric CONTROL RESERVOIR		FX816T
M.blue 10 System with pediatric CONTROL RESERVOIR		FX817T
M.blue 15 System with pediatric CONTROL RESERVOIR		FX818T
M.blue plus System with pediatric CONTROL RESERVOIR		FX819T
M.blue 0 System with CONTROL RESERVOIR		FX820T
M.blue 5 System with CONTROL RESERVOIR		FX821T
M.blue 10 System with CONTROL RESERVOIR		FX822T
M.blue 15 System with CONTROL RESERVOIR		FX823T
M.blue plus System with CONTROL RESERVOIR		FX824T

Component	Material	Product Code
M.blue 0 System with pediatric SPRUNG RESERVOIR		FX825T
M.blue 5 System with pediatric SPRUNG RESERVOIR		FX826T
M.blue 10 System with pediatric SPRUNG RESERVOIR		FX827T
M.blue 15 System with pediatric SPRUNG RESERVOIR		FX828T
M.blue plus System with pediatric SPRUNG RESERVOIR		FX829T
M.blue 0 System with SPRUNG RESERVOIR		FX830T
M.blue 5 System with SPRUNG RESERVOIR		FX831T
M.blue 10 System with SPRUNG RESERVOIR		FX832T
M.blue 15 System with SPRUNG RESERVOIR		FX833T
M.blue plus System with SPRUNG RESERVOIR		FX834T
M.blue 0 System with pediatric SPRUNG RESERVOIR		FX835T
M.blue 5 System with pediatric SPRUNG RESERVOIR		FX836T
M.blue 10 System with pediatric SPRUNG RESERVOIR		FX837T
M.blue 15 System with pediatric SPRUNG RESERVOIR		FX838T
M.blue plus System with pediatric SPRUNG RESERVOIR		FX839T
M.blue 0 System with SPRUNG RESERVOIR		FX840T
M.blue 5 System with SPRUNG RESERVOIR		FX841T
M.blue 10 System with SPRUNG RESERVOIR		FX842T
M.blue 15 System with SPRUNG RESERVOIR		FX843T
M.blue plus System with SPRUNG RESERVOIR		FX844T
M.blue 0 System with pediatric Burrhole RESERVOIR		FX845T
M.blue 5 System with pediatric Burrhole RESERVOIR		FX846T
M.blue 10 System with pediatric Burrhole RESERVOIR		FX847T
M.blue 15 System with pediatric Burrhole RESERVOIR		FX848T
M.blue plus System with pediatric Burrhole RESERVOIR		FX849T

Please Note

Implants partly include metal components, so that metal detectors could respond. Therefore, please carry your patient card with you, especially during Air travel, in order to pass the security checks. If there are any complications, please contact your hospital.

MR Safety Information
MR Conditional

The *M.blue* valve is MR Conditional.
M.blue has been exposed to magnetic forces of 3T in different MRI-scanners. The products were exposed to the magnetic field in different spatial positions.

Non-clinical testing demonstrated that the devices are MR Conditional. A patient with one of these devices can be safely scanned immediately after implantation in an MR system meeting the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 1,400-Gauss/cm (14.0 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg.

In addition, the products have been exposed by changed magnetic flux density. No product has changed the specification after MRI exposure.

M.blue shows slight artifacts due to the use of small magnets inside the valve. An adjustment of the *M.blue* by the MRI exposure could not be determined. A verification of the adjusted opening pressure after MRI exposure is not required.

Do not take the *M.blue plus* Instruments into the MR environment. They are MR Unsafe.

Caution

For people using cardiac pacemakers:
It is possible that the function of the pacemaker is influenced by the implantation of *M.blue*.

Due to the magnets inside the *M.blue plus* Instruments, *M.blue plus* Instruments may not be used in the vicinity of active implants such as heart pacemakers.

Incident Reporting

Any serious incident occuring in relation to the device should be reported to B. Braun Australia Pty Ltd and to the Therapeutic Goods Administration.

Phone: 1800 206 045

www.bbraun.com.au

www.tga.gov.au

Technical alterations reserved

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