MIETHKE

GAV® 2.0
GAV® 2.0 LP

US Instructions for Use

www.miethke.com

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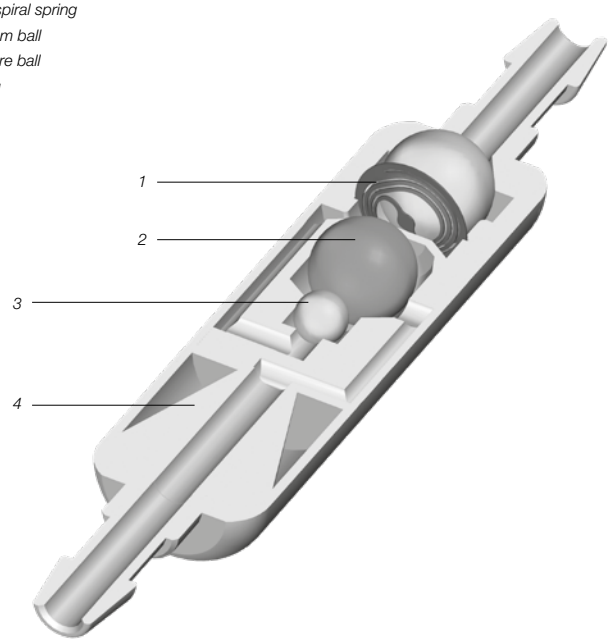


fig. 1: GAV 2.0 in cross section

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

INDICATION

The Miethke Shunt System *GAV 2.0* is used for cerebrospinal fluid (CSF) drainage.

CONTRAINDICATIONS

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.

PRECAUTIONS

Patients must be carefully monitored after implantation. 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.

ADVERSE REACTIONS AND INTERACTIONS

In the treatment of hydrocephalus with shunts, the following complications may arise (as described in the literature): infections, blockages caused by protein and/or blood in the cerebrospinal fluid, over/under drainage, in very rare cases noise development, altered mental status, headaches, lethargy, irritability, vomiting, changes in vision, difficulty walking, loss of consciousness, seizures, hemorrhage, or death. Violent shocks for the outside (accident, fall) may put the integrity of the shunt system at risk.

WARNINGS

The *GAV 2.0* must not be used in conjunction with hydrostatic valves as this may result in increased ventricular pressure outside of the physiological range. In case of doubt, please contact the medical device consultants at Christoph Miethke GmbH & Co. KG.

Frequent pumping can result in excessive drainage and thus lead to pressure conditions outside the normal physiological range. The patient should be properly informed about this risk.

The catheters should only be blocked with a sheathed clamp and not directly behind the valve as they might be damaged otherwise.

Contamination in the solution used for testing can impair the product's performance.

Pressurisation by the single-use syringe should be avoided both at the proximal and the distal end.

Do not resterilize.

TECHNICAL DESCRIPTION

GAV 2.0 is a valve made from titanium. It consists of a ball-cone unit and a gravitational unit. Thus a physiological intraventricular pressure (IVP) can be reached in any body position.

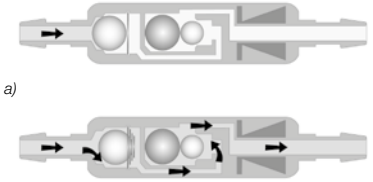
In the proximal part of the *GAV 2.0*, micro spiral spring (1) enables the opening pressure of the ball-cone unit. The gravitational unit in the distal part of the valve consists of a tantalum ball (2) which defines the opening pressure of this unit, and a sapphire ball (3) which enables its precise closure. Coding (4) permits the identification of pressure levels in an X-ray.

FUNCTION OF THE VALVE

The *GAV 2.0* is a position-dependent valve.

Horizontal position

In the horizontal position, the gravitational unit is always open and does not present any resistance. For that reason, the *GAV 2.0* opening pressure in this position is only defined by the ball-cone unit. fig. 2a shows the ball-cone unit in closed status. If the patient's intraventricular pressure (IVP) exceeds the opening pressure of the micro spiral spring, the ball from the cone, thus opening a gap for drainage (fig. 2b).



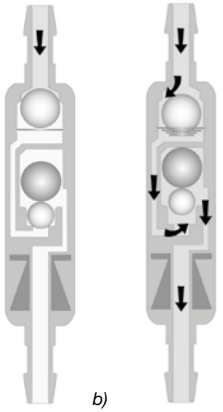
a)

b)

fig. 2: GAV 2.0 in horizontal position
a) closed b) open

Vertical position

When the patient moves into an upright position, the gravitational unit is activated and the opening pressure of the *GAV 2.0* is significantly increased (fig. 3a). In addition to the opening pressure of the ball-cone unit, the weight of the tantalum ball (opening pressure of the gravitational unit) has to be exceeded. Drainage is only possible once the sum of intraventricular pressure (IVP) and hydrostatic pressure is greater than the opening pressure of both units (fig. 3b).



a) *b)*

fig. 3: GAV 2.0 in vertical position
a) closed b) open

SELECTION OF THE APPROPRIATE PRESSURE LEVEL

Horizontal position

Depending on the clinical picture and age of the patient, the opening pressure for this position can be selected between pressure levels 5 and 10 cmH_2O.

Vertical position

Patient size, activity level and potentially increased abdominal pressure (obesity) should be taken into account in selecting the opening pressure for this position (see pressure level recommendations at https://www.miethke.com/en/products/downloads/).

PRESSURE LEVELS RECOGNITION IN X-RAY IMAGES

The selected pressure levels can be detected radiographically after implantation.

Valve opening pressure horizontal	vertical	Coding
5 cmH_2O	20 cmH_2O	
5 cmH_2O	25 cmH_2O	
5 cmH_2O	30 cmH_2O	
5 cmH_2O	35 cmH_2O	
10 cmH_2O	25 cmH_2O	
10 cmH_2O	30 cmH_2O	

fig. 4: GAV 2.0 pressure levels encodings on X-ray

POSSIBLE SHUNT COMPONENTS

The *GAV 2.0* can be ordered as a shunt system in a range of configurations. The configurations can be combined with the accessories presented in brief below. In each case, versions for paediatric hydrocephalus and for normal pressure hydrocephalus (NPH) in adults are available.

Reservoirs

The use of a reservoir in combination with shunt systems allows flushing and extraction of CSF.

Thanks to the one-way flux (flow) system of the *SPRUNG RESERVOIR* and the *CONTROL RESERVOIR*, cerebrospinal fluid can be pumped towards the valve, thus making it possible to check the distal part of the drainage system as well as (proximal) ventricular catheter. During the pump action, access to the ventricular catheter is closed. The use of reservoirs does not increase the opening pressure of the shunt system. A puncture should be performed as perpendicular as possible to the reservoir surface with a maximum cannula diameter of 0.9 mm. 30 punctures are possible without any restrictions.

Burrhole deflector

Because of the tight fit on the ventricular catheter, the burrhole deflector makes it possible to choose the length of catheter penetrating into the skull prior to implantation. The ventricular catheter is deflected at a right angle in the burrhole (see chapter “Implantation”).

TUBE SYSTEMS

The *GAV 2.0* can be ordered as an individual valve unit or as a shunt system with integrated catheters (interior diameter 1.2 mm, exterior diameter 2.5 mm). The supplied catheters do not fundamentally change the pressure-flow characteristics. If catheters by other manufacturers are used, a tight fit must be ensured. In any case, catheters have to be carefully fixed with a ligature to the valve’s titanium connectors.

IMPLANTATION

Positioning the ventricular catheter

Several surgical techniques are available for positioning the ventricular catheter. The required skin incision should be made in form of a lobule pedicled towards the draining catheter. If a burrhole deflector is used, the skin incision should not be located right above the reservoir. To avoid CSF leakage, care should be taken that the dura opening is kept as small as possible after applying the burrhole.

The *GAV 2.0* is available in a range of different configurations: If a burrhole reservoir is used, the ventricular catheter is implanted first. Once the introducing stylet has been removed, the patency of the ventricular catheter can be tested by checking if cerebrospinal fluid is dripping out. The catheter is shortened and the reservoir is connected, whereby the connection is secured with a ligature. A shunt system with prechamber comes with a burrhole deflector. The deflector is used for adjusting the length of catheter to be implanted and for its positioning inside the ventricle. The ventricular catheter is deflected, connected to the prechamber, and the prechamber is put into place. Post procedural inspection of the entire implanted valve and component system should be obtained with either X-ray or CT imaging.

Positioning the valve

The operating principle of the *GAV 2.0* is posture-dependent. For that reason, care must be taken to implant the valve parallel to the body axis. For VP drainage, a suitable position for implantation is behind the ear. After skin incision and tunnelling under the skin, the catheter is pushed forward from the burrhole to the intended valve implantation site, shortened where necessary and secured with a ligature. For LP drainage, the valve is placed in a subcutaneous skin pocket in the abdominal or back region. The valve should not be located directly under the skin incision. The valve is marked with an arrow indicating the distal direction of flow.

Positioning the peritoneal catheter

The access site for the peritoneal catheter is left to the surgeon’s discretion. For example it can be applied para-umbically in a horizontal direction or transrectally at the height of the epigastrium. Likewise, various surgical techniques are available for positioning the peritoneal catheter. The recommendation is to pull the peritoneal catheter using a subcutaneous tunnelling tool from the valve to the intended position, if necessary with the aid of an auxiliary incision. The peritoneal catheter which is usually securely attached to the valve has an open distal end and no wall slits. Following the exposure of the peritoneum or with the aid of a trocar, the peritoneal catheter (shortened if necessary) is pushed forward into the open space of the abdominal cavity.

Reimplantation

Products that have previously implanted must not subsequently be reimplanted into the same or another patient.

VALVE TEST

Preoperative valve test

The most careful way of filling the valve is by aspiration through a sterile single-use syringe attached to the distal end of the catheter. The distal end of the valve is connected and immersed in a sterile physiological saline solution. The valve is patent if saline solution can be extracted (fig. 5).

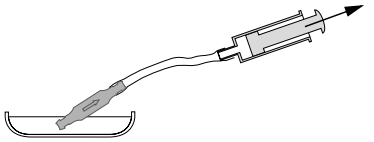


fig. 5: Patency test

Pressurisation by the single-use syringe should be avoided both at the proximal and the distal end (fig. 6).

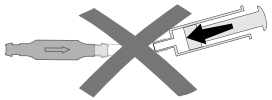


fig. 6: Avoidance of pressurisation

Postoperative valve test

The *GAV 2.0* has been constructed as a reliably functioning unit without pump or test function. The valve test can be performed by flushing, pressure measurement or pumping.

VALVE TEST PRIOR TO IMPLANTATION

Each *GAV 2.0* valve has been tested to ensure that the performance specifications given on the label are always met. The dynamic performance characteristics of the shunt cannot be tested in a static test performed in the operating room. If the surgeon wishes to verify, prior to implantation, that the shunt meets the specifications given by the manufacturer, the test described in the following can be carried out in the operating room:

Caution: Always take care that sterility is maintained and particle contamination is avoided.

Test method

Equipment required for this test:
a) sterile fluid reservoir or water bath
b) sterile fluid 60-cm water manometer with millimeter grading and threebranch faucet at the base
c) sterile syringe, 30 cc to 50 cc
d) sterile 5-µ tip filter
e) sterile tube adapter
f) sterile silicone tube

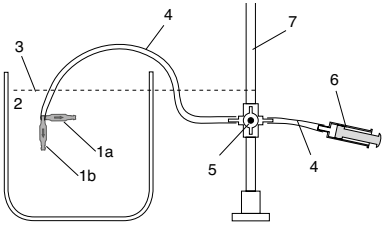


fig. 7: Test setup

1 GAV 2.0 a) horizontal, b) vertical;
2 water bath
3 constant water level
4 silicone tube
5 threeway tap
6 single-use syringe with syringe filter
7 manometer

Setting up the equipment

a) Position the manometer and the water bath in such a way that the zero point of the manometer and the fluid level of the water bath are at the same height (see fig. 7).

b) Fill the syringe, with the 5-µ tip filter attached, with sterile water (Always use the 5-µ tip filter when topping up the syringe.). Remove the tip filter when the syringe is full.

c) Connect the syringe, the manometer and the silicone tube with each other. Use the tube adapter if necessary. (see fig. 7)

d) To release all air from the test assembly, turn the three-way faucet as shown in fig. 8.

e) Immerse the silicone tube in the sterile water bath and rinse it with the sterile water from the syringe.

Calibrating the equipment

a) Turn the three-way faucet as shown in fig. 9 and fill the manometer to at least 5 cmH_2O.

b) With the silicone tube immersed in the water bath, turn the three-way faucet so that the syringe is isolated from the manometer (see fig. 10).

c) Allow the water column in the manometer to drop.

d) The water column should stop dropping at the zero point. Adjust the zero point of the manometer to fluid level of the water bath, if necessary.

e) The manometer has now been calibrated to the zero-level of the water bath. Fixate the manometer to maintain its position in relation to the water bath.

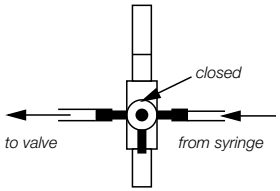


fig. 8

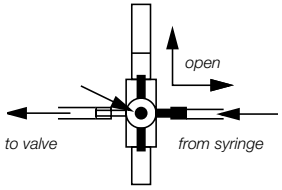


fig. 9

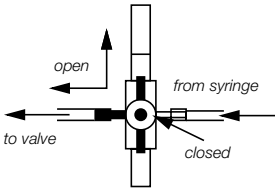


fig. 10

Test procedure

Please note: During the test the shunt must be submerged in the water bath. The zero point of the manometer has to be aligned with the water level of the water bath in order to obtain correct results.

a) Connect the sterile shunt to be tested to the ready assembled, sterile test equipment.

b) Turn the three-way faucet as shown in fig. 9 and fill the manometer to 10 cmH_2O above the expected opening pressure. (Example: For testing a *GAV 2.0* with an opening pressure setting of 5 cmH_2O horizontal and 25 cmH_2O vertical, the manometer is filled to 15 cmH_2O with the shunt in a horizontal position and to 40 cmH_2O with the shunt in a vertical position.)

c) Turn the three-way faucet as shown in fig. 8 so that the manometer is isolated.

d) Remove all air from the shunt and the test setup by carefully rinsing it through with sterile water from the syringe.

e) Immerse the sterile shunt in the sterile water bath. The distal part of the shunt must be under water to obtain valid test results.

f) Carefully maintain a flow through the shunt and turn the threeway faucet as shown in fig. 10 to isolate the syringe. As soon as the three-way faucet is in the correct position, the water column should begin to drop. The syringe is now isolated from the valve and it is not necessary anymore to maintain its flow. Repeat steps b to f if the water column fails to drop.

g) Allow the water level in the manometer to drop for 2 to 2.5 minutes. Read the resulting pressure at the manometer.

TEST RESULTS OF PREIMPLANTATION TEST

The pressure readings obtained by this method should yield the following results.

prone/horizontal valve position:

pressure setting	Acceptable pressure ranges
5 cmH_2O	1-7 cmH_2O
10 cmH_2O	5-12 cmH_2O

vertical valve position:

pressure setting	Acceptable pressure ranges
20 cmH_2O	10 - 22 cmH_2O
25 cmH_2O	12,5 - 27 cmH_2O
30 cmH_2O	15 - 32 cmH_2O
35 cmH_2O	17,5 - 37 cmH_2O

PRESSURE-FLOW CHARACTERISTICS

The following diagrams show the pressure-flow characteristics for the available pressure settings of the *GAV 2.0* (fig. 11). The total opening pressure refers to a reference flow of 5 ml/h. For flow rates of 20 ml/h, stated pressures are approx. 1-2 cmH_2O higher.

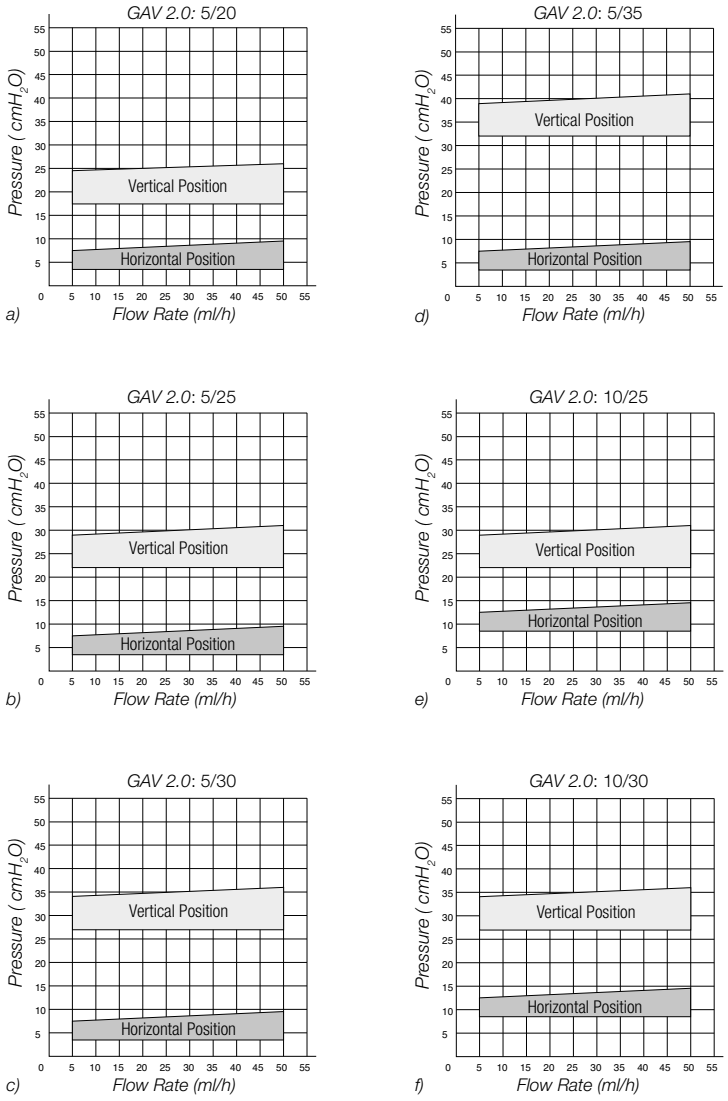


fig. 11: Pressure-flow characteristics for the available pressure settings of the GAV 2.0

FUNCTIONAL SAFETY AND COMPATIBILITY WITH DIAGNOSTIC PROCEDURES

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 cmH_2O during and after implantation. These medical devices have to be stored in a clean and dry environment at all times.

Nuclear magnetic resonance examinations up to a field strength of 3 Tesla or computed tomography examinations can be performed without risk or impairment to the valve function. The valve is MR Conditional (ASTM F2503-13). Supplied catheters are MR Safe. Reservoirs, deflectors and connectors are MR Conditional.

STERILIZATION

The products are sterilized with steam under strictly controlled conditions. The double wrapping in sterile bags ensures sterility for a five-year period. The expiry date is printed on the wrapping of each individual product. If the packaging is damaged, the product must not be used in any circumstances.

REQUIREMENTS OF THE MDD (DIRECTIVE 93/42/EEC)

The Medical Device Directive requires the comprehensive documentation of the whereabouts of medical devices used in humans. The individual identification number of the implanted valve should therefore be recorded in the patient's medical records and patient data card to ensure complete traceability.

Translations of these instructions for use into additional languages can be found on our website (https://www.miethke.com/en/products/downloads/).

MRI SAFETY INFORMATION

The *GAV 2.0* programmable valve was determined to be MR Conditional (ASTM F2503-13). According to the results of in vitro testing, a patient with the *GAV 2.0* may undergo an MRI procedure using an MR system with a static magnetic field of 3T or less. No impact on the performance of the *GAV 2.0* at 3T or less can be expected.

Non-clinical testing demonstrated that the GAV 2.0 valve is MR Conditional. A patient with this device 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 4000-Gauss/cm (40 T/m)
- Maximum MR system reported, whole body averaged absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the *GAV 2.0* valve is expected to produce a maximum temperature rise of 1.5°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 20 mm from the *GAV 2.0* valve when imaged with a gradient echo pulse sequence and a 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X. M5, General Electric Healthcare, Milwaukee, WI) MRI system. As such, the *GAV 2.0* should not be placed in close proximity to a location, which may require an MR image. Below is a chart containing the signal void associated with the *GAV 2.0* as tested to ASTM F 2119-07 using a 3 Tesla MR-scanner Excite General Electric Healthcare. The temperature measurement at 3T and 1,5 T showed no increased temperature caused by the implant in a worst-case scenario (static liquid) test performed at a whole-body averaged SAR of 1.9 W/kg. The results imply, that no additional risk due to radio frequency

induced heating is caused to the patient, if the valves are implanted.
Testing was conducted in accordance to ASTM F2182-11a. The *GAV 2.0* had relatively minor magnetic field interaction, passing the deflection testing of ASTM F2052-15 with no torque produced (ASTM F2213-06) and a 2-degree deflection angle. Therefore the *GAV 2.0* will not present an additional risk or hazard to the patient with the regards to deflection or torque in the environment of a 3 T magnetic resonance tomography.

Artifact information

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal void size	471 mm2	261 mm2	809 mm2	789 mm2
Plane orientation	parallel	perpen-dicular	parallel	perpen-dicular

Postoperative valve test
The *GAV 2.0* has been designed to function properly even without the provision of a pumping device. However, there are ways of testing the unit if a shunt system with a prechamber or a burrhole reservoir is used. Valve tests can be carried out by flushing or pressure measurements.

MEDICAL PRODUCTS CONSULTANTS

In compliance with European directive on medical devices (directive 93/42/EEC), Christoph Miethke GmbH & Co. KG has nominated medical products consultants as contacts for all product-related questions:

Dipl.-Ing. Christoph Miethke
Dipl.-Ing. Roland Schulz
Michaela Funk-Neubarth
Dipl.-Ing. Thoralf Knitter
Dr. Andreas Bunge
Jan Mügel

Please address any enquiries to:
AESCULAP AG
Am Aesculap Platz
D-78532 Tuttlingen · Germany
Phone: +49 7461 95-0
Fax: +49 7461 95-26 00
e-mail: information@aesculap.de

Service address in the US
AESCULAP Inc.
Attn. AESCULAP Technical Services
615 Lambert Pointe Road
Hazelwood, MO, 63042
AESCULAP Repair Hotline
Phone: +1 (800) 214-3392
Fax: +1 (314) 895-4420

Distributor in the US/ Contact in Canada
AESCULAP Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Phone: +1-800-282-9000
www.aesculapusa.com
USA

VARIANTS

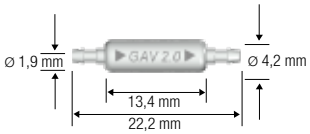


Fig. 8: GAV 2.0 (VP drainage)

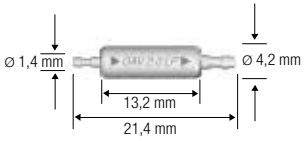


Fig. 9: GAV 2.0 LP (straight)

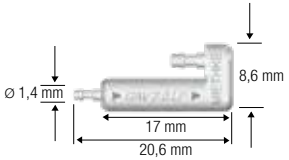


fig. 11: GAV 2.0 LP (U-shaped)

CE 0297

US CE marking according to directive 93/42/EEC

US Technical alterations reserved

Manufacturer:

MIETHKE

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

注册人: Christoph Miethke GmbH & Co. KG 克里斯托福弥提柯股份有限公司
住所: Ulanenweg 2, 14469 Potsdam, Germany
联系方式: www.miethke.com, info@miethke.com

Distributor:

B BRAUN
SHARING EXPERTISE

Aesculap AG | Am Aesculap-Platz | 78532 Tuttlingen | Germany
Phone +49 7461 95-0 | Fax +49 74 61 95-26 00 | www.bbraun.com

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