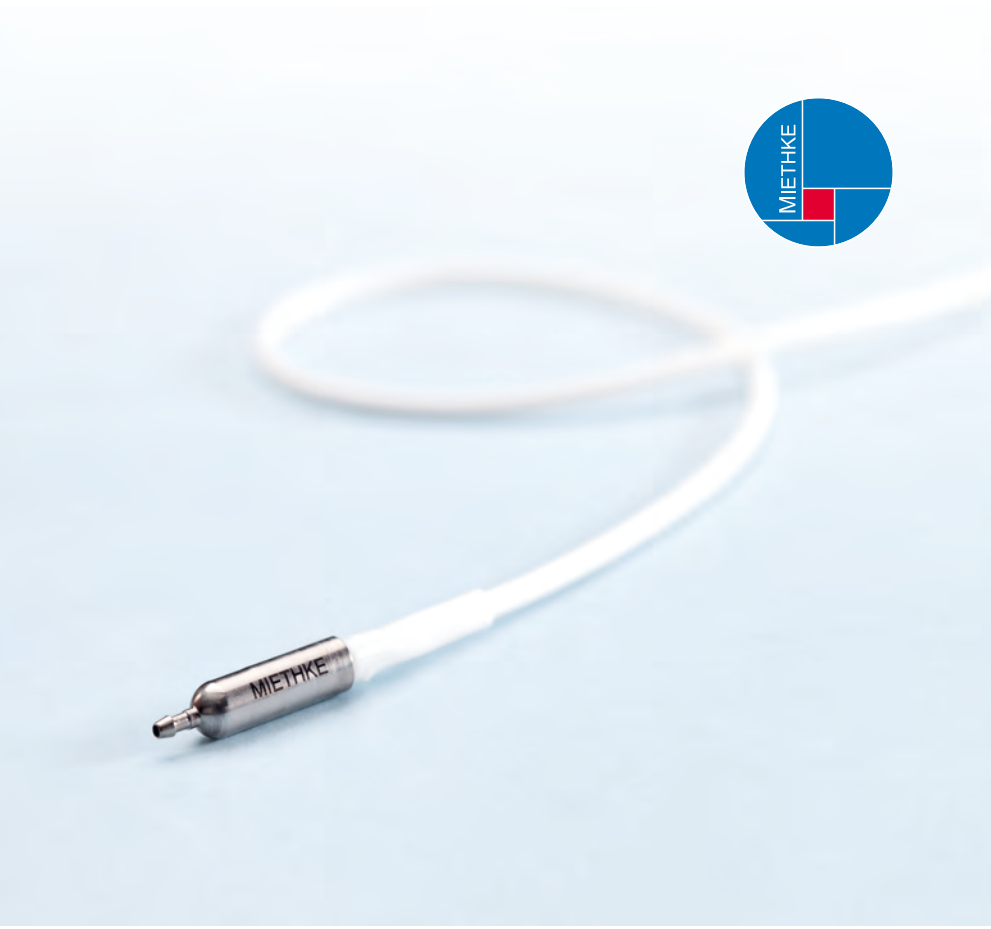

uniGAV®

GB Instructions for use | CN 使用适应症

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CHRISTOPH MIETHKE GMBH & CO. KG

CE 0297

INHALTSVERZEICHNIS

INDICATION

The *uniGAV* is used for draining cerebrospinal fluid (CSF) from the ventricles into the peritoneum in hydrocephalus patients.

TECHNICAL DESCRIPTION

The *uniGAV* is a posture dependent hydrocephalus valve. It consists of a ball-cone unit and a gravitational unit. This ensures that optimal CSF drainage is achieved for each individual patient in any body position.

Fig.1 shows a schematic cross section of the *uniGAV*.
The *uniGAV* is made of a solid titanium body with a well-tried ball-cone unit integrated in its proximal part. A spiral spring (3) defines the opening pressure of the ball-cone unit.
The gravitational unit in the distal part contains a tantalum ball (5), which defines the opening pressure of this valve, and a sapphire ball (6), which ensures the precise closure of the valve.

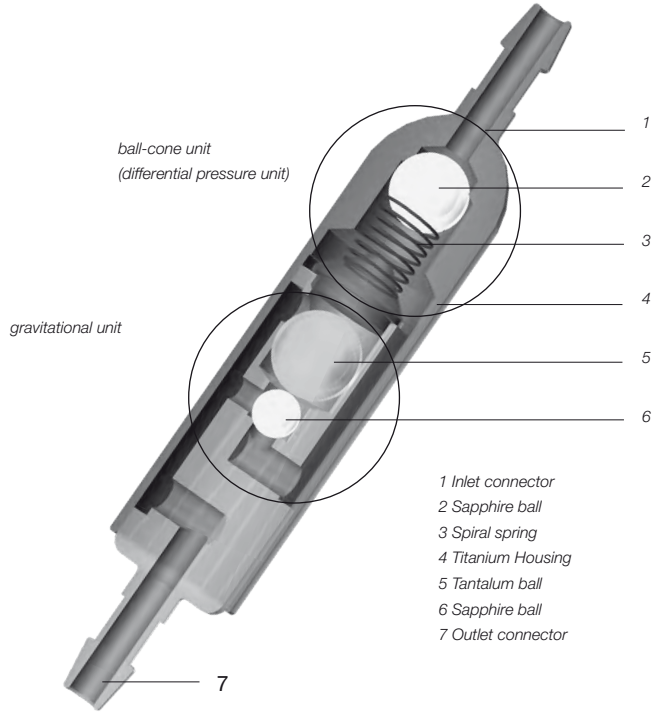


Fig. 1: Schematic cross section of the uniGAV

PHYSICS BACKGROUND

The intraventricular pressure is positive in a healthy human in a horizontal position. To adjust this pressure through shunt drainage, one has to choose the appropriate pressure range, taking into account the abdominal cavity pressure. The resulting IVP is the sum of the shunt opening pressure and the abdominal cavity pressure (fig. 2).

The ventricular pressure in a healthy human in a vertical position becomes slightly negative. To maintain this pressure by means of shunt drainage, the shunt opening pressure has to be significantly higher so that the shunt can compensate the hydrostatic pressure minus the sum of the abdominal cavity pressure.
Conventional shunts open immediately as soon as the patient stands up, which can lead to critical overdrainage.

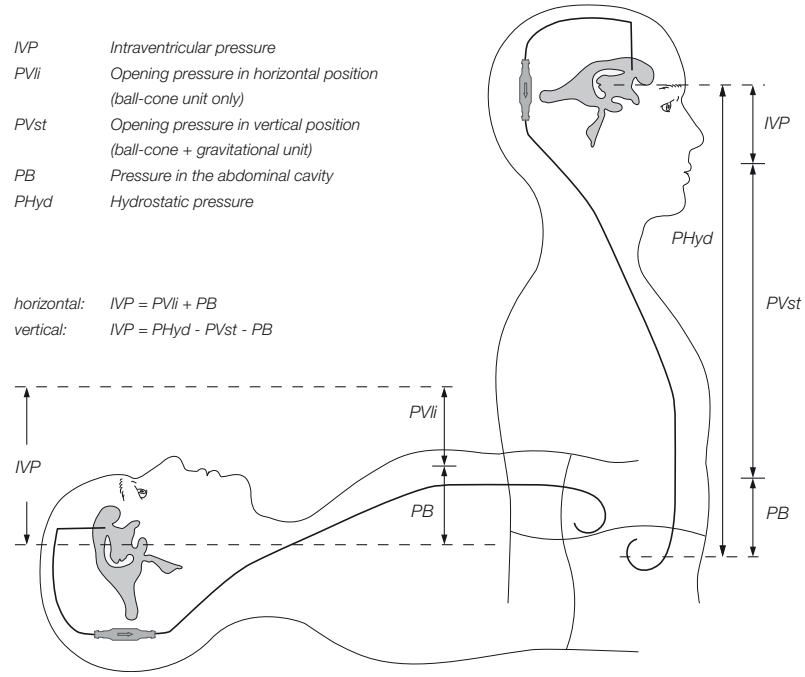
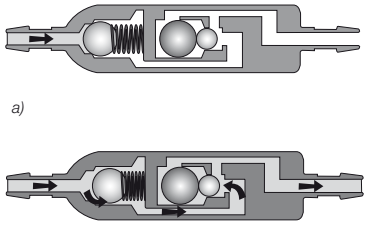


Fig. 2: Calculating the intraventricular pressure

FUNCTION OF THE VALVE

The opening pressure of the *uniGAV* is composed of the opening pressure of the ball-cone unit and the opening pressure of the gravitational unit.

Horizontal position
The operational principle of the *uniGAV* is illustrated in figures 3a and b.
When the patient is in lying position, the gravitational unit is always open and therefore does not present any resistance to the fluid flow.
In fig. 3a, the ball-cone valve is closed. The drainage is blocked. In fig. 3b, the ball-cone unit is shown in the open position. The patient's IVP is increased and the spring force, which otherwise keeps the ball-cone unit closed, is overcome. The closing ball moves out of the cone and a gap opens to allow drainage. The opening pressure of the ball-cone valve is 7 cmH_2O.

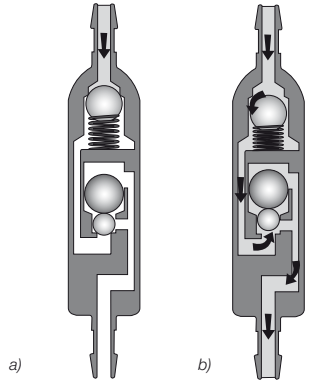


a)

b)

Fig. 3: ball-cone unit in horizontal position
a) closed b) open

Vertical position
The operation of the gravitational valve is position-dependent. As soon as the patient moves into an upright position, the gravitational valve closes, the opening pressure of the *uniGAV* is significantly increased and CSF drainage is blocked (fig. 4a). Only when the sum of the IVP and the hydrostatic pressure exceeds the opening pressure of the *uniGAV*, drainage will be possible again (fig. 4b). The opening pressure of the *uniGAV* in the vertical position is 27 cmH_2O and the sum of the opening pressures of both the ball-cone valve and the gravitational valve (weight of the tantalum ball).
The total opening pressure refers to a reference flow of 5 ml/h. When the flow reach 20 ml/h, the opening pressures are approximately 1-2 cmH_2O higher.



a) b)

Fig. 4: Gravitational unit in vertical position
a) closed b) open

POSSIBLE SHUNT COMPONENTS

The *uniGAV* is available with different shunt accessories. These variants are comprised of a variety of components, which are described below. There are variations for the use by children and adult hydrocephalus patients.
The *borehole reservoir* is positioned in the cranial borehole. It allows measuring the intraventricular pressure, injecting drugs and extracting CSF. Its solid titanium base is highly puncture-resistant. All reservoirs are available with integrated catheters or connectors. The *SPRUNG RESERVOIR* is a special borehole reservoir. As additional new feature of this reservoir CSF can be flushed towards the valve because of a one-way valve in the bottom of the reservoir. By this mechanism a flow in the direction of the ventricular catheter is avoided during the pumping procedure. The opening pressure of the shunt system is not increased by the implantation of the *SPRUNG RESERVOIR.*

The *prechamber* is positioned on the cranium. It allows measuring the intraventricular pressure, injecting drugs, extracting CSF and performing a palpatory ventricle inspection. Its solid titanium base is highly puncture-resistant. A puncture of the prechamber or the *CONTROL RESERVOIR* should be performed as perpendicular to the reservoir surface as possible with a cannula of max. 0,9 mm. 30 times of

punctures are able without any restrictions. A special prechamber is the *CONTROL RESERVOIR*. As an additional new feature of this reservoir, CSF can be flushed towards the valve because of a one-way valve in the proximal inlet of the reservoir. By this mechanism a flow in the direction of the ventricular catheter is avoided during the pumping procedure. The opening pressure of the shunt system is not increased by the implantation of the *CONTROL RESERVOIR.*

Warning note: Frequent pumping can lead to overdrainage and thus to unphysiological pressure conditions. The patient should be informed about the risk.

Due to its tight fit on the ventricular catheter, the *deflector* allows choosing the length of catheter penetrating into the skull prior to implantation. The ventricular catheter is deflected at a right angle in the borehole (see chapter "Variations").

TUBE SYSTEMS

The *uniGAV* has been designed to ensure the optimal ventricular pressure. It is available as a shunt system or as individual valve units with or without an integrated distal catheter (internal diameter 1.2 mm, external diameter 2.5 mm). Individual valve units should be used with catheters of approx. 1.2 mm internal diameter and approx. 2.5 mm external diameter. The connector on the valve allows using catheters of 1.0 mm to 1.5 mm internal diameter. The external diameter of the catheter should be about double the internal diameter. In any case, the catheters must be carefully fixed, with a ligature, to the valve connectors. Kinks in the catheter have to be avoided.
The provided catheters have virtually no effect on the Pressure-flow characteristics.

SURGICAL PROCEDURE

Positioning the ventricular catheter
Several surgical techniques are available for positioning the ventricular catheter. The necessary skin incision should be carried out, preferably, in the shape of a lobule pedicled towards the draining catheter. To avoid CSF leakage, care should be taken that the dura opening is kept as small as possible after applying the borehole. The ventricular catheter is stiffened by the introducing stylet supplied with the product.

The *uniGAV* is available in different shunt variants:
When using a *uniGAV SHUNTSYSTEM with borehole reservoir* or *SPRUNG RESERVOIR,* 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 CSF is dripping out. The catheter is shortened and the borehole reservoir is connected, with the connection secured with a ligature. The skin incision should not be located directly above the reservoir.
The *uniGAV SHUNTSYSTEM with prechamber* or *CONTROL RESERVOIR* comes with a deflector. This *deflector* is used for adjusting the position of deflection before implantation of the ventricular catheter. The catheter is deflected; the prechamber is put into place. The position of the ventricular catheter should be inspected again by postoperative CT or MR imaging.

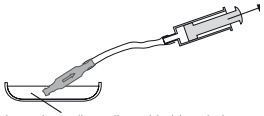
Positioning the valve
The *uniGAV* is a posture-dependent shunt. Therefore, care must be taken that the valve is implanted parallel to the body axis. A suitable implantation site is behind the ear. The site of the implantation has no influence to the function of the valve.
After the skin incision and tunneling under the skin, the catheter is pushed forward, from the borehole to the intended shunt implantation site. The catheter is shortened, if necessary, and secured at the *uniGAV* with a ligature. The shunt should not be located directly under the skin incision.
The valve is marked with an arrow pointing in the direction of flow (arrow pointing to distal or downward).

Caution: We recommend for the connection of a catheter the use of armored clamps. Frequent pumping of a reservoir can lead to overdrainage and thus to unphysiological pressure conditions. The patient should be informed about the risk.

Positioning the peritoneal catheter
The access site for the peritoneal catheter is left to the surgeon's discretion. It can be applied e. g. para-umbilically in a horizontal direction

or transrectally at the height of the epigastrium. Various surgical techniques are available for positioning the peritoneal catheter.
We recommend pulling through the peritoneal catheter, by means of a subcutaneous tunneling tool and perhaps with an auxiliary incision, from the shunt to intended position of the catheter. The peritoneal catheter, which is usually securely attached to the *uniGAV*, has an open distal end, but no wall slits. Following the exposure of, and the entry into, the peritoneum using a trocar, the peritoneal catheter (shortened, if necessary) is pushed forward into the open space in the abdominal cavity.

PREOPERATIVE VALVE TEST



Isotonic sterile sodium chloride solution

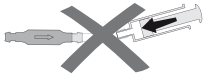


Fig. 5: Patency test

The *uniGAV* can be filled by aspiration through a sterile, single-use syringe attached to the distal end of the catheter. The proximal end of the valve is immersed in a sterile, physiological saline solution. The valve is patent if fluid can be extracted in this way (see Fig. 5).

Caution: Pressure admission through the single-use syringe should be avoided, both at the proximal and the distal end.
Contaminations in the solution used for the test can impair the product's performance.

PRESSURE-FLOW CHARACTERISTICS

The following diagrams show the pressure-flow characteristics of the adjustable valve of the *uniGAV* for the pressure settings 7/27 cmH_2O.
The total opening pressure refers to a reference flow of 5 ml/h. When the flowrates reach 20 ml/h, the opening pressures are approximately 1-2 cmH_2O higher.

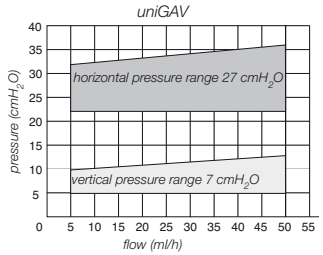


Fig. 6: Pressure-flow characteristics for the pressure settings of the uniGAV

RE-IMPLANTATION

Under no circumstances should products that have had previously been implanted in a patient be subsequently reimplanted in another, because a successfull decontamination of the device cannot be reached without functional degradation.

SAFETY MEASURES

The patients must be carefully monitored after the implantation. Reddening of the skin and inflammation in the area of the drainage tissue could indicate infections at the shunt system. Symptoms such as headache, dizzy spells, mental confusion or vomiting are common occurrences in cases of shunt dysfunction. Such symp-toms, as well as shunt system leakage, necessitate the immediate replacement of the shunt component responsible or of the entire shunt system.

COMPATIBILITY WITH DIAGNOSTIC PROCEDURES

MRI examinations with field strengths of up to 3.0 tesla and CT examinations can be carried without endangering or impairing the functionality of the shunt.
The *uniGAV* is MR Conditional (ASTM F2503-08). All components are visible via X-ray. The provided catheters are MRI Safe. Reservoirs, deflectors and connectors are MR Conditional.

POSTOPERATIVE VALVE TEST

The *uniGAV* has been designed as a safe and reliable unit even without the provision of a pumping device. However, there are ways of testing the valve if a shunt system with a *prechamber* or a *borehole reservoir* is used. Valve tests can be carried out by flushing or pressure measurements.

FUNCTIONAL SAFETY

The valves have been designed for long-term reliable and precise operation. Still, the possibility that the shunt system needs to be replaced for technical or medical reasons, cannot be excluded. The valve and the valve system are able to resist positive and negative pressure up to 200 cmH_2O during and after implantation.

STERILISATION

The products are sterilised with steam under closely monitored conditions. The double wrapping in sterile bags ensures sterility for a period of five years. The expiry date is printed on the wrapping of each individual product. Products taken from a damaged wrapping must not be used under any circumstances.

RESTERILSATION

The functional safety and reliability of resterilized products cannot be guaranteed, therefore resterilisation is not recommended.

NOTE ON THE INSTRUCTIONS FOR USE

The descriptions and explanations given in this document are based on the clinical experience available to date. It is for the surgeon to decide if surgical procedures should be changed according to his or her experience and to surgical practice.

MEDICAL PRODUCTS CONSULTANT

In compliance with the requirements of the European law MDD 93/42/EEC, Christoph Miethke GmbH&Co. KG names medical product consultants as the individuals to be addressed with all queries concerning the products:

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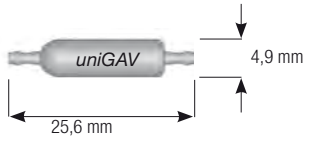
REQUIREMENTS OF THE MDD 93/42/EEC

The MDD calls for the comprehensive documentation of the whereabouts of medical products that are applied in human beings, especially the whereabouts of implants. For this reason, the individual identification numbers of any implanted valves are to be noted in patients' records, so that in the event of any inquiries, the implant can be traced without any difficulties. Each valve is outfitted with a sticker for this purpose.

NOTE ON THE INSTRUCTIONS FOR USE

The descriptions and explanations given in this document are based on the clinical experience available to date. It is for the surgeon to decide if surgical procedures should be changed according to his or her experience and to surgical practice.

GENERAL INFORMATION

Manufacturer	**Christoph Miethke GmbH & Co. KG**
Product name	*uniGAV*
Intended use	Treatment of Hydrocephalus
Intended for one-time use (disposable)	
Store in a clean, dry place	
Drawing of the *uniGAV* with its external dimensions:  Maßstab: 1:1	

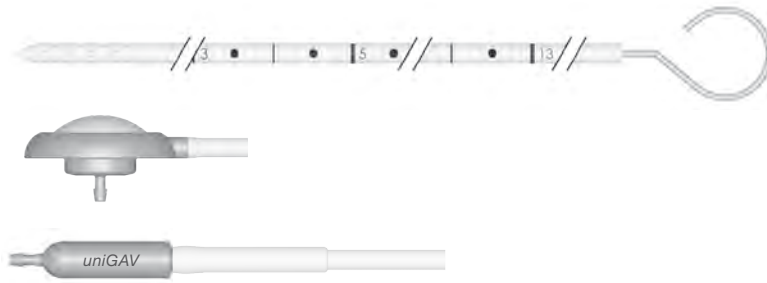
VARIATIONS

The uniGAV is available as a single valve or as a shunt system comprising various components.

uniGAV

uniGAV SHUNTSYSTEM

uniGAV SHUNTSYSTEM with SPRUNG RESERVOIR or *borehole reservoir*
(adult and pediatric)



uniGAV SHUNTSYSTEM with CONTROL RESERVOIR or *prechamber*
(adult and pediatric)

Scale: 1:1

目录

适应症

uniGAV用于脑积水患者，将脑脊液（CSF)从脑室排到腹膜内。

技术说明

uniGAV是一种体位式脑积水分流器。它包含一个锥形球阀和一个重力阀。这种结构可以确保每位患者在任何姿势下获得最佳的脑脊液引流。
注篡事项联邦法律规定，本装置只限医生购买或遵医嘱购买!

两种阀的构造描述如下。图.1是uniGAV剖面图示。uniGAV由坚固的软质外壳构成，有一个可靠的且经过试验验证的锥形球阀(1)整合在其近端。螺旋型弹簧（2）限定锥形球阀的开启压力。远端部分的重力阀包含一个钽制球(3)和一个蓝宝石球(4)，钽制球可限定阀门的开启压力，蓝宝石球可确保阀门的精确关闭。作为选项，可以在阀门远端的末端整合一个接头或硅树脂导管。

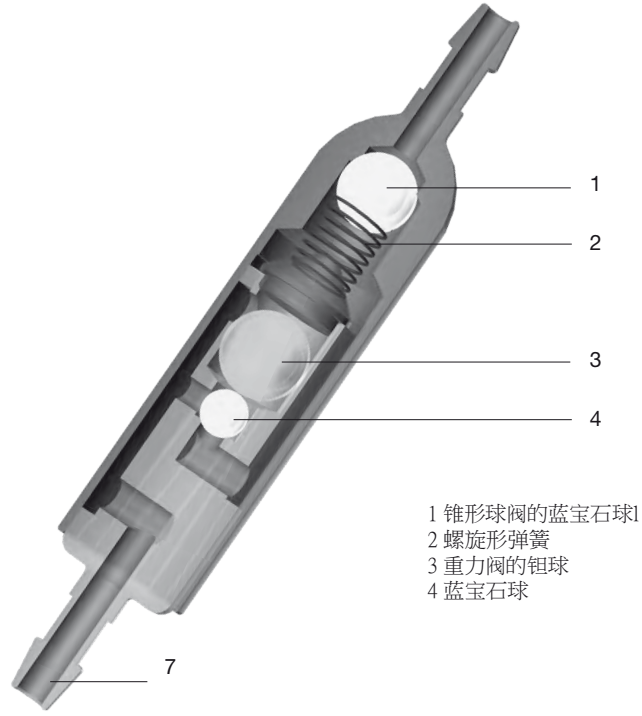


图.1：uniGAV的横切面图示

uniGAV的工作原理

uniGAV的开启压力由锥形球阀的开启压力和重力球阀的开启压力构成。

水平体位

患者平卧时，重力阀总是开启，因此对液流没有任何阻力。

UniGAV的工作原理如图2a和2b所示。在图2a中，锥形球阀关闭。引流被阻断。在图2b中，锥形球阀处于开启位置。患者脑室内压力(IVP)升高，且保持锥形球阀关闭的弹簧力得以克服。关闭球移出锥形座，打开一个缝隙使引流通过。锥形球阀的开启压力是7厘米水柱*。

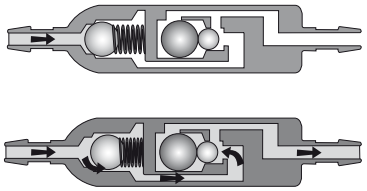


图 2：水平体位锥形球阀 a)关闭 b)开启

直立体位

重力阀的工作与位置有关。一旦患者转为直立姿势，重力阀就关闭，uniGAV的开启压力显著升高，脑脊液引流被阻断(图.3a)。只有当脑室内压力与流体静压力之和超过uniGAV试内开启压力时，引流才能再次开始(图.3b)。处于直立体位时uniGAV的开启压力是锥形球阀开启压力与重力阀开启压力之和〔钽球的重量)。重力阀的开启压力为27厘米水柱。*

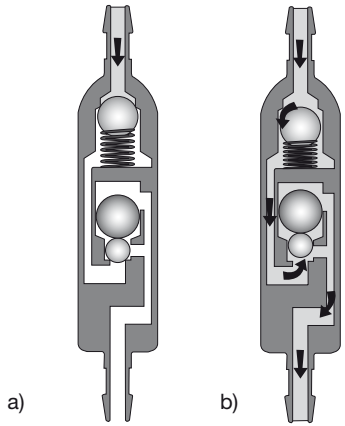


图 3：直立体位的重力阀 a)关闭 b)开启

总开启压力参考5毫升/小时的参照流量。当流速达到20毫升/小时，开启压力大约升高1-2厘米水柱。

物理学背景

健康人处于卧位时，脑室内压力为正压力。如果通过分流器引流来调节压力，必须选择合适的压力范围，同时要考虑腹腔压力。这样形成的脑室内压力是分流器开启压力与腹腔压力之和(图4)。健康人处于直立体位时，脑室内压力略呈负值。如果通过分流器引流来保持此压力，分流器的开启压力必须显著提高，以便分流器能够补偿流体静压力减去腹腔压力与略呈负值的脑室内压力之和。普通的分流器在患者起立后立即开启，这样会导致严重的过度引流。

分流器可能包括的部件

uniGAV可用于不同的分流器系统。这些变体由各种各样的组件构成，下面简要介绍这些部件。有适用于儿童及成人脑积水患者使用的变体。

颅孔储液囊位于颅孔内。可以用来测量脑室内压力、注射药物和抽出脑脊液。储液囊坚固的钦制底座是高度防刺穿的。所有的储液囊都装有导管或接头。

Sprung储液囊是一种专用的颅孔储液囊。这种储液囊的一个新特点就是在其底部有一个单向阀，可以使脑脊液流向阀门。基于这种原理，可以避免在抽吸过程中沿脑室导管方向的流动。Sprung储液囊的植入不会使分流器系统的开启压力升高。

Flushing储液囊是一个前置室，位于颅骨上。可以用来测量脑室内压力、注射药物、抽出脑脊液和进行脑室触摸检查。储液囊坚固的钦制底座是高度防刺穿的。控制储液囊是一种专用的前置室。与Sprung储液囊相似，由于在其近端入口有一个单向阀，可以使脑脊液流向阀门。基于这种原理，可以避免在抽吸过程中沿脑室导管方向的流动。分流器系统的开启压力不会升高。

由于转向器紧密贴合在脑室导管上，因此在植入前转向器可用来决定穿透进入颅内的导管长度。脑室导管在颅孔内做直角转向(参看第19页“变体”一章)。

IVP 脑室内压力
PVli 水平位置的开启压力(仅锥形球阀)
PVst 水平位置的开启压力(锥形球阀+重力阀)
PB 腹腔压力
PHyd 流体静压力

水平: $IVP = P_{Vli} + P_B$
直立: $IVP = P_{Hyd} - P_{Vst} - P_B$

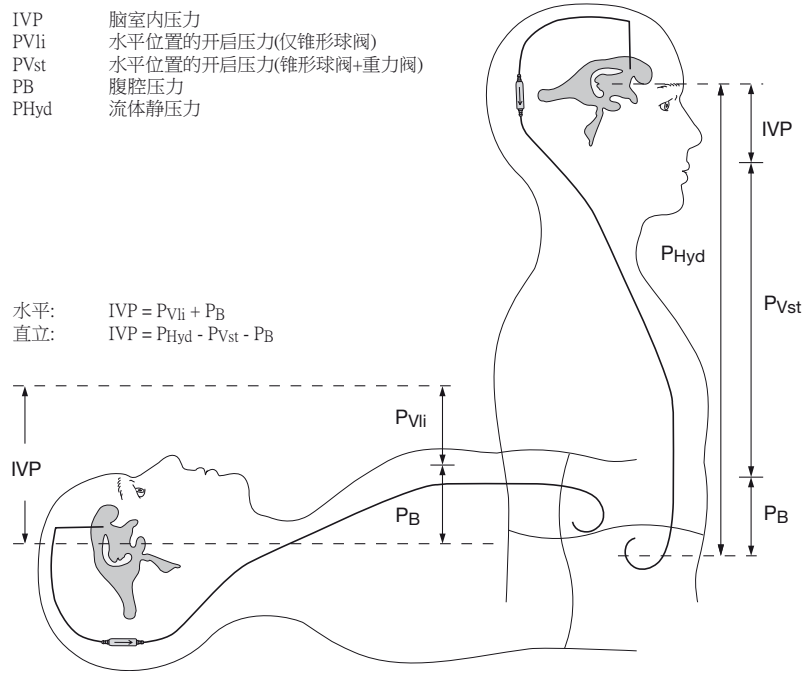


图 4：水平和直立位置时分流器的压力情况

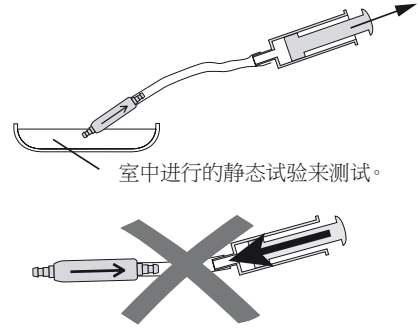
导管系统

uniGAV用作分流器系统，或者作为单独的带有或不带有一体式远端导管的阀门装置。Christoph Miethke GmbH & Co.KG公司生产的导管专门用于uniGAV。阀上的接头可用于内径1.0毫米至1.5毫米的导管。导管的外径应为内径的大约两倍。我们推荐单个阀门装置与内径约1.2毫米、外径约2.5毫米的导管配合使用。在任何情况下，导管都必须用缚线仔细地固定在阀门接头上。必须避免导管扭结。

阀开放性检测

利用连接在导管远端的一次性无菌注射器非常小心地抽吸可以把uniGAV注满。阀的近端浸没在无菌生理盐水溶液中。如果液体可以被抽吸，则阀功能正常。

警告：
应避免通过一次性注射器在近端和远端使压力进入。
试验所用溶液中的污染物会使产品性能受损。



室中进行的静态试验来测试。

图5：功能试验

植入前阀试验

对每个uniGAV阀都进行了试验以确保符合标签上标示的性能指标。分流
器的动态性能特性不能通过在手术等渗的氯化钠溶液.
如果外科医生希望在植入前验证分流器是否符合制造商提供的性能指标，可以在手术室进行以下的试验：

警告：一定要注意保持无菌状态和避免颗粒污染。

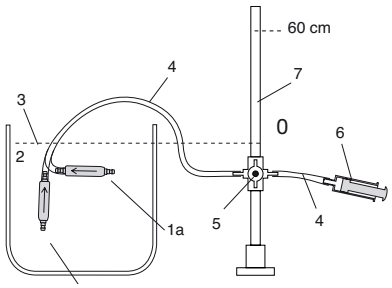
试验方法

试验需要的装置：
a) 无菌液体箱或水槽
b) 无菌60厘米水柱压力计，带毫米分度和底座上的三通旋塞
c) 无菌注射器，30毫升至50毫升
d) 无菌5μ尖端过滤器
e) 无菌导管连接装置
f) 无菌硅树脂导管

装置准备

a) 把压力计和水槽放好，使压力计的零点和水槽的液面处在同一高度(见图6).
b) 把无菌水注入注射器，注射器上装有5μ尖端过滤器(注入注射器时一定要使用5μ尖端过滤器)。注射器注满后取下尖端过滤器。
c) 把注射器、压力计和硅树脂导管彼此连接起来。需要时使用导管连接装置。
d) 如图6所示转动三通旋塞，以便把试验装置组件内全部空气排出。
e) 把硅树脂导管浸入无菌水槽内，用注射器中的无菌水冲洗导管。

装置校准
a) 如图7所示转动三通旋塞，向压力计内注水至压力至少达到5厘米水柱。
b) 硅树脂导管浸在水槽内时，转动三通旋塞，使注射器和压力计隔离(见图9)。
c) 使压力计内的水柱下降。
d) 水柱应下降到零点。必要时，把压力计的零点调到水槽液面的高度。
e) 现在压力计已按照水槽的零点液面校准。把压力计固定，使其保持和水槽的相对位置。



1.uniGAV a)水平，b)直立;2水槽;3恒定的水位;4硅树脂导管;5三通旋塞;6 一次性注射器，带注射器过滤器：7压力计

图6：试验装置

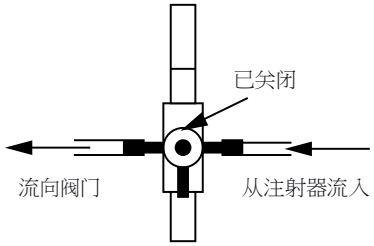


图7

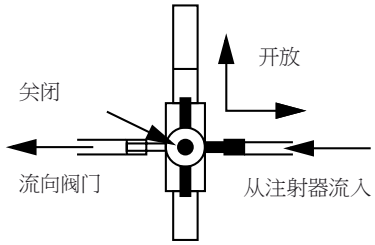


图 8

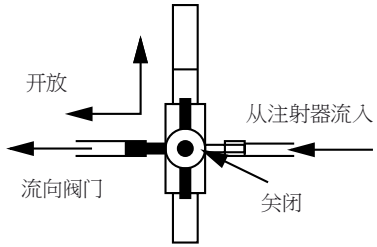


图 9

试验程序

请注意：在试验过程中，分流器必须浸在水槽中。压力计的零点必须和水槽的水面对齐以便获得正确结果。

a) 把要进行试验的无菌分流器连接到已组装好的无菌试验装置上。
b) 按图8所示转动三通旋塞，使压力计注水到高出预定开启压力10厘米水柱(例如：如果试验一个开启压力设置为水平5厘米水
柱、直立25厘米水柱的uniGAV，对于处在水平位置的分流器压力计注水到15厘米水柱，对于处在直立位置的分流器压力计注水到40厘米水柱)。
c) 按图7所示转动三通旋塞，使压力计隔离。
d) 用注射器中的无菌水小心地冲洗分流器和试验装置，把空气全部排出。
e) 把无菌分流器浸入无菌水槽内。分流器的远端部分必须位于水下，以便获得有效的试验结果。
f) 小心地保持通过分流器的液流，并按图9所示转动三通旋塞使注射器隔离。三通旋塞一转到正确位置，水柱就应开始下降。注射器已与阀门隔离，因此没有必要再保持
它的液流。如果水柱没有下降，重复步骤b到f。
g) 允许压力计中的水面下降
2~2.5分钟。读取压力计上最后的压力值。

植入前试验的结果

下表列出了对于若干选定压力范围利用这个方法应获得的结果： 压力范围 容

	压力范围	容许压力范围
水平位置	7厘米水柱	1-10厘米水柱
直立位置	27厘米水柱	12-30厘米水柱

表1：植入前试验的结果

压力流量特性

下面的图表显示压力设置为7/27厘米水柱的uniGAV可调节阀的压力流量特性。所使用的导管对压力流量特性无实际影响 流量(毫升/小时)

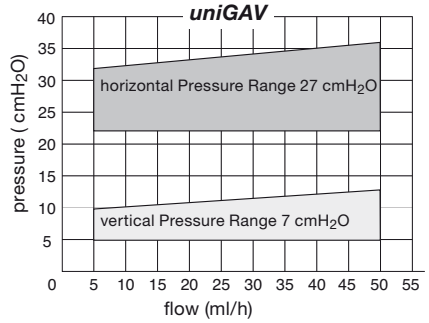


图10：uniGAV某些压力设置的压力流量特性

回流安全试验

本项试验使用与植入前试验相同的装置进行。用注射器小心地给分流器注入无菌盐水溶液，然后再从分流器排出空气(图11).
分流器是逆流动方向连接的(见分流器上的箭头)。分流器的出口必须位于压力计的零水位。压力计注水到14厘米水柱(图12)。
三通旋塞用来开启通向分流器的液流和关闭通向注射器的液流。在这个装置中，从分流器近端部分流出的液体每分钟不应超过两滴0.1毫升) (图13)。

警告事项：
一定要注意保持无菌状态和避免颗粒污染。

手术操作

放置脑室导管
有几种外科操作技术可用来放置脑室导管。要进行必要的皮肤切开，切口最好是朝向引流导管的带柄小叶状或直的切口。为避免脑脊液溢出，应注意在钻入颅孔以后要使硬脑膜开口保持尽可能小。脑室导管用随产品提供的芯杆加强

uniGAV有不同的分流器型式：
如果使用带Sprung储液囊或颅孔储液囊的uniGAV分流器系统，脑室导管首先植入，导引丝抽出后，就可以通过检查脑脊液是否滴出检验脑室导管的开放性。剪短导管，连接钻孔储液囊，连接处用结扎线固定，皮肤切口不应位于储液囊的正上方。
带控制储液囊或Flushing储液囊的uniGAV分流器系统有一个转向器。这个转向器用来在植入脑室导管前调节转向位置。使导管转向：把前置室放到适当位置。应借助术后CT或MR成像对脑室导管的位置进行再次检查。

放置uniGAV
uniGAV是与体位相关的分流器，因此，必须注意要使阀门与体轴平行地植入。一个适当的植入部位是耳后。植入位置不会影响阀门功能。
皮肤切开和在皮下建立通道后，把导管向前推，从颅孔推到预定的分流器植入部位。如有必要，把导管剪短，并用结扎线固定在uniGAV上。分流器不得放在皮肤切口的正下方。阀门上有一个指明流向的箭头(箭头指向远端或下面)。

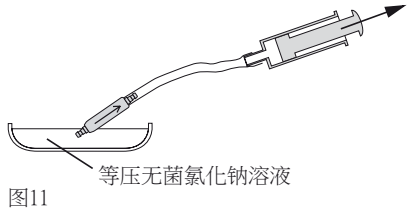


图11

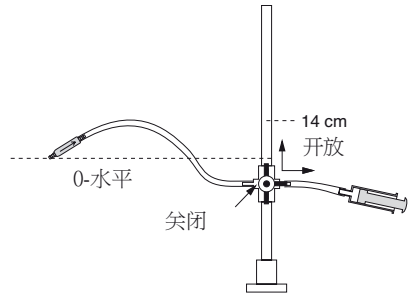


图.12

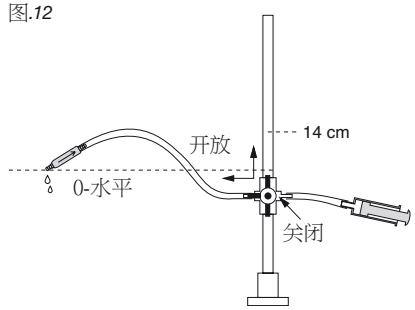


图13

警告事项：
建议使用带甲夹钳连接导管。不可把调节阀植入在阀门难于定位和触摸的部位(例如伤疤下面)。频繁抽吸会导致过度引流，从而导致非生理性压力状态。应使患者了解这种危险。

放置腹膜导管
腹膜导管的进入部位由外科医生自行决定。例如可在脐旁水平方向上进入或在上腹部经直肠进入。放置腹膜导管有各种外科操作技术可供使用。我们建议借助皮下通道工具，或许还要辅助切口，把腹膜导管从分流器拉到导管预定位置。腹膜导管通常都牢固地连接在uniGAV上，它有一个开口的远端，但是没有管壁狭缝。借助套管针使腹膜导管接触并进入腹膜后，腹膜导管(必要时剪短)被向前推进到腹腔的空隙内。

再植入
已经植入过的分流器部件不可再植入到其他患者的体内。

安全措施
植入后必须对患者进行精心监护。引流组织区域的皮肤发红和炎症可能表明分流器系统部位有感染。头痛、头晕、精神错乱或呕吐等症状是分流器工作不正常时的常见现象。出现上述症状以及分流器系统有泄漏时，必须更换分流器有问题的部件或更换整个分流器系统。

与诊断操作的相容性

进行磁场强度3.0泰斯拉以下的核磁共振成像(MRI)检查以及CT检查不会危害或削弱分离的功能。uniGAV对于核磁共振成像是安全的(ASTM-F2503-05)。所有组件可通过X一射线观察到。提供的导管与核磁共振成像是相容的。储液囊、转向器和接头对核磁共振成像是安全的。

警告事项：
在使用磁场的同时如果按压阀门，不排除阀门调整的可能。

术后阀试验

uniGAV的设计使其即使在没有抽吸装置或试验装置的情况下也是安全可靠的。然而，如果使用带有泵室或颅孔储液囊的分流器系统，可以有几种试验装置的方法。可以通过冲洗、压力测定或抽吸来进行阀门试验。

功能安全
阀门的设计可供长期可靠且精确操作使用。仍然不能排除分流器系统由于技术或医疗原因而需要更换的情况。
对使用心脏起搏器者的警告事项：植入uniGAV可能会使心脏起博器的功能受到影响。

灭菌

本产品是在严密监控下进行蒸汽灭菌。产品在无菌袋内双重包装可以确保无菌状态保持五年。有效期印在每件产品的包装上。在任何情况下都不可使用从破损包装中取出的产品。

再次灭菌

不能保证再次灭菌产品的功能安全性及可靠性。

医疗产品顾问

按照欧洲法律医疗器械指令的要求，Christoph Miethke公司指定以下医疗产品顾问接受所有关于产品的咨询：

Dipl.-Ing. Christoph Miethke
Dipl.-Ing. Roland Schulz

Christoph Miethke GmbH & Co. KG
Ulanenweg 2
D-14469 Potsdam
电话：+49(0) 7000 6438453或
电话：+49(0) 331 620 83 0
传真：+49(0) 331 620 83 40
e-mail: info@miethke.com

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Am Aesculap Platz
D-78532 Tuttlingen
电话：+49 (0) 7461 95-0
传真：+49 (0) 7461 95-26 00
e-mail: information@aesculap.de

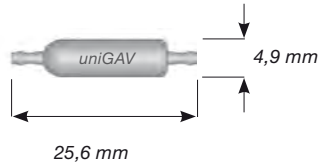
医疗器械指令的要求

医疗器械指令要求对用于人体的医疗产品，尤其是植入物，其所在位置要有全面的文件记录。因此，植入分流器的独立识别编号应记录在患者病历上，以确保产品的完全可跟踪性。

对使用说明的注释

本文件中所作的叙述与说明，其根据是最新获得的临床经验。根据外科医生的经验和手术实践，由医生来决定是否更改手术操作。

一般资料

制造商	Christoph Miethke 公司
产品名称	uniGAV
用途	治疗脑积水
供一次性使用	
存放于清洁干燥处	
分流器简图及其外部尺寸 	

各种变体

uniGAV可用作单个阀门或由各种组件构成的分流器系统。

uniGAV

uniGAV-分流器系统（无储液囊）

uniGAV-具Sprung-或颅孔储液囊分流器系统（成人及儿童）

uniGAV-具Flushing储液囊分流器系统（成人及儿童）

比例尺 1:1

CE 0297

CE-Kennzeichnung gemäß Richtlinie 93/42/EWG
CE marking according to directive 93/42/EEC
Label CE conforme à la directive 93/42/CEE
Identificatión CE en conformidad con la directriz 93/42/CEE
Marchio CE conforme alla direttiva 93/42/CEE

Technische Änderungen vorbehalten
Technical alterations reserved
Sous réserve de modifications techniques
Sujeto a modificationes técnicas
Con riserva di modifiche tecniche

Manufacturer acc. MDD 93/42/EEC:

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