Patient Information

11 Years of Effective Treatment of Pediatric Hydrocephalus with Gravitational Valves

11 Years paediGAV®
A Higher Quality of Living for the Small Patients.

The treatment of the hydrocephalus is one of the most common neurosurgical operations.

Approximately one in every 10,000 children is born with this disorder or acquires it sometime during his/her life. The hydrocephalus is an increase in the fluid (liquor), which is found in the cerebral ventricles and surrounds the brain and spinal cavity. In approximately 80 percent of the cases, a valve system is implanted for therapy (also called shunt system), which conveys the excess fluid from the brain to the abdominal region where it can be reabsorbed.

This disorder also poses a burden for the parents. Apart from the fear prior to the surgery of your child, the worries of the further physical and mental development are also present. Generally, a shunt system accompanies the patient a life long.

The selection of the right shunt system is of great meaning, especially in children, and has a large influence on their later development.

Decisive is a most possible physiological, that is similar to the natural processes, drainage of the brain fluid, independent of the physical position of the patient – lying, sitting, standing, walking or playing...

The Miethke paediGAV® was implanted ten years ago for the first time – the first shunt system, which was especially developed for the treatment of the pediatric hydrocephalus.

Aesculap AG & Ch. Miethke GmbH & Co. KG

paediGAV® is turning 11 years old
paediGAV® Is Turning 11 Years Old

What is special about this valve, or better, what was my reason as neurosurgeon to use this valve?

The name already says it, paediGAV® is a pediatric valve. It is small, thin and still durable so that it can be implanted in infants with very thin skin without having to worry that pressure points occur above the valve, which could lead to a disorder in the wound healing process.

The second part of the name GAV, what does that mean?

GAV stands for gravity assisted valve and means that this valve takes gravity into consideration. This attempts to satisfy the normal, physiological nerve fluid drainage. In people without a shunt, this is regulated when changing positions, for example from lying to standing, in that a complex venous system increases the resistance and therefore the nerve fluid drainage is only possible against this increase of resistance when standing. This prevents low pressure in the head. In children with a shunt system, an increase of resistance must be obtained practically within this system when standing up. This occurs in the paediGAV® with a small tantalum ball. The more upright
the child is, the further the tantalum ball falls from a horizontal into a vertical chamber. The nerve fluid must practically overcome the resistance of this tantalum ball in order to flow off. In this manner gravity is taken into consideration.

Both the consideration of gravity as well as the thin shunt design brought me to implement this valve in children: with success. The valves function as expected after several years.

Just like Hester (see patient report of experiences) who found it amusing that she was just as old as the shunt. Both harmonize well and you can guess how often the little tantalum ball in the valve went through various movements with Hester.

paediGAV® is turning 11 years old
Hester Nast – a Special Girl

Hester’s mother’s pregnancy was normal until the 34th week. A routine examination showed that Hester’s liquor cavities were much too big. The diagnosis in the Prenatal Diagnostic in Nuremberg brought certainty: spina bifida accompanied with hydrocephalus.

Hester’s brain stem was very low and pressed directly on the breathing center, which would lead to massive breathing problems during the birth as the doctors assumed.

In the following weeks, the hydrocephalus increased. In order to relieve the cortex, Hester was born via a Cesarean Section on July 1, 1998 in the 37th week of gestation. Surprising to all, she could breathe from the first breath.

In order to avoid the risk of infection due to continuous puncturing, Hester received an implanted shunt system (paediGAV®, company Miethke) eight days after birth with the pressure levels 4/19. This normalized the hydrocephalus very quickly – with no symptoms of an over or under drainage at any time. Today Hester is still carrying her first valve. The annual examinations confirm that the pressure levels are still adequate for her body size.

Despite her illness – incomplete paralysis and scoliosis – Hester is a bright, cheerful and very curious girl. At the age of four she started kindergarten, at seven she started school. Today Hester is in the third grade of elementary school in Neustadt on the Aisch and keeps up with the other children of the same age.

Art and – hard to believe – swimming are her favorite subjects. “My new diving record is currently 2.70 meters. Three meters is my next target which I am training towards”, the holder of the seahorse badge proudly reported.
Whether on a discovery tour with the new digital camera or when playing with friends or doing somersaults and playing on the carrousel, the little valve above her ear, invisibly hidden under the skin, allows Hester this freedom. The freedom to be able to completely forget her illness on some days and to do what is fun.

Independent and free, just like any other girl her age.

Hester’s hobbies – swimming and art... ... and of course everything that is fun!

Full speed ahead!

...in the garden.
The development of the paediGAV® began about eleven years ago. From our knowledge and clinical experience with pure differential pressure valves and the over drainage that commonly occurs directly therefrom, we were able to implant the first one ten years ago on September 10th, 1998. This first valve has not been in need of revision since then.

The problem of over drainage seems to be prevented by the paediGAV® so that it can especially be implemented in children with slit ventricle syndrome. The revision rate of the shunt has been significantly reduced in our clinic through the implementation of the paediGAV® (Eymann et al 2007 “Pediatric gravitational shunts: initial results from a prospective study” J Neurosurg (3 Suppl Pediatrics) 106:179–184, 2007).

There is however a further advantage: Since the body of the valve is hardly larger in diameter than the catheter, premature babies with a body weight over 1,500 grams can be treated therewith without having to worry about a skin perforation.

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paediGAV® is turning 11 years old
Reliability and Simple Handling

The invention of the hydrocephalus valve is the most pioneering contribution to the maintenance of life in the history of neurosurgery. In 1960, the diagnosis of hydrocephalus was equivalent to a death sentence or a serious handicap. Today, 50% of all children born with a hydrocephalus can have a normal IQ. Serious handicap as a result of a late or insufficient therapy has become an exception.

30 years after introduction of functional valves, serious long term effects in many of the surviving patients indicate the constructive weaknesses of the first valve generation. The laboratory examinations from Dr. Alfred Aschoff, Heidelberg and others identify the tendency to over drainage as a significant disadvantage of this first generation of the so-called differential pressure valves. Among the antisiphon components developed against it, which are offered by numerous producers integrated in valves or as an additional module, the continuously variable resistance regulation of the paediGAV®, which is independent of the body position seems especially natural to us.

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It imitates the body’s own regulation mechanisms, which are also controlled by gravity and allows the patient to influence the liquor drainage within safe borders, intuitively via the head position.

A comprehensive scientific study, which large German and Dutch hydrocephalus centers participated in, confirmed that the paediGAV® held up in an international comparison. Due to the high valve quality, early complications are rather due to the quality of the surgery, the age and the previous illnesses of the patient and the conditions of the intervention. The paediGAV® also offers advantages in this connection since the round and compact construction is hardly larger than the diameter of the catheter. Reliability and simple handling have also contributed to the paediGAV® becoming the valve of first choice at the Independent Work Area Pediatric Neurosurgery of the Charité – Universitätsmedizin Berlin.
We implemented our first paediGAV® eight years ago and in the meantime the valve is our first choice of drainage systems for most forms of the childhood hydrocephalus.

Depending of the individual hydrocephalus, we implement the pressure levels 4/19 or 9/19. We most commonly treat prematurely born babies with a posthemorrhagic hydrocephalus and small patients with cerebral fluid congestion in spina bifida.

We hope to prevent or minimize later occurring results of an over drainage with the introduction of the paediGAV®. We have already had good experience with the implantation of gravity controlled additional valves in patients that are already treated with valves.

Klara was born five years ago with a spina bifida and a hydrocephalus with Chiari malformation. After closure of the open back, we implanted a paediGAV® 9/19. She developed very well and had no neurologic problems apart from a bladder emptying disorder. In the meantime, the central catheter of the valve had to be extended once and a decompression of the back of the head performed since a syringomyelia (cerebral fluid collection)
formed in the spinal cavity. Klara is however doing well and always in a good mood. She still goes to kindergarten and is looking forward to school next year.

As can been seen on the pictures, she is a little whirlwind that likes to run and jump or simply play.

Klara – energetic

I am the captain...
Introducing, ASBH...

The Arbeitsgemeinschaft Spina Bifida und Hydrocephalus e.V. (Work Group Spina Bifida and Hydrocephalus) has been helping people with spina bifida (paraplegia) and/or hydrocephalus (disorder of the cerebral fluid circulation) as well as their families. At the beginning of our self help work, children who were born with these handicaps hardly had a chance to survive. That looks completely different today.

Through improved medical treatment and care, not only did the life expectancy increase but also the quality of life. With early recognition and surgery in infants, children with spina bifida and/or hydrocephalus can develop well, physically and mentally, despite their handicap. They learn to live with their handicap, to adjust to the limitations due to the handicap with targeted training and medical care. For many, this makes it not only possible, but rather natural to lead an independent life, to be mobile, to have a family and career.

Depending on the handicap, the personal limitations are hardly visible or mean a life in a wheelchair. The range reaches from multiple handicaps to college graduates.

The ASBH represents the interests of these people and their families. It advises, releases scientific publications, and organizes schoolings, seminars and recreation. The ASBH works closely with doctors and clinics. It offers the possibility to get information, exchange information and to become involved in more than 70 voluntary self help groups. www.asbh.de

Hydrocephalus Has Many Faces and Many Ages!

When the ASBH was founded in 1966, this was mainly due to the initiative of the first chairman, Paul Bernhart, whose daughter died at a young age due to insufficient shunt treatment. Today, people with hydrocephalus have good life perspective, although the effects of the handicap can be mild to very extensive. The Arbeitsgemeinschaft Spina Bifida und Hydrocephalus represents people with an isolated hydrocephalus as well as people with a hydrocephalus in connection with a spina bifida.
The life styles and needs are often very different but it distinguishes our self help organization that all gather united under the roof of the ASBH and support each other. Hydrocephalus is a handicap, which is often hard to understand for outsiders. Although it may be invisible, the affected people must explain themselves in order to be understood. The spectrum of possible limitations is large. With early shunt treatment with the continuously developing state of medical technology, several people have hardly any limitations but also a serious multiple handicap can be the result. Therefore, the ASBH also has a nation wide network of contact people for hydrocephalus in its regional self help groups so that the affected people can meet and exchange information.

The website www.hydrocephalusseite.de is a virtual meeting place. In autumn of 2008, the 19th guidebook of the ASBH “Hydrocephalus in students” will be published since education is important for optimal development.

Often still unknown is the fact that the hydrocephalus can also occur at a higher age, the so-called age dependent cerebral pressure.

ASBH – Arbeitsgemeinschaft Spina Bifida und Hydrocephalus e.V.

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Strengthening self help means making people strong!
Advice, trainings, seminars and recreation...
...various life styles and needs under one roof!
Christoph Miethke, born in 1960 in Krefeld, grew up with six siblings in a loving and nurturing atmosphere. He was the tinkerer of the family who was always fixing something. After school, he spent his year of civil service in the hospital and discovered a microcosm of the community that fascinated him. It was important to him to be useful and helpful. Christoph Miethke studied medical technology at the Technical University in Berlin. Already as a student, he discovered the problematic of the valve systems for treating hydrocephalus – literally meaning "water-head", a complex neurological disorder – during his work in a medical technology company and already developed first ideas for the improvement. After a successful completion of his studies, his own research ambition and the encouragement of his TU professor from Berlin, Klaus Affeld, brought him to the idea of founding his own company.
The Development of the *paediGAV*®

Ten years after the introduction in the clinical practice, several thousands of patients in numerous countries have been successfully treated with the *paediGAV*®. The use of gravitational valves, also in the pediatric hydrocephalus, has proved itself as an important treatment option.

First considerations of *paediGAV*® arose already in 1996 based on the first scientific analysis of the treatment perspectives, in particular for normal pressure hydrocephalus after implantation of the DualSwitch valve. Many neurosurgeons considered the compensation of the hydrostatic pressure in adult patients obvious; in infants however, the concerns were numerous. Why should a pressure be compensated which could only be relevant for few and short moments, if at all? During the first few weeks and months of life, babies lie most of the time and are only in an upright position for a short period of time in order to burp. Furthermore, the hydrostatic pressure is very low due to the body size. Why a gravitation valve for infants?

The expectation after shunt introduction in infants was obvious:

The treatment was considered more successful the smaller the ventricles became. From numerous discussions I learned that in over 80% of the cases, the ventricles completely collapsed after implantation of a drainage. I found this treatment result very questionable. The early closure of the skull bones resulting in a too small intracranial volume for the physiological growth of the brain as well as the increased occurrence of thickened skull bones after early childhood shunt introduction were and are indication for continuous negative consequences. These observances were not and still are not brought in connection with an over drainage. Rather, the occurrence of an over drainage in infants was described as extremely seldom and unimportant in studies. And that is why collapsed ventricles are not yet seen as an over drainage or as complication.

This does not occur without reason:

With the background of the historical success of a life saving shunt system, the over drainage usually shows long term fatal consequences. Studies seem to show that the treatment success remains independent of the used valve. Surgical aspects superimpose the meaning of the valve function. To imagine that even light negative
pressures can have very negative lasting influence on the development of the child is not easy.

It was and is obvious to me:

That fragile balance between the hydraulic pressure and the tissue pressure resulting from growth does not occur as a coincidence. Main goal of the treatment should be to acquire conditions as close as possible to those known from a healthy child. I am convinced that gravitation valves provide an important contribution in reaching this goal. Even if no proof has been provided so far in any prospective randomized study, there is a large amount of clinical data, which confirms the theoretical basis. The development of the paediGAV® would never have been possible without the dedicated support of many neuro and pediatric surgeons. The open discussion of clinical successes and failures, criticism and encouragement and the willingness to take on new ideas are the basis for the chance of progress and improvement. I am thankful for the advice and assistance in bridging the border between technology and clinical practice.

I see the willingness to cooperate as an assignment to commit myself also in the future as an engineer and manager for the interests of hydrocephalus patient.

Potsdam, June 2008, Christoph Miethke
Kinder brauchen Frieden e.V.  
(Children Need Peace)

In a small bush hospital in Gikonko / Ruanda, in which the operating room is more like a garage, the German doctor Ms. Dr. Uta Düll helps her patients to a new life.

The hospital has 53 beds, which often are shared by more than 100 patients. Plus, up to 150 patients come in daily for outpatient treatment. Even under these extreme conditions she is capable of treating accident surgical problematic cases, to remove tumors and to treat snake bites.

Neurosurgical interventions are becoming increasingly necessary. However, Ms. Dr. Düll can only help the children with a hydrocephalus if she receives the necessary shunt systems. Through donations from Aesculap and Miethke, 14 children with a hydrocephalus have already received the valuable help in the form of a paedi-GAV® and therewith also the chance of leading a normal life.

The helpers do not only donate the medical material, but also comfort to contribute to the well being and the happiness of the children. Ms. Dr. Uta Düll works together with the association "Kinder brauchen Frieden" e.V. (Children Need Peace).

The association, which was founded in 1993 cares for – only with voluntary helpers – the children in the war zones around the world. Currently the main help areas are in the project countries Croatia, Bulgaria, Rwanda, Sri Lanka, Pakistan and the Republic of the Congo. Continuous help programs such as food and medical supplies, school and work training, building and maintenance of homes as well as foster child projects should contribute to the future of the children.
The help is solely financed from donations. You can find further information in the internet under: www.kinder-brauchen-frieden.de

The helpers do not only donate medical material... ...but also comfort to contribute to the well being of the children.
The Instrument Must Be Exact

Good music lives from harmony. And that can only be achieved by the musician with a precise and valuable instrument. The success of the surgeon is also dependent on the precision and quality of his instruments. Only a reliable and safe valve, which is designed for the individual person allows the drainage of cerebral fluid without problems.

The Christoph Miethke GmbH & Co. KG was founded in 1992. The company is located in a heritage protected building of a former casern in the center of Potsdam. The company develops and produces neurosurgical products for the therapy of the hydrocephalus. In cooperation with Aesculap, a branch of the B. Braun Melsungen AG, these products are marketed and sold worldwide. Each Aesculap-Miethke paediGAV® valve is precisely checked before it is implemented. It consists of more than 20 individual pieces which are produced with most modern CNC manufacturing. In the manufacturing, highest requirements of exactness are posed since the individual pieces are exactly fitted together in the assembly. In the reception control, the individual elements of the paediGAV® valve are tested for their manufacturing tolerance.
Only tested parts find their way to the next step, the assembly. Here specialists put the individual elements together under clean room conditions. During the production, all quality relevant components are continuously checked.

In order to assure a safe, precise function of the products, each individual valve is carefully calibrated by hand. Numerous function tests are performed during the production and finally with the completed product. All important data is determined and recorded.

If the valves have passed the final examination, they are packed germfree and ecologically sterilized according to DIN EN ISO 17665-1. Each Aesculap-Miethke valve receives its own serial number. In this manner, all relevant valve parameters can be traced also many years after implantation.
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ASBH guidebooks

„Ihr Kind mit Hydrocephalus”
ISBN 3-934821-09-X

„Pflegetagebuch für Kinder mit Spina bifida und Hydrocephalus”
ISBN 3-934821-07-3

„Hydrocephalus und Du”
ISBN 3-934821-04-9

„Pflegetagebuch für Kinder mit isoliertem Hydrocephalus”
ISBN 3-934821-06-5

„Leben mit Spina bifida und Hydrocephalus”
ISBN 3-980 1420-8-6

„Hydrocephalus”
ISBN 3-980 3513-1-9

„Hydrocephalus im Erwachsenenalter”
ISBN 3-980 3513-7-8

„Menschen mit Spina bifida und Hydrocephalus”
ISBN 3-980 1420-6-X
Antisiphon components
Additional valves for prevention of over drainage

CNC production
“Computerized Numerical Control” characterizes a computer controlled method of controlling and regulating machine tools.

Differential pressure valve
Standard valve with only one opening pressure independent of body position of the patient

Cerebrospinal fluid
Brain and spinal cavity are surrounded by a clear fluid, which is produced in the brain and is in connection with the internal liquor cavities. That is why it is called brain or nerve water. It protects the sensitive structures from external influences.

Hydrostatic pressure
Characterizes the pressure, which additionally affects the valve when the patient stands up. Due to the height difference between shunt tip (catheter in ventricle) and the shunt end (catheter in abdomen) a physical siphoning occurs at the valve when standing up. Without the suitable protection device (antisiphoning), an over drainage can occur.

Hydrocephalus
Congenital or continuous expansion of the liquor cavities of the brain due to disproportions between liquor production and resorption or due to a disorder of the liquor circulation.

Intracranial
Within the skull

Cortex
Cerebral cortex

Liquor
Cerebrospinal fluid (nerve water)

Liquor cavities
Cavities of the brain and spinal cavity filled with cerebrospinal fluid (nerve water)

Meningocele
A simple, light form of spina bifida in comparison with the other two types Only the membranes of the spinal cavity (= meninges) are curved by open vertebrae under the skin. The cyst resulting therefrom is visible. It can be surgically removed.

Nerve water
See cerebrospinal fluid

Normal pressure hydrocephalus
Characterizes a special type of hydrocephalus, which mainly occurs in older people (age related hydrocephalus). The symptoms are similar to dementia.
Prenatal diagnostic
Examination of the unborn child

Prospective
In studies, one speaks of "prospective" if the material is not collected for the examination up to the moment of the question. A prospective study is focused on the future. In comparison, "retrospective" studies in which already present data is examined.

Randomizing
Typically, two treatments are compared with each other in one study. The assignment of the treatment occurs according to coincidence, like when tossing a coin. This should prevent systematic errors, e.g. that according to the expectations or preconceptions of the tester a group only receives the lighter cases.

Rickham capsule
A capsule implanted under the skin, which is connected with the liquor cavities via a catheter. Cerebrospinal fluid can be drained from the patient through a puncture of the capsule.

Slit ventricle
Abnormal reduction of the cerebral cavities on the side due to continuous drainage of cerebrospinal fluid (over drainage).

Slit ventricle syndrome
Generally a slit ventricle syndrome is when the symptoms occur through the formation of slit ventricles.

Scoliosis
Sideways bending of the spinal column (with simultaneous rotation of the vertebrae), which can no longer be completely erected.

Spina bifida
Malformation in the area of the spinal column

Under drainage
Characterizes a complication after shunt implantation due to insufficient drainage of cerebrospinal fluid

Over drainage
Characterizes a complication after shunt implantation due to excess drainage of cerebrospinal fluid