

proSA[®]

Rx Only

The adjustable gravitational valve for the treatment of hydrocephalus



Aesculap Neurosurgery

AESCULAP[®]

Aesculap and MIETHKE

Alliance for Innovation



Aesculap AG, Tuttlingen, Germany

When two strong partners combine their know-how, it often leads to innovative and groundbreaking solutions which could not be achieved independently by either of the partners.

Following this philosophy, Aesculap and MIETHKE have been working together since 1993. Our aim was and still is to develop better solutions for the complex treatment of hydrocephalus.

The *proSA*[®] valve represents the latest development in gravitational technology from MIETHKE. *proSA* adds the benefits of adjustability to the proven performance of the ShuntAssistant[™], giving surgeons the ability to adjust shunt pressure specifically for the upright positions, where patients are at the greatest risk of overdrainage. Combined with a differential pressure valve, *proSA* provides physiological drainage that can be maintained in any body position, from supine to upright.

proSA—adjustability where it matters most.

proSA Features and Benefits

- Proven gravitational technology provides increased resistance as the patient moves to an upright position.
- Enables the surgeon to provide different opening pressures for supine and standing positions, managing overdrainage complications and patient discomfort.
- Wide pressure range: 0–40 cm H₂O allows for patient customization.
- Titanium housing allows the *proSA* valve to be made very small, but still have large flow paths to help reduce the risk of obstruction.
- Can be implanted as part of a new shunt system or easily added to an existing system, adding the benefits of gravitational technology.
- “Active-Lock” MR Brake helps prevent inadvertent pressure changes in MRI (*MR Conditional under the following conditions; 1.5T and 3T, maximum spatial gradient of 7.2T/m and first level controlled mode*).

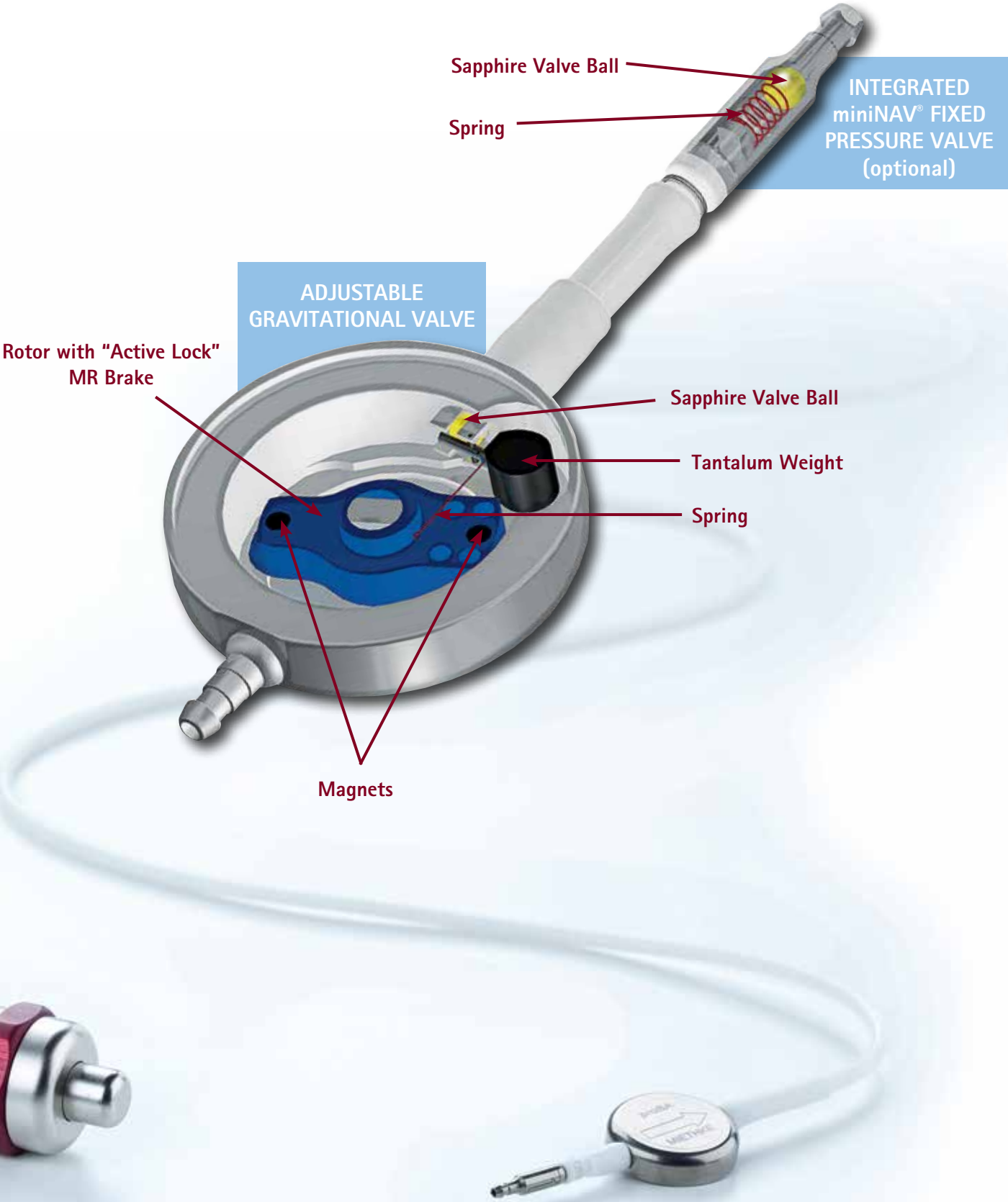
“With gravitational valves, we use gravity to control gravity, making a normal life possible. Control of gravity is about standing tall.”

—Christoph Miethke (pictured below, right)



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Design



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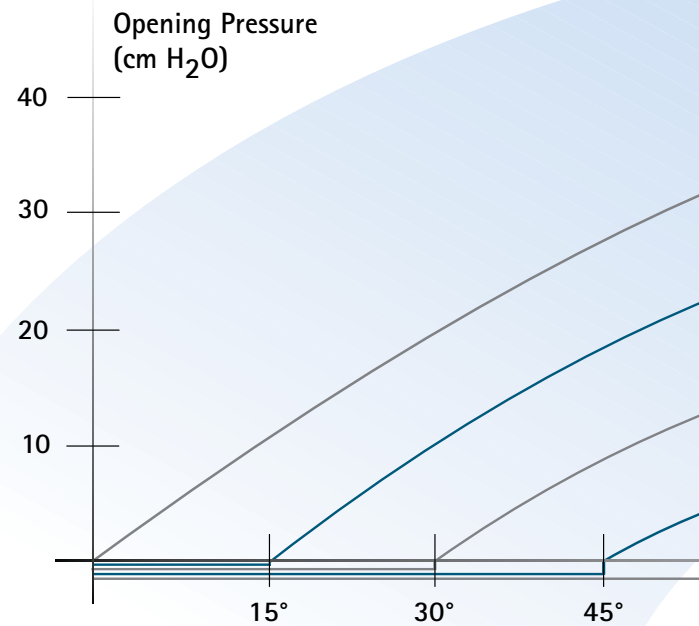
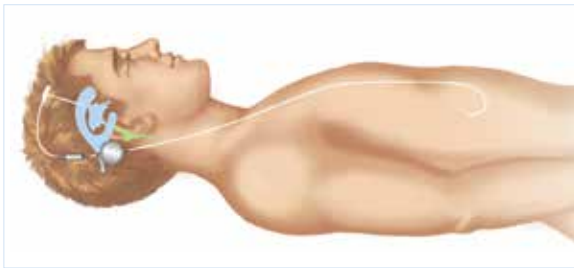
Function

For proper function of the proSA system, the gravitational unit must be implanted in line with the patient's body axis.

Supine Function

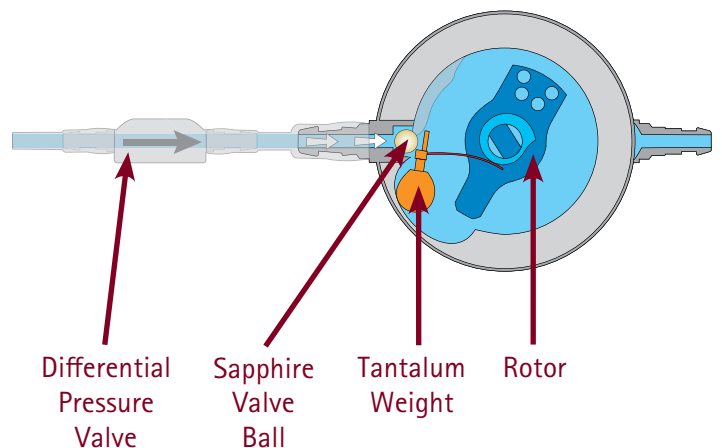
To optimize the treatment for each patient with proSA, one opening pressure should be selected for the supine position and another should be selected for the upright position. When the patient is in the lying position, intraventricular pressure is maintained solely by the differential pressure valve.

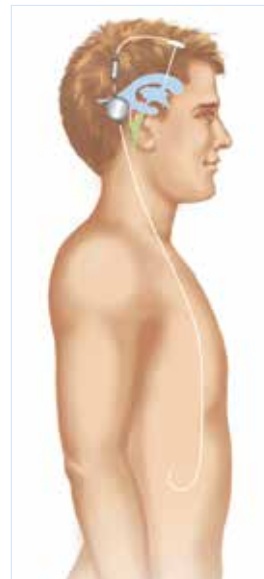
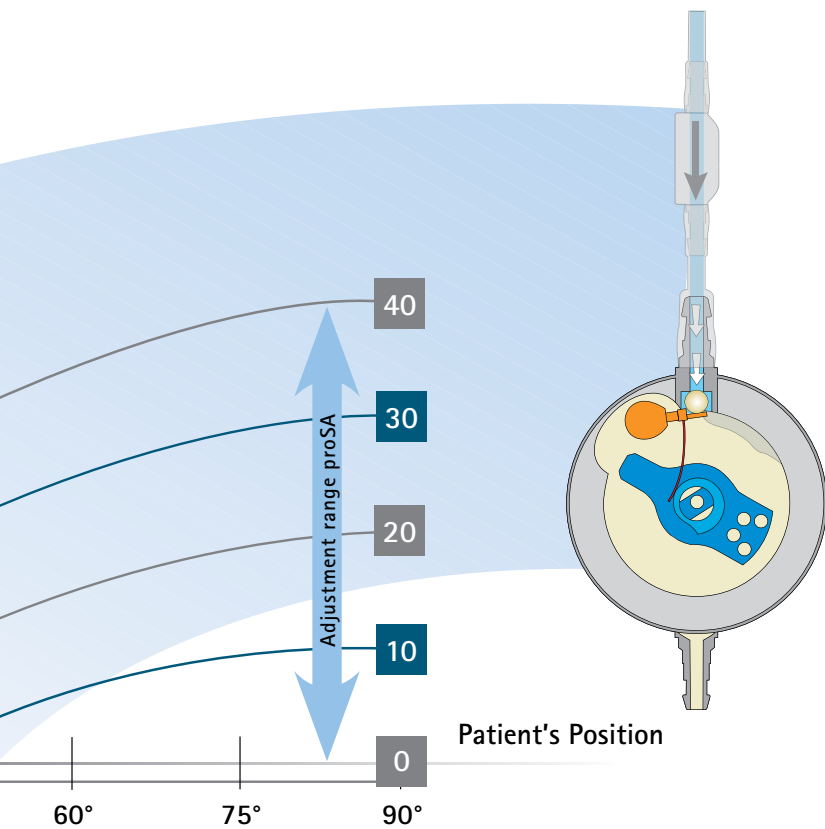
- The setting of the differential pressure valve keeps the intracranial pressure within physiological limits.
- The gravitational unit does not influence the opening pressure in this position.



* The graph only represents the opening pressure of the proSA. For the opening pressure of the shunt system as a whole, the opening pressure of the differential pressure unit has to be added in.

Adjustable Gravitational Unit





Upright Function

When the patient moves to an upright position, the gravitational unit is automatically activated and resistance is added.

- The Tantalum Weight in the gravitational unit is pulled down by gravity, adding resistance to the Sapphire Valve Ball, which increases the opening pressure of the valve.
- CSF flow must now overcome the opening pressure of both the differential pressure valve and the gravitational unit, thus the overall pressure of the shunt system is increased, keeping the intraventricular pressure within physiological limits.
- The increased opening pressure in the upright position effectively prevents overdrainage, which can occur as a result of siphoning.

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Components and Adjustment Instruments

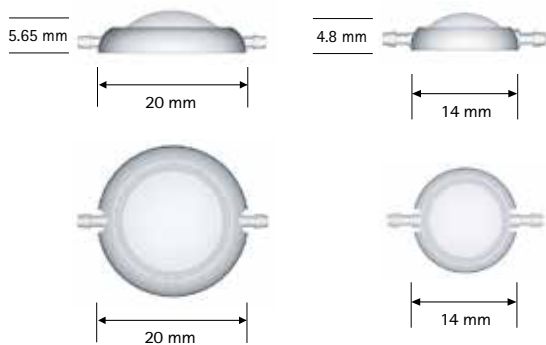
proSA is available separately or with integrated adjustable or fixed pressure valves, catheters and reservoirs.

See Hydrocephalus Management Systems Brochure (DOC447) for details and ordering information.

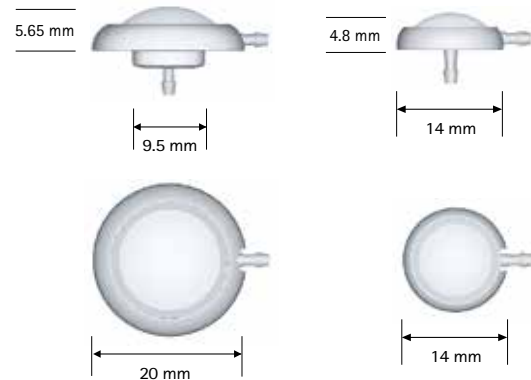
Scale 1:1



Flushing and Control Reservoirs



Burrhole and Sprung Reservoirs



proSA Adjustment Instrument Set

proSA can be adjusted after implantation using our patented, hand-held adjustment tools. The simple adjustment tools can be used to adjust the proSA from 0-40 cm H₂O to help manage your patient's condition at any location.

NOTE: To confirm that the valve setting has not been altered by exposure to the MRI scanner, the pressure setting of the adjustable gravitational unit can be checked with the proSA verification tool.



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Pressure Selection

proSA Pressure Selection

Some considerations for *proSA* pressure selection include patient height, weight, activity level, medical condition and age. The opening pressure of the differential pressure valve should be selected based on the patient's clinical presentation and indication. Refer to product IFU for more information.



- The gravitational unit can be set to a value between 0 and 40 cm H₂O.
- The taller the patient, the higher the pressure level of the gravitational unit.
- The shorter the patient or more overweight, the lower the pressure level of the gravitational unit.
- The more immobile the patient, the lower the pressure level of the gravitational unit.

The pressure of the shunt system in the supine position is maintained by the setting of the differential pressure valve only. In the upright position, the pressure is the total of the differential pressure valve setting and the pressure of the gravitational unit.

Recommended settings only; may vary according to patient and medical history.

DIFFERENTIAL PRESSURE VALVE

Patient Type	Recommended Setting
Standard (children, NPH patients)	5 cm H ₂ O
Defensive (patients with extremely wide ventricles and highly elevated ICP or aqueductal stenosis)	10 cm H ₂ O
Special (patients with pseudotumor cerebri)	15 cm H ₂ O

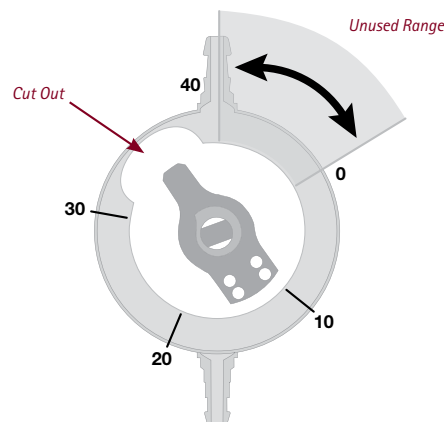
GRAVITATIONAL UNIT

Patient Type	Recommended Valve
Children up to 5 years	20 cm H ₂ O
Children over 5 years Adults up to 60 years	25 cm H ₂ O
Adults over 60 years	20 cm H ₂ O

proSA X-ray Verification

The setting of the *proSA* valve can be easily identified on post-operative x-rays by placing an x-ray template (supplied) over the radiographic image.

NOTE: The cut out section of the valve should be used to match the template. In the event the image is reversed, simply flip the template over. The smaller, tapered end of the rotor points to the current setting.



This *proSA* valve is set at 35 cm H₂O.



This *proSA* valve is set at 31 cm H₂O.

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INDICATIONS FOR USE: The Miethke proSA[®] Adjustable Shunt System is intended to shunt cerebrospinal fluid (CSF) from the lateral ventricles of the brain into the peritoneum.

See Instructions For Use for additional information, including warnings and precautions.

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