SHUNTASSISTANT® 2.0

MIETHKE

Take the headaches out of treating hydrocephalus

Rx Only

INDICATIONS FOR USE: The Miethke Shunt System *SHUNTASSISTANT (SA 2.0)* is used for cerebrospinal fluid (CSF) shunting.

Aesculap Neurosurgery

AESCULAP®

SHUNTASSISTANT® 2.0

Take the headaches out of treating hydrocephalus

Overdrainage is one of the most common causes of complications in hydrocephalus treatment.[1-3]

On average, at least every 5th shunted patient experiences overdrainage.[2-4]

Common valve technology does not protect sufficiently against overdrainage symptoms.

Overdrainage can cause severe complications, such as hygromas and hematomas.

1 Freimann FB, Sprung C. Shunting with gravitational valves–can adjustments end the era of revisions for overdrainage-related events? J Neurosurg. 2012 Dec;117(6):1197-204.

2 Lemcke J, Meier U, Müller C, Fritsch MJ, Kehler U, Langer N, Kiefer M, Eymann R, Schuhmann MU, Speil A, Weber F, Remenez V, Rohde V, Ludwig HC, Stengel D. Safety and efficacy of gravitational shunt valves in patients with idiopathic normal pressure hydrocephalus: a pragmatic, randomised, open label, multicentre trial (SVASONA). J Neurol Neurosurg Psychiatry. 2013 Aug;84(8):850-7.

3 Sundstrom N, Lagebrant M, Eklund A, Koskinen LD, Malm J. Subdural hematomas in 1846 patients with shunted idiopathic normal pressure hydrocephalus: treatment and long-term survival. J Neurosurg. 2017 Oct;27:1-8.

4 Boon AJ, Tans JT, Delwel EJ, Egeler-Peerdeman SM, Hanlo PW, Wurzer HA, Avezaat CJ, de Jong DA, Gooskens RH, Hermans J. Dutch Normal-Pressure Hydrocephalus Study: randomized comparison of low- and medium-pressure shunts. J Neurosurg. 1998 Mar;88(3):490-5.

SHUNTASSISTANT® 2.0

The Valve

Gravitational Technology

Depending on the body position of the patient, the *SHUNTASSISTANT 2.0* valve gradually adapts the opening pressure automatically and counteracts possible overdrainage.

Combination with Differential Pressure Valves

The *SHUNTASSISTANT 2.0* valve proves its strength in combination with other valves. As overdrainage protection, it can be combined with differential pressure valves (fixed or adjustable), either as an initial solution or as a secondary add-on device for patients with existing complications.

Design

The slim, cylindric design enables a fast and easy implantation and is suitable for adults as well as pediatric hydrocephalus treatment.

Additional LP-Variants

SHUNTASSISTANT® 2.0 is also suitable for lumbar drainage due to two special variants

SHUNTASSISTANT 2.0 LP Valve

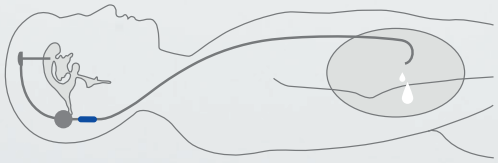
straight

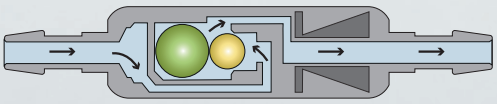
SHUNTASSISTANT 2.0 LP Valve

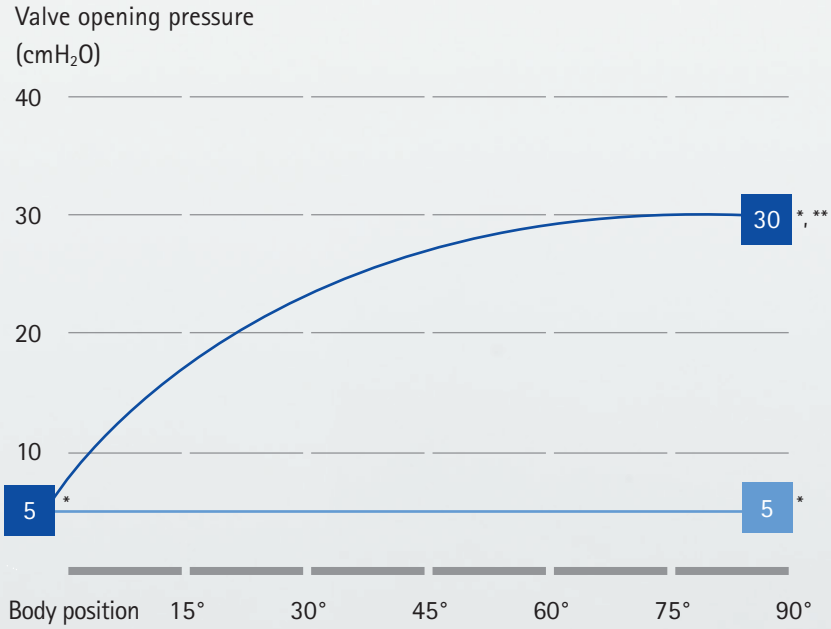
with deflection, u-form

SHUNTASSISTANT® 2.0

Function and Body Position





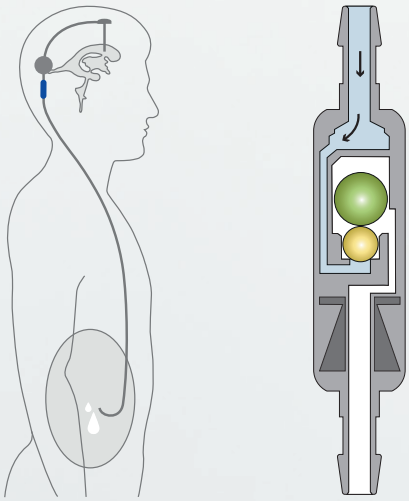


with the SHUNTASSISTANT 2.0 valve

without the SHUNTASSISTANT 2.0 valve

* In the example shown, an additional differential pressure valve with opening pressure of 5 cmH_2O, as well as the *SHUNTASSISTANT 2.0* valve with 25 cmH_2O have been selected.

** The *SHUNTASSISTANT 2.0* valve and the additional differential pressure valve form the total sum of valve opening pressure.



Horizontal Body Position

In the horizontal position, the *SHUNTASSISTANT*® *2.0* valve is always open and does not present any resistance. The opening pressure is exclusively determined by an additional differential pressure valve in this body position.

An implantation parallel to the body axis of the patient helps ensure a precise and reliable performance of the *SHUNTASSISTANT 2.0* valve.

Vertical Body Position

When the patient moves into an upright position, the *SHUNTASSISTANT 2.0* valve is activated by the tantalum ball (green) and adapts the valve opening pressure automatically.

The functionality of the *SHUNTASSISTANT 2.0* valve in different body positions is demonstrated in the MIETHKE® App.

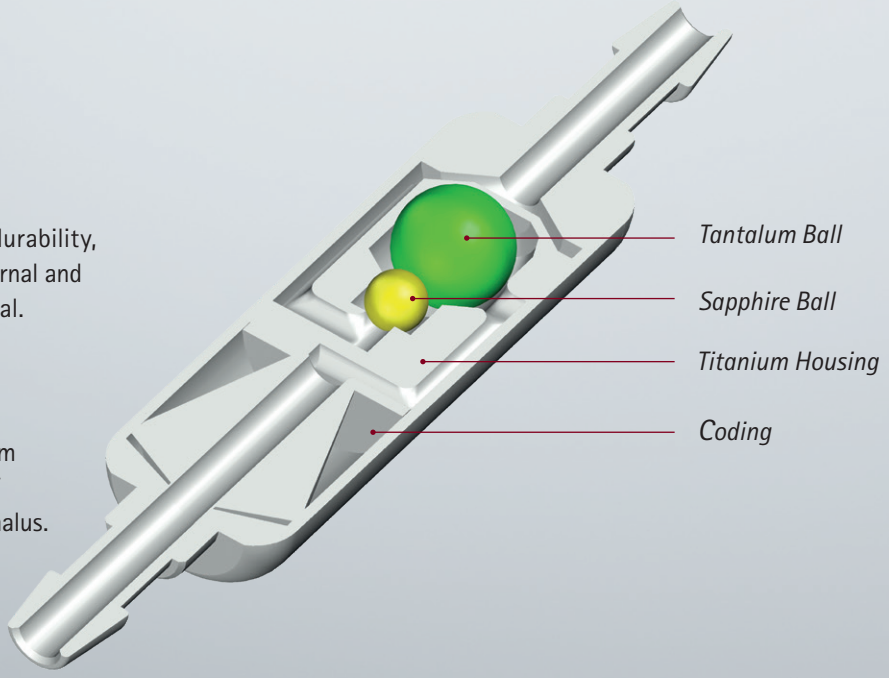
SHUNTASSISTANT® 2.0

X-ray Recognition and Pressure Recommendation

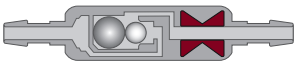
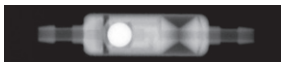
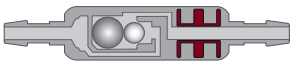
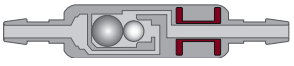
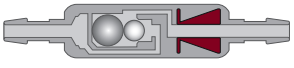
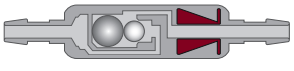
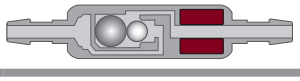
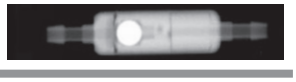
X-ray Recognition
The integrated X-ray coding enables detection of the pressure levels after implantation.

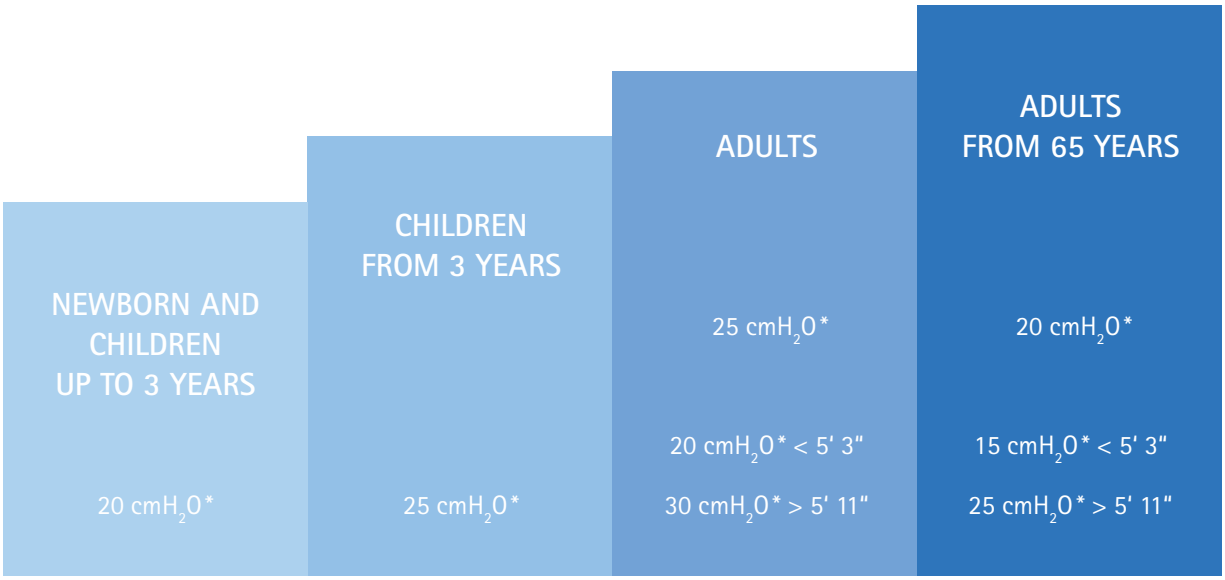
Precision
The valve material titanium assures high precision, durability, reliability and biocompatibility. It helps prevent external and subcutaneous pressure influences and is MR Conditional.

Pressure Levels
The 6 pressure levels offered cover the patient spectrum from newborn to the elderly and allow a wide range of applications in the therapeutic treatment of hydrocephalus.



Pressure Level Variants

Pressure Level	X-ray Coding	Radiography Image
10 cmH_2O		
15 cmH_2O		
20 cmH_2O		
25 cmH_2O		
30 cmH_2O		
35 cmH_2O		



* This is a non-binding recommendation. The treating physician will decide each case individually.

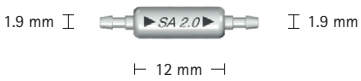
Pressure Recommendation

The choice of the appropriate pressure level of the *SHUNTASSISTANT® 2.0* valve depends on several other factors, including age, degree of activity, size and height of the patient.

The values given apply to mobile patients. For patients with little mobility or a high BMI, a lower pressure level should be chosen for the gravitational unit.

Ordering Information

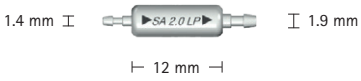
SHUNTASSISTANT® 2.0
Valve



Order	Opening Pressure
FX100T	10 cmH_2O
FX101T	15 cmH_2O
FX102T	20 cmH_2O
FX103T	25 cmH_2O
FX104T	30 cmH_2O
FX105T	35 cmH_2O

Valve: d_o = 4.2 mm
Connector: d_o= 1.9 mm

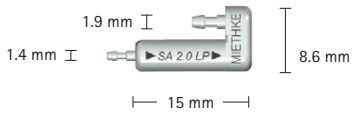
SHUNTASSISTANT 2.0 LP
Valve LP, Straight



Order	Opening Pressure
FX106T	10 cmH_2O
FX107T	15 cmH_2O
FX108T	20 cmH_2O
FX109T	25 cmH_2O
FX110T	30 cmH_2O
FX111T	35 cmH_2O

Valve: d_o = 4.2 mm
Connector: d_o= 1.4 mm
for connection with lumbar catheter
Connector: d_o= 1.9 mm
preferably used with
Catheter: d_i = 1.2 mm, d_o= 2.5 mm

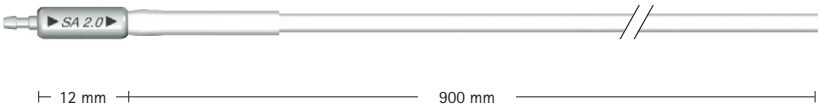
SHUNTASSISTANT 2.0 LP
Valve LP, U-form



Order	Opening Pressure
FX112T	10 cmH_2O
FX113T	15 cmH_2O
FX114T	20 cmH_2O
FX115T	25 cmH_2O
FX116T	30 cmH_2O
FX117T	35 cmH_2O

Valve: d_o = 4.2 mm
Connector: d_o= 1.4 mm
for connection with lumbar catheter
Connector: d_o= 1.9 mm
preferably used with
Catheter: d_i = 1.2 mm, d_o= 2.5 mm

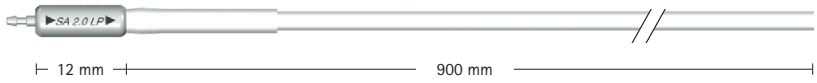
SHUNTASSISTANT® 2.0
Valve with Distal Catheter
(900 mm)



Order	Opening Pressure
FX118T	10 cmH_2O
FX119T	15 cmH_2O
FX120T	20 cmH_2O
FX121T	25 cmH_2O
FX122T	30 cmH_2O
FX123T	35 cmH_2O

Valve: d_o = 4.2 mm
Connector: d_o= 1.9 mm
Catheter: d_i = 1.2 mm, d_o= 2.5 mm

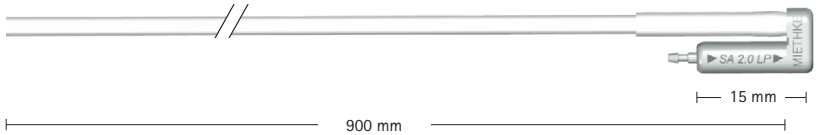
SHUNTASSISTANT 2.0 LP
Valve LP, Straight
with Distal Catheter (900 mm)



Order	Opening Pressure
FX124T	10 cmH_2O
FX125T	15 cmH_2O
FX126T	20 cmH_2O
FX127T	25 cmH_2O
FX128T	30 cmH_2O
FX129T	35 cmH_2O

Valve: d_o = 4.2 mm
Connector: d_o= 1.4 mm
for connection with lumbar catheter
Connector: d_o= 1.9 mm
Catheter: d_i = 1.2 mm, d_o= 2.5 mm

SHUNTASSISTANT 2.0 LP
Valve LP, U-form
with Distal Catheter (900 mm)



Order	Opening Pressure
FX130T	10 cmH_2O
FX131T	15 cmH_2O
FX132T	20 cmH_2O
FX133T	25 cmH_2O
FX134T	30 cmH_2O
FX135T	35 cmH_2O

Valve: d_o = 4.2 mm
Connector: d_o= 1.4 mm
for connection with lumbar catheter
Connector: d_o= 1.9 mm
Catheter: d_i = 1.2 mm, d_o= 2.5 mm

See Instructions for Use for additional information including Contraindications, Warnings and Precautions.

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