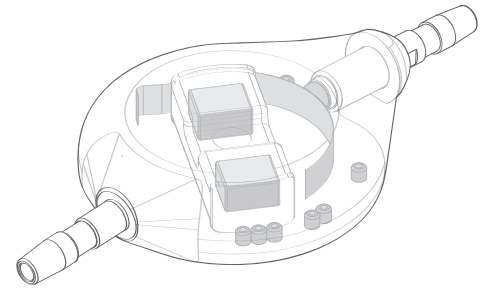


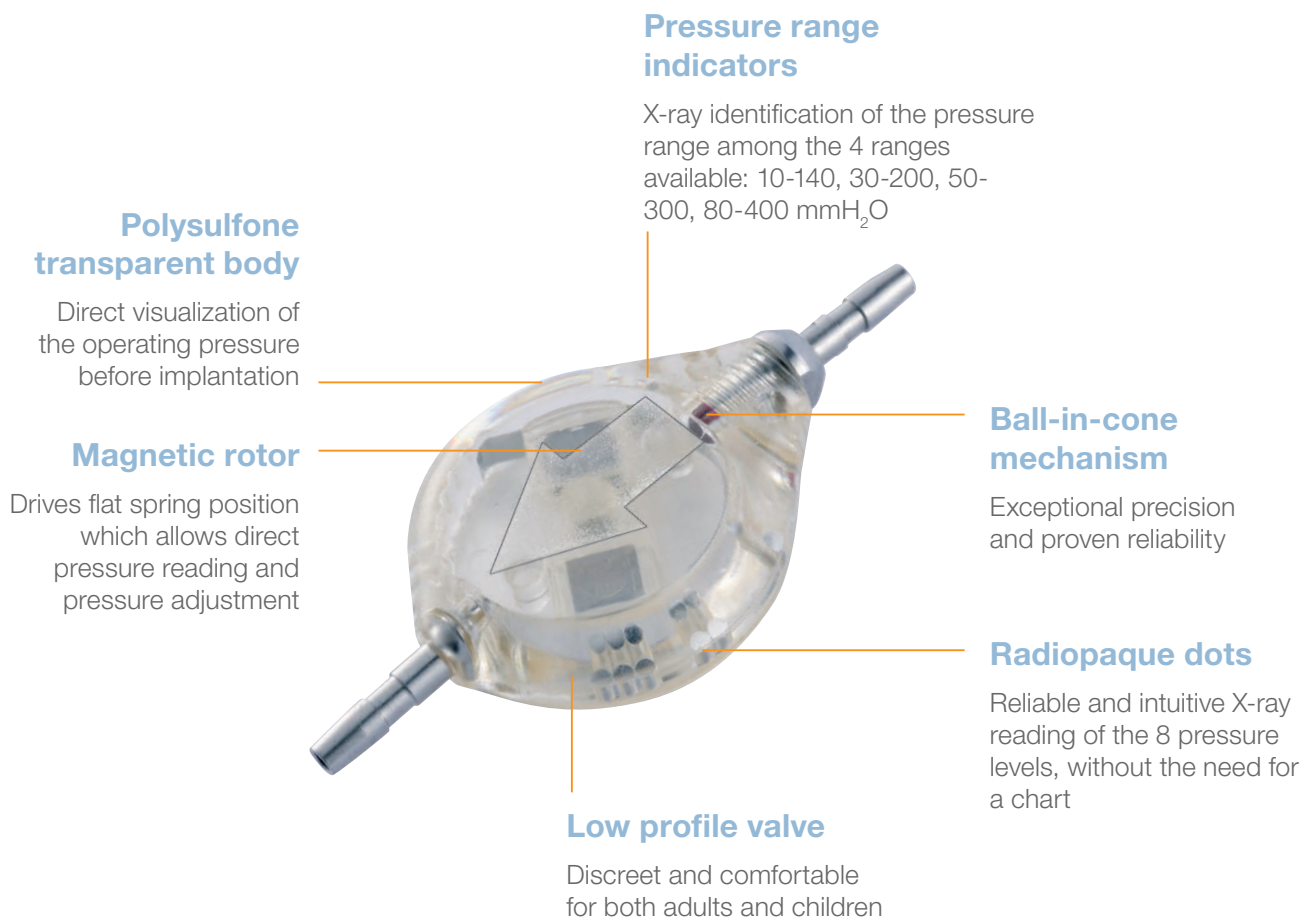
Sophy[®] Mini SM8

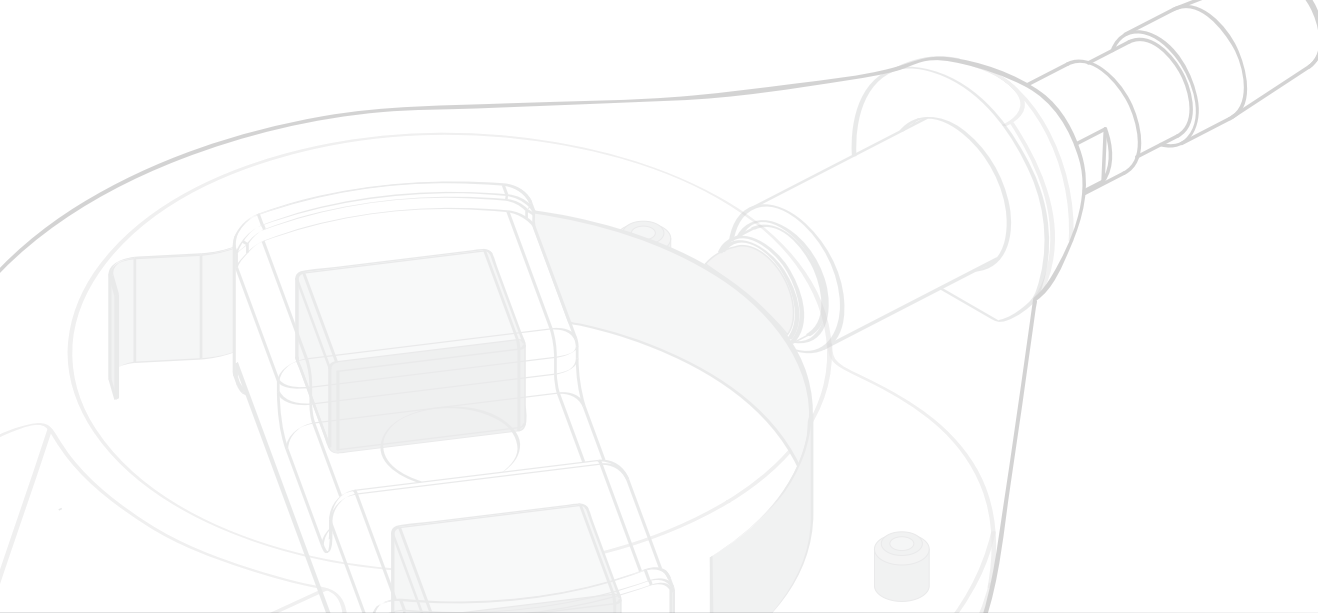
The Sophy[®] Mini adjustable pressure valve



Sophy[®] Mini SM8 Valve

The Sophy[®] Mini Adjustable valve is a low-profile high precision ball-in-cone valve, with a magnetic rotor. Its operating pressure can be adjusted percutaneously, with a dedicated non-invasive adjustment kit, to match an individual patient's changing clinical needs.





In addition to the standard model (30-200 mmH₂O), Sophy® Mini SM8 also offers a **unique special pressure range**: one low pressure valve and two high pressure valves. Thus a choice is provided, depending on the experience of the practitioner, to meet very special needs^(1,2).

Valve	SM8-140	SM8	SM8-300	SM8-400
Identification of the pressure range	0 dot	1 dot	2 dots	3 dots
X-ray identification of the pressure range				
mmH ₂ O	10-140	30-200	50-300	80-400

The Sophy® Mini SM8-140 and SM8 can be associated with SiphonX®, an anti-siphon device, which adds 200 mmH₂O in vertical position.

1. Bergsneider, M., Miller, C. *et al.*, 2008. Surgical Management of Adult Hydrocephalus - Neurosurgery - 62, 643-660.

2. Takahashi, Y., 2001 - Withdrawal of shunt systems - clinical use of the programmable shunt system and its effect on hydrocephalus in children. Child's Nervous Syst. 17(8), 472-477.

Sophy® Mini Adjustment Kit

The Sophy® Mini Adjustment Kit:

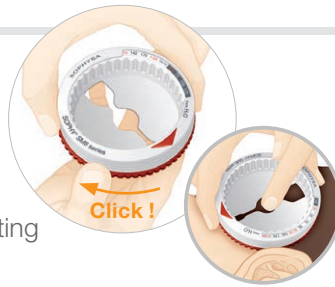
- allows easy, precise and fast procedure
- enables a painless adjustment
- offers direct pressure reading with the compass
- is provided in a shielded case
- includes a Sophy® Mini SM8 demo valve

Locator

Choice of the pressure range

Able to display the 4 pressure ranges available thanks to a rotating ring graduated in mmH₂O.

Localization of the valve under the skin



Magnet

Allows the rotation of the magnetic rotor to adjust the valve pressure



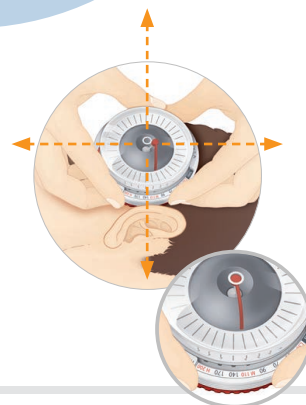
Compass

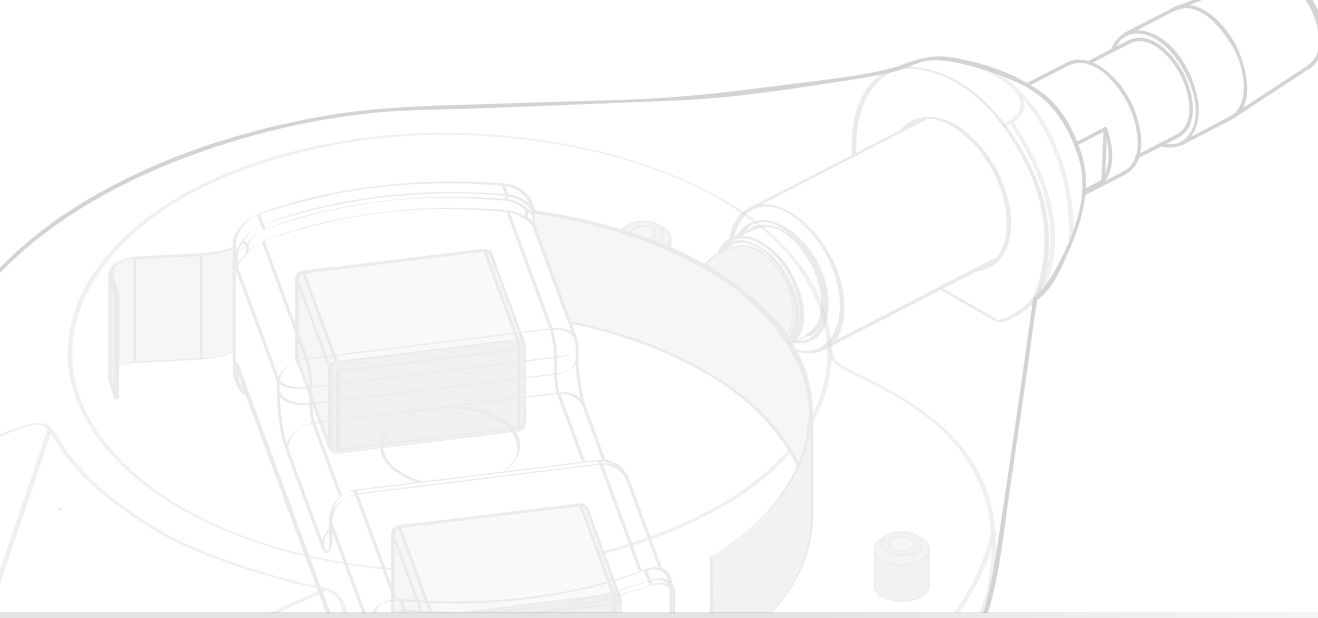
Localization of the valve center (for locator centering)

Thanks to its patented mechanism, it is possible to locate the valve center through the skin and thus fine-tune the positioning of the Locator.

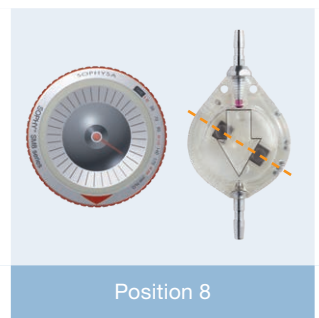
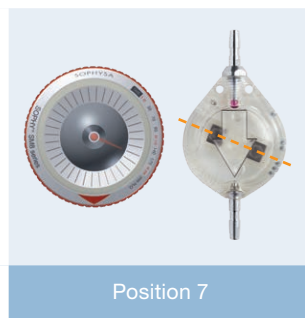
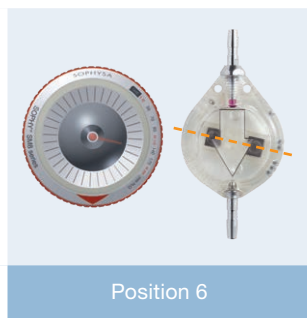
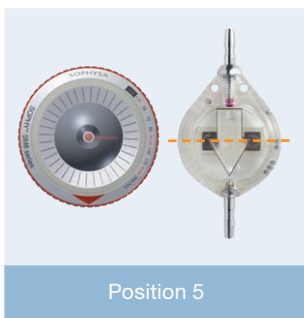
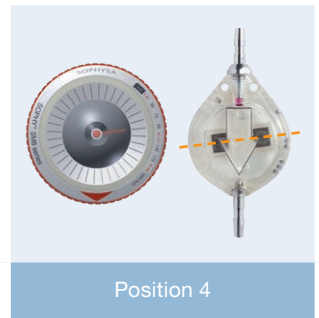
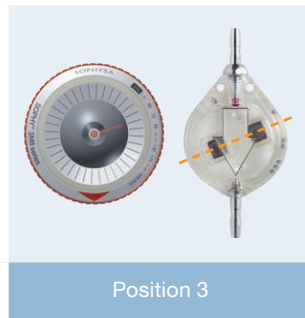
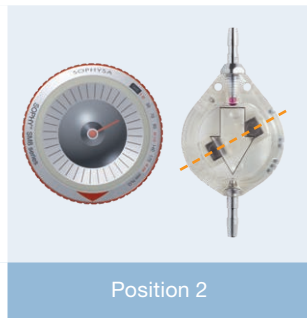
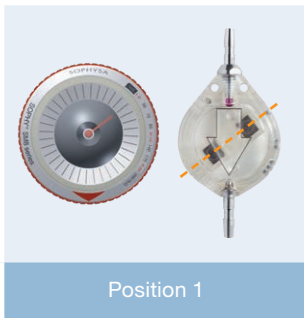
Pressure reading

Allows a precise and reliable reading of the selected pressure.





Direct pressure reading is obtained using the adjustment kit compass: the compass needle is aligned with the position of the magnetic rotor.



Sophy[®] Mini SM8 Kits

The Sophy[®] Mini SM8 Adjustable valve is available in kits for intracranial, pectoral or lumbo-peritoneal shunting.

Intracranial or pectoral valve implantation

The Sophy[®] Mini SM8 kits include:

- A pre-attached distal catheter (length = 110 cm)
- A separate proximal catheter

The proximal catheter can be selected depending on practitioner needs:

- Straight (length = 23 cm)
- Right angle with a reservoir (intracranial length = 6 or 7 cm)

Kits with Straight Ventricular Catheter



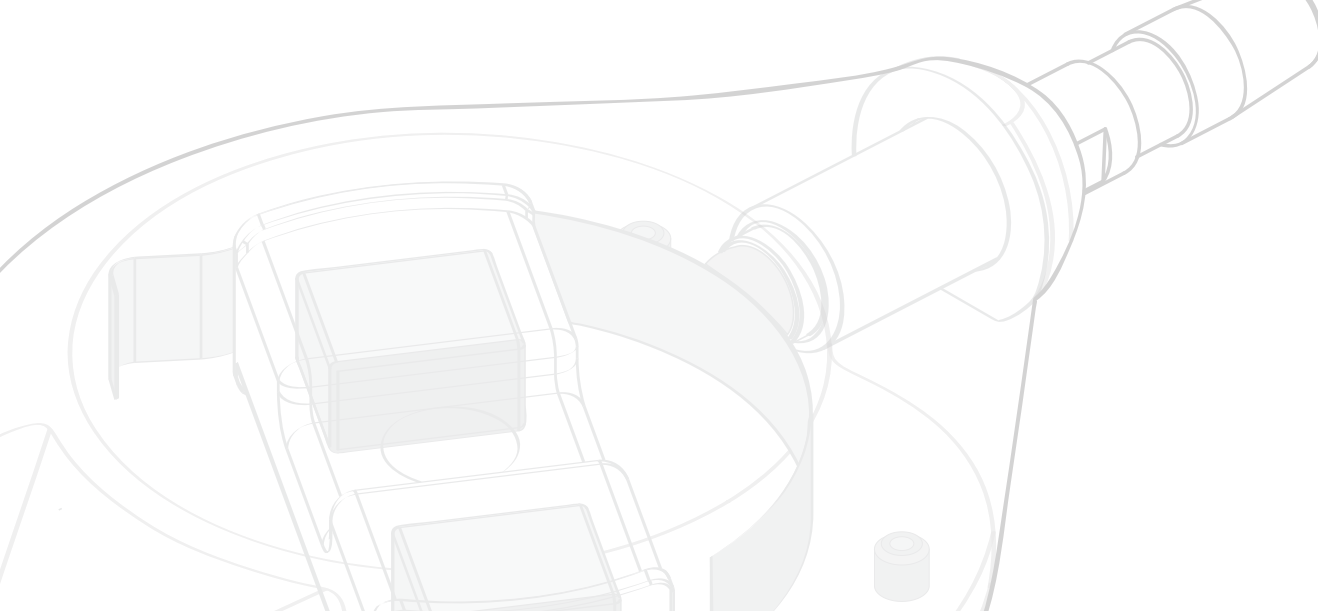
Kits with Right Angle Ventricular Catheter

For intracranial implantation



For pectoral implantation

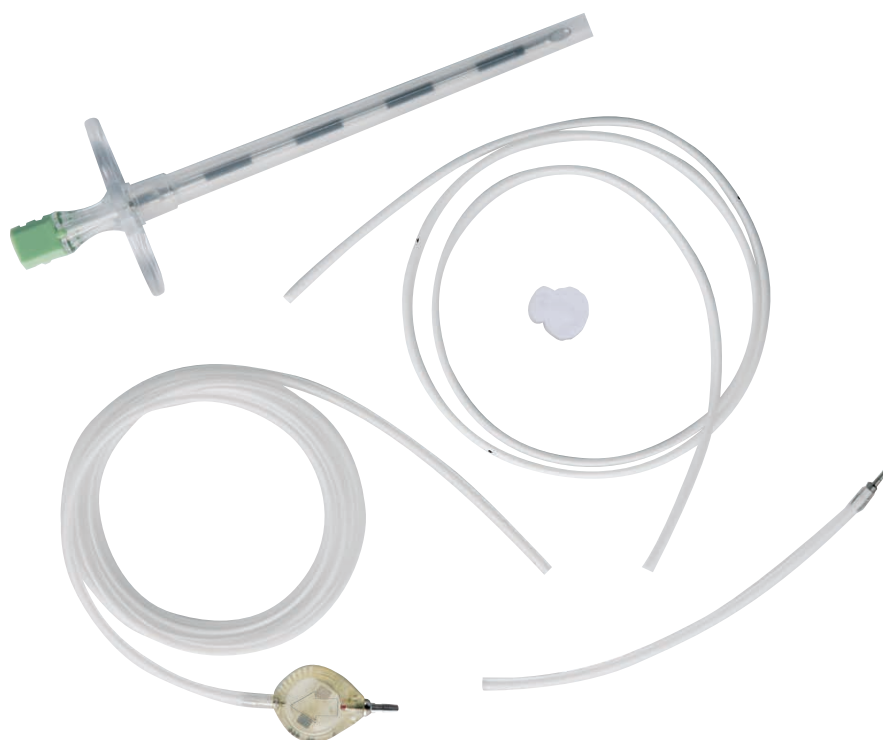




Lumbo-peritoneal shunting

The Sophy® Mini SM8 lumbo-peritoneal shunting kit includes:

- A Sophy® Mini Adjustable Valve SM8 with a preconnected peritoneal catheter
- A female Luer-Lock connector to be connected to the peritoneal catheter should priming be necessary
- An open-end lumbar catheter
- An intermediary catheter with an integral asymmetric step-down connector to allow the connection between the valve and the lumbar catheter
- A Tuohy needle



SM8-2040


Reference	Designation	Position							
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Valve only		1	2	3	4	5	6	7	8
	SM8	Sophy® Mini Adjustable Valve, 30-200							
	SM8-140	10	25	40	60	80	100	120	140
	SM8-300	50	75	100	125	150	180	220	300
	SM8-400	80	120	150	190	230	270	330	400

Reference	Designation	Position							
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	SM8A	Sophy® Mini Adjustable Valve, 30-200, Antechamber							
	SM8B	Sophy® Mini Adjustable Valve, 30-200, Burr-Hole Reservoir							

SiphonX®, anti-siphon device (+ 200 mmH₂O in vertical position)

	SX-200	Gravitational anti-siphon device SiphonX®							
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Complete valve kits Sophy® Mini valve kits include a separated ventricular catheter and a preconnected distal catheter

Straight ventricular catheter	SM8-2010	Sophy® Mini SM8 Kit							
	SM8A-2010	Sophy® Mini SM8A Kit							
	SM8B-2010	Sophy® Mini SM8B Kit							
Right angle ventricular catheter for intracranial implantation	SM8-2020	Sophy® Mini SM8 Kit (Intracranial length = 6 cm)							
	SM8-2021	Sophy® Mini SM8 Kit (Intracranial length = 7 cm)							
Right angle ventricular catheter for pectoral implantation	SM8-2030	Sophy® Mini SM8 Kit (Intracranial length = 6 cm)							
	SM8-2031	Sophy® Mini SM8 Kit (Intracranial length = 7 cm)							
Lumbo-peritoneal shunting	SM8-2040	Sophy® Mini SM8 LP shunt kit							

Adjustment kit

	SAK	Sophy® Adjustment Kit (includes Locator SAK-LI-1, Compass SAK-RI, Magnet SAK-SI and a Sophy® Mini SM8 Demo valve SM8-DEMO-00)							
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 Fax: +1 219 663 7741
 contactusa@sophysa.com

Distribution:

DC-SM8(EN)Rev001 - 11/2024. The adjustable Sophy® valve is intended for the treatment of hydrocephalus by shunting the Cerebrospinal Fluid (CSF) to the abdominal cavity or the right atrium of the heart. For more information, please refer to the instructions for use. Adjustable Sophy® valve - classe III - CE0459. Adjustable Kit Sophy® - classe I. The adjustable Sophy® valve is a registered trademark of Sophysa. For the exclusive use of healthcare professionals. Non-contractual visuals. All rights reserved. © Sophysa.