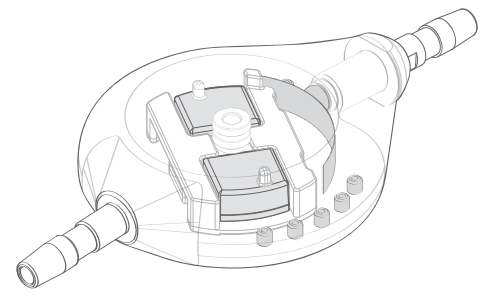


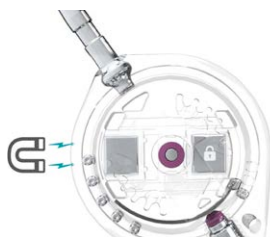
Polaris[®]

The first MRI-stable
adjustable valve



Polaris[®] valve

As the first MRI-stable adjustable valve, **Polaris[®]** has been designed with patients' safety in mind. It offers precision and reliability for more confidence for the clinicians and greater protection to the patient.



Safety

- Patented magnetic lock for MRI-stability (up to 3 T)
- Transparent body to visually control the pressure setting prior to the implantation



Precision & reliability*

- Ball-in-cone and flat spring mechanism
- 80,000+ patients



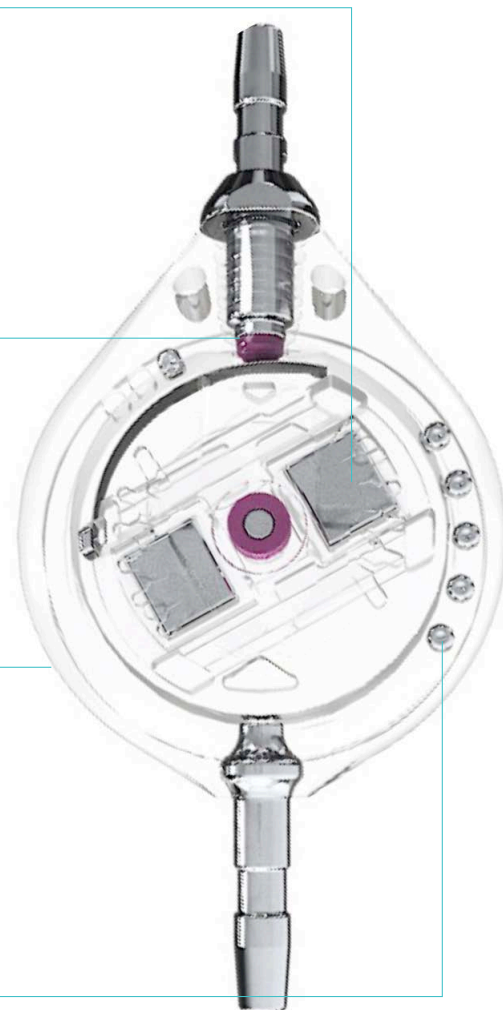
Comfort for the patient

- Programmable in any patient position
- Low profile valve



Direct pressure reading

- Alignment of the indicator light with the pressure value on the locator ring



Polaris[®] video

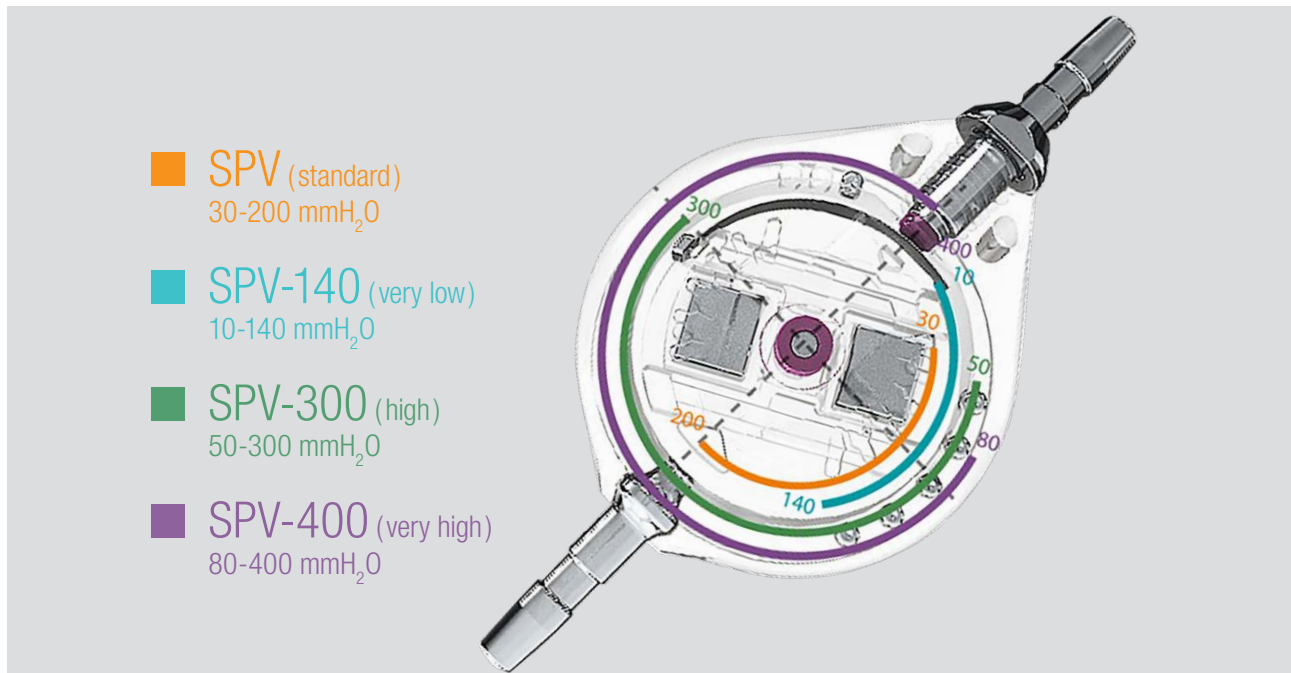
The Polaris[®] valve can be associated with SiphonX[®], an anti-siphon device, which adds 200 mmH₂O in vertical position.

*Example: for a pressure of 200 mmH₂O, 10 ml/h, the precision is +/-30 mmH₂O.
For the other pressures and the measurement protocol, please refer to the Instruction For Use.
Well-known ball-in-cone and flat spring mechanism used for over 15 years on Polaris range. Refer to Polaris CER410 document.

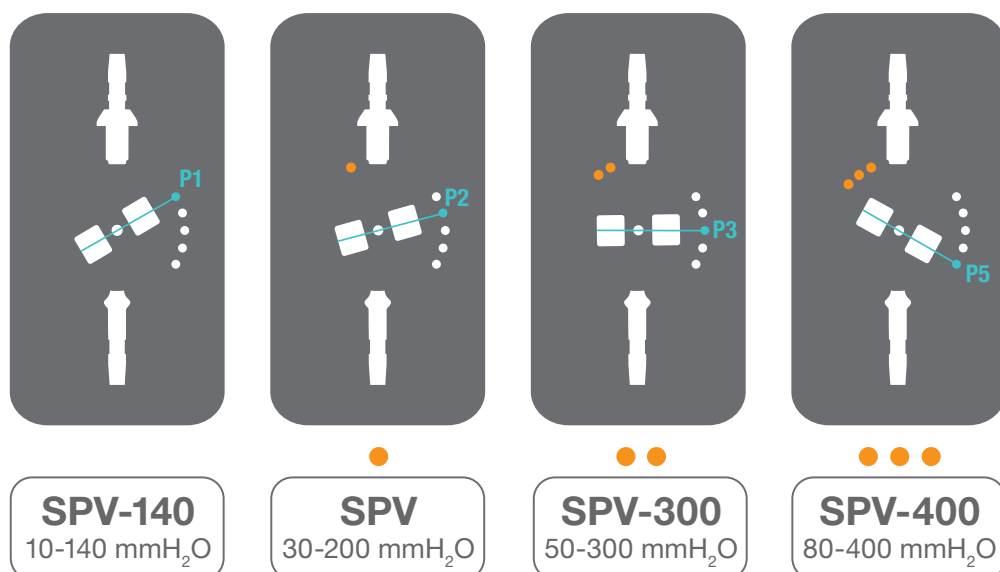
A Range for Various Clinical Needs

Three special pressure variants complete the standard model (SPV, 30-200 mmH₂O) to cover a large panel of clinical needs.^(1,2)

- 4 pressure ranges from 10 to 400 mmH₂O (standard, very low, high and very high pressure)
- Adjustable valve thanks to the magnetic rotor
- 5 pressure settings per range



Detecting the model and reading the pressure (P1 to P5) with an X-ray

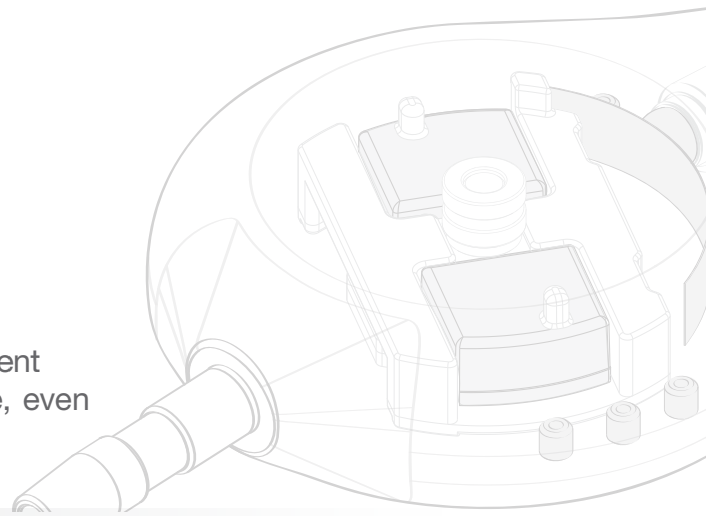


1. Bergsneider, M., Miller, C. *et al.*, 2008. Surgical Management of Adult Hydrocephalus - Neurosurgery - 62, 643-660.

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.

Guided and Easy Valve Adjustment

With the **Electronic Compass**, the Polaris® adjustment kit makes the valve adjustment easier at any angle, even through thick skin*.



1

Locator

Location of the valve

2

Electronic Compass

Location of the valve magnetic center and pressure reading in any patient position

3

Mechanical Compass

Location of the valve magnetic center and pressure reading

4

Magnet

Valve unlocking and new pressure adjustment



2

To be inserted into PAK2

*Up to 12 mm skin thickness. For success in setting a new pressure, we recommend an implantation depth up to 8 mm. Refer to the Instructions For Use. Data on file.

Recognized Safety and Efficiency



The Journal of Neurosurgery

“This study demonstrated that only the Sophysa Polaris valve retained the pressure settings after exposure to 3-Tesla static and radiofrequency magnetic field”.

Inoue T., Kuzu Y., *et al.* The Effect of 3-Tesla Magnetic Resonance Imaging on Various Pressure-Programmable Shunt Valves. *The journal of neurosurgery: pediatrics* 2, 2005, 103: 163-165.

Child's Nervous System

“This new shunt device offers the diagnostic benefit of high field magnetic resonance imaging in shunt dependant patients who need an adjustable valve”.

Lüdemann W., Rosahl S., *et al.* Reliability of a new adjustable shunt device without the need for readjustment following 3-Tesla MRI. *Child's nervous system*, 2005, 21: 227-229.

Child's Nervous System

“The Polaris valve [...] offers the advantage of remaining unmodified during exposure to MRI machines or other external magnets as we observed”.

Martinez-Lage J., Almagro M. J., *et al.* Management of Neonatal Hydrocephalus: feasibility of use and safety of two programmable (Sophy and Polaris) valves. *Child's nervous system*, 2008, 24: 549-556.

Cerebrospinal Fluid Research

“The Polaris valve is a reliable, adjustable valve. [...] the Polaris cannot be accidentally re-adjusted by an external magnetic field”.

Allin D., Czosnyka M., *et al.* Investigation of the hydrodynamics properties of a new MRI-resistant programmable hydrocephalus shunt. *Cerebrospinal fluid research*, 2008, 21: 5-8.

Child's Nervous System








“The settings of the Polaris valve could not be altered by any magnetic toy at any distance, due to its architecture”.

Zuzack T., Balmer B., *et al.* Magnetic toys: forbidden for pediatric patients with certain programmable shunt valves? *Child's nervous system*, 2009, 25: 161-164.

Neurol. Med. Chir. (Tokyo)

“The Polaris valves [...] were immune to unintentional reprogramming by the portable game machine”.

Nakashima K., Nakajo T. *et al.* Programmable Shunt Valves: In Vitro Assessment of Safety of the Magnetic Field Generated by a Portable Game Machine. *Neurol. Med. Chir. (Tokyo)*, 2011, 51, 635-638.

	Reference	Designation	Position				
Valve only							
	SPV	Polaris® Adjustable Valve, 30-200	30	70	110	150	200
	SPV-140	Polaris® Adjustable Valve, 10-140	10	40	80	110	140
	SPV-300	Polaris® Adjustable Valve, 50-300	50	100	150	220	300
	SPV-400	Polaris® Adjustable Valve, 80-400	80	150	230	330	400
Valve with antechamber							
	SPVA	Polaris® Adjustable Valve, 30-200, Antechamber	30	70	110	150	200
	SPVA-140	Polaris® Adjustable Valve, 10-140, Antechamber	10	40	80	110	140
	SPVA-300	Polaris® Adjustable Valve, 50-300, Antechamber	50	100	150	220	300
	SPVA-400	Polaris® Adjustable Valve, 80-400, Antechamber	80	150	230	330	400
Valve with burr-hole reservoir							
	SPVB	Polaris® Adjustable Valve, 30-200, Burr-Hole Reservoir, (30, 70, 110, 150, 200 mmH ₂ O)					
Valve with SiphonX® antisiphon device (+ 200 mmH₂O in vertical position)							
	SPV-SX	Polaris® Adjustable Valve, 30-200, SiphonX®					
	SPV140-SX	Polaris® Adjustable Valve, 10-140, SiphonX®					
	SPVA-SX	Polaris® Adjustable Valve, 30-200, Antechamber, SiphonX®					
	SPVA140-SX	Polaris® Adjustable Valve, 10-140, Antechamber, SiphonX®					
Complete valve kits Polaris® valve kits include a separated ventricular catheter and a preconnected distal catheter							
	SPV-2010	Polaris® SPV Kit					
	SPVA-2010	Polaris® SPVA Kit					
	SPVB-2010	Polaris® SPVB Kit					
Adjustment kit							
	PAK2	Polaris® Adjustment Kit-2 (includes Locator PAK2-LI, Compass PAK2-RI, Magnet PAK2-SI and a Polaris® demo valve SPV-DEMO-00)					
	PAK3-ERI	Electronic Compass					