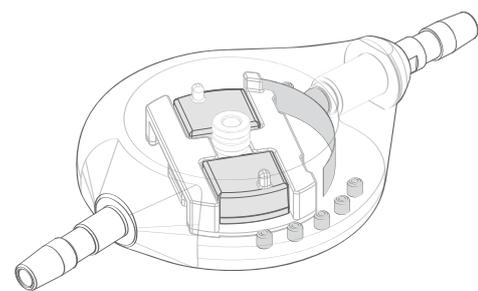


Polaris[®]

The first MRI-stable
adjustable valve



Polaris[®] Valve

The adjustable Polaris[®] valve is a major breakthrough for the safety of patients thanks to the patented self-locking system of the rotor.

This magnetic lock has been designed to resist unintentional operating pressure changes due to knocks or exposure to magnetic fields, especially during MRI examinations.

It offers the patient an unequalled security against the clinical risks associated with those dysadjustments.

Magnetic rotor

Drives flat spring position which allows direct pressure reading and pressure adjustment

+

Magnetic lock

Avoids unintentional pressure changes due to knocks or magnetic fields.

Polysulfone transparent body

Direct visualization of the pressure level before implantation.

Pressure range indicators

X-ray identification of the pressure range among the 4 ranges available: 10-140, 30-200, 50-300, 80-400 mmH₂O.

Ball-in-cone and flat spring mechanism

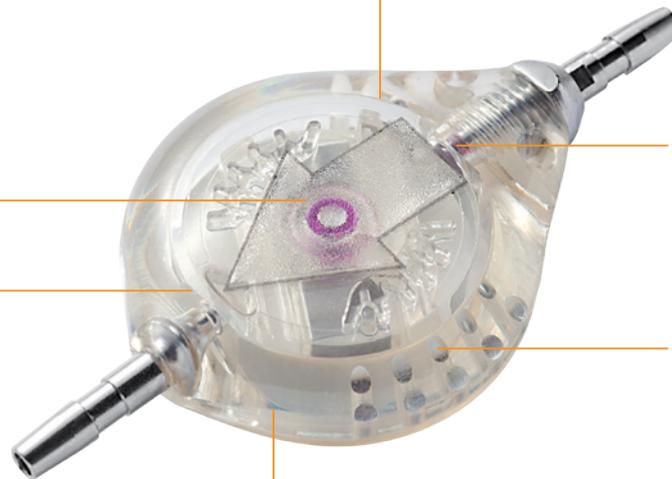
Exceptional precision and proven reliability.

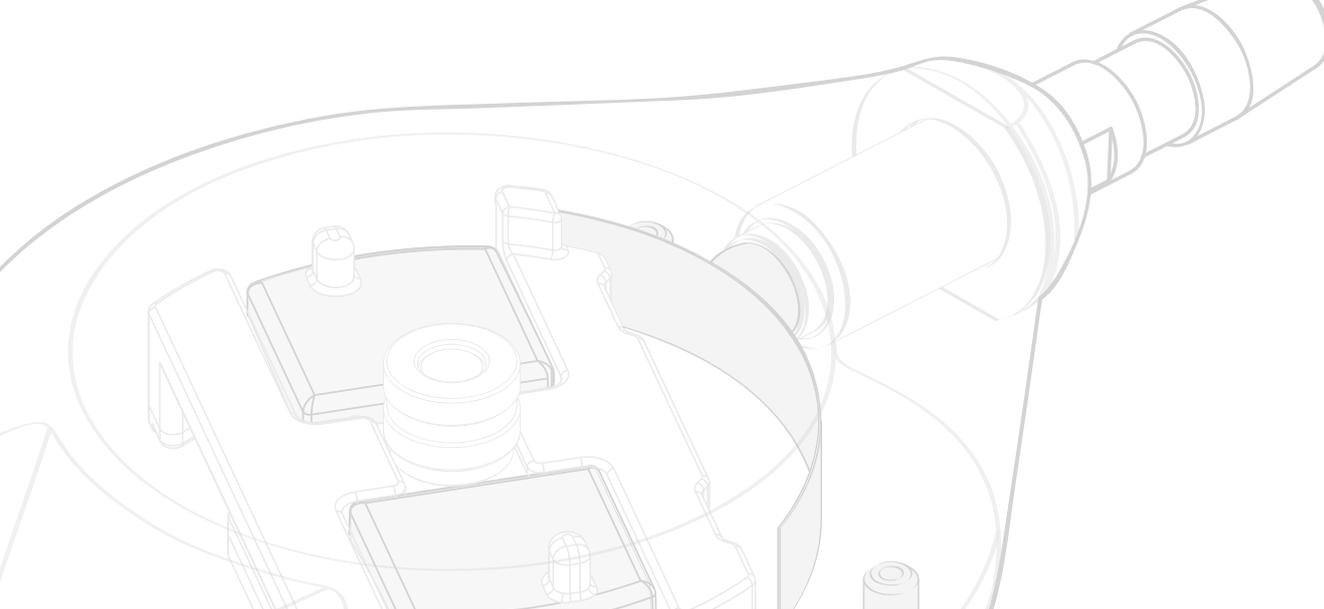
Radiopaque dots

Reliable and intuitive X-ray reading of the 5 pressure levels, without the need for a chart.

Low profile valve

Discreet and comfortable for both adults and children.





A proven efficiency

The Journal of Neurosurgery

“This study demonstrated that only the Sophy 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-Teslas 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.

A unique self-locking system

The safety of adjustable valves has become a major concern for neurosurgeons because of the growing use of electromagnetic devices in daily life^(1,2,3,4,5) and the development of high power MRI (3-Tesla)^(6,7).

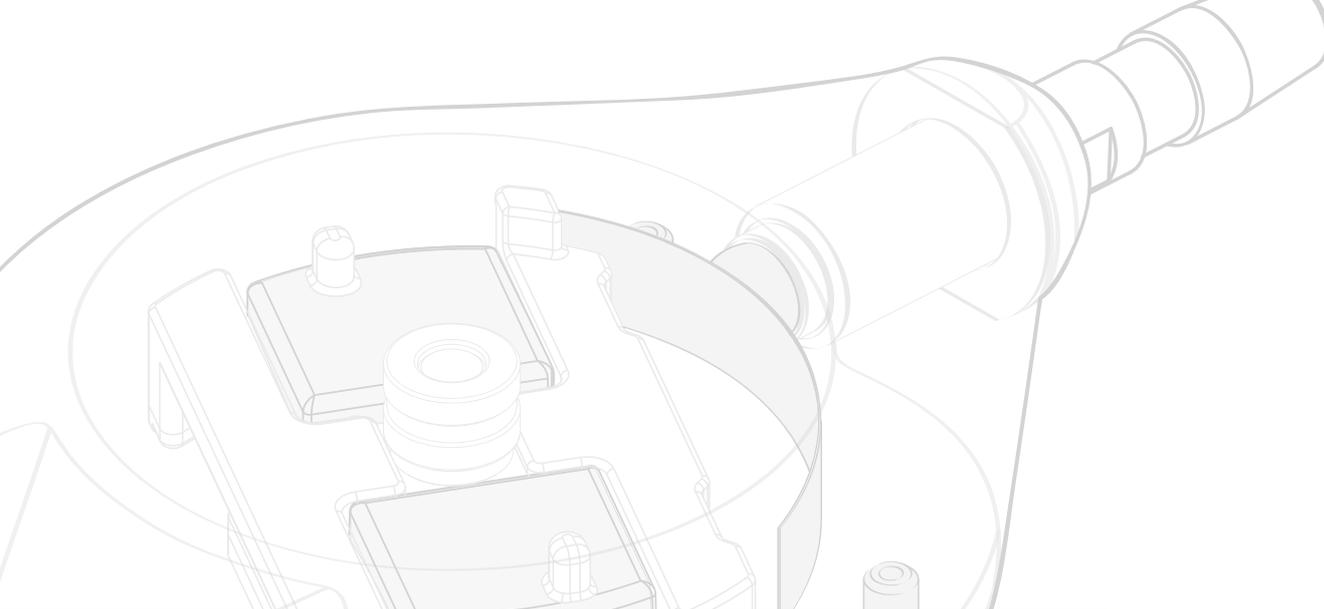
Indeed, these devices are liable to modify the selected pressure accidentally, with the risk of disrupting CSF drainage and causing serious complications for the patient.

The Polaris[®] valve is a major breakthrough for the safety of patients implanted with adjustable valves.

Its exclusive locking mechanism enables it to resist:



1. Miwa, K., Kondo, H., *et al*, 2001 - Pressure changes observed in Codman-Medos programmable valves following magnetic exposures and filling. *Child's Nervous Syst.* 17, 150-153.
2. Utsuki, S., Shimizu, S. *et al*, 2006 - Alteration of the Pressure Setting of a Codman-Hakim Programmable Valve by a Television. *Neurol. Med. Chir. (Tokyo)* 46, 405-407
3. Nomura S., Fujisawa, H., *et al*, 2005 - Effect of cell phone magnetic fields on adjustable cerebrospinal fluid shunt valves - *Surgical Neurology.* 63, 467-468.
4. Zuzak, T., Balmer, B., *et al*, 2009 - Magnetic toys: forbidden for pediatric patients with certain programmable shunt valves? *Child's Nervous Syst.* 25, 161-164.



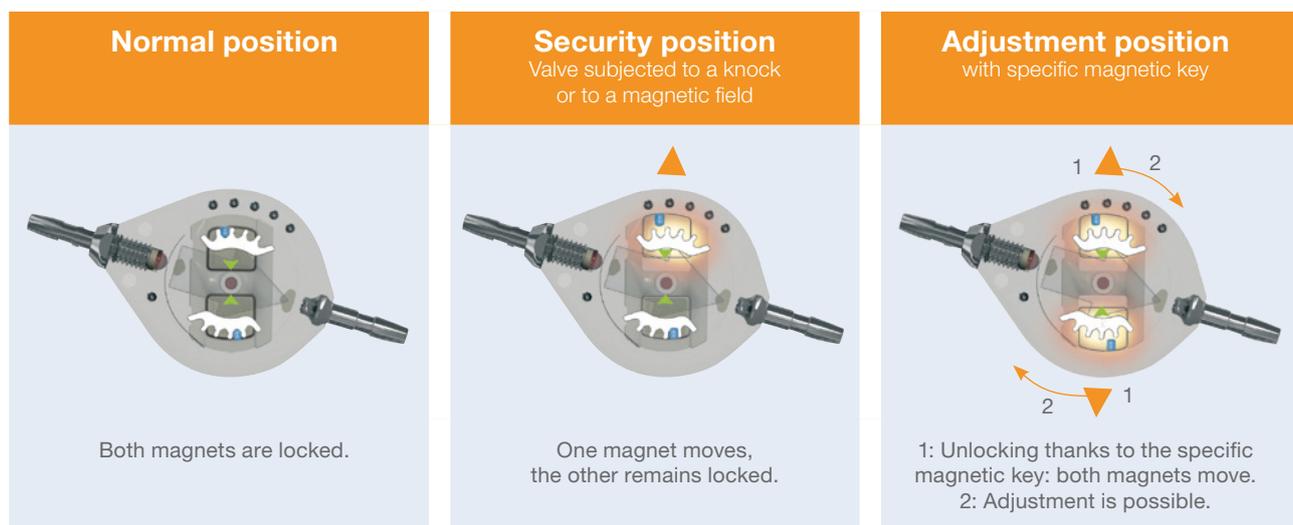
The Polaris® magnetic lock is based on the permanent reciprocal attraction of two mobile micro-magnets of opposite polarity.

This “magnetic lock” holds the rotor in the selected position, thus preventing any accidental change in operating pressure if the valve is exposed to magnetic fields.

In fact, in the presence of a standard magnetic field (unidirectional) the two micro-magnets are attracted in the same direction.

So only one of the two magnets moves in the direction of the field, while the other remains locked.

Changing the operating pressure of the valve first requires the simultaneous unlocking of the two micro-magnets in the valve by a specific magnetic key. The rotor can then turn freely on its central axis.



5. Anderson, R., Waller, M *et al*, 2004 - Adjustment and malfunction of a programmable valve after exposure to toy magnets. J. Neurosurg, (Pediatrics 2). 101, 222-225.

6. Inoue, T., Kuzu, Y., *et al*, 2005 - The effect of 3-tesla Magnetic Resonance Imaging on various Pressure-Programmable Shunt Valves. J. Neurosurg, (Pediatrics 2), 103, 163-165.

7. Knauff, U., Nitsch, J. 1999 - On the Electromagnetic Susceptibility of Adjustable Valves for the treatment of Hydrocephalus. International Symposium on Electromagnetic Compatibility, October 5-7, 1999, Magdeburg, Germany.

Polaris® Adjustment Kit

The Polaris® Adjustment Kit :

- allows easy, precise and fast procedure
- permits a painless adjustment
- offers a direct pressure reading with the Compass
- is provided in a shielded case
- includes a Polaris® 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

Unlocking of the valve

New pressure adjustment

A true "magnetic key", it makes fast unlocking and precise valve adjustment possible due to the exclusive combination of several powerful magnets.



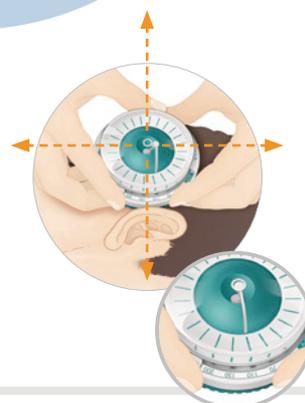
Compass

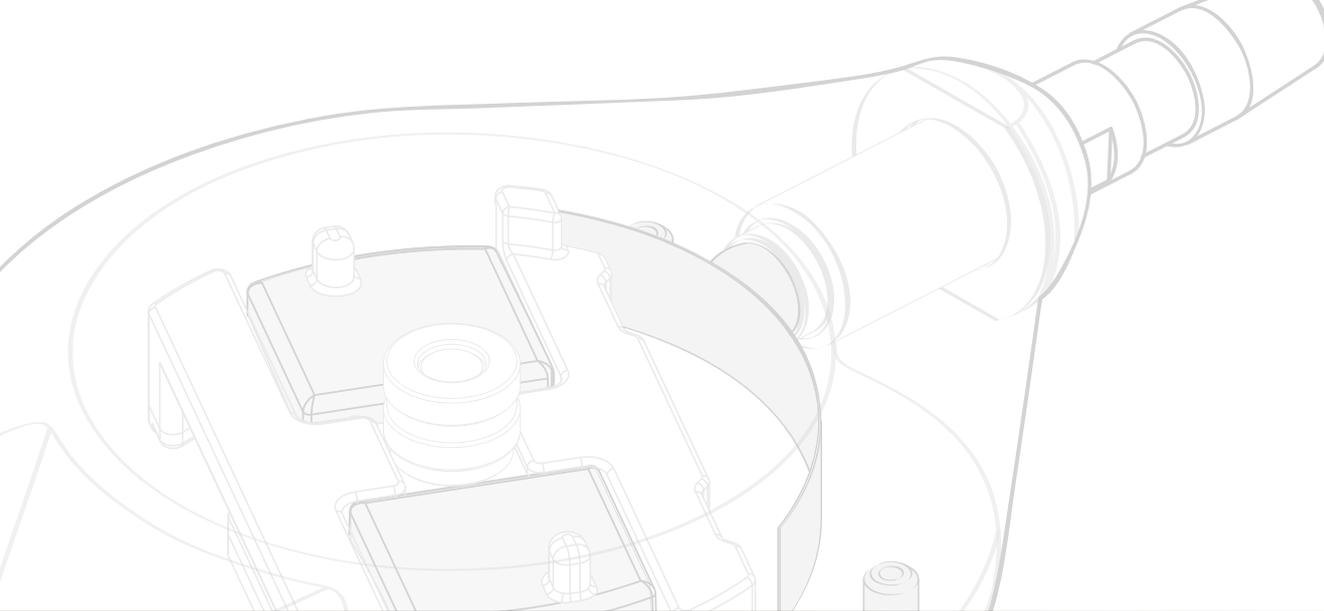
Localization of the valve center (for Locator centering)

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

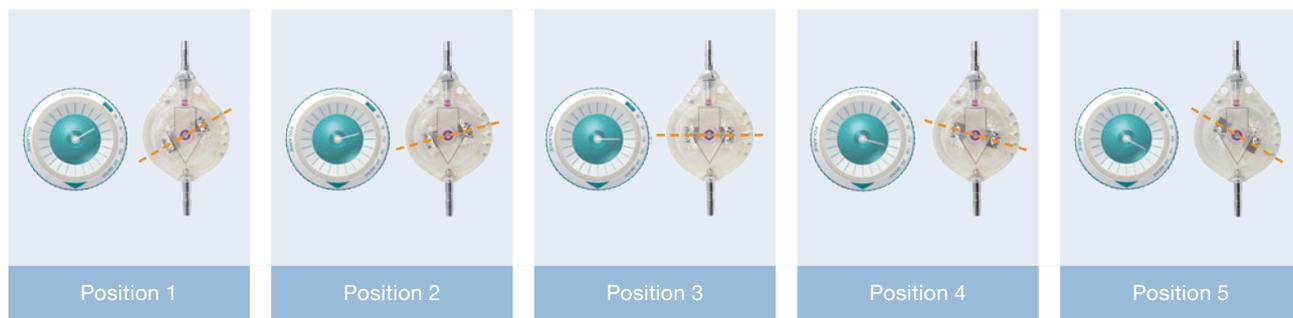
Pressure reading

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.



In addition to the standard model (30-200 mmH₂O), Polaris® 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 specific clinical needs.^(1,2)

Valve	SPV-140	SPV	SPV-300	SPV-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 Polaris® valve can be associated with SiphonX®, an anti-siphon device, which adds 200mmH₂O 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.

		Reference	Designation	Position				
Valve only				1	2	3	4	5
	SPV	Polaris® Adjustable Valve, 30-200	Pressure (mmH ₂ O)	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				Position				
	SPVA	Polaris® Adjustable Valve, 30-200, Antechamber	Pressure (mmH ₂ O)	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 mmH₂O)						
Valve with SiphonX® antisiphon device (+ 200 mmH ₂ O 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)						

Distribution: