SOPHYSA
At the heart of the **brain**

# POLARIS® VALVE

*Adjustable pressure valve for CSF shunting – Sterile, single-use*

***An information leaflet for patients implanted with a Polaris valve***

*Revision 004 - February 2025*

## 1. What is hydrocephalus?

You / your child / a member of your family received a Polaris valve implant to treat hydrocephalus.

Hydrocephalus relates to disorders linked to the circulation of the cerebrospinal fluid (CSF) produced by the brain.

CSF is a clear and transparent fluid that surrounds the brain and spine, flows within the natural spaces, and returns to the venous blood circulation being absorbed in specific areas.

It acts as a shock absorber to protect the brain, carries essential nutrients to feed it and evacuates wastes.

In some cases, the CSF flow is disturbed, builds up in the cranium, generating increased pressure on the brain. This is hydrocephalus, referring to “water on the brain” in Greek.

***It is because the liquid that is in my head does not drain correctly that I must be treated!***

Hydrocephalus may be congenital (developed before or at birth) or acquired, resulting from damages to the brain after a head injury of other event (stroke, meningitis …).

Hydrocephalus may also appear in adults aged 50 years or older, but the cause is usually unknown.

Usual symptoms in infants include abnormal increase of the head circumference, vomiting, sunset eyes…

In adults, raised intracranial pressure may produce headaches, vomiting, visual disturbance etc.

**Each person is affected differently so you should speak with your doctor or specialist for individual information**.

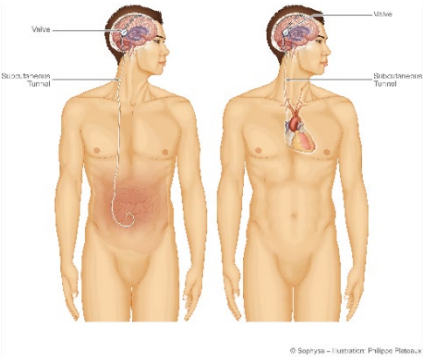
## 2. Why a valve inside my body?

Though some drugs may temporarily control specific Hydrocephalus, surgery is one of the effective treatments that consists of implanting a CSF shunt.

Your neurosurgeon assessed the suitability for this treatment for you and chose the most appropriate operating method for you.

An internal CSF shunt system is a thin tube implanted in the brain that pumps the CSF where it is in excess and drains it to another location in your body (abdomen – Ventricular Peritoneal Shunt or VPS, or directly the heart – Ventricular Atrial Shunt or VAS).

In some rare cases, the shunt is placed in the lumbar area (Lumbo-Peritoneal Shunt or LPS).




The Polaris valve, inserted into the pathway and usually placed under the skin of your skull, is intended to control the drainage of the collected CSF (direction and flow).

***The liquid in excess must be removed but not too much!***

The implantation of the sterile and single-use Polaris valve has been performed by trained and qualified personnel only, such as your neurosurgeon, in strict aseptic conditions.

## 3. Options

Depending on the model your neurosurgeon selected for you, other devices may be pre-connected to the valve.

**Reservoir**

The reservoir may be used by your doctor to assess the patency of your shunt during check-up visits or to access the CSF for injections and/or samples.

2 models exist, depending on the orientation of the inlet, linear (type A) or perpendicular (type B).

**Anti-siphon**

This device can help limiting some possible uncomfortable sensations when you suddenly move from lying down to standing up.

| | |
|---|---|
|  | Reservoir type A + valve |
|  | Reservoir type B + valve |
|  | Valve + anti-siphon |
|  | Reservoir type A + valve + anti-siphon |
|  | Reservoir type B + valve + anti-siphon |

To know which configuration you received, see the reference specified on your patient card after the REF symbol and refer to the section 13.

## 4. Patient population?

The Polaris valve you are implanted with can be used on patients of all ages, including pre-term infants.

It is adjustable so depending on the evolution of your clinical state, its operating mode may be changed after implantation directly by your doctor, without the need of a new surgery.

## 5. What is the valve lifetime?

As most of other hydrocephalic patients, you may be required to keep your implant throughout your whole life, but it allows you to lead a normal daily life.

Even though the mechanical performances of the product have been tested over a 5-year period, the valve can stay implanted as long as no complication arise.

## 6. What about my daily life with a Polaris valve?

As treatment is a lengthy process, surveillance will be pursued by your doctor over a long period of time.

***Polaris lets me lead a normal daily life but requires compliance with the monitoring protocol specified by my doctor.***

The post-operative follow-up is done at the hospital (consultation, imaging service, emergency room), in the clinic or in your doctor's office.

Even though the valve body is made of a non-deformable material which protects the internal mechanism, you should avoid all activity exposing the device to direct shocks (violent sports, etc.). In case of

involuntary direct shock, you should ask your doctor to check your shunt.

The Polaris valve does not content any phthalate, natural or synthetic latex.

The valve being implanted on the skull, vibrations due to the CSF flow may be felt.

The valve contains magnetic parts, but it has been specifically designed to stay insensitive to the influence of external standard magnetic fields.

- magnetic fields generated by airport security scanners, microwave ovens, mobile phones, high tension cables, and TV,
- permanent household magnets such as those present in toys, audio headsets and loudspeakers,
- magnetic fields created by electric motors operating in equipment such as razors, hairdryers, hair trimmers…

## 7. May I undergo an MRI?

The valve includes metallic parts that may create disturbance during imagery (artifact). So, do not forget to indicate to the medical personnel that you have an implanted valve and present your patient card (refer to the section 10).

You can undergo an MRI examination, even immediately after the device has been implanted.

The mechanism of the Polaris valve is designed to withstand standard conditions for MRI examination (3 Tesla or less) without effect on the operation.

**You are likely to feel slight discomfort during an MRI examination.**

## 8. What should my doctor know about MRI examinations with a Polaris valve?

According to the dedicated standard (ASTM F2503), the Polaris valve is considered as “MR Conditional”. It means that there are examinations conditions to be respected by your radiologist to undergo an MRI.

**Examinations conditions**

– MRI with a static magnetic field limited to 1.5 or 3 Tesla

– Spatial gradient magnetic field limited to 19 T/m

– Whole body averaged SAR (Specific Absorption Rate) for 15-minute exposure limited to:

- 2 W/kg (normal operating mode)
- 4 W/kg (Mode of first level controlled operation)

**MRI-related heating**

When the examination conditions described above are met, tests show, after a 15-minute exposure, a 3.4 °C maximum global heating, including a 3.2 °C environmental heating and a **0.2 °C heating related to the device**.

The rise in temperature caused by the exposure to a 3-Tesla MRI is negligible and does not have any physiological consequence for the patient.

**Artifacts**

The Polaris valve micro-magnets are potential source of artifacts on MRI images.

Your radiologist should be aware that in a sagittal plane, image artifacts may reach the following widths on a 3-Tesla MRI:

- Spin Echo sequences: 59 mm
- Gradient Echo sequences: 71 mm

**MRI Stability**

Sophysa adjustable valves feature micro-magnets that enable the valve adjustment through the skin with a specific external magnet. An MRI machine being a powerful magnet, it may attract these micro-magnets and modify the settings in certain cases of valve rotation, particularly at the tunnel entrance where magnetic field variations are strongest.

However, the Polaris valve has a patented magnetic locking system. It protects the valve from the effects of magnetic fields, thus, limiting the risks of accidental pressure changes.

The MRI stability of Polaris has been proven by the most exhaustive qualification tests possible, and no cases of accidental pressure change have been reported to date by radiologists. Polaris is therefore considered MRI stable.

However, as a precautionary measure, the exam should take place within or close to an establishment with a neurosurgery service equipped with the proper adjustment kit, to re-adjust the valve pressure, should it be necessary.

***I must remain immobile in the immediate proximity of the tunnel and inside it during the MRI examination to limit the risk of an accidental pressure change.***

***I must inform the doctor following my treatment of any MRI examination, related or not to hydrocephalus, so they can select the proper establishment for the MRI examination.***

## 9. When should I consult my doctor?

Even if the risk of complication is low, you need to know that certain complications may arise after the implantation.

The main complications of shunts are obstruction, infection and overdrainage. These complications require prompt attention by your doctor.

***I must closely follow the post-operative monitoring protocol to early detect any signs of complication.***

**Obstruction**

Obstruction is the most frequent complication in shunt systems. It can occur at any point in a shunt.

Obstruction of the shunt leads to the loss of control of hydrocephalus, rapidly reflected by recurrence of the symptoms and signs of raised intracranial pressure.

If an obstruction is confirmed by your doctor and if it cannot be reduced, revision surgery or removal of the valve must be envisaged.

**Infection**

Erythema, edema, and skin erosions along the length of the shunt may be an indication of an infection, as well as a prolonged, unexplained fever.

If case of infection, your doctor will proceed to the removal of the system in conjunction with a specific treatment.

**Overdrainage**

In children, overdrainage may be detected by a depression of the fontanelles or overlap of the scalp bones.

Adults can present with a variety of symptoms such as vomiting, auditory or visual disorders, drowsiness or even headaches in the upright position but

which improve in the supine position.

Depending on clinical observations and medical imaging, the doctor can reduce the symptoms of overdrainage by externally adapting the setting of the Polaris valve.

**Other**

In children, growth of the body may progressively lead to the expulsion of the catheter tips from their site of insertion (migration), or to shunt breakage. Longer catheter to link the valve to the heart or the abdomen is thus used to prevent breaks and migration.

In adults and unrelated to body growth, migration may also occur.

Ventricular Peritoneal Shunt (VPS) may cause abdominal complications.

These malfunctions require the shunt to be repositioned immediately.

Cases of cranial wound breakdown or cutaneous necrosis over the implantation site are possible.

Cases of allergy to silicone have been described, as well as cases of epilepsy during the implantation.

Blood clots and cells contained in the CSF could lodge into the valve mechanism and cause changes in the operation.

***If I experience any unusual symptom of if I need information, I contact my neurosurgeon.***

## 10. Do I have to own any documents?

A patient card is filled in and given to you by the neurosurgeon during your stay in the hospital for the implantation. You should always carry your patient card with you, as it provides information concerning the implanted device (reference, specific settings if any, etc.). This information is important and necessary for your medical follow-up.

You are encouraged to digitize your patient card once filled out to secure its information in case you lose it or if the card becomes difficult to read over time.

**Symbols on your patient card (if applicable)**

| | |
|---|---|
|  | Patient Name or patient ID |
|  | Date of implantation |
|  | Name and Address of the implanting healthcare institution/provider |
|  | Information website for patients |

**Information on your patient card**

Your patient card is initially filled-in by the surgeon following the implantation and updated by the medical personnel at each follow-up if needed.

| | |
|---|---|
| **Type of shunt** | Type of shunt implanted:<br>– ventriculoperitoneal (V-P)<br>– ventriculoatrial (V-A)<br>– lumboperitoneal (L-P)<br>– other |
| **Valve implantation site** | Implantation site chosen for the valve (skull, chest or other) and implantation side: L (left) or R (right) |
| **Initial pressure setting** | Pressure initially chosen by the neurosurgeon for the valve implantation |
| **Anti-siphon** | Presence or absence of an anti-siphon formation website for patients |
| **Reservoir** | Presence or absence of a reservoir |
| **Stick the valve diagram here** | Valve diagram provided with the valve in the dedicated area |

| | |
|---|---|
| **Date** | Date of the new setting of the valve |
| **New pressure setting** | New pressure setting chosen by the neurosurgeon |
| **Notes** | Any notes by the doctor that may be helpful in the future |

## 11. Who to contact in case of a problem?

If any unexpected and serious problem occurs with this valve, please inform:

- the Therapeutic Goods Administration (TGA) https://www.tga.gov.au

  You can report the problem online using this link

  (https://aems.tga.gov.au/) or email the TGA directly at

  adr.reports@tga.gov.au

- the manufacturer SOPHYSA using the contact in the last page

  contact@sophysa.com or

  contact@sophysa.us

## 12. Information about the device composition?

Raw materials contained in Polaris valve

| Material | Percentage (%) |
|---|---|
| Stainless steel | 30 |
| Titanium T40 | 1,1 |
| Polysulfone (PSU) | 57 |
| Phynox | 0.4 |
| Synthetic Ruby (Corundum) | 1.5 |
| Samarium-Cobalt | 10 |

Raw materials contained in the CSF collection tube (ventricular catheter)

| Ref | Material | Percentage (%) |
|---|---|---|
| BO19-xx BO15 | Silicone | 96.5 |
| | Barium sulfate | 3.4 |
| | Tantalum | 0.1 |

Raw materials contained in the tube to the abdomen or heart (atrial/peritoneal catheters)

| Ref | Material | Percentage (%) |
|---|---|---|
| B905S | Silicone | 94.7 |
| | Barium sulfate | 5.3 |
| B905S-20 | Silicone | 94.6 |
| | Barium sulfate | 5.3 |
| | Tantalum | 0.1 |

Raw materials contained in the reservoir

| Ref | Material | Percentage (%) |
|---|---|---|
| Type A | Silicone | 89.5 |
| | Polypropylene (homopolymer) | 8.7 |
| | Barium sulfate | 1.8 |
| Type B | Silicone | 85.3 |
| | Polypropylene (homopolymer) | 11.5 |
| | Barium sulfate | 3.2 |

Raw materials contained in SiphonX (SX-200) anti-siphon device

| Material | Percentage (%) |
|---|---|
| Polysulfone (PSU) | 57.9 |
| Silicone | 6.8 |
| Synthetic ruby | 0.8 |
| Tantalum | 34.5 |

## 13. What is the exact implanted model?

To know the exact model that has been implanted, compare the reference specified on your patient card after the REF symbol with the ones in the following tables.

Polaris adjustable pressure valve

| | |
|---|---|
| **SPV** | Polaris® adjustable valve; 30-200 mm$H_2O$ |
| **SPV-140** | Polaris® adjustable valve; 10-140 mm$H_2O$ |
| **SPV-300** | Polaris® adjustable valve; 50-300 mm$H_2O$ |
| **SPV-400** | Polaris® adjustable valve; 80-400 mm$H_2O$ |

## Polaris valve pre-attached with reservoir type A

| | |
|---|---|
| **SPVA** | Polaris® adjustable valve SPV / antechamber |
| **SPVA-140** | Polaris® adjustable valve SPV-140 / antechamber |
| **SPVA-300** | Polaris® adjustable valve SPV-300 / antechamber |
| **SPVA-400** | Polaris® adjustable valve SPV-400 / antechamber |

## Polaris valves pre-attached with reservoir type B

| | |
|---|---|
| **SPVB** | Polaris® adjustable valve SPV / antechamber |

## Polaris adjustable pressure valve for CSF shunting with preattached SiphonX® gravitational anti-siphon device

| | |
|---|---|
| **SPV-SX** | Polaris® adjustable valve, 30-200 with SiphonX® |
| **SPV-140-SX** | Polaris® adjustable valve, 10-140 with SiphonX® |

## Polaris adjustable pressure valve for CSF shunting with preattached reservoir and SiphonX® gravitational anti-siphon device

| | |
|---|---|
| **SPVA-SX** | Polaris® adjustable valve, 30-200 with antechamber and SiphonX® |
| **SPVB-SX** | Polaris® adjustable valve, 30-200 with burr hole reservoir and SiphonX® |
| **SPVA-140-SX** | Polaris® adjustable valve, 10-140 with antechamber and SiphonX® |

## Shunt kits for cranial implantation

| | |
|---|---|
| **SPV-2010** | Complete adjustable Polaris® kit - 30-200 $mmH_2O$ |
| **SPVA-2010** | Complete adjustable Polaris® kit- 30-200 $200mmH_2O$ / antechamber |
| **SPVB-2010** | Complete adjustable Polaris® kit - 30-$200mmH_2O$ / burr hole reservoir |

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