

SOPHY® MINI ADJUSTABLE VALVE
Adjustable pressure valve for CSF shunting – Sterile, single-use



***An information leaflet for patients
implanted with a Sophy SM8 valve***

Revision 000 - September 2023

1. What is hydrocephalus?

You / your child / a member of your family received a Sophy SM8 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.

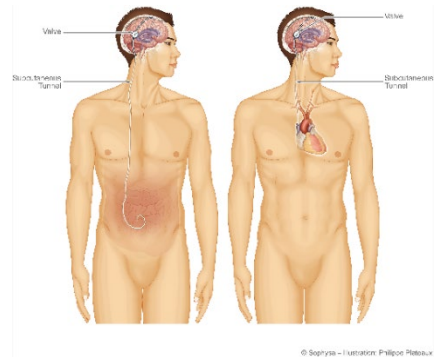
2. Why a valve inside my body?

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 Sophy SM8 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 Sophy SM8 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.



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 Sophy SM8 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 Sophy SM8 valve?

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



Sophy SM8 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 Sophy SM8 valve does not contain 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 Sophy SM8 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 Sophy SM8 valve?

According to the dedicated standard (ASTM F2503), the Sophy SM8 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 3.6 °C maximum global heating, including a 3.4 °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 Sophy SM8 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: 77 mm



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 Sophy SM8 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: – ventriculoperitoneal (V-P) – ventriculoatrial (V-A) – lumboperitoneal (L-P) – 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 Sophy SM8 valve

Material	Percentage (%)
Stainless steel	28.9
Titanium T40	0.1
Polysulfone (PSU)	57.9
Phynox	0.6
Synthetic Ruby (Corundum)	0.6
Samarium-Cobalt	11.9

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

Ref	Material	Percentage (%)
BOx0	Silicone	96.5
	Barium sulfate	3.4
	Tantalum	0.1

PROx	Silicone	92.1
	Polypropylene (homopolymer)	2.9
	Barium sulfate	5
PLOx	Silicone	91.4
	Polypropylene (homopolymer)	0.9
	Barium sulfate	7.7

Raw materials contained in the tube to the abdomen (lumboperitoneal catheters)

Ref	Material	Percentage (%)
Lumbar catheter	Silicone	86
	Barium sulfate	14
Intermediary catheter	Silicone	83.5
	Barium sulfate	4.7
	Titanium	11.8
Peritoneal catheter	Silicone	83.7
	Barium sulfate	16.3

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

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.

Sophy SM8 adjustable pressure valve

SM8	Sophy® Mini adjustable valve / 8 press. 30-200
SM8-140	Sophy® Mini adjustable valve / 8 press. 10-140
SM8-300	Sophy® Mini adjustable valve / 8 press. 50-300
SM8-400	Sophy® Mini adjustable valve / 8 press. 80-400

Sophy SM8 valve pre-attached with reservoir type A

SM8A	Sophy® adjustable valve 30-200 with antechamber
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Sophy SM8 valves pre-attached with reservoir type B

SM8B	Sophy® adjustable valve 30-200 with burr hole reservoir
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Shunt kits for cranial implantation

SM8-2000	Sophy® kit preattached
SM8-2010	Sophy® kit preattached with BO19-10
SM8-2020	Sophy® kit preattached with PRO6
SM8-2021	Sophy® kit preattached with PRO7
SM8-400-2010	Sophy® 80-400 kit preattached with BO19-10
SM8A-2010	Sophy® kit preattached with BO19-10 and antechamber
SM8B-2010	Sophy® kit preattached with BO19-10 and burr hole reservoir

Shunt kit for lumbo-peritoneal implantation (LPS)

SM8-2040	Lumbo-peritoneal Sophy® kit preattached
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Shunt kits for pectoral implantation

SM8-2030	Sophy® kit preattached with PLO6
SM8-2031	Sophy® kit preattached with PLO7



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