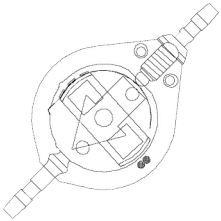
SOPHYSA
At the heart of the **brain**



EN

SOPHY® MINI MONOPRESSURE VALVE

Fixed pressure valve for CSF shunting – sterile, single use

Instructions for Use

NT111_EN_US
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WARNING
Federal (USA) law restricts this device to sale by or on the order of a physician.

WARNING
Read the Instructions for Use carefully prior to use.

1. Indications

The Sophy Mini Monopressure valve is designed for the treatment of hydrocephalus by shunting the Cerebrospinal Fluid (CSF) to the abdominal cavity or right atrium of the heart.

2. Patient populations

This device can be used on patients of all ages, excluding pre-term infants.

3. Environment of use

The shunt systems using the Sophy Mini Monopressure valve are sterile single-use devices. They must only be used in healthcare facilities (public or private).

The implantation of these systems is performed in operating rooms in strict aseptic conditions.

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

Implantation of these systems must only be carried out by a neurosurgeon.

The device is not intended for use in a patient's home. Patients are never expected to use the device by themselves.

4. Contraindications

This device is not intended for any use other than those indicated in these Instructions for Use.

The contraindications are the following:

- established or suspected infections along the length of the shunt (meningitis, ventriculitis, peritonitis, septicemia or bacteremia) or any infection present in any part of the body whatsoever,
- patients on anticoagulant therapy, or presenting with bleeding diathesis, or with hemorrhagic CSF, as the presence of blood in the system could lead to an obstruction in the system),
- ventriculo-atrial shunts in patients suffering from congenital cardiopathies or other malformations of the cardiopulmonary system.

WARNING
Do not use an external shunting device (drainage bag, etc.) in series with a valve as the two systems could interfere with each other and disrupt control of the drainage.

WARNING
As part of the product performance verifications, only the shunt hydrodynamic performances after exposure to a contrast medium (such as Omnipaque 300) were checked. Compatibility with other drugs has not been evaluated.

5. Figures

All the illustrations are given for a medium pressure valve.

The same configurations exist in low and high pressure.

Figure 1. Sophy Mini Monopressure valve (SM1-M, SM1A-M, SM1B-M). Top and side views.

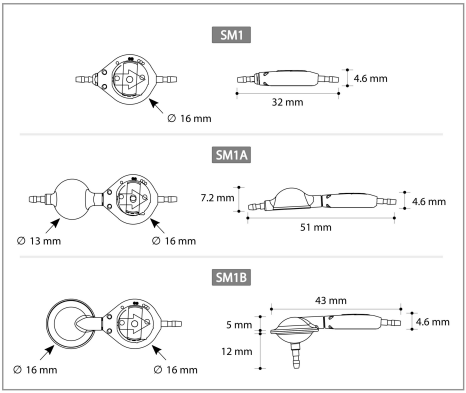
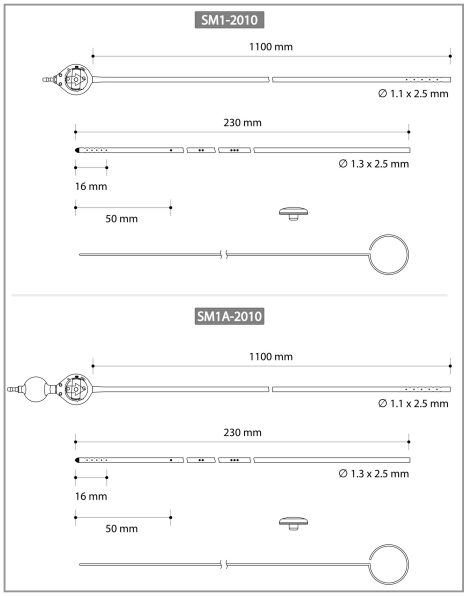
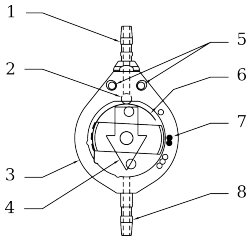


Figure 2. Composition of a complete Sophy Mini Monopressure SM1-2010M (without reservoir) and SM1A-2010M (with antechamber reservoir) kit.



6. Description and operating principle of the Sophy Mini Monopressure valve

Figure 3. The Sophy Mini Monopressure valve



***1-** Inlet connector, **2-** Ruby ball, **3-** Valve body, **4-** Arrow, **5-** Suture holes, **6-** Semi-circular spring, **7-** Titanium radiopaque points , **8-** Outlet connector*

The Sophy Mini Monopressure valve (See *Figure 1*, *Figure 3*) is a single-use implantable device.

The Sophy Mini Monopressure valve makes unidirectional drainage of the Cerebrospinal Fluid (CSF) possible.

The CSF arrives in the valve through the inlet connector [1], passes through the body of the valve [3] and leaves through the outlet connector [8].

The connectors are made of stainless steel and the body of the valve is in polysulfone.

On either side of the inlet connector [1] are suture holes [5] which make it possible to attach the valve to the subcutaneous tissues to prevent the valve from migrating.

On the upper surface of the valve an arrow shows the direction of CSF flow through the valve. This helps to position the valve correctly during implantation.

On the lower surface of the valve there is an individual serial number.

The valve body contains a ball-in-cone mechanism which determines the operating pressure of the valve.

The principle is based on the pressure exerted on a ruby ball [2] by a flat, semi-circular spring [6].

In conditions of normal use this mechanism provides an anti-reflux function and is not sensitive to temperature variations.

The valve body, which cannot be deformed, protects the mechanism from mechanical shocks and makes it insensitive to the surrounding tissues. Therefore, the valve operation does not depend on the implantation site.

It also prevents attempts at pumping or puncturing the valve and makes it insensitive to variations in percutaneous pressure.

The Sophy Mini Monopressure valve does not contain natural or synthetic latex.

Valve pressure setting

Titanium radiopaque points [7] inserted on the right-hand side of the valve body help identifying the model of the valve, which exists in 3 configurations (see *Section 7. Configurations of the Sophy Mini Monopressure valve (p. 6)*).

Table 1. Table of pressures for Sophy Mini Monopressure valves

References concerned	**SM1-L** **SM1-2010L** **SM1A-L** **SM1A-2010L** **SM1B-L**	**SM1-M** **SM1-2010M** **SM1A-M** **SM1A-2010M** **SM1B-M**	**SM1-H** **SM1-2010H** **SM1A-H** **SM1A-2010H** **SM1B-H**
Radio-opaque dots	1 radio-opaque dot •	2-radio-opaque dots ••	3 radio-opaque dots •••
Pressure (mmH_2O)	50 Low	110 Medium	170 High

The overpressure tests carried out show that the valve can withstand an overpressure of 2 mH_2O (or 2.8 PSI). Mechanically, a stop is located behind the spring to limit damage in case of overpressure. The ball-in-cone mechanism can resist a negative pressure thanks to the presence of the anti-reflux function.

7. Configurations of the Sophy Mini Monopressure valve

There are 3 different pressures for the Sophy Mini Monopressure valve, Low (L), Medium (M) and High (H).

Sophy Mini Monopressure valves are available in 3 models:

– without a reservoir (SM1),
– with an integrated flat bottom antechamber (SM1A),
– with an integrated burr-hole reservoir (SM1B).

Models SM1 and SM1A are available as the valve alone or as a complete kit (*Figure 1* & *Figure 2*).

Sophysa offers a complete range of radio-opaque proximal and distal catheters which allow the CSF to flow to the valve and from the valve to the peritoneum or right atrium respectively, depending upon the type of shunt chosen by the neurosurgeon.

To be complete a Sophy Mini Monopressure shunt system must consist of a proximal catheter, a Sophy Mini Monopressure valve and a distal catheter (atrial or peritoneal).

8. Calibration of pressures

The valves are calibrated on the basis of a flow rate of 10 ml/h.

Each valve is tested individually. The measurement concerns the upstream pressure of a 10 ml/h flow of water passing through the valve and the Sophysa proximal and distal catheters.

The calibration is performed taking into account the resistance of the catheters. Thus the pressures given on the valve labels correspond to the resistance of the valve alone.

Distal catheters (for example: B905S) add their own resistance to the shunt.

Their catheter resistance is:

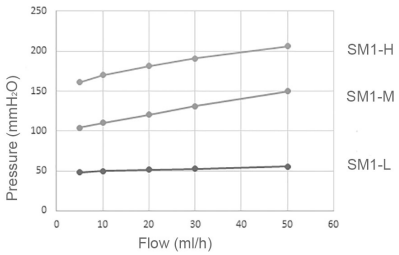
– less than 11 mmH_2O per meter of catheter at 10 ml/h;
– less than 15 mmH_2O per meter of catheter at 20 ml/h.

Their hydrodynamical resistance is less than 0.60 mmH_2O/ml/h.

Reservoirs and ventricular catheters have a negligible influence on shunt resistance.

The calibration of Sophy Mini Monopressure valves is performed with a tolerance of -10/+15 mmH_2O on the measured pressures.

Figure 4. Flow Rate-Pressure Curves for the SM1 model



The curve displayed above is obtained by varying the applied differential pressure for each pressure and measuring the resulting flow rate. The values are given for the valve alone, disregarding the resistance of the catheters.

The pressure values for each position are detailed in *Table 2* for 10 ml/h and 20 ml/h flow rates. For each valve, the actual pressure values belong to an interval determined by the tolerance range detailed in *Table 2*.

Table 2. Pressure values and tolerance ranges for each position - **SM1**

	at 10 ml/h (mmH_2O)	at 20 ml/h (mmH_2O)	Tolerance range (mmH_2O)
SM1-L	50	55	± 15
SM1-M	110	125	± 25
SM1-H	170	190	± 35

The effects on the device operating pressure of changes in the position of the patient and of sub-cutaneous pressure are negligible.

9. Sterilization

The Sophy Mini Monopressure valves and valve kits are packed individually in double peel-off, sterile, non-pyrogenic packaging, sterilized with ethylene oxide.

WARNING
This product is intended for single use only.

It is intended to be used once only for a single patient.

Do not re-sterilize or re-use after unpacking and/or explantation.

WARNING
Resterilization can damage the product, potentially leading to patient injury. Reuse of this device may change its mechanical or biological features and may cause device failure, allergic reactions or bacterial infections.

WARNING
Do not use the product if the sterile packaging is open or damaged, or if the expiry date has passed.

NOTE
Sophysa cannot be held responsible for the performance of any product that has been re-sterilized and/or re-used, nor for any complications which might result from this.

10. Choosing a valve model

The choice of Sophy Mini Monopressure valve model is left to the initiative of the neurosurgeon, depending on their clinical experience and the clinical needs of the patient.

CAUTION
Choosing a pressure inadequate to the patient's needs can induce a risk of overdrainage or underdrainage that may require revision surgery.

CAUTION
Use an SM1A (antechamber), an SM1B (burr hole reservoir) model, or one of the SM1 models combined with a ventricular catheter with reservoir if it is desired to use the shunt system to check the patency of the shunt, to sample the CSF or for injections.

NOTE
Implantation of ventriculo-atrial shunts using preconnected valve kits (valves with preattached distal catheter) could present difficulties relating to shunt length adaptation at the atrium.

11. Implanting a Sophy Mini Monopressure valve

WARNING
CSF shunts should not be implanted in the case of hemorrhagic CSF or for the drainage of hemorrhagic collections. The presence of blood in the drainage system can lead to obstruction.

WARNING
Implantation must only be done by a neurosurgeon.

WARNING
When using a valve with non-preconnected catheters, always suture the catheters to the valve connectors before implantation.

WARNING
Do not use the product if the product label is absent or incomplete and return the product to Sophysa.

WARNING
Before implantation, check the packaging and valve integrity.

Do not perform functional or pressure tests, as all valves are pre-calibrated and tested during manufacturing. Any additional test may increase the risk of infection and contamination. At the end of surgery, always confirm CSF flow and shunt system patency.

WARNING
Prolonged contact between the silicone and an iodine-based solution might impair the catheter mechanical properties and durability. In case of contact, it is recommended to clean the catheter with normal saline.

CAUTION
Do not perform the implantation of a shunt without having a replacement shunt system available in case it is required.

CAUTION
The choice of the catheter (dimensions) is left to the initiative of the neurosurgeon, depending on the clinical needs of the patient.

CAUTION
Do not use metallic forceps to handle or ligate catheters. The silicone is fragile and may be cut or pierced.

NOTE
During the implantation, check at every step the proper flow of CSF in the shunt in order to satisfy the conditions for optimal drainage of the CSF.

Visually check that the sterile packaging has not been damaged in any way, and that the expiry date is still valid. If in doubt, take another valve or valve kit.

Observe aseptic neurosurgical practices when implanting a Sophy Mini Monopressure valve.

The implantation of a shunt including a Sophy Mini Monopressure valve may be performed in several ways. The surgeon will choose the technique depending upon their experience and the clinical status of the patient.

They must select the implantation area taking into account the fact that the valve is a potential source of artifacts when an MRI examination is performed (see *Behavior during Magnetic Resonance Imaging (MRI)*).

The final implantation of the device must satisfy the conditions for optimal drainage of the CSF.

11.1. Ventricular catheter

NOTE
The Sophy Mini SM1 monopressure valve is also available with integral reservoirs (antechamber or burr-hole type) in complete kits (including a valve with pre-attached peritoneal catheter and a separate ventricular catheter)

CAUTION
Avoid any contact of the silicone with contaminating elements.

1. Introduce the catheter into the ventricle using the introducing stylet supplied for this purpose.
2. If necessary, adjust the implantation depth of the ventricular catheter with the right angle adapter supplied. Position it in the axis of the burr hole.

   CAUTION
   Catheters may become occluded if they are kinked excessively.
3. Purge the catheter of air with the CSF.
4. If necessary, check that the reservoir is properly filled, and then clamp.
5. Connect and delicately ligate the catheter to the inlet connector of the valve (or that of the reservoir for valve models with integrated reservoirs).

   WARNING
   Ensure that the arrow on the upper surface of the valve is correctly oriented in the direction of the flow. Assembly of the valve in the opposite direction would prevent any drainage.
6. Release the clamp.

11.2. Valve

NOTE
In the case of valves with an integrated reservoir or catheter, do not attempt to detach the reservoir or catheter from the valve. Detachment of the reservoir may unscrew the connector closure screw and uncalibrate the valve.

1. Purge the valve of air. To prevent any risk of introducing an air bubble, it is recommended that the valve be left to fill directly with the patient's CSF. In the majority of cases, the valve fills immediately.

   WARNING
   Do not fill or purge the valve with any liquid other than the patient's CSF or normal saline before implantation to avoid any risk of deposits in the valve, which could lead to an obstruction in the shunt system or a blockage in the valve mechanism.

2. Check that the valve is correctly filled with CSF and there are no air bubbles inside the valve. If this is not the case, continue to purge. The presence of air bubbles could cause a significant change to the operating pressure initially chosen.
3. Check that the arrow on the upper surface of the valve is visible and correctly oriented in the direction of the CSF flow.

WARNING
Always secure the valve to the underlying tissues using the designated suture holes or connectors. Migration of the shunt may compromise CSF drainage and cause complications.

11.3. Anti-siphon device SiphonX® (if required)

The decision to add a SiphonX® gravitational anti-siphon device to a shunt is left to the discretion of the neurosurgeon, depending on the clinical needs of the patient.

The implantation of a shunt including a SiphonX® gravitational anti-siphon device may be performed in several ways. However, thoracic implantation of the SiphonX® may facilitate the positioning of the device perfectly parallel to the vertical axis of the patient's body.

The surgeon will choose the technique depending upon their experience and the clinical status of the patient.

They must select the implantation area taking into account the fact that the anti-siphon device is a potential source of artifacts when an MRI examination is performed (see the Instructions for Use of the SiphonX® gravitational anti-siphon device for more information on its behavior during Magnetic Resonance Imaging (MRI)).

To incorporate a SiphonX® gravitational anti-siphon device SiphonX® SX-200 model into a shunt:

WARNING
Do not implant the SiphonX gravitational anti-siphon device without suturing it to the valve outlet connector.

NOTE
Steps *1* and *2* only apply when using a SiphonX sold individually (thus, not pre-attached).

1. Take a distal catheter (reference B905S or B905S-20).
2. On its proximal end (the end without perforation), cut off at least 2 cm of catheter.
3. Position the anti-siphon device downstream of the valve. Delicately ligate the catheter to the outlet connector of the valve and the inlet connector of the SiphonX® using non-absorbable suture material.
4. Check that the anti-siphon device arrow is correctly oriented in the direction of the CSF flow.
5. Position the SiphonX® absolutely parallel to the vertical axis of the patient's body for optimal function (see Figure 6 in the Instructions for Use of the SiphonX® gravitational anti-siphon device).

   WARNING
   For optimum operation of a Sophy Mini Monopressure valve with a SiphonX gravitational anti-siphon device, make sure the assembly is positioned parallel to the axis of the patient's body.

   If the assembly is not completely vertical when the patient is standing (or sitting), the pressure added by the device to that of the valve will not result in the expected pressure.

   CAUTION
   Handle distal catheters with care during subcutaenous placement. Gentle manipulation is allowed, but excessive force may damage the catheter or cause disconnection from the shunt system.

   CAUTION
   Orient the arrow located on the body of the SiphonX® gravitational anti-siphon device correctly in the direction of the flow. Assembly in the opposite direction will not allow the SiphonX® to fulfill its role correctly.

6. To prevent any risk of introducing an air bubble, purge the SiphonX® of air by letting the "Valve + SiphonX®" assembly be filled directly with the patient's CSF. For this, make sure it is kept horizontal. In the majority of cases the "valve + anti-siphon device" assembly fills immediately.
7. Check that the "Valve + SiphonX®" assembly is correctly filled with CSF and there are no air bubbles inside the valve.
   If this is not the case, continue to purge. The presence of air bubbles could cause a significant change to the operating pressure of the device.
8. Check the flow of CSF.
9. Connect and ligate the outlet connector on the anti-siphon device to the distal catheter of the shunt.

11.4. Distal catheter

NOTE
To be complete a Sophy Mini Monopressure valve must consist of a distal catheter preconnected to the outlet connector of the valve.

1. Immerse the catheter in normal saline.

CAUTION
Avoid any contact of the silicone with contaminating elements.

2. In the case of an implantation of ventriculo-atrial shunts using preconnected valve kits, cut off a piece of the catheter on its distal end in order to adapt the length to the procedure. The length of the portion to be cut is left to the discretion of the neurosurgeon, depending on the clinical needs of the patient.
3. Tunnel the distal catheter.
4. If this is not a preconnected model, connect the proximal end of the catheter to the valve outlet connector and ligate it delicately.
5. Check the flow of CSF.
6. Adapt the length of the catheter.
7. Bury the distal end of the catheter in the chosen area.

11.5. Checking the CSF Flow

To make sure that the CSF flows properly throughout the valve and catheters, especially for patients with low intracranial pressure or if the valve is set to a high pressure (as the valve or the "Valve + SiphonX®" assembly may not fill spontaneously in this case), proceed as follows.

- Check that the SiphonX® device, if present, is properly horizontal.
- Place the distal catheter on the valve outlet connector, or place a catheter on the SiphonX® outlet connector.
- Slowly aspirate the CSF from the catheter, using a syringe.
- For the valves equipped with a reservoir (SM1A and SM1B models), press the dome of the reservoir to allow the CSF to fill the valve.

12. Other post-operative procedures

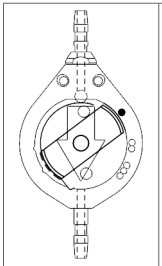
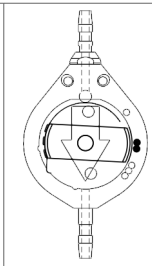
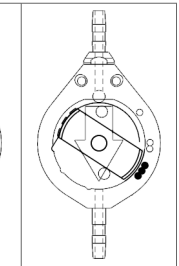
12.1. Post-operative X-ray examination: identification of the valve model and pressure reading

NOTE
During the radiological examination, orientate the patient so that the X-ray source points perpendicularly onto the valve body.

In this way identifying the valve by its radiopaque point is made easy.

Locate the valve inlet connector, wider due to the presence of a nut.

The radio-opaque dots to the right of the inlet connector are used to identify the pressure of the valve:

		
SM1-L (Low Pressure)	SM1-M (Medium Pressure)	SM1-H (High Pressure)
1 radio-opaque dot •	2 radio-opaque dots ••	3 radio-opaque dots •••

12.2. Testing patency (post-operative)

NOTE
This control is possible with SM1A (antechamber) and SM1B (burr hole reservoir) type models. For the SM1 type models, a proximal catheter with reservoir must be used.

There are two steps for the post-operative test on the patency of the shunt. These steps only apply to shunts equipped with reservoirs.

1. Testing the patency of the proximal catheter.
2. Patency test downstream of the reservoir (valve and distal catheter).

12.2.1. Testing the patency of the proximal catheter

NOTE
This control is possible with SM1A (antechamber) and SM1B (burr hole reservoir) type models. For the SM1 type models, a proximal catheter with reservoir must be used.

Press the catheter with a finger just after the valve outlet connector.

With another finger, press the reservoir to make the CSF flow back into the proximal catheter. A reservoir that cannot be compressed easily or does not fill quickly may indicate there is an obstruction in the proximal catheter.

12.2.2. Patency test downstream of the reservoir (valve and distal catheter)

NOTE
This control is impossible with an SM1B type model (burr hole reservoir) because there is no access to the ventricular catheter upstream of the reservoir.

Press the catheter with a finger just before the reservoir, then with another finger press the reservoir to push the CSF through the valve and distal catheter. A reservoir that cannot be compressed easily may indicate an obstruction either of the valve or the distal catheter.

WARNING
Do not rely only on the characteristics of the patency test to diagnose an obstruction in the shunt system. Obstruction of a shunt system can occur in any of its components and should be diagnosed first of all by the clinical data and additional examinations.

12.3. Sampling the CSF and injection

Access to the CSF is obtained by pricking the reservoir with a 24 G (or smaller diameter) Huber needle.

The integral reservoir on the SM1A and SM1B models is designed for occasional use.

CAUTION
Its watertight performance is reduced after very frequent pricking into the dome.

- To inject in the proximal direction, compress the catheter just after the valve outlet connector.
- To inject in the distal direction, compress the catheter upstream of the reservoir.

WARNING
Use gentle pressure with care when injecting or sampling. Small-volume syringes can generate high pressure and may damage the shunt system.

WARNING
Make sure to only inject into the dome of the reservoir to prevent the needle from piercing the bottom of the reservoir.

WARNING
Check the patency of the shunt before performing any injections or CSF sample.

Do not inject into, or take samples from, the CSF if any shunt obstruction is overt.

Significant overpressure could damage the shunt.

CAUTION
Avoid excessive pressure by injecting slowly (approximately 1 ml/15 s) when administering fluid through the catheter, since this may damage the shunt.

NOTE
Elective injection in the distal direction is not possible with a model of the SM1B type (burr hole reservoir) because there is no access to the ventricular catheter upstream of the reservoir.

13. Complications / side effects

Complications which may result from the implantation of a CSF shunt system include the inherent risks in the use of drugs, any surgical intervention and the insertion of a foreign body.

CAUTION
Patients treated with a shunt system must be closely monitored post-operatively in order to detect any signs of complications early.

The doctor is responsible for educating the patient or their family about CSF shunt systems, in particular describing the complications linked to implanted shunt systems as well as giving explanations about possible alternative therapies.

The main complications of shunts are obstruction, infection and overdrainage. These complications require the rapid intervention of a doctor.

Expressed rates in brackets regard complications outbreaks based on related clinical investigations or those performed with shunts involving equivalent valves.

13.1. Obstruction

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

The ventricular catheter can be obstructed by a blood clot, cerebral tissue or even tumoral cells.

The tip of the ventricular catheter can also become embedded in the choroid plexus or in the ventricular wall, either directly or following a collapse of the walls due to overdrainage.

The cardiac catheter can be colonized by a thrombus while the appearance of a clot around the catheter could cause an embolism in the pulmonary circulation.

The peritoneal catheter may become obstructed by the peritoneum or by intestinal loops.

Kinking or twisting of the catheter may cause partial or complete shunt obstruction.

Loss of patency in a shunt may also be the result of an obstruction by fragments of cerebral tissue or by biological deposits (protein deposits, etc.).

Obstruction of the shunt will quickly result in underdrainage, i.e in the reappearance of the signs and symptoms of intracranial hypertension.

These symptoms and signs vary from one patient to another and over time.

- In infants and young children, the symptoms may consist of an abnormal increase in the size of the skull, swelling of the fontanelles, dilatation of scalp veins, vomiting, irritability with loss of attention, downward displacement of gaze and sometimes convulsions.
- In older children and adults, the raised intracranial pressure due to hydrocephalus is responsible for headaches, vomiting, visual disturbances, diplopia, drowsiness, slowed movements, gait disorders, psychomotor retardation, possibly causing total disability.

If an obstruction is confirmed and a patency test does not make it possible to reduce the obstruction, revision surgery or removal of the device must be envisaged.

13.2. Infection

Chronic malfunction of the shunt could cause a leak and a discharge of CSF along its length increasing the risk of infection.

Local or systemic infection is another possible complication of CSF shunt systems. It is generally secondary to the colonization of the shunt by cutaneous germs. Nevertheless, as for all foreign bodies, any local or systemic infection can colonize the shunt. Erythema, edema and skin erosions along

the length of the shunt may be an indication of an infection of the shunt system.

Considering the localization of the shunt system, meningitis and ventriculitis can also start from a shunt infection, as well as septicemia, favored by a deterioration of the general state.

Prolonged, unexplained fever may also be the result of an infection of the shunt system.

If there is infection, removal of the system is indicated in conjunction with the start of a specific treatment by a general or intrathecal route.

13.3. Overdrainage

Overdrainage can result in a collapse of the ventricles (slit ventricle syndrome) and the appearance of a subdural hematoma or subdural fluid collection.

In children, depression of the fontanelles, overlapping of the scalp bones, craniosynostosis, even a craniostenosis or a change from communicating hydrocephalus to obstructive hydrocephalus by stenosis of the Aqueduct of Sylvius could occur.

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.

However, immediate drainage of a subdural hematoma may be indicated.

13.4. Other

Failure of a shunt system can occur and may also be linked to disconnection or breakage of its various components.

Catheter kinking can result in flow restriction.

Catheter breakage can result in the immediate stop of the CSF flow or in CSF leakage or overdrainage, or the CSF flow may also continue temporarily through the fibrous subcutaneaous tract between the broken fragments. As a consequence, patients can present with severe hydrocephalus or mild, more insidious symptoms.

The use of smaller diameter catheters is associated with a higher risk of breakage, perhaps due to higher mechanical stress generated by the reduced cross section.

The shunt migration can occur with both the ventricular catheter, and the distal catheter. The ventricular catheter may migrate inside the ventricle. The peritoneal catheter may migrate into the peritoneal cavity under the action of the peristaltic waves of the intestine, while an atrial catheter may migrate into the right-hand cavities of the heart following the blood flow or migrate towards pulmonary circulation.

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

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

Peritoneal shunts may cause abdominal complications such as peritonitis, perforation or occlusion of a viscus, abscess, fluid collection, peritoneal metastases or pseudocysts (or abdominal pseudocyst).

These malfunctions require the shunt to be repositioned immediately.

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

Over time, fibrous adhesions may fix the ventricular catheter in the choroid plexus or the cerebral tissue. If removal is being considered, gentle rotation of the catheter about its axis may make it possible to free it. The catheter must never be withdrawn forcibly. If it cannot be removed without force, it is preferable to leave it in place rather than risk the development of an intraventricular hemorrhage.

Cases of allergy to silicone have been described.

Cases of epilepsy after implantation of a ventricular shunt have been described.

The ruby ball in the valve can potentially take up an off-center position on its housing due to the presence of a cluster of cells or protein deposits. Among others, such situations can cause:

- loss of pressure control in the valve potentially increasing the risk of overdrainage,
- an impaired anti-reflux function.

Blood clots, cerebral cells or tumoral cells contained in the CSF could lodge in the valve mechanism, which would have the potential to cause changes in the operating characteristics of the valve.

Complications related to the procedure are misplacement/mispositioning of the catheter, ventricular bleeding and contusion.

Locating parts of the shunt with an X-ray may be difficult in case of bad image quality or parallax if the X-ray source was not perpendicular to the valve's plane. Another X-ray examination, consequently, an additional radiation dose may be required.

All the shunt materials are non-pyrogenic, however temporary intraoperative inflammation may occur due to the surgery and the insertion of a foreign body.

Depending on the patient's hearing sensitivity, a discomfort may be experienced due to the noise and vibrations that may be generated by the CSF flow through the shunt.

14. Precautions for the daily life of the patient

An Implant Card is supplied with the device. It enables the neurosurgeon to consult and update information relating to the implanted device (reference, pressure, implantation site, etc.) systematically and to ensure that the illness is properly monitored.

WARNING

The doctor is responsible for informing the patient or their family that the person fitted with a shunt must avoid any activity that may subject this shunt to direct shocks (violent sports, etc.) as these are likely to damage it.

CAUTION

The patient must be warned that vibrations due to the CSF flow may possibly be felt because of the implantation of the valve on the skull.

CAUTION
If the patient has lost their Implant Card, or if the card is too damaged or torn, contact Sophysa to ask for a new one on their behalf.

NOTE
The patient should be warned that it is important to carry their Implant Card at all times. This card gives information on the medical situation of the patient to all medical personnel.

NOTE
The patient should be encouraged to digitize their Implant Card once filled out to secure its information in case they lose their card or if the card becomes difficult to read over time.

15. Storage

Keep in the original packaging.

Keep in a cool, dry place, away from sun light and heat.

16. Processing of the products after use

16.1. Product return

To return a faulty product, contact a Sophysa representative to obtain the explanatory return form to be provided.

Immerse the product in sterile water. Do not do anything else to the product so that its condition during analysis is as representative as possible.

NOTE
Never use normal saline likely to form deposits in the catheter, or in the valve body which could block the rotor.

16.2. Product elimination

An unpacked, used or explanted valve must be destroyed in accordance with the procedures in force in the medical establishment.

CAUTION
Not following proper procedures in force for disposal of biohazards in the medical establishment may have microbial hazards of explants with potentially infectious substances of human origin.

17. Monitoring of the product safety

As part of its continual improvement program, Sophysa asks its customers to inform it and the legal authority of the country of any unexpected and serious problems that occur with the product.

18. Warranty

The performance and safety of the valves or valve kits is ensured only with the compatible components (such as catheters, catheter set, anti-siphon device and antechambers) designed, tested and manufactured by Sophysa.

Sophysa warrants the performance and safety of this medical device under the normal conditions of the intended use of the device, adapted to its intended purpose and use, and in accordance with these Instructions for Use.

The medical device must be stored and transported in an environment and under conditions that also comply with the information in these Instructions for Use. These storage and transport conditions have been tested and validated by Sophysa. Thus, Sophysa does not grant any other express or implicit guarantee as for the good conservation and the safety of the product in other premises than its own which would not respect these conditions. Likewise, no express or implicit guarantee is granted by Sophysa as to the suitability of the product for the use which will be made of it, or its adaptation to a particular use, except within the indications and the intended purpose of the product, or when it has been transformed, modified or repaired except within the instructions of Sophysa.

Under no circumstances, Sophysa can be held responsible in case of damages, for any incident and/or complication, resulting from damage or prejudice arising directly or indirectly from the unsuitable use of the device and/or a use of the device which fail to conform or the non-respect of its conditions of maintenance, cleaning, storage or transport.

19. Symbols

	Catalogue number
	Serial number
	Medical Device
	Unique Device Identification
	Manufacturer
	Date of manufacture
	Consult Instructions for Use
	Do not use if package is damaged
	Sterilized using ethylene oxide
	Double sterile barrier system
	Non-pyrogenic

	Do not reuse
	Do not resterilize
	Keep dry
	Keep away from sunlight
	Use-by-date
	MR Conditional
	By prescription only
	The product packaging and labelling can be recycled and/or has been made of recyclable materials.

20. Filling out the Implant Card

Each implantable product is packaged with an Implant Card (IC) and traceability labels.

The surgeon is responsible for filling out this Implant Card and giving it to the patient.

20.1. Symbols - Implant Card

This table explains the symbols that are specific to the Implant Card. The other symbols present on the Implant Card are explained in *Symbols*.

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

20.2. Guidance for filling out the Implant Card

Field to be completed by healthcare institution/provider	Instructions for completion
	Indicate the name of the patient or patient ID
	Indicate the name and address of the healthcare institution/provider
	Indicate the date of implantation
Type of shunt	Check the box corresponding to the type of shunt implanted: – ventriculoperitoneal (V-P) – ventriculoatrial (V-A) – other
Valve implantation site	Indicate the implantation site chosen for the valve (skull, chest or other) and check the box corresponding to the side : L (left) or R (right)
Pressure setting	Indicate the pressure setting of the valve
Anti-siphon	Check the proper box to indicate the presence or absence of an anti-siphon
Reservoir	Check the proper box to indicate the presence or absence of a reservoir
Stick the valve diagram here	Stick the valve diagram provided with the valve in the dedicated area

21. MRI Safety Information

NOTE

Choose a Sophy® Mini Monopressure Valve implantation site away from areas of significant clinical interest, such as tumor, that may require repeated future MRI examination. The metal components in Sophy® Mini Monopressure Valve are a potantial source of artifacts on MRI images. The size of these artifacts could be very large in size in relation to the size and shape of the valve.

NOTE

The patient must be informed that they are likely to feel slight discomfort during an MRI examination.

MR Conditional	
Non-clinical testing has demonstrated that a shunt consisting of a Sophy Monopressure Valve SM1 (including connectors, and possibly reservoirs and SiphonX gravitational anti-siphon device) and its catheters are MR Conditional in accordance with the ASTM F2503-20 standard definition. A patient fitted with this device can be safely scanned in an MR system meeting the following conditions. Failure to follow these conditions may result in injury.	
Parameter	**Notes**
Static Magnetic Field Strength (B_0)	1.5 T / 3.0 T

MR Conditional	
Type of Nuclei	Hydrogen
Static Magnetic Field (B_0) Orientation	Horizontal, cylindrical bore
Maximum Spatial Field Gradient (SFG)	1.5 T: 80.69 T/m (8069 G/cm) 3 T: 40.35 T/m (4035 G/cm)
RF Polarization *Note: Formerly called "RF Excitation)*	Circularly Polarized (CP)
RF Transmit Coil	Integrated Whole Body Transmit RF coil. Detachable Extremity Transmit RF coil, **excepted RF Transmit Head coil**.
RF Receive Coil	Any receive RF coil may be used.
MR System (RF) Operating Modes or Constraints	Normal Operating Mode
Whole Body Averaged SAR	Whole Body Averaged SAR ≤ 2 W/kg
Head SAR	Head SAR ≤ 3.2 W/kg
Patient Characteristics	One device implanted per patient.
Scan Duration and Wait Time	Scan for 1 hour with one or more MR imaging pulse sequences (scans or series) followed by a wait time of 15 minutes before resuming scanning. **NOTE** Autoscanning / Autoscan Mode is considered continuous scanning. **NOTE** Short pauses between scan sequences are considered part of the scan time.
MR Image Artifact	The presence of this item may produce an MR image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact.

22. References

22.1. References covered by this IFU

Table 3. Sophy® Mini Monopressure valves for CSF shunting

SM1-L	Sophy® Mini Monopressure valve, Low Pressure Fixed pressure valve, 50 mmH_2O
SM1-M	Sophy® Mini Monopressure valve, Medium Pressure Fixed pressure valve, 110 mmH_2O
SM1-H	Sophy® Mini Monopressure valve, High Pressure Fixed pressure valve, 170 mmH_2O
SM1A-L	Sophy® Mini Monopressure valve, Low Pressure, Antechamber Fixed pressure valve, 50 mmH_2O. Integral antechamber.
SM1A-M	Sophy® Mini Monopressure valve, Medium Pressure, Antechamber Fixed pressure valve, 110 mmH_2O. Integral antechamber.
SM1A-H	Sophy® Mini Monopressure valve, High Pressure, Antechamber Fixed pressure valve, 170 mmH_2O. Integral antechamber.
SM1B-L	Sophy® Mini Monopressure valve, Low Pressure, Burr hole reservoir Fixed pressure valve, 50 mmH_2O. Integral "burr hole" type reservoir.
SM1B-M	Sophy® Mini Monopressure valve, Medium Pressure, Burr hole reservoir Fixed pressure valve, 110 mmH_2O. Integral "burr hole" type reservoir.
SM1B-H	Sophy® Mini Monopressure valve, High Pressure, Burrhole reservoir Fixed pressure valve, 170 mmH_2O. Integral "burr hole" type reservoir.

Table 4. Shunt kits for cranial implantation

SM1-2010L	Sophy® Mini Monopressure Low Pressure Valve Kit B905S/BO19-10 Fixed pressure valve, 50 mmH_2O, with preconnected peritoneal catheter (B905S). Straight ventricular catheter (BO19-10).
SM1-2010M	Sophy® Mini Monopressure Medium Pressure Valve Kit B905S/BO19-10 Fixed pressure valve, 110 mmH_2O, with preconnected peritoneal catheter (B905S). Straight ventricular catheter (BO19-10).
SM1-2010H	Sophy® Mini Monopressure High Pressure Valve Kit B905S/BO19-10 Fixed pressure valve, 170 mmH_2O, with preconnected peritoneal catheter (B905S). Straight ventricular catheter (BO19-10).
SM1A-2010L	Sophy® Mini Monopressure SM1A Low Pressure Valve Kit B905S/BO19-10 Fixed pressure valve, 50 mmH_2O, integral antechamber, with preconnected peritoneal catheter (B905S). Straight ventricular catheter (BO19-10).
SM1A-2010M	Sophy® Mini Monopressure SM1A Medium Pressure Valve Kit B905S/BO19-10 Fixed pressure valve, 110 mmH_2O, integral antechamber, with preconnected peritoneal catheter (B905S). Straight ventricular catheter (BO19-10).
SM1A-2010H	Sophy® Mini Monopressure SM1A High Pressure Valve Kit B905S/BO19-10 Fixed pressure valve, 170 mmH_2O, integral antechamber, with preconnected peritoneal catheter (B905S). Straight ventricular catheter (BO19-10).

Technical specifications and list of product references may be modified without notice.

Availability may vary according to country.

22.2. List of compatible shunt products

Find here the shunt products that are compatible with the valves:

- SiphonX® anti-siphon device.
- Sophysa ventricular catheters
- Sophysa distal catheters

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