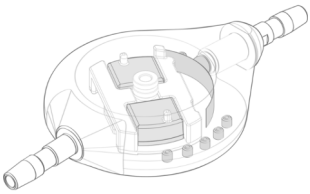
SOPHYSA
At the heart of the brain



Instructions for use

POLARIS® VALVE

Adjustable pressure valve for CSF shunting

Sterile, single use

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ENGLISH

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FIGURE 1A - POLARIS® ADJUSTABLE PRESSURE VALVE (SPV, SPVA, AND SPVB MODELS). TOP AND SIDE VIEWS.

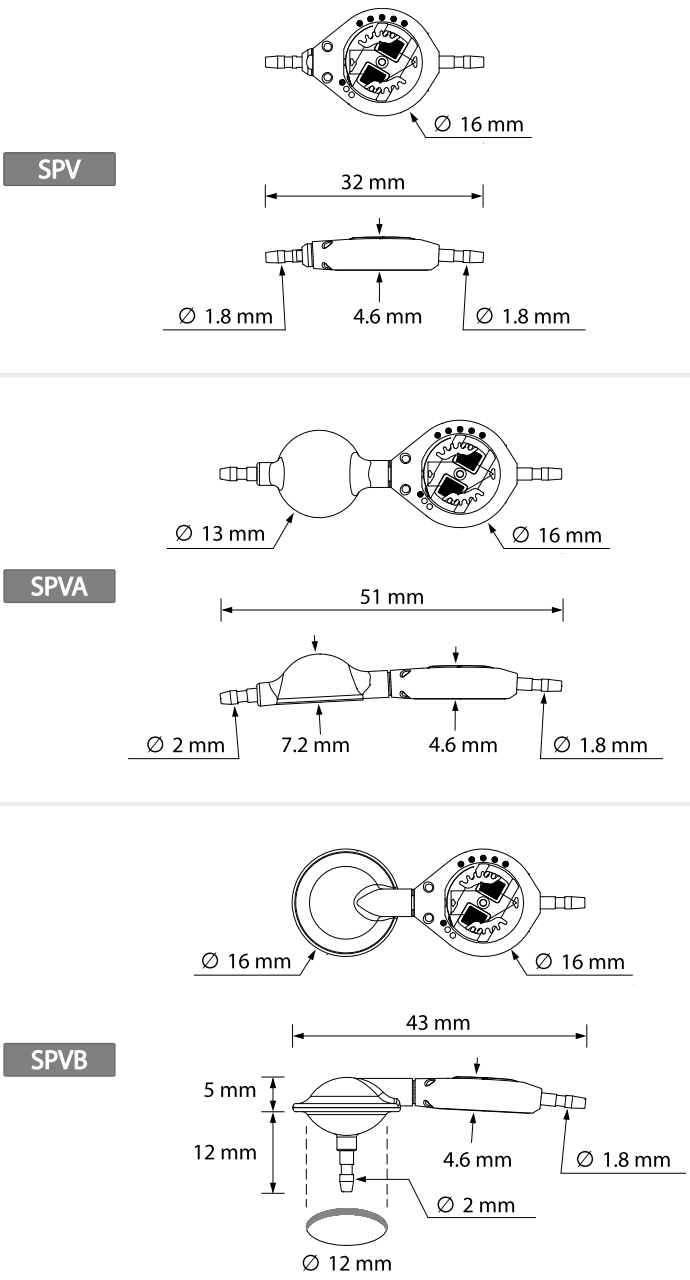


FIGURE 1B –POLARIS® ADJUSTABLE PRESSURE VALVE (SPV-SX, SPVA-SX AND SPVB-SX MODELS). TOP AND SIDE VIEWS.

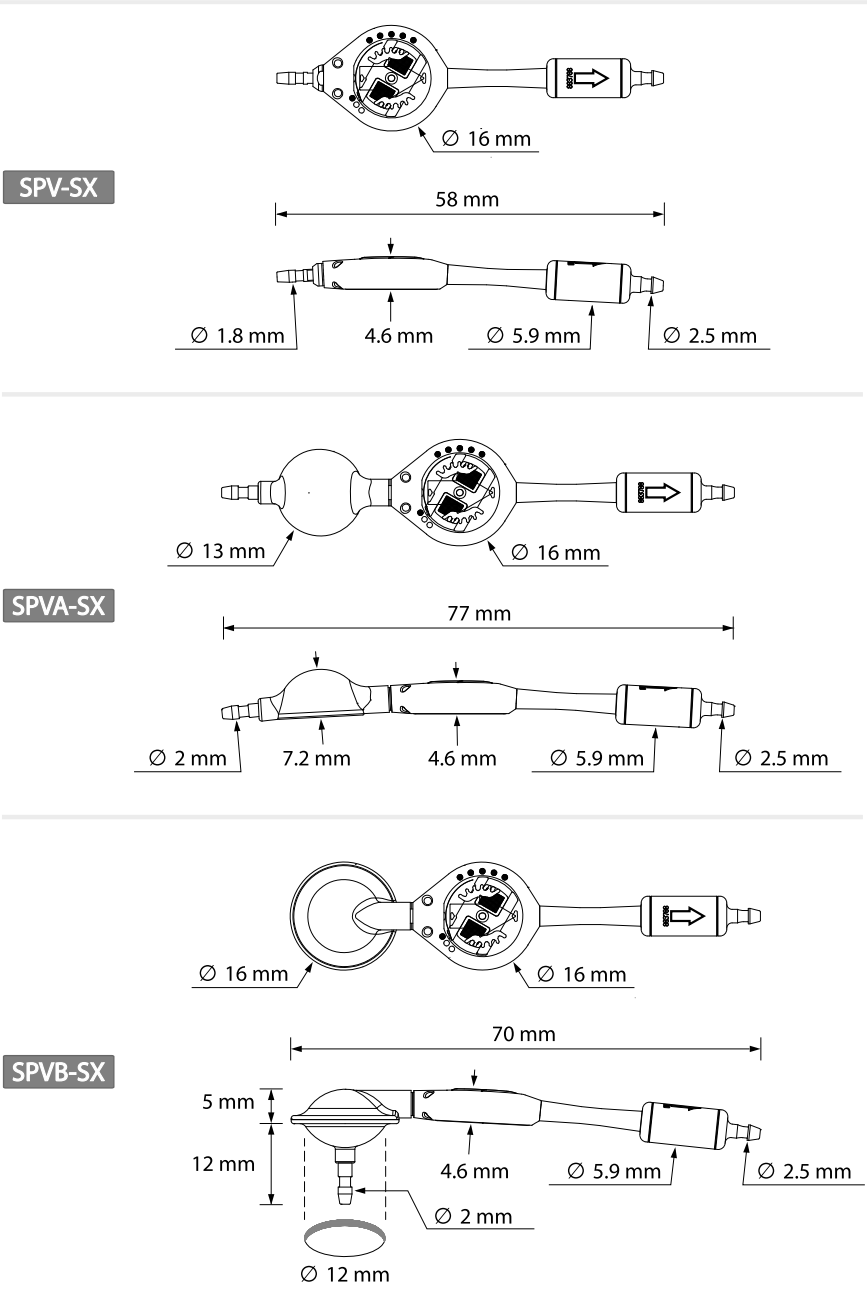
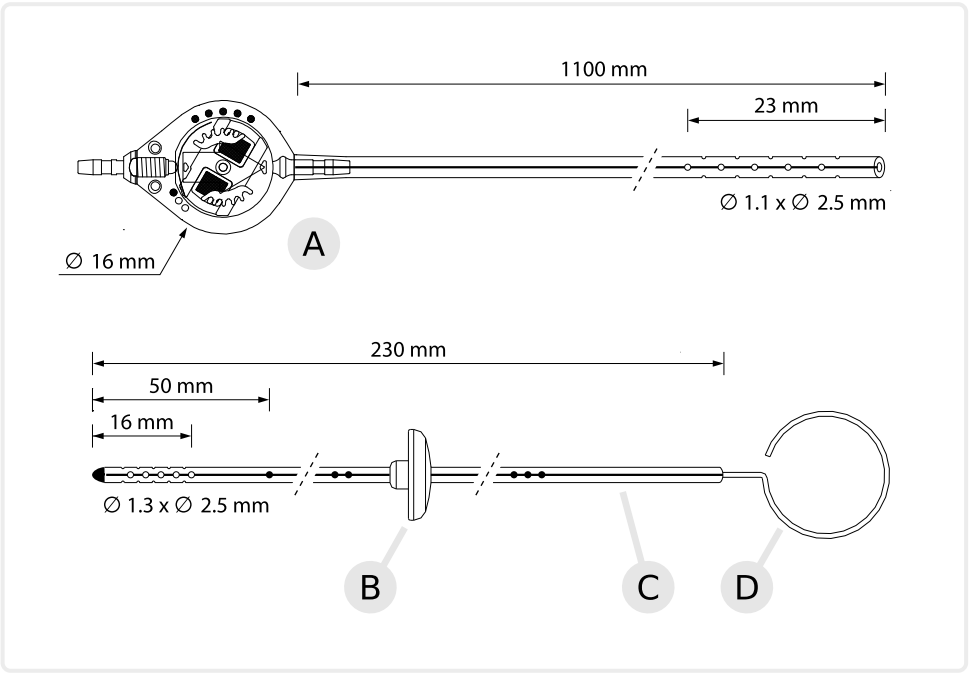


FIGURE 2 - COMPOSITION OF A COMPLETE POLARIS® KIT (SPV-2010 MODEL).



A SPV valve with pre-attached peritoneal catheter.

B Right angle adapter.

C Straight ventricular catheter.

D Introducing stylet.

WARNING

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

Read the Instructions for Use carefully before adjusting the valve operating pressure.

1. Indications

The Polaris® adjustable pressure 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. Contra-indications

The contra-indications 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 with congenital cardiopathies or other malformations of the cardio-pulmonary system

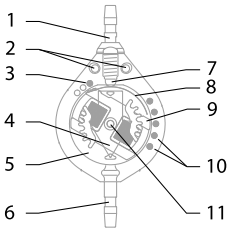
However, if the clinical benefit outweighs these contraindications, the implantation of a shunt in such cases is performed under the responsibility of an experienced neurosurgeon. The clinical condition of the patient must, therefore, be subject to increased surveillance.

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.

3. Description and Operating Principle of the Polaris®

FIGURE 3 : THE POLARIS® VALVE



3.1. A PRECISION VALVE

The Polaris® adjustable pressure valve (*Figures 1&3*) is a single use implantable device.

The Polaris® adjustable pressure valve allows drainage of Cerebrospinal Fluid (CSF) in a given direction.

The CSF arrives in the valve through the inlet connector [1], passes through the body of the valve [5] and leaves through the outlet connector [6].

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 [2] which make it possible to attach the valve to the sub-cutaneous tissues to prevent the valve from migrating.

On the upper surface of the valve an arrow [4] 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.

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.

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

The Polaris® valve is phthalate-free and is not made with natural rubber latex or synthetic latex.

3.2. ADJUSTABLE PRESSURE

The resistance of the Polaris®valve can be adjusted without re-operating, in order to adapt it to the clinical evolution of the patient.

The principle is based on the pressure variation exerted on a ruby ball [7] by a flat, semi-circular spring [8] at different points on its curvature.

The spring is attached to a rotor [9] which is able to rotate inside the valve body on its central axis which is made of ruby and titanium [11].

The operating pressure of the Polaris® valve is determined by the angular position of its rotor.

There are 5 pressures available in each Polaris® model. These correspond to the 5 possible positions of the rotor.

For any Polaris® model, position No. 1 corresponds to the lowest pressure and position No. 5 to the highest pressure.

Titanium radio-opaque studs [10] inserted on the righthand side of the valve body indicate the 5 positions of the rotor/spring assembly (*Cf. §9 - Post-operative X-ray examination*).

The Polaris® valve exists in 4 different pressure ranges (*cf. Table of pressure ranges*).

To the left of the inlet connector there are radio-opaque points [3] which identify the pressure range of the valve (*Figures 3 & 9, and §9 - Post-operative X-ray examination*).

Table of Operating Pressures for Polaris® valves

References concerned		SPV-140 SPVA-140	**SPV, SPV-2010 SPVA, SPVA-2010 SPVB, SPVB-2010**	SPV-300 SPVA-300	SPV-400 SPVA-400
Identification of the range		0 point	**1 point**	2 points	3 points
Available pressures (mmH_2O)	1	10	**30**	50	80
	2	40	**70**	100	150
	3	80	**110**	150	230
	4	110	**150**	220	330
	5	140	**200**	300	400

3.3. MAGNETIC LOCK

The rotor of the Polaris® valve includes a patented magnetic locking system.

This self-locking system is based on the permanent reciprocal attraction of 2 mobile micro-magnets of opposite polarity [12]

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 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 magnet.

Once unlocked, the rotor can then turn freely on its central axis.

4. Principle of the Polaris® Valve adjustment

For more information, refer to the instruction for use of the Adjustment Kit.

The operating pressure of a valve can be adjusted in order to adapt to the clinical evolution of the patient.

Changing the operating pressure of the Polaris® valve is performed percutaneously using an adjustment kit made up of 3 parts:

- **Locating Instrument (Locator)**
- **Reading Instrument (Compass)**
- **Setting Instrument (Magnet)**

The components of the Polaris® adjustment kit are packaged, non-sterile, in a re-usable box.

The Polaris® adjustment kit is not made with natural or synthetic latex.

The Polaris® adjustment kit is designed specifically for setting Polaris® adjustable valve pressures.

4.1. LOCATING INSTRUMENT

The Locating Instrument (**Locator**) is used to locate the valve under the skin, an essential step in reading and adjusting the operating pressure.

The Locator houses the Reading Instrument and the Adjustment Instrument in turn.

It enables Polaris® valves to be adjusted whatever their pressure range (cf. Table of Operating Pressure Ranges).

WARNINGS

Do not use a Polaris® adjustment kit without previously identifying the valve model and making sure that the pressure range shown on the Locator corresponds to this model.

Over-drainage or under-drainage can result from taking a reading and/or making an adjustment with a different pressure range on the Locator from that of the implanted valve model.

To adjust a valve the Locator must display the pressure range for the valve model to be adjusted. The Locator must be perfectly positioned above the implant.

The green arrow shows the direction of flow of the CSF, and makes it possible to position the Locator correctly in relation to the valve.

The Locator center cut-out area in the shape of an imprint of the valve is used to position the Locator as close as possible to the implant.

4.2. READING INSTRUMENT

The Reading Instrument (**Compass**) fits into the Locator and enables a reliable, accurate direct reading of the operating pressure value for the valve.

PRECAUTION

When reading the pressure setting, make sure that the Magnet or any other ferromagnetic object is not within a distance of less than 0.5 m around the Compass so that this reading cannot be falsified by the influence of magnetic fields.

The **Compass** shows the position of the valve rotor. This corresponds to the operating pressure that has been read.

The operating pressure reading is determined by the alignment of the Compass needle with one of the lines on the contour of the Compass and the corresponding pressure value in the reading area of the Locator.

4.3. SETTING INSTRUMENT

The Setting Instrument (**Magnet**) is made up of a specific assembly of magnets designed to allow the adjustment of the operating pressure for the Polaris® valve.

PRECAUTION

Changing the valve pressure must only be done by a neurosurgeon, or other qualified person.

The Magnet is inserted into the Locator.

The insertion of the Magnet into the Locator makes it possible:

— - to unlock the valve,
— - to adjust the operating pressure by rotating the Magnet.

Clockwise rotation increases the operating pressure of the valve, while counter-clockwise rotation reduces it.

NOTE

If a valve is pre-connected to a SiphonX® gravitational anti-siphon device, when adjusting take into account the fact that the SiphonX® adds up to 200 mmH_2O to the valve operating pressure.

NOTE

Do not attempt to turn the Magnet if it is not centered in the Locator, or if it is not completely inserted into the Locator. Unlocking of the valve rotor could be compromised.

A green marker pointing to the pressure values in the Locator reading area and the "clicks" produced when the Magnet rotates make it possible to determine the successive operating pressures set by the Magnet.

Removing the Magnet activates the automatic re-locking of the valve rotor due to the mutual attraction of the two mobile micro-magnets.

PRECAUTIONS

Always take the Magnet out off the Locator vertically. This ensures optimum locking of the rotor in its new position. Failure to remove the Magnet from the Locator vertically risks changing the selected position and/or causing incorrect locking of the rotor.

Do not store or handle the Magnet near any device likely to be affected by a powerful magnetic field.

Do not place the Magnet close to a powerful magnetic field (e.g. MRI). It could become a dangerous projectile or its performance could be affected.

Handle the Magnet with care near metallic objects (e.g. hospital furniture). They could be violently attracted.

5. Configurations of the Polaris® valve

The Polaris® adjustable pressure valve is available in 4 different pressure ranges, each of which offers 5 pressures (*cf. §3 - Table of Pressure Ranges*).

The Polaris® valves in the " standard " pressure ranges (30-200 mmH_2O) are available in 3 models :

— without a reservoir (SPV),
— with an integrated reservoir of the antechamber type (SPVA),
— with an integrated reservoir of the burr hole type (SPVB).

These 3 models are available as the valve alone or as a complete kit which includes a ventricular catheter, and a preconnected peritoneal catheter (*Figures 1 & 2*).

The Polaris® valves in the " special " pressure ranges (10-140, 50-300, and 80-400 mmH_2O) are available in 2 models :

— without a reservoir (SPV-140, SPV-300 and SPV-400)
— with an integrated reservoir of the antechamber type (SPVA-140, SPVA-300 and SPVA-400).

These "special pressure" valves are not available as complete kits; only the valve is available.

The standard pressure Polaris® valves (SPV, SPVA and SPVB), as well as **the special low pressure valves** (SPV-140 and SPVA-140), are also available with a SiphonX® "gravitational" anti-siphon device, pre-connected downstream of the valve.

SiphonX® makes it possible to add additional resistance to the operating pressure of the Polaris® valve. This resistance depends on the position of the patient (*cf. §6 - Table of Operating Pressures for Polaris® valves with pre-attached SiphonX®*).

The 5 corresponding models (SPV-SX, SPVA-SX, SPVB-SX, SPV140-SX and SPVA140-SX) are only available as the valve alone form (with pre-attached anti-siphon device) and are not available as complete kits.

Sophysa offers a complete range of ventricular and distal radio-opaque 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.

A complete Polaris® shunt system must consist of a ventricular catheter, a Polaris® valve and a distal catheter (atrial or peritoneal).

Each Polaris® valve is packaged with a Patient Identification Card (PIC) and traceability labels.

The surgeon is responsible for filling in this Patient Identification Card and giving it back to the patient.

6. Measurement Unit and Calibration of Operating Pressures

The pressures mentioned are in mmH_2O.

1 mmH_2O corresponds to 9.807 Pa or 0.074 mmHg.

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 disregarding the resistance of the catheters.

6.1. CASE OF CLASSICAL VALVES (WITHOUT SIPHONX®)

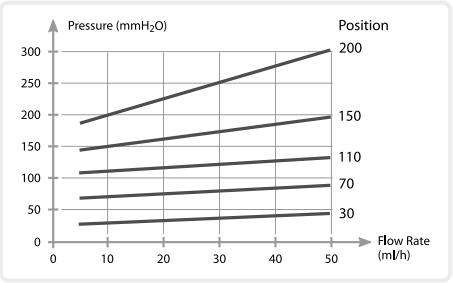
Thus the pressures given on the valve labels correspond to the resistance of the valve alone.

The catheters add their own resistance to the shunt.

The reservoirs are not considered to have any particular resistance.

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

FIGURE 4 : FLOW RATE-PRESSURE CURVES FOR THE SPV MODEL



This curve is obtained by varying the applied pressure for each pressure setting and measuring the resulting flow rate. The values are given disregarding the resistance of the catheters.

Table of mean values at 10ml/h for each position setting of the Polaris® valve, and corresponding values at 20ml/h:

Polaris® valve position setting	**at 10 ml/h (mmH_2O)**	at 20 ml/h (mmH_2O)
Position 1	**30**	35
Position 2	**70**	75
Position 3	**110**	115
Position 4	**150**	160
Position 5	**200**	225

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

6.2. CASE OF A VALVE PRECONNECTED TO A SIPHONX® GRAVITIATIONAL ANTI-SIPHON DEVICE.

In this case, the position of the patient has a direct influence on the system operating pressure (*cf. Table hereafter*):

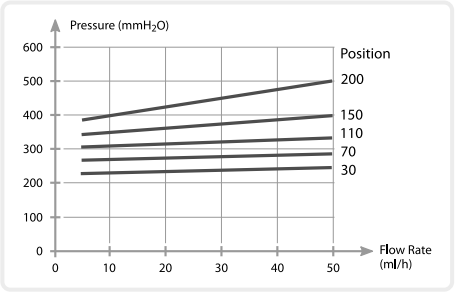
Table of Operating Pressures for Polaris® valves with pre-attached SiphonX®

References concerned		SPV-140-SX SPVA-140-SX		**SPV-SX, SPVA-SX, SPVB-SX**	
SiphonX®		0°	90°	0°	90°
					
Available pressures (mmH_2O)	1	10	210	30	230
	2	40	240	70	270
	3	80	280	110	310
	4	110	310	150	350
	5	140	340	200	400

When the "Valve + SiphonX®" assembly is horizontal, SiphonX® does not add any additional resistance to the operating pressure of the Polaris® valve, and the assembly therefore behaves like a valve on its own (*cf. Figure 4*).

When the "Valve + SiphonX®" assembly is vertical, SiphonX® adds 200 mmH_2O to the operating pressure of the Polaris® valve (*cf. Figure 5*).

FIGURE 5 : FLOW–PRESSURE CURVES FOR THE SPV-SX MODEL (SPV WITH A PRE-ATTACHED GRAVITATIONAL ANTI-SIPHON DEVICE SIPHONX® IN VERTICAL POSITION.



This curve is obtained by varying the applied pressure for each pressure setting and measuring the resulting flow rate.

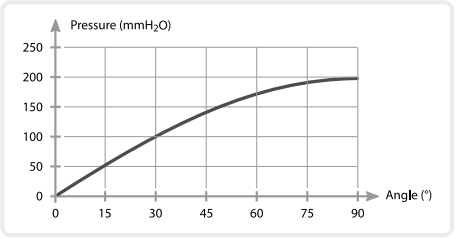
The values are given disregarding the resistance of the catheters.

Thus the pressures given on the labels of SPV-SX model correspond to the resistance of the "Valve + SiphonX®" assembly.

The catheters add their own resistance to the shunt.

For all intermediate inclinations between the horizontal and the vertical, SiphonX® adds a resistance which depends on the angle of inclination (*Cf. Figure 6*)

FIGURE 6 : OPERATING PRESSURES FOR THE SIPHONX®, SX-200 MODEL DEPENDING ON ITS INCLINATION, WHATEVER THE FLOW RATE BETWEEN 5 AND 50 ML/H



This curve is obtained by applying the following method: the measurement concerns the upstream pressure of a 10ml/h flow of water passing through the SiphonX® and the Sophysa proximal and distal catheters and by varying the angle from 0° (horizontal) to 90° (vertical). The same curves are obtained for flow rates between 5 and 50ml/h.

The control measurement is performed disregarding the resistance of the catheters.

7. Behavior during Magnetic Resonance Imaging (MRI)

A shunt consisting of a Polaris® valve (including connectors, and possibly reservoirs and SiphonX® gravitational anti-siphon device) and its catheters, is considered as " MR Conditional " in accordance of the definition in the standard, ASTM F-2503.

A patient fitted with a Polaris® valve can undergo an MRI examination, even immediately after the device has been implanted.

The results of in vitro tests have demonstrated that the Polaris® valve does not present any danger in the following examination conditions :

— MRI with a static magnetic field limited to 3-Tesla and with a spatial gradient magnetic field limited to 19 T/m;
— Whole body averaged SAR (Specific Absorption Rate) limited to 2 W/kg for 15 minutes exposure at 3 Tesla.
— Whole body averaged SAR (Specific Absorption Rate) limited to 2 W/kg for 15 minutes exposure at 1.5 Tesla.
— No gradient magnetic fields limitation.

WARNING

Even though the self-locking system of the valve was designed not to be sensitive to magnetic fields, it is recommended that the pressure setting of the valve is checked before and after the MRI examination or following exposure to a powerful magnetic field. Please see additional recommendation under section §9.4.1-Reading of operating pressure after implantation.

NOTE

The patient must be informed that he/she is likely to feel slight discomfort, which is completely inoffensive, during an MRI examination.

PRECAUTIONS

During MRI examinations, make sure the patient remains immobile in the immediate proximity to the tunnel and inside it.

If there is a rotational movement on the valve simultaneous with exposure to a powerful magnetic field (for example: 3-Tesla MRI) there is a possible risk of the pressure being accidentally changed.

Choose a Polaris® valve implantation site away from areas of significant clinical interest, such as a tumor, that may require repeated future MRI examinations. Indeed the micro-magnets in Polaris® valve are a potential 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.

Tests have demonstrated that the performance (operating pressures calibration), magnetic properties and functionality (valve can still be adjusted and self-locking mechanism of the rotor remains functional) of the Polaris® valve are not affected by repeated exposure to MRI examinations from 1.5-Tesla to 3-Tesla (30,000 Gauss).

The Polaris® valve's mechanism is designed to prevent accidental changes in operating pressure under standard conditions for MRI examination at 3-Tesla or less, as long as there is no rotational movement on the valve during MRI exposure.

The tests conducted in accordance with the standard, ASTM F 2182, showed that the rise in temperature caused by exposure to 3-Tesla MRI was negligible and had no physiological consequences for the patient.

Tests conducted in accordance with standards, ASTM F 2213 and ASTM F 2052, showed that the torque and displacement force induced by a magnetic field of 3 Tesla or less did not present any risks for the patient.

8. Sterilization – Decontamination of Polaris® Valves and Valve Kits

The Polaris® valves and valve kits are packed individually in double peel-off, sterile, pyrogen-free packaging, sterilized with ethylene oxide.

WARNING

Do not use the valves or valve kits if the sterile packaging is open or damaged, or if the expiry date has passed.

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.

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.

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.

9. Instructions

9.1. CHOICE OF VALVE MODEL

The initiative of chosing the Polaris® valve model is left to the neurosurgeon and depends upon the clinical needs of the patient.

PRECAUTIONS

Do not use pre-connected valve kits (valves with pre-attached distal catheter) for ventriculo-atrial shunts.

There could be implantation difficulties relating to the shunt length adaptation at the atrium.

Use an SPVA (antechamber) type model, an SPVB (burr hole reservoir) type model, or one of the SPV 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.

9.2. ADJUSTMENT OF A POLARIS® VALVE BEFORE IMPLANTATION: SELECTION OF THE OPERATING PRESSURE

Refer to *§§4 – Principle of the Polaris® Valve Adjustment,* , and for more information, refer to the instruction for use of the Adjustment Kit.

Before opening the packaging which guarantees the sterility of the valve, it is necessary to adjust the rotor in the

position that corresponds to the pressure selected for the implantation by the surgeon, depending on the patient's needs.

The double sterile packaging of each Polaris® valve includes a housing provided specially for a Polaris® adjustment kit, which makes it possible to adjust the sterile Polaris® valve through the packaging.

PRECAUTION

Do not unpack or implant the valve without previously adjusting it to the initial operating pressure defined by the neurosurgeon.

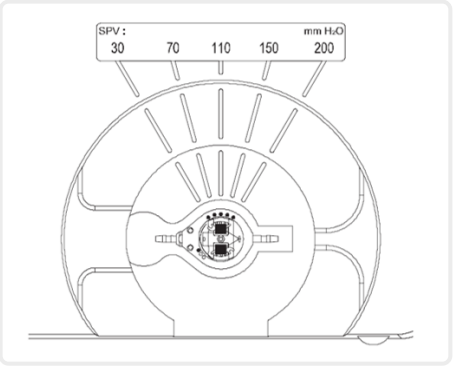
WARNING

Do not use the adjustment kit in the operative field. As the adjustment kit cannot be sterilized, using it during the operation would cause a high risk of infection for the patient.

9.2.1. Identification of the valve model (Step 1a)

Identify the reference and/or the pressure range for the Polaris® valve to be adjusted: refer to the labeling on the packaging.

FIGURE 7: DETAILS OF THE DOUBLE STERILE PACKAGING FOR A POLARIS® VALVE SPV



NOTE

Reading of the setting position can also be performed visually without using the Polaris® adjustment kit, as the rotor is visible through the valve and the double sterile packaging.

9.2.2. Choice of Locator reading area (Step 2b)

Se reporter au §4 - Principe de réglage de la valve Polaris® - Instrument de Localisation.

On the Locator, display the pressure range of the valve model identified in *step 1a*.

9.2.3. Positioning the Locator (Step 3a)

Place the **Locator** in the slot provided for it on outside of the packaging tray, centered above the valve, with the green arrow on the Locator pointing in the direction of the CSF flow as shown by the arrow on the valve.

9.2.4. Positioning the Compass and Reading the Pressure (Step 4a)

Refer to §4 – Principle of the Polaris® Valve Adjustment-Reading Instrument

Place the **Compass** in the **Locator** using the guide pins: align the lines on the Compass with the pressure values engraved on the Locator.

On the **Locator** read the operating pressure shown by the **Compass** needle.

NOTE

Reading of the setting position can also be performed visually without using the Polaris® adjustment kit, as the rotor is visible through the valve and the double sterile packaging.

9.2.5. Positioning the Magnet and Adjusting the Pressure (Step 5a)

Refer to §4 – Principle of the Polaris® Valve Adjustment-Setting Instrument.

Remove the **Compass**, align the line on the Magnet with the pressure read in Step 4b, and insert the **Magnet** in the **Locator** aligning the marker on the Magnet with the initial setting position.

Hold the Locator with one hand.

Slide the **Magnet**, back and forth quickly along the axis of the initial position of the pressure setting, to unlock the valve rotor, then replace it correctly in the center of the **Locator**.

Turn the **Magnet** to the position chosen as the operating pressure for the valve which is to be implanted.

Remove the **Magnet** vertically from the Locator to ensure effective re-locking of the valve rotor at the new operating pressure position.

9.2.6. Verification of the pressure setting (Step 6a)

Refer to §4 - Principle of the Polaris® Valve Adjustment-Reading Instrument.

The verification is performed using the **Compass** in accordance with the procedure described in Step 4a.

9.2.7. Recording the operating pressure chosen for the implantation (Step 7a)

Note the pressure value read in *Step 6a* on the Polaris® Patient Identification Card (PC-SPV).

9.3. IMPLANTATION TECHNIQUE

Implantation of a Polaris® valve must take account of current aseptic neurosurgical practices.

The implantation of a shunt including a Polaris® valve may be performed in several ways.

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

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

The surgeon 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 (*cf. § 7 " Behavior during Magnetic Resonance Imaging (MRI)"*).

PRECAUTION

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

WARNING

Do not carry out an additional test before implantation: each valve has been individually calibrated and checked.Any pre-operative pressure tests will increase the risk of infection.

9.3.1. Ventricular Catheter

— Introduce the catheter into the ventricle using the introducing stylet supplied for this purpose.
— 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.
— Purge the catheter of air with the CSF.
— If necessary, check that the reservoir is properly filled, and then clamp.
— Connect and delicately ligate the catheter to the inlet connector of the valve (or that of the reservoir for valve models with integrated reservoirs). Check that the arrow located on the upper surface of the valve is correctly oriented in the direction of the flow. The clamp can then be released.

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.

PRECAUTION

Due to the fragility of the silicone, using metallic forceps for inserting catheters and for ligating them onto connectors is not recommended. This would create a risk of cutting or piercing the catheters.

9.3.2. Valve

PRECAUTIONS

Polaris® models must be implanted on a bony surface, under sub-cutaneous tissue less than 8 mm thick.

The selected implantation site must be sufficiently unencumbered to facilitate detection of the valve by the Locator when adjustments are made later (space of at least 4 cm all around the valve, away from the ear and the neck).

If these precautions are not observed, there may be difficulties with adjustment or it may even be impossible to make an adjustment, due to poor localization of the valve by the Locator or the Magnet moving the rotor insufficiently.

WARNING

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 or catheter 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.

   However, in patients with low intracranial pressure or if the valve is set to a high pressure, the valve cannot fill spontaneously. In this case :

   — place a piece of catheter on the outlet connector and slowly aspirate the CSF using a syringe fitted with a Luer connector,

   or even:

   — press the dome of the reservoir to allow the CSF to fill the valve (SPVA and SPVB models).

   PRECAUTION

   Do not fill or purge the valve with any liquid other than the patient's CSF or water for injection (WFI) 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.

PRECAUTION

Do not implant the valve without suturing it to the underlying tissues by its two connectors or by the suture holes provided for this. If the shunt system migrates the drainage may stop and other complications ensue.

WARNING

Before suturing the valve to the underlying tissues, check that the arrow on the upper face of the valve is visible.

If the arrow is not visible this means that the valve has been implanted the wrong way up (upside – down). In this case, direct reading with the Compass will be reversed, for example: a high reading (No.5) for a valve set to a low position (No.1). This could cause serious clinical consequences (over- or underdrainage). In this situation, contact Sophysa for adjustment instructions.

9.3.2.1. Case of a valve preconnected to a SiphonX® gravitational anti-siphon device

To prevent any risk of introducing an air bubble, it is recommended that the "Valve + SiphonX®" assembly be left to fill 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.

PRECAUTION

For optimum operation of a Polaris® valve with a pre-attached SiphonX® gravitational anti-siphon device, make sure the assembly is positioned parallel to the axis of the body of the patient.

9.3.3. Peritoneal Catheter

1. Make a short peritoneal incision in the peri-umbilical region.
2. Tunnel the distal catheter.
3. Connect the proximal end of the catheter to the valve outlet connector and ligate it delicately.
4. Check the flow of CSF.
5. Adapt the length of the catheter.
6. Bury the distal end of the catheter in the peritoneal cavity.

PRECAUTION

Due to the fragility of the silicone, using metallic forceps for inserting catheters and for ligating them onto connectors is not recommended. This would create a risk of cutting or piercing the catheters.

9.4. READING AND/OR CHANGING THE OPERATING PRESSURE OF A POLARIS® AFTER IMPLANTATION

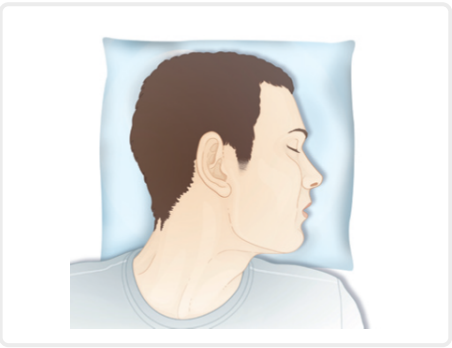
Refer to *§4 – Principle of the Polaris®* Valve Adjustment, and for more information, refer to the instruction for use of the Adjustment Kit.

PRECAUTION

The operation scar and/or post-operative edema can make positioning the Locator painful and inaccurate. This could then cause difficulties in adjustment or even make it impossible.

For the adjustment, the patient should be positioned such that the valve implantation site is easy to access. Having valve horizontal is recommended.

FIGURE 8 – RECOMMENDED POSITIONING OF THE PATIENT



9.4.1. Pressure reading only

9.4.1.1. Identification of the valve model (Step 1b)

Identify the reference and/or the pressure range for the Polaris® valve to be adjusted: refer to the Patient Identification Card or to the patient's medical record (traceability label) and/or perform an X-ray examination of the valve (*cf. §9.5 - Post-operative X-ray control examination*).

9.4.1.2. Choice of Locator reading area (Step 2b)

Refer to *§4 – Principle of the Polaris® Valve Adjustment-Locating Instrument.*

On the Locator, display the pressure range of the valve model identified in *Step 1b*.

9.4.1.3. Positioning the Locator (Step 3b)

Palpate the valve implantation site in order to determine both the location and orientation of the valve.

The inlet and outlet connectors at each end of the valve and the reservoir (if fitted) are the easiest components to locate. Find these first.

Place the **Locator** on the implant site with its axis aligned with that of the valve connectors, and with the green arrow pointing in the direction of the CSF flow.

Center the Locator above the valve as well as possible: locate the valve by palpating it through the cut-out in the center of the Locator.

Press the Locator firmly against the valve so as to center and immobilize the valve.

9.4.1.4. Positioning the Compass and Reading the Pressure (Step 4b)

Refer to *§4 – Principle of the Polaris® Valve Adjustment - Reading Instrument.*

Hold the Locator with one hand.

Place the **Compass** in the **Locator** using the guide pins: align the lines on the Compass with the pressure values engraved on the Locator.

On the **Locator** read the operating pressure shown by the **Compass** needle.

9.4.1.5. Confirmation of the reading

In the recommended implantation conditions, X-ray examination is optional because the pressure can be read directly using the adjustment kit. However, X-ray confirmation is recommended in the following cases:

— if there is a discrepancy between the pressure read in *Step 4b* and the value read in *Step 1b on the Patient Identification Card (PC-SPV) and/or on the X-ray performed for the valve model identification,*
— if the valve has been implanted too deeply, under subcutaneous tissue more than 8mm thick (*cf. §9.3, Implantation technique - Valve*),
— if the user is not familiar with the use of the kit;
— after an MRI examination.

9.4.2. Setting a new pressure

Refer to *§9.4.1 - Operating pressure setting after implantation: READING ONLY, Steps 1b-4b.*

9.4.2.1. Orientation of the Locator (Step 5b)

It is recommended that the positioning of Locator in relation to the axis of the valve is fine-tuned as follows:

— Remove the **Compass** and insert the **Magnet** into the **Locator** with the green marker on the Magnet facing the initial position of the pressure setting.
— Slide **Magnet** back and forth quickly along the axis of the valve rotor current position as just determined in

order to unlock the rotor, then return it to a position centered in the **Locator**.

— Turn the **Magnet** slowly, until it passes the extreme position the furthest away from the initial position (No. 1 or No. 5).

— Remove the Magnet vertically and insert the **Compass** into the **Locator** in accordance with *Step 4b*.

If the adjustment is correctly performed, the **Compass** will confirm that the extreme position has been reached.

If the Compass needle does not align exactly to this operating pressure value (No. 1 or No. 5), slightly adjust the orientation of the **Locator** (rotation) in order to align the **Compass** needle on the corresponding mark.

If the needle has not moved at all, reattempt the adjustment process after repeating the back and forth motion with the Magnet.

This sequence also makes it possible to confirm that the valve can be adjusted (unlocking and rotation of the rotor).

9.4.2.2. Setting the pressure (Step 6b)

Refer to *§4 – Principle of the Polaris® Valve Adjustment-Setting Instrument*

Until the last adjustment (end of *Step 7b*), hold the **Locator** firmly with one hand in the precise position defined in *step 5b*.

Remove the **Compass** and insert the **Magnet** into the **Locator** with the green marker on the Magnet facing the lowest or highest pressure reached in *Step 5b*.

Move the **Magnet** quickly back and forth along the axis of the lowest or highest position in *Step 5b*. Then reposition it correctly in the center of the **Locator**.

Turn the **Magnet** slowly in the other direction until the new position chosen as the operating pressure for the implanted valve is reached.

Remove the **Magnet** vertically from the Locator to ensure effective re-locking of the valve rotor at the new operating pressure position.

9.4.2.3. Verification of the pressure setting (Step 7b)

Refer to *§4 – Principle of the Polaris® Valve Adjustment - Reading Instrument*

Verification is performed using the **Compass** in accordance with the procedure described in Step 4b.

NOTE

Setting the selected operating pressure cannot always be performed at the first attempt. It is possible that the procedure will have to be repeated once or several times, in order to ensure that the desired pressure setting is obtained.

PRECAUTION

Adjusting the pressure using a Polaris® adjustment kit requires experience. If the user is not familiar with the use of the kit, it is recommended that the pressure adjustment be confirmed with an X-ray.

It is advisable to monitor the patient carefully for 24 hours following any change in the valve operating pressure setting.

9.4.2.4. Recording the new operating pressure (Step 8b)

Note the pressure read in *Step 7b* on the Polaris® Patient Identification Card (PC-SPV).

9.5. POST-OPERATIVE X-RAY EXAMINATION: IDENTIFICATION OF THE VALVE MODEL AND PRESSURE READING

NOTE

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

In this way identifying the valve by its radio-opaque point is made easy.

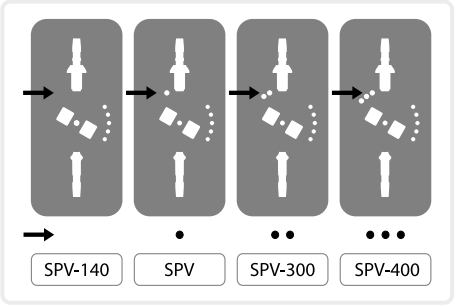
The radio-opaque points to the left of the inlet connector are used to identify the pressure range of the Polaris® valve: :

Number of radio-opaque points	zero	one •	two ••	three •••
Maximum operating pressure (mmH_2O)	140	200	300	400

NOTE

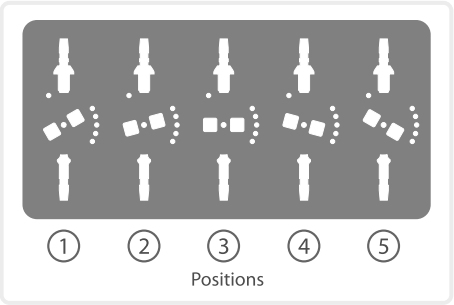
The pressure range of the implanted valve is shown on the Patient Card, in the description of the valve model used.

FIGURE 9 – RADIOGRAPHIC IDENTIFICATION OF THE DIFFERENT MODELS OF THE VALVE POLARIS® .



It is easy to read the pressures on a radiological image (*Figure 10*).

Figure 10 – Confirmation of the operating pressure (radiological views of the valve SPV model)



On the Polaris® valve, each of the five valve pressures is located by the position of the radio-opaque identification point for the corresponding operating pressure.

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

The position for the lowest operating pressure (Position No. 1) is the position located nearest to this connector.

If the right-hand valve rotor micro-magnet is facing the radio-opaque point nearest the inlet connector, the valve is set at the lowest pressure (Position No. 1).

Then, moving clockwise away from the inlet connector, each of the following radio-opaque points corresponds to a higher pressure.

The radio-opaque point furthest away from the valve inlet connector corresponds to the highest pressure (Position No. 5).

9.6. PATENCY TEST (POST-OPERATIVE)

There are two steps for the post-operative test on the patency of the shunt :

9.6.1. Testing the patency of the ventricular catheter

NOTE

This test is possible with SPVA (antechamber) and SPVB (burr hole reservoir) type models. For the SPV type model, a ventricular catheter with reservoir must be used.

Pinch 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 ventricular catheter. A reservoir that cannot be compressed easily or does not fill quickly may indicate there is an obstruction in the ventricular catheter.

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

NOTE

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

Pinch 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.

PRECAUTION

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.

9.7. SAMPLING THE CSF AND INJECTION

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

The integral reservoir on the SPVA and SPVB type models is designed for occasional use.

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.

NOTE

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

Ensure that the base of the reservoir is not crossed with the needle.

PRECAUTIONS

Do not inject into, or take samples from, the CSF without having tested the shunt patency. Significant overpressure could damage the shunt if it is known that there is an obstruction.

Do not inject too fast or inject too great a volume. The increase in pressure could damage the shunt.

Do not use a syringe with a volume of less than 10cc for injections or taking samples. Too great a pressure could damage the shunt.

9.8. POTENTIAL CAUSES OF ADJUSTMENT DIFFICULTIES AND SUGGESTED MEASURES

Poor positioning of the Locator in relation to the center of the valve or incorrect orientation of this Locator in relation to the axis of the connectors may lead to an inaccurate or incorrect reading of the operating pressure on the Compass and/or difficulties in making adjustments with the Magnet.

Before anything else, check that the **Locator** is correctly positioned and oriented above the valve (*cf. Steps 3b " Positioning the Locator " and 5b " Orientation of the Locator " in the §9.4 - Operating pressure setting after implantation*).

PRECAUTION

It is necessary to ensure that the Locator is correctly centered above the valve and that its base is parallel to the valve surface.

Being off-center by more than 2 mm or any inclination in relation to the valve could cause an incorrect pressure reading or incomplete unlocking of the rotor, making it impossible for the rotor to rotate and thus the pressure to be changed.

However, there may be other causes for difficulties in adjustment:

— Excessively thick sub-cutaneous tissue above the valve (8 mm) caused, for example, by post-operative edema, a hematoma or cicatricial tissue would make the localization of the valve inaccurate, thus causing complications in the pressure adjustment procedure.
— The presence of debris or deposits inside the valve could also make adjustment using the usual procedure difficult.

A special procedure may then be applied to facilitate the adjustment of the valve, possibly using a fluoroscopic examination:

1. Palpate the valve implantation site in order to determine both the location and orientation of the valve.

   The inlet and outlet connectors at each end of the valve and the reservoir (if fitted) are the easiest components to locate. Find these first.

2. Place the Compass without the Locator directly onto the implantation site and centered above the valve in the best possible manner.

   Note the direction of the Compass needle, aligned on the axis of the rotor of the implanted valve.

3. Remove the Compass and place the Magnet directly on the implantation site, oriented in the direction of the rotor located in the previous step.
4. Slide the Magnet back and forth quickly along the axis of the current position to unlock the valve rotor. Ensure that the Magnet remains in the plane of the valve. Repeat this procedure several times if necessary until the valve rotor is unlocked. Then reposition the Magnet in a position centered over the valve.
5. Then turn the Magnet until the new position desired is reached. Confirm the new setting using the Compass or with an X-ray.

The implantation of a valve not performed under the recommended conditions (*cf. §9 – Implantation technique*) may lead to a Compass reading of a pressure value inconsistent with the patient record or the clinical status of the patient.

In this case, an X-ray removes any doubt. It is the absolute proof of a successful adjustment and the correct direction of the implantation.

Finally, pressure adjustment is impossible if the valve is positioned the wrong way up (upside down).

10. Precautions for the Daily Life of the Patient

A Patient Identification Card (PC-SPV) is supplied with the Polaris® valve. It enables the neurosurgeon to consult and update information relating to the implanted device (reference, operating pressure, implantation site, etc.) systematically and to ensure that the illness is properly monitored.

PRECAUTION

The patient should be warned that it is important to carry his/her Patient Identification Card (PC-SPV) at all times . This card gives information on the medical situation of the patient to all medical personnel.

The magnetic self-locking system of the Polaris® valve is designed to make the magnetic rotor insensitive to the influence of standard magnetic fields.

As a result, the following are not likely to affect the valve operating pressure:

— magnetic fields generated by walk-through scanners in airports, microwave ovens, cordless telephones, 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…

The doctor is responsible for informing the patient or his/her 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.

PRECAUTION

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.

11. 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.

PRECAUTION

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 his/her 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 over-drainage. These complications require the rapid intervention of a doctor.

11.1. 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 end 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, a consequence of over-drainage.

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.

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 the reappearance of the signs and symptoms of intracranial hypertension.

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

In infants and young children, the symptoms may be an abnormal increase in the size of the skull, a bulge in the fontanelles, dilation of the scalp veins, vomiting, irritability with a lack of attention, downward deviation of the eyes, and sometimes convulsions.

In older children and adults, intracranial hypertension due to hydrocephalus may be the cause of headaches, vomiting, blurred vision, diplopia, drowsiness, slowing of movements, gait disorders or psychomotor slowing which could lead to total invalidity.

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.

11.2. 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.

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

Septicemia, favored by an alteration in general status, can start from a shunt infection.

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.

11.3. OVERDRAINAGE

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

In children, depression of the fontanelles, overlapping of the scalp bones, 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.

Depending on clinical observations and medical imaging, the doctor can reduce the symptoms of overdrainage and correct the ventricle size by changing the operating pressure of the Polaris® valve.

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

11.4. OTHER

Failure of a shunt system may also be linked to disconnection of its various components.

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.

Perforation or occlusion of abdominal viscera by the peritoneal catheter could occur.

Growth of the body may progressively cause the catheters to exit their insertion sites.

These malfunctions require the shunt to be repositioned immediately.

Cases of 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 should never be withdrawn forcibly. If it cannot be taken out without forcing, it is preferable to leave it in place rather than risk an intra-ventricular 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 regulatory function in the valve potentially increasing the risk of overdrainage.
— an impaired anti-reflux function.

The mobility of the rotor could be impeded by an aggregation of cells or a protein deposit. This could make it impossible to adjust the valve with the Magnet.

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.

12. Conditions for storage

Keep in the original packaging.

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

13. Processing of the products after use

13.1. DESTRUCTION AFTER USE

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

13.2. RETURN OF PRODUCTS

If an explanted valve needs to be returned to Sophysa for analysis, it must be returned immersed in water, indicating if necessary whether cleaning has been performed.

Never use a saline solution likely to form deposits in the valve body which could block the rotor.

In order to assess the returned product properly, it must be accompanied by an explanatory Return to Manufacturer Authorization form.

14. Guarantee

The performance of the Polaris® adjustment kit is only ensured with the Polaris® range of valves, designed, tested and manufactured by Sophysa.

Sophysa guarantees that this medical device is free of any material and manufacturing defects. Apart from this guarantee, Sophysa does not provide any other guarantee, express or implicit, including commercialization or adaptation for a particular use. Sophysa cannot be held responsible for any incident, complication, damage or prejudice occurring directly or indirectly from the use of this device. Sophysa does not authorize anyone whomsoever to take responsibility on its behalf for its products.

The performance of adjustable Polaris® valves is only guaranteed with the range of silicone catheters and accessories designed, tested and manufactured by Sophysa. However, it is possible to use other brands of catheters provided that their internal diameter is identical to that of the catheters recommended by Sophysa.

15. Symbols

REF — Catalog number

Manufacturer

Caution, see the Instructions for Use

STERILE EO — Sterilized using Ethylene Oxide

Do not re-use

Do not re-sterilize

Use by

LOT — Batch code

SN — Serial number

MR — MR Conditionnal

Consult Instructions for use on our website: www.sophysa.us

www.sophysa.us

16. References

Polaris® adjustable pressure valves for CSF shunting

SPV	**POLARIS® ADJUSTABLE VALVE; 30-200 mmH_2O** Adjustable pressure valve, 5 pressures: 30 (Low), 70, 110 (Medium), 150, 200 (High) mmH_2O.
SPV-140	**POLARIS® ADJUSTABLE VALVE; 10-140 mmH_2O** Adjustable pressure valve, 5 pressures: 10 (Low), 40, 80 (Medium), 110, 140 (High) mmH_2O.
SPV-300	**POLARIS® ADJUSTABLE VALVE; 50-300 mmH_2O** Adjustable pressure valve, 5 pressures: 50 (Low), 100, 150 (Medium), 220, 300 (High) mmH_2O.
SPV-400	**POLARIS® ADJUSTABLE VALVE; 80-400 mmH_2O** Adjustable pressure valve, 5 pressures: 80 (Low), 150, 230 (Medium), 330, 400 (High) mmH_2O.
SPVA	**POLARIS® ADJUSTABLE VALVE SPV / ANTECHAMBER** SPV valve, 5 pressures: 5 pressures: 30 (low), 70, 110 (Medium), 150, 200 (High) mmH_2O, with integrated antechamber.
SPVA-140	**POLARIS® ADJUSTABLE VALVE SPV-140 / ANTECHAMBER** SPV-140 valve, 5 pressures: 10 (low), 40, 80 (Medium), 110, 140 (High) mmH_2O, with integrated antechamber.
SPVA-300	**POLARIS® ADJUSTABLE VALVE SPV-300 / ANTECHAMBER** SPV-300 valve, 5 pressures: 50 (low), 100, 150 (Medium), 220, 300 (High) mmH_2O, with integrated antechamber.
SPVA-400	**POLARIS® ADJUSTABLE VALVE SPV-400 / ANTECHAMBER** SPV-400 valve, 5 pressures: 80 (low), 150, 230 (Medium), 330, 400 (High) mmH_2O, with integrated antechamber.
SPVB	**POLARIS® ADJUSTABLE VALVE SPV / BURR HOLE RESERVOIR** SPV valve, 5 pressures: 30 (Low), 70, 110 (Medium), 150, 200 (High) mmH_2O, with integrated burr hole reservoir.

Polaris® adjustable pressure valves for CSF shunting with pre-attached SiphonX® gravitational anti-siphon device

SPV-SX	**Polaris® adjustable valve, 30-200 with SiphonX®** SPV valve, 5 pressures: 30 (Low), 70, 110 (Medium), 150, 200 (High) mmH_2O, with pre-attached 200 mmH_2O gravitational device.
SPVA-SX	**Polaris® adjustable valve, 30-200 with antechamber and SiphonX®** SPV valve, 5 pressures: 30 (Low), 70, 70.110 (Medium), 150, 200 (High) mmH_2O with integrated antechamber and pre-attached 200 mmH_2O gravitational device.
SPVB-SX	**Polaris® adjustable valve, 30-200 with burr hole reservoir and SiphonX®** SPV valve, 5 pressures: 30 (Low), 70, 110 (Medium), 150, 200 (High) mmH_2O, with integrated burr-hole reservoir and pre-attached 200 mmH_2O gravitational device.
SPV-140-SX	**Polaris® adjustable valve, 10-140 with SiphonX®** SPV valve, 5 pressures: 10 (Low), 40, 80 (Medium), 110, 140 (High) mmH_2O with pre-attached 200 mmH_2O gravitational device.
SPVA-140-SX	**Polaris® adjustable valve, 10-140 with antechamber and SiphonX®** SPV valve, 5 pressures: 10 (Low), 40, 80 (Medium), 110, 140 (High) mmH_2O ,with integrated antechamber and pre-attached 200 mmH_2O gravitational device.

SHUNT KITS FOR CRANIAL IMPLANTATION

SPV-2010	**COMPLETE ADJUSTABLE POLARIS® KIT - 30-200 mmH_2O** SPV valve, 5 pressures: 30 (Low), 70, 110 (Medium), 150, 200 (High) mmH_2O with Pre-attached peritoneal catheter (B905S). Right ventricular catheter (BO19-10)
SPVA-2010	**COMPLETE ADJUSTABLE POLARIS® KIT- 30-200 200mmH_2O / ANTECHAMBER** SPVA valve, 5 pressures: 30 (Low), 70, 110 (Medium), 150, 200 (High) mmH_2O with Pre-attached peritoneal catheter (B905S). Right ventricular catheter (BO19-10)
SPVB-2010	**COMPLETE ADJUSTABLE POLARIS® KIT - 30-200mmH_2O / BURR HOLE RESERVOIR** SPVB valve, 5 pressures: 30 (Low), 70, 110 (Medium), 150, 200 (High) mmH_2O with Pre-attached peritoneal catheter (B905S). Right ventricular catheter (BO19-10)

DEVICE FOR READING AND ADJUSTING THE OPERATING PRESSURE OF THE POLARIS® VALVE

PAK2	**Polaris® valve adjustment kit**

Technical specifications and List of product references may be modified without notice. For all dimensions indicated in this document, tolerances are: ± 5 %.

Availability may vary according to country.

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