SOPHYSA

*Instructions for use*

# SiphonX® GRAVITATIONAL ANTI-SIPHON DEVICE

Valve accessory for limiting the siphon effec t during CSF drainage

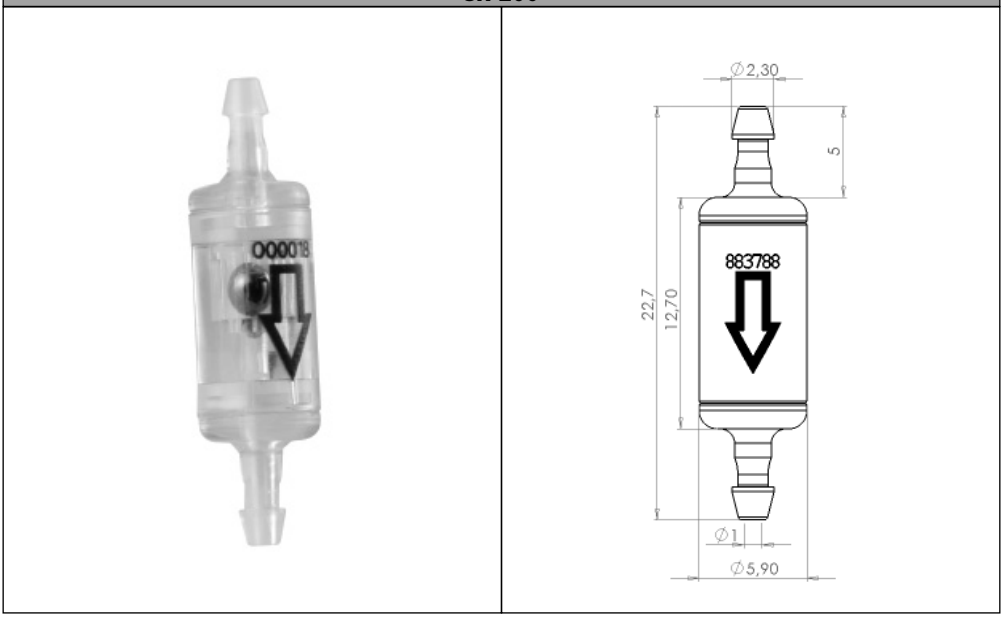
Sterile, single use

ENGLISH

# *Instructions for use*

*Figure 1: SiphonX® gravitational anti-siphon device (Model SX-200)*

**SX-200**




***Warnings:***
Federal (USA) Law restricts this device to sale by or on the order of a physician.
Read the instructions for use carefully before implanting the device.

## 1. Indications

The SiphonX® gravitational anti-siphon device is designed to control the siphon effect during the treatment of hydrocephalus by shunting Cerebrospinal Fluid (CSF).

***Warning:***
The SiphonX® gravitational anti-siphon device must absolutely be used in conjunction with a CSF shunt valve.

## 2. Contra-indications

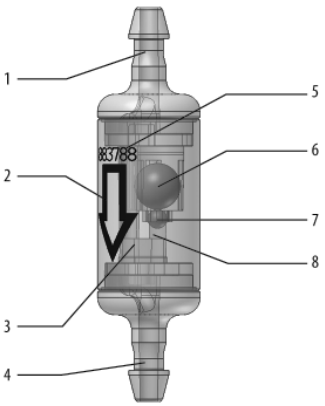
As it is absolutely essential that the SiphonX® gravitational anti-siphon device is combined with a CSF shunt valve, the contra-indications for the device are the following:

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

However, if the clinical benefit outweighs these contra-indications, 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.

## 3. Description and Operating Principle of the SiphonX®

*Figure 2: The SiphonX® gravitational anti-siphon device*



The SiphonX® gravitational anti-siphon device *(Figures 1&2)* is a single use implantable device.

The SiphonX® enables additional resistance to be added to the operating pressure of a CSF drainage valve.

The SiphonX® is placed downstream of the shunt valve so that the CSF arrives in the anti-siphon device from the valve through the inlet connector [1]. It then passes into the body of the anti-siphon device [3] and leaves it through the outlet connector [4].

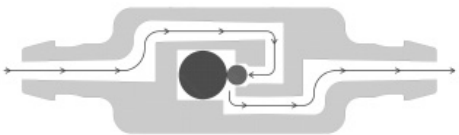
On the body of the device an arrow [2] shows the direction of CSF flow through the device. This helps to position the SiphonX® correctly during implantation.
Above this arrow is a unique serial number [5].

The operational principle of the SiphonX® gravitational anti-siphon device is based on the resistance to the flow exerted by the weight of tantalum weighting ball [6], which presses on a ruby ball [7]. This ruby ball [7] occludes the aperture for the passage of the CSF [8].

The operating pressure of the SiphonX® gravitational anti-siphon device is determined by the inclination of the device from the vertical axis.

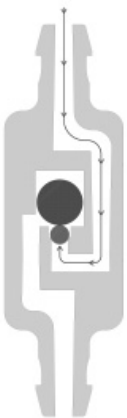
When the SiphonX® is in the horizontal position, the ruby ball is not subjected to the weight of the tantalum ball and so does not occlude the aperture [8] of the device.
The SiphonX® is therefore open and does not add any additional resistance to the operating pressure of the valve *(Cf. Figure 3)*.

*Figure 3: The SiphonX® in horizontal position : open*



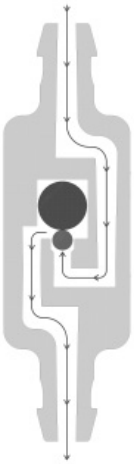
When the SiphonX® is in the vertical position, the ruby ball is subjected to the full weight of the tantalum ball, occludes the aperture *(Cf. Figure 4)* and the device adds 200mm$H_2$0 to the operating pressure of the valve.

*Figure 4: The SiphonX® in vertical position : closed*



If the pressure applied to the shunt exceeds the sum of the operating pressures of the valve and the anti-siphon device, the device opens: the CSF pushes the ruby ball and the weighting ball and flows through the outlet connector *(Cf. Figure 5)*.

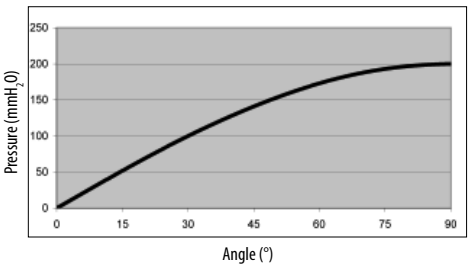
*Figure 5: The SiphonX® in vertical position : open*



For example, for a valve set to 110mm$H_2$0, the resistance of the "Valve + SiphonX®" assembly is 110+200 = 310mm$H_2$0 for a patient in the vertical position and 110+0 =110mm$H_2$0 for a patient in the horizontal position.

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

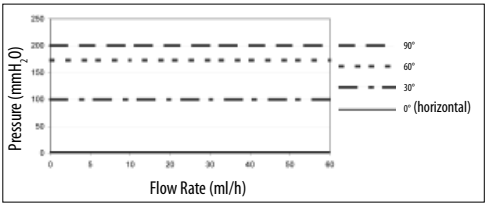
*Figure 6: Operating pressures for the SiphonX®, SX-200 model, depending on its inclination, whatever the flow rate between 5 and 50ml/h*




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 measurement is performed disregarding the resistance of the catheters.

*Figure 7: Flow Rate - Pressure Curves for the SiphonX® gravitational anti-siphon device (SX-200 Model)*




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

In conditions of normal use this mechanism is not sensitive to temperature variations.

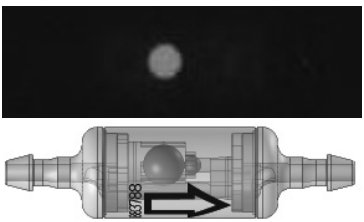
The anti-siphon device body, which cannot be deformed, makes the device insensitive to variations in percutaneous pressure.

The connectors and the anti-siphon device body are made of polysulfone.

The SiphonX® gravitational anti-siphon device is a latex-free product.

The tantalum ball is clearly visible on an X-ray.

*Figure 8: Radiographic image of the SiphonX® SX-200*



## 4. Configurations of the SiphonX®

The SiphonX® gravitational anti-siphon device, Model SX-200, is supplied on its own without a catheter.

Sophysa offers a range of both adjustable and monopressure valves on which the SiphonX® can be fitted, as well as a complete range of radio-opaque catheters which allow the CSF to flow to the valve and anti-siphon device, and then on to the reabsorption site chosen by the neurosurgeon.

A complete shunt system that includes a SiphonX® gravitational anti-siphon device must consist of a proximal catheter, a valve, an anti-siphon device and a distal catheter.

The SiphonX® operating pressures has a tolerance interval of +/-15mm$H_2O$ compared with the pressures shown on the label.

## 5. Measurement Unit and Control of Operating Pressures

The operating pressures mentioned are in mm$H_2O$.
1 mm$H_2O$ corresponds to 9.807 Pa.

Each SiphonX® gravitational anti-siphon device is tested individually: the measurement concerns the upstream pressure of a 10ml/h flow of water passing through the anti-siphon device and the Sophysa proximal and distal catheters.

This measurement is performed for three different inclinations of the device: 0° (horizontal), 90° (vertical) and 30° (intermediate angle).

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

Thus the pressures given on the SX-200 model labels correspond to the resistance of the SiphonX® alone, the catheters and the valve, which must be combined with the SiphonX®, adding their own resistance to the shunt.

## 6. Behavior during Magnetic Resonance Imaging (MRI)

The performance and functionality of the SiphonX® gravitational anti-siphon device are not affected by repeated exposure to MRI examinations at 3 Tesla (30,000 Gauss) or less.

The SiphonX® gravitational anti-siphon device is considered as "MR Safe" in accordance with the definition in the standard, ASTM F-2503-05.

The rise in temperature caused by exposure of the SiphonX® to 3 Tesla MRI is negligible and has no physiological consequences for the patient.

The torque and displacement force induced by a magnetic field of 3 Tesla or less are nil and so do not present a risk for the patient.

***Precaution:***
Do not implant a SiphonX® gravitational anti-siphon device in an area that is likely to need to be examined under MRI.
The tantalum weighting ball in a SiphonX® gravitational anti-siphon device is a potential source of artifacts on MRI images. The size of this could be as large as the implant.

## 7. Sterilization and Packaging

The SiphonX® gravitational anti-siphon devices are provided sterile and pyrogen free. The SiphonX® are provided individually in double sterile packaging. The product is sterilized using ethylene oxide.

***Warnings:***
Do not use the devices if the sterile packaging is open or damaged, or if the expiry date has passed.

Anti-siphon devices are single use devices. Do not re-sterilize or re-use after unpacking and/or explantation.

***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.

## 8. Instructions

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

**Implantation Technique**

Implantation of a SiphonX® gravitational anti-siphon device must take account of current aseptic neurosurgical practices.

The implantation of a shunt including a SiphonX® gravitational anti-siphon device may be performed in several ways.
The surgeon will choose the technique depending upon his experience and the clinical status of the patient.
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 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 *(cf. § 6 "Behavior during Magnetic Resonance Imaging (MRI)")*.

***PRECAUTION:***
DO NOT PERFORM THE IMPLANTATION OF AN ANTI-SIPHON DEVICE WITHOUT HAVING A REPLACEMENT DEVICE AVAILABLE IN CASE IT IS REQUIRED.

***WARNING:***
DO NOT CARRY OUT ANY ADDITIONAL TESTS BEFORE IMPLANTATION.
EACH SIPHONX® GRAVITATIONAL ANTI-SIPHON DEVICE HAS BEEN INDIVIDUALLY CHECKED. ANY PRE-OPERATIVE PRESSURE TESTS WILL INCREASE THE RISK OF INFECTION.

For the implantation of the shunt, refer to the instructions for use for the implants used.

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

- Connect 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®.
- Check that the anti-siphon device arrow is correctly oriented in the direction of the CSF flow.
- Position the SiphonX® absolutely parallel to the vertical axis of the patient's body for optimal function *(Cf. Figure 6 and § 3 "Description and Operating Principle")*.

***PRECAUTIONS:***
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 FULFIL ITS ROLE CORRECTLY.

THE SIPHONX® GRAVITATIONAL ANTI-SIPHON DEVICE MUST BE POSITIONED PARALLEL TO THE AXIS OF THE PATIENT'S BODY.
IF THE SIPHONX® 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.

DO NOT PLACE THE DEVICE IN A MANNER THAT REQUIRES PULLING THE DEVICE SUBCUTEANOUSLY. PULLING THE DEVICE BY THE DISTAL CATHETER MAY LEAD TO DISCONNECTION OF THE CATHETER FROM THE DEVICE.

- Purge the SiphonX® of air:

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.
However, in patients with low intracranial pressure or if the valve is set to a high pressure, the "Valve + SiphonX®" assembly may not fill spontaneously.
In this case:
check that the Siphon-X® is properly horizontal,
then:
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 if possible.

- 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.

- Check the flow of CSF.

- Connect and ligate the outlet connector on the anti-siphon device to the distal catheter of the shunt.

If it is necessary to check the shunt system after implantation, refer to the instructions for use for the valve used.

## 9. Precautions for the Daily Life of the Patient

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 IF THE DEVICE IS FITTED ON THE SKULL.

## 10. 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 main complications of shunts are obstruction, infection and over-drainage. These complications require rapid intervention by the physician.

Refer to the instructions for use for the shunt implant used, for a description of possible complications associated with the shunt.

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

Cases of allergy to silicone have been described.

The presence of a aggregation of cells or a protein deposit on the seat of the anti-siphon device could keep it open. This could then induce a loss of the regulatory function of the anti-siphon device in the vertical position, potentially increasing the risk of overdrainage.

Blood clots, cerebral cells or tumoral cells contained in the CSF could lodge in the SiphonX® gravitational anti-siphon device, which would have the potential to cause changes in the operating characteristics of the SiphonX®, or even to cause its obstruction.

## 11. Guarantee

Sophysa guarantees that this medical device is free from defects in material or manufacturing. Apart from this guarantee, Sophysa does not grant any other guarantee, express or implicit, including marketing or adaptation for a specific use. Sophysa cannot be held responsible for any incident, complication, damage or prejudice resulting directly or indirectly from the use of this device. Sophysa does not authorize anyone to take responsibility on its behalf for its products.
The performances of SiphonX® gravitational anti-siphon devices are 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 or valves provided that the internal diameter of the catheters is identical to that of the catheters recommended by Sophysa.

## 12. Processing of the products after use

**Destruction after use**

An unpacked, used or explanted SiphonX® gravitational anti-siphon device must be destroyed in accordance with the procedures in force in the medical establishment.

**Return of products**

If an explanted device 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 anti-siphon body which could block the device.

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

## 13. Symbols

| | |
|---|---|
| REF | Catalog reference |
|  | Manufacturer |
|  | Caution, see the Instructions for Use |
|   | Sterilization Method using Ethylene Oxide |
|  | Do not re-use |
|   | Do not re-sterilize |
|  | Use by |
| LOT | Batch code |
| SN | Serial number |
|   | Consult Instructions for Use on our website: www.sophysa.us |

# *References*

| Name/Description | Reference |
|---|---|
| **SiphonX® gravitational anti-siphon device**<br>Accessory adding resistance to a valve: +0mm$H_2O$ (Horizontal Position), +200mm$H_2O$ (Vertical Position). | **SX-200** |
| **Polaris® adjustable valve, 30-200 with SiphonX®**<br>SPV Valve, 5 pressures: 30 (Low), 70, 110 (Medium), 150, 200 (High) mm$H_2O$ with pre-attached 200mm$H_2O$ gravitational anti-siphon device. | **SPV-SX** |
| **Polaris® adjustable valve, 30-200 with antechamber and SiphonX®**<br>SPV valve, 5 pressures: 30 (Low), 70, 110 (Medium), 150, 200 (High) mm$H_2O$, with integrated antechamber and pre-attached 200mm$H_2O$ gravitational anti-siphon device. | **SPVA-SX** |
| **Polaris® adjustable valve, 30-200 with burr hole reservoir and SiphonX®**<br>SPV valve, 5 pressures: 30 (Low), 70, 110 (Medium), 150, 200 (High) mm$H_2O$, with integrated burr hole reservoir and pre-attached 200mm$H_2O$ gravitational anti-siphon device. | **SPVB-SX** |
| **Polaris® adjustable valve, 10-140 with SiphonX®**<br>SPV Valve, 5 pressures: 10 (Low), 40, 80 (Medium), 110, 140 (High) mm$H_2O$ with pre-attached 200mm$H_2O$ gravitational anti-siphon device. | **SPV-140-SX** |
| **Polaris® adjustable valve, 10-140 with antechamber and SiphonX®**<br>SPV valve, 5 pressures: 10 (Low), 40, 80 (Medium), 110, 140 (High) mm$H_2O$, with integrated antechamber and pre-attached 200mm$H_2O$ gravitational anti-siphon device. | **SPVA-140-SX** |

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

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