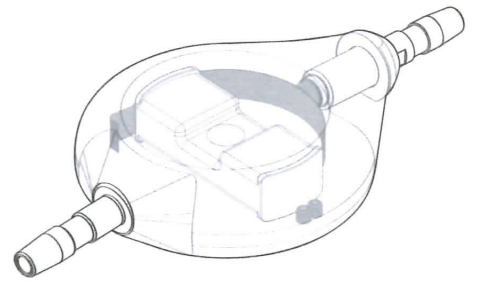


Lot 4.2

Lot 4.3

Sophy® Mini SM1

The Sophy® Mini
monopressure valve



Sophy[®] Mini SM1 Valve

The Sophy[®] Mini Monopressure valve (SM1) is a low-profile high precision ball-in-cone valve. It has the small size, the shape of the Sophysa Adjustable Valves and is made of the same material.

Low profile valve

Discreet and comfortable for both adults and children.

Polysulfone transparent body

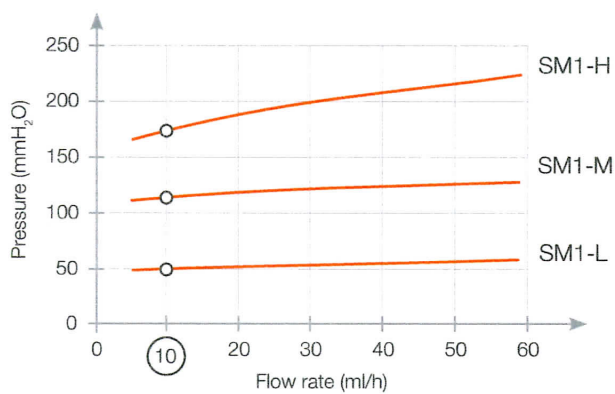


Ball-in-cone mechanism

Exceptional precision and proven reliability.

Operating pressure indicators

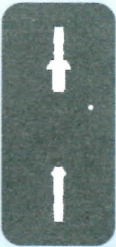
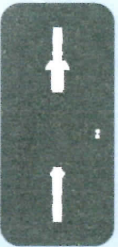

X-ray identification of the operating pressure among the 3 pressures available: 50, 110 and 170 mmH₂O.



Three operating pressures are available:

- Low = 50 mmH₂O
- Medium = 110 mmH₂O
- High = 170 mmH₂O

Direct x-ray identification of the operating pressure is possible thanks to radiopaque dots on the valve.

Valve	SM1 - L	SM1 - M	SM1 - H
Identification of the operating pressure	1 dot •	2 dots ••	3 dots •••
X-ray identification of the operating pressure			
mmH ₂ O	50	110	170

The Sophy® Mini SM1 can be associated with SiphonX®, an anti-siphon device, which adds 200 mmH₂O in vertical position.

	Reference	Designation
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Valve only



SM1-L	Sophy® Mini Monopressure Valve, Low Pressure, 50 mmH ₂ O
SM1-M	Sophy® Mini Monopressure Valve, Medium Pressure, 110 mmH ₂ O
SM1-H	Sophy® Mini Monopressure Valve, High Pressure, 170 mmH ₂ O

Valve with antechamber



SM1A-L	Sophy® Mini Monopressure Valve, Low Pressure, Antechamber
SM1A-M	Sophy® Mini Monopressure Valve, Medium Pressure, Antechamber
SM1A-H	Sophy® Mini Monopressure Valve, High Pressure, Antechamber

Valve with burr-hole reservoir



SM1B-L	Sophy® Mini Monopressure Valve, Low Pressure, Burr-Hole Reservoir
SM1B-M	Sophy® Mini Monopressure Valve, Medium Pressure, Burr-Hole Reservoir
SM1B-H	Sophy® Mini Monopressure Valve, High Pressure, Burr-Hole Reservoir

SiphonX®, anti-siphon device (+ 200 mmH₂O in vertical position)



SX-200	Gravitational anti-siphon device SiphonX®
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Complete valve kits Sophy® Mini SM1 valve kits include a separated ventricular catheter and a preconnected distal catheter



SM1-2010L	Sophy® Mini SM1 Low Pressure Valve Kit
SM1-2010M	Sophy® Mini SM1 Medium Pressure Valve Kit
SM1-2010H	Sophy® Mini SM1 High Pressure Valve Kit



SM1A-2010L	Sophy® Mini SM1A Low Pressure Valve Kit
SM1A-2010M	Sophy® Mini SM1A Medium Pressure Valve Kit
SM1A-2010H	Sophy® Mini SM1A High Pressure Valve Kit

SOPHYSA
At the heart of the brain

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Distribution:

Product Designation

Straight ventricular catheters for CSF drainage from the lateral ventricles of the brain

References

BO19-10 / B019 / B019-20 / B015

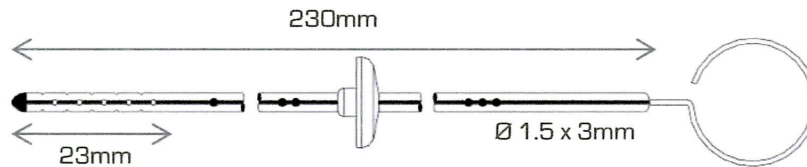
Product Description

Sophysa ventricular catheters are implantable products specifically designed for CSF drainage from the lateral brain ventricles. These catheters are made from silicone. Various models are available.

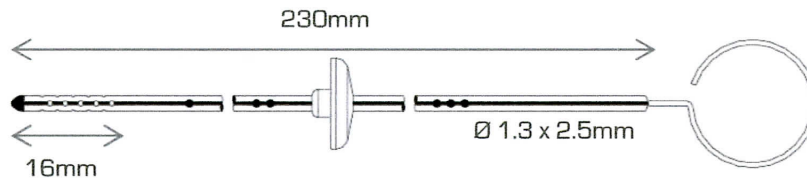
Straight Ventricular catheters

Available in different sizes for both children and adults, they are made of transparent silicone elastomer, with a radiopaque stripe entirely embedded within the silicone wall, and with a tantalum-labelled tip. All models are delivered with right angle adapter and introducing stylet.

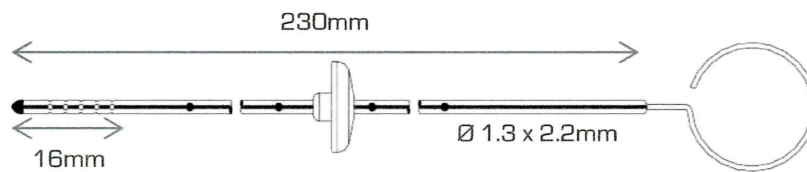
- **Straight Ventricular Catheter (B019)** : radiopaque strip, black length markers at 5, 10, 15cm from the proximal tip.



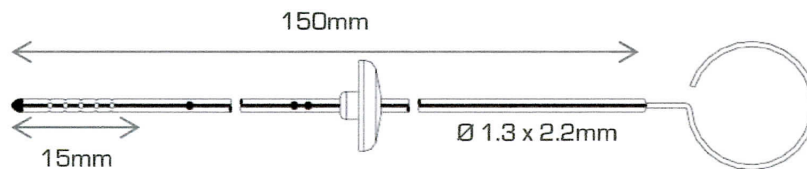
- **Standard Straight Ventricular Catheter (BO19-10)** : radiopaque strip, tantalum-labelled tip, black length markers at 5, 10, 15cm from the proximal tip.



- **Graduated Straight Ventricular Catheter (B019-20)** : radiopaque strip, tantalum-labelled tip, black length markers every cm starting 2cm from the proximal tip.



- **Pediatric Straight Ventricular Catheter (B015)** : radiopaque strip, tantalum-labelled tip, black length markers at 5 and 10cm from the proximal tip.



Composition

- Latex free
- Phthalate free

Catheters	Silicone elastomer	Catheter transparent
	Barium sulphate	Radiopaque stripe
	Tantalum	Catheter tip

Indications

Sophysa ventricular catheters are indicated for the treatment of hydrocephalus, and are intended to drain CSF from lateral ventricles of the brain.

They constitute part of a shunt designed to ensure drainage of cerebrospinal fluid from the ventricles to the Sophysa valve.

Contra-indications

Sophysa ventricular catheters are not designed, sold or proposed for use in any other indication.

CSF shunts are contraindicated in patients treated with anticoagulants or suffering from a haemorrhagic diathesis.

Ventriculo-atrial shunts are contraindicated in the patients with congenital heart disease or other malformations of the cardiopulmonary system.

Implantation of a ventriculo-peritoneal or ventriculo-atrial shunt should be avoided in the presence of infection.

Packaging

• Sophysa ventricular catheters are supplied with an introducer stylet. They are individually packaged in a double sterile packaging.

• 1 box includes:

- ❖ Catheter
- ❖ Introducer stylet
- ❖ Right-angle clip
- ❖ Instructions for use
- ❖ Traceability labels

Reference document

NT112



Sterilization / Expiry date

• Sterilized with ethylene oxide

• Shelf life: 5 years

Cleaning & Decontamination

• Non applicable: Single use product



Classification & Registration

• Europe : Class III - The medical devices are CE marked and meet the essential requirements of the MDD 93/42/EEC amended by the Directive 2007/47.



• USA : Class 2 - According to the FDA, the medical devices are substantially equivalent (for the indication of use stated above) to legally marketed predicate devices, marketed in the USA

Sophysa is ISO 13485 certified.



Product Designation

Distal catheters for CSF drainage from the valve to the right atrium or peritoneal cavities

References

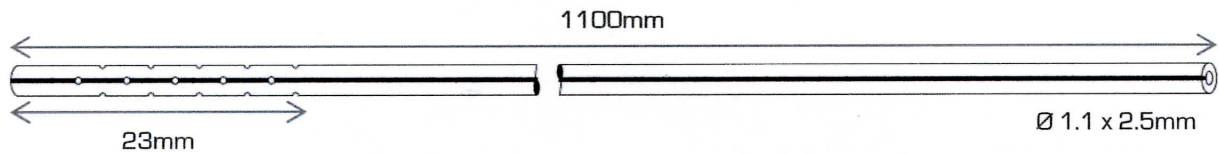
B905S / B905S-10 / B905S-20

Product Description

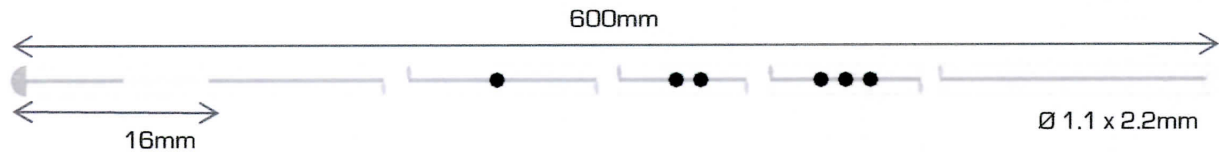
Sophysa atrial/peritoneal catheters are implantable products specifically designed for CSF drainage from the valve to the right atrium of the heart, or to the peritoneal cavity in hydrocephalus cases.

These catheters are made of silicone elastomer and include a radiopaque stripe entirely embedded within silicone wall. The transparency of the catheters allows optimal visualization of the CSF flow. Various models are available.

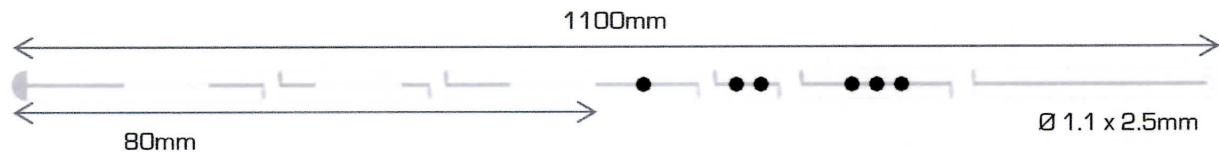
- **Distal atrial/peritoneal catheter (B905S):** Open and multiperforated tip. *Lot 4.3*



- **Anti-reflux atrial catheter (B905S-10):** With an anti-reflux functionality, closed end with lateral non calibrated slits, graduations at 10, 20, 30cm from the distal tip. *Lot 4.2*



- **Anti-reflux peritoneal catheter (B905S-20):** With an anti-reflux functionality, closed end with lateral non calibrated slits, graduations at 10, 20, 30cm from the distal tip.



Composition

- Latex free
- Phthalate free

Catheters	Silicone elastomer	Catheter transparent
	Barium sulphate	Radiopaque stripe
	Tantalum labelled ink	Catheter tip

Indications

Sophysa atrial/peritoneal catheters are indicated for the treatment of hydrocephalus.

They constitute part of a shunt designed to ensure drainage of cerebrospinal fluid from the Sophysa valve to the abdominal cavity or right atrium of the heart.

Contra-indications

Sophysa atrial/peritoneal catheters are not designed, sold or proposed for use in any other indications.

CSF shunts are contraindicated in patients treated with anticoagulants or suffering from a haemorrhagic diathesis.

Ventriculo-atrial shunts are contraindicated in the patients with congenital heart disease or other malformations of the cardiopulmonary system.

Implantation of a ventriculo-peritoneal or ventriculo-atrial shunt should be avoided in the presence of infection.

Packaging

• Sophysa atrial/peritoneal catheters are individually packaged in a double sterile packaging.

• 1 box includes:

- ❖ Catheter
- ❖ Instructions for use
- ❖ Traceability labels

Reference document

NT113



Sterilization / Expiry date

• Sterilized with ethylene oxide

• Shelf life: 5 years

Cleaning & Decontamination

• Non applicable: Single use product



Classification & Registration

• Europe : Class III - The medical devices are CE marked and meet the essential requirements of the MDD 93/42/EEC amended by the Directive 2007/47.

• USA : Class 1 and 2 – According to the FDA, the medical devices are substantially equivalent (for the indication of use stated above) to legally marketed predicate devices, marketed in the USA



Sophysa is ISO 13485 certified.

