

Product Designation

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

References

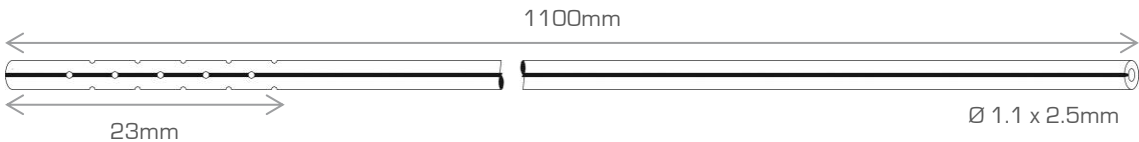
B905S / B905S-10 / B905S-20

Product Description

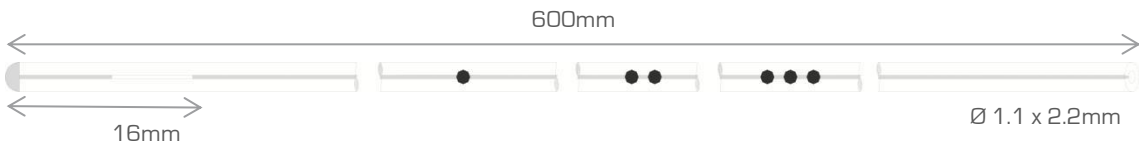
Sophysa atrial/peritoneal catheters are implantable products specifically designed for CSF drainage from the valve to the right atrium of the heart, or to the peritoneal cavity in hydrocephalus cases.

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.

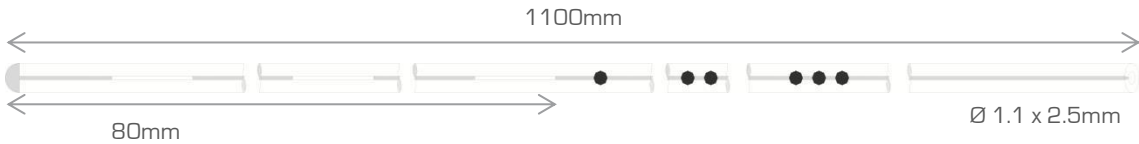
- Distal atrial/peritoneal catheter (B905S): Open and multiperforated tip.



- 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.



- 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.

