

Product Designation

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

References

BO19-10 / BO19 / BO19-20 / BO15

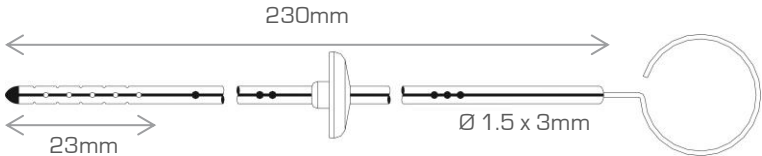
Product Description

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.

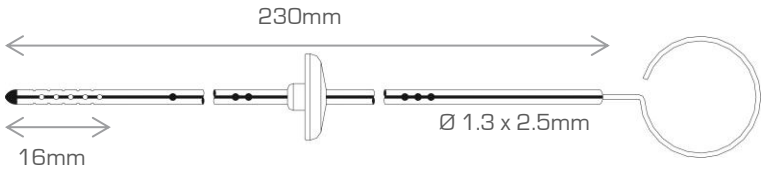
Straight Ventricular catheters

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.

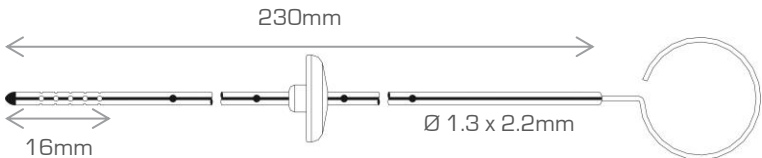
- Straight Ventricular Catheter (BO19) : radiopaque strip, black length markers at 5, 10, 15cm from the proximal tip.



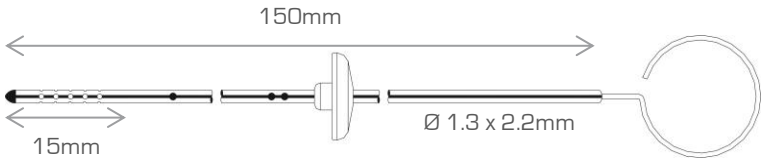
- Standard Straight Ventricular Catheter (BO19-10)** : radiopaque strip, tantalum-labelled tip, black length markers at 5, 10, 15cm from the proximal tip.



- Graduated Straight Ventricular Catheter (BO19-20) : radiopaque strip, tantalum-labelled tip, black length markers every cm starting 2cm from the proximal tip.



- Pediatric Straight Ventricular Catheter (BO15) : 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.

