

TECHNICAL FILE

PVC umbilical catheter

270.06

62.2.2.

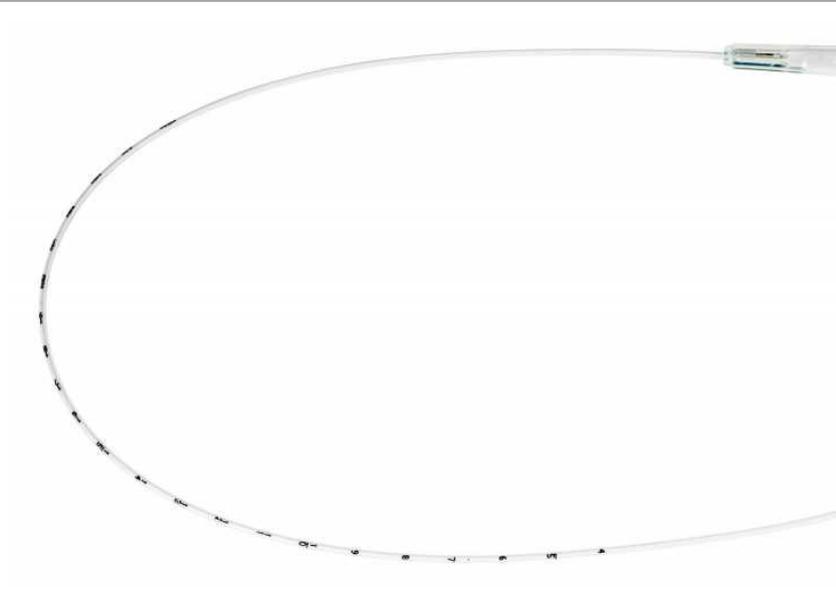
Dated : 30-01-2020

1 Administrative information relating to the company

1.1	Name : Vygon SA	
1.2	Address : 5 rue Adeline - 95440 Ecouen, France	Fax : + 33 (0)1 34 29 19 34 E-mail : questions@vygon.com Website : www.vygon.com
1.3	Medical Device vigilance Representative : Laurent GUILLARDEAU	Tel : +33 (0)1 39 92 65 69 Fax : +33 (0)1 39 92 64 82 E-mail : quality@vygon.com

2 Information about the device or equipment

2.1	Generic name : Umbilical catheter
2.2	Commercial name : PVC umbilical catheter
2.4	Medical Device Class : IIa Applicable EU Directive : 93/42/CEE in accordance with Appendix n° : II Notified body N° : 0459 Medical Device Manufacturer : Vygon
2.5	Description of the device : Catheter in radiopaque and transparent PVC, can be used for umbilical venous catheterisation (parenteral nutrition, drug administration, exchange transfusion, blood sampling...) or for umbilical arterial catheterisation (blood gas analysis, blood pressure measurement...) Distance markings every centimetre from 4 to 25 cm. Open and smoothed distal tip to reduce vascular trauma. Available in 6 catheter diameters: 3.5* - 4 - 5 - 6 - 7 and 8 Fr Length: 37 cm * to be ordered under code 270.03



2.6 Packaging / Containers

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
270.06	1 (Supple blister pack)	15 (Carton box)	15 (Carton box)	225 (Carton box)

Single unit packaging

REF 270.06 6Fr - L. 37cm - 52ml/min - PVC **VYCON**
Value Life

ORX / XRO / XRC Code ACL 7158313

Umbilical catheter / Cathéter ombilical /
Catéter umbilical / Nabelkatheter / Catetere ombilicale /
Umbilicale katheter / Cateter umbilical / Navelkatetrar

Rx Only        0459 

USA only   5°C (41°F)  43°C (104°F)

VYCON - 5 rue Adeline 95440 Ecoeur - FRANCE

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(01)X3660812XXXXX(17)XXXXX(30)XXXX(10)XXXXXXXX

Box

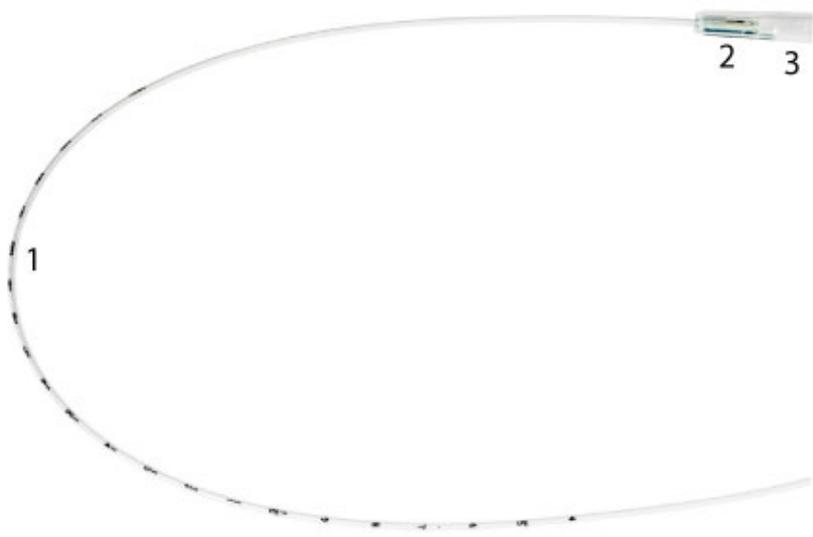


Technical features :

Code	Catheter				
	Length cm	Ext. Ø mm	Ø Fr	Flow rate ml/min	Prim. vol. ml
270.06	37	2.00	6	52	0.51

2.7 Composition of the device and Accessories : 270.06

COMPONENTS	MARKER	MATERIALS
Catheter	1	PVC
Hub	2	PVC
Obturator	3	PE
Protector		PE

	 <p>For components which are likely to come into contact with the patient and/or administered products, additional points : Latex-free DEHP-free Does not contain any products of animal or biological origin Pyrogen-free</p>
2.8	<p>Indications : Catheter inserted in the umbilical vein or in the umbilical artery of the newborn. Umbilical venous catheter are used in case of neonatal emergency, for a short period of time (few days). It allows: the infusion of parenteral nutrition, the administration of drugs, exchange - transfusion...) The umbilical arterial catheter is used in case of neonatal emergency for blood gas monitoring, blood pressure measurement...</p>

3 Accessories

4 Sterilization process

	<p>Sterile Medical Device : YES 62.2.2. Sterilus Sterilization made for the device : Ethylene oxide</p>
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5 Conditions of conservation and storage

5.1	<p>Normal conservation and storage conditions : Storage environment temperature: between 5 and 40°C. Store protected from moisture and sunlight.</p>
5.2	<p>Special precautions : Please refer to the IFU in the packaging.</p>
5.3	<p>Duration of product validity : 60 months</p>

6 Security of use

Technical security :
Please refer to the IFU in the packaging.

7 Instructions for use

7.1 Instructions :
Please refer to the IFU in the packaging.

7.2 Indications :
Catheter for venous or arterial umbilical catheterization

7.3 Precautions :
Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reaction or bacterial infections.

Please refer to the IFU in the packaging.

7.4 Contra indications :
Omphalitis, omphalocele, peritonitis ...

8 Additional information relating to the product

Do not use this product for monitoring, diagnosis, control or treatment of a defect of the heart or the central venous system.