

## TECHNICAL FILE

### PVC umbilical catheter

270.08

Dated : 30-01-2020

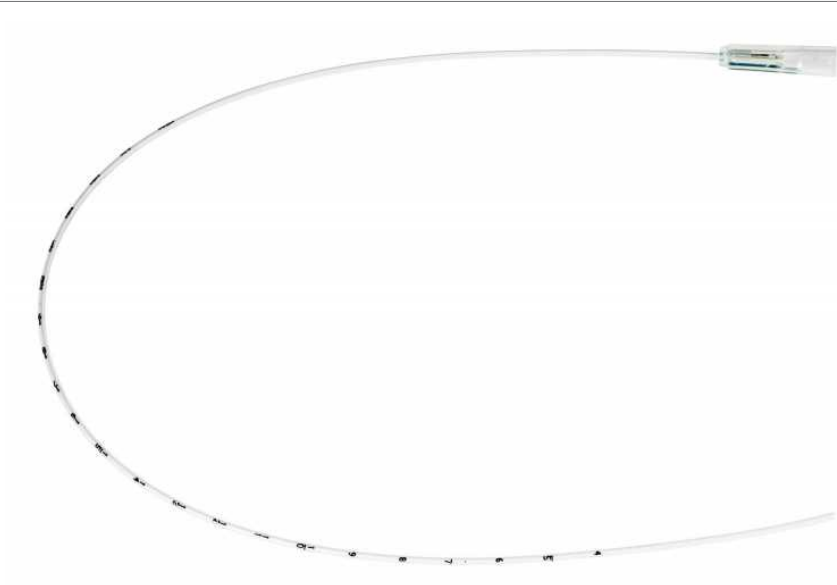
62.3.2.

#### 1 Administrative information relating to the company

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

#### 2 Information about the device or equipment

2.1	<b>Generic name :</b> Umbilical catheter
2.2	<b>Commercial name :</b> PVC umbilical catheter
2.4	<b>Medical Device Class :</b> IIa <b>Applicable EU Directive :</b> 93/42/CEE <b>in accordance with Appendix n° :</b> II <b>Notified body N° :</b> 0459 <b>Medical Device Manufacturer :</b> Vygon
2.5	<b>Description of the device :</b> 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



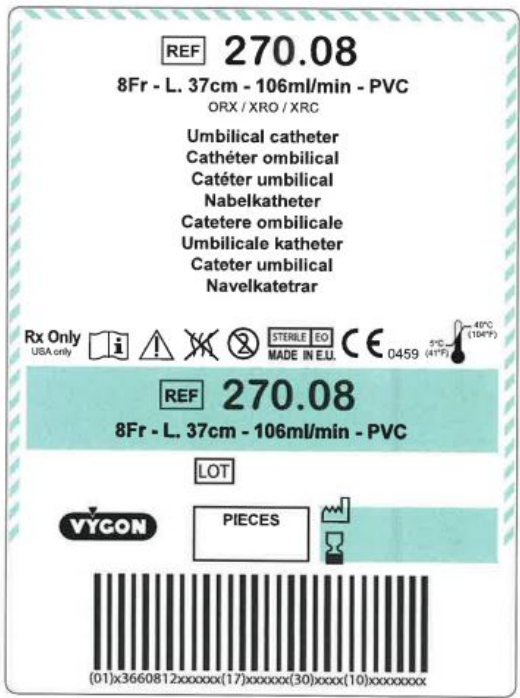
**2.6 Packaging / Containers**

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
270.08	1 (Supple blister pack)	15 (Carton box)	15 (Carton box)	225 (Carton box)

**Single unit packaging**



**Box**

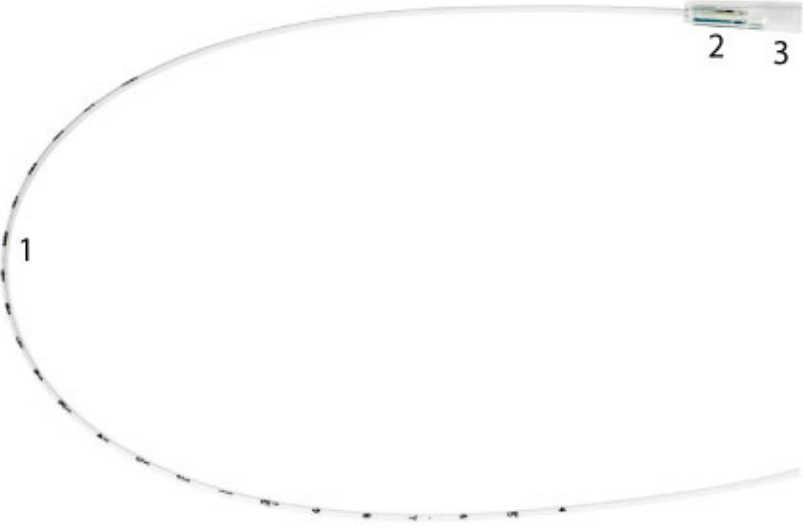


**Technical features :**

Code	Catheter				
	Length cm	Ext. Ø mm	Ø Fr	Flow rate ml/min	Prim. vol. ml
270.08	37	2.50	8	106	0.75

**2.7 Composition of the device and Accessories : 270.08**

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

	 <p><b>For components which are likely to come into contact with the patient and/or administered products, additional points :</b>          Latex-free          DEHP-free          Does not contain any products of animal or biological origin          Pyrogen-free</p>
2.8	<p><b>Indications :</b>          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><b>Sterile Medical Device :</b> YES      <b>62.3.2. Sterilus</b>  <b>Sterilization made for the device :</b> Ethylene oxide</p>
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### 5 Conditions of conservation and storage

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

## 6 Security of use

	<b>Technical security :</b> Please refer to the IFU in the packaging.
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## 7 Instructions for use

7.1	<b>Instructions :</b> Please refer to the IFU in the packaging.
7.2	<b>Indications :</b> Catheter for venous or arterial umbilical catheterization
7.3	<b>Precautions :</b> 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	<b>Contra indications :</b> 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.
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