

## TECHNICAL FILE

PVC feeding tube

310.06

Dated : 26-11-2018

### 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	
2.2	<b>Commercial name :</b> PVC feeding tube
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> PVC feeding tube for neonatal / paediatric use with closed distal tip, 2 lateral eyes, radiopaque line and markings every centimetre from 5 to 35 cm. Feeding tube of French size 4 Fr, 5 Fr, 6 Fr and 7 Fr are 40 cm long; feeding tubes of French size 8 Fr, 9 Fr, 10 Fr and 12 Fr are 50 cm long. The proximal end of the feeding tube features a female flexible mount with cap to seal the tube when it is not being used (all sizes except 12 Fr feeding tube). The proximal end of the 12 Fr feeding tube is a funnel connector without cap. The female flexible mount with cap is colour-coded according to the diameter of the tube.  Recommended duration of use: up to 5 days



**2.6 Packaging / Containers**

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
310.06	1 (Supple blister)	50 (Carton box)	50 (Carton box)	600 (Carton box)

**Single unit packaging**

REF **310.06** 06Fr - L.40cm - PVC Code ACL 6281365

ORX-XRO-RXC

Enteral feeding tube / Sonde de nutrition enterale / Sonda para alimentaci3n enteral / Ernahrungssonde / Sonde per alimentazione enterale / Voedingssondes / Sonda de alimentac3o enteral / Malningssond

Rx Only

CE 0459

VYGON - 3 rue d'Alsace - 92400 Courcouronnes - FRANCE

XX XX XX XX XXXX XX

(01)310608120000011700000013000001100000000

**Box**

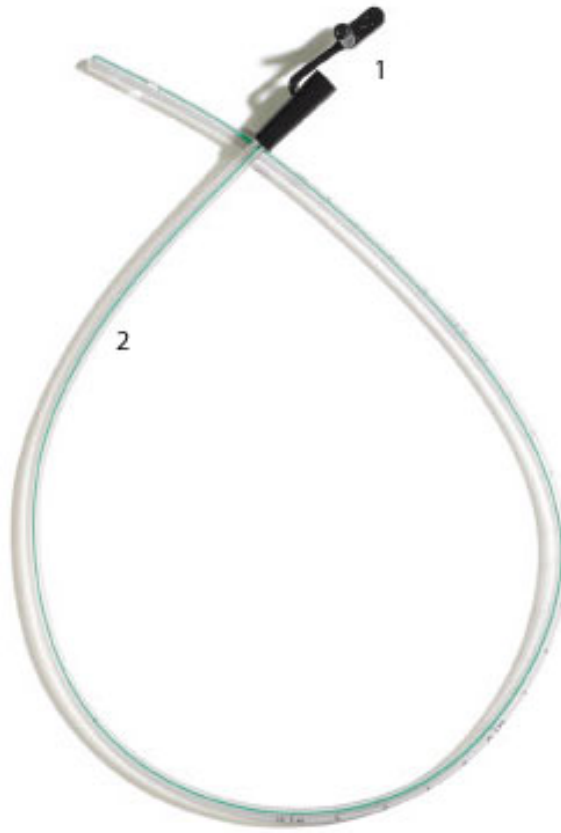


**Technical features :**

Code	Tube					Colour code
	Length cm	Int. Ø mm	Ext. Ø mm	Diameter Fr	Priming volume ml	- colour
310.06	40	1.20	2.00	6	0.48	Green

**2.7 Composition of the device and Accessories : 310.06**

COMPONENTS	MARKER	MATERIALS
Flexible mount with cap	1	PVC
Tubing	2	PVC



**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

**2.8 Indications :**  
PVC naso-gastric feeding tube for short-term enteral nutrition.

### 3 Accessories

### 4 Sterilization process

**Sterile Medical Device :** YES  
**Sterilization made for the device :** Ethylene oxide

### 5 Conditions of conservation and storage

<b>5.1</b>	<b>Normal conservation and storage conditions :</b> Storage environment temperature: between 5 and 40°C. Store protected from moisture and sunlight.
<b>5.2</b>	
<b>5.3</b>	<b>Duration of product validity :</b> 60 months

## 6 Security of use

## 7 Instructions for use

<b>7.1</b>	
<b>7.2</b>	<b>Indications :</b> PVC naso-gastric feeding tube for short-term enteral nutrition.
<b>7.3</b>	<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.
<b>7.4</b>	

## 8 Additional information relating to the product

	Recommended duration of use: less than 1 week. Because of the migration of the PVC softeners in contact with gastric juices, the tube becomes more and more rigid.
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