

TECHNICAL FILE

PVC feeding tube

310.10

5.

Dated : 07-10-2022

1 Administrative information relating to the company

1.1	Name : Vygon	
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	
2.2	Commercial name : PVC feeding tube
2.4	Medical Device Class : IIa Applicable regulation : 93/42/CEE in accordance with Appendix n° : II Notified body N° : 0459 Medical Device Manufacturer : Vygon
2.5	Description of the device : 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 4Fr, 5Fr, 6Fr and 7Fr are 40 cm long; feeding tubes of French size 8Fr, 10Fr and 12Fr 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 12Fr feeding tube). The proximal end of the 12Fr 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
310.10	1 (Supple blister)	50 (Carton box)	50 (Carton box)	600 (Carton box)

Single unit packaging

REF **310.10** 10Fr - L.50cm - PVC Code ACL 6237134

ORX-XRO-RXC

Enteral feeding tube / Sonde de nutrition entérale / Sonda para alimentación enteral / Ernährungssonde / Sonda per alimentazione enterale / Voedingssondes / Sonda de alimentação enteral / Matningssond

Rx Only

MADE IN CHINA

CE 0159

VYGON - 3 rue Alfred Thiers - Evreux - FRANCE



XX XX XX XX XXXX XX



(01) x3660812xxxxxx(17) xxxxxx(30) xxxxx(10) xxxxxxxx



Technical features :

Code		Tube			Colour code
	Length cm	Int. Ø mm	Ext. Ø mm	Diameter Fr	- colour
310.10	50	2.00	3.30	10	Black

2.7 Composition of the device and Accessories :

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

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

6 Security of use

7 Instructions for use

7.1	
7.2	Indications : PVC naso-gastric feeding tube for short-term enteral nutrition.
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.
7.4	

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.
--	--