

TECHNICAL FILE

Tubaflex gastric tube

390.14

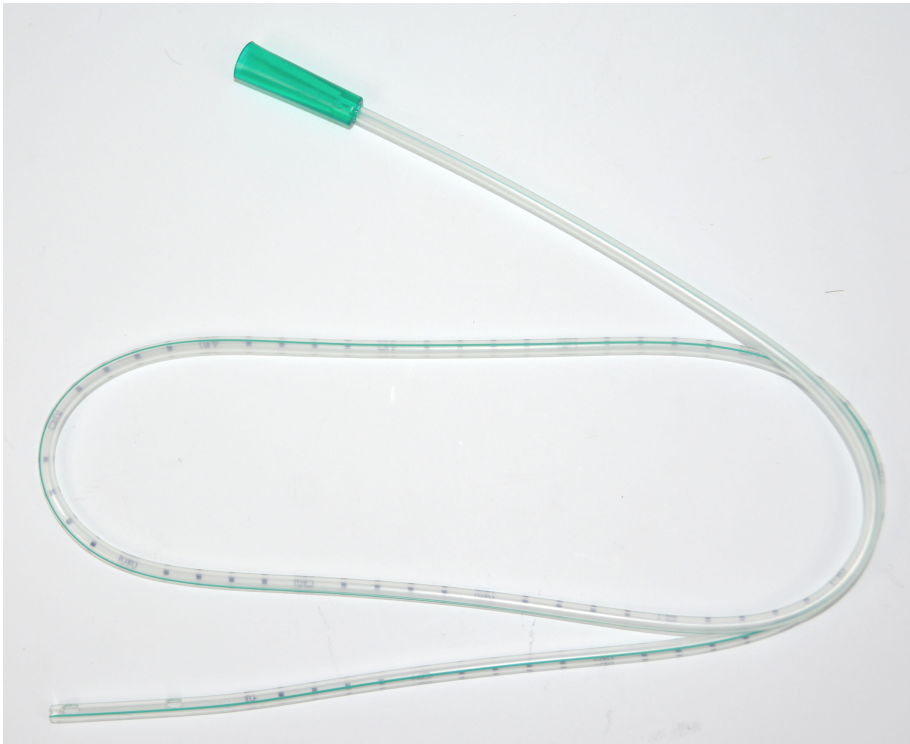
Dated : 06-01-2021

1 Administrative information relating to the company

1.1	Name : Vygon SAS	
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 : Tubaflex gastric tube
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 : Transparent and radiopaque gastric tube in PVC for children and adults with open and smoothed distal end and 4 lateral eyes. Tubaflex is 100 cm long and with centimetric graduations from 5 to 75 cm. The proximal connector of Tubaflex in size 12 Fr, 14 Fr, 16 Fr, 18 Fr and 21 Fr is a flexible funnel without cap. The proximal connector of Tubaflex in size 10 Fr is a flexible female mount with a cap.



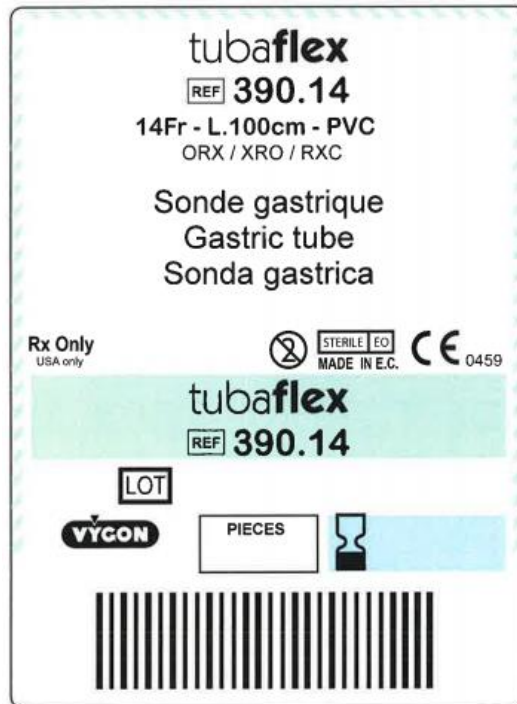
2.6 Packaging / Containers

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
390.14	1 (Peel-pack)	50 (Carton box)	50 (Carton box)	300 (Carton box)

Single unit packaging



Box

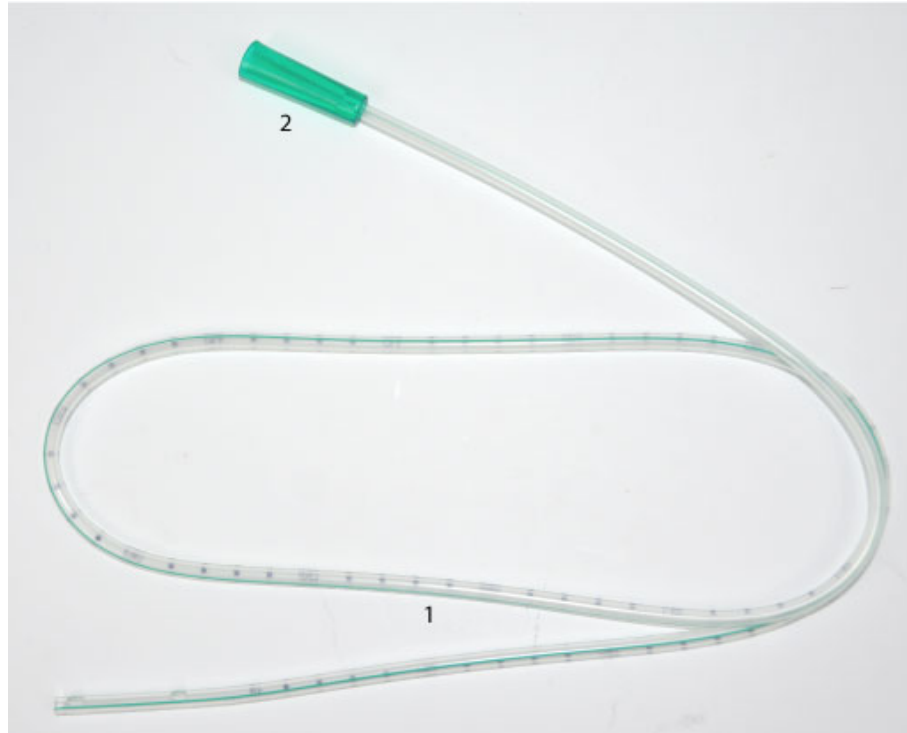


Technical features :

Code	Tube	
	Length cm	Diameter Fr
390.14	100	14

2.7 Composition of the device and Accessories : 390.14

COMPONENTS	MARKER	MATERIALS
Tube	1	PVC
Proximal connector	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 gastric tube for short-term enteral feeding or gastric sampling.

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 Special precautions :**
Please refer to the IFU in the packaging.
- 5.3 Duration of product validity :** 60 months

6 Security of use

	Technical security : Please refer to the IFU in the packaging.
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7 Instructions for use

7.1	Instructions : Please refer to the IFU in the packaging.
7.2	Indications : Gastric tube for feeding, gastric samplings/aspiration, lavage ...
7.3	Precautions : Please refer to the IFU in the packaging. 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