

TECHNICAL FILE

Tracheostomy tube with low pressure cuff

523.33

Dated : 03-01-2022

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	Generic name : Tracheostomy tube	
2.2	Commercial name : Tracheostomy tube with low pressure cuff	
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 : Tracheostomy tube transparent PVC tube with radiopaque line and low-pressure cuff. Adjustable collar and tape. This device is available in 5 sizes: 26Fr, 30Fr, 33Fr, 38Fr and 40Fr.	



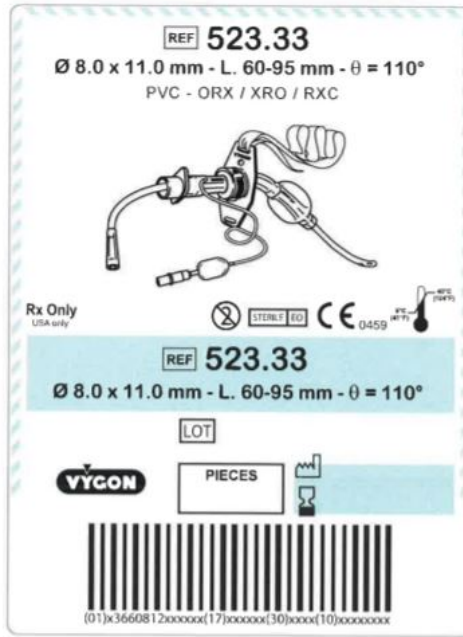
2.6 Packaging / Containers

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
523.33	1 (Supple blister)	1 (Carton box)	1 (Carton box)	90 (Case box)

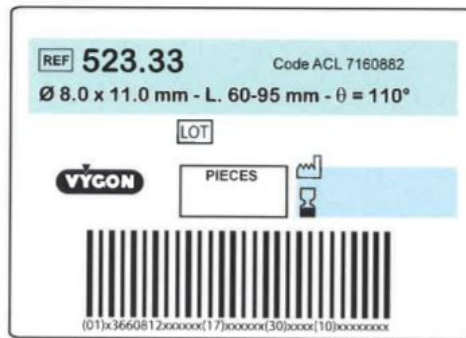
Single unit packaging



Box



Case labelling

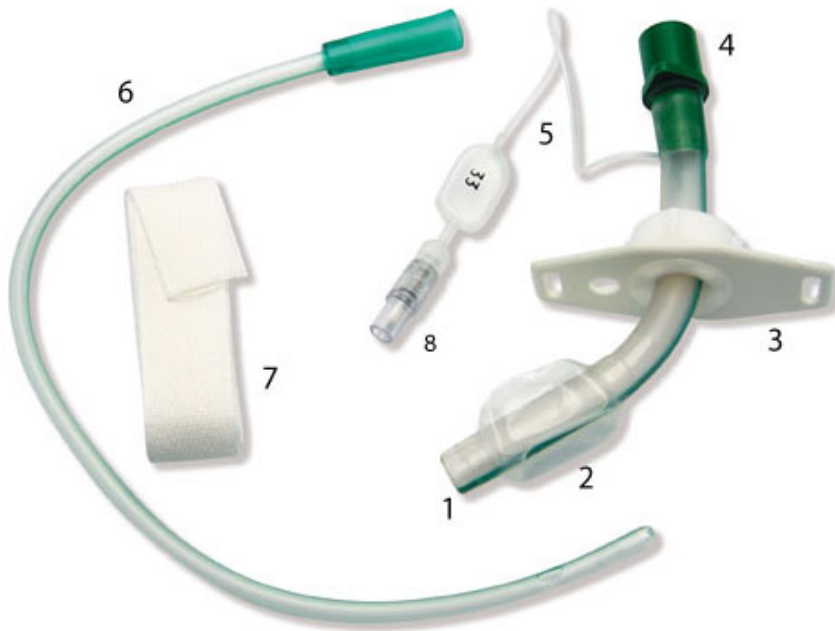


Technical features :

Code	Tube				
	Range of lengths mm	Int. Ø mm	Ext. Ø mm	Traditional size Fr	Curve Degree
523.33	60-95	8	11	33	110

2.7 Composition of the device and Accessories :

COMPONENTS	MARKER	MATERIALS
Canula tube	1	PVC
Cuff	2	PVC
Flange	3	PA
Nut	3	POM
Adapter	4	ABS
Inflation line	5	PVC
Tube / funnel	6	PVC
Tape	7	Polyester
Anti-return valve	8	Stain. steel/PVC/UP/Nitrile



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 :
Tracheostomy

3 Accessories

4 Sterilization process

	<p>Sterile Medical Device : YES</p> <p>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	
5.3	<p>Duration of product validity : 60 months</p>

6 Security of use

7 Instructions for use

7.1	
7.2	<p>Indications : Tracheostomy</p>
7.3	<p>Precautions : Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reaction or bacterial infections.</p>
7.4	

8 Additional information relating to the product