

TECHNICAL FILE

Control suction tube

535.06

Dated : 12-08-2019

1 Administrative information relating to the company

1.1	Name : Vygon SA	
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 : Control suction 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 : Tracheal and bronchial suction catheter. Open tip. Proximal connector with lateral eye for finger tip control (with integral closing cap). Fr 4 – 5 – 6 – 7 – 8 – 10: with 2 lateral eyes Centimetre graduations from 5 to 20 cm. Length 29 cm Fr 12 – 14 – 16 – 18: no lateral eyes Centimetre graduations from 5 to 20 cm. Length 42 cm



2.6 Packaging / Containers

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
535.06	1 (Supple blister)	50 (Carton box)	50 (Carton box)	450 (Case box)

Single unit packaging

	<p>REF 535.06 Ø2.0 mm - 06Fr - L.290 mm PVC - ORX / XRO / RXC Control suction catheter / Sonde pour aspiration contrôlée Sonda para aspiración controlada / Absaugkatheter mit Sogregulierung Sonda per aspirazione controllata / Regelbare aspirationsonde Sonda para aspiração controlada / Sugkateter med regelbart sug</p> <p>VYCON - 5 rue Adeline 95440 Ecouen - FRANCE</p>	<p>PVC - ORX / XRO / RXC Code ACL 7161433</p> <p>VYCON Value Life</p> <p>Rx Only USA only</p> <p>STERILE EO MADE IN E.C. CE 0459</p>
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Box

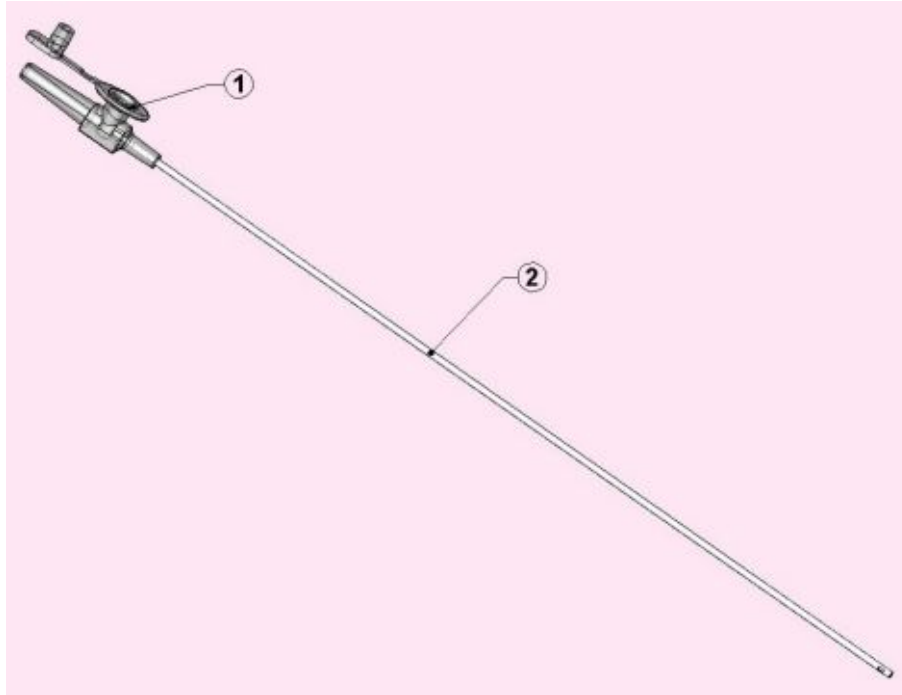


Technical features :

Code	Tube	
	Length cm	Ext. Ø Fr
535.06	29	6

2.7 Composition of the device and Accessories : 535.06

COMPONENTS	MARKER	MATERIALS
Connector	1	PVC
Tube	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 :
Tracheal and bronchial suction catheter with connector for finger-tip suction control

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 : Tracheal and bronchial suction catheter with connector for finger-tip suction control
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