

TECHNICAL FILE

Paediatric soft endotracheal tube

5520.25

27.

Dated : 22-02-2023

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 : Plain endotracheal tube
2.2	Commercial name : Paediatric soft endotracheal 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 : The paediatric endotracheal tubes without cuff (code 5520.xx) consist of: - a green soft PVC tube with radio-opaque line and a secondary lumen within the wall of the tube. This secondary lumen is for tracheal injection (e.g. delivery of surfactant) or airway pressure monitoring. The secondary lumen does not reduce the main lumen of the endotracheal tube. The distal end of the tube is bevelled by 38°. They have a 17mm intubation depth mark at the distal end. There are half-centimetre markings from 3 to 13cm on codes 5520.20 / 5520.25 / 5520.30 / 5520.35 and markings every centimetre from 9 to 21cm for codes 5520.40 and 5520.45. - a lateral port with PVC tubing and female Luer-lock hub for surfactant delivery. - a 15mm standard adaptor to connect the endotracheal tube to the ventilator.



2.6 Packaging / Containers

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
5520.25	1 (Supple blister)	20 (Box)	20 (Box)	240 (Case)

Single unit packaging



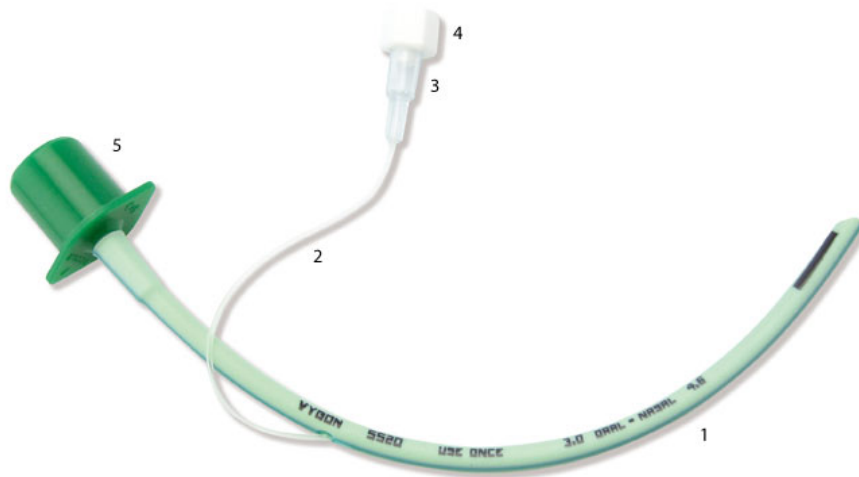
Box

Technical features :

Code		Tube			Secondary lumen	
	Length mm	Int. Ø mm	Ext. Ø mm	Ø mm	Flow rate ml/min	
5520.25	165	2.5	4.1	0.55	3.35	

2.7 Composition of the device and Accessories :

COMPONENTS	MARKER	MATERIALS
Tube	1	PVC
Lateral tube	2	PVC
Female Luer-lock hub	3	ABS
Cap	4	PE
Adaptor	5	PP
Adaptor (only 5520.45)	5	ABS



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 :

The endotracheal tubes without cuff are introduced orally or nasally into the trachea of a newborn, infant or child when it is considered that the use of a endotracheal tube with cuff could result in these patients with severe tracheal lesions.

They are used to compensate a failure of breathing in general anesthesia, intensive care, resuscitation ... They are, most often, connected to an artificial respirator assisting the patient whose spontaneous breathing is insufficient or impossible.

The additional lumen allows tracheal instillation (eg surfactant) or control of airway pressures.

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	<p>Indications :</p> <p>The endotracheal tubes without cuff are introduced orally or nasally into the trachea of a newborn, infant or child when it is considered that the use of a endotracheal tube with cuff could result in these patients with severe tracheal lesions.</p> <p>They are used to compensate a failure of breathing in general anesthesia, intensive care, resuscitation ... They are, most often, connected to an artificial respirator assisting the patient whose spontaneous breathing is insufficient or impossible.</p> <p>The additional lumen allows tracheal instillation (eg surfactant) or control of airway pressures.</p>
7.3	<p>Precautions :</p> <p>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

	<p>The use of a similar endotracheal tube (code 5516) for surfactant administration is described in:</p> <p>"A Randomized Comparison of Surfactant Dosing via a Dual-lumen Endotracheal tube in Respiratory Distress Syndrom", Adoll Valls-i-Soler et al., Pediatrics, 1998, vol. 101</p>
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