

TECHNICAL FILE

Lectroflex
220.010

Dated : 22-02-2023

1 Administrative information relating to the company

1.1	Name : Vygon	
1.2	Address : 5 rue Adeline - 95440 Ecoen, 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 : Extension tube for I.V. catheters
2.2	Commercial name : Lectroflex
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 : Triple-layer extension tube (PVC/EVA/PE)* for IV catheters with 1 male Luer-lock end and 1 female Luer-lock end. Diameter: 2,5 x 4,0 mm - Pressure tested at 10 kg/cm ² (145 PSI) Available in 7 lengths : 13.5 cm (code 220.010), 25 cm (code 220.020), 50 cm (code 220.050), 70 cm (code 220.070), 100 cm (code 220.100), 150 cm (code 220.150) and 200 cm (code 220.200). *See additional information.



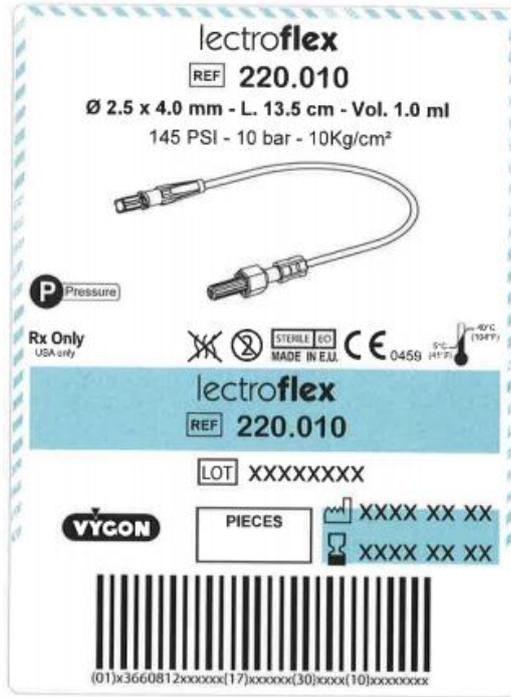
2.6 Packaging / Containers

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
220.010	1 (Supple blister)	25 (Carton box)	25 (Carton box)	300 (Case)

Single unit packaging



Box



Technical features :

Code	Extension tube			
	Length cm	Int. Ø mm	Ext. Ø mm	Prim. vol. ml
220.010	13.5	2.5	4.0	1.0

2.7 Composition of the device and Accessories :

COMPONENTS	MARKER	MATERIALS
Female end	1	PC
Tube	2	PE / EVA / PVC
Male end	3	PC
Male locking device	4	PC
Cap		PE
Protector		PE



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
- Pyrogen-free

2.8 Indications :
Add-on device for IV catheters: extension tube.

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 : Add-on device for IV catheters: extension tube.
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

	<p>PE lined PVC extension tube.</p> <p>This extension tube is made of 3 layers. The outer layer is in PVC, the inner layer is in Polyethylene without additives, material presenting a high chemical inertness and the intermediate layer is Ethyl Vinyl Acetate, material linking the inner and the outer layers.</p> <p>This structure allows to minimize interactions with drugs and leaching of plasticizers from the PVC into the administered solutions.</p>
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