

TECHNICAL FILE

Lectroflex
220.050

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

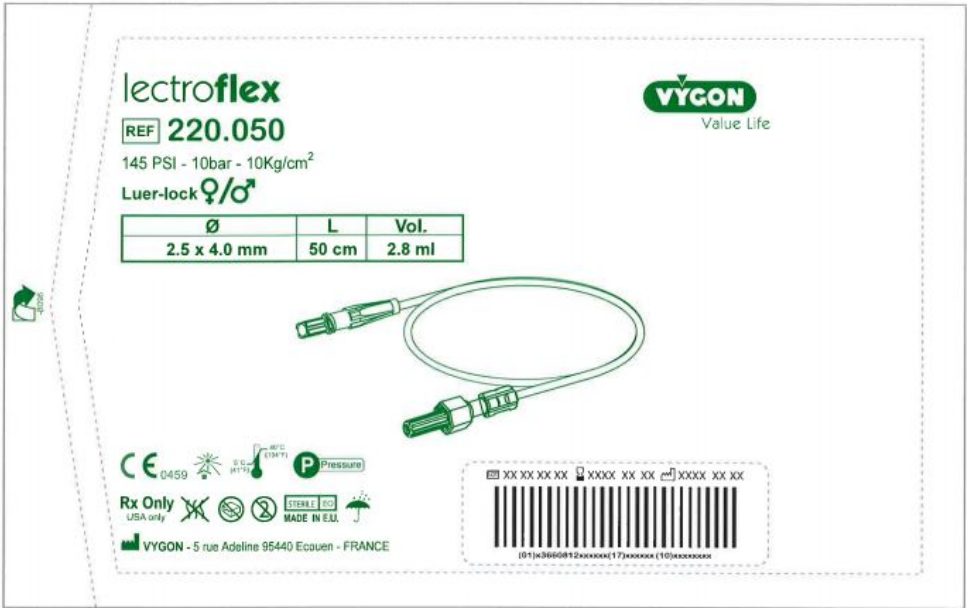
2.1	Generic name : Extension tube for I.V. catheters
2.2	Commercial name : Lectroflex
2.4	Medical Device Class : IIa Applicable regulation : 93/42/CEE in accordance with Appendix n° : II Notified body N° : 0459 Medical Device Manufacturer : Vygon
2.5	Description of the device : Triple-layer extension 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.



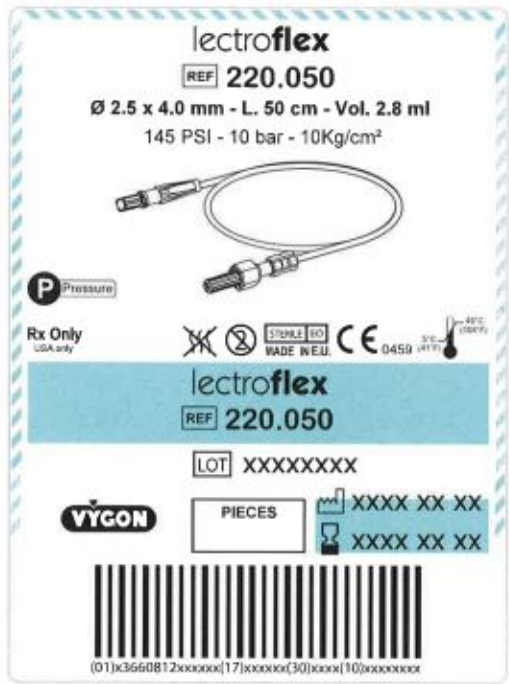
2.6 Packaging / Containers

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
220.050	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
220.050	50	2.5	4.0	2.80

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

Special precautions :

Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reaction or bacterial infections.

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

	PE lined PVC extension tube. 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. This structure allows to minimize interactions with drugs and leaching of plasticizers from the PVC into the administered solutions.
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