

TECHNICAL FILE

Male Luer-lock to male Luer-lock extension tube

221.200

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	
2.2	Commercial name : Male Luer-lock to male Luer-lock extension 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 : Triple layer extension tube (PVC/EVA/PE)* for IV catheters with two male Luer-lock ends. Available in 4 lengths: 50 cm (code 221.050), 100 cm (code 221.100), 150 cm (code 221.150) and 200 cm (code 221.200). Diameter: 2.5 x 4.0 mm. Pressure tested at 10 kg/cm ² (145 psi). *See additional information.



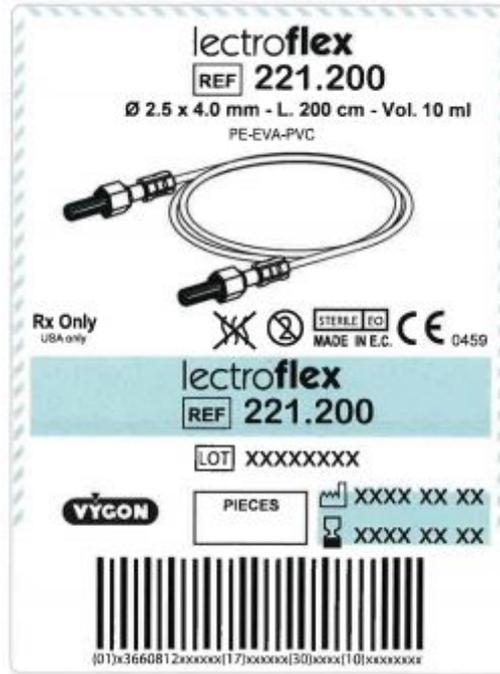
2.6 Packaging / Containers

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
221.200	1 (Supple blister pack)	25 (Box)	25 (Box)	150 (Case)

Single unit packaging



Box

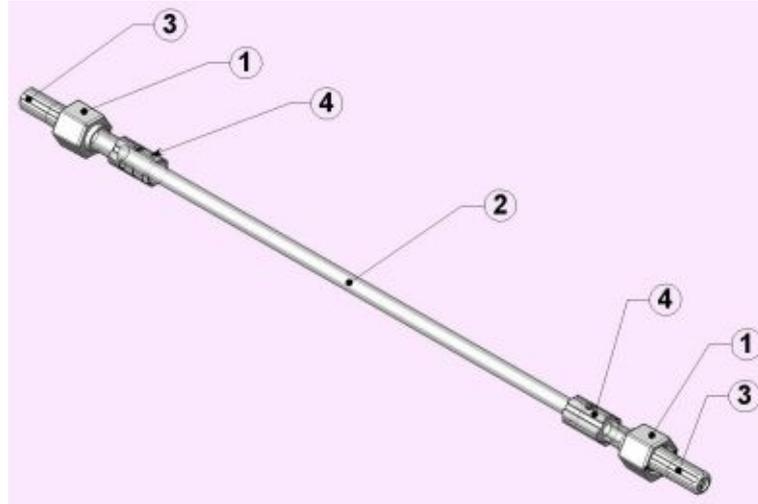


Technical features :

Code	Extension tube			
	Length cm	Int. Ø mm	Ext. Ø mm	Prim. vol. ml
221.200	200	2.5	4.0	10.00

2.7 Composition of the device and Accessories :

COMPONENTS	MARKER	MATERIALS
Male rotating device	1	PC
Tube	2	PE / EVA / PVC
Cap	3	PE
Hub	4	PC



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 intravenous catheter - Catheter extension tube
 Example of use: I.V. catheter - Extension tube code 221 - Ramp of stopcocks with female/female Luer-lock ends.

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 intravenous catheter - Catheter 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.