

TECHNICAL FILE

Polyethylene extension tube

71100.20

Dated : 06-04-2022

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 : Polyethylene 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 : Extension tube for intravenous catheter, or arterial catheter with male Luer-lock / female Luer-lock ports. Extension tube for syringe pumps. This extension tube is recommended for the administration of solutions or drugs which give rise to interactions with PVC (adsorption, absorption, migration of plasticizers). Tested at 40 bar (580 PSI) The extension tubes code 71100.xx have an internal / external diameter of 1.0 x 2.0 mm. The extension tubes code 71101.xx have an internal / external diameter of 1.5 x 2.5 mm.



2.6 Packaging / Containers

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
71100.20	1 (Supple blister pack)	50 (Carton box)	50 (Carton box)	300 (Carton box)

Single unit packaging



Box



Technical features :

Code	Extension tube				
	Length cm	Int. Ø mm	Ext. Ø mm	Flow rate ml/min	Prim. vol. ml
71100.20	200	1.0	2.0	11	2.0

2.7 Composition of the device and Accessories :

COMPONENTS	MARKER	MATERIALS
Protector	1	PE
Male Luer-lock connector	2	PE
Tube	3	PE
Female Luer-lock connector	4	PE
Male stopper	5	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 :
 Polyethylene extension tube for intravenous or arterial catheter.
 Extension tube for syringe-pumps.

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	
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