

TECHNICAL FILE

Male Luer-lock obturator

886.00

Dated : 06-01-2021

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 obturator
2.4	Medical Device Class : I Applicable regulation : 93/42/CEE in accordance with Appendix n° : Vs Notified body N° : 0459 Medical Device Manufacturer : Vygon
2.5	Description of the device : Polyethylene male Luer-lock obturator. It can be used to close any female Luer-lock port of a catheter, extension tube, stopcock, ramp of stopcocks etc...

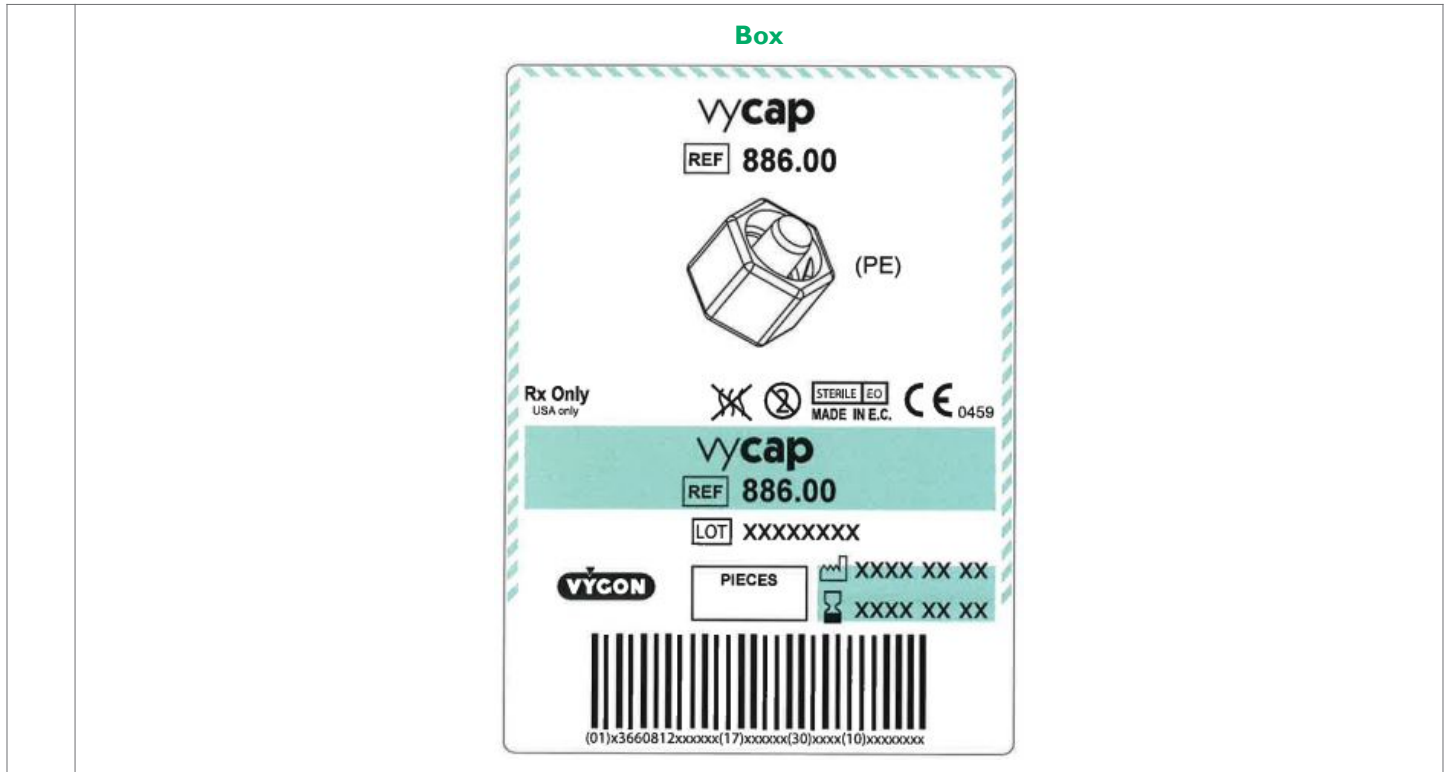


2.6 Packaging / Containers

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
886.00	1 (Supple blister pack)	100 (Carton box)	100 (Carton box)	4800 (Carton box)

Single unit packaging





2.7 Composition of the device and Accessories :

COMPONENTS	MARKER	MATERIALS
Stopper	1	PE



2.8 Indications :

Add-on device for I.V. catheters. This stopper can be used to close any female Luer-lock port (e.g. on I.V. catheters, extension lines, stopcocks, ramps of stopcocks etc...).

3 Accessories

4 Sterilization process

<p>Sterile Medical Device : YES Sterilization made for the device : Ethylene oxide</p>

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

	Technical security : EN 20594/Part 1 EN 1707/Part 2
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7 Instructions for use

7.1	
7.2	Indications : Add-on device for I.V. catheters. This stopper can be used to close any female Luer-lock port (e.g. on I.V. catheters, extension lines, stopcocks, ramps of stopcocks etc...).
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