

TECHNICAL FILE

Vyclic 3-way stopcock

70876.20


Dated : 06-01-2021

33.

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 : Three-way stopcock
2.2	Commercial name : Vyclic 3-way stopcock
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 : Lipid-resistant three-way stopcock with one male Luer-lock port and two female Luer-lock ports. All Luer-lock ports are protected by a cap to avoid touch contamination after opening the blister pack. Features of the product: - "Clic for security": the user feels digitally the position chosen. - Safety Luer-lock connector preventing accidental disconnections - Code 876.20 is supplied with identification caps : . blue for venous use . red for arterial use Vyclic meets the requirements of ISO norm 8536-10 : tested at 2 bar during 15 minutes. Codes 876.20/21 : white stopcock with identification caps (red and blue) Code 70876.20: white stopcock without identification caps Code 70876.22 : blue stopcock Code 70876.23 : red stopcock
	

2.6	Packaging / Containers				
	Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
	70876.20	1 (Supple blister pack)	50 (Carton box)	50 (Carton box)	600 (Carton box)

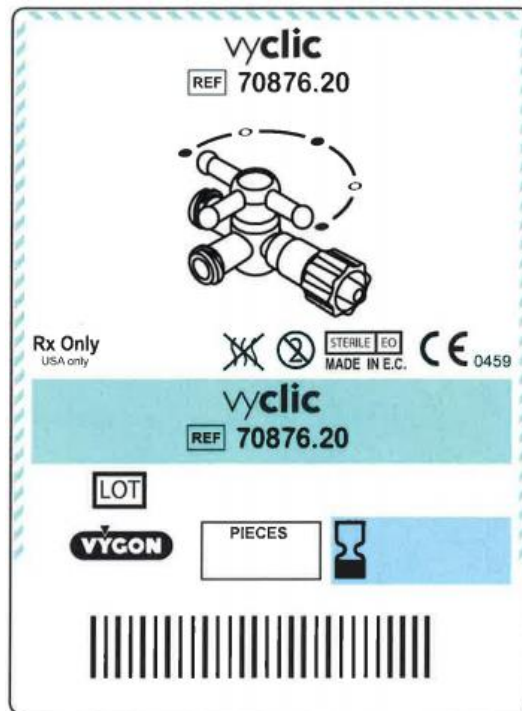
Single unit packaging



Box



Case labelling

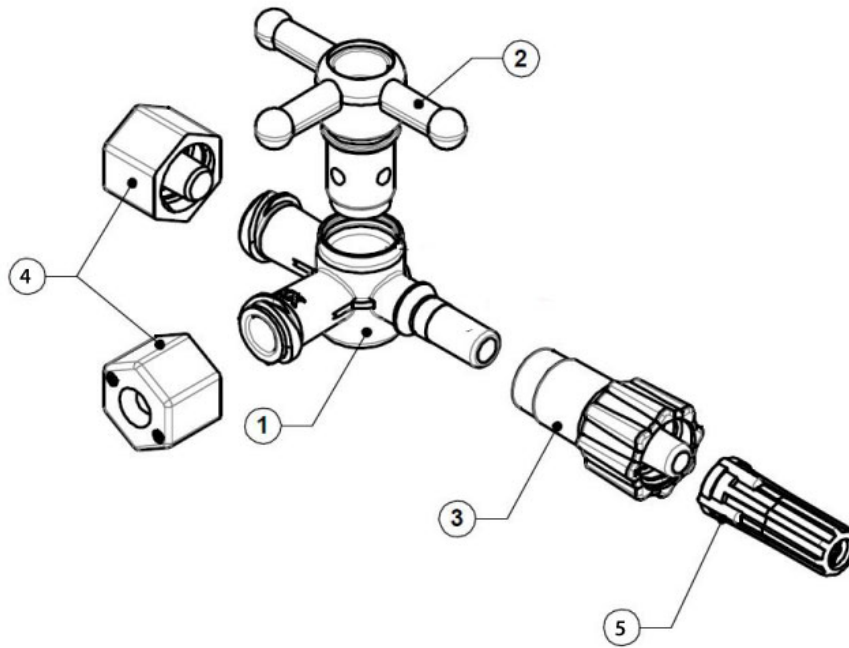


Technical features :

Code	Stopcock
	Priming volume ml
70876.20	0.24

2.7 Composition of the device and Accessories :

COMPONENTS	MARKER	MATERIALS
Body of stopcock	1	PC
Key	2	POM
Male locking collar	3	PP
Cap	4	PE
Protector	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 :

The Vyclic 3-way stopcock is mainly intended as an accessory for I.V. catheters (simultaneous infusions, drug injections, blood sampling ...).

It can also be used in an arterial line for blood sampling and arterial pressure monitoring.

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

	Technical security : ISO 8536-10
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7 Instructions for use

7.1	
7.2	Indications : The Vyclic 3-way stopcock is mainly intended as an accessory for I.V. catheters (simultaneous infusions, drug injections, blood sampling ...). It can also be used in an arterial line for blood sampling and arterial pressure monitoring.
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