

TECHNICAL FILE

Biovalve Safe

106.082

Dated : 10-08-2016

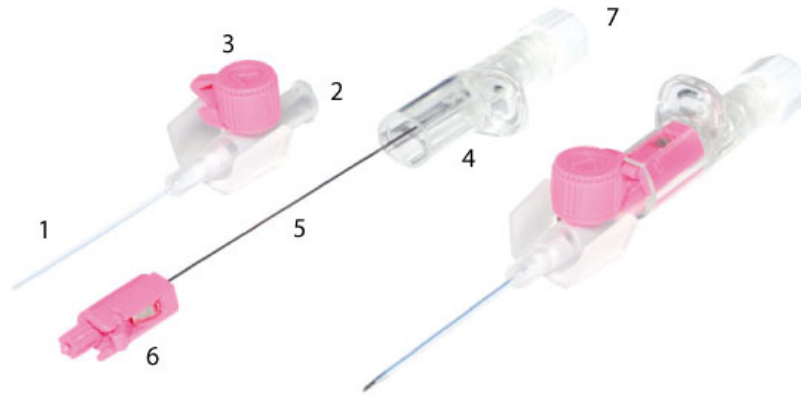
1 Administrative information relating to the company

1.1	Name : Vygon	
1.2	Address : 5 rue Adeline - 95440 Ecoeu, 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 : Biovalve Safe
2.4	Medical Device Class : IIa Applicable EU Directive : 93/42/CEE in accordance with Appendix n° : II Notified body N° : 0459 Medical Device Manufacturer : Vygon
2.5	Description of the device : Biovalve Safe is a ported peripheral IV cannula designed to protect the health-care worker from accidental infections due to needlestick injury or blood splatter. It integrates an engineered passive safety system. Biovalve Safe is available in 6 sizes: 22G - 20G - 18G - 17G - 16G and 14G.
	

2.6	Packaging / Containers					
	Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case	
	106.082	1 (Rigid blister)	50 (Carton box)	50 (Carton box)	500 (Case)	
	Single unit packaging					
	Technical features :					
	Code	Short I.V. cannula				
		Length mm	Ext. Ø mm	Diameter G	Flowrate ml/min	Colour code colour
	106.082	25	0.9	22	36	Blue
2.7	Composition of the device and Accessories : 106.082					
	COMPONENTS		MARKER		MATERIALS	
	Cannula		1		PTFE	
	Cannula hub		2		PP	
	Snap cap		3		PP	
	Needle hub		4		Styrene Butadiene	
	Needle		5		Stainless steel	
	Safety system		6		POM / Stainless steel	
	Cap		7		PE	
	Protector				PP	



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 :
Short-term intravenous therapy puncturing peripheral veins (back of the hand, forearm).

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

MRI compatibility : Compatible

7 Instructions for use

7.1	Instructions : See the IFU on the packaging.
7.2	Indications : Short-term intravenous therapy puncturing peripheral veins (back of the hand, forearm).
7.3	
7.4	

8 Additional information relating to the product