

TECHNICAL FILE

Double lumen Multicath

157.207

Dated : 16-08-2021

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	Generic name : Double-lumen CVC
2.2	Commercial name : Double lumen Multicath
2.4	Medical Device Class : IIa Applicable regulation : 93/42/CEE in accordance with Appendix n° : VII Notified body N° : 0481 Medical Device Manufacturer : Vygon
2.5	Description of the device : Multicath 2 (adult model) is a double-lumen polyurethane radiopaque central venous catheter generally inserted in the internal jugular or subclavian vein using the Seldinger technique. It features 2 totally separate lumen on the whole length of the catheter. The extension tubes of each lumen have different length, different coloured hubs and are marked "DISTAL" and "PROXIMAL" so as to easily identify the different infusion lines. Multicath 2 code 157.167 is 16 cm long. Multicath 2 code 157.207 is 20 cm long. The user has the choice of 2 types of introducer: 1 puncture needle (70 mm long, 18G) or 1 PTFE short I.V. cannula (70 mm long, 18G). Multicath 2 is supplied in a rigid blister pack containing: - 1 double-lumen polyurethane catheter with fixation wings and graduations every centimetre from 5 cm from distal tip. - 1 puncture needle 70 mm long, Ø1.06 x 1.26mm, 18G - 1 short IV cannula 18G - 1 "J" guidewire with guide-advancer, 60 cm long - 1 dilator - 2 clamps - 2 injection caps - 1 syringe (5 ml) - 1 scalpel - 1 supplementary fixation wing.



2.6 Packaging / Containers

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
157.207	1 (Rigid blister in APET)	5 (Carton box)	5 (Carton box)	45 (Case)

Single unit packaging

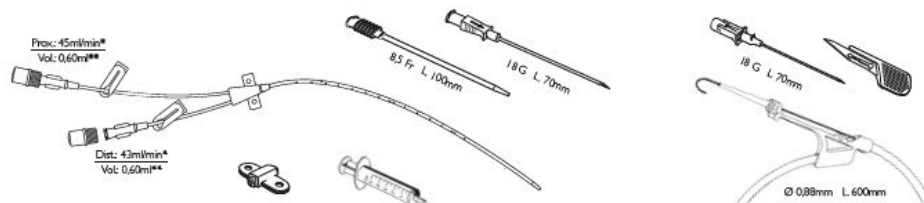
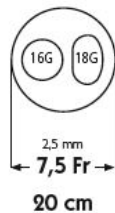
multicath2

(PUR - XRO / ORX / RXC)

REF. / Art.-Nr. / Code **157.207**

2 lumen catheter-set / Cathéter 2 lumières /
Cathéterset 2 lumene / 2-lumiges Katheter-Set /
Set Cateters a 2 lumi / 2-lumen Katheter-set /
Conjunto de cateter de 2 lúmen / 2 lumen kateter kit

Size / Taille / Tamaño / Größe /
Măsura / Grootte / Tamanho / Storlek

Length / Longueur / Longitud / Länge /
Lunghezza / Lengte / Comprimento / Längd

* Flow Rate, Débit, Fluj, Fluente, Fluss, Fluo, Débito, Flúidvloedigheid
Pack content may vary / Représentation non contractuelle / Abbildungen nicht verbindlich / Rappresentazione non contrattuale / Niet-bindende afbeelding / O conteúdo da embalagem pode variar / Forpackningens illustration varier

VYGON

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www.vygon.de

CE 0481
Made in Germany
1053C / Stand 2018-08

Symbol/Symbols
ISO 7000 / ISO 15923


2L - 7,5Fr - 20cm



multicath2

VYGON

Box

multicath2
REF 157.207

Ø2.5mmx200mm 7.5Fr

2 lumen catheter-set

Cathéter 2-lumières

Catéter-set 2 lumene

2-lumiges Katheter-Set

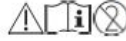
Set catetere a 2 lumi

2-lumen catheter-set

Conjunto de cateter de 2 lumen

2 lumen kateter kit

Катетер 2-просветный в наборе


Rx only
USA only

STERILE **EO** **CE** 0481

multicath2
REF 157.207

LOT 060220GZ

5

 2025-02-06

 2020-02-06


(01) 33660812120426 (17) 250206 (30) 5 (10) 060220GZ

Case labelling

multicath2
REF 157.207

Ø2.5mmx200mm 7.5Fr

2 lumen catheter-set

Cathéter 2-lumières

Catéter-set 2 lumene

2-lumiges Katheter-Set

Set catetere a 2 lumi

2-lumen catheter-set

Conjunto de cateter de 2 lumen

2 lumen kateter kit

Катетер 2-просветный в наборе


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STERILE **EO** **CE** 0481

multicath2
REF 157.207

LOT 060220GZ

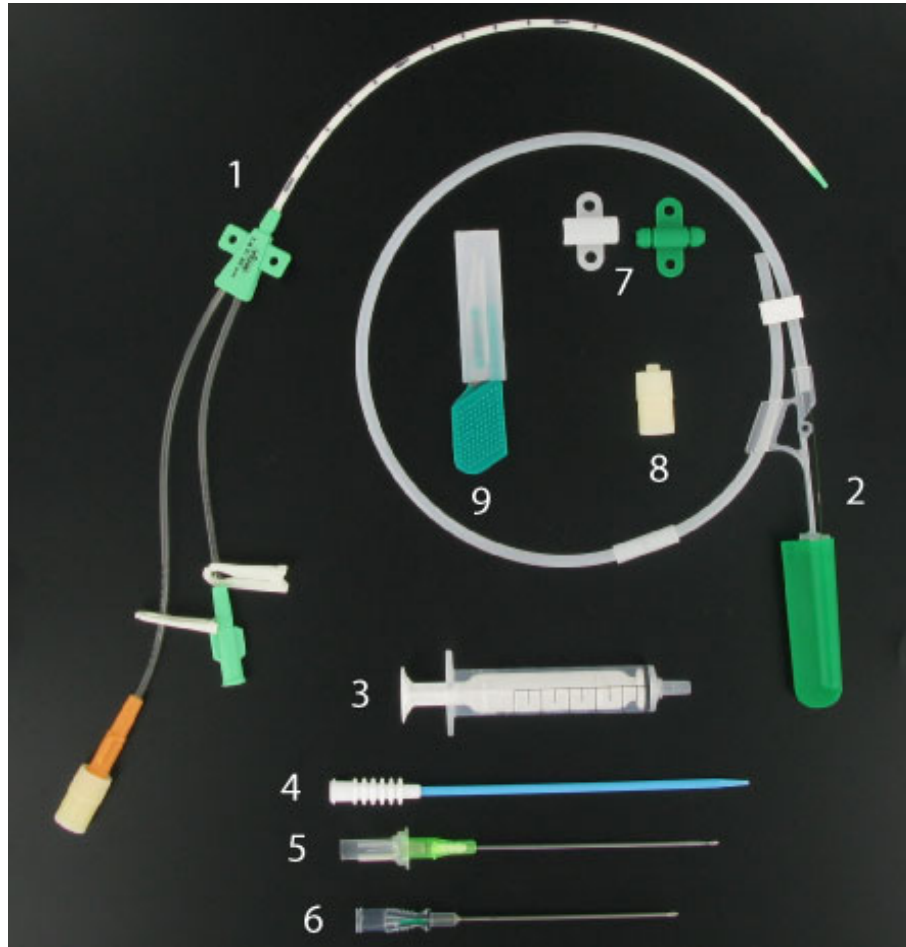
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 2025-02-06

 2020-02-06


(01) 53660812120420 (17) 250206 (30) 45 (10) 060220GZ

	Technical features :											
	Code	Catheter			Distal lumen			Proximal lumen			Guidewire	
		Length cm	Ext. Ø mm	Ø Fr	Ø G	Flow rate ml/min	Prim. vol. ml	Ø G	Flow rate ml/min	Prim. vol. ml	Length cm	Ø mm
	157.207	20	2.5	7.5	16	43	0.60	18	45	0.60	60	0.88
2.7	Composition of the device and Accessories :											
	COMPONENTS					MARKER			MATERIALS			
	Catheter / hubs					1			PU / PA			
	Clamps					1			PC			
	J guidewire and guide advancer					2			Stainless steel/PP/PE/ABS			
	Syringe 5ml					3			PP/Synthetic isoprene			
	Dilator					4			PP / PE			
	Short IV cannula					5			Stain. steel./PP/PTFE/PE			
	Puncture needle					6			Stainless steel / ABS / PE			
	Secondary fixation wing					7			EDPM-PP/ POM			
	Injection cap					8			ABS/Polyisoprene			
	Scalpel					9			Stainless steel/ABS/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 :

Double-lumen CVC inserted by the Seldinger technique for:

- parenteral nutrition
- fluid loading
- transfusion of blood or blood products
- simultaneous administration of medications, even those presenting chemical incompatibilities
- repeated blood samplings
- central venous pressure measurements...

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	Special precautions : Please refer to the IFU in the packaging.
5.3	Duration of product validity : 60 months

6 Security of use

	Technical security : Please refer to the IFU in the packaging.
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7 Instructions for use

7.1	Instructions : Please refer to the IFU in the packaging.
7.2	Indications : Double-lumen CVC for infusion, transfusion, blood sampling.
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. Please refer to the IFU in the packaging.
7.4	Contra indications : Please refer to the IFU in the packaging.

8 Additional information relating to the product

	Do not use this product for monitoring, diagnosis, control or treatment of a defect of the heart or the central venous system.
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