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

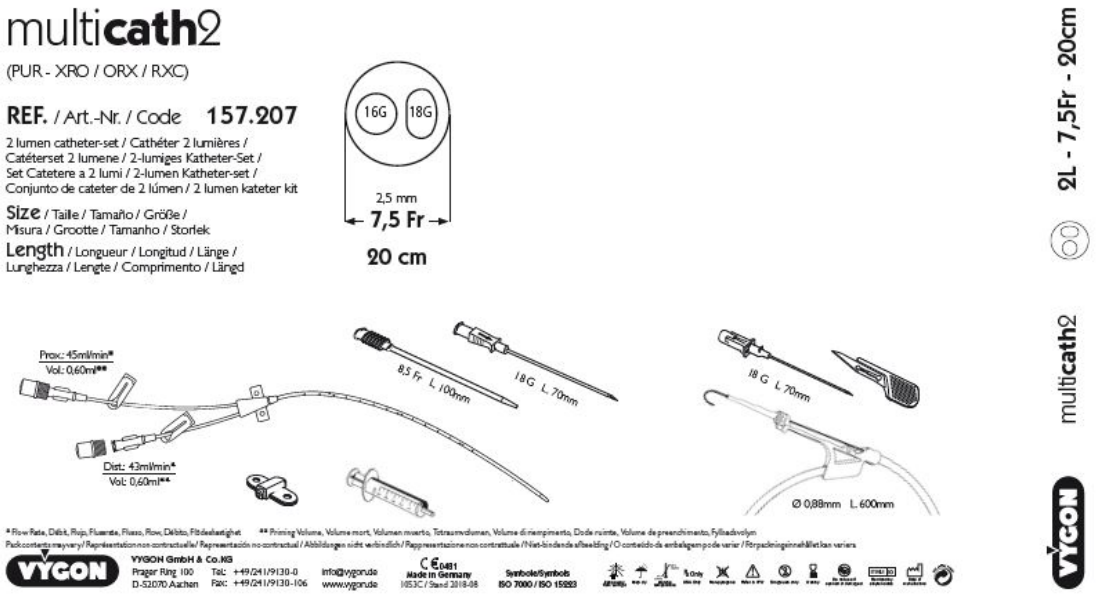
2 Information about the device or equipment

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.

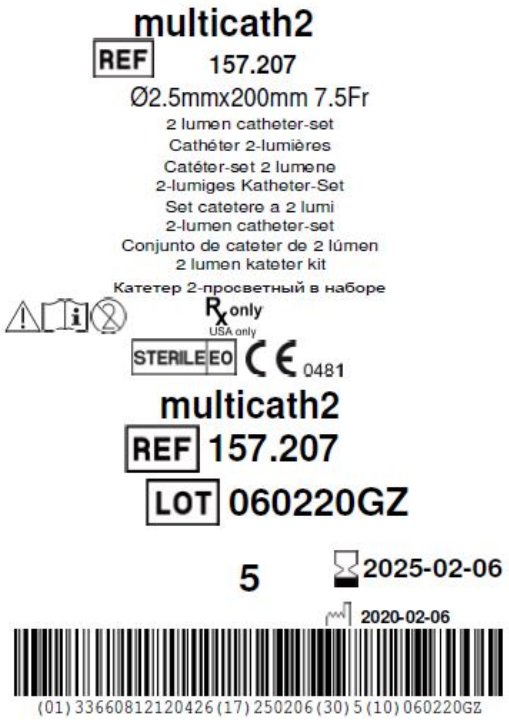
2.6 Packaging / Containers

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)

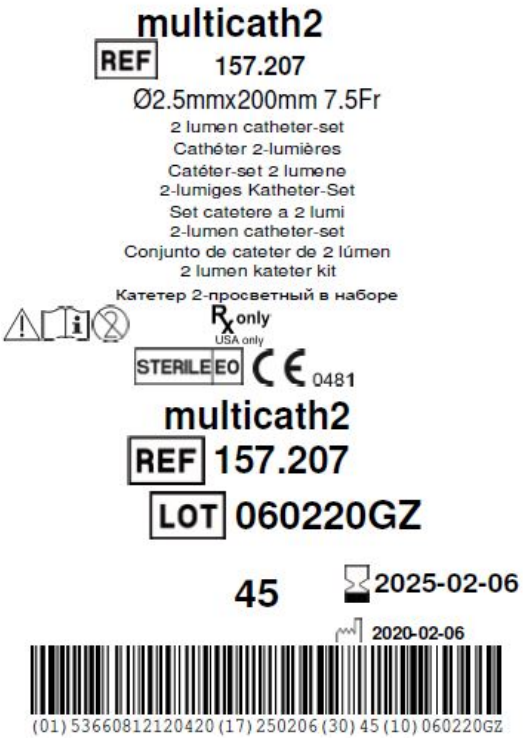
Single unit packaging



Box



Case labelling



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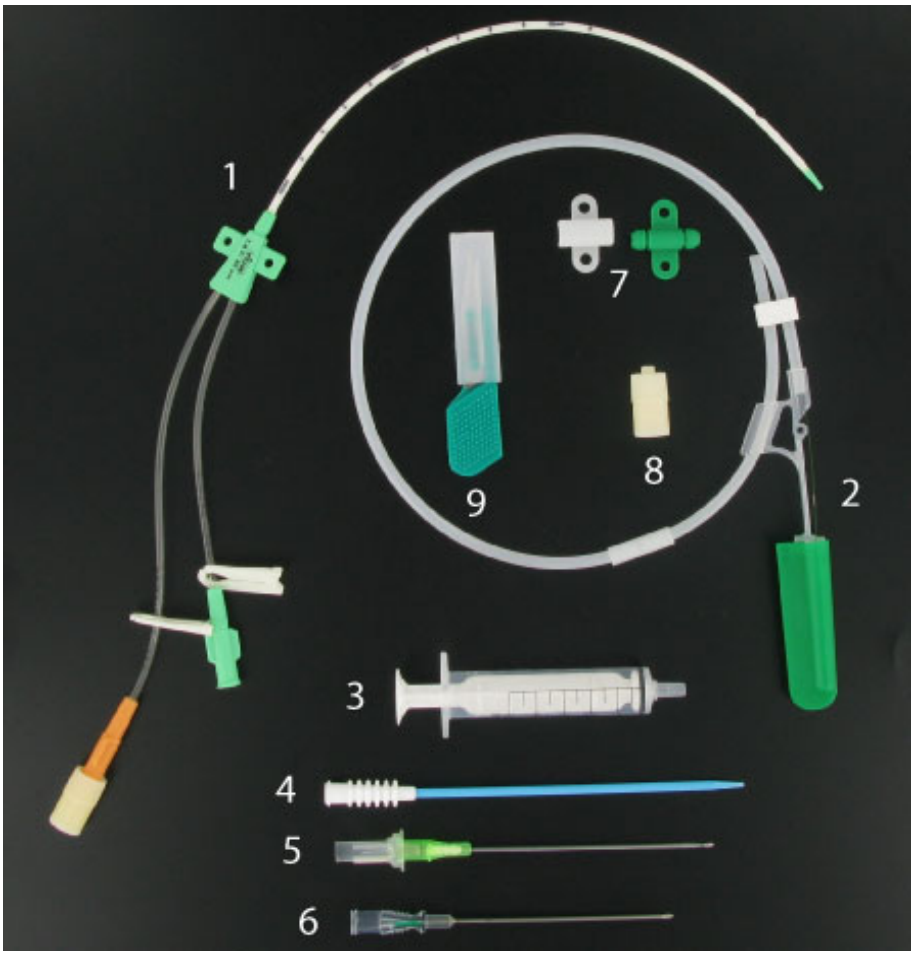
Technical features :

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.

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.