

TECHNICAL FILE

Multicath3 Expert UP

8155.272

Dated : 02-12-2021

13.

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 : Multi-lumen Central Venous Catheter
2.2	Commercial name : Multicath3 Expert UP
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 :

Multicath3 expert UP is an antimicrobial XRO polyurethane central venous catheter introduced by Seldinger technique.

The ionic silver antimicrobial agent (Agion) is integrated within the bulk polyurethane material to minimise the risk of catheter-related bloodstream infection risks. Silver ions are released slowly to ensure efficacy during the dwell time of the catheter.

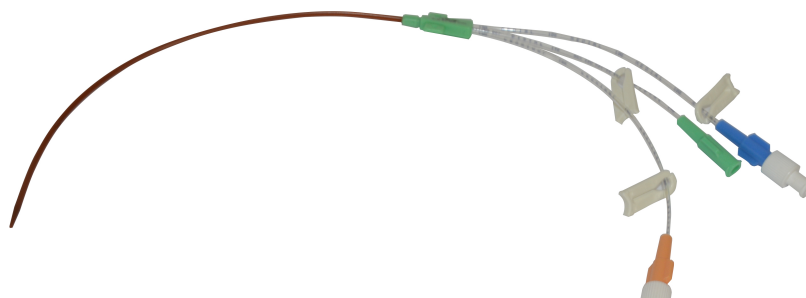
It consists of 3 lumens completely separated on the total length of the catheter. Each lumen leads, at the distal tip of the catheter, to a distinct hole. At the proximal end, the lumens of the catheter are connected to extension tubes of different lengths. Each extension tube includes a different coloured hub and is marked "Distal", "Medial", and "Proximal" so as to identify easily the different infusion lines.

Multicath3 expert UP is available in 4 lengths: 12.5cm (code 8155.072), 16cm (code 8155.172), 20cm (code 8155.272), or 30cm (code 8155.372).

It is presented in a rigid blister pack containing:

- 1 polyurethane catheter (totally radiopaque) with fixation wings and centimetric graduations from 9cm from distal tip. Smooth distal end,
- 1 safety needle (Seldisafe) 18G, 70mm, to avoid needlestick injuries,
- 1 safety scalpel,
- 1 BLS valve (Blood Less System) on the Seldisafe to limit blood loss and air embolism,
- 1 adaptor for pressure transducer,
- 1 Teflon-coated "J" Nitinol guidewire (particularly kink-resistant) with guide-advancer,
- 1 dilator 8Fr / Length: 100mm,
- 3 blind hub caps,
- 1 5ml syringe,
- 1 supplementary fixation wing for 16, 20, and 30cm catheters,
- 1 ECG cable (combcard) for 16, 20, and 30cm catheters.

Multicath3 expert UP catheters contain photo reactive silver compounds. To protect the catheters from the light, they are delivered with a blind sheath.



2.6 Packaging / Containers

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
8155.272	1 (Rigid blister)	5 (Carton box)	5 (Carton box)	45 (Case box)

Single unit packaging

multicath3expert UP

(PUR - XRO / ORX / RXC)

REF. / Art.-Nr. / Code / Арт 8155.272

3 lumen catheter-set / Cathéter 3 lumières / Catéterset 3 lumene /

3-lumiges Katheter-Set / Set Catetere a 3 lumi /

3-lumen Katheter-set / Conjunto de cateter de 3 lumen /

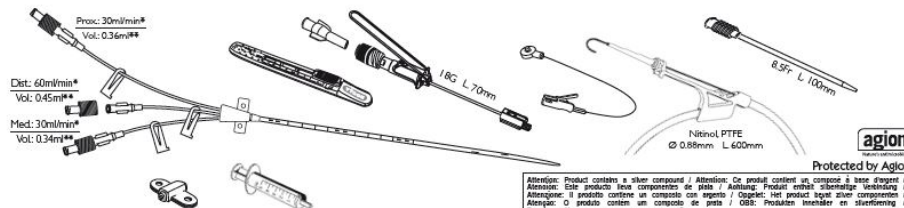
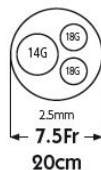
3 lumen kateter kit / Катетер 3-просветный в наборе

Size / Taille / Tamaño / Größe / Мисура /

Grootte / Tamanho / Storlek / Размер

Length / Longueur / Longitud / Länge /

Lunghezza / Lengte / Comprimento / Längd / Длина



* Flow Rate, Débit, Flujo, Flussrate, Flusso, Flow, Debit, Förderstrom, Скорость потока

Pack contents may vary /

Représentation non contractuelle /

Abbildungen nicht verbindlich /

Rappresentazione non contrattuale /

Niet bindende afbeelding /

O conteúdo da embalagem pode variar /

Fotografierungen sind ohne Gewähr /

Содержимое упаковки может отличаться

VYGON

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CE 0481

Made in Germany

3L - 7.5Fr - 20cm



multicath3expert UP



Box

multicath3expert UP

REF 8155.272

(2,7mm x 200mm) 7,5 Fr

3 Lumen catheter set

Cathéter, 3-lumières

Catéterset 3 lumene

3-lumiges Katheter-Set

Set catetere a 3 lumi

3-lumen catheter-set

Conjunto de cateter de 3 lumen

3 lumen kateter kit

Rx Only

STERILE EO

CE 0481

multicath3expert UP

REF 8155.272

LOT 250319GA

5

2022-03-25

2019-03-25



(01) 33660812110717 (17) 220325 (30) 5 (10) 250319GA

Case labelling

multicath3expert UP

REF 8155.272

(2,7mm x 200mm) 7,5 Fr

3 Lumen catheter set
Cathéter, 3-lumières
Catéterset 3 lumene
3-lumiges Katheter-Set
Set catetere a 3 lumi
3-lumen catheter-set
Conjunto de cateter de 3 lumen
3 lumen kateter kit

Rx Only
USA Only


STERILE

EO



CE

0481

multicath3expert UP
REF 8155.272
LOT
250319GA
45


2022-03-25



2019-03-25



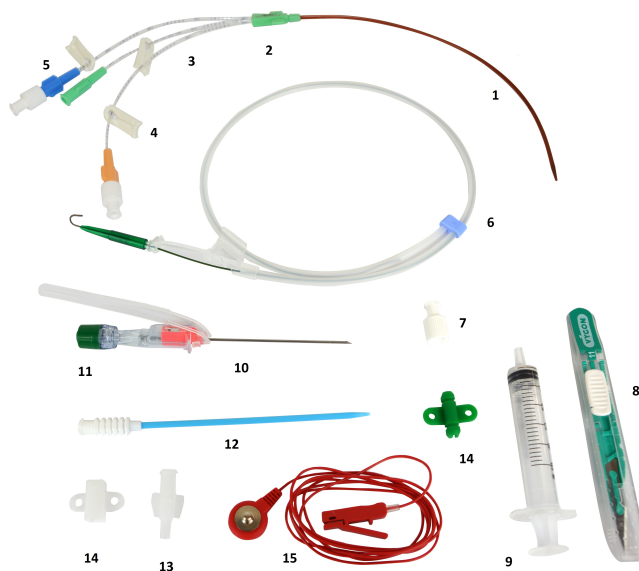
(01) 53660812110711 (17) 220325 (30) 45 (10) 250319GA

Technical features :

Code	Catheter			Distal lumen			Medial lumen			Proximal lumen			Guidewire	
	Length cm	Ø Fr	Ext. Ø mm	Ø G	Flow rate ml/min	Prim. vol. ml	Ø G	Flow rate ml/min	Prim. vol. ml	Ø G	Flow rate ml/min	Prim. vol. ml	Length cm	Ø mm
8155.272	20	7.5	2.5	14	60	0.45	18	30	0.34	18	30	0.36	60	0.88

2.7 Composition of the device and Accessories :

COMPONENTS	MARKER	MATERIALS
Catheter	1	PU / Silver ions
Fixation wing	2	PU
Extension tubes	3	PU
Clamps	4	PC
Hub	5	PA
Guidewire/Guide-advance	6	NiTi / MABS / PP
Caps	7	PE
Scalpel	8	Stainless steel
Syringe	9	PP/Synthetic isoprene
Seldisafe	10	Stain. steel/SB/PC/PP/POM
BLS Valve	11	SI / ABS
Dilator	12	PP / PE
Transducer adaptor	13	PE
Fixation wings (16/20/30cm)	14	EDPM-PP/ POM
ECG lead (16/20/30cm)	15	PVC/PP/Stain. steel/Copper



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 : Multicath expert UP are polyurethane multi-lumen central venous catheters introduced by a classic Seldinger technique, generally into the internal jugular, subclavian and femoral veins (other access sites are also possible). Suitable for short and medium term therapy up to 29 days, allowing: infusion of fluids, medications, blood or blood products, measurement of central venous pressure, intermittent injections, blood sampling...
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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 : 36 months

6 Security of use

Technical security :
Respect usual hygiene and security rules.

7 Instructions for use

7.1	Instructions : Please refer to the IFU in the packaging.
7.2	Indications : Multicath expert UP are polyurethane multi-lumen central venous catheters introduced by a classic Seldinger technique, generally into the internal jugular, subclavian and femoral veins (other access sites are also possible). Suitable for short and medium term therapy up to 29 days, allowing: infusion of fluids, medications, blood or blood products, measurement of central venous pressure, intermittent injections, blood sampling...
7.3	Precautions : Please refer to the IFU in the packaging. Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reaction or bacterial infections.
7.4	Contra indications : Please refer to the IFU in the packaging.

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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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