

TECHNICAL FILE

Lifecath

2191.425

11.

Dated : 16-08-2022

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 : Silicone I.V. catheter with Dacron cuff
2.2	Commercial name : Lifecath
2.4	Medical Device Class : III Applicable regulation : 93/42/CEE in accordance with Appendix n° : VII Notified body N° : 0481 Medical Device Manufacturer : Vygon
2.5	<p>Description of the device :</p> <p>Lifecath is a silicone central venous catheter with subcutaneous cuff for long-term venous access. The subcutaneous tissues colonize the cuff which ensures a secure and efficient fixation of the catheter.</p> <p>The extra-vascular section of the catheter features a reinforced section with clamping site, clamp and a non-removable proximal hub. The tunnelling of the catheter must be carried out before inserting the catheter in the vein.</p> <p>Lifecath can be inserted either by venous cut-down (catheter only) or by percutaneous puncture (kit with peel-apart Desilet). The fixation wings are only used during the 2 or 3 first weeks after placement of the catheter to secure it against motion, thus ensuring a quicker colonization of the Dacron cuff by the subcutaneous tissues.</p> <p>The tray catheter with introducer (a peel-apart Desilet) code 2191.273, 2191.425, 2191.506, 2191.667 and 2193.960 contains:</p> <ul style="list-style-type: none"> - 1 silicone catheter with Dacron cuff (maximum pressure: 3.5 bar) - 1 tunnelling needle (Note: code 2193.960 is supplied with 2 tunnelling rods - plastic and metallic) - 1 fixation wing (not available in the tray code 2191.273) - 1 scalpel <p>The tray catheter only (see technical files codes 2191.27, 2191.42, 2191.50, 2191.66 and 2193.96) contains:</p> <ul style="list-style-type: none"> - 1 silicone catheter with Dacron cuff (maximum pressure 3.5 bar) - 1 tunnelling needle (Note: code 2193.96 is supplied with 2 tunnelling rods - plastic and metallic) - 1 fixation wing (not available in the tray code 2191.27)



2.6 Packaging / Containers

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
2191.425	1 (Double wrapped blister pack with Tyvek lid)	1 (Carton box)	1 (Carton box)	20 (Case)

Single unit packaging

Art.-Nr. /REF P Only
USA Only

2191.425 **lifecath broviac**
 ø0.7mmx1.35mm 4.2Fr L 75cm

Catheterset with tunneling device and introducer
 Cathéter kit avec tunnelisateur et introducteur
 Set de catéter con tunelizador e introductor
 Katheterset mit Untertunnelungstrokar und Einführbesteck
 Kit catetere con tunnelizzatore e introdotore
 Katheterkit met tunnelisator en introducer
 Kit de cateter con tunelizador e introdutor
 Kateterset med tunneleringsanordning och introducer

1 pcs / st / pz **190419GA**

2024-04-19 2019-04-19

VERB. BIS **STERILE** **CE 0481*** **LOT**

37085.006/Stand 1997.06



(01) 03660812111775 (17) 240419 (30) 1 (10) 190419GA

Box

lifecath broviac

REF 2191.425

ø0.7mmx1.35mm 4.2Fr L 75cm

Catheterset with tunneling device and introducer
 Cathéter kit avec tunnellisateur et introducteur
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 Katheterkit met tunnelisator en introducer
 Kit de cateter com tunelizador e introdutor
 Kateterset med tunneleringsanordning och introducer

lifecath broviac

REF 2191.425

LOT 190419GA

20 2024-04-19
 2019-04-19

(01) 53660812111770 (17) 240419 (30) 20 (10) 190419GA

Case labelling

REF **VYGON**

2191.425 **lifecath broviac**

4.2Fr 1L

LOT 190419GA

2024-04-19 **2019-04-19**

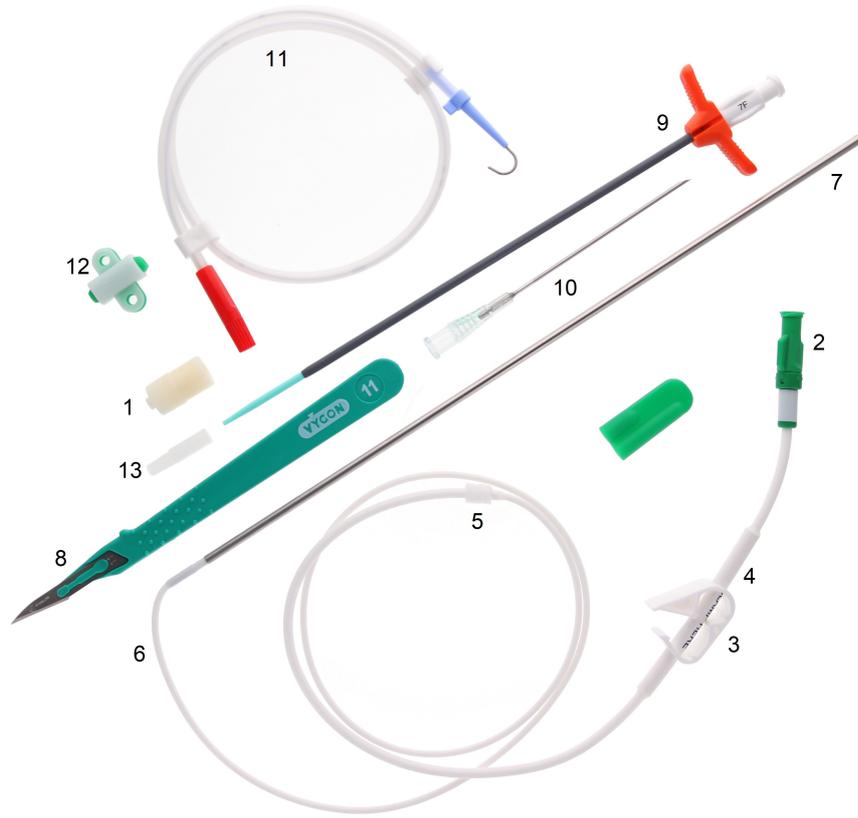
insertion date / pose le / fecha de colocación /
 platziert am / data di insertimento / ingebracht op /
 data de colocação / datum för isättning

19016-001 / Stand 2016 / 9

Technical features :

Code	Peel-apart Desilet	Catheter						
	- Fr	Useful length cm	Total length cm	Int. Ø mm	Ext. Ø mm	Ø Fr	Flow rate ml/min	Prim. vol. ml
2191.425	4.5	50	75	0.7	1.35	4.2	5.0	0.35

2.7 Composition of the device and Accessories :		
COMPONENTS	MARKER	MATERIALS
Injection stopper	1	ABS/Polyisoprene
Female Luer-lock hub	2	POM
Clamp	3	POM
Reinforced tube	4	Si
Subcutaneous cuff	5	Dacron
Catheter	6	Si
Tunnelling needle	7	Stainless steel
Tunnelling needle 2191.960	7	Plastic
Peel-apart sheath	9	PTFE / PE / PP
Scalpel	8	Stainless steel
Needle	10	Stainless steel / ABS / PE
J straightener / guide / tube	11	Stain. steel./PP/PTFE/PE
Fixation wings (except 2193.960)	12	EDPM-PP/ POM
Cap	13	PA



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 :

Long-term venous catheter indicated for:

- prolonged permanent or intermittent parenteral feeding in hospital or at home
- chemotherapy during treatment of solid tumors or hemopathy
- transfusion of blood products
- chemotherapy intensifications and bone marrow transplants
- various treatment administered to AIDS patients (antiviral drugs, nutrition, etc...)

3 Accessories

4 Sterilization process

Sterile Medical Device : YES
Sterilization made for the device : Ethylene oxide

5 Conditions of conservation and storage

5.1	<p>Normal conservation and storage conditions : Storage environment temperature: between 5 and 40°C. Store protected from moisture and sunlight.</p>
5.2	<p>Special precautions : Please refer to the IFU.</p>
5.3	<p>Duration of product validity : 60 months</p>

6 Security of use

	<p>Technical security : Please refer to the IFU.</p>
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7 Instructions for use

7.1	<p>Instructions : Please refer to the IFU.</p>
7.2	<p>Indications : Long-term venous catheter indicated for:</p> <ul style="list-style-type: none"> - prolonged permanent or intermittent parenteral feeding in hospital or at home - chemotherapy during treatment of solid tumors or hemopathy - transfusion of blood products - chemotherapy intensifications and bone marrow transplants - various treatment administered to AIDS patients (antiviral drugs, nutrition, etc...)
7.3	<p>Precautions : Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reaction or bacterial infections.</p> <p>Please refer to the IFU.</p>
7.4	<p>Contra indications : Please refer to the IFU.</p>

8 Additional information relating to the product

	<p>The priming volume and flow rate which are given in the "Technical features" have been calculated for the complete catheter before the length is adjusted by the physician.</p>
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