

TECHNICAL FILE
Double-lumen lifecath
 2293.95

Dated : 14-03-2016

1 Administrative information relating to the company

1.1	Name : Vygon	
1.2	Address : 5 rue Adeline - 95440 Ecoen, 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 double-lumen CVC for long-term use
2.2	Commercial name : Double-lumen lifecath
2.4	Medical Device Class : III Applicable EU Directive : 93/42/CEE in accordance with Appendix n° : VIII Notified body N° : 0481 Medical Device Manufacturer : Vygon

2.5 Description of the device :

Lifecath Biflux is a totally radiopaque double-lumen silicone catheter with subcutaneous cuff for long-term venous access (parenteral nutrition, administration of medication, chemotherapy...)

Lifecath Biflux can either be inserted by a surgical technique, venous cut-down (catheter only) or by percutaneous puncture (kit with peelaway Desilet introducer).

LIFECATH BIFLUX WITHOUT INTRODUCER is supplied in a rigid blister pack (in a double packaging) containing:

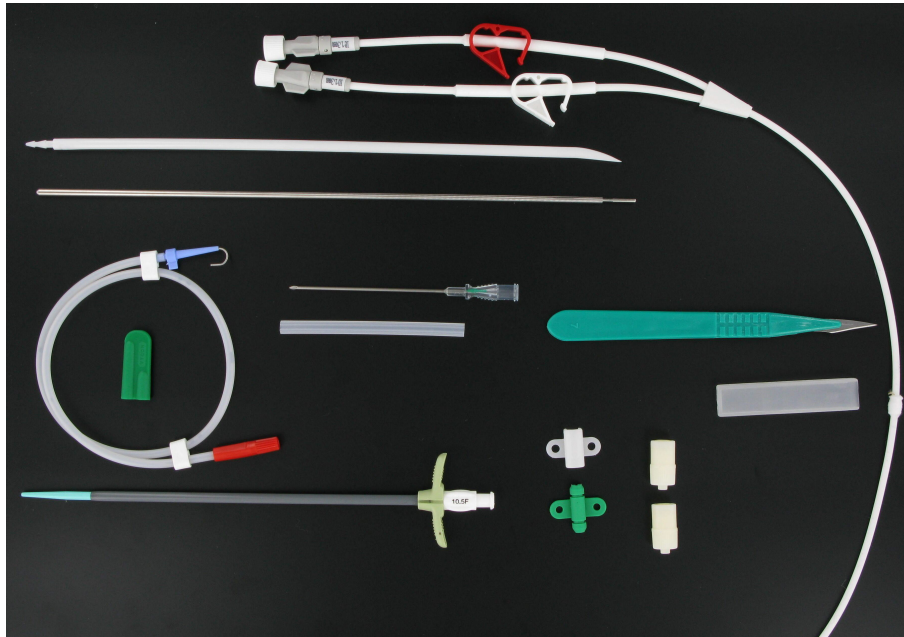
- 1 double-lumen silicone catheter with subcutaneous cuff
- 2 tunnelling rods (plastic and metallic)
- 1 supplementary fixation wing (only available for 7Fr and 9Fr catheters)
- 2 injection caps

LIFECATH BIFLUX WITH INTRODUCER is supplied in a rigid blister pack (in a double packaging) containing:

- 1 double-lumen silicone catheter with subcutaneous cuff
- 1 peelaway Desilet introducer code 1146.xx
- 1 scalpel
- 2 tunnelling rods (plastic and metallic)
- 1 supplementary fixation wing (only available for 7Fr and 9Fr catheters)
- 2 injection caps

Note: The supplementary fixation wings supplied with the 7Fr and 9Fr catheter is only used during the first 2/3 weeks, time necessary for the subcutaneous tissues to colonize the cuff and fix the catheter.

Silicone catheters with subcutaneous cuff for long-term venous access are also available in single lumen (codes 2191 and 2193) or triple-lumen (code 2224.100): See corresponding technical file.



2.6 Packaging / Containers

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
2293.95	1 (Dble pack: peelpack (PE) + rigid blister (APET))	1 (Carton box)	1 (Carton box)	20 (Case)

Single unit packaging

Art.-Nr. / REF  **VYCON**

2293.95 **LIFECATH – BIFLUX**
9,5 Fr

Catheter with tunnelling needle and desilet
Katheter mit Untertunnelungstrokar und Einführbesteck
Cathéter avec tunnelisateur et Desilet
Catetere con un ago per tunnelizzazione ed introduttore Desilet
Catéter con una aguja de tunelización y introductor desilet
Catheter met tunnelingsnaald en introductor type Desilet

2L, L = 93 cm, ϕ 3.00mm
0 pcs / st / pz

VERM. RIS  STERILE EO  CE 0481  LOT

(01)3660012014021 (17)291231 (30)6 (10)995599



32981006-01.ind 1997-06

Box

Art.-Nr. / REF  **VYCON**

2293.95 **lifecath biflux**
9,5Fr 2L, L = 93 cm, ϕ 3.00mm

Catheter with tunnelling needle and desilet
Katheter mit Untertunnelungstrokar und Einführbesteck
Cathéter avec tunnelisateur et Desilet / Catetere con un ago per tunnelizzazione ed introduttore Desilet
Catéter con una aguja de tunelización y introductor desilet
Catheter met tunnelingsnaald en introductor type Desilet
Cateter com tunelizador e kit de introdução
Kateter med tunneleringsnål och desilet

1 pcs / st / pz
2020 - 11 141015GA

VERM. RIS  STERILE EO  CE 0481  LOT



(01)03660812014021 (17)201130 (30)1 (10)141015GA

32981006-01.ind 1997-06

Case labelling

lifecath biflux

REF 2293.95

9,5Fr 2L, L = 93 cm, ø 3.00mm

Catheter with tunnelling needle and desilet
 Katheter mit Untertunnelungstrokar und Einführbesteck
 Cathéter avec tunnellisateur et Desilet / Catetere con un
 ago per tunnelizzazione ed intruduttore Desilet
 Catéter con una aguja de tunelización y introductor desilet
 Catheter met tunnelingsnaald en introducer type Desilet
 Cateter com tunelizador e kit de introdução
 Kateter med tunneleringsnål och desilet

Rx Only     0481
 USA Only

lifecath biflux

REF 2293.95

LOT 141015GA

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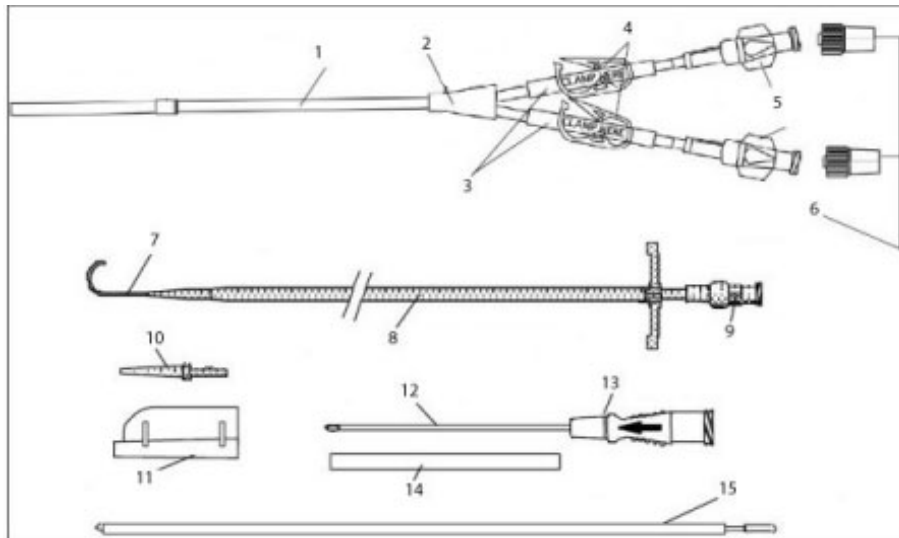
(01)53660812014026 (17)201130 (30)20 (10)141015GA

Technical features :

Code	Lumen 1			Lumen 2			Catheter only or with introducer	Catheter			
	Int. Ø mm	Flowrate ml/min	Priming volume ml	Int. Ø mm	Flowrate ml/min	Priming volume ml		Useful length cm	Total length cm	Ext. Ø mm	Ø Fr
2293.95	1.3	37	1.44	1.3	37	1.44	With introducer	55	90	3.0	9.5

2.7 Composition of the device and Accessories : 2293.95

COMPONENTS	MARKER	MATERIALS
Catheter	1	SI
Bifurcation hub	2	SI
Extension tubes	3	SI
Clamps	4	PP
Proximal hubs	5	POM
Injection caps	6	ABS/Polyisoprene
J guidewire	7	Stainless steel
Peel away sheath	8	PTFE
Dilator hub	9	PP
J straightener	10	PP
Guide protector	11	PP
Needle	12	Stainless steel
Needle hub	13	ABS
Needle protector	14	PE
Metallic tunneller	15	Stainless steel
Platic tunneller	15	Plastic



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	<p>Indications : Long-term central venous catheter for:</p> <ul style="list-style-type: none"> - parenteral nutrition at home or in the hospital - chemotherapy - transfusion - repeated blood samplings - treatment for HIV patients (parenteral nutrition, antiviral drugs...)
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3 Accessories

4 Sterilization process

	<p>Sterile Medical Device : YES Sterilization made for the device : Ethylene oxide</p>
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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	
5.3	<p>Duration of product validity : 60 months</p>

6 Security of use

	<p>Technical security : Biological safety: ISO 10993</p> <p>Technical safety: ISO 10555 ISO 594</p>
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7 Instructions for use

7.1	
7.2	<p>Indications : Double-lumen silicone catheter with subcutaneous cuff for long-term venous access.</p>
7.3	
7.4	

8 Additional information relating to the product