

## TECHNICAL FILE

Lifecath

2191.273

19.

Dated : 16-08-2022

### 1 Administrative information relating to the company

1.1	<b>Name :</b> Vygon	
1.2	<b>Address :</b> 5 rue Adeline - 95440 Ecouen, France	<b>Fax :</b> + 33 (0)1 34 29 19 34 <b>E-mail :</b> questions@vygon.com <b>Website :</b> www.vygon.com
1.3	<b>Medical Device vigilance Representative :</b> Laurent GUILLARDEAU	<b>Tel :</b> +33 (0)1 39 92 65 69 <b>Fax :</b> +33 (0)1 39 92 64 82 <b>E-mail :</b> quality@vygon.com

### 2 Information about the device or equipment

2.1	
2.2	<b>Commercial name :</b> Lifecath
2.4	<b>Medical Device Class :</b> III <b>Applicable regulation :</b> 93/42/CEE <b>in accordance with Appendix n° :</b> VII <b>Notified body N° :</b> 0481 <b>Medical Device Manufacturer :</b> Vygon
2.5	<p><b>Description of the device :</b></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. <i>su poodiniu fiksatoriumi augan iu audinius manžete</i></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"> <li>- 1 silicone catheter with Dacron cuff (maximum pressure: 3.5 bar) <i>atlaikantis sl g 3.5 bar</i></li> <li>- 1 tunnelling needle (Note: code 2193.960 is supplied with 2 tunnelling rods - plastic and metallic)</li> <li>- 1 fixation wing (not available in the tray code 2191.273)</li> <li>- 1 scalpel</li> </ul> <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"> <li>- 1 silicone catheter with Dacron cuff (maximum pressure 3.5 bar)</li> <li>- 1 tunnelling needle (Note: code 2193.96 is supplied with 2 tunnelling rods - plastic and metallic)</li> <li>- 1 fixation wing (not available in the tray code 2191.27)</li> </ul>



J formos praved jas 0.5mm x 30

su minkštu atviru atraumatiniu galu

išorin je kateterio dalyje papildoma kateterio sekcija su montuota vieta užspaudimui ir spaustuku

**2.6 Packaging / Containers**

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
2191.273	1 (Double wrapped blister pack with Tyvek lid)	1 (Carton box)	1 (Carton box)	20 (Case box)

**Single unit packaging**

Art.-Nr. /REF **2191.273** **lifecath broviac** **Broviac tipo**  
 ø0.5mmx0.95mm 2.7Fr L 75cm **Ilgis 75cm**  
 Catheterset with tunneling device and introducer  
 Cathéter kit avec tunnelisateur et introducteur **dycis 2,7Fr, vidinis diametras 0,5mm, išorinis diametras 0,95mm - ne daugiau 1mm**  
 Set de catéter con tunelizador e introductor  
 Katheterset mit Untertunnelungstrokar und Einführbesteck  
 Kit catetere con tunnelizzatore e introduttore  
 Katheterkit met tunnelisator en introducer  
 Kit de cateter com tunelizador e introdutor  
 Kateterset med tunneleringsanordning och introducer

**1 pcs / st / pz**  
**2024-04-19** 2019-04-19 **190419GA**

VERM. B10 **STERILE** **CE 0481** **LOT**

33083-1006/25x14 1997-06



(01) 03660812111751 (17) 240419 (30) 1 (10) 190419GA

**Box**

**lifecath broviac**



**REF 2191.273**

ø0.5mmx0.95mm 2.7Fr L 75cm

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

Rx Only **rentgenokontrastinis**

STERILE EO CE 0481

**lifecath broviac**

**REF 2191.273**

**LOT 190419GA**

**20** 2024-04-19

2019-04-19



(01) 53660812111756 (17) 240419 (30) 20 (10) 190419GA

**Case labelling**

REF



**2191.273**

**lifecath broviac**

**2.7Fr 1L**

**LOT 190419GA**

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

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

53035-001 / Steril 2016 / 9

**Technical features :**

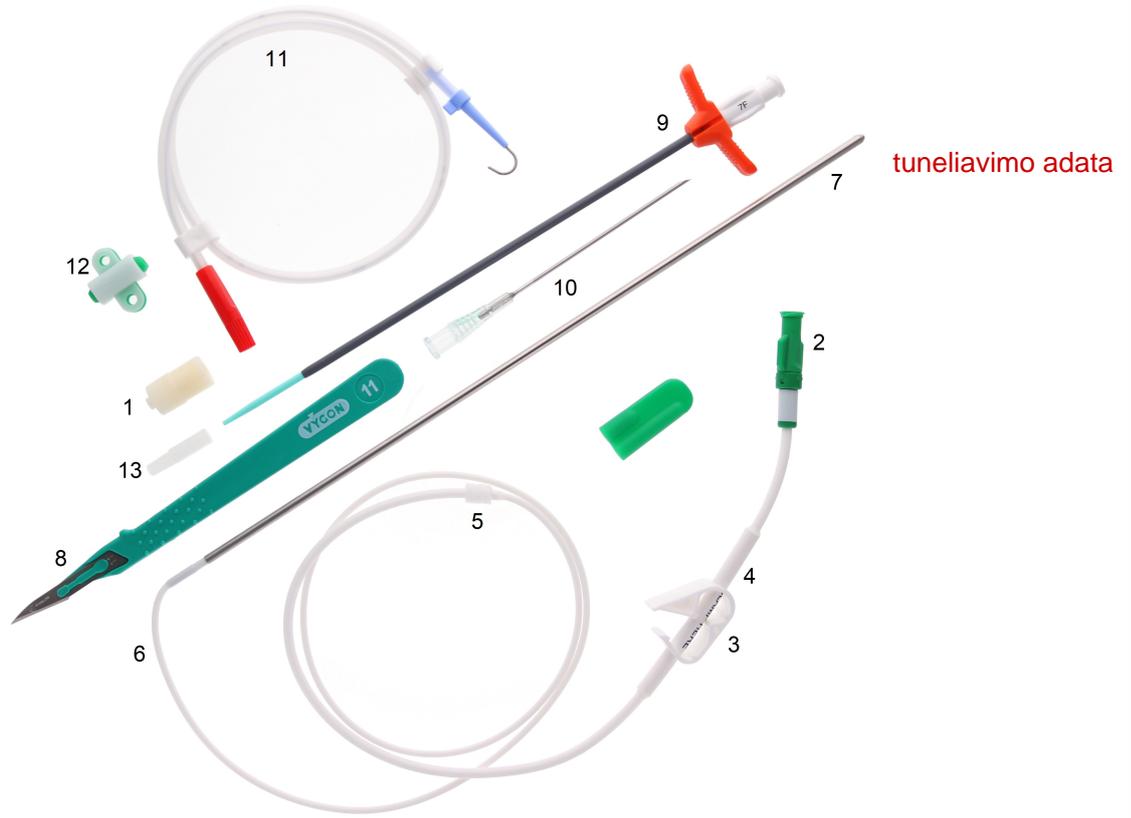
Code	Catheter						Peel-apart Desilet	
	Useful length cm	Total length cm	Int. Ø mm	Ext. Ø mm	Ø Fr	Flow rate ml/min	Prim. vol. ml	- Fr
2191.273	50	75	0.5	0.95	2.7	1.0	0.25	3

naudojamas ilgis 50cm,  
 bendras ilgis 75cm

T km s  
 greitis  
 1ml/min užpildymo  
 t ris  
 0,25ml

**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 <b>Silikoninis</b>
Tunnelling needle <b>tuneliavimo adata</b>	7	Stainless steel
Tunnelling needle 2191.960	7	Plastic
Scalpel	8	Stainless steel
Peel-apart sheath	9	PTFE / PE / PP
Needle / hub	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

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

## 6 Security of use

	<b>Technical security :</b> Please refer to the IFU.
--	---

## 7 Instructions for use

7.1	<b>Instructions :</b> Please refer to the IFU.
7.2	<b>Indications :</b> Long-term venous catheter indicated for: <ul style="list-style-type: none"> <li>- prolonged permanent or intermittent parenteral feeding in hospital or at home</li> <li>- chemotherapy during treatment of solid tumors or hemopathy</li> <li>- transfusion of blood products</li> <li>- chemotherapy intensifications and bone marrow transplants</li> <li>- various treatment administered to AIDS patients (antiviral drugs, nutrition, etc...)</li> </ul>
7.3	<b>Precautions :</b> 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.
7.4	<b>Contra indications :</b> Please refer to the IFU.

## 8 Additional information relating to the product