

TECHNICAL FILE

Lifecath PICC

1294.14

18.

Dated : 06-01-2021

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 : Polyurethane PICC catheter
2.2	Commercial name : Lifecath PICC
2.4	Medical Device Class : III Applicable regulation : 93/42/CEE in accordance with Appendix n° : VIII Notified body N° : 0481 Medical Device Manufacturer : Vygon

2.5 Description of the device :

Lifecath PICC is a peripherally inserted central venous catheter (basilic, cephalic, brachial vein...) in BIOSTABLE POLYURETHANE for medium or long-term venous access. It is available both as single lumen (codes 1294.13/14/15) in size 3Fr, 4Fr and 5Fr and as a double lumen catheter (code 1294.245) in size 4.5Fr.

Lifecath PICC is supplied in a rigid blister pack (with double packaging) containing:

- 1 totally radiopaque catheter (60 cm long) in biostable polyurethane (suited for long-term venous access up to several months if the IV therapy of the patient requires it) with centimetre marking and numerical markings every 5 cm and with integral extension tube (9 cm long)
- 1 metallic stylet to make the catheter more rigid and thus make insertion easier
- 1 "T" proximal connector. The lateral port of the T connector can be used to inject saline solution with a syringe to lubricate the stylet and make its removal easier or to inject saline solution in case of venous spasm to open the path to the catheter
- 1 peelaway short IV cannula introducer
- 1 Bionector code 896
- 1 measuring tape
- 1 Griplik, device for catheter fixation
- 2 traceability labels

Lifecath PICC can be used for hospitalised patients or for home treatment.

PICC candidates :

- Radiation, burns, trauma, surgical procedures ... involving the chest and neck area
- Patients with respiratory problems or tracheostomized patients
- Limited availability of peripheral access negating opportunity for peripheral site rotation

Advantages of PICC catheters :

- Avoids repeated and painful venipunctures with I.V. cannulae and the trauma associated with these punctures, as well as damage and loss of peripheral veins.
- Peripheral insertion of a central venous catheter reduces potential risks in comparison to jugular or subclavian insertion (pneumothorax, haemothorax, arterial puncture, pinch-off syndrome in a clavicular approach, air embolism, etc.)
- The catheter can be inserted outside the operating theatre (at bedside or at home).

Lifecath PICC is also available with :

- a MST introducer with 50 cm long guidewire for standard MST placement by nurse (if legislation authorizes it) or by authorized practitioner : see technical file codes 1294.113/114/115/345,
- a MST introducer with 67 cm long guidewire for placement under fluoroscopy : see technical file codes 1294.414/415/445,
- a MST introducer with 135 cm long guidewire for placement under fluoroscopy and over the wire : see technical file codes 1294.514/515/545.



Case labelling

REF 1294.14		REF 1294.14	
 2021-07-02	LOT 020718GA	 2021-07-02	LOT 020718GA
 2018-07-02		 2018-07-02	
Insertion Date		Insertion Date	



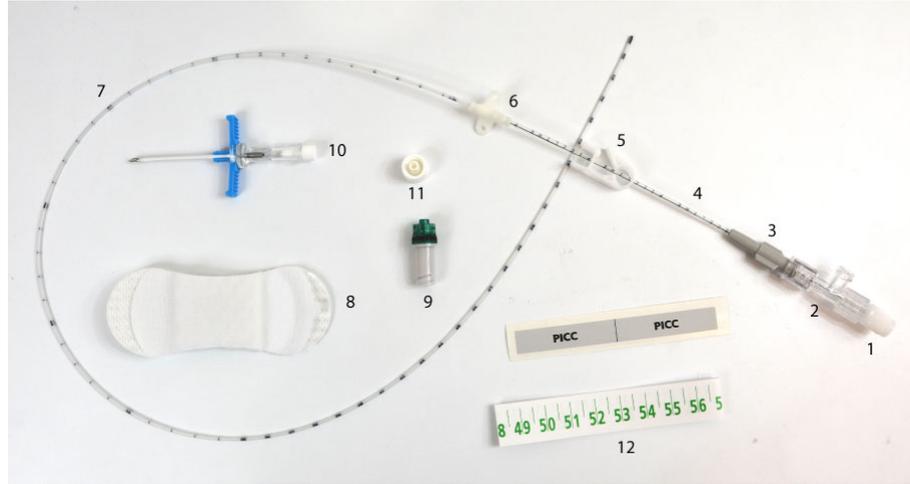
(01)03860812012270(17)210702(30)1(10)020718GA

Technical features :

Code	Catheter					Peelable short catheter introducer	
	Length cm	Ext. Ø mm	Ø Fr	Flow rate ml/min	Prim. vol. ml	Length mm	Ø G
1294.14	60	1.35	4	9.4	0.66	32	15

2.7 Composition of the device and Accessories :

COMPONENTS	MARKER	MATERIALS
Styilet hub	1	POM / Stainless steel
T proximal connector	2	PC
Catheter hub	3	PA
Extension line tubing	4	PU
Clamp	5	PC
Fixation wing	6	PU
Catheter tube	7	PU
Grip-Lok	8	PP/Acrylic/PU/Polyester
Bionector	9	PC/Stain. steel/Polyisoprene
Peelable cannula	10	Stainless steel / PE / SBC



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 :

- Peripherally inserted central venous catheter for mid- to long-term (>30 days) IV therapy and in particular :
- Administration of hyperosmolar solutions, antibiotics, chemotherapy and other drugs which are irritant to the peripheral vessels
 - Temporary catheterisation while awaiting insertion of a long-term catheter with subcutaneous cuff or one with an implantable port
 - Patients with injuries or burns to the chest and neck, patients who are to undergo radiotherapy in this area or patients who are suffering from respiratory problems.

3 Accessories

4 Sterilization process

	<p>Sterile Medical Device : YES</p> <p>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 :</p> <p>Storage environment temperature: between 5 and 40°C. Store protected from moisture and sunlight.</p>
5.2	
5.3	<p>Duration of product validity : 36 months</p>

6 Security of use

	<p>Technical security : Meets the requirements of ISO 10555</p> <p>Biological security : Meets the requirements of ISO 10993</p>
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7 Instructions for use

7.1	
7.2	<p>Indications : Peripherally inserted central venous catheter for mid- to long-term (>30 days) IV therapy and in particular :</p> <ul style="list-style-type: none"> - Administration of hyperosmolar solutions, antibiotics, chemotherapy and other drugs which are irritant to the peripheral vessels - Temporary catheterisation while awaiting insertion of a long-term catheter with subcutaneous cuff or one with an implantable port - Patients with injuries or burns to the chest and neck, patients who are to undergo radiotherapy in this area or patients who are suffering from respiratory problems.
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. Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reaction or bacterial infections.</p>
7.4	

8 Additional information relating to the product

	<p>Do not use this product for monitoring, diagnosis, control or treatment of a defect of the heart or the central venous system.</p>
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