

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 :

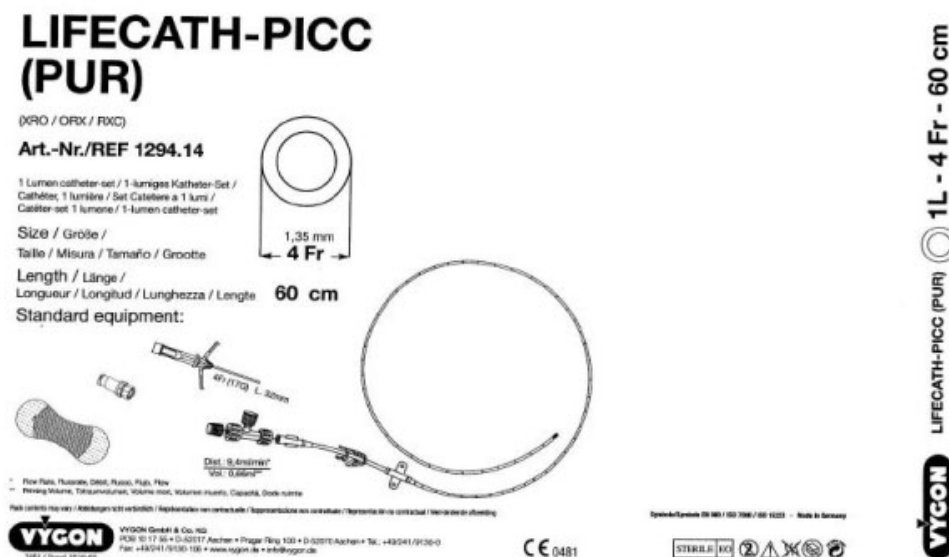
- a MST introducer with 50 cm long guidewire for standard MST placement by nurse (if legislation authorizes it) or by authorized practitioner : see technical file codes 1294.113/114/115/345,
- a MST introducer with 67 cm long guidewire for placement under fluoroscopy : see technical file codes 1294.414/415/445,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



2.6 Packaging / Containers

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
1294.14	1 (Double wrapped blister pack with Tyvek lid)	10 (Carton box)	10 (Carton box)	10 (Case box)

Single unit packaging



Box

lifecath PICC pur

REF 1294.14

(PUR) 4Fr 1L 60cm

Catheter Set with peelable cannula

Cathéter avec canule pelable

Catéter con cánula pelable

Katheterset mit spaltbarer Kanüle

Set con catetere e cannula apribile

Catheter set met splijtbare canule

Cateter com cânula descartável

Kateter mit delbar nål

Rx Only 
USA Only

STERILE EO   0481

lifecath PICC pur

REF 1294.14

LOT 020718GA

10

 2021-07-02

2018-07-02



(01) 53660812012275 (17) 210702 (30) 10 (10) 020718GA

Case labelling

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



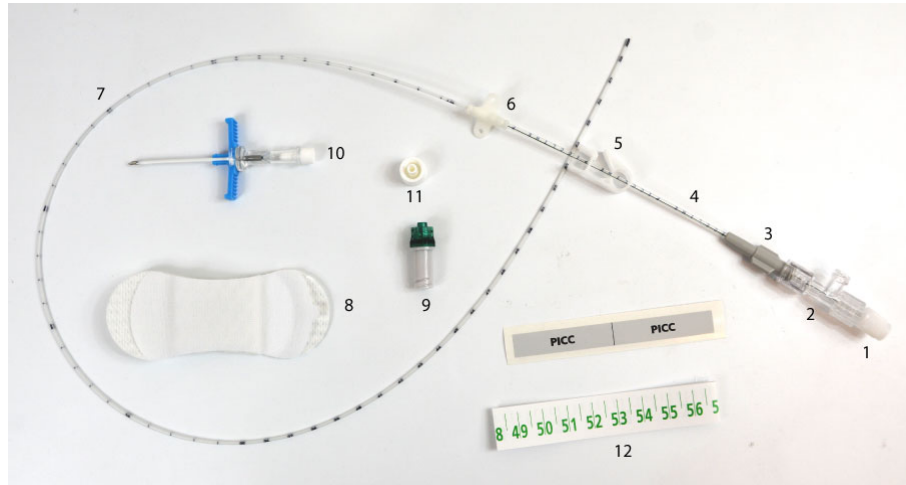
(01)03660812012270(17)210702(30)1(10)020718GA

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

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

5.3 Duration of product validity : 36 months

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

	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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