

TECHNICAL FILE

Lifecath PICC with MST (guidewire 50 cm)

1294.113

Dated : 26-11-2018

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1 Administrative information relating to the company

1.1	Name : Vygon SA	
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 : Peripherally inserted central venous catheter
2.2	Commercial name : Lifecath PICC with MST (guidewire 50 cm)
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 PICC is a peripherally inserted central catheter (basilic vein, cephalic vein, median cubital vein...) in biostable polyurethane available as single or double lumen catheter. This catheter is inserted with a MST peelaway introducer (Micro-Seldinger technique) allowing to puncture the vein with a very thin needle (21 G).
Lifecath PICC code 1294.113/114/115 is a single lumen catheter in 3 Fr, 4 Fr and 5 Fr.
Lifecath PICC code 1294.345 is a double-lumen catheter in 4.5 Fr.

Lifecath PICC is supplied in a double packaging (peel-pack + rigid blister pack in APET) containing :

- 1 radiopaque catheter in biostable polyurethane. This material allows to keep the catheter in place over a long period of time of many months if necessary. The catheter features centimetric graduations and numerical markings every 5 cm. The polyurethane extension tube (length 9 cm) is an integral part of the catheter.
- 1 stainless steel stylet making the catheter slightly more rigid to facilitate its insertion
- 1 "T" piece proximal adapter allowing the injection of saline solution through the lateral port to prime the catheter or to open the passage in case of venous spasm and to lubricate the stylet for easy removal.
- 1 Micro-Seldinger introducer (see hereunder the components of this introducer)
- 1 Bionector code 896
- 1 measuring tape
- 1 Griplock securement device
- 2 traceability labels

The Micro-Seldinger introducer includes :

- 1 echogenic safety puncture needle 21G (to avoid the risk of needle-stick injury)
- 1 syringe 10 ml
- 1 Nitinol straight guidewire (50 cm long)
- 1 guide advancer
- 1 peelaway Desilet 7 cm
- 1 scalpel

Lifecath PICC can be used for periods of a few weeks (2 or 3) to several months.
It is suitable for both hospitalised patients and 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 theater (at bedside or at home).

Lifecath PICC is also available with :

- a peelaway short IV cannula introducer : see technical file codes 1294.13/14/15/245
- 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

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
1294.113	1 (Double wrapped blister pack with Tyvek lid)	10 (Carton box)	10 (Carton box)	10 (Case box)

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Box

lifecath picc pur



REF 1294.113

(PUR) 3Fr 1L 60cm

Catheter Set with breakaway sheath for MST
Katheterset mit spaltbarem Einführbesteck für MST
Cathéter avec introducteur pelable pour MST
Catéter con faja pelable para MST
Set con catetere e introduttore a guaina apribile per MST
Catheter set met splijtbare introducer voor MST
Conjunto de cateter com introdutor descartável para MST
Kateter kit med breakaway sheath för MST

Rx Only
USA Only



STERILE EO



CE 0481

lifecath picc pur

REF 1294.113

LOT 110615GA

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2018 - 07



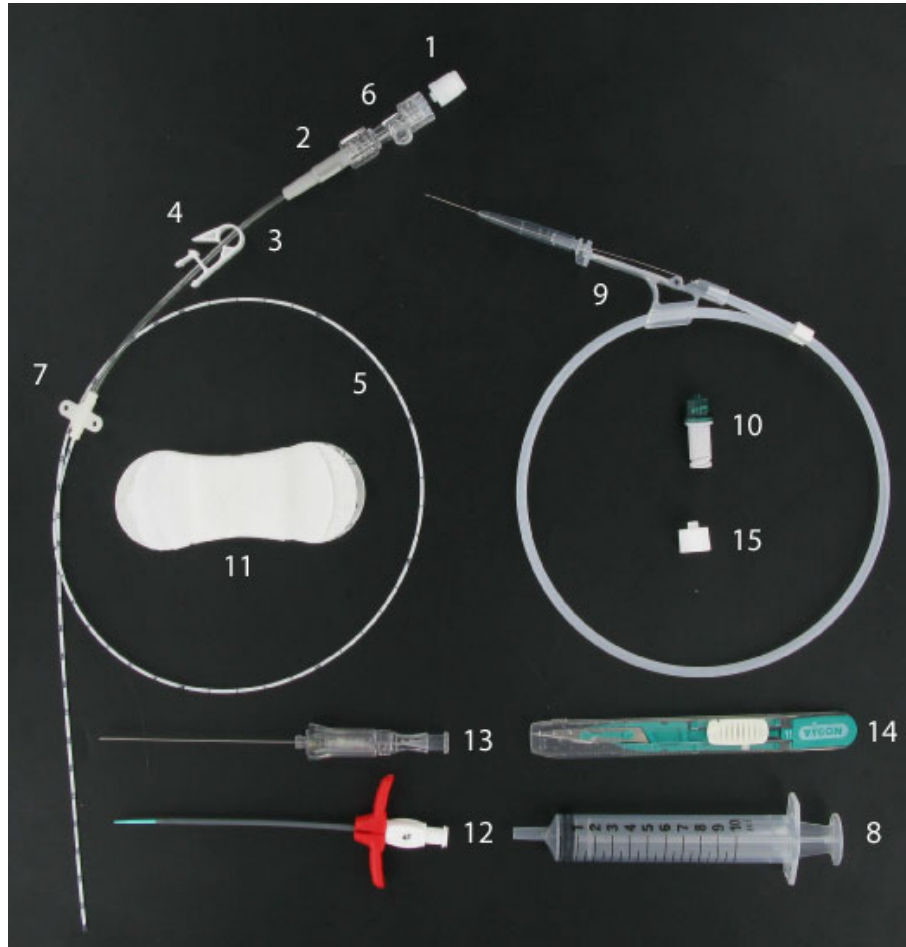
(01) 53660812067640 (17) 180731 (30) 10 (10) 110615GA

Technical features :

Code	Catheter							Guidewire
	Length cm	Int. Ø mm	Ext. Ø mm	Ø Fr	Prim. vol. ml	Flow rate by gravity ml/min	Lumen -	Length cm
1294.113	60	0.5	1.0	3	0.46	1.6	1	50

2.7 Composition of the device and Accessories : 1294.113

COMPONENTS	MARKER	MATERIALS
Hub of stylet	1	POM / Stainless steel
Catheter hub	2	PA
Extension tube	3	PU
Clamp	4	PC
Catheter tube	5	PU
Proximal T connector	6	PC
Fixation wings	7	PU
Syringe	8	PP
Guide and guide advancer	9	PP/PE/Nitinol/ABS
Bionector	10	PC/Stain. steel/Polyisoprene
Griplok	11	PP/Acrylic/PU/Polyester
Peelaway Desilet	12	PP/PTFE/PE
Puncture needle	13	MABS/Stainless steel/PES/PE
Scalpel	14	Stainless steel
Cap	15	PP



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 sub-cutaneous cuff or one with an implantable port
 - Patients with injuries or burns to the chest and neck, patients who are to undergo radiotherapy on 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

	Technical security : Meets the requirements of ISO 10555 Biological security : Meets the requirements of ISO 10993
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7 Instructions for use

7.1	
7.2	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 sub-cutaneous cuff or one with an implantable port - Patients with injuries or burns to the chest and neck, patients who are to undergo radiotherapy on this area or patients who are suffering from respiratory problems.
7.3	Precautions : Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reaction or bacterial infections.
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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