

TECHNICAL FILE

Arterial Leadercath (PE)

115.12

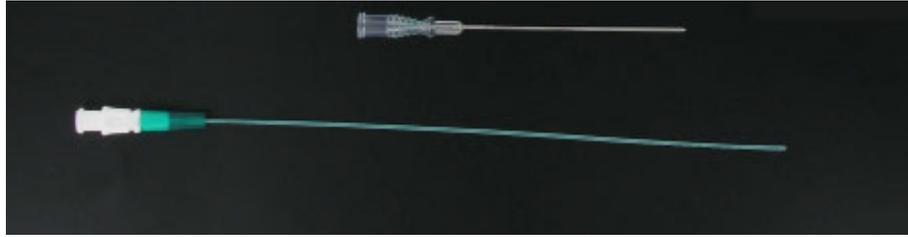
Dated : 22-02-2023

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 : Arterial catheter for pressure measurement
2.2	Commercial name : Arterial Leadercath (PE)
2.4	Medical Device Class : IIa Applicable regulation : 93/42/CEE in accordance with Appendix n° : II Notified body N° : 0459 Medical Device Manufacturer : Vygon
2.5	<p>Description of the device :</p> <p>Arterial Leadercath is a catheter for arterial access inserted by the Seldinger technique. Although it can be inserted in a variety of arteries, the most common sites for the placement of this catheter are the radial and the femoral artery.</p> <p>The Seldinger technique makes arterial puncture easier particularly in hypotensive patients with a weak peripheral pulse and when arteries are atherosclerosed or narrow.</p> <p>The product is supplied in a rigid blister pack containing:</p> <ul style="list-style-type: none"> - 1 introducer needle, - 1 straight guidewire, - 1 transparent and radiopaque catheter in polyethylene with winged hub (except codes 115.12/15/17, hub without wings). <p>Codes 115.12, 115.15 and 115.17 contain also:</p> <ul style="list-style-type: none"> - 1 polyethylene extension tube (30cm long), - 1 syringe 5 ml, - 1 three-way stopcock, - 1 drape towel 45 x 60cm.



2.6 Packaging / Containers

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
115.12	1 (Rigid blister pack (APET))	5 (Carton box)	5 (Carton box)	45 (Carton box)

Single unit packaging

Box

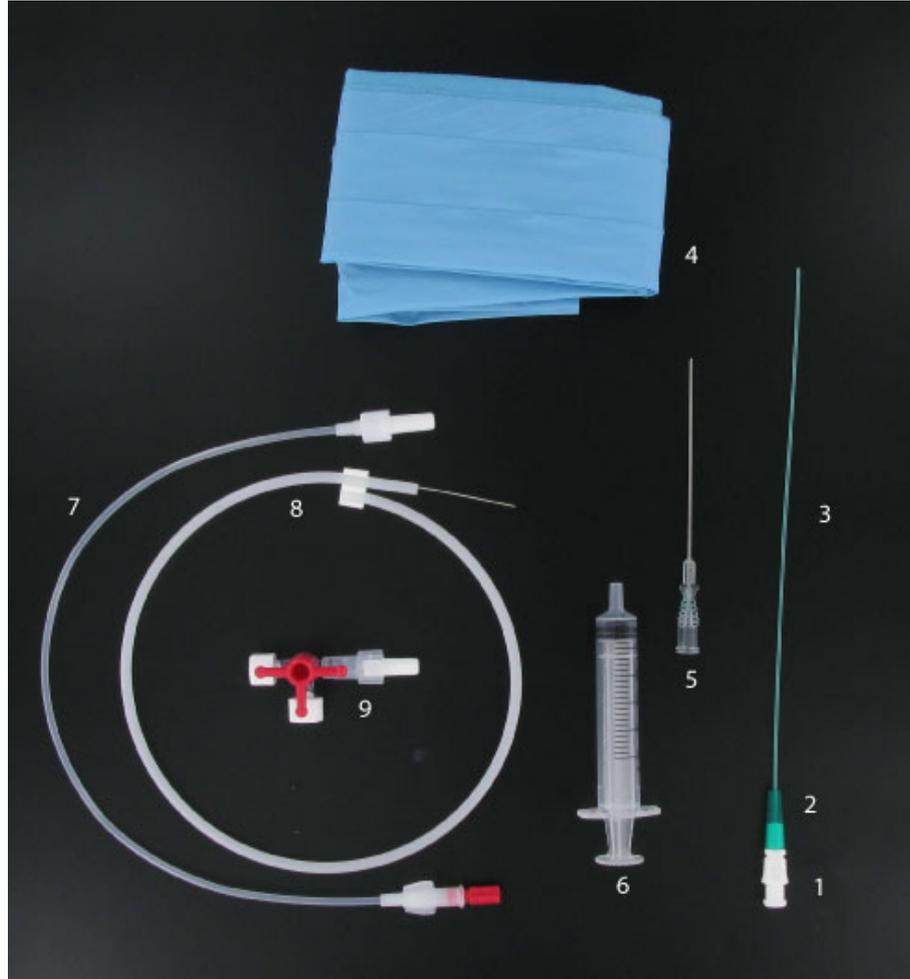


Technical features :

Code	Catheter						Puncture needle				Guidewire	
	Length cm	Int. Ø mm	Ext. Ø mm	Gauge G	Ø Fr	Flow rate ml/min	Length mm	Int. Ø mm	Ext. Ø mm	G G	Length cm	Ø mm
115.12	18	0.8	1.2	18	4	34	68	0.8	1.1	19	46	0.71

2.7 Composition of the device and Accessories :

COMPONENTS	MARKER	MATERIALS
Catheter hub	1	PE
Catheter	2	PE
Anti-kink collar	3	PVC
Drape towel	4	PP / PE
Introducer needle	5	Stainless steel / MABS / PE
Syringe (code 115.12/15/17)	6	PP / TPE
Extension tube (code 115.12/15/17)	7	PE
Guidewire / protector	8	Stainless steel / PE
3-way stopcock (code 115.12/15/17)	9	PC/POM/PE/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 :

Arterial Leadercath is a catheter for arterial puncture (radial, femoral, brachial, pedal...).

Arterial Leadercath is used:

- for blood gas measurements (PaO₂, PaCO₂...)
- invasive arterial pressure monitoring

This catheter can also be used intravenously for infusions and drug administrations.

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	Special precautions : Please refer to the IFU in the packaging.
5.3	Duration of product validity : 60 months

6 Security of use

	Technical security : Please refer to the IFU in the packaging.
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7 Instructions for use

7.1	Instructions : Please refer to the IFU in the packaging.
7.2	Indications : Arterial Leadercath is a catheter for arterial puncture (radial, femoral, brachial, pedal...). Arterial Leadercath is used: - for blood gas measurements (PaO ₂ , PaCO ₂ ...) - invasive arterial pressure monitoring This catheter can also be used intravenously for infusions and drug administrations.
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. Please refer to the IFU in the packaging.
7.4	Contra indications : Please refer to the IFU in the packaging.

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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