

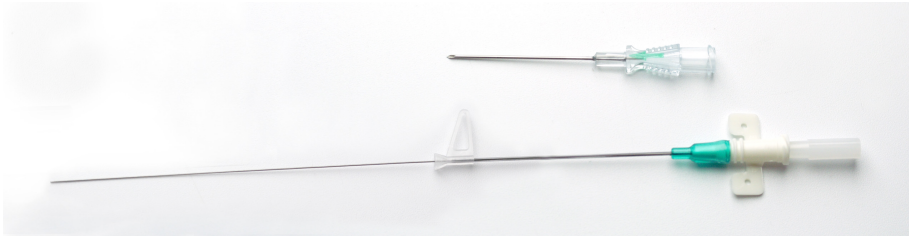
TECHNICAL FILE
Arterial Leadercath (PUR)
5115.112

Dated : 07-04-2016

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 (Seldinger technique)
2.2	Commercial name : Arterial Leadercath (PUR)
2.4	Medical Device Class : IIa Applicable EU Directive : 93/42/CEE in accordance with Appendix n° : II Notified body N° : 0459 Medical Device Manufacturer : Vygon
2.5	Description of the device : 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. The Seldinger technique makes arterial puncture easier particularly in hypotensive patients with a weak peripheral pulse and when arteries are atherosclerosed or narrow. The product is supplied in a rigid blister containing: - 1 stainless steel puncture needle, - 1 transparent polyurethane catheter with 3 radiopaque lines and fixation wings, - 1 straight metallic guidewire, - 1 guidewire introducer device (only supplied with codes 5115.094/096/098).
	

2.6 Packaging / Containers

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
5115.112	1 (Rigid blister in APET)	20 (Carton box)	20 (Carton box)	180 (Carton box)

Single unit packaging



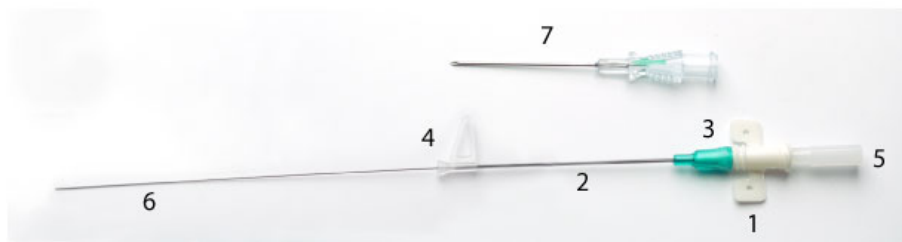
Box



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	Ext. Ø mm
5115.112	12	0.8	1.3	18	4	40	54	0.8	1.1	19	30	0.64

2.7 Composition of the device and Accessories : 5115.112		
COMPONENTS	MARKER	MATERIALS
Hub	1	PU
Tube	2	PU
Anti-kinking device	3	PVC
Guidewire introducer	4	EVA
Cap	5	PE
Guidewire	6	Stainless steel
Puncture needle	7	Stainless steel / ABS / PE



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	<p>Indications : Arterial Leader-Cath is a catheter for arterial puncture (radial, femoral, brachial, pedal...).</p> <p>Arterial Leader-Cath is used:</p> <ul style="list-style-type: none"> - for blood gas measurements (PaO₂, PaCO₂...) - invasive arterial pressure monitoring
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3 Accessories

4 Sterilization process

<p>Sterile Medical Device : YES</p> <p>Sterilization made for the device : Ethylene oxide</p>

5 Conditions of conservation and storage

5.1	<p>Normal conservation and storage conditions : Storage environment temperature: between 5 and 40°C. Store protected from moisture and sunlight.</p>
5.2	
5.3	<p>Duration of product validity : 60 months</p>

6 Security of use

7 Instructions for use

7.1	
7.2	Indications : Arterial Leader-Cath is a catheter for arterial puncture (radial, femoral, brachial, pedal...). Arterial Leader-Cath is used: - for blood gas measurements (PaO ₂ , PaCO ₂ ...) - invasive arterial pressure monitoring
7.3	
7.4	

8 Additional information relating to the product