

TECHNICAL FILE

Arterial Leadercath

5115.112

Dated : 22-02-2023

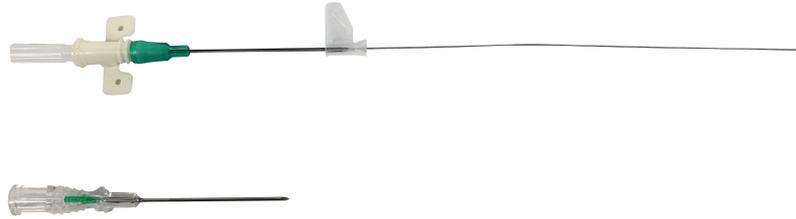
22.

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
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	Description of the device : Arterial Leadercath are single lumen polyurethane radio-opaque arterial catheters. These catheters are introduced by a classic Seldinger technique. They are indicated for a short term therapy up to 30 days for new born (>3.5kg), child and adult arterial catheterization to perform invasive continuous arterial pressure measurement or to allow repeated arterial blood sampling. Common insertion sites are the radial, brachial, and femoral arteries. Less frequently used insertion sites are the ulnar, axillary, posterior tibial, and dorsal pedis arteries. Contents: One radio-opaque catheter (which features an anti-kinking sleeve) and accessories/components to allow its insertion: - One puncture needle, - One straight stainless steel radio-opaque guidewire with one supple extremity, - Codes 5115.094/096/098 feature a centering guidewire introducer, which helps to insert the catheter over the guidewire.



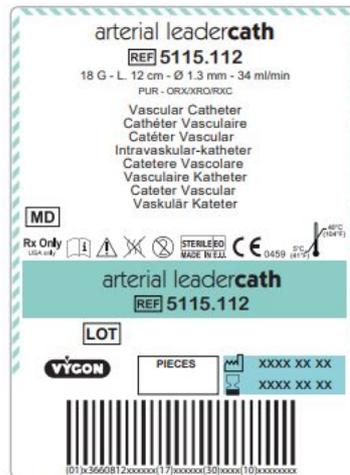
2.6 Packaging / Containers

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



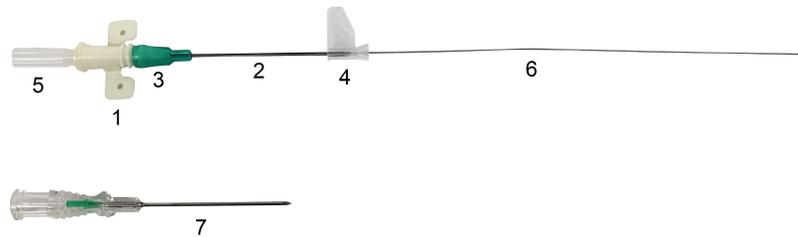
Box



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	34	54	0.8	1.1	19	29	0.64	

2.7 Composition of the device and Accessories :

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 / MABS / 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 Indications :

They are indicated for a short term therapy for arterial catheterization to perform invasive continuous arterial pressure measurement or to allow repeated arterial blood sampling.

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 : Storage environment temperature: between 5 and 40°C. Store protected from moisture and sunlight.</p>
5.2	<p>Special precautions : Please refer to instructions for use included in the packaging.</p>
5.3	<p>Duration of product validity : 60 months</p>

6 Security of use

	<p>Technical security : Please refer to instructions for use included in the packaging.</p>
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7 Instructions for use

7.1	<p>Instructions : Please refer to instructions for use included in the packaging.</p>
7.2	<p>Indications : They are indicated for a short term therapy for arterial catheterization to perform invasive continuous arterial pressure measurement or to allow repeated arterial blood sampling.</p>
7.3	<p>Precautions : Please refer to instructions for use included in the packaging. 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	<p>Contra indications : Please refer to instructions for use included in the packaging.</p>

8 Additional information relating to the product