

TECHNICAL FILE

Arteriosel

115.0901

Dated : 29-03-2022

19.

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

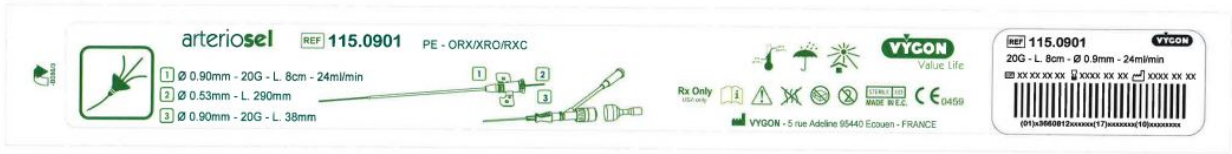
2.1	Generic name : Arterial catheter
2.2	Commercial name : Arteriosel
2.4	Medical Device Class : IIa Applicable regulation : 93/42/CEE in accordance with Appendix n° : II Notified body N° : 0459 Medical Device Manufacturer : Vygon
2.5	<p>Description of the device :</p> <p>ArterioSel is a transparent arterial catheter with radiopaque lines introduced using the Seldinger technique and equipped with a puncture needle allowing visualization of the arterial pulsations without blood spillage on needle insertion. The Seldinger technique makes arterial puncture easier particularly in hypotensive patients with a weak peripheral pulse and when arteries are atherosclerosed or narrow.</p> <ul style="list-style-type: none"> - The puncture needle is fitted with a visualization chamber allowing to confirm that the vessel punctured is an artery (pulsatile movement of the blood). The needle is also fitted with a silicone BLS valve (BLS: bloodless system) to avoid loss of blood during vessel puncture and a funnel hub to facilitate the insertion of the guidewire. - The arterial catheter can be inserted in a variety of arteries, but the most common sites for the placement of this catheter is the radial artery. <p>ArterioSel is presented in a rigid blister pack containing:</p> <ul style="list-style-type: none"> - 1 transparent and radiopaque catheter in polyethylene with winged hub - 1 straight guidewire - 1 puncture needle with: a) 1 BLS silicone valve, b) 1 funneled hub, c) 1 visualization chamber <p>ArterioSel code 115.6981 is also supplied with an extension tube fitted with an Autoflush.</p> <p>ArterioSel is also available with a 4Fr, 18cm long catheter for femoral placement (see technical file 115.1201).</p>



2.6 Packaging / Containers

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
115.0901	1 (Rigid blister pack (APET))	20 (Carton box)	20 (Carton box)	180 (Carton box)

Single unit packaging



Box

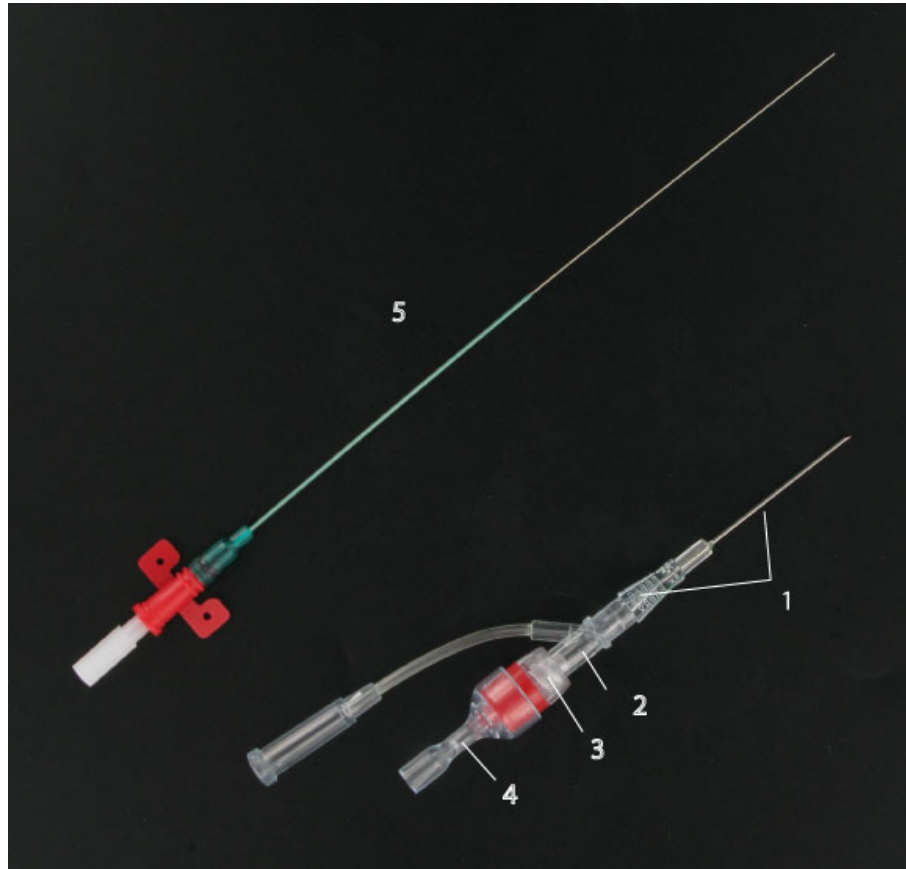


Technical features :

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	Ø mm
115.0901	8	0.6	0.9	20	3	24	38	0.6	0.9	20	29	0.53

2.7 Composition of the device and Accessories :

COMPONENTS	MARKER	MATERIALS
Needle	1	Stainless steel / MABS / PE
Y connector	2	MABS
BLS valve	3	PC / SI / MABS
Funneled hub	4	SB
Catheter	5	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 :

Arteriosel is a catheter for arterial puncture (radial, brachial...)

Arteriosel is used

- for blood gas measurements (Pa O₂, Pa CO₂...)
- invasive arterial pressure monitoring.

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 catheter inserted by Seldinger technique for blood gas analysis and arterial pressure measurement.
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	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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