

## TECHNICAL FILE

Arteriosel

115.0901

Dated : 29-03-2022

19.

### 1 Administrative information relating to the company

|     |   |   |
|-----|---|---|
| 1.1 | <b>Name :</b> Vygon   |   |
| 1.2 | <b>Address :</b><br>5 rue Adeline - 95440 Ecouen, France                | <b>Fax :</b> + 33 (0)1 34 29 19 34<br><b>E-mail :</b> questions@vygon.com<br><b>Website :</b> www.vygon.com |
| 1.3 | <b>Medical Device vigilance Representative :</b><br>Laurent GUILLARDEAU | <b>Tel :</b> +33 (0)1 39 92 65 69<br><b>Fax :</b> +33 (0)1 39 92 64 82<br><b>E-mail :</b> quality@vygon.com |

### 2 Information about the device or equipment

|     |  |
|-----|--|
| 2.1 | <b>Generic name :</b> Arterial catheter  |
| 2.2 | <b>Commercial name :</b> Arteriosel  |
| 2.4 | <b>Medical Device Class :</b> IIa<br><b>Applicable regulation :</b> 93/42/CEE<br><b>in accordance with Appendix n° :</b> II<br><b>Notified body N° :</b> 0459<br><b>Medical Device Manufacturer :</b> Vygon  |
| 2.5 | <p><b>Description of the device :</b></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"> <li>- 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.</li> <li>- 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.</li> </ul> <p>ArterioSel is presented in a rigid blister pack containing:</p> <ul style="list-style-type: none"> <li>- 1 transparent and radiopaque catheter in polyethylene with winged hub</li> <li>- 1 straight guidewire</li> <li>- 1 puncture needle with: a) 1 BLS silicone valve, b) 1 funneled hub, c) 1 visualization chamber</li> </ul> <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> |



**Box**

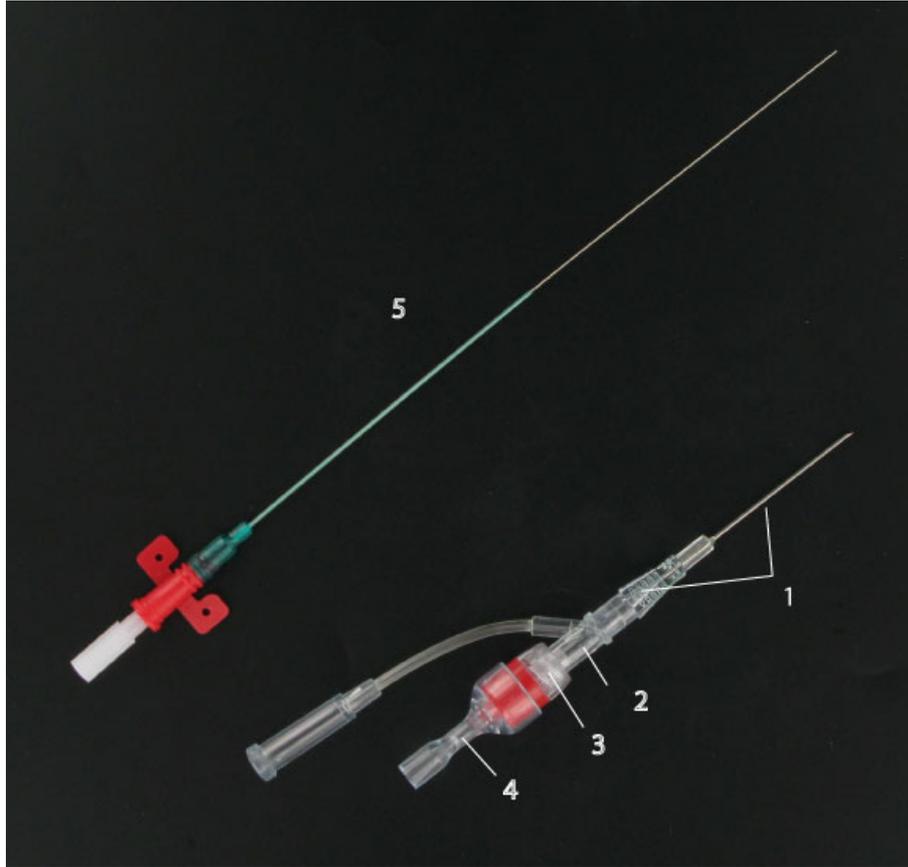


**Technical features :**

| Code     | Catheter     |              |              |            |         |                     | Puncture needle |              |              |        | Guidewire    |         |
|----------|--------------|--------------|--------------|------------|---------|---------------------|-----------------|--------------|--------------|--------|--------------|---------|
|          | Length<br>cm | Int. Ø<br>mm | Ext. Ø<br>mm | Gauge<br>G | Ø<br>Fr | Flow rate<br>ml/min | Length<br>mm    | Int. Ø<br>mm | Ext. Ø<br>mm | G<br>G | Length<br>cm | Ø<br>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 O<sub>2</sub>, Pa CO<sub>2</sub>...)
  - 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 | <p><b>Normal conservation and storage conditions :</b><br/>Storage environment temperature: between 5 and 40°C. Store protected from moisture and sunlight.</p> |
| 5.2 | <p><b>Special precautions :</b><br/>Please refer to the IFU in the packaging.</p>   |
| 5.3 | <p><b>Duration of product validity :</b> 60 months</p>  |

## 6 Security of use

|  |  |
|--|--|
|  | <p><b>Technical security :</b><br/>Please refer to the IFU in the packaging.</p> |
|--|--|

## 7 Instructions for use

|     |   |
|-----|---|
| 7.1 | <p><b>Instructions :</b><br/>Please refer to the IFU in the packaging.</p>  |
| 7.2 | <p><b>Indications :</b><br/>Arterial catheter inserted by Seldinger technique for blood gas analysis and arterial pressure measurement.</p>                                     |
| 7.3 | <p><b>Precautions :</b><br/>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><b>Contra indications :</b><br/>Please refer to the IFU in the packaging.</p>  |

## 8 Additional information relating to the product

|  |   |
|--|---|
|  | <p>Do not use this product for monitoring, diagnosis, control or treatment of a defect of the heart or the central venous system.</p> |
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