

## TECHNICAL FILE

### Male Luer-lock to male Luer-lock extension tube 221.050

Dated : 22-02-2023

#### 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

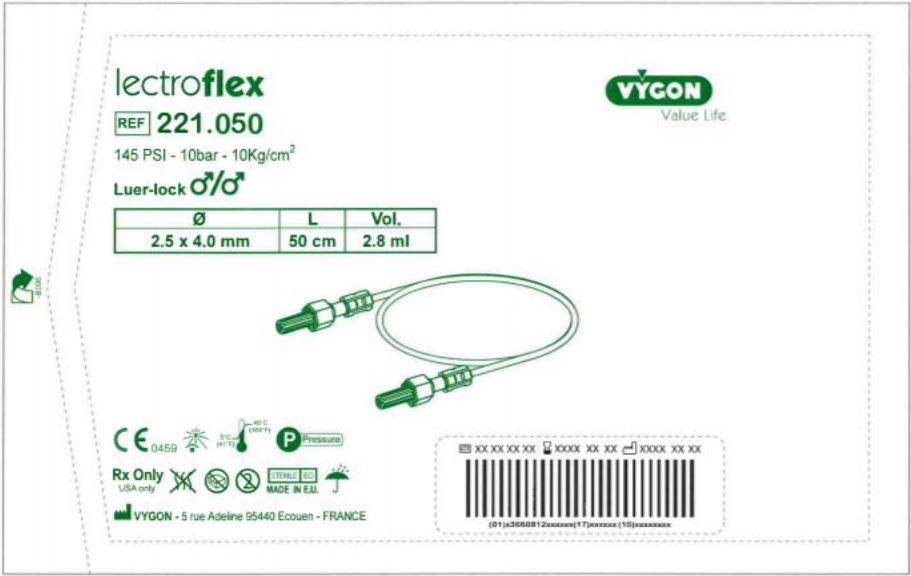
|     |                                                                                                                                                                                                                                                                                                                                                                                    |
|-----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2.1 |                                                                                                                                                                                                                                                                                                                                                                                    |
| 2.2 | <b>Commercial name :</b> Male Luer-lock to male Luer-lock extension tube                                                                                                                                                                                                                                                                                                           |
| 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 | <b>Description of the device :</b><br>Triple layer extension tube (PVC/EVA/PE)* for IV catheters with two male Luer-lock ends.<br><br>Available in 4 lengths: 50 cm (code 221.050), 100 cm (code 221.100), 150 cm (code 221.150) and 200 cm (code 221.200).<br><br>Diameter: 2.5 x 4.0 mm. Pressure tested at 10 kg/cm <sup>2</sup> (145 psi).<br><br>*See additional information. |



2.6 Packaging / Containers

| Code    | Single unit packaging   | Multi unit packaging | Minimum delivery quantity | Case       |
|---------|-------------------------|----------------------|---------------------------|------------|
| 221.050 | 1 (Supple blister pack) | 25 (Box)             | 25 (Box)                  | 300 (Case) |

Single unit packaging



### Box

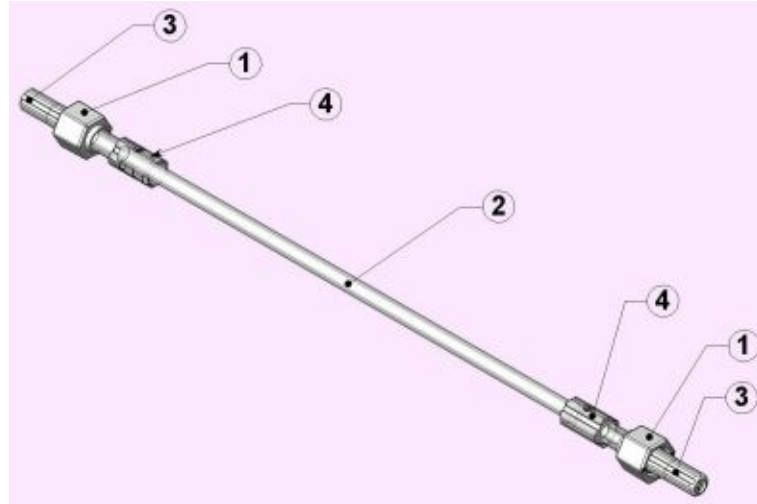


### Technical features :

| Code    | Extension tube |              |              |                  |
|---------|----------------|--------------|--------------|------------------|
|         | Length<br>cm   | Int. Ø<br>mm | Ext. Ø<br>mm | Prim. vol.<br>ml |
| 221.050 | 50             | 2.5          | 4.0          | 2.80             |

### 2.7 Composition of the device and Accessories :

| COMPONENTS           | MARKER | MATERIALS      |
|----------------------|--------|----------------|
| Male rotating device | 1      | PC             |
| Tube                 | 2      | PE / EVA / PVC |
| Cap                  | 3      | PE             |
| Hub                  | 4      | PC             |



**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 :**  
Add-on device for intravenous catheter - Catheter extension tube  
Example of use: I.V. catheter - Extension tube code 221 - Ramp of stopcocks with female/female Luer-lock ends.

### 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**

- 5.3 Duration of product validity :** 60 months

### 6 Security of use

### 7 Instructions for use

|     |                                                                                                                                                                         |
|-----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 7.1 |                                                                                                                                                                         |
| 7.2 | <b>Indications :</b><br>Add-on device for intravenous catheter - Catheter extension tube                                                                                |
| 7.3 | <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. |
| 7.4 |                                                                                                                                                                         |

## 8 Additional information relating to the product

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>PE lined PVC extension tube.</p> <p>This extension tube is made of 3 layers. The outer layer is in PVC, the inner layer is in Polyethylene without additives, material presenting a high chemical inertness and the intermediate layer is Ethyl Vinyl Acetate, material linking the inner and the outer layers.</p> <p>This structure allows to minimize interactions with drugs and leaching of plasticizers from the PVC into the administered solutions.</p> |
|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|