

## TECHNICAL FILE

### Connect-A-set 3

70141.00

Dated : 06-01-2021

#### 1 Administrative information relating to the company

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

#### 2 Information about the device or equipment

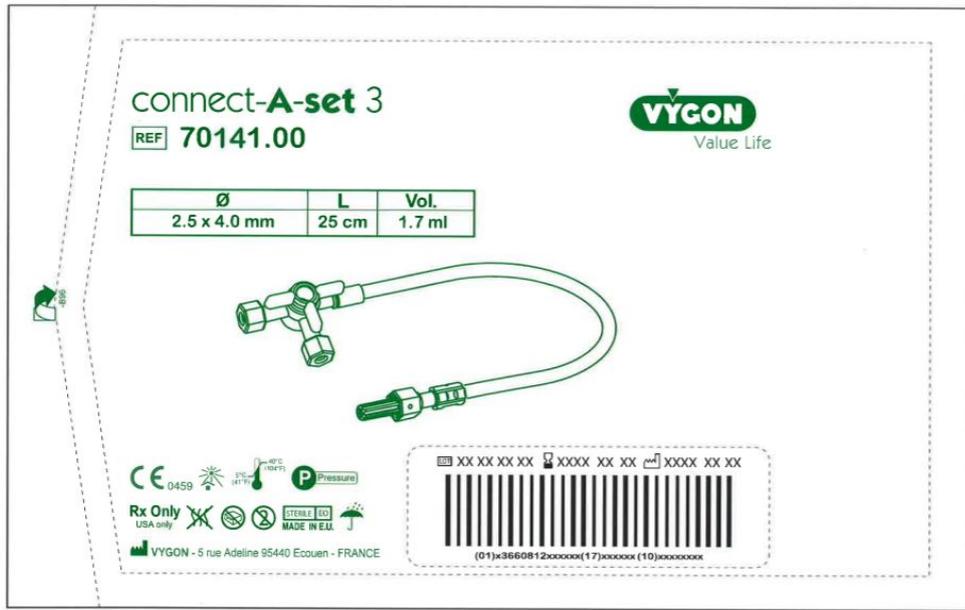
<b>2.1</b>	<b>Generic name :</b> Extension tube for IV catheters
<b>2.2</b>	<b>Commercial name :</b> Connect-A-set 3
<b>2.4</b>	<b>Medical Device Class :</b> IIa <b>Applicable regulation :</b> 93/42/CEE <b>in accordance with Appendix n° :</b> II <b>Notified body N° :</b> 0459 <b>Medical Device Manufacturer :</b> Vygon
<b>2.5</b>	<b>Description of the device :</b> Triple layer extension tube (PVC/EVA/PE)* for peripheral I.V. cannula or central venous catheter with 3-way stopcock molded in a lipid-resistant raw material. Internal diameter: 2.5mm - External diameter: 4.0mm. Tested to 10kg/cm <sup>2</sup> (145 PSI)  Code 141 is available in 3 lengths: 13.5cm (code 141.01), 25cm (code 141.00) and 80cm (code 141.80). Code 70141 is available in 5 lengths: 13.5cm (code 70141.01), 25cm (code 70141.00), 50cm (code 70141.05), 80cm (code 70141.80) and 100cm (code 70141.10).  Code 141: The side port of the stopcock is fitted with an injection cap for intermittent drug injections. Code 70141: The side port of the stopcock is fitted with a simple male Luer-lock cap.  *See additional information.



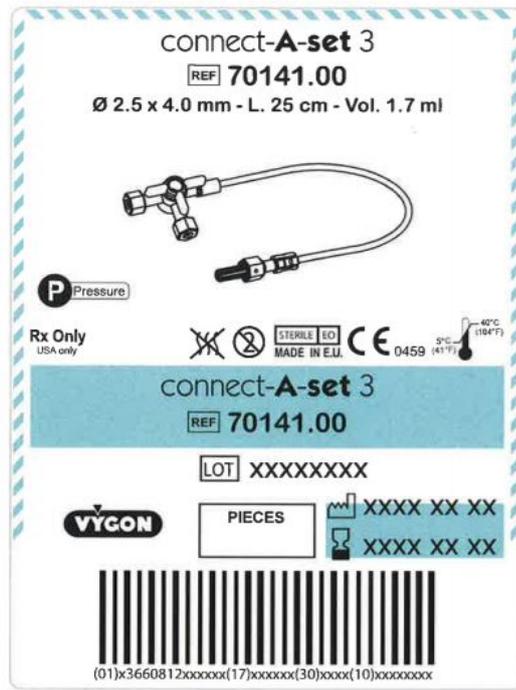
**2.6 Packaging / Containers**

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
70141.00	1 (Dble pack.: Internal (PE) bag+supple blister pack )	50 (Carton box)	50 (Carton box)	300 (Carton box)

Single unit packaging



Box



Technical features :

Code	Extension tube			
	Length cm	Int. Ø mm	Ext. Ø mm	Prim. vol. ml
70141.00	25	2.5	4.0	1.70

**2.7 Composition of the device and Accessories :**

COMPONENTS	MARKER	MATERIALS
Body of stopcock	1	PC
Key of stopcock	2	PE
Cap	3	PE
Tube	4	PE / EVA / PVC
Male Luer-lock connector	5	PC
Male locking device	6	PC
Protector	7	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 :**

Extension tube with 3 way stopcock for peripheral IV cannula or central venous catheter.

3 Accessories

4 Sterilization process

	<p><b>Sterile Medical Device :</b> YES</p> <p><b>Sterilization made for the device :</b> Ethylene oxide</p>
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5 Conditions of conservation and storage

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

6 Security of use

7 Instructions for use

7.1	
7.2	<p><b>Indications :</b> Extension tube for short I.V. cannula or central venous catheter for gravity infusions.</p>
7.3	<p><b>Precautions :</b> Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reaction or bacterial infections. 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	

8 Additional information relating to the product

	<p>PE lined PVC extension tube. 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. This structure allows to minimize interactions with drugs and leaching of plasticizers from the PVC into the administered solutions.</p>
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