

## TECHNICAL FILE

Octopus for TIVA

841.361

Dated : 10-03-2016

### 1 Administrative information relating to the company

1.1	<b>Name :</b> Vygon	
1.2	<b>Address :</b> 5 rue Adeline - 95440 Ecoen, France	<b>Fax :</b> + 33 (0)1 34 29 19 34 <b>E-mail :</b> questions@vygon.com <b>Website :</b> www.vygon.com
1.3	<b>Medical Device vigilance Representative :</b> Agnès MIGNOT	<b>Tel :</b> 01 39 92 63 51 <b>Fax :</b> 01 39 92 64 82 <b>E-mail :</b> quality@vygon.com

### 2 Information about the device or equipment

2.1	<b>Generic name :</b> Multi-lumen extension tube
2.2	<b>Commercial name :</b> Octopus for TIVA
2.4	<b>Medical Device Class :</b> IIa <b>Applicable EU Directive :</b> 93/42/CEE <b>in accordance with Appendix n° :</b> II <b>Notified body N° :</b> 0459 <b>Medical Device Manufacturer :</b> Vygon

**2.5 Description of the device :**

Octopus for TIVA is a triple lumen catheter extension tube specifically designed for total intravenous anaesthesia by target controlled infusion.

Octopus for TIVA features:

- 3 separate lumens
- as short as possible (10 cm long) with low priming volume (0.38 ml)
- equipped with non-return valves
- colour coded clamps to prevent any risk of confusion

Octopus for TIVA can be used in the operating theatre and in the recovery room.

Characteristics of the Octopus for TIVA:

Lumen 1, 2 and 3: int. – ext. Ø 1.5 x 2.5 mm – Length 10 cm

Priming volume 0.38 ml (per lumen) – Flow rate 110 ml / min (x 3)

The benefits of Octopus 841.361

**ACCURATE**

Three lumen 10 cm extension tubes with an internal diameter offering excellent accuracy for administration.

**CHEMICALLY INERT**

The Octopus tubing is made of polyurethane: reduced risk of drug adsorption/absorption; no release of plasticizers.

**PRACTICAL**

Obturator caps are supplied to close and protect the female Luer-lock ports when not in use.

**PREVENTS DRUG INTERACTIONS**

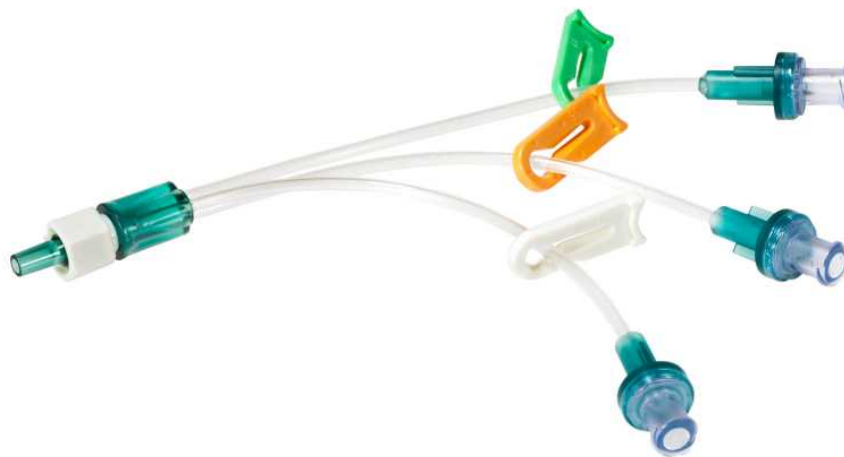
Medications do not mix until they arrive in the cannula, thereby preventing drug interactions.

**SECURITY**

Proximal non-return valves prevent backtracking and accidental bolus delivery.

**PREVENTS CONFUSION**

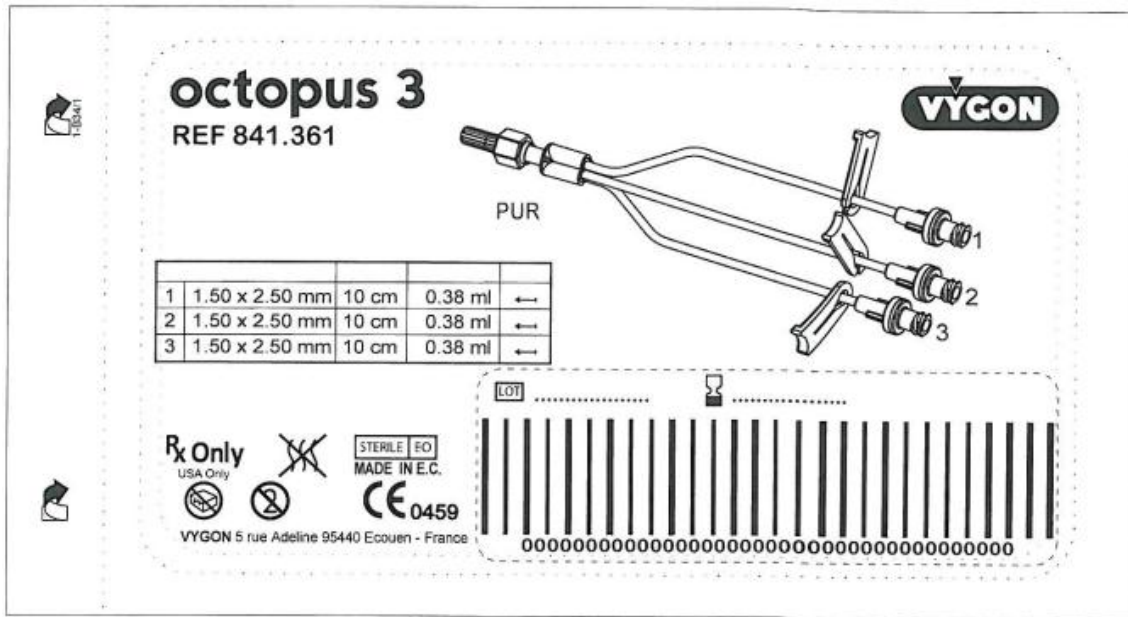
A different colour code is used for each lumen.



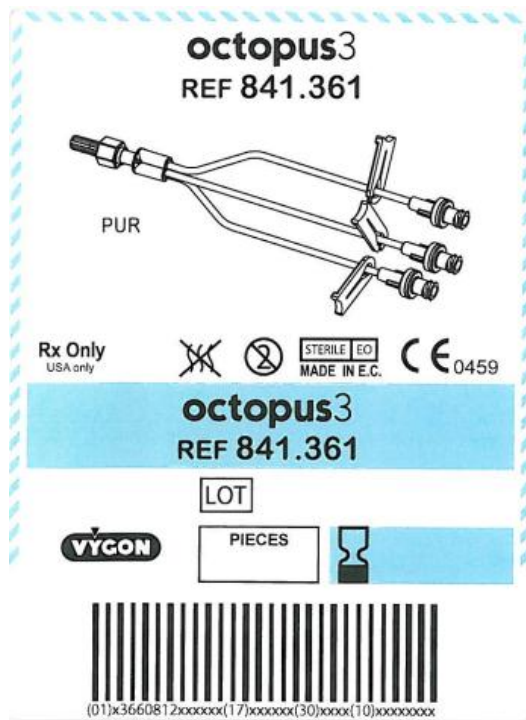
**2.6 Packaging / Containers**

Code	Single unit packaging	Multi unit packaging	Minimum delivery quantity	Case
841.361	1 (Supple blister pack)	10 (Carton box)	10 (Carton box)	240 (Case)

Single unit packaging



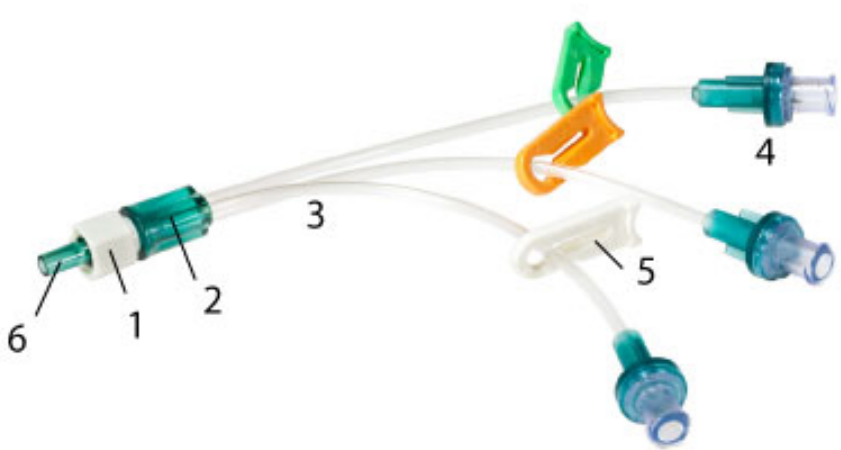
Box



Technical features :

Code	Extension tube					
	Length cm	Int. Ø mm	Ext. Ø mm	Prim. vol. ml	Flow rate ml/min	Total priming volume ml
841.361	10 (x3)	1.50 (x3)	2.50 (x3)	0.38 (x3)	110 (x3)	0.93

2.7 Composition of the device and Accessories : 841.361		
COMPONENTS	MARKER	MATERIALS
Mobile locking device	1	PC
Connector	2	ABS
Tube	3	PU
Non-return valve	4	PC / Si
Clamp	5	PC
Protector	6	PE
Cap		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 :**  
 Triple-lumen extension tube for TIVA (total intravenous anaesthesia) by target controlled infusion.

**3 Accessories**

**4 Sterilization process**

**Sterile Medical Device :** YES  
**Sterilization made for the device :** Ethylene oxide

**5 Conditions of conservation and storage**

5.1	<b>Normal conservation and storage conditions :</b> Store protected from heat, moisture and light.
5.2	
5.3	<b>Duration of product validity :</b> 60 months

6 Security of use

7 Instructions for use

7.1	
7.2	<b>Indications :</b> Triple-lumen extension tube for TIVA (total intravenous anaesthesia) by target controlled infusion.
7.3	
7.4	

8 Additional information relating to the product