FSN Ref: 20 0041 **FSCA Ref: VGL2020-0014**

Date: 12/02/2020

Urgent Field Safety Notice
RECALL Octopus code 842.312 batch 130919AF

For Attention of : Person responsible of Medical Devices Safety / vigilance – Passed on to all user departments and users

Contact details of local representative
VYGON local distributor

FSN Ref: 20 0041 **FSCA Ref: VGL2020-0014**

Urgent Field Safety Notice (FSN)
RECALL Octopus code 842.312 batch 130919AF

	1. **Information on Affected Devices**
1	1. **Device Type**
	Octopus is a 3 lumens extension line with safety connectors and non-return valves
1	**2. Commercial name**
	Octopus
1	**3. Primary clinical purpose of device(s)**
	Octopus is an IV extension line with 3 ways , safety connectors and anti-return valves for injection and infusion of drugs and parenterals.
1	**4. Device Model**
	842.312
1	**5. Affected lot number**
	130919AF

2 **Reason for Field Safety Corrective Action (FSCA)**		
2	**1. Description of the product problem**	
	Potential risk of disconnection of the green hub from its tube on the lumen of the extension line.	
2	**2. Hazard giving rise to the FSCA**	
	Potential leakage or complete disconnection during the manipulation or preparation of the lines	
3.	**3. Type of Action to mitigate the risk**	
3.	**1. Action To Be Taken by the User** ☑ **Identify Device** ☑ **Quarantine Device** ☑ **Return Device**	
3.	**2. Customer Reply Required**	**Reply form within 1 week** **Devices return within 1 month**
3.	**3. Action Being Taken by the Manufacturer** Product Removal /Recall	

4. General Information		
4.	**1. Manufacturer information**	
	a. Company Name	**VYGON**
	b. Address	5 Rue Adeline 95440 ECOUEN FRANCE
4.	**2.** The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	**3. Name/Tiltle**	Christine OBER Postmarket QA/RA Director
	Transmission of this Field Safety Notice	
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*	