

**Urgent Field Safety Notice - FSCA
RECALL Dolphin®**

FSN Ref: CAPA23-059 Rev02 EN

Date: September 5th 2023

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

Contact details of local representative (name, e-mail, telephone, address etc.)

VYGON
5 Rue Adeline
95440 ECOUEN France

Email : VGLFSN@vygon.com

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1. Information on Affected Devices																		
1	1. Device Type(s)																	
	Dolphin Inflation Device is used during angioplasty procedures to inflate balloon catheter, control pressure and deflate the balloon catheter. Dolphin Inflation Device is packaged in a single sterile thermosealed blister.																	
1	2. Commercial name(s)																	
	DOLPHIN Inflation Device																	
1	3. Primary clinical purpose of device(s)																	
	Dolphin Inflation Device is used during angioplasty procedures to inflate balloon catheter, control pressure and deflate the balloon catheter.																	
1	4. Device Model/Batch(es) number(s)																	
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Reference code / VYGON code</th> <th style="text-align: left;">Batches number</th> </tr> </thead> <tbody> <tr> <td>0185NA / VPE0185NA</td> <td>23045082 23045140 23065058</td> </tr> <tr> <td>0185NATW / VPE0185NATW</td> <td>23045001 23045029 23045052 23045065</td> </tr> <tr> <td>0185NDCN / VPE0185NDCN</td> <td>23035113 23045184</td> </tr> <tr> <td>0185NF / VPE0185NF</td> <td>23045117</td> </tr> <tr> <td>0185NR / VPE0185NR</td> <td>23045103</td> </tr> <tr> <td>0185PD / VPE0185PD</td> <td>23035097 23045174</td> </tr> <tr> <td>0185QL / VPE0185QL</td> <td>23035079 23035114 23065030</td> </tr> </tbody> </table>		Reference code / VYGON code	Batches number	0185NA / VPE0185NA	23045082 23045140 23065058	0185NATW / VPE0185NATW	23045001 23045029 23045052 23045065	0185NDCN / VPE0185NDCN	23035113 23045184	0185NF / VPE0185NF	23045117	0185NR / VPE0185NR	23045103	0185PD / VPE0185PD	23035097 23045174	0185QL / VPE0185QL	23035079 23035114 23065030
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2 Reason for Field Safety Corrective Action (FSCA)	
2	1. Description of the product problem
	PEROUSE MEDICAL became aware about complaints concerning a defective packaging of DOLPHIN inflation device. The blister may have a visible crack in the side.
2.	2. Hazard giving rise to the FSCA
	If the DOLPHIN inflation device blister is cracked, the medical device may lose its sterility.
3. Type of Action to mitigate the risk	
	1. Action To Be Taken by the User
3.	<ul style="list-style-type: none"> x Identify the Device x Quarantine the Device x Return the Device
3.	2. By when should the action be completed?
	September 19 th 2023
3.	3. Action Being Taken by the Manufacturer
	Recall product

4. General Information	
4.	The Competent (Regulatory) Authority of your country has been informed about this communication to customers.
4.	Manufacturer information
	a. Company Name
	PEROUSE MEDICAL
	b. Address
	Route du Manoir 60173 IVRY LE TEMPLE - FRANCE
	c. Website address
	N/A
4.	d. Name/Signature
	Nathalie BAUDE Matérovigilance Correspondent Quality Manager

5. Return acknowledgement to sender		
	Email	VGLFSN@vygon.com
	Postal Address	VYGON 5 rue Adeline 95440 ECOUEN FRANCE
	Deadline for returning the customer reply form	September 19 th 2023

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	Transmission of this Field Safety Notice
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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</p>