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)

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		
3.	**1. Action To Be Taken by the User** x Identify the Device x Quarantine the Device x Return the Device	
3.	**2. By when should the action be completed?**	September 19th 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** **Matériovigilance Correspondent** **Quality Manager**

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

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	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