PEROUSE
A Vygon company

Establishment Name
For the Attention of the Pharmacy and the Devices Vigilance Correspondent
Address 1
Address 2
Postcode – Town

Ivry le Temple, March 28 mars 2017

URGENT – SAFETY VOLUNTARY CORRECTIVE ACTION n° R1703879 – DOLPHIN Inflation device (March 2017)

Dear Sir or Madam,

PEROUSE MEDICAL would like to inform you by this communication of the implementation of a safety voluntary corrective action regarding some DOLPHIN inflation devices batches, whose references are listed below.

Products list :

Catalogue reference	Designation	Impacted batch number
0185NA ; 0185ND ; 0185NR ; 0185PD ; 0185QL ; CL3030 ; 0185TD ; 0185TS	DOLPHIN Inflation Device CALIBER Inflation Device	Batch code starting from : **1504**XXXX to **1512**XXXX **1601**XXXX to **1612**XXXX

All batches affected by this safety corrective action are all DOLPHIN inflation device batches packaged by PEROUSE MEDICAL since April 2015.

Problem description :

PEROUSE MEDICAL has been informed, by a few customers, of a potential defect of the DOLPHIN inflation device primary packaging (blister), which may compromise the device sterility. Indeed, the blister shows, in some cases, a clear crack, visible and always located at the same place (near the handle or the pressure gauge).

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SAS au capital de 1 316 702 euros
SIREN 317 883 999 RCS Beauvais
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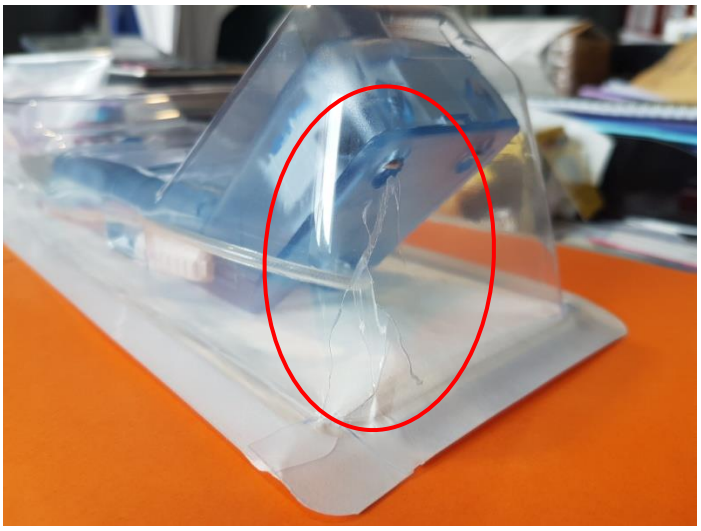
Picture 1 : Example of crack observed near the DOLPHIN inflation device handle



Picture 2 : Example of crack observed near the DOLPHIN inflation device pressure gauge

PEROUSE MEDICAL has already carried an internal inspection of its entire inventories, and confirms that the identified rate of defectiveness is very low. However, as a measure of prevention, PEROUSE MEDICAL has decided to carry a safety corrective action by informing all its customers of a potential primary packaging defect.

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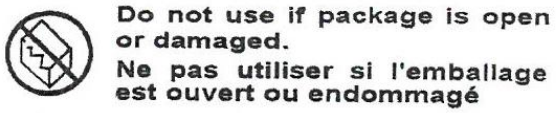
Patient risk:

There is no risk for the patient as long as the following instructions are respected.

Indeed, this defect, when it occurs, is detectable by the user during the inspection required for this type of device prior to use, as indicated on the labelling of each unit-of-use (logo and mention related to the packaging integrity), and in the Instruction For Use (IFU). Please see picture 3 below.



Picture 3 : Indications present on every labelling of unit-of-use and IFU

In the opposite case, the patient risk is a risk of microbial contamination (infection) caused by the use of a product, which sterility would not be preserved due to a primary packaging damage.

To date, no adverse effect, regarding health and safety of patients, potentially connected to this problem, was notified to PEROUSE MEDICAL.

Actions to be taken by the user :

Our data of traceability indicate that your establishment received potentially impacted products.

As such, we kindly request you to:

1- Inspect attentively your stock to determine if you still have in your ownership devices among which the references and batch codes are listed in front page

2- Control the potential damage of the blister according to the pictures above and the instructions mentioned on the labelling and the Instruction For Use: any damaged and/or cracked blister must be immediately discarded.

3- Use the compliant products without risk, after control. Indeed, the primary packaging will not deteriorate in time. If, to date, there is no crack in the blister, then the integrity of the product is not compromised.

4- Do not use the non-compliant products.

5- Complete and sign the attached reply form (Appendix A), then return it to us within 5 working days following the reception of this letter, and keep a copy.

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6- Contact our customer service for the modalities of return, replacement and associated support at **+33 (0)3.44.08.17.17** or by fax at +33 (0)3.44.08.17.18
or by email at pm_sce.adv@vygon.com or by mail at the following address:

PEROUSE MEDICAL
Route du Manoir
60173 Ivry le Temple
France

7- Communicate the safety information to any person concerned in your establishment (in particular Interventional Radiologists, Vascular Surgeons, Operating Theatre Nurses) and to all end customers to which the product were transferred.

Assistance :

Your assistance regarding the precise control and enumeration of the impacted devices is essential.

For any question or further information, you can contact:

- Your regional manager

- Our customer service

- Our vigilance correspondent, Ms. Claire ANDRE: by phone at +33 (0)3.44.08.17.07 or by email at the following address: candre@vygon.com

Competent authorities, in particular the ANSM, were informed about this safety corrective action.

As you know, PEROUSE MEDICAL commits to supply effective and high-quality medical devices to its customers. We take this commitment seriously, and in rare occasions, an action like this one is necessary to hold our objectives in this sense. We apologize for the inconvenience created by this measure to guarantee patients safety, and we thank you for your understanding.

We want already to inform you that the next dispatched batches of DOLPHIN inflation device will be subject to reinforced packaging.

Claire ANDRE
Corporate Quality Director
Vigilance Correspondent

Annexe :
Annexe A : Reply Form

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Annexe A : Reply Form

PEROUSE MEDICAL
Customer service
Safety corrective action form n° **R1703879**
pm_sce.adv@vygon.com
Fax : +33 (0)3.44.08.17.18

DOLPHIN inflation devices according to the list of references and batches impacted

Thanks to check the appropriate boxes :

1- I have identified some products potentially impacted by the safety action :

☐ I controlled and found non-compliant products

☐ I made contact with PEROUSE MEDICAL customer service, in order to organise the products return and replacement, on the (add date) : _____

Affected references	Batch number	Non-compliant quantity to return

☐ I controlled and did not found non-compliant products. The return quantity is null. A copy of this form is archived in our establishment.

2- I have not identified in our stock products potentially impacted by the safety action

☐ The return quantity is null. A copy of this form is archived in our establishment.

I certify to have read and understood this information and the associated risks, and to have passed it on to all people concerned in my establishment.

Establishment : .....

Name / Title :.....

Phone number :.....

Date and signature : .....