PEROUSE MEDICAL
135, route neuve
69540 Irigny
France
Tel : 00 33 472 39 74 14
Fax : 00 33 478 51 89 67

Nom établissement
Adresse
Adresse ligne 2
Code postal - Ville

To the attention of XXX

Irigny, March 21, 2013

By e-mail and registered letter

VOLONTARY BATCH RECALL

OF FLAMINGO Inflations Devices

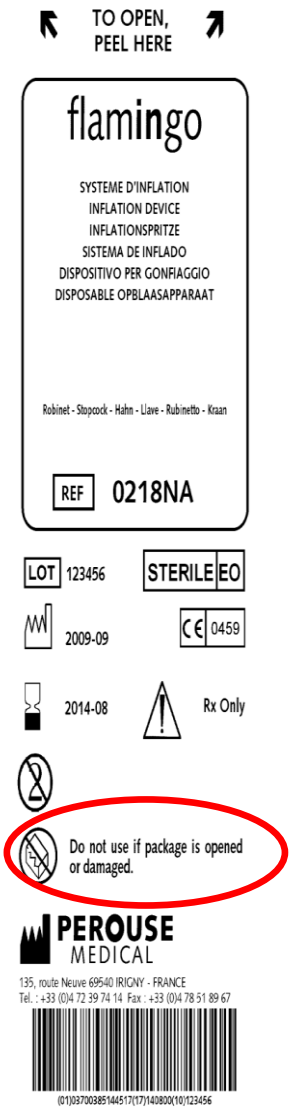
Dear Madam, Dear Sir,

This communication is to inform you of the implementation by PEROUSE MEDICAL of a voluntary batch recall of 24 batches of FLAMINGO Inflation devices.

ITEM: PEROUSE MEDICAL identified a potential defect altering the integrity of the Flamingo's packaging on YY batches referenced in the inventory sheet attached, specific to your company. No adverse effects regarding the patients have been reported to date.

PRODUCTS AFFECTED: FLAMINGO Inflation devices (whose references are specified in the attached inventory sheet).

DESCRIPTION OF POTENTIAL FAILURE: the primary packaging, constituted of a blister, has, in some cases, a crack leading to a risk of loss of sterility of the device. This defect, when it occurs, is detectable by the user during the inspection required for this type of device prior to use, as shown on the labeling of each unit of the primary packaging presented herafter (logo and references related to the integrity of the packaging).



Example: Blister labeling for the reference 0218NA

WHY WE ARE GETTING IN TOUCH WITH YOU: Our traceability system indicates us that your company received some of the medical devices concerned.

WHAT WE ARE ASKING YOU:

- Stop immediately distributing in your country Flamingo Inflation Devices concerned by this recall.
- Take the necessary measures to inform all your customers to stop using immediately Flamingo Inflation Devices concerned by this recall.
- Make an inventory of your stock of Flamingo Inflation Devices within your company.
- Quarantine the products concerned and start to complete the inventory sheet, required by European Competent Authorities, even if you have no more products concerned.

- If you have delivered any of the devices concerned by this recall to your clients, please notify them and carry out batch(es) withdrawal following your own internal procedures
- Communicate this information at all staff within the end user' establishment qualified to utilize this product.
- Fully complete, sign and send back the inventory sheet to Irigny site's Quality and Regulatory Affairs Department Fax: +33 478 51 89 67 or by e-mail at s.vide@perousemedical.com before **March 29, 2013.**
- Pay attention to this notification until all the products concerned by this recall are collected from your Company and from all your clients.
- At the receipt of the inventory sheet, our customer service will contact you in order to organize with you the details of the return of the products and will send you a return authorization slip necessary to the treatment of your case.
- **The isolated batches will have to be sent back with the sheets (inventory and return slip)**

ASSISTANCE: For all additional questions, please contact:

- Your personal commercial contact at PEROUSE MEDICAL,
- PEROUSE MEDICAL's customer service (+33 472 39 74 13 or +33 472 39 74 16)
- Our vigilance correspondent Mrs. Séverine VIDÉ, at +33 344.08.17.68 or (s.vide@perousemedical.com) for all regulatory questions about this batch recall.

COMPLEMENTARY INFORMATION: ANSM (French Competent Authority) was informed of this voluntary batch recall on March 20th, 2013.

We apologize for any inconvenience to you and your business and we thank you in advance for your comprehension and your cooperation.

[redacted]
Deputy General Manager
Quality and Regulatory Director

VOLONTARY RECALL OF BATCHES

FLAMINGO INFLATION DEVICES

List of batches concerned

Reference	Batches concerned
0218NF	12101266
0218KR	12101208
0218KT	12101207
	12101464
0218NA	12101578
0218NA	12101164
	12101526
0218ND	12101165
0218ND	12101163
	12101527
	12101577
0218ND	12101166
0218PM	12101160
	12101265
0218PM	12101579
0218QN	12101167
0218QN	12101162
0218ST	12101273
	12101564
0218TR	12101161
0218TS	12091415
0218TT	12091418
0253NA	12101452
0253NQ	12101451

135, route neuve
69540 Irigny
France
Tel : 00 33 472 39 74 14
Fax : 00 33 478 51 89 67
Email : s.vide@perousemedical.com

To:	XXXXXX
Company:	**XXXXXX**
Fax number or e-mail :	XXXXXX
From:	**Séverine Vidé** PEROUSE MEDICAL Vigilance Correspondant
Date:	**March 21, 2013**
N° of pages :	**XX**

VOLONTARY BATCH RECALL

FLAMINGO INFLATION DEVICE

INVENTORY SHEET

1. **Identify any FLAMINGO devices belonging to the batch(es) identified in the table below, delivered to your company by PEROUSE MEDICAL**
2. **Declares, with reference to the quantities delivered by PEROUSE MEDICAL to your company, that :**

    a. The following quantity of Flamingo inflation devices covered by this batches withdrawal has been **identified in stock and quarantined** ***(→complete column (1))***
    b. The following quantity of Flamingo inflation devices covered by this batches withdrawal **has been distributed/sold** ***(→complete column (2))***
    c. The following quantity of Flamingo inflation devices covered by this batches withdrawal **has been recovered from your clients** ***(→complete column (3))***
    d. The following quantity of Flamingo inflation devices covered by this batches withdrawal has been **already used by your clients** ***(→complete column (4))***

3. **Please complete the inventory form even if you have no more stock within your company or within your customers**

			Column (1)	*Column (2)*	*Column (3)*	*Column (4)*
References concerned	Batch number	Quantity delivered	Quantity identified in stock and put in quarantine	Quantity distributed/sold	Quantity recovered from your customers	Quantity used by your customers
			(to be returned to PEROUSE MEDICAL)		*(to be returned to PEROUSE MEDICAL)*	

Date of receipt of this notification by the distributor: _____

4. **To be returned by fax at +33 4 78 51 89 67 or by e-mail at s.vide@perousemedical.com**
5. **Enclose a copy of the inventory form with the returned products and the authorization return slip.**

We thank you for your cooperation,

Distributor's and contact name	**Date:**
Phone's number :	**Signature Company stamp**