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

[redacted]

Irigny, January 28th, 2013

By registered letter

VOLONTARY BATCH RECALL

OF ELS SYRINGES

Dear Madam, Dear Sir,

This communication is to inform you of the implementation by PEROUSE MEDICAL of a voluntary batch recall of 34 batches of ELS SYRINGES.

ITEM: PEROUSE MEDICAL identified a potential defect due to the presence of a plastic particle in the syringe body on batches referenced in the inventory sheet attached, specific to your company. No adverse effects regarding the patients have been reported to date.

PRODUCTS AFFECTED: ELS SYRINGE (whose references are specified in the attached inventory sheet).

DESCRIPTION OF POTENTIAL FAILURE: The syringe body could present a plastic particle (less than 2 mm of length) which could be injected with the contrast media.

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

WHAT WE ARE ASKING YOU:

- Stop immediately distributing in your country/using in your establishment ELS syringe concerned by this recall.
- Take the necessary measures to inform all your customers to stop using immediately ELS SYRINGE concerned by this recall.
- Make an inventory of your stock of ELS SYRINGE 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 **February 4th, 2014.**
- 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 HEURTIER-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) and Bfarm were informed of this voluntary batch recall on January 28th, 2013.

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

Séverine HEURTIER-VIDE
Corporate Quality Manager

VOLONTARY RECALL OF BATCHES

ELS SYRINGES

List of batches concerned

Référence	Numéro de lot
0137RK	13031454
	13041385
	13051087
	13061117
	13061243
	13061490
	13061612
	13081252
	13091550
0137RL	13031336
	13031456
	13051086
	13061116
	13061242
	13061704
	13071385
	13071611
	13081276
	13081385
	13091490
	13101270
	13101726
0137RM	13041436
	13061705
	13091549
0137RN	13031076
	13051381
	13061576
0137RP	13041323
	13041618
	13061575
	13101248
0137RR	13051382
0137RS	13101135

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

To:	[redacted]
Company:	[redacted]
[redacted]	[redacted]
From:	**Séverine Vidé** PEROUSE MEDICAL Vigilance Correspondant
Date:	**January 28th, 2014**
N° of pages :	**2**

VOLONTARY BATCH RECALL

ELS SYRINGES

INVENTORY SHEET

1. **Identify any ELS SYRINGE 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)*	
0137RR	**13051382**	**800**				

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**