

to

Pharmacist in charge of sterile medical device

Materiovigilance

Lissieu, 10/01/2018

N/Réf : DM/ R-EM/ 20180110/A

Objet : RECALL Extension line of Manifold

### **URGENT RECALL OF MEDICAL OFFICE**

Dear,

Last month we have recalled some manifold reference batches with extensions because there is a risk of separation of the male luer tip extensions provided with the infusion rails.  
In the management of our materiovigilance and following various exchanges with the ANSM, we decided to voluntarily recall all references of female ramps with an LLM / LLM extension manufactured before January 30<sup>th</sup>, 2017, in accordance with our CAPA 2016 1 76. (Lot starting with 17A. 16 ... 15 ... 14 ... 13 ...)  
We are well aware of the impact that such a lot recall can have with your services but the goal of this action is to secure the use of our ramps.

Since January 30, 2017, corrective action has been put in place, and its effectiveness has been measured.

We therefore ask you to proceed to the immediate withdrawal of all units of the products listed below in your health facility and to keep them at your disposal as soon as possible.  
We would be grateful if you could inform us as soon as possible, the quantities to take back, by return of the form attached. Following this we will contact you to sand the terms of this replacement.

We therefore ask you to proceed with the immediate recall of all units from the products listed below in your healthcare facility and to keep them at our disposal as soon as possible.  
We would be grateful if you would kindly inform us as soon as possible of the quantities to be returned by returning the enclosed form. Following this we will contact you to sand the terms of this replacement.



ISO 9001 ISO 13485

#### **Service Commercial**

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At :  
Delphine Molinari ALLARD  
Correspondant matériovigilance  
[assistag@cairlgl.fr](mailto:assistag@cairlgl.fr)  
Fax : 0033 (0)4.78.43.77.07

This recall follow the decision of the ANSM dated 2<sup>nd</sup> march 2018, so The Health authority is informed of this decision and will keep them informed of the progress of the operation.

We thank you for your cooperation and to present our apologies for the inconvenience incurred. Cair LGL makes every effort to resolve this issue as soon as possible.

Remaining at your disposal for any further information, please accept, Madam, Sir, the assurance of our highest consideration.



Delphine MOLINARI ALLARD  
Correspondant Matériovigilance  
Quality & regulatory Director

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**FORM FOR PRODUCTS REPLACEMENT  
RECALL  
Extension line of Manifold**

**To Complande and randurn upon receipt :**

Mail : [assistaq@cairgl.fr](mailto:assistaq@cairgl.fr)  
Fax : 0033 (0)4.78.43.77.07

Establishment :

Name / Quality of the person who completed the form:

We hereby confirm having read the notice of recall.

Our stock has been verified, including user services and the results are:

- We no longer have any copies of the product concerned in our stocks
- We have in stock and we ask Cair LGL to take back / exchange the following products:

Manifolds of 2 Stopcocks		Manifolds of 3 Stopcocks		Manifolds of 4 Stopcocks	
Lot and quantity		Lot and quantity		Lot and quantity	
RPB2301		RPB3301		RPB4301	
RPB2302		RPB3302		RPB4302	
RPB2302 S		RPB3302M		RPB4302A	
RPB2305		RPB3302S		RPB4302B	
RPB2305 A		RPB3305		RPB4305	

RPB2305 B		RPB3305A		RPB4305A	
RPB2305 M		RPB3305B		RPB4305B	
RPB2305 MA		RPB3305M		RPB4305M	
RPB2305 MB		RPB3305MA		RPB4305MA	
RPB2307		RPB3305MB		RPB4305MB	
RPB2310		RPB3305S		RPB4310	
RPB2310 A		RPB3307		RPB4310A	
RPB2310 B		RPB3310		RPB4310B	
RPB2310 M		RPB3310A		RPB4310M	
RPB2310 MA		RPB3310B		RPB4310MA	
RPB2310 MB		RPB3310M		RPB4310MB	
RPB2312I		RPB3310MA		RPB4312I	
RPB2315		RPB3310MB		RPB4315	
RPB2315 A		RPB3315		RPB4315A	
RPB2315 B		RPB3315A		RPB4315B	
RPB2315 M		RPB3315B		RPB4315M	
RPB2315 MA		RPB3315M		RPB4315MA	
RPB2315 MB		RPB3315MA		RPB4315MB	

RPB2320		RPB3315MB		RPB4320	
RPB2320 A		RPB3320		RPB4320A	
RPB2320 B		RPB3320A		RPB4320B	
RPB2320 M		RPB3320B		RPB4320M	
RPB2320 MA		RPB3320M		RPB4320MA	
RPB2320 MB		RPB3320MA		RPB4320MB	
RPB2325		RPB3320MB		RPB4325	
		RPB3325		RPB4325A	

Manifolds of 5 Stopcocks		Manifolds of 6 Stopcocks		Manifolds avec Neutraclear			
Lot and quantity		Lot and quantity		Lot and quantity		Lot and quantity	
RPB5301		RPB6305		RNC230 5		RNC532 0	
RPB5302 M		RPB6305 A		RNC230 5A		RNC532 0A	
RPB5305		RPB6305 B		RNC231 0		RNC630 5	
RPB5305A		RPB6305 M		RNC231 0A		RNC630 5A	
RPB5305B		RPB6305 MA		RNC231 5		RNC631 0	
RPB5305 M		RPB6305 MB		RNC231 5A		RNC631 0A	
RPB5305 MA		RPB6310		RNC232 0		RNC631 5	
RPB5305 MB		RPB6310 A		RNC232 0A		RNC631 5A	

*Au commencement, il y avait un patient...*

RPB5310		RPB6310		RNC330 5		RNC632 0	
RPB5310A		RPB6310 M		RNC330 5A		RNC632 0A	
RPB5310B		RPB6310 MA		RNC331 0			
RPB5310 M		RPB6310 MB		RNC331 0A			
RPB5310 MA		RPB6315		RNC331 5			
RPB5310 MB		RPB6315 A		RNC331 5A			
RPB5315		RPB6315 B		RNC332 0			
RPB5315A		RPB6315 M		RNC332 0A			
RPB5315B		RPB6315 MA		RNC430 5			
RPB5315 M		RPB6315 MB		RNC430 5A			
RPB5315 MA		RPB6320		RNC431 0			
RPB5315 MB		RPB6320 A		RNC431 0A			
RPB5315R K1A		RPB6320 B		RNC431 5			
RPB5320		RPB6320 M		RNC431 5A			
RPB5320A		RPB6320 MA		RNC432 0			
RPB5320B		RPB6320 MB		RNC432 0A			
RPB5320 M		RPB6325		RNC530 5			
RPB5320 MA				RNC530 5A			
RPB5320 MB				RNC531 0			

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*Au commencement, il y avait un patient...*

RPB5325	
RPB5330B	
RPB5340	
RPB5340A	

RNC531 0A	
RNC531 5	
RNC531 5A	

Contact person for the exchange (with his contact offtails mail / tel / adresse):

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