



Au commencement, il y avait un patient...

to

Pharmacist in charge of sterile medical device

Materiovigilance

Lissieu, 22/03/2018

N/Réf : DM/ R-RO/ 20180322/A

Objet : RECALL 3 Ways Stopcock , sterilization by irradiation

URGENT RECALL OF MEDICAL DEVICE

Dear,

Following the inspection of the ANSM from 29/11/2017 to 2/12/2017 at our premises as well as the decision of the sanitary police of 2 March 2018, Cair LGL proceeded to the recall of the irradiated 3-way stopcock. During this inspection, the evidence of lipid-resistance of the irradiated 3-way stopcock was considered insufficient to guarantee the claim made by Cair LGL.

Indeed, Stopcocks on the market before May 2017 were sterilized by irradiation. Since May 2017, 3-way stopcocks placed on the market have been sterilized by ethylene oxide.

We therefore ask you to proceed to the immediate recall of all units of the products listed below whose lot numbers are prior to May 2017: 17E ..., in your health facility and to keep them at our disposal as soon as possible.

We are well aware of the impact that such a recall can have on your services but the goal of this action is to secure the use of our stopcocks.

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 set the terms of this operation (recovery - exchange).



Service Commercial

Tél. +33 (0) 4 78 43 78 25
Fax +33 (0) 4 78 43 77 78
commercial@cairlgl.fr

Service Commandes

Tél. +33 (0) 4 78 43 76 43
Fax +33 (0) 4 78 43 77 09
commande@cairlgl.fr

Service Export

Tél. +33 (0) 4 78 43 77 44
Fax +33 (0) 4 78 43 77 09
export@cairlgl.fr



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At :

Delphine Molinari ALLARD
Correspondant matériovigilance
assistaq@cairlgl.fr
Fax : 0033 (0)4.78.43.77.07

This recall follows the decision of the ANSM dated 2nd March 2018. 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 ALLARD
Correspondant Matériovigilance
Quality & regulatory Director



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Fax +33 (0) 4 78 43 77 09
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Fax +33 (0) 4 78 43 77 09
export@cairlgl.fr

FORM FOR PRODUCTS REPLACEMENT
RECALL
Irradiated 3-way Stopcocks

To Complete and return upon receipt :

Mail : assistaq@cairlgl.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:

Batch numbers concerned beginning with : 17E, 17D, 17C, 17B, 17A, 16, 15, 14, 13.

Code product	Quantity
RO301M	
RO301	
RO305	

Person to contact for the recovery (with his mail / tel / address):