



Au commencement, il y avait un patient...

For the attention of the

Pharmacist in charge of Sterils Medical
Devices

The local Materiovigilance Correspondent

Lissieu, 27/01/2020

N/Réf : DA_A_Mobile Ring Infusion_20200127_A

Subject: Warning / Safety Information – Reference DM
Infusion Stopcock with mobile ring

URGENT FIELD SAFETY NOTICE

Dear Sir or Madam,

As part of our materiovigilance management, CAIR LGL has decided to proceed with a product safety communication concerning infusion stopcocks using male luer connexions with mobile ring.

We would like to inform you that we have implemented an instruction of use to explain the practices of use, the contraindications of the male luer with mobile ring present on our infusion stopcocks.

In the case of interconnection between 2 stopcocks or 1 stopcock and 1 infusion manifold, any manipulation on one of the 2 stopcock must be done with extreme vigilance to avoid separation of the 2 devices.

Likewise, this type of interconnection must be reserved for bedridden patients without possible lifting (put in a chair) and during all manipulations such as bed repairs, the connection must be checked before and afterwards.

The risk of patient can be a leak of the drug or a risk of air intake into the tube.

In all these cases, Cair LGL recommends either the use of a manifold with multi stopcock or the use of stopcock with a luer connection with rotation.



ISO 9001 - ISO 13485

Service Commercial

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export@cairgl.fr



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This communication must be forwarded to everyone within your organization who should be informed.

Meanwhile, please confirm receipt of this communication by returning the form below.

Given that this this warning is in response to a materiovigilance procedure, the relevant authorities have been informed of this decision and we are keeping them up to date on the progress of the operation.

We would like to thank you for your cooperation.

By means of this alert, CAIR LGL further commits to its determination to supply you with secure and effective products.

We remain at your disposal for any additional information.

Yours sincerely,

Delphine ALLARD
Materiovigilance Correspondent



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ACKNOWLEDGEMENT OF RECEIPT FORM SAFETY COMMUNICATION /
N/Ref : *DA_A_Mobile Ring Perfusion _20200127_A*
REF – INFUSION STOPCOCK WITH MOBILE RING

To be completed and returned

Email : FieldAction@cairlgl.fr

Fax : 0033 (0)4 37 64 60 09

Establishment (Stamp)

We hereby certify receipt of the safety communication / important notice sent by CAIR LGL on 17/02/2020 and its transmission to everyone needing to be informed of it within our organization.

The safety communication / notice has been read and understood.

Name / Position of the person who completed the form

Date :

Signature