

For the attention of the Pharmacist in charge of sterile medical devices

For the attention of the Medical Device Vigilance Associate

Lissieu, 21/11/2018

Our ref.: DM/ 181109/ Vacuum control valve

**MEDICAL DEVICE FIELD SAFETY NOTICE
VACUUM CONTROL VALVE**

Dear Sir/Madam,

CAIR LGL has received customer complaints with regard to ineffective suction of devices incorporating vacuum control valves. A suction fault upon use has been reported, despite the compliance of daily checks.

Following an investigation into the devices concerned, we have observed certain cases in which the seal has deteriorated or become damaged. This has occurred after the valve has been installed for a certain period of time on a hospital's wall-mounted suction system, which has been active without the product being used on a regular iterative basis.

In order to ensure their safe use, we wish to clarify the recommendations in terms of usage time for these products.

The existing claim as to a 48-hour usage time relates only to use with suction on a patient. Based upon the validation process for the product, our device is able to withstand 7 days of continuous vacuum pressure at 750 mm of mercury. Therefore, we recommend a maximum time of 7 days under vacuum pressure without use on a patient and to maintain a 48-hour usage limit (iterative suction) on a patient, notwithstanding the observation of a total time under vacuum pressure at 750 mm of mercury of 7 days.

There are several possible cases:

- If connected to an inactive wall-mounted vacuum system (no vacuum pressure), the hygiene rules of the hospital should determine when the device is replaced.
- If connected to an active wall-mounted vacuum system without being used, the device must be replaced after 7 days.
- If connected to an active wall-mounted vacuum system, use of the device on a patient must not exceed 48 hours, notwithstanding the observation of a maximum total period under vacuum pressure of 7 days:

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Example 1: If the device is used after 1, 2, 3, 4 or 5 days of being connected to the wall-mounted vacuum system, it must be replaced after 48 hours of use on a patient.

Example 2: If the device is used after 6 days of being connected to the wall-mounted vacuum system, it must not be used for more than 24 hours, and the total period under active vacuum pressure must be 7 days.

An instruction of use in on going to take in account all these elements and will be joined to the products since validation.

Please take note of this information and communicate it to staff using the device in your healthcare facility.

The competent authority has been informed of this procedure.

We wish to thank you for your collaboration and offer our sincere apologies for any inconvenience.

We remain at your disposal should you require any further information.

Yours faithfully,



Delphine ALLARD
Quality & Regulatory Director
Medical Device Vigilance Associate

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