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COUNTRY: SUBSIDIARY OR DISTRIBUTOR
Contact Name:
Tel:
Fax:
Email:

Urgent Field Safety Notice

Type of Action: AWARENESS

Devices: The following AbCan Disposable Co2 Absorbers 1.1L for use with the Getinge® (formerly Maquet®) Anaesthesia Delivery Systems Flow-i™ C20, C30, C40, Flow-C™ and Flow-E™.

REF:	DESCRIPTION
2199001	AbCan Spherasorb™ Disposable Co2 Absorber White to Violet 1.1L
2199003	AbCan LoFlosorb™ Disposable Co2 Absorbers Green to Violet 1.1L

LOT Numbers:

REF:	LOT NUMBERS
2199001	1190929, 1190930, 1200719, 1201724, 1201864, 1202798
2199003	1191191

Manufacturer: Intersurgical Ltd

FSCA-identifier: 285497 **Date:** 21/08/2020

Attention: Medical Device Safety Officers (MDSO)

Distribution: All Theatre, Anaesthetic department clinical staff and users of the above products.

Type of action: All users of the products and lot numbers listed above must follow the instructions described in the Actions section below before use.

Description of the problem: With the increased focus on prevention of cross-contamination during the current COVID-19 pandemic, it has been brought to our attention that some users are now connecting an additional filter to the inspiratory port of the anaesthetic machine for increased protection of the patient. Unfortunately, the placement of a filter on the inspiratory port restricts attachment of the AbCan Disposable Co2 Absorber. This may result in a leak between the Absorber and the anaesthetic machine. Even in the event that secure attachment of the Absorber can be achieved, replacement of the absorber during a long procedure will most likely require the detachment of the inspiratory limb with a potential loss of anaesthetic agent and ventilation to the patient.

Action to be taken by the user:

Do not use the AbCan Disposable Co2 Absorber if it is local hospital or department policy to attach a filter on the inspiratory port of the anaesthetic machine.

Even if you are able to achieve a secure connection of the absorber before use, if you attach a filter to the inspiratory port, you will not be able to replace the absorber if required during a procedure without disconnecting the inspiratory limb in the process.

NB: This is an advisory notice not a recall of the listed products/Lots. If the AbCan is used without a filter on the Inspiratory port of the machine, the function, safety and performance of the AbCan is not affected and you can continue to use them.

Corrective Action being taken by manufacturer Intersurgical:

We are urgently reviewing this situation to identify a solution to this problem when a filter is connected to the inspiratory port of the anaesthetic machine.

The undersigned confirms this notice has been notified to the appropriate Regulatory Agency.

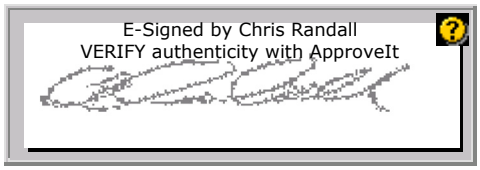
Transmission of this Field Safety Notice:

This notice should be transmitted to all those who need to be aware within your organisation, or to any organisation where these potentially affected devices have been transferred.

Intersurgical apologises for any inconvenience this may cause. If you have any questions, please contact your distributor or local Intersurgical representative.

The relevant National Authorities have been advised about this Field Safety Corrective Action.

Please maintain awareness of this Field Safety Notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.



Chris Randall, Quality Manager, Intersurgical

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Contact Name:
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Field Safety Notice Response Form

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Hospital/Facility Name: _____

Hospital/Facility Address: _____

_____

Please complete the section below, and send it back to **Subsidiary or Distributor contact email**

☐ We confirm we have received this FSN and have distributed it within our facility as necessary.
☐ **Distributors Only:** We confirm we have received this FSN and have distributed it to our customers that have been supplied with the potentially affected products listed above.

Form Completed and Returned by:

Name: ……

Position: ……

Phone No: ……

E-mail: ……

Date: ……..