

URGENT FIELD SAFETY NOTICE

DAR™ Breathing System, Mapleson B and C configurations

DAY MONTH, 2014

FSN Reference: DAR™ Breathing System, Mapleson B/C 10/14

Dear Covidien Customer,

The purpose of this letter is to advise you that Covidien is conducting a Field Safety Corrective Action (FSCA) on the DAR™ Breathing System, Mapleson B and C configurations related to an issue identified from customer complaints. We have determined that product exposure to ultraviolet (UV) light and/or elevated temperatures when stored outside of its packaging can impact the breathing bag material and may lead to tears in the breathing bag which may compromise product performance.

Labeling for breathing systems that were manufactured prior to July 2013 does not contain limitations and warnings for limiting exposure to ultraviolet light and/or elevated temperatures. Covidien is requesting that you identify and remove those products from use. The inventory should be returned to Covidien. Credit will be given for all returned inventory.

Actions to be performed for this field safety correction:

- Review the inventory of DAR™ Breathing System, Mapleson B and C configurations within your facility and remove lot numbers below 130700001X from use and segregate to prevent usage.
Lot Numbers Identifier: lot 130700001X → manufactured in July 2013
(13=Year, 07=Month, 00001=Progressive number, X)
- Please complete the attached Return Verification Form in its entirety. Fax or e-mail the completed form using the contact details stated on the form.
- Even if you do not have affected product to return, please complete the enclosed verification form and fax or e-mail it back to Covidien. This allows us to verify that you have received this notice and inspected your inventory.
- Please forward this notice to all colleagues within your organisation who need to be made aware of it or to any organisation/persons where the potentially affected devices have been transferred.

Additional important information:

- As described in the IFU, immediately before use on a patient, visually inspect circuit components, check functioning and patency of circuit and check circuit integrity under pressure.

- Prior to use, keep the breathing bag protected from ultraviolet light and elevated temperatures and store them in the ambient environment conditions similar to where they will be used.
- To reduce the risk of damage keep product protected in its shipping carton as long as possible.

This notification is being issued with the knowledge of the [add local Competent Authority].

If the product was purchased from a distributor, please contact your provider for their return process or consult the information provided to you by your distributor with this notice.

If you have any questions about this notice or if you wish to report any issues with a Mapleson B and C breathing system, please contact your local Covidien representative at **COUNTRY SPECIFIC TELEPHONE NUMBER** so we may complete the required regulatory reporting processes.

We apologize for any inconvenience this may cause and thank you for your prompt attention to this matter.

Sincerely,

LOCAL RA NAME