

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

ITEM	Description
309/13122	URM - MAPLESON C ADULTI
309/13130	URM - MAPLESON C NEONATALE
309/13150	URM - MAPLESON C PEDIATRICO
309/13155	URM - MAPLESON C ADULTI
309/13157	URM - MAPLESON C ADULTI
309/13176	URM - MAPLESON C ADULTI
309/13185	URM - MAPLESON C ADULTI
309/13235	URM - MAPLESON C ADULTI
309/13237	URM - MAPLESON C ADULTI
309/13238	URM - MAPLESON B ADULTI
309/13242	URM - MAPLESON C ADULTI
309/13250	URM - MAPLESON C PEDIATRICO
309/13263	URM - MAPLESON C ADULTI
309/13266	URM - MAPLESON C ADULTI
309/13307	URM - MAPLESON C NEONATALE
309/13362	URM - MAPLESON C ADULTI
309/13371	URM - MAPLESON C ADULTI
309/13432	URM - MAPLESON C ADULTI
309/13434	URM - MAPLESON C NEONATALE
309/13472	URM - MAPLESON C PEDIATRICO
309/13547	URM - MAPLESON C AD. X KONTRON
309/13552	URM - MAPLESON C ADULTI
309/13554	URM - MAPLESON C ADULTI
309/13555	URM - MAPLESON C ADULTI
309/13558	URM - MAPLESON C ADULTI
309/13641	URM - MAPLESON C ADULTI
309/13707	URM - MAPLESON C NEONATALE
309/13709	URM - MAPLESON C PEDIATRICO
309/13716	URM - MAPLESON C NEONATALE
309/13718	URM - MAPLESON C ADULTI
309/13722	URM - MAPLESON C ADULTI
309/14046	URM - MAPLESON C ADULTI
309/14049	URM - MAPLESON C PEDIATRICO
309/14057	URM - MAPLESON C ADULTI
309/14059	URM - MAPLESON C ADULTI
309/6310	URM - MAPLESON C ADULTI
309/6312	URM - MAPLESON B ADULTI
309/6314	URM - MAPLESON C ADULTI
309/6351	URM - MAPLESON C NEONATALE
309/6353	URM - MAPLESON C PEDIATRICO
309/6355	URM - MAPLESON C NEONATALE
309/6358	URM - MAPLESON C ADULTI
309/6392	URM - MAPLESON C ADULTI
309/6409	URM - MAPLESON C AD. X SIEMENS
309/6416	URM - MAPLESON C ADULTI
309/6419	URM - MAPLESON C ADULTI

309/6420	URM - MAPLESON C ADULTI
309/6460	URM - MAPLESON C ADULTI
309/6463	URM - MAPLESON C AD. X KONTRON
309/6493	URM - MAPLESON C ADULTI
309/6498	URM - MAPLESON C ADULTI
309/6525	URM - MAPLESON B ADULTI
309/6529	URM - MAPLESON C ADULTI
309/6539	URM - MAPLESON C NEONATALE
309/6557	URM - MAPLESON C ADULTI
309/6563	URM - MAPLESON C PEDIATRICO
309/6586	URM - MAPLESON C ADULTI
309/6612	URM - MAPLESON C ADULTI
309/6614	URM - MAPLESON C NEONATALE
309/6615	URM - MAPLESON C PEDIATRICO
309R14254	URM - MAPLESON C ADULTI
309S14164	URM - MAPLESON C ADULTI
309S14165	URM - MAPLESON C ADULTI
309S14166	URM - MAPLESON C ADULTI
309S14168	URM - MAPLESON C ADULTI
309S14169	URM - MAPLESON C PEDIATRICO
309S14212	URM - MAPLESON C PEDIATRICO
309S14215	URM - MAPLESON C ADULTI
309S14216	URM - MAPLESON C ADULTI
309S14217	URM - MAPLESON C ADULTI
309S14219	URM - MAPLESPN C PEDIATRICO
309S14220	URM - MAPLESON C NEONATALE
309S14251	URM - MAPLESON C ADULTI
309S14252	URM - MAPLESON C ADULTI
309S14257	URM - MAPLESON C ADULTI
309S14259	UNITA'RESPIRATORIA MANUALE
309S14260	UNITA'RESPIRATORIA MANUALE
309S15003	URM- MAPLESON C ADULTI
309S15009	URM - MAPLESON C ADULTI
309S15010	URM - MAPLESON C ADULTI