

**PRODUCT ADVISORY NOTICE
EMEA0759**

Homepump C-Series with DEHP-free tubing non 5-FU Compatible

March 03, 2017

ATTENTION: DIRECTOR, PURCHASING DEPARTMENT

Dear Valued Halyard Health Customer:

What is the reason for this Voluntary Product Advisory Notice Follow-up?

Halyard Health (formerly known as I-Flow/Kimberly-Clark Health Care) had previously received reports indicating that the I-Flow/Kimberly-Clark-branded single-use infusion pumps Homepump C-Series, with DEHP-free tubing, may experience a reduction of flow when infusing the chemotherapy drug named 5-Fluorouracil (also known as “5-FU”). That situation may result in the patient not receiving the full chemotherapy treatment within the expected timeframe.

In December 2015 and April 2016, Halyard Health notified all users to not infuse 5-Fluorouracil (5-FU) with I-Flow/Kimberly-Clark-branded Homepump C-Series with DEHP-free tubing. Moreover, a red warning sticker was applied on the label of the affected products Halyard Health had under control to inform users to not infuse 5-Fluorouracil (5-FU).

This notice is intended to inform all users holding the affected devices listed below (i.e., I-Flow/Kimberly-Clark-branded pumps that do not carry the red warning sticker) to quarantine these and contact a Halyard Health Representative to define next steps. This request is intended to help reduce potential confusion as Halyard Health is beginning to distribute corrected Homepump C-Series, with DEHP-free tubing, labeled under the Halyard Health brand and without the red warning label since these pumps may now be used with 5-FU.

Which Products are impacted?

The I-Flow/Kimberly-Clark pumps that were impacted by a potential reduction in flow of 5-FU included all lots of Homepump C-Series with DEHP-free tubing, which are labeled under the I-Flow/Kimberly-Clark brand label and that do not include the red warning sticker, as listed below.

Homepump C-Series Standard Elastomeric Pumps (with DEHP-free tubing)			
Reference	Model	Filling volume	Flow
103488002	C125050-10	125 ml	5 ml/hr
103488302	C270050-10	270 ml	5 ml/hr
103488402	C270100-10	270 ml	10 ml/hr
103489202	C060020-10	60 ml	2 ml/hr
103489402	C100020-10	100 ml	2 ml/hr
103489302	C100005-10	100 ml	0.5 ml/hr
103488102	C270010-10	270 ml	1 ml/hr
103488202	C270020-10	270 ml	2 ml/hr

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Homepump C-Series Silicone Elastomeric Pumps (with DEHP-free tubing)			
Reference	Model	Filling volume	Flow
101355701	C060020	60 ml	2 ml/hr
101356301	C125050	125 ml	5 ml/hr
103488001	C125050-10		
103489201	C060020-10	60 ml	2 ml/hr
101356101	C100020	100 ml	2 ml/hr
103489401	C100020-10		
101356001	C100005	100 ml	0.5 ml/hr
103489301	C100005-10		

What should I do in response to this Product Advisory Notice?

- distribute this advisory notice to all healthcare facilities who have received the products listed above without the red warning sticker.
- instruct those facilities to inform all concerned personnel. At a minimum, this should include the personnel of the Pharmacy and/or the department in charge of filling the single use infusion pump.
- complete the FSN Acknowledgement Form provided in Annex 1 and return it within five (5) days of receipt via e-mail to piq.emea@HYH.com or fax to No: +32 (0)2 711 26 95
- In case you will still have in stock inventory of the I-Flow/Kimberly-Clark Homepump C-Series that do not carry the red warning sticker cautioning against their use with the 5-FU, please complete annex 2 in addition to annex 1, listing exhaustively all quantities and lots available, and send it with annex 1 via e-mail to piq.emea@HYH.com or fax to No: +32 (0)2 711 26 95.
- Once annex 1 and 2 (where applicable) have been completed and transferred, please contact a Halyard Health representative to define next steps.

If you require further assistance, please contact your Halyard Health Representative. The Competent Authorities in your country have been informed of this Field Safety Corrective Action. Consequently, your reply to this communication completing annex 1 and annex 2 (in case you will have stock of the affected products) is compulsory. Please be informed that the Competent Authorities can request from you the traceability records of the affected products mentioned in this Field Safety Notice.

We thank you for your assistance and we apologize for any inconvenience this may cause.

Sincerely,
Thomas Kozma, PhD
Director, Regulatory Affairs
Halyard Health, Inc.

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Annex 1: Customer Response Form

Please FAX a copy of this form to No: +32 (0)2 711 26 95, or send it via email at piq.emea@hyh.com, within 5 business days of receipt of this notice.

Facility: «Name»
«Address»
«City», «State» «Zip»

Our records indicate that you may have in stock certain I-Flow/Kimberly-Clark Homepump C-Series that do not carry the red warning sticker cautioning against their use with the 5-FU.

Please complete this form, indicating if you have inventory of the affected products, specifying the lot number and available quantity.

Please return this form to the above fax number as soon as possible. We expressly point out that the reply is mandatory, as the competent authority can request proof of the whereabouts of the goods in individual cases.

After reception of this form duly completed, Halyard Health representative will contact you to define next steps.

- I certify that this facility has read and understood the information provided in the FSN
- I certify that this facility does NOT have stock of the affected products mentioned in this FSN
- I certify that all the stock of the affected products available at this facility is exhaustively listed in the table below (Annex 2: List of available stock of affected products)

(Signature)

(Date)

(Name – print)

(Title – print)

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Annex 2: List of affected products available

Please FAX a copy of this form to No: +32 (0)2 711 26 95, or send it via email at piq.emea@hyh.com, within 5 business days of receipt of this notice.

Lot No.	Product Description	Product Reference (Please use the reference provided on the 1 st column of the table displayed on the 1 st page)	Quantity

[] I certify that all the stock of the affected products available at this facility is exhaustively listed in the table above

(Signature) _____
(Date)

(Name – print)

(Title – print)