

Voluntary Product Advisory Notice - Distributors
Homepump C-Series Silicone Elastomeric Pumps (non-DEHP)

26 April 2016

ATTENTION: DIRECTOR, PURCHASING DEPARTMENT / QUALITY-REGULATORY AFFAIRS DEPARTMENT.

Dear Valued Halyard Health Customer:

What is the reason for this Voluntary Product Advisory Notice?

Halyard Health (formerly known as Kimberly-Clark Health Care) has recently received reports indicating that the single-use Homepump C-Series Silicone Elastomeric Pumps (non-DEHP) may experience a reduction of flow when infusing the chemotherapy drug named 5-Fluorouracil (also known as “5-FU”). The situation resulted in the patient not receiving the full treatment within the expected timeframe. Halyard Health’s investigation and extensive testing is on-going and preliminary findings suggest the potential root cause is associated with 5-Fluorouracil (5-FU) crystalizing and blocking flow due to interactions with the non-DEHP tubing included with the pumps. Therefore, Halyard Health is notifying all users to not infuse 5-Fluorouracil (5-FU) with Homepump C-Series Silicone Elastomeric Pump (non-DEHP), until further notice. There have been no reports of injuries associated with this condition to date.

Which Products are impacted?

This Product Advisory Notice applies to all H Homepump C-Series Silicone Elastomeric Pump (non-DEHP) as listed below, and only applies to infusion of 5-Fluorouracil (5-FU).

Homepump C-Series Silicone Elastomeric Pumps (without DEHP)			
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?

This notice is intended to inform all users to not infuse 5-Fluorouracil (5-FU) with Homepump C-Series Silicone Elastomeric Pump (non-DEHP), until further notice. Please:

- Distribute this advisory notice to all healthcare facilities who have received the products listed above,
- 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 Response Form by checking the box and FAX the completed form to +32 (0)2 711 26 95 OR E-MAIL to piq.emea@hyh.com within 5 business days of receipt of this notice.
- Inform your local competent authority on medical devices about this Advisory Notice.

Halyard Health is completing the investigation to prevent the recurrence of this issue. If you require further assistance, please contact your Halyard Health Representative. We thank you for your assistance and we apologize for any inconvenience this may cause.

Sincerely,

[Redacted Signature]

Product Advisory Notice - Distributors
Homepump C-Series Silicone Elastomeric Pumps (non-DEHP)

Response Form

Dear Valued Halyard Health Customer: XXXXXXX

Our records indicate that your facility has received **Homepump C-Series Silicone Elastomeric Pumps (non-DEHP)** as listed above.

After you have read the FSN please tick box:

I certify that this facility has read and understood the actions required in this Product Advisory Notice

I certify that I have informed my local competent authority of this Advisory Notice.

Please FAX/E-MAIL a copy of this completed Response Form to +32 (0)2 711 26 95/piq.emea@hyh.com within 5 business days of receipt of this notice.

Name-print:

Title-print:

Signature:

Date: