Medtronic

Urgent Field Safety Notice

MEDIVATORS HEMOCOR HPH® Hemoconcentrator - sold and distributed by Medtronic Models HPH-400TS, HPH-700, HPH-1000TS / Medtronic Perfusion Tubing Pack Recall

August 2015

Medtronic reference: FA676

Dear Risk Manager,

Medtronic was recently notified that Medivators has initiated a product recall for a subset of their Hemocor High Performance Hemoconcentrators, due to low ultrafiltration performance that is below product specification. A copy of the Urgent Medical Device Recall letter provided by Medivators is included for reference and contains more information on this issue and associated potential safety risk.

Medivators includes a single lot (759491A) of model HPH-700 in this recall. Based on additional information provided by the manufacturer, Medtronic has made the precautionary decision to also include specific lots of models HPH-400TS and HPH-1000TS and a 2nd lot of model HPH-700. These potentially affected units have been distributed as stand-alone devices and in specific lots of Medtronic Perfusion Tubing packs. A list of potentially affected model and lot numbers is included in Appendix A.

Through August 11, 2015, Medtronic has received a report from two hospitals, each with multiple events related to this Hemoconcentrator performance issue. **None of the reported events include any patient injuries or adverse events.** Our records indicate that your facility has received one or more potentially affected stand-alone Hemoconcentrator and / or one or more Medtronic Perfusion Tubing Packs that contain potentially affected Hemoconcentrators.

For affected product that has been used, no action is necessary and patients should continue to be managed in accordance with your standard patient management protocol.

In order to mitigate risks associated with this issue, Medtronic is requesting that you carry out the actions below, which are consistent with the recommendations included in Medivators' attached Urgent Medical Device Recall.

- Immediately quarantine and return any potentially affected Hemoconcentrators or Medtronic Perfusion Tubing Pack models with the corresponding lot numbers as shown in the table below to Medtronic. Your Medtronic representative will assist.

Please share this notification with others in your organization as appropriate. If product within scope of this recall has been forwarded to another facility, please notify the facility of the issue and assist with the return of affected product. Medtronic has notified the applicable regulatory authority of this issue.

Medtronic has notified the Competent Authority of your country of this action.

If you have any questions, please do not hesitate to contact your Medtronic representative.

We appreciate your cooperation and apologize for the inconvenience that this issue may cause.

Sincerely,

Medtronic

Appendix A: Potentially Affected Hemoconcentrators Model / Lot number:

Type	Model #	Lot #
Stand-Alone	HPH-700	759491A
		762355A
Stand-Alone	HPH-400TS	759884A
Stand-Alone	HPH-1000TS	759625A
Medtronic Perfusion Tubing Packs (with potentially affected Hemoconcentrator)	7U65R2	209050007
	8C72R4	209087876
	6N21R2	209107465
	BB7M38R11	209135076
	TL2Q68R17	209162502
	HY8R66R3	209195930
	HY2U43R9	209241496
	8C72R4	209241613
	BB5J59R19	209270018
	6B65R3	209270092
	TL7M46R7	209297994
	TL2Q68R17	209298091
	7U65R2	209298094
	M074704B	209310403
	M230002A	209326025
	BB7M38R11	209373545
	M450013B	209388464
	BB8N86R4	209396017
	HY2U43R9	209401269
	8C72R4	209401312
	M650123A	209415313
	HY8R55R	209431890
	TL7M46R7	209464644
	M971406C	209512240
	M450013B	209556873
	7U65R2	209621268
	M394415A	209644548
	M450013B	209653827

MEDIVATORS
A Cantel Medical Company

Date: August 4, 2015

RE: Urgent Medical Device Recall of MEDIVATORS® Hemocor HPH700 High Performance Hemoconcentrators Lot 759491A

Dear Valued Customer,

Based on internal analysis, Medivators has identified that some quantity of **Hemocor HPH700 High Performance Hemoconcentrators Lot 759491A** may exhibit low ultrafiltration performance that is below product specification. Reduced ultrafiltration performance may result in prolonged hemodilution, potentially require change out of the device during the procedure, and/or may cause delay in treatment. However the importance of ultrafiltration utilized to moderate potassium levels differs from patient to patient, and the hemoconcentrator's ultrafiltration performance also may not have a direct impact to the patient during a procedure. Hemodilution/Hemoconcentration is closely monitored by the physician and staff in the operating room, and if hemoconcentrator performance issues are observed during a procedure, they can be corrected quickly. Medivators is voluntarily recalling the affected lot number.

This letter serves as formal notification of the voluntary recall of this product; which involves the following lot number:

Lot Number	Product Number
759491A	HPH700

Our records indicate that your facility was shipped the affected product. Please check your inventory and determine if you have any of the affected lot number listed above. If you do, please quarantine the affected product to assure it is not used and contact Medivators Product Manager Suzanne London at (763)-553-3348 or slondon@medivators.com for return instructions as well as credit for or no-charge replacement of the affected product. Please complete and return the enclosed response form to document your response and aid in the effective implementation of this recall.

Sincerely,

Brent Geiger
Director Regulatory Compliance
Medivators Inc.
bgeiger@medivators.com
763-553-3345