AVANOS

URGENT: PRODUCT RECALL
CORFLO* Percutaneous Endoscopic Gastrostomy (PEG) Kit

October 4, 2019

Dear Valued Customer:

What is the Reason for this Recall?

Avanos Medical has received reports stating that the connector piece to the PEG tube does not pass over the guidewire. If you have received any **CORFLO* PEG Kit** devices, including device branded under Halyard Health, from the lots listed below, please follow the instructions provided regarding the requested actions. Only certain lots of the following product codes: 30-4020, 30-4320, 50-4016E1, and 50-4020E1 are impacted. Please refer to Table 1.

The PEG tube may be blocked at the center of the adapter. The blockage may be visible to the user and if present, the connector piece to the PEG tube will not pass over the guidewire during placement. The PEG tube cannot be used, and the PEG procedure may be delayed or aborted. In one report of a prolonged procedure received by Avanos, the procedure was completed using an alternative product.

No injuries or adverse events have been received by Avanos regarding this issue to date.

Which Products are Impacted?

This Recall applies to the following **CORFLO* PEG Kits** summarized in the following Table and were shipped from March 13, 2019 to July 26, 2019.

(Please note the remaining components of the CORFLO PEG Kit are not affected in this Recall. This Recall only impacts the PEG Tube.)*
Table 1

Product Code	Description	Lot
30-4020	CORFLO* PEG Kit	0203145253 0203081127
30-4320	CORFLO* PEG Kit	0002994173 0202974008 0202907370 0203201718 0203241065
50-4016E1	CORFLO* PEG Kit with ENFit® Connector	0203137961 0203172166
50-4020E1	CORFLO* PEG Kit with ENFit® Connector	0203069043
Impacted Devices might be branded as Halyard Health.		

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What should I do in response to this Recall?

Unused Inventory
Please evaluate your unused inventory of CORFLO* PEG Kit to determine if any impacted products remain within your inventory. Please discontinue using impacted product and quarantine according to your facility's procedures.

Please immediately complete the attached Recall Acknowledgement Form (Attachment 1) and return a copy of the form to Avanos in the USA: by email to:
avanos4178@stericycle.com or by FAX to 888-807-1084.

Outside the USA, please send by email to:
avanos4178OUS@stericycle.com or by FAX to +44 (0) 20 7660 1462.

Please respond within five (5) business days of receipt of this letter.

Inventory Already Used
If you received any of the impacted products but they are no longer in your inventory, please complete the attached Recall Acknowledgement Form (Attachment 1).

Please send this form to Avanos in the USA: by email to:
avanos4178@stericycle.com or by FAX to 888-807-1084.

Outside the USA, please send by email to:
avanos4178OUS@stericycle.com or by FAX to +44 (0) 20 7660 1462.

If you require further assistance, please contact Avanos by email at:
avanos4178@stericycle.com or by FAX to 888-807-1084.

Outside the USA, please send by email to:
avanos4178OUS@stericycle.com or by FAX to +44 (0) 20 7660 1462.

You may also contact Avanos Customer Service at exportcustomercare@avanos.com.

Avanos is completing an investigation to prevent recurrence of this issue. Thank you for your assistance, and we apologize for any disruptions to patient care this issue may cause your clinical facility.

Sincerely,

Thomas Kozma, Ph.D.
Director, Regulatory Affairs

Enclosure: Attachment 1 – Recall Acknowledgement Form

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ATTACHMENT 1: Recall Acknowledgement Form

Avanos records indicate that one or more models of the potentially impacted CORFLO* PEG Kit (identified in the Table below) was shipped to your clinical facility.

Please complete this form to acknowledge that you have understood this Product Recall letter.

If impacted product remains within your existing inventory/control, do not use the product. Please indicate below the quantity of cases/units for return and the original PO # for products requiring replacement.

Ship Product to: USA: Stericycle, Inc., 2670 Executive Dr., Indianapolis, IN 46241
Outside USA: 500 Charley Wood, Road, Knowsley Industrial Park, Merseyside L33 7SG UK

An Avanos Customer Service Representative will contact you if you have potentially impacted products remaining in your inventory.

Impacted Product Code	Description	Lot Number	Quantity Returned (Cases)	Original PO Number, if available
30-4020	CORFLO* PEG Kit	0203145253		
		0203081127		
30-4320	CORFLO* PEG Kit	0002994173		
		0202974008		
		0202907370		
		0203201718		
		0203241065		
50-4016E1	CORFLO* PEG Kit with ENFit® Connector	0203137961		
		0203172166		
50-4020E1	CORFLO* PEG Kit with ENFit® Connector	0203069043		

[ ] Please check this box if you have no inventory of impacted products.

Account No.	Facility Name
Contact Name	Phone Number
Signature/ Date	email contact

Please return a copy of this Recall Acknowledgement Form to Avanos.
In USA by email to: avanos4178@stericycle.com or by FAX to 888-807-1084.
Outside USA by email to: avanos4178OUS@stericycle.com or by FAX to +44 (0) 20 7660 1462.

Please respond within 5 business days of receipt of this letter.