



URGENT: FIELD SAFETY NOTICE
CORFLO* Percutaneous Endoscopic Gastrostomy (PEG) Kit

REF: FCA-2020-001

March 27, 2020

Dear Valued Avanos Customer:

Avanos Medical (formerly Halyard Health) is initiating a field safety notice for specific lots of the CORFLO* Percutaneous Endoscopic Gastrostomy (PEG) kit after investigating 3 complaints related to an occlusion or partial occlusion in the PEG tube adjacent the ring bumper. This field safety notice is being issued because an occluded PEG tube may not be fully functional (i.e. it may not be possible to administer the typical volumes of fluids, feed, or medication once placed or pass it over the guidewire if placed using a push technique) and may therefore require a PEG tube replacement.

What is the Reason for this Field safety notice?

Avanos Medical (formerly Halyard Health) has received 3 complaint reports stating that the CORFLO* PEG tube may be blocked (occluded). Avanos reviewed its inventory of subassemblies and found the defect rates to be 1.4% for full occlusion and 2.2% for partial occlusion. A PEG tube that is occluded may not be functional and the PEG procedure may be delayed or aborted. A new PEG tube placement may be required to continue with the procedure. ***There is no need for concern in patients who have had potentially affected PEGs placed that function normally, which are de facto unoccluded.***

Avanos has not received reports of serious injury or adverse events regarding this issue. The overall risk to patient health is Medium for a fully occluded tube.

Avanos is committed to patient safety. Due to the potential risk of occluded PEG tubes, Avanos has elected to issue this field safety notice regarding the affected product, and hereby requests that you **quarantine all affected devices until further notice** from us.

Which Products are Impacted?

This Field safety notice applies to the following **CORFLO* PEG Kit** product code and lot number combinations summarized in Table 1 that were manufactured after April 8, 2019.

(This Field safety notice only impacts the PEG Tube. Please note the remaining components of the CORFLO PEG Kit are not affected in this Field safety notice)*

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Table 1: Impacted Product Codes and lot numbers for European countries. Note that impacted devices may be branded as Halyard Health.

United Kingdom

Product Code	Product Description	Lot Number
50-4016E1	CORFLO* PEG Kit with ENFit® Connector	0020008354, 0020008547, 0020008666
50-6012E1	CORFLO* PEG Kit with ENFit® Connector	0203251785
50-6016E1	CORFLO* PEG Kit with ENFit® Connector	0002994170, 0203241062, 0203214905,

Ireland

Product Code	Product Description	Lot Number
50-6012E1	CORFLO* PEG Kit with ENFit® Connector	0203251785
50-6016E1	CORFLO* PEG Kit with ENFit® Connector	0002994170, 0203241062, 0203214905

France

Product Code	Product Description	Lot Number
50-6012E2	CORFLO* PEG Kit with ENFit® Connector	0002997217, 20011368
50-6016E2	CORFLO* PEG Kit with ENFit® Connector	0203261079, 20012261,
50-6020E2	CORFLO* PEG Kit with ENFit® Connector	0203214901, 0203239804, 0203248168, 20011369

Czech Republic,

Product Code	Product Description	Lot Number
50-6012E2	CORFLO* PEG Kit with ENFit® Connector	0002997217,

Germany

Product Code	Product Description	Lot Number
50-6012E2	CORFLO* PEG Kit with ENFit® Connector	0002997217,



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Italy

Product Code	Product Description	Lot Number
50-6012E1	CORFLO* PEG Kit with ENFit® Connector	0203251785
50-6016E1	CORFLO* PEG Kit with ENFit® Connector	0203214905, 0020003029,

Netherlands

Product Code	Product Description	Lot Number
50-6016E1	CORFLO* PEG Kit with ENFit® Connector	0002994170, 0203214905,

Romania

Product Code	Product Description	Lot Number
50-6016E1	CORFLO* PEG Kit with ENFit® Connector	0203214905, 0203261078

Sweden

Product Code	Product Description	Lot Number
50-6520	CORFLO* PEG Kit with ENFit® Connector	0203241063

What should I do in response to this Field safety notice?

Our records show that your facility has received one or more lots of the affected products. Consequently, Avanos requires that you immediately take the following actions **until further notice from Avanos**:

- **DISCONTINUE** using the specific product / lot code combinations provided in Table 1
- **CHECK** all storage and usage locations to determine if any impacted product remains within your possession

Unused Inventory

- **SEGREGATE** and **QUARANTINE** the devices according to your facility's procedures
- **IMMEDIATELY COMPLETE** and **RETURN** the attached Field safety notice Acknowledgement Form (Attachment 1) to Avanos.
 - Please send by email to Avanos3862OUS@stericycle.com or by FAX to +44 0800 069 8520.

Due to supply problems, Avanos is not able to provide replacement CORFLO PEG product or alternative products (such as MIC*PEG) currently. Please contact customer service in case there is a product shortage that impacts patient care.

Avanos is aligning follow-up steps with the respective competent authorities to ensure that this field action can be executed as is appropriate to the current market situations.

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Inventory Already Used

- **IMMEDIATELY COMPLETE** the attached Field safety notice Acknowledgement Form (Attachment 1) checking the box indicating that you have no inventory
- **RETURN** the form to Avanos
 - Please send by email to Avanos3862OUS@stericycle.com or by FAX to +44 0800 069 8520.

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

If you require further assistance, please contact Avanos by email at Avanos3862OUS@stericycle.com.

Please maintain a copy of this letter for your records.

The Competent Authority of your country has been informed about this Field Safety Notice.

Avanos has taken the necessary steps to prevent future shipment of the affected products. Avanos is completing an investigation to prevent recurrence of this issue. Please share this communication within your organization, with other organizations where affected devices have been transferred, and any other associated organizations that may be impacted by this action.

Thank you for your assistance, and we appreciate your prompt attention in this matter. We apologize for any disruptions to patient care this issue may cause your clinical facility.

Sincerely,



Thomas Kozma, Ph.D.
Director, Regulatory Affairs

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ATTACHMENT 1: Field safety notice Acknowledgement Form

Our records indicate that one or more models of the potentially impacted CORFLO* PEG Kits was shipped to your clinical facility.

Please complete this form to acknowledge that you have received and understand this Field safety notice letter.

If impacted product remains within your existing inventory/control, segregate and quarantine these products, and do not use any until further notice. Please complete the form below indicating the Product Code, Lot Number, Quantity of cases/units and the original PO # if available.

Impacted Product Code	Lot Number	Quantity in inventory	Original PO Number, if available

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

Account No.	Facility Name
Contact Name	Phone Number
Signature/Date	E-mail
Name of Distributor	

Please return a copy of this Field safety notice Acknowledgement Form **within 5 business days of receipt of this notice** to Avanos:

- By email to Avanos3862OUS@stericycle.com or by FAX to +44 0800 069 8520.