

## Field Safety Notice – Urgent Limited Digestive Health and Acute Pain Portfolio

NHS Normanton

FCA-2021-005

02 November 2021

Dear Sir, Madam,

Avanos Medical (formerly Halyard Health) is issuing a Field Safety Notice for the devices listed in **Annex 1** after we became aware that some products had been shipped to you without the Instructions For Use (IFU) included in the packaging.

### What is the reason for this Field Safety Notice?

This Field Safety Notice is being issued because the Instructions For Use are an integral part of the device and may need to be consulted for appropriate usage of the devices. Where applicable, if patients use the devices directly, the appropriate patient information leaflets are included in the packaging.

### Which products are impacted?

This FSN pertains to the Avanos products identified in **Annex 1** that you have received between **1<sup>st</sup> January** and **11<sup>th</sup> October 2021**.

### What should I do in response to this Field Safety Notice?

Our ship history records show that your facility has received one or more of the affected products. There is no immediate hazard for the patient, as the devices have an established clinical use and can be safely used by healthcare professionals without the IFU if they are comfortable doing so. If there is a need to consult the IFU, there is a link and QR code on the packaging that indicates the location of an electronic version of the IFU.

**Therefore, affected products can be shipped to hospitals and professional users with the instructions on how to obtain an electronic copy of the IFU.** An end user communication is attached to this FSN to that effect.

The following options are available to obtain a copy of the IFU.

### HOW DO I FIND THE eIFU?

#### TWO WAYS TO FIND eIFU





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**Limited Digestive Health and Acute Pain Portfolio**

**RETURN** the completed **Annex 1** to [EMEAFieldAction@avanos.com](mailto:EMEAFieldAction@avanos.com) **within five (5) business days of receipt of this letter.**

If you require further assistance, please contact Avanos at [EMEAFieldAction@avanos.com](mailto:EMEAFieldAction@avanos.com).

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

Please maintain a copy of this letter for your records.

Avanos has taken the necessary steps to prevent future shipment of products that are missing the IFU and is completing an investigation to prevent recurrence of this issue.

We thank you for your assistance and appreciate your prompt attention in this matter.

We apologize for any disruptions this issue may cause your facility.

Sincerely,

Klien van Dam  
Director, Quality and Regulatory Affairs EMEA

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### ANNEX 1

These products may have been shipped to you without IFUs between **1<sup>st</sup> January** and **11<sup>th</sup> October 2021**. The products can be used safely without IFU in accordance with the hazard analysis performed by Avanos, when end users are informed how to access the electronic version of the IFU online.

Customer Name \_\_\_\_\_ Title \_\_\_\_\_

Telephone \_\_\_\_\_ Email \_\_\_\_\_

Date \_\_\_\_\_

Digestive Health	Acute Pain
MIC* & MIC-KEY* Enteral Feeding Tube Kits	ON-Q* Systems (Pumps & Catheters, with Luer Lock & NRFit)
CORFLO* NG/NI TUBES	ON-Q* Expansion Kits: Catheters with Luer Lock & NRFit (Soaker, SilverSoaker)
Initial Placement Kits (Avanos Introducer Kit, MIC* & CORFLO* PEG and PEJ)	