AVANOS

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

NHS Supply Chain Rugby

FSCA-2021-005 09 September 2021

Dear Valued Customer,

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. 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. 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**.

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

Our ship history 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:

1. **DISCONTINUE** distribution of the products reported in **Annex 1** and remove all affected units from your inventory.
2. **CHECK** all storage and usage locations to determine if any impacted product remains within your possession.
3. **UNUSED INVENTORY**
    a. **SEGREGATE** and **QUARANTINE** the devices according to your facility's procedures.
    b. **COMPLETE Annex 1** (attached) in full.
    c. **RETURN** the completed **Annex 1** to EMEAFieldAction@avanos.com **within five (5) business days of receipt of this letter**.
    d. **DESTROY** the affected devices according to your facility's procedures.
    e. **SEND** the certificate of destruction to EMEAFieldAction@avanos.com.

4. **INVENTORY ALREADY DISTRIBUTED**
    a. **NOTIFY** your customers and provide them with the "Customer letter" that is provided in attachment to this letter.

If you require further assistance, please contact Avanos at 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.

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.

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

Avanos records indicate you have received the affected product listed in this annex.

INSTRUCTIONS

1. **PROVIDE** your contact details as indicated below.
2. **REPORT** the quantity of affected product(s) and lot(s) at your facility in the table below.
3. **RETURN** the completed **Annex 1** via email to EMEAFieldAction@avanos.com **within five (5) business days of receipt of this letter**.
4. **ATTACH** a list of your affected customers (if any).
5. **TO REPLACE PRODUCTS**
   a. Contact Customer Service CustomerService.UK.IE@avanos.com to arrange replacement product.
   b. Avanos will replace the products free of charge.

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Annex 1

Customer Name_____Title_____

Telephone_____Email_____

Date_____

Digestive Health

Product Code	Product Commercial Name	Lot Number	Quantity to be Scrapped (Units)
104456401 8110-22	AVNS,MICBOL GASTRO TUBE 22F ENFIT	20021689	
104623002 51-4602	AVNS,CRSCP NJ TUBE 12FR 152CM WGT ENFIT	30111646	

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Annex 1

Customer Name_____Title_____

Telephone_____Email_____

Date_____

Acute Pain

Product Code	Product Commercial Name	Lot Number	Quantity to be Scrapped (Units)