AVANOS

5405 Windward Parkway
Alpharetta, GA 30004

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www.avanos.com

Urgent Medical Device Field Safety Notice Update:

Updated User Documents For CORTRAK* 2 Enteral Access System (EAS)

Date

Dear Customer,

This letter serves as your notice that **Avanos has made important updates to the** Indications for Use in the Operator's Manual **for CORTRAK*2 Enteral Access System**.

The update clarifies that the confirmation of NG/NI tubes placed using CORTRAK* 2 should be confirmed per institutional protocol. Additionally, Avanos strongly recommends that **Anonymous Account Mode** should no longer be used.

The updated Operator's Manual, Quick Reference Guide and Troubleshooting Tips can be downloaded by visiting https://eifu.avanos.com/AVA/en/all and entering the product codes or unique device identifier ("UDI") listed below.
Should you wish to receive a physical copy of the user documents, please provide your full contact details in Attachment 2.

Impacted products:

Product Code	UDI	Product Description	Serial Number
20-0950	00350770472010	CORTRAK*2 Enteral Access System (EAS)	All
P20-0950	00350770472065	CORTRAK*2 Enteral Access System (EAS) Loaner Unit	All
20-0950	10680651472011	CORTRAK*2 Enteral Access System (EAS) Halyard version	All
P20-0950	10680651472066	CORTRAK*2 Enteral Access System (EAS) Loaner Unit – Halyard version	All

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What should I do in response to this Field Safety Correction Action?

Our records show that you and/or your facility have received one or more of the affected products. Avanos requests that you take the following actions:

- **From the CORTRAK* EAS in your facility:**
  1. **Remove the obsolete versions of the documents listed below, and**
  2. **Replace the obsoleted documents with the new versions included with this letter:**
     - **Operator's Manual**
     - **Quick Reference Guide**
     - **Troubleshooting Tips**
  3. **Complete** and **return** the attached Acknowledgement Form (Attachment 1) to Avanos, via email at emeafieldaction@avanos.com. **Please respond within five (5) business days of receipt of this letter.**

If you have questions or require further assistance, please contact Avanos via email at emeafieldaction@avanos.com.

Please maintain a copy of this letter for your records. Share this communication within your organization, with other organizations where affected devices have been transferred, and with any other associated organizations that may be impacted by this action.

Thank you for your assistance. We appreciate your prompt attention in this matter and apologize for any disruptions this issue may have caused to your facility.

Sincerely,

Klien van Dam
EMEA Director, Quality and Regulatory Affairs
Avanos Medical Belgium BV

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Attachment 1

Acknowledgment Form

Please complete this form to acknowledge that you have received this Field Safety Notice and have removed all obsolete versions of the below documents from our **CORTRAK* EAS** and replaced them with the new versions provided:

1. **Operator's Manual**
2. **Quick Reference Guide**
3. **Troubleshooting Tips**

Customer Name_____Title_____

Telephone_____Email_____

Date_____

Please return a copy of this Acknowledgement Form to Avanos within 5 business days of receipt of this notice via email at emeafieldaction@avanos.com.

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Attachment 2

Request for a Physical Copy of User Documents

Please send a physical copy of the updated **CORTRAK* EAS** user documents to the following contact details:

Contact Name	
Health Institution	
Address	
City	
Postcode	
Country	