AVANOS

URGENT: FIELD SAFETY NOTICE

CORTRAK* 2 Enteral Access System (EAS)

25 March 2022

Dear Valued Avanos Customer,

Avanos Medical is issuing a voluntary Field Safety Notice (FSN) for the CORTRAK* 2 Enteral Access System (EAS) due to reports of 60 injuries and 23 patient deaths related to misplacement of nasogastric feeding tubes while using the CORTRAK* 2 Enteral Access System, since 2015. Of these incidents, one occurred in the UK and all other incidents occurred in the USA. All incidents have been reported to the appropriate Health Authorities.

Avanos Medical, Inc. is committed to patient safety and improving patient outcomes. Therefore, Avanos is initiating a voluntary FSN for all CORTRAK* 2 Enteral Access System (EAS) devices, Model 20-0950 and P20-0950 (Avanos, Halyard Health, and Corpak brands). To further promote safe use of the CORTRAK* 2 Enteral Access System, Avanos is making updates to the labeling in the Operator's Manual and training documents to emphasise that confirmation of NG/NI tubes placed using CORTRAK* 2 should be confirmed per institutional protocol. Additionally, Anonymous Account Mode will be retired later this year through a software update, to ensure that there are appropriate records of NG/NI tube placements archived in the system. You will receive the new operating manuals when these are available.

This FSN pertains to the products identified below:

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 CORRECTION?

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:

- **COMPLETE** and **RETURN** the attached Acknowledgement Form (**Attachment 1**) to Avanos via email to EMEAFieldAction@avanos.com.
- **STOP** using the Anonymous Account Mode feature of the CORTRAK* 2 device, immediately.
- **CONFIRM** placement of the NG/NI tube per institution protocol.
- Device should only be used by qualified, trained users. If you need additional training, please contact your local field sales representative.

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

As a reminder, users should always use extreme caution in patients who are combative or who move excessively during placement as the receiver unit may move, impacting the placement tracing.

If a deviation from the midline is seen on the All-In-One Monitor display during advancement in the upper quadrants, or resistance is encountered:

- **STOP** advancement of the system.
- **REMOVE** the tube and stylet and assess the patient for injury per institutional protocol.

If you have questions or require further assistance, please contact Avanos via email 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. Share this communication within your organisation, with other organisations where affected devices have been transferred, and with any other associated organisations that may be impacted by this action.

Avanos is committed to patient safety. We are taking the necessary steps to quickly provide the updated Operator's Manual, Quick Reference Guide, and training materials.

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

Sincerely,

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

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ATTACHMENT 1: FIELD CORRECTION ACKNOWLEDGEMENT FORM (CUSTOMER)

Our records indicate that the **CORTRAK* 2 Enteral Access System (EAS)** was shipped to your facility.

Please complete this form to acknowledge that you have received and understand this Field Safety Notice (FSN).

Impacted Product Code	Product Description
20-0950	CORTAK*2 Enteral Access System (EAS)
P20-0950	CORTAK*2 Enteral Access System (EAS) – Loaner Unit
20-0950	CORTRAK*2 Enteral Access System (EAS) – Halyard version
P20-0950	CORTRAK*2 Enteral Access System (EAS) – Loaner Unit – Halyard version

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 to EMEAFieldAction@avanos.com