AVANOS

URGENT: FIELD CORRECTION
CORTRAK* 2 Enteral Access System (EAS)

March 21, 2022

Dear Valued Avanos Customer,

Avanos Medical is conducting a voluntary field correction 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.

Avanos Medical, Inc. is committed to patient safety and improving patient outcomes. Therefore, Avanos is initiating a voluntary field correction for all CORTRAK* 2 Enteral Access System (EAS) devices, Model 20-0950 and P20-0950 (Avanos, Halyard Health, and Corpak brand). Avanos is making updates to the labeling in the Operator's Manual and training documents stating that the 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. You will be notified when new labeling is available and when you may remove this notification from your product.

Impacted product:

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

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:

- **CHECK** all storage and usage locations to determine if any impacted product remains within your possession.
- **ATTACH THIS LETTER** to the Operator's Manual until a revised Operator's Manual, Quick Start Guide and Troubleshooting Tip Cards are available.
- **COMPLETE** and **RETURN** the attached Acknowledgement Form (***Attachment 1***) to Avanos.
    - Via email to avanos-fca002@iqvia.com Phone Number (855) 365-3981
- **STOP** using the Anonymous Account Mode feature of the CORTRAK* 2 device, immediately.
- **CONFIRM** placement of the NG/NI tube per institution protocol
- **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:

    1) **STOP** advancement of the system.

    2) **REMOVE** the tube and stylet and assess the patient for injury per institutional protocol.

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- 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.

If you have questions or require further assistance, please contact Avanos via email at avanos-fca002@iqvia.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.

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,

Lisa Clark
Senior Manager, Global Post Market Surveillance
Avanos Medical, Inc.