URGENT FIELD SAFETY NOTICE

AVANOS* CORFLO* Nasogastric / Nasointestinal Feeding Tubes and AVANOS* CORTRAK* 2 NASOGASTRIC / NASOINTESTINAL FEEDING TUBE With Electromagnetic Transmitting Stylet

FCA-2025-003

25 July, 2025

Dear Valued Avanos Customer,

Avanos Medical, Inc. is committed to patient safety and improving patient outcomes. Avanos has received reports from customers experiencing issues of unresolvable clogging, bursting, and/or tearing when using Nasogastric (NG) tubes. The severity of possible harm associated with this failure mode may be severe. Avanos has initiated an investigation to determine the root cause of these failures, and we are committed to taking the necessary steps to inform our affected customers so that they may take appropriate action. As an initial action, Avanos has implemented updates to the Instructions for Use (IFU) for the AVANOS* CORFLO* Nasogastric / Nasointestinal Feeding Tubes and AVANOS* CORTRAK* 2 NASOGASTRIC / NASOINTESTINAL FEEDING TUBE with Electromagnetic Transmitting Stylet to clarify device lifetime and the best ways to deal with a blocked tube.

The purpose of this letter is to advise you that Avanos Medical is providing a **Field Safety Notice** (FSN) regarding the AVANOS* CORFLO* Nasogastric / Nasointestinal Feeding Tubes and AVANOS* CORTRAK* 2 NASOGASTRIC / NASOINTESTINAL FEEDING TUBE With Electromagnetic Transmitting Stylet. The IFU has been updated to provide clearer guidance regarding device lifetime and unclogging recommendations. The changes were written and approved in December 2024 and were released for use in March 2025. Impacted devices are listed in ATTACHMENT 1.

HEALTH RISKS (POSSIBLE OUTCOMES OF FAILURE)

Possible outcomes could result with any of the following infrequently occurring factors as a result of use or misuse of any feeding tube or its replacement:

- Pneumothorax
- GI perforation
- Aspiration
- Airway obstruction
- Tissue irritation or necrosis
- Allergic reaction
- Contamination
- Delay in diagnosis
- Delay or miss dose of medication or nutrition and related complications or the need for additional medical procedures.

TYPE OF ACTION BY THE COMPANY

Avanos wants to ensure optimal patient safety by promoting awareness and minimizing the risk of potential harm. Therefore, while the product may continue to be used by qualified, trained users, Avanos has made updates to the IFU as indicated below.

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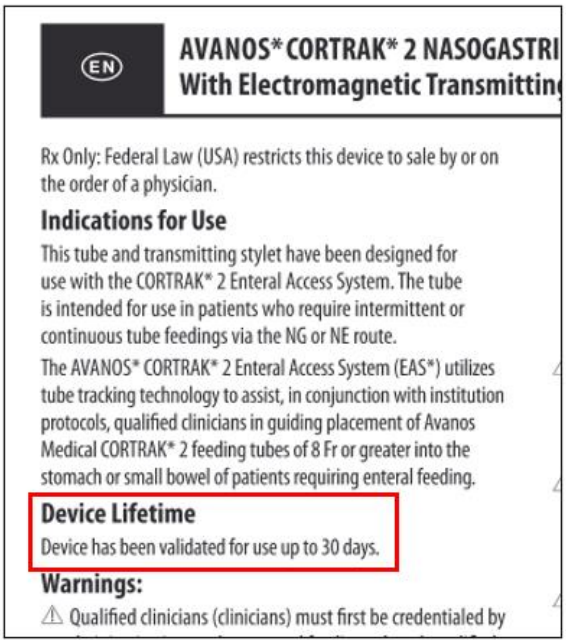
GUIDANCE FROM INSTRUCTIONS FOR USE

The updated Instructions for Use (IFU) provide the following guidance for the device lifetime, tube maintenance and unclogging recommendations:



EN

AVANOS* CORTRAK* 2 NASOGASTRI
With Electromagnetic Transmittin

Rx Only: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Indications for Use

This tube and transmitting stylet have been designed for use with the CORTRAK* 2 Enteral Access System. The tube is intended for use in patients who require intermittent or continuous tube feedings via the NG or NE route.

The AVANOS* CORTRAK* 2 Enteral Access System (EAS*) utilizes tube tracking technology to assist, in conjunction with institution protocols, qualified clinicians in guiding placement of Avanos Medical CORTRAK* 2 feeding tubes of 8 Fr or greater into the stomach or small bowel of patients requiring enteral feeding.

Device Lifetime

Device has been validated for use up to 30 days.

Warnings:

⚠ Qualified clinicians (clinicians) must first be credentialed by

Figure 1 - Device lifetime indication in the IFU

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The Warning section was relocated below "Device Lifetime" and above "Tube Insertion," and removed from the body of the IFU:

Indications for Use

The AVANOS* CORFLO* Feeding Tube is intended for use in those patients who require intermittent or continuous tube feedings via the nasogastric or nasoenteric route.

Device Lifetime

Device has been validated for use up to 30 days.

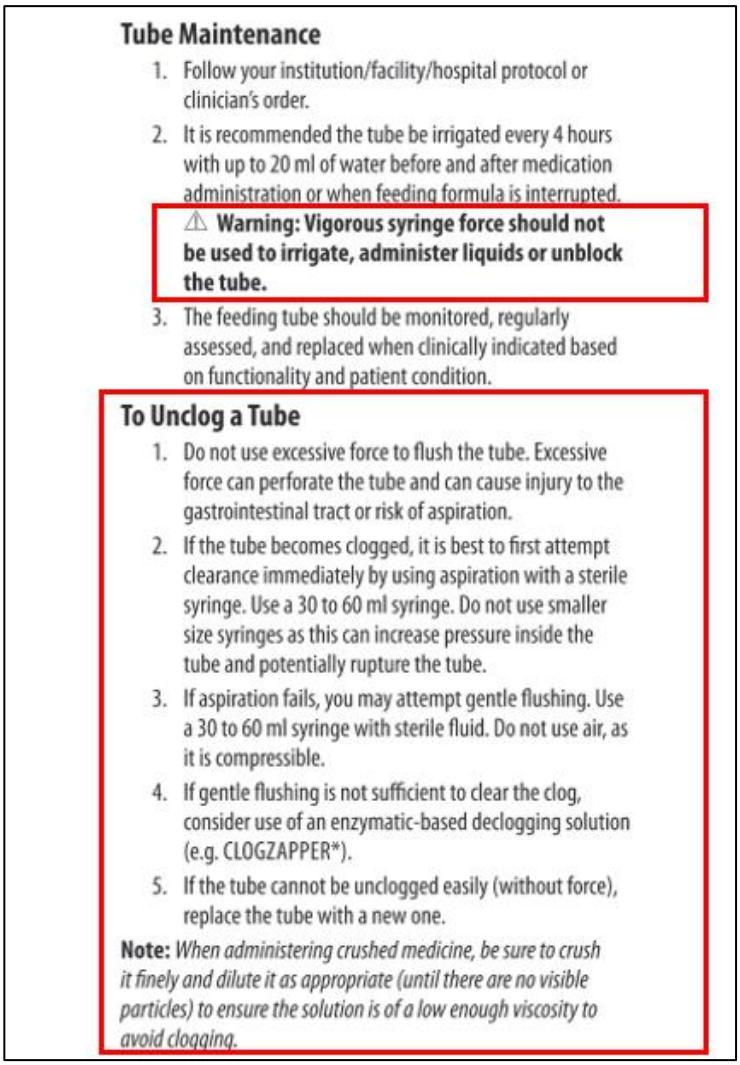
⚠ Warnings

- **The patient should not lean forward, nor should the head and neck be extended.**
- **Premeasurement of tubing length is essential. Do not insert excess. Occlusion may result from kinking of tube.**
- **Coughing may indicate passage of tube into trachea. If tracheal passage is suspected, remove tube. Absence of coughing does not confirm tube placement in the stomach.**
  If resistance is encountered, immediately remove tube. Notify clinician. Care should be taken if any type of endotracheal device is in place, as it may guide feeding tube into trachea.
  Misplacement of the feeding tube into trachea or lungs may result in serious injury.
- **Tube position in the stomach must be confirmed prior to flushing and use.**
- **Never reinsert stylet when tube is in patient.**
- **Vigorous syringe force should not be used to irrigate, administer liquids or unblock the tube.**

Tube Insertion

This feeding tube is to be inserted by trained and competent individuals or clinicians following institution/facility/hospital protocols

Additionally, a warning was relocated into the "Tube Maintenance" section, and a new section "To Unclog a Tube" was added:



Tube Maintenance

1. Follow your institution/facility/hospital protocol or clinician's order.
2. It is recommended the tube be irrigated every 4 hours with up to 20 ml of water before and after medication administration or when feeding formula is interrupted.

⚠ **Warning: Vigorous syringe force should not be used to irrigate, administer liquids or unblock the tube.**

3. The feeding tube should be monitored, regularly assessed, and replaced when clinically indicated based on functionality and patient condition.

To Unclog a Tube

1. Do not use excessive force to flush the tube. Excessive force can perforate the tube and can cause injury to the gastrointestinal tract or risk of aspiration.
2. If the tube becomes clogged, it is best to first attempt clearance immediately by using aspiration with a sterile syringe. Use a 30 to 60 ml syringe. Do not use smaller size syringes as this can increase pressure inside the tube and potentially rupture the tube.
3. If aspiration fails, you may attempt gentle flushing. Use a 30 to 60 ml syringe with sterile fluid. Do not use air, as it is compressible.
4. If gentle flushing is not sufficient to clear the clog, consider use of an enzymatic-based declogging solution (e.g. CLOGZAPPER*).
5. If the tube cannot be unclogged easily (without force), replace the tube with a new one.

Note: *When administering crushed medicine, be sure to crush it finely and dilute it as appropriate (until there are no visible particles) to ensure the solution is of a low enough viscosity to avoid clogging.*

Figure 2 - Included consolidated information on Tube Maintenance and Unclogging in the IFU

WHAT SHOULD I DO IN RESPONSE TO THIS FIELD SAFETY NOTICE?

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

- To confirm receipt of this FSN and to indicate that you have read and implemented the actions to be taken, **COMPLETE** and **RETURN** the attached Acknowledgement Form (**Attachment 2**) to Avanos via email to AvanosFieldAction@sedgwick.com.

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- The AVANOS* CORFLO* Nasogastric / Nasointestinal Feeding Tubes and AVANOS* CORTRAK* 2 NASOGASTRIC / NASOINTESTINAL FEEDING TUBE With Electromagnetic Transmitting Stylet devices may continue to be used by qualified, trained users. If you need additional training, please contact your local field sales representative.
- If you have experienced adverse reactions or quality problems during the use of the AVANOS* CORFLO* Nasogastric / Nasointestinal Feeding Tubes and AVANOS* CORTRAK* 2 NASOGASTRIC / NASOINTESTINAL FEEDING TUBE With Electromagnetic Transmitting Stylet, please reach out to our Partners in Quality nurses to report the issue at PIQ.EMEA@avanos.com and also report the incidents to the concerned competent authority.

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

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.

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,

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ATTACHMENT 1: AFFECTED DEVICE IDENTIFICATION

This FSN pertains to the products identified below:

Product Codes	UDI/GTIN	Product Description	Serial Number
40-7368	0350770CFTN00079GG	CORFLO Nasogastric / Nasointestinal Feeding Tube with Weight and ENFit	All
40-7431			
40-7432	0350770CFTN00079GG	CORFLO Nasogastric / Nasointestinal Feeding Tube, Sterile, Non-Weighted	All
70-7438			
40-9431	0350770CFTN00079GG	CORFLO Nasogastric / Nasointestinal Feeding Tube with ENFit Connector and Stylet	All
40-9551			
42-1226	0350770CNTS00079P9	CORFLO Nasogastric / Nasointestinal Feeding Tube with ENFit Connector	All
42-1362			

Product Codes	UDI/GTIN	Product Description	Serial Number
42-2438	0350770CNTS00079P9	CORFLO Nasogastric / Nasointestinal Feeding Tube, Sterile, Non-Weighted	All
42-7361			
42-7366			
42-7368			
42-7558			
42-8226			
42-9156	0350770CNTS00079P9	CORFLO Nasogastric / Nasointestinal Feeding Tube with Stylet with ENFit Connector *(Continued on next page)*	All
42-9225			
42-9226			
42-9228			
42-9361			
42-9366			
42-9368			
42-9431			
42-9432			
42-9438			
42-9551			

42-9558			
50-4602			
51-4602			
51-9601			
40-9551TRAK2	00350770460536	CORTRAK 2 Nasogastric / Nasointestinal Feeding Tube with Electromagnetic Transmitting Stylet with ENFit® Connector	All
40-9558TRAK2	00350770460550		
42-9361TRAK2	00350770460895		
42-9362TRAK2	00350770460901		
42-9368TRAK2	00350770460932		
42-9431TRAK2	00350770460949		
42-9551TRAK2	00350770460987		
42-9558TRAK2	00350770461007		

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ATTACHMENT 2: FIELD SAFETY NOTICE ACKNOWLEDGEMENT FORM (CUSTOMER)

Please return a copy of this Acknowledgement Form to Avanos within five (5) business days of receipt of this notice via email to AvanosFieldAction@sedgwick.com

Our records indicate that the **AVANOS* CORFLO* Nasogastric / Nasointestinal Feeding Tubes and/or AVANOS* CORTRAK* 2 NASOGASTRIC / NASOINTESTINAL FEEDING TUBE With Electromagnetic Transmitting Stylet** is in use at your facility.

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

Hospital Name: _____

Name: _____

Date: _____

Note:

- This form is to verify that an electronic version is received.