FIELD SAFETY NOTICE

AVANOS* Introducer Kit for Gastrostomy Feeding Tubes

FCA-2025-002 rev. 2

18 June, 2025

Dear Valued Avanos Customer,

Avanos Medical, Inc. is committed to patient safety and improving patient outcomes. Avanos has recently received several reports where the gastropexy sutures in the AVANOS* Introducer Kit for Gastrostomy Feeding Tubes have broken during or shortly after initial placement. The severity of possible harm associated with this failure mode is severe. Avanos has initiated an investigation to the root cause of this failure, and we are taking the necessary steps to quickly inform our affected customers so that they may take appropriate action.

The purpose of this letter is to advise you that Avanos Medical is providing a **Field Safety Notice** (FSN) regarding the AVANOS* Introducer Kit for Gastrostomy Feeding Tubes, which is intended to facilitate the primary placement of the AVANOS* MIC* and MIC-KEY* brand of Gastrostomy Feeding Tubes. Housed inside the kits are the AVANOS* Gastrointestinal Anchor Set with SAF-T-PEXY* T-Fasteners that are intended to affix the stomach to the anterior abdominal wall facilitating primary placement of the AVANOS* MIC* and MIC-KEY* brand Enteral Feeding Tube.

DEVICE IDENTIFICATION

This FSN pertains to the products identified below:

Product Code	UDI/GTIN	Product Description	Serial Number
98430	00350770984308	Introducer Kit for Gastrostomy Feeding Tube, 16Fr Dilator	All
98431	00350770984315	Introducer Kit for Gastrostomy Feeding Tube, 18Fr Dilator	All
98432	00350770984322	Introducer Kit for Gastrostomy Feeding Tube, 20Fr Dilator	All
98433	00350770984339	Introducer Kit for Gastrostomy Feeding Tube, 22Fr Dilator	All
98434	00350770984346	Introducer Kit for Gastrostomy Feeding Tube, 24Fr Dilator	All
98701	00350770987019	Gastrointestinal Anchor Set, SAF-T-PEXY* T-Fasteners	All

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HEALTH RISKS (POSSIBLE OUTCOMES OF FAILURE)

These sutures are used in threes to create a gastropexy. If a suture breaks during or shortly after a gastrostomy or gastropexy, the other two sutures should maintain the gastropexy. However, if they do not, possible outcomes of this failure include but are not limited to: gastrostomy failure (loss of stoma integrity), gastropexy failure (stomach no longer secured to abdominal wall), peritonitis, free abdominal air, gastric leakage, bleeding, delayed healing, fistula formation, sepsis, or death.

Actual complications and their severity depend on the stage of the placement procedure at time of suture break, the type of technique used for placement, the number of sutures that break, and patient specific variables.

ACTIONS TAKEN BY AVANOS

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 would like to reiterate the following guidelines and best practices for correct placement of the gastropexy sutures.

Please note the following contraindications and warning:
Contraindications include, but are not limited to ascites, colonic interposition, portal hypertension, gastric varices, peritonitis, aspiration pneumonia and morbid obesity.

Warning: Verify package integrity of each pouch prior to opening. Do not use if package is damaged or sterile barrier is compromised. Do not reuse, reprocess, or resterilize this medical device. Reuse, reprocessing, or resterilization may 1) adversely affect the known biocompatibility characteristics of the device, 2) compromise the structural integrity of the device, 3) lead to the device not performing as intended, or 4) create a risk of contamination and cause the transmission of infectious diseases resulting in patient injury, illness, or death.

Please note that the Instructions for Use contain guidance related to gentle use of the product and avoidance of excessive tension during placement.

GUIDANCE FROM INSTRUCTIONS FOR USE

The AVANOS* Introducer Kit for Gastrostomy Feeding Tube Instructions for Use (IFU) provides the following guidance for placement of the gastropexy sutures. Figure references may be found on page two (2) of the IFU:

Placing the SAF-T-PEXY*:
Absorption of the suture is essentially complete within 90 to 110 days.

Warnings:
• The kinetics of gastric wall adhesion to the anterior abdominal wall relative to suture absorption must be considered prior to using the SAF-T-PEXY* device when a compromised healing response is anticipated, especially when adhesion of the gastric wall to the anterior abdominal wall is not expected within 14 days.
• T-Fasteners may migrate and be retained in the gastric mucosa, abdominal musculature, or subcutaneous tissues and in rare circumstances have exited through the skin adjacent

to the stoma site.
• If performing an early replacement gastrostomy within the first few weeks after initial SAF-T-PEXY* placement, verify that the adhesion of the gastric wall to the interior abdominal wall is established and maintained. Consider use of an additional T-Fastener to ensure proper early replacement of gastrostomy.

Note: *It is recommended to perform a three-point gastropexy that approximates an equilateral triangle to help ensure secure and uniform attachment of the gastric wall to the anterior abdominal wall. An alternate pattern may need to be identified if placing a low volume balloon gastrostomy tube.*

1. Place a skin mark at the tube insertion site and define the gastropexy pattern by placing three skin marks equidistant (approximately 2 cm apart) from the tube insertion site and in a triangle configuration. Allow adequate distance between the insertion site and SAF-T-PEXY* placement so as to prevent interference of the anchor set and balloon once inflated. (Fig 3)

2. Locally anesthetize the skin and peritoneum at each puncture site.

3. Carefully remove the pre-loaded SAF-T-PEXY* device from the protective sheath and maintain slight tension on the trailing suture, noting that the suture is held to the needle by a retaining snap on the side of the needle hub.

4. Attach a Luer slip syringe containing 1-2 ml of sterile water or saline to the needle hub. (Fig 4)

5. Under endoscopic guidance, insert the preloaded SAF-T-PEXY* slotted needle with a single sharp thrust through one of the marked corners of the triangle until it is within the gastric lumen. (Fig 5) The simultaneous return of air into the syringe and endoscopic visualization confirms correct Intragastric position. After confirmation of correct position, remove the syringe from the device.

6. Release the suture strand. Bend the locking tab on the needle hub. (Fig 6) Firmly push the inner hub into the outer hub until the locking mechanism clicks into place. (Fig 7) This will dislodge the T-Bar from the end of the needle and lock the inner stylet into position. (Fig 8)

7. Withdraw the needle while continuing to gently pull the T-Bar until it is flush against the gastric mucosa, avoid having the T-Bar exert excessive tension onto the gastric mucosa. Discard the needle according to facility protocol.

8. Gently slide the suture lock down to the skin surface of the abdominal wall. A small hemostat may be clamped above the suture lock to temporarily hold it in place. **Caution:** Do NOT place hemostat below the suture lock, or between the suture lock and the abdominal wall, as damage to the suture may occur.

9. Repeat the procedure until all three anchor sets have been inserted in the corners of the triangle. After the three SAF-T-PEXY* devices are properly positioned, gently pull on the sutures to appose the stomach to the anterior abdominal wall avoiding exerting excessive tension on the suture. Close the suture lock with the supplied hemostat until an audible "click" is heard securing the suture. Any excess suture

length may be cut and removed. (Fig 9)

Note: *For additional suture security, a knot may be tied in the suture strand at the surface of the suture lock.*

Post Procedure:

1. Inspect the stoma and gastropexy sites daily and assess for signs of infection, including: redness, irritation, edema, swelling, tenderness, warmth, rashes, purulent or gastrointestinal drainage. Assess for any signs of pain, pressure or discomfort.

2. After the assessment, routine care should include cleansing the skin around the stoma site and gastropexy sites with warm water and mild soap, using a circular motion, moving from the tube and external bolsters outward, followed by a thorough rinsing and drying well. The sutures may be left to be absorbed or they may be cut when deemed appropriate if indicated by the placing physician. Letting the sutures be absorbed or cutting them will allow the T-bars to pass through the gastrointestinal system. After the sutures dissolve (or are cut) the suture locks may be removed and discarded.

Note: *It is recommended not to cut the sutures within two weeks post procedure.*

Should a suture (s) break post-placement, the treating health care provider should assess the patient and decide on an appropriate course of management.

WHAT SHOULD I DO IN RESPONSE TO THIS FIELD CORRECTION?

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 1**) to Avanos via email to EMEAFieldAction@avanos.com.
- The AVANOS* Introducer Kit for Gastrostomy Feeding Tubes device 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* Introducer Kit for Gastrostomy Feeding Tube, 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.

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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: FIELD CORRECTION 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 EMEAFieldAction@avanos.com

Our records indicate that the **AVANOS* Introducer Kit for Gastrostomy Feeding Tubes** 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.