

AVANOS MEDICAL, INC.

URGENT MEDICAL DEVICE RECALL

PRE-FILLED SYRINGES IN MIC* Gastric - Jejunal Feeding Tube Kits

January 2024

Dear Valued Avanos Customer,

The purpose of this letter is to advise you that Avanos Medical Inc. is voluntarily recalling specific lots of MIC* Gastric - Jejunal Feeding Tube Kits (see Table 1). These kits contain a syringe pre-filled with sterile water which is used to inflate the retention balloon of the feeding tube. Avanos has learned that the manufacturer of these pre-filled syringes, Nurse Assist, LLC, is recalling the syringes along with other pre-filled sterile water products. The reason for this recall is that they have determined that the water inside these devices cannot be verified as having the required sterility assurance level (SAL) of 10^{-6} . Due to the recall of these pre-filled syringes by Nurse Assist, Avanos has made the decision to recall the MIC* Gastric - Jejunal Feeding Tube Kits product codes and lots listed below in Table 1.

While the sterile water in the Nurse Assist, LLC pre-filled syringe is used to fill the retention balloon of the MIC* Gastric - Jejunal Feeding Tube, there is a small risk that the water will come into contact with a patient's surgical site. Any open wound exposed to non-sterile products could potentially put the patient at risk of infection. The pre-filled syringe is the only item in the kit which is affected by the Nurse Assist recall. All other components of the kit have been sterilized. Out of an abundance of caution, however, Avanos is asking their customers to scrap or return all affected MIC* Gastric - Jejunal Feeding Tube Kits.

Actions to be taken by your facility:

Avanos is requesting the removal of all affected MIC* Gastric - Jejunal Feeding Tube Kits from facilities. You are requested to take the following steps:

- Please continue to **perform normal post op care for any newly placed MIC GJ tube**. Per the Daily Care & Maintenance Check List found in the product Instructions for Use:
 - Assess the patient for any signs of pain, pressure or discomfort.
 - Assess the stoma site for any signs of infection, such as redness, irritation, edema, swelling, tenderness, warmth, rashes, purulent, or gastrointestinal drainage.
 - Assess the patient for any signs of pressure necrosis, skin breakdown, or hypergranulation tissue.
- **Report any adverse events** involving these products immediately to PIQ@avanos.com
- **Check** all storage facilities and warehouse locations for affected products and **quarantine** them.

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- **Complete** the Customer Response Form. which can be found online: <https://iqvia-response.my.site.com/mt/fca?cid=avanos-fca-2024-001>, or by using the QR code provided in the **Field Correction Acknowledgement Instructions** accompanying this letter.
- **Destroy** all affected lots in your inventory per your facility's procedures
 - **Alternatively** if you are unable to destroy your affected inventory, please indicate so on the form and you will be provided information on how to return product for destruction.
 - **A refund will be provided to you** based on the quantity of affected product you have indicated on the Customer Response Form.
- **Distributors only: alert your affected customers of this recall.** We ask that you work with them to destroy affected product and provide them refunds as per your internal processes. Provide to Avanos an updated response using the Customer Response Form to receive refunds or credit for your customers' affected products.
- Please reach out to avanos-fca-2024-001@iqvia.com or call (855) 201-1355 with any questions or concerns regarding these instructions.

Due to previous shortages of the pre-filled syringes, as well as the current recall, Avanos is currently selling kits assembled without a pre-filled syringe. These kits have the same product code and are identical to the regular MIC* Gastric - Jejunal Feeding Tube Kits, however they will have an orange sticker on them indicating that the pre-filled syringe is not included. Avanos has already sourced a new supplier of sterile, pre-filled syringes and expects kits with these syringes to be available soon.

TABLE 1: Affected products

Product Name	Product Code	Lot Number		
MIC* Gastric-Jejunal Feeding Tube Kit with ENFit® Connector - Endoscopic/Radiologic Placement - 16 Fr	8250-16	30180762	30242039	30265374
		30226671	30254749	30268260
		30226823	30265005	30270862
		30233440	30266483	30247089
		30238985		
MIC* Gastric-Jejunal Feeding Tube Kit with ENFit® Connector - Endoscopic/Radiologic Placement - 16 Fr	8250-16-15	30226822	30242228	30253956
MIC* Gastric-Jejunal Feeding Tube Kit with ENFit® Connector - Endoscopic/Radiologic Placement - 16 Fr	8250-16-22	30184814	30247088	30262508
		30226821	30253955	
MIC* Gastric-Jejunal Feeding Tube Kit with ENFit® Connector - Endoscopic/Radiologic Placement - 16 Fr	8250-16-30	30226820	30247087	30258135
		30231400	30250300	30265373
		30238125		

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MIC* Gastric-Jejunal Feeding Tube Kit with ENFit® Connector - Endoscopic/Radiologic Placement - 18 Fr	8250-18	30181846	30238984	30259225
		30184760	30250140	30259566
		30185381	30251089	30261699
		30226672	30250169	30262040
		30229833	30254748	30264284
		30233376	30255675	30267593
		30233439	30256486	30268259
		30235094	80402128	30270505
		30238124		
MIC* Gastric-Jejunal Feeding Tube Kit with ENFit® Connector - Endoscopic/Radiologic Placement - 18 Fr	8250-18-22	30184824	30240302	30257066
		30228970	30247094	
MIC* Gastric-Jejunal Feeding Tube Kit with ENFit® Connector - Endoscopic/Radiologic Placement - 18 Fr	8250-18-30	30181900	30247092	30265004
		30226819	30252989	30265372
		30228969	30253953	30270861
		30240301	30259565	
MIC* Gastric-Jejunal Feeding Tube Kit with ENFit® Connector - Endoscopic/Radiologic Placement - 22 Fr	8250-22	30184759	30238983	30256485
		30185380	30242226	30259224
		30186750	30242037	30262039
		30221235	30252072	30264283
		30226670	30252985	30267123
		30226818	30252998	30268258
		30228968	30255676	30270504
		30238123	30254747	30270860
MIC* Gastric-Jejunal Feeding Tube Kit with ENFit® Connector - Surgical Placement - 16 Fr	8260-16	30181845	30226850	30290828
		30223861	30256484	
MIC* Gastric-Jejunal Feeding Tube Kit with ENFit® Connector - Surgical Placement - 18 Fr	8260-18	30185408	30242225	30264282
		30233438	30259226	30290830
MIC* Gastric-Jejunal Feeding Tube Kit with ENFit® Connector - Surgical Placement - 22 Fr	8260-22	30256483	30259564	30290829
MIC* Gastric-Jejunal Feeding Tube Kit - Endoscopic/Radiologic Placement - 16 Fr	0250-16	30180718	30226817	30251106
		30181870	30229831	30251988
		30184758	30240299	30254746
		30186768	30244886	30258134
		30194327	30248036	30267592

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		30226669	30248348	
MIC* Gastric-Jejunal Feeding Tube Kit - Endoscopic/Radiologic Placement - 16 Fr	0250-16-15	30185370	30249243	30256710
		30194326		
MIC* Gastric-Jejunal Feeding Tube Kit - Endoscopic/Radiologic Placement - 16 Fr	0250-16-22	30226808		30238975
MIC* Gastric-Jejunal Feeding Tube Kit - Endoscopic/Radiologic Placement - 16 Fr	0250-16-30	30184813	30190699	30235093
		30186749	30226816	30245070
MIC* Gastric-Jejunal Feeding Tube Kit - Endoscopic/Radiologic Placement - 18 Fr	0250-18	30181844	30238885	30256210
		30181869	30239857	30256482
		30184757	30238982	30257069
		30185369	30240298	30258133
		30186748	30240451	30259563
		30189492	30243197	30261698
		30190698	30242224	30262037
		30195869	30244885	30264281
		30226668	30250139	30267591
		30226815	30251984	30268254
		30228967	30254745	30270503
		30229830	20108481	30270858
		30238122		
MIC* Gastric-Jejunal Feeding Tube Kit - Endoscopic/Radiologic Placement - 18 Fr	0250-18-22	30186747	30238981	30253948
		30188504	30248034	30256709
		30226814		
MIC* Gastric-Jejunal Feeding Tube Kit - Endoscopic/Radiologic Placement - 18 Fr	0250-18-30	30181868	30195868	30240450
		30184756	30200971	30244884
		30185379	30226813	30248033
		30186767	30228966	30248345
		30189491	30229829	30254744
		30190697	30238121	30259562
		30194325		

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MIC* Gastric-Jejunal Feeding Tube Kit - Endoscopic/Radiologic Placement - 22 Fr	0250-22	30178410	30231399	30256209
		30181843	30238120	30256481
		30181867	30238512	80402126
		30184755	30238980	80402127
		30185368	30240484	30257064
		30195736	30240297	30259561
		30192113	30240449	30261697
		30195735	30250138	30262036
		30198033	30250166	30268253
		30226667	30252990	30270502
		30226812	30253947	30270857
		30228965	30254743	
MIC* Gastric-Jejunal Feeding Tube Kit - Surgical Placement - 16 Fr	0260-16	30195867	30258131	30267590
		30245069		
MIC* Gastric-Jejunal Feeding Tube Kit - Surgical Placement - 18 Fr	0260-18	30181880	30239856	30250160
		30185383	30244880	30262027
		30195858	30250593	30290826
		30238884		
MIC* Gastric-Jejunal Feeding Tube Kit - Surgical Placement - 22 Fr	0260-22	30180717	30238511	30265343
		30186745	30250165	30290827
		30236828	30259560	

We apologize for any disruptions this may cause to your business. If you have any questions concerning the information provided here, please reach out to avanos-fca-2024-001@iqvia.com or call (855) 201-1355.

Ujjal Chakravartty

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Adverse reactions or quality problems experienced with the use of this product may be reported to Avanos Medical Inc at PIQ@Avanos.com, or directly to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

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