

Manufacturer name: Avanos Medical

About the Recall: This notice has been issued because Avanos has updated the Instructions for Use (IFU) to include additional complications associated with the use of all AVANOS MIC-KEY* Gastric-Jejunal Feeding Tubes. This IFU labeling is supplied with the product and provides users and patients information about the intended purpose, proper use, and risks associated with use of the device.

Products(s) numbers/models that are affected:

MMS #	MFG #	Description	Affected Lot(s)
733089	0270-16-3.0-45	TUBE, MICKEY TRANSGASTRIC STR 3.0CM 16FR	ALL
648852	0270-16-1.7-22	TUBE, FEEDING MIC 16FR 1.7CM KIMCLK	ALL
462194	0270-22-3.5-45	TUBE, TRANSGASTRIC JEJUNAL 22FR 3.5CM	ALL
1020030	8270-18-2.0-22	TUBE, FEED JEJUNAL MIC-KEY GJ W/ENFIT CONN 18FR 2.0CM	ALL
1020035	8270-18-3.0-45	TUBE, FEED JEJUNAL MIC-KEY GJ W/ENFIT CONN 18FR 3.0-4CM	ALL
1094962	0270-18-1.7-30	TUBE, FEEDING JEJUNAL MIC-KEY LOW PROFILE 18FR 30CM	ALL
518039	0270-16-2.0-22	TUBE, TRANSGASTRIC JEJUNAL 16FR 2.0CM	ALL
709628	0270-16-2.7-45	TUBE, MIC-KEY JEJUNAL 16FR 2.745CM	ALL
781148	0270-16-1.5-15	BUTTON KIT, ENTERAL MIC JEJUNAL 16FR 1.5CM 15CM	ALL
784996	0270-16-2.7-30	TUBE, TRANSGASTRIC MICKEY JEJUNAL 16RF 2.7 30CM	ALL
781170	0270-22-3.0-45	BUTTON KIT, ENTERAL MIC JEJUNAL 22FR 3.0CM 45CM	ALL
1020027	8270-16-3.0-45	TUBE, TRANSGASTRIC JEJUNAL MICKEY GJ W/ENFIT CONN 16FR 3.0CM	ALL
625984	0270-16-1.5-30	TUBE, TRANSGASTRIC JEJUNAL 16FR 1.5CMX3.0CM	ALL
472958	0270-22-2.5-45	TUBE, TRANSGASTRIC JEJUNAL 22FR 2.5CM	ALL
1020036	8270-18-3.5-45	TUBE, FEED JEJUNAL MIC-KEY GJ W/ENFIT CONN 18FR 3.5CM	ALL
1020037	8270-22-3.0-45	TUBE, FEED JEJUNAL MIC-KEY GJ W/ENFIT CONN 20FR 3.0CM	ALL
1020021	8270-16-1.5-30	TUBE, FEED JEJUNAL MIC-KEY GJ W/ENFIT CONN 16FR 1.5CM	ALL
1020026	8270-16-2.0-30	TUBE, FEED JEJUNAL MIC-KEY GJ W/ENFIT CONN 16FR 2.0CM	ALL
1165660	8270-16-1.7-45	TUBE, FEED GASTRIC JEJUNAL W/ENFIT CONN 16FR 1.7CM (1/CS)	ALL
1166823	8270-18-1.7-30	TUBE KIT, FEEDING MIC-KEY GASTRIC JEJUNAL 18FR 1.7CM	ALL
951654	0270-18-1.7-45	TUBE, FEEDING JEJUNAL MICKEY LOW PROFILE 18FR	ALL
1203666	8270-18-6.0-45	TUBE KIT, FEEDING MIC-KEY GASTRO JEJUNAL 18FR 6.0CM	ALL
1178130	8270-16-1.5-22	TUBE, FEED JEJUNAL MIC-KEY GJ W/ENFIT CONN 16FR 1.5CM	ALL
664869	0270-18-1.5-30	TUBE, FEEDING JEJUNAL 18FR KIMCLK	ALL
671343	0270-16-2.5-30	TUBE, FEEDING MIC-KEY 16FR KIMCLK	ALL
696296	0270-16-2.5-30	TUBE, TRANSGASTRIC JEJUNAL 16FR 2.5X30CM	ALL
636260	0270-16-1.2-15	TUBE, FEEDING MIC 16FR 1.2CM KIMCLK	ALL
1209609	0270-18-5.5-45	TUBE, FEEDING MIC-KEY GJ N/ENFIT	ALL
1214993	8270-18-1.7-22	TUBE KIT, FEEDING MIC-KEY GASTRIC JEJUNAL EXT SET 18FR 1.7CM	ALL
1117228	0270-22-2.7-45	TUBE, FEEDING GASTRIC-JEJUNAL MIC-KEY LOW-PROF 22FR 2.7CM	ALL

MMS #	MFG #	Description	Affected Lot(s)
634989	0270-22-2.0-45	TUBE, TRANSGASTRIC JEJUNAL 22FR 2.0CM	ALL
746826	0270-18-3.5-45	TUBE, FEED JEJUNAL MIC KEY 18FR	ALL
781067	0270-16-1.2-30	BUTTON KIT, ENTERAL MIC JEJUNAL 16FR 1.2CM 30CM	ALL
781068	0270-18-2.5-30	BUTTON KIT, ENTERAL MIC JEJUNAL 18FR 2.5CM 30CM	ALL
781069	0270-18-2.0-30	BUTTON KIT, ENTERAL MIC JEJUNAL 18FR 2.0CM 30CM	ALL
781070	0270-18-3.0-45	BUTTON KIT, ENTERAL MIC JEJUNAL 18FR 3.0CM 45CM	ALL
781071	0270-18-1.2-30	BUTTON KIT, ENTERAL MIC JEJUNAL 18FR 1.2CM 30CM	ALL
780605	0270-18-2.0-22	BUTTON KIT, ENTERAL MIC JEJUNAL 18FR 2.0CM 22CM	ALL
781065	0270-18-1.5-22	BUTTON KIT, ENTERAL MIC JEJUNAL 16FR	ALL
1020019	8270-16-1.2-30	TUBE, FEED JEJUNAL MIC-KEY GJ W/ENFIT CONN 16FR 1.2CM	ALL
1020031	8270-18-2.0-30	TUBE, FEED JEJUNAL MIC-KEY GJ W/ENFIT CONN 18FR 2.0CM	ALL
781065	0270-18-1.5-22	BUTTON KIT, ENTERAL MIC JEJUNAL 16FR	ALL
1020019	8270-16-1.2-30	TUBE, FEED JEJUNAL MIC-KEY GJ W/ENFIT CONN 16FR 1.2CM	ALL
1020031	8270-18-2.0-30	TUBE, FEED JEJUNAL MIC-KEY GJ W/ENFIT CONN 18FR 2.0CM	ALL

URL Link(s) to Manufacturer Notice/Web Site:

<https://eifu.avanos.com/AVA/en/all>

Actions to be taken by customer/Patient:

Continued use of the device is advised by the manufacturer as this is not a recall but a safety notice of any potential risk. Below is a grid of the missing additional risks that were initially missing on the packaging.

MIC-KEY® Gastric-Jejunal Feeding Tube Kits (Non-ENFit®)	MIC-KEY® Gastric-Jejunal Feeding Tube Kits (ENFit®)
Missing: Perforation, Aspiration, Hemorrhage, and Intussusception	Missing: Hemorrhage and Aspiration
<p>Complications</p> <p>The following complications may be associated with any Gastric-Jejunal Feeding Tube:</p> <ul style="list-style-type: none"> • Skin Breakdown • Hypergranulation Tissue • Intraperitoneal Leakage • Infection • Stomach or Duodenal Ulcers • Pressure Necrosis 	<p>Complications</p> <p>The following complications may be associated with any Gastric-jejunal feeding tube:</p> <ul style="list-style-type: none"> • Skin Breakdown • Hypergranulation Tissue • Intraperitoneal Leakage • Infection • Stomach or Duodenal Ulcers • Pressure Necrosis • Perforation • Intussusception