State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

California Device Recall Information Sheet

Avanos Medical Inc Recalls MIC* Gastric-Jejunal Feeding Tubes: ENFit Connectors and, Endoscopic/Radiological Placement GJ-Tube due them containing a pre-filled syringe that is recalled

Recall Date	Product Description	Recalling Firm	Recall Reason
3/13/2024	**MIC* Gastric-Jejunal Feeding Tube with ENFit Connectors** a) MIC* Gastric-Jejunal Feeding Tube Kit with ENFit Connector - Endoscopic/Radiologic Placement - 16 Fr, Product Code 8250-16; b) MIC* Gastric-Jejunal Feeding Tube Kit with ENFit Connector - Endoscopic/Radiologic Placement - 16 Fr, Product Code 8250-16-15; c) MIC* Gastric-Jejunal Feeding Tube Kit with ENFit¿ Connector - Endoscopic/Radiologic Placement - 16 Fr, Product Code 8250-16-22; d) MIC* Gastric-Jejunal Feeding Tube Kit with ENFit¿ Connector - Endoscopic/Radiologic Placement - 16 Fr, Product Code 8250-16-30; e) MIC* Gastric-Jejunal Feeding Tube Kit with ENFit¿ Connector - Endoscopic/Radiologic Placement - 18 Fr, Product Code 8250-18; f) MIC* Gastric-Jejunal Feeding Tube Kit with ENFit¿ Connector - Endoscopic/Radiologic Placement - 18 Fr, Product Code 8250-18-22; g) MIC* Gastric-Jejunal Feeding Tube Kit with ENFit¿ Connector - Endoscopic/Radiologic	**Avanos Medical, Inc.** Alpharetta, Georgia	This device is being recalled due to it containing a sterile pre-filled syringe subsequently recalled by Nurse Assist.

	Placement - 18 Fr, Product Code 8250-18-30; h) MIC* Gastric-Jejunal Feeding Tube Kit with ENFit¿ Connector - Endoscopic/Radiologic Placement - 22 Fr, Product Code 8250-22; i) MIC* Gastric-Jejunal Feeding Tube Kit with ENFit¿ Connector - Surgical Placement - 16 Fr, Product Code 8260-16; j) MIC* Gastric-Jejunal Feeding Tube Kit with ENFit¿ Connector - Surgical Placement - 18 Fr, Product Code 8260-18; k) MIC* Gastric-Jejunal Feeding Tube Kit with ENFit¿ Connector - Surgical Placement - 22 Fr, Product Code 8260-22		
3/13/2024	**MIC* Gastric-Jejunal Feeding Tube, Endoscopic/Radiologic Placement, GJ-Tube** a) MIC* Gastric-Jejunal Feeding Tube Kit - Endoscopic/Radiologic Placement - 16 Fr, Product Code 0250-16; b) MIC* Gastric-Jejunal Feeding Tube Kit - Endoscopic/Radiologic Placement - 16 Fr, Product Code 0250-16-15; c) MIC* Gastric-Jejunal Feeding Tube Kit - Endoscopic/Radiologic Placement - 16 Fr, Product Code 0250-16-22; d) MIC* Gastric-Jejunal Feeding Tube Kit - Endoscopic/Radiologic Placement - 16 Fr, Product Code 0250-16-30; e) MIC* Gastric-Jejunal Feeding Tube Kit - Endoscopic/Radiologic Placement - 18 Fr, Product Code 0250-18; f) MIC* Gastric-Jejunal Feeding Tube Kit - Endoscopic/Radiologic Placement - 18 Fr, Product Code 0250-18-22; g) MIC* Gastric-Jejunal Feeding Tube Kit - Endoscopic/Radiologic Placement - 18 Fr, Product Code 0250-18-30; h) MIC* Gastric-Jejunal Feeding Tube Kit - Endoscopic/Radiologic	**Avanos Medical, Inc.** Alpharetta, Georgia	This device is being recalled due to it containing a sterile pre-filled syringe subsequently recalled by Nurse Assist.

	Placement - 22 Fr, Product Code 0250-22; i) MIC* Gastric-Jejunal Feeding Tube Kit - Surgical Placement - 16 Fr, Product Code 0260-16; j) MIC* Gastric-Jejunal Feeding Tube Kit - Surgical Placement - 18 Fr, Product Code 0260-18; k) MIC* Gastric-Jejunal Feeding Tube Kit - Surgical Placement - 22 Fr, Product Code 0260-22;		

Recall Class	Product Identification	Distribution	Affected Dates
I	**MIC* Gastric-Jejunal Feeding Tube with ENFit Connectors** A) Product Code 8250-16, UDI/DI 350770445410, Batch Numbers: 30180762, 30226671, 30226823, 30233440, 30238985, 30242039, 30254749, 30265005, 30266483, 30265374, 30268260, 30270862; b) Product Code 8250-16-15, UDI/DI 350770445427, Batch Numbers: 30226822, 30242228, 30253956; c) Product Code 8250-16-22, UDI/DI 00350770445434, Batch Numbers: 30184814, 30226821, 30247088, 30253955, 30262508, 30226820; d) Product Code 8250-16-30, UDI/DI 00350770445441, Batch Numbers: 30231400, 30238125 30247087, 30250300, 30258135, 30265373; e) Product Code 8250-18, UDI/DI 00350770445458, Batch Numbers: 30181846, 30184760, 30185381, 30226672, 30229833, 30233376, 30233439, 30235094, 30238124, 30238984, 30250140, 30251089, 30250169, 30254748, 30255675, 30256486, 80402128, 30259225, 30259566, 30261699, 30262040, 30264284, 30267593, 30268259,	2443 Units in California California	March, 2024 and prior

	30270505; f) Product Code 8250-18-22, UDI/DI 00350770445465, Batch Numbers: 30184824, 30228970, 30240302, 30247094, 30257066; g) Product Code 8250-18-30, UDI/DI 00350770445472, Batch Numbers: 30181900, 30226819, 30228969, 30240301, 30247092, 30252989, 30253953, 30259565, 30265004, 30265372, 30270861; h) Product Code 8250-22, UDI/DI 00350770445489, Batch Numbers: 30184759, 30185380, 30186750, 30221235, 30226670, 30226818, 30228968, 30238123, 30238475, 30238983, 30242226, 30242037, 30252072, 30252985, 30252998, 30255676, 30254747, 30256485, 30259224, 30262039, 30264283, 30267123, 30268258, 30270504, 30270860; i) Product Code 8260-16, UDI/DI 00350770445496, Batch Numbers: 30181845, 30223861, 30256484, 30290828; j) Product Code 8260-18, UDI/DI 00350770445502, Batch Numbers: 30185408, 30233438, 30242225, 30259226, 30264282, 30290830; k) Product Code 8260-22 UDI/DI 00350770445519, Batch Numbers: 30256483, 30259564, 30290829		
I	**Mic* Gastric-Jejunal Feeding Tube, Endoscopic/Radiologic Placement, Gj-Tube** a) Product Code 0250-16, UDI/DI 00350770954806, Batch Numbers: 30180718, 30181870, 30184758, 30186768, 30194327, 30226669, 30226817, 30229831, 30240299, 30244886,	3100 Units in California California	March, 2024 and prior

	30248036, 30248348, 30251106, 30251988, 30254746, 30258134, 30267592; b) Product Code 0250-16-15, UDI/DI 00350770954813, Batch Numbers: 30185370, 30194326, 30249243, 30256710; c) Product Code 0250-16-22, UDI/DI 00350770954820, Batch Numbers: 30226808, 30238975; d) Product Code 0250-16-30, UDI/DI 00350770954837, Batch Numbers: 30184813, 30186749, 30190699, 30226816, 30235093, 30245070; e) Product Code 0250-18, UDI/DI 00350770954844, Batch Numbers: 30181844, 30181869, 30184757, 30185369, 30186748, 30189492, 30190698, 30195869, 30226668, 30226815, 30228967, 30229830, 30238122, 30238885, 30239857, 30238982, 30240298, 30240451, 30243197, 30242224, 30244885, 30250139, 30251984, 30254745, 20108481, 30256210, 30256482, 30257069, 30258133, 30259563, 30261698, 30262037, 30264281, 30267591, 30268254, 30270503, 30270858; f) Product Code 0250-18-22, UDI/DI 00350770954851, Batch Numbers: 30186747, 30188504, 30226814, 30238981, 30248034, 30253948, 30256709; g) Product Code 0250-18-30, UDI/DI 00350770954868, Batch Numbers: 30181868, 30184756, 30185379, 30186767, 30189491, 30190697, 30194325, 30195868, 30200971, 30226813, 30228966, 30229829, 30238121, 30240450, 30244884, 30248033, 30248345, 30254744,		

	30259562; h) Product Code 0250-22, UDI/DI 00350770954875, Batch Numbers: 30178410, 30181843, 30181867, 30184755, 30185368, 30195736, 30192113, 30195735, 30198033, 30226667, 30226812, 30228965, 30231399, 30238120, 30238512, 30238980, 30240484, 30240297, 30240449, 30250138, 30250166, 30252990, 30253947, 30254743, 30256209, 30256481, 80402126, 80402127, 30257064, 30259561, 30261697, 30262036, 30268253, 30270502, 30270857; i) Product Code 0260-16, UDI/DI 00350770954882, Batch Numbers: 30195867, 30245069, 30258131, 30267590; j) Product Code 0260-18, UDI/DI 00350770954899, Batch Numbers: 30181880, 30185383, 30195858, 30238884, 30239856, 30244880, 30250593, 30250160, 30262027, 30290826; k) Product Code 0260-22, UDI/DI 00350770954905, Batch Numbers: 30180717, 30186745, 30236828, 30238511, 30250165, 30259560, 30265343, 30290827		

For additional information, please visit the FDA website ENFit connectors , endoscopic/radiologic placement GJ tube