PRODUCT RECALL NOTIFICATION

Advantus Health Partners

Avanos Recalls MIC Gastric – Jejunal Feeding Tube Kits Containing Sterile Water Based Products Under Recall by Nurse Assist

NOTIFICATION DATE: 1/16/2024
LAST REVISED ON: 3/19/2024
SUPPLIER/CATEGORY: Feeding Pumps Sets, Devices and Tubes

SITUATION

- Avanos Recalls MIC Gastric – Jejunal Feeding Tube Kits Containing Sterile Water Based Products Under Recall by Nurse Assist
- Placement kits in direct response to Nurse Assist recall of 0.9% sodium chloride irrigation USP and sterile water for irrigation USP, over sterility concerns. These kits include the recalled Nurse Assist supplied syringes, pre-filled with sterile water.
- The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

BACKGROUND

- Avanos Medical MIC Gastric-Jejunal Feeding Tube and MIC Gastric-Jejunal Feeding Tube with ENFit Connectors are designed for patients who require simultaneous gastric decompression and jejunal feeding.

ASSESSMENT

Who May be Affected:

- Health care providers using MIC Gastric-Jejunal Feeding Tube - Endoscopic/Radiologic Placement kit and MIC Gastric-Jejunal Feeding Tube with ENFit Connectors - Endoscopic/Radiologic Placement kit.
- People who receive care using MIC Gastric-Jejunal Feeding Tube - Endoscopic/Radiologic Placement kit and MIC Gastric-Jejunal Feeding Tube with ENFit Connectors - Endoscopic/Radiologic Placement kit.

Avanos Affected Devices Due to Nurse Assist, LLC Pre-Filled Syringe Recall product list can be located at website below.

https://www.fda.gov/media/176591/download?attachment

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RECOMMENDATIONS

This letter requested customers to:

- Check all inventory and storage facilities and warehouse locations for affected products and quarantine them.
- Continue to perform normal post op care for any newly placed MIC GJ tube.
- Follow the Daily Care & Maintenance Check List found in the product Instructions for Use:
- Report any adverse events involving these products immediately to PIQ@avanos.com.
- Destroy all affected lots in your inventory per your facility's procedures.
- Customers in the U.S. with questions about this recall should contact Avanos by emailing.
- avanos-fca-2024-001@iqvia.com or calling 1-855-201-1355.
- Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program