September 7, 2018

To: Manufacturers of Enteral Feeding Tubes
Health Care Professionals
Hospital Purchasing Departments and Distributors

Subject Line: The FDA Encourages Use of Enteral Device Connectors that Reduce Risk of Misconnection and Patient Injury

Dear Colleagues,

The U.S. Food and Drug Administration (FDA) is concerned by continued reports of misconnections with enteral devices. To reduce the risk of misconnections and patient injury, the FDA recommends hospitals and clinicians use enteral devices with connectors that meet the International Organization for Standardization (ISO) 80369-1 or ISO 80369-3 standard, or that are otherwise designed to reduce the risk of misconnections. There are currently marketed enteral connectors that meet the 80369-3 standards, many of which are identified by the tradename ENFit.

Misconnections between enteral devices and other medical devices, such as tracheostomy tubes, have been associated with patient death and serious injuries. Since 2011, the FDA has received reports of 2 deaths, 24 serious injuries, and 32 device malfunctions related to enteral misconnections. The FDA is also concerned that many misconnections, including enteral misconnections, are not reported, or are reported as medication errors.

Medical device misconnections may occur when one type of medical device is mistakenly attached to another type of medical device that performs a different function. Because the connectors on these devices are easy to use and may be compatible with different medical devices, users can mistakenly connect unrelated systems to one another.

In 2015, the FDA published a guidance document, Safety Considerations to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral Applications, which recommends manufacturer's design and test enteral connectors based on the ISO 80369 series standards to reduce the risk of misconnections. The FDA also issued a letter to manufacturers of enteral products, health care providers, and hospital purchasing departments about the danger of misconnections in 2010.

The FDA is aware that some people who rely on enteral tube-feeding at home have concerns about using the 80369-3 connectors. The 80369-3 connectors have slightly narrower openings than some connectors on the market. People who use larger diameter gravity-feeding tubes, such as 24 French, may experience longer feed times if they switch to 80369 connectors. The FDA has conducted testing of commercial pre-packaged formula[i] and blenderized diets through 80369-3 connectors and has concluded that flow rates may be slightly slower, but this does not pose a safety concern. Additional resources are available from the Oley Foundation and the Feeding Tube Awareness Foundation.

The FDA continues to work with standards organizations, federal partners, professional societies, patient advocacy groups, individual patients and other stakeholders. The FDA works with these groups to reduce the chance of medical device misconnections, ensure patient safety, and facilitate the availability of products that work for the multitude of patient populations, uses, and care environments.

The FDA's Recommendations to Support the Transition to Enteral Devices with 80369-3 Compliant Connectors

Recommendations for manufacturers:

- Consider suggestions provided by the Joint Commission to implement appropriate "designed incompatibility" measures to prevent dangerous misconnections of tubes and catheters.
- Evaluate patient needs and develop safe and effective enteral devices.
- Implement design changes to meet the ISO standards to reduce the likelihood of errors and provide safeguards for safe use of these devices and products.
- Implement an appropriate strategy that will lead to the eventual removal of legacy devices that have an increased risk for misconnection.

Recommendations for health care professionals:

- Use enteral devices that meet the ISO standards and are intended to reduce the risk of misconnection.
- Check the labeling or check with the distributor or manufacturer to determine whether your connectors meet the ISO standards.
- Organize a plan for your organization to implement the use of these new devices.
- Do not modify or adapt devices since that may defeat their safety system.
- Minimize the use of transition adapters (a device component that forms an intermediary connection between two incompatible medical devices).
- Do not use cross-application connectors.
- Trace all lines back to their origin when reconnecting devices.
- Route tubes and catheters that have different purposes in unique and standardized directions, to avoid accidental misconnections.

Recommendations for hospital purchasing departments and distributors:

- Purchase enteral devices that comply with the new ISO 80369-1 or ISO 80369-3 series standards to reduce the risk of misconnection.
- Ensure that an adequate inventory of the new devices is available to purchasers.

More information about medical device misconnections is available on the FDA website Medical Device Connectors.

The FDA appreciates your attention to this matter. If you have any questions, please contact the Center for Devices and Radiological Health's Division of Industry Communication and Education (DICE) at DICE@FDA.HHS.GOV, 800-638-2041, or 301-796-7100.

Sincerely,

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[i] Myers, et. al. In Vitro Performance Testing of Legacy and ENFit Gastrostomy Tube Devices Under Gravity Flow Conditions, Original Communication Journal of Parenteral and Enteral Nutrition, American Society for Parenteral and Enteral Nutrition, DOI: 10.1002/jpen.1159, wileyonlinelibrary.com