GEDSA
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Feb. 18, 2016

GEDSA Guidance Supporting ISO 80369-3 ENFit™
Enteral Connectors and the Home Enteral Nutrition Patient/Caregiver

In an effort to improve patient safety and prevent wrong route delivery of fluids and gases (tubing misconnections) there is an ongoing effort led by the International Organization for Standardization (ISO) to specify designs of small-bore connectors for various clinical applications (ISO 80369). The second Draft International Standard for enteral connectors (ISO 80369-3) was voted on and approved by 96% of voting countries. The Final Draft International Standard 80369-3 is currently out for ballot and is anticipated to be approved, published and recognized in 2016.

ISO 80369-3 defines a connector that is recommended for use on enteral devices in order to avoid misconnection events that are known to have caused patient deaths. The ISO 80369-3 enteral connector in the reverse orientation is commonly known as the trademarked name ENFit. Actual enteral devices will be defined in a new standard, ISO 20695, enteral feeding systems, that is currently under development.

While 80369-3 is a voluntary standard, global adoption of these connectors is critical to the best interest of improved patient safety. The connectors are designed to reduce the risk of tubing misconnections and the avoidance of any disruption in therapy through the use of a universal enteral connector.

With use of the ENFit connector system, the majority of enteral feeding patients should experience minimal changes in their routine. Laboratory testing has found the ENFit connector to perform similarly to current products intended and labeled for enteral use. However, home users who get nutrition from tube feedings made at home from blenderized solid foods have expressed concern based on the perceived differences in feeding tube performance. The primary concern being raised is the potential increase in time that it may take for their blenderized solid foods to flow through the ENFit connector. It is anticipated that ISO 20695 will address these concerns.

Performance testing has been completed to confirm consistent flow rates between existing and new ENFit enteral feeding systems using 20Fr and smaller gastrostomy tubes (including low profile devices such as the MIC Key). Results may vary depending on the consistency and make up of blenderized solid foods and the design and material used in a specific manufacturer's device. GEDSA is working with regulatory, technical and clinical experts to conduct additional testing to gain a more robust understanding of flow rates and the force required for bolus feeding across a broader range of blenderized solid foods, larger tube sizes (22Fr and larger gastronomy tubes) and materials.

The input provided by those patients and caregivers at home who are concerned with the option of using ENFit has been valuable to manufacturers. Work is underway to evaluate device requirements for home enteral nutrition patients using blenderized diets. Some GEDSA member manufacturers have committed to keep existing product on the market until additional testing identifies if a more optimal approach is needed. Check with your supplier representative to determine product availability of current (legacy) and new enteral devices with ENFit connectors.

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The Global Enteral Device Supplier Association (GEDSA) is a 501(c)6 nonprofit trade association formed to help introduce international standards for healthcare tubing connectors. Comprised of manufacturers, distributors, and suppliers of enteral nutrition devices worldwide, GEDSA facilitates information flow about the three-phase initiative, which is designed to increase patient safety and optimal delivery of enteral feeding by reducing the risk of tubing misconnections.

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