

## **GEDSA Position Statement on the FDA's Letter to Healthcare Providers**

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GEDSA fully supports the recent letter on "The Use of Enteral Device Connectors that Reduce Risk of Misconnection and Patient Injury" issued by the FDA on September 7, 2018 (<https://tinyurl.com/FDA-80369-3>) and applauds the FDA for its release. GEDSA expects this letter to serve as the catalyst for accelerated U.S. market adoption of safer compliant connectors, as defined by the International Standards Organization (ISO) 80369-3, commonly known by the federally registered trademarked name ENFit®. GEDSA and its supporting organizations urge manufacturers, distributors/suppliers and health care providers to actively participate in the adoption of new ENFit® connectors as called for in the FDA's letter.

### Industry Expectations Following the FDA Letter Release

Aligned with the FDA's recommendations on this patient safety initiative, GEDSA and its members are committed to the timely conversion to ISO 80369-3 compliant ENFit® devices. GEDSA plans to immediately establish a task force with healthcare providers and patient organizations to develop a coordinated phase out plan for connectors that do not meet ISO 80369-3, to accelerate adoption. In addition to increasing patient safety by reducing the risk of misconnections, this effort will help ensure prompt compliance with the FDA's recommendation for all stakeholders.

### Hospital and Clinician Expectations Following the FDA Letter Release

All hospitals and clinicians are encouraged to work with their supplier representatives to align on a transition date, provide training and secure supply of ENFit® feeding devices. Visit [www.StayConnected.org](http://www.StayConnected.org) for more information and up to date resources, training materials, and support for conversion to 80369-3 compliant devices, commonly known as ENFit®.

### Background and Additional Information on the ISO 80369 Series

In an effort to prevent wrong route delivery of fluids and gases (tubing misconnections), the International Organization for Standardization (ISO) developed the ISO 80369 series to specify small-bore connector designs for various clinical applications, starting with enteral (ISO 80369-3). The Final Draft International Standard 80369-3 has been approved, published and commenced global adoption. ISO has published a similar standard for peripheral anesthesia, ISO 80369-6, and additional connector standards are being developed for other areas such as urology and cardiovascular. The published standard addresses a range of issues including improved connector usability, engineering assessments, and other technical content supporting the common goal of improved patient safety by preventing wrong route connections. The transition to the new ISO 80369 compliant connectors can improve patient care by greatly minimizing the risk of adverse events.

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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.

ENFit is a federally registered trademark of GEDSA in multiple jurisdictions throughout the world.

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