Global Enteral Device Supplier Association
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ENFit ® Connector Conversion Schedule for the U.S.

The Global Enteral Device Supplier Association (GEDSA) announced today that member manufacturers will phase out legacy feeding devices and transition adaptors starting **July 1st, 2020** in order to comply with guidance from the U.S. Food and Drug Administration (FDA)[1], Joint Commission[2] and Centers for Medicare & Medicaid Services[3] (CMS) to reduce medical tubing misconnections and improve patient safety. GEDSA members will monitor the transition through robust post market surveillance, following FDA guidance, and are prepared to adjust supply and product needs accordingly.

The ISO 80369 series is a family of small-bore connectors created by the International Organization for Standardization (ISO) to maximize patient safety by reducing the risk of medical tubing misconnections. ISO 80369-3, commonly known as ENFit, is approaching a 100 percent adoption rate throughout Europe with the Middle East, Australia and New Zealand following behind. Europe has been using ENFit connectors for over two years without a single known reported adverse event. Along with North America, GEDSA actively supports advancing adoption throughout Latin America and Asia to improve patient safety worldwide and comply with regulatory guidance in each country.

Important Dates for the U.S. Device and Adaptor Conversion to ISO 80369-3 Safety Standards:

GEDSA member manufacturers have aligned to only produce ISO 80369-3 compliant devices with ENFit connectors according to the following deadlines:

Date	Action	Example
July 1st, 2020	Legacy feeding tubes and cross-application adaptors will no longer be manufactured	
January 1st, 2021	Transition sets and adaptors sold separately from other devices will no longer be manufactured	

[1] The U.S. Food and Drug Administration. (2018, September 7). The FDA Encourages Use of Enteral Device Connectors that Reduce Risk of Misconnection and Patient Injury. Retrieved from https://www.fda.gov/media/115846/download

[2] The Joint Commission Online. (2018 September 12). Quality and safety. Retrieved from https://www.jointcommission.org/assets/1/23/JC_Online_Sept_12.pdf

[3] The Centers for Medicare & Medicaid Services. (2018, October 4). Enteral Device Connectors that Reduce Patient Injury. Retrieved from https://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Provider- Partnership-Email-Archive-Items/2018-10-04- eNews.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending#_Toc526322347

[4] Legacy devices consist of enteral device connectors that are not ISO 80369-3 compliant

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GEDSA is focused on supporting everyone for a smooth transition to this patient safety initiative. Please view GEDSA's list of recommendations for each group below.

Recommendations for Patients and Caregivers:

- Use available resources to learn more about the risk of misconnections and why enteral device connecters have changed. Visit Stayconnected.org and Feeding Tube Awareness Foundation for more information.
- Ask your retail pharmacist, health care professional or home medical equipment supplier about ENFit and recommendations they have for a successful transition.
- Patients can access more information via their respective enteral device suppliers.

Recommendations for Healthcare Professionals:

- Create a plan for your organization to complete a full conversion to ENFit connectors. Visit GEDSA's YouTube channel to watch the success of other organizations who have implemented ENFit.
- Educate your patients and healthcare colleagues about changes in enteral connectors.
- Communicate the ENFit conversion with the broader healthcare community in your area. Reach out to info@gedsa.org for more information about scheduling an ENFit regional summit in your area.
- Visit StayConnected.org for free resources to aid in your ENFit adoption process.

Recommendations for Hospital Purchasing Departments and Distributors:

- Identify all the enteral devices being used in your facility, determine supply needs and develop a transition plan.
- Reach out to your enteral device supplier to understand the conversion process and collect more information.
- Following the FDA's recommendations, purchase enteral devices that comply with the new ISO 80369-1 or ISO 80369-3 series standards.
- Ensure that an adequate inventory of the new devices is available to purchasers.

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About GEDSA:

The Global Enteral Device Supplier Association (GEDSA) is a 501(c)6 nonprofit trade association formed to help introduce international safety 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.

Current GEDSA Members:

Abbott
AbbVie
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Avanos
Baxter
B Braun
Boston Scientific
Cair Lgl
Cardinal Health
Cedic/Entek
Cook Medical
Dale Medical
Fresenius Kabi
GBUK
IMI
KB Medical
Medela
Medline
Moog
NeoMed
Nestle
Nutricia
Nipro Corporation
Q Medical Devices
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GEDSA Supporting Organizations:

AAMI
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