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July 1, 2016

Guidance on Adoption of ISO 80369-3 Standard ENFit® Connectors in California

To reduce the risk of wrong route delivery of fluids and gases (tubing misconnections) there is an ongoing effort led by the International Organization for Standardization (ISO) to address small-bore connectors for healthcare applications. The objective of the ISO 80369 series of standards is to specify designs of small-bore connectors for various clinical applications to reduce the likelihood of tubing misconnections. The Final Draft International Standard 80369-3 has been approved and will be published and recognized. The standard provides guidance to manufacturers for production of an enteral connector that would meet California legislation AB 444.

Effective immediately, as stated in AB 444[1], health facilities including general acute care hospitals, acute psychiatric hospitals, skilled nursing facilities, and special hospitals in the State of California[2] will be "prohibited from using an enteral feeding connector that would fit into a connector other than the type it was intended for, unless an emergency or urgent situation exists and the prohibition would impair the ability to provide health care". The ISO 80369-3 standard connector design in the female to male orientation that addresses this legislation is a registered trademark name commonly known as ENFit.

ENFit Tip Syringes are critical to support the introduction of feeding tubes with ENFit connectors. Syringes are used for flushing, hydration, bolus feeding and enteral administration of medication. Feeding tubes and medication ports on feeding sets with ENFit male connectors will intentionally be incompatible with current Luer, oral, or catheter tip syringes. While one large syringe supplier has indicated they will not support this ENFit worldwide patient safety initiative[3] many other suppliers have been aggressively working to provide an adequate supply of ENFit Tip Syringes to collectively meet market demand.

In the past, concerns were raised regarding dose accuracy of low volume medications, when delivered with standard ISO 80369-3 syringes. A technical team of industry experts worked collaboratively to select and vet a solution to address small volume dose accuracy. The solution has become known as the ENFit Low Dose Tip (LDT) Syringe design. Performance of this design was tested by an accredited third party lab and was found to be capable of delivering accurate doses consistent with current male orientated syringes and better than existing female orientated syringes. A summary of the results can be found at StayConnected.org. The LDT design also fits appropriately into current practice and maintains compatibility with other ENFit devices. The LDT syringe design has been reviewed and gained FDA 510(k) clearance for two manufacturers and is now ready for market introduction and will support the broader transition to ENFit.

The conversion to the ENFit connector system impacts the entire enteral feeding system across all health care settings. To avoid disruption of therapy, a careful and methodical transition to new connectors is recommended over the course of 2016 across the United States. Introduction of ENFit may vary depending on your supplier(s) timing. GEDSA encourages manufacturers to introduce, and healthcare facilities to adopt, ENFit Tip Syringes and feeding tubes as soon as possible to meet the California

[1] CA Assembly Bill 444, 2015 Cal.Stat. 2015
[2] California Health & Safety Code, 1279.7, section 1250
[3] Becton Dickinson Enteral Syringes: Updated Letter to Customers, October 2015
http://www.bd.com/hypodermic/products/enteral/pdfs/customer-letter-October-2015.pdf

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mandate. GEDSA and its supporting organizations strongly suggest you work with your supplier representative and distributor network to understand their specific plans for conversion. In particular, you should confirm that your syringe supplier has adequate supply of syringes before you convert to ENFit feeding tubes.

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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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