

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 specify designs of small-bore connectors for various clinical applications to reduce the likelihood of tubing misconnections. Until the Final Draft International Standard 80369-3 is approved and the final standard is published, there is an FDA recognized AAMI/CN3 US Provisional standard in place. The AAMI standard provisionally provides guidance to manufacturers for production of an enteral connector which would meet California legislation AB 444

As stated in AB 444¹, effective July 1, 2016 health facilities including general acute care hospitals, acute psychiatric hospitals, skilled nursing facilities, and special hospitals in the State of California² will be prohibited to use enteral feeding devices with connectors which would be compatible to connect with devices intended for applications other than enteral". The ISO 80369-3 connector design in the opposite direction is a trademarked name commonly known as ENFit™.

ENFit tip syringes are critical to support the introduction of feeding tubes with the ENFit connectors for flushing, hydration, bolus feeding and enteral administration of medication. Feeding tubes and medication ports on feeding sets with new ENFit male connectors will not be compatible with current Luer, oral, or catheter tip syringes. While one large syringe supplier has indicated they will not support this worldwide patient safety initiative³ many other suppliers have been aggressively working to provide adequate supply of ENFit tip syringes to collectively meet market demand.

Recent concerns have been raised regarding accuracy of low doses of medication (< 2.0mL). A technical team of industry experts have worked collaboratively to identify a solution to address dose accuracy with a new ENFit low dose tip design. This design has been validated demonstrating the ability to deliver an accurate dose consistent with current practice with 95% confidence, fits appropriately into current practice and maintains compatibility with other ENFit devices. The ENFit low dose tip syringe is anticipated to be ready for market introduction in 2016 pending regulatory clearance.

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 in the first half of 2016 to meet the California 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 must confirm that your syringe supplier has adequate supply of syringes before you convert to ENFit feeding tubes.

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>

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.

GEDSA Members:

A. Hopf GmbH	Corpak MedSystems	Medtronic/Covidien
Abbott Nutrition	Cook Medical	Moog
Alcor Scientific	Dale Medical	NeoMed
Amsino	Degania Medical	Nestle Health Science
B Braun	Enteral UK	Nutricia
Bard	Fresenius-Kabi	Qosina
Baxter	Halyard Health	Smith's Medical
Boston Scientific	Intervene	Vesco Medical
Cair Lgl	Medela	VR Medical/Ameritus
Cedic	Medicina	Vygon
Codan	Medline	Xeridien

Supporting Organizations:

AAMI	CHPSO	Novation
AHRMM	HealthTrust	NPSF
A.S.P.E.N.	ISMP	Oley Foundation
ASHP	The Joint Commission	PENG
ASHRM	MedAssets	PINNT
AVA	MNI	Premier
BAPEN	NHS	Tube Feeding Awareness Foundation
CHA	NNNG	