GEDSA
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November 17th, 2016

GEDSA Position Statement in support of ISO 80369-6

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 80369-6 that focuses on Neuraxial connectors has been approved and recognized.

The new ISO 80369-6 connector looks similar to the current connectors, but is about 20% smaller and has a unique design specific to Neuraxial connectors. Color is not included in the standard, however many manufacturers are choosing yellow as a plunger color to indicate NRFit syringes to easily differentiate them in procedural kits that are often used in healthcare settings. The direction of flow for the NRFit connectors remains unchanged in the male to female orientation.

The standard provides guidance to manufacturers for production of Neuraxial/epidural connectors which meet California legislation AB 444. As stated in AB 444[1], "Commencing January 1, 2017, a health facility is prohibited from using an epidural 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. Violation of these provisions is a misdemeanor." The ISO 80369-6 Neuraxial connector addresses this legislation. For a list of products that are included in this scope can be found of the www.StayConnected.org website.

GEDSA and its members strongly encourage the adoption new standard connectors (NRFit™) for the following reasons:

- Provides a simple way to reduce the risk of Neuraxial and regional anesthesia misconnections and improve patient safety.
- Reduces the chance of an unintentional cross-connection with any other connector intended for non-Neuraxial and non-regional anesthesia routes.
- Avoids exposure to legal challenges if further wrong-route incidents take place which otherwise could have been prevented by use of ISO 80369-6 compliant devices.

Introduction of NRFit will vary upon your geographical location and subject to each manufacturers FDA 510(k) clearance. GEDSA and its StayConnected members have communicated to have adequate supply of all the necessary products by Q2 2017. To avoid disruption of therapy, a careful and methodical transition to new connectors is recommended over the course of 2017 throughout the world. Check with your supplier representative on precise timing and product availability. For further documents on the NRFit connectors visit www.StayConnected.org.

[1] CA Assembly Bill 444, 2015 Cal.Stat. 201

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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 and ISO 80369-6, Neuraxial devices worldwide, GEDSA facilitates information flow about the three-phase initiative, which is designed to increase patient safety by reducing the risk of tubing misconnections.

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