GEDSA
ADVANCING PATIENT SAFETY

Global Enteral Device Supplier Association
1025 Rose Creek Drive STE 620-164
Woodstock, GA 30189

(614) 800-5458
info@gedsa.org
www.stayconnected.org

GEDSA Guidance Supporting ISO 80369-6 Neuraxial Connectors known as NRFit®

In an effort to prevent incorrect delivery routes of fluids and gases, referred to as tubing misconnections, there is an ongoing global initiative, led by the International Organization for Standardization (ISO), to address small-bore tubing connectors for healthcare applications. This global initiative is also supported by the Joint Commission[1] and the FDA[2]. The overall 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 published standards include misconnection risks assessments, connector usability studies, engineering assessments, and other technical content supporting the common goal of improving patient safety. The neuraxial standard, ISO 80369-6, discussed below is commonly known by its US and internationally registered trademarked name NRFit.

GEDSA and its supporting organizations urge manufacturers, distributors/suppliers, and health care providers to be active participants in the adoption of the safer ISO 80369-6 / NRFit connectors. The design and orientation of these connectors significantly limits the ability to insert common male connectors into a female port. Because this change impacts the entire neuraxial administration system, across all health care settings, a careful and methodical transition to these new safer connectors is recommended. Some regions, such as Japan, have fully and successfully implemented the new connectors.

ISO 80369-6 / NRFit Syringe

A successful transition will include the use of the safer NRFit connectors in all areas and on all components of the neuraxial administration system: prep, patient access, and application materials such as filter needles, filter straws, syringes, procedural needles, catheters, and pump disposables.

To comply with ISO 80369-6 and ensure patient safety, GEDSA is recommending to manufacturers and healthcare providers the adoption of new NRFit connectors in North America, Europe, the Middle East, Africa, Australia, and New Zealand as soon as possible with adequate supplies of the NRFit neuraxial administration products. Check with your supplier representative for more precise timing in your area. Visit https://stayconnected.org/nrfit/ for up-to-date information on this important patient safety initiative.

[1] https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/sea_53_connectors_8_19_14_final.pdf
[2] https://www.fda.gov/media/83412/download

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

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

GEDSA NRFit Members:

B. Braun Medical	BD	Flat Medical
Medovate	Moog	Nipro
Rungiang Medical	Venner	Vygon

GEDSA Supporting Organizations:

AAMI	AHRMM	ASPEN
ASHP	ASHRM	AVA
BRASPEN	ECRI Institute	EuroPharmat
Feeding Tube Awareness Foundation	HealthTrust	ISMP
The Joint Commission	MNI	Medication Safety Collaboration
Morrison	NPSF	NutritionDay in the US
Oley Foundation	Premier	Vizient