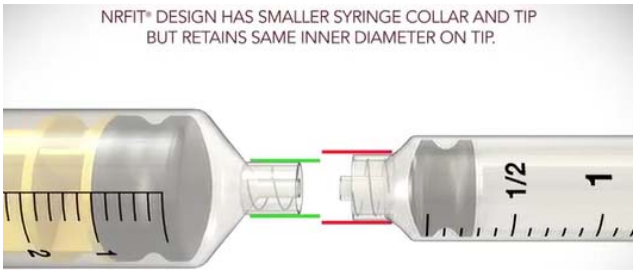
GEDSA Guidance on the introduction of NRFit®

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.

Respiratory	Enteral	Urological	Limb Cuff	*Neuraxial*	Intravascular
-2	-3	-4	-5	*-6*	-7

NRFit products availability from manufacturers will begin during the second quarter of 2017 with introductions rolling out during the summer with the goal of having full availability in the early 2018 pending regulatory clearances. Hospitals should contact individual companies concerning timing and make plans based on having sufficient inventory to support their conversion. Visit Stayconnected.org (hyperlink in PDF) for a list of suppliers and NRFit resources.

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.



Introduction of NRFit will vary upon your geographical location and subject to each individual manufacturers FDA 510(k) clearance. GEDSA and its StayConnected members have communicated to have adequate supply of all the necessary products by the first half of 2018. To avoid disruption of therapy, a careful and methodical transition to new connectors is recommended over the course of 2018.

List of products impacted by ISO 80369-6

Epidural/Spinal Applications

- 0.2 Micron Disc Filter
- 0.2 Micron Needle Filter
- Adapter for epidural blood patch
- Blood Patch Kit
- Drawing Up Needle
- Drawing Up Straws
- Epidural Administration Sets
- Epidural Filter
- Epidural Needle
- Epidural Stopcocks
- Filter Needle
- Individually Packaged Slip Syringes
- Infusion Pump Accessories
- LOR Syringes
- Patient Access Catheter Connector
- Slip Syringes
- Spinal Introducer
- Spinal Manometer
- Spinal Needle
- Syringe to Syringe Transfer Device
- Three way tap

Major Regional Anesthesia

- Individually packaged draw up needles
- Individually packaged Lock Syringes
- Nerve block needles
- Syringe Caps

Continuous Wound Infusion

- Catheter for Wound Infusion
- Individually Packaged Draw up Needles
- Individually Packaged Lock Syringes
- Silastic LA Infusion Device

Equipment for Specialist Training

- CSF Pressure Transducer Sets
- External Ventricular Accessories
- External Ventricular Drains
- Huber Needles
- Omnaya Reservoir Needles
- RF Accessories
- RF Needles
- Spinal Catheters

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.

Stay Connected Members:

B Braun
BD
Baxter
Halyard
Intervene
Smiths Medical
Teleflex
Vygon

Supporting Organizations:

AAMI
AHRMM
A.S.P.E.N.
ASHP
ASHRM
AVA
HealthTrust
ISMP
The Joint Commission
MNI
NNNG
NPSF
Oley Foundation
PENG
PINNT
Premier
Tube Feeding Awareness Foundation
Vizient