Frequently Asked ENFit® Questions

Can a syringe that is NOT ENFit be an ISO syringe/an ISO solution?

Yes.
ISO 80369-3 defines the geometry, material characteristics and functional performance of a standard connector pair made of one male half and one female half. The standard does not define the orientation of the connectors within the enteral feeding system.

The term "ENFit" implicitly means a connector design that complies with ISO 80369-3 while also defining the orientation of the connectors within the enteral feeding system (female on the administration device and male on the receiving device).

Patients are mobile and have the ability to travel between healthcare settings and implementing a single design is strongly encouraged by GEDSA, supporting organizations including ASPEN, ISMP, EPSG, ASHP and other clinical practice organizations. This is a global standard directed to drive standardization for caregivers, manufacturers, and clinician's world-wide. GEDSA strongly encourages the standardization of not only the ISO 80369-3 compliant connector but the specific orientation (direction of flow) as outlined in the ENFit System (and as proposed in the ISO 20695 enteral device standard). This ensures compatibility between components, avoids the need for adapter's long term, and drives continuity and portability of care for the patients.

Therefore, it is possible to have an ISO compliant ISO 80369-3 connector, which is not compatible/compliant with ENFit. However, it is strongly encouraged that there be a single global solution.

What is the advantage to having only one system in use?

This is a worldwide effort where patient portability is a critical issue that should be addressed with one system, in order to maintain continuity of care, reduce patient risks, and ensure ease of use for the caregiver.

What is the orientation of the ENFit system and why is this important?

To ensure compatibility between components of an ISO 80369-3 compliant system, ENFit has a specified orientation. In an ENFit system, all administration sets (pump sets, gravity sets, bolus feeding devices) and ENFit Tip syringes have an ISO 80369-3 female connector that mates to the ISO 80369-3 male connector on the feeding tube (NG Tube, G-Tube, PEG, J-Tube).

GEDSA members have aligned to the ENFit orientation so that all components, regardless of supplier, will fit together without the long term use of adapters.

ISO 80369-3 System Orientation

Component	ENFit System	
Syringe	Female	
Feeding Tube	Male	
Admin Set (distal end)	Female	

Is the new low dose syringe that is being reviewed by the FDA an ISO design standard?

Yes, the ENFit Low Dose Tip (LDT) syringe has been thoroughly reviewed and received FDA 510(k) clearance for at least two manufacturers. Other manufacturers are currently in the process of gaining 510(k) clearance for their ENFit LDT syringes. The LDT syringe is designed specifically to deliver a high degree of dose accuracy while meeting the requirements of ISO 80369-3.

Is the connector orientation specified in ISO 80369-3 or in any other ISO standard?

The orientation is not defined in ISO 80369-3, however it is currently included in the approved committee draft of ISO 20695 enteral device standard.

Was the new low dose syringe evaluated/validated by the standards group for potential misconnections with other devices?

Yes. The Low Dose Tip (LDT) syringe design has been validated through rigorous performance testing, usability, human factors testing and misconnection risk analysis. The ENFit LDT syringe has been thoroughly reviewed and received FDA 510(k) clearance for at least two manufacturers. Other manufacturers are currently in the process of gaining FDA 510(k) clearance for their ENFit LDT syringes.

Does the ISO 80369-3 allow for manufacturers to choose from two designs?

No. ISO 80369-3 defines the geometry, material characteristics and functional performances of a standard connector pair made of one male half and one female half.

Was the new ENFit Low Dose Tip syringe evaluated/validated for potential misconnections with other devices?

Yes. All ENFit connectors, including the ENFit Low Dose Tip (LDT) design, have been validated through a misconnection risk analysis as required by the general standard ISO 80369-1 on small-bore connectors. The (LDT) syringe has been reviewed and gained FDA 510(k) clearance for at least two manufacturers. Other manufacturers are currently in the process of gaining FDA 510(k) clearance for their ENFit LDT syringes.

Does the new ENFit Low Dose Tip syringe "misconnect" with any other devices?

The LDT was tested to determine if it misconnected with other devices. A few potential connections existed which, after complete assessment, were determined to have a very low risk level. The risk assessment methodology followed the same methodology utilized by ISO TC 210 JWG4 when evaluating all of the small bore connectors included within the ISO 80369 series. It is important to note that there is not a single connector included within the ISO 80369 series that is entirely free of misconnection potential. Each connector has been accepted on the basis that the benefits significantly outweigh the risks.

What were the results of the new ENFit Low Dose Tip syringe design testing?

Performance testing of syringes with the LDT was performed by an accredited third party lab to quantify the accuracy of the syringe within the enteral system (i.e. accuracy of dose when delivered through an enteral catheter). Legacy products were also tested by this lab to establish a baseline for existing products. The results indicated that the ENFit LDT Syringes provided equivalent to or better performance results as compared to other connectors used worldwide. Results from the Performance Testing, Usability Testing and Misconnection Risk Analysis were submitted and thoroughly reviewed by the FDA. As of 6/17/2016 at least two manufacturers have received FDA 510(k) clearance for their ENFit Low Dose Tip syringes. Other manufacturers are currently in the process of gaining FDA 510(k) clearance for their ENFit LDT syringes.

Is the performance data available for review?

Yes. A summary of the LDT performance data is available at www.stayconnected.org

When do we expect FDA approval for the new low dose tip syringe?

As of June 17th, 2016 the FDA has granted FDA 510(k) clearance to at least two manufacturers submissions for the ENFit Low Dose Tip Syringe. Other manufacturers are currently in the process of gaining FDA 510(k) clearance for their ENFit LDT syringes.