



# ISO 80369

**Small-bore connectors for liquids  
and gases in healthcare applications**



# Presenter/Speaker Personal Disclosure

- › Presenter's Name: Rikki Lynn Doyle
- › I have no current or past relationships with any commercial entities
- › Speaking Fees for current program:
  - I have received a speaker's fee from PTSA for this learning activity



# Presentation Structure

- › What is ISO 80369?
- › A Short History of the Luer
- › Describe Tubing Misconnections
- › ISO 80369 and Patient Safety
- › ISO 80369 standard series: The 7 parts
- › Alberta Health Services Transition to ENFit
- › Test your knowledge
- › Q&A



# Learning Objectives

By the end of this presentation:

- › 1. Participants will learn the purpose and scope of ISO 80369
- › 2. Participants will learn how compliance with ISO 80369 can improve patient safety
- › 3. Participants will learn what Alberta Health Services has done to work towards meeting the ISO 80369 standard



# What is ISO 80369?

- › International Organization for Standardization
- › 80369 is a series of medical device standards that cover small bore connectors for direct individual patient care
- › The standards were developed to improve patient safety

## ISO 80369-1

- General Requirements and Overview

## ISO 80369-2

- Breathing Systems and Driving Gases
- Airway

## ISO 80369-3

- Enteral and Gastric
- Stomach
- **ENFit**

## ISO 80369-4

- Urinary Collection
- Urethra

## ISO 80369-5

- Limb Cuff Inflation
- Tourniquets and BP Cuffs

## ISO 80369-6

- Neuraxial
- Spine

## ISO 80369-7

- Intravenous
- Arteries and Veins
- **The Luer**

# Short History of the Luer



Image from: Brown, J The Life and Death of the Luer, MD&DI Online

- Hermann Wulfing-Lüer first manufactured the luer syringe in 1894, 130 years ago
- Invented by Karl Schneider....???? Or Jeanne Luer
- The simple design went on to be an effective connector for a wide variety of medical applications
- In 1925 Fairleigh S. Dickinson filed a US patent for a modification that would come to be known as the LUER-LOK





[Looking Back: Ramstein air show crash > Office of Special Investigations > Display \(af.mil\)](#)



Prefilled syringes - Prefilled syringe automated inspection & end-product testing - Scientific Figure on ResearchGate. Available from: [https://www.researchgate.net/figure/Photograph-of-Luer-lock-tip-and-cap\\_fig2\\_324546890](https://www.researchgate.net/figure/Photograph-of-Luer-lock-tip-and-cap_fig2_324546890) [accessed 19 Feb, 2024]



# What is a tubing misconnection?

- › *“Tubing, catheter and syringes are a fundamental aspect of daily health provision for the delivery of medications and fluids to patients. The design of these devices is such that it is possible to inadvertently connect the wrong syringes and tubing and then deliver medication or fluids through an unintended and therefore wrong route. This is due to the multiple devices used for different routes of administration being able to connect to each other”*





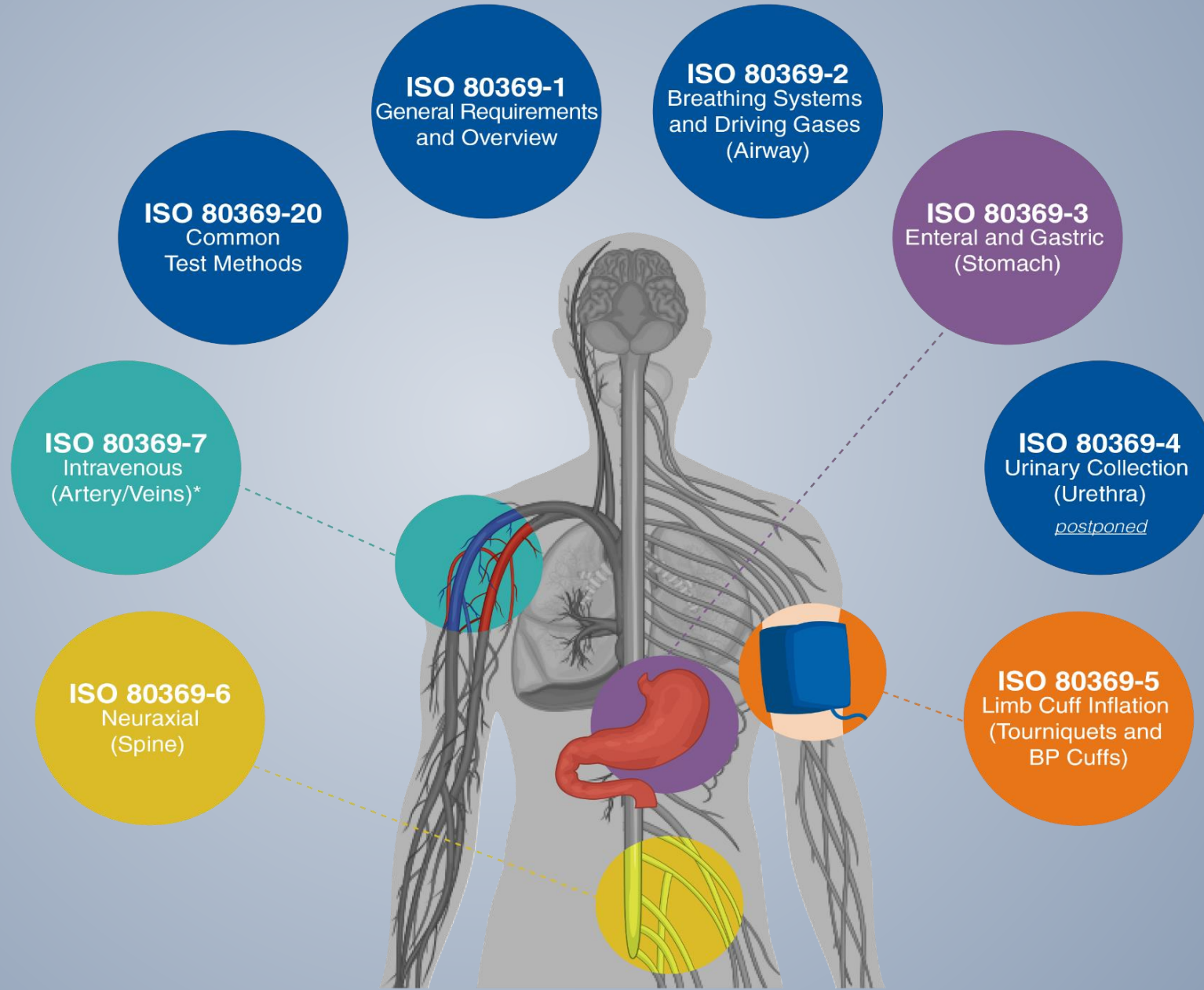
## [In Their Own Words – YouTube](#)

From [stayconnected.org](http://stayconnected.org)

## Examples of Medical Device Misconnections | FDA

- › An anesthetist and a mid wife mistakenly connected an epidural set to a patient's IV tubing as a result epidural medicine was delivered to the IV causing patient death.
- › A child in a pediatric ICU had both an IV line and a trach tube. The IV tubing was mistakenly connected to the trach cuff port. The IV fluid over-expanded the trach cuff to the point of breaking and continuous IV fluids entered the child's lungs resulting in the child death.
- › A patient was found with her Foley catheter disconnected from its drainage bag. One end of the catheter was still in her bladder and the other end was connected to her nasogastric (NG) tube. Urine was noted to be flowing into her NG tube. The NG tube was connected to suction and more than 300 mL of urine drained. The patient's vital signs were stable, and her laboratory results were within normal limits





In 2023 Alberta Health Services took the initiative to transition over and meet the global standard changing our supply of enteral feeding products and accessories to be ENfit compliant!

**FIGURE 2**

### **Comparison of Syringe Tips<sup>6</sup>**

ENFit syringes less than 5 mL were redesigned with a low-dose tip and paired with new dispensing adaptors, like transfer straws, to increase dosing accuracy and avoid inadvertent overdosing due to drug accumulation in the “moat” at the syringe tip.





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Test your knowledge!

What year was the first glass luer syringe manufactured in Paris, France?



Test your knowledge!

How many parts in total  
does ISO 80369 include?





# Test your knowledge!

In 1988 a massive disaster triggered investigations that eventually led to the development of ISO 80369. At what airbase did the disaster occur?



Test your knowledge!

What bodily system is part 6 of the standard associated with?



Wiepking F, Van Zundert A, Martin JP, Cazalaà JB, Buttner R. The all-glass Luer syringe: Historical facts around concepts, introduction and patents. *Anaesth Crit Care Pain Med*. 2021 Aug;40(4):100921. doi: 10.1016/j.accpm.2021.100921. Epub 2021 Jun 28. PMID: 34197975. [The all-glass Luer syringe: Historical facts around concepts, introduction and patents - PubMed \(nih.gov\)](#)

Brown J. The Life or Death of the Luer. *Medical Device and Diagnostic Industry*. 2012 Aug 20. [The Life and Death of the Luer \(mddionline.com\)](#)

Milamed, Debra, Karen Brown, Edward Murphy. "Luer's Lure: From an International Standards Perspective." *Anesthesiology* 117, no. 6 (2012): 1358-1363. DOI: 10.1097/aln.0b013e318275e78f

Stay Connected Initiative by GEDSA <https://stayconnected.org>

Gedsa Worldwide, In Their Own Words, June 16, 2020 Video found at: [In Their Own Words – YouTube](#)

World Health Organization, "Avoiding Catheter and Tubing Mis-Connections", *Patient Safety Solutions*, volume 1, solution 7, May 2007. [ps-solution7-avoiding-catheter-and-tubing-miss-connections.pdf \(who.int\)](#)

US Food Drug Administration, Examples of Medical Device Misconnections, 02/23/2023. [Examples of Medical Device Misconnections | FDA](#)

Health Canada, Tubing misconnection errors and the anticipated redesign of small bore (Luer) connectors, 2015. [Health Product InfoWatch - March 2015 - Canada.ca](#)

Questions?

