March 11, 2019

Patient Safety Update: Reducing Tubing Misconnections

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Presenter Disclosures

- The presenters have no financial relationship with any commercial interests pertinent to this presentation.

- This program may contain the mention of products/brands/suppliers/drugs presented in a case study or comparative format using evidence-based research. Such examples are intended for educational and informational purposes and should not be perceived as an endorsement of any particular supplier, product, brand, drug or approach.

Learning Objectives

At the end of this session, participants should be able to:

1. Describe the risks involved with medical device tubing misconnections
2. Discuss design changes that meet ISO standards to reduce the likelihood of errors
3. Explain FDA recommendations for enteral device manufacturers
4. Recommend an appropriate strategy leading to the eventual removal of legacy devices that have an increased risk for misconnection within one's own facility or healthcare system

Dedicated Association

Mike Cusack, MBA

Executive Director | GEDSA (Global Enteral Device Supplier Association)

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Global Enteral Device Supplier Association

- Industry's collective voice
- GEDSA formed on Oct. 1, 2013 as a federal 501(c)(6) non-profit trade association
- Composed of wide array of stakeholders
- Introduced ISO 80369 series in medical device tubing connectors
- Patient safety focused
- Inclusive not exclusive

GEDSA Members

ABBOTT
A. HOPF
ALCOR SCIENTIFIC
AVANOS
BAXTER
B BRAUN
BOSTON SCIENTIFIC
CAIR LGL
CARDINAL HEALTH
CEDIC
CODAN
COOK MEDICAL
COOK MEDICAL
DALE MEDICAL
FRESENIUS KABI
GBUK
IMI
KB MEDICAL
MEDELA
MEDICINA
MEDLINE
MOOG
NEOMED
NESTLÉ
NIPRO
NUTRICIA
QOSINA
Q MEDICAL DEVICES
SMITHS MEDICAL
UCOMFOR
VESCO MEDICAL
VENNER MEDICAL
VYGON
XERIDIEM

GEDSA Supporting Organizations

The Issue & Risks

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The Issue

- Universal connectors allow misconnections between unrelated systems
- Tubing misconnection | an inadvertent connection of tubing from the medical device for one delivery system to a system that serves a completely different function

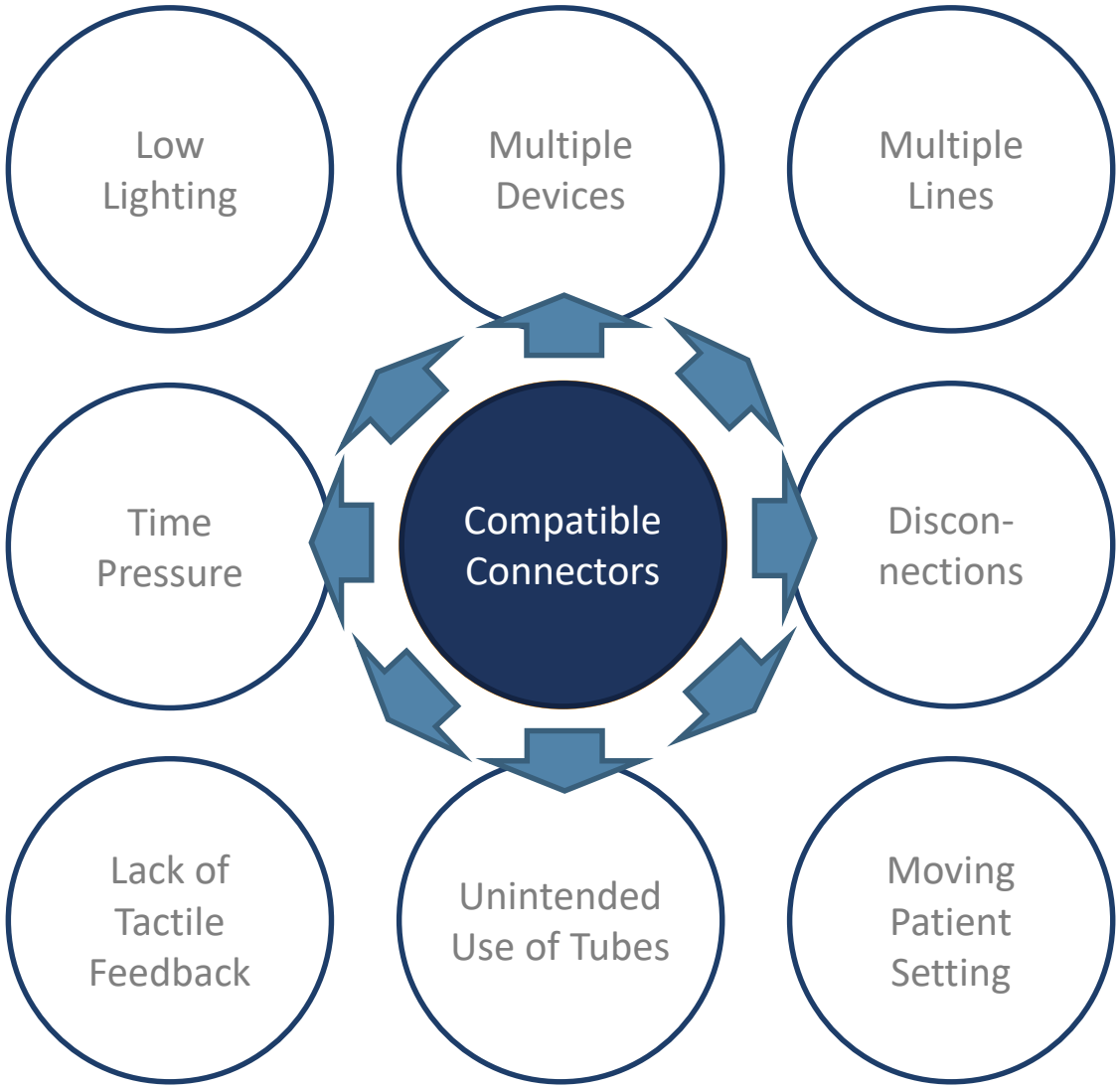
Photo courtesy of FDA

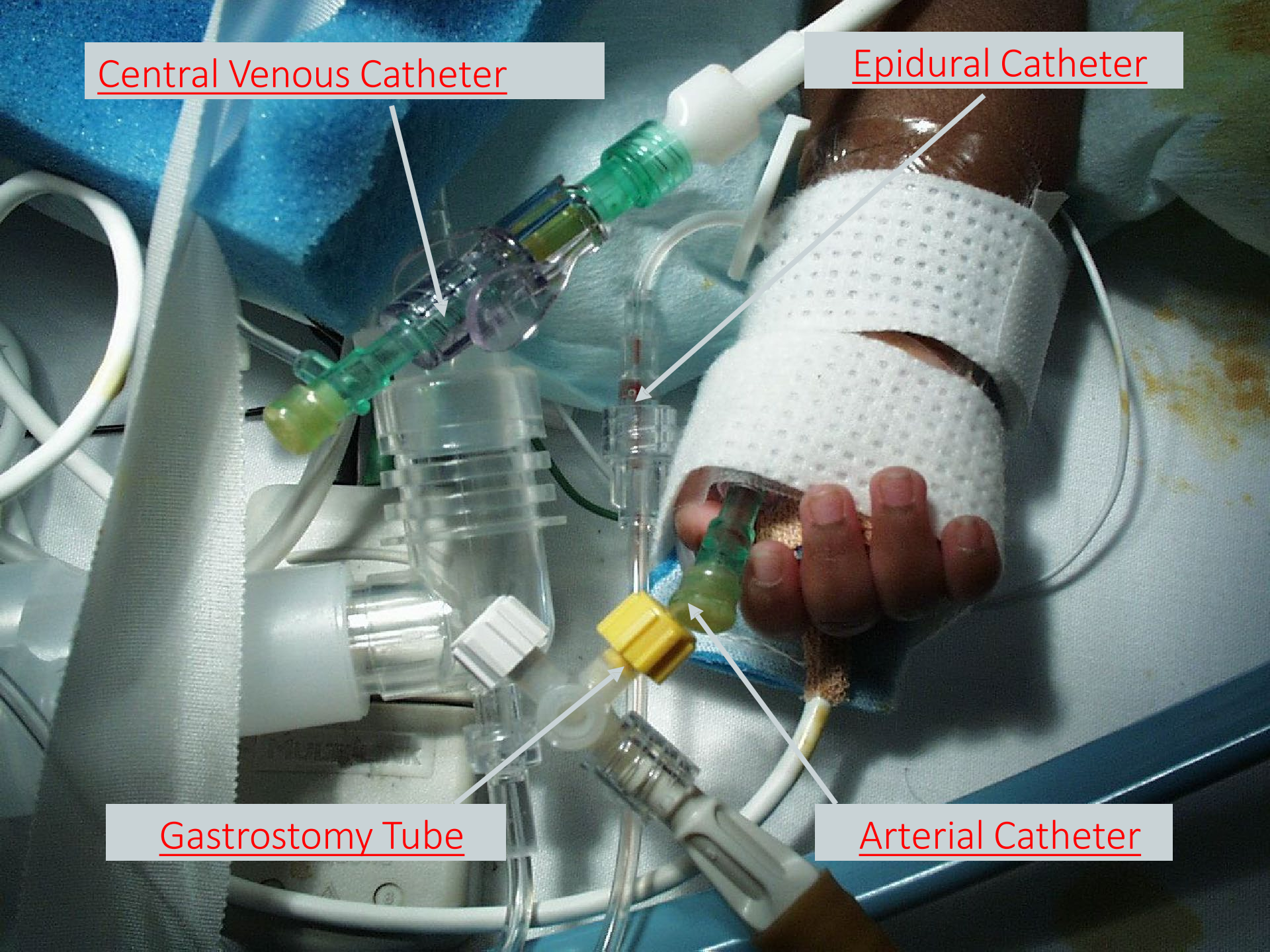
A serious adverse patient safety event resulting in harm & possible death

TUBING MISCONNECTIONS ADVERSE EVENTS:

- IV tubing misconnected to a nasal cannula used to deliver oxygen—the patient survived after being treated for congestive heart failure
- Epidural infusion set connected to a peripheral IV, delivering epidural medication to bloodstream, resulting in patient death
- Feeding tube connected to an in-line ventilator suction catheter, delivering feeding contents into the patient's lungs, resulting in death
- Heparin lock (peripheral IV route) connected to an automatic blood pressure cuff, delivering air to the bloodstream, causing death
- Feeding tube was coupled with a peripheral line of a pregnant woman, resulting in enteral nutrition delivered directly into the bloodstream; neither the 35-week-old fetus nor the woman survived

Reasons for Misconnections




Central Venous Catheter
Epidural Catheter
Gastrostomy Tube
Arterial Catheter

International Standardization

- Increased awareness
- Practice guidance, alerts by professional and regulatory organizations
- Purpose of ISO: Develop new international standards that would prevent interconnectivity
- Implement “incompatibility by design” features

A Global Effort to Enhance Patient Safety

Stay Connected

GEDSA

Glossary – ISO 80369 Small-Bore Connector Standards

- -1 = general. Umbrella term for all that fall underneath this overall category of small bore tubing

Currently have alternatives available in the market:

- -3 = Enteral
- -6 = Neuraxial

Future iterations to impact:

- -2 = Respiratory (in process)
- -4 = Urological (planned)
- -5 = Limb Cuff (published March 2016)
- -7 = Intravascular (being finalized)

ISO Design Standards Developed for System-specific Applications

80369 Series

-1 = General requirements

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

Requirements:

- Retain Luer connectors for hypodermic and IV applications
- Develop unique connectors for each clinical delivery system
- Not connectable with others in the series including Luer or needleless connector ports
- Rigid or semi-rigid
- Passes misconnection, risk analysis, usability/human factors testing

ISO Design Standards Developed for System-specific Applications

80369 Series

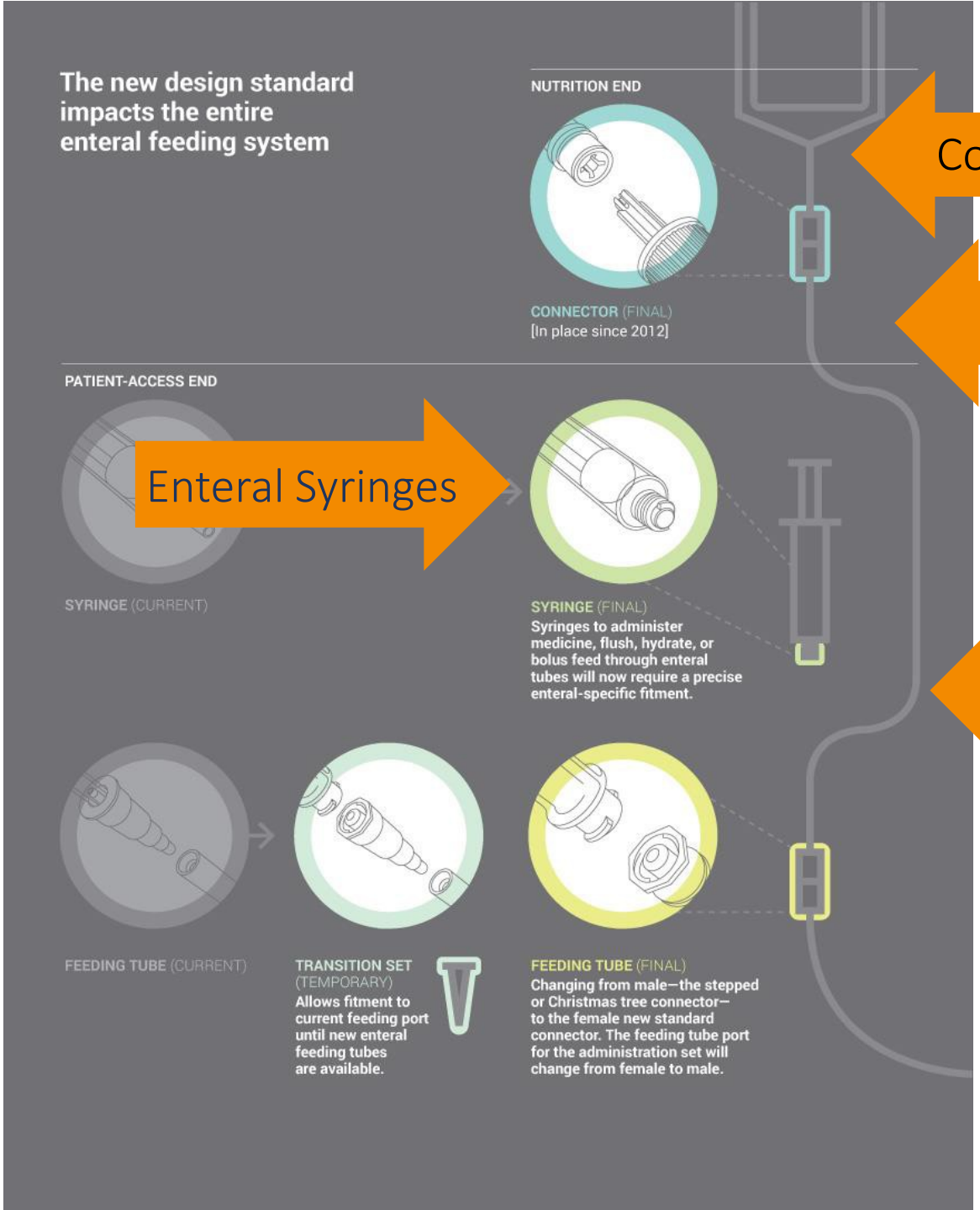
-1 = General requirements

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

Neuraxial System

- 80369-6 standard published March of 2016 and recognized by the FDA
- Smaller outer collar and tip, no change in size to inner barrel
- Visual identifiers – yellow plungers and components/NRFit Logo
- Physically incompatible with standard Luer connectors and Enfit® (ISO compliant connectors)

DESIGN CHANGES TO REDUCE ADVERSE EVENTS


The new design standard impacts the entire enteral feeding system
NUTRITION END
CONNECTOR (FINAL)
[In place since 2012]
PATIENT-ACCESS END
SYRINGE (CURRENT)
SYRINGE (FINAL)
Syringes to administer medicine, flush, hydrate, or bolus feed through enteral tubes will now require a precise enteral-specific fitment.
FEEDING TUBE (CURRENT)
TRANSITION SET (TEMPORARY)
Allows fitment to current feeding port until new enteral feeding tubes are available.
FEEDING TUBE (FINAL)
Changing from male—the stepped or Christmas tree connector—to the female new standard connector. The feeding tube port for the administration set will change from female to male.
Completed
Feeding Set
Enteral Syringes
Extension Set
Feeding Tube

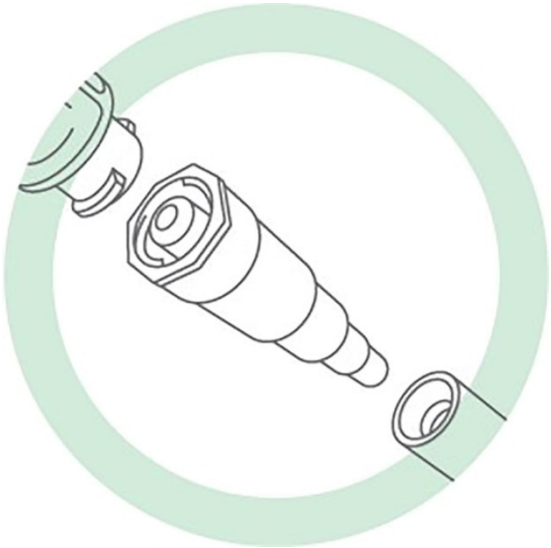
Administration Sets for Enteral Feeding

Transition Sets

- Most suppliers of administration sets have already converted to ISO compliant and included a transition connector (Adapter)
- Transition Connectors will no longer be needed with ISO compliant feeding tubes

Types of Administration Sets

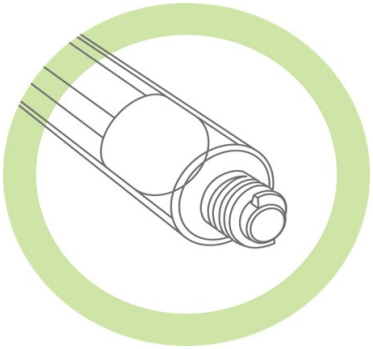
- Spike & Bag Pump Sets
- Gravity Feeding Sets
- Other Bolus Feeding Devices

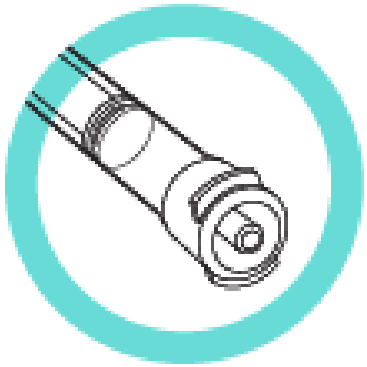


Syringes Used for Enteral Feeding

Types of syringes commonly used for feeding, flushing and administering medication

- Enteral/Oral Syringes (E/O syringes)
- Luer Slip Tip Syringes
- Catheter Tip Syringes
- Common size syringes (.5, 1, 3, 5, 6, 10, 20, 35, 60 mL)
- Safety Syringes

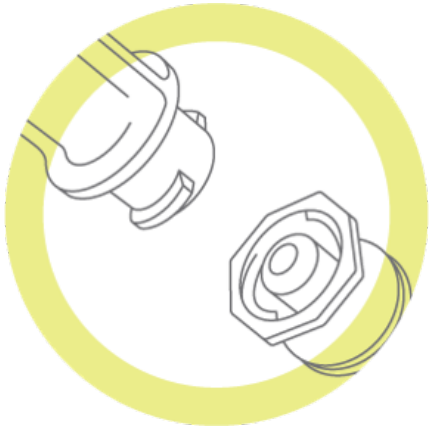




Feeding Tubes Impacted

Types of tubes commonly used for feeding

- Gastrostomy (G-Tube)
- Low Profile Feeding tubes and corresponding extension sets
- Nasograstric (NG-Tube)
- Nasojejunal (NJ-Tube)
- Gastrojejunal (GJ-Tube
- PEG Tube Y-Ports



Pharmacy & Other Ancillary Items Impacted

- Bottle fill caps
- Medication bottle adapters
- Fill Straws
- Syringe caps
- Tamper evident solutions
- Prefilled syringes
- Light protective solutions

Off-label Use

- Any devices not indicated for enteral feeding will not be impacted
- Examples of off-label feeding tubes
  - Foley Catheters
  - Red Rubber Catheters
  - Other Urinary Catheter
- Check with your supplier representative regarding tubes specifically designed for drainage like Salem Pumps
- Luer syringes will remain on the market but will not be compatible

ISO Compliant Feeding Sets – currently in the market

Temporary Transition

Transition Connector

Legacy

NEW

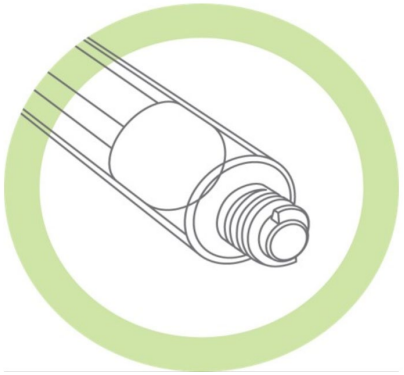
ISO compliant | Connector from Administration Set

ISO compliant | Feeding Tube Port

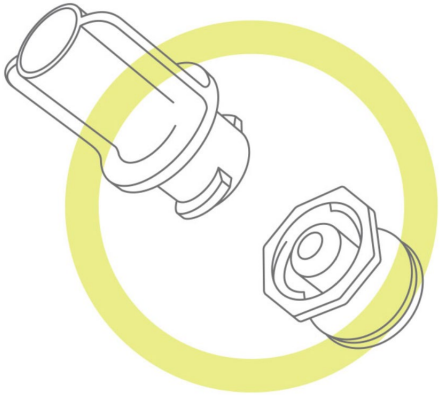
New Connector Performance

- Positive connection avoids “feeding the bed”

- Flow rate and pressure similar to current devices
  - Validated by FDA and Mayo Clinic in:
  1. Mayo Clinic’s “Use of Blenderized Tube Feeding in Adult and Pediatric Home Enteral Nutrition Patients”
  2. FDA’s ”Impact of Design Changes in Gastrostomy Tube (G-tube) Devices for Patients Who Rely on Home-Based Blenderized Diets for Enteral Nutrition”
  - Blenderized diets testing shows no safety concern



- Accurate dosing in NICU settings
  - LDT (low dose tip) design gives equivalent performance



- Will not connect with other therapies
  - Examples: Intravascular, Neuraxial, Respiratory, etc.

Europe Leads Global Adoption of ISO 80369-3 connectors

North America
- < 20%
- Law (AB444) in CA effective July 1, 2016

Europe
- > 80% depending on market
- UK, Netherlands, France, Italy, Belgium > 90% transitioned

Asia
- < 5% adoption
- 2019 for China & Japan

South America
< 5%

Australia/NZ
> 75% adoption

Eastern Europe, Middle East & Africa
< 30%

* Adoption rates are only rough estimates based on feedback from manufacturers, GPOs, hospitals and other stakeholders throughout the world

Progress & Next Steps

- GEDSA fully supports the Sept. 2018 FDA Letter and CMS Statement
- Expect to obtain supporting statement from the Joint Commission

Next steps:

- Stakeholder task force to develop a phase out plan for legacy connectors
- Ensure prompt compliance with the FDA/CMS releases
- Visit www.stayconnected.org for updates
- GEDSA Tools & Resources: Brochures, Presentations, FAQs & Checklists at www.stayconnected.org
- GEDSA Regional Summits
  - Free to attend and free to host
  - Sole Requirements: provide meeting room and drive attendance
- Interactive Teaching Station – Hands on tool that allows clinicians, hospital staff and patients/caregivers to touch new connectors
- Tool Kit

U.S. FOOD & DRUG ADMINISTRATION

Enteral Devices Misconnection and Patient Injury: FDA September 7, 2018 Letter

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Gastroenterology Devices Branch
Division of Reproductive, Gastro-Renal, and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration

March 11, 2019

Objective

Review FDA recommendations of the September 7, 2018 Letter to Manufacturers of Enteral Feeding Tubes, Health Care Professionals and Hospital Purchasing Departments and Distributors.

Concerns

- FDA is concerned by continued reports of misconnections with enteral devices.

- To reduce the risk of misconnections and patient injury, hospitals and clinicians should use enteral devices with connectors that meet the International Organization for Standardization (ISO) 80369-1 or ISO 80369-3 standard, or that are otherwise designed to reduce the risk of misconnections.

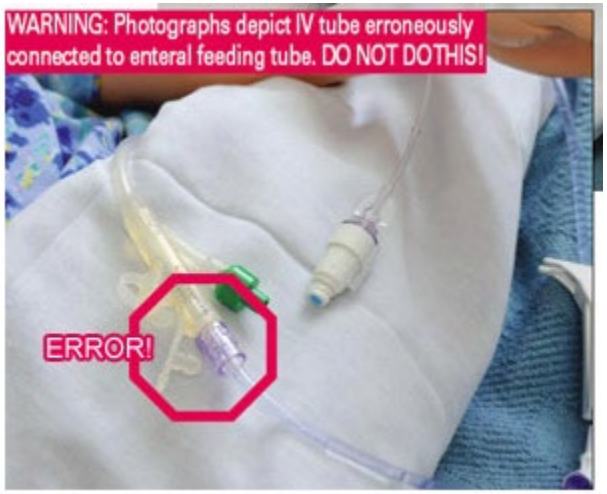
Background

- Misconnections between enteral devices and other medical devices have been associated with patient death and serious injuries.

- Since 2011, FDA has received reports of 2 deaths, 24 serious injuries, and 32 device malfunctions related to enteral misconnections. The FDA is also concerned that many misconnections, including enteral misconnections, are not reported, or are reported as medication errors.

Background

- Medical device misconnections may occur when one type of medical device is mistakenly attached to another type of medical device that performs a different function. Because the connectors on these devices are easy to use and may be compatible with different medical devices, users can mistakenly connect unrelated systems to one another.



Background

2015

- FDA published a guidance document, *Safety Considerations to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral Applications*.

- Recommends manufacturer's design and test enteral connectors based on the ISO 80369 series standards to reduce the risk of misconnections.

2010

- FDA issued a letter to manufacturers of enteral products, health care providers, and hospital purchasing departments about the danger of misconnections.

Concerns

- FDA is aware that some people who rely on enteral tube-feeding at home have concerns about using the 80369-3 connectors.

- The 80369-3 connectors have slightly narrower openings than some connectors on the market.

- FDA has conducted testing of commercial pre-packaged formula and blenderized diets through 80369-3 connectors and has concluded that flow rates may be slightly slower, but this does not pose a safety concern.

- Additional resources are available from the Oley Foundation and the Feeding Tube Awareness Foundation.

Background

The FDA continues to work with standards organizations, federal partners, professional societies, patient advocacy groups, individual patients and other stakeholders.

FDA works with these groups to reduce the chance of medical device misconnections, ensure patient safety, and facilitate the availability of products that work for the multitude of patient populations, uses, and care environments.

To Manufacturers

- Implement design changes to meet the ISO standards to reduce the likelihood of errors and provide safeguards for safe use of these devices and products.

- Implement an appropriate strategy that will lead to the eventual removal of legacy devices that have an increased risk for misconnection.

- Evaluate patient needs and develop safe and effective enteral devices.

- Consider suggestions provided by the Joint Commission to implement appropriate “designed incompatibility” measures to prevent dangerous misconnections of tubes and catheters.

To Health Care Professionals

- Use enteral devices that meet the ISO standards and are intended to reduce the risk of misconnection.
- Check the labeling or check with the distributor or manufacturer to determine whether your connectors meet the ISO standards.
- Organize a plan for your organization to implement the use of these new devices.
- Do not modify or adapt devices since that may defeat their safety system.

To Health Care Professionals

- Minimize the use of transition adapters (a device component that forms an intermediary connection between two incompatible medical devices).
- Do not use cross-application connectors.
- Trace all lines back to their origin when reconnecting devices.
- Route tubes and catheters that have different purposes in unique and standardized directions, to avoid accidental misconnections.

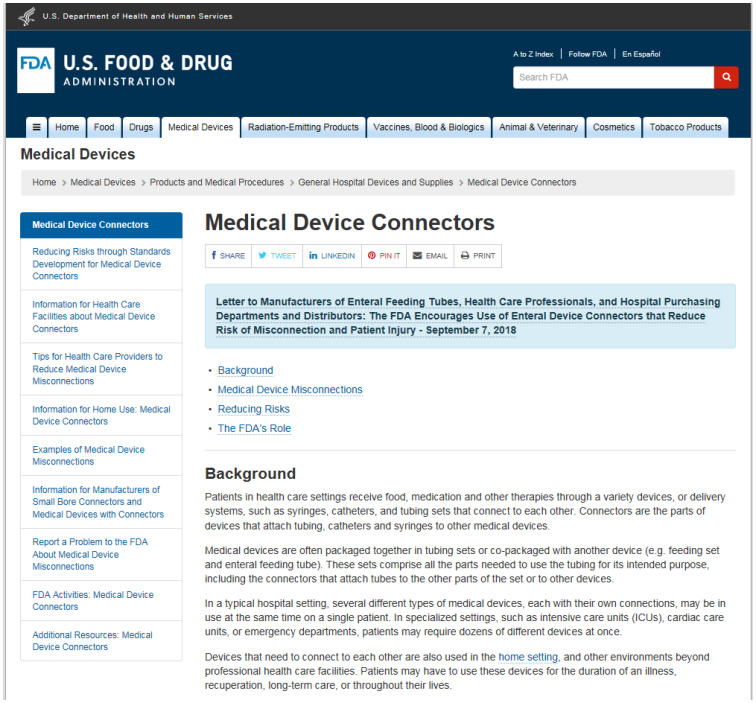
To Hospital Purchasing Departments and Distributors

- Purchase enteral devices that comply with the new ISO 80369-1 or ISO 80369-3 series standards to reduce the risk of misconnection.

- Ensure that an adequate inventory of the new devices is available to purchasers.

Additional Information

- More information about medical device misconnections is available on the FDA website Medical Device Connectors: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/TubingandLuerMisconnections/default.htm



HealthTrust Member Implementation: Trinity Health

Nancy Preston, RN, BSN, CRNI

Director of Strategic Sourcing | Trinity Health

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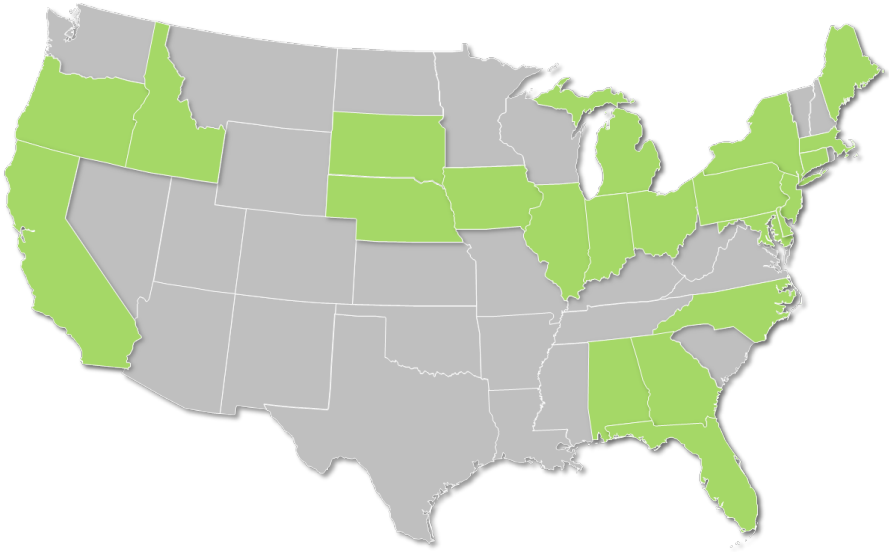
Trinity Health Conversion Journey

Trinity Health's 22-state Diversified System Today

Trinity Health



$18.3B In Revenue

1.5M Attributed Lives

$1.1B Community Benefit Ministry

133K Colleagues

7.8K Employed Physicians & Clinicians

28K Affiliated Physicians

94 Hospitals* in 22 states

23 Clinically Integrated Networks

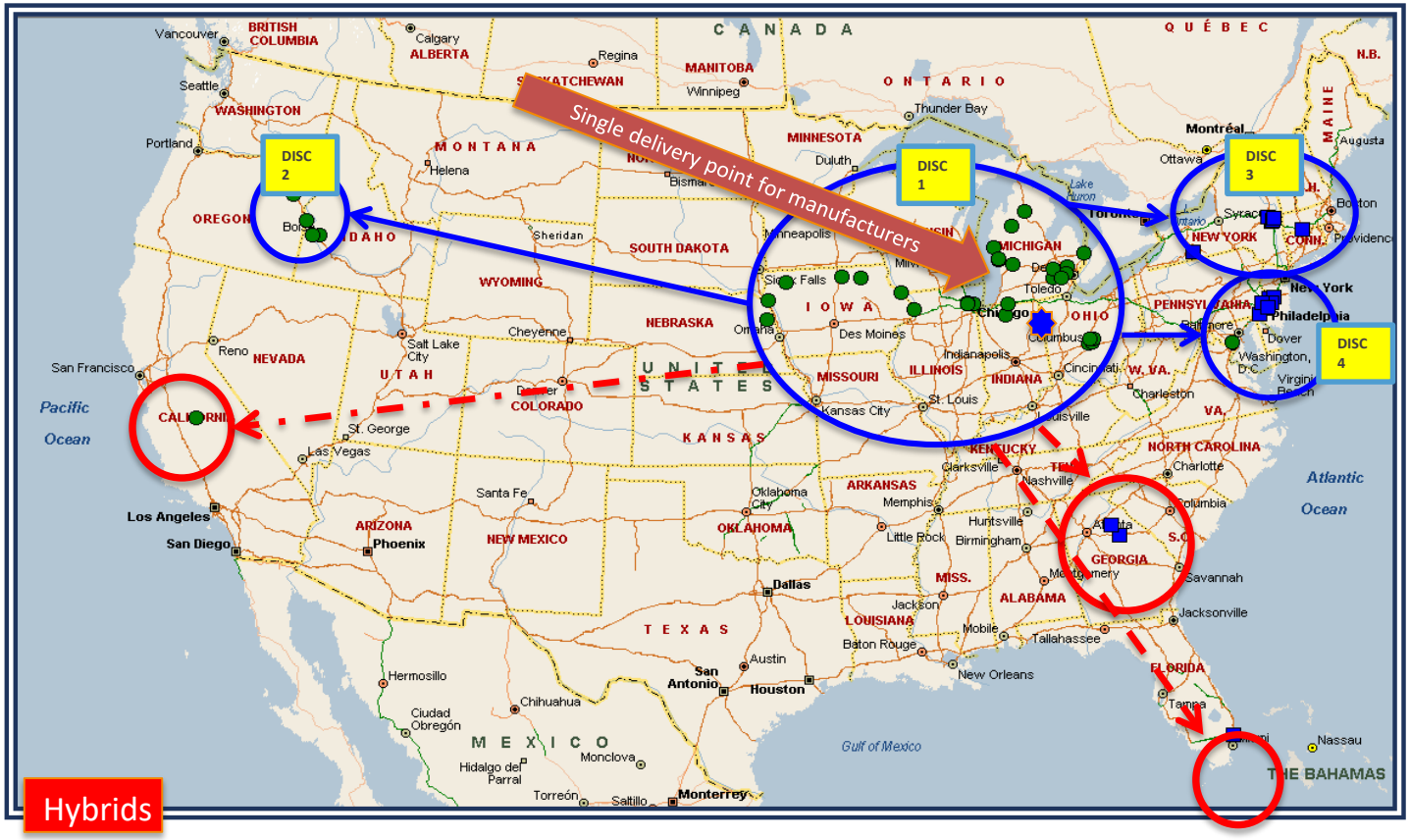
17 PACE Center Locations

109 Continuing Care Locations

*Owned, managed or in JOAs or JVs.

Trinity Health **DISC** Network

Dedicated **I**ntegrated **S**ervice **C**enter



Trinity Health's Conversion Steps

- S: Supplier Communication – product changes, timing
- T: Training - Plan for all care areas, caregivers and patients
- E: Education - Ensure education materials reflect new product needs
- P: Process - Multidisciplinary team to guide the process, A to Z
- S: Supply Management - Conversion Plan, Inventory Management, Distribution Plan, Return policies during conversion and supplier engagement

Trinity Health

Conversion and Implementation Plan

Trinity Health uses a conversion toolkit to operationalize the conversion process across all our ministries and care areas. “DNU – Conversion Document”

- Item lists with approved contracts
- From-to list
- Current Marketshare
- Supplier contact list and conversion planner
- Supporting materials
- Contract Information
- Target dates and deadlines
- Posted on our Share Point page with sourcing and contract information

Conversion and Implementation Plan

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	**Vendor Recommended Cross Reference**												
2							**Alternate Supplier**						
3	**Current Manufacturer**						**Vendor A's ISO Compliant Design**						
4	Supplier Name	Catalog#	Facility Item Identifier	Description	UOM	UOM Factor	Cross Key	xSupplier's Name	Catalog#	Facility Item Identifier	Description	UOM	UOM Factor
5	Vendor A	361		Tube, Feeding,6FRX50CM, Nutri	BX		Direct	Vendor A	461420E	269587	Polyur fit 5.5FRx20"WEI	CA	10
6	Vendor A	105202	343180	Syringe, Monoject 20 ML	CA	50	Direct	Vendor A	435SE	269588	Monoject 35ML Enfit Sy	CA	160
7	Vendor B	155720	341633	Tube eeed 5FX5N w/Depth	CA	50	Direct	Vendor A	460802E	269591	PVCF/Tube 5FXR16"Wer	CA	50
8	Vendor B	60ES	372172	Set IV Ext 60inKangaroo	CA	50	Direct	Vendor A	60ENS	269611	Monoject 12ML Enfit Sy	CA	50
9	Vendor C	BAS12E0		12ML Ameer Syringe	CA	1	Direct	Vendor A	412SE	269609	Monoject 1ML Enfit Syri	CA	480
10	Vendor C	BAS13E0		1ml Oral Syringes	CA	1	Direct	Vendor A	401SE	269904	3ML Syringe	CA	240
11	Vendor C	BAS1E0		3ml Oral Syringes	CA	1	Direct	Vendor A	400SE	269612	Monoject 6ML Enfit Syri	CA	400
12	Vendor C	BAS3EO		6 ml Oral Syringes	CA	1	Direct	Vendor A	406SE	269607	Monoject 60ML Enfit Sy	CA	400
13	Vendor D	######	420650	Syringe Oral 60ML ORG ST	CA	100	Direct	Vendor A	46071SE	269610	PVCFITTIVE^.5FRX4CM	CA	1250
14	Vendor E	31006	417888	Tube Feeding PYC 6FR 40CM	BX	50	Direct	Vendor A	888268060	269617	SALEMSMP TUBE 6FR 24	CA	50
15	Vendor E	34006	253613	Tube Gastric 2LUM 60CM	CA	10	Direct	Vendor A	888826491E	269602	SALEMSMP TUBE 8FR 24	CA	40
16	Vendor E	34008	253614	Tube Gastric 2LUM 80CM	CA	10	Direct	Vendor A	46142E	269603	SLMSMP PVC TBE 10FRE	CA	40
17	Vendor E	34010	253623	Tube Gastric 2LUM 90CM	CA	10	Direct	Vendor A	46170E	269599	POLURFIT 5FRX20"	CA	50
18	Vendor E	361052	343157	Tube, Feeding, 5FRX50CM, Nutri	BX	50	Direct	Vendor A	401SE	269594	POLURFIT8FRX20"	CA	40
19	Vendor E	361082		Tube, Feeding, 5FRX80CM, Nutri	BX		Direct	Vendor A	406SE	269597	Monoject 1ML Enfit Syri	CA	40
20	Vendor E	1015012	343176	Syringe, 1ML, Nutrisafe	BX	100	Direct	Vendor A	412SE	269604	Monoject 6ML Enfit Syri	CA	240
21	Vendor E	1015052	343178	Syringe, 5ML, Nutrisafe	BX	100	Direct	Vendor A	415SE	269607	Monoject 12ML Enfit Sy	CA	400
22	Vendor E	1015102	343179	Syringe, Nutrisafe, 2, 10ML	BX	100	Direct	Vendor A	422SE	269609	Monoject 6ML Enfit Syri	CA	480
23	→	Item List	Current Item	Final Detail and Market Share	Vendor Contact Info			Conversions					

Trinity Health's story

Wide Impact

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Conversion to ISO compliant will have an impact on multiple clinical areas and settings.

- Custom packs
- Process from infrequent users
- Off label uses for devices today
- Pharmacy dosing, storage and delivery
- Light protection
- Fecal Management Systems

Trinity Health's story

Transitions of Care

- Include non-acute stakeholders
- Homecare, Hospice, Senior Living, DME Providers, Physician Offices, Outpatient clinical services
- Educational opportunities and materials
- Administration/feeding sets
- Feeding Tubes
- Syringes for bolus feeds, residuals, medication
- Share your timelines
- Discharge documentation
- Include your supplier partners in this process

Trinity Health's story

Trinity Health

Supplier Relationship

- Conversion to ISO compliant represents an investment in money and resources
- Not all suppliers will be moving forward and will exit the marketplace
- Some are not engaged with Stay Connected and represent additional variance and confusion.

Considerations as you select your ISO Compliant Suppliers:

- Timeline to market
- Ability to support conversion in all care areas
- Challenge with understanding financial impact as some luer products remain for use in other applications – syringes and accessories
- Discern between marketing and ISO compliant standard functions. Examples: color of disposables
- Don't forget distribution channel

Citations

- Department of Health and Human Services. (2013, April). Guidance for Industry - Food and Drug Administration. Retrieved April 5, 2018, from https://www.bing.com/cr?IG=D3ECC38062AE41DE9B35C6C7B28FB93C&CID=1EDAD2A4288469B83DF2D968292B68B6&rd=1&h=xO4bmG3bsKKryWo5llwGTngyDavryHLPXZadTe_2hr4&v=1&r=https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM349009.pdf&p=DevEx,5068.1

- Simmons, D., Symes, L., Guenter, P., & Graves, K. (2011).The Joint Commission, December 3, 2014. New ISO Tubing Connector Standards: A Follow up to the Sentinel Event Alert (webinar) https://www.jointcommission.org/.../New_ISO_Tubing_Connector_Standards_Webinar
- Tubing Misconnections. Nutrition in Clinical Practice, 26(3), 286-293.Retrieved April 5, 2018, from doi:10.1177/08845336114061344
- “SC Home Page.” StayConnected by GEDSA, stayconnected.org/

Links to Other Resources

- ECRI Institute guidance publication

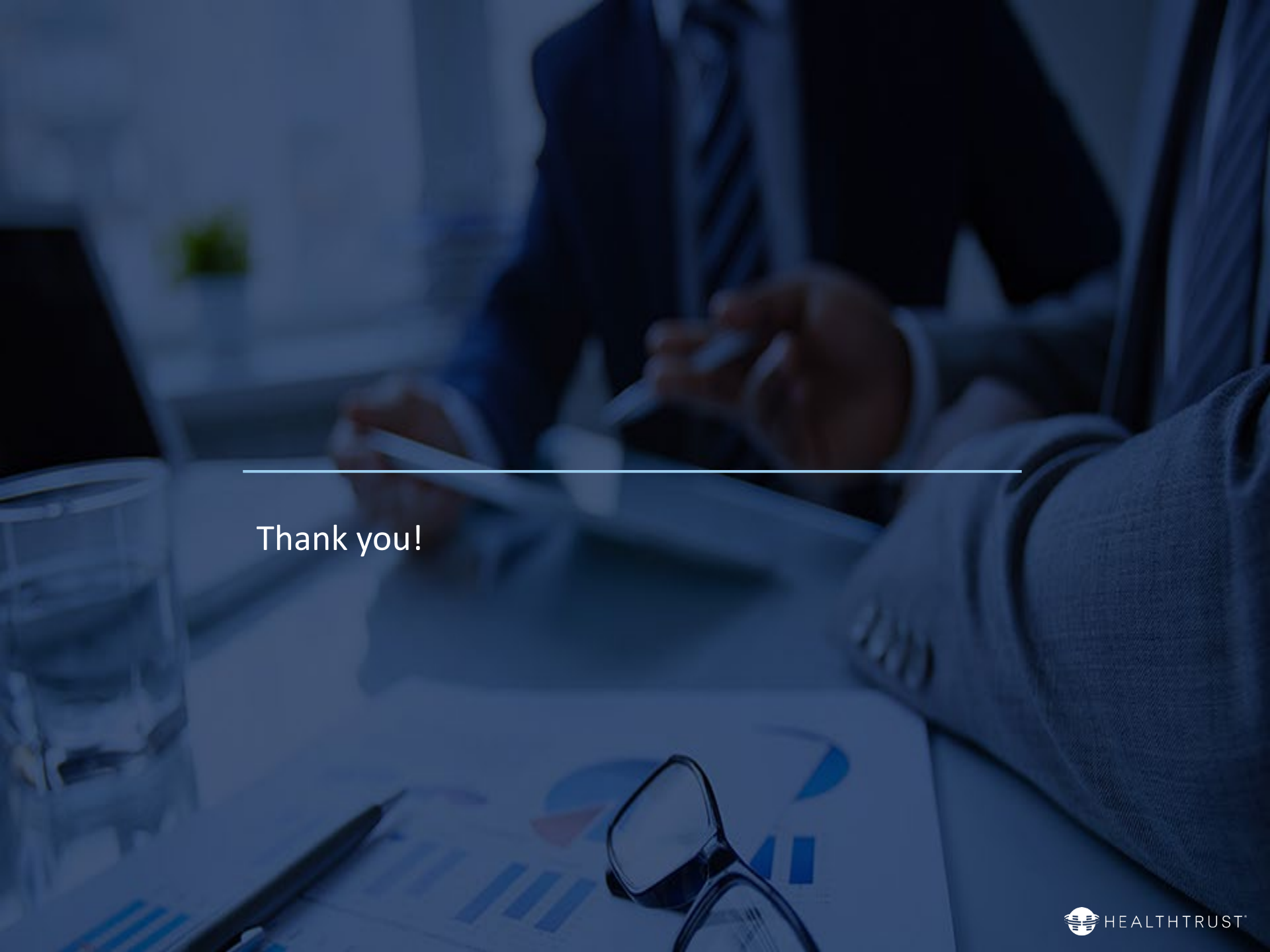
https://www.ecri.org/components/HDJournal/Pages/ENFit-for-Preventing-Enteral-Tubing-Misconnections.aspx?tab=2

- GEDSA Toolkit

http://stayconnected.org/wp-content/uploads/2017/06/Tool-kit-file-for-website.v2.pdf

- GEDSA Medical Guidelines Research and Position Statements

http://stayconnected.org/enfit-medical-guidelines/



Thank you!

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