PREMIER

Welcome
Advisor Live® Webinar
December 4, 2018

Transitioning to ENFit® Connectors: A Safer Enteral Feeding System

Will Begin Shortly

Listen to Today's Audio:800.680.6953

Download today's slides at www.premierinc.com/events

Advisor Live® Webinar
Transitioning to ENFit® Connectors: A Safer Enteral Feeding System

December 4, 2018

Listen to Today's Audio:800.680.6953

Logistics

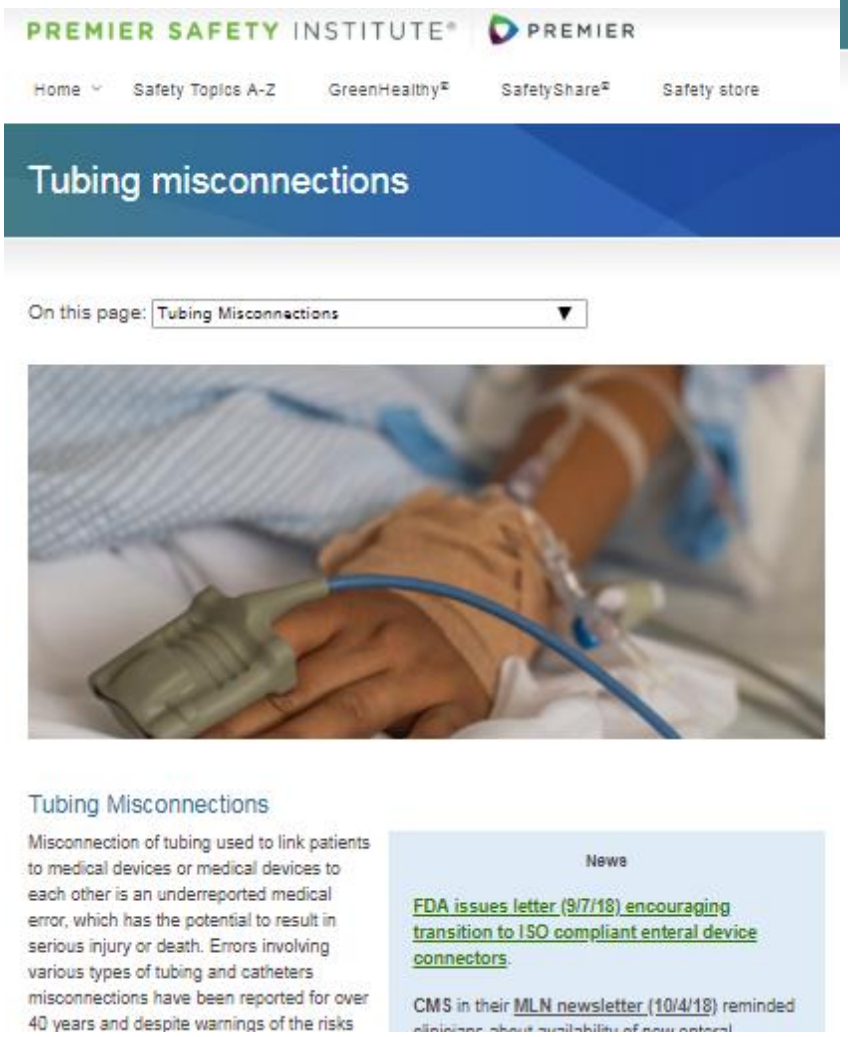
AUDIO
Dial in to our operator assisted call, 800.680.6953

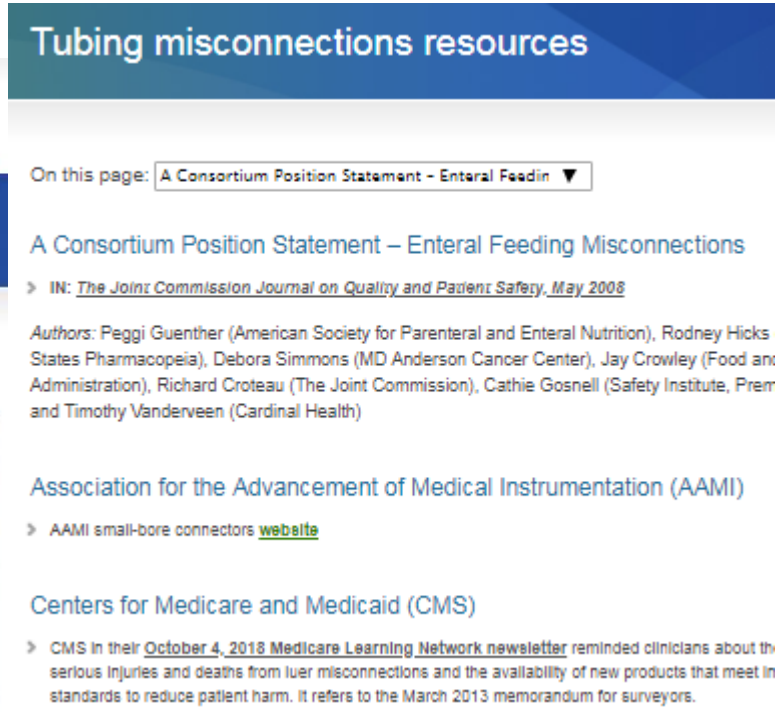
NOTES
Download today's slides from the event post at premierinc.com/events

QUESTIONS
Use the "Questions and Answers"

RECORDING
This webinar is being recorded.
View it later on-demand at premierinc.com/events

Premier Safety Institute
www.premierinc.com/tubingmisconnections





Resources from:
AAMI, ASPEN, CMS,FDA, GEDSA, ECRI, ISMP, Joint Commission, Stay Connected

*Source or Footnote = Arial Regular 8pt

Today's Speakers

Moderator: Gina Pugliese RN MS

Vice President Emeritus , Premier Safety Institute ®

Debby Kasper, RDN, LDN

Director, Premier Inc.

Mark J. Antonino, MS

Food and Drug Administration (FDA)
Center for Devices and Radiologic Health (CDRH)

Mike Cusack, MBA

Executive Director, GEDSA Global Enteral Device Supplier Association

Amy Monroe, RN, BSN

Corporate Manager, Strategic Sourcing, McLaren Health Care

Transitioning to ENFit® Connectors: A Safer Enteral Feeding System

Debby Kasper, RDN, LDN
Premier, Inc.

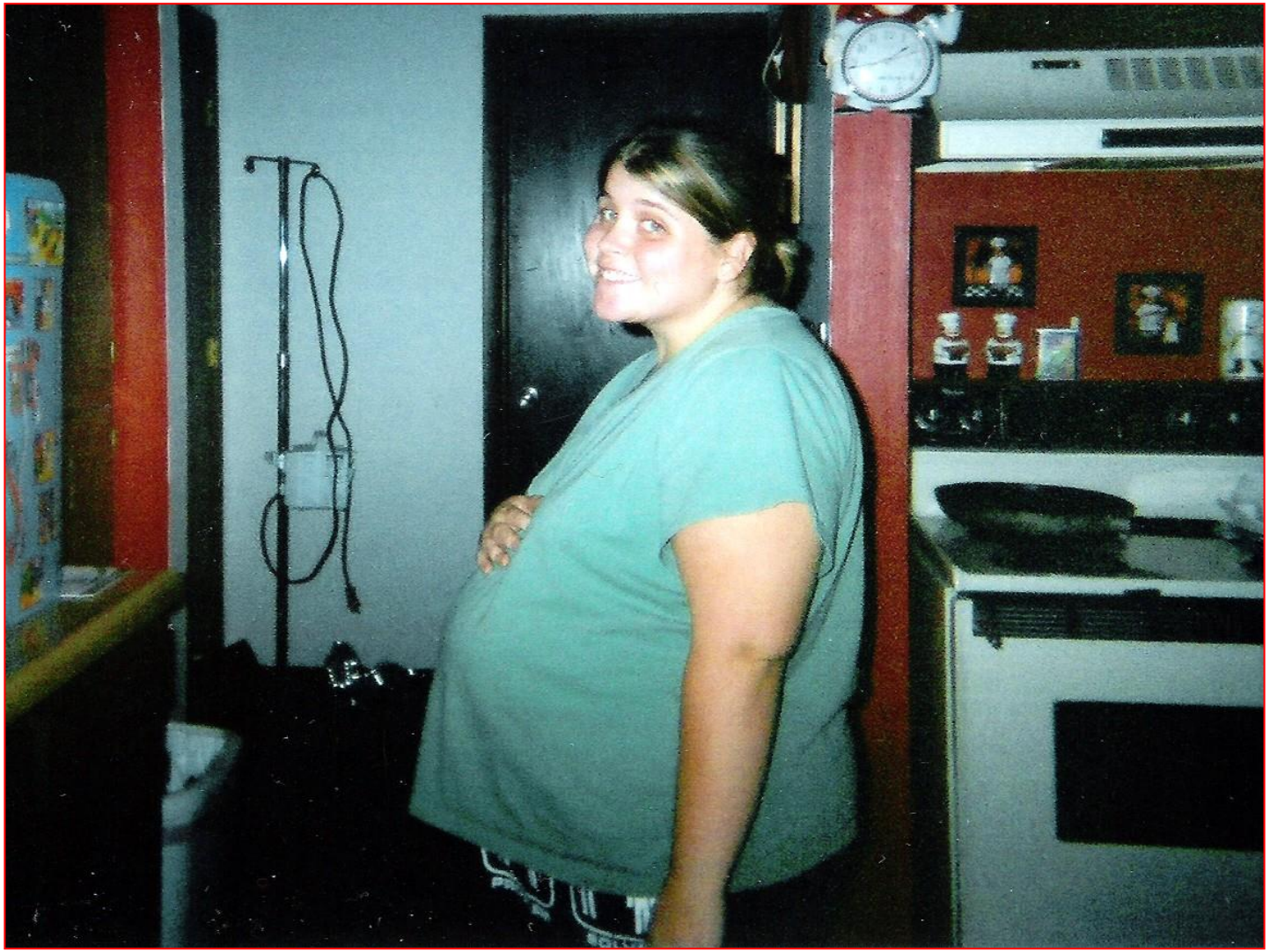
Standardization of IV Connectors

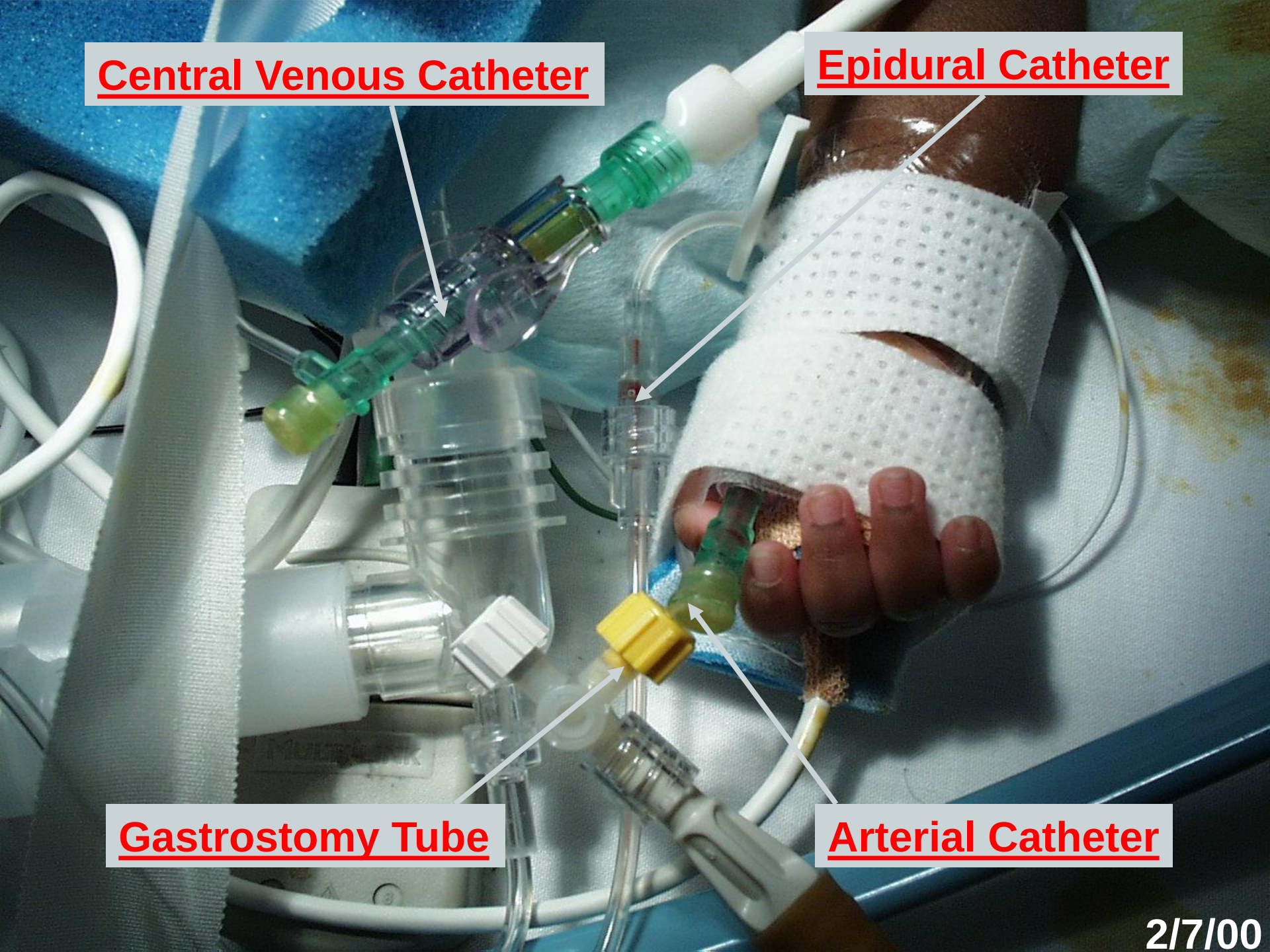
- US Air Force Base in Ramstein, Germany
- Blue Angels Air Show, a mid-air collision
- 70 spectators killed and 100’s injured
- Injured treated jointly by American military and German first responders
- The German *Rekord* and US *Luer* connectors were incompatible
- Need for an international connector became evident
- Led to the international adoption of the Luer standard as the small bore tubing connector

The Problem

- 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
- A serious adverse patient safety event resulting in harm and possible death

Photo courtesy of FDA

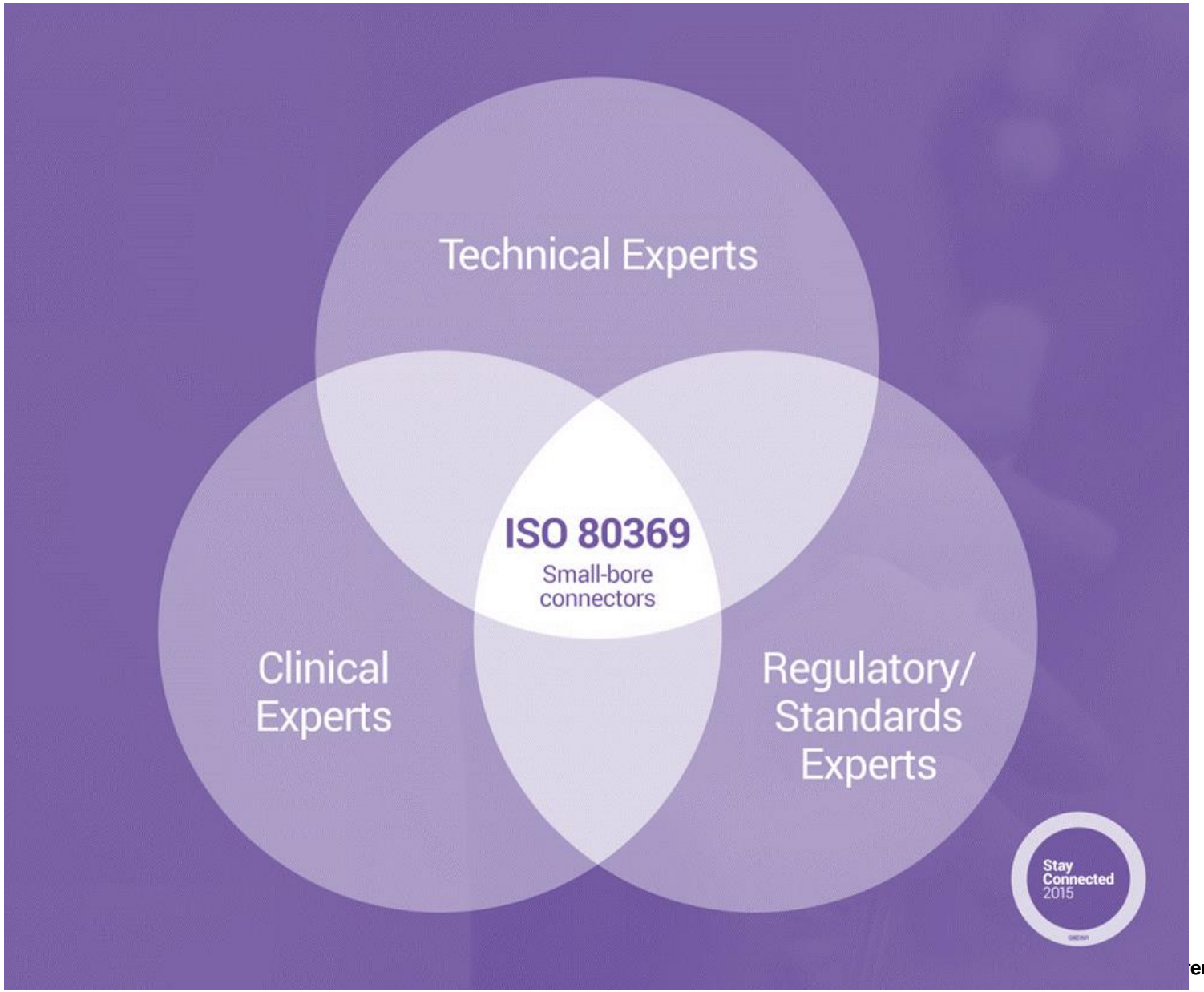



Central Venous Catheter
Epidural Catheter
Gastrostomy Tube
Arterial Catheter
2/7/00

International Standardization

- Awareness increased
- Practice guidance, alerts by professional and regulatory organizations
- ISO purpose to develop new international standards that would prevent interconnectivity
- **Implement “incompatibility by design” features**

The global effort to enhance patient safety



ISO design standards for system-specific applications

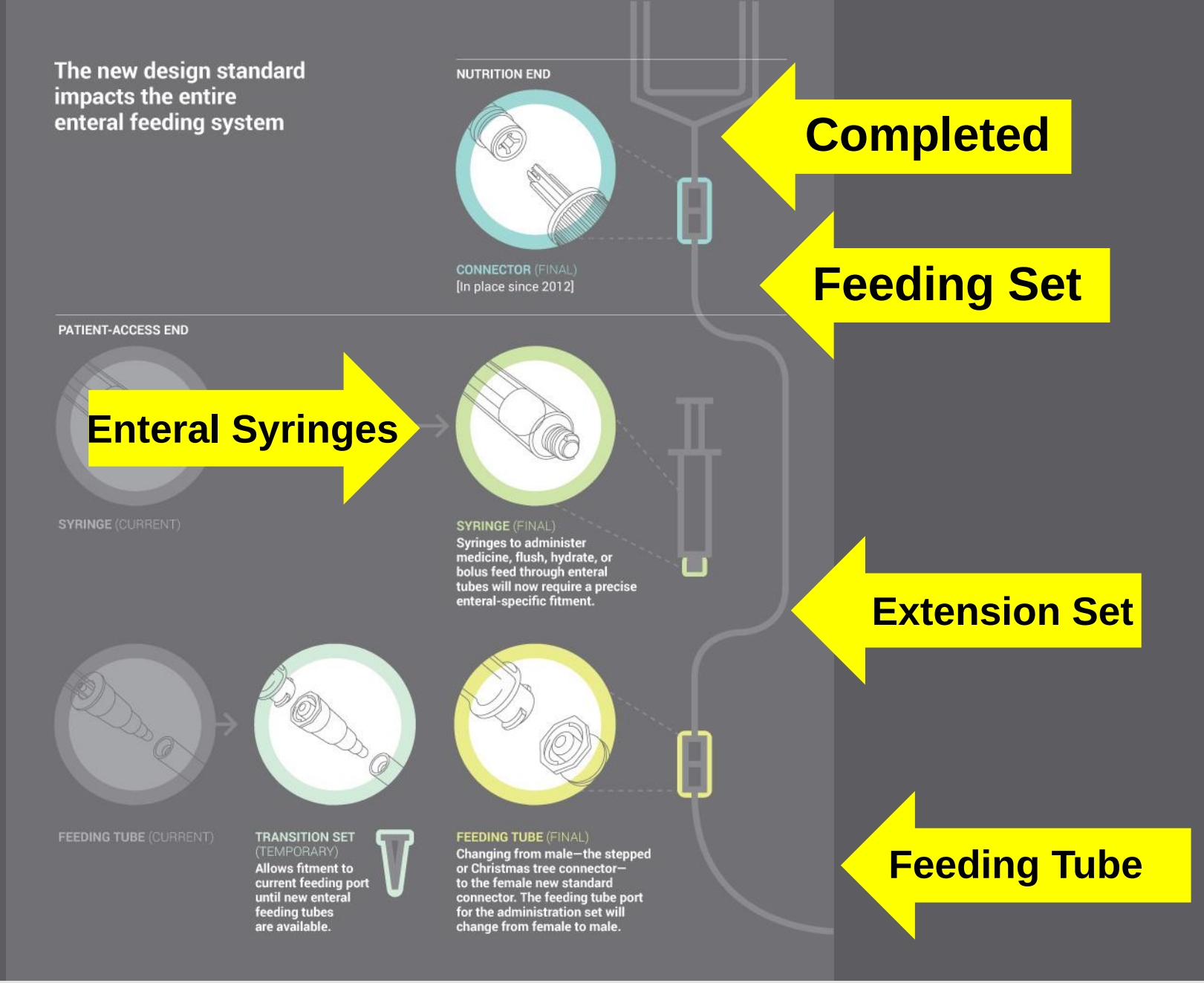
80369 Series

-1 General requirements

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

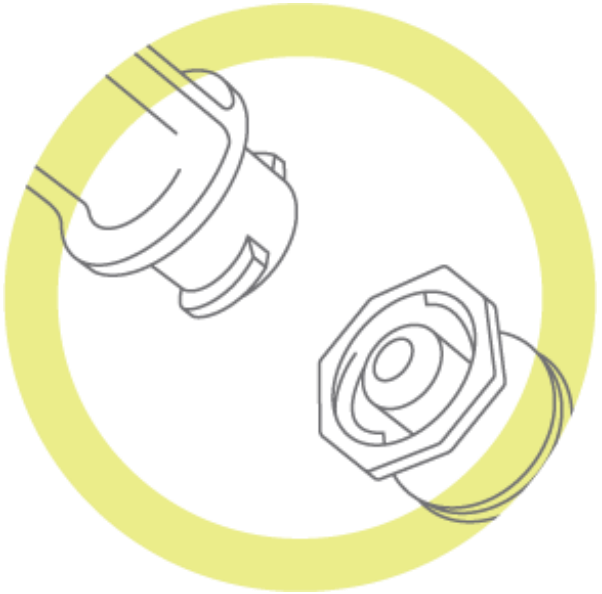
Requirements:

- 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


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

ENFit ®

- After much testing, discussion and international consensus, ENFit ® was selected as the connection design for enteral feeding
- Feeding sets, syringes, feeding tubes have all been transitioned
- Product is available in the market
- Product is available to order
- The time to convert is NOW



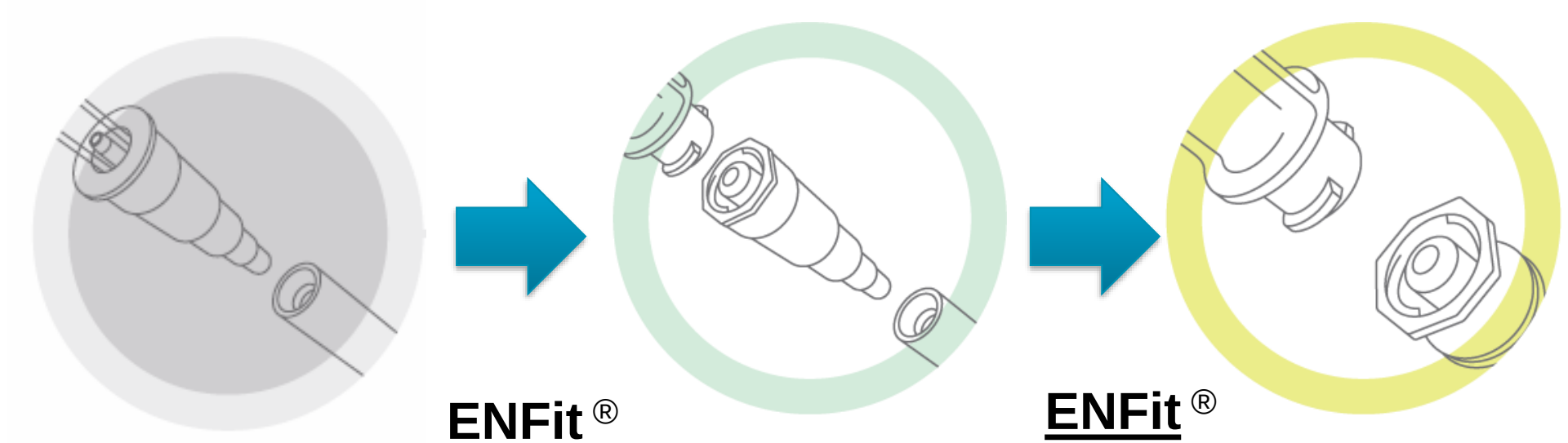
ENFit® Feeding Sets – currently in market

Current

Temporary Transition

Transition Connector

NEW



ENFit® Connector from Administration Set

ENFit® Feeding Tube Port

ISO 80369-3 Global Adoption Status

Global Adoption is Well Underway with Europe Leading*

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

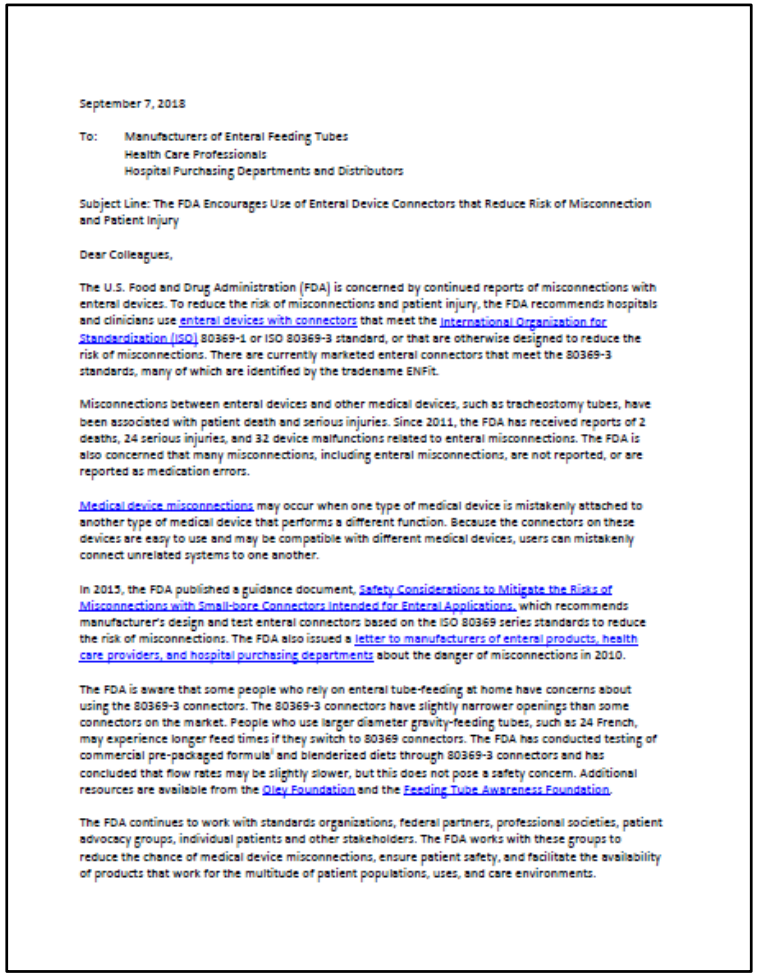
South America
- < 5%

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

FDA Letter Released September 7, 2018



September 7, 2018

To: Manufacturers of Enteral Feeding Tubes
Health Care Professionals
Hospital Purchasing Departments and Distributors

Subject Line: The FDA Encourages Use of Enteral Device Connectors that Reduce Risk of Misconnection and Patient Injury

Dear Colleagues,

The U.S. Food and Drug Administration (FDA) is concerned by continued reports of misconnections with enteral devices. To reduce the risk of misconnections and patient injury, the FDA recommends hospitals and clinicians 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. There are currently marketed enteral connectors that meet the 80369-3 standards, many of which are identified by the tradename ENFit.

Misconnections between enteral devices and other medical devices, such as tracheostomy tubes, have been associated with patient death and serious injuries. Since 2011, the 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.

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.

In 2015, the FDA published a guidance document, Safety Considerations to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral Applications, which recommends manufacturer's design and test enteral connectors based on the ISO 80369 series standards to reduce the risk of misconnections. The FDA also issued a letter to manufacturers of enteral products, health care providers, and hospital purchasing departments about the danger of misconnections in 2010.

The 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. People who use larger diameter gravity-feeding tubes, such as 24 French, may experience longer feed times if they switch to 80369 connectors. The 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.

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

CMS Communication October 4, 2018

CMS Communication

Communication to their local and national partner associations and subscribers.

Enteral Device Connectors that Reduce Patient Injury

- State Luer misconnections continue to result in serious injuries and deaths
- The creation of industry standards and new products provides an opportunity to reduce patient harm.
- Made reference to the Food and Drug Administration (FDA) communication

CMS Communication Original Memo - Released March 2013

Actions for Surveyors

- During a complaint investigation for an adverse event involving misconnection of devices with Luer connectors, surveyors must determine whether the facility has taken actions to ensure systems are in place to prevent recurrence of this type of adverse event.
- When conducting standard surveys, surveyors should consider asking healthcare personnel what steps they take to prevent Luer misconnections.

Neuraxial Connector - NRFit®

- 80369-6 standard published March, 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® connectors.

Adapted from GEDSA

80369 Series

- **Blood pressure and limb tourniquet cuffs/devices**: **IEC 80369-5:2016** was published in March 2016
- **Breathing or respiratory systems** such as anesthesia machines and ventilators used to facilitate a patient's breathing: In process
- **Intravascular or hypodermic devices: ISO/FDIS 80369-7** standard is being finalized
- **Urethral and urinary devices: Planned**

In Conclusion

- After careful consideration and testing, an international committee chose ENFit ® as the design for the enteral connector
- It is an open use design
- It is compliant with the 80369-3 standard
- Product is in the market
- The time to convert is NOW

*Source or Footnote = Arial Regular 8pt

PREMIER

Transitioning to ENFit® Connectors: A Safer Enteral Feeding System

Mark J. Antonino, MS
Food and Drug Administration (FDA)
Center for Devices and Radiologic Health (CDRH)

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

Mark J. Antonino, M.S.
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

December 4, 2018

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.

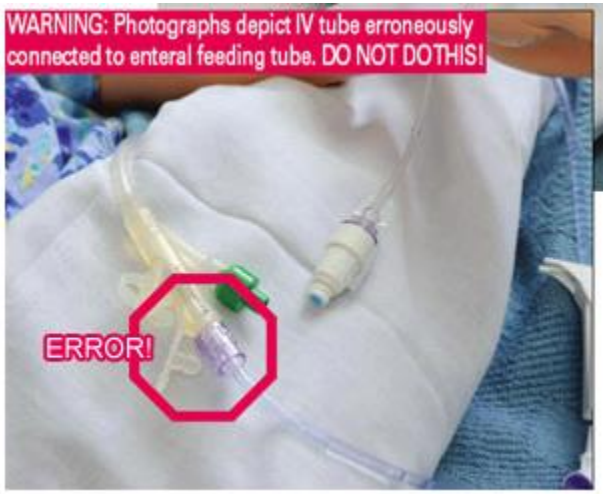
Background

- 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.

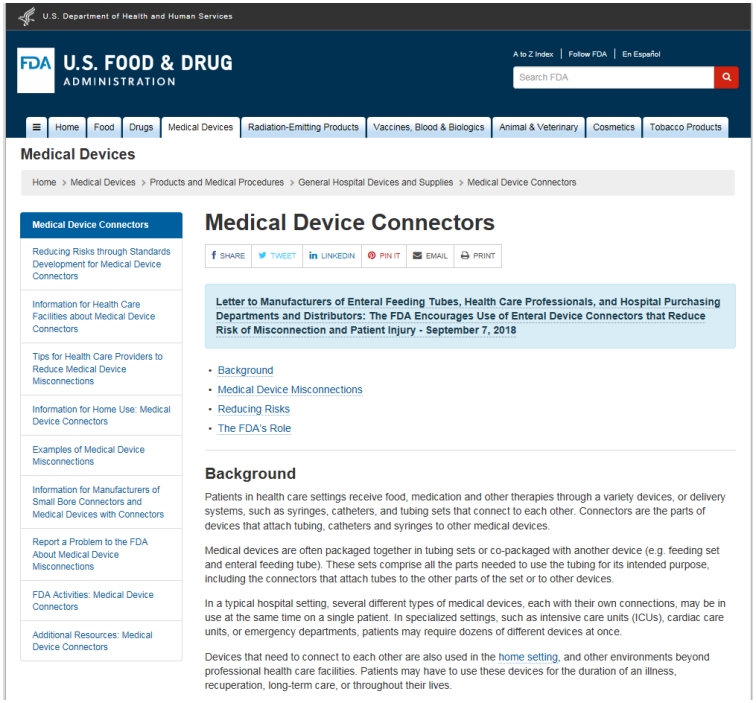
To Hospital Purchasing Departments and Distributors

- 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



Transitioning to ENFit® Connectors: A Safer Enteral Feeding System

Mike Cusack, MBA
GEDSA Global Enteral Device

Global Enteral Device Supplier Association (GEDSA)

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

GEDSA's MISSION

Promote initiatives
surrounding safe and optimal delivery
of enteral feeding and connectivity.


GEDSA Members
ABBOTT
A. HOPF
ALCOR SCIENTIFIC
AVANOS
BAXTER
B BRAUN
BOSTON SCIENTIFIC
CAIR
CARDINAL HEALTH
CEDIC
CODAN
COOK MEDICAL
DALE MEDICAL
DEGANIA
FRESENIUS KABI
IMI
MEDELA
MEDLINE
MOOG
NEOMED
NESTLÉ
NUTRICIA
QOSINA
SMITHS MEDICAL
UCOMFOR
VESCO MEDICAL
VYGON
XERIDIEM

Supporting Organizations

GEDSA Position Statement

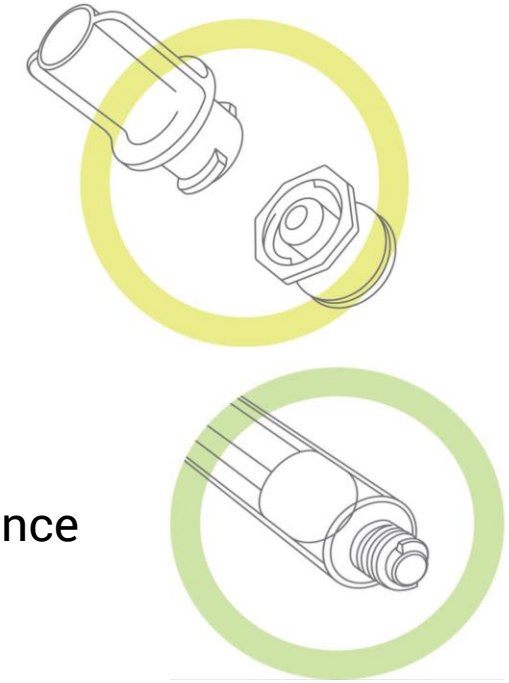
- Fully supports the recent FDA Letter and CMS Statement

- Next steps:
  - Stakeholder task force to develop a phase out plan for legacy connectors.
  - Ensure prompt compliance with the FDA/CMS releases

- Please visit stayconnected.org for full position statement.

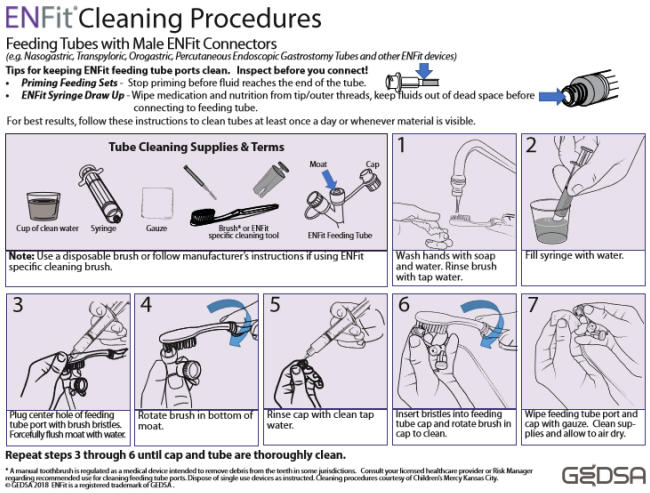
ENFit Connector Performance

- Positive connection avoids the “feeding the bed”
- Flow rate and pressure similar to current devices
  - Validated by FDA and Mayo Clinic
  - Blenderized diets testing shows no safety concern
- Accurate dosing in NICU settings
  - LDT (low dose tip) design gives equivalent performance



ENFit Cleaning Procedure

- Children's Mercy Kansas City and ASPEN co-developed and validated
- Clean daily or if residue is visible
- Available on Stayconnected.org
- Submitted to NCP (Nutrition in Clinical Practice)



Component Supply

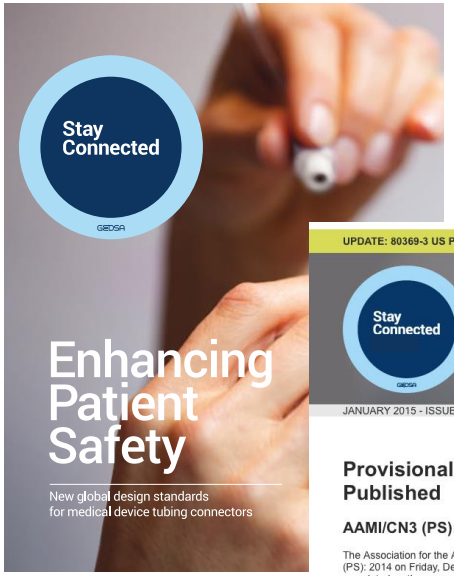
GEDSA manufacturers have confirmed adequate supply

- New suppliers have entered the market
- Multiple bottle cap sizes launched and available
- Tamper evident caps launched and available

Healthcare facilities

- Provide forecast demand 8-12 weeks ahead of a “Go-Live” date
- Validate second source suppliers/distributors to meet demand

GEDSA Tools & Resources:
Brochures, Presentations, FAQs & Checklists
www.stayconnected.org



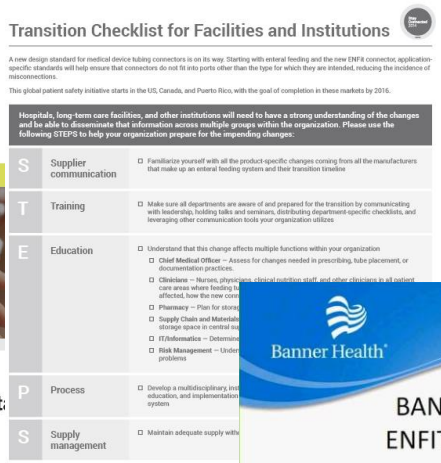
JANUARY 2015 - ISSUE 10

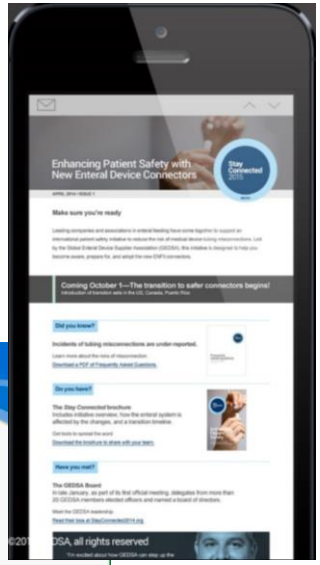
Provisional American National St… Published

AAMI/CN3 (PS): 2014 Published

The Association for the Advancement of Medical Instrumentation (AAMI) published AAMI/CN3 (PS): 2014 on Friday, December 12, 2014. This US provisional standard is a result of the work completed on the second Draft International Standard (DIS) 80369-3 through the International Organization of Standardization (ISO) process. With the adoption of ISO 80369-3 published standard the US provisional standard will be replaced by a parallel adoption of ISO 80369-3 and the text will be aligned to the ISO standard.

The next step in the process is for the US Food and Drug Administration (FDA) to recognize this US Provisional Standard. Along with this recognition, the FDA also intends to provide additional guidance and assist in a clear regulatory pathway for all manufacturers impacted by the ISO 80369 small bore connectors. This marks a significant step forward in the introduction of new, safer connectors starting with the new ENFit connector enteral administration sets in Q1 2015. Click here for the US, Canada, and Puerto Rico timeline and additional details on the introduction.





GEDSA Regional Summits

- Free
- Sole requirements: provide meeting room and drive attendance
- Meeting Objectives: awareness, education, and lessons learned
- Vendors share their ENFit products

Recently held regional summits:

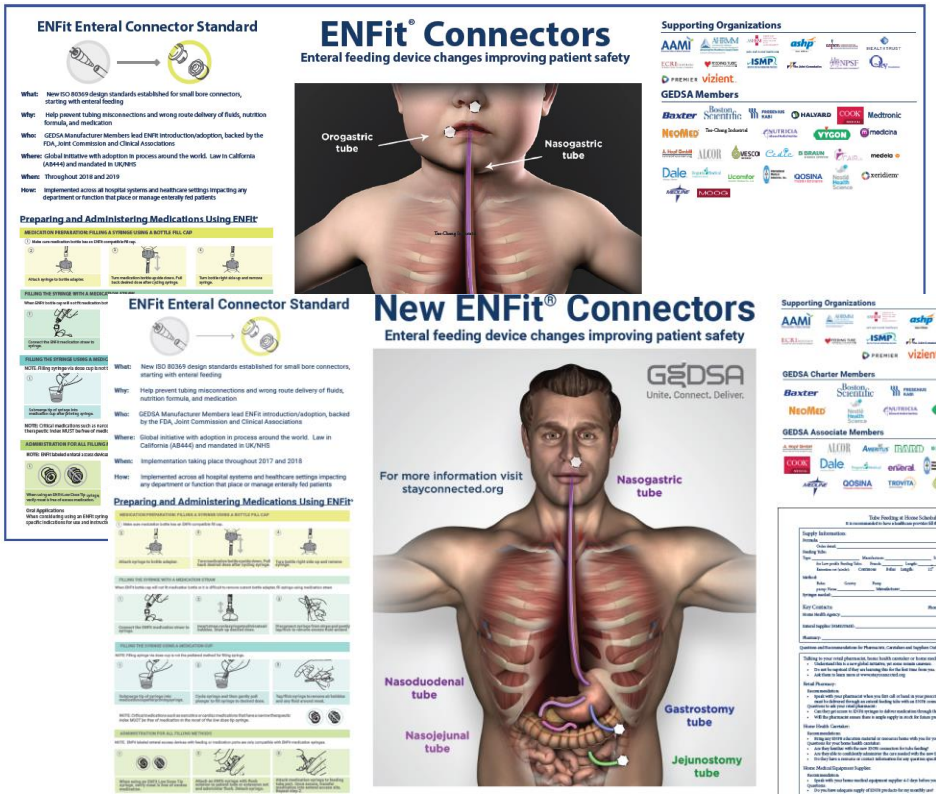
- Children's Hospital of Los Angeles
- Indianapolis Coalition of Patient Safety
- Children's Hospital Colorado and University of Colorado Health
- Children's Hospital of Philadelphia
- University of North Carolina Medical Center

ENFit Tool Kits

Description:
Tool for developing hands-on experience

Includes:
- ENFit Background
- Medication Preparation & Administration Guide
- Patient Discharge Instructions & Talk Sheet
- Interactive Demonstration Model
- ENFit product bins
- StayConnected Wristlets & Brochures
- Transition Team Manual
- Assembly Instructions
- Available in Adult or Pediatric
- ENFit product samples available for additional cost

Email Info@gedsa.org to place your order



In conclusion

- ENFit is ISO compliant
- ENFit is available and global adoption has begun
- There are implementation resources and tools
- The time to convert is now

Transitioning to ENFit® Connectors: A Safer Enteral Feeding System

Amy Monroe, RN, BSN
McLaren Health Care

Agenda

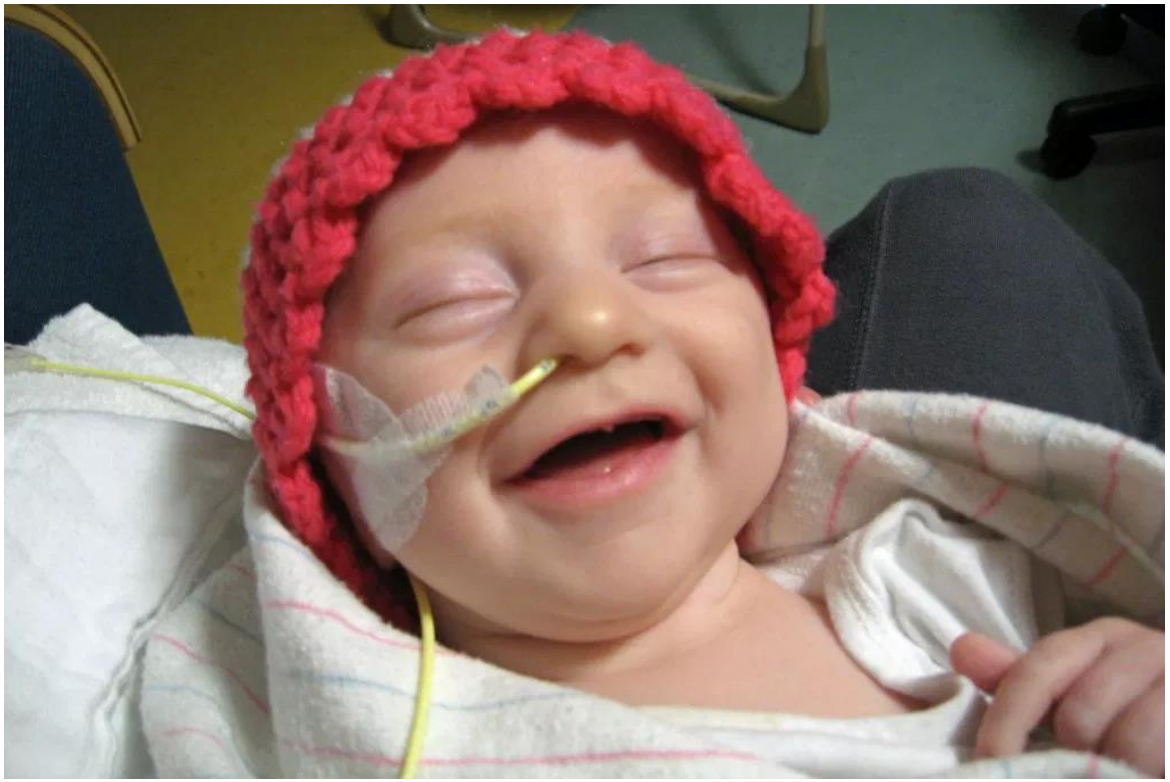
- Who is impacted
- Who needs to be involved in the change
- What steps we took to prepare for successful implementation
- When we began the transition
- Where were changes implemented
- How we implemented
- How we continue to provide follow up
- Why are we implementing right route connections

McLaren
HEALTH CARE

McLaren Health Care Service Area

Our patients are impacted!

- Nutrition
- Fluids
- Medications
- Therapies



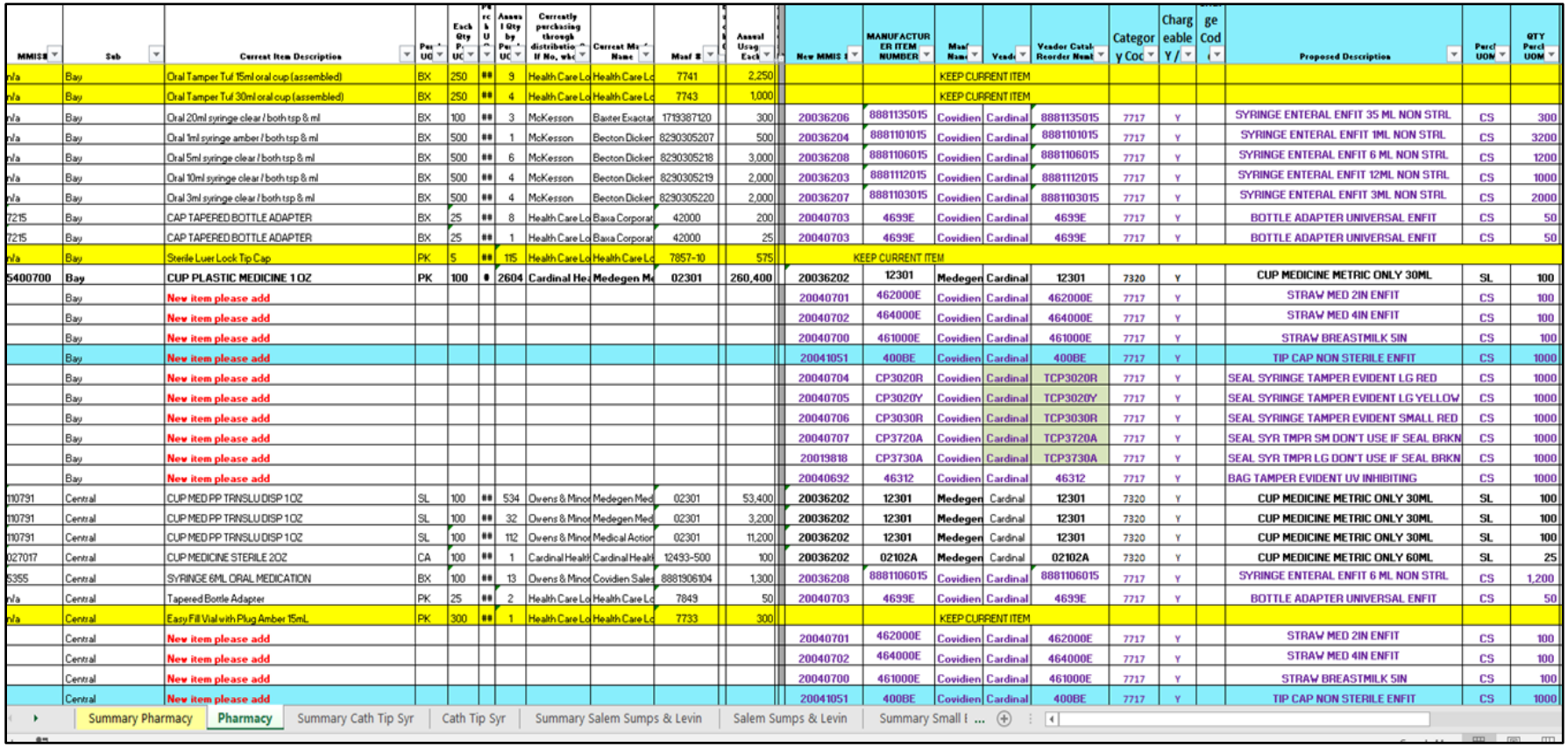
Other individuals impacted

- Nurses/Caregivers
- Pharmacy
- Home Care
- Supply Chain
- Providers/Surgeons

Who needs to be involved to create successful implementation?

- Top down approach to engaging stakeholders:
  - CNO, CMO, Directors of Pharmacy, Directors of Surgery, Directors of Nursing Education, Case Management/Discharge Planning
  - Required from subsidiary leadership identified point persons for each care area or discipline
  - Outlined the known quantities as well as areas of perceived potential exposure
  - Called on all clinical corporate level groups to educate on the initiative, then to facilitate process and planning

Steps taken to prepare for implementation

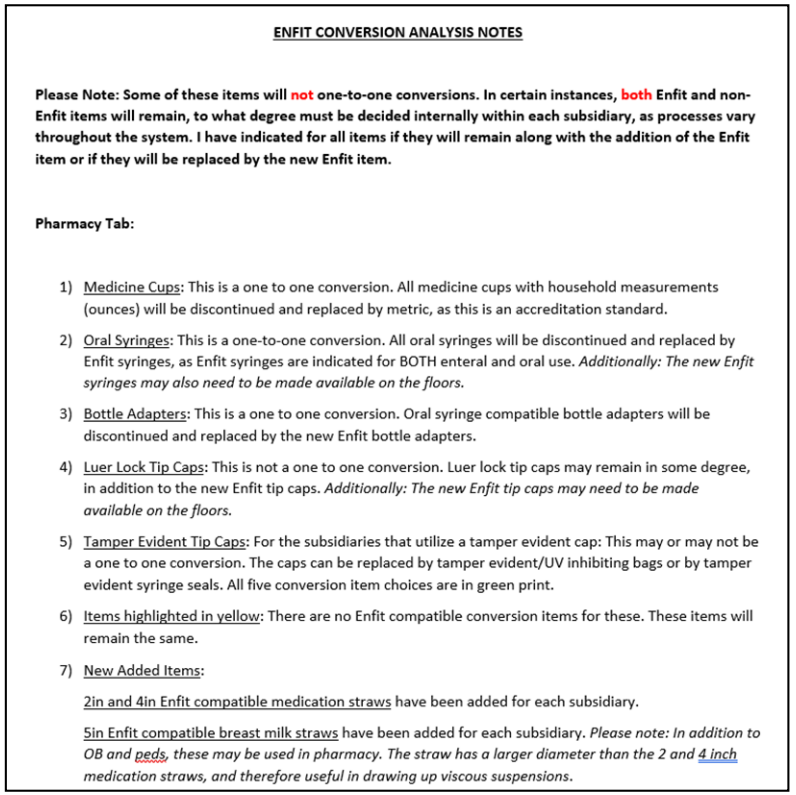


MMIS #	Sub	Current Item Description	Par UOM	Each Qty Per UOM	Pack UOM	Annual Qty by Par UOM	Currently purchasing through distribution? If No, why	Current Mfr Name	Mnuf #	Annual Usage Each	New MMIS #	MANUFACTURER ITEM NUMBER	Mnuf Name	Vendor	Vendor Catal Reorder Num	Category Code	Chargeable Y/N	Charge Code	Proposed Description	Purch UOM	QTY Purch UOM
n/a	Bay	Oral Tamper Tuf 15ml oral cup (assembled)	BX	250	##	9	Health Care Lo	Health Care Lo	7741	2,250			KEEP CURRENT ITEM								
n/a	Bay	Oral Tamper Tuf 30ml oral cup (assembled)	BX	250	##	4	Health Care Lo	Health Care Lo	7743	1,000			KEEP CURRENT ITEM								
n/a	Bay	Oral 20ml syringe clear / both tsp & ml	BX	100	##	3	McKesson	Baxter Exactar	1719387120	300	20036206	8881135015	Covidien	Cardinal	8881135015	7717	Y		SYRINGE ENTERAL ENFIT 35 ML NON STRL	CS	300
n/a	Bay	Oral 1ml syringe amber / both tsp & ml	BX	500	##	1	McKesson	Becton Dicker	8290305207	500	20036204	8881101015	Covidien	Cardinal	8881101015	7717	Y		SYRINGE ENTERAL ENFIT 1ML NON STRL	CS	3200
n/a	Bay	Oral 5ml syringe clear / both tsp & ml	BX	500	##	6	McKesson	Becton Dicker	8290305218	3,000	20036208	8881106015	Covidien	Cardinal	8881106015	7717	Y		SYRINGE ENTERAL ENFIT 6 ML NON STRL	CS	1200
n/a	Bay	Oral 10ml syringe clear / both tsp & ml	BX	500	##	4	McKesson	Becton Dicker	8290305219	2,000	20036203	8881112015	Covidien	Cardinal	8881112015	7717	Y		SYRINGE ENTERAL ENFIT 12ML NON STRL	CS	1000
n/a	Bay	Oral 3ml syringe clear / both tsp & ml	BX	500	##	4	McKesson	Becton Dicker	8290305220	2,000	20036207	8881103015	Covidien	Cardinal	8881103015	7717	Y		SYRINGE ENTERAL ENFIT 3ML NON STRL	CS	2000
7215	Bay	CAP TAPERED BOTTLE ADAPTER	BX	25	##	8	Health Care Lo	Baxa Corporat	42000	200	20040703	4699E	Covidien	Cardinal	4699E	7717	Y		BOTTLE ADAPTER UNIVERSAL ENFIT	CS	50
7215	Bay	CAP TAPERED BOTTLE ADAPTER	BX	25	##	1	Health Care Lo	Baxa Corporat	42000	25	20040703	4699E	Covidien	Cardinal	4699E	7717	Y		BOTTLE ADAPTER UNIVERSAL ENFIT	CS	50
n/a	Bay	Sterile Luer Lock Tip Cap	PK	5	##	115	Health Care Lo	Health Care Lo	7857-10	575	KEEP CURRENT ITEM										
5400700	Bay	CUP PLASTIC MEDICINE 1 OZ	PK	100	0	2604	Cardinal Hea	Medegen Me	02301	260,400	20036202	12301	Medegen	Cardinal	12301	7320	Y		CUP MEDICINE METRIC ONLY 30ML	SL	100
	Bay	New item please add									20040701	462000E	Covidien	Cardinal	462000E	7717	Y		STRAW MED 2IN ENFIT	CS	100
	Bay	New item please add									20040702	464000E	Covidien	Cardinal	464000E	7717	Y		STRAW MED 4IN ENFIT	CS	100
	Bay	New item please add									20040700	461000E	Covidien	Cardinal	461000E	7717	Y		STRAW BREASTMILK 5IN	CS	100
	Bay	New item please add									20041051	400BE	Covidien	Cardinal	400BE	7717	Y		TIP CAP NON STERILE ENFIT	CS	1000
	Bay	New item please add									20040704	CP3020R	Covidien	Cardinal	TCP3020R	7717	Y		SEAL SYRINGE TAMPER EVIDENT LG RED	CS	1000
	Bay	New item please add									20040705	CP3020Y	Covidien	Cardinal	TCP3020Y	7717	Y		SEAL SYRINGE TAMPER EVIDENT LG YELLOW	CS	1000
	Bay	New item please add									20040706	CP3030R	Covidien	Cardinal	TCP3030R	7717	Y		SEAL SYRINGE TAMPER EVIDENT SMALL RED	CS	1000
	Bay	New item please add									20040707	CP3720A	Covidien	Cardinal	TCP3720A	7717	Y		SEAL SYR TMPR SM DON'T USE IF SEAL BRKN	CS	1000
	Bay	New item please add									20019818	CP3730A	Covidien	Cardinal	TCP3730A	7717	Y		SEAL SYR TMPR LG DON'T USE IF SEAL BRKN	CS	1000
	Bay	New item please add									20040692	46312	Covidien	Cardinal	46312	7717	Y		BAG TAMPER EVIDENT UV INHIBITING	CS	1000
110791	Central	CUP MED PP TRNSLU DISP 1 OZ	SL	100	##	534	Ovens & Minor	Medegen Med	02301	53,400	20036202	12301	Medegen	Cardinal	12301	7320	Y		CUP MEDICINE METRIC ONLY 30ML	SL	100
110791	Central	CUP MED PP TRNSLU DISP 1 OZ	SL	100	##	32	Ovens & Minor	Medegen Med	02301	3,200	20036202	12301	Medegen	Cardinal	12301	7320	Y		CUP MEDICINE METRIC ONLY 30ML	SL	100
110791	Central	CUP MED PP TRNSLU DISP 1 OZ	SL	100	##	112	Ovens & Minor	Medical Action	02301	11,200	20036202	12301	Medegen	Cardinal	12301	7320	Y		CUP MEDICINE METRIC ONLY 30ML	SL	100
027017	Central	CUP MEDICINE STERILE 2OZ	CA	100	##	1	Cardinal Health	Cardinal Health	12493-500	100	20036202	02102A	Medegen	Cardinal	02102A	7320	Y		CUP MEDICINE METRIC ONLY 60ML	SL	25
5355	Central	SYRINGE 6ML ORAL MEDICATION	BX	100	##	13	Ovens & Minor	Covidien Sales	8881906104	1,300	20036208	8881106015	Covidien	Cardinal	8881106015	7717	Y		SYRINGE ENTERAL ENFIT 6 ML NON STRL	CS	1,200
n/a	Central	Tapered Bottle Adapter	PK	25	##	2	Health Care Lo	Health Care Lo	7849	50	20040703	4699E	Covidien	Cardinal	4699E	7717	Y		BOTTLE ADAPTER UNIVERSAL ENFIT	CS	50
n/a	Central	Easy Fill Vial with Plug Amber 15mL	PK	300	##	1	Health Care Lo	Health Care Lo	7733	300			KEEP CURRENT ITEM								
	Central	New item please add									20040701	462000E	Covidien	Cardinal	462000E	7717	Y		STRAW MED 2IN ENFIT	CS	100
	Central	New item please add									20040702	464000E	Covidien	Cardinal	464000E	7717	Y		STRAW MED 4IN ENFIT	CS	100
	Central	New item please add									20040700	461000E	Covidien	Cardinal	461000E	7717	Y		STRAW BREASTMILK 5IN	CS	100
	Central	New item please add									20041051	400BE	Covidien	Cardinal	400BE	7717	Y		TIP CAP NON STERILE ENFIT	CS	1000

Summary Pharmacy | Pharmacy | Summary Cath Tip Syr | Cath Tip Syr | Summary Salem Sumps & Levin | Salem Sumps & Levin | Summary Small I ...

Implementation preparation

- Supply Chain prepared a text document to speak to each item
- Each affected product and clinical area had a full text rationale to ensure clarity of communication



ENFIT CONVERSION ANALYSIS NOTES

Please Note: Some of these items will not one-to-one conversions. In certain instances, both Enfit and non-Enfit items will remain, to what degree must be decided internally within each subsidiary, as processes vary throughout the system. I have indicated for all items if they will remain along with the addition of the Enfit item or if they will be replaced by the new Enfit item.

Pharmacy Tab:

1) Medicine Cups: This is a one to one conversion. All medicine cups with household measurements (ounces) will be discontinued and replaced by metric, as this is an accreditation standard.
2) Oral Syringes: This is a one-to-one conversion. All oral syringes will be discontinued and replaced by Enfit syringes, as Enfit syringes are indicated for BOTH enteral and oral use. *Additionally: The new Enfit syringes may also need to be made available on the floors.*
3) Bottle Adapters: This is a one to one conversion. Oral syringe compatible bottle adapters will be discontinued and replaced by the new Enfit bottle adapters.
4) Luer Lock Tip Caps: This is not a one to one conversion. Luer lock tip caps may remain in some degree, in addition to the new Enfit tip caps. *Additionally: The new Enfit tip caps may need to be made available on the floors.*
5) Tamper Evident Tip Caps: For the subsidiaries that utilize a tamper evident cap: This may or may not be a one to one conversion. The caps can be replaced by tamper evident/UV inhibiting bags or by tamper evident syringe seals. All five conversion item choices are in green print.
6) Items highlighted in yellow: There are no Enfit compatible conversion items for these. These items will remain the same.
7) New Added Items:

   2in and 4in Enfit compatible medication straws have been added for each subsidiary.

   5in Enfit compatible breast milk straws have been added for each subsidiary. *Please note: In addition to OB and peds, these may be used in pharmacy. The straw has a larger diameter than the 2 and 4 inch medication straws, and therefore useful in drawing up viscous suspensions.*

- Custom packs
- Direct order from areas that infrequently order
- Off label uses for tubes
- Unit dose vs. multi dose from pharmacy
- Med Omnis/Pyxis
- Light protection
- Fecal management systems

When did we start?

- System transition began with Phase 1 of ENFit, tube feeding sets
  - Stage 1 of ENFit became available in our area in late 2014/early 2015
  - Supply Chain messaging began in late 2014

- ENFit as agenda item on all product related discussion across all disciplines
  - ENFit stayed on various agendas as a placeholder for updates as Phase 2 delays were encountered

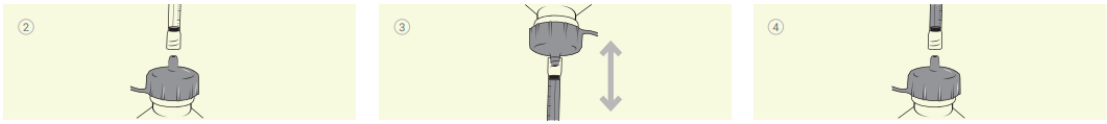
- Once FDA approval was obtained for redesigned items, planning for Stages 2 (med admin implements) and 3 (implanted and nonimplanted tubes) resumed

Procedure for Inpatient Settings:
Preparing and Administering Medications Using ENFit®

GEDSA
Unite. Connect. Deliver.

MEDICATION PREPARATION: FILLING A SYRINGE USING A BOTTLE FILL CAP

Step 1. Make sure that the medciation bottle has an ENFit compatible fill cap.



Step 2. Attach syringe to the bottle adapter.

Step 3. Turn medication bottle upside down. Pull back desired dose after cycling syringe.

Step 4. Turn bottle right side up and remove syringe.

FILLING THE SYRINGE WITH A MEDICATION STRAW

When an ENFit bottle cap will not fit the medication bottle or it is impossible to remove the current bottle adapter, fill the syringe using a medication straw.

Step 1. Connect the ENFit medication straw to syringe.

Step 2. Insert straw, cycle syringe to eliminate air bubbles. Draw up desired dose.

Step 3. Disconnect syringe from straw and gently tap/flick to remove excess fluid around moat.

FILLING THE SYRINGE USING A MEDICATION CUP

NOTE: Filling the syringe via a dose cup is not the preferred method for filling the syringe.

ENFit® Tool Kit

A hands on teaching tool to demonstrate ENFit connections.

DIMENSIONS:

Closed: 18.5" x 6" x 13"

Set up: 31" x 23" x 13"

$25 + Shipping & Handling

WHAT'S INCLUDED?

- Interactive Demonstration Model
- ENFit Background
- Medication Preparation Guide
- Patient Discharge Talk Sheet
- Transition Team Manual
- StayConnected Wristlets & Brochures
- ENFit product bins
- Assembly Instructions

INTENDED USERS:

Anyone directly impacted by the ENFit transition including: nurses, educators, administrators, pharmacists, home care providers, supply chain managers, risk managers, patient safety officers, distributors, HME, DME enteral tube feeders, and caregivers.

HOW TO ORDER:

Email info@gedsa.org

Implementation planning for phases 2 and 3

Kick off meetings- crucial to successful roll out!

- No way to know or project how all areas within an institution or organization currently practice or use products today

Discharge planning

- Involve those responsible for discharge planning as early as possible

Educate partners in the community on ENFit and its implementation- early and often!

How phases 2 and 3 were implemented

- In short, a Big Bang
- Suggested initial order quantities provided to each subsidiary along with order placement date
- Proposed alternative methods o for placing supplies

- 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

Implementation follow up

ENFit phase 3 has been somewhat protracted for my organization due to manufacturer delays in having full line of both implanted and nonimplanted tubes available.

- Our strategy has been to push out updates on tube availability on a quarterly basis with a refreshed cross reference analysis
- Our implanted tube rep has repeatedly revisited our procedural areas to provide physician and staff education each time a new SKU becomes available
- We continue to push out tube information updates through the same channels Surgical Services, Nursing, Medical Staff Education, etc.

Specific questions from end users in my system

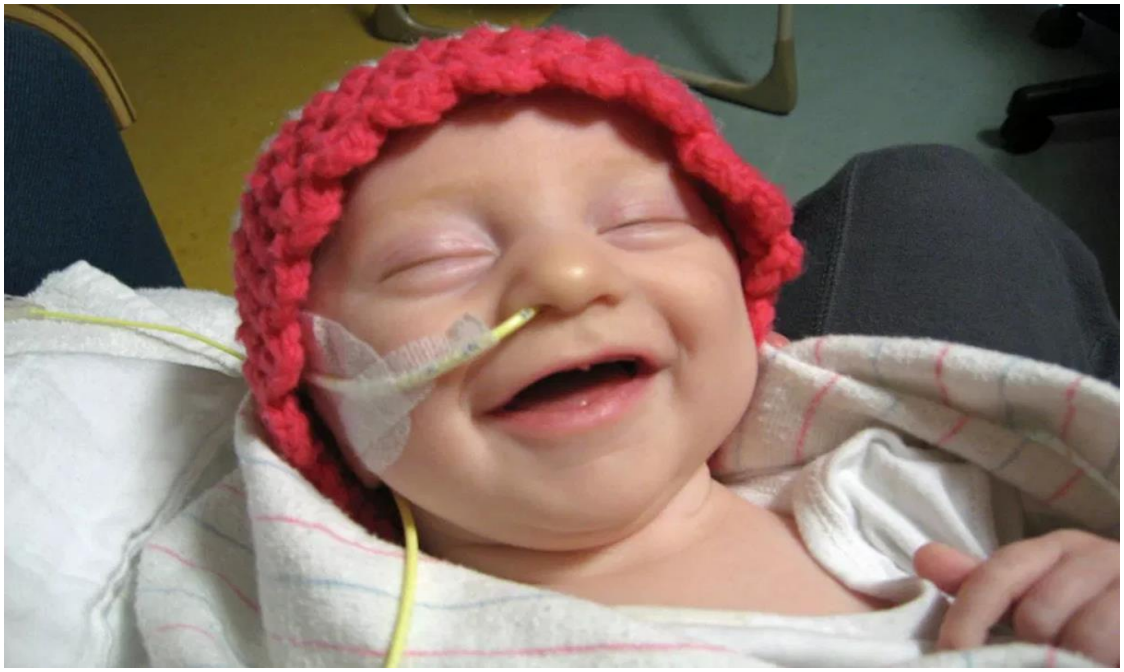
- Can we select color coded ENFit items?
  - Color coding is not included in the ISO 80369 standards.
  - FDA specifically recommends NOT using color coding as a safety mechanism (Department of Health and Human Services, 2013)
  - Despite FDA guidance cautioning against color coding, trend towards color coding persists and is a selling feature for some ENFit manufacturers
  - Individual Vendors may have specific colors for their ENFit designed products, but this will vary by manufacturer
  - Bottom line-The color of a product is not a safety feature!

- Can we use an adapter instead of bringing in all these different items?
  - Fair question in light of the need to manage space requirements
  - End users may not initially appreciate that creating a system strategy around use of adapters does not eliminate the risk of wrong route misconnection

- Uses for slip tip syringes won’t go away with implementation of ENFit
- It may be necessary to make accessible the full complement of ENFit items (in reasonable quantities) in the majority of care areas
- Bottle adapters, tip caps, straws, etc. that may not have previously been needed in certain areas may be needed following ENFit implementation

Why are we doing this?

Because we know that route specific connectors can substantially reduce or eliminate the risk of harm and death.



Industry Support and Reference I found helpful

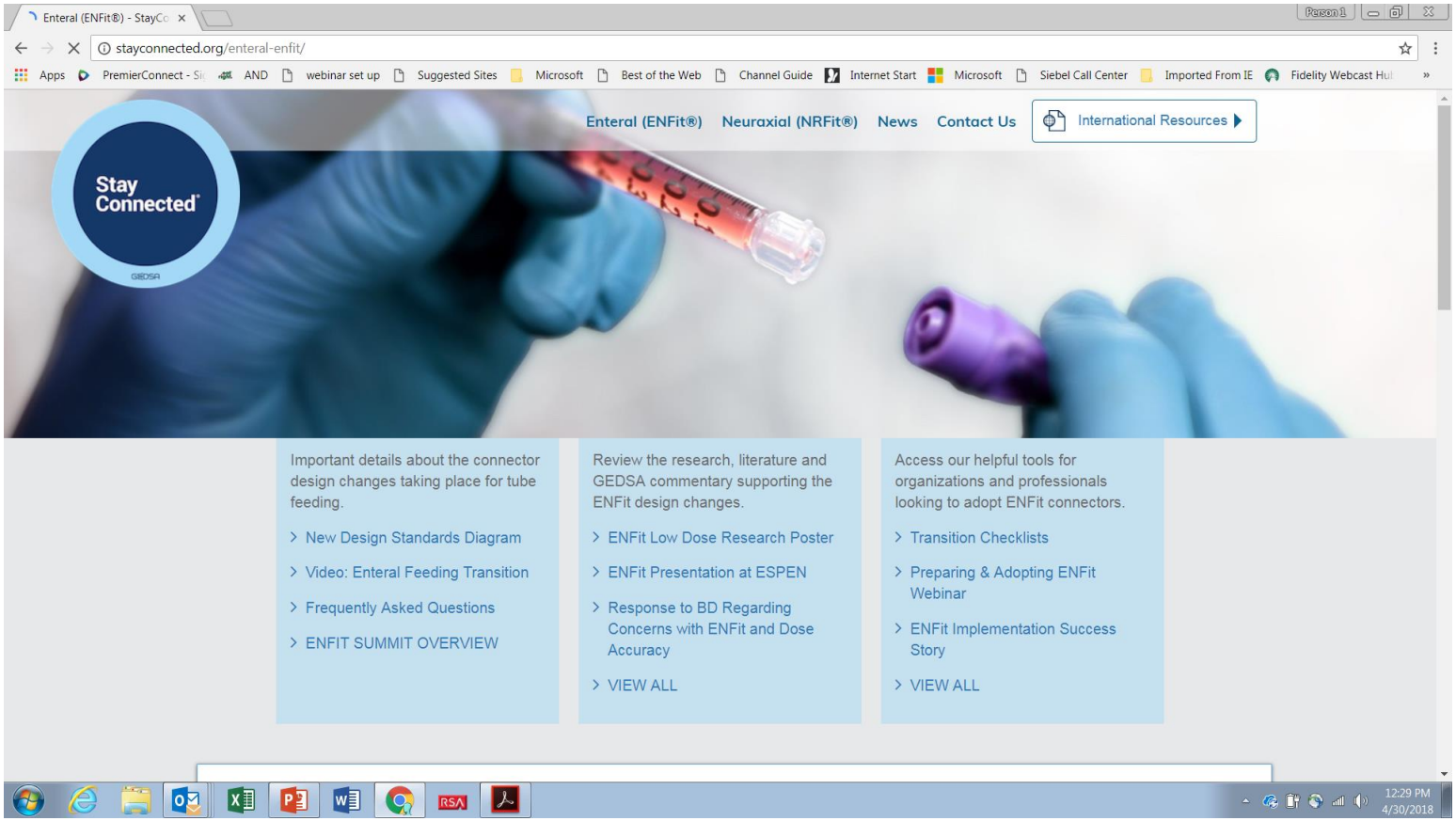
- ECRI published a guidance article for public use, to urge facilities to become ENFit compliant (Excellent high level overview)

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

- Safe Medication Practices www.ismp.org
- ASPEN https://www.nutritioncare.org/
- Premier Safety Institute www.premierinc.com/tubingmisconnections
- Premier supply chain resources

GEDSA Website

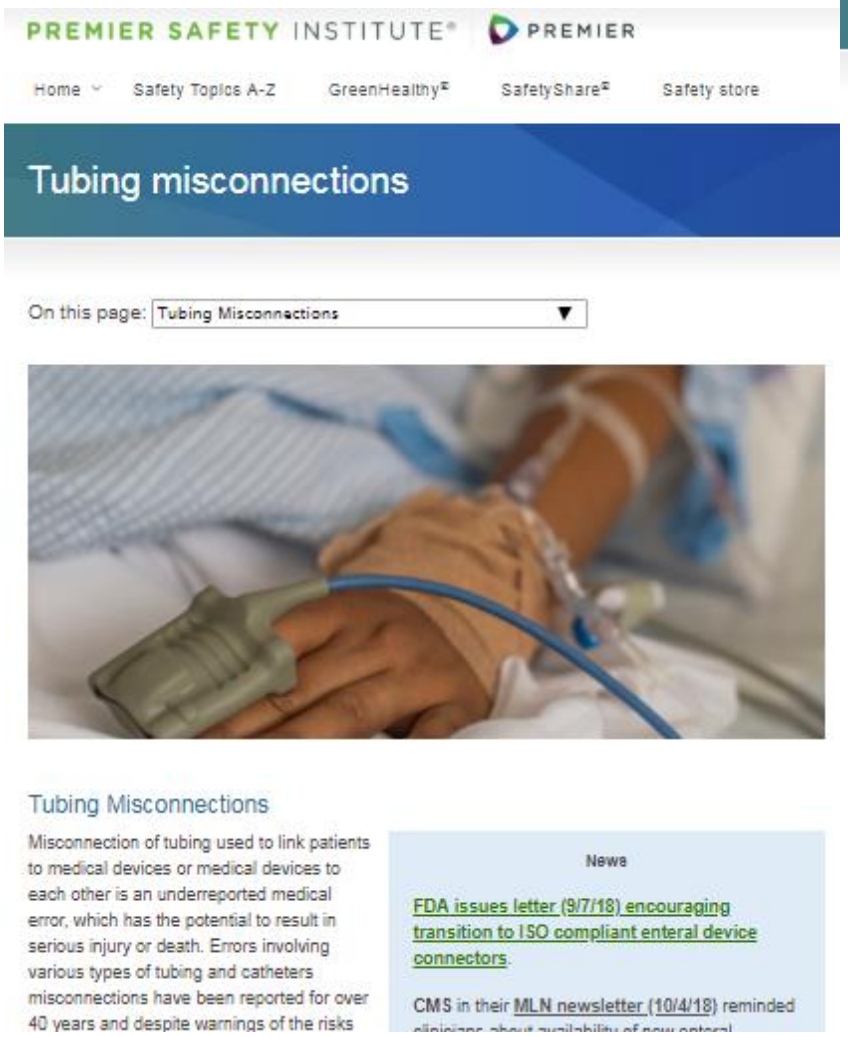
www.stayconnected.org

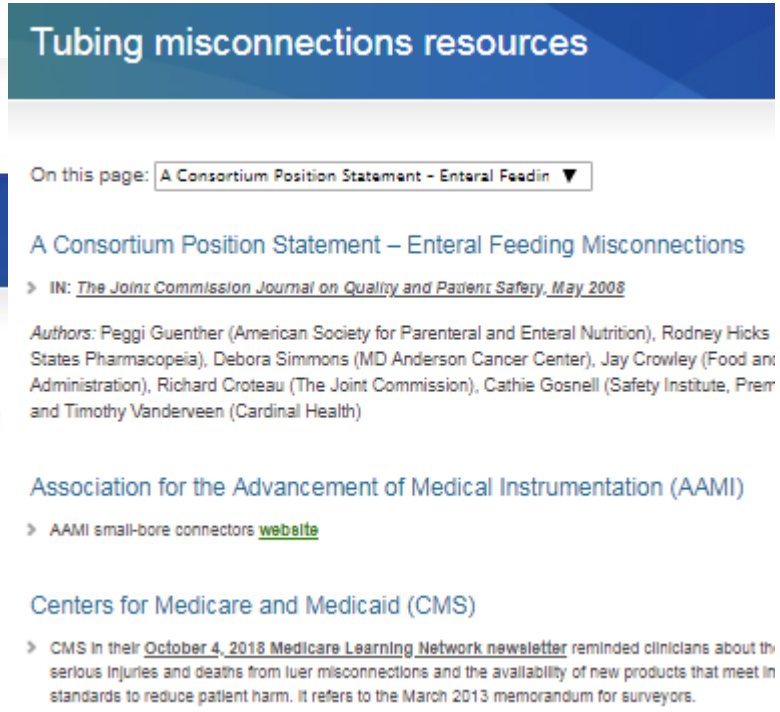


In Conclusion

- Switching to the ENFit enteral feeding system is the right thing to do for patient safety
- It involves much planning
- Involve key stakeholders
- Communication is the key
- It is an ongoing process

Premier Safety Institute
www.premierinc.com/tubingmisconnections





Resources from:
AAMI, ASPEN, CMS,FDA, GEDSA, ECRI, ISMP, Joint Commission, Stay Connected

*Source or Footnote = Arial Regular 8pt

Questions?

Today's Speakers

Moderator: Gina Pugliese RN MS

Vice President Emeritus , Premier Safety Institute ®

Debby Kasper, RDN, LDN

Director, Premier Inc.

Mark J. Antonino, MS

Food and Drug Administration (FDA)
Center for Devices and Radiologic Health (CDRH)

Mike Cusack, MBA

Executive Director, GEDSA Global Enteral Device Supplier Association

Amy Monroe, RN, BSN

Corporate Manager, Strategic Sourcing, McLaren Health Care

Speakers Contact Information

Debby Kasper, RDN, LDN

Director

Premier, Inc.

debby_kasper@premierinc.com

Mark J. Antonino, MS

Food and Drug Administration (FDA)

Center for Devices and Radiologic Health (CDRH)

Mark.Antonino@fda.hhs.gov

Mike Cusack, MBA

Executive Director

GEDSA Global Enteral Device Supplier Association

Mike@gesda.org

Amy Monroe RN, BSN

Corporate Manager Clinical Sourcing

Supply Chain Management

McLaren Health Care

amy.monroe@mclaren.org