PRIMERAS JORNADAS:

ACTUALIZACIÓN EN NUTRICIÓN PARA FARMACÉUTICOS ESPECIALISTAS EN FARMACIA HOSPITALARIA

Solicitada acreditación S.N.S.

Aplicación de las nuevas normas ISO en el material fungible de nutrición enteral. Mejorando la seguridad del paciente.

Dra. Mariola Sirvent
Grupo HLA-Vistahermosa
Alicante

Aplicación de las nuevas normas ISO en el material fungible de nutrición enteral. Mejorando la seguridad del paciente.

1. Exponer las causas que han provocado el cambio de diseño en el material fungible empleado para administrar Nutrición Enteral.
2. Explicar con detalle en qué consisten estos nuevos cambios.
3. Dar a conocer la situación actual de estos productos en el mercado español
4. Recomendaciones para implantar el cambio

Enteral Misconnection

Definition: An inadvertent connection between an enteral feeding system and a non-enteral system such as an intravascular catheter, peritoneal dialysis catheter, tracheostomy, medical gas tubing,etc.

Also known as a wrong route error or small bore misconnection

Guenter et al. *The Joint Commission Journal on Quality and Patient Safety* May 2008;34:285-292

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American Society for Parenteral and Enteral Nutrition

Current Literature

Contributing Editor—Praveen Goday, MBBS, CNSP
Pediatric Gastroenterology and Nutrition,
Medical College of Wisconsin, Milwaukee, Wisconsin

Nutrition in Clinical Practice
Volume 23 Number 6
December 2008 664-665

10.1177/0884533608326324
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Enteral Feeding Misconnections: A Consortium Position Statement

P Guenter, RW Hicks, D Simmons, et al

Because of the voluntary nature of adverse event reporting systems and the fear of consequences of reporting serious mistakes resulting in patient harm, the published reports may represent only a small portion of actual incidents. A review of the USP MED-MARX and USP–Institute for Safe Medications Practices (ISMP) Medication Errors

24 casos comunicados en 7 años;
1/3 de consecuencias fatales;
Comunicación voluntaria; frecuencia infraestimada

Reported Enteral Misconnections and Related Factors (Jan. 2000–Dec. 2006 USP data)

Related Factors	Cases	Sentinel Events	% Sentinel Event
Use of Syringe Pump and IV Tubing	1	0	0%
Use of Ready-to-Hang Enteral Containers/Bags and IV Tubing	3	2	66%
Enteral Meds Administered IV (Used IV Syringe)	13	3	23%
Other Solution Intended for Enteral Route given IV	4	2	50%
Enteral Tube Not in Place, Med Given IV	3	1	33%
Total	24	8	33%

Guenter et al. *The Joint Commission Journal on Quality and Patient Safety* (2008).

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Impact of Misconnections

A 24-year-old woman was 35 weeks pregnant hospitalized for vomiting and dehydration. A bag of ready to hang enteral feeding was brought to the floor, and the nurse, assuming it was total parenteral nutrition, which the woman had received on previous admissions, pulled regular intravenous tubing from floor stock, spiked the bag, and started the infusion of tube feeding through the patient's peripherally inserted central catheter line. The fetus died—and then the mother. Guenter et al. *The Joint Commission Journal on Quality and Patient Safety* May 2008;34:285-292.

Una equivocación fatal que acabó en tragedia

La enfermera que alimentó a Ryan pudo confundir dos tubos idénticos

ELENA G. SEVILLANO

Madrid - 15 JUL 2009

La enfermera que alimentaba a Ryan pudo confundir los tubos. Los dos eran iguales. Un error que algunos especialistas tildan "de manual". La alerta de no confundir los cables es de las primeras cosas que aprenden estos profesionales. Los expertos analizan al detalle lo sucedido. Aunque lo que realmente pudo pasar se sabrá tras la investigación.

Invited Review

Enteral Feeding Misconnections: An Update

Nutrition in Clinical Practice
Volume 24 Number 3
June/July 2009 325-334

10.1177/0884533609335174
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Peggi Guenter, PhD, RN, CNSN[1]; Rodney W. Hicks, PhD, MSN, MPA, ARNP[2]; and Debora Simmons, MSN, RN, CCRN, CCNS[3]

Financial disclosure: none declared.

Enteral misconnections are defined as inadvertent connections between enteral feeding systems and nonenteral systems such as intravascular lines, peritoneal dialysis catheters, tracheostomy tube cuffs, medical gas tubing, and so on. Sentinel event data and causative factors are outlined along with potential solutions to prevent such medical errors. The solutions can be grouped into 3 areas: (1) education, awareness, and human factors; (2) purchasing strategies; and (3) design changes. Updates on safety innovations and programs are presented. (*Nutr Clin Pract*. 2009;24: 325-334)

Keywords: enteral nutrition; safety

Invited Review

Tubing Misconnections: Normalization of Deviance

Debora Simmons, RN, MSN, CCRN, CCNS[1,2];
Lene Symes, RN, PhD[1]; Peggi Guenter, RN, PhD, CNSN[3];
and Krisanne Graves, RN, MSN, CPHQ[1]

Financial disclosure: none declared.

Nutrition in Clinical Practice
Volume 26 Number 3
June 2011 286-293

10.1177/0884533611406134
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Analizan 116 casos comunicados;
21 con consecuencias fatales (fallecimiento)

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ADMINISTRATI

Home Food Drugs

Medical Devices

Home › Medical Devices

Reducing Risks Associa
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ISMP

Institute for Safe Medication Practices

A Nonprofit Organization Educating the Healthcare Communit

Home Support ISMP Newsletters Webinars

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PREVENTIN

From the July 15, 2010 iss

Catheter/tubing misconne
fatal event. Over Memorial
gastrointestinal disorder, d
given via a central line intra

In May 2010, another report
an upper gastrointestinal stu
child. *Am J Health-Syst Pharm*
(CVC) in place for antibiotic t
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child was discharged 4 days l

Luer connector systems, comm
syringes, have been at the hear
reported problems is the fact th
administration sets and syringes
transferred to a parenteral syrin
administration of the drug via a

Below are examples of the type o
which we've described in this new

- IV infusions connected to ep
- Syringe containing IV medica
- IV tubing connected to inflati
- Sequential compression devic
administration set
- Oxygen tubing connected to p

development for
devices.

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Tubing Miscon
Patient Safety

Pa Patient Saf Advis 2010 J

ABSTRACT

Som e patients may hav
m edication and nutritio
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January 2008 and Se
Pennsylvania Patient
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Introduction

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Joint Commis
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Pharmacopei
intended for IV deliveryconnected
strategies and recommendations, which are included
below.

There are many types of misconnections; however, this article will focus on liquid-to-liquid and

aspen

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TUBE FEEDING MISCONNECTIONS: FATAL MEDICAL MISTAKES

Key Position Statement Released on Addressing This Often Deadly Error

Silver Spring, MD-April 15, 2008 The American Society for Parenteral and Enteral Nutrition announces the release of a pivotal position paper entitled **Enteral Feeding Misconnections: A Consortium Position Statement**, published in the May issue of *The Joint Commission Journal on Quality and Patient Safety*. The position statement brings to light an important and often fatal complication in which tube feeding formula is accidentally connected to intravenous or other lines or catheters for which it was not intended.

Patients receiving tube feeding therapy, or enteral nutrition, are unable to feed themselves and are frequently among the most critically ill patients. They often have many other types of tubes such as IVs, oxygen, or drainage tubes. An enteral tube feeding should be placed into the stomach and when it is mistakenly hooked to another of these many tubes, this is called an enteral misconnection.

One family sadly affected by this complication recently told their story to the lead author of the paper. A young pregnant woman was erroneously given tube feeding formula into her IV line, resulting in the death of her 35-week fetus, and shortly thereafter, the death of the patient as well. The patient's mother stated, *"There were multiple mistakes made by more than one person that led to the death of my daughter and granddaughter. Human error, short staffing, and disregard for hospital standards all played a role in this tragedy. However, I believe if the enteral feeding bag had not been accessible to regular IV tubing the other mistakes would not have come into play."*

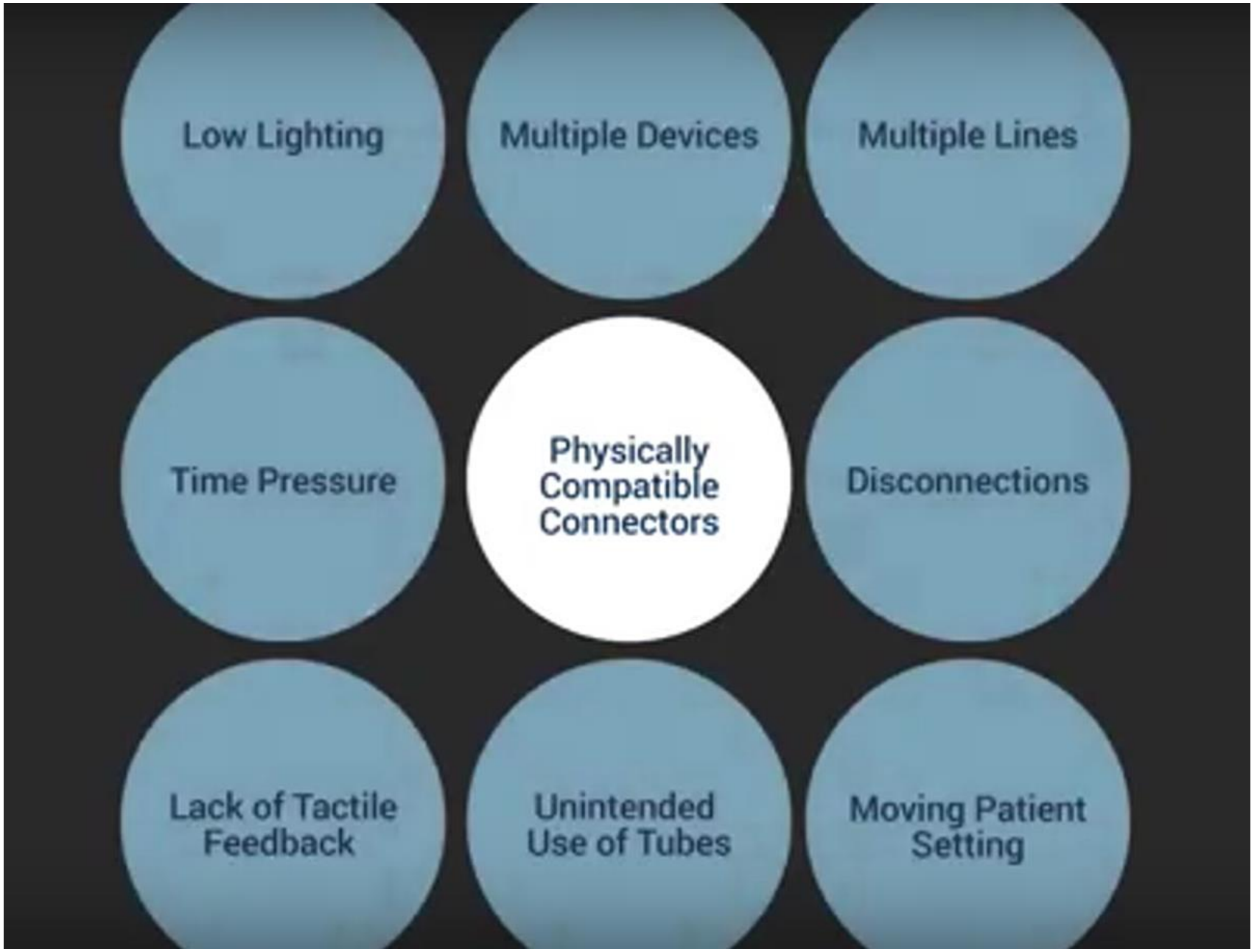
This enteral feeding misconnections article includes a definition of the problem, descriptions and concerns with existing enteral feeding systems in the marketplace, and contributing factors that can lead to this complication. Recommended solutions are also highlighted, including changes in health care education and human factors, better purchasing strategies, and manufacturing design changes. Addressing this problem requires cooperation from the enteral equipment industry, health care purchasing groups and clinicians.

ce the collaboration of the position paper consortium began, and through advocacy efforts many others, stakeholders are beginning discussions to initiate improvements. facturers are implementing significant changes in enteral system designs and with the tion of clinicians, hopefully no patient or family will have to endure this type of tragedy

Questions

this article and a companion article by Simmons

ENTERAL MISCONNECTIONS: CONTRIBUTING FACTORS



Enteral Misconnections: Contributing Factors

Human Factors

- Healthcare clinician fatigue
- Distraction
- Lighting

Physical and Design Factors

- Compatible tubing between unlike systems
- ★ Luer connectors
- Use of IV syringes for oral meds
- Universal Spike for bags

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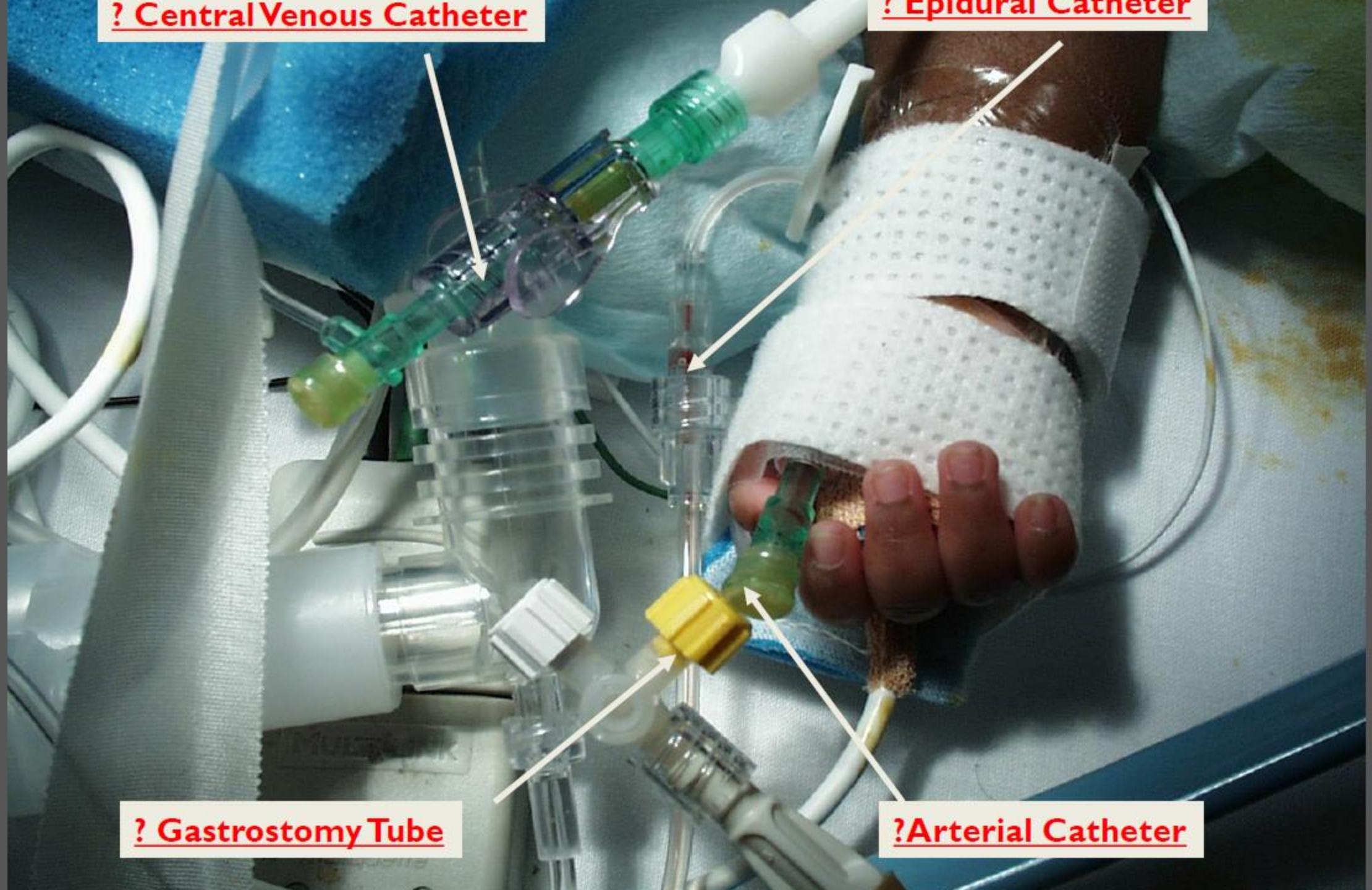
Aplicación de las nuevas normas ISO en el material fungible de nutrición enteral. Mejorando la seguridad del paciente.

A small-bore connector is a connector with

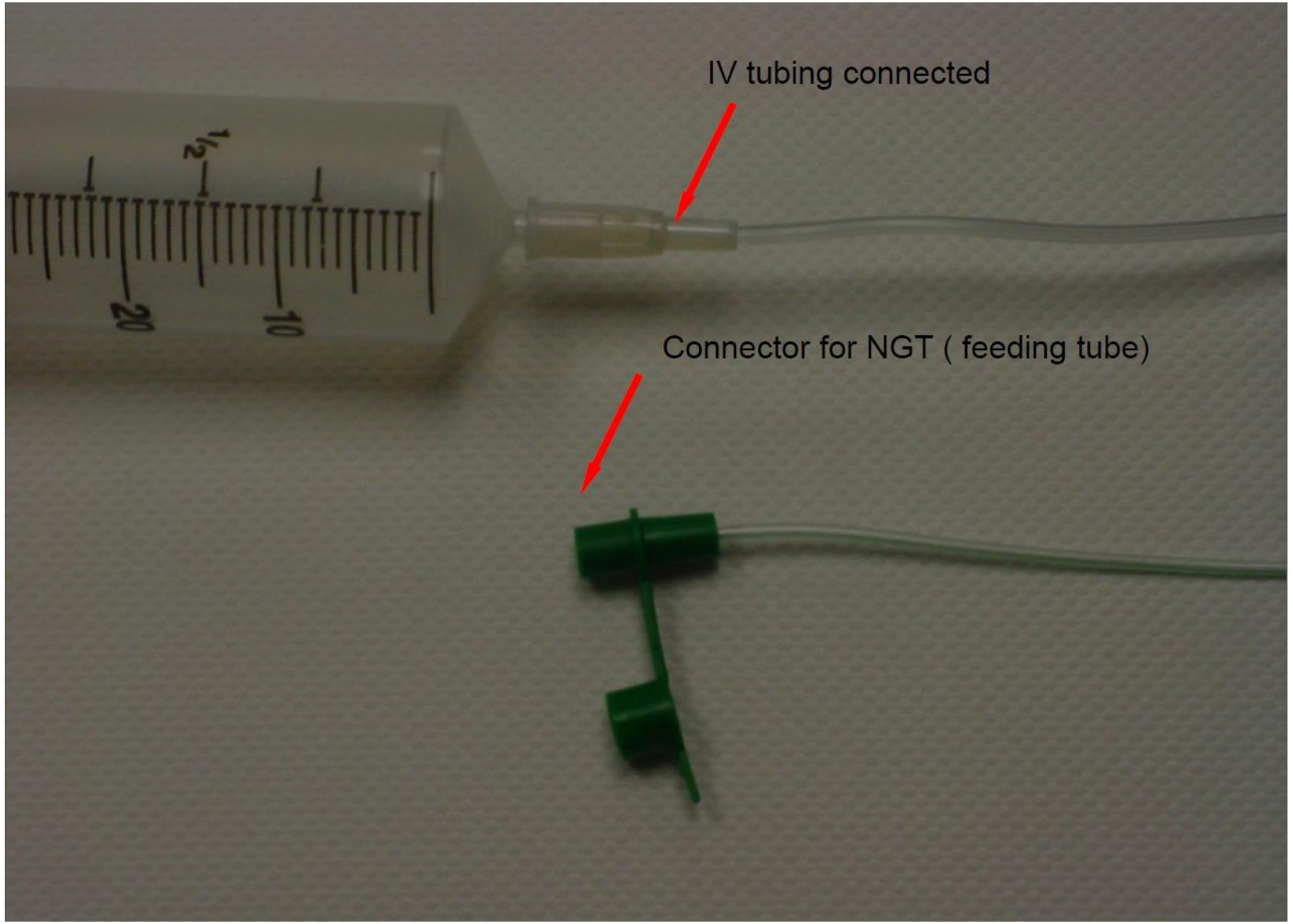
- an inner diameter of less than 8.5 mm
- used to link or join medical devices, components, and accessories
- for the purpose of delivering fluids or gases.

A Luer connector is a classic type of a small-bore connector used commonly in the healthcare setting- **a universal connector.**


? Central Venous Catheter
? Epidural Catheter
? Gastrostomy Tube
?Arterial Catheter

Aplicación de las nuevas normas ISO en el material fungible de nutrición enteral. Mejorando la seguridad del paciente.

Las conexiones universales permiten acoplar una jeringa i.v. a una sonda de alimentación y a una línea i.v.



A Global Effort to Enhance Patient Safety

Stay Connected

ISO 80369-3:2016(en) Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications

An additional part on connectors for urethral and urinary applications is planned.

Introduction

This part of ISO 80369 was developed because of several incidents, with catastrophic consequences, resulting from firstly, the administration of inappropriate medication into the alimentary canal and secondly, from ENTERAL solutions being administered via incorrect routes, including intravenously and into the airway. Many incidents were reported leading to international recognition of the importance of these issues, and a need was identified to develop specific CONNECTORS for MEDICAL DEVICES and their ACCESSORIES used to deliver feed via the ENTERAL route.

The ISO 80369 series has been developed to prevent misconnection between SMALL-BORE CONNECTORS used in different APPLICATIONS. ISO 80369-1 specifies the requirements necessary to verify the designs of SMALL-BORE CONNECTORS to ensure that

a) they do not misconnect with other SMALL-BORE CONNECTORS, and

b) they safely and securely connect with their mating half.

ISO 80369-20 contains the common TEST METHODS to support the performance requirements for SMALL-BORE CONNECTORS.

This part of ISO 80369 specifies the design, the dimensions, and the drawings of SMALL-BORE CONNECTORS intended to be used in ENTERAL APPLICATIONS. Annex D to Annex G describe the methods by which this design has been assessed. Other parts of ISO 80369 include requirements for SMALL-BORE CONNECTORS used in different APPLICATION categories.

CONNECTORS manufactured to the dimensions set out within this part of ISO 80369 are dimensionally incompatible with any of the other CONNECTORS for APPLICATIONS identified in the ISO 80369 series for SMALL-BORE CONNECTORS, except as indicated in G.2. If fitted to the relevant MEDICAL DEVICES and ACCESSORIES, these CONNECTORS are to reduce the RISK of medication and liquid nutritional formula intended for ENTERAL administration from being delivered via an alternative route, such as intravenously or via an airway device.

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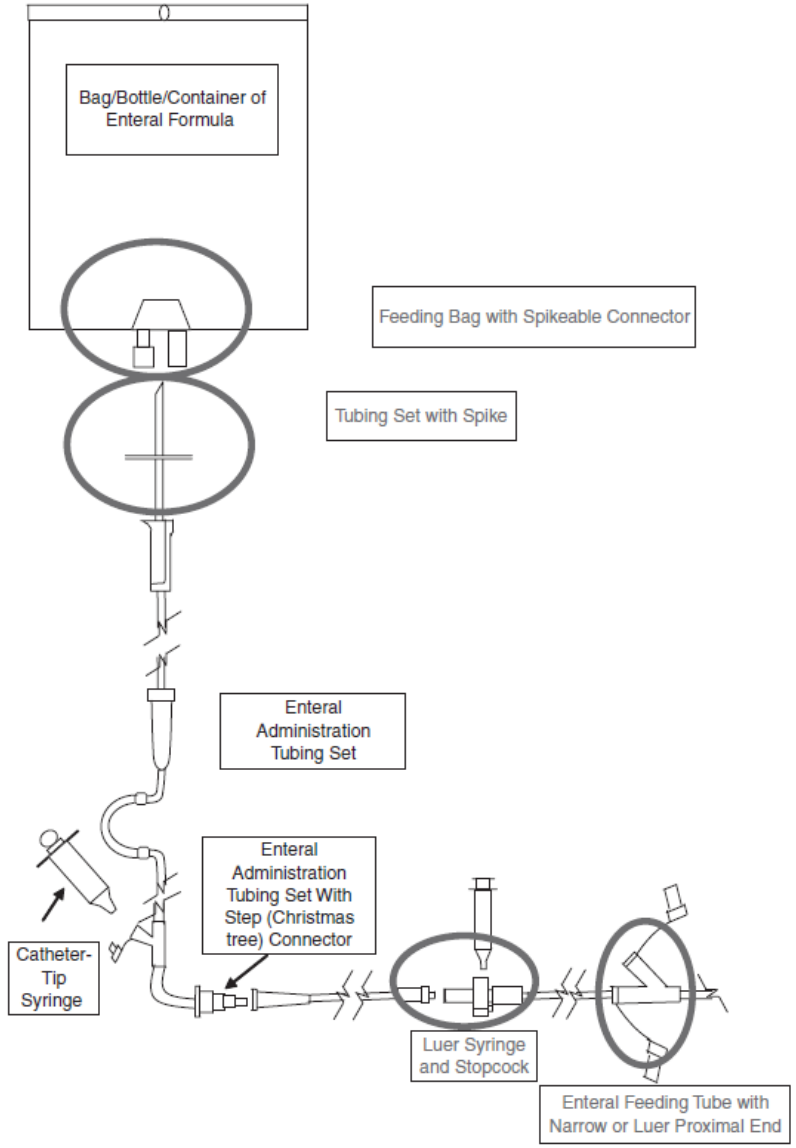
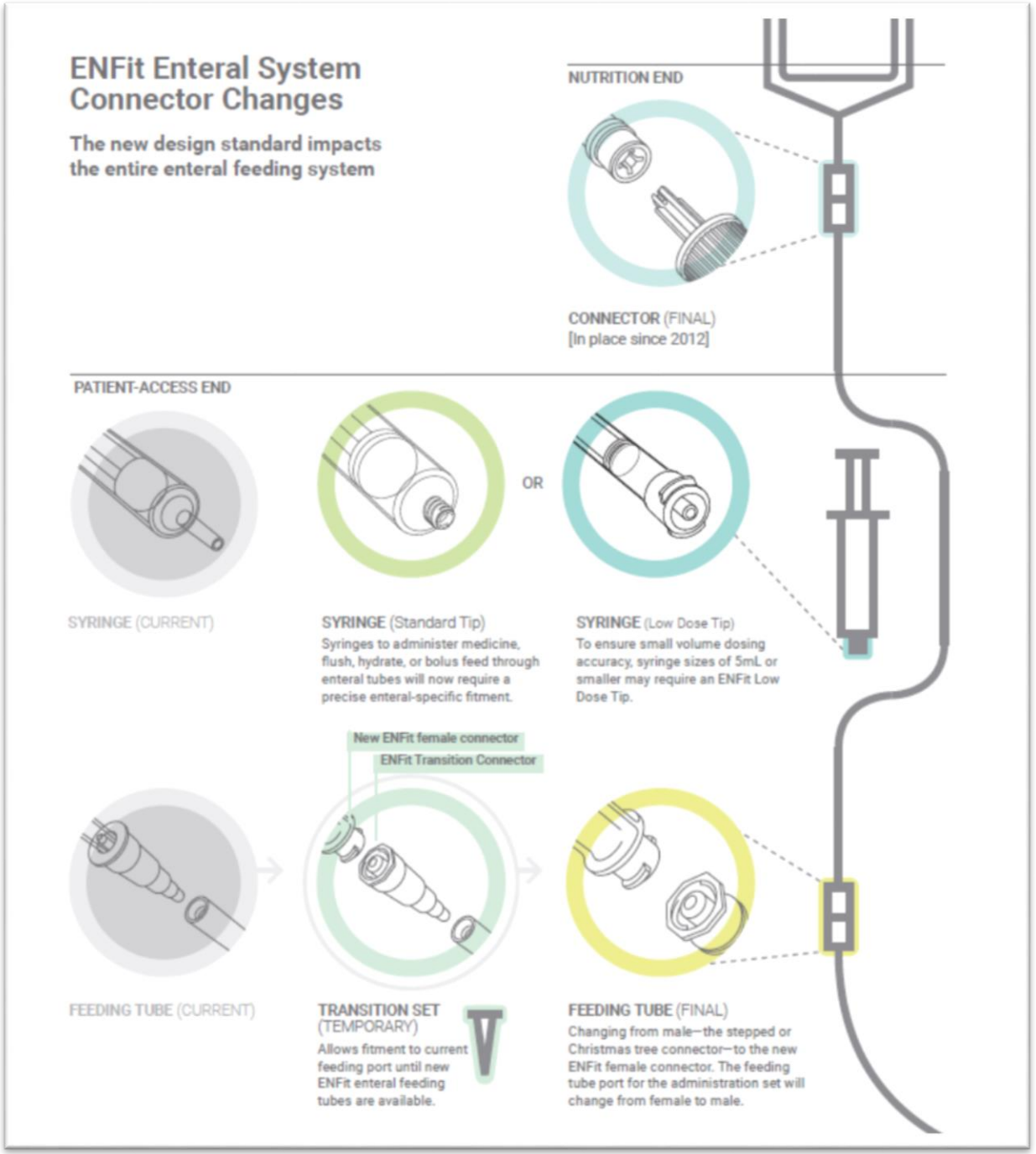
Puntos de Riesgo de Errores

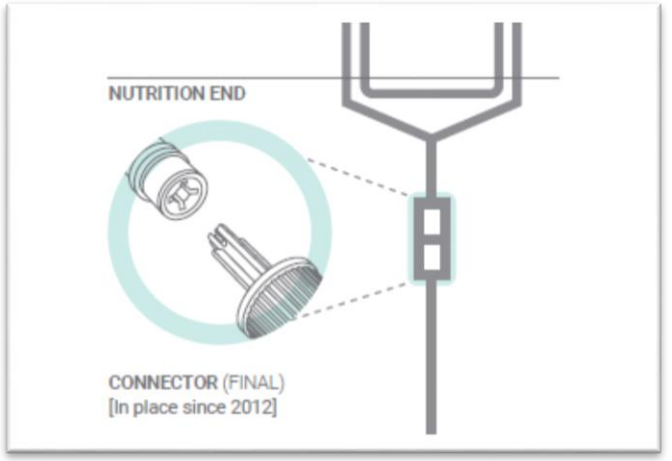


Los cambios realizados afectan a todo el sistema de administración



EQUIPO DE ADMINISTRACIÓN. CONEXIÓN PROXIMAL

DE



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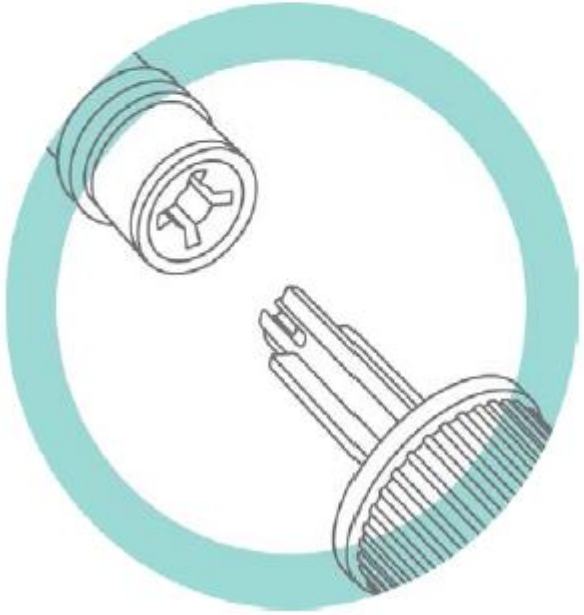
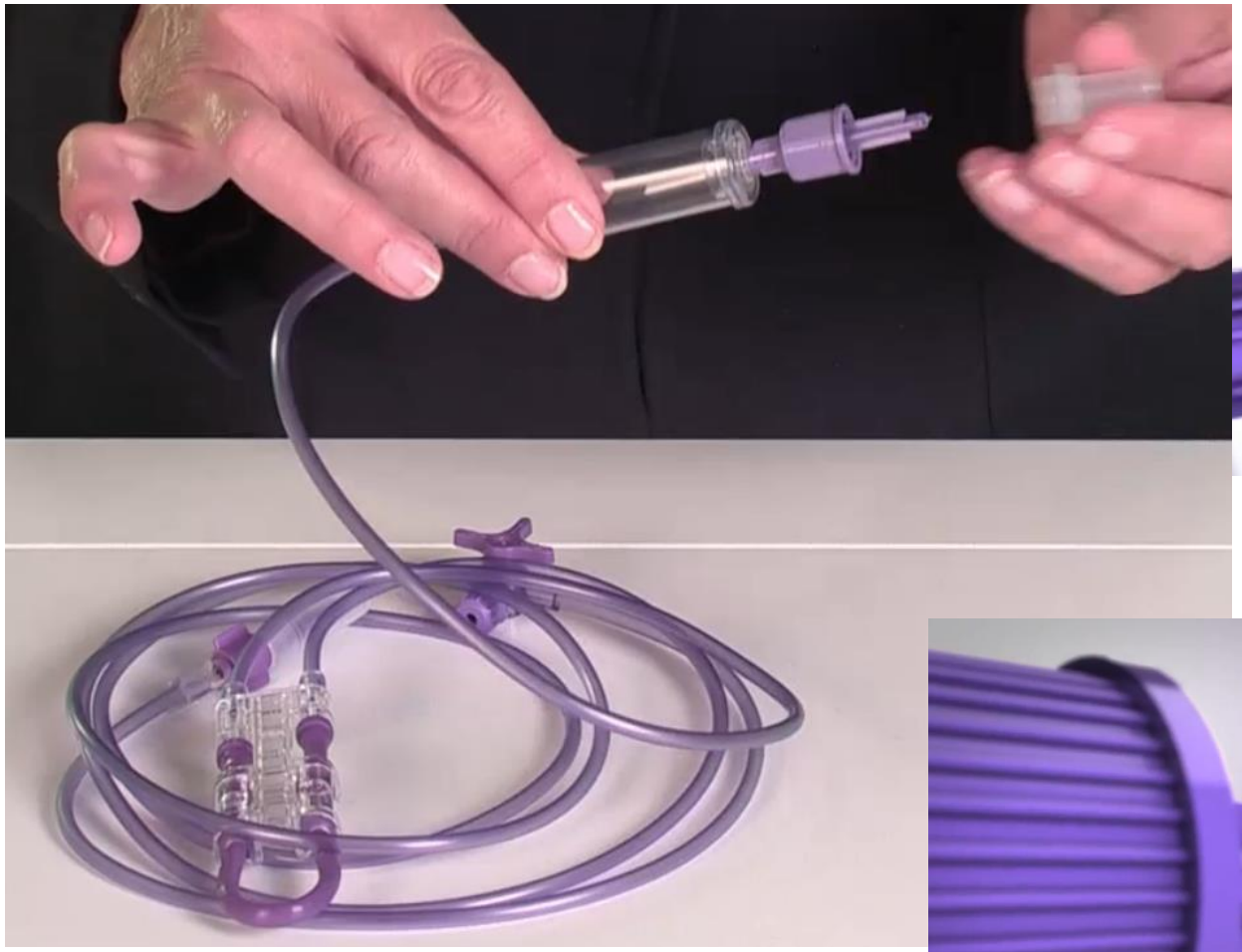
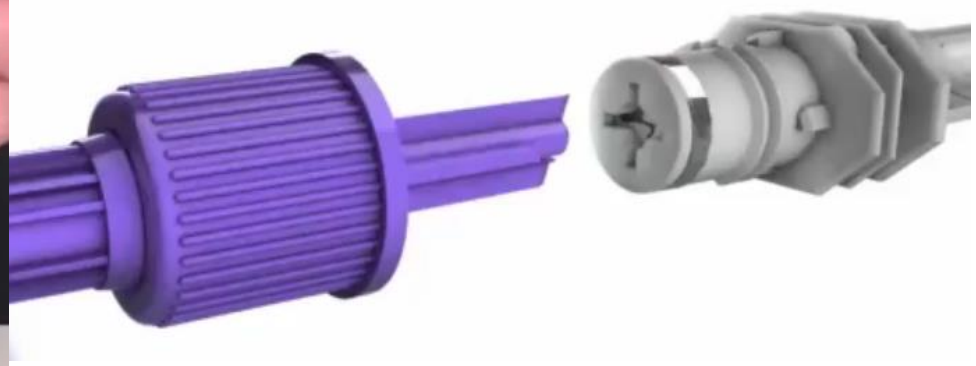
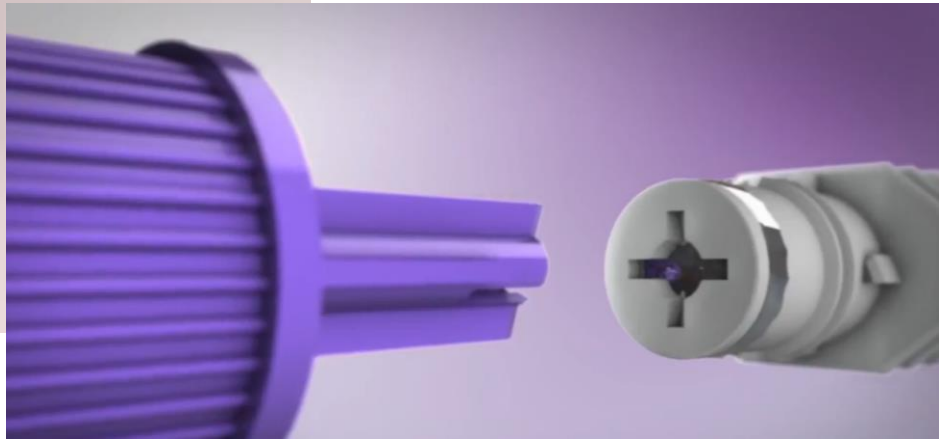


Previene la utilización de equipos de infusión intravenosos para la administración de nutrición enteral

EQUIPO DE ADMINISTRACIÓN. CONEXIÓN PROXIMAL







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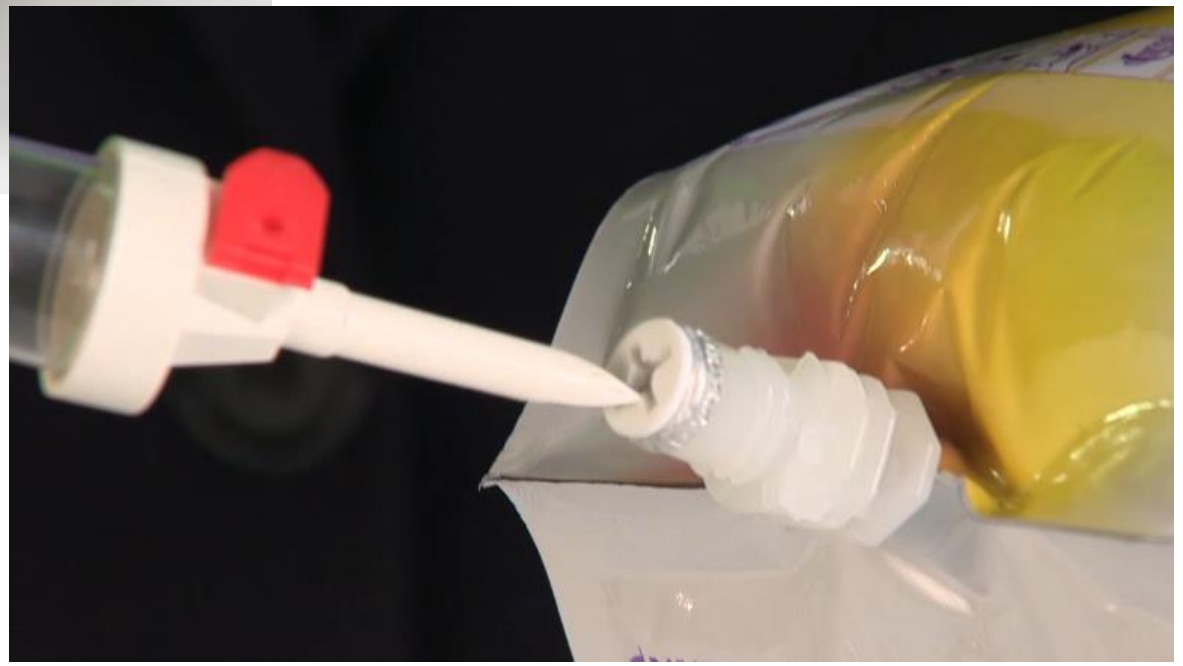
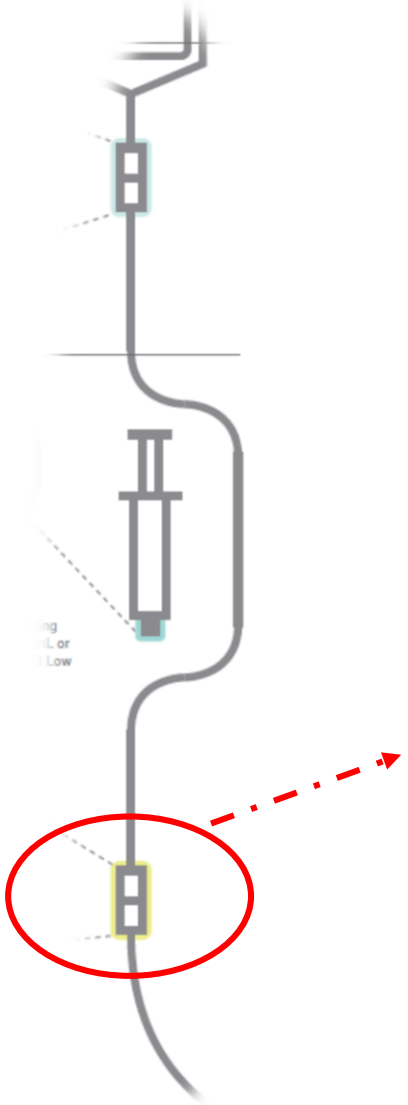


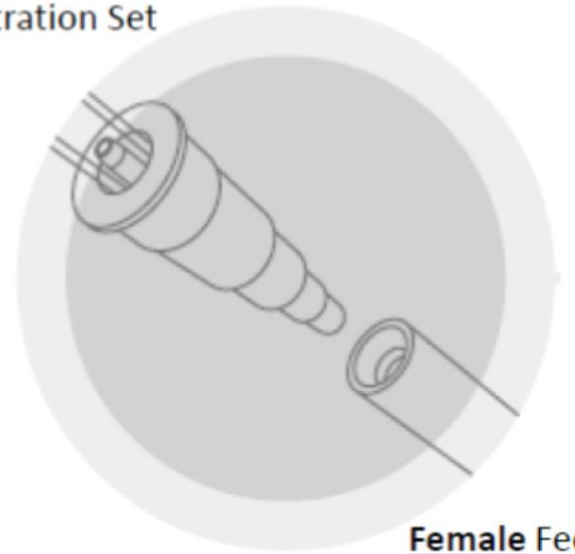
EQUIPO DE ADMINISTRACIÓN. CONEXIÓN PROXIMAL

EQUIPO DE ADMINISTRACIÓN. CONEXIÓN CON SONDA



CURRENT

Male Stepped or "Christmas Tree" Connector from Administration Set

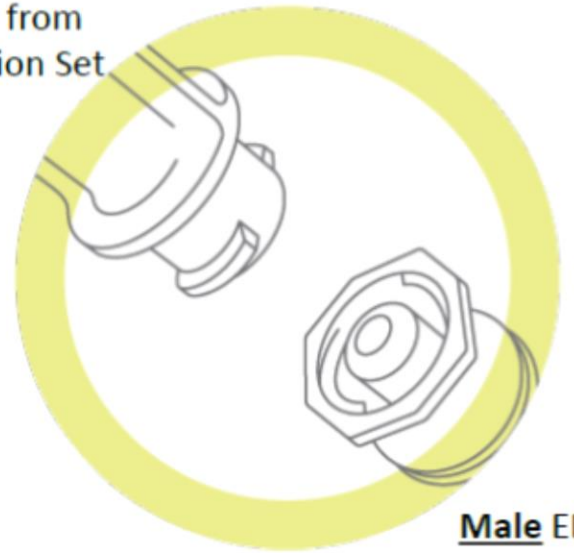


Female Feeding Tube Port

NEW

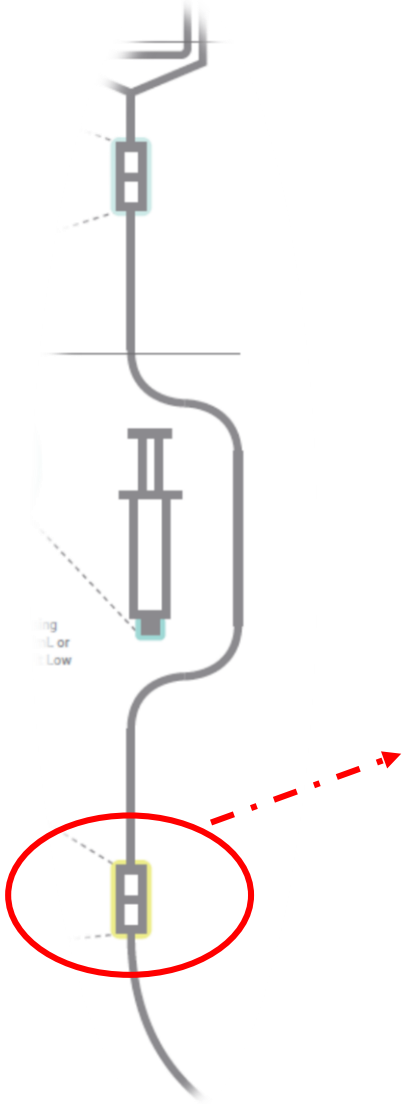
ENFit

Female ENFit Connector from Administration Set

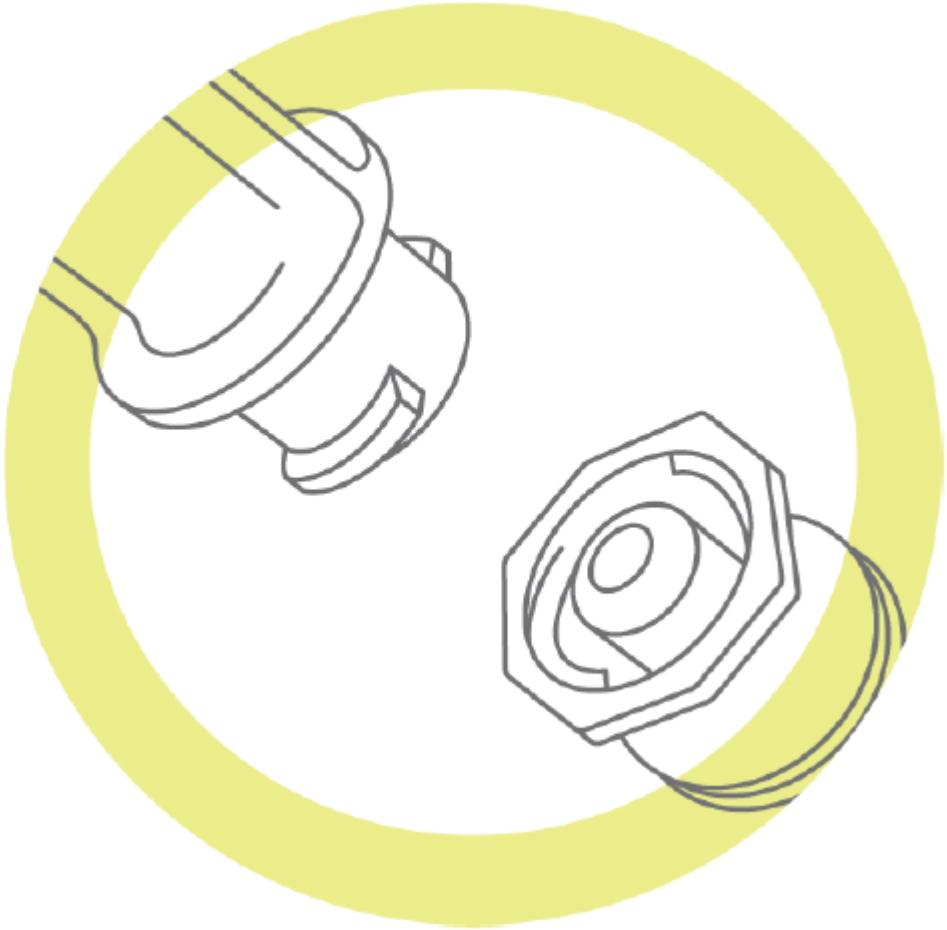


Male ENFit Connector for Feeding Tube

EQUIPO DE ADMINISTRACIÓN. CONEXIÓN CON SONDA

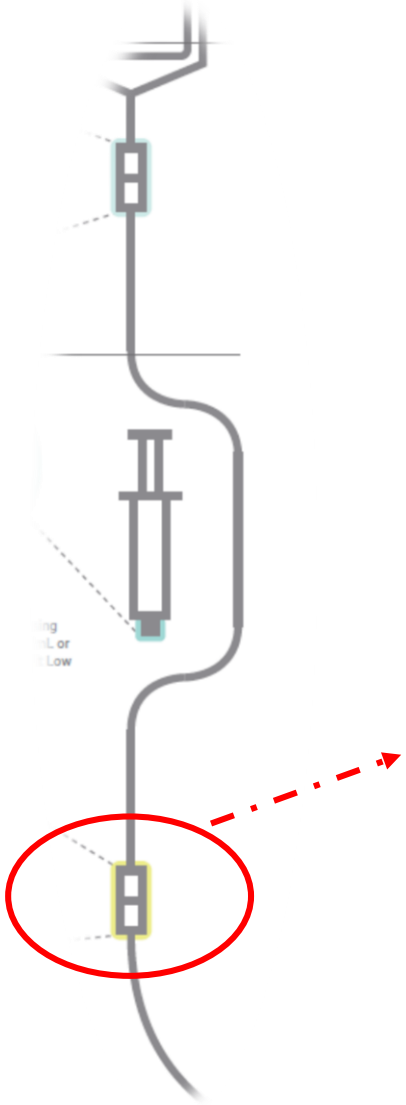


ENFit CONEXIÓN SONDA



- Cambia de conector hembra a conector macho
- Evita desconexiones accidentales
- Debe estar disponible en todo tipo de sondas (SNG, PEG, sonda yeyunal,…)

EQUIPO DE ADMINISTRACIÓN. CONEXIÓN CON SONDA



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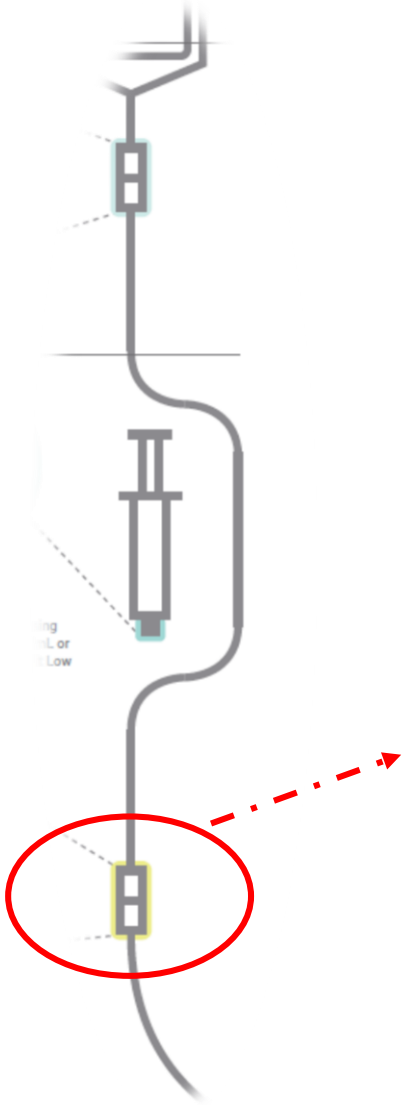
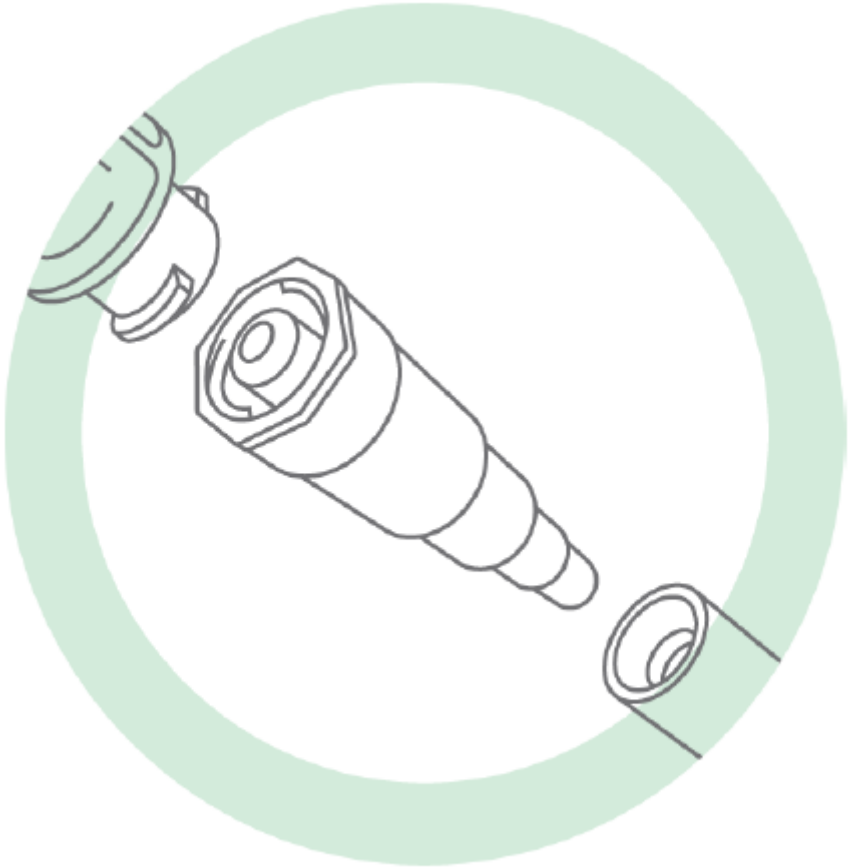
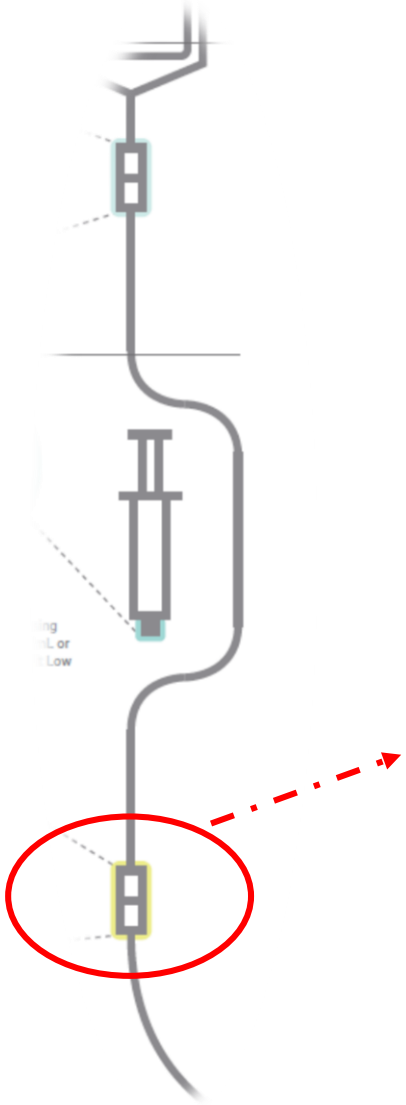


CONECTOR DE TRANSICIÓN



- **Permite conectar el nuevo equipo de administración con conector EnFit a las sondas de alimentación con conexión cónica o hembra**

EQUIPO DE ADMINISTRACIÓN. CONEXIÓN CON SONDA



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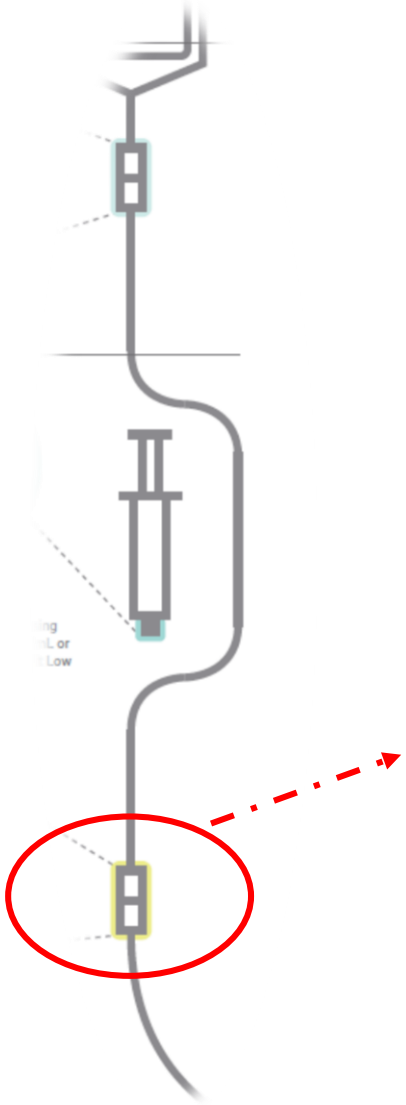
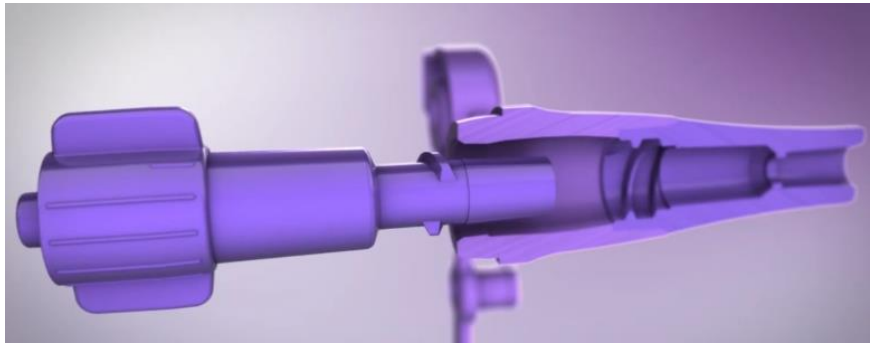
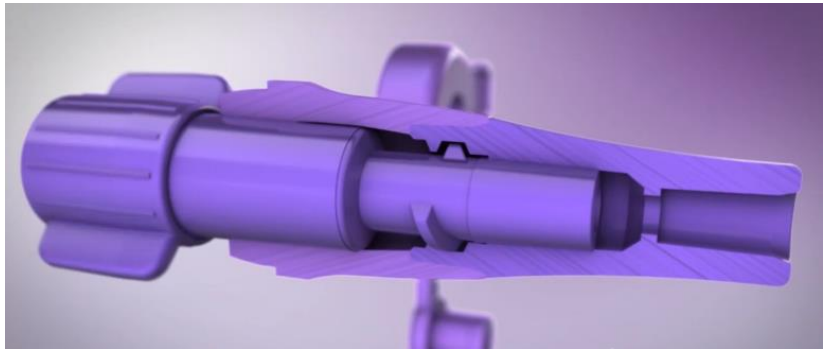


CONECTOR DE TRANSICIÓN: SISTEMA EN-Lock





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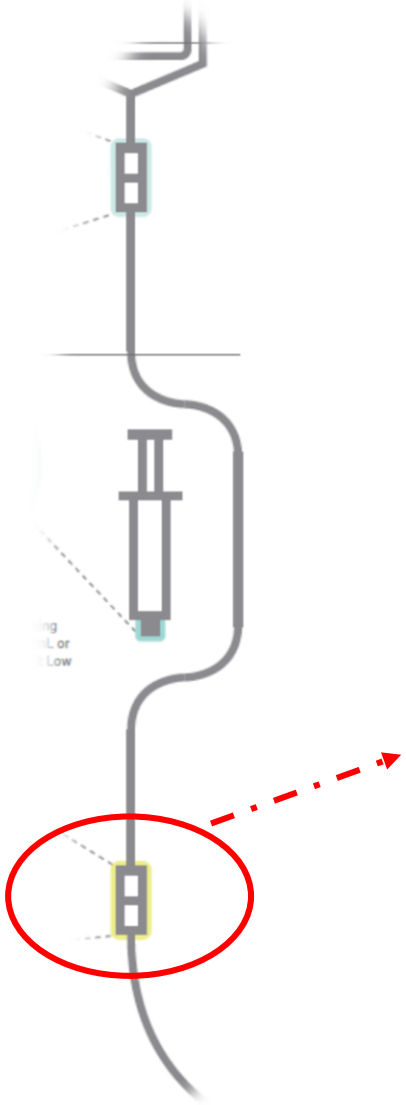
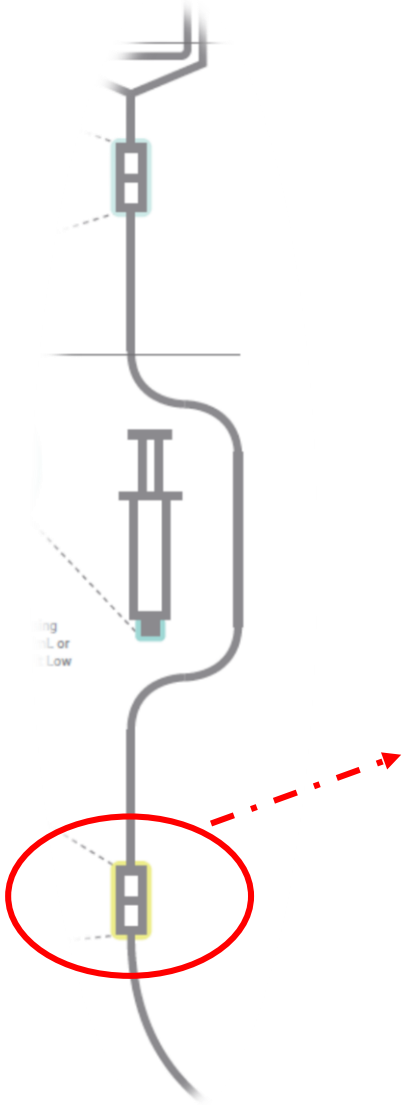
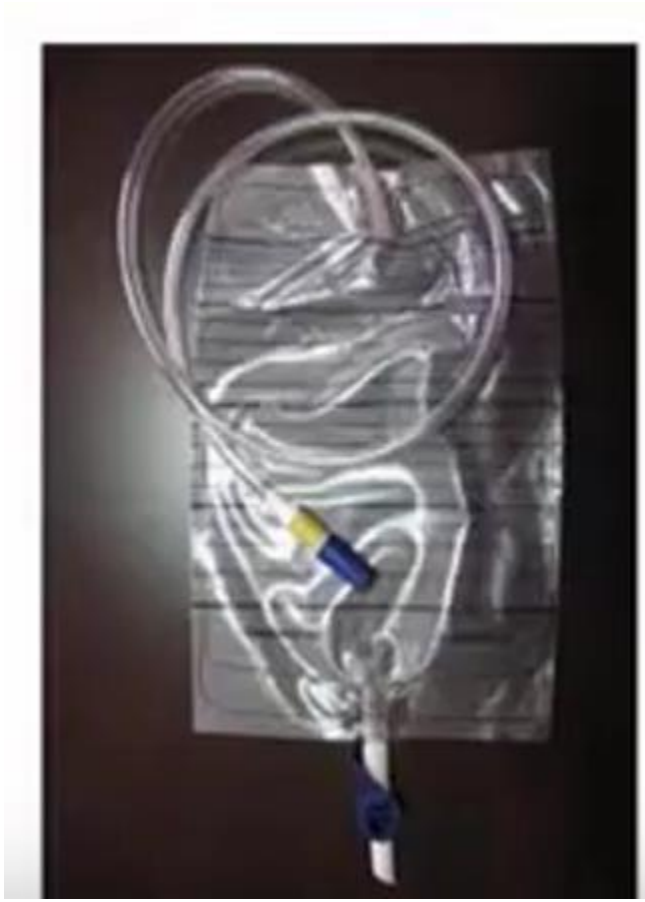


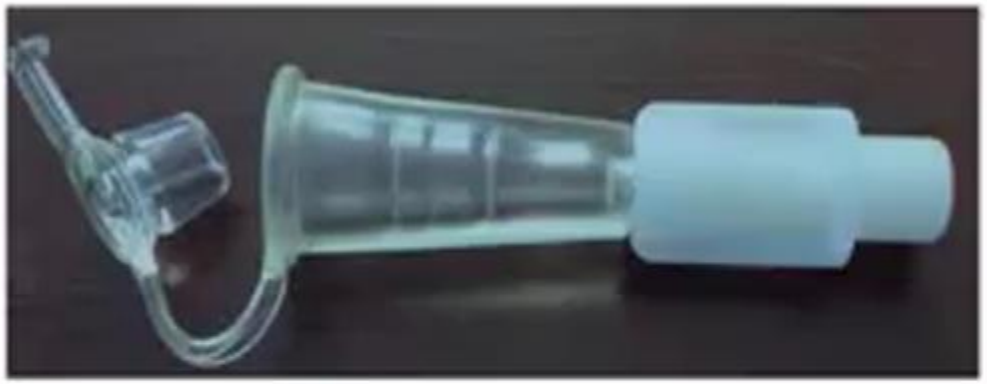
CONECTOR DE TRANSICIÓN:
SISTEMA EN-Lock

EQUIPO DE ADMINISTRACIÓN. CONEXIÓN CON SONDA

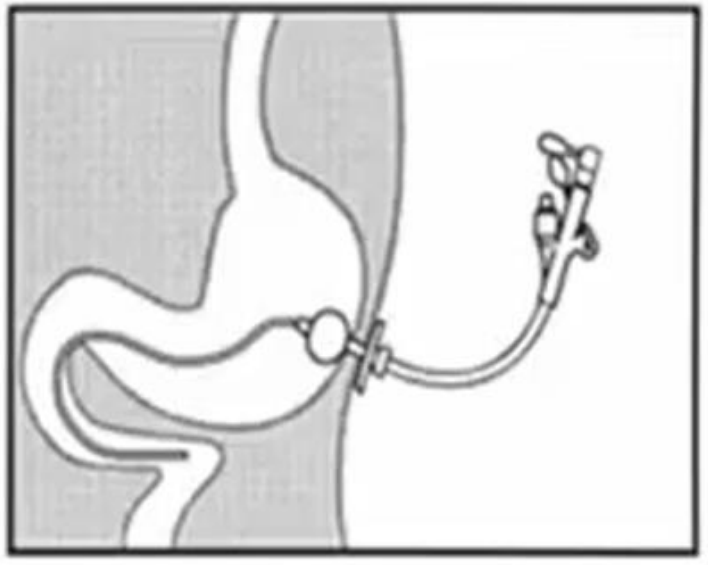


CONECTOR PARA DRENAJES

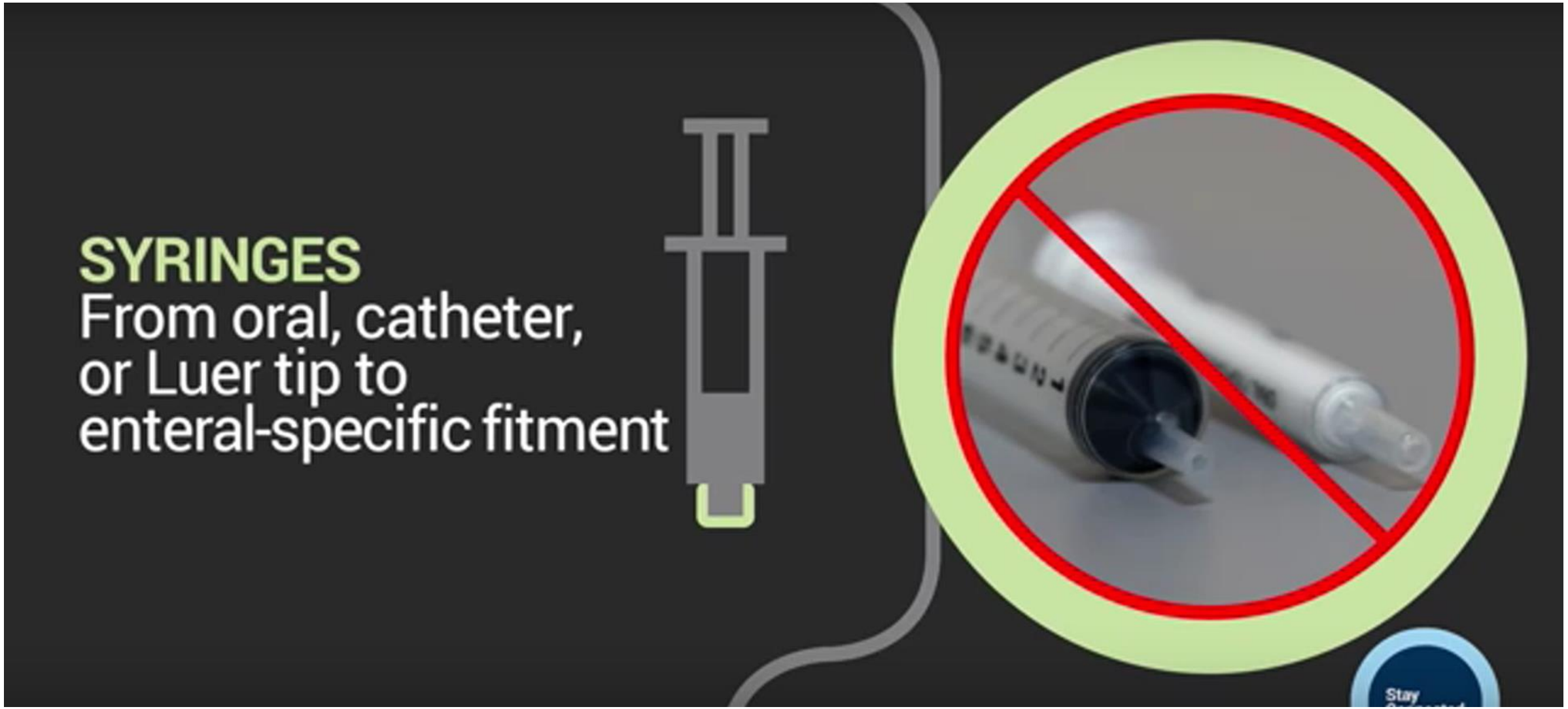




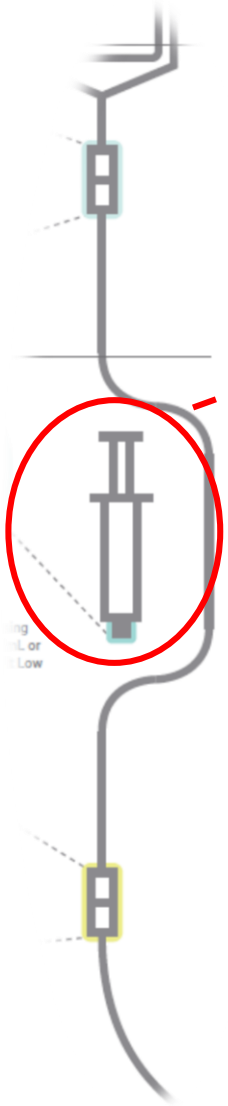
EQUIPO DE ADMINISTRACIÓN. CONEXIÓN CON SONDA



JERINGAS DE ADMINISTRACIÓN-CONEXIÓN ENFit



JERINGAS DE ADMINISTRACIÓN-CONEXIÓN ENFit



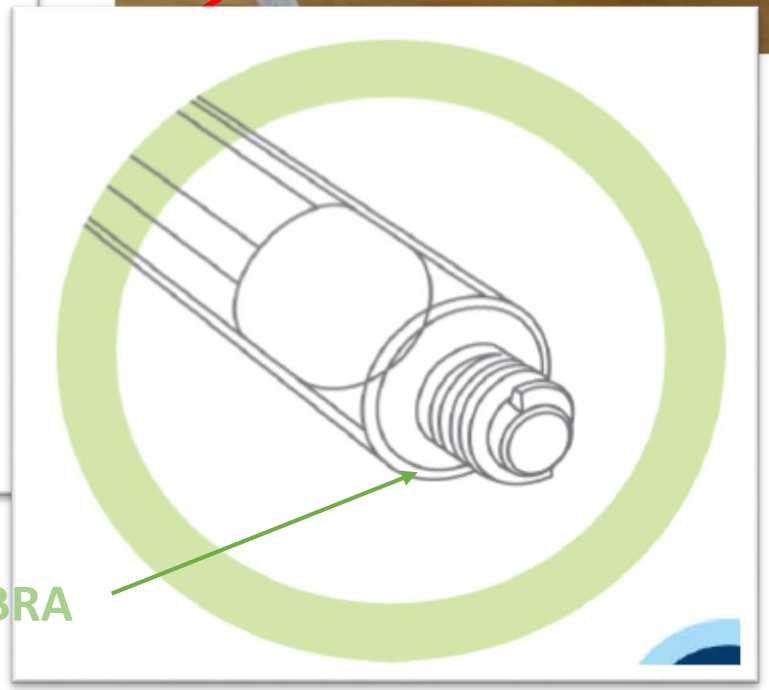
PATIENT-ACCESS END

SYRINGE (CURRENT)

OR

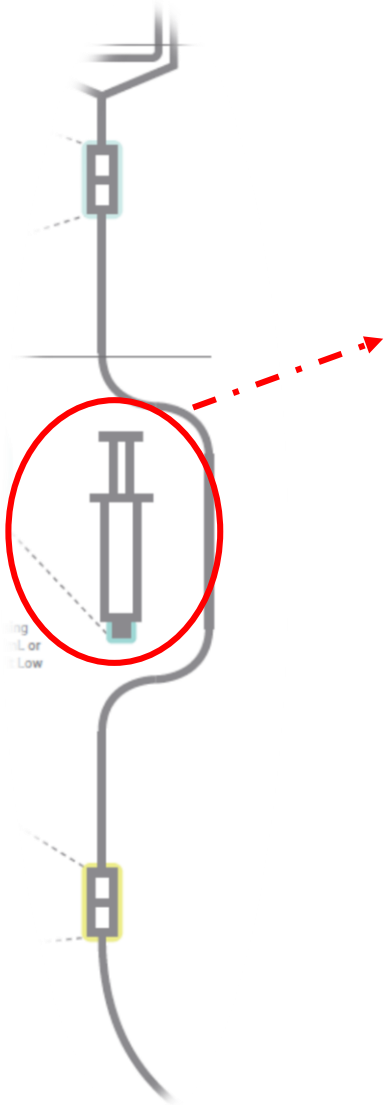
SYRINGE (Standard Tip)

Syringes to administer medicine, flush, hydrate, or bolus feed through enteral tubes will now require a precise enteral-specific fitment.



Conector HEMBRA

JERINGAS DE ADMINISTRACIÓN-CONEXIÓN ENFit



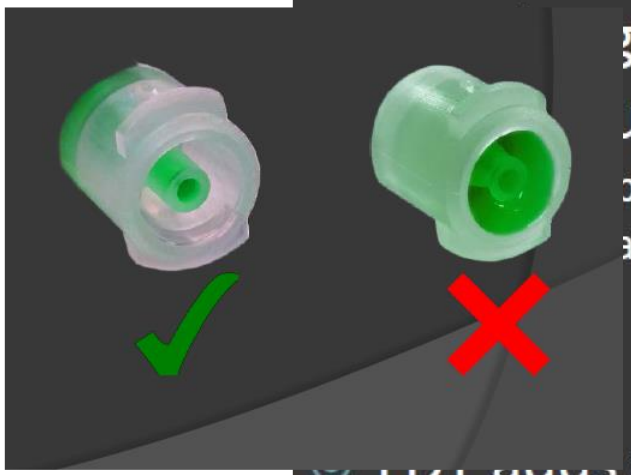
Proposed ENFit® Low Dose Tip Syringe

- Designed to specifically address dose accuracy concerns.
- Standard ENFit female syringe tip with an internal tip lumen.
- Orientation/configuration is similar to Luer lock syringes*

Stay Connected

ENFit® Dose Accuracy Solution

- The ENFit® Low Dose Tip *(LDT)* syringe
  - gned to specifically address the
  - uracy concerns
  - roposed for inclusion into ISO 20695
  - and is under review by the committee



- LDT adds an internal male lumen to the standard ENFit® female syringe
  - This mimics the functionality of traditional male oral/enteral syringe designs

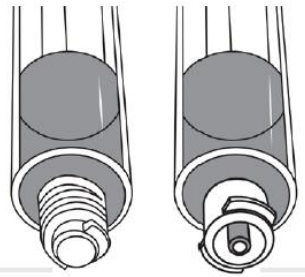
Procedure for Inpatient Settings:

Preparing and Administering Medications Using ENFit®

MEDICATION PREPARATION: FILLING A SYRINGE USING A BOTTLE FILL CAP

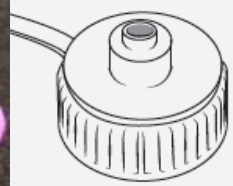
Always con … ıre guidelines for
general filli … :ndations.

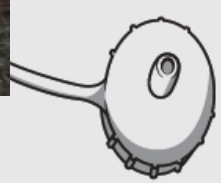
Current fill … procedure will
demonstrat …



ENFit Standard Tip Syringe

ENFit Low Dose Tip Syringe

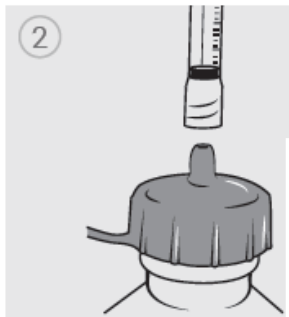




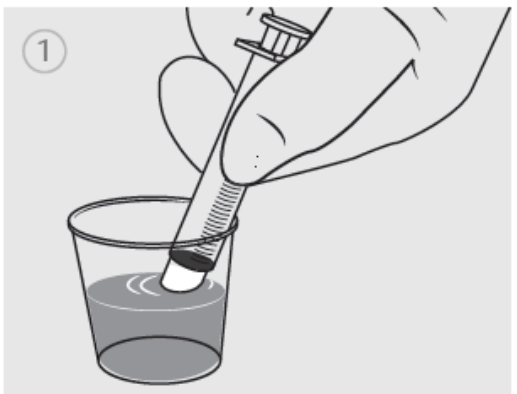
…cation
…ess-in
…dapter

Procedure for Inpatient Settings:

Preparing and Administering Medications Using ENFit®

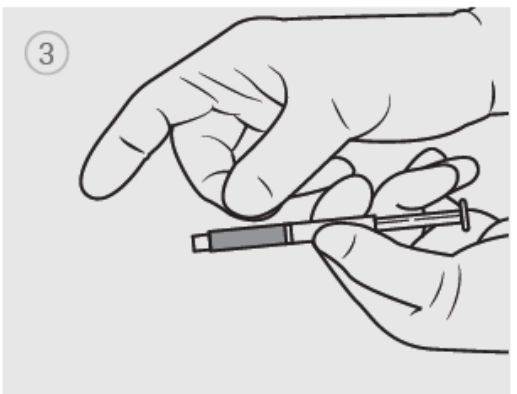


Step 2. Attach the syr
to the bottle adapter.

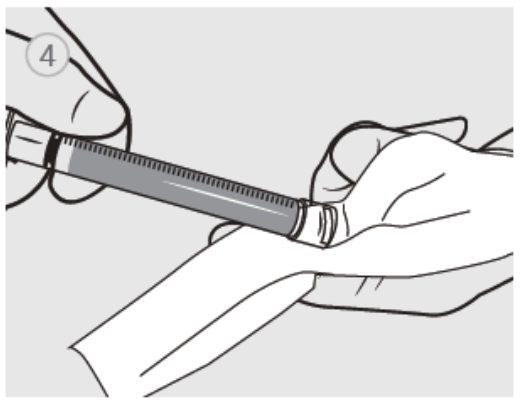


Step 1. Submerge tip of syringe into medication cup after priming syringe.

Step 2. Cycle the syringe and then gently pull up on the plunger to fill syringe to desired dose.



Step 3. Tap/flick the syringe to remove air bubbles.



Step 4. Wipe off end of syringe to remove excess medication in tip.

NOTE: Critical medications such as narcotics or cardiac medications that have a narrow therapeutic index MUST be free of medication in the moat of the low dose tip syringe.

Transition dates for Europe, Middle East, Africa, Australia & New Zealand

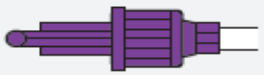
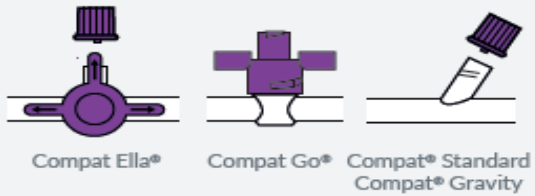
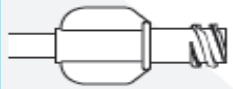
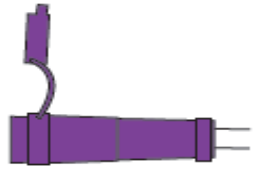
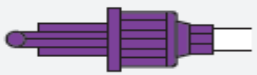
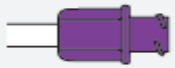
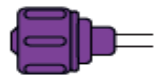
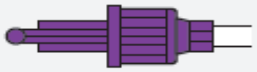
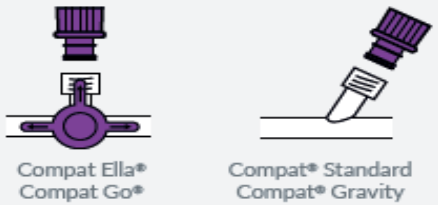
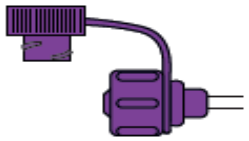
Q3 2015
Administration Sets with ENFit female connector,
ENFit Transition Connector and ENFit male access port

Q4 2015
Enteral-specific syringes with ENFit female connector

Q1 2016
Feeding tubes with
ENFit male connector

Stay Connected

2017

	Nutrition Connector	Medication Port	Distal End	Adapter	Feeding Tube
Until January 2016[2]	**Current**				
		 Compat Ella® Compat Go® Compat® Standard Compat® Gravity		 Funnel[1,3] ENLock®	 ENLock®
	ENPlus®	ENLock® Luer®, Oral®	Luer®		
From October 2015[2]	**1) ENFit™ Transition Sets**				
		 Compat Ella® Compat Go® Compat® Standard Compat® Gravity		 Funnel[1,3,5] ENLock®	 ENLock®  ENFit®
	ENPlus®	ENFit®/ENLock® Luer®, Oral®	ENFit®		
Q4 2015[2]	**2) ENFit™ medication dispensers**				
	Medication dispensers become available from relevant GEDSA members.				
Q1/Q2 2016[2]	**3) ENFit™ Feeding Tubes & ENFit™ Final Sets**				
		 Compat Ella® Compat Go® Compat® Standard Compat® Gravity			 ENFit®
	ENPlus®	ENFit®	ENFit®		

Get ready for the new ENFit® connector

Transition Checklist for Pharmacies

New design standards for medical device tubing connectors are now in place. Starting with enteral feeding and the new ENFit connector ISO 80369-3, application-specific standards will help ensure that connectors do not fit into ports other than the type for which they are intended, reducing the incidence of misconnections.

Every organization has a different process for implementing change, but all require a well-informed, properly prepared cross functional team. Use the following STEPS as a discussion guide for your transition team.

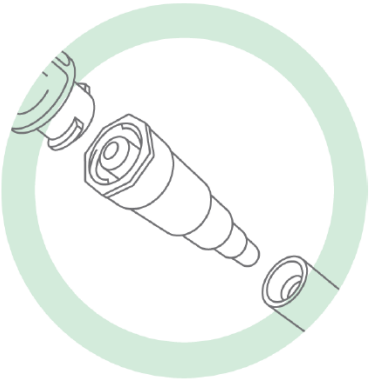
Pharmacies play a crucial role in this transition. You will put the new products into clinicians', patients', and caregivers' hands, so your knowledge and preparedness is key. This is not intended to be a complete list, but use the STEPS below to get started:

S	**Supplier communication**	☐ Familiarize yourself with all the product-specific changes ☐ Practice new connections with all products including feeding sets, enteral-specific syringes, feeding tubes ☐ Understand anticipated timing of the transition
T	**Training**	☐ Train all pharmacy staff on new processes ☐ Communicate importance of connector changes to enhance patient safety ☐ Explain and demonstrate how new feeding sets will change ☐ Identify a super user for filling prescriptions for medications to be given via feeding tube on each shift and seek hands-on training opportunities
E	**Education**	☐ Direct product-specific questions to the manufacturer/supplier ☐ Direct procedural questions to a multidisciplinary transition team
P	**Process**	☐ Assemble a multidisciplinary transition team to review procedures and protocols to include new ENFit connectors ☐ Assess and update medication preparation and delivery protocols and processes to incorporate new enteral syringes ☐ Develop communication mechanisms between prescribers, nursing and pharmacy to identify patients who need medications through a feeding tube ☐ Inform prescribers and nursing staff that medication orders must specify route—enteral (tube) or oral (mouth), and not say "PO" for both. Until ENFit connectors are fully transitioned, the order must also indicate which connection the patient is using
S	**Supply management**	☐ Assess storage space and work flow for enteral-specific syringe line ☐ Determine need for both oral/catheter tip and enteral-tip syringes, which may be adequate for most oral use, except neonatal or some pediatric use ☐ Reduce excess inventory levels of oral/catheter tip syringes ☐ Determine supply levels and sizes of syringes with new ENFit connector and order once available ☐ Delineate between oral/catheter tip and enteral-tip syringes in storage to help ensure proper deployment and use

Table 3. Purchasing Strategies to Minimize Risk of Enteral Misconnections[6]

- Avoid buying enteral equipment that can mate with female Luer connectors. More specifically, avoid purchase of gastrointestinal tubes that have female Luer connectors.[10]
- Purchase adequate numbers of enteral pumps so that IV pumps are not used for enteral delivery in adult patients.
- Ensure that hospital policies restrict the purchase of enteral feeding sets to only those that are compliant with the American National Standards Institute/Association for the Advancement of Medical Instrumentation (ANSI/AAMI) standard ID54. This effectively excludes feeding sets that can mate with female Luer connectors. These devices must also be clearly labeled (e.g., "Not for IV Use"). [11]
- Avoid buying prefilled enteral feeding containers, except for those with design technology labeled "non-IV compatible." Package the enteral administration set with the enteral feeding bag or container before it is sent to the patient care unit. (The set should be secured to the bag, perhaps with a rubber band, or request that the manufacturer supply preattached sets).[13]
- Obtain enteral pumps that feature an automatic flush mode so that clinicians will not need to manually flush lines and therefore be less likely to install an adapter or Luer device between the enteral administration set and the feeding tube.[14]
- Reduce the purchases of adapters and connectors that can be used to make enteral feeding sets compatible with female Luer connectors.
- Purchase oral syringes instead of Luer syringes to deliver medications into the enteral feeding system. Develop pharmacy department recommendations to select the correct syringe type, along with dispensing and proper labeling protocols. Have oral syringes available in all areas where enteral formula and enteral/oral medications are being prepared for administration.
- Convene a multidisciplinary task force charged with performing a prepurchase evaluation before making a purchasing decision with regard to enteral feeding systems.[14]
- Seek manufacturers who produce the safest systems.

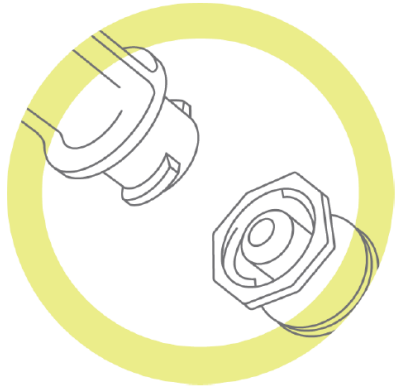
Cambios en los procedimientos de enfermería



- **Comprobar localización de la sonda**
- **Comprobar residuo gástrico**

- Utilizar la jeringa ENFit con la sonda de alimentación ENFit, o bien, utilizar la jeringa ENFit con el adaptador a la sonda convencional (extremo proximal cónico)

- Limpieza del extremo proximal de la sonda de alimentación (conector macho) para eliminar los residuos de nutrición enteral y prevenir crecimiento microbiano: cepillado diario con agua tibia



Consideraciones adicionales:

- Revisar los stocks de las dotaciones.
- Es necesario disponer de jeringas ENFit y jeringas cono alimentación (para drenajes)
- Formación del personal en el manejo de los nuevos conectores.
- Cuidado con las altas y traslados a otros centros o residencias; confirmar previamente que conocen estos dispositivos, y que se encuentran disponibles. Con ello evitaremos reingresos innecesarios. Adjuntar siempre por precaución algunas jeringas ENFit.
- Precaución con las sondas de yeyunostomía: antes de su colocación confirmar que puede adaptarse a un equipo de administración de NE. No es factible el uso de jeringas, pues se requiere infusión continua. Los adaptadores estarán disponibles en el mercado durante cierto tiempo, pero la tendencia es a desaparecer.

Aplicación de las nuevas normas ISO en el material fungible de nutrición enteral. Mejorando la seguridad del paciente.

Dra. Mariola Sirvent
Grupo HLA-Vistahermosa
Alicante

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NUTRICIÓN CLÍNICA

sefh
Sociedad Española
de Farmacia Hospitalaria