Amsterdam UMC
Universitair Medische Centra

MEDIQ

COBRA MEDICAL

Harm Meijer
Accountmanager Cobra Medical

Industrie standaard ENFit

- ENFit hoe? wat? en waarom?
- Innovaties
- MDR
- Problemen uit de praktijk

ENFit hoe? wat? en waarom?

NY Times

MONEY & POLICY

U.S. Inaction Lets Look-Alike Tubes Kill Patients

By GARDINER HARRIS AUG. 20, 2010

Thirty-five weeks pregnant, Robin Rodgers was vomiting and losing weight, so her doctor hospitalized her and ordered that she be fed through a tube until the birth of her daughter.

But in a mistake that stemmed from years of lax federal oversight of medical devices, the hospital mixed up the tubes. Instead of snaking a tube through Ms. Rodgers's nose and into her stomach, the nurse instead coupled the liquid-food bag to a tube that entered a vein.

Putting such food directly into the bloodstream is like pouring concrete down a drain. Ms. Rodgers was soon in agony.

"When I walked into her hospital room, she said, 'Mom, I'm so scared,' " her mother, Glenda Rodgers, recalled. They soon learned that the baby had died.

"And she said, 'Oh, Mom, she's dead.' And I said, 'I know, but now we have to take care of you,' " the mother recalled. And then Robin Rodgers — 24 years old and already the mother of a 3-year-old boy — died on July 18, 2006, as well. (She lived in a small Kansas town, but because of a legal settlement with the hospital, her mother would not identify it.)

Mismatch:
Voedingssonde wordt verward met IV:
Ongeboren baby en moeder overlijden

The Joint Commission

Onafhankelijke non-profit organisatie
Accrediteert en certificeert ongeveer 21.000 zorg organisaties en programma's in de VS

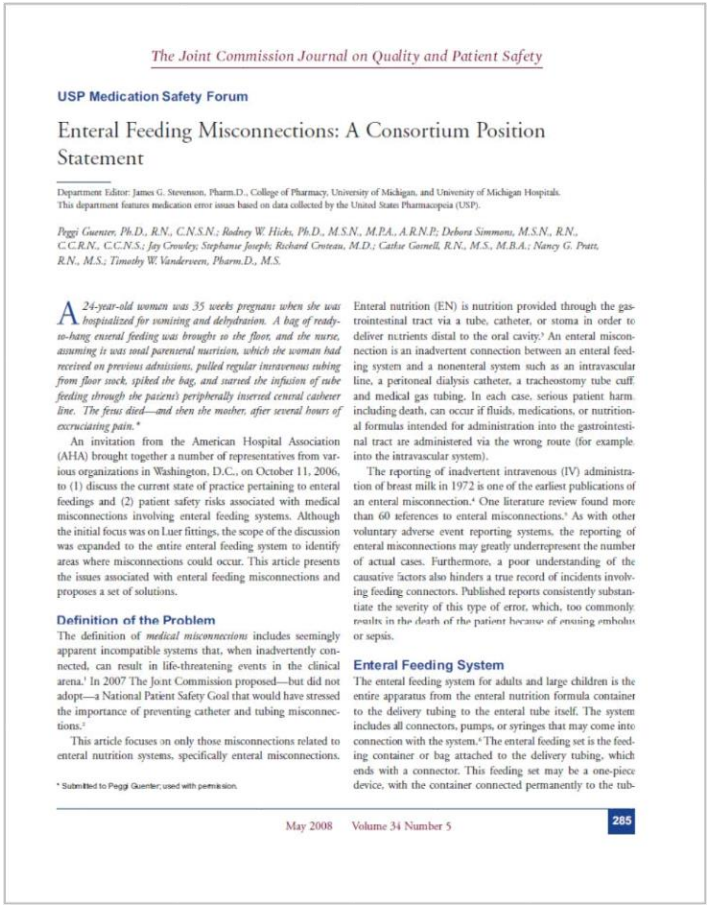

Sentinel Event Alert

A complimentary publication of The Joint Commission
Issue 53, August 20, 2014

Managing risk during transition to new ISO tubing connector standards

Misconnectie geschiedenis

- 2006 Sentinel Event Alert Tubing Misconnections from "The Joint Commission" (Issue 36, April 3, 2006)
- "A persistent and potentially deadly occurrence"
- Urgency: product manufacturers implement "designed incompatibility", to prevent dangerous misconnections of tubes and catheters



The Joint Commission Journal on Quality and Patient Safety

USP Medication Safety Forum

Enteral Feeding Misconnections: A Consortium Position Statement

Department Editor: James G. Stevenson, Pharm.D., College of Pharmacy, University of Michigan, and University of Michigan Hospitals. This department features medication error issues based on data collected by the United States Pharmacopeia (USP).

Peggi Guenter, Ph.D., R.N., C.N.S.N.; Rodney W. Hicks, Ph.D., M.S.N., M.P.A., A.R.N.P.; Debora Simmons, M.S.N., R.N., C.C.R.N., C.C.N.S.; Jay Crowley; Stephanie Joseph; Richard Croteau, M.D.; Cathie Gottell, R.N., M.S., M.B.A.; Nancy G. Pratt, R.N., M.S.; Timothy W. Vanderveen, Pharm.D., M.S.

*A 24-year-old woman was 35 weeks pregnant when she was 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 she 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, after several hours of excruciating pain.**

An invitation from the American Hospital Association (AHA) brought together a number of representatives from various organizations in Washington, D.C., on October 11, 2006, to (1) discuss the current state of practice pertaining to enteral feedings and (2) patient safety risks associated with medical misconnections involving enteral feeding systems. Although the initial focus was on Luer fittings, the scope of the discussion was expanded to the entire enteral feeding system to identify areas where misconnections could occur. This article presents the issues associated with enteral feeding misconnections and proposes a set of solutions.

Definition of the Problem

The definition of *medical misconnections* includes seemingly apparent incompatible systems that, when inadvertently connected, can result in life-threatening events in the clinical arena.[1] In 2007 The Joint Commission proposed—but did not adopt—a National Patient Safety Goal that would have stressed the importance of preventing catheter and tubing misconnections.[2]

This article focuses on only those misconnections related to enteral nutrition systems, specifically enteral misconnections.

* Submitted to Peggi Guenter; used with permission.

Enteral nutrition (EN) is nutrition provided through the gastrointestinal tract via a tube, catheter, or stoma in order to deliver nutrients distal to the oral cavity.[3] An enteral misconnection is an inadvertent connection between an enteral feeding system and a nonenteral system such as an intravascular line, a peritoneal dialysis catheter, a tracheostomy tube cuff, and medical gas tubing. In each case, serious patient harm, including death, can occur if fluids, medications, or nutritional formulas intended for administration into the gastrointestinal tract are administered via the wrong route (for example, into the intravascular system).

The reporting of inadvertent intravenous (IV) administration of breast milk in 1972 is one of the earliest publications of an enteral misconnection.[4] One literature review found more than 60 references to enteral misconnections.[5] As with other voluntary adverse event reporting systems, the reporting of enteral misconnections may greatly underrepresent the number of actual cases. Furthermore, a poor understanding of the causative factors also hinders a true record of incidents involving feeding connectors. Published reports consistently substantiate the severity of this type of error, which, too commonly results in the death of the patient because of ensuing embolus or sepsis.

Enteral Feeding System

The enteral feeding system for adults and large children is the entire apparatus from the enteral nutrition formula container to the delivery tubing to the enteral tube itself. The system includes all connectors, pumps, or syringes that may come into connection with the system.[6] The enteral feeding set is the feeding container or bag attached to the delivery tubing, which ends with a connector. This feeding set may be a one-piece device, with the container connected permanently to the tub-

Guenter P, Hicks RW, Simmons D, et al. *Enteral Feeding Misconnections: A Consortium Position Statement.* The Joint Commission Journal on Quality and Patient Safety. 2008; 34:285-292.

The Joint Commission

2008 Joint Commission

Enteral Feeding Misconnections: A Consortium Position Statement

- Enterale misconnecties blijven een bedreiging vormen
- Nieuwe standaarden zouden ontwikkelt moeten worden
- Grondige evaluatie nodig van huidige producten en protocollen
- Reduceren van risico's: opleiding en training Goede PEG zorg praktijken
- Dialoog met fabrikanten, aanmoedigen oplossingen te ontwikkelen die aan de AAMI standaard voldoen (Association of Advancement of Medical Instrumentation) – *vergelijk met ISO*

Conclusie:

Zolang de mogelijkheid op enterale misconnecties blijft bestaan, blijft een veiligheidsrisico bestaan voor de patiënt

GEDSA

ENFit

ISO International Organization for Standardization

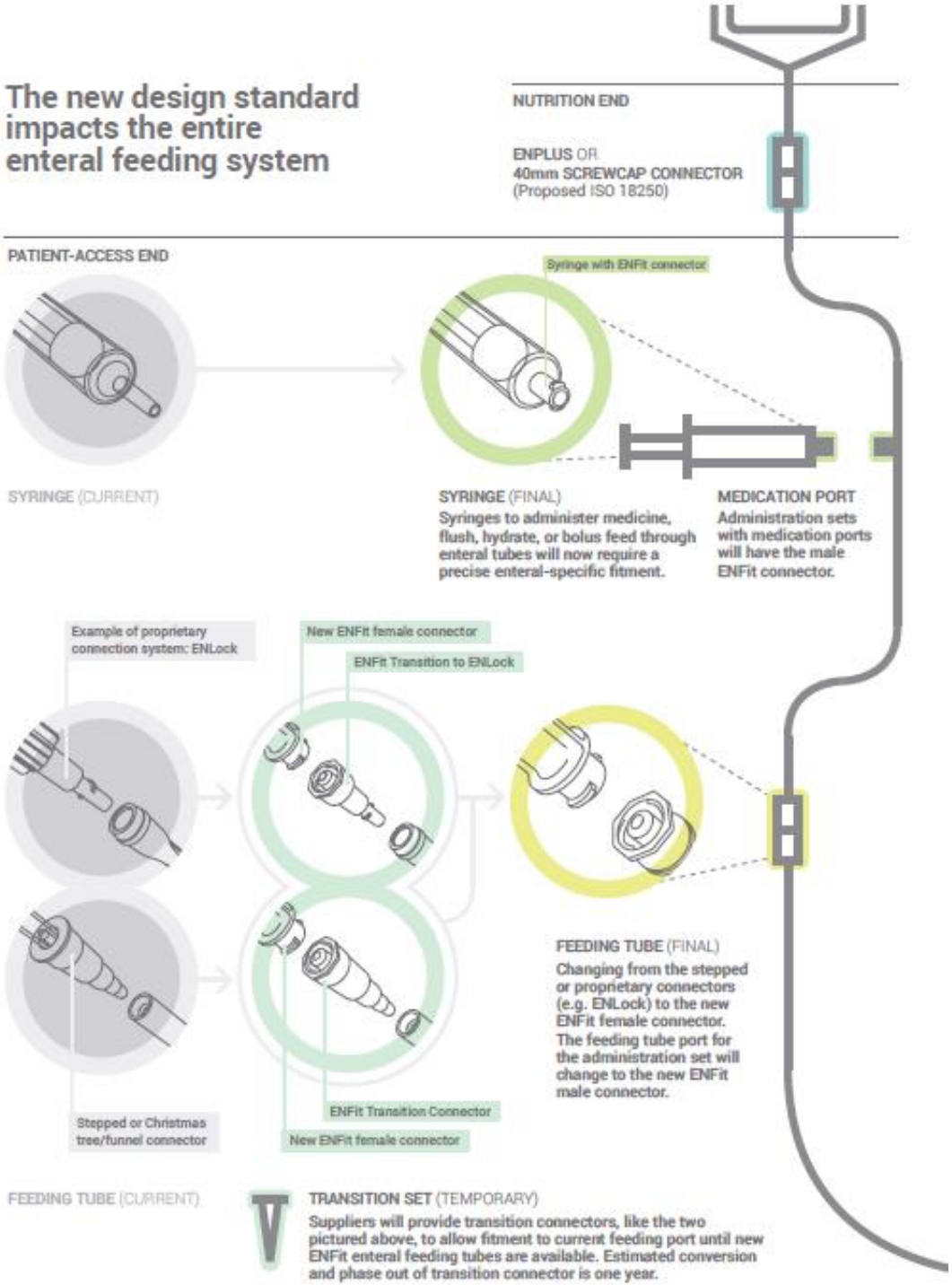
ENFit® ISO 80369-3

- Nieuwe internationale standaard
- Doel: gestart in 2015 om veiligheid voor patiënten te verbeteren
- Project Stay Connected 2015-2016
- Output: Producteisen voor kleine boring connectoren voor vloeistoffen en gassen om misconnecties te voorkomen
- Enterale voedings connectoren: ENFit

Enhancing Patient Safety

New global design standards
for enteral device tubing connectors

Medilime



Voedings eind

Extensie set met medicatie poort

Voedingssonde of button

Patiënt

Medilime

2011

Completion and adoption of foundational standard ISO 80369-1 that sets general requirements for safer connectors.

NUTRITION END CONNECTOR

2012

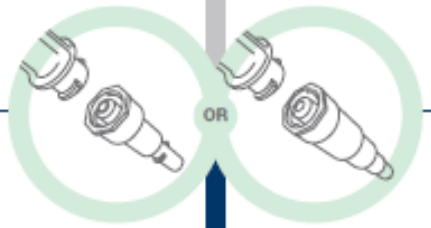
Introduction of new ENPlus connection system. Proposed ISO 18250 standard to include ENPlus connector and existing 40mm Screwcap.

2013

Formation of the Global Enteral Device Supplier Association (GEDSA) to introduce new standard connectors.

2014

The *Stay Connected* initiative for using safer connectors is launched and the Awareness phase of the enteral connector transition begins.



2015 Q3

PATIENT-ACCESS END TRANSITION SET

Transition sets available.

Administration sets will have the new ENFit female connector and the limited-use transition connector to facilitate compatibility between the new ENFit system and the original stepped/funnel port or proprietary ports like ENLock.

Q4

PATIENT-ACCESS END SYRINGE

Enteral-specific syringes available.

The new connector requires the new ENFit syringe that can be used for medicine, flush, and bolus feeding. The luer-tipped syringe will not fit the new ENFit male connector tube.

2016 Q1

PATIENT-ACCESS END FEEDING TUBE

New enteral feeding tubes with ENFit connector available.

The final step of the transition will be the proliferation of the new ENFit male connector port. After the new ENFit male connectors are in place and have been fully adopted in the market, the transition adapters may not be needed.

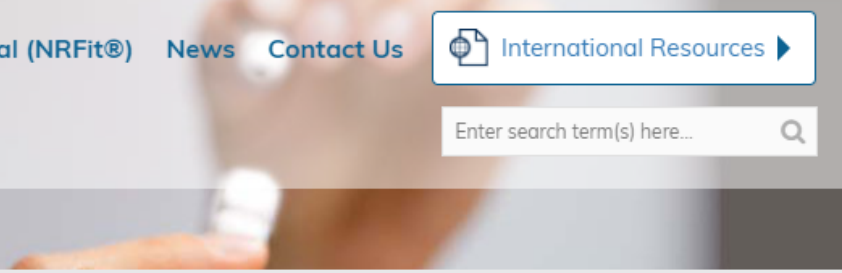
Tijdpad:

2012 ENPlus ISO 18250
2013 GEDSA

2015 Transitie setjes nog acceptabel (bolus/ENLock)

2015 Enteraal specifieke voedingsspuit

2016 Voedingssonde met ENFit



Our Goal : Reduce Medical Tubing Misconnections | Improve Patient Safety

ISO

A New Connection Standard

ISO standard 80369 was established to prevent tubing misconnection.

READ THE STANDARD

ENFit®

Enteral (ENFit®)

Enteral feeding is transitioning to the new ISO 80369-3 standard for tubing connectors.

LEARN MORE

NRFit™

Neuraxial (NRFit™)

Neuraxial connectors are transitioning to the new ISO 80369-6 design standard.

LEARN MORE

Most Popular

The U.S. FDA's letter on enteral connectors that meet the ISO 80369-3 standard

GEDSA White Paper on Safe Enteral Connectors

ENFit Cleaning Procedures: *Feeding Tubes with Male ENFit Connectors*

ENFit Cleaning Procedures: *Low Profile Feeding Tubes Extension Sets*

De ENFit Transitie

Year	Title
September 2016	ISMP Syringe Leaking
August 2016	GEDSA Position Statement
November 2015	GEDSA Position Statement
July 2015	ISMP Alert
May 2015	GEDSA Position Statement
April 2015	ISMP Alert
2014	Joint Commission Sentinel Event Alert
August 2014	ISMP Nurse Advise ERR
	GEDSA Booklet

The Joint Commission

ISMP Institute for Safe Medication Practices

GEDSA

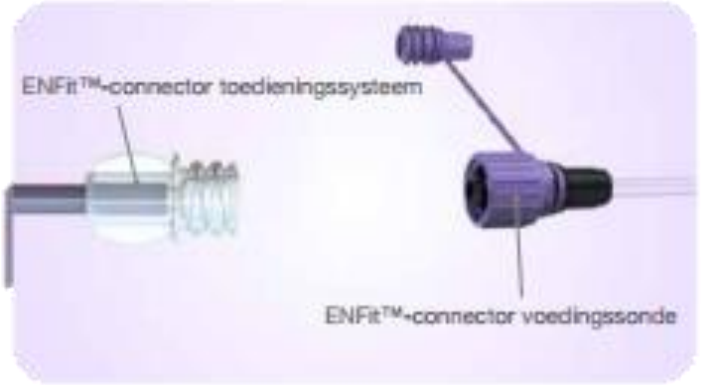
Global Enteral Device Supplier Association

Situatie Nederland

- Ervaring invoering En-lock
- 3 Bijeenkomsten
    * COBRA Medical
    * Nutricia
    * Fresenius
    * Nestle
    * Convidien
    * Vygon
    * Abbott

Transitiesets (pompsets)

Verschillen per fabrikant !



Innovaties

COBRA MEDICAL

Medilime Tummy button

COBRA MEDICAL

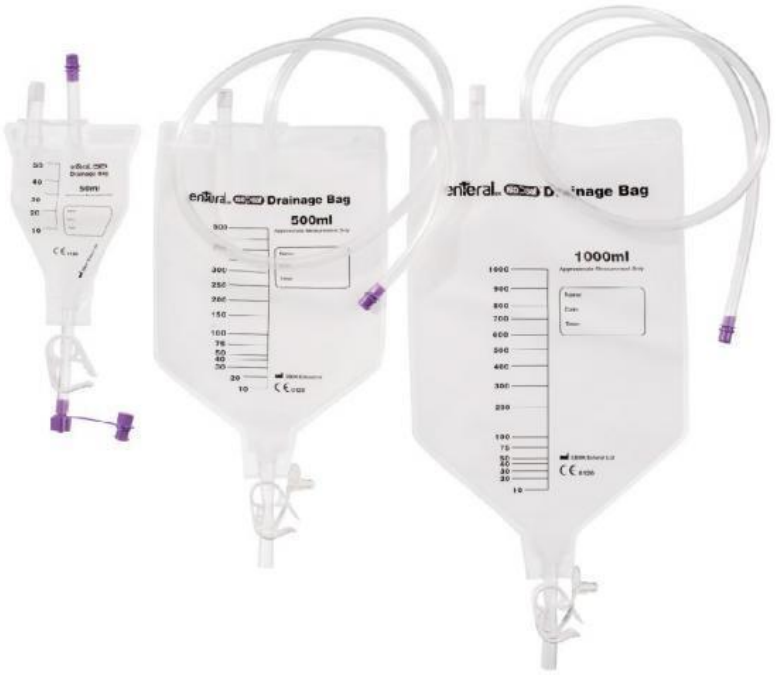
Verlengslangetjes

COBRA MEDICAL

ENFit spuiten

COBRA MEDICAL

Neus maag sondes, hevel zakken



COBRA MEDICAL

Medilime

ENFit Accessoires

COBRA MEDICAL

Medilime

MDR

Nieuwe wetgeving MDR

- Medical Device Regulation
  - Introductie 26 mei 2020 (nieuwe producten)
  - 2024 voor bestaande producten
- Notified bodies UK & D
- Gehele keten krijgt ermee te maken
  - Raw materials → Fabrikanten → Distributeurs/ leveranciers → Eindgebruikers
- Gevolgen voor de zorg
  - Prijs
  - Assortiment

Problemen uit de praktijk

ENFit gerelateerde problemen

- Voeding adhesies
- Invloed medicatie
- Te hard vastdraaien ENFit

ENFit® Cleaning Procedures

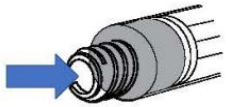
Medilime

Feeding Tubes with Male ENFit Connectors

(e.g. Nasogastric, Transpyloric, Orogastric, Percutaneous Endoscopic Gastrostomy Tubes and other ENFit devices)

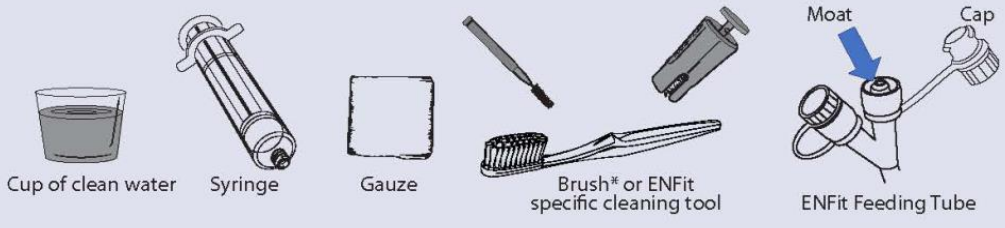
Tips for keeping ENFit feeding tube ports clean. Inspect before you connect!

- ***Priming Feeding Sets*** - Stop priming before fluid reaches the end of the tube.
- ***ENFit Syringe Draw Up*** - Wipe medication and nutrition from tip/outer threads, keep fluids out of dead space before connecting to feeding tube.



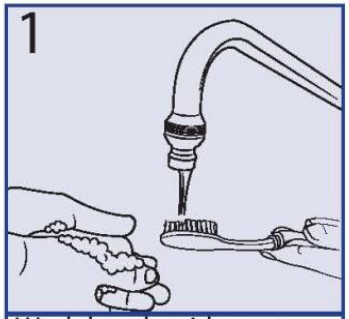
For best results, follow these instructions to clean tubes at least once a day or whenever material is visible.

Tube Cleaning Supplies & Terms



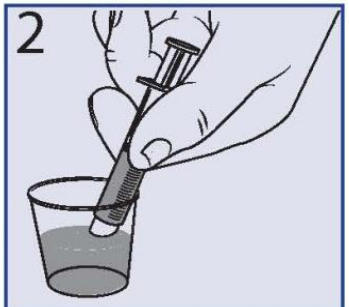
Note: Use a disposable brush or follow manufacturer's instructions if using ENFit specific cleaning brush.

1



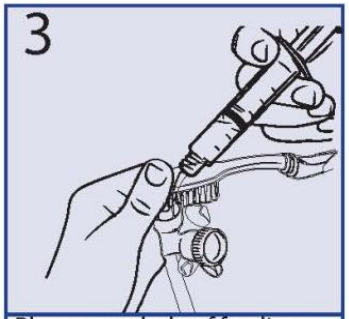
Wash hands with soap and water. Rinse brush with tap water.

2



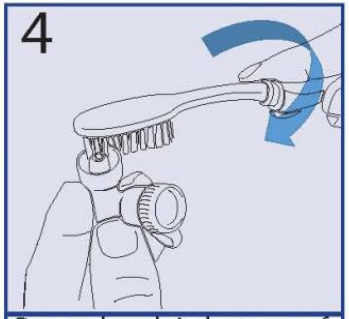
Fill syringe with water.

3



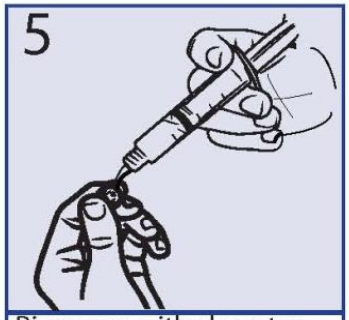
Plug center hole of feeding tube port with brush bristles. Forcefully flush moat with water.

4



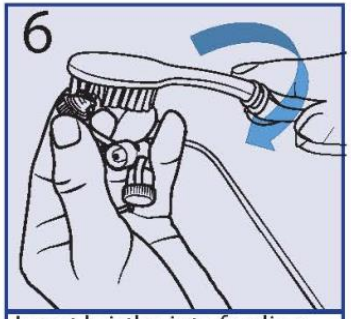
Rotate brush in bottom of moat.

5



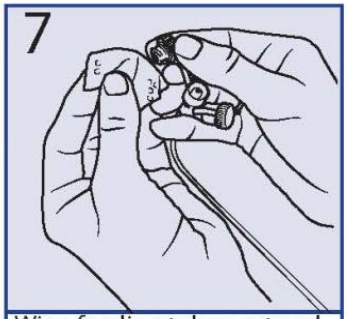
Rinse cap with clean tap water.

6



Insert bristles into feeding tube cap and rotate brush in cap to clean.

7



Wipe feeding tube port and cap with gauze. Clean supplies and allow to air dry.

Repeat steps 3 through 6 until cap and tube are thoroughly clean.

* A manual toothbrush is regulated as a medical device intended to remove debris from the teeth in some jurisdictions. Consult your licensed healthcare provider or Risk Manager regarding recommended use for cleaning feeding tube ports. Dispose of single use devices as instructed. Cleaning procedures courtesy of Children's Mercy Kansas City.

GEDSA

ENClean Brush

Medilime

Lekkage

- Plaats van het fistel
- Lengte van het fistel / lengte van de catheter
- Bijkomende problemen:
  - Scoliose
  - Spasme
  - Vertraagde maagontlediging

Lekkage: meestal de oplossing zoeken in de lengtemaat van de sonde.

Wild vlees

Oplossingen:

* Voorkomen????
* Behandelen
  * zilvernitraat
  * chirurgisch
  * corticosteroïden
  * niets doen is ook een optie

Hoe lang gaat een disposable spuit mee?

Vilans protocol

- Gebruik spuiten client gebonden
- Vervang de spuit elke 24 uur.
- Vervang de spuit ook als deze beschadigd is, of als de client een schimmelinfectie heeft , waar dan ook op het lichaam
- Maak spuiten die worden hergebruikt na gebruik schoon met een sopje en leg stamper en huls los van elkaar te drogen op een schone en droge doek of in een uitlekbakje waarin geen water kan blijven staan

COBRA MEDICAL