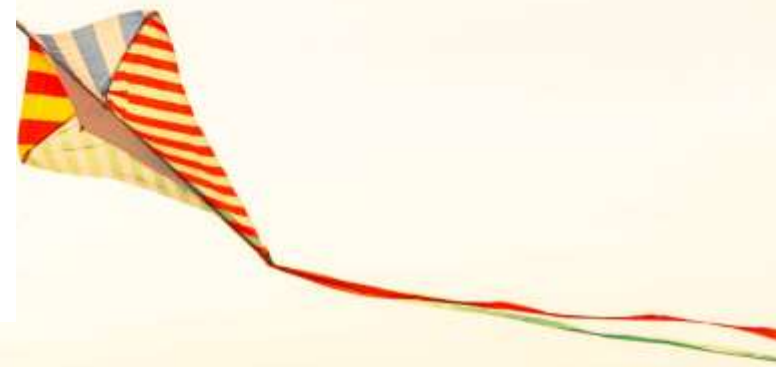




Distributor of *Medilime*
Tummy Button



PEG zaken
5 November 2019

Harm Meijer



Inhoud

- HISTORY
 - Geschiedenis van voedingssondes
- DESIGN
 - Ontwerp van de Tummy Button van MediLime
- TROUBLE SHOOT
 - ENFit gerelateerde problematiek

Medilime

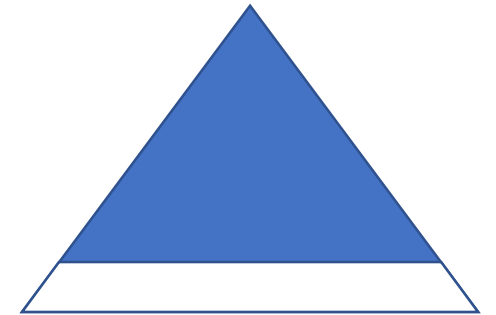
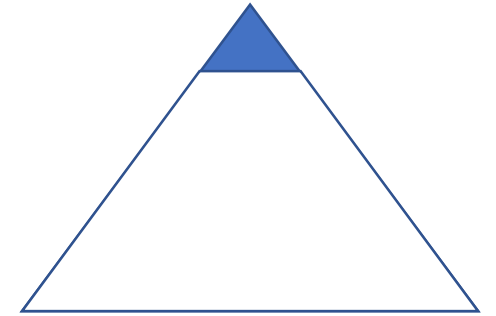




History

Gezondheid

- WHO, 1948 – Gezondheid is een toestand van volledig fysiek, geestelijk en sociaal welbevinden en niet louter het ontbreken van ziekte of gebrek.
- Huber, 2011 – Gezondheid is het vermogen zich aan te passen en een eigen regie te voeren, in het licht van de fysieke, emotionele en sociale uitdagingen van het leven.





Enterale voeding

- ✧ Tot 19de eeuw: melk
- ✧ 20ste eeuw: toevoeging van voedingssupplementen (boter, room, olie, suiker, eieren, bouillon, sap)
- ✧ Karnemelk ter voorkoming van diarree
- ✧ Gebruik van groente en vlees (gepureerd)
- ✧ 1970: Nutricia ontwikkelt de eerste sondevoeding gebaseerd op groente
- ✧ Huidige sondevoeding (gebaseerd op melk) geoptimaliseerd voor verschillende type patiënten
- ✧ Blended diet

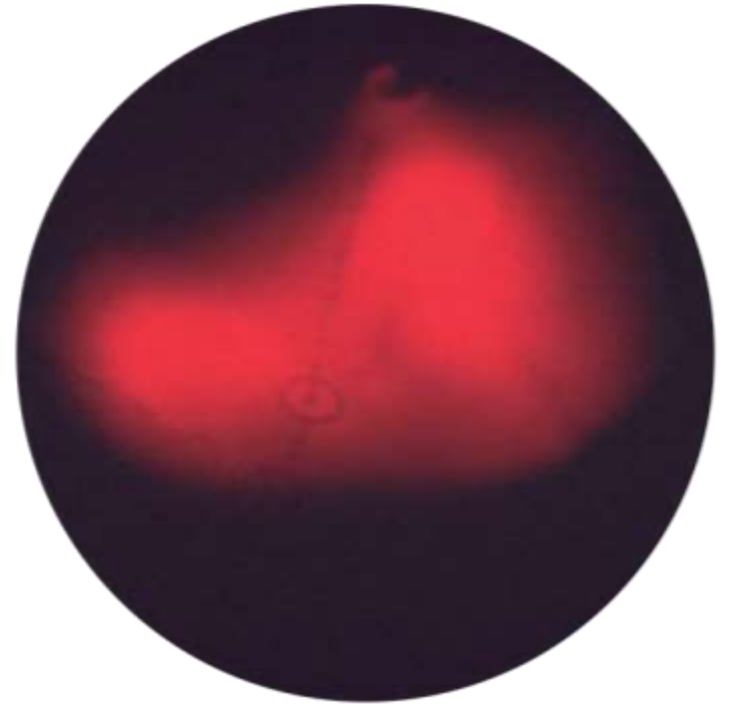
Neus maag sondes

- Metalen buis (rectaal)
- 1600: ontwikkeling van de basis voor sondes zoals we die nu kennen
- 1600 - nu: experimenteren met verschillende materialen en diameters (French maten 20 - 6)
 - 17de eeuw: leer
 - 18de eeuw: walvis botten
 - 19de eeuw: rubberen buizen en slangen
 - 20ste eeuw: Polyvinyl Chloride, Polyurethane, Silicone

PEG

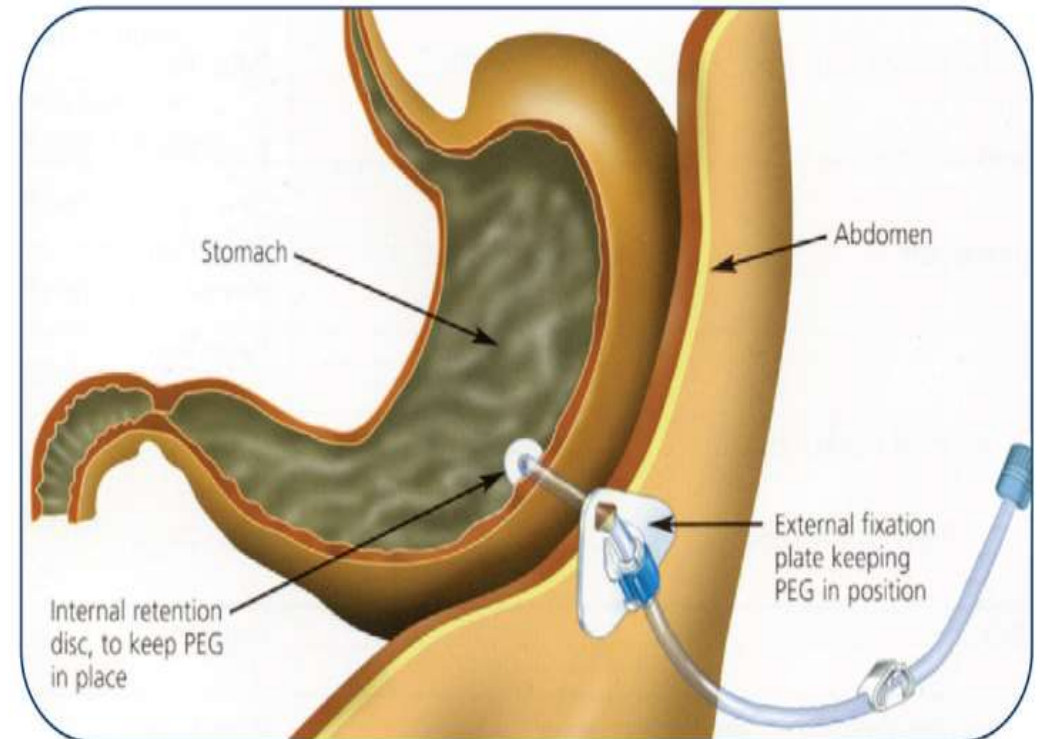
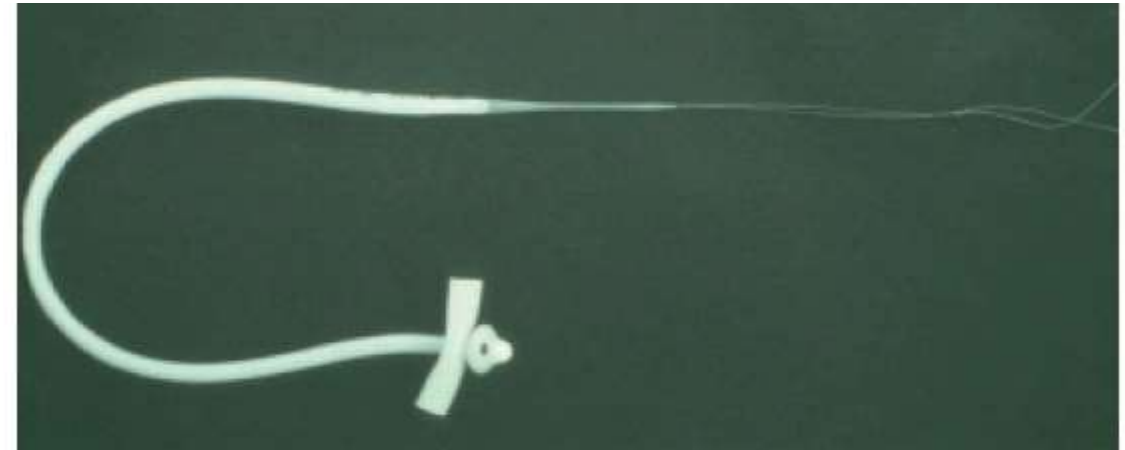
- **Percutaneous Endoscopic Gastrostomy**

- “The room was dark, and a glow emanated from the abdomen of a tiny baby on the operating table.” - *Dr. Jeffrey Ponsky*



Eerste PEG

- 1979: Plaatsing van de eerste PEG catheter door een kinder MDL arts
- Dr. Michael Gauderer (Cleveland, Ohio)

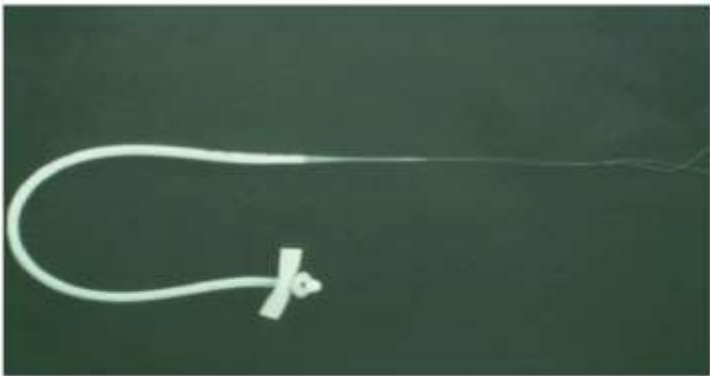




PEG Ontwikkeling

- Optimalisatie proces door dierproeven
- Eerste serie: bij 5 kleine kinderen
- 1980: eerste plaatsing bij ouderen (allen neurologische afwijking na CVA)
- Mei 1980: presentatie over PEG catheters tijdens DDW in Salt Lake City
- Dr. Ponsky: “eenvoud van de PEG procedure is cruciale factor voor succes en acceptatie van de PEG bij arts en patiënt”

PEG's



Na de PEG ?

- When the PEG has to be changed
- Replacement tubes (Medilime gastric tube)
- Buttons (Medilime Tummy Button)





Design

Waarom ENFit ?

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.

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



GEDSA

- ◆ Global Enteral Device Supplier Association
- ◆ ISO Werkgroep industriëlen
- ◆ Industrie standaard ISO 80369-3
- ◆ ENFit ter voorkoming van misconnecties



International
Organization for
Standardization



Enhancing Patient Safety

New global design standards
for enteral device tubing connectors

Systeem

The new design standard impacts the entire enteral feeding system

PATIENT-ACCESS END



SYRINGE (CURRENT)



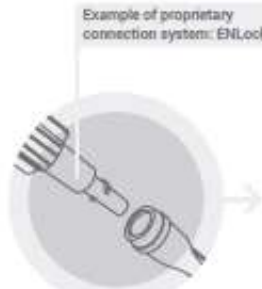
Syringe with ENFit connector

SYRINGE (FINAL)

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

MEDICATION PORT

Administration sets with medication ports will have the male ENFit connector.



Example of proprietary connection system: ENLock

Stepped or Christmas tree/funnel connector



New ENFit female connector

ENFit Transition to ENLock

ENFit Transition Connector

New ENFit female connector



FEEDING TUBE (FINAL)

Changing from the stepped or proprietary connectors (e.g. ENLock) to the new ENFit female connector. The feeding tube port for the administration set will change to the new ENFit male connector.

FEEDING TUBE (CURRENT)

TRANSITION SET (TEMPORARY)

Suppliers will provide transition connectors, like the two pictured above, to allow fitment to current feeding port until new ENFit enteral feeding tubes are available. Estimated conversion and phase out of transition connector is one year.

NUTRITION END

ENPLUS OR
40mm SCREWCAP CONNECTOR
(Proposed ISO 18250)

Voedings eind



Extensie set met
medicatie poort



Voedingssonde of
button

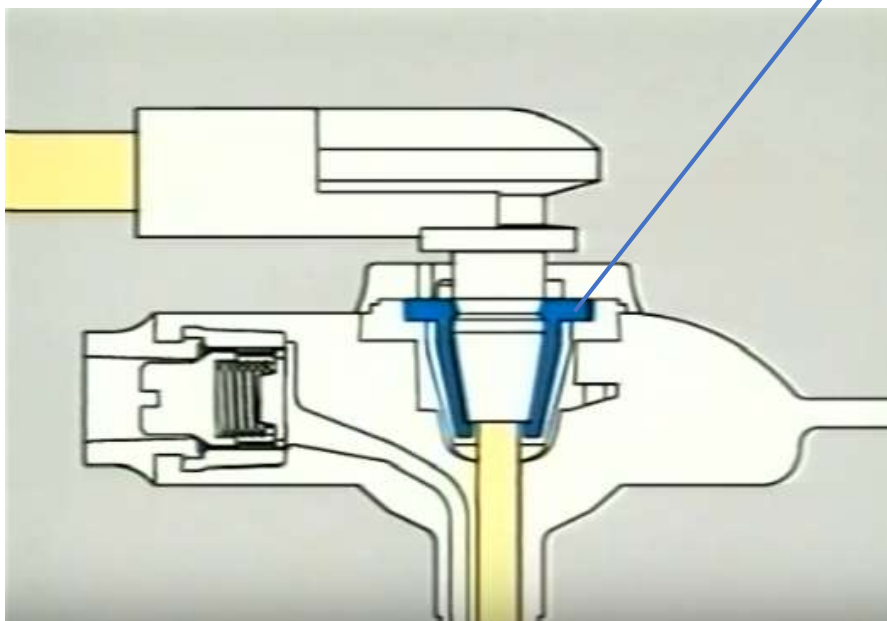


Patiënt

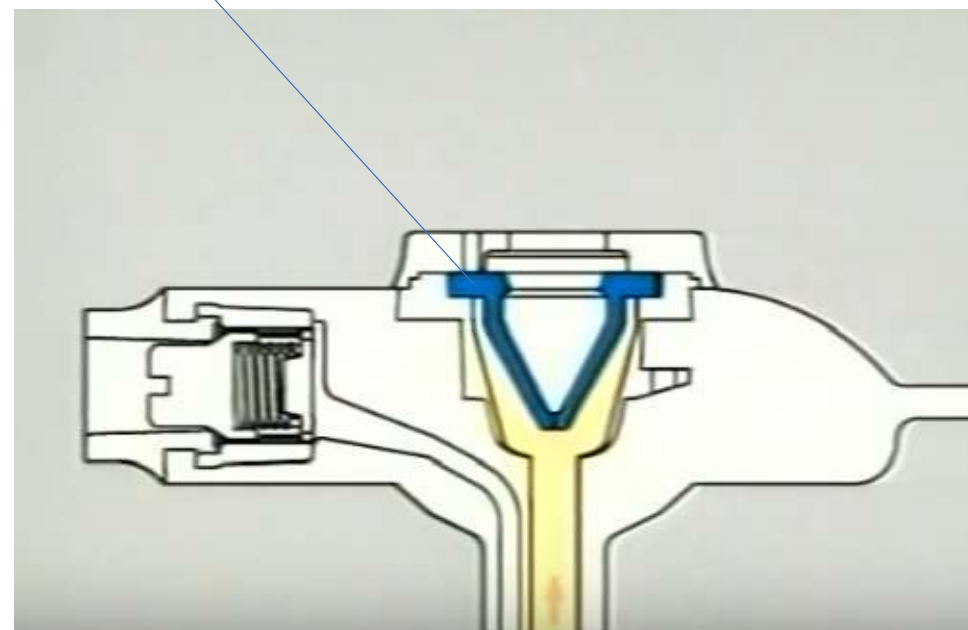
Tummy Button



Anti-reflux klep

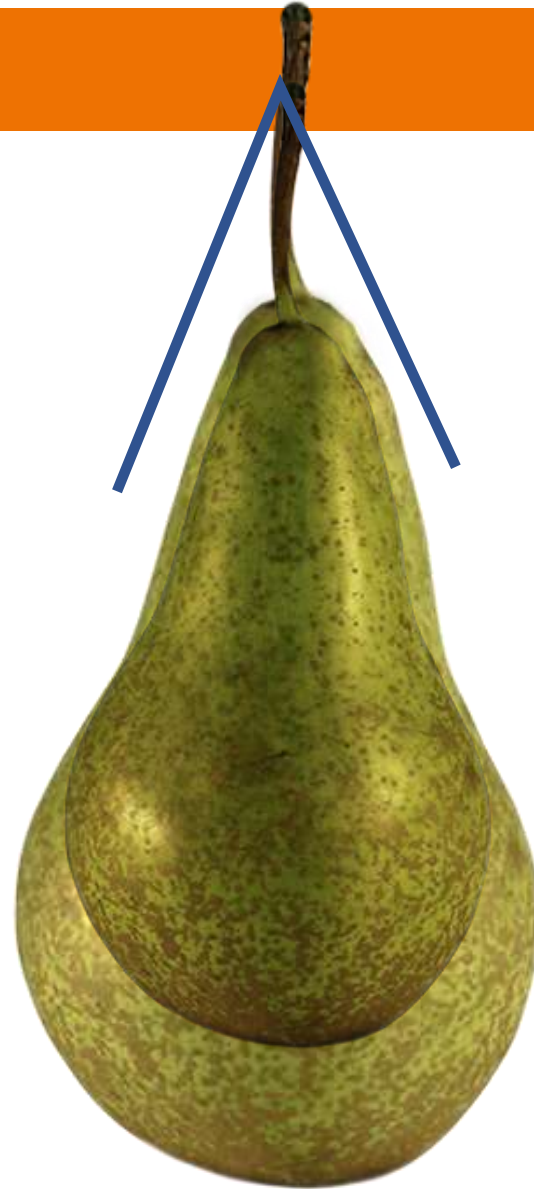
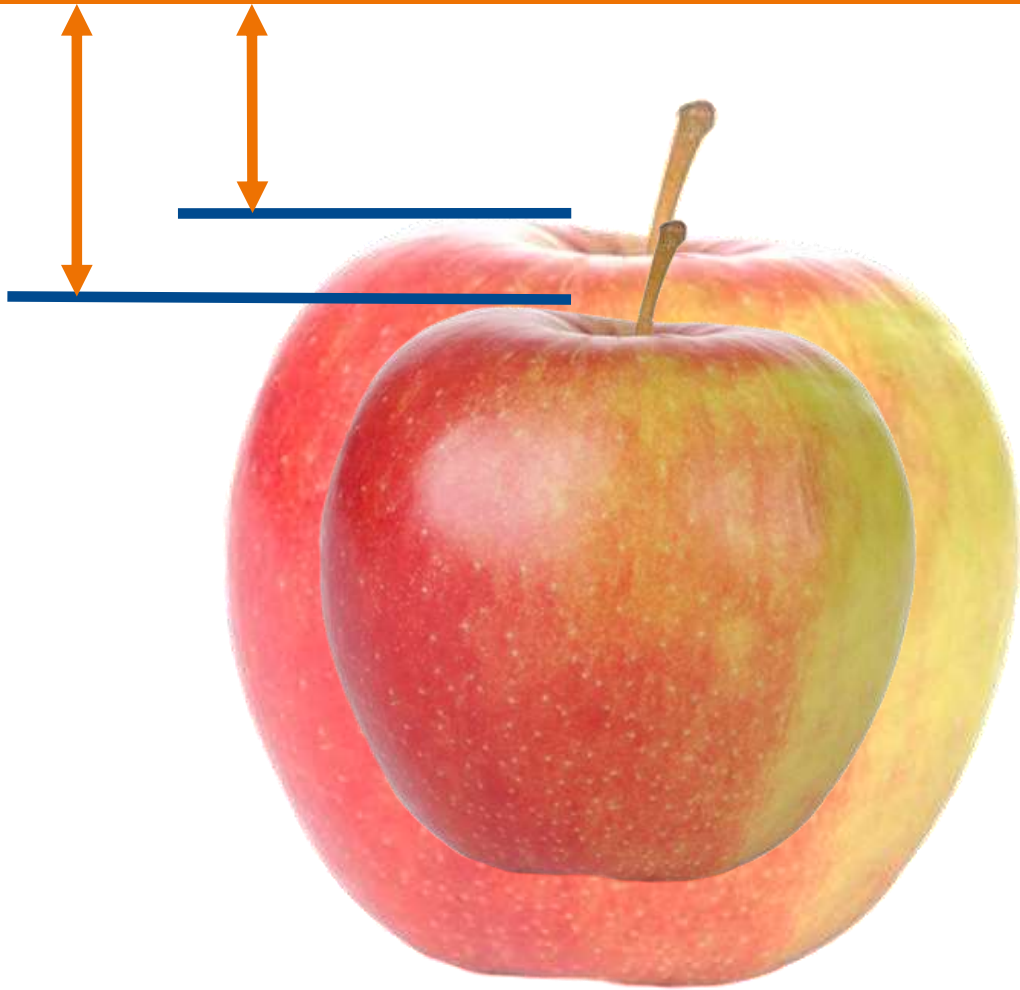


OPEN



DICHT

Appel vs Peer



Tummy Button set



Extension set

- “High flow” button connectie (ideaal voor gebruik met een voedingspomp)
- Verbeterd materiaal dat sterke medicatie weerstaat
- Cobra Medical is de enige leverancier van verlengslangen met de paarse connectoren
- Perfect toepasbaar op alle buttons
- Meer grip voor een soepele plaatsing



Extension set

- 2 maten: 30 en 60 cm
- Polyuretaan, hoogwaardig, DEHP vrij, Latex vrij
- Enkel + Y-aansluiting
- Innovaties
 - High Flow Connector*
 - Large ENFit
 - Swivel lock
 - Bolus slang



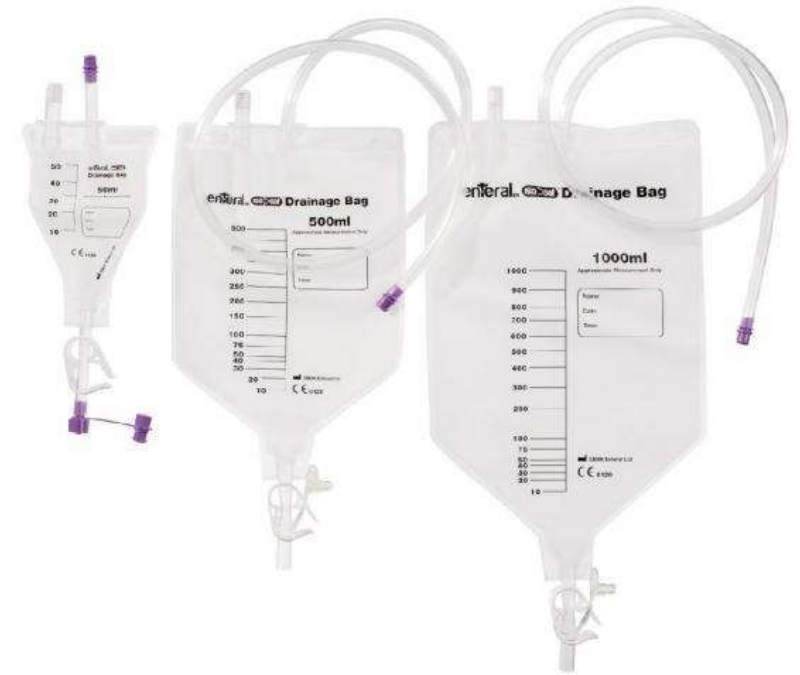
ENFit voedingsspuitten

- MediLime, huismerk
 - 1 ml, low dose, with wings
 - 3 ml, low dose, with wings
 - 6 ml
 - 10ml
 - 20ml
 - 60ml, excentrisch
- Disposable in ziekenhuizen
- Instellingen, Thuiszorg?



Accessoires

- Neus maag sondes
 - Kinderen
 - Volwassenen
- Drainage zakken
- pH strips



Accessoires

- Bottle adapters
- ENFit caps
- Rietjes
- Naalden
- Stoma plugjes





Trouble shoot

ENFit gerelateerde problemen

- ◆ Aangekoekte sondevoeding
- ◆ Invloed medicatie
- ◆ Te hard vastdraaien ENFit



ENFit® Cleaning Procedures

Feeding Tubes with Male ENFit Connectors

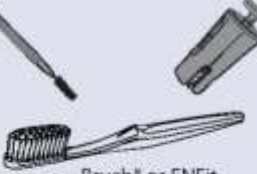
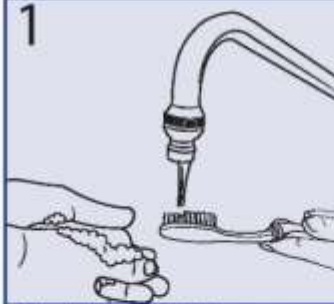
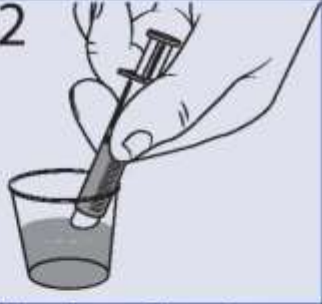
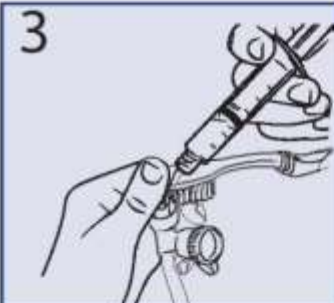
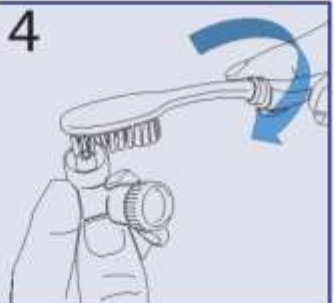
(e.g. Nasogastric, Transpyloric, Orogastric, Percutaneous Endoscopic Gastrostomy Tubes and other ENFit devices)

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				
 Cup of clean water	 Syringe	 Gauze	 Brush* or ENFit specific cleaning tool	 ENFit Feeding Tube
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.
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GEDSA

ENClean Brush

- Afsluiten sonde
- ENFit borsteltje
- Voor één cliënt
- Herbruikbaar maximaal 30 dagen



Lekkage

- Door de button // langs de button
- Plaats van het fistel
- Lengte van het fistel / lengte van de katheter
- Bijkomende problemen:
 - Scoliose
 - Spasme
 - Vertraagde maagontlediging



Lekkage oplossing

- Lengtemaat van de sonde
- NIET dikkere Charriere maat

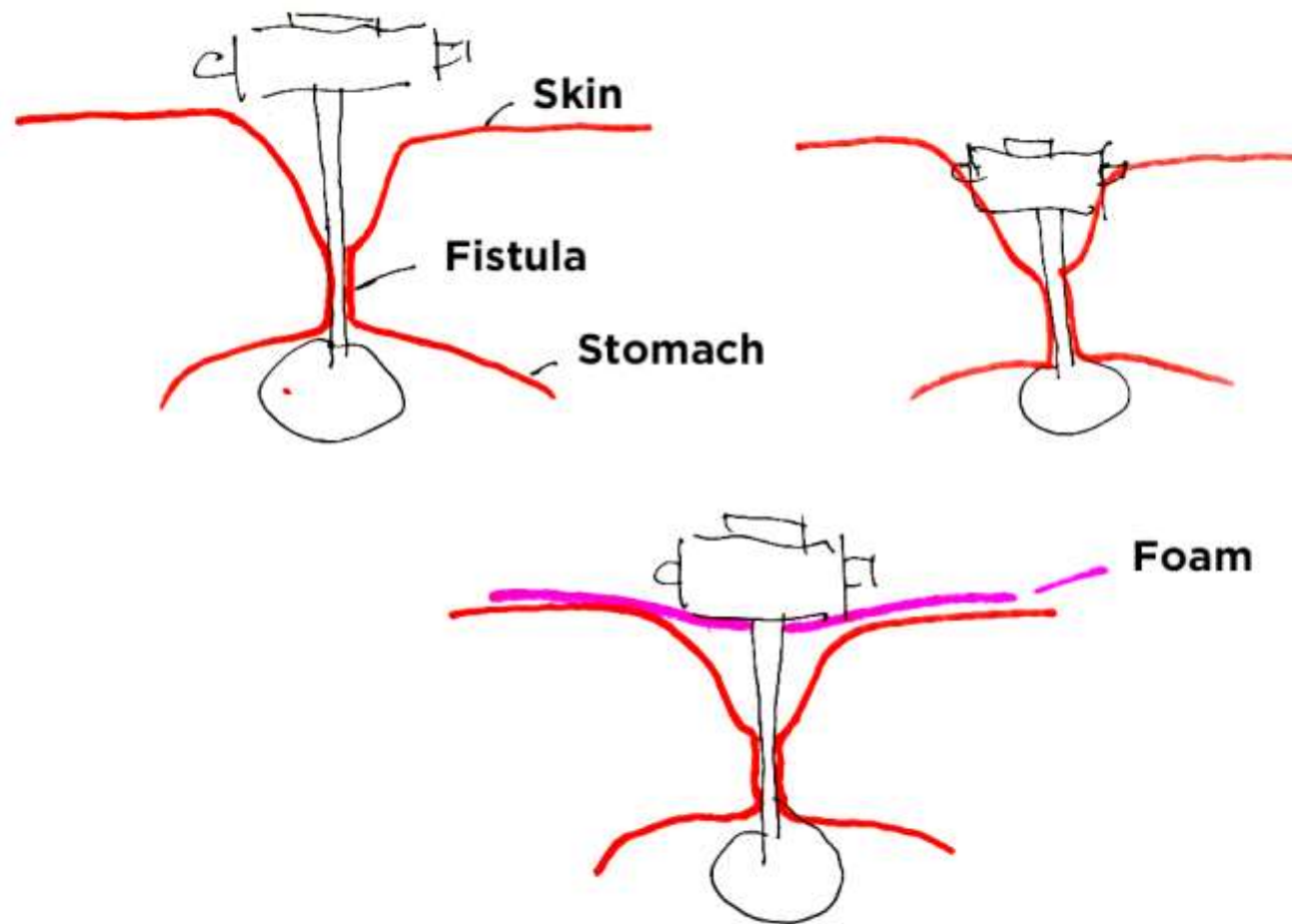


Huidproblemen

- Metalline compres
 - Blijft niet aan huid/wond plakken
 - Ventileert
 - Absorbeert
- Schuimverband
 - Absorbeert
 - Zacht
 - Bij huidplooien



Huidproblemen



Dank u

Medilime

