

# Randomized Controlled Trial Assessing the Effectiveness of Two Cleaning Regimens for ENFit® Connectors

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**E**nteral feeding tubes are used in all healthcare settings to provide nutrition, fluids, and medications to patients who cannot sustain growth, nutritional health, or hydration via the oral route. All these patients have the potential for an enteral misconnection, which is defined as a wrong route administration of an enteral formula or medication into a tracheostomy tube, intravenous catheter, or any other medical device (Guenter & Lyman, 2016). Over 116 such misconnections have been reported in a seminal review of existing literature, with 18% of affected patients dying from an embolus or sepsis (Simmons, 2011). One described incident involved a pregnant woman whose enteral formula was administered intravenously in error, with the subsequent death of the mother and fetus.

In 2006, The Joint Commission issued a Sentinel Event Alert calling for design changes in feeding tube connections so a misconnection would not be possible (Guenter & Lyman, 2016). In 2008, the International Organization of Standardization (ISO) convened a working group to rework all connections to feeding tubes to a new standard: ISO 80369-3. This new standard has a unique design so any fluid destined for a feeding tube cannot be administered elsewhere. The small-bore connector, known as ENFit® to clinicians, is now ready for patient

*This cleaning validation study compared two regimens and brushes for cleaning ENFit® connectors. Results showed the more diligent regimen was most effective, regardless of the type of cleaning brush used.*

use (Global Enteral Devices Suppliers Association [GEDSA], 2020). While the ENFit design addressed one primary patient safety concern, another concern has come to light: how to clean the distal end of the feeding tube that contains a moat (see Figure 1), allowing the accumulation of residue from enteral formula or a liquid medication. Nurses are concerned this design will be challenging to keep clean, allowing bacterial growth.

The newly engineered ENFit connectors are ready for patient use but there is no standard approach for cleaning the tube's distal end. The

only published recommendation in the literature suggests at least daily cleaning of the connector (Guenter & Lyman, 2016). For this reason, the investigators contacted the U.S. Food and Drug Administration (FDA) for guidance in designing a study to provide evidence to guide nursing practice.

### Purpose

The primary purpose of this study was to address dried residue in ENFit connectors in two ways: evaluate two cleaning regimens after cleaning an ENFit connector

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**Note:** This study was funded by the Global Enteral Devices Suppliers Association.

**Conflict of Interest Statement:** None of the authors has any conflict of interest to disclose regarding this research.

### Background

Enteral feeding tubes are used in healthcare settings for any age patient. Morbidity and mortality from enteral misconnections warranted a shift from a luer connector to an enteral connector designed to be incompatible with other connectors. The ENFit® connector design poses a cleaning challenge as the distal end allows formula/medication accumulation, making disconnections difficult.

### Aim

Assess the efficacy of ENFit connectors cleaning regimen when residue is dried.

### Methods

Participant nurses were given two ENFit connectors: one with visible chocolate-flavored formula residue, one apparently clean but inoculated with an invisible environmental marker (DAZO™). Nurses were assigned randomly to two groups: 60 were assigned a diligent cleaning process, 60 assigned to a less-strict cleaning process. Thirty nurses in each group were given firm-bristled toothbrushes as cleaning tools, and 30 were given commercially designed ENFit commercial cleaning brushes.

### Results

A significant difference was found in the proportion of ENFit connectors with no residue between the more-diligent and the less-diligent cleaning regimens (30.7% vs. 13.1%,  $p=0.001$ ). There was no difference in the proportion of ENFit connectors with no residue when using a toothbrush versus the ENFit commercial cleaning brush ( $p=0.075$ ).

### Limitations

Participants may not have followed the cleaning regimen instructions thoroughly or may have copied a nearby participant's procedure.

### Conclusions

Using the more-diligent cleaning procedure resulted in a significantly higher proportion of ENFit connectors without residue, regardless of the type of brush used. Routine cleaning of ENFit connectors is recommended even if there is no residue.

PubMed was completed, along with a search of Lippincott and Elsevier Nursing Procedures, for keywords *enteral tubes*, *feeding tubes*, and *cleaning protocols*. The first search was done in 2015 (studies published 1995-2015) and a second in 2017 (studies published 2015-2017).

### Ethics

This research was reviewed by the Institutional Review Board and the Institutional Biosafety Committee of the study institution and was deemed not human research.

### Sample Selection

Clinical nurses and senior nursing students from a large pediatric teaching hospital in the midwestern United States were recruited from inpatient and ambulatory care areas as volunteers for the study. Research personnel read an enrollment script explaining the protocol and nurses who chose to participate then gave verbal consent. No consent form was required for this study because participants were not being studied, per se.

A sample of 60 per cleaning regimen group would have 80% power to detect the difference between zero residue proportions of 80% and 56% (Chow, 2008). This is based on a chi-square test and uses a significance level of 0.05. Chi-square tests or Fisher's exact tests were used for any group comparisons (e.g., comparing two cleaning regimens). The kappa statistic was used to examine inter-rater reliability for reviewers; values 0.61-0.80 were considered substantial (McHugh, 2012).

### Design and Method

The process of cleaning involves the removal of visible residue, such as a liquid medication or enteral formula, until the item is deemed safe to use (FDA, 2017). Several factors should be considered for a cleaning regimen involving the distal end of a feeding tube that will remain in place during the cleaning procedure. No cleaning agents or chemicals can be used because they

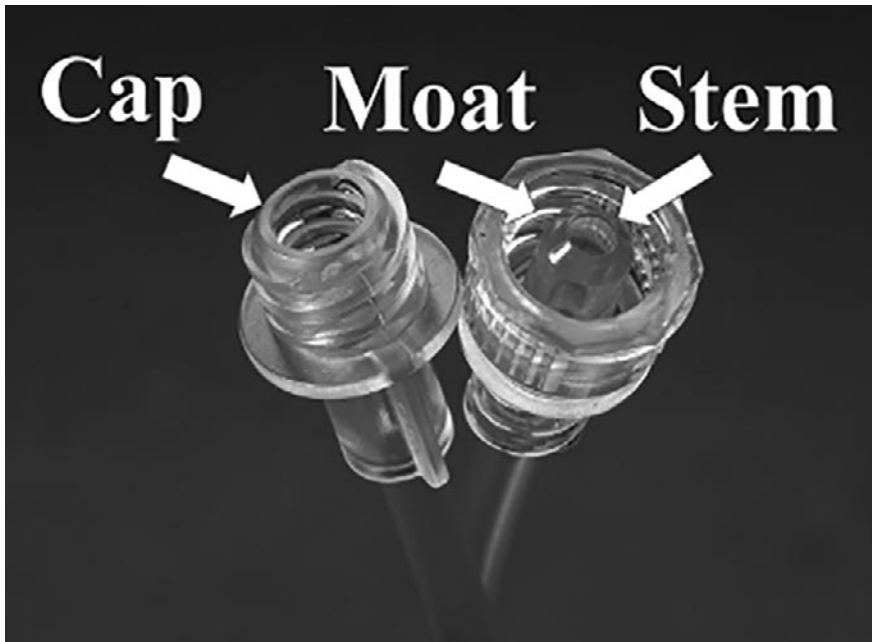
with visible residue using a ranking scale to score the effectiveness of the procedure, and evaluate two cleaning regimens after application of a nonvisible environmental marker gel using ultraviolet (UV) light and ranking scale to score the effectiveness of the procedure. The secondary purpose was to compare the efficacy of an ENFit commercial cleaning brush specifically developed to clean ENFit connectors with a firm-bristled toothbrush.

### Review of the Literature

The American Society for Parenteral and Enteral Nutrition (ASPEN)

recently published new Safe Practices for Enteral Nutrition Therapy (Boullata, 2017). Recommendations in this document specifically address infection prevention issues, including use of sterile water in hospital settings for enteral formula preparation, flushing the tube, fluid bolus, and medication administration. While the document recommends keeping the feeding apparatus clean, details about how to do this are not provided. No data exist in the literature to guide nursing practice in cleaning the previous (legacy) connector system or the new ENFit connector system. A literature search of CINAHL and

**FIGURE 1.**  
ENFit Connector



could go into the tube and the patient inadvertently. Water thus needs to be used. The procedure must be able to reach all soiled parts of the device (FDA, 2017). In this situation, the ENFit design has internal threads that are difficult to clean unless a brush is used, particularly when there is dried residue (see Figure 1).

A cleaning regimen must be validated using at least two cleaning methods involving test soils with visual inspection of the device before and after cleaning. A test soil is defined as a substitute for the actual substance that would contaminate a medical device. The validation process must involve two phases: a more-diligent cleaning regimen and a less-diligent cleaning regimen in which the regimen is not followed ideally (FDA, 2017). Finally, a tool such as a brush must be used to clean the connector. Researchers did not know if an ENFit commercial cleaning brush or a firm-bristled toothbrush would be effective, but the cost of an ENFit commercial cleaning brush raised concern about use in the home setting.

The first substance used as a test soil was a chocolate-flavored enteral formula, which allowed easy visual inspection of the connector when using a clear ENFit connector. This flavored product typically would not be administered via feeding tube, but its isotonic version is administered commonly via feeding tube in a clinical setting. DAZO™, as the second test soil, is an environmental gel only visible with UV light; it is used to detect how effectively a surface has been cleaned (Ecolab Healthcare, 2020). The product is applied in a hospital room after a patient is discharged. After environmental services staff have cleaned the room, a UV light is used to assess effective removal of DAZO as a surrogate of effective cleaning. For this study, DAZO mimics soil that cannot be seen due to the connector's color.

A more diligent cleaning regimen involved pulse-flushing the moat with water before using the brush, vigorous rotation of the brush in the moat, longer time cleaning with the brush, and repetition of the cycle based on visual assessment of the ENFit connector.

Pulse flushing is intermittent vigorous water delivery into the moat of the connector using a syringe to soften dried residue.

The primary outcome of interest was the proportion of ENFit connectors with no visible residue after cleaning. Scale rankings were as follows: 0=no residue, 1=some residue remaining, 2=significant amount of residue remaining.

Nurses ( $N=120$ ) were assigned randomly to the more-diligent cleaning regimen or the less-diligent cleaning regimen. Nurses then cleaned an ENFit connector with visible chocolate-flavored enteral formula residue and an invisible DAZO-inoculated ENFit connector ( $N=240$  ENFit connectors). Half the nurses used a firm-bristled toothbrush and half used an ENFit commercial cleaning brush. For this multiphase study, nurses were blinded to the type of cleaning instructions they were given in cleaning procedures (more diligent vs. less diligent). No effort was made to isolate nurses doing the different cleaning regimens; nurses sitting next to each other might have received different cleaning regimens. Participants were asked to document the date and a visual assessment using an ordinal scale for cleaning procedure effectiveness (0=no residue remaining, 1=some residue visible, 2=significant amount of residue remaining).

After they were clean, the ENFit connectors were evaluated separately by two investigators using the same ordinal scale and blinded to the cleaning procedure. All ENFit connectors were numbered using indelible ink in numerical order and were tracked using those numbers. A professional photographer provided color pictures of ENFit connectors inoculated with chocolate-flavored enteral formula and DAZO to represent each score and serve as templates for the investigators.

### Phase 1

This phase was designed to document the cleaning procedure's efficacy when enteral formula was administered via a feeding set

(defined as a feeding bag with attached tubing) to an ENFit connector in an ideal situation, resulting in no enteral formula residue accidentally spilling into the moat. A liquid medication (1.5 ml liquid Tylenol®) was administered using the procedure outlined by published education materials (GEDSA, 2020). With no accidental spillage of medication into the connection moat, there was no visible residue in the ENFit connectors. Using a 24-gauge needle and 1-ml syringe, five dots of DAZO were placed on top of the ENFit adapter. The remaining of the 0.1 ml volume was instilled on the adapter's grooves and at the base of the moat. Two investigators independently scored the cleaning effectiveness using a visual scaling system (0=no residue seen with ultraviolet light; 1=minimal residue seen with ultraviolet light on rim, grooves, and moat; 2=significant residue seen with ultraviolet light on rim, grooves, and moat).

### Phase 2

For this phase, a test soil of 0.1-0.2 ml chocolate-flavored enteral formula was instilled into the moat. The ENFit cap was then placed over the distal end of the feeding tube to mimic enteral formula accidentally spilling into the moat at the end of an intermittent feeding. The enteral formula remained in the ENFit connector for 3 hours to simulate the typical time for an intermittent feeding schedule. All ENFit connectors were labeled and placed in a sealed bag with a brush and a cleaning instruction sheet to be used by a nurse participant. Assignment of the more-diligent cleaning regimen or the less-diligent cleaning regimen was done randomly by an investigator. The specific procedures are detailed in Tables 1 and 2.

### Findings

Using the more-diligent cleaning regimen, 144 ENFit connectors were cleaned (58 with an ENFit commercial cleaning brush and 56 with a firm-bristled toothbrush); 122 were cleaned using the less-diligent cleaning regimen (64 with an ENFit

**TABLE 1.**  
**Protocol A Cleaning Procedure: The More-Diligent Cleaning Regimen**

1. Supplies needed:
  - Gauze pad
  - Sterile water
  - Enteral syringe – 3 or 6 ml
  - Brush for cleaning ENFit connector
    - ENFit commercial cleaning brush
    - Firm-bristled toothbrush
  - Cotton-tipped applicator
2. Perform hand hygiene.
3. Uncap the ENFit connector and clean the cap with a sterile water-soaked gauze pad.
4. Plug the stem of the ENFit connector with the cotton-tipped applicator end (not the end with the cotton attached).
  - a. This will prevent residue from entering the tube during flushing.
5. Flush the moat of the ENFit connector with 2-3 ml of sterile water using a pulsating motion.
6. Flick the remaining water out of the moat.
7. Remove the cotton-tipped applicator from the stem.
8. Using a brush dipped in sterile water, clean the grooves and bottom of the moat using a vigorous rotating motion for 10-15 seconds.
9. Rinse the brush in sterile water.
10. Replace the cotton-tipped applicator end into the stem.
11. Flush the moat with 2-3 ml of sterile water using the same pulsating motion.
12. Remove the cotton-tipped application.
13. Replace the brush dipped in sterile water and clean with the same vigorous rotating motion.
14. If there is visible residue remaining, repeat the process until the residue is gone.
15. Remove excess water from the moat and cap.
16. Rinse the brush in sterile water.
17. Dry the ENFit connector with gentle tapping, drying with washcloth, and allow to air dry.

**TABLE 2.**  
**Protocol B Cleaning Procedure: Less-Diligent Cleaning Regimen**

1. Supplies needed:
  - Gauze pad
  - Sterile water
  - Enteral syringe – 3 or 6 ml
  - Brush for cleaning ENFit connector
    - ENFit commercial cleaning brush
    - Firm-bristled toothbrush
2. Perform hand hygiene.
3. Uncap the ENFit connector and clean the cap with the water-soaked gauze.
4. If using a firm-bristled toothbrush, make sure some of the center bristles are in the lumen (or stem) of the ENFit connector to block it.
5. Using a brush dipped in sterile water, clean the grooves and the bottom of the moat using a rotating motion for 10 seconds.
7. Dip the brush in sterile water and clean the grooves and the bottom of the moat using a rotating motion for 10 seconds.
8. Dip the brush in sterile water and clean the grooves and the bottom of the moat using a rotating motion for 10 seconds.
9. Remove the excess water from the moat and re-cap.

commercial cleaning brush and 58 with a firm-bristled toothbrush). The numbers were different from planned because four more participants received instructions to follow the less-diligent cleaning regimen than originally intended; some tubes were lost by participants. The two blinded independent raters received the numbered tubes. These two reviewers provided their scoring about the photo templates.

Inter-rater reliability was substantial between the two investigators for the ordinal level score, weighted kappa=0.68 (95% CI 0.61, 0.76), and for the dichotomous outcome of residue presence versus no residue, kappa=0.76 (95% CI 0.66, 0.86). Because the inter-rater reliability was substantial, a combined investigator score was used for all analyses except 20 instances in which investigators did not agree; in these instances, one of their responses was chosen randomly for use. Agreement between the nurses and the combined investigators also was assessed and found to be poor (kappa=0.03, 95% CI -0.05, 0.10). Nurses found 107 (84%) and 110 (75%) of the more-diligent versus less-diligently cleaned ENFit connectors to have zero residue. In comparison, investigators found only 35 (31%) and 13 (16%) of the ENFit connectors to have zero residue, respectively.

When combining all ENFit connectors cleaned with the more-diligent cleaning regimen and then all the connectors cleaned with the less-diligent cleaning regimen, a significant difference was found in the proportion of ENFit connectors with no residue (30.7% vs. 13.1%,  $p=0.0010$ ). When separating this by the test soil material, results are mixed. When the chocolate-flavored enteral formula was used as the test soil, a significant difference was found between the more-diligent and the less-diligent cleaning regimens (53.6% with zero residue vs. 19.7%,  $p=0.0001$ ). However, when using DAZO as the test soil, no significant difference was found between the cleaning regimens. No difference was found in cleaning effectiveness between the ENFit

## *Nurses need to be role models for patients and caregivers when accessing ENFit connectors.*

commercial cleaning brush and the firm-bristled toothbrush (26.2% vs. 16.7%,  $p=0.0745$ ).

### Discussion

While this study was conducted at a children's hospital, cleaning the ENFit connector is the same regardless of patient population. This study, the first to address cleaning of ENFit connectors, involved no actual patients. The ENFit design was developed due to The Joint Commission's call for a method to prevent misconnections of enteral feeding products that could allow for intravenous administration of medications or enteral formula. Because previous legacy products had no published cleaning standards, a cleaning protocol was developed in consultation with the infection prevention staff at the study hospital, FDA, GEDSA, and clinicians. Based on the FDA's recommendations, no bacterial cultures were obtained in this study to evaluate the bioburden because this is a clean rather than a sterile procedure.

The cleaning procedure had many steps but nurses did not express concern about the number of steps required to clean dried residue. They viewed the cotton-tipped applicator used to plug the connection as protecting the patient during an actual cleaning. Sterile water was used per ASPEN recommendations (Boullata, 2017). Since instituting this procedure at the study institution, no reports have been received of the cotton-tipped applicator breaking during the cleaning of feeding tubes.

The more-diligent cleaning regimen was determined to be more effective in removing visible residue. The difference in efficacy was statistically significant in the visually evident (chocolate-flavored enteral formula) residue, but not in

the invisible (DAZO) residue. This suggests participants may not have cleaned as diligently when they did not see anything visible to clean compared to visible residue. The discrepancy highlights the importance of following the more-diligent cleaning procedure regardless of the connector's appearance.

This study used clear ENFit connectors to allow easier visualization of residue within the moat. Not all ENFit products will have clear ENFit connectors, making it more important the more-diligent cleaning regimen is followed consistently.

Nurse evaluation of cleaning effectiveness and reviewers' evaluation of cleaning effectiveness did not correlate well. This suggests a need to stress diligence in adherence to the cleaning protocol to ensure no residue is visible. Participating nurses did not benefit from comparing their connectors with the professional photos that served as a template for the investigators who scored the connectors. While this might have helped with the connectors with visible soil, the images would not have helped with DAZO-inoculated connectors unless the nurse participants also had a UV light.

The ENFit commercial cleaning brush and the firm-bristled toothbrush were equally effective in removing visible and nonvisible residue. Pre-study trials using the standard hospital-provided soft-bristled toothbrushes demonstrated inferior cleaning results, which led to the purchase of firm-bristled toothbrushes. In a home care setting, using a firm-bristled toothbrush would be a cost-effective option for cleaning.

The ENFit connectors with visible dried residue presented a challenge when attempting to open the cap because the dried residue adhered the cap to the moat,

emphasizing the importance of cleaning the cap. The dried residue was more effectively removed after water was pulse-flushed into the moat of the ENFit product to soften the debris. The firm-bristled toothbrush and the ENFit commercial cleaning brush cleaned the products more effectively when they were wet. The stem of a cotton-tip applicator was used to occlude the opening in the center of the moat to prevent residue from entering the lumen for indwelling tubes such as nasogastric or trans-pyloric tubes when pulse-flushing with room temperature sterile water. After this study, clinicians at the site implemented an additional step of pulse-flushing sterilized water through low-profile extension sets or soaking in sterilized water before cleaning. It is essential to tap all excess water out of the moat. For extension tubing, the moat should be left uncapped to air dry after cleaning to prevent pathogen growth in closed environments with moisture present. When air drying cannot be achieved, gauze should be used to dry the moat before closure of the connection.

## Limitations

A limitation of this preliminary study included difficulty following the cleaning protocol because clinicians struggled with the terms *moat*, *cap*, and *stem* for the ENFit connector. This was remediated by investigators answering questions when asked. In addition, some participants may have mimicked other participants' technique while unaware that multiple protocols existed due to the proximity of nurses during the cleaning process. A final limitation of this study could be considered the discrepancy in rater versus nurse participant scoring of cleaning regimen effectiveness. This was a surprising finding that warrants further investigation. This preliminary study aimed to look at cleaning at one time point and not over repeated uses of the ENFit connector. The needed frequency of the cleaning regimen also was not investigated.

## Recommendations for Future Research

Future research should examine frequency of cleaning and storage of ENFit connectors when not in use. While the study attempted to simulate a real-life experience, a clinical study using actual patients to implement cleaning intervals would provide additional valuable information. Examination of the residue's bacterial growth was outside the scope of this study but could be addressed in future studies.

## Nursing Implications

For clinical practice, researchers suggest nurses follow the more-diligent cleaning regimen in sequence, pulse-flush water into the ENFit connectors and extension tubing for low-profile devices, wet the bristles on the brush before cleaning, and use a vigorous rotating motion with a firm-bristled toothbrush or ENFit commercial cleaning brush. The process should be repeated until all visible residue is removed. Clinicians need to perform diligent cleaning even if visible residue is not present. Adequate cleaning will prevent adherence of the female and male connections from dried enteral medications and formula.

Education is an essential component of nursing practice now that ENFit connectors are being used. At the study hospital, a color pictograph was developed for inpatient and home care that teaches staff and caregivers how to clean these connectors. Nurse education should include how to prevent residue in the moat along with how to clean effectively. This encompasses how to administer formula and medications without spillage into the moat. Nurses need to be role models for patients and caregivers when accessing ENFit connectors. Periodic quality improvement monitoring of feeding tube connectors is recommended.

## Conclusion

This study found using good technique in enteral formula and

enteral medication administration (Phase 1) resulted in no visible residue of the ENFit connectors. The cleaning protocol included enteral formula and medication as residue agents to simulate the use of common products administered through enteral access devices of both low and medium viscosity. Invisible residue (DAZO) was used because not all manufacturers make clear connectors, creating a challenge for caregivers and healthcare staff to see existing residue in the grooves or moat. When clinicians cleaned DAZO-inoculated ENFit connectors using the same procedure as the connectors with visible chocolate-flavored enteral formula residue, more DAZO was visible using a UV light; this suggested less diligence on the part of the clinician when no residue was visible. This result validates the need for more diligent cleaning whether residue is visible or not visible in the ENFit connector. [MSN](#)

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