



- *product design & development consultants*
- *designing the future of medical devices*

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ENFit male patient side connector vs. existing connectors

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I. Abstract:

An analysis is prepared comparing the design and flow rate characteristics between the proposed ISO 80369-3 (ENFit) male patient side connector and the existing gastrostomy tube (G-tube) feeding connectors.

The comparison is important in illustrating the major substantial reduction in volume flow rate in the proposed ENFit male patient side connector as compared to existing G-tube connectors.

While 80369-3 does not specify the flow orientation of the ENFit connectors, AAMI/ISO has purported that risk analysis has been performed on the ENFit male patient side connector. Further, samples and information from GEDSA has always shown the ENFit male connector as the patient side connector. 80369-3 notes that it was determined that “some potential unacceptable risk misconnections” occur when the male is located on the delivery side. As such, this review focuses on the ENFit male patient side connector.

Both the ENFit male connector and existing connectors remain as part of the patient’s tube. The relevance of volume flow reduction in the ENFit male connector, therefore, directly affects patient care especially when used with bolus syringe fed, viscous, blenderized food.

A dimensional and volume flow comparison is presented. The ENFit connector resulted in a substantial reduction in volume flow as compared to the existing G-tube connectors. This seems to present issues of difficulty in blenderized food administration, gravity and pump formula administration, increased ENFit connector clogging and associated replacement costs, and added nursing care costs.

Tests results comparing the ENFit connector system (ENFit female syringe and ENFit male patient side connector) versus the existing connector system (60cc catheter tip syringe and 24fr bolus patient side connector) revealed that it takes 3x as long to empty 60cc of IsoSource 1.5 formula using the ENFit system versus the existing system. Tests were done with and without the connector attached to a PEG tube.

This document also touches upon cost impacts, contamination issues, lack of clinical trials, and syringe dead space issues.

While this document does not discuss the unsafe misconnections associated with ENFit (misconnection with certain airway tracheal tubes, I.V. luer ports, and vascular needle connectors), those unsafe misconnections still remain a concern of GI Design Associates.

Two YouTube videos from GI Design Associates further highlight these concerns:

Video 1:

<http://tinyurl.com/ENFit>

or <https://www.youtube.com/watch?v=nL9flCX5Iyg>

Video 2:

<http://tinyurl.com/ENFit2>

or <https://www.youtube.com/watch?v=gC1XQIEwwCY>

The proposed 80369-3 standard and resulting ENFit connector should not be adopted because:

- 1) The patient side connector should have an internal diameter of at least 4.0mm, and possibly larger, with a continuous laminar flow instead of crevices.
- 2) Real world/real patient practical evaluation and trials with blenderized food through an ENFit syringe and through an ENFit male patient side connector has not occurred.
- 3) Real world clinical performance testing demonstrating that the ENFit male patient side connector is substantially equivalent in flow to the existing connector has not occurred.
- 4) Consideration of the abilities and limitations/dexterity of the at-home tube feeder community has not been provided.

The following details support the above recommendation of non-adoption of the 80369-3 standard.

II. Background

The design and utilization of the existing large bore G-tube replaceable and fixed connectors, in conjunction with the large bore enteral bolus syringes, has been used by clinicians, caregivers and patients for at least the last 25 years.

A. Present Tube Connectors

At present, the G-tube (whether a percutaneous endoscopic gastrostomy PEG tube or a balloon replacement g-tube) utilizes a feeding tube connector which remains as part of the G-tube for an extended period of time.

Most existing connectors have a large bore, female, funnel shaped connector which readily accepts:

- all enteral formula administration sets
- all enteral bolus feeding syringes

PEG tubes have been known to stay with patients for up to a year and sometimes more. Balloon replacement tubes are typically removed and replaced every 90 days.

1) replaceable or fixed

Tubes utilize a connector:

- PEG tube connectors are replaceable and changed every 30 days.
- Many balloon replacement tubes have fixed connectors, which necessarily are discarded with the tube, approximately every 90 days.

2) extreme proximal opening of 6mm

The large bore extreme proximal entrance opening usually exceeds 6mm inner diameter such that it will not connect to an I.V. luer slip tip or luer lock connector.

3) inner diameter of 4.65mm

The most popular G-tube size is 24fr. The existing connector of this tube has a minimum inside diameter of 4.65mm.

B. Catheter tip syringe - large bore 3.82mm opening

Most enteral bolus feeding syringes are:

- large bore catheter tip
- 60cc
- 3.82 mm inner diameter flow path

C. Medicare Part B reimbursement

- Balloon replacement tubes are reimbursed 1 every 90 days (code B4087).
- Patient side connectors are not reimbursable.

III. Description of Proposed ENFit 80369-3 Connector

AAMI/ISO has proposed a design change to the existing G-tube connector. The ENFit male connector proposes to be safer in preventing misconnection between the connector and I.V. luers and tracheostomy tubes. GI Design disagrees that ENFit is a safer connector. Rather, it presents more misconnection opportunities than the existing connector. The details of these ENFit misconnections is not the focus of this review.

The impact of the proposed design change and its performance limitations are a part of this review.

The greatest impact of the new proposed design is the fact that it utilizes an internal screw thread design with male stem and moat, with a substantially reduced internal flow volume.

- | | |
|---|------------------------|
| ▪ ENFit Patient Side Connector: | 2.95 mm inner diameter |
| ▪ Existing 24fr Patient Side Connector: | 4.65 mm inner diameter |

IV. Description of the Drawings (shown at pages 23-25)

Fig. 1 on page 23 of this document is an internal flow volume drawing of an existing bolus feeding connector as part of a 24fr PEG tube (Cook Endoscopy BFA-24 as part of PEG placement kits).



current patient side
24fr bolus connector

As can be seen from Fig. 1, the existing connector has a large bore proximal entrance of about 6.3 mm, with a minimum internal diameter of 4.65 mm. The entire internal flow path is funnel shaped and smooth such that routine flushing/irrigation of the connector will keep the flow path clear of clogged debris.

Fig. 2 on page 23 is an internal flow volume drawing of the proposed male ENFit connector as part of a 24fr PEG tube.

The proposed ENFit design which uses an internal female screw thread with a male stem and moat area. The ENFit connector has an inner diameter (I.D.) of only 2.95 mm, compared to 4.65 mm of the existing connector shown in Fig. 1.

Fig. 3 on page 24 is an internal flow volume drawing comparing the 4.65 mm internal diameter of an existing 24fr bolus feeding connector (Cook Endoscopy BFA-24 as part of PEG placement kits) with the proposed 2.95 mm I.D. of the ENFit connector.

There is shown an enlarged 20 to 1 scaled volume flow path drawing comparing the existing 24fr bolus connector with the constricted ENFit connector.

The formula for determining the volume through a tube is: $V = D^4$

V is the volume flow.

D is the internal diameter.

Using this formula, the existing 24fr bolus connector has a volume flow value of 467.5 compared to the proposed ENFit volume flow value of only 75.7.

- | | |
|----------------------------------|------------------------|
| ▪ ENFit Patient Side Connector: | 2.95 mm inner diameter |
| ▪ Existing 24fr Bolus Connector: | 4.65 mm inner diameter |

The ENFit connector has an 84% lower flow volume versus the existing 24fr bolus connector.



Fig. 4 on page 25 is an internal flow volume drawing comparing the 3.94 mm internal diameter of an existing universal/Y-port connector (Cook Endoscopy UFA-24) with the 2.95 mm I.D. of the ENFit connector.

Using the formula, the existing 24fr universal/Y-port connector has a volume flow value of 240.1 compared to the proposed ENFit volume flow value of only 75.7.

- ENFit Patient Side Connector: 2.95 mm inner diameter
- Existing 24fr Universal/Y-port Connector: 3.94 mm inner diameter

The ENFit connector has a 68.5% lower flow volume vs. the existing 24fr universal y-port connector.



current
universal/Y-port
connector

V. Impact on Administering Commercially Available Enteral Formula Via Gravity Method – Test Results

The ENFit's substantially lower flow volume (68.5% lower than existing 24fr Y-port connector) will result in considerable problems when delivering commercially available enteral formula via the gravity method.

A substantial increase in delivery time when using gravity feeding in conjunction with ENFit male patient side connectors was revealed.

TEST #1: GI Design conducted testing using:

- ENFit male connector, ENFit 60cc syringe, ISOSource 1.5 formula.
 - ENFit male connector, ENFit 60cc syringe, orange juice with pulp.
 - 24fr bolus connector, 60cc catheter tip syringe, ISOSource 1.5 formula.
 - 24fr bolus connector, 60cc catheter tip syringe, orange juice with pulp.
- A. Test Results using ISOSource 1.5 Formula:
Initial test results when using ENFit connector prototypes, ENFit gravity syringe and IsoSource 1.5 formula:
- **Increase in delivery time of up to 3.7 times** when using ENFit compared to existing connector and catheter tip syringe.
- B. Test Results using Orange Juice with Pulp:
Initial test results when using ENFit connector prototypes, ENFit gravity feed syringe and orange juice with pulp:
- **Orange juice clogged at 8 seconds into flow, delivering only 35 ml (58%) of the 60ml ENFit syringe feed.** Meanwhile, 60ml of ISOSource 1.5 formula was delivered within 7 seconds using existing connector and catheter tip syringe.

TEST #1 can be seen at:

<http://tinyurl.com/ENFit>

or <https://www.youtube.com/watch?v=nL9flCX5Ixg>

TEST #1

Flow Test Results

time to empty 60cc syringe through connector, not attached to tube

	Iso-Source 1.5	Orange Juice with Pulp
Catheter tip 60cc syringe and bolus adapter for 24fr tube. (Cook Endoscopy BFA-24)	8 seconds to empty 60cc syringe	7 seconds to empty 60cc syringe
Catheter tip 60cc syringe and universal adapter for 24fr tube. (Cook Endoscopy UFA-24)	8 seconds to empty 60cc syringe	7 seconds to empty 60cc syringe
ENFit 60cc syringe and ENFit male connector	30 seconds to empty 60cc syringe (3.75 x longer than existing products)	Clogged at 8 seconds. Delivered only 35cc (only 58%) of 60cc syringe.

The clogging of the ENFit system after delivering only 35cc of orange juice with pulp would seem indicative of the clogging that can be expected when using blenderized food.

TEST #2 attached to a PEG tube. GI Design conducted testing using:

- A 20fr PEG tube, ENFit male connector, ENFit 60cc syringe, ISOSource 1.5 formula.
- A 20fr PEG tube, 20fr Y-connector, a 60cc catheter tip syringe, ISOSource 1.5 formula.
- A 24fr PEG tube, ENFit male connector, ENFit 60cc syringe, ISOSource 1.5 formula.
- A 24fr PEG tube, 24fr bolus connector, 60cc catheter tip syringe, ISOSource 1.5 formula.

Test Results revealed that the time to empty a 60cc syringe using ISOSource 1.5 in a 20fr and 24fr PEG tube was **3x longer** when using an ENFit system versus existing connectors.

ENFit, therefore, is not essentially equivalent to existing connectors.

Test #2 can be seen at:

<http://tinyurl.com/ENFit2>

or <https://www.youtube.com/watch?v=gC1XQIEwwCY>

TEST #2
Gravity Flow Comparison

ISOSource 1.5 Formula
ENFit Connector (ENFit) vs. Existing Connector (Conn)

20fr PEG

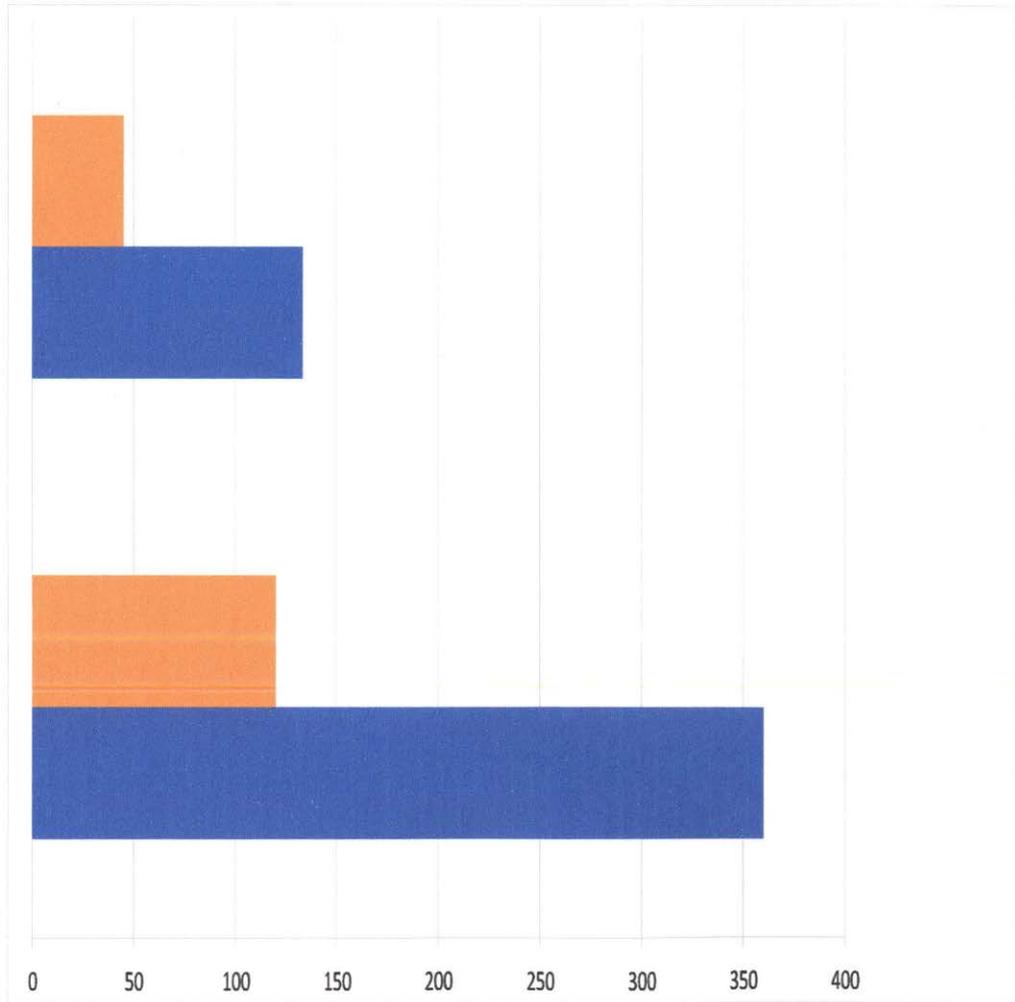
ENFit 45ml/min

Conn 133ml/min

24fr PEG

ENFit 120ml/min

Conn 360ml/min



mL/minute @ room temperature

GI DESIGN ASSOCIATES
October 2015



In addition, pump pressures will probably have to increase accordingly to delivery the same volume of needed formula in the same period of time due to the constriction and bottle neck of ENFit connector internal diameter of only 2.95 mm vs. 3.94 mm of the existing 24fr Y-connector.

VI. Impact on Administering Blenderized Food

The ENFit male patient side connector design presents an even more troublesome volume flow constriction point (versus gravity feed and pump feed) when used with blenderized viscous food. For various reasons, blenderized food has become more commonplace with home care tube feeders.

Blenderized food can be either home blenderized or the commercial type. While commercial types can be very thick and viscous, home cooked blenderized foods can be granular and fibrous, virtually impossible to pass through the ENFit constriction.

Some patients cite various clinical advantageous to home blenderized food and others express the normalcy and psychological benefits of preparing a meal and then blenderizing for tube administration.

Other patients may find it difficult to tolerate commercial formula due to disease or allergy. In this case, the user would consider the blenderized diet to be a medical necessity.

Personal nutrition requirements and options with resulting psychological benefits should not be frustrated, disrupted or eliminated with any new proposed design.

Further, the proposed ENFit connector can only be used with a compatible ENFit syringe and not with a traditional large bore enteral catheter tip syringe.

As such, due to the constricted dimension of the ENFit connector, it is doubtful that blenderized food could even flow through the constricted opening. If any blenderized food does happen to flow through the constricted opening, clogging of the ENFit connector is a most assured event.

ENFit may indeed force users toward commercial nutrition as opposed to home blenderized food because it will not be possible to blend fine enough.

A. Practical Experience

The existing universal/Y-port connector is the preferred connector for use with gravity or pump delivery sets. However, the Y-port is not routinely used for bolus feeding of blenderized food, because experience has dictated that the 3.94 mm flow volume I.D. of the Y-port is prone to clogging if blenderized food is not sufficiently diluted or ground/blended.

As such, bolus fed patient tends to utilize the larger bolus connector.

Existing patient side connectors have over 25 years of clinical usage with acceptance with all feeding modalities. It is difficult, however, to imagine a small 2.95 mm diameter on the proposed ENFit patient side connector being able to accommodate blenderized food.

While clogging with the existing 3.94 mm Y-port is already problematic for home blenderized foods, the ENFit connector is significant smaller at 2.95 mm.

Certainly the ENFit connector will not be able to accommodate most blenderized food at all.

B. GEDSA Assertion

The following statement found on the GEDSA website has no relevance.

The assertion **does not take into account the patient side connector**. The ENFit male patient side connector is not the same bore size as the existing patient side connector. Therefore, ENFit is not consistent with current practice.

Further, it is known that blenderized food currently passes through a large-bore syringe and a large bore patient side connector. Therefore, ENFit is not consistent with current practice, as ENFit requires blenderized food to pass through small bore ENFit connections (at the patient side AND at the delivery side).

Consequently, it is virtually impossible for blenderized food to be administered through an ENFit syringe, resulting in disruption of therapy.

From GEDSA website: <http://www.stayconnected.org/media/pdfs/GEDSA-blenderized-FAQ.pdf> (p. 4, question 5)

Question: Will thicker formulas and blenderized foods pass through the new ENFit connector?

Answer: The ISO 80369-3 enteral feeding design standards were developed with current practice in mind and specific requirements to avoid any **disruption of therapy**. The bore size (or hole) in the ENFit connector was **designed to be consistent** with the current connector (commonly called "**Christmas tree**" or "stepped adapter"). Therefore, feeding through devices with the ENFit connector is intended to be consistent with current practice. For more information, contact the manufacturer of the enteral device directly.

The answer to the question above is incorrect.

The following is correct:

Patient side:

- The ENFit patient side bore is 2.95 mm.
- Existing patient side bore is 4.65 mm (24fr bolus connector).
- Therefore ENFit is not consistent with current practice.

Delivery side:

- Blenderized food is fed through existing 4mm syringes.
- ENFit two-part mated system is only 2.95 mm.
- Therefore it is not consistent with current practice.

VII. Crushed Medication

Many patients require the administration of crushed medication into their feeding tube. A patient side connector with a bore of 2.9 mm will make the delivery of crushed meds via a syringe extremely difficult, or virtually impossible.

VIII. Dexterity Issues

Reference is made to FDA Document, “Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management Identifying, Understanding, and Addressing Use-Related Hazards By Kaye and Crowle, July 2000:

“3.2.2 Medical Device Users

Users need devices that they can use safely and effectively. To assure that these needs are met, it is necessary to understand abilities and limitations of the intended users. Important characteristics of user populations include: Coordination (manual dexterity).”

“5.8 Verify and Validate User Interface Design

Verification confirms that the specific functional and operational requirements for the design of a device user interface have been met.

The process for verifying individual user interface requirements will likely require focused effort for each. Validation establishes that the device meets the needs of the intended users.

The primary need of medical device users is the ability to use the devices safely and effectively under the actual use conditions. Applying usability testing approaches can directly validate a user interface design. For the purpose of validation, it is particularly important to use a production version of the device, representative device users, actual or simulated use environments, and to address all aspects of intended use.

....Some degree of testing of the entire system under realistic conditions with representative users is warranted.”

It should be noted that while approximately 300,000 home tube feeders will be affected by the proposed ENFit change, it appears that contrary to FDA Human Factors Engineering document, no “actual use conditions” have been validated.

Why has such a large population and their use needs been seemingly ignored in total throughout the process?

The FDA document is clear, yet has been ignored with respect to ENFit.

“...it is necessary to understand abilities and limitations of the intended users. Important characteristics of user populations include: Coordination (manual dexterity).”

Many at home tube feeders are very independent. They are able, with one hand, to make the press fit connection between syringe and tube.

However, the ENFit screw thread design will make one-handed connection impossible, thereby eliminating user independence and creating dependency.

Many tube feeders have limited dexterity or the use of only one arm/one hand due to the side effects of radiation. Such limited use of extremities makes the screw thread design an impossibility for these, at present, independent individuals.

The FDA document is clear, yet has been ignored with respect to ENFit.

“Some degree of testing of the entire system under realistic conditions with representative users is warranted”

IX. No Real World Clinical Trial Use

It appears that AAMI/ISO working groups have not conducted any real world/real patient disclosed clinical field trials confirming performance of the proposed ENFit connector utilizing all the various modes of delivery of enteral nutrition such as:

- Formula bolus syringe.
- Formula gravity and pump feeding.
- Blenderized food feedings.

Such real patient clinical field trials seem absolutely necessary before any adoption of this ISO Standard since it will have a **tremendous impact on the entire enteral nutrition population worldwide.**

The need for multiple clinical field trials using the ENFit connector is especially important due to the drastic reduction in flow volumes of the proposed ENFit male patient side connector compared to the existing connectors.

Reference is made again to FDA Document, “Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management Identifying, Understanding, and Addressing Use-Related Hazards By Kaye and Crowle, July 2000:

“5.8 Some degree of testing of the entire system under realistic conditions with representative users is warranted”

Absent these real world/real patient clinical trials, the ISO ENFit standard should not be adopted.

X. Not Essentially Equivalent

From all the above, it is clearly evident that the ENFit male patient side connector is not essentially equivalent to the existing patient side connectors that received government regulatory clearance over the last 25 years.

It would seem that proof of essential equivalency should include:

1. Flow volume characteristics.
2. Clinical performance testing as evidenced by real world/real patient clinical field trials.

If the proposed ENFit male patient side connector had the same flow volume characteristics, then perhaps bench studies would suffice. However, that is not the case.

As such, the proposed ENFit male patient side connector should only receive regulatory clearance based upon **clinical performance testing**.

XI. Impact on Healthcare Costs

While there is a national focus on reducing healthcare costs, it appears an introduction of the ENFit connector will serve to increase costs. Specifically:

- a) Clogging: Nursing time to unclog the ENFit patient side male connector.
- b) Contamination: Nursing time to clean the deep crevice “moat area” (routinely clean to keep from becoming encrusted, and for contamination concern) on the ENFit patient side male connector.
- c) Costly Connector Replacements: More frequent replacement of the tube ENFit connector – connectors are currently not Medicare reimbursable. ENFit patient side connectors will clog frequently thereby leading to frequent replacement.

Because of the difficulty/impossibility of cleaning ENFit patient side connectors, frequent and perhaps daily replacement will be required.

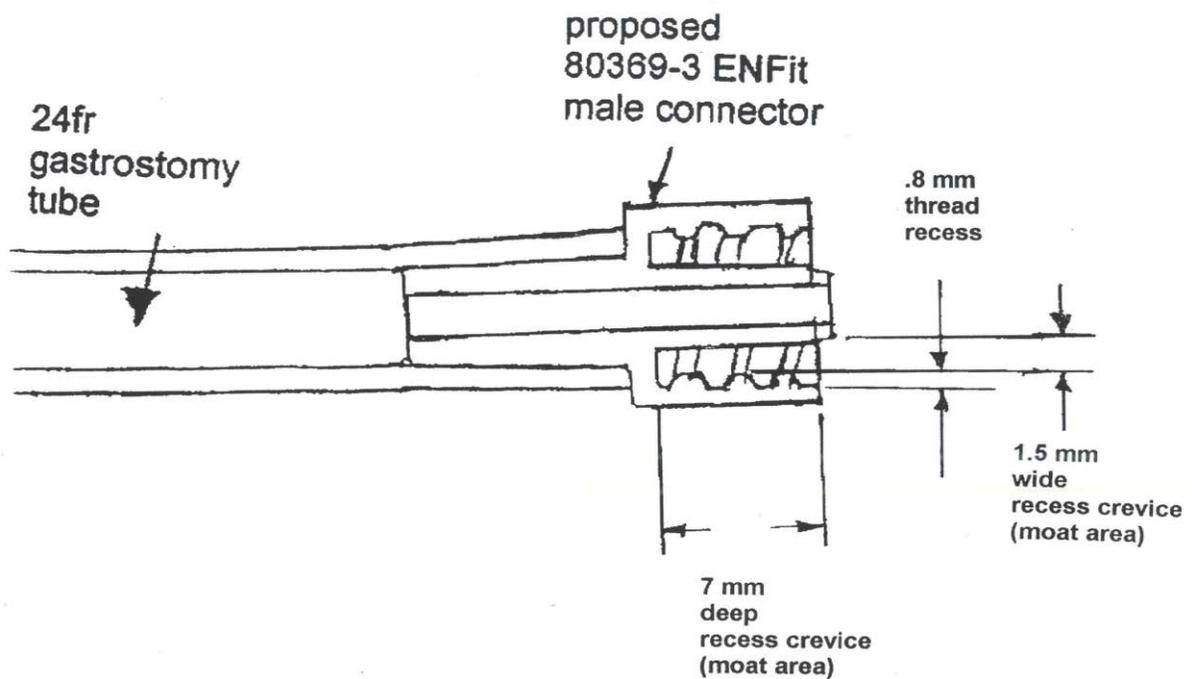
- d) Costly Tube Replacements: Many existing balloon replacement tubes have fixed Y-ports. The entire tube is replaced and Medicare reimbursable at 90 days. It is envisioned that ENFit balloon replacement tubes with fixed ENFit Y-ports will not be able to last 90 days as they will become clogged and rendered not-usable. As such, the tube will have to be replaced even though only covered by Medicare at 90 days. Alternatively, ENFit balloon replacement gastrostomy tubes with removable/replaceable ENFit connectors will have to be replaced often –

this at an added expense versus existing balloon replacement gastrostomy tubes.

Clogging can mean that users cannot feed themselves until they travel to an Emergency Department to seek help.

XII. Contamination Concerns

Build up of formula and debris in the moat area of the male patient side connector presents significant contamination concerns. Such a build up may lead to bacterial proliferation increasing risk to the patient and adding to patient treatment costs.



Will at home users and alternate care nursing staff have to utilize special tools/brushes and water basins to clean this 7 mm x 1.5 mm crevice area to ensure proper infection control is maintained?

What will be the added cost of these cleaning devices?

What will be the added nursing staff time and associated costs of cleaning the crevice/moat area after each feeding?

Will the build up of debris and formula in the crevice moat area result in the inability to properly connect the formula administration set, thereby leading to frequent replacement of the male patient side connector?

How much will the new male, patient side connector cost and what is its average product life-span?

Again, real world/real patient testing should be done to answer these important questions.

XIII. Positive Lock Between Tube and Formula Delivery Set: Tube Pull-Out

Present connectors form a press-fit connection with the formula delivery set. During 4-hour pump feeds, if the extension set gets caught on a bed or wheelchair or the patient rolls over, the connections may separate under certain force.

However, with the ENFit system, the tube to delivery set connection is positively locked. Therefore, if the delivery set tubing is tugged upon, the force of the tugging will be exerted upon the tube itself, **leading to premature inadvertent tube removal and loss of administered formula.**

Premature and inadvertent tube removal may result in a hospital visit to the replace the tube.

Real world/real patient testing would reveal the extent of tube pull out with the ENFit system versus the existing system. Such testing has not been done.

XIV. Syringe Dead Space

The ENFit syringe now holds more volume in its dead space.

Underdosing:

Using an ENFit syringe (filled with an ENFit adapter) for oral administration (without an ENFit adapter) could lead to clinically significant underdosing.

Overdosing:

There also may be doses that nurses must prepare from pre-labeled unit dose cups of liquid medications, especially in hospitals without 24-hour pharmacy services. If an ENFit syringe without an ENFit filling device is used to draw up medications from a cup, the air in the dead space will form a bubble that must be removed for accurate dose measurement. If this is connected to an ENFit feeding tube, any remaining liquid in the ENFit syringe tip might be injected into the feeding tube, causing an overdose.

Complex human factors and patient care needs clearly dictate that the safe use of ENFit devices must not be wholly dependent on the perfect performance of nurses and pharmacists to always use the correct device in the correct manner in every unique situation.

The Syringe Dead Space issue does not exist with current catheter tip syringes. ENFit will introduce this new, potentially catastrophic situation into the enteral tube feeder market.

This is contrary to the long embraced oath: "Do No Harm."

XV. Summary of Analysis

It is clearly evident that the proposed ENFit male patient side connector has a severely reduced volume flow when compared to the existing connector.

The existing patient side connector has over 25 years of real world clinical usage with both commercial formula and blenderized food. As such, it appears any new ENFit connector should utilize an inner diameter of 4.65mm. This dimension is critical to the performance of the gastrostomy tube, keeping in mind that the connector remains with the tube for a period of time (usually up to 30 days).

End user validation has not been performed and consideration of the abilities and limitations/dexterity of the at-home tube feeder community has not been provided.

According to the FDA document by Kaye and Crowle, *“testing of the entire system under realistic conditions with representative users is warranted.”* Such testing has not taken place with ENFit.

GI Design Associates testing with orange juice with pulp, through the ENFit system, resulted in clogging of the ENFit connector after administering only 35cc. This would seem indicative of the clogging that can be expected when using blenderized food.

The syringe dead space issue can be catastrophic to the infant population. ENFit male misconnections with trach tubes, rigid IV luer side ports, and needle cannulas also pose potential for catastrophic outcomes.

Crushed medications through the 2.9mm I.D. ENFit system appears to not have been studied and will most assuredly be problematic or impossible to administer.

From our analysis, it appears ENFit causes more problems that it solves. The oath “do not harm” apparently has been violated.

While the intention of the ISO/ANSI 80369-3 standard was to provide a safer design, the specific design of ENFit provides for even greater misconnection potential and does not meet the needs of real end users. We note again, about 300,000 individuals are at-home tube feeders.

While science, medicine, and medical devices seek to move forward and positively progress to the benefit of the larger population, from our results and analysis we conclude ENFit is a step backward in device design.

XVI. Recommendation

The impact of 80369-3 would be felt in a negative way for years to come by all G-tube patients and more severely by those who choose the blenderized food option (or in some cases medically necessary).

The proposed 80369-3 standard and resulting ENFit connector should not be adopted because:

- 1) The patient side connector should have an internal diameter of at least 4.0mm, and possibly larger, with a continuous laminar flow instead of crevices to accommodate various modes of delivery and nutrition as well as crushed medication.
- 2) Real world/real patient practical evaluation and trials with blenderized food through an ENFit syringe and through an ENFit male patient side connector has not occurred.
- 3) Real world/real patient clinical performance testing demonstrating that the ENFit male patient side connector is substantially equivalent in flow to the existing connector has not occurred.
- 4) Consideration of the abilities and limitations/dexterity of the at-home tube feeder community has not been provided.

We ask ISO voting members to consider the end user and the added difficulty, risks, reduction in options, and reduced independence ENFit would impose upon them.

It is clear from the above information: ENFit does not serve the greater good.

We urge voting members to vote NO on this proposal.

FIG. 1

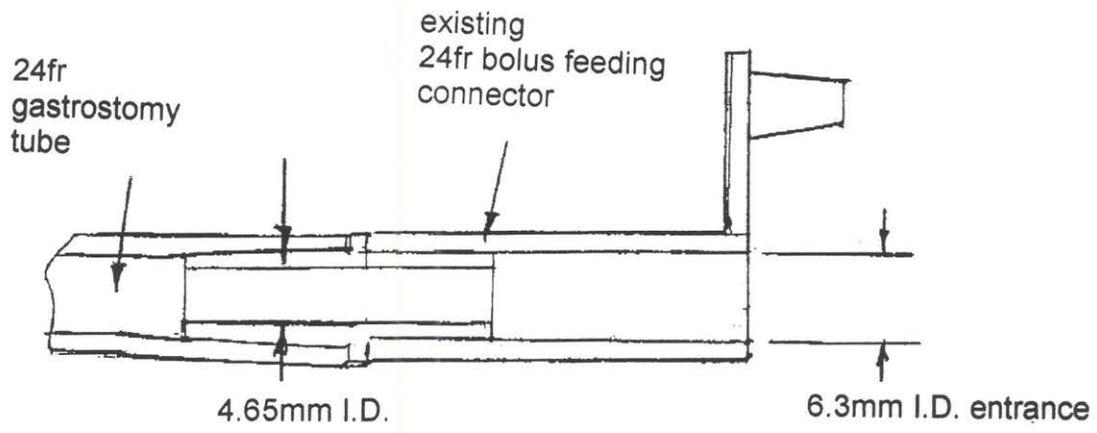
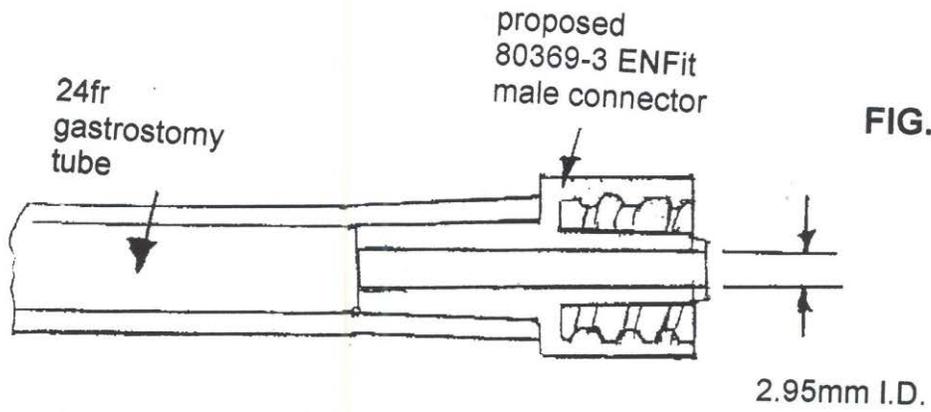
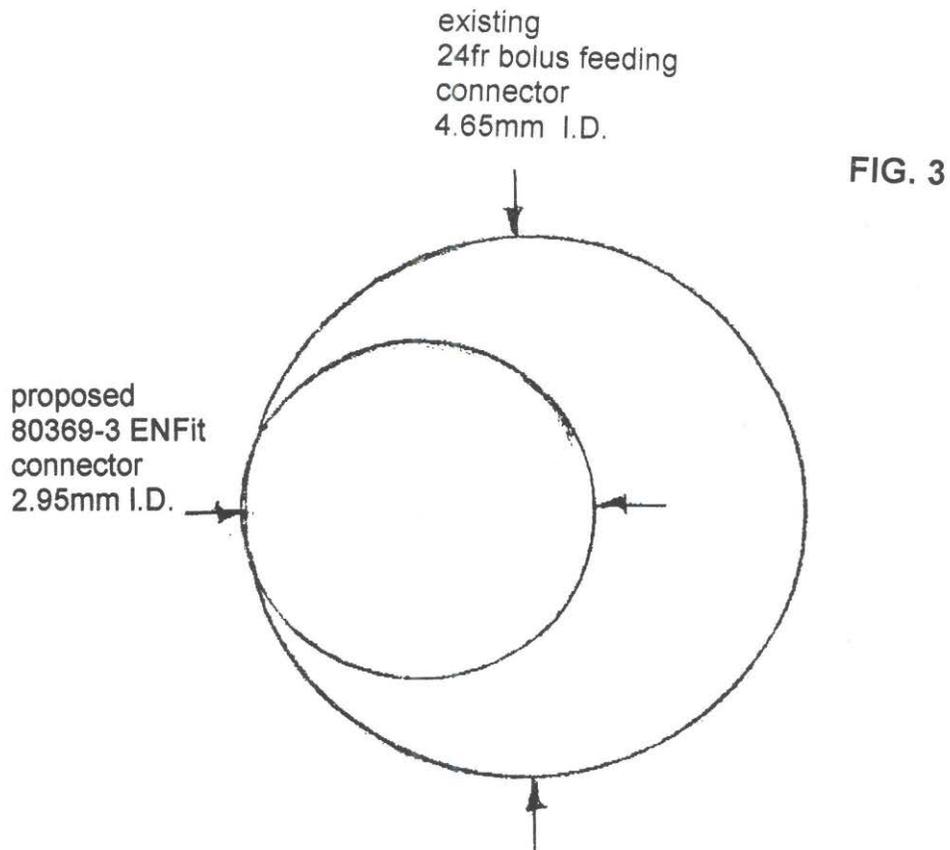


FIG. 2



Note:
Drawing to scale: 2x actual size



Note:

1) Drawn to scale: 20x actual size

2) Flow volume: $V=D^4$

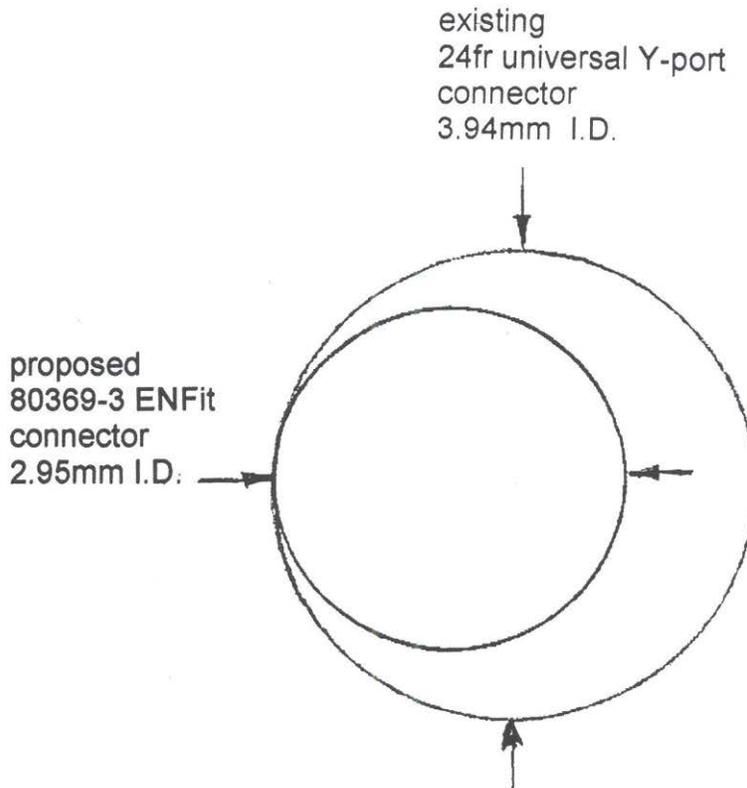
Flow volume of existing 24fr bolus connector = 467.5

ENFit flow volume = 75.7

- | | |
|----------------------------------|------------------------|
| ▪ ENFit: | 2.95 mm inner diameter |
| ▪ Existing 24fr Bolus Connector: | 4.65 mm inner diameter |

The ENFit connector has an 84% lower flow volume versus the existing 24fr bolus connector.

FIG. 4



Note:

1) Drawn to scale: 20x actual size

2) Flow volume: $V=D^4$

Flow volume of existing 24fr universal/Y-port connector = 240.1

ENFit flow volume = 75.7

- | | |
|---|------------------------|
| ▪ ENFit: | 2.95 mm inner diameter |
| ▪ Existing 24fr Universal/Y-Port Connector: | 3.94 mm inner diameter |

The ENFit connector has a 68.5% lower flow volume versus the existing 24fr universal/Y-port connector.