Award Number: W81XWH-09-2-0097

TITLE: Development and Technology Transfer of the Syncro Blue Tube (Gabriel) Magnetically Guided Feeding Tube

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14. ABSTRACT **Technical Abstract**: Further Development and Technology Transfer of the Syncro BLUETUBE™ (Gabriel) Magnetically Guided Feeding Tube. New Primary Investigator, Sabry Gabriel,MD. Proposals for Phase 1 (FY 08 $424,000.00) & Phase 2 (FY 09 $1,361,000.00).**Background**: The successful administration of enteral feeding tubes directly into the small bowel (post-pyloric position) has long been viewed as a superior clinical alternative in the feeding of seriously ill patients. Successfully achieving the bedside placement of small bowel feeding tubes has historically met with very low success rates and is the root cause of significant delays in time to feeding. This results in a significant level of patient morbidity and mortality, and accounts for a substantial portion of the costs incurred within the ICU setting.

Objective: This project will address two separate and serious problems. 1.) The inability of clinicians to easily and safely achieve a small bowel placement at the bedside. 2.) Address the complication of enteral feeding tubes inadvertently intubating the trachea.

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER	19a. NAME OF RESPONSIBLE PERSON USAMRMC
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Standard Form 298 (Rev. 8-98)

SPECIAL NOTE: The Principal Investigator before July 2012 was: Gary Wakeford then President , Syncro Medical Innovations, Inc. He was assigned to this project since its inception and through June 2012.

The ownership of Syncro Medical changed hands in July 2012 and the new ownership has taken over responsibility for the completion of this project. The newly assigned P.I., Dr. Sabry Gabriel provided this final report, covering the time frame of September 2009 through April 2017. The company was awarded an aggregate of three years, no cost extension of time to complete the proposed work per approved modification number 5, 6 &7. Delays in completing the work were mainly due to design improvements and time required to secure FDA 510K 160787 clearance. FDA clearance was awarded August 9, 2016 for 510K160787

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I. Introduction

Year one of this project focused on demonstrating the effectiveness of the Syncro-BlueTube magnetically guided, small bowel feeding tube and developing a smaller version of the technology (8 Fr.). The basic design of the technology is to provide an easy and highly effective manner in which to achieve small bowel placement at the bedside. The reliability and effectiveness of the Syncro-BlueTube in achieving the small bowel placement was clearly demonstrated and this portion of the project has met with strong success K072787. A smaller 8 French version was also developed and has achieved FDA 510(K) clearance K110005. The project also developed effective online training for successful clinical technology transfer.

Year two of this project was devoted to developing a clinical protocol for a large-scale clinical study properly powered to fully validate a perceived ability of the technology. Two clinical studies (independent of this DOD project) indicated the Syncro-BlueTube offered strong potential to eliminate the serious complication of inadvertent intubation of the trachea during feeding tube insertion. The developed study protocol is properly powered to achieve statistical significance in each of the study parameters. Year two was also dedicated to completing the initial research and analysis of various technologies that were considered to have the potential (when used in conjunction with the Syncro-BlueTube) to eliminate the current need for X-ray confirmation of proper placement of an enteral feeding tube. The development of the clinical study was completed and submitted to the DOD for tier one and tier two approval and the initial research was completed in analyzing the various technologies for positive placement confirmation.

Year three focused on securing formal approval of the clinical study and to start the enrollment of patients. This year also focused on delivering the necessary data to determine which technology offered the best probability of eliminating the need for an X-ray to positively confirm proper placement of an enteral feeding tube. HRPO approval was secured for the study to be conducted at UPMC.

Year four the company ownership changed back to the original founder and technology inventor, and the company was relocated back from Young's Town Ohio to Macon, Georgia. During year four and after company relocation, more emphasis was placed on further technology improvement with the addition of a balloon at the tube distal end. Several prototypes were developed and tested. However, due to technical manufacturing challenges, the company was not able to produce a tube with all the desired new features, that would be suitable for clinical use.

Year five the company successfully produced the proposed tube with balloon to facilitate distal tube migration with normal peristalsis. Initial testing revealed easy clogging by kinking. This has resulted in redesign of the tube wall using stainless steel wire enforcement to prevent tube kinking and occlusion. In vitro testing revealed leaks at the junction of balloon inflation port and this was corrected by end of year five.

Year six the company focused on securing 510K FDA notification clearance for the device. This involved submission of a completed expedited 510K application that was rejected by the FDA with demand to submit traditional 510K application. During the review process the FDA requested several additional validation testes that were completed except for subacute and

chronic toxicity. In the interim the company updated the research protocol and all associated documents for submission to Navicent Health Medical Center and HRPO to obtain necessary approvals to begin the clinical study in mid December 2015. Due to inability to complete required biocompatibility tests during the 180 days FDA review period, we received a non-substantially equivalent letter with the option to resubmit a new FDA 510K application when the required tests are completed.

Year seven (September 2015- September 21, 2016) the company focused on securing FDA approval for the improved feeding tube with balloon and wire-enforced wall to prevent occlusion by kinking. All biocompatibility tests were completed, additional bench top mechanical tests and misconnection tests were conducted. A new 510K160787 was submitted to the FDA March 2016 and clearance received August 2016. During same time, Navicent Health Medical Center IRB approval was secured with exclusion of pregnant women and children. HRPO review, recommendations and approval received.

Year eight: (September 21, 2016 – April 2017) clinical study conducted and as of June 10th 2017, 44 patients were enrolled in the intervention arm of the study and 50 in the control arm of the study with very positive results. The improved device name is called: Gabriel Feeding Tube with Balloon (GFTB). It is available in size 12 Fr, 10 Fr and 8 Fr. The device is available with regular stylet for all 3 sizes or magnetically guided stylet for size 12 Fr.

I. Body

1. Clinical Studies

Syncro Medical Innovations, Inc. has worked closely with the UPMC Health System in analyzing the ability of the Syncro-BlueTube technology to achieve the primary goals of

1.) Easily and safely achieving small bowel placement at the bedside, even when in the hands of an inexperienced clinician.

2.) Demonstrating the ability of the base technology to be used to significantly reduce or eliminate the current complication of the inadvertent intubation of the trachea during feeding tube insertion.

Two separate studies have achieved these goals. The studies were completed within the UPMC Health Care System and one is published in JPEN and referenced in the appendix. (See pages 23-26)

The specific data and results of these studies were reported in the Annual report of Oct 2011. The primary objectives were met. It was shown that the Syncro-BlueTube insertion procedure was easily learned and adopted by hospital personnel and the success rates were significantly better than what had been historically achieved with standard modalities in use. The technology also appeared to have the potential to eliminate the serious complications of inadvertent tracheal intubation, which is known to occur in 2% of all feeding tube insertions. (Aguilar-Nascimento JE, Kudsk KA. Clinical costs of feeding tube placement. *J Parenter Enter Nutr*. 2007; 31(4):269-73).

To fully validate this aspect of the technology, a formal clinical protocol for the DOD funded study has been completed. The protocol has been properly powered to achieve statistical significance in each of the study areas. The study has been approved to enroll 100 patients in totality. A review of the protocol will give the reviewer an appreciation for the size and scope of the study, along with the potential of the study to improve the current standard of care within the enteral feeding sector.

Syncro Medical has worked with DOD staff to secure HRPO approval of all of the study documents and clinical study began September 21st 2016 after FDA clearance was received in August 2016. Project final report submitted June 11th, 2017 and DOD support ended April 25th 2017.

The study was conducted at the Navicent Health Medical Center (NHMC), previously called The Medical Center of Central Georgia (MCCG). The NHMC is a university affiliated, level I trauma community hospital. It has 730 beds and all the needed resources and enthusiasm needed to complete the study. Adequate number of tubes and accessories were manufactured to complete the study as planned.

The following documents were submitted and received approval prior to initiation of the study:

-Study protocol

- Informed consent and assent form

- Data collection form for Gabriel Feeding Tube with Balloon (GFTB)

- Data collection form for the standard feeding tube

- GFTB tube insertion instruction with use of the external magnet

- GFTB tube insertion instruction without use of the external magnet

- Standard feeding tube insertion instruction

- Enrollment inclusion and exclusion criteria

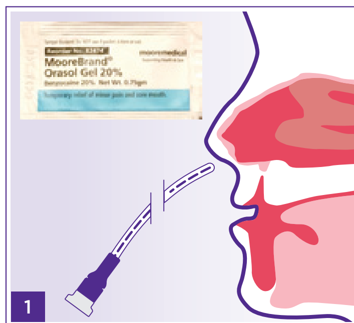
- Research monitor

- Adverse event reporting form

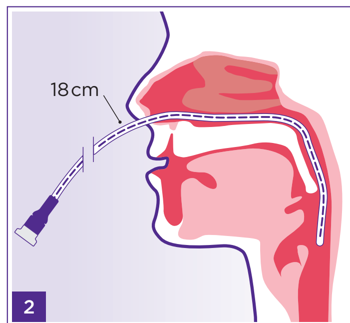
- Data safety and monitoring plan

2. Publication:

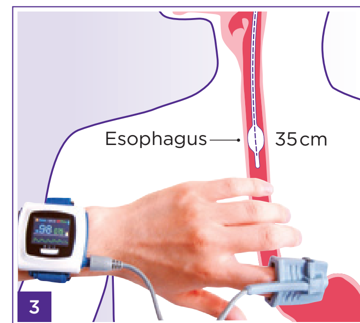
A simple 8.5 x11 flyer was developed for quick explanation of the feeding tube placement procedure.



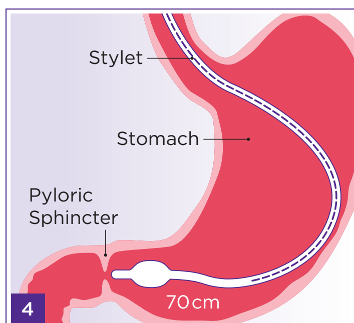
Before inserting the Gabriel® Feeding Tube into the nostril, **apply provided numbing gel to nostril** using the cotton-tipped swab provided. Wait two minutes.



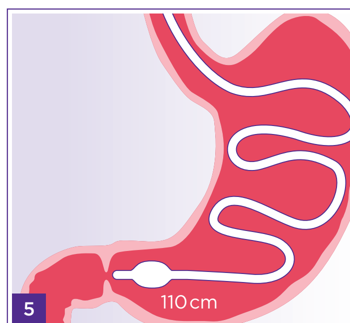
Insert the tube toward the back of the head to the nasopharynx, then into the esophagus. When the **18 cm mark** is at the nostril, **ask the patient to swallow** in order to advance the tube into the esophagus.



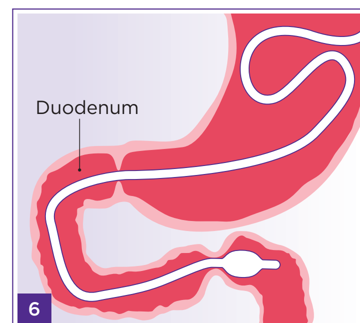
At the **35 cm mark** (mid-esophogus) **inflate the balloon** and **check the patient's pulse oximetry.**



Continue advancing the Gabriel® Feeding Tube down the esophagus and into the stomach. When the tube reaches the **70 cm mark, pull the stylet out 40 cm** (halfway).



Now advance the tube to the 110 cm mark. At the **110 cm mark, secure the tube** with medical tape and remove the stylet completely allowing enough tube slack inside the stomach.



Peristalsis will now advance the Gabriel® Feeding Tube into the small intestine.

Illustrations and design by Burt&Burt / 020217

The following abstract was submitted to MHSRS:

Abstract # MHSRS-17-0660 for Burn & Intensive Care

Background: Enteral feeding is essential for severe trauma, burn and head injury patients who are unable to swallow or consume an oral diet. Enteral feeding tubes are associated with rare but serious complications. Feeding tube misplacement in the lung, although rare (2%), is associated with high mortality rate (50%).

Over the last decade gastric feeding became widely accepted among clinicians because the preferred post-pyloric feeding frequently resulted in delayed initiation of feeding with poor total calorie intake, delayed recovery and healing.

An ideal feeding tube should minimize tracheal misplacement, allow early gastric feeding with high potential for post-pyloric migration without extra skills or costly procedures.

The Gabriel feeding tube with balloon was developed with support from the DOD (W81XWH-09-2-0097) to accomplish these goals.

Materials and method: The feeding tube has a 3 ml balloon at its distal end. The tube wall is very thin, flexible but does not occlude by kinking as it is enforced with a spiral wire.

The feeding tube kit contains a numbing gel, applicator for numbing gel, lubricant, syringe, skin adhesive and securing tape. All components are essential for the procedure and add only few grams to the tube's kit.

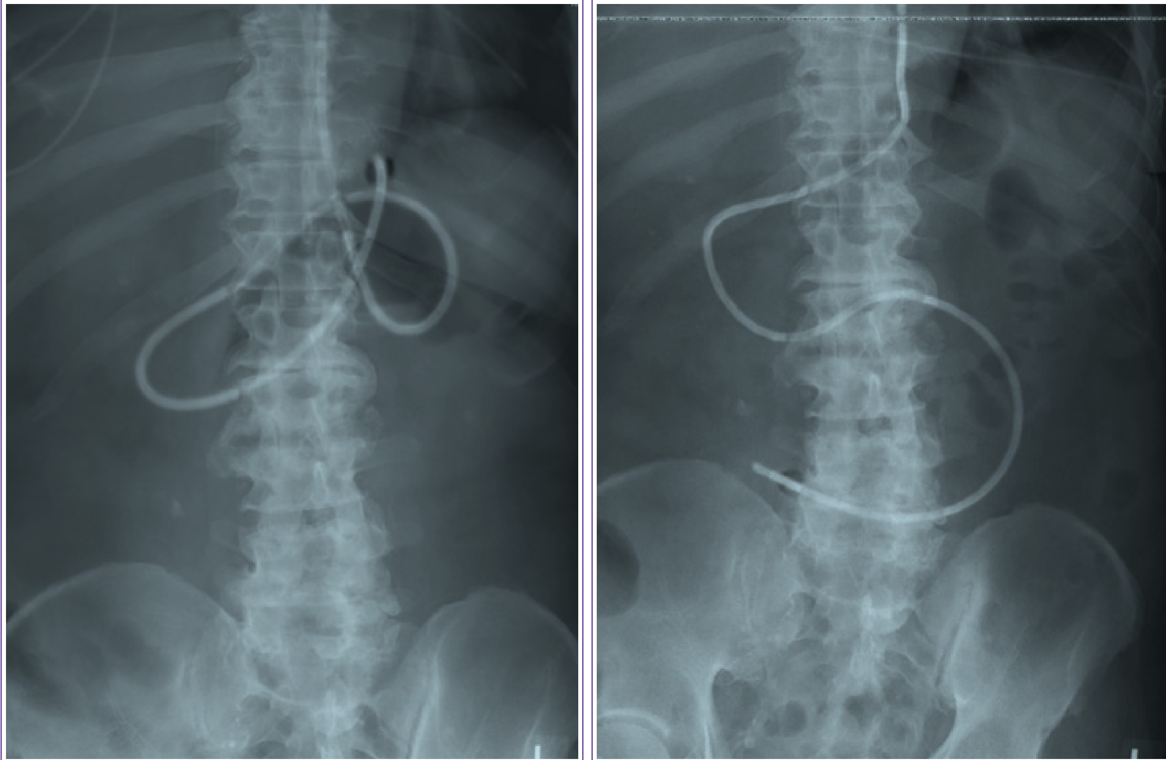
The tube is inserted through topically anesthetized nostril. At the 35 cm depth mark, mid-esophagus, the balloon is inflated. If pulse oximetry does not drop, a confirmation of esophageal placement rather than lung or tracheal placement is established within few seconds. Feeding tube is further advanced to the 70 cm mark and the stiffening stylet is pulled out 40 cm and an additional 40 cm of the tube is advanced through the nose to the 110 cm mark. The tube's distal end balloon remains inflated, and the tube is secured at the nose.

Enteral feeding can begin immediately with head of bed elevated 30 degrees once gastric placement is confirmed by x-ray. The coiled feeding tube in the stomach will not occlude by kinking and it provides slack that allows tube to advance distally by the effect of natural peristalsis on the bolus-sized balloon.

Results: Most feeding tubes advanced post pyloric to the duodenum or jejunum within 24 hours. Gastric feeding was initiated in all patients within one hour. There was no misplacement in the trachea or lung and no pneumothorax. Two tubes were occluded, one by Nexium and another by Flomax. Both medicines are capsules that contain granules. In general an alternative non-granulated medicine should be used in any feeding tube.

Conclusion: The Gabriel feeding tube with balloon provides means for early enteral feeding. The feeding tube balloon and pulse oximetry were used to minimize the risk of misplacement in the lung and pneumothorax. Most of the feeding tubes advanced to the small bowel, reducing the risk of gastro esophageal reflux related aspiration pneumonias. Tube placement does not require costly fluroscopy or endoscopy. Any nurse who can place a nasogastric tube can place this feeding tube without need for extra skills or special training.

The following is a sample case from the study showing typical tube migration:



GABRIEL®
FEEDING TUBE WITH BALLOON

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3. Research and Development of positive confirmation Device

The GFTB provides five bedside confirmation steps:

- Absence of bubbling when tube proximal end is under water and tube distal end is above the diaphragm.
- Decline in pulse oximetery more than 5 points if the tube balloon is inflated in the trachea

- Light turns on when the tube distal end is below the diaphragm using the magnetically guided version..
- pH paper color changes from red to yellow to green as the tube advances distally.
- Fresh bile is retrieved once the tube distal end is placed distal to the second part of the duodenum.

To mitigate tube misconnection risk, tube connection illustration was developed and received FDA clearance:

Gabriel® Feeding Tube with Balloon

*is intended to connect to feeding sets as shown below.

Connection to feeding set steps option #1:

Step 1

- Insert main port tethered cap into the feeding set eyelet.

Step 2

- Insert feeding set tapered end into the main port.

Step 3

- Cover the side port.
- Use side port when needed for flushing or administration of medicine.

Connection to feeding set steps option #2:

Step 1

- Use Lopez 3 way Valve, C.R.Bard Part # 0056000.

Step 2

- Insert clear end of valve into feeding tube main port.
- Insert feeding set into Lopez valve blue tube. Cap side ports.

Step 3

- To flush feeding tube or administer medication: Turn stopcock towards the feeding set, insert catheter tip syringe into side port.
- Turn stopcock towards that port again to resume feeding, recap port.

All aspects of the technology transfer for this project including online training were completed in year two. With the change in tube design, additional work was necessary and a new “Instruction for use” brochure was developed to be included with each feeding tube.

Instruction for use for GFTB with and without use of external magnet was modified to satisfy the FDA review and approval process:

CPT code 43761

Caution: Bedside Misconnection Risks

The Gabriel ® Feeding Tube with Balloon has a caution label attached at its proximal end. On one side “Enteral Use Only” is printed , The opposite side has instructions on deflating the balloon before removal. This label is to alert staff that the Gabriel Feeding Tube with Balloon is for enteral use only and to be aware of potential bedside misconnections. Bedside misconnections can cause serious injury to the patient. The connectors listed below are known to potentially engage and connect to the Gabriel® Feeding Tube with Balloon. Please ensure that connections with the following and similar items are not made:

- Female Luer Lock with Wings (.229” minor diameter and .304” across tabs)
- Nebulizer Oxygen Port • Foley Balloon Cuff Port • Christmas Tree Oxygen Connector
- Tracheotomy Cuff Port • Endo Tracheal Tube cuff port • Corrugated Oxygen Nipple

This Gabriel Feeding Tube’s connector is intended to connect to enteral feeding pump lines, enteral feeding gravity set lines and the Lopez 3 way Valve, C.R. Bard Part # 0056000

Contents

- Gabriel® Feeding Tube with Balloon preassembled with stylet
- pH paper range 0-13 on water absorbing towel
- Steri-strip tape to secure tube at end of procedure
- Skin adhesive
- 10cc Luer lock syringe
- Cotton swab
- Numbing gel
- Lubricating gel

Additional Materials Needed:

1. 2 cups
2. Gloves
3. 2 x 2 Gauze
4. 60cc Luer lock syringe

Gabriel® Feeding Tube with Balloon ordering information:

Tube Size	Length	Reorder #
8 Fr	100 cm	GFTB 408
10 Fr	130 cm	GFTB 410
12 Fr	130 cm	GFTB 412

Precautions

- **Do Not MRI. Tube is MR unsafe.**
- Tube balloon (3ml) and pilot balloon (2ml) must be deflated before removal from patient. Please remove all 5 ml.
- Please read all illustrated instructions for the procedure prior to use.
- For technical questions please call (478) 335-8311

U.S. Patent #5,431,640 #6,173,199B1 and #6,126,647 – Canadian Patent # 2,160,512 , # 2,331,129 & 2,370,851 – Australia Patent #768072, South Africa patent #2001/10204 – Mexico Patent # 231578
European Patent # 1076580, registered in Austria # E.273.039, Belgium, Switzerland, Liechtenstein, Cyprus, Germany, Denmark, Spain, Finland, France, United Kingdom, Greece #200440402894, Ireland, Italy, Luxembourg, Monaco, Netherlands, Portugal, and Sweden.
European Patent #2192885 – German Patent #69825635 – Japan #2000-617963 – Israel Patent application #146,53

Designed and specification developed by:
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Tube in a sealed bag manufactured by:
Kindwell Medical Equipment, Co., Ltd
Tianjin, China

Convenience kit assembled by:
Oscor, Inc.
Palm Harbor, Florida USA

Expiration Date: 18 months from manufacturing date

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Printed August 2016

- Radio-opaque, Disposable (intended for single patient use only, non-sterile tube)
- **Purple** color proximal Y connector
- **Purple** color 2 ml pilot balloon at proximal end and 3 ml inflatable balloon at distal end.
- Single line mark at 50cm (corresponds to placement at lower end of esophagus)
- Double line mark at 80cm (corresponds to placement at duodenal bulb)
- Triple line mark at 110cm (corresponds to distal duodenal placement)
- Preassembled with stylet
- Read all Precautions on the back page of this insert before use.
- **Caution: Federal law restricts this device to sale by or on the order of a physician.**
- **Indications for use:** The Gabriel Feeding Tube with balloon functions as a conduit to facilitate enteral feeding, and may be used in adult or elderly patients who cannot consume an adequate diet orally. Small bowel feeding may be indicated for patients with functioning gut who require short to moderate term feeding support, such as post-trauma patients, burn patients, general trauma patients, high-risk patients prone to tube misplacement complications, and patients in whom malnutrition exist, or may result, secondary to an underlying disease or condition.

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1.
- Place pH paper towel on a side table.
- Apply numbing gel to one nostril and lubricating gel to the tube distal end.
- Insert the tube towards the back of the head to the nasopharynx, then into the esophagus.
- Ask patient to swallow when 18 cm mark is at the nostril.

2.
When the 35 cm mark is at the nostril, the tube tip should be in the mid esophagus. Insert the proximal end of the tube under water surface. **Absence** of rhythmic bubbling with respiration is suggestive of correct esophageal placement. Cough should be absent in conscious patients.

3.
- Using a syringe, inflate the tube distal end balloon and pilot balloon with 5 cc of air.
- Observe pulse-oximetry. A drop of 5 points or more indicates misplacement in the trachea. Deflate balloon and withdraw to 18 cm mark then reinsert into esophagus.
- **Optional:** Tube balloons can be inflated with 5 cc water and patient turned on right side down to facilitate distal tube placement. When the 70 cm mark is at the nostril, remove the stylet gradually as you insert more of the tube.

4.
- Insert tube until the 80 cm mark is at the nostril.
- Start removing the stylet, about 20 to 30 cm, as you insert the feeding tube until the 100 cm mark is at the nostril.

5.
- Check the pH at the bedside using pH paper. If pH paper changes to red, orange or yellow color, this indicates correct gastric placement.

6.
- Inject 60 cc of warm water to stimulate gastric peristalsis.

7.
Peristalsis will help tube balloon to migrate deeper into the intestine. Aspirate should contain bile with pH=8 (turns pH paper to dark green color) when the tube passes through the 2nd part of the duodenum.

8.
- Remove the stylet.
- Apply skin prep-site solution to the nose, then secure the tube at 100 cm mark using steri-strip tape.

9.
- Obtain abdominal x-ray to confirm gastric or intestinal placement before initiation of feeding. X-ray is the gold standard to confirm final tube placement. Tube migration can be monitored by abdominal x-ray as needed.

10.
- Initiate feeding and maintain as tolerated by the patient.
- Deflate tube balloons after 48 hours or before removal.

Precaution: Do not use with feeding pumps that can generate pressure greater than 40 psi.

11.
- Flush tube with warm water (20-30ml) prior to and after administering medications, every 3-4 hours during continuous feeding, and after intermittent feedings.

Precaution: Do not use a syringe smaller than 30cc when irrigating the feeding tube.

pH GRADIENT

pH 7 · pH 3 · pH 4 · pH 5 · pH 6 · pH 7 · pH 8 · pH 7.5 · Ligament of Treitz

Color of aspirate	Clear saliva	Turbid, gastric contents	Less turbid	Clear *	Golden bile	Faint bile
Color of pH paper						
pH Value	7	0 - 5	6	7	8	7.5
Location of Tube Tip	Esophagus	Stomach	Pylorus	Part of duodenum 1st	Part of duodenum 2nd 3rd & 4th	Jejunum

Sabry Gabriel, M.D.

Instruction for use for GFTB with use of the external magnet:

CPT code 43761

Caution: Bedside Misconnection Risks

The Gabriel ® Feeding Tube with Balloon has a caution label attached at its proximal end. On one side "Enteral Use Only" is printed , The opposite side has instructions on deflating the balloon before removal. This label is to alert staff that the Gabriel Feeding Tube with Balloon is for enteral use only and to be aware of potential bedside misconnections. Bedside misconnections can cause serious injury to the patient. The connectors listed below are known to potentially engage and connect to the Gabriel® Feeding Tube with Balloon. Please ensure that connections with the following and similar items are not made:

- Female Luer Lock with Wings (.229" minor diameter and .304" across tabs)
- Nebulizer Oxygen Port • Foley Balloon Cuff Port • Christmas Tree Oxygen Connector
- Tracheotomy Cuff Port • Endo Tracheal Tube cuff port • Corrugated Oxygen Nipple

This Gabriel Feeding Tube's connector is intended to connect to enteral feeding pump lines, enteral feeding gravity set lines and the Lopez 3 way Valve, C.R. Bard Part # 0056000

Contents

- Gabriel® Feeding Tube with Balloon
- LED light indicator
- pH paper, range 0-13
- Topical numbing gel
- Lubricating gel
- Skin adhesive
- Cotton swab
- Tube Securing Tape
- 10cc syringe

Additional Materials Needed:

1. 60cc Luer lock syringe
2. 2x2 gauze
3. 2 cups
4. Gloves
5. Gabriel® External Magnet

Optional Accessories

Disposable external magnet cover
Luer lock cap
Tube securing strap
3-way valve

Gabriel® Magnetically Guided Feeding Tube with Balloon ordering information:

Tube Size	Length	Reorder #
8 Fr	100 cm	GFTB-MS 408
10 Fr	130 cm	GFTB-MS 410
12 Fr	130 cm	GFTB-MS 412

Gabriel® External Magnet ordering information:

Magnet weight	Magnet color	Reorder #
7 Pounds	Light Blue	GM 307
5 Pounds	Purple	GM 305
3 Pounds	Yellow	GM 303

Precautions

- **Do Not MRI. Tube is MR unsafe.**
- Tube balloon (3ml) and pilot balloon (2ml) must be deflated before removal from patient. Please remove all 5 ml.
- Do not use this device in pregnant females as the large gravid uterus alters the anatomy of the gastrointestinal tract.
- Do not use in patients with automatic defibrillators.
- Do not use this device in patients with implanted permanent cardiac pacemakers unless under supervision of a cardiologist who is readily available to check and re-program the pacer if needed. The risk of complications associated with poor nutrition in critically ill patients may exceed the risk associated with possible temporary malfunction of the pacemaker. Attending physician judgment is needed in individual situations.
- Do not apply the external magnet directly to open wounds or to patients with right lower rib fractures in order to avoid injuries to internal organs and tissues.
- The external magnet used for placement of the Gabriel® Feeding Tube is strong and heavy. It is not recommended for use by individuals who cannot comfortably control and maneuver a heavy weight.
- The strong external magnet should be kept at least 12 inches away from mechanical watches, credit cards, metallic surfaces, computer monitors, computer software, computer hardware, and all similar objects and electronics.
- The external magnet should be wiped clean with common hospital cleaners after use on every patient.
- Please read all illustrated instructions for the procedure prior to use. For technical questions please call (478)335-8311

U.S. Patent #5,431,640 #6,173,199B1 and #6,126,647 – Canadian Patent # 2,160,512 , # 2,331,129 & 2,370,851 – Australia Patent #768072, South Africa patent #2001/10204 – Mexico Patent # 231578
European Patent # 1076580, registered in Austria # E.273.039, Belgium, Switzerland, Liechtenstein, Cyprus, Germany, Denmark, Spain, Finland, France, United Kingdom, Greece #200440402894, Ireland, Italy, Luxembourg, Monaco, Netherlands, Portugal, and Sweden.
European application # 00930762.0 – German Patent # 69825635 – Japan #2000-617963 – Israel Patent application #146,53

Designed and specification developed by:
Syncro Medical Innovation, Inc.
Macon, Georgia USA
www.syncromedical.com
Tel: (234) 855-1605
Fax: (716) 809-3504

Tube in a sealed bag manufactured by:
Kindwell Medical Equipment, Co., Ltd
Tianjin, China

Convenience kit assembled by:
Oscor, Inc.
Palm Harbor, Florida USA

Expiration Date:
18 months from
manufacturing date

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Gabriel®

Feeding Tube with Balloon

12 French Tube

52 in (130 cm)

Product # GFTB-MS 412

A Magnetically Guided Feeding Tube with Balloon

Preassembled With Magnetic Stylet

- Radio-opaque, Disposable (intended for single patient use only, non-sterile tube)
- Proximal purple color Y connector
- 3 ml inflatable balloon at distal end and 2 ml pilot balloon at proximal end
- Single line mark at 50cm (corresponds to placement at lower end of esophagus)
- Double line mark at 80cm (corresponds to placement at duodenal bulb)
- Triple line mark at 110cm (corresponds to distal duodenal placement)
- Stylet distal end magnet with magnetic field sensor and proximal end red LED light indicator
- To be used with Gabriel® external magnet (Blue 7 Lb.) (Purple 5 Lb.) (Yellow 3 Lb.)
- Read all Precautions on the back page of this insert before use.
- **Caution: Federal law restricts this device to sale by or on the order of a physician.**
- **Indications for use:** The Gabriel Magnetically Guided Enteral Feeding Tube functions as a conduit to facilitate enteral feeding, and may be used in adult or elderly patients who cannot consume an adequate diet orally. Small bowel feeding may be indicated for patients with functioning gut who require short to moderate term feeding support, such as post-trauma patients, burn patients, general trauma patients, high-risk patients prone to tube misplacement complications, and patients in whom malnutrition exist, or may result, secondary to an underlying disease or condition.

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1.
- Cut the pH paper into 1/2" pieces and place on a folded towel.
- Connect the light indicator to the socket at proximal end of the stylet.
- To check the light indicator, allow the tube tip to be attracted to the external magnet; the red light indicator should illuminate.
- Apply lubricant or numbing gel to one nostril. Then insert the tube towards the back of the head to the nasopharynx, then into the esophagus.

2. When the 35 cm mark is at the nostril, the tube tip should be in the mid esophagus. Insert the proximal end of the tube under water surface. Absence of rhythmic bubbling with respiration is suggestive of correct esophageal placement. Cough should be absent in conscious patients. Inflate the feeding tube balloon with 5 ml of air or water. Observe pulse-oximetry. A drop of 5 points or more indicates misplacement in the trachea. Deflate balloon and withdraw to 18 cm mark then reinsert into esophagus.

3. Advance the tube until the first mark (50 cm) is at the nostril. Apply the external magnet to the epigastric area and continue advancing the tube until the light indicator illuminates. This confirms successful capture of the tube by the external magnet.

4. Slowly insert tube while continuing to move the magnet towards the right upper quadrant of the abdomen (RUQ), area of the gall bladder. Start as close as possible to the mid line, aim towards the vertebral column, and gradually move the magnet towards the mid axillary line. Advance the feeding tube until the 2nd mark (80 cm) is at the nostril. The light indicator should remain illuminated. Keep the magnet at the same location while rocking it gently for at least one minute to ensure passage through the pyloric sphincter. Ensure the patient's bed is horizontal if more distal placement is desired.

5. Advance more of the tube through the nose until some resistance is met. The tube tip should be at the duodenal bulb, just post the pyloric sphincter. You may check pH of the aspirate at this point. The duodenal bulb is usually empty. Aspirate can be obtained by injecting 5cc of tap water, then aspirating duodenal washing. Check the pH at the bed side using pH paper; it should be neutral, pH 7, color shade light green. (If pH paper color changes to yellow this indicates placement at the pyloric antrum. If pH paper changes to red or orange, this indicates gastric placement and the tube should be withdrawn until the 1st mark is at the nose. Repeat previous steps.)

6. Peristalsis will help advance the tube inflated distal end balloon. Move the external magnet 4" to the RLQ to attract the tube tip toward the end of the 2nd part of the duodenum. The light indicator should remain on. Aspirate should contain bile with pH=8 (turn pH paper to dark green color) if the tube is successfully passed through the 2nd part of the duodenum. The 1st part of the duodenum travels posteriorly before it turns inferiorly into the 2nd part. You may need to apply the external magnet posteriorly over the costo-vertebral angle (right renal area) to attract the tube tip into the 2nd part of the duodenum.

7. Advanced the tube through the nose to the third mark (110 cm) while moving the external magnet along the C shaped course of the duodenum. When the light indicator illuminates while the external magnet is over the left upper quadrant of the patient's abdomen, the tube tip should be at the fourth part of the duodenum, area of ligament of Trietz. Aspirate should be bile tinged with pH-7.5 to 8.

8. As the tube further migrates into the jejunum, the strongly alkaline bile is more diluted and pH usually = 7 again, but aspirate still is bile tinged.

9. Remove the stylet. Secure the tube at the 80 cm mark to patient's nose and obtain an abdominal x-ray. X-ray is the gold standard to confirm final tube placement. Remove the light indicator.

10. Initiate feeding and maintain as tolerated by the patient.

Precaution: Do not use with feeding pumps that can generate pressure greater than 40 psi.

11. Flush tube with warm water (20-30ml) prior to and after administering medications, every 3-4 hours during continuous feeding, and after intermittent feedings. Deflate tube balloons after 48 hours or before removal. **Precaution: Do not use a syringe smaller than 30cc when irrigating the feeding tube.**

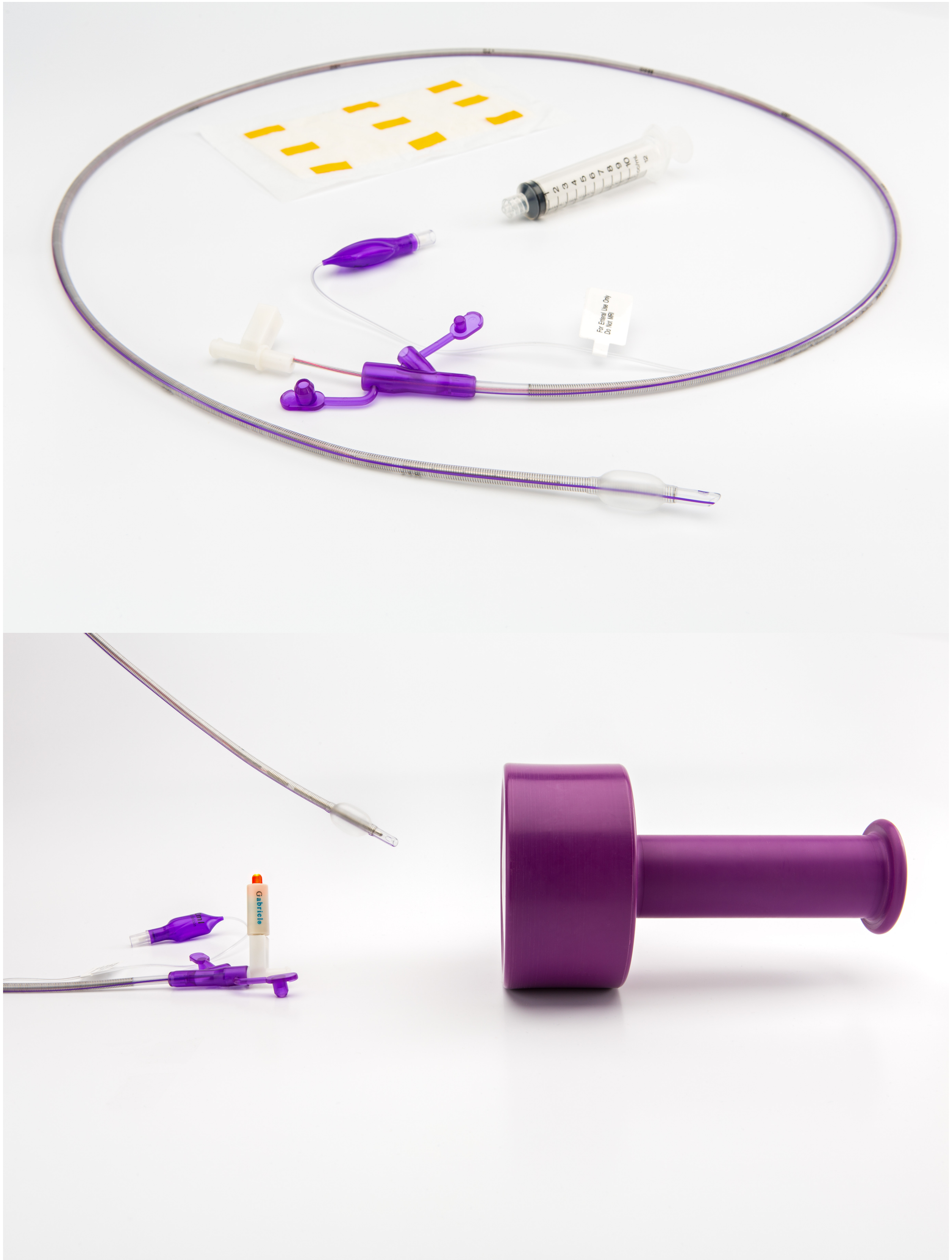
pH GRADIENT

pH 7, pH 3, pH 4, pH 5, pH 6, pH 7, pH 8, pH 7.5, Ligament of Treitz

Color of aspirate	Clear saliva	Turbid, gastric contents	Less turbid	Clear *	Golden bile	Faint bile
Color of pH paper						
pH Value	7	0 - 5	6	7	8	7.5
Location of Tube Tip	Esophagus	Stomach	Pylorus	Part of duodenum 1st	2nd 3rd & 4th	Jejunum

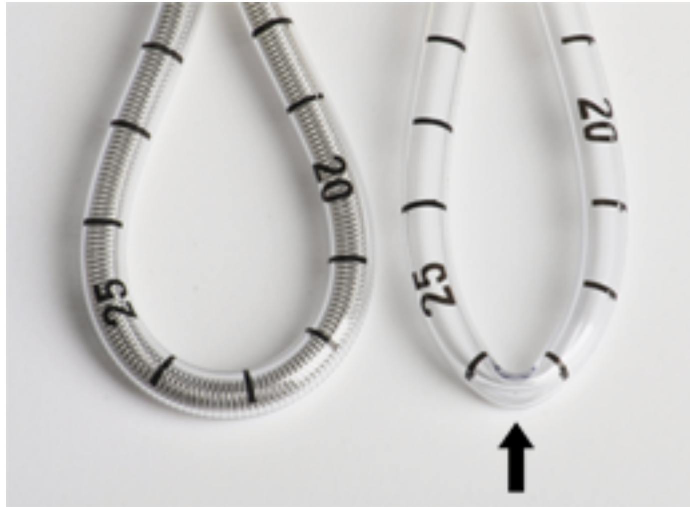
Sabry Gabriel, M.D.

12 French Gabriel Feeding Tube with Balloon:



GFTB with magnetic stylet (above), and without magnetic stylet (below).

After July 2012, building on knowledge gained from the work funded by the DOD, during the development of the trachea avoidance feature, prototypes were built and tube occlusion by kinking was observed. A stainless steel wire reinforcement of the PVC feeding tube thin wall was developed and solved that problem. All necessary bench top tests and biocompatibility tests were completed before FDA approval was granted.



A different assembly method was used for the stylet components, maintaining the same original functionality and reducing the manufacturing cost to ensure viability of syncro Medical Innovations in the market place.

Smart Magnet

The smart electric magnet work was completed in year three and conclusion reached that it was not safe for clinical application.

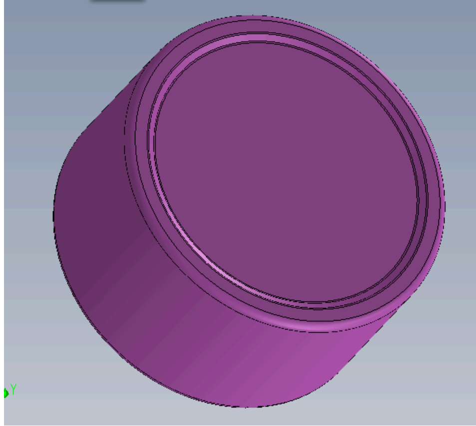
Bedside confirmation using pH paper:

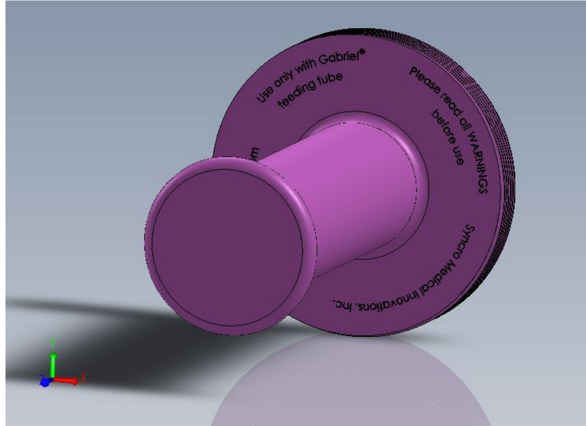
pH paper is provided with each feeding tube pre-cut on a water absorbing, disposable towel. This resulted in reduction of procedure time.

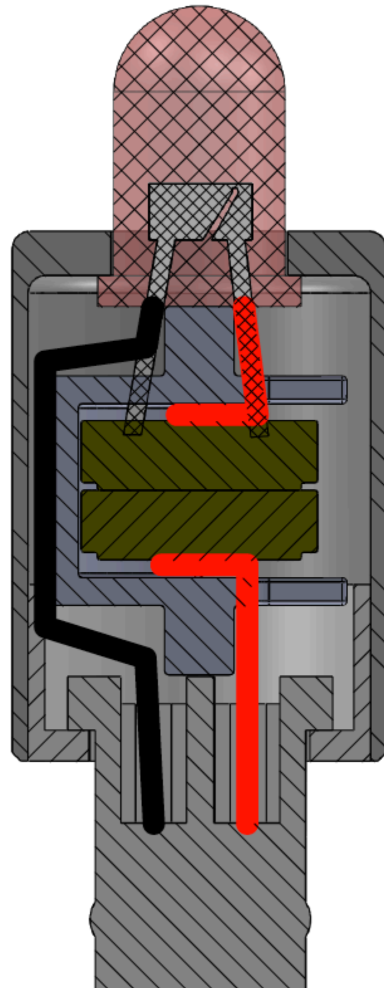
We recommend observing absence of decline in pulse oximetery after inflating the tube balloon at the 35 cm depth mark as a quick, reliable, bedside indicator of tube placement in the esophagus. As of today, there were no feeding tubes misplaced in the lung in the GFTB arm of the study.

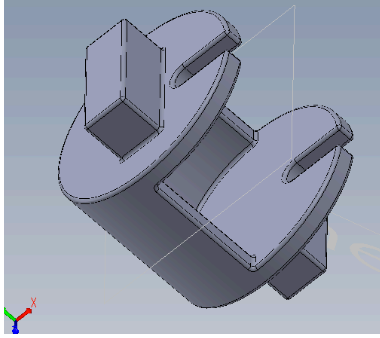
III. Key Research Accomplishments

- Produced kink resistant, wire reinforced feeding tube with balloon that is very soft and very flexible after removal of the stylet. This degree of flexibility allows peristalsis to propel the tube distal end balloon deeper into the duodenum without need for the external magnet. This is expected to reduce procedure time and allow wider range of health care providers who lessknowledgeable of anatomy to successfully insert this feeding tube.
- Addition of tube distal end balloon
- Development of a two-part permanent magnet handle that allows for replacement of the damaged magnet cover without discarding the permanent magnet itself. The use of the magnetically guided feature is valuable for patients with pancreatitis and poor peristalsis for various reasons.
- Change of stylet assembly method, utilizing heat shrink FEP tube instead of wire and glue, resulting in a more secure construct and less expensive assembly.
- Simplified LED- battery assembly design to eliminate 7 soldering points. This design increases manufacturing yields and provides an easy way to correct reversed polarity during assembly.
- Obtained FDA approval for the device K160787




Use only with Gabriel®
feeding tube
Please read all WARNINGS
before use
Syncro Medical Innovations, Inc.





II. Reportable Outcomes

Syncro Medical Innovations has filed an additional patent as follows:

U.S. Patent Application Serial No. 61/739,836
Feeding Tube with Inflatable Balloon Component

Obtained FDA clearance for 510K160787 August 2016

Registered Trademark for the device. “Gabriel ®”
Changed tube and magnet color to purple in compliance with the new industry standard.

Contracted Nelson Labs for new tube material biocompatibility testing.
The following tests were conducted:

- Cytotoxicity
- Sensitization and irritation test
- Toxicity test

Contracted Mercer University School of Engineering to conduct bench tests needed for FDA approval.

The following tests were conducted:

Tube tensile test on Y connector to tube shaft
Tensile test on balloon inflation tube connection to tube shaft
Balloon burst test after submersion in simulated gastric acid at 98 degrees
Tube fluid flow test on size 8 Fr, 10 Fr and 12 Fr
Revised instruction for use with clear illustration of tube intended connections
Tested tube to determine suitable shelf life as requested by the FDA
Conducted all requested tests based on industry standards for feeding tubes.

No cost extension to complete the clinical study by April 25, 2017.
Pre-market notification 510K clearance received August 2016

Local IRB approval and HRPO approval for clinical trial renewed September 2016
Conducted clinical study between September 2016 and June 2017

III. Conclusion

We have completed the stated goals in the statement of work. Our main accomplishments were:

- Developed a feeding tube that can be placed at the bedside by any health care person who can place any naso-gastric tube without additional training.
- Minimized or eliminated the risk of feeding tube misplacement in the trachea or lung. With that, the risk of pneumothorax is eliminated or significantly reduced. No pneumothorax occurred in our clinical study.
- Utilized readily available bedside pulse oximetery to establish correct esophageal placement by inflating tube distal end balloon at 35 cm depth mark and observing no change in oxygen saturation.
- Added a balloon at the feeding tube distal end that facilitate distal migration into small bowel by peristalsis
- Enforced tube wall to prevent occlusion by kinking
- Made the feeding tube very soft and flexible therefore easy to migrate distally by peristalsis. Tube does not occlude by kinking despite being very soft and flexible. This improves patient care and increase patient comfort.
- Developed simple-to-follow one page pictoral instruction for use.
- Obtained FDA approval for the device.
- Filed for patent for the device.
- Further improved the tube proximal end connector with EnFit type connector to eliminate misconnection risk in compliance with the new industry initiative standard ISO 80369-3. In that regard, a new FDA submission is planned.

- It is our conclusion and recommendation that one abdominal x-ray is needed for final tube placement confirmation. This single x-ray is needed for patient safety and for medico-legal purposes. The majority of patients who need enteral feeding are critically ill. This technology has eliminated the need for chest x-ray, fluoroscopy and endoscopy for the insertion procedure.

IV. References

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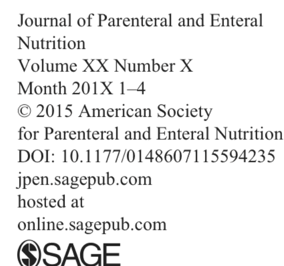
V. Appendices

Appendix 1- Publication at JPEN
Appendix 2 –FDA approval letter, indication for use and summery statement



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Placement of a Magnetic Small Bowel Feeding Tube at the Bedside: The Syncro-BlueTube

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Abstract

Background: Current methods of achieving postpyloric enteral access for feeding are fraught with difficulties, which can markedly delay enteral feeding and cause complications. Bedside tube placement has a low success rate, often requires several radiographs to confirm position, and delays feeding by many hours. Although postpyloric enteral tubes can reliably be placed in interventional radiology (IR), this involves greater resource utilization, delays, cost, and inconvenience. We assessed the utility of bedside enteral tube placement using a magnetic feeding tube (Syncro-BlueTube; Syncro Medical Innovations, Macon, GA, USA) as a means to facilitate initial tube placement. *Methods:* We recorded the time to insertion, location of tube, success rate, and need for radiographs in a series of patients given magnetic feeding tubes (n = 46) inserted by our hospitalist service over an 8-month interval. *Results:* Of the 46 attempted magnetic tube placements, 76% were successfully placed in the postpyloric position, 13% were in the stomach, and 11% could not be placed. In 83% of the magnetic tubes, only 1 radiograph was needed for confirmation. The median time to placement was 12 minutes (range, 4–120 minutes). *Conclusion:* The use of a magnetic feeding tube can increase the success rate of bedside postpyloric placement, decrease the time to successful placement, and decrease the need for supplemental radiographs and IR. (*JPEN J Parenter Enteral Nutr*. XXXX;xx:xx-xx)

Keywords

enteral access; nutrition; enteral nutrition; outcomes research/quality; nutrition support practice; adult; life cycle; GI access

Clinical Relevancy

This is a report of our experience in placing a magnetic postpyloric tube at the bedside. Current methods of obtaining postpyloric feeding tube placement are fraught with difficulties. Using the Syncro-BlueTube (Syncro Medical Innovations, Macon, GA, USA), we were able to place a tube into the postpyloric position in 76% of patients with a median insertion time of 12 minutes and requiring only 1 confirmatory radiograph in 84% of patients. We believe that this device has the potential to improve current methods for reliably placing postpyloric feeding tubes into hospitalized patients.

Introduction

Early enteral feeding in hospitalized patients has proven benefits including improved wound healing, enhanced immune function, preservation of gastrointestinal structure, and improved clinical outcomes.[1,2] The issue of gastric versus small bowel delivery of nutrition has been controversial, with some earlier studies showing a possible benefit to small bowel feeding, such as increased caloric delivery and decreased incidence of ventilator-associated pneumonia (VAP).[3,4] Two recent studies addressed the issue of gastric versus small bowel feeding. The first is a randomized controlled trial (ENTERIC study) in which 181 mechanically ventilated patients with increased gastric residual volumes were randomized to gastric or postpyloric feeding.[5] The authors found no difference in the proportion of standardized estimated energy requirement that was delivered, nor was there a difference in rates of VAP, major gastrointestinal bleeding, or mortality. However, as the authors noted in the discussion, patients were enrolled an average of 42 hours after intensive care unit (ICU) admission, and > 90% of patients had commenced gastric feeding at the time of randomization. In addition, they used a spontaneously migrating frictional nasojejunal tube, and confirmation of placement was seen in 89% of patients a median of 15 hours after placement. All of these factors may have limited their ability to find an advantage for the nasojejunal feeding. The second

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study was a systematic review and meta-analysis of all randomized controlled studies between 1990 and March 2013 that address the issue of gastric versus small bowel feeding.[6] The conclusion was that the delivery of nutrition into the small bowel may be associated with a lower incidence of ICU acquired pneumonia. There was also a signal for increased nutrition intake with small bowel feeding, although there was considerable statistical heterogeneity for this outcome. These authors also note that biases such as publication and selection bias of smaller studies included in the analysis may make these findings circumspect. Notwithstanding these studies, the Canadian Clinical Nutrition Support Guidelines continue to recommend the use of routine small bowel feeding in hospital units where obtaining small bowel access is feasible without logistic difficulties (ie, transport to interventional radiology [IR]).[7]

Feeding is typically achieved through a small bore nasogastric or nasoduodenal tube. The most widely used devices are placed blindly and rely on gravity and peristalsis to achieve postpyloric placement of the tip of the tube. Often, multiple radiographs are required to verify the position, and this can delay tube feeding for days.[8] There have been several small, single center studies of various specific blind methods with high success rates such as the 10/10/10 method,[9,10] the corkscrew method,[11] and the air injection method.[12] However, these techniques are operator dependent, have not been widely adopted, and can require multiple confirmatory radiographs. More common in clinical practice is that small bowel placement is not achieved, and the tip of the feeding tube is left in the stomach.

Small bowel tubes may be reliably placed in the IR suite under fluoroscopic guidance. However, this procedure requires moving patients to the radiology department, takes nurses away from the ICU, is available only during certain hours of the day and on weekdays, and can be costly. Given these issues, improved methods for achieving early postpyloric tube position are needed. One such method is the use of magnetic guidance.

In this report, we describe our experience in training our hospitalists in a tertiary care teaching hospital to place the Syncro-BlueTube (Syncro Medical Innovations, Macon, GA, USA) to ascertain if the use of this device could improve our ability to quickly and effectively insert small bowel feeding tubes at the bedside.

Methods

The Syncro-BlueTube is an FDA-approved magnetic enteral feeding tube system. The tube consists of a polyurethane tube and a central guidewire with a neodymium magnetic tip at the distal end. On the proximal end is an LED that illuminates when the tip of the tube is within 4 inches of the external handheld large magnet. The external magnet serves both to attract the tube as well as signal its proximity to the tip. The tube is compatible with magnetic resonance imaging since the tube magnet rests at the tip of the removable guidewire. The tube and external magnet are shown in Figure 1.

Figure 1. The Syncro-BlueTube system. Reprinted with permission from Syncro Medical Innovations. © 2015, Syncro Medical Innovations. All rights reserved.

Between September 2010 and April 2011, the hospitalists in our tertiary care teaching hospital made themselves available around the clock to place the Syncro-BlueTube. Indications for consulting the hospitalist for tube placement included either the inability to pass a traditional small bore tube past the nasopharynx or the desire for small bowel feeding. Attending physicians in medicine, neurology, critical care medicine, and surgery in our institution were made aware of this service. Patients were included as they were referred by these services for tube placement. Patients who had trauma to the neck that precluded placing the magnet behind the neck and patients with abdominal surgery resulting in altered anatomy were excluded. This study was sanctioned by the quality and safety committee of the hospital since the tube was FDA approved and was being used as standard practice prior to this study.

For training purposes, an animated video was shown to the hospitalist performing the procedure for the first time. A hospitalist more experienced with tube placement was present during the first 2 placements to make sure the protocol was followed. During tube insertion, the magnet was positioned behind the neck as the tube was passed through the nasopharynx with the intent of directing it posteriorly into the esophagus to avoid tracheal intubation. The tube was then advanced to 50 cm and the magnet was moved to the epigastrium in order to detect it in the stomach. As the tube continued to be advanced, the magnet was moved progressively to the right upper quadrant, keeping magnetic contact with the tip of the tube until deep placement was achieved and the tube could no longer be tracked. Placement position was then verified by plain film radiography.

For each patient who received a tube, we recorded the beginning and ending times of the procedure, the indication,

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Table 1. Patient Characteristics.

Patient Characteristic	No. of Patients
Total patients	46
Male	23
Age, mean ± SD, y	64 ± 17
Body mass index, mean ± SD	31 ± 13
Intensive care unit	35
Indication	
Small bowel feeding	39
Inability to pass traditional tube	7

Table 2. Results of Magnetic Tube Placement.

Result	No. (%)
Success rate	
Small bowel placement	35 (76)
Gastric placement	6 (13)
Failed placement	5 (11)
Complication	
Epistaxis	3 (7)
Kinked tube	1 (2)
Interference by orogastric tube	1 (2)
	Median (Range)
Median time to place tube, min	12 (4–120)

the outcome (either success or failure to achieve small bowel placement), and if not successful, the reason for failure. We also counted the number of radiographs that were required for each Syncro-BlueTube to confirm placement.

Results

Forty-six consecutive patients received a Syncro-BlueTube between September 2010 and May 2011. Table 1 shows baseline characteristics of patients and Table 2 shows the results of tube insertion attempts. Males and females were distributed evenly in our study population. The mean age was 64 (SD 17) years and the mean body mass index was 31 (SD 13). Most of the patients were in the ICU (35 patients, or 76%). The majority of tubes both in the ICU and on medical-surgical floors were ordered for small bowel placement (85%). There were 35 (76%) successful small bowel placements and 6 (13%) gastric placements. Feeding tubes in 5 patients (11%) could not be passed: 3 because of epistaxis, 1 tube was found to be kinked after placement and the guidewire could not be removed, and 1 tube could not be placed due to interference by the presence of an orogastric tube. The median time to placement was 12 minutes (range, 4–120 minutes). No tubes were placed in the bronchial tree. Of the 7 tubes that were requested because of inability to insert a traditional tube past the nasopharynx, 6 were successfully placed, and the 1 that failed was placed to 40 cm and then was coiled in the stomach.

Twenty-nine patients (83%) with the magnetically placed tube required 1 radiograph, 4 patients (11%) required 2 radiographs, and 2 patients (6%) required 3 radiographs to confirm placement in the postpyloric position.

Discussion

In our report of 46 patients receiving the magnetic Syncro-BlueTube, we showed a success rate of 76% of achieving small bowel placement and a median procedure time of 12 minutes, and 84% of these patients required only 1 radiograph for confirmation. Also, there were 6 patients who were able to receive a feeding tube when a traditional nasogastric tube could not be passed. The most frequent complications of the magnetic tube included inability to pass the tube and epistaxis. In contrast, in the ENTERIC study, small bowel placement of feeding tubes was successful in 79% after a median of 15 hours and 2 radiographs. Given our success rate, median time to placement, and small number of radiographs required, we believe that the use of the magnetically guided feed tube represents a significant improvement over the current method of blind insertion at the bedside. Since the tubes were placed by hospitalists who were on duty around the clock, placement was not restricted by day of the week or hour of the day. In contrast, having a small bowel tube placed reliably in IR is both expensive and limited to the working hours of the week in most institutions. Although the precise cost of sending a patient to IR for a postpyloric tube is difficult to obtain, the hospital charge is > $1000 with fluoroscopy time and radiology physician charges. There is also increased risk and cost of transporting a patient from the ICU to IR, which includes taking nurses away from patient assignments and the increased risk of aspiration.[13] Therefore, any intervention that can reduce the need for transport to IR will reduce costs and increase patient safety. The cost of the Syncro-BlueTube is approximately $125, and even a modest reduction in IR use would justify the cost of the tube. Although the study was not powered to show a reduction in bronchial placement, we believe that the technique of holding the magnet behind the neck as the tube is passed through the nasopharynx has the potential to reduce the chances of tracheal placement. None of our patients with the magnetic tube had bronchial placement. This technique may also allow placement of tubes that would be difficult to pass through the nasopharynx, since the large magnet attracts the tube when held behind the neck.

Obesity did not affect the procedure as distal tube light activation occurred similarly in all patients regardless of body mass index. In 1 patient with abdominal distention secondary to acute pancreatitis, magnet maneuvering of the tube tip was limited by abdominal pain from a distended abdomen. However, the tube was successfully placed in the postpyloric position.

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Limitations of our study include a trial design that was observational and not randomized or controlled for comorbidities or severity of illness. This lack of randomization may have led to selection bias in referring patients for the magnetic tube.

In summary, the use of magnetic enteral feeding tubes is a safe bedside procedure that has the potential to increase the number of patients who receive postpyloric feeding, decrease the average time to starting enteral feeding, decrease the number of confirmation radiographs, and decrease costs.

Statement of Authorship

A. S. Akers and M. Pinsky contributed to the conception/design of the research and critically revised the manuscript; A. S. Akers contributed to the acquisition, analysis, and interpretation of the data and drafted the manuscript; M. Pinsky contributed to the analysis and interpretation of the data. Both authors agree to be fully accountable for ensuring the integrity and accuracy of the work and read and approved the final manuscript.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 9, 2016

Syncro Medical Innovations, Inc.
℅ William G. McLain
Consultant
Keystone Regulatory Services, LLC
342 E. Main Street, Suite 207
Leola, PA 17540

Re: K160787
Trade/Device Name: Gabriel Feeding Tube with Balloon
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT
Dated: June 24, 2016
Received: June 28, 2016

Dear William McLain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the Gabriel Feeding Tube with Balloon have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

In addition, we have determined that your device kit contains Benzocaine Gel 20% which is subject to regulation as a drug.

Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Douglas Silverstein -S
2016.08.09 16:40:37 -04'00'

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160787

Device Name
Gabriel Feeding Tube with Balloon

Indications for Use *(Describe)*

The Gabriel Feeding Tube with balloon functions as a conduit to facilitate enteral feeding, and may be used in adult or elderly patients who cannot consume an adequate diet orally. Small bowel feeding may be indicated for patients with functioning gut who require short to moderate term feeding support, such as post-trauma patients, burn patients, general trauma patients, high-risk patients prone to tube misplacement complications, and patients in whom malnutrition exist, or may result, secondary to an underlying disease or condition.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

A 510(K) Summary

A.1 Submission Correspondent and Owner

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A.2 Date Summary Prepared

August 9, 2016

A.3 Device Trade Name

Gabriel Feeding Tube with Balloon

A.4 Device common name

Feeding Tube

A.5 Device classification name

Tube, Feeding. 78 KNT at 21 CFR Part 876.5980

A.6 Legally Marketed Device To Which The Device Is Substantially Equivalent

Predicate Device

Syncro Blue Tube Magnetically Guided Enteral Feeding Tube (K110005)

Reference Device

Rusch Miller-Abbott Tube (K010797).

A.7 Description Of The Device

The Gabriel Feeding Tube with Balloon serves as a conduit through which enteral feeding solutions are directly infused into the patients small bowel. During placement of the tube, a lubricant and or numbing gel is applied to the nostril.

For the version of the tube with stylet with magnetic tips, an external magnet is used to assist the physician in placing the tube into the small bowel. Like the predicate device, the modified device has a stylet with a reed switch positioned near its distal tip. The reed switch is connected by wires to an external LED/battery pack that lights in response to the presence of the external steering magnet. The reed switch is encased in a lead-free glass tube and metal shield and is attached to the distal end of the stylet. The wires used to connect the distal reed switch to the LED are polyurethane insulated copper and are wrapped around the core of the stylet and contained inside the outer PTFE layer, thus keeping it out of the fluid path. The distal tip of the stylet contains magnets which are attracted to the steering magnet. The inflated feeding tube balloon allows peristalsis to advance the feeding tube distally.

For the version of the tube with the non-magnetic stylet, the tube is manually inserted by the physician. The stylet, is non patient contacting, made out of seven braided filaments 305 stainless steel wire and is 3 cm shorter than the feeding tube.

The stylet is removed and tube taped at the nose and placement verified by pH paper and abdominal x-ray. Like the predicate device, the modified Gabriel Feeding Tube with Balloon has a stylet. The inflated feeding tube balloon allows peristalsis to advance the feeding tube distally.

The external tube is extruded over reinforcing monofilament stainless steel wire that prevents occlusion by kinking. The outer patient contacting layer is made from DEHP-free PVC.

A.8 Intended Use

The Gabriel Feeding Tube with balloon functions as a conduit to facilitate enteral feeding, and may be used in adult or elderly patients who cannot consume an adequate diet orally. Small bowel feeding may be indicated for patients with functioning gut who require short to moderate term feeding support, such as post-trauma patients, burn patients, general trauma patients, high-risk patients prone to tube misplacement complications, and patients in whom malnutrition exist, or may result, secondary to an underlying disease or condition.

A.9 Technological Characteristics

The proposed device has the same technological characteristics as the predicate device. Specifically, both feed tubes function by providing a conduit for enteral feeding. For the magnetic version of the device, the insertion methods are identical to the Syncro (K110005) predicate device in that they utilize identical techniques for placing the tube. Both the proposed magnetic and non-magnetic devices have similar technological characterists related to the reference device Rusch Miller-Abbott Tube (K010797) in that the balloon facilitates placement using the GI tract's peristaltic action.

A.10 Non-Clinical Testing

Tests were performed to demonstrate substantial equivalence in the following areas:

- Non-Magnetic Stylet Hub Pull Test
- Flexibility and Pushability Test
- Comparison Volumetric Flow Rate Test
- Connection Testing
- Aspiration through the feeding tube test do document that gastric fluid can be aspirated through 8 Fr, 10 Fr, and 12 Fr Gabriel feeding tube with balloon
- Gabriel Feeding Tube with Balloon leakage test after filling tube balloon with colored water
- Gabriel Feeding Tube with Balloon System liquid flow and leakage test
- Gabriel Feeding Tube with Balloon shaft tensile test
- Gabriel Feeding Tube with Balloon Shaft to Y Connector Tensile Test
- Gabriel Feeding Tube with Balloon Shaft to Balloon inflation port Tensile Test

A.11 Biocompatibilty

Materials were tested for cytotoxicity, sensitization, irritation, acute and sub-chronic toxicity. The materials were confirmed to be biocompatible.

A.12 Clinical Testing

No clinical testing was performed in association with this submission.

A.13 Conclusions

The results of the comparison of design, materials, intended use and technological characteristics demonstrate that the device is as safe and effective as the legally marketed predicate devices.