GRAVITAS MEDICAL

Entarik™ G2 NI Feeding Tube

for use with Entarik G2-N System

Operator's Manual

IFU-04-2407 Rev A

Introduction

This manual covers the function and proper use of the Entarik G2 NI Feeding Tube (FT) with the Entarik G2-N System. Do not use or operate the Entarik G2 NI Feeding Tube until you have read and understood this manual and the separate instructions included with the Entarik G2-N Feeding Tube System.

The **Entarik G2 NI Feeding Tube** is a nasoenteric or orogastric feeding tube with a single lumen (feed lumen) for the administration of nutrition, fluids and medications. Impedance and temperature sensor wires are located in the walls of the feeding tube. The tube (applied part) has electrode rings on the surface and comes into physical contact with the patient. The Entarik G2 NI FTs are provided sterile.

The Entarik G2 NI Feeding Tube, when connected to the **Entarik G2 Monitor**, forms the **Entarik G2-N Feeding Tube System**. The Monitor is a portable electronic device that serves to measure and record impedance and temperature data from the sensors on the Feeding Tube and provides information to the operator to aid in initial placement and monitoring of feeding tube position.

CAUTION

The Entarik G2 NI Feeding Tube and Entarik G2-N Feeding Tube System are only intended for use by a physician, or on the order of a physician.

CAUTION

Investigational device. Limited by Federal (or United States) law to investigational use.

Indications for Use

Entarik G2 NI Feeding Tubes (FTs) are intended for the administration of nutrition, fluids and medications by the nasoenteric or orogastric route for neonatal patients who have an intact gastrointestinal tract but are physically unable to manage nutritional intake through normal mastication and deglutition.

The Entarik G2 NI FTs are provided sterile.

Actions

Acts as a conduit for food, fluid, air, and medications to the patient's stomach.

Contraindications

- Use caution with patients who have anomalies or disease of the nose, throat, or esophagus.
- The use of this product is contraindicated in patients with basilar skull fracture.
- The use of this product is contraindicated in patients with known sensitivities or allergies to the device components.

Warnings

- Coughing or any other symptom of respiratory distress may indicate that the device has been misplaced in the trachea. If this is suspected, remove the tube and stylet and reinsert. Absence of coughing does not confirm tube placement in stomach. If resistance is encountered, immediately remove tube.
- At any point during the procedure if continuous resistance is felt the device should be withdrawn and then reinserted.
- During placement, there is a general risk for malposition in the respiratory tract. Delivery of fluids into the airway may result in serious injury, ALWAYS confirm appropriate positioning of the feeding tube using institutional protocol (e.g., x-ray) prior to initiating fluid delivery. Should the feeding tube enter the tracheobronchial tree during a tube placement, damage to the lung or esophagus could occur. Use caution when placing the device.
- Pneumothorax, upper GI perforation, and aspirational pneumonia are rare, but have been reported during the use of this type of device. Use caution when placing the device.
- This is a disposable device intended for single patient use. Do not reuse.
- Entarik G2 NI Feeding Tube configurations are sterile if the package is unopened and undamaged. Do not use if package has been compromised. Do not re-sterilize.
- This disposable device should only be used with the Entarik G2 Monitor.
- Feeding tubes should never be transferred from one patient to another.
- Entarik G2 NI Feeding Tubes are for short-term use only (less than 30 days).
- Maintaining the patient in a High-Fowlers or Semi-Fowlers position may reduce regurgitation or aspiration. If using this position, do not lean patient forward.
- Never insert a stylet into an indwelling tube (if stylet is used).
- Feeding tube may only be used with the included stylet. A stylet from another product may not be used with the Entarik G2 NI Feeding Tube.
- MR Unsafe - The Entarik G2 NI Feeding Tube is NOT Safe for use in magnetic resonance (MR) environments
- This device should only be inserted by a trained clinician.
- Never clean the feeding tube with solvents or detergents
- Vigorous syringe force should not be used to irrigate, administer liquids or unblock the tube.
- The Entarik G2 NI Feeding Tube is intended for enteral feeding, fluids and medication administration, but has the potential to misconnect with small bore connectors of other healthcare applications. This nasoenteric/orogastric feeding tube should not be used with connectors from other healthcare applications.
- The feeding tube shall be disposed of as medical waste in accordance with hospital, administrative and local government policy
- Avoid leaving tubing and cords where infants, children, or those deemed at high risk for medical line entanglement, can become entangled. Be aware that if these items become wrapped around a patient's neck, there is an increased risk of strangulation or death. Caregivers of patients who are at risk for entanglement should discuss with their health care provider how to properly manage their lines and properly monitor patients based on their needs while in use.

- Kinking of the feeding tube is permitted only at the "Kink Zone" (item 8 below). **Avoid kinking the feeding tube shaft.**

Precautions

- Do not use if products or package are damaged. Check packaging before using.
- Do not autoclave
- Feeding tubes should be flushed frequently to prevent clogging and to detect leakage. Suggested flushing schedule:
    a. Before and after each feeding
    b. Before and after administering medication
    c. Once every four hours during continuous feeding or between intermittent feedings
    d. Each time the feeding set is disconnected
    e. Each time the feeding container is filled /changed
    f. Each time the pump is stopped
- Use only tap or sterile water to flush. DO NOT use solutions containing meat tenderizer to flush or open a clogged feeding tube.
- Administration of medications should be guided by hospital policy. Many liquid preparations contain Sorbitol which tends to interact with enteral formulas and clog the feeding tube. Thoroughly crush tablets, excluding enteric tablets which should never be crushed; however, always consult with your pharmacist regarding which tablets should be crushed for feeding tube administration. Always flush a feeding tube with water following administration of medicine or fluids.
- When aspirating stomach contents with a syringe, push and pull the syringe plunger repeatedly to prevent abrasion of stomach wall due to suction.
- Feeding Tube cable should be routed off of floor and away from high traffic areas

Device Description

Entarik G2 NI Feeding Tube

The Entarik G2 NI Feeding Tube is a nasoenteric/orogastric feeding tube made of a radiopaque polyurethane material that includes an array of stainless-steel electrode sensors on its external surface. The feeding tube is a single use device intended for short-term use (less than 30 days). A detailed description of the device is provided below:

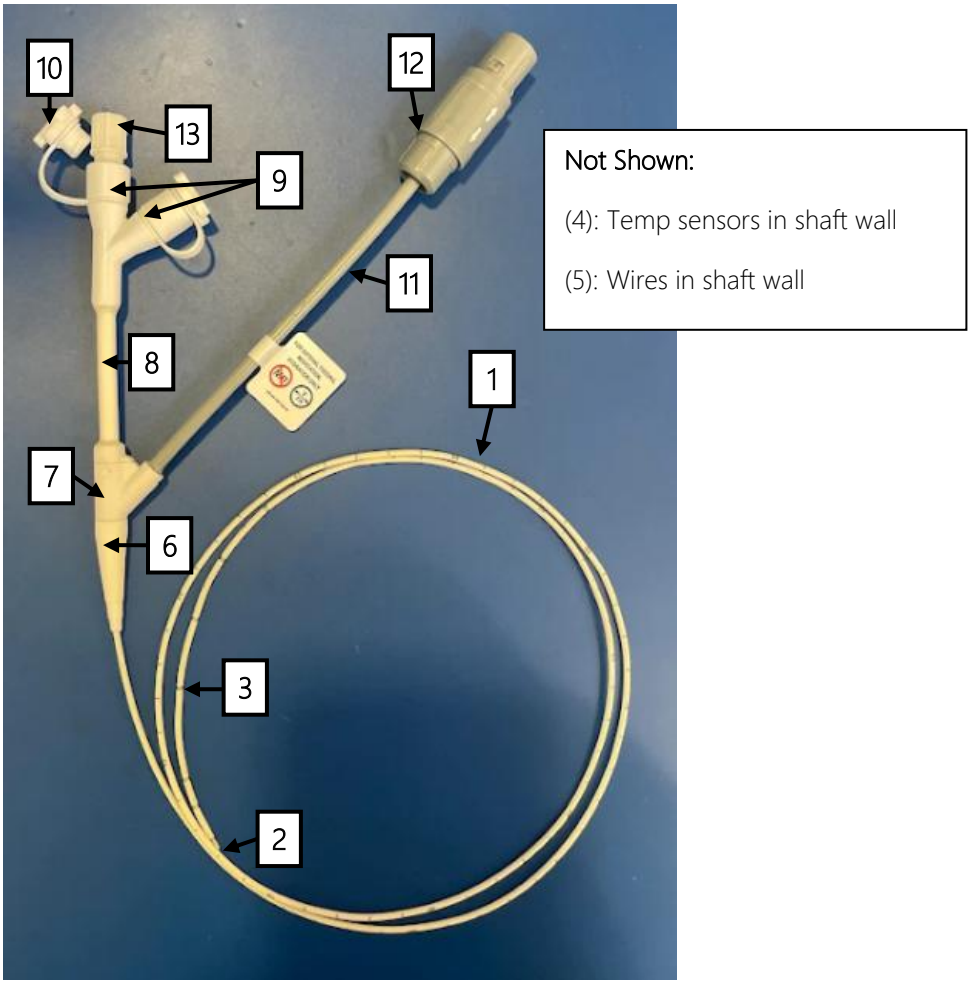


FIG. 1: Entarik G2 NI Feeding Tube

The feeding tube is comprised of the following components:

1. Shaft with depth markers consisting of polyurethane exterior, PTFE inner liner, and internal braided wire encapsulated in shaft wall.
2. Atraumatic passivated 316 L grade stainless steel feeding tip/electrode
3. Impedance and ECG sensing electrodes made from passivated 316 L grade stainless steel
4. Temperature sensors (internal, not shown).
5. Internal braided wires encapsulated in shaft wall (internal, not shown).
6. Polyurethane shaft strain relief.
7. Cable Break-off made of ABS.
8. Kinkable polyurethane shaft.
9. ENFit™ Feeding Port made of ABS.
10. ENFit Feeding Port cap made of ABS.
11. Electrical cable with thermoplastic polyurethane outer jacket.
12. Electrical connector.
13. Stylet (optional).

Package Contents

Contents:

(1) Entarik G2 NI Feeding Tube without Stylet or with Stylet (removable, optional for use)
   a. NI (Neonate) Feeding Tube Sizes: 5Fr and 8Fr

Part Numbers

Entarik G2 Monitor: FGN-04-2064

Extension Cable: MSP-04-1959

Entarik G2 NI Feeding Tubes – *With* Stylet

Product Line	Feeding Tube		Sterility	Part Number
	Size (Fr)	Length (cm)		
Neonatal Products (NI) For patients < 110 cm tall *(With* Stylet)	5	90	Sterile	FGS-04-2065
	8	109	Sterile	FGS-04-2069

Entarik G2 NI Feeding Tubes – *Without* Stylet

Product Line	Feeding Tube		Sterility	Part Number
	Size (Fr)	Length (cm)		
Neonatal Products (NI) For patients < 110 cm tall *(Without* Stylet)	5	90	Sterile	FGS-04-2366
	8	109	Sterile	FGS-04-2370

- Do not use if package is damaged
- Short-term use (less than 30 days)
- Discard after use
- For enteral nutrition only
- Store at room temperature
- To be used as part of the Entarik G2-N Feeding Tube System

Note: Entarik G2 Monitor is a reusable device that is provided separately.

Directions

1. Read all **warnings** and **precautions** prior to tube insertion.
2. Explain the procedure to the legally authorized representative (LAR) of the patient.
3. Place patient on their back, ideally with the head of bed raised.
4. Remove Entarik G2 NI Feeding Tube from packaging.
   a. Note: Stylet is packaged with the feeding tube (if applicable). If not using Stylet remove from the feeding tube and dispose.
5. Place caps on any open ENFit ports.

6. Turn on Entarik G2 Monitor (See Entarik G2-N Feeding Tube System Instructions for Use for monitor operation and use with the feeding tube).
7. Plug feeding tube electrical connector into the extension cable (provided with the monitor), and plug the extension cable into the Entarik G2 Monitor receptacle.
8. Determine the nostril for insertion if inserting via nasal route.
9. Lubricate feeding tube tip with water-based lubricant (optional).
10. Insert feeding tube using standard feeding tube insertion techniques:
    a. Direct feeding tube posteriorly, aiming tip parallel to the nasal septum and superior surface of the hard palate.
    b. Advance tube to nasopharynx allowing the tip to seek its own passage.
11. Follow instructions on Entarik G2 Monitor to aid in final placement of the feeding tube into the stomach.
    a. WARNING: Coughing may indicate passage of tube into trachea. If suspected, remove the tube and reinsert once the patient is comfortable. If resistance is encountered remove tube.
    b. Particular care should be taken if an endotracheal tube is in place, as it may tend to guide the feeding tube into the trachea.
12. Use standard Institutional protocol (e.g., x-ray) to confirm the feeding tube is in the stomach prior to administration of any fluids.
13. Remove Stylet if used during FT insertion.
    a. If resistance to Stylet removal is encountered, flush tube with water to facilitate removal.
    b. WARNING: Never insert Stylet into feeding tube when tube is in the patient.
14. Secure feeding tube into position per institutional protocol.
15. Connect the ENFit male connector on the feeding tube to an enteral feeding syringe or an enteral feeding set. Only the syringe or feeding set designed with ENFit connector can be securely connected to the feeding tube
16. Confirm that the feeding tube is connected to an enteral port only and NOT an I.V. set.

Ability to Connect to Non-Enteral Medical Devices

The Entarik G2 NI Feeding Tube has ENFit connectors which were designed to prevent misconnections between enteral devices and other devices used in various medical applications. However, the design of the ENFit connector cannot overcome all chances of misconnection. There is a possibility of misconnection of the feeding tube connector with the following types of connectors: the sockets of anesthetic and respiratory equipment (including cones and sockets of ISO 5356-1:2004 and ISO 5356-2:2006 as well as Nipples of EN 13544-2:2002), conical oxygen tubing, connectors for breathing systems and driving gas applications, connectors for intravenous applications, connectors

for urethral/urinary applications, connectors for neuraxial applications and conical connectors for limb cuff inflation applications.

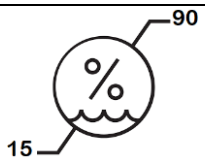
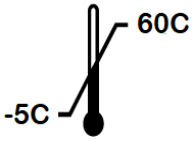
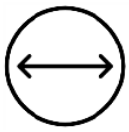
Technical Support

For technical support, please call **Gravitas Medical, Inc. at +1 (650) 516-6508** or send an email to support@gravitasmedinc.com.

Symbols Glossary

The required symbols below relate to the labeling for the Entarik G2 NI Feeding Tube. Explanations of the symbols are included in this glossary.

Symbol	Description
	**Refer to Instruction Manual** Indicates a requirement to read and understand the Operator's Manual and other accompanying instructions before use of the device. ISO 7010-M002
	**Rx Only** Federal law restricts this device to sale by or on the order of a physician (licensed healthcare practitioner). 21 CFR Part 801 § 801.109(b)(1)
	**Do Not Re-Use** Indicates that the device is intended for use on a single patient. ISO 7000-1501
	**MR Unsafe** Indicates that a component may be hazardous if introduced into magnetic resonance (MR) environments. ASTM F 2503
	**Sterilized using Ethylene Oxide** Indicates that the device has been sterilized using ethylene oxide. IEC 60417-2501
	**Do Not Use if Package is Damaged** Indicates the device should not be used if the package has been damaged or opened. ISO 7000-2606

Symbol	Description
	Keep Dry Indicates the device needs to be protected from moisture. ISO 7000-0626
	Humidity Limitation The device can be safely exposed to a range of humidity between 15% and 90%. ISO 7000-2620
	Temperature Limit The device can be safely exposed to temperatures between -5ºC to 60ºC. ISO 7000-0632
	Use-By date Indicates the use-by date. IEC 60417-2607
	Manufacturer Indicates the manufacturer of the device. IEC 60417-3082
	Lot Number (Batch code) Indicates lot number of the Entarik G2 NI Feeding Tube ISO 7000-2492
	Catalog Number Indicates the model number of the Entarik G2 NI Feeding Tube IEC 60417-2493
	Quantity Indicates the quantity of Entarik G2 NI Feeding Tubes in the package
	Outer Diameter Indicates the outer diameter of Entarik G2 NI Feeding Tube
	Length Indicates the length of Entarik G2 NI Feeding Tube
	Patient Height Indicates the patient height that is compatible with a Entarik G2 NI Feeding Tube

Entarik™ is a trademark of Gravitas Medical, Inc.

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