GRAVITAS MEDICAL, INC.

# Entarik™ Feeding Tube

## Operator's Manual

IFU-04-1403 Rev A

## Introduction

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

The **Entarik Feeding Tube** is a nasogastric feeding tube with a single lumen (feed lumen) for the administration of nutrition, fluids and medications. Additional, isolated lumens for 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 Feeding Tube, when connected to the **Entarik Monitor**, forms the **Entarik 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 Feeding Tube and Entarik Feeding Tube System are only intended for use by a physician, or on the order of a physician.

## Indications for Use

The Entarik Feeding Tube is intended for the administration of nutrition, fluids and medications by the nasoenteric route for patients who have an intact gastrointestinal tract but are physically unable to manage nutritional intake through normal mastication and deglutition.

## Actions

Acts as a conduit for food, fluid, 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 environments with an ambient temperature above 30°C (86°F).
- 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- At any point during the procedure if continuous resistance is felt the device should be withdrawn and then reinserted.
- 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.** The presence of an endotracheal device tends to guide the feeding tube into the trachea. 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.
- This disposable device should only be used with the Entarik Monitor.
- Feeding tubes should never be transferred from one patient to another.
- Entarik 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 Gravitas feeding tube.
- **MR Unsafe** – The Entarik 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 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 nasogastric 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

## Precautions

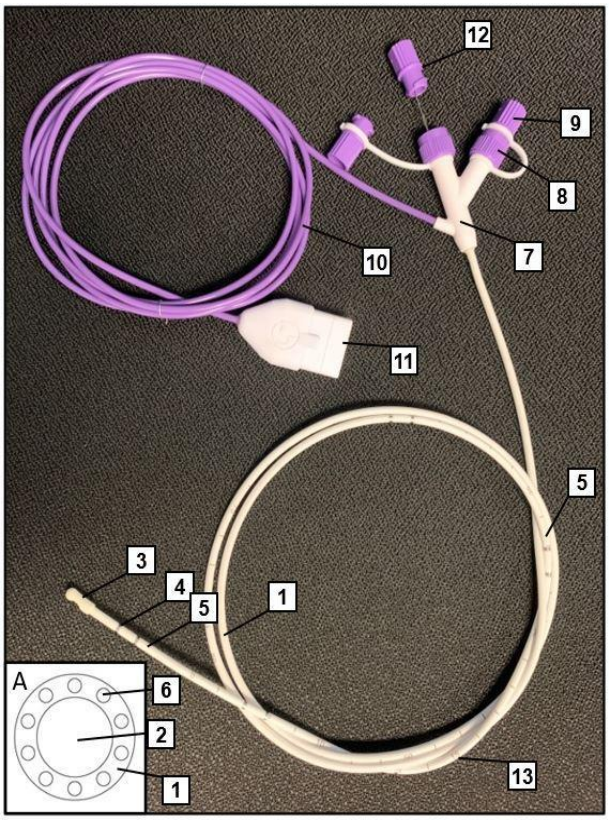
- Do not use if products are damaged. Check packaging before using.
- Do not autoclave
- Feeding tubes should be flushed frequently to prevent clogging and to detect leakages. Suggested flushing schedule:
    a. Before and after each feeding
    b. Before and after administering medication
    c. Once 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 of 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 Feeding Tube

The Entarik Feeding Tube is a nasogastric 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:




- Multi-lumen shaft (1) with central feed lumen (2) and atraumatic feed tip (3)
- Impedance electrodes x 10 (4) and temperature sensors x3 in tube wall (5)
- Isolated wire lumens in the feeding tube wall (6)
- Y connector (7) joins feeding tube shaft, feeding/stylet ports and electrical cable

- ENFit feeding/stylet ports x 2 **(8)** with caps **(9)**
- Electrical cable **(10)** and electrical connector/plug-in for Entarik Monitor **(11)**
- Stainless steel Stylet **(12)** is included to assist with insertion (optional use).
- External depth markings on the tube **(13)** to track/record insertion depth

## Package Contents

Contents:

(1) Entarik Feeding Tube (8Fr or 12Fr) with Stylet (removable, optional for use)

- Non-Sterile
- 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 Feeding Tube System

Note: Entarik 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 patient (if conscious).
3. Place patient in high Fowler's or sitting position. Do not lean patient forward.
4. Remove Entarik Feeding Tube from packaging.
    a. Note: Stylet is packaged with the feeding tube for optional use. If not using Stylet remove from the feeding tube.
5. Place caps on any open ENFit ports.
6. Turn on Entarik Monitor (See Entarik Feeding Tube System Instructions for Use for monitor operation and use with the feeding tube).
7. Plug electrical connector into the feeding tube connector receptacle on the Entarik Monitor.
8. Determine the nostril for insertion.
9. Lubricate feeding tube tip with water-based lubricant (optional).
10. Naso-oral numbing spray or local anesthetic jelly may also be used for patient comfort (optional).
11. 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.

c. Patient may swallow sips of water during advancement to assist guidance into the esophagus.

12. Follow instructions on Entarik 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.

13. Use standard Institutional protocol (e.g., x-ray) to confirm the feeding tube is in the stomach prior to administration of any fluids.

14. Remove Stylet.

    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.

15. Secure feeding tube into position per institutional protocol.

16. 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

17. 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

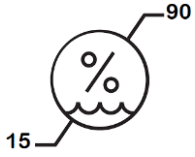
The Entarik Feeding Tube has ENFit connectors which were designed to prevent misconnections between enteral devices and other devices used in various medical applications. However, the design of the ENFit connector cannot overcome all chances of misconnection. There is a possibility of misconnection 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.

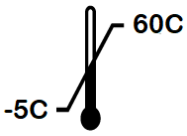
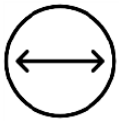
## Technical Support

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

## Symbols Glossary

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

| Symbol | Description |
|---|---|
|  | Refer to Instruction Manual<br>Indicates a requirement to read and understand the Operator's Manual and other accompany instructions before use of the device.<br>ISO 7010-M002 |
|  | Rx Only<br>Federal law restricts this device to sale by or on the order of a physician (licensed healthcare practitioner).<br>21 CFR Part 801 § 801.109(b)(1) |
|  | Do Not Re-Use<br>Indicates that the device is intended for use on a single patient.<br>ISO 7000-1501 |
|  | MR Unsafe<br>Indicates that a component may be hazardous if introduced into magnetic resonance (MR) environments.<br>ASTM F 2503 |
|  | Device is Not Sterile<br>Indicates that the device that is normally provided sterile in the same or similar packaging has not been sterilized.<br>ISO 7000-2609 |
|  | Do Not Use if Package is Damaged<br>Indicates the device should not be used if the package has been damaged or opened.<br>ISO 7000-2606 |
|  | Keep Dry<br>Indicates the device needs to be protected from moisture.<br>ISO 7000-0626 |
|  | Humidity Limitation<br>The device can be safely exposed to a range of humidity between 15% and 90%.<br>ISO 7000-2620 |

| | |
|---|---|
|  | Temperature Limit<br>The device can be safely exposed to temperatures between -5ºC to 60ºC.<br>ISO 7000-0632 |
|  | Use-By date<br>Indicates the use-by date.<br>ISO 60417-2607 |
|  | Manufacturer<br>Indicates the manufacturer of the device.<br>ISO 60417-3082 |
|  | Lot Number (Batch code)<br>Indicates lot number of the Entarik Feeding Tube<br>ISO 7000-2492 |
|  | Catalog Number<br>Indicates the model number of the Entarik Feeding Tube<br>ISO 60417-2493 |
|  | Quantity<br>Indicates the quantity of Entarik Feeding Tubes in the package |
|  | Outer Diameter<br>Indicates the outer diameter of Entarik Feeding Tube |
|  | Length<br>Indicates the length of Entarik Feeding Tube |

Entarik™ is a trademark of Gravitas Medical, Inc.

Manufactured by:
Gravitas Medical, Inc.
101 Mississippi St, San Francisco, CA 94107
www.gravitasmedinc.com
1 (650) 516-6508
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Patent: www.gravitasmedinc.com/patents