ENVIZION

ENvue® Electromagnetic Placement System

Enteral Feeding Tube with Embedded Electromagnetic Sensor and Pre-inserted Stylet with ENFit® compatibility.

For Use with ENvue System

1 EACH SINGLE PATIENT USE

NOT MADE WITH NATURAL RUBBER LATEX

Duration of Use: Up to 30 days

Caution

Clinician must read the ENvue System User Manual and the directions included with this feeding tube thoroughly prior to tube insertion. Facility protocol for insertion of any feeding tube should also be followed.

Indications for Use

1. The ENvizion® Enteral Feeding Tube (EFT) has been specifically designed for use with the ENvue® System and is intended for placement in the stomach or small intestine.
2. It is intended for use in adult patients who require intermittent or continuous feeding via the oro/nasoenteric route. The EFT is intended only to be used with a feeding pump and is not compatible with gravity-based feeding bags.

Storage

The Enteral Feeding Tube should be stored in a cool dry place and should be protected from direct sunlight.

How Supplied:

The Enteral Feeding Tube is supplied non-sterile with pre-inserted stylet as follows:

8 Fr to 12 Fr (2.67 mm to 4 mm); 91 to 140 cm (36 to 55 in) working length with marks every 5 cm (2 in) along working length

Features

- Medical grade polyurethane
- Pre-inserted stainless-steel stylet
- Electromagnetic passive sensor embedded within feeding tube for use with the ENvue System
- Centimeter markings (approx.) printed on tube to aid placement and check migration
- Radiopaque tube and tip
- ENFit Connector

Contraindications

The use of this product is contraindicated for pregnant women, pediatric, and neonatal use.

Warnings:

The Enteral Feeding Tube has been demonstrated to be MR Conditional once the stylet has been removed. Please read the MRI Safety information below and follow the conditions and instructions for MRI compatibility.

Only clinical personnel familiar with the placement of oro/ nasoenteric tubes should perform tube placements.

The Enteral Feeding Tube connection is intended to connect to enteral devices. If not connected to an enteral device, this may cause serious patient injury.

Lubricate the tube generously with distilled water or water-soluble jelly prior to insertion. DO NOT use petroleum-based products as they may be harmful to the respiratory tract.

Coughing may indicate passage of tube into trachea which may cause serious injury. If this is suspected, remove tube and reinsert once patient is comfortable.

If resistance is encountered, remove tube. Notify physician. Particular care should be taken if any type of endotracheal device is in place, as it may tend to guide feeding tube into trachea.

Misplacement of the feeding tube into trachea or lungs may result in serious patient injury.

Do not push forward the tube without looking at screen or without viewing an image from the display. User must verify proper visualization of the tubing proceeding down the oro/nasoenteric pathway. If placement system display is not available, revert to standard of care for placement of enteral feeding tubes and confirm placement with X-ray or pH measurement.

When administering nutrition to the patient via a pump, pressure should not exceed 15 psi. Excessive pressure may cause damage to stomach lining.

Do not use excessive syringe force to irrigate, administer liquids or unblock the tube. This may damage the tubing or cause patient harm.

Monitor patient for: nasal erosion, sinusitis, esophagitis, esophagotracheal fistula, gastric erosion and pulmonary and/or infections.

The Enteral Feeding Tube position must be confirmed per institution protocol (i.e. X-ray, pH measurement, etc.).

Do not reuse or sterilize! ENvizion EFT should be discarded after one procedure as it is extremely difficult to sterilize adequately after being exposed to biological materials and may cause adverse patient reactions if reused. Cleaning and/or sterilizing the product may alter its structural properties.

Cautions:

Exercise caution with patients with a history of head trauma, facial trauma, esophageal disease and patients with potential for vomiting.

Do not force the ENvue Enteral Feeding Tube during insertions or removals; damage to the oral/nasal passage and mucosa and bleeding may occur.

Inspect the device prior to use; do not use a device that appears to be damaged.

If patient cannot be positioned correctly, additional care must be taken during insertion to avoid esophageal damage.

Failure to remove the stylet may cause leaks or excessive feeding pump alarms.

Do not reinsert the stylet into the feeding tube after placement.

Notes:

For patients who cannot provide visual or physiological feedback to the clinician during tube placement (i.e. unconscious, missing the gag reflex) additional confirmation techniques may be indicated prior to feeding.

Directions for Insertion

1. Review the Placement Procedures outlined in the ENvue Electromagnetic Placement System User's Manual.
2. Explain procedure to patient if applicable.
3. Position the patient in accordance with facility protocol for feeding tube placement.
4. Position the Electromagnetic Placement System Cart next to the bedrail of the patient's bed at the level of the xiphoid process, which permits easy viewing of the display during the feeding tube placement procedure.

5. Follow the display menu for step-by-step instructions.
6. Connect the feeding tube with pre-inserted stylet and the embedded electromagnetic sensor to the Patient Cable by lining up the arrow and triangle.
7. Measure length of tube to be inserted per facility protocol. Use the printed centimeter marks on the tube to aid insertion and check for tube migration.
8. Provide cooperative patient with glass of water and straw.
9. Lubricate with distilled water or water-soluble jelly if desired. If more than several minutes elapse before tube insertion is attempted, additional dipping of tip may be required
10. If insertion via nose, determine preferred nostril for insertion. Direct tube posteriorly, aiming tip parallel to nasal septum and superior surface of hard palate. Advance tube to nasopharynx, allowing tip to seek its own passage.

    or

11. Insert the tube into the oral cavity and then direct tube downward through the oropharynx to the pre-measured length.
12. As the feeding tube with embedded electromagnetic sensor is advanced into the patient, the relative position of the tube tip will appear on the display upon passing the suprasternal notch.

Refer to the ENvizion Electromagnetic Placement User Manual for troubleshooting and guidance regarding placement of the tube.

13. If pathway of the tube on the display shows a severe curve to the right or left above the xiphoid process anatomical landmark, (see Figures 1-2) immediately pull back on feeding tube and adjust placement to show a straight line towards the horizontal axis.

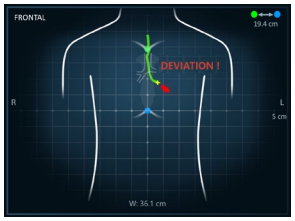


Figure 1

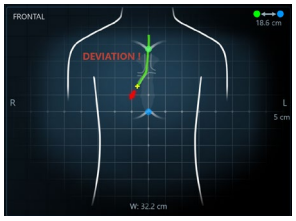


Figure 2

14. Slowly advance the tube into the stomach or small intestine as desired. Refer to the display to aid proper placement. Advance the tip of the tube across the greater curvature of the stomach (refer to Figure 3), watching the track as it crosses the mid-line into the duodenum. Some manipulation of the proximal end of the tube may be needed to encourage the passage across the mid-line. Refer to the display until advancement across the mid-line and into the duodenum occurs (refer to Figure 4).

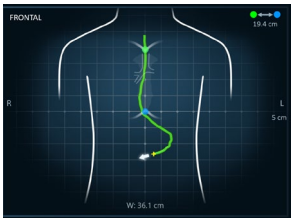


Figure 3

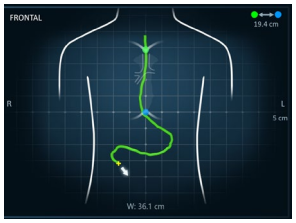


Figure 4

15. The tip passing the midline axis on the display suggests passage into the duodenum. An increase in depth, as indicated on the Axial View or Lateral View (refer to Figure 5) would be a further indication of duodenal placement. The tube track traversing back across the midline (as indicated in Figure 4), suggests placement of the feeding tube in the small intestine.

Figure 5

16. When the desired tube tip position has been achieved, press "Finish" on the screen or disconnect Placement tube from Patient cable.
17. Attach ENFit® compatible syringe and flush with 20 cc of water. Detach syringe and remove stylet from feeding tube by gently pulling it back until the entire stylet is outside the tube.

Do not reinsert the stylet into the feeding tube after placement.

18. Secure with a holder or tape per hospital protocol.
19. Confirm tube position by either X-Ray or pH measurement.
20. Attach administration set and begin feeding per physician's order and use institution protocol.

ENvue Enteral Feeding Tube Position Check

To check the position of the ENvue Feeding tube:

1. Position the ENvue System Cart next to the bedrail of the patient's bed at the level of the patient's Xiphoid process that permits easy viewing of the display during the feeding tube placement procedure.
2. Connect the ENvue feeding tube to the Patient Cable by lining up the arrow and triangle.
3. Follow the display menu for step-by-step instructions for tube position check.
4. Disconnect Feeding tube from Patient Cable.
5. Confirm placement of tube by either X-ray or pH measurement if required.

Disposal

1. To remove tube, gently withdraw through nostril.
2. This product may be a potential biohazard. Handle and dispose of in accordance with accepted facility policy.
3. The entire product may be incinerated.

MR
MR Conditional

MRI Safety Information

Non-clinical testing and electromagnetic/thermal simulations demonstrated that the ENvizion Medical Enteral Feeding Tube is MR Conditional once the stylet has been removed. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-T and 3-T, only
- Maximum spatial gradient magnetic field of 4,000-Gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg in the Normal Operating Mode for 15 min. (i.e., per pulse sequence)
- A quadrature driven (i.e., circularly polarized, CP) transmit RF coil should be used for MRI, only.
- Use the transmit/receive RF body coil or transmit RF body coil/receive-only RF head coil for the MRI exam. Body-part specific transmit/receive RF coils (e.g., knee, foot/ankle, wrist, etc.) may be used for MRI.
- Do not use a transmit /receive or transmit-only RF head coil for MRI.

Under the scan conditions defined, the ENvizion Medical Enteral Feeding Tube is expected to produce a maximum temperature rise of less than 3.6˚C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the device extends approximately 10-mm from the ENvizion Medical Enteral Feeding Tube when imaged using a gradient echo pulse sequence and a 3-T MR system.

WARNING:

Special positioning of the ENvizion Medical Enteral Feeding Tube is required to ensure patient safety with respect to MRI-related heating. Failure to follow the positioning instructions below may lead to serious patient injury.

The ENvizion Medical Enteral Feeding Tube must be placed in the specific geometry shown in the figure below. The required configuration is the foldback configuration as shown in Figure 6, below. Do not perform MRI with the ENvizion Medical Enteral Feeding Tube in a straight configuration.

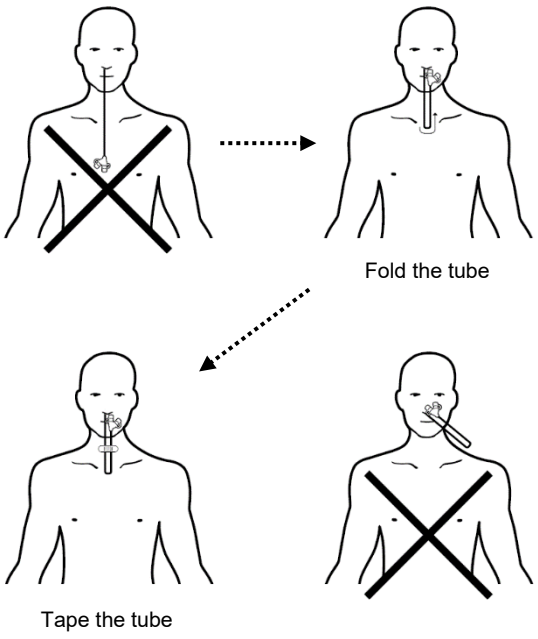
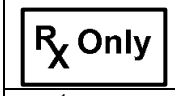


Figure 6

Additional MRI Safety Information:

Only the ENvizion Medical Enteral Feeding Tube is permitted to be in the patient undergoing the MRI exam. Do not bring the ENvue system into the MR system room. The ENvue System is MR Unsafe (refer to the ENvue System User Manual).

Explanation of Graphical Symbols

	Consult instructions for use
	Single Use ONLY, Do not re-use
	Catalog number
	Batch code
	Prescription only
	Keep dry
	MR Conditional
	Use-by date
	Manufacturer
	Package Quantity
	Do NOT use if package is opened or damaged. Product may be compromised.

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