EnteroTracker® Instructions for Use

INDICATIONS FOR USE

The EnteroTracker® is a device for the collection of fluid/mucus from the upper gastrointestinal tract of adult and pediatric patients.

PRECAUTIONS

No significant complications have been reported, and no known contraindications exist. Physicians should evaluate the patient's ability to swallow a capsule and if any components of the EnteroTracker® may be problematic for the patient.

Patients should not eat for 2 hours and should not drink for one hour prior to the procedure. A patient may be unable to swallow the capsule because of gagging or may vomit after doing so. The patient may drink as much water as needed to prevent gagging during both swallowing and dwell time. Gagging upon retrieval of the string may occur. On rare occasions where the entire string was swallowed, no ill effects were identified.

The EnteroTracker® has not been evaluated for safety in the Magnetic Resonance (MR) environment. Prescribing physicians should be aware and notify patients that the device contains a stainless-steel ball which renders the patient incompatible with MRI testing until the ball has been expelled in the stool.

The device is intended for single use only and should be stored and transported in a dry environment.

European Union Notice: If any serious incident occurs in relation to the device, the user or patient should report the incident to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

DESCRIPTION

The EnteroTracker® should be administered by a healthcare professional or other trained personnel and supervised by a physician.

The EnteroTracker® capsule is supplied in pouches, each pouch containing a single device. Also supplied with the device is a single piece of fixation tape and a pH marker. The EnteroTracker® is a single use item. Store in a dry place.

The EnteroTracker® capsule allows physicians to collect biofluid samples from the upper gastrointestinal (GI) tract. The device is comprised of an ingestible capsule that contains a weighted ball and a highly absorbent nylon string (see Figure 1). The looped portion of the string is secured externally to the patient's cheek with the supplied fixation tape.

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Key functional elements of the EnteroTracker®:

Element	Composition	Functionality
String	Woven nylon	Deployed in the upper gastrointestinal tract to absorb mucosal fluid
Capsule	Vegetarian cellulose or gelatin	Deploys the string as it is swallowed
Ball	Stainless steel	Weights the capsule to help move it down the gastrointestinal tract when swallowed
Fixation Tape	Adhesive tape or patch	Secures the proximal end of the string to the cheek after swallowing
pH stick	Wood, pH Indicating Wax	Allows marking the string for pH zones after retrieval

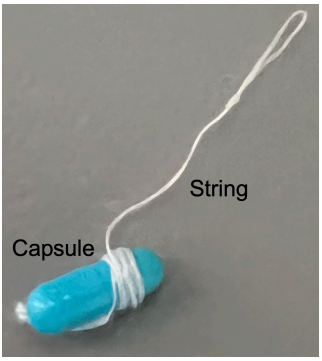


Figure 1. EnteroTracker® Capsule

The capsule is swallowed by the patient. The string unwinds from the capsule as it enters the patient's upper GI tract, where it absorbs the biofluids of interest. The capsule dissolves in the stomach. The weighted ball is released, passes through the GI tract and is expelled naturally in the stool. After a period designated by the physician, the string is retrieved slowly through the mouth.

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Figure 2. pH marker

The supplied pH marker is used to indicate the pH on the collected string sample to inform digestive region respective of string region. The pH marker is a wooden stick that is dipped into a pH indicating wax (see Figure 2) and allows the physician/technician to determine the string portion of interest. The string can then be analyzed for the cells, biofluids, and biological markers that have been absorbed and entrapped within the string.

The procedure is described in detail below.

CAPSULE PROCEDURE

1. Put on medical gloves and remove capsule from pouch.
2. Unwind the proximal string from around the capsule without pulling more string out of the capsule.
3. Wrap the proximal end of the pulled string around the patient's finger once and instruct the patient to keep hold of the string.
4. Instruct the patient to swallow the capsule with water with the string remaining wrapped around the patient's finger. Instruct the patient to continue drinking water until the capsule has been swallowed.
5. Secure the looped end of the string to the patient's cheek with fixation tape or other non-allergic tape. With a permanent marker, mark the string that lies on the corner of the patient's mouth; this is the 0-cm mark.
6. After this, the patient should not drink or eat anything until the string is removed. Water can be used to prevent gagging if needed.
7. The string should remain in the patient's upper GI tract for a period designated by the physician. During this time, prepare for string processing as needed for the specific processing application. Refer to additional documentation as needed.

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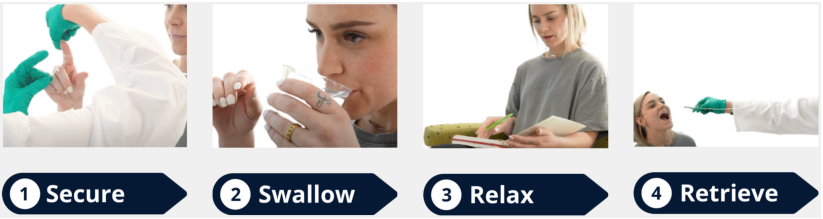


Figure 3. Capsule procedure steps.

STRING PROCESSING

8. Retrieve the vial containing the Buffer Solution provided with the EnteroTracker® from refrigerated storage. Record patient information on vial label.
9. Prepare a surface for cutting the string by placing the Parafilm® (paper side up) and measuring tape or cutting board out flat on clean surface. Remove the paper from the Parafilm®.
10. When the string has been in the patient for the recommended time (1 hour for esophageal sampling), un-tape the string from the cheek and ask the patient to open their mouth wide. Pull the string out of the mouth at a slow, even rate. This should take no more than 5 seconds.
11. Lay the string out flat and straight on a clean surface.
    a. With the optional accessory kit: Lay out the Parafilm®. Align the 0-cm mark on the string with 0 cm on the tape measure.
    b. The optional cutting board can be used as an alternative to the Parafilm® and tape measure.
12. Starting at 20 cm for children and 25 cm for adults, touch the string with the pH marker at approximately 2-cm intervals to identify the esophageal, gastric, and small intestinal sections of the string.
13. The gastric section should turn red/orange (acid, pH <4), while all other sections should be yellow/green (alkaline, pH >7).

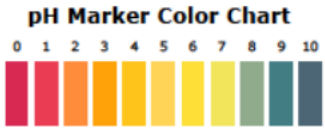


Figure 4. pH Marker Color Chart

If pH marking does not show a clear pH change indicating the gastric section, use the following equations to calculate the length at which the esophageal section ends.

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a. Equations for Esophageal Length
    i. Children: 5 + 0.252 X height (cm)
    ii. Adults: 6.7 + 0.226 X height (cm)

14. To harvest the esophageal section of the string, mark the beginning of the esophageal section 7 cm from the 0 cm mark made in Capsule Procedure point #5. Mark the end of the esophageal section at 2 cm from the beginning of the gastric section (pH <4). Use the included tweezers and scissors to cut the esophageal section of the string.
15. Place the esophageal section of the string into the vial containing the Buffer Solution. Make sure the string is submerged in the Buffer Solution.
16. Once the string is in the Buffer Solution, secure the lid of the vial and flip the vial over 7-8 times. Ensure that the string is once again submerged in the Buffer Solution at the bottom of the vial after flipping.
17. Place the tube in the provided sealable plastic bag and expel air from the bag before resealing.
18. Discard the remaining portions of the string in an appropriate location.

NOTE:
Confirm hours of operation with the lab prior to shipment. If storage of the sample is necessary prior to shipment, place samples in freezer until ready to prepare shipment. Sample must remain frozen throughout shipment.

SHIPPING

THAWED SAMPLE WARNINGS:

Not following the listed instructions below increase the risk of samples thawing during shipment.

- Sample shall be fully frozen before being prepared for shipping.
- Only refrigerant packs provided by EnteroTrack shall be used when shipping samples obtained using the EnteroTracker.
- Refrigerant packs shall be fully frozen before being prepared for shipping. Some refrigerant packs provided in Shipping Kits require a freezer that is set below -10 °C (14 °F) to fully freeze.
- Follow all instructions for sample preparation, packing, and shipping.

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Test results obtained from thawed samples can be used for research purposes only. Re-administration of the EnteroTracker to patients will be required in order to obtain clinical results.

A physical copy of additional instructions for preparing a sample shipment can be found within the Shipping Set assembly provided by EnteroTrack. These instructions vary based on the type of Shipping Set provided. They can also be found online

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