

Cautions for Capsule Endoscopy Patient

Your physician has determined that you should undergo an examination called “capsule endoscopy” as part of your medical evaluation.

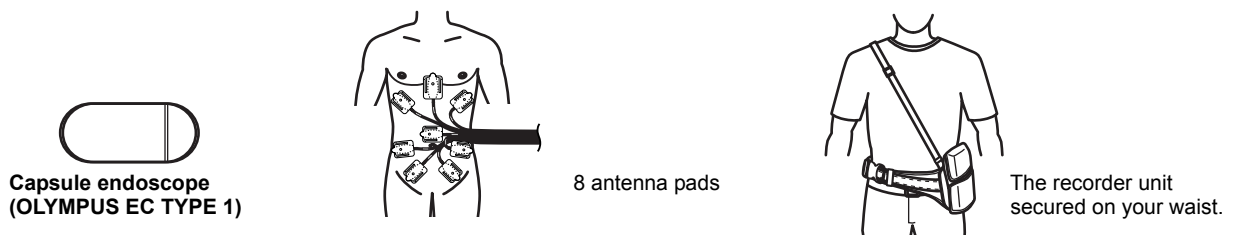
The OLYMPUS CAPSULE ENDOSCOPE SYSTEM is indicated for visualization of the small intestine mucosa as an adjunctive tool in the detection of abnormalities of the small intestine mucosa. The Red Color Detection Function is intended to mark frames of the video suspected of containing blood or red areas.

The capsule endoscope (Olympus EC type 1) has only been studied in patients with obscure gastrointestinal bleeding. Obscure gastrointestinal bleeding is bleeding of an unknown origin or source that persists or recurs in the small intestine. The analysis of acquired capsule images requires a physician trained in endoscopy.

You will be asked to ingest the Olympus EC type 1 for this examination. The capsule takes pictures as it moves through your digestive system. The pictures are transmitted from the capsule via the 8 antenna pads attached to your abdominal area to the recorder unit secured on your waist. All the pictures are stored on the recorder unit. The antenna lead set and the recorder unit are removed after about 8 hours and the recorded images are viewed by a physician trained in endoscopy. The image recording time of the Olympus EC type 1 is 8 hours and the Olympus EC type 1 may not transverse the entire small bowel during that time. Therefore, it is possible that the examination of the small bowel will be incomplete. It is important that you follow the instructions below to attach the equipment properly and prevent equipment damage and/or failure so that your physician can obtain accurate results.

During the examination, there is a slight possibility of unexpected retention of the capsule. In the worst case, surgical removal of the capsule may be required. Patients with one of the following conditions cannot undergo the examination.

- Patients with a cardiac pacemaker, implanted cardiac defibrillator or other implanted electronic devices.
- Patients with known intestinal strictures, adhesions, diverticulum, obstruction or fistulas that may block the passage of the capsule endoscope.
- Patients with significant difficulty in swallowing a tablet as large as capsule endoscope.
- Patients with known swallowing disorders.
- Patients who cannot undergo surgery to remove the capsule when retention of the capsule occurs.
- Pregnant women.
- Patients with known significant delay in passing through of the capsule endoscope in the gastrointestinal tract.
- Patients diagnosed as radiation enteritis.



[Before the Examination]

- You must abstain from eating or drinking (but if necessary, minimum quantity of water may be taken) 8 hours before the examination.
- If you are on medication, please consult your physician(s) to determine if added precautions need to be taken during and/or after the examination.
- Your physician may wish to give you an intestine cleansing agent (laxative, gastrointestinal lavage) as a part of this examination, in such a case, follow your physician's instruction.
- Avoid wearing a dress or a one-piece-suit. Wear a separate top and a bottom so that the antenna lead cables can be connected to the recorder unit that is fitted to your waist.
- Your body hair may need to be shaved in order to securely adhere the antenna leads.
- Adhesive covers will be used to attach the antenna leads to your abdominal area.
- The antenna lead must not be removed for about 8 hours. If you experience any discomfort (i.e., skin irritation or pain) while the antenna lead is attached, please inform your physician.
- Ingest the capsule endoscope with a sip of water. Do not bite the capsule endoscope.

[During the Examination]

- The capsule endoscope contains metal parts. While the capsule endoscope is in your body, stay away from equipment (e.g., MRI equipment) that generates strong magnetic fields. Otherwise, you may injure your internal organs.
- If you experience stomach pain, discomfort, or nausea after ingesting the capsule endoscope, consult your physician immediately.
- Do not drink for 2 hours after ingesting the capsule endoscope. Do not eat for 4 hours after ingesting the capsule endoscope. But you may drink minimum quantity of water if necessary.
- Stay away from any equipment that generates strong electromagnetic fields (such as MRI equipment, amateur (ham) radio, etc.) . Do not use radio transmitting devices such as keyless entry devices or stay in an area where other persons may use them frequently, in order to reduce the possibility of dropped video frames caused by the use of these devices.
- Since the capsule endoscope contains a radio transmitter, you cannot fly in an airplane until the examination is completed.
- If you will be receiving other medical treatments during the examination, consult your physician beforehand.
- Reddening or irritation of the skin may sometimes be caused by the adhesive on the antenna lead cover. If this is observed, consult a physician immediately.
- Do not operate the equipment unless permitted by your physician. Handle the equipment with care. Refer to the following:
 - ◆ Do not remove the equipment from the harness.
 - ◆ Do not operate the equipment switches.
 - ◆ Do not bump or drop the equipment.
 - ◆ Do not run or move wildly.
 - ◆ Do not pull or bend the antenna lead cables.
 - ◆ Do not wet the equipment with water or any other liquids.
- After about 8 hours, the examination equipment will be removed according to your physician's instructions.

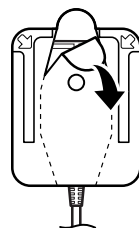
[After the Examination]

- The capsule endoscope contains metal parts. While the capsule endoscope is in your body, stay away from any equipment (i.e., MRI equipment) that prohibits the wearing of metallic objects in close proximity to it. Otherwise, you may injure your internal organs.
- The capsule endoscope will be excreted naturally in your feces. Please observe the capsule endoscope in your feces.
- If the capsule endoscope is not excreted within two weeks after the examination, consult your physician. When excretion of the capsule endoscope is not confirmed, you may need to undergo an X-ray examination. If the result of the X-ray examination shows retention of the capsule endoscope, it has to be retrieved by either a surgical operation or a conventional endoscopic procedure within 30 days from ingestion.

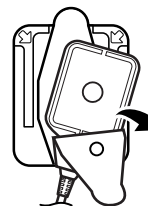
[Reference Information]

When instructed by your physician, remove the antenna lead as follows. Keep the recorder unit in the harness, and handle carefully so as not to exert excessive force on the antenna lead cables.

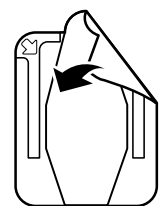
① Pull down the tab.



② Remove the antenna lead from its cover.



③ Peel off the antenna lead cover.



Please provide your emergency contact number.

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