

Patient Instructions for Undergoing Capsule Endoscopy Study

Your physician has determined that as part of your medical evaluation you should undergo an examination known as Capsule Endoscopy. This procedure involves swallowing a small (the size of a large vitamin pill) Given[®] Imaging M2A[®] Capsule which will pass naturally through your digestive system while taking pictures of the small intestine. The images are transmitted to electrodes which are placed on your abdomen. The electrodes are attached to a walkman-like Given[®] DataRecorder[™] which saves all the images. It is located in the RecorderBelt[™], which is worn around your waist. After 10 hours, you will remove the RecorderBelt and return it to your physician for processing. The Capsule is disposable and will be passed naturally in your bowel movement. In the rare case that it will not be excreted naturally, it will need to be removed endoscopically or surgically. In order for your physician to get the most accurate information from this examination, you will need to follow the instructions below:

The Day before Capsule Endoscopy

1. After lunch on the day before the Capsule Endoscopy examination, start the liquid diet your physician prescribed. From midnight the evening before the Capsule Endoscopy, do not eat or drink except for necessary medication with a sip of water.
2. Do not take any medication beginning 2 hours before undergoing the Capsule Endoscopy.
3. Abstain from smoking 24 hours prior to the Capsule Endoscopy.
4. Male patients with a lot of chest/abdominal hair should shave their abdomen 6 inches (15 centimeters) above and below the navel on the day of the examination. If it is difficult for you to shave your abdomen, please contact your physician's office to arrange to have this done in advance.

Day of Capsule Endoscopy

1. Arrive at your physician's office at the prescribed time for your Capsule Endoscopy dressed in loose fitting, two-piece clothing.
2. At your physician's office, you will have a pre-procedure interview. During this interview you should be informed that Capsule Endoscopy is associated with a small chance of intestinal obstruction. You will be checked-in and asked to give your informed consent.
3. The electrodes will be applied to your abdomen with adhesive pads and will be connected to the DataRecorder which you will wear in a belt around your waist. After that you will be instructed to ingest the Capsule.

After Ingesting the M2A[®] Capsule

1. After ingesting the Capsule, do not eat or drink for at least 2 hours. After 2 hours you may have clear liquids, and after 4 hours you may have a light snack. After the examination is completed, you may return to your normal diet. The above instructions apply unless your physician specifies otherwise. Contact your physician immediately if you suffer from any abdominal pain, nausea or vomiting during the Capsule Endoscopy.
2. After ingesting the Capsule and until it is passed, you should not be near any source of powerful electromagnetic fields such as one created near an MRI device or amateur (ham) radio.
3. Occasionally, some images may be lost due to radio interference (e.g. from amateur radio transmitter, MRI, etc.). On rare occasions this may result in the need to repeat the Capsule Endoscopy examination. In this case, the physician will advise you to stay within the premises of the clinic during the Capsule Endoscopy to prevent this problem from recurring.
4. A Capsule Endoscopy lasts approximately 10 hours and is considered complete according to your physician's instructions. Do not disconnect the equipment or remove the belt at any time during this period. Since the DataRecorder is actually a small computer, it should be treated with utmost care and protection. Avoid sudden movement and banging of the DataRecorder.
5. During the Capsule Endoscopy, you will need to verify every 15 minutes that the small light on top of the DataRecorder is blinking twice per second. If, for some reason it stops blinking at this rate, record the time and contact your physician, but continue the study. You should also record the time and nature of any event such as eating, drinking, your activity and unusual sensations. Return the Event Form with these notes to your physician at the time you return the equipment.
6. Avoid any strenuous physical activity especially if it involves sweating and do not bend over or stoop during the Capsule Endoscopy.

After Completing Capsule Endoscopy

- 1) You will be instructed by your physician on how to return the equipment at the end of Capsule Endoscopy. If you were instructed to remove the equipment by yourself, do the following:
 - a) Disconnect the electrodes from the DataRecorder;
 - b) Take off the RecorderBelt (with the DataRecorder and Battery Pack);
 - c) Disconnect the Battery Pack from the DataRecorder
 - d) Place DataRecorder and Battery Pack in a safe place. To remove the electrodes from your abdomen, do not pull the leads of the electrodes! Peel off each adhesive sleeve starting with the non-adhesive tab without removing the electrode from the adhesive sleeve. Place the electrodes with the rest of the equipment.
- 2) The DataRecorder stores the images of your examination. Handle the

DataRecorder, RecorderBelt, electrodes and Battery Pack carefully. Do not expose them to shock, vibration or direct sunlight, which may result in loss of information. Return all of the equipment to your physician's office as soon as possible.

- 3) If you did not positively verify the excretion of the Capsule from your body, and you develop unexplained post procedure nausea, abdominal pain or vomiting, contact your physician for evaluation and possible abdominal X-ray examination.
- 4) **Do not undergo an MRI while the capsule is inside your body!** This may result in serious damage to your intestinal tract or abdominal cavity. If you did not positively verify the excretion of the Capsule from your body, you should contact your physician for evaluation and possible abdominal X-ray before undergoing an MRI examination.