

Patient Instructions for Undergoing Capsule Endoscopy

Your physician has determined that as part of your medical evaluation, you should undergo a test known as Capsule Endoscopy. This procedure involves ingesting 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 intestine. The images are transmitted to a sensor array, which is placed on your abdomen. These sensors are attached to the walkman-like Given Data Recorder that is worn around your waist and which will save all the images. After 8 hours the Given Data Recorder will be taken off and returned to your physician for processing. The M2A Capsule is disposable and will be excreted naturally in your bowel movement. In the rare case that it will not be excreted naturally, it will have to be removed endoscopically or surgically.

In order for your physician to get the most accurate information from this test, you will need to follow the directions listed below:

- 1. Do not eat or drink for 8 hours prior to undergoing your Capsule Endoscopy.
- 2. For males: On the day prior to the Capsule Endoscopy, shave your abdomen 6 inches above and below the navel. If it is difficult for you to shave your abdomen, please contact your physician's office to arrange to come in earlier to have this done. (Coumadin patients, please use an electric razor.)
- 3. Please arrive at your physician's office at the prescribed time for your Capsule Endoscopy.
- 4. At your physician's office, you will go through a pre-procedure interview. During this interview, you should be informed that the Capsule Endoscopy is associated with a small chance of intestinal obstruction. You will be checked in and asked to give your informed consent.
- The Sensor Array will be applied to your abdomen with adhesive pads and will be connected to the Data Recorder, which you will wear in a belt, around your waist. You will then be instructed to ingest the M2A Capsule.

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M2A^(TM) Capsule

M2A^(TM) Capsule

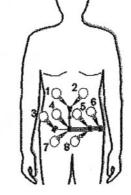
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- 3. Please arrive at your physician's office at the prescribed time for your Capsule Endoscopy.
- 4. At your physician's office, the Sensor Array will be applied to your abdomen with adhesive pads and will be connected to the Given[®] Data Recorder which is worn on a belt around your waist. You will then be instructed to ingest the M2A[®] Capsule.
- 5. After ingesting the M2A[®] Capsule, do not eat or drink for 2 hours. After 2 hours you may drink water. After four hours you may have a light snack. After completion of the study, you may return to your normal diet. Contact your physician immediately if you have any abdominal pain, nausea or vomiting anytime after ingesting the M2A[®] Capsule.



Given® Data Recorder worn on the belt

- After ingesting the M2A[®] Capsule and until it is excreted, you should not be near any source of powerful electromagnetic fields such as one created near an MRI device or amateur (ham) radio.
- 7. 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 procedure. In such a case, the Doctor will advise you to stay within the premises of the clinic for the duration of the capsule procedure to prevent this problem from recurring.
- 8. The Capsule Endoscopy will last 8 hours. During the Capsule Endoscopy try to avoid any strenuous physical activity. Do not bend or stoop during the Capsule Endoscopy. In addition, you should not remove the belt at any time during this period.
- 9. Every 15 minutes during the Capsule Endoscopy you will need to verify that the small green/blue light on top of the recorder is blinking. If for some reason it stops, please record the time and contact your physician. Also record the time and the nature of any event such as eating, drinking and unusual sensations. Return these notes to your physician at the time you return the equipment.
- 10. At the end of 8 hours, the Given® Data Recorder, Belt, and Sensor Array can be removed and returned as instructed by your physician. To remove the Sensor Array and Given® Data Recorder Belt, first disconnect the Sensor Array from the Given®



Sensor array applied on the abdomen

Data Recorder, then remove the Belt with the Given[®] Data Recorder and Given® Recorder Battery Pack in it. Disconnect the Given[®] Recorder Battery Pack from the Given[®] Data Recorder and then put them in a safe place. After removing the Belt, peel the Adhesive Sleeves off your abdomen without removing them from the

sensors and place the Sensor Array with the rest of the equipment. Do not pull the wires of the Sensors to assist in removing the Sensors from your abdomen! After removal leave the sensors in the Adhesive Sleeves. They will be removed at your physician's office.

- 11. The Given[®] Data Recorder holds the images of your examination. Handle the Given[®] Data Recorder, Belt, Sensor Array and Given[®] Recorder 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.
- The M2A[®] Capsule is disposable and it will be excreted naturally in your bowel movement.

Capsule Endoscopy Event Form

Patient Na	me I ID no:	en Collection
Time	Event (eating, drinking and unusual sensations)	(all care)
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