

Section: Division of Nursing

PROCEDURE

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HACKETTSTOWN REGIONAL MEDICAL CENTER

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Minor Procedure
(Scope)

TITLE: CAPSULE ENDOSCOPY

PURPOSE: To outline nursing methodology for assisting in the procedure for Capsule Endoscopy.

DEFINITION: Capsule Endoscopy is a non-invasive and ambulatory procedure that permits visualization of the patient's gastrointestinal tract, especially the small intestine. The capsule is propelled through the GI tract by peristalsis.

SUPPORTIVE DATA: Capsule Endoscopy was developed to diagnoses diseases of the small bowel, an area that has been relatively inaccessible to direct examination in the past. It is the gold standard for detecting diseases in the small bowel.

WARNING: The safety of the use of Capsule Endoscopy has not been established in the following cases:

- The safety of this device has not been established in pregnancy.
- The safety of this device in patients with significant gastrointestinal diverticular disease is unknown.
- This device has not been tested in pediatric population (children 18 and below) and safety in young children is unknown.
- Patients should avoid electromagnetic fields (MRI) during capsule endoscopy and until excretion of the capsule is verified.

INDICATIONS: The Given[®] Diagnostic System is intended for visualization of the small bowel mucosa. It may be used as an adjunctive tool in the detection of abnormalities of the small bowel.

CONTRAINDICATIONS: Capsule Endoscopy is contraindicated for use under the following conditions:

- In patients with known or suspected GI obstruction, strictures or fistulas based on the clinical picture or pre-procedure testing and profile.
- In patients with cardiac pacemakers or other implanted electromedical devices.
- In patients with swallowing disorders

EQUIPMENT:

1. M2A[®] Capsule
2. Given[®] Diagnostic System Workstation
3. Data Recorder
4. Sensor Array
5. Adhesive sleeves
6. Sensor Template (only with RAPID 1.3 or lower, **DON'T USE WITH RAPID 1.4 OR HIGHER**)
7. Battery Pack
8. Recorder Belt
9. Battery Charger
10. Alcohol and gauze
11. Benzine as needed for adhesive removal
12. Razor for hairy abdomens
13. Tape measure
14. Scale
15. Blank CD-R 700mB
16. Glass of water
17. 2cc of Mylicon drops (if applicable, **ONLY** per physician's instructions)

CONTENTS:

PROCEDURE:

1. Provide patient with instructions for undergoing capsule endoscopy.
2. Charge the battery the evening before the exam.
3. Assemble equipment.
4. Prepare SensorArray by inserting sensors into sleeves. Remove adhesive strips and seal shut.
5. Assess the patient, verifying that he/she had a clear liquid diet since after lunch the day before and NPO for a minimum of 10 hours. Necessary medication can be taken up to 2 hours before capsule ingestion (or per physician's specific instructions).
6. Measure the patient's waist, height and weight.
7. Check patient in on the Rapid workstation under the **Tools** heading, **Check In and Download**.
8. Enter the mandatory information as well as height, weight, waist size, data recorder number and capsule lot number.
9. Initialize the Data Recorder (this might take up to 10 minutes). During this time, perform the following:
 - a. Fit Recorder Belt
 - b. Apply SensorArray
 - c. MD consents the patient
10. Have patient dress and leave surplus SensorArray wire out of skirt/trousers.
11. When initialization is complete, disconnect Data Recorder. Write on label patient's ID and apply to Data Recorder.
12. Connect recorder to battery pack and insert into Recorder Belt (**check that LED is on and then goes off**).
13. Put on Recorder Belt.
14. Connect SensorArray to Data Recorder. **Ensure the red heart is facing outward or toward you.**
15. Take the M2A capsule out of blister pack and keep in its holder.
16. Perform the "Pre-Ingestion Test" of the M2A and Diagnostic System by holding M2A in its holder close to the sensors for a minimum of 15 seconds. The Data Recorder LED should blink at a recording rate of 2 blinks per second. If, for any reason, the Data Recorder is disconnected from the SensorArray or the battery pack prior to capsule ingestion, the procedure should be resumed from point 8.
17. Instruct the patient to swallow the M2A with water containing 2cc Mylicon (ONLY if ordered by physician)
18. Verify that the Data Recorder is blinking at the rate of 2 blinks per second. Instruct the patient to notify you immediately if the LED stops blinking.
19. Review intra-procedure instructions along with contact numbers.
20. Instruct patient to avoid undergoing an MRI while the capsule is inside their body and that unless they have positively verified the excretion of the capsule, the patient should contact their physician for evaluation and possible abdominal x-ray before undergoing an MRI examination.
21. Review the Capsule Endoscopy Event Form that the patient should complete.
22. Instruct patient when to return to facility with equipment.
23. After 8 hours, disconnect SensorArray from Data Recorder.
24. Remove Recorder Belt.
25. Provide post-capsule endoscopy instructions to the patient. Ensure understanding.
26. Remove SensorArray from patient's abdomen. Clean with alcohol. Use benzine if necessary to remove adhesive residue.
27. Recharge Battery Packs.
28. Perform download on Rapid workstation.
29. While download is in progress, turn the monitor off for patient confidentiality. (**NOT** the hard drive).
30. Provide CD-R containing Rapid video to physician for review.
31. Remove patient label from the Data Recorder after data has been successfully downloaded.
32. After physician has completed review of capsule study, copy RAPID video and findings to formatted CD. Label CD with patient ID. Delete study directory from E-drive and recycle bin.
33. Provide printed report containing marked pictures to Medical Records.

HACKETTSTOWN COMMUNITY HOSPITAL
Minor Procedures Department

PATIENT INSTRUCTIONS FOR UNDERGOING CAPSULE ENDOSCOPY

Your physician has determined that as part of your medical evaluation, you should undergo an examination 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 the SensorArray[™] which is placed on your abdomen. The Sensor Array[™] is 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 8 hours, you will return to the hospital to have the RecorderBelt[™] removed 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 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 10 p.m. the evening before 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 Capsule Endoscopy.
3. Abstain from smoking 24 hours prior to undergoing Capsule Endoscopy.
4. Male patients should shave their abdomen 6 inches (15cm) 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 the hospital at the prescribed time for your Capsule Endoscopy dressed in loose-fitting, two-piece clothing.
2. At the hospital, 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 SensorArray[™] 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 M2A[®] Capsule.

After ingesting the M2A[®] Capsule

1. After ingesting the M2A[®] Capsule, do not eat or drink for at least 2 hours. You may then have water only. Four hours after ingesting the M2A[®] Capsule, you may have a light snack and a beverage. After the examination is completed, you may return to your normal diet. The above instructions related to eating apply, unless your physician specifies otherwise. Contact your physician immediately if you suffer from any abdominal pain, nausea or vomiting during Capsule Endoscopy.
2. 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.

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. Capsule Endoscopy lasts approximately 8 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 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. 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 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 Capsule Endoscopy.

After completing Capsule Endoscopy

1. You will be instructed on how to return the equipment at the end of Capsule Endoscopy. **Please do not remove any equipment unless instructed to do so.** If you were instructed to remove the equipment by yourself, do the following: (a) Disconnect the SensorArray™ 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 SensorArray™ from your abdomen, do not pull the leads of the SensorArray™! Peel off each adhesive sleeve starting with the non-adhesive tab without removing the sensor from the adhesive sleeve. Place the SensorArray™ with the rest of the equipment. Return all of the equipment to the Minor Procedures Department as soon as possible.
2. The DataRecorder™ stores the images of your examination. Handle the DataRecorder™, RecorderBelt™, SensorArray™ and Battery Pack carefully. Do not expose them to shock, vibration or direct sunlight, which may result in loss of information.
3. If you did not positively verify the excretion of the M2A® 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. Undergoing an MRI while the capsule is inside your body may result in serious damage to your intestinal tract or abdominal cavity. If you did not positively verify the excretion of the M2A® capsule from your body, you should contact your physician for evaluation and possible abdominal X-ray before undergoing an MRI examination.

Capsule Endoscopy Event Form

Please record the time and nature of any event such as eating, drinking, your activity and any unusual sensations. Return the Event Form at the end of your exam to the Minor Procedures department.

Patient name: _____ Procedure Date: _____

Time	Event (eating, drinking, activity, unusual sensations)

Vertical text on the right edge of the page, possibly a scanning artifact or page identifier.

MINOR PROCEDURES
CAPSULE ENDOSCOPY

INITIALIZATION FORM

Please obtain information during admission assessment for initialization for data recorder prior to exam.

First name: _____

Middle name: _____

Last name: _____

Medical Record #: _____

Gender: Male Female

Birth date: / / _____

Height (inches): _____

Weight (inches): _____

Waist (inches): _____