

Sample* CapsoCam Plus® Prep Instructions

*Instructions are provided as an example to physicians for a patient prep that will likely achieve a clean small bowel and a favorable procedure outcome. Each patient's individual condition should be considered by the physician when prescribing prep instructions. Patients with known motility issues (e.g., delayed gastric emptying, gastric retention, frequent constipation, challenging accessibility during colonoscopy, etc.) may need a more aggressive or modified prep.

This prep was developed by physicians with their patients to achieve three primary endpoints: (1) optimal visualization of the small bowel, (2) fastest capsule passage and (3) loosest stool to facilitate retrieval with a goal to maximize the clinical outcome of your patient's capsule endoscopy study.

Patient Prep Instructions for Capsule Endoscopy with CapsoCam Plus®

Morning Ingestion Appointment

*NOTE: If taking an oral iron supplement, please stop 4 full days prior to the test.

Your Capsule Endoscopy procedure is scheduled at: _____

Address: _____

Day _____ Date _____ Time _____

Day Before Procedure

Day:	Eat normally for breakfast followed by a light lunch. Then begin clear liquid diet for the remainder of the day/night before the procedure. (Nothing colored red to drink).
Day: Time: 7:00 pm	Mix seven (7) capfuls (119 grams) of Polyethylene glycol (MiraLAX®, ClearLax, PureLax, GaviLax, LavaClear brands) with 32 oz. of water or non-red electrolyte replacement drink and drink all contents.
Day: Time: 9:30 pm	At 9:30 pm, take 0.6 ml of Mylicon® drops mixed well with 8 oz of water. This will reduce bubbles in the GI tract. Nothing to drink after 10pm. Small sips of water with medications allowed.

Day of Procedure

Day: Time: Morning	Hold medications until 2 hours after swallowing capsule unless your doctor deems it necessary, then take small sips of water with medications.
Day: Time:	Two (2) hours prior to scheduled capsule swallowing time, mix 1 capful (17 grams) of Polyethylene glycol (MiraLax, ClearLax etc.) with full glass of water or non-red electrolyte replacement drink. The Polyethylene glycol bottle top is a measuring cap marked to contain 17 grams of powder when filled to the indicated line.
Day: Time:	Arrive at Office/Clinic.
Time:	Swallow CapsoCam Plus capsule with 0.6 ml of Mylicon drops in 8 oz of water.
Time:	Resume clear liquids 2 hours after swallowing the capsule.
Time:	Four (4) hours after swallowing capsule, mix 17 grams of Polyethylene glycol (MiraLax, ClearLax etc.) with full glass of water or non-red electrolyte replacement drink, drink all of the contents.
Time:	You can enjoy a light lunch any time after drinking the last dose of Polyethylene glycol (MiraLax, ClearLax, etc.). Please document what you have for lunch. _____ Eat normally for dinner. No further diet restrictions are necessary.

Important Patient Information

- For best results, strictly follow the instructions. The capsule will typically take 3-30 hours to pass. If you haven't passed the capsule at 72 hours after capsule ingestion, contact your physician.

- To watch the retrieval video instructions, visit

<https://capsovision.com/patient-resources/what-to-expect-with-capsocam/>



- To avoid a repeat of this study, please adhere to your retrieval instructions until capsule is retrieved. Continue to use the Retrieval Pan provided until the capsule is retrieved.
- Return the capsule back to your physician as instructed.

Returning the Capsule: 1 of 2 options chosen by your Healthcare Provider

- ☐ If provided a pre-labeled padded envelope in your take-home kit, place the capsule inside the capsule container. Ensure the lid of the capsule container is closed, put the capsule container into the zip bag and seal it. Place the zip bag with the capsule container inside in the envelope, seal and drop the envelope off at any FedEx drop box or physical FedEx location.
- ☐ Place the capsule inside the capsule container. Ensure the lid of the capsule container is closed. Return the capsule to the physician's office during normal working hours.

Please call our office at: _____ if you have any questions.

Purchasing the Prep Medication

Note: Prep Medication comes in a variety of sizes: When purchasing your preparation medication, ensure you get enough for the whole prep.

Polyethylene glycol (MiraLAX®, ClearLax, PureLax, GaviLax, LavaClear brands). Purchase a container(s) which has at least 153 grams (you will likely have some left over).

Mylicon Drops - Smallest bottle possible... all you will need is 1.2 ml total.

M2A® Capsule-Informed Consent Form
Procedure at Novi Office.

Explanation of the Procedure:

Your physician has recommended the M2A® Capsule Endoscopy for assessment of your gastrointestinal tract, specifically looking for problems associated with the small bowel. Your physician has advised you of your need for this examination. The following information is presented to help you understand the reasons for, and the possible risks of, this procedure.

You will be scheduled to arrive at the Novi office in the early morning. We will take brief history and will attach some sensors to your abdomen. These sensors are attached to a portable recorder that you will wear in a belt around your waist. You will then swallow the M2A® Capsule and you will be able to leave the Office and go about your daily activities during the examination. You will be asked to return to the office approximately eight (8) hours after you ingest the capsule. The doctor wants you to call the office immediately should you develop nausea, vomiting or abdominal pain after ingesting the capsule. Overall, risks for the procedure are low, but please review the following:

Risks and Possible Complications Involved with the M2A® Capsule Endoscopy:

1.

Capsule Endoscopy MAY NOT be recommended if you have, or have had, any of the following: Abdominal Surgery, Crohn's Disease, and Radiation Therapy to the abdomen, difficulty swallowing, a previous intestinal obstruction or Diabetes. Your physician will discuss the risks associated with the above factors and will advise you accordingly.
2.

Capsule Endoscopy is NOT recommended if you have a pacemaker, or are pregnant. Capsule Endoscopy is not currently recommended for children.
3.

The risks associated with the capsule are that the capsule may become lodged in the gastrointestinal tract creating a blockage, which may require surgical removal. The capsule could also find a fistula or small defect in the bowel and become lodged or perforate the intestine, also requiring surgical removal and/or resection of that area of the bowel.
4.

I am aware that I should avoid MRI machines during the procedure and until the capsule passes following the exam.
5.

I understand that due to variations in a patient motility, the capsule may only image part of the small intestine. It is also possible that due to interference, some images may be lost and this may result in the need to repeat the capsule procedure.

I certify that I understand the information regarding M2A® Capsule Endoscopy. I have been fully informed of the risks and possible complications thereof. I consent to swallowing the M2A capsule to create a visual record of my gastrointestinal tract for professional purposes.

I hereby authorize and permit my doctor and whomever he may designate as his assistant(s) to perform a M2A® Capsule Endoscopy upon me. If a situation arises which is not an emergency, I understand that every attempt will be made to inform me of any additional treatment or procedures required and their subsequent risks. I am aware that the practice of medicine and surgery is not an exact science and I acknowledge that no guarantees have been made to me concerning the results of this procedure.

Patient Signature (or Legal Representative)

Date

Witness Signature

Date

8/19/2014

A. Notifier:

B. Patient Name:

C. Identification Number:

Advance Beneficiary Notice of Noncoverage (ABN)

NOTE: If Medicare doesn't pay for D. _____ below, you may have to pay.

Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the D. _____ below.

D.	E. Reason Medicare May Not Pay:	F. Estimated Cost
M2A Video Capsule Endoscopy Procedure Code # 91110	Policy Coverage states: Obscure GI bleed & Angiodysplasia Suspected & Know Crohns Disease Small Bowel Neoplasm Malabsorption Syndrome Colitis *Prerequisites are Colonoscopy, EGD, also for Dx: Crohns add Small bowel x-ray	\$1400.00 Medicare rate 2014 Fee Schedule \$966.19

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
 - Ask us any questions that you may have after you finish reading.
 - Choose an option below about whether to receive the D. _____ listed above.
- Note:** If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

G. OPTIONS: Check only one box. We cannot choose a box for you.

☐ **OPTION 1.** I want the D. _____ listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but **I can appeal to Medicare** by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.

☐ **OPTION 2.** I want the D. _____ listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. **I cannot appeal if Medicare is not billed.**

☐ **OPTION 3.** I don't want the D. _____ listed above. I understand with this choice I am **not** responsible for payment, and **I cannot appeal to see if Medicare would pay.**

H. Additional Information:

This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call **1-800-MEDICARE** (1-800-633-4227/TTY: 1-877-486-2048). Signing below means that you have received and understand this notice. You also receive a copy.

I. Signature:

J. Date:

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