

PILLCAM™ COLON 2 SYSTEM

Patient procedure checklist

The PillCam™ COLON 2 system is a minimally technology that provides a clear view of your colon. The system includes a capsule with two miniature cameras that capture images as it travels through your gastrointestinal tract. The images are transmitted to a recorder you wear, so there is no need to retrieve the capsule. Use the following guidelines to prepare for the days leading up to your procedure.

One day prior to the procedure

1 The day prior to your exam you should only consume clear liquids. To maintain hydration and help clean your colon, approximately 8 glasses (8 oz each) of clear liquids throughout the day should be consumed. Acceptable clear liquids include:

- Apple and white grape juice
- Clear carbonated or sports drinks
- Tea or black coffee
- Popsicles or flavored gelatin
- Water
- Bubblegum or hard candy (hard candy should be dissolved slowly)

NOTE: NO RED OR PURPLE COLORS. NO BROTH OR SOUP.

TIP: You will want to have enough of the approved clear liquids available to also consume during the procedure.

2 PEG (Poly-ethylene glycol 3350 plus electrolytes) is a laxative plus electrolytes solution used to cleanse the bowel.¹ At **NOON**, reconstitute the PEG powder by pouring water into the container to the fill line, replacing the lid, and gently shaking. Once mixed, the 4 L of solution should be refrigerated until it is time to consume.

3 Between **7 p.m.–9 p.m.**, drink **half** of the PEG solution. After 9 p.m., continue your clear liquid diet. **Consult your physician prior to taking medication within an hour of consuming the PEG solution.**

TIP: You may find it helpful to use a straw to drink the solution. As needed, you may also take small sips of other clear liquids between glasses of the PEG solution. Another option is to use lemon wedges, lemon drops, or other approved hard candy between doses of PEG.

Day of the procedure

1 The morning of your exam, take required medication as instructed by your physician.

2 Finish the remaining PEG solution within two hours. **Do not drink anything else after completing your PEG solution** until you are instructed to do so by the clinic staff.

3 **You cannot have anything by mouth one hour prior to taking the PillCam™ COLON 2 capsule.**

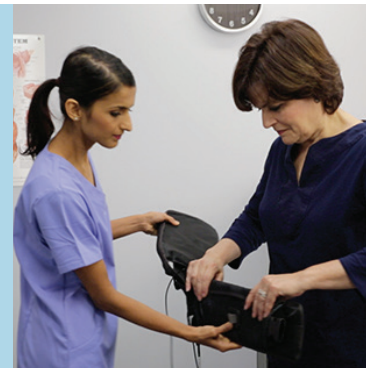
4 Upon arrival at your physician's office and one hour after you have finished ingesting the PEG solution, you will be ready to ingest the PillCam™ COLON 2 capsule.

5 If the sensor array is being used, it will be attached to your abdomen with adhesive pads. If the sensor belt is being used, it will be connected over your clothing and around your waist.

6 The sensor array or sensor belt will be connected to a data recorder that fits in a pouch with a strap. Once the PillCam™ COLON 2 capsule is ready, you will then swallow the capsule with water.

7 **Do not take anything else by mouth until your first instruction from the data recorder.**

8 You can resume most of your normal activities, as instructed by your physician, for the remaining steps of the exam. The data recorder will provide you with alerts and prompts as the procedure progresses.



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Alerts and instructions as prescribed by your physician

Alert 0

If you receive this alert, you should take one Reglan® 10 mg tablet by mouth with a sip of water. Reglan® is a medicine that helps the stomach to empty.² **Do not have anything else by mouth until your next alert and remain active.**

Alert 1

When you receive this alert it is time to take SUPREP® liquid. SUPREP® liquid is a laxative that will cause bowel movements and is used as a boost to propel the capsule through the colon. SUPREP® liquid must be mixed with water before ingesting.

To mix: Remove one bottle of SUPREP® liquid from the kit. Using the cup provided in the kit, pour one 6 oz bottle of SUPREP® liquid solution into the cup and add 10 oz of water (16 oz fill line). Stir and drink all of the solution.

Once finished, **drink an additional 34 oz of water. You can continue a clear liquid diet.**

You may remain active, doing most of your daily activities, without laying down or sleeping until the end of the procedure. You will wait for your next alert, which may be "End of Procedure" or "Alert 2".

Alert 2

Three hours later if you receive this alert, you will need to take a lower dose of SUPREP® liquid.

To mix: Remove the second bottle of SUPREP® liquid from kit. Using the cup provided in the kit, pour ½ of the 6 oz bottle (3 oz) of SUPREP® liquid solution into the cup and add 5 oz of water, making a total of 8 oz of solution. Stir and drink all of the solution.

Once finished, **drink an additional 34 oz of water.**

You should continue your clear liquid diet and remain active. You will wait for your next alert, which may be "End of Procedure" or "Alert 3".

Alert 3

Two hours later if you receive this alert, you will need to insert a 10 mg bisacodyl suppository, which is a laxative that causes bowel movements,⁴ into your rectum and let it dissolve.

You should continue your clear liquid diet and continue to be active. You will wait for your next alert, which may be "End of Procedure" or "Alert 4".

Alert 4

Two hours later if you receive this alert, you will need to eat a standard light meal. Once you have eaten your meal, continue drinking plenty of fluids, remain active, and wait for the "End of Procedure" alert.

Alert

End of procedure alert icon  When you receive the  alert, this signals the end of your procedure. This alert can occur anytime after you have received Alert 1.

Once you receive this alert you may: Remove the equipment and return it to the office as instructed by the physicians' staff. Your physician will review the image results and determine the best next steps for your care.

Consult your doctor for more information on capsule endoscopy with the PillCam™ COLON 2 system.

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. Rx only.

Risk information: Potential adverse events associated with the use of this device may include delayed or no excretion of the capsule, aspiration, obstruction, perforation, and mucosal injury or bleeding. In some instances, intervention is required to remove the capsule. The risks associated with colon preparation are allergies or other known contraindications to any preparation agents or medications used for the PillCam™ COLON 2 system regimen, according to laxative medication labeling and per physician discretion. Medical, endoscopic, or surgical intervention may be necessary to address any of these complications, should they occur. After ingesting the PillCam™ COLON 2 capsule, and until the capsule is excreted, patients should not be near any source of powerful electromagnetic fields, such as one created near an MRI device. Please refer to the product user manual or medtronic.com/gi for detailed information.

References: 1. http://www.nulytely.com/Collateral/Documents/GoNuLytely/NuLYTELY_181.pdf. Obtained 4.21.2016. 2. <http://www.webmd.com/drugs/2/drug-6177/reglan-oral/details>. Obtained 4.30.2014. 3. <http://www.suprekit.com/about-suprep.htm>. Obtained 4.21.2016. 4. <http://www.drugs.com/cdi/bisacodyl-suppositories.html>. Obtained 4.21.2016.