

M2A™ Capsule (CAP2A)

Package Insert

ID#=O8PGIVENIMAGING

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

⚠ **Caution:** US Federal Law restricts this device to sale by or on the order of a physician.

⚠ **Read this package insert in its entirety before using the M2A™ Capsule**

Note: Changes or modifications not expressly approved by Given could void authority to operate the Given® Imaging Diagnostic System.

Introduction

The M2A™ Capsule is an ingestible imaging capsule, which acquires video images while traveling along the patient's gastrointestinal tract, propelled by natural peristalsis until it is excreted.

The M2A™ Capsule contains a miniscule color video camera with a flash, batteries, a transmitter and an antenna to transmit the acquired images. All of these are encapsulated in a 26mm long and 11mm wide ingestible capsule made of biocompatible plastic.

Indications

The Given® Diagnostic Imaging System is intended for the detection of pathologies as an adjunctive tool in the diagnosis of small bowel gastrointestinal disorders and diseases.

The Given® Diagnostic Imaging System may be used in hospitals, outpatient clinics and physician offices. After the M2A™ Capsule is ingested the patient is not restricted to a medical environment.

Contraindications

The M2A™ Capsule is contraindicated for use under the following conditions:

- In patients suspected to suffer from intestinal obstruction based on the clinical picture or pre-procedure testing and profile.
- In patients with cardiac pacemakers or other implanted electromedical devices.
- During pregnancy
- With patients who have known or suspected gastrointestinal obstruction or strictures. Prior abdominal surgery is a relative contraindication to the use of the M2A™ Capsule.

Directions for Use

- The physician should give the patient “Patient Instructions for Undergoing Capsule Endoscopy”, printable from the RAPID™ Application and he/she should verify that the patient understands the instructions.
- The physician should instruct the patient to fast for 8 hours before the test and for males to shave their abdomen 6 inches above and below the navel on the day of the test.
- When the patient comes to the clinic on the day of the test, the physician should proceed according to instructions in the User Manual.
- The physician should have the Sensor Array applied to the patient’s abdomen and connected to the recorder in the Recorder Belt worn around his/her waist.
- The physician should take the M2A™ Capsule out of its blister and test it according to instructions in the User Manual.
- If the tests are passed, the physician should instruct the patient to ingest the M2A™ Capsule with a sip of water.
- If for any reason, after activating the M2A™ Capsule by removing it from its blister, the patient is not taking the M2A™ Capsule, it should be deactivated by replacing it, in its holder, to the blister. The capsule should stop blinking. If it does not stop on the first attempt, turn the capsule in its holder and replace in blister until blinking stops.
- **Under normal conditions, the time elapsed between activating the capsule and ingesting it should not exceed 1 minutes.**
- Before the patient leaves the clinic, the physician should verify that the patient has a copy of “Patient Instructions for Undergoing Capsule Endoscopy” printable from the RAPID™ Application and he/she should verify that the patient understands the instructions.

Warnings

- The M2A™ Capsule should be used only after consulting a physician.
- A thorough understanding of the technical principles, clinical applications and risks associated with the M2A™ Capsule is necessary before using this product.
- The patient should thoroughly understand how he/she is required to behave during Capsule Endoscopy.
- In patients with strictures of the GI tract, the M2A™ Capsule can potentially cause intestinal obstruction resulting in the need for hospitalization and surgery. The use of the M2A™ Capsule in patients with strictures of the GI tract is contraindicated.
- If there is reasonable doubt concerning the integrity of the M2A™ Capsule, it should not be used until consulting with an authorized Given® representative and should be deactivated by returning it in its holder into its blister.
- The M2A™ Capsule should not be used after its expiration date.
- The M2A™ Capsule is not to be ingested before it has been ascertained by a physician that there is no other M2A™ Capsule or other swallowable diagnostic device within the patient.
- The patient should be instructed to avoid biting the M2A™ Capsule prior to swallowing.

- After ingesting the M2A™ Capsule and until it is excreted, the patient should not be near any source of powerful electromagnetic fields such as one created near an MRI device.
- If after ingesting the M2A™ Capsule the patient has any abdominal pain, nausea or vomiting, he/she should contact the physician immediately.
- This M2A™ Capsule must be stored, in a safe place out of the reach of children and/or infants.
- If contrary to instructions a patient ingested two capsules, he/she should be instructed to contact the physician immediately.
- If a child has accidentally swallowed an unused or spent M2A™ Capsule, he should be brought immediately to a hospital.
- The M2A™ Capsule should be ingested only in the presence of authorized personnel. The patient should be instructed not to let his/her relatives, neighbors or acquaintances use the M2A™ Capsule.
- This device has not been tested in pediatric population (children 18 and below) and safety in young children is unknown.

How will the M2A™ Capsule affect the daily routine of the patient?

The patient will have to prepare for Capsule Endoscopy in the following manner:

- The patient will have to abstain from eating or drinking for 8 hours before undergoing this test.
- The patient may take medication up till two hours before and resume once again two hours after M2A ingestion, with a sip of water.
- The patient will have to shave his abdomen 6 inches above and below the navel on the day of the test (for males).
- At the physician's office, a Sensor Array will be put on the patient's abdomen and will be connected to a recorder worn on a belt around his/her waist for the duration of the test. The patient will then be instructed to ingest the M2A™ Capsule.
- After ingesting the capsule, the patient will have to abstain from eating or drinking for another 2 hours. After 2 hours the patient may drink water. Four hours after ingesting the capsule the patient may have a light snack. After completion of the study the patient may return to normal diet.
- The test will last 8 hours. During the test the patient will have to avoid any physical activity that involves sweating. The patient will have to abstain from bending or stooping during the test. The patient must be instructed to never remove the belt during the test.
- At the end of 8 hours, the Sensor Array and Recorder Belt can be removed and returned as instructed to the physician.
- The M2A™ Capsule is disposable and it will be excreted naturally in the patient's bowel movements.

Drug Interactions

- The patients may take their usual prescribed medication up till two hours before and resume once again two hours after M2A™ Capsule ingestion, with a sip of water.

- If the patient is on any medication that may delay gastric emptying (e.g., calcium channel blocking agents), it is recommended that the taking of this medication be delayed till after the capsule endoscopy is complete. This, however, should be discussed with the patient's treating physician.

Adverse Events

- In patients with strictures of the gastrointestinal tract, the M2A™ Capsule can potentially cause intestinal obstruction resulting in the need for hospitalization and surgery. The use of the M2A™ Capsule in patients with strictures of the gastrointestinal tract is contraindicated.
- Based on the experience gained so far, there is no adverse event related to the proper use of the M2A™ Capsule.

Storage

- The M2A™ Capsules should be stored in a dry place away from magnetic sources.
- To prevent capsule activation, keep the M2A™ Capsules in the blister box until use.
- Even if stored in their original containers and according to recommendations, the M2A™ Capsules can be kept for a limited period only. Please note the expiration date of the capsules.

Labeling

⚠ Read instructions before use

② Single Use



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