



# OVERVIEW OF CAPSULE ENDOSCOPY- “PILL CAMERA”

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**Abstract:** Capsule endoscopy (CE) - “Pill Camera” is a new diagnostic tool available for evaluation of small intestine where this area was not previously accessible by using traditional endoscopic methods. Its processes were a multivitamin sized pill was swallowed with small amount of water that travels via intestinal tract to colon to transmit images. It contains a camera on both sides along with radio transmitter and battery. Length of the capsule is 31mm. It is a non-invasive diagnostic technique which is quick and easy. It is useful to detect polyps, inflammatory bowel diseases (Chron’s disease), celiac diseases, ulcers, tumors. CE is initially used in small bowel later on it is used for colon, stomach and esophagus. 21CFR Part 806.1300 Regulations of Capsule endoscopy (CE) deals with “Ingestible Telemetric Gastrointestinal capsule imaging system”. This article provides an overview of capsule endoscopy with its regulations, types, components, working procedure and applications in medical field.

**IndexTerms** – Pill camera, Capsule Endoscopy(CE), Regulations, Small bowel, Esophagus

## I. INTRODUCTION<sup>1, 2, 3, 4</sup>

Technology is expanding day-by-day in Universe. As there is a great progress in manufacturing of products, humans are thinking in innovative way. At present, technology has developed to manufacture products at “Molecular Level” known as **NANO TECHNOLOGY**. Nanotechnology means manipulation of miniscule matter of useful materials, devices and systems. Objects are measured in Nanometers. These products were made available at lower cost than before. This advancement of technology has effective use and application in medical field. One of the most effective and useful application for Advanced technology is Endoscopy process that is used to diagnose the problems associated with gastrointestinal tract.

It is a medical process used to record images of the gastrointestinal tract that helps to detect disease. It is a swallowable Pill Camera that captures images when peristalsis takes place through the gastrointestinal tract. It captures two images per second and approx. 2,600 HD images. After upper and lower gastrointestinal flexible endoscopy have failed to produce, a diagnosis, capsule endoscopy is used. Capsule endoscopy (CE) is currently employed as a first-line treatment for diseases of the small bowel in this Advanced Technology era. Inflammatory bowel diseases like Crohn’s disease, gastrointestinal cancers, ulcers, digestive diseases, unexplained bleedings, small bowel tumors, portal hypersensitivity enteropathy, celiac disease, and other disorders were detected via capsule endoscopy. Capsule after ingestion it usually excretes through patient’s feces within 24-48hrs. Colon capsule endoscopy is a colorectal cancer screening method that offers alternative to standard colonoscopy.

Major complication observed through CE is “Capsule retention” which means presence of capsule for more than two weeks in digestive tract, wherever if necessary surgery is done. Common reasons for the retention of capsule are CD, Obstructive tumor and diaphragm diseases. People with Obstruction Gastrointestinal Bleeding were at low risk where people with obstruction symptoms are at high risk.

## II. HISTORY<sup>4, 5, 6, 7</sup>

In the early 1980s, Gavriel Iddan Israeli engineer and Israeli Doctor Eitan Scapa developed Capsule endoscopy in Boston, Massachusetts. Using a fiber-optic cable, two partners initially built a Charged Couple Device (CCD) Camera-based imaging system. This first design had excessive power consumption and image data transfer duration of 10 minutes. In 1993, Iddan came up with an idea of separation of the system into three parts: transmitter, the camera and recorder connected to a sensory array on the patient’s abdomen, as well as the software that allows a physician to analyze the data at leisure. This new design was made possible by replacing the CCD camera with a CMOS (complementary metal-oxide semiconductor) camera. This camera use only 1% of the energy used by its CCD equivalents. This three-part imaging system is still in use today. This technology was initially developed by Gavriel Iddan and Paul swain by swallowing first pill in 1997.

The FDA approved the first capsule endoscope for patient use in 2001. As capsule endoscopy research has developed, improved wireless and energy-efficient technologies have enabled the development of increasingly image processing systems and compact capsules with many more in development.

### III. Types of Capsule endoscopy <sup>8, 9, 10</sup>

Till now, various imaging platform of Capsule Endoscopy includes:

1. Pill cam SB2/SB3-Small intestine
2. Pill cam ESO2- Esophageal imaging
3. Pill cam Colon 2- Large bowel
4. Agile Patency capsule-Second generation

In additional Small bowel capsule systems are:

- Chinese OMOM pill (Jin shan Science and technology Chongquin, China)
- Olympus Endoscopy(Olympus Japan)
- American Capso Cam SV-1
- Korean Miro pill

➤ Currently FDA approved along with CE certification are only Small bowel (SB) system and Olympus Endocapsules.

### IV. REGULATIONS <sup>11</sup>

#### 21 CFR PART- SECTION 876.1300

#### INGESTIBLE TELEMETRIC GASTROINTESTINAL CAPSULE IMAGING SYSTEM - Contains.

- **Identification:** The small bowel mucosa is visualized using an ingestible telemetric gastrointestinal capsule imaging device as an additional tool to detect small bowel diseases. Capsule itself equipped with a wireless camera that takes images of small bowel. It contains a recording/receiving unit, an antenna array, a data storage device, and computer software that process the images and accessories.

I. **Classification:** Class II (special controls). The special control is the FDA's recommendation.

### V. PILL SIZED CAMERA <sup>2, 4, 6</sup>

Just imagine for the detection of problem a vitamin sized pill embedded with camera travel with ease through your body and taking pictures for physical examination by doctor. Previously they used to identify the problem only through surgery. CE helps physician to diagnose the small intestine i.e., the lining of GI tract. Pill sized capsule given to swallow with small amount of water that contains a light source and takes pictures. It contains a camera on both sides along with radio transmitter and battery. Length of the capsule is 31mm. It produces two frames per second with approximately 56000 high-quality images. These images are sent to a recording device that helps to detect various diseases like ulcers, polyps, tumors, Inflammatory bowel disease (Crohn's disease). To diagnose various diseases pill camera which is swallowed produces data like Imaging, pH, Pressure and also temperature.

### VI. COMPONENTS OF PILL CAMERA <sup>3, 6</sup>

Images that are obtained by Capsule Endoscopy (CE) are useful for further examination, so they must be received and recorded. The study takes place for approximately 7-8 hrs. A patient undergoing CE should bear an antenna array that is worn over the abdomen that contains leads that are connected to the recording unit. Antenna array along with battery pack are worn on regular clothing. The recording unit is capable to record thousand of pictures captured by pill cam and they are received by an antenna.

Significantly there are 5 platform components. They are as follows:

1. Pill cam Capsule –Small Bowel or Esophagus.
2. A Sensory Array Belt
3. The Data Recorder
4. The Real Time Viewer.
5. Work Station and Rapid Software

#### 1. PILL CAM CAPSULE

##### Small Bowel (SB)

FDA has given its approval for Small bowel. It has typical lighting controls with one side image and produces two images per second. A total examination of 8 hrs it gives about 50,000 images.

##### Esophagus (ESO)

The Food and Drug Administration has given its approval for Esophagus. It provides 14 photos every second and includes automated light management with two-sided images. The total examination of fewer than 30 minutes for about 20 minutes gives 2,600 images.

#### 2. A SENSOR ARRAY BELT

The Sensor array contains data cable, sensor pads, chargeable battery, and a receiver bag. Numerous cables were placed to the abdomen and connected to a belt-mounted data recorder. The recording device along with battery pack is held by a belt worn around abdomen. Sensors help to evaluate and identify the position of capsule.

### 3. THE DATA RECORDER

A small portable recording device that is fixed to a sensor belt, weighs up to 470gms. Data recorder stores images for doctor's examination. Sensory array helps to receive and record data that is obtained by camera which is worn on patient's body. It receives and stores of about 5000 to 6000 JPEG images on a 9GB hard disk. Don't expose them to shock, sunlight, or Vibration as it results in loss of information. They should be handled very carefully.

### 4. THE REAL TIME VIEWER

It is a handled device containing rapid reader software and a color LCD monitor that analyze for its proper functioning before the procedure and confirms exact location of the capsule.

### 5. WORK STATION AND RAPID SOFTWARE

Its main function is to report and process the images and data. "Rapid application software" is computer equipped software, helps to download the images that is directly obtained through the recorder. This software helps in conversion of images into a movie and view color 3D images for doctors. A specially configured computer workstation is connected to the recording device. The entire process that is examined was downloaded in computer and made accessible in digital video for physician. Work station software allows the viewers to watch it in both forward and reverse mode as well as name individual frames and video snippets. Full color images of normal anatomical and pathological abnormalities were evaluated.

## VII. GENERAL INSTRUCTIONS TO BE FOLLOWED IN PRIOR TO CE PROCEDURE <sup>3</sup>

1. The instructions given by your doctor to be followed strictly without fail. If you are having any queries regarding the process keep in front of your doctor and clear it.
2. You should provide list of all your medications you are using, it should include both prescription and non-prescription drugs.
3. Inform your doctor if you have any allergies.
4. Before the test contact your doctor whether to take daily medications or not.
5. Discuss with your doctor about, if you are having diabetes or have undergone any surgery to stomach, or having any heart related issues.
6. 2 h before test you shouldn't take any medicines.

## VIII. WORKING PROCEDURE<sup>12, 13, 14, 20</sup>

1. Initially, sensors are placed on the stomach with the help of sticky patches that are linked to a recording tool. During the whole test, they are to be worn around your waist.
2. With a tiny amount of water, the capsule is consumed in either a sitting or standing position.
3. Can go for a normal routine. The Recording tool should be near your belly so that it can take images.
4. You may drink liquids after 2 hours of swallowing of capsule & 4 hours after you swallow the capsule you may take light snacks. May have a normal meal after 8 hours of swallowing a capsule.
5. During the test, observe that light will blink on recording tool whenever an image is taken. If you have a bowel movement during the test, be sure the light is still blinking to know that the capsule didn't pass into the toilet. This says that the test is complete.
6. If in any case it stops blinking continuously you can call your doctor.
7. After 12h of the time preferred by your doctor, you can meet and return the sensors and the data recorder.
8. After the test gastroenterologist will download the data and view the color video of the picture. The test result will be given in a couple of days.
9. The camera pill is moving and comes out through a natural bowel movement.
10. If in any case, you didn't see that pill has passed or if your doctor notices that it doesn't reach the large intestine then an X-Ray may be needed after two weeks of the test.

### Note:

- 1 You need not take shower during the test.
- 2 You should stay active & don't do any physical exercises or bend during the test.
- 3 Purgatives or surfactants like propylene glycol given to patients to ease the passage of capsule through bowl.

## IX. RISKS <sup>12, 14, 15</sup> Capsule Endoscopy is considered as a safe method to diagnose bleeding and any other GI disorders directly.

1. There may be chance of getting capsule struck in digestive tract.
2. If the capsule passes through stricture there may be risk of bleeding if there is any inflammation or tissue damage.
3. In rare cases bowel obstructions may take place, procedure known as Double-balloon enteroscopy used that gently compel the capsule past the site of obstruction.

## X. CONTRAINDICATIONS <sup>16</sup>

1. Contraindicated in people with bowel obstruction.
2. People with dysphasia.
3. Pregnant women
4. Person with pacemaker or implanted with any other cardiac devices.

**XII. ADVANTAGES**<sup>3, 6, 7</sup>

Capsule endoscopy has various advantages over traditional endoscopic methods. The small intestine, which might be difficult to access during an upper endoscopy or colonoscopy, can be examined using this treatment.

- There are no side effects to worry about.
- Miniature proportions.
- Images of excellent quality
- Contains non-harmful material.
- Procedure is straightforward
- Having high specificity and sensitivity.
- Reduces the danger of sedation
- There was little preparation and anaesthesia is not required.

**XIII. DISADVANTAGES**<sup>3, 6, 13, 17</sup>

The current design prevents the free flow of capsules due to gastrointestinal blockage. Pacemaker patients and pregnant women confront challenges. Here are some of the drawbacks:

- Expensive and non-recyclable.
- Standard diagnostic endoscopy is not replaced by CE.
- It doesn't replace any other gastrointestinal imaging treatment, which is usually done after a regular endoscopy and colonoscopy.
- If the camera becomes stuck for any reason, it will have to be removed surgically.
- It cannot be halted or manipulated after its ingestion and it cannot be guided in order to acquire detailed information.
- It is not utilized to go for biopsy administer treatment, or to identify surgically correctable abnormalities.

**XIV. APPLICATIONS**<sup>18, 19, 20</sup>

Basically Pill Camera is mainly used in Medical field to examine and diagnose disease internally. Your doctor may ask you to go for Capsule Endoscopy when

1. To diagnose cause of unexpected bleeding in small intestine as known as gastrointestinal bleeding.
2. To detect inflammatory bowel diseases like Crohn's disease (CD).
3. To identify tumours in small intestine or in any other part of digestive tract.
4. To diagnose various celiac diseases.
5. To examine your esophagus where it is approved to evaluate the muscular tube which connects mouth and stomach to check for any abnormalities.
6. People suffering with inherited syndrome that lead to form polyps in small intestine.
7. If the results were unclear from X-rays or any other imaging system to get clear identification about particular disease need to go for CE.

**CONCLUSION**

Capsule endoscopy has quickly evolved into a valuable tool for examining the mucosa of intestine. It is extremely efficient and provides a great amount of data in short term of time. In today's world, nanotechnology is gaining increasing popularity, and the pill camera is one of the examples of technological accomplishment. The reason for usage of capsule endoscopy will steadily grow as the technology advances, and diagnostic yield will improve. From various studies have found that capsule endoscopy is more advanced approach that is best appropriate for diagnosing the small intestine, colon, and jejunum. As technology is progressively increasing, capsule endoscopy may become the standard type of endoscopy for many GI illness in future.

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