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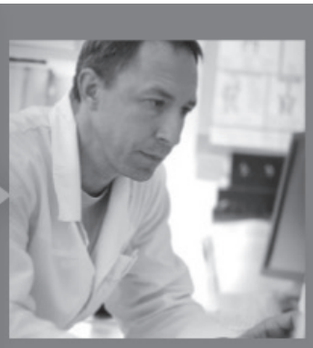
Capso CAM PLUS



INSTRUCTIONS FOR USE

CapsoCam Plus®

(2795)

CE 0197

English

Indications for Use

The CapsoCam Plus SV-3 video capsule system is intended for visualization of the small bowel mucosa in adults. It may be used as a tool in the detection of abnormalities of the small bowel.

Device Description

CapsoCam Plus is a single-use, ingestible video capsule that acquires and stores endoscopy examination images in on-board memory while moving through the gastrointestinal tract, propelled by natural peristalsis. The patient retrieves the capsule using the provided retrieval kit and returns it to the physician (or mails the capsules to the download center in a pre-paid envelope) where the capsule is processed and data is downloaded. The images can be reviewed on a computer or tablet. The capsule is typically excreted within 3 to 30 hours after being swallowed.

CapsoCam Plus Accessories

- CapsoRetrieve Retrieval Kit: intended to collect the excreted CapsoCam Plus capsule.
- CapsoView software: intended for the download of images from CapsoCam Plus capsules, generation of video files, review of videos, annotation of images, and generation of reports.
- CapsoAccess Capsule Data Access System: intended for accessing data from the CapsoCam Plus capsule.
- CapsoCloud cloud-based software: intended to manage patient's CapsoCam Plus exam images and to review and analyze images.

Ratings

IP68
Type BF applied part
3.1V DC battery-powered
10mA
Class II

Device Common Name

System, Imaging, Gastrointestinal, Wireless, Capsule

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Operating Range

Device operates *in vivo*. *Ex vivo* it operates within the following environmental ranges—
Temperature: 41°-104° F (5°-40° C)
Humidity: 5% to 95%
Atmospheric Pressure: 59kPa to 105kPa

Operating Environment

The intended use environments for CapsoCam Plus include home, hospital, transport and ambulatory environments.

Contraindications

The CapsoCam Plus video capsule is contraindicated in patients:

- Who have known or suspected gastrointestinal obstructions, strictures or fistula
- Who are pregnant
- Who have gastroparesis
- Who have a swallowing disorder

Patient Condition

The physician should consider performing a small bowel series before utilizing this device in patients who are suspected to have strictures or fistulas. See Risks on Page 4 for additional risks related to specific patient conditions.

Adverse Events

Potential adverse events associated with the use of this device may include:

- Obstruction, perforation, and mucosal injury or bleeding
- Aspiration of the capsule
- Delayed or no excretion of the capsule
- In some instances, intervention is required to remove the capsule

Cautions

- Ensure that only personnel, who are trained on the CapsoCam Plus Capsule Endoscope System operating procedures use the system.

- In a small number of cases, the CapsoCam Plus capsules may not image the entire small bowel due to variations in GI motility or anatomy.
- The final diagnosis should only be made by physicians who are trained in the interpretation of capsule endoscopy images.

Benefits

- The CapsoCam Plus Capsule is a tool for visualization of the GI tract, specifically the small bowel.
- The diagnostic data is stored onboard the capsule, allowing patients to undergo the procedure without the need to wear external receiver equipment.
- CapsoCam Plus offers a simple, safe and less-invasive alternative to traditional imaging procedures. The procedure does not require sedation or radiation.

Risks

- All medical procedures carry some risks. Information in this manual should not be used as a substitute for discussions with healthcare providers about diagnosis and treatment.
- CapsoCam Plus capsule endoscopy is not for every patient. CapsoCam Plus is contraindicated in patients with known or suspected gastrointestinal obstruction, strictures or fistulas, patients who are pregnant, patients with gastroparesis and patients with swallowing disorders.
- Capsule retention, defined as having a capsule remain in the digestive tract for more than 72 hours, has been reported in less than 2% of all capsule endoscopy procedures.
- Causes of capsule retention cited in the literature include: NSAID strictures, Crohn's disease, small bowel tumors, intestinal adhesions, ulcerations, and radiation enteritis.
- Summaries in published literature identify the risk of capsule retention to be approximately 1.5% for

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obscure bleeding, 1.4% for suspected Crohn's disease, 5% for known Crohn's, and 2.1% for neoplastic lesions. [1], [2].

[1] Cave et al. Endoscopy 2005; 37: 1065-1067.
[2] Zhuan et al. GI Endoscopy 2010; 71: 280-286.

Bowel Preparation

Physicians will prescribe the bowel preparation for their patients.

Preparation for Use

- Inspect the foil seal. Do not use if any breakage in the foil seal or in the foil itself is observed.
- Prepare a glass or bottle of water. The recommended amount of water is 0.5 liter (~16 fluid ounces).

Directions for Use

1. Open the capsule package by peeling back the foil cover.
2. Using gloves, remove the plastic lid covering the capsule.
3. Grasp the capsule carefully and then pull it out and away from the package. **Take care to not drop the capsule on the floor.**
4. Within approximately ten seconds of being removed from the magnet, the capsule LEDs will begin blinking, indicating that the capsule has been activated.

   If the capsule has not activated within 20 seconds after removing it from the package, place the battery-end of the capsule against the magnet in the package and repeat step 4 again. If the capsule still fails to activate, the capsule is malfunctioning and should be replaced.

   Once you have confirmed that the capsule is flashing, the capsule is ready to be swallowed.
5. The capsule should be placed inside the patient's mouth and swallowed with the entire glass of water. The patient should avoid biting the capsule. The capsule should be swallowed within 10 minutes of removing it from the package. If the patient is unable to swallow the capsule within

this period, return the capsule to the package with the battery-end of the capsule touching the magnet inside the package, which will deactivate the capsule.

6. The patient may engage in normal daily activities while the capsule moves through the digestive tract. The patient should consult the physician if they have questions about engaging in a particular activity.
7. The capsule is typically excreted between 3 and 30 hours after swallowing. Retrieve the capsule by following the Capsule Retrieval Kit Instructions for Use.

Warnings

Laser Radiation— Class 1M Laser
Do not view directly with optical instruments

- The capsule shall be ingested under the supervision of authorized medical personnel.
- Patients should not have an MRI exam performed until the capsule has been excreted. Possible patient injury and medical complications could occur.
- Patient should avoid biting the CapsoCam Plus capsule prior to swallowing.
- If the capsule is damaged in any way, including by forceful biting, the patient should not swallow the capsule.
- If the capsule is not excreted after 72 hours, the physician should be contacted.
- Store CapsoCam Plus capsules and their packages in a safe place, out of the reach of children and infants.
- If a child has accidentally swallowed a CapsoCam Plus capsule, or the embedded package magnets, seek immediate medical attention.
- Keep package, including embedded magnet, at least 2 inches (5cm) away from pacemakers and other active-implant medical devices.
- Do not modify the capsule without authorization from the manufacturer.

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- Patients should not board an aircraft until the capsule has been excreted.
- CapsoCam Plus needs special precautions regarding EMC and needs to be utilized according to the EMC information provided in this manual.
- Portable and mobile RF communications equipment can affect CapsoCam Plus.
- The use of accessories, transducers and cables other than those specified by CapsoVision, Inc. may result in increased EMISSIONS or decreased IMMUNITY of the CapsoCam Plus.
- CapsoCam Plus should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, CapsoCam Plus should be observed to verify normal operation in the configuration in which it will be used.
- A negative or normal result obtained by the CapsoCam Plus capsule does not exclude the presence of pathology and if symptoms persist, further evaluation should be performed.
- If intestinal fistulas, strictures, or stenoses are suspected, or the patient has had prior abdominal or pelvic surgery, the physician should consider performing a procedure to ascertain patency for an object the size of the CapsoCam Plus capsule.
- After ingesting the CapsoCam Plus 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.
- Patients must contact the physician immediately if, after ingesting CapsoCam Plus capsules, they experience any abdominal pain, nausea, or vomiting.
- The CapsoCam Plus capsule should not be administered to patients below eighteen (18) years of age.
- Thorough understanding of the technical principles, clinical applications and risks associated with the CapsoCam Plus Capsule Endoscopy System is necessary before using this

product. Read the entire manual before using the system for the first time.

- To prevent the patient from being exposed to unforeseen risks during passage of the CapsoCam Plus capsule, make sure the patient thoroughly understands the procedure, and provide the patient with a copy of the Patient Instructions.
- In patients with suspected strictures of the GI tract, any CapsoCam Plus capsule can potentially cause intestinal obstruction resulting in the need for hospitalization and surgery.
- Do not use CapsoCam Plus after its expiration date.
- When swallowing the capsule, there is a possibility of choking, or capsule aspiration. If the patient exhibits any clinical signs of capsule aspiration (labored breathing, wheezing, involuntary coughing, etc.) follow appropriate emergency procedures.

Storage

Store the CapsoCam Plus capsule under normal indoor environmental conditions. Do not remove the CapsoCam Plus capsule from the packaging until just prior to use.

Handling of Excreted and Retrieved CapsoCam Plus Capsules

Physician should provide instructions to the patient for returning the capsule to the clinic or office, or provide a prepaid mailing envelope for the retrieved capsule to be mailed directly to a download center where the capsules will be processed.

Cleaning of Excreted CapsoCam Plus Capsule

Returned capsules should be handled with gloves and cleaned and disinfected as follows:

1. Clean the capsule using ENZOL® Enzymatic Cleaner (or equivalent) according to the manufacturer's instructions, thoroughly scrubbing

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the capsule with a soft bristle brush (paying special attention to the dimple at the bottom of the capsule) as necessary to remove all debris.

2. Disinfect the capsule using Revital-Ox™ Resert® High Level Disinfectant (or equivalent) and rinse thoroughly, according to the manufacturer's instructions.
3. Dry capsule completely.

Data Download at Clinic

Prior to downloading data from the used capsule, it must be cleaned, disinfected, and dried. See the CapsoView Instructions for Use for downloading instructions.

Disposal

Dispose of capsule and packaging as per local ordinances.

Warranty

CapsoVision warrants that this capsule is free from defects in both materials and workmanship. Suitability for use of the capsule functionality for any procedure shall be determined by the user. CapsoVision shall not be liable for incidental or consequential damages of any kind. The above warranties are in lieu of all other warranties, either express or implied, including any warranty of any merchantability or fitness for use.

Applicable Standards

ANSI/AAMI 60601-1
IEC 60601-1-2
EN ISO-10993

Accuracy of the Device

A clinical study evaluated the performance of the CapsoVision CapsoCam SV-1 compared with the Given Imaging PillCam® SB2 in 121 subjects (age 18 & 85) at 7 Investigational Sites. Downloaded capsule images from both capsule endoscopes were forwarded to independent readers, who were blinded to the subject clinical information or suspected diagnosis. Each set of images, for both

capsules, were assessed by a group of three (3) independent readers. Readers reported their findings (Normal, Abnormal, and if Abnormal, the most clinically significant Primary Diagnosis) in the appropriate Clinical Report Forms. If any of the three (3) readers in the group disagreed with the Primary Diagnosis, or complete exam (identified as a capsule that reaches the cecum while still recording), the findings were discussed by members of the group until a 2/3 majority or consensus agreement for Primary Diagnosis was reached.

The performance of the CapsoVision CapsoCam SV-1 was evaluated based on the Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) using the 2 of 3 readers. The PPA was estimated to be 69.05% with lower and upper 95% confidence limits of 53.97% and 80.93%, respectively. The NPA was estimated to be 81.94% with lower and upper 95% confidence limits of 71.52% and 89.13%, respectively.

CapsoCam Plus performs in the same manner as CapsoCam SV-1.

Concordance of Overall Impression by Capsule (Per-Protocol Population) - Majority Agreement				
CapsoCam®	PillCam®			
		Abnormal	Normal	Totals
	Abnormal	29	13	42
	Normal	13	59	72
	Totals	42	72	114

Concordance (95% CI)	77.19 (68.68, 83.93)
Positive Agreement (95% CI)	69.05 (53.97, 80.93)
Negative Agreement (95% CI)	81.94 (71.52, 89.13)
McNemar's Test of Agreement p-value	1.0000
Kappa Statistic	0.5099

The Co-Primary endpoint of the study was to compare the percent of CapsoCam® SV-1 completed exams to the PillCam® SB2 in subjects with suspected SB disease. Completed exams were defined as capsules, which reach the cecum while the capsule continues recording images. Battery life was to be referenced by video capture time. The number of completed CapsoCam® SV-1 videos to be compared to the number of completed PillCam® SB2 videos and a percentage calculated. The difference in proportion of completed exams was calculated and a 95% confidence interval for correlated proportions was calculated. Non-inferiority was established if the lower confidence limit did not exceed -15%.

The co-primary endpoint was met with a lower two-sided 95% confidence limit of -0.028%.

Summary and analysis of capsules that reach the cecum (PP Population)				
	PillCam®			
CapsoCam®		"Reach the cecum" n (%)	"Did not reach the cecum" n (%)	Total n (%)
	"Reach the cecum" n (%)	109 (95.6)	3 (2.6)	112 (98.2)
	"Did not reach the cecum" n (%)	1 (0.9)	1 (0.9)	2 (1.8)
	Total n (%)	110 (96.5)	4 (3.5)	114 (100.0)

Difference in Proportions of "Reach the cecum" between CapsoCam® and PillCam®	0.018
95% two-sided confidence interval for the difference	-0.028, 0.069

NOTE 1 If at least one reader observed the capsule reaching the cecum, the exam would be considered completed.
NOTE 2 The Newcombe -Wilson score method 10 was used to compute the 95% CI for correlated proportions. In order for the non-inferiority to be established, the lower limit of the 95% CI for the difference of the proportions between the CapsoCam® and PillCam® will have to be greater than -15%

The Secondary endpoint of the study was assessment of the proportion of primary diagnostic yields (normal, vascular lesions, ulcerative lesions, mass/polyp, blood or other) of CapsoCam® SV-1 and PillCam® SB2 in subjects with suspected SB disease based on the result of 2 out of 3 readers in agreement or the consensus group result. Both positive percent agreement (PPA) and negative percent agreement (NPA) were calculated as supportive measures. The table below demonstrates the concordance rate of normal and abnormal, clinically significant primary diagnoses.

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Concordance of Primary Diagnosis by Capsule (Per-Protocol Population) -Majority Agreement								
	PillCam®							
		Normal	Vascular	Mass/Polyp	Blood	Ulcerative	Other	Totals
CapsoCam®	Normal	57	6	2	2	4	0	71
	Vascular	7	14	1	0	1	1	24
	Mass/Polyp	1	0	0	0	0	0	1
	Blood	0	0	0	1	0	0	1
	Ulcerative	4	1	1	0	9	0	15
	Other	1	0	0	0	0	1	2
	Totals	70	21	4	3	14	2	114

Negative Agreement (95% CI)	[57/70]	81.43%	(70.77, 88.81)
Vascular Positive Agreement (95% CI)	[14/21]	66.67%	(45.37, 82.81)
Mass/Polyp Positive Agreement (95% CI)	[0/4]	0.00%	(0.00, 48.99)
Blood Positive Agreement (95% CI)	[1/3]	33.33%	(6.15, 79.23)
Ulcerative Positive Agreement (95% CI)	[9/14]	64.29%	(38.76, 83.66)
Other Positive Agreement (95% CI)	[1/2]	50.00%	(9.45, 90.55)

NOTE 1 All confidence intervals are exact based on the Wilson Score Method.
NOTE 2 Concordance is based on 2 reader agreement or consensus group result.

Essential Performance

Data integrity during image capture and download, laser Class 1M, and single-use are considered to be the essential performance of the CapsoCam Plus capsule.

Federal Communication Commission (FCC) Compliance

The CAPSOVISION system (CapsoCam Plus) complies with Part 15 of the United States FCC rules and with international standards for electromagnetic compatibility regarding its use.

Caution!

Federal law restricts this device to sale by or on the order of a physician.If you have any questions please contact CapsoVision Customer Care at (408) 624-1488.

(Table 1)

Guidance and manufacturer's declaration – electromagnetic emissions		
The CapsoCam Plus is intended for use in the electromagnetic environment specified below. The customer or the user of the CapsoCam Plus should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The CapsoCam Plus uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The CapsoCam Plus is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.

(Table 2)

Guidance and manufacturer's declaration – electromagnetic immunity			
The CapsoCam Plus is intended for use in the electromagnetic environment specified below. The customer or the user of the CapsoCam Plus should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
(50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment.

(Table 3)

Guidance and manufacturer's declaration – electromagnetic immunity			
The CapsoCam Plus is intended for use in the electromagnetic environment specified below. The customer or the user of the CapsoCam Plus should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test Level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not Applicable	Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 0.18\sqrt{P}$ 80 MHz to 800 MHz $d = 0.35\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range.[b]
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	20 V/m	

(Table 3 continued)

			Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CapsoCam Plus is used exceeds the applicable RF compliance level above, the CapsoCam Plus should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CapsoCam Plus.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

(Table 4)

Recommended separation distances between portable and mobile RF communications equipment and the CapsoCam Plus

The CapsoCam Plus is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CapsoCam Plus can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CapsoCam Plus as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum output power of transmitter	**Separation distance according to frequency of transmitter**	
W	m	
	80 MHz to 800 MHz $d = 0.18\sqrt{P}$	800 MHz to 2.5 GHz $d = 0.35\sqrt{P}$
0.01	0.02	0.04
0.1	0.06	0.11
1	0.18	0.35
10	0.57	1.1
100	1.8	3.5

For transmitters rated at a maximum output power not listed above, the recommended separation distance *(d)* in meters *(m)* can be estimated using the equation applicable to the frequency of the transmitter, where *(P)* is the maximum output power rating of the transmitter in watts *(W)* according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Symbols Glossary			
Symbol	**Meaning**	**Symbol**	**Meaning**
REF	Manufacturer's catalogue number		Do not reuse this product
	Caution: Consult accompanying documents	EC REP	Contact/European representative of manufacturer
CE	Product meets European standards for safety and quality		Use by date (with accompanying date)
	Instructions are included and must be read	SN	Item serial number (with accompanying number)
	Special disposal for electronic waste required		Manufacturer
℞ Only	Prescription use only For sale by or on the order of a physician		Laser Radiation–Class 1M Laser Product Do not view directly with optical instruments
LOT	Item Lot Number (with accompanying number)		Type BF applied part
104˚F (40˚C) 41˚F (5˚C)	Temperature Limitation	MR	MR unsafe
	Date of manufacture	QTY	Quantity
105kPa 59-105kPa	Atmospheric pressure limitation		Do not use if package is damaged
95% 5%	Humidity limitation		

Manufacturer

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Conformity Assessment Body

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