

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MICROGIZZMOS, LLC,

Plaintiff,

v.

GIVEN IMAGING, INC., GIVEN
IMAGING LTD., COVIDIEN, LP, and
MEDTRONIC PLC,

Defendants.

C.A. No. _____

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Microgizzmos, LLC files this complaint for patent infringement against Defendants Given Imaging, Inc. (“GII”), Given Imaging Ltd. (“GIL”), Covidien, LP (“Covidien”), and Medtronic plc (“Medtronic”) (collectively, “Defendants”) and alleges as follows:

PARTIES

1. Microgizzmos, LLC is an Illinois limited liability company with a principal place of business at 5N244 Prairie Lakes Blvd., Saint Charles, Illinois 60175.
2. Upon information and belief, Defendant Given Imaging, Inc. is a corporation organized under the laws of Delaware, with its principal place of business at 3950 Shackleford Road, Suite 500, Duluth, GA 30096-1852. On information and belief, GII (or its agents) makes, sells, offers to sell, and/or imports products in the United States, including in this Judicial District, and introduces infringing products into the stream of commerce knowing that they would be sold and/or used in this Judicial District and elsewhere in the United States. GII may be served with process through its registered agent, Corporation Service Company, 251 Little Falls Dr., Wilmington, Delaware 19808.

3. Upon information and belief, Defendant Given Imaging Ltd. is a corporation organized under the laws of Israel, with its principal place of business at 2 Hacarmel St., New Industrial Park POB 258, Yokne'am, 20692, Israel. On information and belief, GIL (or its agents) makes, sells, offers to sell, and/or imports products in the United States, including in this Judicial District, and introduces infringing products into the stream of commerce knowing that they would be sold and/or used in this Judicial District and elsewhere in the United States.

4. Upon information and belief, Covidien is a limited partnership organized and existing under the laws of Delaware with its principal place of business at 15 Hampshire Street, Mansfield, Massachusetts 02048. On information and belief, Covidien (or its agents) makes, sells, offers to sell, and/or imports products in the United States, including in this Judicial District, and introduces infringing products into the stream of commerce knowing that they would be sold and/or used in this Judicial District and elsewhere in the United States. Covidien may be served with process through its registered agent, Corporation Service Company, 251 Little Falls Dr., Wilmington, Delaware 19808.

5. Upon information and belief, Medtronic is a public limited company organized under the laws of Ireland with its principal executive offices located at 20 On Hatch, Lower Hatch Street, Dublin 2, Ireland, and Operational Headquarters located at 710 Medtronic Parkway, Minneapolis, Minnesota 55432. On information and belief, Medtronic (or its agents) makes, sells, offers to sell, and/or imports products in the United States, including in this Judicial District, and introduces infringing products into the stream of commerce knowing that they would be sold and/or used in this Judicial District and elsewhere in the United States.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States, Title 35 of the United States Code. Accordingly, this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has specific and general personal jurisdiction over Defendants pursuant to due process and/or the Delaware Long Arm Statute, due to Defendants having availed themselves of the rights of benefits of Delaware by incorporating under Delaware law and/or due to their substantial business in this forum, including: (i) at least a portion of the infringement alleged herein; and (ii) regularly doing or soliciting business, engaging in other persistent courses of conduct, and/or deriving substantial revenue from goods and services provided to individuals in Delaware and in this Judicial District. Defendants have more than minimal contacts with this District, and maintenance of this action within this District would not offend traditional notions of fair play and substantial justice.

8. Venue is proper in this District under 28 U.S.C. §§ 1391(b)-(c) and 1400(b) because Defendants are either foreign entities or subject to personal jurisdiction in this District.

9. Joinder of the Defendants in this action is proper pursuant to 35 U.S.C. § 299. As alleged in more detail below, the allegations of infringement against Defendants arise out of the same series of occurrences relating to the making, using, importing into the United States, offering for sale, or selling of the same accused products, and questions of fact common to each Defendant will arise in this action.

INVENTORS AND THE PATENTED INVENTIONS

10. Dr. Tarun Mullick, Mr. Ramgopal Nair, Dr. Sudhir K. Dutta, and Dr. Padmanabhan P. Nair are the inventors of U.S. Patent No. 7,039,453 (the “Asserted Patent”). A true and correct copy of the Asserted Patent is attached hereto as **Exhibit A**.

11. Dr. Tarun Mullick, M.D., is a Board-certified Therapeutic-Interventional Gastroenterologist. He completed medical school at Johns Hopkins University with degrees in medicine and biophysics, followed by an internal medicine residency at Johns Hopkins, a gastrointestinal fellowship at the Cleveland Clinic in 2002, served on the faculty at UVA, and is a successful doctor in private practice. His honors and awards include being the recipient of the President's Plenary Session National Research Awards for the American College of Gastroenterology, receiving two Governors' awards for the American College of Physicians top research award, and the Humanitarian Award for Patient Care for Chicago Hospitals. Dr. Mullick has also served as Editor of Gastroenterology and Endoscopy News for New Research and Clinical Breakthroughs from 2002-2018.

12. Mr. Ramgopal Nair is an engineer by training and works as a successful engineering consultant. He is a named inventor on several patents issued in the United States.

13. Dr. Sudhir K. Dutta, M.D., has been the director of the Division of Gastroenterology at Sinai Hospital since 1991. He is board-certified in internal medicine. He is a professor of medicine at the University of Maryland School of Medicine and the past president of the American College of Nutrition. His honors and awards include two Lawlor awards from the American College of Gastroenterology and the C. Lockard Conley Award of the American College of Physicians. In 2000, Baltimore magazine selected him as one of its Top Doctors. He is the recipient of a Center for Disease Control grant for colon cancer screenings in Baltimore.

14. Dr. Padmanabhan P. Nair, Ph.D., has over 45 years of research experience in the biomedical field. He has held several key positions in academia and in the U.S. government. He was a Fulbright scholar to the Johns Hopkins University at the McCollum-Pratt Institute, elected Fellow of the AAAS, and a member of several prestigious professional societies. For twenty-one

years, he was Director of Medical Research at Sinai Hospital of Baltimore. For over a decade, he was associated with the USDA's Beltsville Human Nutrition Research Center. He is currently Adjunct Professor of International Health at Johns Hopkins University.

15. Microgizzmos owns the Asserted Patent by assignment from the inventors. The Asserted Patent was filed as Application No. 09/759,398 on January 12, 2001, issued as a patent on May 2, 2006, and claims priority to provisional application No. 60/180,960 filed on February 8, 2000.

16. The Asserted Patent is entitled "Miniature Ingestible Capsule" and generally relates to a miniature non-digestible capsule that is ingested by a human for performing internal visual diagnostic functions. More specifically, the invention relates to minimally-invasive, noninterventional, non-tethered imaging device for internal examination of the gastrointestinal ("GI") tract that are significantly more convenient, comfortable, lower in cost, and more advanced compared with traditional invasive diagnostic methods such as colonoscopy, sigmoidoscopy, esophagogastroduodenoscopy, and push enteroscopy. (Ex. A, 1:11-18.)

17. The GI tract comprises the esophagus, stomach, small intestine, and colon. Physicians traditionally image the interior of the GI tract to aid in the diagnosis and treatment of many illnesses such as ulcers, growths, cancers, and bleeding spots. More specifically, these conditions include colorectal cancer, colonic polyposis, inflammatory bowel disease, irritable bowel syndrome, Barrett's esophagus, peptic ulcer disease, and dyspepsia. (Ex. A, 1:22-29.)

18. Diseases of the GI tract, such as colorectal cancer, are responsible for a significant number of deaths. For example, in the United States, colorectal cancer is the second leading cause of cancer deaths and is expected to cause more than 50,000 deaths in 2021 alone. However, a patient's prognosis improves, and overall treatment costs decline, with early

detection. (Ex. A, 1:30-36.) Therefore, regular screening is desirable to catch disease development early.

19. Unfortunately, regular screening for diseases such as colorectal cancer is not performed for much of the populace due to the high cost and, more importantly, the reluctance of a healthy population to undergo an invasive procedure again and again for surveillance against cancer. As a result, early diagnosis is missed, resulting in many patients not being diagnosed until disease reaches an advanced stage, limiting treatment options and increasing healthcare costs. (Ex. A, 1:43-49.)

Failures of Prior Art Technology

20. At the time of filing, the only low-cost, noninvasive screening tests for colorectal cancer were fecal occult blood tests, which look for the presence of fecal occult blood in stool specimens. But these tests exhibit poor sensitivity since malignant growths of the colon must be fairly large before they start to bleed. Furthermore, there are many other reasons for bleeding into the GI tract (e.g., ulcers), leading to low test specificity and a high probability of false positives. (Ex. A, 1:52-60.)

21. Alternatively, there were (and still are) several invasive diagnostic procedures for diagnosing diseases and conditions of the GI tract.

22. First, a common diagnostic procedure for colonic examination is colonoscopy. This procedure involves the optical examination of the entire colon using a device known as a colonoscope. A colonoscope is a flexible tube containing a fiber-optic imaging and illuminating device and a device to resect portions of the surface of the intestinal tract. The colonoscope is inserted into the rectum and can be maneuvered to the ileo-cecal junction (the start of the colon). (Ex. A, 2:4-11.)

23. The operator views the image on a video display. The medical team performing this procedure usually comprises a gastroenterologist, specially trained nurses, and, at times, an anesthesiologist. Polyps (tumors) are identified visually and biopsied. Considering the cost of the colonoscopy alone, a yearly colonoscopy for all patients over past a certain age would be expensive. Thus, colonoscopy for asymptomatic patients is seldom prescribed. (Ex. A, 2:12-24.)

24. Second, the sigmoidoscope is similar to a colonoscope, but can only be used to image the lower two-thirds of the colon. Although simpler than a colonoscope, its operation still requires the presence of a highly trained physician and often requires patient sedation. (Ex. A, 2:25-29.)

25. Third, the esophagogastroduodenoscope is used to image the upper gastrointestinal tract, namely, the esophagus, the stomach, and the duodenum. It is inserted through the mouth. Again, its operation requires a highly trained physician and often requires patient sedation. (Ex. A, 2:30-34.) This procedure is performed on patients with various symptoms that include nausea, vomiting, abdominal bloating, abdominal pain, heartburn, reflux, family history of cancer, jaundice, weight loss, anemia, and gastrointestinal bleeding. Considering the cost of endoscopy and the sedation requirement, it would be prohibitively expensive to perform esophagogastroduodenoscopy on all patients with symptoms. (Ex. A, 2:30-46.)

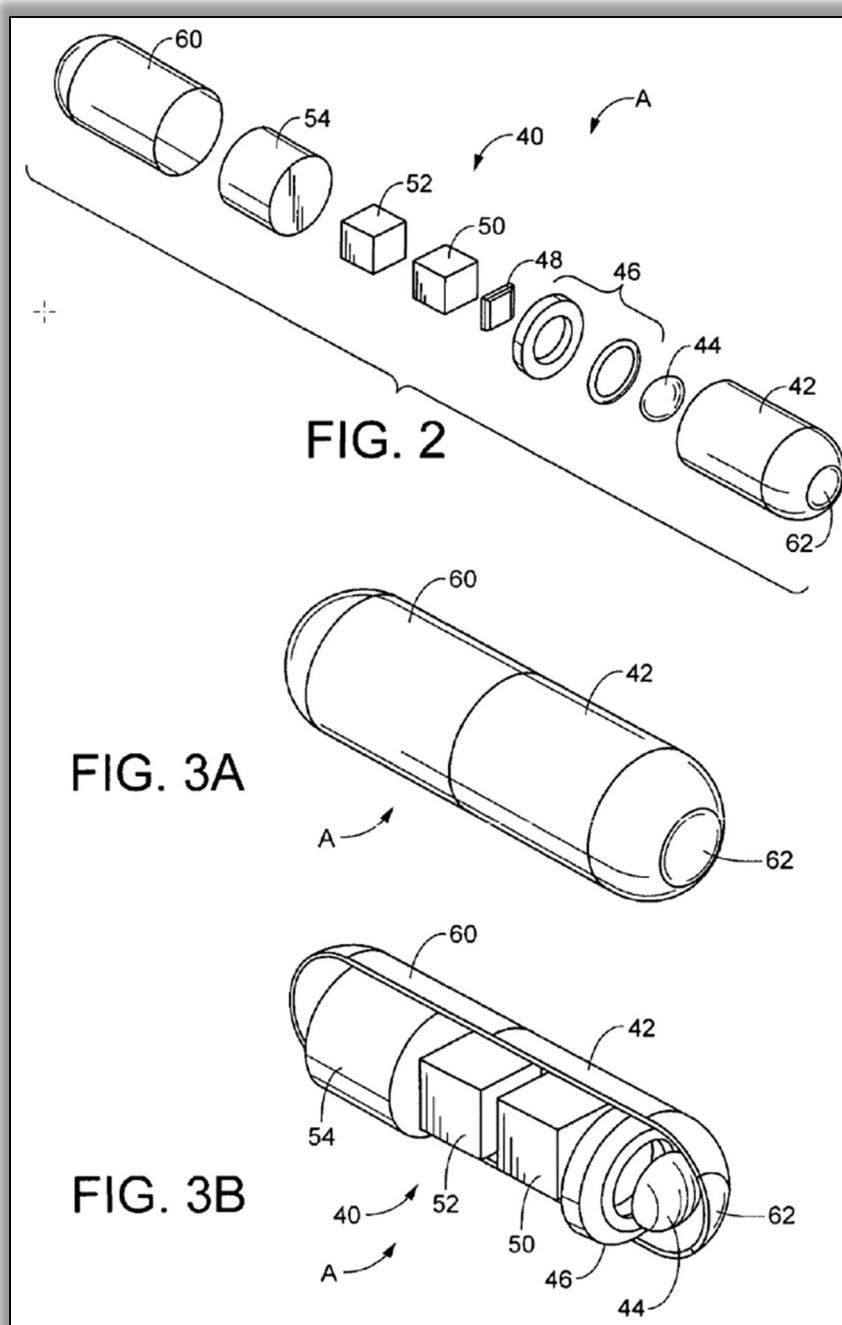
26. Fourth, the push-enteroscope is used to image the third and fourth portions of the duodenum and the proximal jejunum. It is inserted through the mouth, and its operation requires the presence of a highly trained physician and requires sedation. The push-enteroscope may be used to detect arteriovenous malformations and small intestinal tumors. (Ex. A, 2:47-52.)

27. Unfortunately, these diagnostic techniques suffer from numerous shortcomings including: (1) they are invasive and uncomfortable to the patient, requiring sedation so that a flexible fiberoptic tube can be inserted into the GI tract, which is a major limitation of these tests in their application to healthy asymptomatic individuals for repeated examinations, (2) they are expensive and require specially trained doctors and nurses, and (3) these procedures are inconvenient, requiring the patient to take a purgative, fast overnight, and remain incapacitated during the procedure. (Ex. A, 3:13-23.)

Microgizzmos' Patented Inventions Overcame Prior Art Technology

28. Overcoming the above-identified technical failures and shortcomings of the prior art, the inventions described and claimed in the Asserted Patent are directed to a miniature ingestible capsule that can be swallowed by a patient and that images the GI tract as it travels. (Ex. A, 3:42-45.)

29. The specification of the Asserted Patent generally describes a non-digestible capsule comprising an impermeable anterior and posterior membrane, a transparent window, an imaging device, a transmitter, and a power supply, and an external unit comprising a data reception device and a recording device. In one embodiment, a miniature color imaging device, such as a CCD array and lens, and an illumination device, such as an RGB diode array or similar low-power white light source, provide real-time color images of the GI tract. (Ex. A, 3:40-4:51; Figs. 2, 3A & 3B.)



30. As it travels through the body, images of the GI tract are transmitted from the capsule device to an external reception device where they can be displayed on a monitor or recorded for later playback. (Ex. A, 3:61-64.) This allows a patient to conveniently carry out normal daily activities while collecting valuable diagnostic information that can be used to detect

potential diseases, such as cancer, without sedation, a lengthy doctor's office visit, or the need for highly trained personnel, all of which lead to decreased health care costs and increased accessibility. (Ex. A, 5:4-17.)

OVERVIEW OF DEFENDANTS' INFRINGEMENT OF THE ASSERTED PATENT

31. Defendant Medtronic is one of the largest medical technology, services, and solutions companies in the world. In its 2021 fiscal year, ending April 30, 2021, Medtronic had worldwide revenue of \$30.1 billion. Net sales in this same fiscal year within Medtronic's "Respiratory, Gastrointestinal, & Renal" division, of which the infringing PillCam products and systems are a part, totaled \$3.65 billion.

32. Defendant Covidien is a wholly-owned subsidiary of Medtronic. On January 26, 2015, Medtronic acquired Defendant Covidien in a cash and stock transaction valued at \$50.0 billion. As a result of that acquisition, Covidien became a wholly-owned subsidiary of Medtronic and the majority of Covidien's pre-acquisition operations were included in Medtronic's Minimally Invasive Therapies Group. Covidien had net sales for its 2014 fiscal year of \$10.7 billion.

33. On information and belief, Defendant GIL is a wholly-owned subsidiary of Covidien, and is a medical technology company specializing in diagnostic products related to gastrointestinal tract disorders, such as the Accused Products. Covidien purchased Defendant GIL in February 2014 for approximately \$860 million, prior to Covidien itself being acquired by Medtronic.

34. On information and belief, Defendant GII is a subsidiary of GIL, and manufactures, markets, sells, offers for sale, imports, and/or distributes the infringing products and systems in the United States.

35. Medtronic markets, advertises, and offers for sale the infringing products and systems, including through its website, www.medtronic.com. For example, the PillCam SB 3 Capsule is shown on Medtronic’s website listed under “Covidien Products” and includes product details, ordering information, and a link to contact a sales representative to purchase this product:

The screenshot displays the Medtronic website interface. At the top left is the Medtronic logo. To its right are navigation links: Covidien Products, Clinical Solutions, Clinical Education, and Support. Further right, there is a location indicator for 'United States' and a 'Contact Us' button. A search bar is positioned below these elements. The breadcrumb trail reads: Medtronic / Covidien Products / Capsule Endoscopy / PillCam™ SB 3 System. The main content area features a dark blue banner with the text 'PILLCAM™ SB 3 SYSTEM' and a blue 'CONTACT US' button. Below this, a white box contains an image of the PillCam SB 3 Capsule. To the right of the image, the product is titled 'PillCam™ SB 3 Capsule'. Underneath the title are two expandable sections: 'PRODUCT DETAILS' with a plus sign and 'ORDER INFORMATION' with a right-pointing arrow. A blue 'CONTACT US' button is located below these sections.

See <https://www.medtronic.com/covidien/en-us/products/capsule-endoscopy/pillcam-sb-3-system.html> (last visited December 22, 2021).

36. On information and belief, Medtronic also controls and receives financial benefits from Covidien, GIL, and GII resulting from Defendants' infringement of the Asserted Patent. For example, in Medtronic's most recent 10-K filing, Medtronic lists "Gastrointestinal and endoscopy products, including the PillCam capsule endoscopy systems" within its "Respiratory, Gastrointestinal, & Renal" division, and reports its own sales and revenue figures, including sales revenue from this division.

Defendants' Knowledge of the Asserted Patent

37. Defendants have long been aware of Microgizzmos' Asserted Patent and their infringement of the Asserted Patent.

38. For example, on or about May 26, 2006, the inventors' patent counsel sent Given Imaging, Inc. a letter informing the company of the existence of the Asserted Patent by number and title, and its relevance to the "Pill Cam" product that "Given Imaging has been making and selling," and requesting a response.

39. Further, the Asserted Patent was cited as a prior art reference in the *inter partes* reexamination of U.S. Patent No. 7,009,634, assigned to Given Imaging Ltd, initiated on September 11, 2012 (Reexamination Control No. 95/002,175). During that reexamination, which concluded in May 2018, significant arguments were presented by Given Imaging concerning the Asserted Patent. In addition, Gavriel Iddan, Vice President of Innovation and co-founder of Given Imaging, submitted declarations dated January 17, 2013, in connection with the reexamination concerning the Asserted Patent. Furthermore, Gavriel Meron, a co-founder of Given Imaging Ltd., submitted declarations dated January 19, 2013, and January 27, 2013, in connection with the reexamination. Still further, Dov Avni, the former head of the Video Team and former head of Advanced Technologies at Given Imaging Ltd., also submitted a declaration

dated January 18, 2013, in the reexamination. The reexamination proceedings and the declarations submitted therein demonstrate knowledge and awareness of the Asserted Patent that is imputed to Given Imaging and the other above-identified Defendants. *See also* Appeal 2016-006933, Decision on Appeal at footnote 1 (PTAB Oct. 19, 2017) (“Patent Owner also identified Covidien Sales LLC, Covidien LP, and Medtronic, PLC as additional real parties in interest.”).

40. The Asserted Patent and/or its published application have been cited and referenced by either a patent applicant or the USPTO in more than 400 patents and applications, including at least 88 patents and published applications assigned to one or more Defendants, including U.S. Patent Nos. 7,553,276, 7,628,753, 7,637,865, 7,778,356, 7,801,584, 7,805,178, 7,872,667, 7,998,065, 8,125,516, 8,185,185, 8,194,123, 8,335,362, 8,396,327, 8,441,530, 8,516,691, 8,681,209, 8,873,816, 9,078,579, 9,113,846, 9,324,145, 9,364,139, 9,375,202, 9,386,208, and 9,432,562.

COUNT I
(Willful Infringement of U.S. Patent No. 7,039,453)

41. Plaintiff incorporates herein by reference the allegations in the foregoing paragraphs as though fully set forth herein.

42. Defendants have directly infringed one or more claims of the Asserted Patent, in violation of 35 U.S.C. § 271(a). Exemplary claims of the Asserted Patent are set forth below, but Plaintiff’s claims in this action, and Defendants’ infringement, are not limited to these exemplary claims.

A. Defendants’ Direct Infringement of Claim 1

43. Defendants’ PillCam devices are miniature capsule imaging devices. Defendants make, use, sell, offer to sell, and/or import within this District and elsewhere in the United States, infringing PillCam imaging devices (the “Infringing Imaging Devices”).

44. Defendants' Infringing Imaging Devices include, without limitation, all of Defendants' imaging devices that operate as described in the Infringement Count, as well as comparable models. Defendants' Infringing Imaging Devices include, but are not limited to, the following exemplary devices:

- PillCam COLON 1 Capsule;
- PillCam COLON 2 Capsule;
- PillCam SB Capsule (previously known as M2A Capsule);
- PillCam SB 2 Capsule;
- PillCam SB 3 Capsule;
- PillCam UGI Capsule;
- PillCam Crohn's Capsule;
- PillCam ESO Capsule;
- PillCam ESO 2 Capsule; and
- Defendants' reasonably similar capsule endoscopy products containing an imaging device and a transmitter.

45. Defendants have directly infringed Claim 1 literally and/or under the doctrine of equivalents, by, among other things, making, using, offering for sale, selling, and/or importing within this District and elsewhere in the United States, without license or authority, infringing products, including without limitation Defendants' Infringing Imaging Devices. Claim 1 reads:

1. An imaging device comprising:

a membrane defining an internal cavity and being provided with a window on one of two opposite ends of said membrane, said window and said membrane each having a substantially identical curvature, said membrane having a substantially oval configuration;

a lens disposed parallel and adjacent to said window;

a light source disposed in relation to said lens for providing illumination to outside of said membrane through said window;

an imaging array disposed in relation to said lens, wherein images from said lens impinge on said imaging array; and

a transmitter disposed in relation to said imaging array for transmitting a signal from said imaging array to an associated transmitter outside of said membrane, said lens, light source, imaging array, and transmitter being enclosed within said internal cavity.

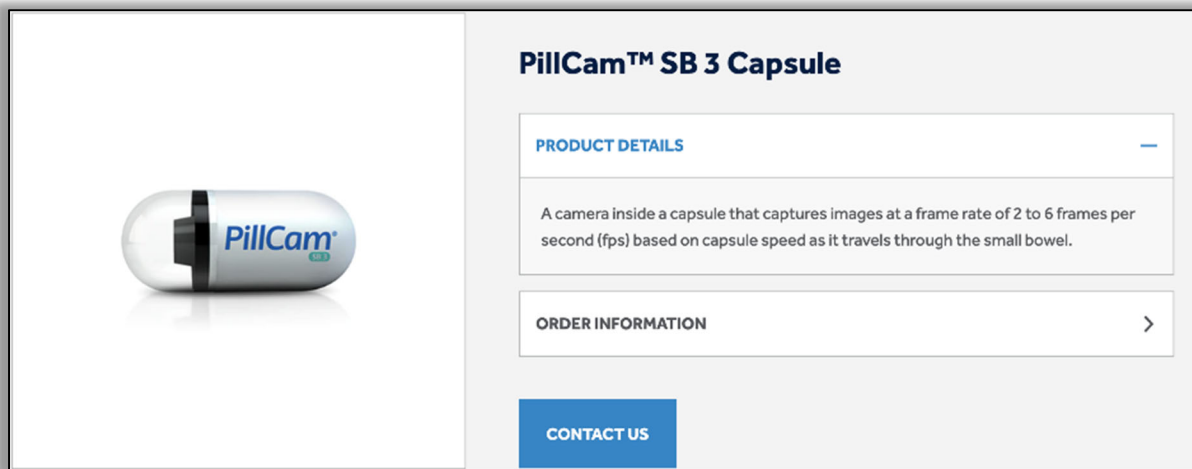
46. Defendants' acts of making, using, offering for sale, selling, and/or importing infringing products, including but not limited to their Infringing Imaging Devices and related products satisfy, literally or under the doctrine of equivalents, each and every claim element of the Asserted Patent, including but not limited to elements of claims 1-4, 9, and 10.

47. For example, Defendants' Infringing Imaging Devices infringe claim 1 of the Asserted Patent because they are imaging devices that have (1) a membrane defining an internal cavity and a window on one of the two opposite ends of the membrane, where the window and the membrane each have a substantially identical curvature, and the membrane has a substantially oval configuration; (2) a lens disposed parallel and adjacent to the window; (3) a light source disposed in relation to the lens for providing illumination to outside of the membrane through the window; (4) an imaging array disposed in relation to the lens where images from the lens impinge on the imaging array; and (5) a transmitter disposed in relation to the imaging array for transmitting a signal from the imaging array to an associate transmitter outside of the membrane. Further, (6) the lens, light source, imaging array, and transmitter of Defendants' Infringing Imaging Devices are enclosed within the internal cavity.

48. Defendants' PillCam SB capsule products, illustrated below, are representative of Defendants' Infringing Imaging Devices.¹

¹ For clarity, Plaintiff contends that all the Infringing Imaging Devices are constructed and operate in a similar manner, and, therefore, infringe the Asserted Patent.

49. Defendants' Infringing Imaging Devices, including PillCam SB products, are imaging devices.

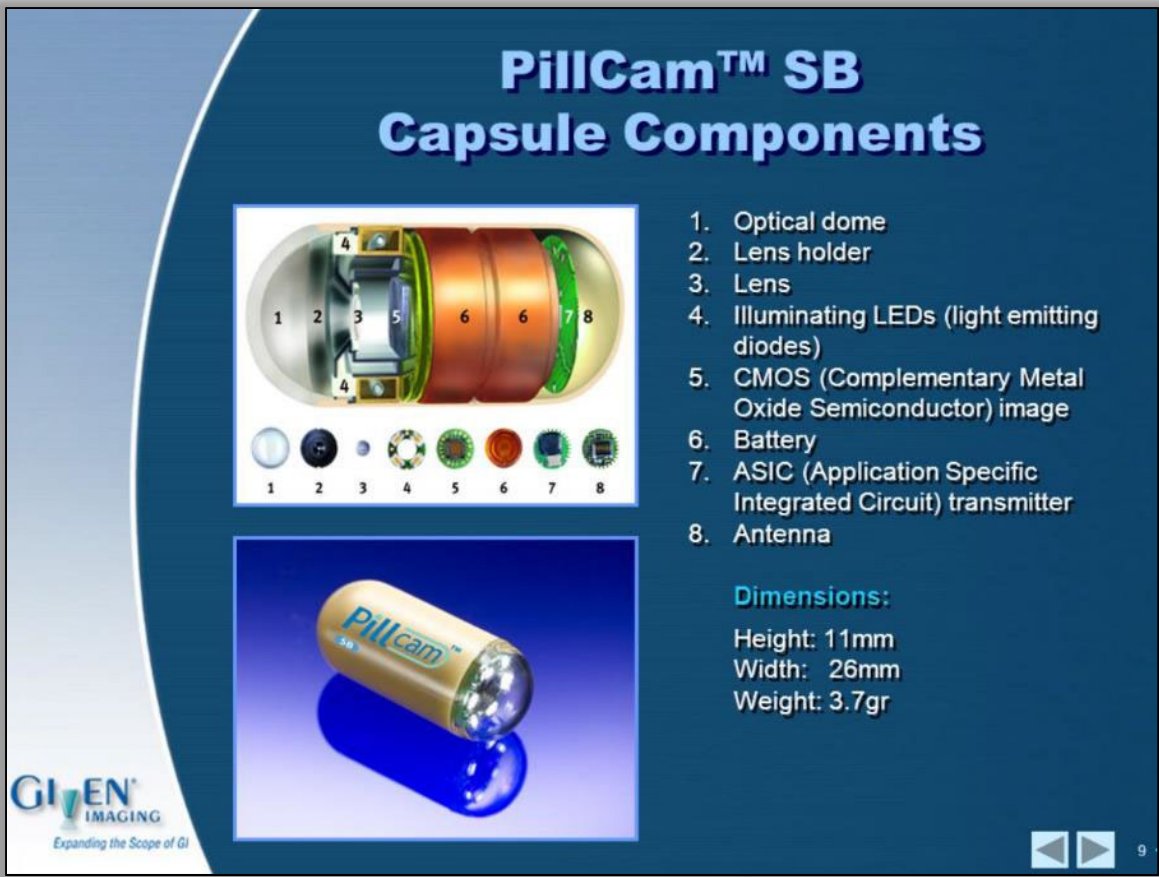


See <https://www.medtronic.com/covidien/en-us/products/capsule-endoscopy/pillcam-sb-3-system.html> (last visited December 14, 2021).

50. Defendants' Infringing Imaging Devices, including PillCam SB products, have a membrane defining an internal cavity and a window on one of the two opposite ends of the membrane, where the window and the membrane each have a substantially identical curvature, and the membrane has a substantially oval configuration. See ¶ 49 *supra*.



See https://www.youtube.com/watch?v=bH6i3bfie_E (last visited December 13, 2021).



See Given Imaging Presentation at p. 9 available at <https://slideplayer.com/slide/6074146/> (“Given Imaging Presentation”) (last visited December 14, 2021).

51. Defendants’ Infringing Imaging Devices, including PillCam SB products, include a lens disposed parallel and adjacent to the window. See Given Imaging Presentation at p. 9; ¶ 50 *supra*.



See https://www.youtube.com/watch?v=bH6i3bfie_E (last visited December 14, 2021).

PillCam Capsules

PillCam capsules are video cameras designed specifically for imaging the intestinal tract. Each capsule is equipped with a tiny battery, a transmitter with antenna, and LEDs (light-emitting diodes) for each video camera head. These components are enclosed in a biocompatible plastic casing. A capsule is about the size of a large vitamin pill.

After activation and ingestion, the capsule is propelled by peristalsis through the gastrointestinal tract. During this process, the video cameras acquire images and the transmitter sends them, via the sensors, to the PillCam recorder for storage.

The PillCam Capsule Endoscopy System supports the following PillCam capsule types, optimized for use in different bowel segments and equipped with either one or two video heads:

- PillCam SB
- PillCam COLON
- PillCam Crohn's
- PillCam UGI

See PillCam Capsule Endoscopy User Manual at p. 4 available at

<https://manuals.medtronic.com/content/dam/emanuals/mitg/DOC-2928->


[02%20PillCam%20Desktop%20SW%20v9%20UM%20EN.pdf](https://manuals.medtronic.com/content/dam/emanuals/mitg/DOC-2928-02%20PillCam%20Desktop%20SW%20v9%20UM%20EN.pdf) (“PillCam User Manual”) (last visited December 14, 2021).

PillCam SB2/3

PillCam SB capsules: Small bowel

PillCam SB capsules contain one video camera:

- PillCam SB 2 is a fixed frame rate second generation capsule.
- PillCam SB 3 is a third generation capsule with enhanced imaging capabilities with adaptive frame rate (AFR).

The image shows two white, pill-shaped capsules. The top one is labeled 'PillCam SB2' and the bottom one is labeled 'PillCam SB3'. Both capsules have a small lens and a light source on their side.

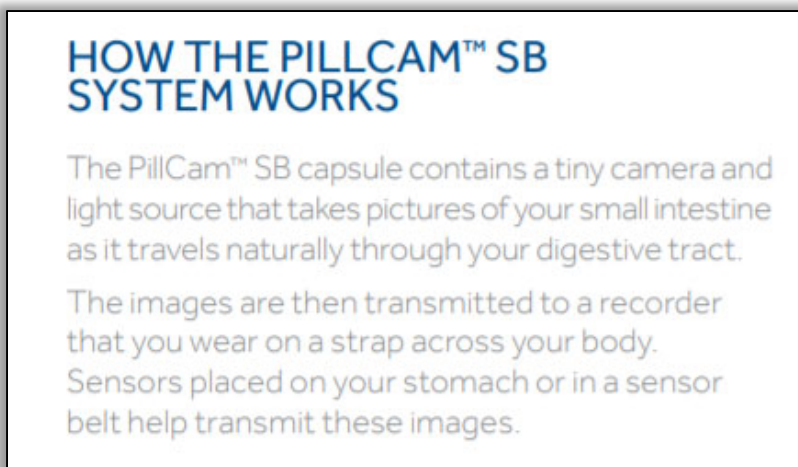
See id. at p. 5.

52. Defendants' Infringing Imaging Devices, including PillCam SB products, have a light source disposed in relation to the lens for providing illumination to outside of the membrane through the window. *See* Given Imaging Presentation at p. 9; ¶ 50 *supra*; PillCam User Manual at p. 4.

PillCam SB 2 Capsule

Properties			
Physical	Dimensions	Length: 26.3 mm Diameter: 11.4 mm	
	Weight	2.9 g	
	Material	Biocompatible plastic	
Optical	Illumination	4 white light emitting diodes	
	# of imaging heads	1	
	Field of view		156° (Optical field of view at 4.5 mm from top cover per ISO-8600-3)
			130° (Optical field of view from entrance pupil per FDA Method)
	Effective visibility	Distance: 3 cm	
	Min. detectable object	At least 0.1 mm	
	Frequency	434.1 MHz	
	Band width	1.6 MHz	
	Modulation	MSK	
	ERP [nW]	16	
Operational	Frame rate	either 2 or 4 fps (two capsule versions)	
	Operating time	≥ 8 hours	
	Chemical safety	Resistant to dissolution in pH=2 to pH=8	
	Battery type	Silver Oxide batteries, Mercury Free	
	Operating temperature	20-40 °C	
	Storage temperature	0-25 °C	

See PillCam User Manual at p. 204.

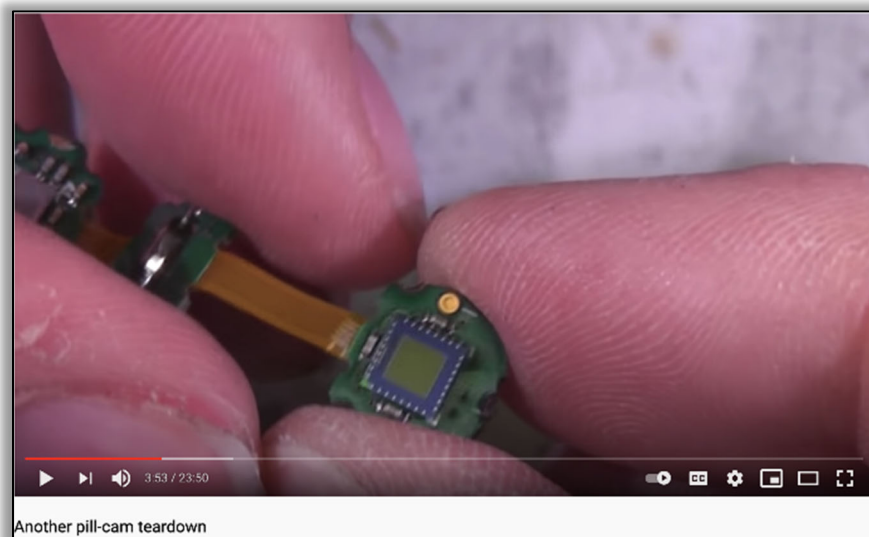


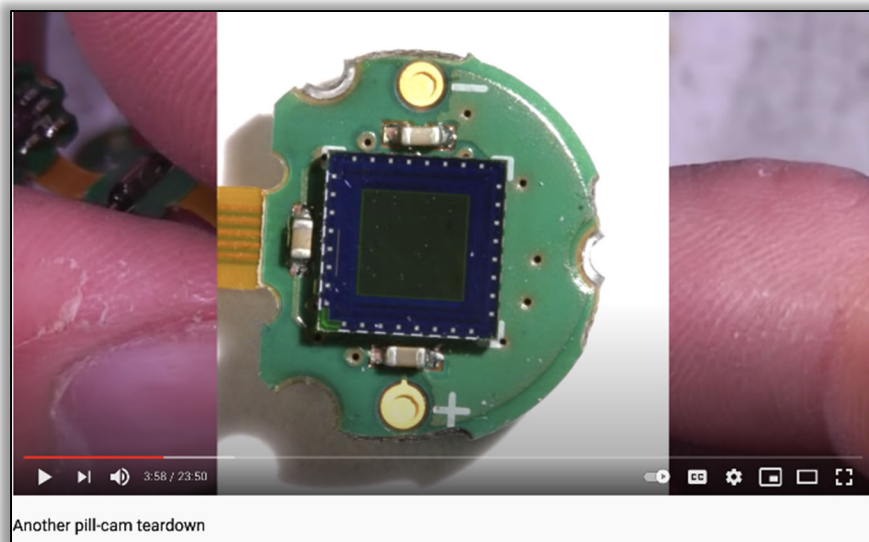
See PillCam SB System Patient brochure available at

<https://www.ncdhp.com/uploads/files/PillCam-Brochure.pdf> (last visited December 14, 2021)

(“PillCam SB Patient brochure”).

53. Defendants’ Infringing Imaging Devices, including PillCam SB products, also include an imaging array disposed in relation to the lens, where images from the lens impinge on the imaging array. See Given Imaging Presentation at p. 9; ¶ 50 *supra*.






See https://www.youtube.com/watch?v=bH6i3bfie_E (last visited December 13, 2021).

Technical features of the capsule

The Given M2A (Given Imaging; Yoqneam, Israel) video CE is a pill-shaped wireless device with a slippery coating for easy ingestion and measures 11 mm × 26 mm. It is composed of a white light-emitting diode as light source, lens, imaging chip, batteries and a radio transmitter with internal antenna. The image field is 140 degrees and magnification is × 8[4]. Once swallowed, the capsule moves through the intestine *via* peristalsis and is excreted in the stool. The camera takes two images per second as it sweeps the intestine and transmits these to eight lead sensor arrays, arranged in a specific manner and taped to the anterior abdominal wall, connected to a recording device in the belt for the duration of the battery life, which is 6-8 h. Once the study is completed, the recording device and sensor arrays are removed and the images (50 000-60 000 images total) are downloaded to a computer with reporting and processing of images and data (Rapid, Given Imaging) software that displays the video images on a computer monitor.

See <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2675082/> (last visited December 14, 2021).

54. Defendants' Infringing Imaging Devices, including PillCam SB products, have a transmitter disposed in relation to said imaging array for transmitting a signal from the imaging array to an associated transmitter outside of the membrane. See Given Imaging Presentation at p. 9; ¶ 50 *supra*.




PillCam™ SB 3 Sensor Belt

PRODUCT DETAILS

Patients undergoing capsule endoscopy with the PillCam™ SB 3 system may wear the sensor belt to receive transmission data from PillCam™ SB 3 capsule. The belt is worn around the patient's waist over a single layer of clothing and can be adjusted to achieve the most comfortable fit.

ORDER INFORMATION

CONTACT US



PillCam™ SB 3 Sensor Array

PRODUCT DETAILS

The PillCam™ SB 3 sensor array features an 8-lead sensor, which is placed on the patient's body to receive transmission data from the PillCam™ SB 3 capsule.

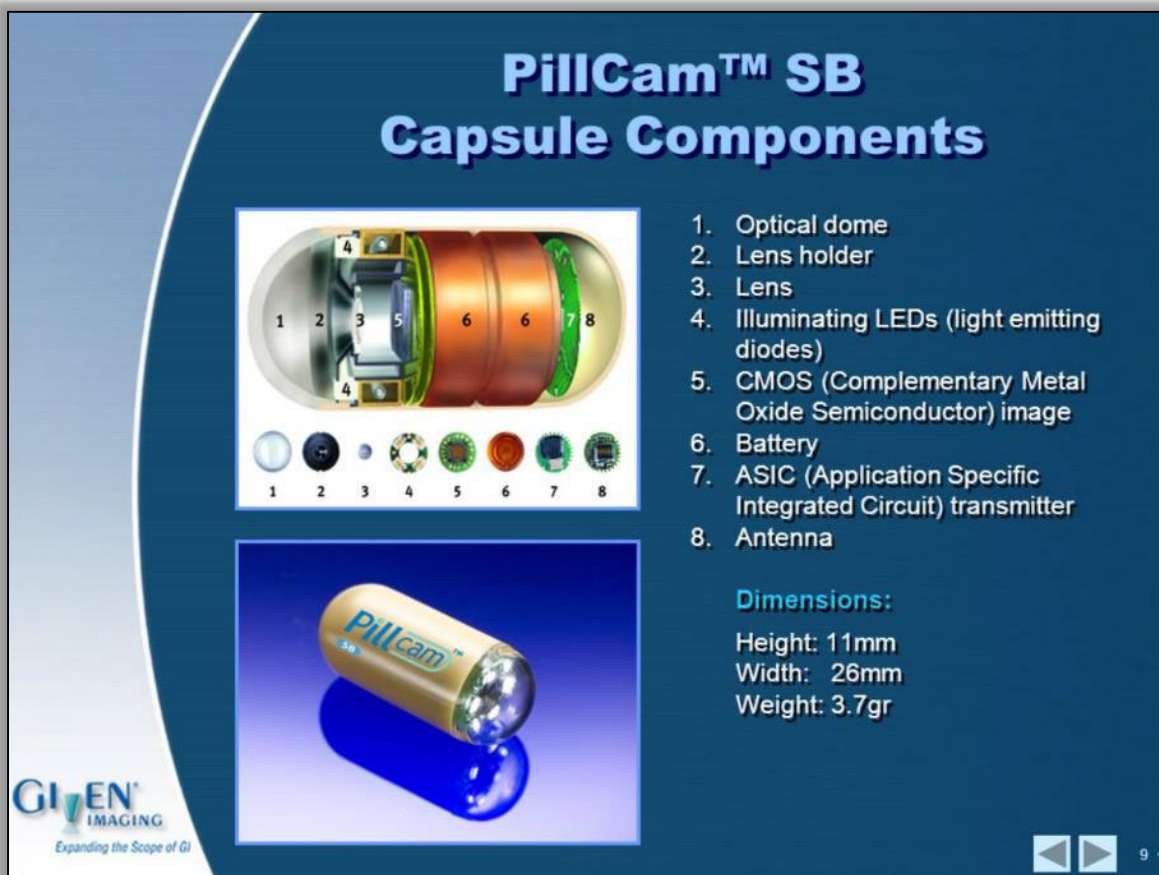
ORDER INFORMATION

CONTACT US

See <https://www.medtronic.com/covidien/en-us/products/capsule-endoscopy/pillcam-sb-3-system.html> (last visited December 13, 2021); *see also*

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2675082/> (last visited December 13, 2021).

55. Defendants' Infringing Imaging Devices, including PillCam SB products, are imaging devices in which the lens, light source, imaging array, and transmitter of are enclosed within the internal cavity.



See Given Imaging Presentation at p. 9.

B. Defendants' Direct Infringement of Claim 12

56. Defendants' capsule endoscopy systems are imaging systems. Defendants make, use, sell, offer to sell, and/or import within this District and elsewhere in the United States, infringing capsule endoscopy systems (the "Infringing Imaging Systems").

57. Defendants' Infringing Imaging Systems include, without limitation, all of Defendants' imaging systems that operate as described in the Infringement Count, as well as

comparable models. Defendants' Infringing Imaging Systems include, but are not limited to, the following exemplary systems:

- PillCam COLON 1 Capsule and associated products;
- PillCam COLON 2 System;
- Pillar SB Capsule and associated products (the PillCam SB Capsule was previously known as the M2A Capsule);
- PillCam SB 2 Capsule and associated products;
- PillCam SB 3 System;
- PillCam ESO Capsule and associated products;
- PillCam ESO 2 Capsule and associated products;
- PillCam UGI System;
- PillCam Crohn's System;
- Defendants' reasonably similar endoscopy imaging systems.

58. Defendants have directly infringed Claim 12 literally and/or under the doctrine of equivalents, by, among other things, making, using, offering for sale, selling, and/or importing within this judicial district and elsewhere in the United States, without license or authority, infringing products, including without limitation Defendants' Infringing Imaging Systems.

Claims 12 reads:

12. An imaging system comprising:

a capsule, said capsule comprising:

an anterior membrane, said membrane comprises a window, said membrane and said window having substantially identical curvatures to each other;

a posterior membrane connected to said anterior membrane, said anterior membrane and said posterior membrane define an internal cavity, said

anterior membrane and said posterior membrane define a substantially oval shaped capsule;

a lens disposed parallel to and adjacent said window;

a light source and projection device disposed in relation to said lens for providing illumination to outside of said anterior membrane;

an imaging array disposed in relation to said lens, wherein images from said lens impinge on said imaging array;

a first transmitter disposed in relation to said imaging array;

a pose beacon positioned in relation to said first transmitter;

said lens, light source and projection device, imaging array, first transmitter, and pose beacon are enclosed within said internal cavity;

a second transmitter located outside of said capsule, said first transmitter transmits a signal from said imaging array to said second transmitter;

a pose detection system outside of said capsule, said pose detection system tracks said pose beacon; and

a recording and display device, said pose detection system relays tracking information to said recording and display device.

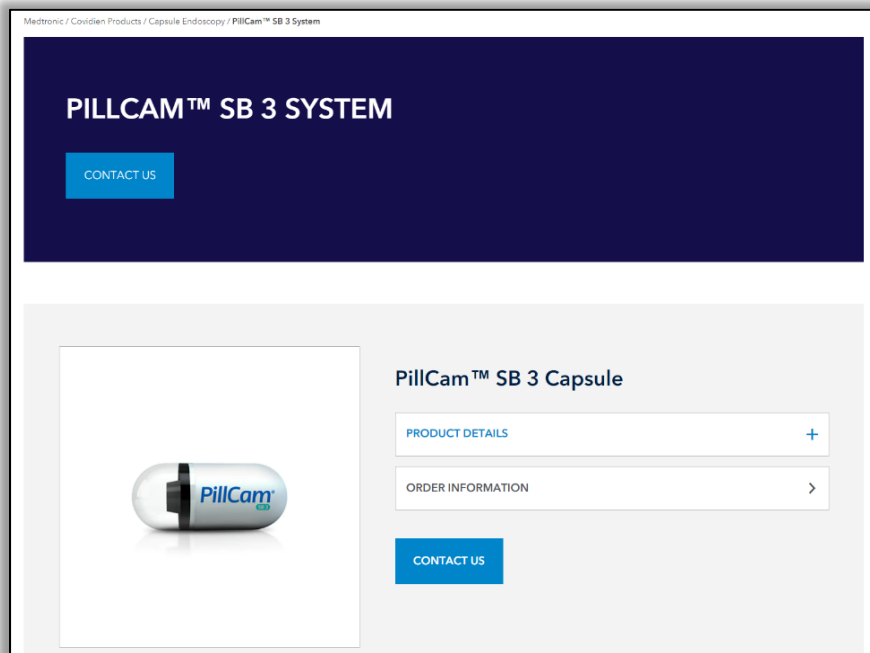
59. Defendants' acts of making, using, offering for sale, selling, and/or importing infringing products, including but not limited to their Infringing Imaging Systems, and related products satisfy, literally or under the doctrine of equivalents, each and every claim element of the Asserted Patent, including but not limited to elements of claim 12.

60. For example, Defendants' Infringing Imaging Systems infringe claim 12 of the Asserted Patent because they include (1) an anterior membrane that comprises a window, where the membrane and the window have substantially identical curvature to each other; (2) a posterior membrane connected to the anterior membrane, where the anterior membrane and posterior membrane define an internal cavity and define a substantially oval shaped capsule; (3) a lens disposed parallel and adjacent to the window; (4) a light source and projection device disposed in relation to the lens for providing illumination to outside of said anterior membrane;

(5) an imaging array disposed in relation to the lens where images from the lens impinge on the imaging array; (6) a first transmitter disposed in relation to the imaging array; (7) a pose beacon positioned in relation to the first transmitter; (8) the lens, light source, imaging array, first transmitter, and pose beacon of Defendants' Infringing Imaging Capsules are enclosed within the internal cavity; (9) a second transmitter located outside the capsule, where the first transmitter transmits a signal from the imaging array to the second transmitter; (10) a pose detection system outside the capsule that tracks the pose beacon; and (11) a recording and display device, where the pose detection system relays tracking information to the recording and display device.

61. Defendants' PillCam SB Systems, illustrated below, are representative of Defendants' Infringing Imaging Systems.

62. Defendants' Infringing Imaging Systems, including PillCam SB Systems, include capsule imaging devices.



See <https://www.medtronic.com/covidien/en-us/products/capsule-endoscopy/pillcam-sb-3-system.html> (last visited December 13, 2021).

63. Defendants' Infringing Imaging Systems, including PillCam SB Systems, include an anterior membrane that comprises a window, where the membrane and the window have substantially identical curvature to each other. *See* ¶ 62 *supra*.



See https://www.youtube.com/watch?v=bH6i3bfie_E (last visited December 13, 2021).

PillCam Capsules

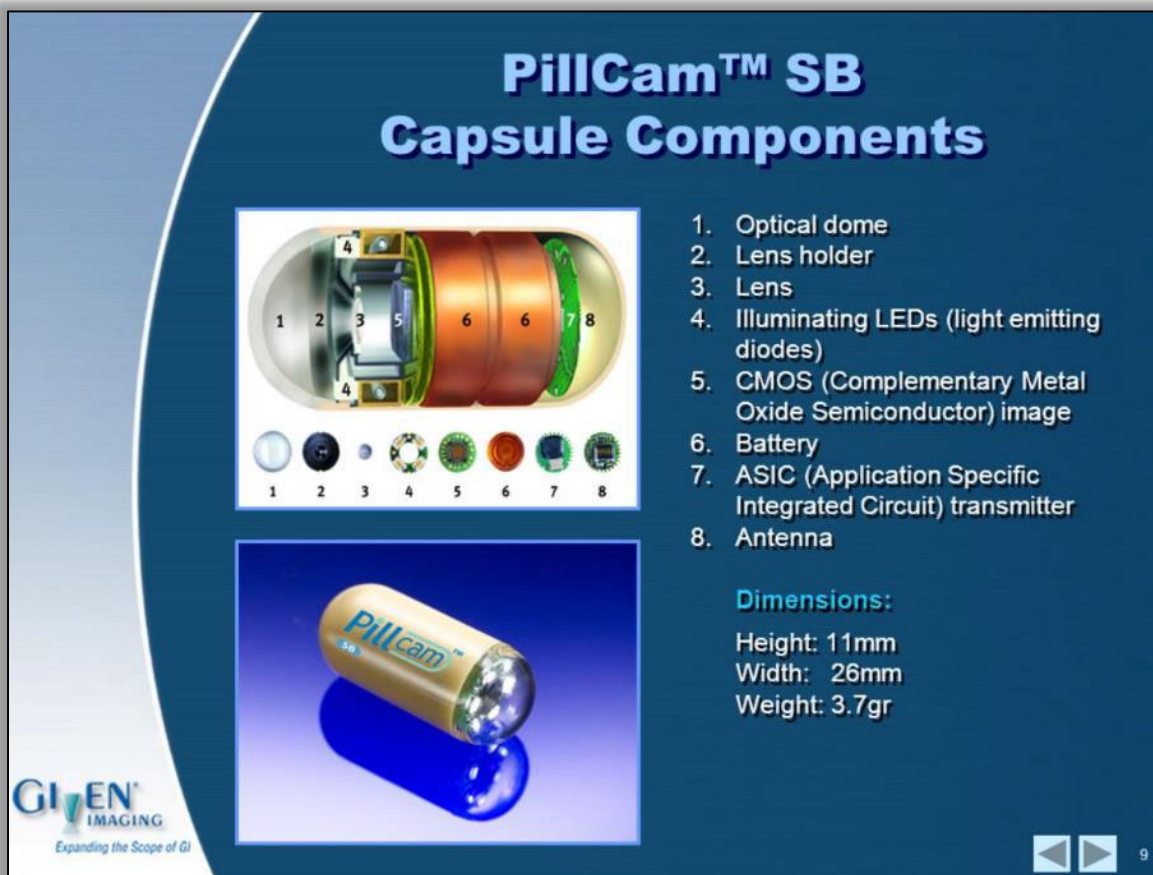
PillCam capsules are video cameras designed specifically for imaging the intestinal tract. Each capsule is equipped with a tiny battery, a transmitter with antenna, and LEDs (light-emitting diodes) for each video camera head. These components are enclosed in a biocompatible plastic casing. A capsule is about the size of a large vitamin pill.

After activation and ingestion, the capsule is propelled by peristalsis through the gastrointestinal tract. During this process, the video cameras acquire images and the transmitter sends them, via the sensors, to the PillCam recorder for storage.

The PillCam Capsule Endoscopy System supports the following PillCam capsule types, optimized for use in different bowel segments and equipped with either one or two video heads:

- PillCam SB
- PillCam COLON
- PillCam Crohn's
- PillCam UGI

See PillCam User Manual at p. 4.



See Given Imaging Presentation at p. 9.

64. Defendants' Infringing Imaging Systems, including PillCam SB Systems, include capsules comprising a posterior membrane connected to the anterior membrane, where the anterior membrane and posterior membrane define an internal cavity and define a substantially oval shaped capsule. *See* ¶ 63 *supra*.

65. Defendants' Infringing Imaging Systems, including PillCam SB Systems, include a lens disposed parallel and adjacent to the window. *See* Given Imaging Presentation at p. 9; ¶ 63 *supra*.



See https://www.youtube.com/watch?v=bH6i3bfie_E (last visited December 13, 2021).

PillCam Capsules

PillCam capsules are video cameras designed specifically for imaging the intestinal tract. Each capsule is equipped with a tiny battery, a transmitter with antenna, and LEDs (light-emitting diodes) for each video camera head. These components are enclosed in a biocompatible plastic casing. A capsule is about the size of a large vitamin pill.

After activation and ingestion, the capsule is propelled by peristalsis through the gastrointestinal tract. During this process, the video cameras acquire images and the transmitter sends them, via the sensors, to the PillCam recorder for storage.

The PillCam Capsule Endoscopy System supports the following PillCam capsule types, optimized for use in different bowel segments and equipped with either one or two video heads:

- PillCam SB
- PillCam COLON
- PillCam Crohn's
- PillCam UGI

See PillCam User Manual at p. 4.

PillCam SB2/3

PillCam SB capsules: Small bowel

PillCam SB capsules contain one video camera:

- PillCam SB 2 is a fixed frame rate second generation capsule.
- PillCam SB 3 is a third generation capsule with enhanced imaging capabilities with adaptive frame rate (AFR).



See PillCam User Manual at p. 5.

66. Defendants' Infringing Imaging Systems, including PillCam SB Systems, also have a light source and projection device disposed in relation to the lens for providing illumination to outside of the anterior membrane. See Given Imaging Presentation at p. 9; ¶ 63 *supra*; PillCam User Manual at p. 4.

PillCam SB 2 Capsule

Properties			
Physical	Dimensions	Length: 26.3 mm Diameter: 11.4 mm	
	Weight	2.9 g	
	Material	Biocompatible plastic	
Optical	Illumination	4 white light emitting diodes	
	# of imaging heads	1	
	Field of view		156° (Optical field of view at 4.5 mm from top cover per ISO-8600-3)
			130° (Optical field of view from entrance pupil per FDA Method)
	Effective visibility	Distance: 3 cm	
	Min. detectable object	At least 0.1 mm	
	Frequency	434.1 MHz	
	Band width	1.6 MHz	
	Modulation	MSK	
	ERP [nW]	16	
	Operational	Frame rate	either 2 or 4 fps (two capsule versions)
Operating time		≥ 8 hours	
Chemical safety		Resistant to dissolution in pH=2 to pH=8	
Battery type		Silver Oxide batteries, Mercury Free	
Operating temperature		20-40 °C	
Storage temperature		0-25 °C	

See PillCam User Manual at p. 204.

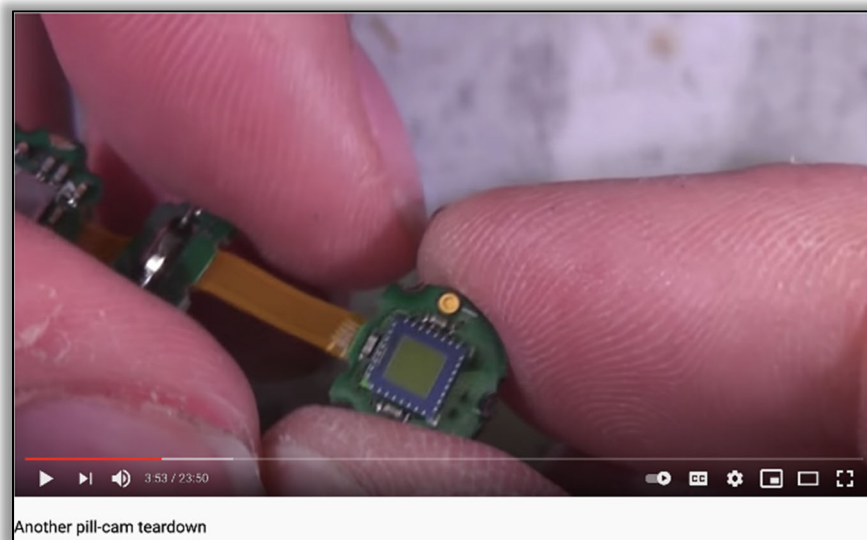
HOW THE PILLCAM™ SB SYSTEM WORKS

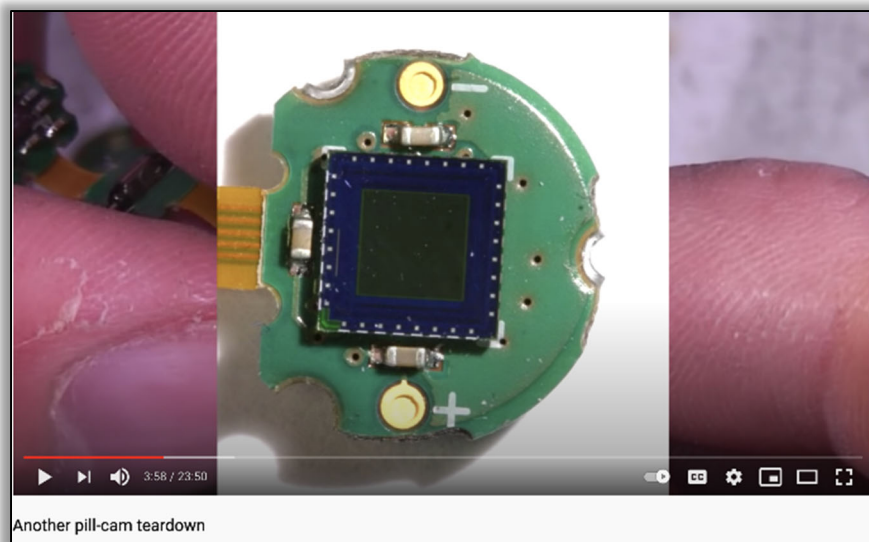
The PillCam™ SB capsule contains a tiny camera and light source that takes pictures of your small intestine as it travels naturally through your digestive tract.

The images are then transmitted to a recorder that you wear on a strap across your body. Sensors placed on your stomach or in a sensor belt help transmit these images.

See PillCam SB System Patient brochure.

67. Defendants' Infringing Imaging Systems, including PillCam SB Systems, include an imaging array disposed in relation to the lens, where images from the lens impinge on the imaging array. See Given Imaging Presentation at p. 9; ¶ 63 *supra*.





See https://www.youtube.com/watch?v=bH6i3bfie_E (last visited December 13, 2021).

Technical features of the capsule

The Given M2A (Given Imaging; Yoqneam, Israel) video CE is a pill-shaped wireless device with a slippery coating for easy ingestion and measures 11 mm × 26 mm. It is composed of a white light-emitting diode as light source, lens, imaging chip, batteries and a radio transmitter with internal antenna. The image field is 140 degrees and magnification is × 8[4]. Once swallowed, the capsule moves through the intestine *via* peristalsis and is excreted in the stool. The camera takes two images per second as it sweeps the intestine and transmits these to eight lead sensor arrays, arranged in a specific manner and taped to the anterior abdominal wall, connected to a recording device in the belt for the duration of the battery life, which is 6-8 h. Once the study is completed, the recording device and sensor arrays are removed and the images (50 000-60 000 images total) are downloaded to a computer with reporting and processing of images and data (Rapid, Given Imaging) software that displays the video images on a computer monitor.

See <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2675082/> (last visited December 13, 2021).


68. Defendants' Infringing Imaging Systems, including PillCam SB Systems, include a first transmitter disposed in relation to the imaging array. See Given Imaging Presentation at p. 9; ¶ 63 *supra*; PillCam User Manual at pp. 4.

PillCam SB2/3

PillCam SB capsules: Small bowel

PillCam SB capsules contain one video camera:

- PillCam SB 2 is a fixed frame rate second generation capsule.
- PillCam SB 3 is a third generation capsule with enhanced imaging capabilities with adaptive frame rate (AFR).



See PillCam User Manual at p. 5.

THE M2A CAPSULE [Also called wireless capsule] is a disposable device, measuring 11 × 26 mm (slightly larger than a large vitamin capsule) and weighting 3.7 g. The 2 dome, cylinder shaped capsule is made of a biocompatible plastic with a smooth surface that allows the peristalsis of the intestinal tract to advance the capsule through the lumen. The M2A capsule contains a complimentary metal oxide silicon chip camera, a lens, an illumination light-emitting diodes, energy source and radiotelemetry transmitter. The capsule battery life is about eight hours which is sufficient for imaging the small intestine. The M2A capsule has two operation modes; active and beacon. When the battery power is depleted, the transmitter switches the capsule to the beacon mode. In this mode, it relays the information to the recorder about the location of the capsule allowing the RAPID system to track the capsule in its pathway for 10 additional hours. The disposable capsule is constructed of specially sealed biocompatible material resistant to digestive fluids. The capsule transmits video signals and data in real time.

See <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3387769/> (last visited Dec. 13, 2021); see also <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2675082/> (last visited Dec. 13, 2021).

69. Defendants' Infringing Imaging Systems, including PillCam SB Systems, also include a pose beacon positioned in relation to said first transmitter. See Given Imaging Presentation at p. 9; ¶ 63 *supra*.


PillCam video capsule localization is based on off-line processing of the strength of the radio frequency signals emitted from the PillCam video capsule as received by each of the eight sensors. The information helps estimate the relative two-dimensional location of the PillCam video capsule with respect to the umbilicus (e.g., abdominal quadrant).

See, e.g., PillCam User Manual at p. 18; see also

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3387769/> (last visited December 13, 2021); see also <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2675082/> (last visited December 13, 2021).

70. The lens, light source and projection device, imaging array, first transmitter, and pose beacon are enclosed within the internal cavity of Defendants' Infringing Imaging Systems, including PillCam SB Systems. See Given Imaging Presentation at p. 9; ¶ 63 *supra*; PillCam User Manual at p. 4.

71. Defendants' Infringing Imaging Systems, including PillCam SB Systems, include second transmitters located outside the capsule, where the first transmitter transmits a signal from the imaging array to the second transmitter.




PillCam™ SB 3 Sensor Belt

PRODUCT DETAILS

Patients undergoing capsule endoscopy with the PillCam™ SB 3 system may wear the sensor belt to receive transmission data from PillCam™ SB 3 capsule. The belt is worn around the patient's waist over a single layer of clothing and can be adjusted to achieve the most comfortable fit.

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PillCam™ SB 3 Sensor Array

PRODUCT DETAILS

The PillCam™ SB 3 sensor array features an 8-lead sensor, which is placed on the patient's body to receive transmission data from the PillCam™ SB 3 capsule.

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PillCam™ Recorder 3

PRODUCT DETAILS

The PillCam™ recorder 3 is a recording device with a built in real-time viewer, which is worn by the patient during the PillCam™ procedure. Following the procedure, the physician downloads the images from the PillCam™ recorder 3 for interpretation.

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The image shows a white and black handheld device with a screen. The screen displays a patient's name 'John Frank', ID '322215', and 'COLON2'. The device has a blue circular button on the right side and a 'GIFEN' logo at the bottom.

See <https://www.medtronic.com/covidien/en-us/products/capsule-endoscopy/pillcam-sb-3-system.html> (last visited December 13, 2021).

PillCam recorder DR3

The PillCam recorder DR3 is a compact battery operated unit worn by the patient during PillCam capsule endoscopy. The PillCam recorder DR3 consists of a receiver, a transmitter, and a memory device for storing the data transmitted by the PillCam capsule. The battery of the PillCam recorder DR3 is charged while the PillCam recorder is in its cradle.



PillCam Sensor Arrays and Sensor Belts

The data transmitted from the capsule is received by sensors and transferred to the PillCam recorder. These sensors are either placed on the patient as a sensor array or incorporated as part of the sensor belt.

The PillCam sensor array and belt are connected to the PillCam recorder by a flexible cable.



Note

The PillCam Capsule Endoscopy System components do not contain any natural rubber latex components.

See PillCam User Manual at p. 7; *see also*

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2675082/> (last visited 12/13/21).

72. Defendants' Infringing Imaging Systems, including PillCam SB Systems, comprise a pose detection system outside the capsule which tracks the pose beacon. *See* <https://www.medtronic.com/covidien/en-us/products/capsule-endoscopy/pillcam-sb-3-system.html> (last visited December 13, 2021); ¶ 71 *supra*; PillCam User Manual at p. 7.

Applying the PillCam Sensor Array

The sensor array allows the PillCam recorder to collect localization data during a procedure. The prescribing physician may request this. The checklist that follows lists the equipment you need in order to attach the sensor array to the patient.

See PillCam User Manual at p. 55.

GI Map

The GI Map provides a graphical representation of the small bowel and colon and shows the progress of the capsule in the in the small bowel/colon. A white dot indicates the estimated position of the current frame being viewed. The passage time appears at the bottom of the image. For PillCam SB videos, an estimate of the percentage of the small bowel viewed appears in the top left corner.

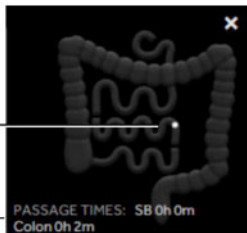


Note

Localization of the capsule is only an estimate. Use of reader defined landmarks may improve this tool. Discretion should be used when relying on the capsule progress indicator and localization tools to make diagnostic or treatment decisions.

Estimated capsule progress

Passage Time

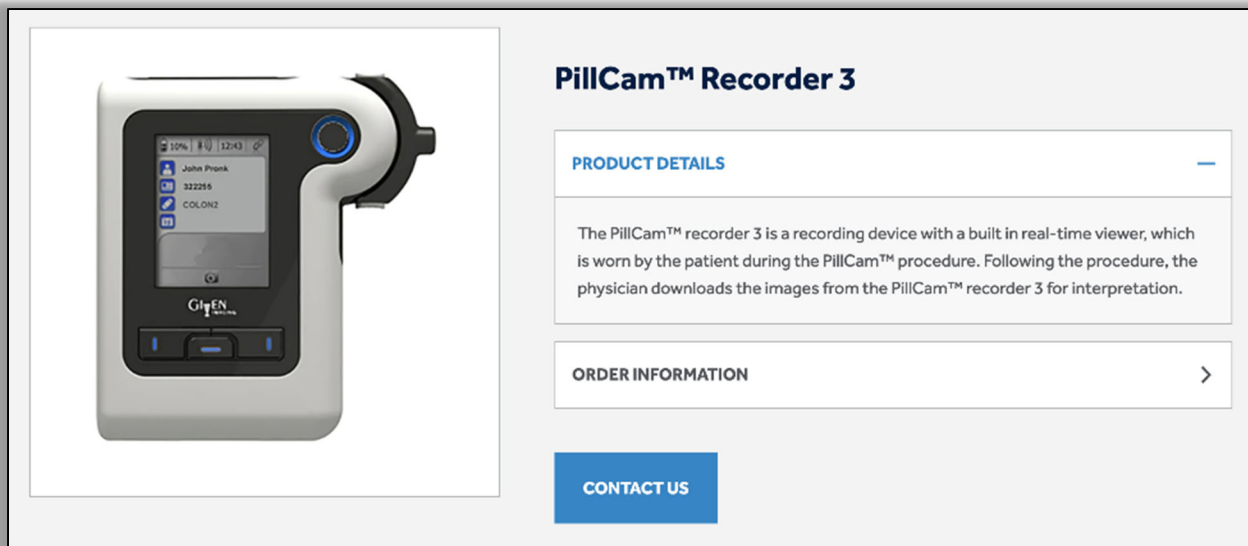


See PillCam User Manual at p. 160; *see also*

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3387769/> (last visited December 13, 2021); *see*

also <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2675082/> (last visited December 13, 2021).

73. Defendants' Infringing Imaging Systems, including PillCam SB Systems, also include a recording and display device where the pose detection system relays tracking information to the recording and display device. *See* PillCam User Manual at p. 7.



PillCam™ Recorder 3

PRODUCT DETAILS —

The PillCam™ recorder 3 is a recording device with a built in real-time viewer, which is worn by the patient during the PillCam™ procedure. Following the procedure, the physician downloads the images from the PillCam™ recorder 3 for interpretation.

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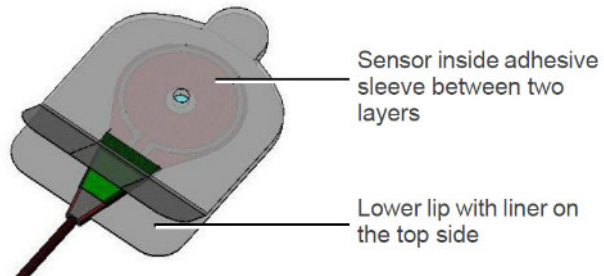
See <https://www.medtronic.com/covidien/en-us/products/capsule-endoscopy/pillcam-sb-3-system.html> (last visited December 13, 2021).

Applying the PillCam Sensor Array

The sensor array allows the PillCam recorder to collect localization data during a procedure. The prescribing physician may request this.

To prepare the sensor array:

1. Insert each sensor into an adhesive sleeve. The sensor markings (dots or **this side up**) should face away from the adhesive side of the sleeve.
2. To secure the sensor in the sleeve, remove the liner from the topside of the lower lip at the opening of the adhesive sleeve and press both lips together.
3. Place the sensors on the patient according to the sensor location guide (see [SB Sensor Locations](#) on page 94).



See PillCam User Manual at p. 92.

Attaching the Sensors to the PillCam Recorder

The PillCam recorder is worn by patients during the procedure in the recorder pouch with the shoulder strap or in the recorder belt with suspenders. Make sure that these accessories fit the patient comfortably.

See PillCam User Manual at p. 95; *see also*

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3387769/> (last visited December 13, 2021); *see also* <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2675082/> (last visited December 13, 2021).

C. Defendants' Willful Infringement

74. Defendants' infringement of the Asserted Patent was knowing, deliberate, and willful. Defendant GII first learned of the Asserted Patent, and their infringement thereof, no later than May 26, 2006. As detailed above, shortly after the Asserted Patent issued, a letter was sent to GII notifying GII of the Asserted Patent's potential relevance to the Accused Products. On information and belief, shortly after this letter was sent, an attorney stating he worked in-house for GII found Dr. Mullick's phone number and called him in response to the letter identifying the Asserted Patent. Accordingly, GII knew of the Asserted Patent on or shortly after May 26, 2006.

75. Defendant GIL, as the corporate parent of GII at the time, was also aware of the Asserted Patent. As noted above, GIL cited the Asserted Patent as a prior art reference in the *inter partes* reexamination of GIL's U.S. Patent No. 7,009,634, which was initiated on September 11, 2012 (Reexamination Control No. 95/002,175). That reexamination concluded in May 2018— and spanned the period when Defendant Covidien acquired Defendant GIL in February 2014 and when Defendant Medtronic acquired Defendant GIL in January 2015. During these reexamination proceedings, GIL's co-founder, Gavriel Iddan, also submitted a declaration identifying Defendants Covidien and Medtronic as being real parties in interest in this reexamination proceeding. These facts further demonstrate that each of the Defendants had the

knowledge and awareness of the Asserted Patent, either directly or indirectly, and that the Accused Products infringed the Asserted Patent.

76. However, Defendants continued to commit acts of direct infringement despite knowing their actions constituted infringement of the valid and enforceable Asserted Patent, despite a risk of infringement that was known or so obvious that it should have been known to Defendants, and/or even though Defendants otherwise knew or should have known that its actions constituted an unjustifiably high risk of infringement of that valid and enforceable patent. Under these circumstances, Defendants' conduct was egregious. Defendants' knowing, deliberate, and willful infringement of the Asserted Patent entitles Microgizzmos to increased damages under 35 U.S.C. § 284.

PRAYER FOR RELIEF

Plaintiff prays for the following relief:

1. A judgment that Defendants have willfully infringed one or more claims of the Asserted Patent;
2. An award of damages adequate to compensate for the infringement, and in no event less than a reasonable royalty for Defendants' acts of infringement, and increased damages from Defendants' willful infringement, in accordance with 35 U.S.C. § 284;
3. A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to Plaintiff its reasonable attorneys' fees against Defendants.
4. A judgment and order requiring Defendants to provide accountings and to pay supplemental damages to Plaintiff, including, without limitation, prejudgment and post-judgment interest; and
5. Any and all other relief to which Plaintiff may show itself to be entitled.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury of all issues so triable.

Dated: December 23, 2021

Respectfully submitted,

OF COUNSEL:

FARNAN LLP

Paul J. Skiermont
Steven W. Hartsell
Sheetal S. Patel
Kevin P. Potere
SKIERMONT DERBY LLP
1601 Elm St. Ste. 4400
Dallas, TX 75201
(214) 978-6600
pskiermont@skiermontderby.com
shartsell@skiermontderby.com
spatel@skiermontderby.com
kpotere@skiermontderby.com

/s/ Michael J. Farnan
Brian E. Farnan (Bar No. 4089)
Michael J. Farnan (Bar No. 5165)
919 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 777-0300
bfarnan@farnanlaw.com
mfarnan@farnanlaw.com

Attorneys for Plaintiff
Microgizzmos, LLC

Charles C. Koole
SKIERMONT DERBY LLP
800 Wilshire Blvd., Ste. 1450
Los Angeles, CA 90017
Phone: (213) 788-4500
Fax: (213)788-4545
ckoole@skiermontderby.com