

Medtronic

PillCam™ Genius SB kit

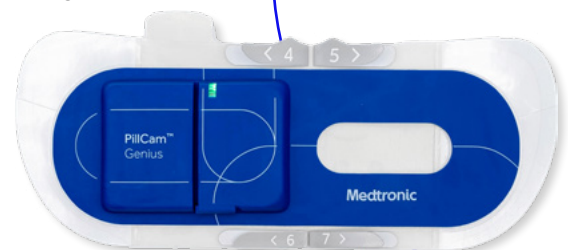
The link to the future of capsule endoscopy

PillCam™ Genius SB is a limitless solution that increases flexibility & introduces more freedom to PillCam™, the trusted partner in capsule endoscopy.

Designed to streamline procedures – our single-use capsule and link device enable ingestion from the comfort of your own home, during telehealth appointments and can be simply returned in-person or by mail.¹ The PillCam™ Genius SB kit brings a new freedom for physicians and patients by being able to perform capsule endoscopy when it is needed most.



PillCam™ Genius
SB kit



PillCam™ Genius
SB link device

Introducing the link device

Discover flexibility in your capsule endoscopy practice

The single-use PillCam™ Genius SB kit removes the burden of capsule management. With the introduction of the link device, no longer will urgent cases interrupt scheduled capsule procedures because of hardware constraints.

With the PillCam™ Genius SB kit, you are always ready for the next patient.

Enhancing capsule endoscopy experience

PillCam™ Genius link device is a single-use device intended for storing images received from the PillCam™ Genius SB capsule, sending commands to the PillCam™ Genius SB capsule and providing notifications to the patient while adhered to the patient's body.¹



Enables

- ✓ Procedural flexibility
- ✓ Increased procedure capacity
- ✓ Increased patient access
- ✓ At-home ingestions via telehealth
- ✓ Comfortable discrete procedures for patients

Without

- ✗ Upfront capital purchase
- ✗ Charging or sanitizing recorders
- ✗ Interrupting scheduled patients for urgent procedures
- ✗ Bulky wearables for the patient
- ✗ Future procedures relying on patients returning the recorder

Healthcare is on the move, and capsule endoscopy is no different

Since the COVID-19 pandemic, patients expect flexibility in where and how they receive care. The PillCam™ Genius SB kit allows new flexibility to capsule endoscopy by making both the traditional facility-based ingestion and the at-home ingestion convenient. The design of the kit and link device is purpose-built to facilitate at-home ingestions during a telehealth appointment for the appropriate patient.¹



How does at-home ingestion work?

1. Patients are given a kit during an in-office consultation.
2. Schedule a telehealth appointment for the ingestion.
3. During the telehealth visit, the patient is guided through the link device application. Numbered pull tabs streamline the link device application to the patients lower abdomen.
4. The patient wears the link device throughout the duration of the procedure. The patient will be alerted by the link device's haptics and sounds that the procedure is over.
5. The link device is removed by the patient and returned to the physician's office in-person or via mail, using the envelope in the kit (postage not included).

How do patients feel about the at home capsule ingestions?

- A recent study of 105 patients from the United Kingdom found that **100%** of patients were able to successfully swallow the capsule at home.²
- Over **80%** of patients would elect to repeat the procedure at home.²





Each PillCam™ Genius SB kit contains one pre-paired Genius SB capsule and link device.¹



The Real Time Viewer application (RTV) allows providers to use an iPad to view up to thirty minutes of the study in real-time in two minute increments, while the patient is in the clinic.¹



During the procedure setup process, a 2D barcode scanner is used to enter the kit's information into the PillCam™ Genius Sync Agent.¹ Facilities can choose to use an existing barcode scanner or opt to purchase one from Medtronic.

The PillCam™ Genius SB capsule endoscopy system consists of the following components:

Item	Item number	Count
PillCam™ Genius SB capsule endoscopy kit	FGS-0688	1 Kit (ea)
	FGS-0689	5 Kits (ea)
PillCam™ desktop software v9.7	FGS-0802 (US)	1 License
PillCam™ desktop software v9.7, upgrade	FGS-0803 (US)	1 License
Data cable	FGS-0504	2 Units (ea)
Barcode scanner	FGS-0808	1 Unit (ea)
Genius sync agent, off-line	FGS-0806	1 Unit (ea)

References

- 1. PillCam™ Genius SB System User Manual. PT00183137. November 2023.
- 2. Parisi I, Hosea AV, Stoffel S, et al Evaluation of the safety, efficacy and feasibility of 'at-home' capsule endoscopy *Frontline Gastroenterology* Published Online First: 26 February 2024. doi: 10.1136/flgastro-2023-102565

Adverse Events: Potential adverse events associated with the use of this device may include delayed or no excretion of the PillCam™ Genius SB capsule, aspiration, obstruction, perforation, and mucosal injury or bleeding. In some instances, intervention is required to remove the PillCam™ Genius SB capsule. Additional adverse events can include skin reactions to the PillCam™ Genius link device adhesive.

Please refer to the PillCam™ Genius SB System User Manual for further information.

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