

Quick reference guide

Reading a PillCam™ Crohn's Study in PillCam™ Software v9

Home screen

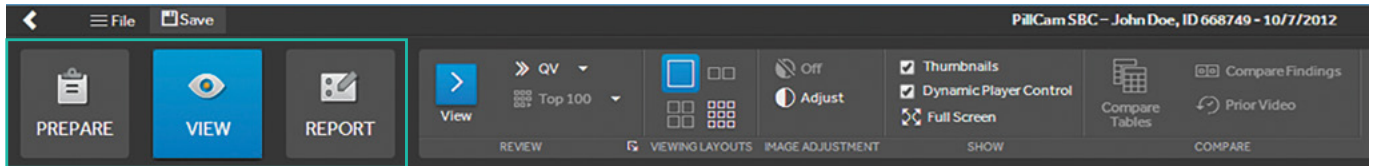
1. Open PillCam™ desktop software v9. From the home screen, click on **View Study**.



To open a video, click on **Study Manager**, **Open Video**, or **Recent Videos**.

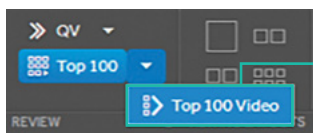
New toolbar

2. The new PillCam™ software v9 ribbon has three tabs: Prepare, View, and Report.

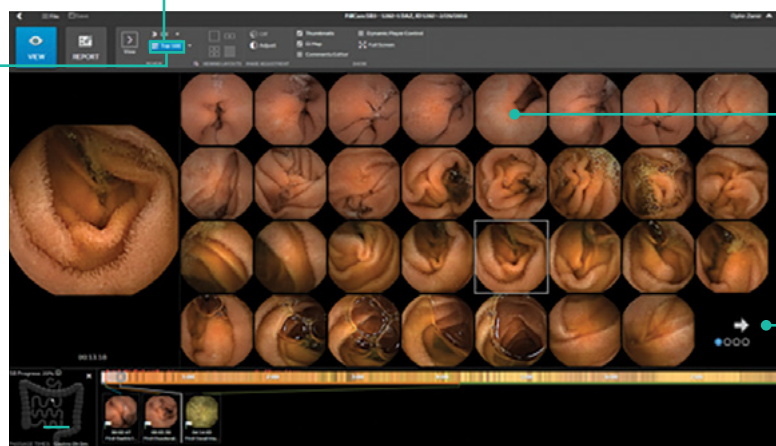


New feature: Top 100

3. The Top 100 features the 100 most clinically relevant images in a PillCam™ Crohn's study, focused on frames containing lesions and bleeding.



Images can be displayed as a short video.



Images can be displayed as a page view.

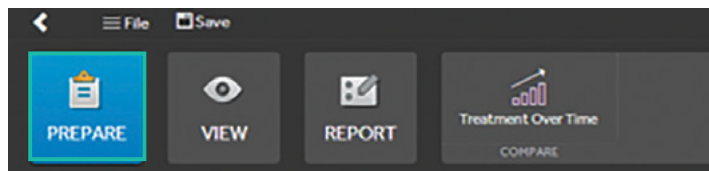
Scroll to see the rest of images.

Red marks above the time bar show the Top 100 images.



Prepare Screen

1. Open PillCam™ Desktop Software v9.
From the home screen, click on View Study.
The study will open in the Prepare Screen.



Key Features

2. The Prepare Screen allows you to review patient history, previous study findings, and previous summaries and recommendations. The prior study selected will be available for comparison throughout the review and report phases.

Select prior study

Patient information (read only)

Enter reason for referral

View/edit current medications

Proceed to Video View

Prior Study GI Table and GI Map

Overview of prior study's GI Table and GI Map, showing quantitative assessment by segment in the small bowel and colon. Provides baseline for comparison to current study.

SEGMENT	MSL	MCL	EXTENT %	IMAGES
SB I	2	1	10 - 30	
SB II	1	1	0 - 10	
SB III	2	2	30 - 60	
Colon	3	1	10 - 30	

SUB SEGMENTS			
Duo.	Not Involved	TI	Involved
R. Colon	Involved	L. Colon	Involved



Prior Study Information

Prior study's reason for referral, procedure information and findings, and summary and recommendations. Allows for quick review of patient history.

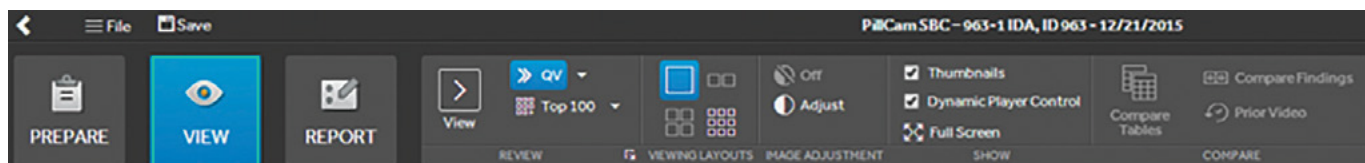
REASON FOR REFERRAL:
Long-standing CD patient with recent re-flare of disease.
Base-line assessment of mucosal status due to newly initiated biological therapy.

PROCEDURE INFORMATION AND FINDINGS:
Mild to moderate involvement of the SB, with duodenal involvement and TI involvement. Severe disease in the distal left colon.

SUMMARY AND RECOMMENDATIONS:
Diffuse disease involvement of the SB and colon. Continue biological therapy with re-assessment of mucosal responsiveness in 1 year.

View Screen

1. Click on View Study from ribbon or from Prepare tab.
2. The View Screen is for full study review, including segmentation of the small bowel and colon and assessment of disease activity in the GI Table and Map.



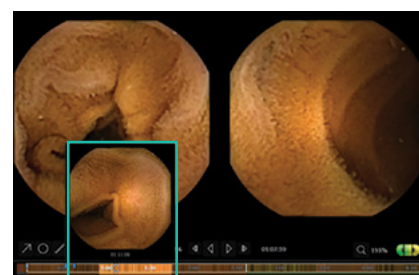
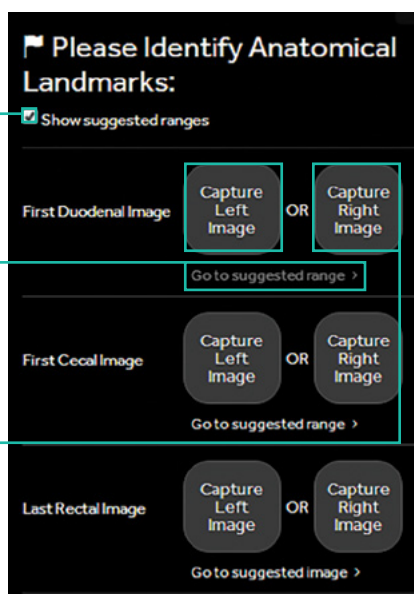
Segmentation

To segment the small bowel and colon, mark the first duodenal, first cecal, and last rectal landmarks.

New auto-suggested range feature provides time range where landmark most likely exists (check to enable).

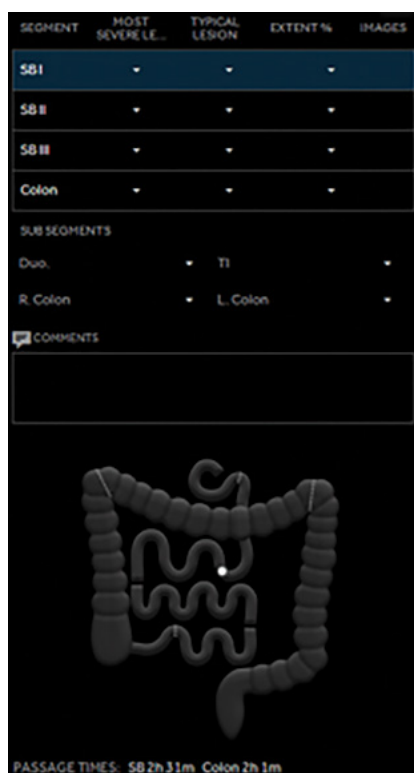
Go to the suggested range and scroll to search for landmark manually.

Capture left or right image as First Duodenal Landmark and repeat sequence for First Cecal and Last Rectal landmarks.

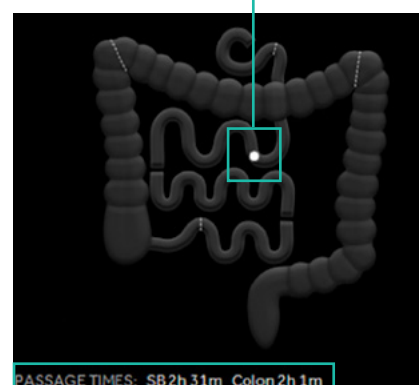


Tip: Hover over time bar to see preview of images to assist in landmarking.

Once all landmarks have been identified, segmentation is complete and the GI Table and GI Map is displayed.



Capsule progress displayed as a dot on the map.



Passage time for the small bowel and colon is automatically calculated.

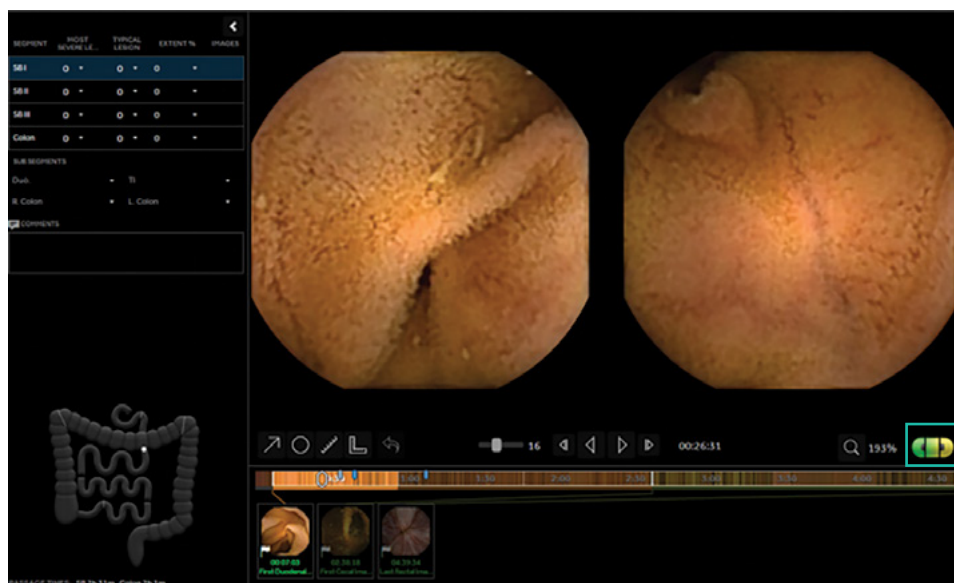
View Screen

Disease Evaluation

After segmentation, each segment should be reviewed to assess disease activity for three parameters.

- **Most Severe Lesion (MSL)** – Most severe lesion in segment.
- **Most Common Lesion (MCL)** – Most common lesion severity in segment.
- **Extent %** - The extent of disease in segment.

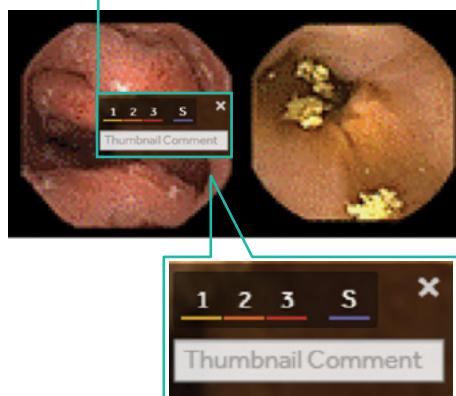
SEGMENT	MOST SEVERE LE...	TYPICAL LESION	EXTENT %	IMAGES
SB I	1	1	10 - 30	
SB II	2	1	0 - 10	
SB III	2	2	30 - 60	
Colon	3	3	60 - 100	



Start at the first duodenal image and begin review of the study using both heads of the capsule at once.

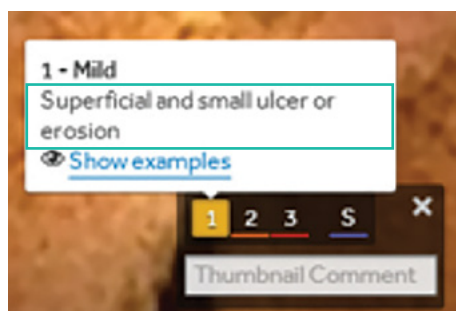


When you see a lesion, click on image in the center of the screen to stop video. Click once more on the image to enable the severity ruler.



The severity ruler allows you to grade the severity of the lesion as:

1. Mild
2. Moderate
3. Severe
- S - Stricture



A mini atlas is available to show images classified as mild, moderate, and severe. Access by clicking on severity grade (1,2,3 or S) and then **Show Examples**.

View Screen

Disease Evaluation

Continue reviewing the segment, only capturing and grading lesions of escalating severity. The **Most Severe Lesion** that you grade will automatically populate to the GI Table.

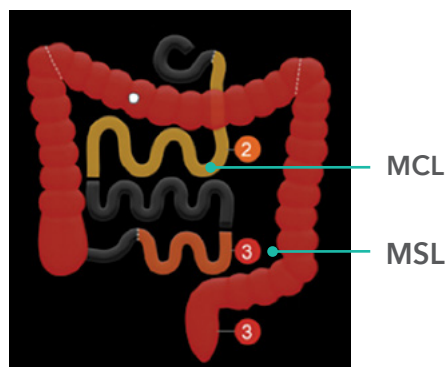
At the end of the segment, assess the **Most Common Lesion** (most common lesion type within the segment) and **Extent %** of the segment with disease activity. Repeat for each segment.

SEGMENT	MOST SEVERE LE...	TYPICAL LESION	EXTENT %	IMAGES
SBI	2	1	0 - 10	
SBII	0	0	0	
SBIII	3	2	10 - 30	
Colon	3	3	60 - 100	
SUB SEGMENTS				
Duo.	Not Involved	TI	Not Involved	
R. Colon	Involved	L. Colon	Involved	

Mark each sub-segment (duodenum, terminal ileum, right colon and left colon), as involved or not involved.

The Most Severe Lesion (MSL) and Most Common Lesion (MCL) are graphically represented on the GI Map.

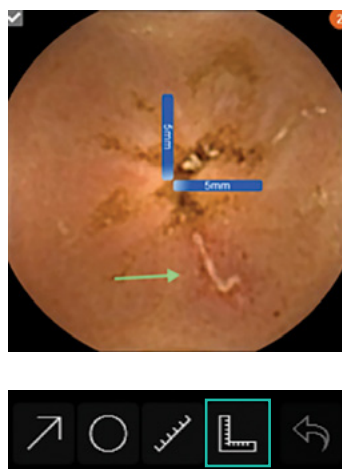
- **MSL** - displayed as a circle with the severity grade in the middle, next to each segment
- **MCL** - displayed as color of the entire segment.



Ulcer Size Estimation (USE)

Tool to estimate size of ulcer based on 5 mm scale.

The size of the ruler lines change visually based on the capsule's depth of view, however the ruler measures a constant 5 mm length.

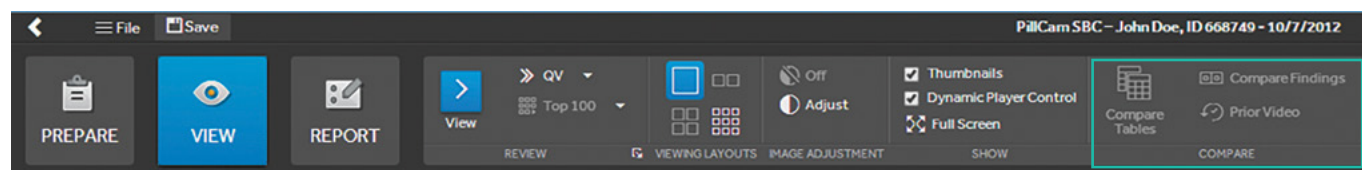


Select USE icon from markings bar.

View Screen

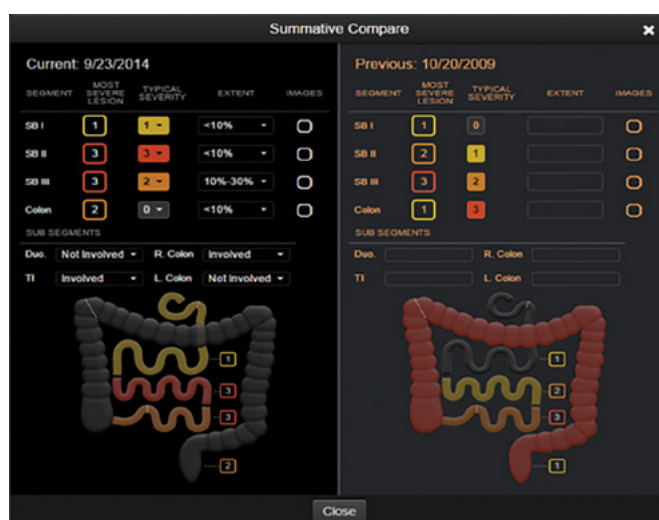
Comparison Modes

Comparison modes are available to assess disease progression by segment over time. The study for comparison is selected in the Prepare Screen.



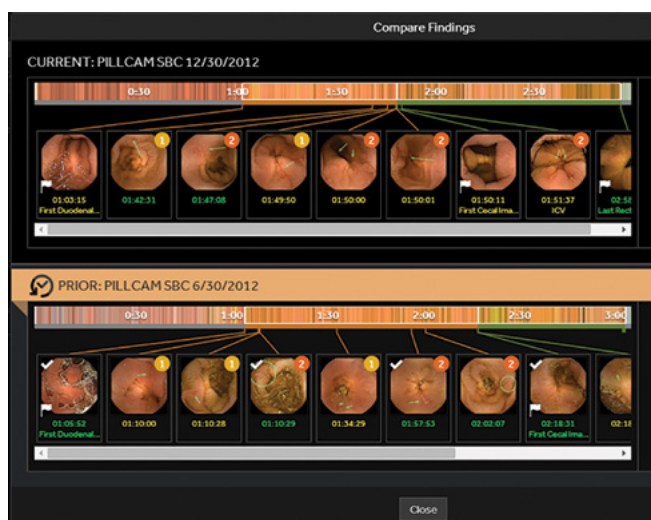
Compare Tables

Compare current and prior GI Table and Map.



Compare Findings

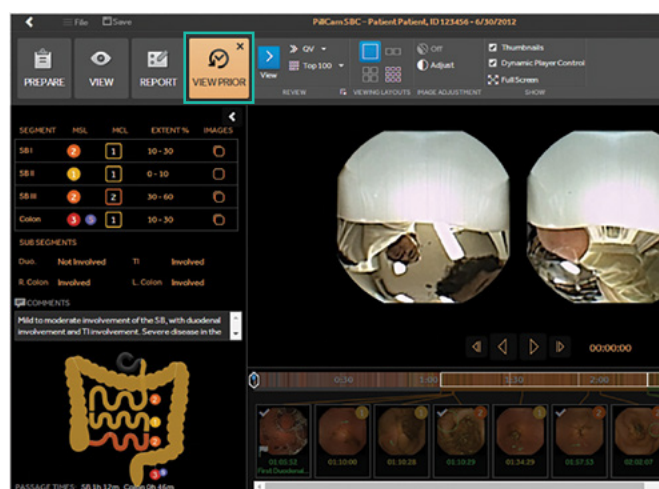
Compare current and prior findings.



Compare Prior Video

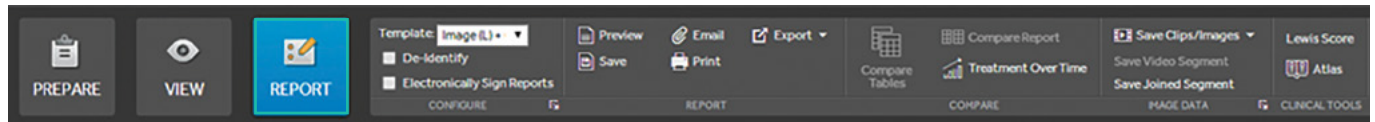
View prior study video as a secondary tab within the study.

Note: This study is "view only" so you cannot edit the findings (e.g. capture or delete thumbnails, etc.).



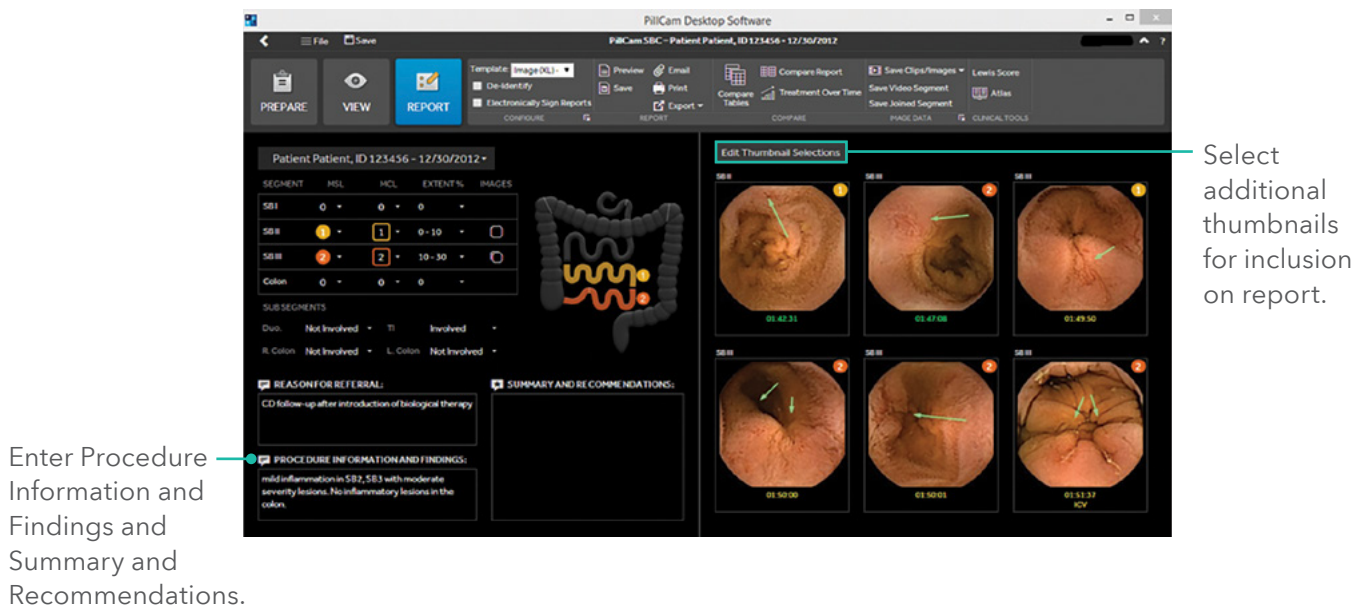
Report Screen

1. After reviewing the study under View, select the Report icon to create report.



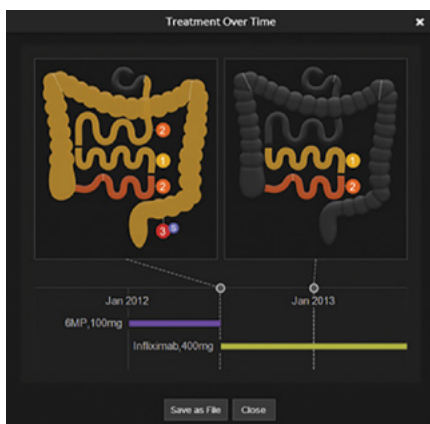
Key Features

2. Report Screen is pre-populated with findings from GI Table and Map. The thumbnails marked as the Most Severe Lesion in each segment are automatically selected for inclusion in the report.



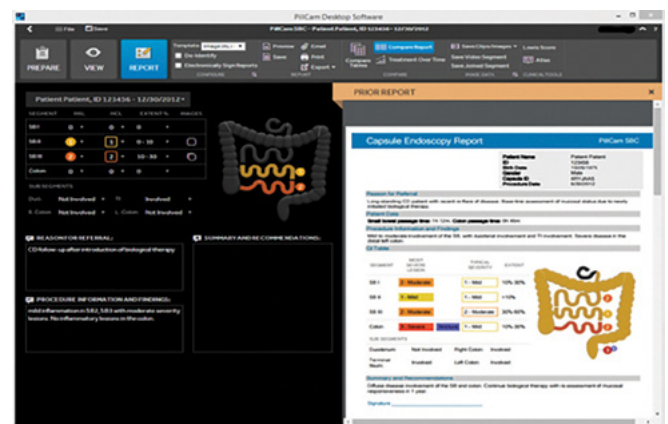
Treatment Over Time

Select in Report ribbon - Provides comparison of GI Maps with medication history to assess treatment effectiveness by segment.



Compare Report

Select in Report ribbon - Compare current vs prior report summary.





Visit
medtronic.com/covidien/uk
for more information

Risk Information: The risks of the PillCam™ Crohn's system include capsule retention, aspiration, and skin irritation. The risks associated with colon preparation are allergies or other known contraindications to any preparation agents or medications used for the PillCam™ Crohn's regimen, according to laxative medication labeling and per physician discretion. Medical, endoscopic, or surgical intervention may be necessary to address any of these complications, should they occur. After ingesting the PillCam™ Crohn's 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. Please refer to the product user manual or pillcamcrohncapsule.eu for detailed information.

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