Demonstrated Accuracy\textsuperscript{1-3}

The PillCam™ COLON 2 system provides \textit{thorough, accurate visualization} of the colon and detects a large number of polyps.

\begin{figure}
\centering
\includegraphics[width=\textwidth]{chart.png}
\caption{Number of Patients with Polyps Identified\textsuperscript{1-3}}
\end{figure}

### Diagnostic Yield\textsuperscript{4}

In one study, the PillCam™ COLON 2 system \textbf{identified significant polyps in 24 patients} after incomplete colonoscopy, while CT Colonography identified polyps in 12 patients from that same group.\textsuperscript{2*}

\* Total sample of 98 patients. True positives as verified by follow-up colonoscopy. Each modality had one false positive. Out of 24 patients with significant polyps, the PillCam™ COLON 2 system correctly identified each of them.
PILLCAM™ COLON 2 SYSTEM

Clinical Findings

Performance Summary

In four clinical trials, colon capsule endoscopy after incomplete colonoscopy yielded the following results.4-7

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Polyp Yield</th>
<th>Significant Polyp Yield</th>
<th>OC + CE Completion</th>
<th>Colon Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spada4</td>
<td>97</td>
<td>53%</td>
<td>25%</td>
<td>98%</td>
<td>0</td>
</tr>
<tr>
<td>Baltes5</td>
<td>74</td>
<td>49%</td>
<td>28%</td>
<td>95%</td>
<td>1</td>
</tr>
<tr>
<td>Nogales6</td>
<td>96</td>
<td>45%</td>
<td>NR</td>
<td>93%</td>
<td>2</td>
</tr>
<tr>
<td>Negreanu7</td>
<td>30/67</td>
<td>36%</td>
<td>31%</td>
<td>NR</td>
<td>2</td>
</tr>
</tbody>
</table>

For more information, please contact your Medtronic sales representative and visit pillcamcolon.com

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. Rx only.

Indications for Use: The PillCam™ COLON 2 capsule endoscopy system is intended to provide visualization of the colon. It may be used for detection of colon polyps in patients after an incomplete optical colonoscopy with adequate preparation, and a complete evaluation of the colon was not technically possible.

In addition, it is intended for detection of colon polyps in patients with evidence of gastrointestinal bleeding of lower GI origin. This applies only to patients with major risks for colonoscopy or moderate sedation, but who could tolerate colonoscopy and moderate sedation in the event a clinically significant colon abnormality was identified on capsule endoscopy.

Risk Information: The risks of the PillCam™ COLON 2 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™ COLON 2 system 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™ COLON 2 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. A normal or negative capsule endoscopy examination does not exclude the possibility of colon polyps or colon cancer. Please refer to the product user manual or medtronic.com/gi for detailed information.

References:

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