G-EYE™ endoscopes
The smart innovation in enhancing detection capabilities
## PENTAX Medical GI integrated offer
### Along the clinical pathway

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<th>Detection</th>
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<th>Verification/Confirmation</th>
<th>Therapy</th>
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<td>NaviAid™ AB</td>
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<tr>
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<td>i10 series</td>
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<tr>
<td>G-EYE™</td>
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</tbody>
</table>

### Clinical Background
- G-EYE™
- i10 series
- RetroView
- MagniView
- EM
- WavSTAT4
- EUS

### Positioning
- Product
- Clinical Application
- Technical Details
- Summary
- Services
»The biggest diagnostic challenge in colonoscopy is to improve dysplasia detection and **reduce the miss rate** in detection of polyps and adenomas to prevent colorectal cancer (CRC), especially in the proximal colon.

Detected lesions need to be carefully characterized for a successful therapy.«
Main Challenge
Early detection

Cancer deaths worldwide

Colorectal malignancies is one of the leading causes of cancer-related deaths in the world. The early detection and timely removal of preneoplasms has been demonstrated to significantly improve patient survival.

Main Opportunities
Advanced detection and therapy

The **proximal colon** has a higher prevalence of harder to distinguish adenomas, flat or serrated lesions. In addition, these lesions are commonly located on or behind a mucosal fold making them **harder to detect** with standard endoscope.

**G-EYE™, HD+ colonoscopes** has been developed to **enhance detection capabilities** by **straightening intestinal folds** and **smoothening colon topography**.
Main Opportunities
G-EYE™ Colonoscopy – What for?
Our Promise
G-EYE™ endoscopes

Advanced detection in an HD+ G-EYE™ endoscope to increase the endoscopic findings, some initial studies show 56% higher Adenoma Detection Rate (more than double ADR) and up to 81% additional detection rate, (incremental adenoma find rate) with G-EYE™ endoscope.*

* Adenoma Detection Rate relative to standard colonoscope, the results of two tandem studies
Key Benefits

Features

- Constant leakage testing
- Improved HD+ image quality
- Improved visualization
- Unique controlled withdrawal™
- Easy operation
- Enhancing detection capabilities
- Stabilization during intervention

G-EYE38-i10 & G-EYE34-i10F

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### Key Benefits
**G-EYE™ endoscopes (1/2)**

<table>
<thead>
<tr>
<th>1. Enhancing detection capabilities</th>
<th>Straightening intestinal folds and smoothening colon topography to find the adenomatous lesions hiding behind or between the folds.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Improved HD+ image quality</td>
<td>Next generation megapixel CCD for improved HD+ image quality. Crisp, clear and bright endoscopic image combined with exceptional field of view for a superior visualisation of the mucosa.</td>
</tr>
<tr>
<td>3. Improved visualization</td>
<td>Centralizing endoscope optics in combination with HD+ and i-scan improves visualisation-</td>
</tr>
<tr>
<td>4. Unique Controlled Withdrawal™</td>
<td>Eliminating bowel slippage with Unique Controlled Withdrawal™</td>
</tr>
</tbody>
</table>
### Key Benefits

**G-EYE™ endoscopes (2 / 2)**

<table>
<thead>
<tr>
<th></th>
<th>Stabilization during intervention</th>
<th>Colonoscope’s stabilization during intervention results in a <strong>faster and more controlled intervention</strong>.</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Constant leakage testing</td>
<td>Spark2C air supply unit ensures constant monitoring and leak testing <strong>before and during the entire</strong> procedure.</td>
</tr>
<tr>
<td>6</td>
<td>Easy operation</td>
<td>G-EYE™ endoscope has a <strong>permanently integrated reusable balloon</strong> and Spark2C unit is easy and intuitive to use.</td>
</tr>
</tbody>
</table>
Product overview
For best clinical results

G-EYE™ endoscopes are compatible with

- G-EYE 38-i10F / F2 / L
- Spark 2C
- G-EYE 34-i10F
- EPK-i5000
- EPK-i7000
Clinical Application
Detect and characterise

Procedure related
- Enhanced visualization of the mucosa behind folds by withdrawing the endoscope with G-EYE™ balloon partially inflated
- Stabilization during intervention
- The option of slim insertion tube of G-EYE™ scope
- Rapid visualization of the deep small bowel in push-and-pull technique with AB on demand dispoble

Patient related
- Patient undergoing screening or surveillance colonoscopy for colorectal cancer
- Patient with smaller polyps and flat lesions
- Polypectomy at difficult localizations like the right flexure
- Patient with difficult sigmoid colon, small patient (female gender) and redundant colon
- Patients with Irritable Bowel or Crohn’s Disease
Clinical Application
Detect and define

Enhance your endoscopic options with HD+ and i-scans setting

HD+
Flat lesion
- Fast detection with significant improvement in the visibility and evaluation of minute lesions
- Integrated zoom function for more detailed inspection

i-scan
Surface Enhancement
- i-scan SE retains the natural colour tones
- Accentuation of tissue structures
- Mucosal enhancement potentially supports the detection of flat lesions

i-scan
Tone Enhancement
- Allows more accentuated display of mucosal structures which may support lesion characterization
- Virtual chromoendoscopy may help to improve endoscopic diagnosis
G-EYE™ has the potential to strongly improve diagnostic outcomes of patients undergoing screening or surveillance colonoscopy for colorectal cancer by increasing the adenoma detection rate. Besides, G-EYE™ allows superior stabilization of the endoscope even at difficult localizations like the right flexure for optimized endoscopic therapy. Moreover, in combination with the newly introduced NaviAid™ AB system, G-EYE™ would allow rapid visualization of the deep small bowel in push-and-pull technique. Therefore, G-EYE™ has the potential to revolutionize our current approach of endoscopic diagnosis and therapy.

Prof. Neumann
University of Erlangen-Nuremberg, Germany

» My initial experience with using the G-EYE™ is very positive, it allows controlled withdrawal and is easy to use. I was able to detect more flat lesions with it. In addition it also helped to stabilise the scope tip to carry out complex polypectomy.«

Dr. Ishaq
Russells Hall Hospital, Dudley, UK

» My initial experience with using G-EYE™ is very positive, it allows controlled withdrawal and is easy to use. I was able to detect more flat lesions with it. In addition it also helped to stabilise the scope tip to carry out complex polypectomy.«

Prof. Gralnek
Rambam Medical Center, Haifa, Israel
Pilot Study
G-EYE™ colonoscopy

Study design: Safety & effectiveness; Single-center; 50 patients

Results:
- G-EYE™ endoscope is safe
- Device is easy to use
- While balloon is deflated – no change in endoscope handling
- Insertion / withdrawal times – similar to standard colonoscopy
- Detection rates – approximately 100% higher than published literature for standard colonoscopy
Adenoma/Polyp Detection Rate
G-EYE colonoscopy vs. Standard colonoscopy

- Standard Colonoscopy:
  - ADR: 21.0%
  - PDR: 30.4%

- G-EYE Colonoscopy:
  - ADR: 44.0%
  - PDR: 55.3%
Study design: Tandem (back-to-back); Randomized; Multi-center (Israel & Europe); 126 patients

Results:
- 81% additional adenoma detection
- 8% miss rate
- 56% higher Adenoma Detection Rate

<table>
<thead>
<tr>
<th>Adenomas</th>
<th>Group A (Standard 1st)</th>
<th>Group B (G-EYE™ 1st)</th>
</tr>
</thead>
<tbody>
<tr>
<td>First pass</td>
<td>21</td>
<td>37</td>
</tr>
<tr>
<td>Second pass</td>
<td>17</td>
<td>3</td>
</tr>
<tr>
<td>Additional detection (%)</td>
<td>81%</td>
<td>8.1%</td>
</tr>
<tr>
<td>Adenoma Detection rate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADR (%)</td>
<td>25.9%</td>
<td>40.4%</td>
</tr>
</tbody>
</table>
Probability of missing an adenoma found to be 10 times higher (!) when using standard colonoscope vs. G-EYE™ colonoscope
G-EYE™ detected at least one adenoma in 50% more patients
# G-EYE™ HD+ Video Endoscopes
## Specifications (1 / 2)

<table>
<thead>
<tr>
<th>Spec</th>
<th>G-EYE38-i10L/F</th>
<th>G-EYE38-i10F2</th>
<th>G-EYE34-i10F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Field of view (°)</td>
<td>140</td>
<td>140</td>
<td>140</td>
</tr>
<tr>
<td>Ø Insertion tube (mm)</td>
<td>13.2</td>
<td>13.2</td>
<td>11.6</td>
</tr>
<tr>
<td>Ø Distal end (mm)</td>
<td>13.2</td>
<td>13.2</td>
<td>11.5</td>
</tr>
<tr>
<td>Ø Instrument channel (mm)</td>
<td>3.8</td>
<td>3.8</td>
<td>3.8</td>
</tr>
<tr>
<td>Working length (mm)</td>
<td>1,700 / 1,500</td>
<td>1,500</td>
<td>1,500</td>
</tr>
</tbody>
</table>

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- **Clinical Background**
- **Positioning**
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- **Services**
## G-EYE™ HD+ Video Endoscopes

### Specifications (2 / 2)

<table>
<thead>
<tr>
<th>Specs</th>
<th>G-EYE38-i10L/F</th>
<th>G-EYE38-i10F2</th>
<th>G-EYE34-i10F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tip deflection (°)</td>
<td>Up / Down 180 – 180</td>
<td>Right / Left 160 – 160</td>
<td>Up to 60 Up to 60</td>
</tr>
<tr>
<td></td>
<td>integrated reusable balloon</td>
<td>rigidity, permanently</td>
<td>integrated reusable balloon</td>
</tr>
<tr>
<td>Inflated balloon diameter (mm)</td>
<td>Up to 60</td>
<td>integrated reusable balloon</td>
<td></td>
</tr>
<tr>
<td>Remarks</td>
<td></td>
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</table>
# Spark 2 C (Air Supply unit)

## Specifications

<table>
<thead>
<tr>
<th>Specs</th>
<th>Spark 2C</th>
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<tbody>
<tr>
<td>Electrical input (VAC)</td>
<td>100 – 240</td>
</tr>
<tr>
<td>Electrical input frequency (Hz)</td>
<td>50 – 60</td>
</tr>
<tr>
<td>Dimensions (mm)</td>
<td>280 × 95 × 90</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>1.9</td>
</tr>
<tr>
<td>Set pressure tolerance (mbar)</td>
<td>± 10</td>
</tr>
<tr>
<td>Inflated balloon setup pressure (mbar)</td>
<td>Anchoring pressure 70, controlled withdrawal™ pressure 3 intermediate levels</td>
</tr>
</tbody>
</table>
Summary

G-EYE™ endoscopes at a glance

- Advanced detection in an HD+ G-EYE endoscope to increase the endoscopic findings.
- Advanced Therapy

G-EYE38-i10

- Constant monitoring and leak testing before and during the entire procedure
- Controlled withdrawal™

Spark 2C

- Advanced detection in combination with close focus and HD+ image in a slim scope with expanded therapeutic option.
- Advanced Therapy

G-EYE34-i10F

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