G-EYE™ endoscopes

The smart innovation in enhancing detection capabilities

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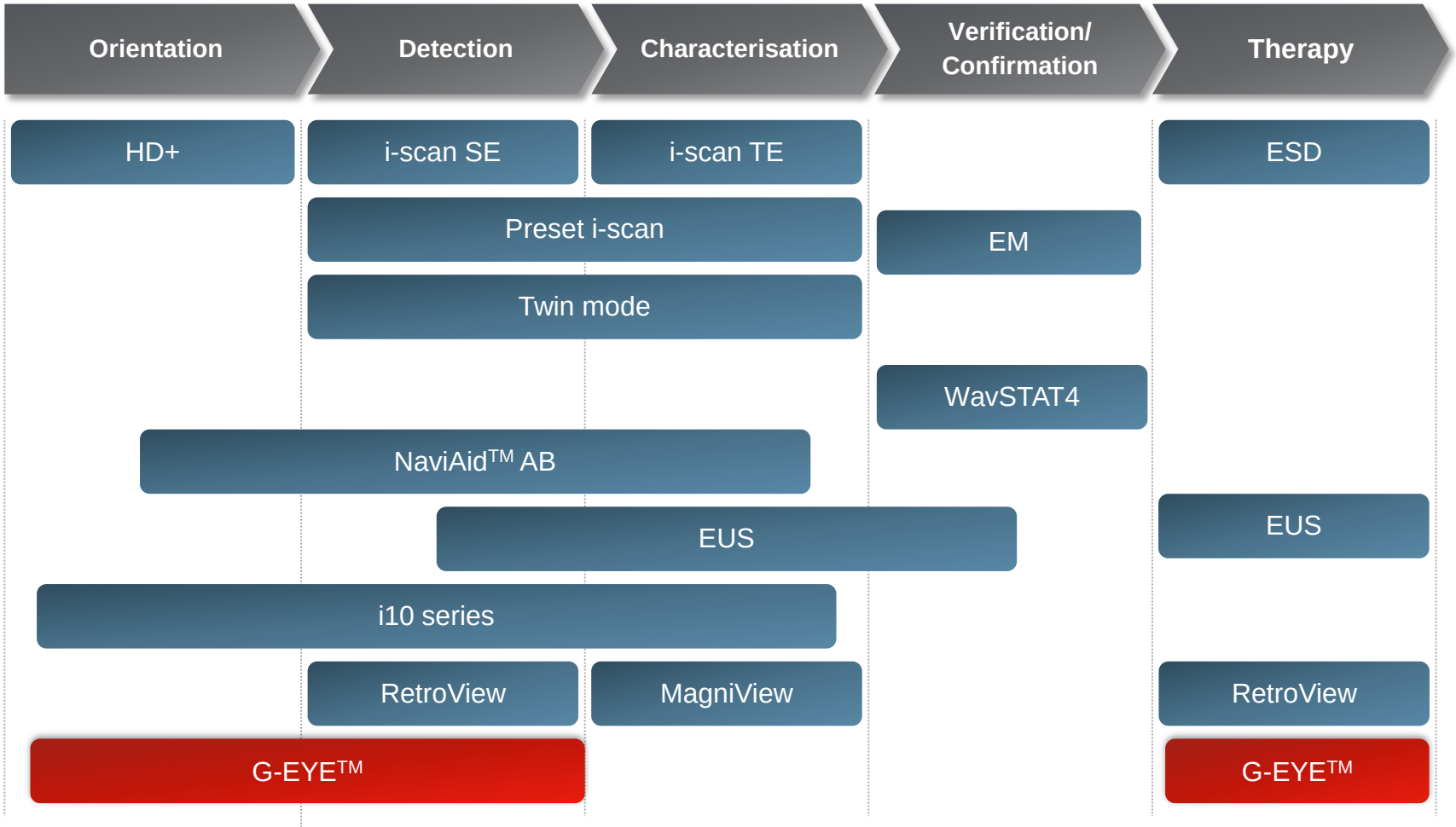
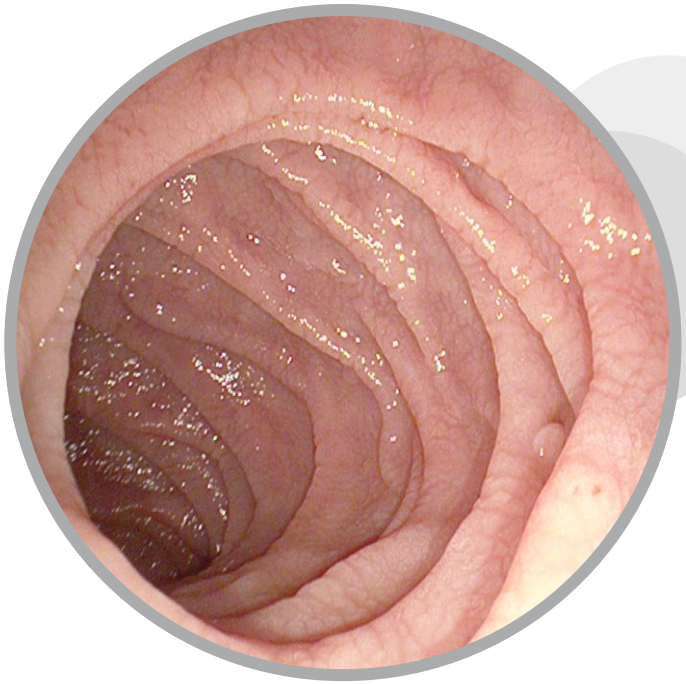
Excellence in Focus

PENTAX Medical GI integrated offer
Along the clinical pathway



Main Challenge
In colonoscopy

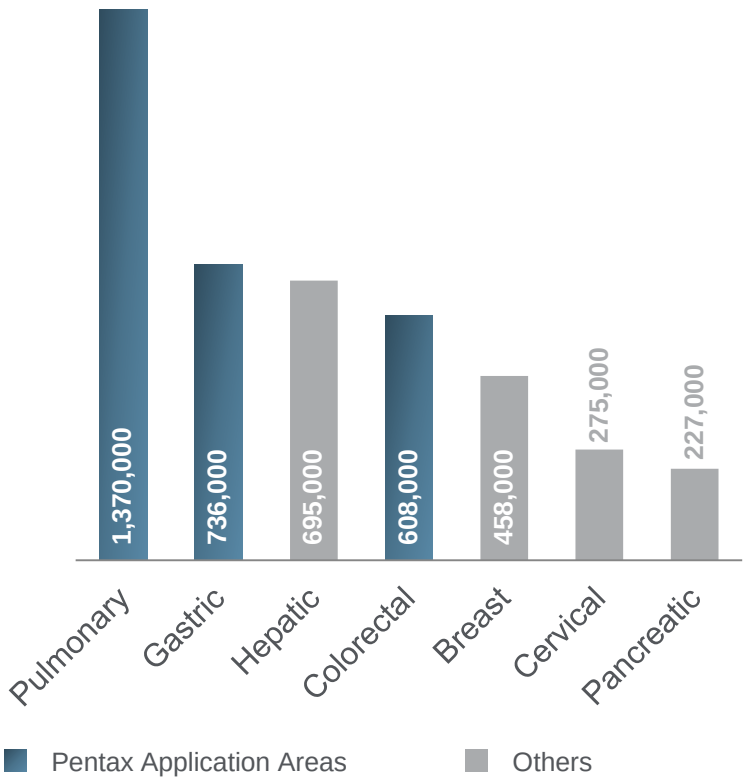


»The biggest diagnostic challenge in colonoscopy is to improve dysplasia detection and **reduce the miss rate** in detection of polyps and adenomas to prevent colorectal cancer (CRC), especially in the proximal colon.

Detected lesions need to be carefully characterized for a successful therapy.«

Main Challenge
Early detection

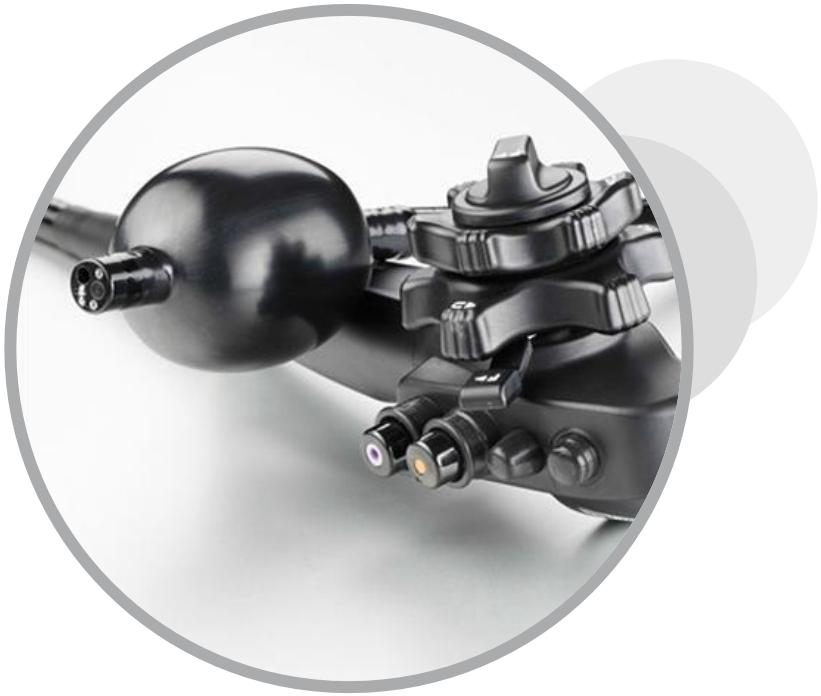
Cancer deaths worldwide



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.**

Source: Leonardo Sosa Valencia and Erika Rodriguez-Wulff: “Topics in Prevention of Diseases in Gastroenterology”; In: Alfonso J. Rodriguez-Morales: Current Topics in Public Health (2008), P. 423.

Main Opportunities
Advanced detection and therapy

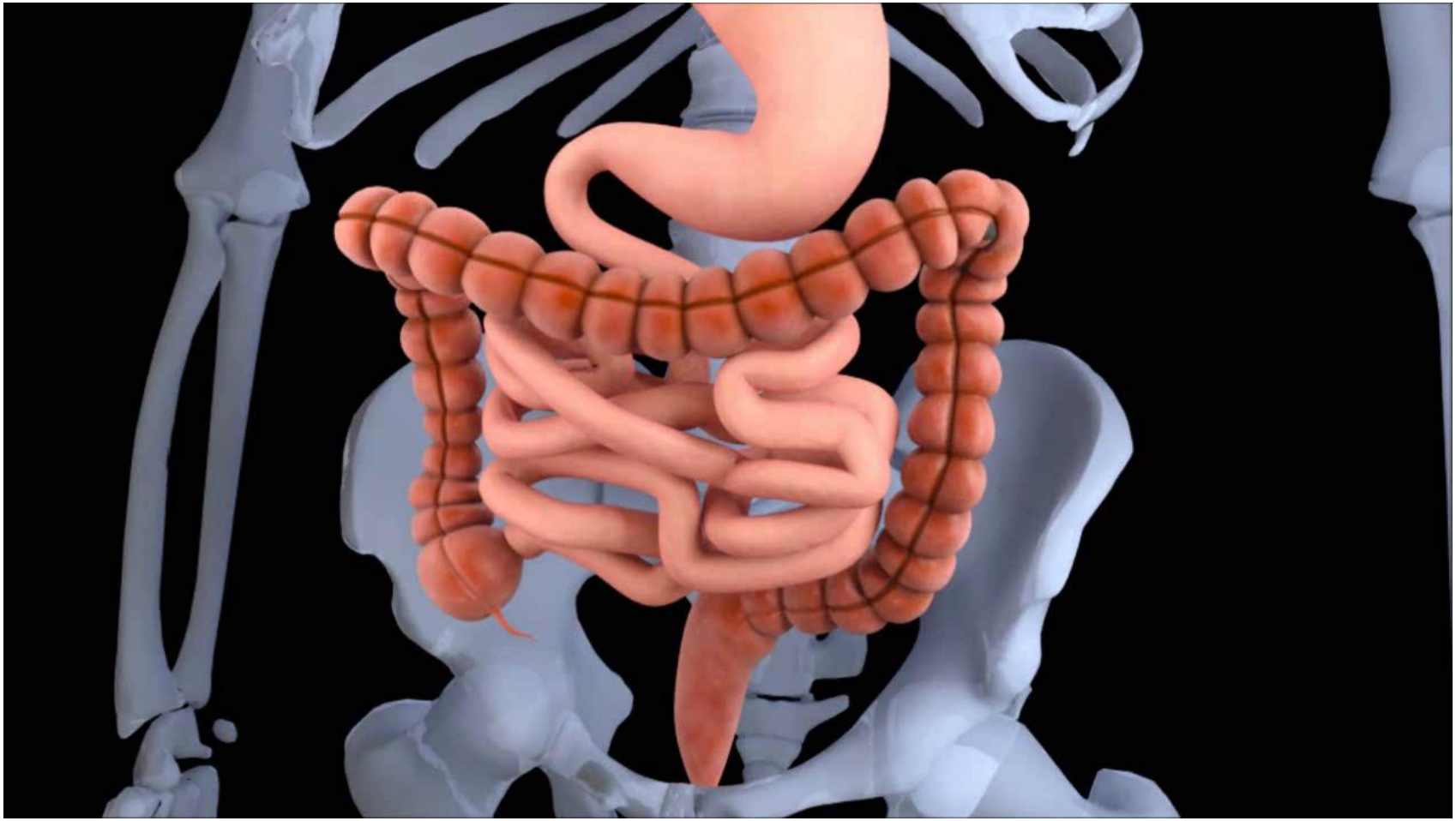


The **proximal colon** has a **higher prevalence** of harder to distinguish adenomas, flat or serrated lesions. In addition, these lesions are commonly located on or behind a mucosal fold making them **harder to detect** with standard endoscope.

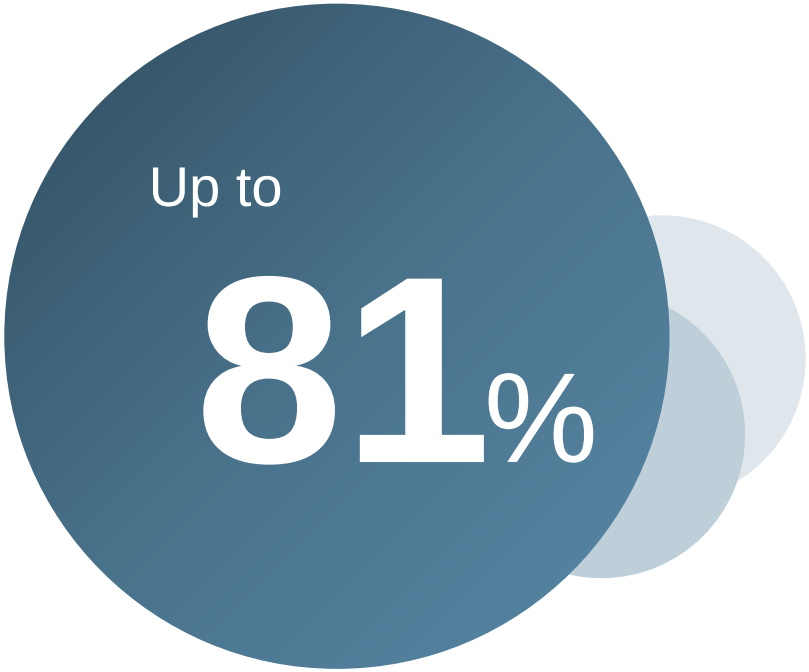
G-EYE™, HD+ colonoscopes has been developed to **enhance detection** capabilities by **straightening intestinal folds** and **smoothening colon topography.**

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

G-EYE38-i10
&
G-EYE34-i10F

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

1 Enhancing detection capabilities	**Straightening intestinal folds** and **smoothening colon topography** to find the adenomatous lesions hiding behind or between the folds.
2 Improved HD+ image quality	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.
3 Improved visualization	**Centralizing** endoscope **optics** in combination **with HD+ and i-scan** improves visualisation-
4 Unique Controlled Withdrawal™	**Eliminating** bowel **slippage** with Unique Controlled Withdrawal™

Key Benefits
G-EYE™ endoscopes (2 / 2)

5 Stabilization during intervention	Colonoscope's stabilization during intervention results in a **faster and more controlled intervention**.
6 Constant leakage testing	Spark2C air supply unit ensures constant monitoring and leak testing **before and during the entire** procedure.
7 Easy operation	G-EYE™ endoscope has a **permanently integrated reusable balloon** and Spark2C unit is easy and intuitive to use.

Product overview
For best clinical results

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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

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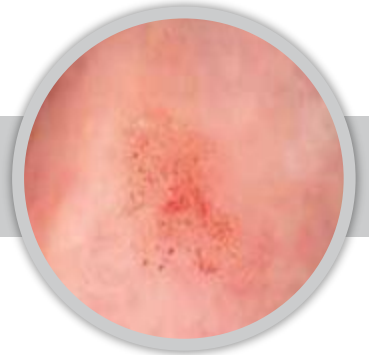
Enhance your endoscopic options with HD+ and i-scans setting

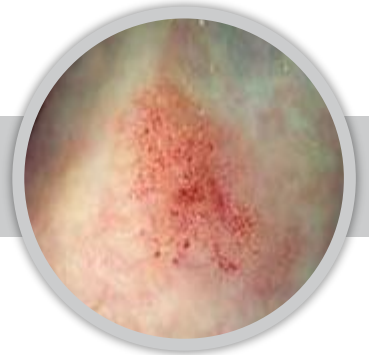
HD+
Flat lesion

- 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

Reference Customers
Original quotations

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» *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.*«

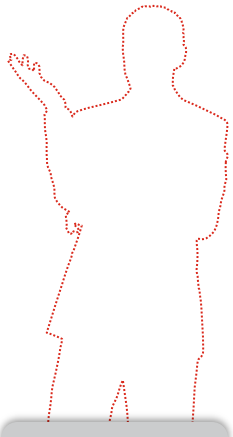
Prof. Neumann
University of Erlangen-Nuremberg, Germany

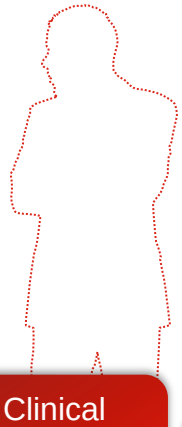
» *My initial experience with G-EYE™ is **very positive**, it allows **controlled withdrawal** and is **easy to use**. I was able to **detect more flat lesions** with it. In addition it also helped to **stabilise the scope tip to carry out complex polypectomy***«

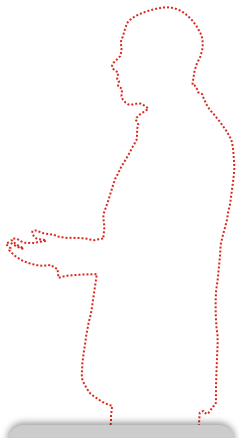
Dr. Ishaq
Russells Hall Hospital, Dudley, UK

» *My personal experience with using the G-EYE™ is that the technology is **easy to use**, **safe**, and provides **greater** polyp / adenoma **detection** as compared to standard colonoscopy.*«

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

Pilot Study
G-EYE™ colonoscopy

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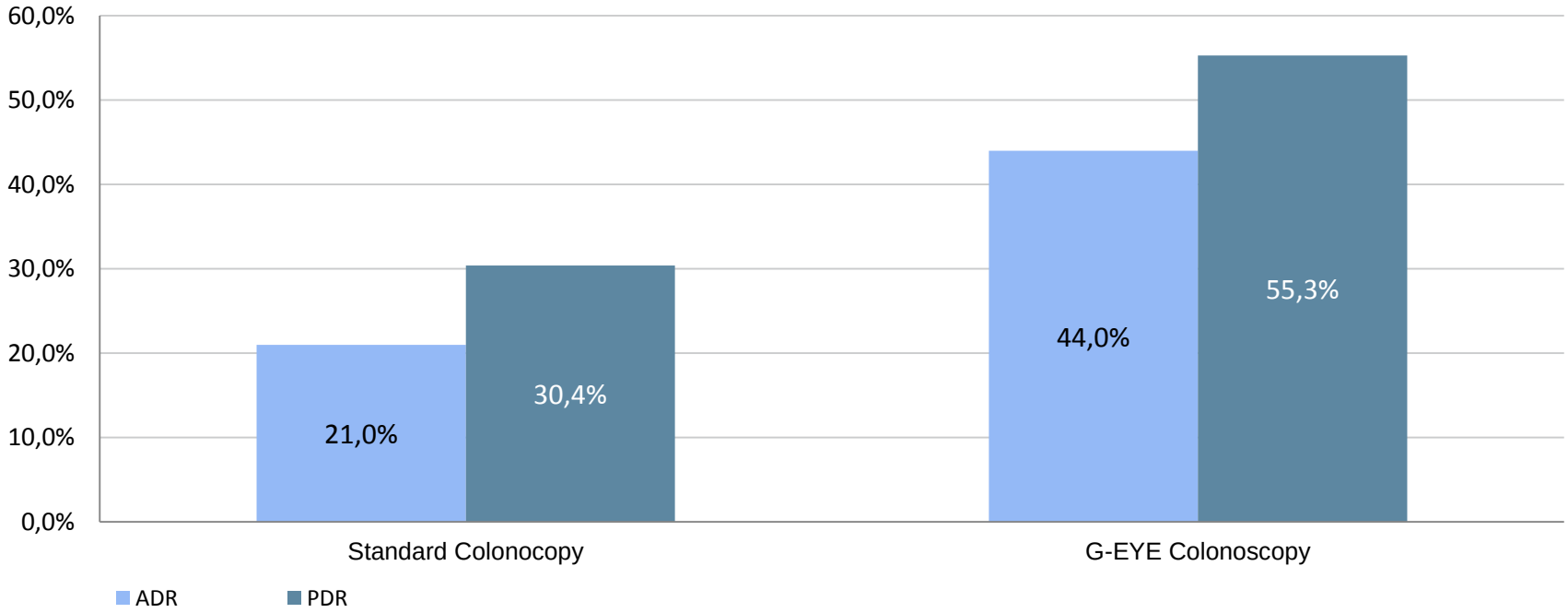
Adenoma/Polyp Detection Rate
G-EYE colonoscopy vs. Standard colonoscopy



Tandem Study
G-EYE™ colonoscopy

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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

Adenomas	Group A (Standard 1st)	Group B (G-EYE™ 1st)
First pass	21	37
Second pass	17	3
Additional detection (%)	81%	8.1%

Adenoma Detection rate	Group A (Standard 1st)	Group B (G-EYE™ 1st)
ADR (%)	25.9%	40.4%

Tandem Study
Advanced colonoscopy techniques

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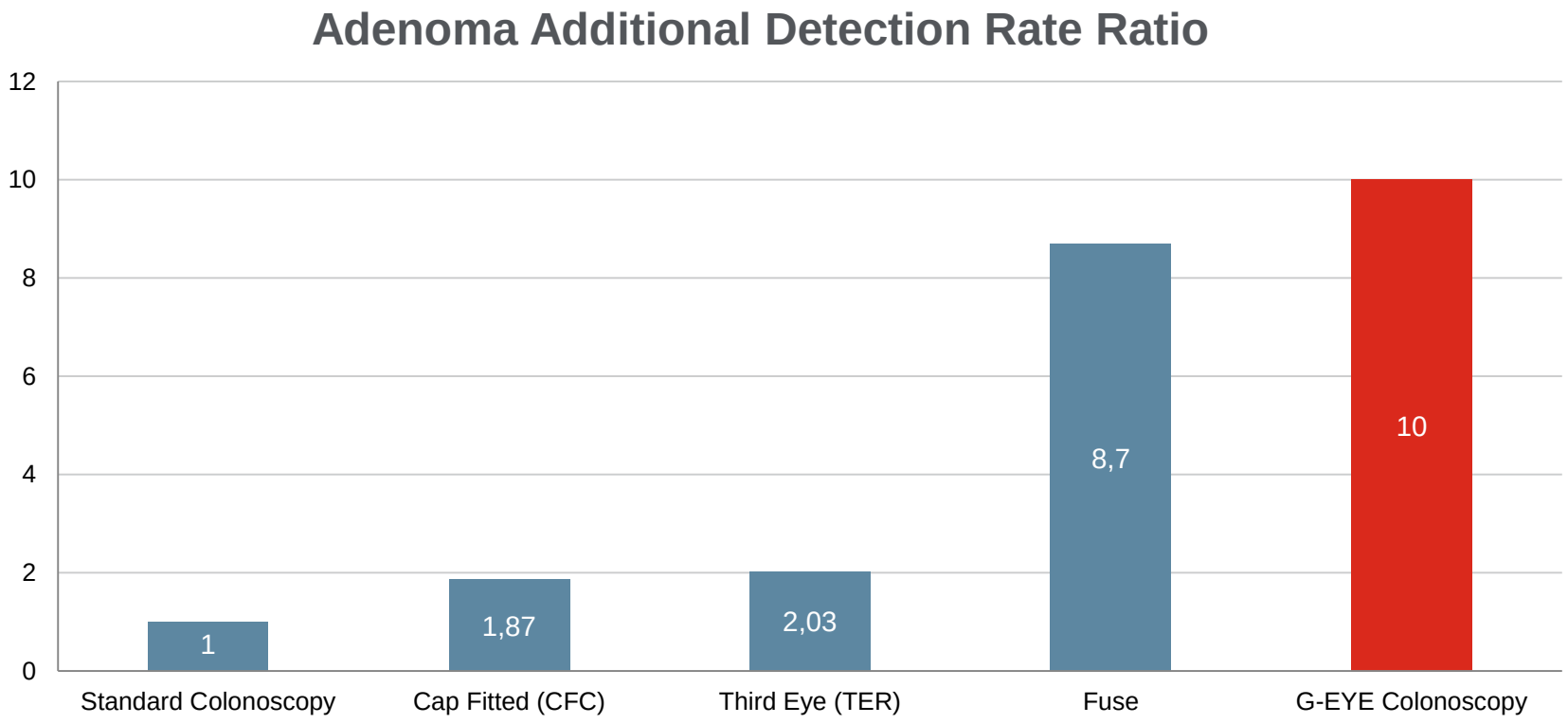

Probability of missing an adenoma found to be 10 times higher (!) when using standard colonoscope vs. G-EYE™ colonoscope

Tandem Study
Advanced colonoscopy techniques

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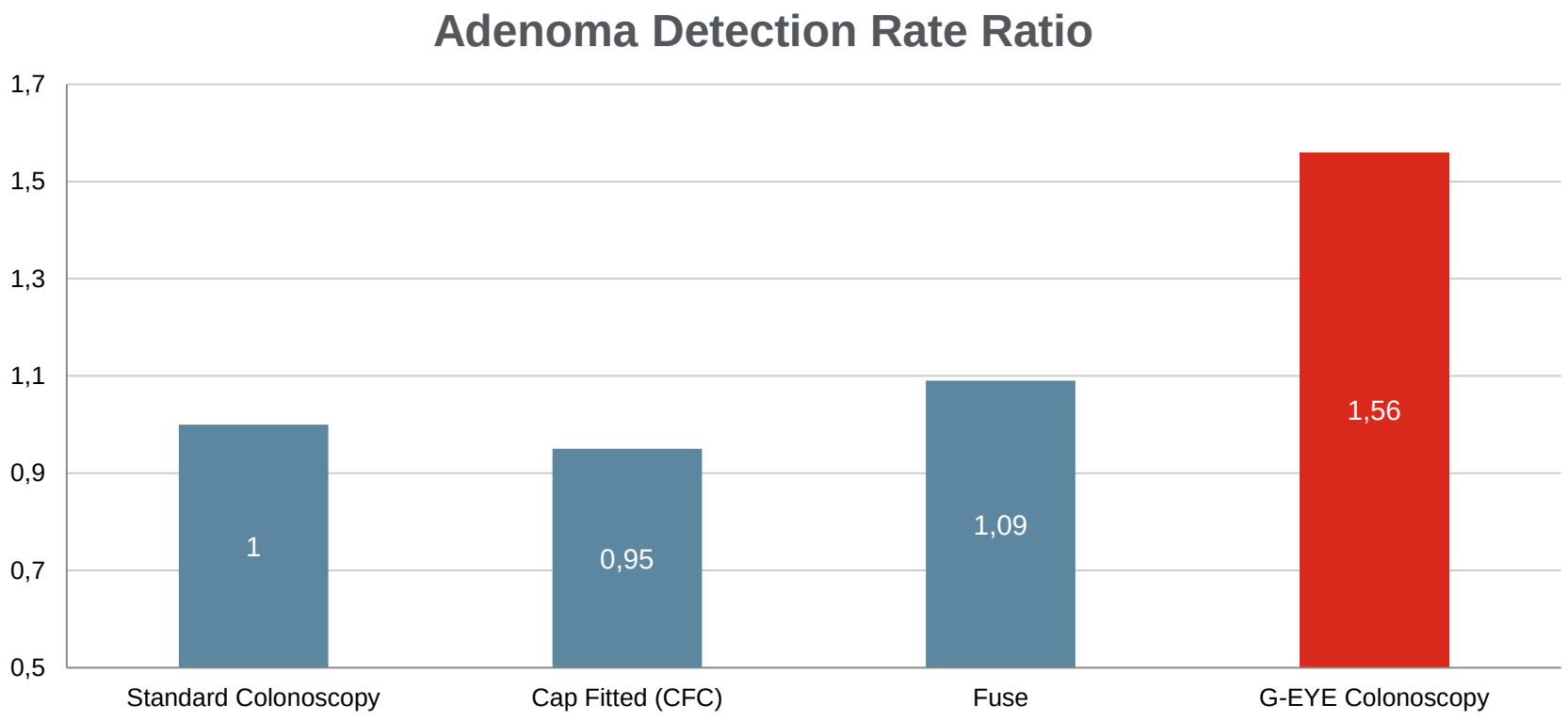

G-EYE™ detected at least one adenoma in 50% more patients

G-EYE™ HD+ Video Endoscopes
Specifications (1 / 2)

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Specs	G-EYE38-i10L/F	G-EYE38-i10F2	G-EYE34-i10F
Field of view (°)	140	140	140
Ø Insertion tube (mm)	13.2	13.2	11.6
Ø Distal end (mm)	13.2	13.2	11.5
Ø Instrument channel (mm)	3.8	3.8	3.8
Working length (mm)	1,700 / 1,500	1,500	1,500

G-EYE™ HD+ Video Endoscopes
Specifications (2 / 2)

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	Specs	G-EYE38-i10L/F	G-EYE38-i10F2	G-EYE34-i10F
Tip deflection (°)	Up / Down	180 – 180	180 – 180	180 – 180
	Right / Left	160 – 160	160 – 160	160 – 160
Inflated balloon diameter (mm)		Up to 60	Up to 60	Up to 60
Remarks		HD+, Water Jet, permanently integrated reusable balloon	HD+, Water Jet, **increased rigidity**, permanently integrated reusable balloon	HD+, Water Jet, permanently integrated reusable balloon

Spark 2 C (Air Supply unit)
Specifications

Specs	Spark 2C
Electrical input (VAC)	100 – 240
Electrical input frequency (Hz)	50 – 60
Dimensions (mm)	280 × 95 × 90
Weight (kg)	1.9
Set pressure tolerance (mbar)	± 10
Inflated balloon setup pressure (mbar)	Anchoring pressure 70. controlled withdrawal™ pressure 3 intermediate levels

Summary
G-EYE™ endoscopes at a glance

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G-EYE38-i10

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

Spark 2C

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

G-EYE34-i10F

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