



**FOR IMMEDIATE RELEASE**  
**3 p.m. on October 7, 2008**  
ACG 2008 ABSTRACT #40

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**National Study Presented at ACG 2008 Confirms  
New Device Functions Like “Rear-View Mirror” to Provide Improved  
View of the Colon**

*Study evaluates the efficacy of new device for detecting polyps that can be missed during colonoscopy*

ORLANDO – Tuesday, October 7, 2008 – At the American College of Gastroenterology Annual Scientific Meeting in Orlando (ACG 2008), renowned gastroenterologist Douglas K. Rex, MD presented results from a multi-institutional clinical study that evaluated the efficacy of the Third Eye® Retroscope®, a new device that is designed to improve the ability of physicians to detect abnormalities in the colon. The Third Eye Retroscope has been cleared for use in the U.S. by the Food and Drug Administration (FDA), as a device to provide retrograde illumination and visualization of the colon.

Dr. Rex, Chancellor's Professor and Professor of Medicine at Indiana University School of Medicine, and Director of Endoscopy at Indiana University Hospital in Indianapolis, presented the study results this afternoon in front of physicians and other industry professionals during the ACG annual conference. The multi-center study evaluated 249 patients at eight sites across the U.S. During the study, patients were examined using a Third Eye Retroscope in combination with a standard colonoscope.

“Our national study indicated that the Third Eye Retroscope, when used in combination with a standard forward-viewing colonoscope, revealed areas that are often hidden from the standard colonoscope,” said Dr. Rex. “The device also enabled detection of 13 percent more polyps and 10.9 percent more adenomas than the colonoscope alone. These results are important to doctors and patients because most cases of colon cancer arise from adenomas.”

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Colorectal cancer is the second greatest cause of cancer death in the U.S. However, most cancers of the lower gastrointestinal (GI) tract can be completely cured if they are detected early. Even more cases can be completely prevented if pre-cancerous adenomas can be removed before they become malignant.

Colonoscopy is widely regarded as the “gold standard” for detection of abnormalities in the colon. However, previous research has revealed that 12-24% of polyps and a significant number of cancers can be missed during colonoscopy. <sup>[1], [2], [3]</sup>

“Although colonoscopy is currently the best method available for colorectal cancer screening, we know that lesions may be missed, especially if they are located behind folds in the colon wall and behind flexures, or tight turns in the colon,” said Scott Dodson, CEO of Avantis Medical Systems, Inc., developer of the Third Eye Retroscope. “The Third Eye Retroscope is designed to solve that problem by making it possible for endoscopists to see the areas behind those folds and flexures. Therefore, we are very pleased with the results of this clinical study. We are also looking forward to an upcoming revised FDA 510(k) filing, and the commencement of new, broader clinical studies of the Third Eye technology.”

Used during colonoscopy, the Third Eye Retroscope is an auxiliary imaging device that provides a backward or “retrograde” view that complements the forward view of the colonoscope.

Developed by Avantis Medical Systems of Sunnyvale, Calif., this innovative new device is passed through the instrument channel of a standard colonoscope. As it emerges from the channel and extends beyond the tip of the colonoscope, the device automatically turns around 180 degrees to provide a retrograde view. The endoscopist observes the forward and retrograde video images simultaneously on a split-screen monitor while the colonoscope is withdrawn through the length of the colon.

According to Dr. Rex, in the 249 patients studied, 262 polyps were identified with the standard colonoscope. “However, using the Third Eye Retroscope in conjunction with the standard colonoscope, an additional 34 polyps were detected, including 15 adenomas,” said Dr. Rex. “Also very importantly, in 11.2 percent of cases, at least one additional polyp was found using the Third Eye Retroscope. In eight of the patients, the polyp detected with the Third Eye Retroscope was the *only* one found.”

In addition to his work as a researcher and professor, Dr. Douglas Rex is also a full-time clinical gastroenterologist at Indiana University Hospital. His major research interests have been in colorectal disease, and in particular, colorectal cancer screening and the technical performance of colonoscopy. He co-authored the colorectal cancer screening recommendations of the American College of Gastroenterology and those of the Gastroenterology Consortium. Dr. Rex has also authored more than 110 original research papers, 50 book chapters, 100 invited papers and editorials and 15 guideline papers.

Additionally, Dr. Rex is an associate editor or editorial board member of several prestigious journals, including *Clinical Gastroenterology and Hepatology*, *Reviews on Gastroenterological Disorders*, *Journal of Clinical Gastroenterology*, *World Journal of Gastroenterology* and *Journal Watch Gastroenterology*. He is Past-President of the ACG and has served as the ACG representative to the National Colorectal Cancer Round Table. From 2000-2006 he chaired the U.S. Multi-Society (ACG, ASGE, AGA, ACP-ASIM) Task Force on Colorectal Cancer.

### **About the Study**

In addition to Indiana University in Indianapolis, IN, study sites included Mayo Clinic, Scottsdale, AZ; University of Michigan, Ann Arbor, MI; Camino Medical Group & El Camino Hospital, Mountain View, CA; Washington University, St. Louis, MO; M.D. Anderson Cancer Center – University of Texas, Houston, TX; and the office of Jerome D. Waye, MD in New York, NY. Although the published abstract covered the initial 214 patients in the study, Dr. Rex's ACG presentation reported the final results for all 249 patients.

### **About the American College of Gastroenterology**

Founded in 1932, the American College of Gastroenterology (ACG) is an organization with an international membership of more than 10,000 individuals from 80 countries. The College is committed to serving the clinically oriented digestive disease specialist through its emphasis on scholarly practice, teaching and research. The mission of the College is to serve the evolving needs of physicians in the delivery of high quality, scientifically sound, humanistic, ethical and cost-effective health care to gastroenterology patients.

The ACG is committed to providing accurate, unbiased and up-to-date health information. Visit the ACG Web site [www.acg.gi.org](http://www.acg.gi.org) to access educational resources for patients and their families spanning the broad range of digestive diseases and conditions – both common and not-so-common. Organized by disease, state and organ system, these educational materials, developed by ACG physician experts, are offered for the information and benefit of patients and the public.

### **About the Technology**

The Third Eye Retroscope is designed to complement, not to replace, standard colonoscopes. Therefore it does not alter existing procedural infrastructure or referral patterns, and does not require major outlay from medical facilities for capital equipment. The device can be used with most of the adult colonoscopes currently produced by the leading manufacturers, as well as some pediatric colonoscopes.

The “chip-on-catheter” platform for the Third Eye Retroscope is also the basis for a number of other products that Avantis is developing for use in gastroenterology and in other medical and surgical specialties. Like the Third Eye Retroscope, most of these innovative devices are designed to be disposable, which eliminates the need for sterilization and the risk of cross-contamination.

### **About Avantis Medical Systems**

Avantis Medical Systems, Inc. is a visualization technology company focused on delivering cost-effective solutions for the improved detection and prevention of cancers of the gastrointestinal (GI) tract.

The seasoned Avantis team is developing solutions for the limitations associated with technologies that are currently used to screen, assess and treat cancer. Avantis has an extensive portfolio of patents covering innovative devices based on the convergent technologies

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of micro-chips, enhanced video processing and catheter-based delivery systems. For more information, visit [www.avantismedical.com](http://www.avantismedical.com).

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<sup>[1]</sup> Pickhardt, P.J.; Nugent, P.A.; Mysliwiec, P.A.; et al. Location of adenomas missed by optical colonoscopy. *Annals of Internal Medicine* 141(5):352-360, 2004.

<sup>[2]</sup> Pabby, A.; Schoen, R.E.; Weissfeld, J.L.; et al. Analysis of colorectal cancer occurrence during surveillance colonoscopy in the dietary Polyp Prevention Trial. *Gastrointestinal Endoscopy* 61(3):385-391, 2005.

<sup>[3]</sup> Rex, D.K.; Cutler, C.S.; Lemmel, G.T.; et al. Colonoscopic miss rates of adenomas determined by back-to-back colonoscopies. *Gastroenterology* 112(1):24-28, 1997.