

## **New Study Published in *Gastrointestinal Endoscopy* Confirms Third Eye<sup>®</sup> Retroscope<sup>®</sup> Improves Detection of Pre-Cancerous Polyps During Colonoscopy**

**-- Retrograde View Shows 23.2 Percent More Adenomas --**

**SUNNYVALE, Calif.** (March 8, 2011) – Avantis Medical Systems, Inc., a technology leader in developing novel catheter-mounted digital imaging devices, today announced that results of a new 448-patient clinical study show that the Third Eye Retroscope increases detection of adenomas, or pre-cancerous polyps, when used during colonoscopy. The study's authors determined that Third Eye colonoscopy detected 23.2 percent additional pre-cancerous adenomas when compared to standard colonoscopy.<sup>1</sup> The study was published in the March issue of *Gastrointestinal Endoscopy*, the leading journal for gastroenterologists, colorectal surgeons and other physicians who perform colonoscopy.

“The data from this study add to the existing body of evidence showing that the Third Eye Retroscope enables physicians to improve their ability to detect adenomas,” said Peter D. Siersema, MD, PhD, Department of Gastroenterology and Hepatology, University Medical Center, Utrecht in the Netherlands. “Despite being highly preventable, colorectal cancer is the second-leading cause of cancer-related deaths in the U.S. and Europe. Tools such as the Third Eye Retroscope can improve patient outcomes, potentially saving lives.”

The Third Eye Retroscope Randomized Clinical Evaluation (“TERRACE”) was a prospective, randomized, controlled study led by Dr. Siersema at nine centers in the U.S. and Europe. In this “tandem” study design, each patient underwent two complete colonoscopy procedures. Patients were randomized into two groups who received either standard colonoscopy followed by Third Eye colonoscopy, or Third Eye colonoscopy followed by standard colonoscopy.

Previous tandem colonoscopy studies have shown a “second-pass effect,” i.e., a second look generally finds additional lesions. In the TERRACE Study, the results for the group who had their second exam with standard colonoscopy served as a proxy for the second-pass effect, and those results were subtracted from the results for Third Eye colonoscopy as the second exam. The difference is the *net* additional adenoma detection rate that can be attributed to use of the Third Eye Retroscope.

The final results showed that Third Eye colonoscopy was able to detect 23.2% additional adenomas that would not have been found with the standard colonoscope alone.

The results of this trial add to the growing body of clinical evidence demonstrating the effectiveness of the Third Eye Retroscope, including two clinical studies published in the March 2010 issue of *Gastrointestinal Endoscopy*. The larger of those studies showed that physicians can detect up to 25 percent additional pre-cancerous adenomas with the Third Eye Retroscope compared to a standard colonoscope alone.<sup>2,3</sup>

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<sup>1</sup> Leufkens AM, DeMarco DC, Siersema PD, et al. Effect of a Retrograde-Viewing Device on Adenoma Detection Rate during Colonoscopy: The “TERRACE” Study. *Gastrointest Endosc* 2011;73:480-9.

<sup>2</sup> Waye JD, Heigh RI, Rex DK, et al. A Retrograde-Viewing Device Improves Detection of Adenomas in the Colon: A Prospective Efficacy Evaluation. *Gastrointest Endosc* 2010;71:551-6.

<sup>3</sup> DeMarco DC, Odstreil E, Lara LF, et al. Impact of Experience with a Retrograde-Viewing Device on Adenoma Detection Rates and Withdrawal Times during Colonoscopy: the Third Eye Retroscope Study Group. *Gastrointest Endosc* 2010;71:542-50.

The Third Eye Retroscope is a catheter-based camera that is inserted through the instrument channel of a standard colonoscope to provide the physician with a retrograde (backward) view of the lining of the colon. This retrograde view can reveal lesions that are hidden behind folds where they can't be seen with the colonoscope's forward view alone. In October 2010, the Centers for Medicare & Medicaid Services (CMS) established a new outpatient pass-through C-code (C1749) for the Third Eye Retroscope, positioning the device for expedited adoption by healthcare providers, who can now submit claims for reimbursement for use of this clinically significant product.

### **About *Gastrointestinal Endoscopy***

*Gastrointestinal Endoscopy* is the official journal of the American Society for Gastrointestinal Endoscopy. *Gastrointestinal Endoscopy* publishes original, peer-reviewed articles on endoscopic procedures used in the study, diagnosis and treatment of digestive diseases. Articles report on outcomes research, prospective studies and controlled trials of new endoscopic instruments and treatment methods. *Gastrointestinal Endoscopy* has become the international forum for the newest developments in the specialty, bringing readers challenging reports from leading authorities throughout the world.

### **About the Third Eye Retroscope and Avantis Medical Systems, Inc.**

Avantis Medical Systems, Inc. markets the Third Eye Retroscope, an FDA-cleared, disposable, catheter-based camera indicated for use with a standard colonoscope to provide an additional view of the colon for diagnostic purposes. Deployed through the instrument channel of a standard colonoscope, the Third Eye provides the physician with a backward view to complement the colonoscope's forward view of the lining of the colon. The device is commercially available to physicians who perform colonoscopies.

The Third Eye is the only technology cleared by the FDA that enhances polyp detection when used in conjunction with a colonoscope. Although colonoscopy is the gold standard for preventing colon cancer by finding and removing polyps and other lesions, clinical literature documents that up to 22-24% of adenomas of all sizes<sup>4,5</sup> and 12% of adenomas over 10 mm in size<sup>6</sup> can be missed. The retrograde view provided by the Third Eye can reveal lesions that are hidden behind folds where they cannot be seen with the colonoscope's forward view alone. The Third Eye has been shown in clinical studies to help physicians find up to 25% more adenomas than a standard colonoscope alone.

Avantis Medical is focused on delivering cost-effective solutions for improved detection and prevention of cancers of the gastrointestinal tract. The company has an extensive portfolio of patents covering innovative devices based on the convergent technologies of micro-chips, enhanced video processing and catheter-based delivery systems. For more information, visit [AvantisMedical.com](http://AvantisMedical.com) or [ThirdEyeRetroscope.com](http://ThirdEyeRetroscope.com).

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<sup>4</sup> Rex DK, Cutler CS, Mark DG, et al. Colonoscopic miss rates of adenomas determined by back-to-back colonoscopies. *Gastroenterology* 1997;112:24-8.

<sup>5</sup> Van Rijn JC, Reitsma JB, Dekker E, et al. Polyp Miss Rate Determined by Tandem Colonoscopy: A Systemic Review. *Am J Gastroenterol* 2006;101:343-50.

<sup>6</sup> Pickhardt PJ, Nugent PA, Schindler WR, et al. Location of adenomas missed by optical colonoscopy. *Ann Intern Med* 2004;141:352-9.