

Third Eye[®] Colonoscopy Shown to Dramatically Increase Adenoma Detection Among Higher Risk Patients

-- Abstract selected as winner of the 2011 ACG International Award --

SUNNYVALE, Calif. (October 31, 2011) – Avantis Medical Systems, Inc., a technology leader in developing novel catheter-mounted digital imaging devices, today announced that results of a new analysis of its latest clinical data will be presented during the American College of Gastroenterology (ACG) 2011 Annual Scientific Meeting in Washington, D.C. The new abstract reports the results of subset analysis of a randomized, controlled trial to determine whether some patients might gain more benefit than others from colonoscopy that includes the use of the Third Eye[®] Retroscope[®], a retrograde-viewing camera. Avantis Medical Systems is exhibiting in booth #919 throughout the conference.

The report, titled “A Retrograde-Viewing Device Improves Adenoma Detection Rate in Colonoscopies for Surveillance and Diagnostic Workup,” was accepted by the ACG for oral presentation during the College’s plenary session on endoscopy on November 2, 2011, and for publication in a supplement to the October issue of the *American Journal of Gastroenterology*.ⁱ The abstract was additionally selected as the winner of the 2011 ACG International Award, which recognizes the best abstract submitted in any category by authors who are not based in the United States or Canada.

After looking at a number of other variables such as age, gender, quality of the bowel preparation and time spent examining the colon, they determined that the only variable that showed significant influence on the advantage provided by the Third Eye Retroscope was the indication for the procedure, i.e., the reason why the patient was having the colonoscopy. For patients who were undergoing colonoscopy for “surveillance” after previous removal of adenomas, the additional adenoma detection rate for Third Eye colonoscopy compared to standard colonoscopy was 35.7%. For patients having a “diagnostic” colonoscopy to look for a reason for symptoms such as anemia, weight loss, changes in bowel habits or rectal bleeding, the additional adenoma detection rate with Third Eye colonoscopy was 55.4%. The pooled results for these two “high risk” groups showed a 40.7% additional detection rate with Third Eye colonoscopy.

“The substantial and statistically significant improvement in adenoma detection rates provided by Third Eye colonoscopy for these groups points to a strong recommendation to use this device on all surveillance and diagnostic colonoscopy patients,” said Avantis Medical Systems’ Chief Medical Officer, Jack Higgins, MD.

The Principal Investigator for the trial was Peter D. Siersema, MD, PhD, who is the Director of the Department of Gastroenterology and Hepatology at University Medical Center Utrecht, in The Netherlands. According to Dr. Siersema, “As concerns about medical costs increase, there is growing interest in finding ways to target new technologies to specific groups of patients who are likely to experience the greatest benefit. While we didn’t demonstrate a significant advantage in screening patients, the evidence for effectiveness in non-screening patients is even more compelling than we had previously realized.”

The subset analysis was performed on results from the Third Eye Retroscope Randomized Clinical Evaluation (TERRACE), a randomized, controlled trial that provided the first head-to-head comparison between standard colonoscopy and Third Eye colonoscopy. Working at four sites in Europe and five in the U.S., the investigators performed two complete colonoscopy exams on each subject – one *with* and one *without* the Third Eye Retroscope. In an article published earlier this year in the journal, *Gastrointestinal Endoscopy*, they had reported the overall results of the study, which showed that with Third Eye colonoscopy they detected 23.2% additional pre-cancerous adenomas that had been missed with standard colonoscopy.ⁱⁱ

Although colonoscopy is the gold standard for preventing colon cancer by finding and removing pre-cancerous adenomas and other polyps, clinical literature documents that up to 21-24% of adenomas of all sizes can be missed.^{iii,iv,v} In one study, 12% of large, advanced adenomas (at least 10 mm in size) were missed during colonoscopy, and two-thirds of the missed adenomas were hidden behind folds.^{vi}

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 12,000 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. www.acg.gi.org

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. It 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. The Third Eye has been shown in clinical studies to help physicians find up to 23-25% more pre-cancerous adenomas than a standard colonoscope alone.^{ii,vii}

The Third Eye is the only technology that consistently enhances adenoma detection when used in conjunction with a colonoscope. Although colonoscopy is the gold standard for preventing colon cancer by finding and removing adenomas, clinical literature documents that up to 21-24% of adenomas of all sizes^{iii,iv,v} and 12% of adenomas over 10 mm in size^{vi} 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.

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.

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 www.AvantisMedical.com or www.ThirdEyeRetroscope.com.

###

Avantis Medical Systems, Inc.
Grant Choe
(408) 636-7237
gchoe@avantismedical.com

ⁱ Siersema P, Rastogi A, Leufkens A, et al. A Retrograde-Viewing Device Improves Adenoma Detection Rate in Colonoscopies for Surveillance and Diagnostic Workup. *Am J Gastroenterol* 2011; 106: S537-8. (Online at <http://download.abstractcentral.com/ACG2011/proofs/67.html>)

ⁱⁱ 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;73:480-90.

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

^{iv} 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.

^v Heresbach D, Barrioz T, Ponchon T, et al. Miss rate for colorectal neoplastic polyps: a prospective multicenter study of back-to-back video colonoscopies. *Endoscopy* 2008;40:284-90.

^{vi} Pickhardt PJ, Nugent PA, Schindler WR, et al. Location of adenomas missed by optical colonoscopy. *Ann Intern Med* 2004;141:352-9.

^{vii} DeMarco DC, Odstrcil 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.