



Clinical Studies Demonstrate Increased Diagnostic Yield during Colonoscopy with Third Eye[®] Retroscope[®] ***Results Presented at the 2009 American College of Gastroenterology***

SUNNYVALE, Calif. (October 28, 2009) - Avantis Medical Systems, Inc., a technology leader in developing novel chip-on-catheter digital imaging devices, announced results from two clinical studies conducted this year that support utilization of the Third Eye[®] Retroscope[®] during colonoscopy.

Data from the “Impact of Experience with the Third Eye Retroscope on Detection Rates and Withdrawal Times during Colonoscopy” (the “DRAW” study) was presented by its principal investigator, Daniel C. DeMarco, MD, of Baylor University Medical Center, Dallas, TX. The study involved 15 endoscopists, each of whom examined 20 patients. Study highlights included:

- 14.8% more polyps detected and 16.0% more adenomas detected when the Third Eye Retroscope was used in conjunction with a standard colonoscope.
- After endoscopists had completed 15 procedures, their mean additional detection rates with the TER were 17.0% for all polyps and 25.0% for adenomas.
- Mean additional detection rates for polyps over 6 mm and 10 mm were 23.2% and 22.6%, respectively. Mean additional detection rates for adenomas over 6 mm and 10 mm were 24.3% and 19.0%, respectively.

“We designed the DRAW study to look at the “learning curve” for the Third Eye Retroscope and determine the additional polyp detection rate that an endoscopist who is experienced with the device can expect,” said Dr. DeMarco. “We found a statistically-significant increased detection rate for adenomas and other lesions, most of which were located behind folds in the colon wall, where they could not be easily seen with the forward-viewing colonoscope but were readily visible with the retrograde-viewing device. In addition, over the course of the 20 cases, average withdrawal time decreased from 10.6 minutes in the first five procedures to 9.2 minutes for procedures 16-20 completed by the physician. ”

Additionally, interim data from the company’s ongoing tandem exam randomized, controlled trial, “Third Eye Retroscope Randomized Clinical Evaluation” (the “TERRACE” study) was presented as a poster by its principal investigator, Dr. Peter D. Siersema, MD, PhD, of University Medical Center Utrecht, The Netherlands. Results from 126 patients indicate that when the Third Eye Retroscope is used in the second procedure, there is a 20.2% higher additional detection rate than when a colonoscope is used alone for the second procedure. During the first procedure, when the colonoscope is used alone, endoscopists are missing 2.57 times more polyps than when the Third Eye Retroscope is used along with the colonoscope.

“The TERRACE study is one of the most clinically rigorous studies to come out in the field of gastroenterology in the last several years,” said Dr. Siersema. “Previous studies had demonstrated the ability of the Third Eye Retroscope to help endoscopists find additional polyps that were hidden behind folds, but this was the first randomized trial of the device using a control group. The preliminary data that we’re presenting here suggest that the Third Eye Retroscope can help an endoscopist find significantly more adenomas and other polyps than when using a standard colonoscope alone.

“Both of these studies are quite exciting in different ways,” said Dr. Jack Higgins, Chief Medical Officer of Avantis Medical Systems. “The DRAW study shows that only a relatively small number of cases are

Avantis Medical Announces Clinical Data

required for an endoscopist to become technically proficient with the device, and that patients can benefit from the use of the device in their colonoscopy even when endoscopists are just beginning to use it in their practices. Meanwhile, the preliminary results for the TERRACE study indicate a significant benefit to patients in terms of increased polyp detection rate, under even the most clinically-rigorous multi-center randomized clinical trial conditions.”

About the American College of Gastroenterology

The American College of Gastroenterology is a recognized leader in educating GI professionals and the general public about digestive disorders. Its mission is to serve the evolving needs of physicians in the delivery of high quality scientific, humanistic and cost-effective health care to gastroenterology patients.

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 and detection 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 colonoscopy. Although colonoscopy is the gold standard for preventing colon cancer by finding and removing polyps and other lesions, clinical literature documents that up to approximately 12-24% of polyps can be missed during examination.^{1 2 3} The Third Eye has been shown in clinical studies to help physicians find 13.2% more polyps than a colonoscope alone.⁴

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.

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³ 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.

⁴ Wayne, J.D.; Rex, D.K.; et al. The Third Eye Retroscope Auxiliary Endoscopy System Improves Detection of Polyps in the Colon – A Prospective Efficacy Evaluation. *Endoscopy Supplement No. I(40): A24, OP1111*, 2008.