



Third[®] Eye Retroscope[®] Increases Diagnostic Yield During Colonoscopy

Clinical Results Presented at Gastro 2009 London, United Kingdom

SUNNYVALE, Calif. (November 25, 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 “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 298 subjects, 15 endoscopists, each examined 20 patients and the 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 rate for adenomas over 6 mm was 24.3%
- Mean additional detection rate for adenomas over 10 mm was 19.0%.

“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.”

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.”

Avantis Medical Announces Clinical Data

“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 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 Gastro 2009

The United European Gastroenterology Federation (UEGF) and the World Gastroenterology Organization (WGO) have joined forces to hold an international conference focused on gastroenterology and digestive health. Gastroenterologists from throughout the world will attend Gastro 2009, which is designed to educate GI professionals regarding basic science and clinical practice related to endoscopy, digestive oncology, nutrition, digestive surgery, hepatology and gastroenterology.

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}

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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CONTACT:
Avantis Medical Systems

Doug Gielow
(408) 636-7263
dgielow@avantismedical.com

¹ Pickhardt PJ, Nugent PA, Mysliwiec PA, et al. Location of adenomas missed by optical colonoscopy. *Annals of Internal Medicine* 2004;141:352-60.

² Pabby A, Schoen RE, Weissfeld JL, et al. Analysis of colorectal cancer occurrence during surveillance colonoscopy in the dietary Polyp Prevention Trial. *Gastrointestinal Endoscopy* 2005; 61:385-91.

³ Rex DK, Cutler CS, Lemmel GT, et al. Colonoscopic miss rates of adenomas determined by back-to-back colonoscopies. *Gastroenterology* 1997;112:24-8.