



Two Studies Published in *Gastrointestinal Endoscopy* Confirm that the Third Eye[®] Retroscope[®] Finds More Pre-Cancerous Polyps during Colonoscopy

SUNNYVALE, Calif. (March 9, 2010) – Avantis Medical Systems, Inc., a technology leader in developing novel catheter-mounted digital imaging devices, today announced the publication of two large clinical studies demonstrating that the Third Eye[®] Retroscope[®] helps physicians find more pre-cancerous polyps in the colon. Both studies were published in the March 2010 issue of *Gastrointestinal Endoscopy*, the leading journal for gastroenterologists, colorectal surgeons and other physicians who perform colonoscopy.

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.

The first study was led by Dr. Jerome D. Waye, Clinical Professor of Medicine at Mount Sinai School of Medicine, New York, NY. Titled "A Retrograde-Viewing Device Improves Detection of Adenomas in the Colon: A Prospective Efficacy Evaluation," the study involved 14 investigators and 249 patients at 8 medical centers in the U.S.¹ The investigators found that the Third Eye improved detection and removal of polyps by 13.2% compared to the colonoscope alone. For adenomas, the polyps that are most likely to become cancers over time, the additional detection rate with the Third Eye was 11.0% for lesions of all sizes.

For medium-size adenomas (at least 6 mm in diameter), the additional detection rate with the Third Eye was 25.0%, and for large adenomas (at least 10 mm), they found 33.3% more with the Third Eye. Thus, the Third Eye not only allowed for identification of more polyps, but its greatest yield was in the detection of larger adenomas, which are further along in the progression to cancer.

"These data have a very real impact on patients, who benefit when the Third Eye helps us find adenomas and other polyps that otherwise might have been missed during colonoscopy," said Dr. Waye. "Colorectal cancer is the second leading cause of cancer deaths in the United States, but it is preventable through the early detection of pre-cancerous lesions. The data show that the Third Eye enhances our ability to detect adenomas, and we believe that will improve long-term patient outcomes."

The second study was led by Dr. Daniel C. DeMarco, Director of Endoscopy at Baylor University Medical Center, Dallas, TX. Titled "Impact of Experience with a Retrograde-Viewing Device on Adenoma Detection Rates and Withdrawal Times during Colonoscopy: the Third Eye Retroscope Study Group," the study involved 298 patients at 9 U.S. sites, and was conducted by 17 investigators who had not previously used the device.²

Overall, beginning with the very first time they used the device, the Third Eye allowed the investigators to find 16.0% more adenomas in addition to those they were able to find with the colonoscope alone. However, after each investigator had gained some experience with the device by performing 15 procedures, their average additional adenoma detection rate with the Third Eye compared to the colonoscope alone was 25.0%. Again considering their overall results from start to finish, the endoscopists found a higher proportion of larger pre-cancerous adenomas that were hidden from the colonoscope by folds, including 24.3% more adenomas at least 6 mm in diameter and 19.0% more adenomas at least 10 mm.

"Previous studies have shown that 22 to 24% of adenomas of all sizes and 12% of adenomas over 10 mm in diameter are missed with the standard colonoscope," said Dr. DeMarco, the Principal Investigator. "This

Avantis Medical Announces Clinical Data

study showed that after completing only 15 procedures with the new device, the investigators achieved a 25% mean additional adenoma detection rate, which resembles the well-documented miss rate for the colonoscope alone. This is exciting because cancer is prevented when we find and remove adenomas before they have a chance to progress to cancer.”

“We are very pleased with the results of these two studies,” said Dr. Jack Higgins, Chief Medical Officer of Avantis Medical Systems. “Collectively, the Wayne study and DeMarco study included results from 547 patients. Both of these studies demonstrated that adenoma detection rates can be significantly improved through use of the Third Eye, especially for the larger adenomas that are most clinically significant. It makes sense that lesions that are hidden behind folds where they can be found only with the Third Eye were likely missed during previous exams, so they’ve had time to grow larger and potentially more dangerous.”

The Third Eye was shown to be extremely safe, and there were no adverse events resulting from use of the device in either of the studies.

About the Studies

The objective of the 249-patient, 8-center study led by Dr. Wayne was to evaluate the added benefit for polyp detection during colonoscopy using a retrograde-viewing device. The study results included:

- 257 polyps (including 136 adenomas) were identified with the colonoscope alone. The Third Eye allowed detection of 34 additional polyps – including 15 additional pre-cancerous adenomas that were hidden from the view of the colonoscope because they were located behind folds.
- For lesions 6 mm or larger, the mean additional detection rates with the Third Eye Retroscope were 18.2% for all polyps and 25.0% for adenomas.
- For lesions 10 mm or larger, the additional detection rates with the Third Eye were 30.8% for all polyps and 33.3% for adenomas.
- In 28 individuals (11.2%), at least 1 additional polyp was found with the Third Eye.

The objective of the 298-patient, 9-center study led by Dr. DeMarco was to evaluate whether experience with the Third Eye Retroscope affects polyp detection rates and procedure times in physicians who were experienced colonoscopists but who had not previously used the Third Eye except during training with a plastic model of the colon. The study findings included:

- Overall, 182 polyps were seen with the colonoscope and 27 additional polyps were detected with the Third Eye Retroscope, a 14.8% increase.
- Overall, 100 adenomas were detected with the colonoscope and 16 more with the Third Eye Retroscope, a 16.0% increase.
- For procedures performed after each physician had completed 15 procedures, the mean additional detection rates with the TER were 17.0% for all polyps and 25.0% for adenomas.
- For lesions 6 mm or larger, the overall additional detection rates with the Third Eye Retroscope were 23.2% for all polyps and 24.3% for adenomas.
- For lesions 10 mm or larger, the overall additional detection rates with the Third Eye were 22.6% for all polyps and 19.0% for adenomas.
- In 27 patients (9.1%), at least 1 additional polyp was found with the Third Eye.

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^{3,4} and 12% of adenomas over 10 mm in size⁵ can be missed. 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 www.AvantisMedical.com or www.ThirdEyeRetroscope.com.

###

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

¹ 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.

² 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.

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

⁴ 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.

⁵ Pickhardt PJ, Nugent PA, Schindler WR, et al. Location of adenomas missed by optical colonoscopy. *Ann Intern Med* 2004;141:352-9.