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## **Study Presented at UEGW International Conference Shows that New Device Significantly Improves Visualization of the Colon**

### ***Third Eye® Retroscope® Improved Polyp Detection by Thirteen Percent***

VIENNA – Tuesday, October 21, 2008 – At the United European Gastroenterology Federation Annual Scientific Meeting in Vienna, Austria (UEGW Vienna 2008), world-renowned gastroenterologist Jerome D. Waye, MD, principal investigator, presented clinical results from a multi-institutional study which evaluated the efficacy of the Third Eye® Retroscope®.

The study, “The Third Eye Retroscope auxiliary endoscopy system improves detection of polyps in the colon – A prospective efficacy evaluation,” showed that the Third Eye Retroscope, when used in combination with a standard colonoscope, detects a significantly higher number of adenomas and other polyps than the colonoscope alone. The Third Eye Retroscope is CE marked, and has also been cleared for use in the U.S. by the Food and Drug Administration (FDA) as a device to provide retrograde illumination and visualization of the colon.

The study results were presented by Principal Investigator Dr. Waye, clinical professor of medicine and chief of the G.I. endoscopy unit at the Mount Sinai Medical Center in New York City, during the Vienna conference yesterday afternoon to physicians and leading industry professionals from around the world. Dr. Waye said in his presentation that the Third Eye Retroscope is a “marvelous piece of engineering” and that “the technology is incredible and quite exciting.” Dr. Waye is a prominent endoscopist known for shaping the field, as well as providing research and advice for many advances of the last few decades.

The multi-center study evaluated 249 patients at eight sites across the United States. During the study, patients were examined using a Third Eye Retroscope in combination with a standard colonoscope.

*Study Presented at UEGW Confirms Device Improves Detection of Polyps in the Colon*

According to Dr. Wayne, in the 249 patients studied, 262 polyps were identified with the standard colonoscope. "However, using the Third Eye Retroscope in conjunction with the standard colonoscope, an additional 34 polyps were detected, including 15 adenomas," said Dr. Wayne. "Also very importantly, in 11.2 percent of cases, at least one additional polyp was found using the Third Eye Retroscope. In eight of the patients, the polyp detected with the Third Eye Retroscope was the *only* one found."

**Colorectal cancer is the second greatest cause of cancer death in Europe and in the U.S.<sup>1</sup>**

However, most cancers of the lower gastrointestinal (GI) tract can be completely cured if they are detected early. Even more cases can be completely prevented if pre-cancerous adenomas can be removed before they become malignant.

Colonoscopy is widely regarded as the "gold standard" for detection of abnormalities in the colon. However, previous research has revealed that 12-24% of polyps and a significant number of cancers can be missed during colonoscopy.<sup>[2], [3], [4]</sup>

"Although colonoscopy is currently the best method available for colorectal cancer screening, we know that lesions may be missed, especially if they are located behind folds in the colon wall and behind flexures, or tight turns in the colon," said Scott Dodson, CEO of Avantis Medical Systems, Inc., developer of the Third Eye Retroscope. "The Third Eye Retroscope is designed to solve that problem by making it possible for endoscopists to see the areas behind those folds and flexures. Therefore, we are very pleased with the results of this clinical study. **We are also looking forward to broader clinical studies of the Third Eye technology in Europe, and have begun discussions with hospitals and research institutions across the E.U.**"

Used during colonoscopy, the Third Eye Retroscope is an auxiliary imaging device that provides a backward or "retrograde" view that complements the forward view of the colonoscope.

Developed by Avantis Medical Systems of Sunnyvale, Calif., this innovative new device is passed through the instrument channel of a standard colonoscope. As it emerges from the channel and extends beyond the tip of the colonoscope, the device automatically turns around 180 degrees to provide a retrograde view. The endoscopist observes the forward and retrograde video images simultaneously on a split-screen monitor while the colonoscope is withdrawn through the length of the colon.

Known for introducing the concept of colonoscopy without fluoroscopy by defining endoscopic landmarks, Dr. Jerome Wayne has authored seven books, innumerable abstracts, and has published almost two hundred scientific papers in peer-reviewed journals. He is president-elect and has been treasurer of OMED, the international organization for digestive endoscopy. In 1980, he was president of the ASGE and in 1982 became president of the American College of Gastroenterology (ACG). He has also received the highest honors awarded by these organizations: the Schindler Award (from the ASGE) and the Founder's Award (from the ACG).

He is organizing the International Congress of Endoscopy, to be held in Los Angeles, Calif. in 2011.

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<sup>1</sup> According to the European Cancer Patient Coalition, Health First Europe and the American Cancer Society.

### **About the Study**

Study sites included Mayo Clinic, Scottsdale, AZ; M.D. Anderson Cancer Center—University of Texas, Houston, TX; Indiana University, Indianapolis, IN; University of Michigan, Ann Arbor, MI; Camino Medical Group & El Camino Hospital, Mountain View, CA; and Washington University, St. Louis, MO. Although the original published abstract reported on the initial 214 patients in the study, Dr. Wayne's UEGW presentation reported on the study's final results including 249 patients.

### **About UEGW Vienna 2008**

The United Gastroenterology Week (UEGW) is the annual congress of the United European Gastroenterology Federation (UEGF). The organization's 16th annual conference, UEGW Vienna 2008, is taking place this week from October 18-22 2008 in Vienna, Austria, where 12,000 scientists representing more than 75 countries are anticipated at the largest European congress of its kind. For more information, visit [www.uegw.org](http://www.uegw.org).

### **About the Technology**

The Third Eye Retroscope is designed to complement, not to replace, standard colonoscopes. Therefore it does not alter existing procedural infrastructure or referral patterns, and does not require major outlay from medical facilities for capital equipment. The device can be used with most of the adult colonoscopes currently produced by the leading manufacturers, as well as some pediatric colonoscopes.

The "chip-on-catheter" platform for the Third Eye Retroscope is also the basis for a number of other products that Avantis is developing for use in gastroenterology and in other medical and surgical specialties. Like the Third Eye Retroscope, most of these innovative devices are designed to be disposable, which eliminates the need for sterilization and the risk of cross-contamination.

### **About Avantis Medical Systems**

Avantis Medical Systems, Inc. is a visualization technology company focused on delivering cost-effective solutions for the improved detection and prevention of cancers of the gastrointestinal (GI) tract.

The seasoned Avantis team is developing solutions for the limitations associated with technologies that are currently used to screen, assess and treat cancer. Avantis 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](http://www.avantismedical.com).

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<sup>[2]</sup> Pickhardt, P.J.; Nugent, P.A.; Mysliwiec, P.A.; et al. Location of adenomas missed by optical colonoscopy. *Annals of Internal Medicine* 141(5):352-360, 2004.

<sup>[3]</sup> Pabby, A.; Schoen, R.E.; Weissfeld, J.L.; et al. Analysis of colorectal cancer occurrence during surveillance colonoscopy in the dietary Polyp Prevention Trial. *Gastrointestinal Endoscopy* 61(3):385-391, 2005.

<sup>[4]</sup> 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.