



## GASTROENTEROLOGY & ENDOSCOPY NEWS

### **FDA Clears HALO90 System for Convenient, Outpatient Treatment of Patients with Barrett's Esophagus** June 2006

On April 26, 2006, **BÂRRX Medical, Inc.**, announced the U.S. Food and Drug Administration clearance of the HALO90 System for use in the coagulation of sites in the gastrointestinal tract, including the treatment of Barrett's esophagus. The **HALO90 System** is designed to be used independently or in conjunction with the commercially available **HALO360 System**, a balloon-based endoscopic ablation system for treating larger, circumferential areas of Barrett's esophagus. Both products are based on patented technology that carefully controls the amount of energy delivered to the tissue so as to safely and effectively remove the diseased tissue and facilitate the regrowth of new healthy tissue. Together, the products offer physicians a safe and convenient solution for the complete removal of Barrett's esophagus.

"The HALO90 System is an exciting development for patients with Barrett's esophagus and for the gastroenterologist and endoscopic surgeon who care for these patients," stated David S. Utley, MD, Chief Medical Officer of BÂRRX Medical in a company press release. "This new device is mounted on the endoscope, allowing a simplified treatment of smaller segments of disease, yet maintaining the ablation depth control demonstrated by the more established HALO360 System."

The HALO90 and HALO360 Systems enable the physician to remove Barrett's esophagus tissue before it has a chance to develop into cancer, akin to the management approaches for other premalignant conditions, such as colon polyps. The HALO90 System features a small electrode mounted on the end of an endoscope and is uniquely able to treat small areas of diseased tissue, offering a convenient, outpatient option for the complete removal of Barrett's esophagus. The ability to safely and effectively remove Barrett's esophagus may reduce the need for lifelong endoscopic surveillance, ease patient anxiety about living with a precancerous condition, and possibly reduce the number of patients who go on to develop esophageal adenocarcinoma. Physicians benefit from the flexibility of the HALO90 System because its procedural simplicity and lower cost enable its use in the ambulatory surgery center and office-based endoscopy unit, in addition to the hospital-based outpatient endoscopy unit.