FDA Grants 510(k) Clearance for Innovative Fuse Gastroscope

EndoChoice

Now doctors performing flexible endoscopy have a new tool available to help them see more anatomy and facilitate diagnoses in the upper GI tract. Traditional gastroscopes that have been available to endoscopists provide a field of view limited to about 140 degrees. EndoChoice® has announced that the FDA had provided 510(k) clearance of its new Fuse™ Gastroscope that has a field of view of 245 degrees. Endoscopes are thin flexible tubes with imaging capabilities that doctors use to view the upper and lower GI tracts of their patients.

EndoChoice engineers have developed a proprietary, new method of designing and manufacturing flexible circuits that allow them to put more small cameras on the tips of flexible endoscopes. This new concept of Full Spectrum Endoscopy™ is changing the field of endoscopy where significant improvements in technology have not occurred in more than 20 years. The new gastroscope joins the revolutionary, endoscopy system line of products released earlier this year by EndoChoice under the Fuse brand. The Fuse Gastroscope has two cameras and the Fuse Colonoscope has three cameras while traditional systems have just one camera.

The Fuse system allows doctors to see nearly twice as much surface area as they can with traditional endoscopes. Because of the folds that occur naturally in the colon and stomach anatomy, problem areas can easily go undetected when using traditional endoscopes. The Fuse system allows GI doctors to see into and behind those folds. The images of the anatomy are displayed on high-definition screens specially arranged to give the doctor a full spectrum view.

Data supporting the Fuse system were presented simultaneously at the American College of Gastroenterology Annual Scientific Session last week in San Diego, California, and at the Union European Gastroenterology Week in Berlin, Germany. Researchers demonstrated the ability to see more with the Fuse system has a statistically significant impact on their ability to find adenomas or

precancerous lesions when compared to traditional single-view endoscopes. "We have a national colorectal cancer screening program in the United States wherein most people should get screened for colorectal cancer, but not all patients follow these guidelines. The data from the Full Spectrum Endoscopy Tandem study would indicate that Fuse is a radical improvement over the tools we've used in the past to fight GI disease," said Douglas K. Rex, Professor of Medicine at Indiana University.

"We are 100% focused on serving the GI professionals so they can give the best possible care to their patients," said Mark Gilreath, Founder and CEO at EndoChoice. "This clearance by the FDA is yet another milestone in our efforts to make the Fuse system available to more hospitals and clinics."