

## New Adjustable Intra-gastric Balloon Appears Well-Tolerated, Demonstrates Significant Weight Loss

*Spatz-FGIA to Present Clinical Data at DDW 2010*

A new adjustable intra-gastric balloon appears to help obese patients lose significant amounts of weight and could be more tolerable than traditional intra-gastric balloons which must be removed after six months. Six month data from a pilot study of Spatz-FGIA Inc.'s Adjustable Balloon System were presented in a poster at Digestive Disease Week (DDW) 2010 in New Orleans (abstract M1507).

"Our excellent results are due, in part, to our ability to adjust the balloon to fit each patient's requirements," stated lead investigator Dr. Evzen Machytka, University Hospital Ostrava, Czech Republic. "We believe that the results of this study underscore the potential of the Spatz balloon as a safer, longer-term non-surgical endoscopic approach to weight management than traditional intra-gastric balloons used today."

The study included 18 patients (15 female, 3 male), average 38 years old, with a mean body mass index (BMI) rating of 39.4 and an mean weight of 114.9 kg (252.8 lbs) who were implanted with the Spatz Adjustable Balloon System. After implantation, the balloons were filled with 400 ccs of saline, on average, to occupy about one-third of these patients' stomachs.

Patients were discharged on three days of liquid diet and were then asked to maintain a 1200 calorie per day diet and take proton pump inhibitors (PPI).

After six months from the time of balloon implantation, four of the five balloons were in place and these four patients were able to lose more than half of their excess weight (50.8% EWL with a mean weight loss of 23.5 kg (51.8 lbs)).

A specially-designed valve on the Spatz Balloon System allows the balloon volume to be adjusted in the patient's stomach via a routine endoscopy procedure. These volume adjustments enabled renewed balloon effect after the first two to three months in this study. Two patients who did not tolerate the balloon in the first two weeks, had their balloon volumes decreased, allowing them to continue with the treatment.

Patients complained of varying degrees of nausea, vomiting or abdominal pain for up to five days, however none of these symptoms required the balloon to be

removed. One patient with moderately severe gastritis (inflammation of the stomach lining) at implantation requested device removal at day 40 due to an upset stomach (dyspepsia). Endoscopy revealed non-healing *H. pylori* gastritis and the device was removed uneventfully. Follow up endoscopy two months later revealed complete healing of the gastritis and eradication of the *H. pylori*.

Investigators plan to extend the study for another six months to determine if an adjustable intra-gastric balloon can be a solution for chronic endoscopic weight loss therapy. "We are very encouraged that the hospital ethics committee has approved extension of the study for a total of 12 months using the original devices," added Dr. Machytka.

"To our knowledge, this will be the first 12 month implant study for intra-gastric balloons in the world," said Dr. Jeffrey Brooks, CEO of Spatz-FGIA Inc. "Given the results to date, we believe that the Spatz Adjustable Balloon system has the potential to overcome limitations with traditional gastric balloons."

**About The Spatz™ Adjustable Balloon System:** The Spatz™ Adjustable Balloon System consists of a balloon mounted on a curled non-crushable catheter, designed to avoid migration into the duodenum. The integrated balloon catheter system straightens over a guidewire, and is passed similar to an orogastric tube, under conscious sedation. Calibrations on the pusher identify the level of insertion. Inflation commences after endoscopic confirmation of balloon position below the GE-junction. An extractable inflation tube housed in the catheter is attached to an extension tube for inflation, snared endoscopically and pulled outside the mouth for volume adjustments while the IGB remains in the stomach. At the end of the implantation period, the IGB is extractable with a snare after deflation.

## OraSure Technologies Receives FDA Approval for OraQuick® HCV Rapid Test, the First Rapid HCV Test Approved for Sale in the U.S.

OraSure Technologies, Inc. announced today that its OraQuick® Hepatitis C ("HCV") Rapid Antibody Test has been approved by the U.S. Food and Drug Administration ("FDA") for use in detecting HCV antibodies in venous whole blood specimens, making it the first



rapid HCV test approved by the FDA for use in the United States.

“The OraQuick HCV test efficiently identifies previously undiagnosed HCV infected individuals who are at risk,” said Eugene R. Schiff, MD, MACP, FRCP, MACG, AGAF, University of Miami School of Medicine. “We at the University of Miami found this test to be user-friendly, practical and an important tool for rapid HCV antibody detection.”

“We believe that the OraQuick® HCV Rapid Antibody Test, with its simplicity and speed, will be a critical tool in identifying more at risk individuals infected with hepatitis C in the U.S., and thus represents a significant market opportunity,” said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. “Obtaining FDA approval of our OraQuick® HCV Rapid Antibody Test for

venous whole blood represents a major milestone for our Company.”

OraQuick® HCV is the only rapid, point-of-care test for the detection of antibodies to the hepatitis C virus in venous whole blood specimens that is approved by the FDA. The test, which utilizes the OraQuick® technology platform, provides results in 20 minutes. The OraQuick® HCV Rapid Antibody Test is the latest rapid test manufactured by OraSure to receive FDA approval. OraSure had previously received FDA approval for its OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test for use with oral fluid, fingerstick and venous whole blood and plasma samples.

In the U.S., there are an estimated 4.1 million Americans, or 1.6 percent of the population, that are or have been infected with HCV. According to the Centers for Disease Control and Prevention (“CDC”), new infections in the U.S. are estimated at approximately 20,000 per year. On a worldwide basis, there are an estimated 180 million people who are chronically infected with HCV, with an estimated 3 to 4 million individuals newly infected each year.

According to the World Health Organization, most cases of HCV infection are currently undiagnosed and up to 80 percent of HCV-positive individuals show no signs or symptoms.

In December 2009, the Company received the CE mark for its OraQuick HCV Rapid Antibody Test for use with oral fluid, whole blood, serum and plasma specimens. The CE mark was required in order to sell the product in the European Union.

As previously announced, OraSure has entered into agreements with Merck & Co. (through its predecessor Schering Plough Corporation) to collaborate on the development and promotion of the OraQuick® HCV test. Under the terms of these agreements, the Company has been and will be reimbursed by Merck for a portion of its costs to develop the test and obtain regulatory approvals. Additionally, Merck will provide promotional support, including detailing the test in the physicians' office market in those countries in which the Company has obtained approval.

**About OraSure Technologies:** OraSure Technologies develops, manufactures and markets oral fluid specimen collection devices using proprietary oral fluid technologies, diagnostic products including immunoassays and other in vitro diagnostic tests, and other medical devices. These products are sold in the United States as well as internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities.

OraSure Technologies is the leading supplier of oral-fluid testing solutions for drugs of abuse and for the detection of antibodies to HIV.

For more information on the Company, please go to [www.orasure.com](http://www.orasure.com).