

The Spatz Adjustable Balloon System® for Weight Loss Becomes the First Intra-gastric Balloon to Receive Regulatory Approval for 1 Year Implantation Time

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JERICHO, N.Y., Nov. 16, 2010 /PRNewswire/ -- Following results of its 12 month study in Europe, **Spatz FGIA, Inc.** has received regulatory approval for extension of the implantation period from six months to 12 months. Intra-gastric balloons for weight loss have been used successfully for the last 17 years outside of the US, however, the risk of balloon deflation with subsequent bowel obstruction has mandated removal of all intra-gastric balloons at six months. The unique anchoring system of the Spatz device protects a deflated balloon from advancing into the intestines, allowing it to be used safely beyond six months.

"While we welcome this extraordinary news, extending the implantation time alone is not enough to produce greater weight loss. Non-adjustable balloons lose their effect within 2 to 4 months, so additional implantation time is not likely to increase weight loss significantly," said Dr. Jeffrey Brooks, founder and CEO of Spatz. "Only an adjustable balloon can offer repeated waves of weight loss, after the balloon volume is adjusted upward," he continued.

The European study has reported an additional 8 kg (17.6 lbs) weight loss following adjustments. In addition, intolerant patients have been successfully adjusted downward, with continued weight loss. Adjustments plus extended implantations have resulted in an average weight loss of 35.5 kg (78 lbs) at the end of one year – achieving loss of 67% of their excess weight. "The potent combination of adjustability and one year implantation is unique to the Spatz device, and will open up a new era in endoscopic weight management," continued Brooks.

"Our gastric balloon specialists have requested adjustability and longer implantation time- and we can now deliver this unique combination," said David Hofstadter, Director of Marketing and Business Development. "We have been overwhelmed with requests from every corner of the planet," he continued, "and we intend to make this a worldwide product."

In the future, Spatz intends to pursue two and three year implantation times, potentially becoming a chronic endoscopic weight management tool. "All devices have been examined in our lab after removal at 12 months, and have remained completely functional," said Eran Hirszowicz, chief engineer. "From an engineering and functional point of view, we see no reason to limit implantation to one year," he continued.

About Spatz FGIA, Inc.

Spatz FGIA, Inc. is a medical device company that has created the next generation gastric balloon for the worldwide obesity epidemic. Now available for commercial use in Europe as well as many countries around the world, the company's flagship product, the **Spatz Adjustable Balloon System®**, offers a unique non surgical solution for the overweight and obese. The 15 minute out-patient procedure reduces stomach capacity to give patients a feeling of satiety. Patients are discharged home within one hour after insertion. It is not approved by the FDA for use in the United States.

For further information, visit www.spatzmedical.com.

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