# Spatz Medical Announces FDA Approval of Spatz3 Gastric Balloon, the First Adjustable Gastric Balloon

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Dr. Jeffrey Brooks, Founder of Spatz-FGIA Inc

FORT LAUDERDALE, FLORIDA, UNITED STATES, October 23, 2021 /EINPresswire.com/ -- Spatz Medical Announces FDA Approval of Spatz3 Gastric Balloon, the First Adjustable Gastric Balloon

• Excellent weight loss results in FDA clinical trials:
- 15% decrease in weight
- 84% success rate
• Safe and effective weight loss solution in more than 40 countries with almost 100,000 placements worldwide

Spatz FGIA, Inc., an international pioneer in gastrointestinal weight loss solutions, today announced that the U.S. Food and Drug Administration (FDA) has approved the Spatz3 Gastric Balloon, the first adjustable gastric balloon system, to aid in weight loss for adult patients struggling with obesity. The Spatz3 is the fifth balloon to receive FDA approval and its pivotal FDA clinical trial results demonstrated a 15% decrease in weight and an 84% success rate.

Although new to the United States, the Spatz Balloon has already been implanted in almost 100,000 patients in over 40 countries and as shown in the FDA study, its distinctive and unique adjustability feature has created an effective and safe weight loss therapy.

The Spatz3 Adjustable Gastric Balloon Innovation

Dr. Jeffrey Brooks, inventor of the Spatz3 adjustable balloon and CEO of Spatz FGIA, Inc. said, “We are proud of our FDA clinical trial results and look forward to bringing this proven technology to the U.S. population. FDA clinical trials are among the most respected because they

are performed under stringent conditions – I.T.T., or intention to treat. This means every patient that is treated is accounted for and cannot be lost to follow-up, offering a true representation of results. The Spatz adjustability function has raised the bar for gastric balloons and has resulted in impressive weight loss results and an outstanding 84% success rate."

The Spatz3 Gastric Balloon

Like other gastric balloons, the Spatz3 is inserted endoscopically while under conscious sedation. During the 15-minute non-surgical procedure, the balloon is placed in the stomach and inflated with saline, and the patient is discharged within one hour.

In the last four decades, the world has seen over 500,000 gastric balloons implanted and that experience, as documented in the medical literature, has taught us that almost all gastric balloon systems lose efficacy by the fourth month, leading to weight loss plateau and weight regain while the balloon is implanted. In addition, abundant medical publications have reported that approximately one in ten gastric balloon patients face premature extraction in the first month due to intolerance, characterized by persistent nausea, vomiting or abdominal pain.

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>
> *Dr. Jeffrey Brooks*

These two issues are addressed by the proprietary adjustment feature of the Spatz balloon, which enables the physician endoscopist the ability to change the balloon volume at any time during the treatment period. The balloon volume adjustment is performed in a 15-minute outpatient endoscopic procedure and is used in the following two scenarios:

• A "down adjustment" to remove 100-150 ml from the balloon to alleviate intolerance and prevent early extraction

• An "up adjustment" to add 200-300 ml to the balloon, which rejuvenates the balloon effect and affords the second round of weight loss

Find out more: [spatzmedical.com/about/how-it-works/](spatzmedical.com/about/how-it-works/)

The Spatz3 Balloon has garnered significant applause from the medical community and its

respected members, including Professor Barham Abu Dayyeh MD, MPH (Professor of Medicine, Director of Advanced Endoscopy, and Vice Chair of Innovation for the Department of Medicine at the Mayo Clinic). Professor Abu Dayyeh said, “A different paradigm is emerging for the management of obesity…to improve or resolve obesity-associated comorbidities. The adjustability feature of the Spatz3 balloon and longer treatment duration maximizes patients’ tolerance and uniquely positions this technology to offer a safe and effective modality to manage obesity in conjunction with a robust lifestyle intervention program.”

Spatz3 FDA Pivotal Clinical Study Results

In the U.S. pivotal Spatz3 clinical trial, 288 patients suffering from obesity (Body Mass Index 30-40 kg/m2) were randomized to treatment or control, with two-thirds randomized to implantation with the Spatz balloon with diet and exercise and one third serving as control patients on diet and exercise alone. During the 14-month pivotal trial all study endpoints were met.

Detailed findings of the trial revealed:
• Spatz Balloon patients lost 15% of their initial weight compared with 3% weight loss in the control group - five times greater weight loss with Spatz3 Balloon.
• Weight maintenance was measured for six months after balloon removal, with 74.3% achieving the weight loss maintenance endpoint.
• The adjustment feature was used to reduce balloon volume for intolerant patients. Twenty-eight intolerant patients underwent down adjustments with removal of 150 ml. Intolerance was alleviated in 82% of these patients, allowing them to complete the entire 8-month treatment period.
• At week 18 (+/- 4 weeks) up adjustments were performed in 71.7% of patients with the addition of 200-300 ml, resulting in additional loss of 15.2% of their excess weight after the 18-week adjustment.
• The overall success rate, defined as achieving at least 10% weight loss, was achieved in 84% of patients.

For more information about Spatz Medical, please visit spatzmedical.com.

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About Spatz Medical
Spatz FGIA, Inc. develops and markets the Spatz3, an all-new category of Adjustable Gastric Balloon for the treatment of obese and overweight patients.* The Spatz3's exclusive adjustability feature delivers the highest success rates (response rates) on the market and brings new opportunities to the field of gastroenterology and bariatric endoscopy, enabling physician endoscopists to change the balloon volume at any time during the treatment period. This presents a solution for patients who are intolerant to gastric balloons, as well as a means of rejuvenation for patients whose weight loss has reached a plateau. Spatz, a global leader in its category, proudly offers its innovative technologies to over 40 markets worldwide and has

implanted its balloons in almost 100,000 patients.

*Approved for use in adults with obesity Body Mass Index (BMI) of 35.0-40.0 kg/m2 or a BMI of 30.0 to 34.9 kg/m2 with one or more major obesity-related comorbid conditions who have failed to achieve and maintain weight-loss with a supervised weight control program.

For more information regarding Spatz3, please visit:
www.SpatzMedical.com

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