

SafeStitch Medical® Announces Encouraging Result of Transluminal Procedure to Correct GERD and Obesity with Two Years Follow Up

The Associated Press

MIAMI--(BUSINESS WIRE)--Jan 22, 2013--SafeStitch Medical®, Inc. (OTCBB:SFES), SafeStitch Medical today reported positive findings in a seven patient preliminary pilot clinical trial using its proprietary transluminal devices to restrict gastric acid reflux in three patients and to cause meaningful weight reduction in two obese patients after two years.

"It's encouraging to see the objective findings of esophageal pH normalization in the three patients with gastroesophageal reflux disease and weight loss of 30-60% in the two obese subjects two years after the procedure. This provides the level of confidence that our transluminal devices and procedure will have durability, which is essential for the success of the procedure," said Dr. Charles Filipi, Chief Medical Officer at SafeStitch Medical; lead on the clinical trial and inventor of the devices. "To the best of our knowledge no other transoral devices have achieved these results. By going through the mouth, there is less risk of infection, and only conscious sedation is required. This should result in lower costs for bariatric and GERD surgery." "SafeStitch plans to expand the pilot study to include additional subjects and to submit an Investigational Device Exemption (IDE) with FDA this year. We plan to seek FDA approval in due course," stated by Dr. Jane Hsiao, Chairman of SafeStitch Medical.

About SafeStitch Medical, Inc. Miami, Florida-based SafeStitch Medical, Inc. is a publicly traded medical device company founded in 2006. Our mission is to develop and market the best in class disposable medical devices to advance minimally invasive surgery for hernia repair, treatment of obesity and other gastroesophageal disorders. SafeStitch Medical has developed and obtained FDA approval to market the AMID Hernia Fixation Device (HFD) for both inguinal and ventral hernia repairs. The AMID HFD allows for faster mesh manipulation, mesh fixation and skin closure. Information about the Company may be found on its website at: www.safestitch.com.

This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), which statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipate," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding our product development and commercialization efforts, and our ability to significantly improve clinical outcomes in patients, as well as other non-historical statements about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects. Many factors, including those described herein and in our filings with the Securities and Exchange Commission, could cause our

SafeStitch Medical® Announces Encouraging Result of Transluminal Procedure

Published on Medical Design Technology (<http://www.mdtmag.com>)

actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include, but are not limited to: whether the limited pilot study will have similar results if expanded to include more patients; whether the transluminal device will have adequate durability; whether any other transoral devices have achieved similar results to our study; whether conducting the procedure through the mouth will result in lower costs; whether we will submit an IDE and whether we will seek FDA approval in due course. The forward-looking statements contained in this press release speak only as of the date the statements were made, and we do not undertake any obligation to update forward-looking statements, except as required under applicable law. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.

CONTACT: SafeStitch Medical, Inc.

Jeffrey G. Spragens, 305-575-4146 jgspragens@safestitch.com or Jim J. Martin, 305-575-4207 jmartin@safestitch.com KEYWORD: UNITED STATES NORTH AMERICA FLORIDA INDUSTRY KEYWORD: SURGERY HEALTH CLINICAL TRIALS MEDICAL DEVICES OTHER HEALTH FDA GENERAL HEALTH SOURCE: SafeStitch Medical, Inc. Copyright Business Wire 2013 PUB: 01/22/2013 09:00 AM/DISC: 01/22/2013 09:00 AM <http://www.businesswire.com/news/home/20130122005502/>

Source URL (retrieved on 01/28/2015 - 2:52am):

http://www.mdtmag.com/news/2013/01/safestitch-medical%C2%AE-announces-encouraging-result-transluminal-procedure-correct-gerd-and-obesity-two-years-follow?qt-most_popular=0&qt-video_of_the_day=0