
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 8, 2010

SAFESTITCH MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other Jurisdiction of Incorporation)	0-19437 (Commission File Number)	11-2962080 (IRS Employer Identification No.)
4400 Biscayne Boulevard, Suite A-100, Miami, Florida (Address of Principal Executive Offices)		33137 (Zip Code)

Registrant's telephone number, including area code: **(305) 575-4600**

(Former name or former address if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 7.01 Regulation FD Disclosure

On June 8, 2010, SafeStitch Medical, Inc. (the “Company”) will present at the Jefferies 2010 Global Life Sciences Conference in New York, New York. A copy of the Company’s presentation slides is furnished as Exhibit 99.2 to this Current Report on Form 8-K and is available on the Company’s website on the day of the presentation at www.safestitch.com.

The information contained in Item 7.01 to this Current Report on Form 8-K and Exhibits 99.1 and 99.2 attached hereto shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing by the Company under the Act.

Item 9.01 Financial Statements and Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated June 7, 2010
99.2	Jefferies 2010 Global Life Sciences Conference Presentation

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

SAFESTITCH MEDICAL, INC.

By: /s/ Adam S. Jackson

Name: Adam S. Jackson

Title: Chief Financial Officer

Date: June 8, 2010

SAFESTITCH MEDICAL, INC. TO PRESENT AT JEFFERIES 2010 GLOBAL LIFE SCIENCES CONFERENCE

MIAMI—(BUSINESS WIRE)—SafeStitch Medical, Inc. (OTCBB: SFES) announced today that senior management will present at the Jefferies 2010 Global Life Sciences Conference on Tuesday, June 8, 2010 at 10:30 AM EDT. The conference will be held at the Grand Hyatt New York in New York City.

SafeStitch senior management will provide a review of recent corporate developments. The Company's presentation slides will be available on the SafeStitch website on the day of the presentation. To access the slides go to the Company's website at www.SafeStitch.com and click on the icon for the Investor Relations home page.

About SafeStitch Medical, Inc.

Miami-based SafeStitch Medical, Inc. is a medical device company primarily developing endoscopic and minimally invasive surgical devices. SafeStitch's product portfolio includes endoscopic gastroplasty devices for bariatric (obesity) surgery and repair of gastroesophageal reflux disorder (GERD), as well as the AMID Stapler™, Standard BiteBlock, Airway BiteBlock and SMART Dilator™. SafeStitch has also started development of devices for excision and diagnosis of Barrett's esophagus and natural orifice transluminal endoscopic surgery (NOTES). Information about the Company may be found on its website at: www.safestitch.com.

Contact:

SafeStitch Medical, Inc., Miami, 305-575-4600

Jeffrey G. Spragens, CEO

Dr. Stewart B. Davis, COO

Adam S. Jackson, CFO

SAFESTITCH

MEDICAL

Where Safety Meets Innovation

Endoscopic and Minimally Invasive Surgical Devices

www.SafeStitch.com

June 2010

OTCBB: SFES

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Safe Harbor Statement

This presentation 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," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning regarding product development and commercialization efforts and other non-historical facts about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described in our filings with the Securities and Exchange Commission, as well as risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments. In addition, forward-looking statements may also be adversely affected by general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. We do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.

Founded 2005

- ▶ Charles J. Filipi, M.D.
 - Professor of Surgery at Creighton University School of Medicine; Past President of the American Hernia Society; Fellow of the American College of Surgeons
- ▶ Phillip Frost, M.D.
 - Chairman, CEO and President of OPKO Health; Chairman of Teva Pharmaceuticals; Former Chairman and CEO of IVAX Corporation
- ▶ Jane Hsiao, Ph.D.
 - Chairman of Non-Invasive Monitoring Systems; Vice-Chairman and CTO of OPKO Health; Former Vice-Chairman of IVAX Corporation
- ▶ Jeffrey G. Spragens
 - Co-founder and former Director of North American Vaccine

Management Team

- ▶ **Jeffrey G. Spragens – Chief Executive Officer and President**
 - Co-Founder and former Director of North American Vaccine Corporation; Co-Founder and Director of Foundation for Peace; Co-Founder of Mint Management and Development

- ▶ **Stewart B. Davis, M.D. – Chief Operating Officer**
 - Managing Partner and Medical Director of Parasol International; Former Asst. Medical Director of Innovia LLC, InnFocus LLC, InnoGraft LLC and InnCardia LLC

- ▶ **Adam S. Jackson – Chief Financial Officer**
 - Chief Financial Officer of Non-Invasive Monitoring Systems, Inc.; Former Senior Vice President, Finance and Senior Vice President, Controller of Levitt Corporation; Former Chief Financial Officer of Romika-USA, Inc.

- ▶ **Joshua Weingard – Chief Legal Officer**
 - CLO of Non-Invasive Monitoring Systems, Inc. and Cardo Medical, Inc.; Former EVP and CLO of NationsHealth Inc; Former Sr. Corporate and Securities Counsel for Andrx Corporation

- ▶ **Charles J. Filipi, M.D. – Chief Medical Officer**
 - Professor of Surgery at Creighton University School of Medicine; Former President of the American Hernia Society

Board of Directors

- ▶ **Jane Hsiao Ph.D.** – Chairman of the Board
- ▶ **Jeffrey G. Spragens**
- ▶ **Charles J. Filipi, M.D.**
- ▶ **Chao Chen, Ph.D.**
 - Chief Operating Officer of UniMed VM, Former Vice President of TaiMed Inc., Formerly with Cordis and Ethicon, subsidiaries of Johnson & Johnson
- ▶ **Richard Pfenniger, Jr.**
 - CEO and President of Continucare Corporation (AMEX: CNU)
- ▶ **Steven Rubin**
 - Executive Vice President of OPKO Health (AMEX: OPK); Former Senior Vice President, General Counsel and Secretary of IVAX Corporation
- ▶ **Kevin Wayne, D.B.A.**
 - Associate Professor of Business Administration at Rivier College; Co-founder and Former Vice President of Onux Medical, Inc.

Medical Advisory Board

- ▶ **Para Chondrosoma, M.D.**
 - University of Southern California (Chairman of Pathology); Esophageal Pathology
- ▶ **Tom DeMeester, M.D.**
 - University of Southern California (Chairman of Surgery); Esophageal Surgery; Expert in Barrett's Esophagus
- ▶ **Glen Lehman, M.D.**
 - Indiana University; Gastroenterology; Expert in Endoscopic GERD Treatment and ERCP
- ▶ **Jeff Peters, M.D.**
 - University of Rochester (Chairman of Surgery); GERD Surgery; expert in Barrett's and esophageal dilation
- ▶ **Raul Rosenthal, M.D.**
 - Cleveland Clinic; Bariatric Surgery; Chairman of the Bariatric Centers of Excellence Accreditation Committee
- ▶ **Richard Rothstein, M.D.**
 - Dartmouth University; Gastroenterology; Expert in GERD, Barrett's Esophagus and NOTES
- ▶ **Scott Shikora, M.D.**
 - Tufts University Medical Center (Chief of Bariatrics); Bariatric Surgery; Former President of the American Bariatric Society
- ▶ **Lee Swanstrom, M.D.**
 - Oregon Clinic; Laparoscopic and Endoscopic Surgery; First Surgeon to perform Transoral NOTES Cholecystectomy in the US

Company Highlights

- ▶ February 2009 – FDA clearance for SMART Dilator™
- ▶ November 2009 – FDA clearance for AMID Stapler™
- ▶ February 2010 – CE Mark for AMID Stapler™
- ▶ June 2010 – Commercial Launch of AMID Stapler™



Locations

- ▶ Miami
 - Headquarters
 - Development Lab
 - Distribution Warehouse
- ▶ Omaha
 - Office
 - Development Lab

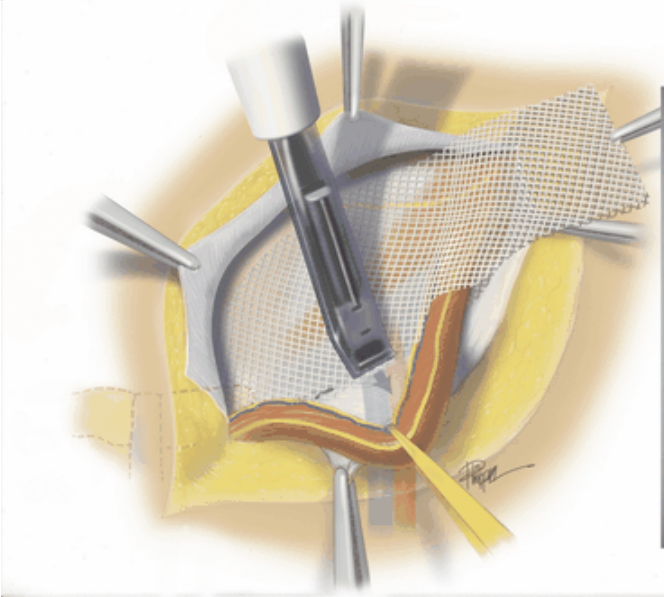


June 2010

AMID Stapler™

- ▶ Ready to launch sales – June 2010
- ▶ 510(k) cleared by FDA – November 2009
- ▶ CE Mark received – February 2010
- ▶ Sales and Marketing Team in place
 - Led by industry veterans, Caron D'Ambruso and J.C. Campbell

AMID Stapler™



AMID Stapler™

- ▶ Up to 1 million inguinal hernia cases per year in the U.S.
- ▶ Approximately 80% of inguinal hernia repairs worldwide utilize the Lichtenstein method of affixing mesh to the herniated abdominal wall
 - Popularized by UCLA's Parviz Amid, M.D.
 - Hand suturing
 - Significant retraction
- ▶ Approximately 100,000 ventral hernia cases per year in the U.S.

AMID Stapler™

For Inguinal & Ventral Hernia repair

- ▶ Developed with input from Dr. Amid
- ▶ Can be used to repair Inguinal and Ventral hernias and to staple skin
- ▶ For Lichtenstein repair, The AMID Stapler™ is expected to make the procedure:
 - Fast
 - Easy
 - Reduce post-operative pain



Pipeline

NOVEL DEVICES and GI Complementary Products

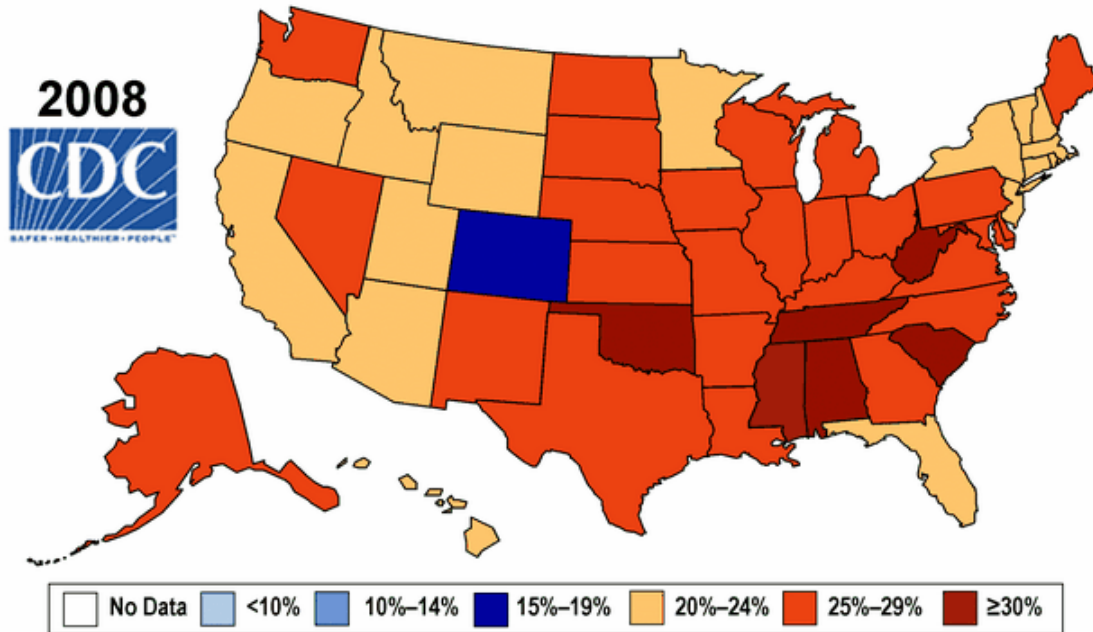
- ▶ **Intraluminal Gastroplasty Kit**
 - For Obesity
 - For GastroEsophageal Reflux Disorder (GERD)
 - Status – Ready for IDE
- ▶ **Intraluminal Fixation Device**
 - Status – 510(k) submitted
- ▶ **Intraluminal Excision Device**
 - Status – 510(k) ready to submit June 2010
- ▶ **Barrett's Excision and Strip Mucosal Device**
 - Status – Prototype in development
- ▶ **SMART Dilator™**
 - Status – 510(k) cleared by FDA
- ▶ **Retention Bite Block – 510(k) exempt**
- ▶ **Airway Bite Block – 510(k) exempt**
- ▶ **T Fastener**
 - Status – Prototype in development
- ▶ **Novel Devices for Natural Orifice Transluminal Endoscopic Surgery (NOTES)**
 - Status – IP filed

Obesity

- ▶ Closely linked to heart disease, diabetes, hypertension and other major health issues
- ▶ ~27% of U.S. population may be obese
- ▶ Treated with diet, exercise, prescription drugs and/or surgery
- ▶ Surgery is most effective treatment
- ▶ Current surgical procedures have become household terms (gastric bypass, stomach stapling, lap band)

Obesity Trends in the U.S.

(BMI ≥ 30 , or ~ 30 lbs. overweight for 5' 4" person)



Source: Behavioral Risk Factor Surveillance System, CDC

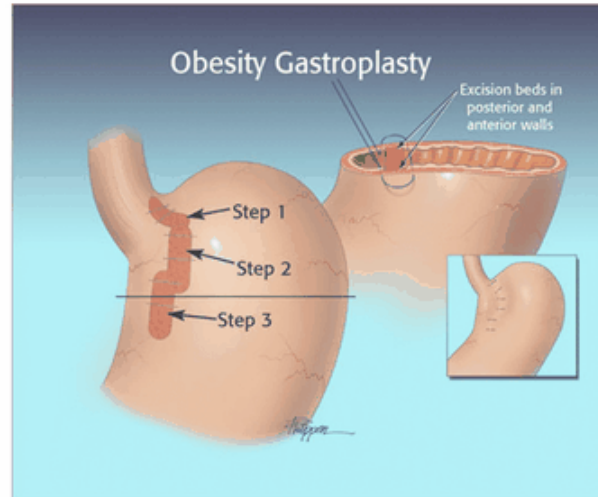
Obesity Surgery

- ▶ 350,000 – 400,000 bariatric procedures are currently performed worldwide each year
 - ▶ Existing procedures cost \$15,000 to \$70,000
 - ▶ Existing procedures involve open abdominal surgery
 - ▶ High risk patients, with high morbidity and mortality for these procedures



SafeStitch Obesity Procedure

- ▶ Advantages:
 - Outpatient procedure
 - Safer
 - Faster recovery
 - Durability of effect
 - Significant cost reduction
- ▶ Clinical trials expected to begin in Q3 2010

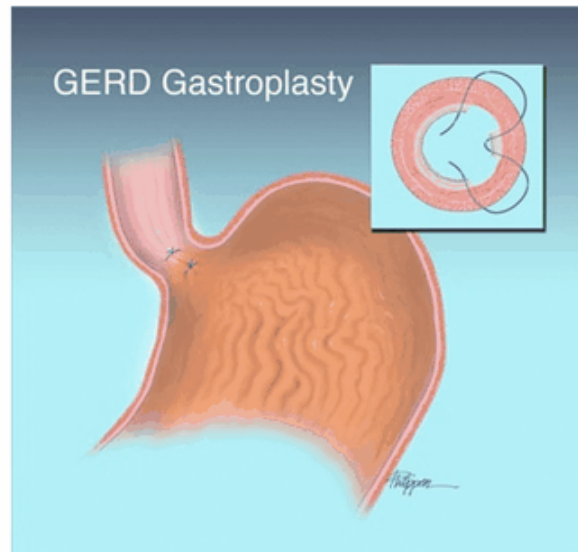


GERD

- ▶ GastroEsophageal Reflux Disorder
 - Heartburn, indigestion
- ▶ Multibillion dollar market in pharmaceuticals alone
- ▶ Recent New England Journal of Medicine papers discuss increased risk of bone fractures with chronic PPI use
- ▶ GERD can lead to Barrett's Esophagus, which may lead to cancer
- ▶ 200,000 to 250,000 GERD procedures are performed worldwide each year

SafeStitch GERD Procedure

- ▶ Same kit as obesity
- ▶ Advantages:
 - Outpatient procedure
 - Safer
 - Easier and Quicker
 - Durability of effect
 - Significant cost reduction
- ▶ Clinical trials expected to begin in Q3 2010



1 Kit, 2 Procedures, 3 Steps

-Obesity and GERD

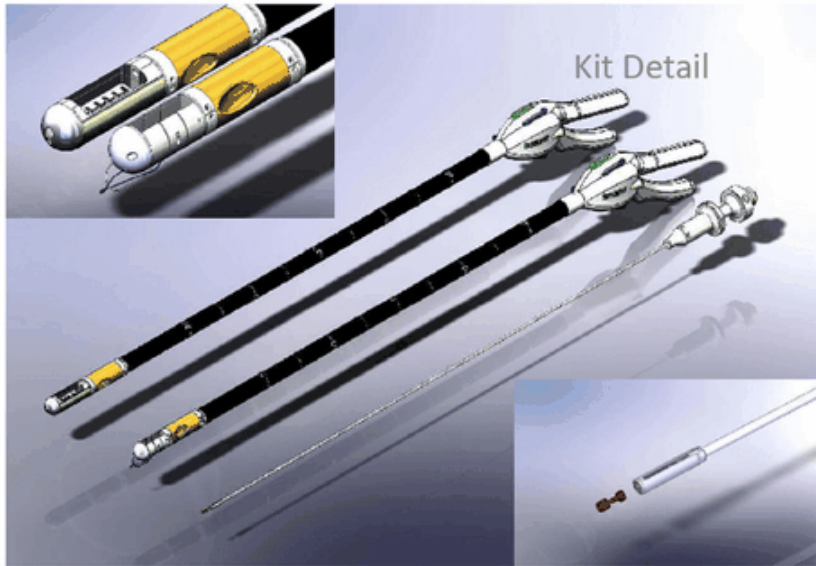
-Excision, Suturing, Knotting

Gastroplasty Devices

EXCISION



SUTURE



KNOTTER



New 510(k)s

▶ Intraluminal Fixation Device

- **Status** – 510(k) submitted
- **Market** – Pouch reduction, Outlet reduction, Gastro-gastro fistula closure, NOTES gastrostomy closure, Esophageal perforation closure, Post colonoscopy rectal sigmoid colon perforation closure, Post endoscopic gastric perforation closure, Gastric sleeve revision, Prosthetic weight loss sleeve fixation to stomach, Gastric ulcer perforation closure, NOTES intraperitoneal applications, Enterotomy closure, Bowel perforation closure, Reinforce sutured closures

▶ Intraluminal Excision Device

- **Status** – 510(k) ready to submit June 2010
- **Market** – Pouch reduction, Outlet reduction, Gastro-gastro fistula closure, Gastric sleeve revision, Biopsy of gastric ulcers suspicious for gastric cancer in US and Asia, Removal of sessile gastric polyps, Biopsy of gastric leiomyomas

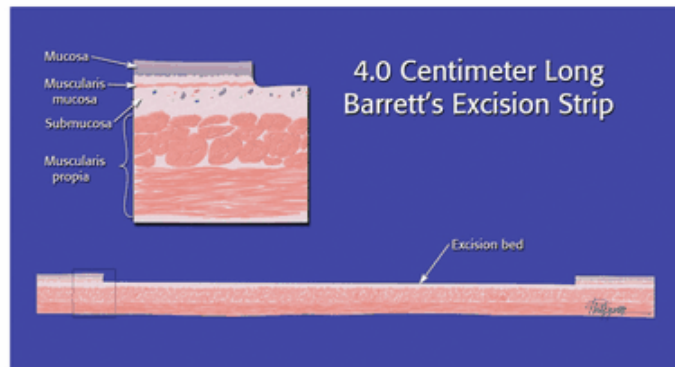
Barrett's Esophagus

- ▶ Condition in which the esophagus changes so that some of its lining is replaced by a type of tissue similar to that normally found in the intestine, intestinal metaplasia
 - GERD is most common cause
 - May lead to esophageal cancer

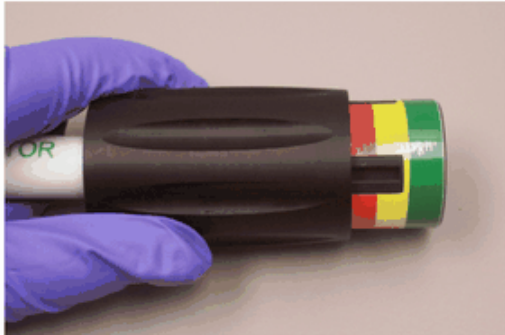
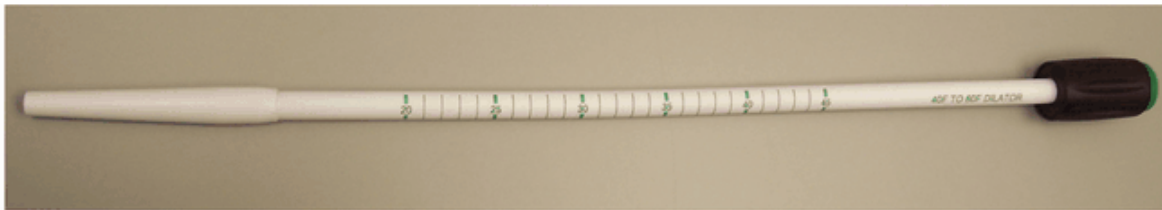


Barrett's Excision and Strip Mucosal Device

- ▶ Approximately 11 million patients worldwide
- ▶ Advantages:
 - Large piece of tissue excised; can be sent for histology
 - Clean margins
 - Easier and Quicker than EMR and RF Ablation
 - Cost reduction



SMART Dilator™



SMART Dilator™

- ▶ 800,000 dilations of esophageal strictures are performed annually in the U.S.; ~2 million Worldwide
- ▶ Perforation Rate: ~1.1%
- ▶ Important Features
 - Visual feedback force gauge handle
 - Tapered tip
 - Endoscope channel through entire device
 - Disposable: other disposable dilators sell for \$150 – \$250
- ▶ Ready to Launch Sales of GI complementary products

Retention Bite Block

- ▶ Approximately 18 – 20M upper endoscopies done per year worldwide and all procedures need bite blocks to prevent injury to endoscopes and the patients' teeth
- ▶ Class I, 510(k) exempt device
- ▶ Advantages:
 - Harder to expel from mouth
 - Softer material
 - Superior crush resistance
 - Larger working inner diameter



Airway Bite Block

- ▶ Approximately 5M upper endoscopies done per year worldwide on obese patients
- ▶ Many obese patients have airway problems during procedures which require intervention
- ▶ Class I, 510(k) exempt device
- ▶ Advantages:
 - Novel design integrating Retention Bite Block and Oral-Pharyngeal airway
 - Softer Material
 - Superior crush resistance
 - Larger working inner diameter



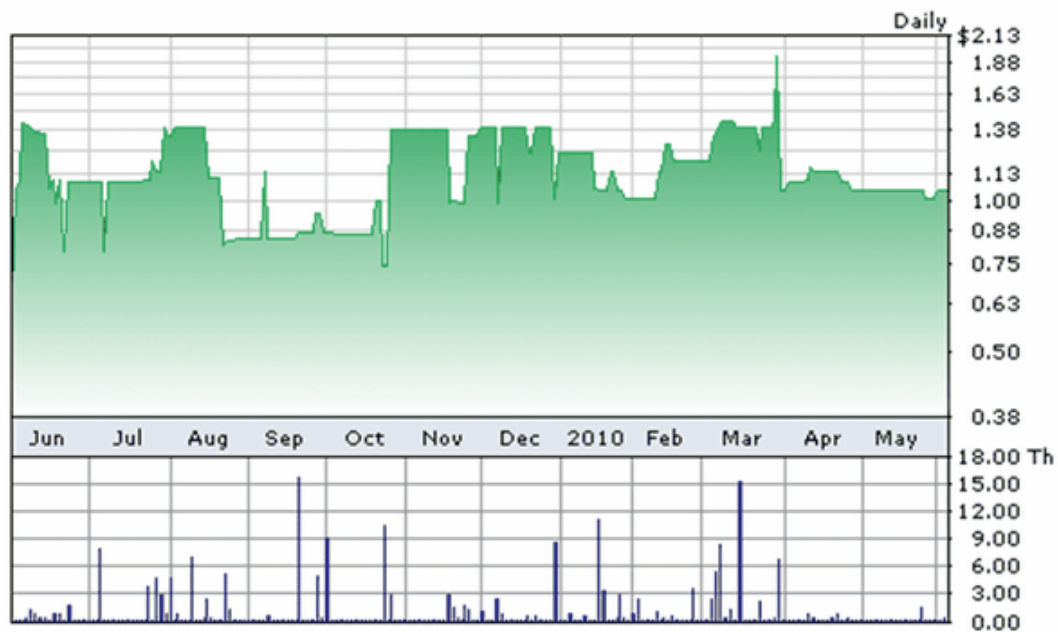
June 2010

Additional Products

- ▶ T Fastener
 - For Upper GI Bleeding and closing gastrotomies following NOTES
 - T Fastener can be placed using multi-firing endoscopic device
 - High mortality rate due to Upper GI bleeding
 - Needs to be treated quickly and effectively

- ▶ Novel Devices for NOTES
 - IP for multiple devices:
 - Magnetic retractors
 - Device for closing gastrotomies following NOTES
 - NOTES access platforms

Stock Performance – SFES



Summary

- ▶ Large, important and growing markets
 - Obesity, GERD, Hernia and Barrett's Esophagus
 - Multibillion dollar markets
- ▶ Unique devices
 - Outpatient and minimally invasive
 - Increased safety for patients
- ▶ Reduce procedural costs
- ▶ Reduce societal costs from obesity and obesity-related diseases

SAFESTITCH

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▶ Contact:

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Adam Jackson – CFO

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