

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

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FORM 8-K

CURRENT REPORT

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

September 21, 2009

Date of Report (Date of earliest event reported)

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**SAFESTITCH MEDICAL, INC.**

(Exact Name of Registrant as Specified in Charter)

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**Delaware**

(State of Other Jurisdiction  
of Incorporation)

**0-19437**

(Commission File Number)

**11-2962080**

(I.R.S. Employer  
Identification Number)

**4400 Biscayne Boulevard, Suite A-100, Miami, Florida**

(Address of principal executive offices)

**33137**

(Zip Code)

**(305) 575-4145**

(Registrant's telephone number, including area code)

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 (see General Instruction A.2. below):

- 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 (17CFR 240.13e-4(c))
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**Item 7.01 Regulation FD Disclosure**

Beginning September 21, 2009, senior executives of SafeStitch Medical, Inc. (the "Company"), will present the slides and additional financial information attached as Exhibit 99.1 to this Current Report on Form 8-K (the "Presentation") at the UBS Global Life Sciences Conference in New York City. A copy of the Presentation is attached hereto as Exhibit 99.1 and is incorporated by reference in this Item 7.01.

The information in this Current Report on Form 8-K (including Exhibit 99.1) is "furnished" and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing by the Company under the Securities Act of 1933, as amended. The information in this Current Report on Form 8-K shall not be deemed an admission as to the materiality of any information required to be disclosed solely to satisfy the requirements of Regulation FD.

**Item 9.01 Financial Statements and Exhibits**

<u>Exhibit Number</u>	<u>Description</u>
99.1	Presentation materials to be given at the UBS Global Life Sciences Conference, September 21-23, 2009.

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**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: September 21, 2009

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**Exhibit Index**

<u><b>Exhibit Number</b></u>	<u><b>Description</b></u>
99.1	Presentation materials to be given at the UBS Global Life Sciences Conference, September 21-23, 2009

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# SAFESTITCH

MEDICAL

Where Safety Meets Innovation

Endoscopic and Minimally Invasive Surgical Devices

[www.SafeStitch.com](http://www.SafeStitch.com)

September 2009

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), regarding product development 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; Multiple commercially successful medical devices
- ▶ **Phillip Frost M.D.**
  - Chairman, CEO and President of OPKO Health; Vice-Chairman of Teva Pharmaceuticals; Former Chairman and CEO of IVAX
- ▶ **Jane Hsiao Ph.D.**
  - Chairman of Non-Invasive Monitoring Systems; Vice-Chairman and CTO of OPKO Health; Former Vice-Chairman of IVAX
- ▶ **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 Business Manager of SafeStitch LLC; 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 and Secretary**

- Chief Operating Officer of SafeStitch LLC; 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.

▶ **Charles J. Filipi M.D. – Medical Director**

- Co-founder and Medical Director of SafeStitch LLC; 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.**
- ▶ **Steven Rubin**
  - Executive Vice President of OPKO Health; Former Senior Vice President, General Counsel and Secretary of IVAX
- ▶ **Richard Pfenniger, Jr.**
  - CEO and President of Continucare Corporation
- ▶ **Kevin Wayne**
  - 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
- ▶ **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

# Corporate Organization

- ▶ Board of Directors
- ▶ Jeffrey Spragens – CEO
- ▶ Stewart Davis M.D.
  - Administration, R&D, Engineering, Prototype Lab, QA/QC, Regulatory
- ▶ Charles Filipi M.D.
  - Research & Development, Pre-clinical and Clinical evaluations
- ▶ Adam Jackson
  - Administration, Accounting & Finance, H.R., Legal
- ▶ Phillip Frost M.D. – Consultant
- ▶ Medical Advisory Board

# Company Highlights

- ▶ Founded September 2005
- ▶ May 2006 – Creighton University license agreement
- ▶ September 2007 – Share exchange with CTSC
  - OTCBB listing
  - \$4M Line of Credit
- ▶ May 2008 – \$4M Common Stock PIPE
- ▶ February 2009 – FDA clearance for SMART Dilator™
- ▶ July 2009 – \$4M Preferred Stock PIPE
- ▶ September 2009 – FDA and CE applications for AMID Stapler™ clearance

# Locations

## ▶ Miami

- Executive Office – 4400 Biscayne Blvd.
- Prototype Lab – Kendall

## ▶ Omaha

- Office – 1209 Harney St.
- Animal Lab (Surgical Suite, Holding Facility and Machine Shop)
- Creighton University



September 2009

# Big Markets, Important Products

## MARKETS

- ▶ Obesity
- ▶ GastroEsophageal Reflux Disorder (GERD)
- ▶ Hernia
- ▶ Barrett's Esophagus

# Big Markets, Important Products

## PRODUCT PIPELINE

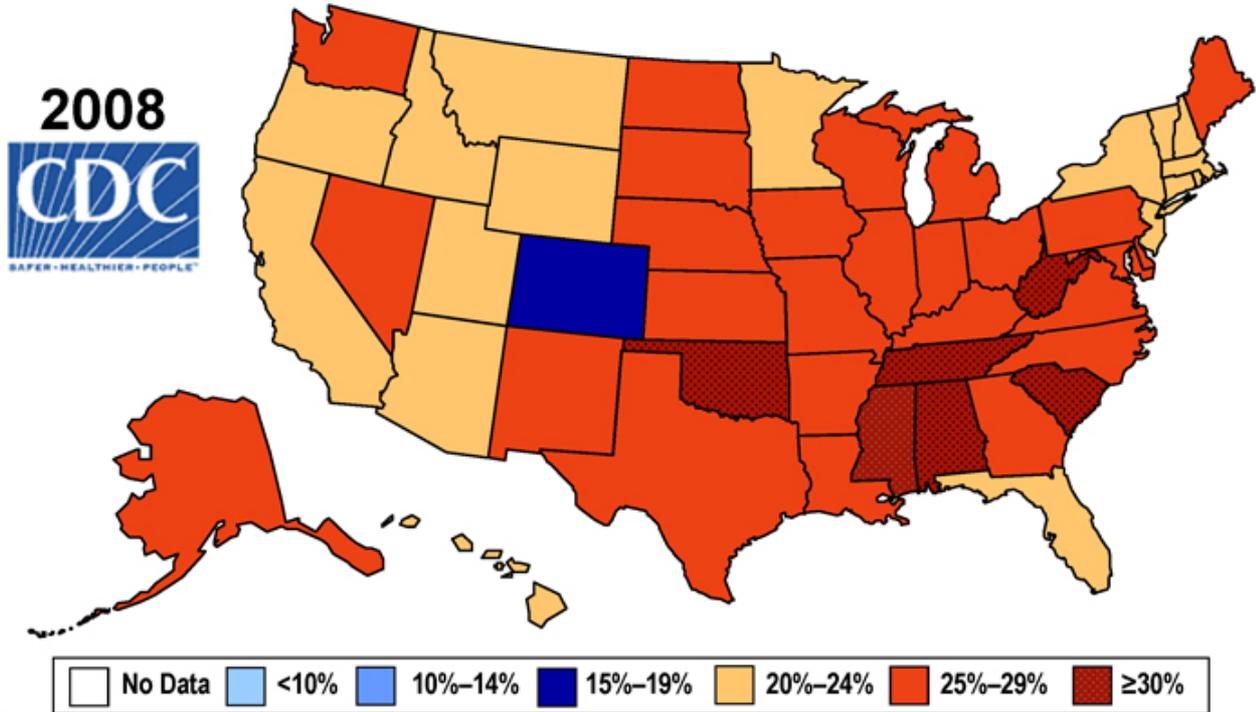
- ▶ Intraluminal Gastroplasty Device
  - For Obesity
  - For GERD
- ▶ AMID Stapler™
- ▶ Barrett's Excision and Strip Mucosal Device
- ▶ SMART Dilator™
- ▶ Retention Bite Block
- ▶ Airway Bite Block
- ▶ T Fastener
- ▶ Novel Devices for Natural Orifice Transluminal Endoscopic Surgery (NOTES)

# Obesity

- ▶ Closely linked to heart disease, diabetes, hypertension and other major health issues
- ▶ 30% of U.S. population may be obese by 2017
- ▶ 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  $\geq 30$ , or  $\sim 30$  lbs. overweight for 5' 4" person)



Source: Behavioral Risk Factor Surveillance System, CDC

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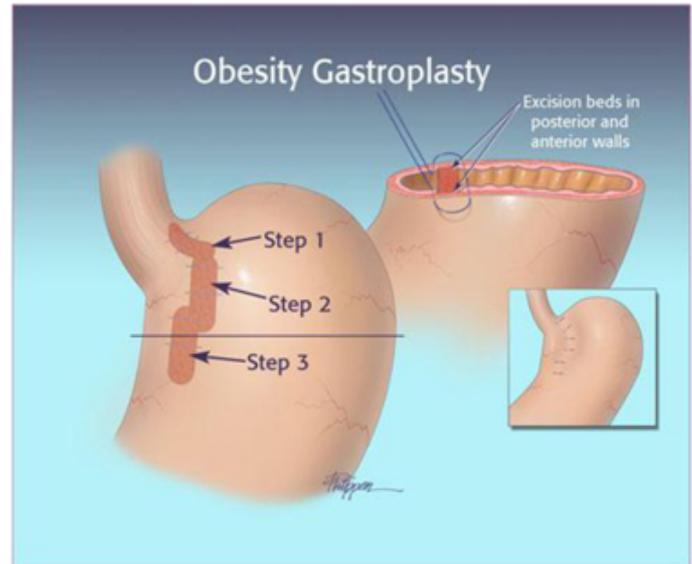
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# Obesity Surgery

- ▶ 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 2010
- ▶ Non-U.S. Sales anticipated 2011, U.S. 2012

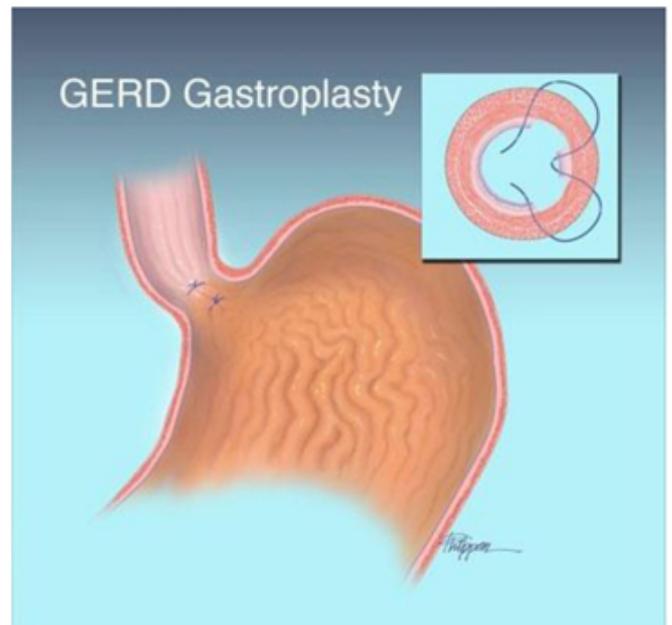


# GERD

- ▶ GastroEsophageal Reflux Disorder
  - Heartburn, indigestion
- ▶ Multibillion market in pharmaceuticals alone
- ▶ GERD can lead to Barrett's Esophagus, which may lead to cancer
- ▶ 200,000 to 250,000 GERD procedures are performed Worldwide each year

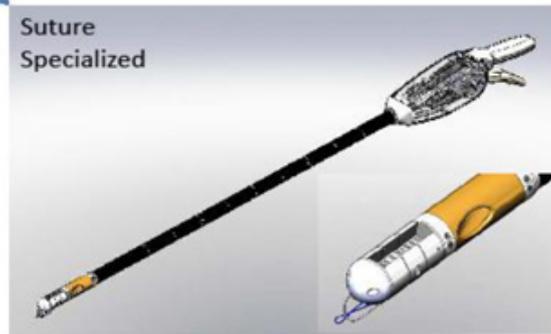
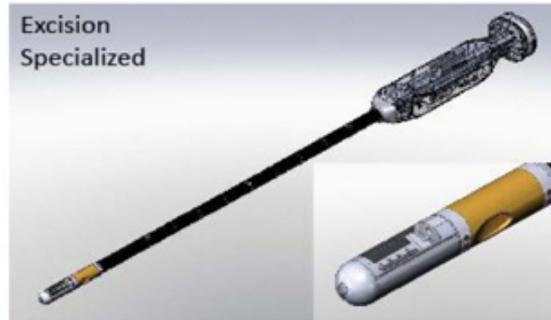
# SafeStitch GERD Procedure

- ▶ Same devices
- ▶ Advantages:
  - Outpatient procedure
  - Safer
  - Easier and Quicker
  - Durability of effect
  - Significant cost reduction
- ▶ Clinical trials expected to begin in 2010
- ▶ Non-U.S. Sales anticipated 2011, U.S. 2012



# Gastroplasty (GERD / Obesity)

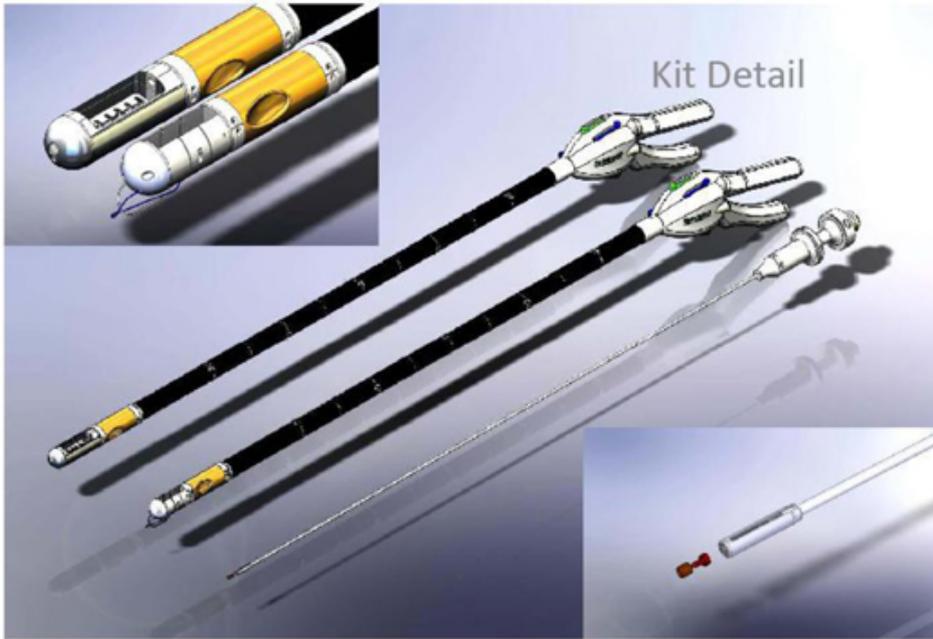
## Device Evolution



# One Kit, Two Procedures

## Gastroplasty Devices

EXCISION  
→  
SUTURE  
→



KNOTTER  
←

# Intraluminal Gastroplasty Kit



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# Hernia

- ▶ 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
- ▶ Up to 200,000 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 safer, faster and easier
  - Reduce post-operative pain
- ▶ Applications for FDA and European clearance September 2009
- ▶ Clinical Evaluations October 2009
- ▶ Sales anticipated Q1 2010

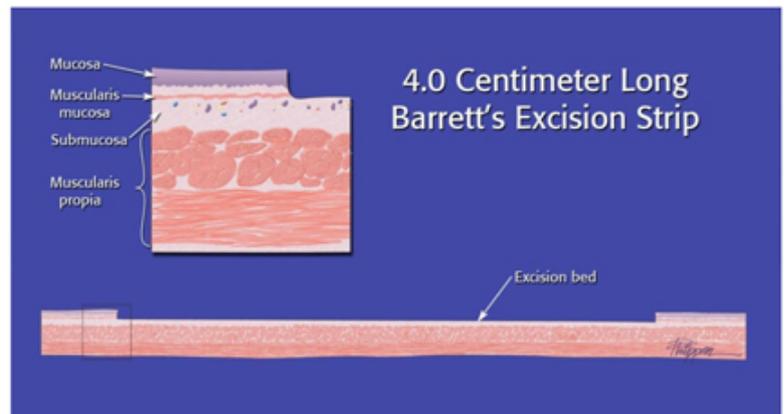


# Barrett's Esophagus

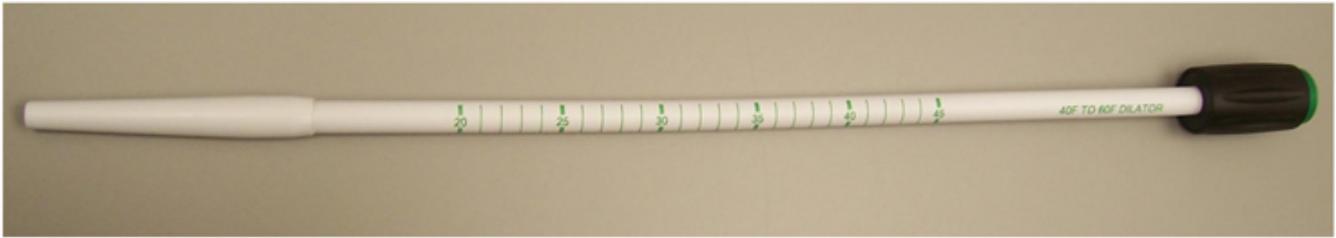
- ▶ Condition in which the esophagus changes so that some of its lining is replaced by a type of tissue similar to that normally found in the intestine, intestinal metaplasia
  - GERD is most common cause
  - May lead to esophageal cancer
- ▶ Approximately 11 million patients Worldwide

# Barrett's Excision and Strip Mucosal Device

- ▶ Advantages:
  - Large piece of tissue excised; can be sent for histology
  - Clean margins
  - Easier and Quicker
  - Cost reduction
- ▶ Clinical Trials expected to begin in late 2010



# SMART Dilator™



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# SMART Dilator™

- ▶ 800,000 dilations of esophageal strictures are performed annually in the U.S.; ~2 million Worldwide
- ▶ Disposable: other disposable dilators sell for \$150 – \$250
- ▶ 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
- ▶ 510(k) FDA clearance received in February 2009
- ▶ IRB approved clinical evaluation completed in 2008
- ▶ Marketing plans are being developed

# 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
- ▶ Clinical evaluation completed in 2008 and marketing plans are being developed



# 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
- ▶ IRB approved clinical evaluation completed in 2008 and marketing plans are being developed



# 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

# Manufacturing

- ▶ Retention and Airway Bite Blocks manufacturing sourced in Taiwan
  - Injection molding
- ▶ SMART Dilator™
  - Injection molding and extrusion to be performed using contract manufacturers



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# 2009 – 2010 Plan

- ▶ FDA Registration of standard and airway bite blocks (Class I, exempt devices which do not require FDA clearance)
- ▶ SMART Dilator™ FDA 510k clearance
- ▶ Final development of AMID Stapler™ and application for FDA 510k and CE clearance
- ▶ Continued development of gastroplasty devices, manufacture units for use in clinical trials and engineering tests
- ▶ Initial marketing and commercialization of AMID Stapler™, retention and airway bite blocks and SMART Dilator™
- ▶ Continued product development of Barrett's Excision Device
- ▶ Early development efforts for NOTES devices for which we have existing intellectual property and licenses
- ▶ Commencement of feasibility and multicenter clinical trials for gastroplasty devices for obesity and GERD

# 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

MEDICAL

Where Safety Meets Innovation

▶ **Contact:**

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Adam Jackson – CFO

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