CONSISTENT, SIMPLIFIED
SLEEVE CREATION

GastriSail™ Gastric Positioning System
Product Information Guide
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The GastriSail™ gastric positioning system is the only bougie on the market with a flexible sail and LED lights. Through its innovative design, the GastriSail™ system provides consistent sleeve creation and illumination throughout the procedure compared with a standard bougie.
1 THREE-IN-ONE DUAL-LUMEN TUBE FOR EVACUATION, SUCTION STABILITY, AND LEAK TESTING²
Multifaceted tube reduces the number of transoral insertions by providing combined functionality for sizing, decompression and leak testing.

2 SAIL EXTENDS TO AID DISSECTION¹ WHEN COMPARED WITH A STANDARD BOUGIE
A secondary sail tube positions the stomach into a non-contracted, natural orientation, bringing the stomach walls together.¹

3 LED GUIDE FOR CONSISTENT SLEEVE CREATION COMPARED WITH A STANDARD BOUGIE
An LED-based illumination line in the “sail” provides visualization and can be used as a guide, for staple line placement.¹
### COMPETITIVE COMPARISON TO A STANDARD BOUGIE

<table>
<thead>
<tr>
<th>Feature</th>
<th>Benefit</th>
<th>Why this matters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dual-Lumen Tube</td>
<td>• One transoral insertion&lt;br&gt;• All-in-one sizing, decompression and leak testing system¹</td>
<td>Competing products may need up to three insertions for sizing, decompression and leak testing, while the GastriSail™ system needs only one transoral insertion.²</td>
</tr>
<tr>
<td>Deployable Sail</td>
<td>• Extends the stomach radially, positioning into a non-contracted, natural orientation¹</td>
<td>Automatic placement of the main tube along the lesser curve and deflection of the tip down toward the pylorus supports efficient placement and positioning of the bougie.</td>
</tr>
<tr>
<td>LED Lights</td>
<td>Visualization of:&lt;br&gt;• The GastriSail™ system as it passes from the esophagus into the stomach&lt;br&gt;• The sail during dissection&lt;br&gt;• The main tube during staple-line placement&lt;br&gt;• Longer length (5.5”) perforations, smaller (0.085”) diameter&lt;br&gt;• Regulated suction provides desired apposition of the anterior and posterior stomach walls and ensures correct calibration&lt;br&gt;• Allows for leak-testing capabilities</td>
<td>LED directional lights allow visualization and the sail provides delineation of the tube and stomach tissue.</td>
</tr>
<tr>
<td>Perforations at Distal Tip</td>
<td></td>
<td>Allows for alignment of anterior and posterior walls.²</td>
</tr>
</tbody>
</table>

#### FEATURES COMPETITIVE COMPARISON

<table>
<thead>
<tr>
<th>GastriSail™ System</th>
<th>Standard French Bougie</th>
<th>ViSiGi 3D™</th>
<th>Gastric Calibration Tube</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sizing</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Leak Test Functionality</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Decompression</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Thermoformed Blunt Tip</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Flexible Sail for Positioning</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>LED Lights for Visualization</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Axial Handle</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>External Markings</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>
DELINEATION AND VISUALIZATION

Stomach samples were scanned to provide 3-D topographical images and to compare delineation of the GastriSail™ system with competitive products.¹

![Images of Standard Bougie, GastriSail™ System, and ViSiGi™](image)

**SUMMARY**

- The longer length of perforations on the GastriSail™ system resulted in a maximum height difference throughout the length of the lesser curvature, while both the standard bougie and ViSiGi 3D™ maintain a maximum height difference only in the top portion of the stomach.
- The perforations along the main tubes of both the GastriSail™ system and ViSiGi 3D™ devices allow for stomach decompression and fixation along the tissue.
- This suction pulls the surrounding tissue closer to the tube, allowing for more patent delineation. The topographical map depicts this patency.

**RESULTS AT A GLANCE⁴**

<table>
<thead>
<tr>
<th>Length of perforations (inches)</th>
<th>Number of perforations</th>
<th>Diameter of perforations (inches)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The GastriSail™ System</td>
<td>The GastriSail™ System</td>
<td>The GastriSail™ System</td>
</tr>
<tr>
<td>5.5</td>
<td>37</td>
<td>0.085</td>
</tr>
<tr>
<td>VSiGi 3D™</td>
<td>VSiGi 3D™</td>
<td>VSiGi 3D™</td>
</tr>
<tr>
<td>4</td>
<td>108</td>
<td>0.11</td>
</tr>
</tbody>
</table>
PRECLINICAL TESTING

In a cadaver lab study, two surgical teams completed 10 sleeve gastrectomies with a standard bougie and the GastriSail™ system to compare the performance of the products, including:

- Consistency through an all-in-one system
- Guided visualization
- Apposition of anterior and posterior walls

**CONSISTENCY IN SLEEVE FORMATION**

The GastriSail™ system had statistically significant diameter consistency, independent of subject, surgeon and location on the sleeve.

<table>
<thead>
<tr>
<th>Test for Equal Variances: Diameter Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>STDev of Diameter</td>
</tr>
<tr>
<td>GastriSail™ System</td>
</tr>
<tr>
<td>Bougie</td>
</tr>
<tr>
<td>P&gt;0.001</td>
</tr>
</tbody>
</table>

**ALLOWS FOR APPPOSITION OF ANTERIOR AND POSTERIOR WALLS**

The GastriSail™ system delivers consistency through an all-in-one system for sizing, decompression and leak testing.

Staple line offset was measured at five points along the greater curvature of the stomach remnant. The GastriSail™ system average offset was closer to the center at each measurement point (p=0.043).

Stenosis or obstruction of the stomach may occur if the stomach remnant is too tight or if torsion of the stomach occurs. Stenosis may be treated with bougie dilation. Torsion occurs when the incisions on the anterior and posterior walls of the stomach are not at an equal distance from the lesser curve of the stomach when the stapler is applied.

75% consensus that maintaining symmetric lateral traction while stapling will reduce the potential for strictures.


The GastriSail™ system shows less constriction in diameter at the incisura angularis than the standard bougie.®

Incisura angularis is an area of concern for surgeons because narrowing in this area can cause a high pressure system and potential leaks.®

Surgeons performing LSG should strive to minimize the risk of creating strictures at the incisura angularis.®

PERCENT CONSTRICTION

The average of the ratio of the diameter at the incisura angularis is the maximum diameter for all the sleeves. Less constriction helps support consistent sizing of the created sleeve.

PROCEDURAL CONSISTENCY

The GastriSail™ system provides consistency, with low variance in diameter along the length of the sleeve.®
February 25, 2015

Covidien
Debbie Peacock
Regulatory Product Manager
60 Middletown Ave.
North Haven, CT 06473

Re: K143088
Trade/Device Name: Gastrisail Gastric Positioning System
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: January 9, 2015
Received: January 12, 2015

Dear Debbie Peacock,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).
You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in...
the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal, and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
**INSTRUCTIONS FOR USE**

**GastriSail™ Gastric Positioning System**

PT0030152

**BEFORE USING THE PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.**

**IMPORTANT:**
- The device, when installed in any position, is not a toy or a substitute for toys.
- The manufacturer cannot be held responsible if the device is misused or damaged.

**DESCRIPTION:**
- The GastriSail™ gastric positioning system is a flexible guidewire placed through a nasogastric or duodenal feeding tube. It is used to assist in the positioning of the stomach during minimally invasive surgical procedures.
- The GastriSail™ system has been designed to latch onto the stomach on an angle that is not perpendicular to the stomach axis to accurately position the stomach during surgery.

**PROCEDURE:**
- Insert the GastriSail™ through the nasogastric or duodenal feeding tube up to the desired position.
- Remove the GastriSail™ from the feeding tube and position it in the stomach.
- Secure the GastriSail™ in place to achieve the desired position.

**ADVERSE REACTIONS AND POTENTIAL COMPLICATIONS ASSOCIATED WITH SYSTEM USE:**
- Nausea, vomiting, and regurgitation
- Blood loss
- Gastric perforation

**GUIDANCE AND MANUFACTURER’S DECLARATION – ELECTROMAGNETIC ENVIRONMENT:**
- The GastriSail™ Gastric Positioning System is designed to be used in electromagnetic environments specified by the user or by the relevant national and global standards.
- The system must be used in accordance with the guidelines provided by the manufacturer, the hospital, and the regulatory bodies.

**GUARANTEE:**
- The manufacturer guarantees the GastriSail™ Gastric Positioning System against defects in materials and workmanship for a period of twelve months from the date of shipment.

**CAUTION:**
- Always consult the user manual before use.
- The device is intended for professional use only.
- The manufacturer is not responsible for any damage caused by misuse or incorrect handling.

**WARNING:**
- Do not use the device if it is damaged or if its components are missing.
- The device is not intended for use by children.

**SPECIAL INSTRUCTIONS:**
- The device must be properly handled and disposed of according to the hospital’s protocol.
- The device must be stored in a clean, dry environment.

**GUIDELINES FOR USE:**
- Follow the instructions provided by the manufacturer and the hospital.
- Use the device only as described in the user manual.
- The device must be cleaned and sterilized as per the hospital’s protocol.

**GUIDELINE FOR STORAGE:**
- Store the device in a clean, dry environment.
- Do not store the device in a humid environment.

**GUIDELINE FOR DISPOSAL:**
- Dispose of the device in accordance with hospital protocol.
- The device must be disposed of in a manner that complies with the hospital’s protocol.

**INFORMATION FOR USE:**
- The device is designed for use in hospital settings.
- The device is not intended for home use.

**IMPORTANT INFORMATION:**
- The device is not intended for use by untrained personnel.
- The device must be used by trained professionals only.

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### Recommended separation distances between portable and mobile-W communication equipment and the GastriSail™ Gastric Positioning System

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (W)</th>
<th>Separation distance according to frequency of transmitter (m)</th>
<th>IEC 61000-4-5, 150 kHz to 80 MHz</th>
<th>IEC 61000-4-5, 80 MHz to 890 MHz</th>
<th>IEC 61000-4-5, 890 MHz to 30 MHz</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1 W</td>
<td>Inapplicable</td>
<td>0.58</td>
<td>0.51</td>
<td></td>
</tr>
<tr>
<td>1 W</td>
<td>Inapplicable</td>
<td>1.1</td>
<td>0.67</td>
<td></td>
</tr>
<tr>
<td>10 W</td>
<td>Inapplicable</td>
<td>1.1</td>
<td>0.67</td>
<td></td>
</tr>
<tr>
<td>100 W</td>
<td>Inapplicable</td>
<td>1.1</td>
<td>0.67</td>
<td></td>
</tr>
</tbody>
</table>

For transmitters having a maximum output power of 100 W, the recommended separation distance in (m) can be calculated using the equations:

- For IEC 61000-4-5, 150 kHz to 80 MHz:
  
  $$d = 64\sqrt{P}$$

- For IEC 61000-4-5, 80 MHz to 890 MHz:
  
  $$d = 3.5\sqrt{P}$$

- For IEC 61000-4-5, 890 MHz to 30 MHz:
  
  $$d = 2.33\sqrt{P}$$

### Additional Cautionary Notes

- **For transmitters with a maximum output power of 100 W, the recommended separation distance in (m) can be calculated using the equations above.**
- **For transmitters using frequencies above 30 MHz, the separation distance is determined by distance control or using absorbers and reflectors.**
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**NOT:** The use of this product is intended for medical use only. Unauthorized use may result in severe injury or death. Always follow the manufacturer’s instructions for use.
MATERIALS MANAGEMENT

ORDERING INFORMATION

<table>
<thead>
<tr>
<th>Reorder Code</th>
<th>Description</th>
<th>Size</th>
<th>Units per box</th>
</tr>
</thead>
<tbody>
<tr>
<td>GPS36†</td>
<td>GastriSail™ Gastric Positioning System</td>
<td>36 Fr</td>
<td>3</td>
</tr>
<tr>
<td>GPS40†</td>
<td>GastriSail™ Gastric Positioning System</td>
<td>40 Fr</td>
<td>3</td>
</tr>
</tbody>
</table>

† Product has a three year shelf life

2. Based on internal testing report #R2274-007-0, Porcine model. Esophageal trauma in vivo analysis. October 2014.