1120 S. Capital of TX Hwy, Bldg. 1, Ste. 300
Austin, Texas 78746
USA
Phone: 512.279.5100
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Urgent Field Safety Notice

BIB/Orbera365 Intragastric Balloon Systems
FSCA-19-001
Field Safety Corrective Action- Labelling Update

Date: July XX, 2019

Attention: Enter Customer Name

Details on affected devices:
The two devices listed below comprising Apollo's Intragastric Balloon System product family are affected by this FSCA.

Name of Device: BIB Intragastric Balloon System
Model Number: B-40800
Lot Number/ SN: N/A- no impact to specific lots or SNs

Name of Device: Orbera365 Intragastric Balloon System
Model Number: B-50012
Lot Number/ SN: N/A- no impact to specific lots or SNs

Description of the problem:
This FSCA does not concern a product malfunction or defect, but an update of the instructions for use (IFU) for the subject devices. These have been updated to communicate residual risks of gastric and esophageal perforation and aspiration, two adverse event types that were not previously listed in the IFUs for the Apollo Intragastric Balloon Systems. The documents have also been updated to include a new precaution related to the pregnancy, which is already listed as a contraindication, and to clarify an existing warning for a deflated balloon potentially leading to a bowel obstruction. The updates are intended to bring about awareness to the user of these noted complications and potentially improve early detection. However, they are not intended to mitigate occurrence rates, as the language does not instruct users to take direct actions that could prevent these events from occurring.

The two updated IFU references for each device system are included as attachments to this FSN and they will be included in the manufactured products as of June 1, 2019:

- Orbera365 Intragastric Balloon System: GRF-00377-00R08
- BIB Intragastric Balloon System: GRF-00200-00R05

Specific changes made to the aforementioned Instructions for Use leaflets are described below. The same changes have been made to each of the two Instructions for Use leaflets.

1. In the 'Warnings and Precautions' section, the following changes were made:
    a. The following statement was modified to add the underlined language "Bowel obstructions can result in surgical treatment or death."
    b. The following statement was added:
    "Patient should be advised to take the necessary precautions to prevent pregnancy prior to placement and throughout the duration treatment, and be instructed to inform you as soon as possible if pregnancy is confirmed during treatment, so that removal of the device can be arranged."
    c. The following statement was modified to add the underlined language "Each patient should be instructed regarding symptoms of deflation, gastrointestinal obstruction, acute pancreatitis, spontaneous inflation, ulceration,

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gastric and esophageal perforation, and other complications which might occur, and should be advised to contact his/her physician immediately upon the onset of such symptoms.

d. The following statement was added:
"Patients with an intragastric balloon that present with severe abdominal pain that have a negative endoscopy and x-ray may additionally require a CT scan to definitively rule out a perforation."

e. The following statement was added:
"In preparation for removal, some patients may have retained contents in the stomach. Some patients may have clinically significant delay in gastric emptying and refractory intolerance to the balloon, necessitating early removal, and possibly leading to other adverse events. These patients may be at higher risk of aspiration upon removal and/or upon administration of anesthetic. The anesthesia team should be alerted to the risk for aspiration in these patients.

2. In the 'Complications' section, the following statement was modified to add the underlined language:
Death due to complications related to intestinal obstruction, gastric perforation, or esophageal perforation, is possible.

Advise on action to be taken by the user:
There is no advice on actions to be taken by the distributor or user.
The updates to the IFU are for informational purposes only to communicate additional residual risks not previously listed in the IFU.

1. Read the present FSN
2. Read the updated IFU
3. Sign and return the "acknowledgment form"
4. No Recall of product

Time schedule for the implementation of the different actions:
All Orbera365 (B-50012) and BIB (B-40800) product manufactured after June 1, 2019 will be packaged with the updated instructions for use.

Contact reference person:
Evelyn Kile
Apollo Endosurgery, Inc.
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Austin, TX 78746
United States
1-512-279-5100
evelyn.kile@apolloendo.com

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

Evelyn Kile

Attachments:
GRF-00377-00R08 – Orbera365 Intragastric Balloon System DFU
GRF-00200-00R05 – BIB Intragastric Balloon System DFU

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Acknowledgement Form:

Complete and return this receipt by e-mail to the following address: evelyn.kile@apolloendo.com

☐ I confirm that I have received and read this FSN (FSN-19-001)

Contact Info _____

Name and Signature_____

Date_____

We thank you for your cooperation and comprehension