Urgent Field Safety Notice

BIB / Orbera / Orbera365 Intragastric Balloon Systems
FSCA-20-002
Labeling Updates and Patient Booklet

Date: July 1, 2021

Dear Customer,

Apollo Endosurgery is conducting this Field Safety Notice (FSN) to inform physicians about routine updates to the labeling on its intragastric balloons. This letter is to identify the affected devices and explain the labeling changes. This communication includes links to the updated documents.

Details on affected devices:
The device/s listed below are subject of this Field Safety Notice.

Name of Device	Model Number	Lot Number/Serial Number
BIB Intragastric Balloon System	B-40800	N/A- no impact to specific lots or SNs
ORBERA Intragastric Balloon System	B-50000	N/A- no impact to specific lots or SNs
ORBERA365 Intragastric Balloon System	B-50012	N/A- no impact to specific lots or SNs

Description of the issue:
As a condition of US Food and Drug Administration (FDA) approval, Apollo Endosurgery conducted a post-approval study to collect further information on the safety and effectiveness of its intragastric balloons. The post approval was completed and the study met its endpoints. The final report was submitted to FDA on 15 January 2020 and FDA's review of the study concluded on 07 April 2020. Results of that study are posted on FDA's website, here[1]. Labeling updates were submitted to FDA for review in June 2020 and subsequently approved by FDA on 02 December 2020.

The Directions for Use (DFUs) for the products listed above have been updated to align with the current US DFU. **No new risks have been identified but some of the language around contraindications, warnings and precautions have been revised to make them consistent with the US DFU.**

The recent post-approval study highlighted the known risk of balloon hyperinflation. Though the root cause is unknown, it is believed that these events may be related to the presence of microorganisms entering the balloon during placement. Consequently, the DFUs have been modified to include additional description of the 'aseptic technique' when filling the balloon. Although the number of patients with this adverse event was small, the formal introduction of this technique during the study appeared to reduce the frequency.

The new DFU(s) includes many changes to improve clarity and consistency. Please review the attached DFU(s) in its entirety. The table below provides a summary of the more significant changes.

DFU	Description of Change
Section 6: Contraindications	Contraindications involving patients with prior surgeries have been combined into a single statement "Prior surgery involving the esophagus, stomach, and duodenum or bariatric"
	The two (2) contraindications involving patients with hernias have been combined into a single statement "A large hiatal hernia of > 5cm or a hernia ≤ 5 cm associated with severe or intractable gastro-esophageal reflux symptoms."
	The contraindication pertaining to the presence of structural abnormality in the esophagus or pharynx has been updated to state that these abnormalities "could impede passage of the delivery catheter and/or an endoscope"
	The section has been updated to include "Achalasia, symptoms suggestive of delayed gastric emptying, or presence of any other severe motility disorder that may pose a safety risk during removal of the device."
	The section has been updated to include patients with a Severe coagulopathy.
	The section has been updated to include patients with a Gastric Mass.

[1] Link: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?t_id=534908&c_id=3558

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DFU	Description of Change
	The section has been updated to include patients with Hepatic insufficiency or cirrhosis conditions.
	The contraindication "Any other medical condition which would not permit elective endoscopy" has been updated to include examples of such conditions.
	The contraindication "Major prior or present psychological disorder" has been updated to include the rationale for this contraindication.
	A contraindication stating "Patients who are unable or unwilling to take prescribed proton pump inhibitor medication for the duration of the device implant" has been added to this section.
Section 7: Warnings	The potential for bowel obstruction, resulting from either a deflated or overfilled balloon, has been reworded.
	The warning "Deflated devices should be removed promptly" has been updated to state that patients should be advised of the risks of this situation and to contact their physician as soon as possible.
	Warnings involving patient conditions that could increase the risk of events of obstruction have been combined into a single statement and updated to include "radiation therapy"
	A warning statement reiterating that balloon removal should occur in the presence of an empty stomach to avoid aspiration has been added.
	Warnings related to Spontaneous hyperinflation have been updated/added to elaborate on possible symptoms, added recommendations for diagnosis of the issue and for the use of endotracheal intubation during removal of hyperinflated balloons. Gastroesophageal reflux and nausea, occurring after the initial accommodative period, were added to the list of possible adverse events associated with hyperinflated balloons. Also, added that X-rays can be used to identify the presence of a hyperinflated balloon. Additionally, a warning was added regarding the potential for aspiration to occur if a hyperinflated balloon ruptures during the removal process and further recommends the use of endotracheal intubation during these situations to mitigate this risk. This event has never actually been reported.
	A warning that "rapid fill rates" should be avoided has been added to this section.
Section 8: Precautions	A Precaution has been added that states that Aseptic Technique should be used when filling the balloon.
	This section was updated to include additional information that further clarifies the effects of delayed gastric emptying and potential treatments.
	A precaution that proton pump inhibitors should be prescribed to mitigate ulcers and gastroesophageal reflux symptoms has been added.
	The precaution that moderating pH in the stomach may prolong the life of the balloon was updated to indicate that these actions may also reduce gastric ulcers and subsequent perforations.
	A precaution that physicians should use a new balloon if "difficulty with the balloon's fill tube is noted during placement (e.g. resistance to balloon filling)" and that the tube should be remain "slack" while filling, was added.
	A precaution stating that the balloon "has not been studied in individuals who have a patulous pylorus, active H. pylori infection, and subjects with either symptoms or a diagnosis of delayed gastric emptying" was added.
	A precaution stating that patients should be advised that anti-cholinergic and psychotropic medications can further delay gastric emptying was added.
Section 8: Precautions Section 12.3: IGB Placement and Filling	The instructions were updated to indicate that this procedure should be performed using aseptic technique (e.g. use of clean or sterile gloves, sterile syringe, etc.) and that hyperinflation may be caused by microbes.

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DFU	Description of Change
Section 12.4: IGB Removal	An introduction to the instructions for balloon removal was added as Step 1. This step reiterates information from the "Warnings" section about the potential for Aspiration.
Section 13: Medical Imaging And Symbols Table	A new section titled "Medical Imaging" was added to indicate that the balloon is MR Safe. Additionally, the symbols table at the end of the DFU have been updated to include the MR Safe Symbol as well as a corresponding description.
Additional Symbols were added at the end of each language section	Medical Device and Consult Instructions for Use (electronic) symbols were added as well corresponding description.
Back of IFU	CE mark number updated to 2797.

The new Directions for Use are available online (https://apolloendo.com/dfus/).

NOTE: No product return or rework is required.

Time schedule for the implementation of the different actions:
All BIB (B-40800) and Orbera365 (B-50012) product manufactured after October 1, 2021 will be packaged with the updated instructions for use. The changes will not be implemented for the Orbera balloon (B-50000) as manufacture of this product for the EU market ceased on February 28, 2019 and worldwide will be ceased this year. Current customers in possession of B-40800, B-50000 and B-50012 will be made aware of the IFU updates through communication of this Field Safety Notice.

Additionally, a patient booklet is expected to be available online by October 01, 2021. There will be two (2) patient booklets, one intended for patients receiving a balloon labelled for 6 months dwell time (B-40800 BIB Intragastric Balloon System and B-50000 ORBERA) and another booklet intended for patients receiving a balloon labeled for a 12-month dwell time (B-50012 Orbera365). The purpose of the patient booklet is to provide patient education on intragastric balloon therapy and emphasize the importance of communicating symptoms of balloon intolerance to their healthcare provider. A new patient implant card is being developed that will direct patients do this booklet.

Actions the customer should take:
Please review the changes described in the table above, and read the attached Directions for Use.

Please complete and return the "Acknowledgement Form" below as soon as possible, or simply reply to the email sent to you indicating 'UNDERSTOOD' in the subject line (in lieu of a signature). Your response should be emailed to:

FSCA-20-002-Intragastric-Balloons@apolloendo.com

Alternatively, you can print this e-mail and return the completed/signed Acknowledgement Form to Apollo Endosurgery, Inc by mail. By returning the completed Acknowledgement Form by email or mail, you acknowledge that you have read and understood this Field Safety Notice.

Your prompt confirmation will prevent repeat email notifications.

If you have any questions on this Field Safety Notice, please send an email to Evelyn Kile at:
(FSCA-20-002-Intragastric-Balloons@apolloendo.com).

Sincerely,

David M. Hooper, Ph.D.
Vice President- Quality Assurance and Regulatory Affairs
Apollo Endosurgery, Inc.

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Client Response Form:

Complete the information below and return this form to the following address e-mail address (preferred):

FSCA-20-002-Intragastric-Balloons@apolloendo.com

or mail to:

Evelyn Kile
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Bldg.1, Ste. 300
Austin, TX 78746

☑ I confirm that I have reviewed this Field Safety Notice (FSN) and the updated Directions for Use.

Name of Institution: _____

Address: _____

Telephone Number: _____

Email: _____

Name: _____ **Title**: _____

Signature (If printed): _____ **Date**: _____

We thank you for your cooperation.