apollo endosurgery

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Urgent Field Safety Notice

BIB/Orbera/Orbera365 Intragastric Balloon Systems
FSCA-18-001
Field Safety Corrective Action- Labelling Update

Date: April XX, 2018

Attention: Enter Customer Name

Details on affected devices:

The three devices listed below comprising Apollo's Intragastric Balloon System product family are affected by this FSCA. There are no specific lot or serial numbers that are affected because there is no systematic recall or request for removal, return or exchange of any devices.

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: Orbera Intragastric Balloon System
Model Number: B-50000
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:

In 2017, the US FDA worked cooperatively with the manufacturers of all fluid-filled intragastric balloons to add specific language to the US Instructions for Use regarding risks associated with acute pancreatitis and spontaneous inflation as these events were noted in post-market medical device reports to the FDA, but these events did not previously occur during any of the pivotal/IDE studies for fluid-filled intragastric balloons. The purpose of the US IFU update was to communicate additional residual risks of acute pancreatitis and spontaneous inflation that had not been noted during the pivotal/IDE studies, and thus not included in the originally approved IFU. The rate of occurrence of these events remained extremely below acceptable occurrence thresholds per Apollo's risk assessment process, so no corrective actions were necessary besides communication of residual risk in the IFU. Apollo is extending this labelling update to the OUS labelling. Apollo initially consulted with our Notified Body (BSI) regarding the appropriate strategy for communication of this update to EU Competent Authorities and BSI recommended that this update be communicated in the form of an Advisory Notice because it is not considered a recall nor any kind of action to reduce risk associated with use of the device. This reasoning is based on the fact that the update to the OUS IFUs is not an 'action to reduce a risk of serious deterioration in the state of health' as per the definition of an FSCA in MEDDEV 2.12.1 Rev.8, but rather a communication of residual risk to users (because the risk level based on risk assessment remains below acceptable occurrence thresholds and does not require risk mitigation and also because Point 7 under Content Deviations of ISO 14971:2012 states that 'according to Annex I of Directive 93/42/EEC...information given to the users does not reduce the

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(residual) risk any further. Accordingly, manufacturers shall not attribute any additional risk reduction to the information given to the users [i.e. information for safety in the labelling]). Accordingly, Apollo sent an Advisory Notice to all EU Competent Authorities in March 2018. Three EU Competent Authorities subsequently requested that this update be communicated through an FSCA, thus Apollo is issuing this FSCA in light of these requests. Apollo recognizes that communication of the risks of spontaneous inflation and acute pancreatitis could potentially reduce the risk of these events happening through eliciting physician awareness; however, according to the MDD and Content Deviations of ISO 14971:2012, Apollo cannot attribute any risk reduction to this labelling communication.

The hazard associated with use of the device is incomplete Instructions for Use regarding communication of residual risks. The risk to the patient is that physicians are unaware of the possible complications of acute pancreatitis and spontaneous inflation, thus proper monitoring of the symptoms may not be performed by physicians. Communication of these risks through this FSCA/FSN could potentially reduce the risks associated with these events through eliciting physician awareness. Once physicians are aware of the risks, the risks of these events occurring are identical between devices used that are currently on the market versus those that will be used after implementation of the IFU modification noted herein.

Apollo is taking the corrective action to update the warnings, precautions and complications sections of the IFU for BIB (B-40800), Orbera (B-50000), and Orbera365 (B-50012) Intragastric Balloon Systems in order to communicate additional residual risks of acute pancreatitis and spontaneous inflation to users, including possible patient symptoms when these complications arise. Distributed product packaged with the previous IFU is not being recalled or requested for return as use of the previous IFUs does not present any risk since the changes to the IFU will be informed to users through this FSCA/FSN. Communication of the risks to users in any form, whether through the FSCA/FSN or the IFU, is meant to potentially reduce the risks associated with these events, thus replacement of the current IFUs with the revised IFUs in distributed product is not necessary so long as users are informed of the residual risks through other means (i.e., this FSN, or modified IFUs).

The three IFU references for each device system being updated are as follows and included as attachments to this FSN:

- Orbera Intragastric Balloon System: GRF-00283-00
- Orbera365 Intragastric Balloon System: GRF-00377-00
- BIB Intragastric Balloon System: GRF-00200-00

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

1. In the 'Warnings and Precautions' section, users were previously instructed to inform their patients regarding symptoms of deflation, gastrointestinal obstruction, ulceration and other complications which might occur. Spontaneous inflation and acute pancreatitis have been added to this list of events for which patients should be instructed to watch for symptoms.
2. In the 'Complications' section, the following paragraphs regarding acute pancreatitis and spontaneous inflation have been added:
    a. Acute pancreatitis as a result of injury to the pancreas by the balloon. Patients experiencing any symptoms of acute pancreatitis should be counseled to seek immediate care. Symptoms may include nausea, vomiting, abdominal or back pain, either steady or cyclic. If abdominal pain is steady, pancreatitis may have developed.
    b. Spontaneous over inflation of an indwelling balloon with symptoms including intense abdominal pain, swelling of the abdomen (abdominal distension) with

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or without discomfort, difficulty breathing, and/or vomiting. Patients experiencing any of these symptoms should be counseled to seek immediate care.

c. Note that continued nausea and vomiting could result from direct irritation of the lining of the stomach, as a result of the balloon blocking the outlet of the stomach, or hyperinflation of the balloon.

The modified Instructions for Use Leaflet for each of the three Intragastric Balloon Systems has been reviewed and approved by Apollo's Notified Body, BSI, as of February 2018.

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 of acute pancreatitis and spontaneous inflation not previously listed in the IFU.

Time schedule for the implementation of the different actions:

The modified Instructions for Use leaflets were released into Apollo's quality system on March 5, 2018 and will be physically printed and packaged with product released for distribution on a rolling basis. This means that existing stock of previous Instructions for Use leaflets will be used up and placed into distribution prior to starting to package and distribute product with the revised Instructions for Use leaflet. Timing of distribution of product in the European Union with the modified IFU is therefore dependent on depletion of existing inventory of the previous IFU for each IGB system. The IFUs are being physically implemented on a rolling basis because use of previous revisions of the IFUs do not present any risk since the changes to the IFU are informative in nature only and because users will be informed of the forthcoming changes to the IFU through this FSN and associated FSCA.

Contact reference person:

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

Kiersten Soderman

Attachments:

GRF-00283-00R05 – Orbera Intragastric Balloon System DFU
GRF-00377-00R07 – Orbera365 Intragastric Balloon System DFU
GRF-00200-00R03 – BIB Intragastric Balloon System DFU