

COVID-19 Response for Current IGB Patients

The ongoing Covid-19 pandemic has forced cancellation of elective endoscopic procedures worldwide. We, at Apollo Endosurgery, are sensitive to the concerns that have arisen for patients with 6-month and 12-month dwell times of our BIB, Orbera, and Orbera365 balloons that either have arrived at their end of therapy removal dates or are soon to do so. Only the 6-month Orbera balloon is approved for use in the United States. We would like to provide our response to these concerns and share important information pertinent to this stressful situation for both providers and patients.

We cannot provide a time specific directive towards an acceptable extended dwell time beyond their established periods of therapy. Any decision as to whether or how long an intragastric balloon will stay in place beyond its respective indicated indwell time period is up to the individual physician managing a balloon patient and the capability of each health system during this pandemic.

The anticipated risk from a prolonged balloon dwell time is deflation of the balloon with migration of the deflated balloon out of the stomach followed by potential small intestinal obstruction. In our global experience, based on complaint data from January 1, 2008 through January 31, 2019, the reported rate of balloon deflation is estimated at 0.25% and obstruction or bowel complication is just 0.06%. Small bowel obstruction is rare during standard balloon dwell periods.

Another potential risk of prolonged balloon dwell time may be gastric perforation resulting from impaired gastric emptying. Any patient in whom symptoms of intolerance such as persistent fullness, upper abdominal discomfort, nausea or vomiting develop at or beyond the expected six or twelve month treatment period should have the balloon removed without delay to avert the risk for perforation. This should be regarded as an emergency removal. It is not known if increased dwell time impacts other risk associated with liquid-filled intragastric balloons.

If you have additional questions or concerns, please contact the Apollo Endosurgery Medical Affairs group at +1 855-551-3123, option 4 or send an email to MedicalAffairs@apolloendo.com.

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