



**Safety notice: intragastric balloon**  
Reference ELB/800-KT3.0/70 – All serial numbers are affected

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**Centre**

To the attention of  
Department

**Street**

**Postcode    City    Country**

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Bagnolet, November 21<sup>st</sup> 2013

Dear Customer,

**Historical background**

Since the launch of the intragastric balloon, some users have informed us of partial deflation cases. Our first improvement was to strengthen the weld of the device (improvement made as from serial number 001913). However, we kept recording cases of partial deflation (rate recorded on 08/11/2013: 15% of products).

Therefore, we wish to remind you of the potential complications related to a balloon deflation: partial deflation can lead to a total deflation, causing balloon migration. The balloon could remain blocked in the digestive system and cause an obstruction which could prove to be fatal for the patient. The obstruction would need to be removed, either endoscopically or surgically. To this date, 2 cases of obstruction have been reported, both were removed endoscopically.

**Preventive actions**

Although the airtightness level of the Easy Life balloon matches that of several other similar devices on the market, we have decided to stop marketing our intragastric balloon (since June 2013) and we are currently working on a solution to improve the levels of airtightness.

**We recommend you do not proceed with any new implantation of the Easy Life Intra gastric balloon identified with the above reference.** If you still hold stock of some products, please return them to us for a full credit.

**Patients'information**

Also, we would like to remind you of the importance of informing patients on all the risks and complications related with a medical device as well as the potential additional complications which are may arise. (Article L111-2 of Health Public Code - FRANCE).

**Action for patients who have had a balloon implanted**

In June 2013 we drew your attention to 3 major points:

- The information to patients on potential signs of deflation.
- The importance of advising patients to immediately contact their physician in any cases of doubt regarding possible deflation or any abnormal symptoms.
- The importances of regular patient reviews and follow up.

Today, in addition of these 3 points, **we insist on the importance of a regular monthly follow-up of patients** and the necessity to urgently meet the patients who currently have a balloon implanted in order to perform a radiological or endoscopic review of the balloon. Each physician will judge the actions to be taken according to each patient: ie balloon to be maintained implanted, adjustment of balloon volume, or retrieval of balloon.

