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

Centre
To the attention of
Department

Street
Postcode City Country

Bagnolet, November 21st 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.

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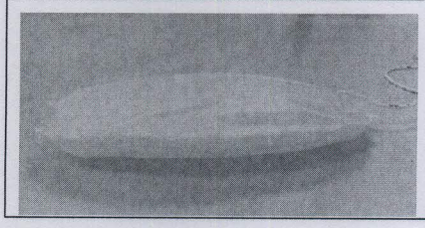
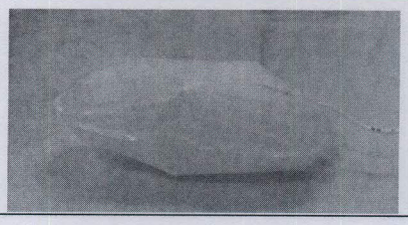
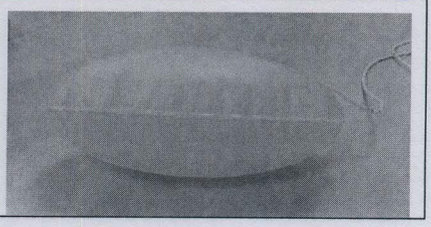
In order to help you in the product analysis, please find below some pictures of the normal aspect of a balloon inflated with different volumes:

Balloon inflated with 400 cc: Flat balloon	Balloon inflated with 600 cc: Soft balloon	Balloon inflated with 800 cc: Rounded balloon
		

If during your review, you identify a balloon with deflated aspect and you decide to retrieve it, please return it for a full credit.

For this, you should contact your supplier, who will inform you of their return procedure:

- **Supplier name:**

Address
City :
Tel:
Fax:

Follow-up of post-market surveillance

Please find attached a 'Safety notice' questionnaire regarding the use of the balloon, we would be grateful if **you could return it to us duly filled in for each implanted balloon**. Of course, if you have already returned this questionnaire, please ignore this request.

Please ensure all the health professionals within your hospital, who use these devices (and in particular the endoscopy operating room) are informed of this notification.

You will also find attached an 'acknowledgement of receipt' for this important safety information, please complete and return as soon as possible.

The competent authority in France, the ANSM, has been informed of this safety notice.

For any additional information regarding this safety notice, please contact the Quality Control Department at Life Partners Europe. (email: a.merle@lifeurope.com).

We apologise for the inconvenience caused by this notice, although it is aimed at guaranteeing patient safety and customer satisfaction and we thank you for your co-operation and understanding in this matter.

Eric Morel d'Arleux
CEO

Amélie Merle
Quality Manager