**TECHNICAL DATA**

**Intragastric balloon -EASY LIFE BALLOON**

**1- DISTRIBUTOR**

LIFE PARTNERS EUROPE  
161 avenue Gallieni – 93170 Bagnolet - France  
Tel.: +33 1 49 88 01 01 / Fax: +33 1 48 59 70 72  
E-mail: life@lifeurope.com  
Website: www.lifeurope.com

Quality Representative  
Quality Manager  
Tel.: +33 1 49 88 01 01  
Fax: +33 1 49 88 83 45  
E-mail: quality@lifeurope.com

**2- INFORMATION ON THE PRODUCT**

Commercial name:

**Easy Life Balloon**

Intragastric balloons « Easy Life Balloon » 400 ml and 800 ml are medical devices meant to be inserted in the stomach. They are implanted by endoscopic route and under endoscopic control only. They are used in the treatment of *patients suffering from morbid obesity*.

*Implantation procedure*
- Air inflation
- Easy implantation under endoscopic control
- Limited initial volume for a better tolerance
- Fewer risks of early retrieval

*Once balloon is inserted*
- Up to 1 year placement
- More opportunities to change feeding habits
- No leaks, perfect airtightness (no valve)

*Volume adjustment*
- Up to 3 successive volume inflations
- Scalable volume after insertion
- Enhanced efficiency thanks to the possibility to inflate and / or deflate

*Easy retrieval*
- Full deflation by air aspiration
- Retrieved by gently pulling on the catheter
- Less aggressive for the oesophageal mucosa (low profile, no valve)

*Control and safety*
- Does not contain any stiff element
- Heavy duty material, hypoallergenic
- Fluoroscopic controls are possible (balloon, catheter and stopper are radio-opaque)

- **IMPLANTATION UP TO 12 MONTHS**
  - **SEVERAL STAGES OF WEIGHT LOSS FOR A BETTER EFFICIENCY**
  - **MORE OPPORTUNITIES TO CHANGE FEEDING HABITS**
  - **BETTER TOLERANCE AND FEWER RISKS OF EARLY RETRIEVAL**
  - **PERFECT AIRTIGHTNESS**
  - **EASY TO RETRIEVE BY PULLING ON THE CATHETER**
## TECHNICAL DATA

<table>
<thead>
<tr>
<th>Reference</th>
<th>Description</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Balloons</strong></td>
<td>sold with 2 reinflation sets</td>
<td><strong>In a cardboard box:</strong></td>
</tr>
</tbody>
</table>
| ELB/800-KT3.0/70 | Intragastric balloon 800 ml inserted in endoscopic route without gastrostomy – Catheter of 3.0 mm diameter | **1 Balloon set (double steril pouch) composed with:**  
1 balloon 800 ml: Balloon coiled around its fitting system composed with: its safety cover, its pusher tube closed with its white cap, its stop-membrane on the catheter and its protective sheath taped to the pusher tube.  
1- Non-return valve  
1- Open clamp  
1- Ribbed cap in its pouch  
4-tracking labels  

**In a plastic pocket**  
1- Instructions for use  
1- Wearer's card  

**2 Re-inflation/deflation kit (in a sterile pouch), composed with:**  
1- Non-return valve  
1- Open clamp  
1- Ribbed cap in its pouch  
4-tracking labels  

**In a plastic pocket**  
1- Instructions for use  
1- Wearer's card |
| **Reinflation kit** | Pack of 1                                                                    | **In a cardboard box:**  
2 Re-inflation/deflation kit (in a sterile pouch), composed with:  
1- Non-return valve  
1- Open clamp  
1- Ribbed cap in its pouch  
4-tracking labels  

**Warning:** no IFU in this packaging. To use in compliance with the IFU delivered in the initial balloon packaging. |
| ELB/KITREG-3.0   | Reinflation kit for intragastric balloon – Catheter 3.0 mm                   |                                                                                                                                                                                                         |

Order unit = Minimum Quantity to Order: 1
## TECHNICAL DATA

### Materials:
- Balloon and catheter: Polyurethane - MRI compatible
- Fluted stopper: Implantable titanium: T40 grade 2 - MRI compatible
- Pusher tube: PTFE
- Sheath: PE
- Medical adhesive: / 
- Other components: Do not come in contact with the patient

### Contains:

<table>
<thead>
<tr>
<th>Component</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latex</td>
<td>☑</td>
<td></td>
</tr>
<tr>
<td>Product of animal origin</td>
<td>☑</td>
<td></td>
</tr>
<tr>
<td>PVC</td>
<td>☑</td>
<td></td>
</tr>
<tr>
<td>Phthalates and DEHP</td>
<td>☑</td>
<td></td>
</tr>
</tbody>
</table>

### Sterility:
- Sterile: ☑ Yes    ✗ No
- Sterilisation mode: ETO
- Number of uses: Single use

### Conservation:
- Storage conditions: Not mentioned
- Use by date: 5 years

### Other data:
- GMDN class: 17202
- Bar code: ☑ Yes    ✗ No
  - Referential: ☑ HIBC    ☑ GS1-128
- Detailing the following information:
  - Reference: ☑ Yes    ✗ No
  - Batch number: ☑ Yes    ✗ No
  - Use by date: ☑ Yes    ✗ No

### Use:
- Duration of implantation: 1 year maximum
- Safety precautions: Cf. IFU
- Use advice (IFU, precaution and contra-indications): Cf. IFU
- Indications (destination CE Mark): Cf. IFU

### Manufacturer:
- Manufactured by: Nova LightSystems
- Country: France

### CE Mark:
- CE Mark granted by EZU Certification, N° of certifying body: 1014
- According to European Directive 93/42/CEE – Appendix II section 3
- Product class: II b