

# Medical Device Alert

## Immediate action

Ref: MDA/2009/040 Issued: 18 June 2009 at 14:00

### Device

Heliosphere Bag® Intra-gastric Balloon manufactured by Helioscopie Medical Implants and distributed in the UK by UK Surgical.

Affected batches supplied in the UK: 08IN328-8 and 08IN328-10.



### Problem

Possible bowel obstruction due to full or partial early deflation of the balloon during the intended six months implantation period caused by a manufacturing welding problem.

### Action by

Those involved in purchasing, supplying and implanting these devices.

### Action

- Cease implantation of affected batches with immediate effect;
- Quarantine and return the remaining stock of the affected batches to the manufacturer;
- Schedule elective removal of implanted affected devices as soon as possible.

### Contact

#### Manufacturer

Chantal Belin, Quality Manager  
Helioscopie Medical Implants  
Tel: +33 474 161818  
Fax: +33 474 161918  
E-mail: [cbelin@helioscopie.fr](mailto:cbelin@helioscopie.fr)

#### UK supplier

Saf Ali: Managing Director  
UK Surgical  
Tel: +44(0)1422 361565  
Fax: +44(0)1422 300171  
E-mail: [saf.ali@uksurgical.com](mailto:saf.ali@uksurgical.com)

### CAS deadlines

Action underway: 25 June 2009  
Action complete: 09 July 2009

[Link to full Medical Device Alert](#)