



COMESA  
Czech Republic

MEDICAL IMPLANTS  
helioscopie



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# heliosphere<sup>®</sup>

## BAG

Intragastric Balloon  
for the non-surgical  
treatment of Obesity

FROM TECHNOLOGY TO HUMAN

## Product description

Heliosphere<sup>®</sup> BAG is a temporary non-surgical intragastric balloon system for the treatment of obesity. The device must not be implanted for a period longer than 6 months.

## Characteristics of the heliosphere<sup>®</sup> BAG

### Air balloon.

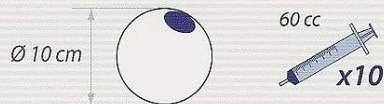
Weighs less than 30 grams.  
Simplified inflation.

### Patented system of cover removal.

Safe deployment.

### Demonstrated tolerance and efficacy.

**VOLUME OF THE INFLATED  
BALLOON: 550 CM<sup>3</sup>**

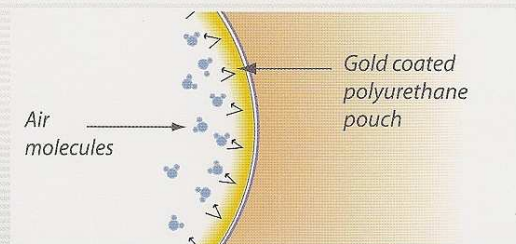


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## Optimised efficacy

Initial inflation volume guaranteed throughout the duration of the implantation by the addition of gold coating process.

### OPTIMISATION OF AIR-TIGHTNESS



## Easier explantation

Reduction of the extraction effort thanks to gold coating.

Wall thicknesses reduction.

### COMPARATIVE EXTRACTION FORCE

without gold coating

with gold coating



\* Average observed on an artificial cardia.

## Indications

*In all cases, the placement of an intragastric balloon must be accompanied by dietary advice and medical monitoring.*

- > Patients with obesity (BMI from 30 to 40) which causes serious medical risks.
- > Patients with Type 2 diabetes which is difficult to control due to the patient being overweight.
- > Patients for whom obesity surgery is indicated (BMI > 40 or BMI > 35 with co-morbidity factors) who have an anaesthetic or surgical contra-indication or who refuse surgery.

## Clinical studies

5 international series, bringing together more than 670 patients, each show the very good efficacy of the heliosphere® intragastric balloon, combined with distinctly improved tolerance.

Weight loss measured was between 9 and 24 kg.

Only 12 to 16% of patients suffered vomiting that lasted for more than 8 days. For the others, the average duration of vomiting was less than 3 days.

Less than 1% of balloons had to be explanted early.

*Tolerance And Efficacy Of An Air-Filled Balloon In Non-Morbidly Obese Patients. . . F. Mion. Obesity Surgery, 2007; 17, 764-769*

*Posters from the World Congress Of IFSO : Air Filled Intragastric Ballon (Bag): Italian Multicentric Results. S. Giovanelli (2007),*

*Heliosphere Intragastric Air Balloon: Our Initial Experience In The Dominican Republic. Dk Ramirez. (2006), Intragastric Balloon For Obesity: Comparative Study With 420 Patients: New Generation Airfilled Vs Liquid-Filled. C Hermida. (2006) or from the UEGW : Primary Experience With Air Filled Intragastric Balloon Confronted To Liquid Intragastric Balloon Literature Data. H. Claudez (2005)*

### Evolution of BMI observed in 207 patients with an initial BMI > 30



*Prospective European database for France, Italy and Belgium*

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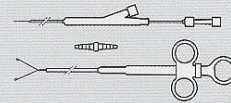


heliosphere®  
**BAG**



- 1 double pouch balloon
- 1 placement kit pre-connected to the balloon
- 1 60cc syringe

heliosphere®  
**BAG-EXTRACT**



- 1 deflation needle
- 1 pair of extraction forceps
- 1 universal connector for the aspiration tube

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