



heliosphere® BAG Pre Op

INTRAGASTRIC AIR BALLOON

Characteristics

Morbid obesity is a serious danger for the health and the quality of patient's life. As a minimally invasive, reversible and comfortable medical implant, HELIOSPHERE® BAG Pre Op is a guarantee of safe and effective pre-operative treatment for morbid obesity.

Non-surgical and minimally invasive

- Implanted in around 30 minutes by endoscopic route without the need to hospitalise the patient.

Inflated with air

- Light, so reduces post-implantation nausea, vomiting and the sensation of pain.

Temporary

- The implant is left in place for 6 months.

Airtight

- Initial volume assured.

Easy to put in place

- Patented cover removal system.

Easy to extract

- Reduction in extraction force and wall thickness.

LNE/G-Med CE marking



VOLUME OF INFLATED BALLOON **650 cm³**

Ø 10,5 cm

60 cc
x12

HELIOSPHERE® BAG Pre Op

Ø 10,5 cm

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

HELIOSPHERE® BAG-EXTRACT

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



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Indications

It is important for the success of the treatment that the use of the HELIOSPHERE® BAG Pre Op intragastric balloon is accompanied by dietetic and medical monitoring.

Morbid obesity (BMI 50-60)

- Serious medical and mortality risks.

Pre-operative

- Lowering of the anaesthetic and surgical risk.

For a Body Mass Index lying between 30 and 40, the use of the HELIOSPHERE® BAG intragastric balloon is recommended.

Results

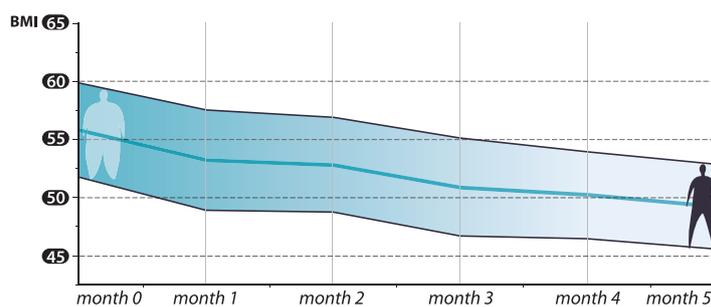
Once inflated, the balloon reduces the nominal volume of the stomach. By acting on the mechano-receptors in the upper part of the stomach, HELIOSPHERE® BAG Pre Op causes a rapid feeling of satiety at meals. The patient eats less and loses weight.

Efficacy

- Reduction in the Body Mass Index to below 50 for the majority of patients.⁽¹⁾
- Lowering of surgical risks thanks to the pre-operative partial reduction in weight.

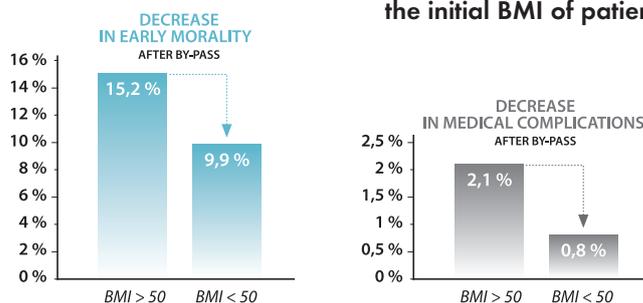
A study observes a direct link between surgical risks and the initial Body Mass Index of patients. The reduction in the BMI before by-pass lowers the risks of medical complications or early mortality.⁽²⁾

Reduction of BMI in 46 patients⁽¹⁾



⁽¹⁾ According to the European prospective database (Observatory of HELIOSCOPE).

Correlation of surgical risks with the initial BMI of patients ⁽²⁾



⁽²⁾ According to the results of the ROUX-EN-Y GASTRIC BY-PASS clinical studies in 1,000 operated patients.

BIBLIOGRAPHY

⁽²⁾ Factors Affecting Morbidity and Mortality of Roux-en-Y Gastric Bypass for Clinically Severe Obesity: An Analysis of 1,000 Consecutive Open Cases by a Single Surgeon. Louis Flancbaum. *J Gastrointest Surg* (2007) 11:500-507

FROM TECHNOLOGY TO HUMAN

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