



Intragastric Balloon

Silicone membrane featuring unidirectional valve system and guiding and filling tube



A QUICK ALTERNATIVE FOR WEIGHT LOSS

- An average of 18% of weight loss is achieved in 6 months of treatment with a non-adjustable intragastric balloon. A 12-month treatment can result in a weight loss greater than that expected for the 6-month treatment.^{1,2}
- The 12-month intragastric balloon provides patients with more time to be adapted to a new routine and food reeducation, preventing recovery of nearly 50% of the weight lost in 9 months.^{1,3}
- Approximately 13% more patients have intolerance with the use of adjustable balloons as compared to the non-adjustable balloons within the same implantation period.^{1,3}
- 78% of the patients who use adjustable balloons do not require any adjustments during the treatment period.^{4,5}

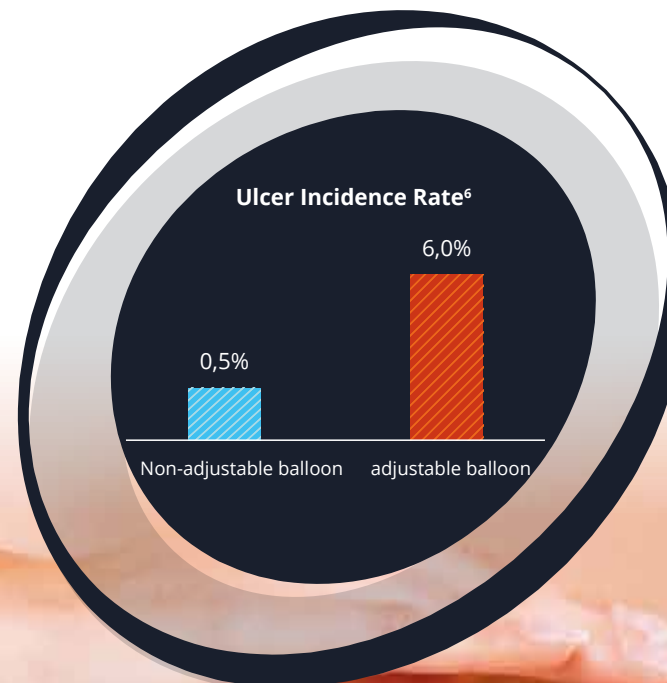
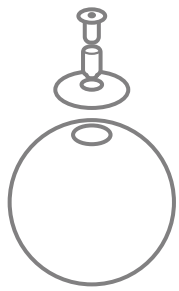


Chart for illustration purposes only

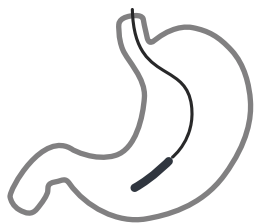




Silicone **membrane** featuring unidirectional **valve system** and **guiding and filling tube**.



It can be filled with **400 to 700 ml** of saline solution and methylene blue (**according to the patient biotype**).



Easy to be placed and removed through endoscopy.



Approved for treatments of up to **12 months**.



ANVISA Registration #: 80020550068
Head Technician: Vanessa Carlos Cardoso
CREA/RS 200553



Manufactured by:
Medicone Projetos e Soluções para a Indústria e a Saúde Ltda
Av. das Indústrias, nº 1585 - Distrito Industrial - Cachoeirinha - Rio Grande do Sul
CEP: 94930-230 - Phone/Fax: (51) 3470-0800 - Email: sac@medicone.com.br
CNPJ: 94.304.672/0001-34 - State Enrollm.: 1770109630
Brazilian Industry

Code / Review: 67374/00

CONTRAINDICATIONS:

Use of the Intragastric Balloon is contraindicated in the following cases:

Pregnant women or women during the breastfeeding period; Handicapped individuals or unwilling to meet the restrictions associated with the diet or with the medical monitoring and their respective instructions during the program to use the Intragastric Balloon; Patients suffering from psychical disturbances; Patients younger than 18 years of age; Patients suffering from severe kidney and/or liver disorders; Patients undergone previous gastric or previous intestinal surgery; Patients suffering from inflammatory disorders of the gastrointestinal tract, gastric ulcer, duodenal ulcer or specific inflammations, such as Crohn's disease, or with tendency to gastrointestinal bleeding in the upper tract, such as esophageal or gastric varicose veins, or acquired intestinal telangiectasia; Individuals suffering from severe cardiopulmonary or organic diseases; Individuals suffering from congenital or acquired anomalies of the gastrointestinal tract, such as atresia or stenoses; with large hiatal hernia; General chemically dependents; Patients suffering from any type of infection in their body; HIV-infected patients; Patients with drug administration that could cause any type of irritation or gastric complication; Patients with reflux esophagitis; Patients with stenosis or esophageal diverticulum; Patients with potentially hemorrhagic injuries, such as varicose veins and; Patients using any anti-inflammatory drugs, anticoagulants, alcoholic beverages or drugs.

Single use and non-reusable.

References:

1. BROOKS, J. ; SRIVASTAVA, E. D.; MATHUS-VLIEGEN, E. M. H. One-year Adjustable Intragastric Balloons: Results in 73 Consecutive Patients in the UK. Springer Science+Business Media New York: Springer, 2014. 7 p. Disponível em: <https://link.springer.com/article/10.1007%2Fs11695-014-1176-3>.
2. NUNES, Gabriel C. et al. Assessment of Weight Loss With the Intragastric Balloon in Patients With different Degrees of Obesity. Surg Laparosc Endosc Percutan: Wolters Kluwer Health, Inc., 2017. Disponível em: https://journals.lww.com/surgical-laparoscopy/Abstract/2017/08000/Assessment_of_Weight_Loss_With_the_Intragastric.27.aspx
3. RUSSO, Teresa et al. BioEnterics Intragastric Balloon (BIB) versus Spatz Adjustable Balloon System (ABS): Our experience in the elderly. International Journal of Surgery: Elsevier Ltd., 2016. 3 p. Disponível em: <http://dx.doi.org/10.1016/j.ijso.2016.06.013>.
4. BROOKS, Jeffrey. One-Year Adjustable Intragastric Balloons: Do They Offer More than Two Consecutive Nonadjustable 6-Month Balloons? A response to Genco et al. Springer Science+Business Media New York: Springer, 2013. 2 p. Disponível em: <https://link.springer.com/article/10.1007/s11695-013-1014-z>.
5. GENCO, Alfredo et al. Adjustable Intragastric Balloon vs Non-Adjustable Intragastric Balloon: Case-Control Study on Complications, Tolerance, and Efficacy. Springer Science+Business Media New York: Springer, 2013. 6 p. Disponível em: <https://link.springer.com/article/10.1007/s11695-013-0891-5>.
6. NETO, Manoel Galvão et al. Brazilian Intragastric Balloon Consensus Statement (BIBC): practical guidelines based on experience of over 40,000 cases. American Society for Metabolic and Bariatric Surgery: Elsevier, 2017. 9 p. Disponível em: <http://dx.doi.org/10.1016/j.sob.2017.09.528>.