

# heliosphere® Newtech

Facts on Heliosphere  
06/2021-1

## Summary:

- The Air-Filled Concept
- The Efficiency
- The Tolerance and Safety
- The Perspective

## The Air-Filled Concept

**Heliosphere** is a unique concept of air-filled intragastric balloon, which makes possible to combine significant weight-loss and patient's every day quality of life.

The result of more than 15 years of experience, **Heliosphere** is only composed of biocompatible and gastric resistant polyurethane and silicone.

Designed to be easily put in place and then removed after six months of treatment by endoscopy, this balloon weighs less than 15g when inflated to its therapeutic volume of 600cc minimum.



Since its introduction on the market, **Heliosphere** has been the subject of several international publications. Nearly 1 in 10 balloons sold as been subject to clinical communications on efficacy, tolerance and safety data.

These results can also be seen through numerous review publications<sup>1,2,3</sup> which place **Heliosphere** among the best balloons currently available on the market.

**Table 3a.** Types of Intragastric Balloons and Their Respective Individual Outcomes.

Balloon type	Weight loss (%)	Implantation	Placement method	Composition	FDA approval
Orbera®	Pooled meta-analysis TWL: 13.6 <sup>37</sup>	6 months	Endoscopic	Silicone Sphere (saline)	Yes; BMI 30-40 kg/m <sup>2</sup> ; Age 22-60
ReShape™	EWL: 31.8 ± 21.3 <sup>38</sup>	6 months	Endoscopic	Silicone Sphere (saline)	Yes; BMI 30-40 kg/m <sup>2</sup> ; Age 22+
Spatz®	EWL: 26.4 <sup>39</sup>	12 months	Endoscopic	Silicone Sphere	No
Heliosphere® Bag	EWL: 33.2 <sup>40</sup>	6 months	Endoscopic	Polyurethane and silicone (Air)	No
MedSil®	EWL: 19.3 ± 12.7 <sup>41</sup>	6 months	Endoscopic	Silicone (Saline)	No
LexBal	EWL: 26.8 ± 12.3 <sup>42</sup>	6 months	Endoscopic	Silicone (Saline)	No
End-Ball®	EWL: 31.1 <sup>43</sup>	6 months	Endoscopic	Polyurethane (Air/Saline)	No
Silimed	EWL: 46.5 ± 36.7 <sup>44</sup>	6 months	Endoscopic	Silicone(Saline)	No
Medicone®	TWL: 18.4 ± 2.9 <sup>45</sup>	6 months	Endoscopic	Silicone (Saline)	No
Semisationary and balloon	EWL: 8.35 ± 6.4 <sup>46</sup>	6 months	Endoscopic	Silicone (Saline)	No

BMI, body mass index; EWL, excess weight loss; TWL, total weight loss.  
The data presented in this table are for representation purposes only. This table, in no manner, depicts the comparison between these devices.

## Publication 2021 :

Table 3a from Goyal, H., et al. (2021). Endobariatric procedures for obesity: clinical indications and available options. *Therapeutic Advances in Gastrointestinal Endoscopy*, 14,

## Références :

- <sup>1</sup> Goyal, H., et al. (2021). Endobariatric procedures for obesity: clinical indications and available options. *Therapeutic Advances in Gastrointestinal Endoscopy*, 14,
- <sup>2</sup> Gollisch, K. S. C., & Raddatz, D. (2020). Endoscopic intragastric balloon: a gimmick or a viable option for obesity?. *Annals of translational medicine*, 8(Suppl 1).
- <sup>3</sup> Espinet-Coll, E. (2017) "Multicenter study on the safety of bariatric endoscopy." *Rev Esp Enferm Dig* 109(5): 350-357.

**Publication 2020 :**

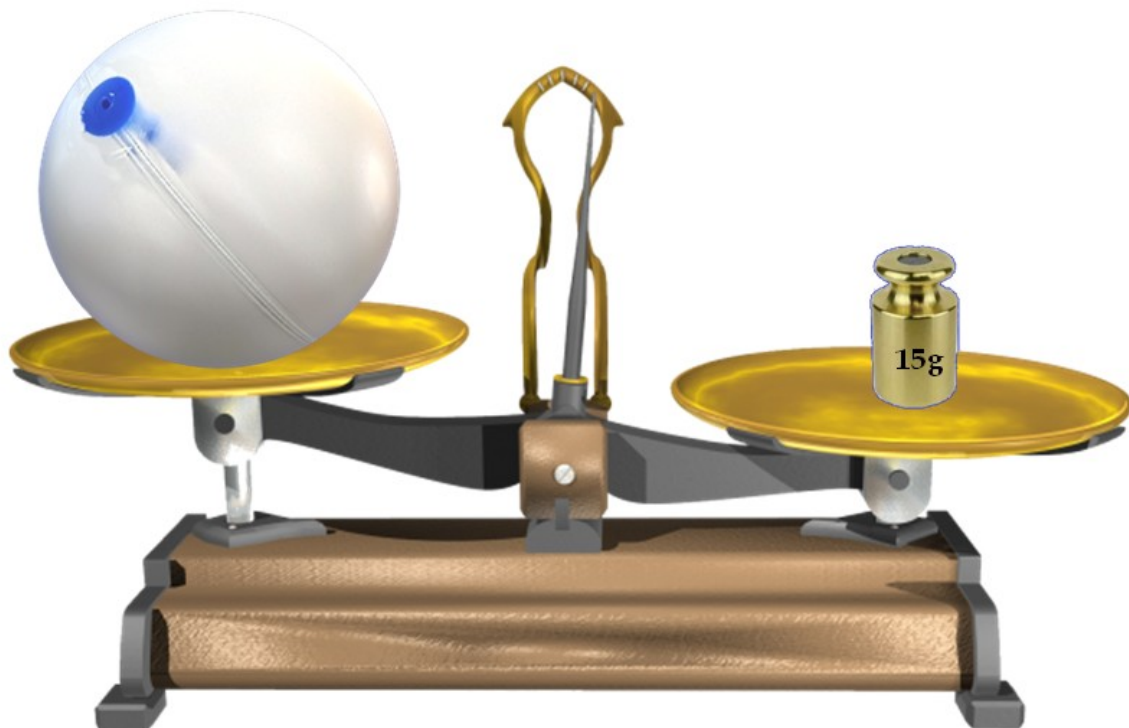
Table 1 from Gollisch, K. S. C., & Raddatz, D. (2020). Endoscopic intragastric balloon: a gimmick or a viable option for obesity?. *Annals of translational medicine*, 8(Suppl 1).

Balloon type	Implant/explant	FDA approved	CE mark	Time <i>in situ</i> (months)	Filling	Volume (mL)	TBWL (%)	EWL (%)	Ref.
Ellipse®	Swallow/excretion	No*	Yes	4	Liquid	450–550	10.0	n/a	(4)
End-Ball®	Endo/endo	No	Yes	6	Liquid/gas	700	17.1	36.5	(5)
Heliosphere® BAG	Endo/endo	No	Yes	6	Air	700	13.4	33.2	(6)
Lexbal®	Endo/endo	No	Yes	6	Liquid	500–800	14.9	26.8	(7)
MedSil®	Endo/endo	No	Yes	6	Liquid	400–700	13.1	n/a	(8)
Obalon®	Swallow/endo	Yes	Yes	6	Gas	3x250	7.1	n/a	(9)
Orbera®	Endo/endo	Yes	Yes	6	Liquid	400–700	10.2	26.5	(10)
Reshape®	Endo/endo	Yes	Yes	6	Liquid	750–900	6.8	25.1	(11)
Spatz3®	Endo/endo	No	Yes	12	Liquid	Adjustable	20.1	45.8	(12)

\*, in progress. FDA, Food and Drug Administration; CE, Communauté Européenne; TBWL, total body weight loss; EWL, excess weight loss; endo, endoscopically; n/a, not applicable.

**The Efficiency : Light to Loose Weight !**

Clinical data on more than 2000 patients show the effectiveness of **Heliosphere** for a 6-month treatment.



A Featherweight Device for HeavyWeight-loss

Study	Country	Year	Number of patients with heliosphere®	Initial BMI (kg/m <sup>2</sup> )	Excess Weight Loss (%)	Weight Loss (kg)
Romney, R <sup>1</sup>	France	2020	110	35,2 ± 4,3	<b>48% ± 33</b>	12,2 ± 5,7
Rizwan, M <sup>2</sup>	Qatar	2017	87	35,1 ± 3,5	<b>19.4% ± 30</b>	7.7 ± 7,8
Coenye <sup>3</sup>	Belgium	2017	250	NR	<b>NR</b>	15 (0-42kg)
Erdem, H <sup>4</sup>	Turkey	2016	75	41,6 ± 6,7	<b>33,2%</b>	NR
Palmisano, S. <sup>5</sup>	Italy	2016	58	39,6 ± 6,9	<b>28,1% ± 20,1</b>	10,1 ± 6,5
Houissa, F <sup>6</sup>	Tunisia	2014	21	49,3 ± 11,9	<b>37,65%</b>	22,8 ± 8,5
Masini, A <sup>7</sup>	Italy	2014	85	>50	<b>20%</b>	27
Kolesnikov, E <sup>8</sup>	Ukraine	2013	68	46,1 ± 3,3	<b>26.4%</b>	16,8 ± 3,1
Lecumberri, E <sup>9</sup>	Spain	2011	82	39,1 ± 5,8	<b>33.2% ± 19.2</b>	14,5 ± 8,2
Sciumé, C. <sup>10</sup>	Italy	2009	50	39.8	<b>NR</b>	16.8
Costil, V <sup>11</sup>	France	2009	79	33,7 ± 1,2	<b>NR</b>	10,5 ± 1,4
Giovanelli, A <sup>12</sup>	Italy	2009	167 BMI<35 353 BMI [35-50] 63 BMI>50	NR	<b>62%</b> <b>51,3%</b> <b>NR</b>	12,2 ± 1,1 19,8 ± 1,2 15,9 ± 2,6
Romney, R <sup>13</sup>	France	2009	75	39,4 ± 1,48	<b>42,5% ± 5,4</b>	15,2 ± 1,9
Galvao ,N <sup>14</sup>	Brazil	2009	236	34,8	<b>42% (15-72)</b>	NR
Hermida, C <sup>15</sup>	Spain	2006	192	37,7 ± 4,5	<b>NR</b>	24,7 ± 10,9
Ramirez, DK <sup>16</sup>	Dominican R.	2006	64	38,9	<b>51%</b>	17,2

## The Tolerance and Safety : Light to Avoid Side Effects !

With excellent tolerance, **Heliosphere** preserves the patient's quality of daily life.

Over 97% of patients complete their 6-month treatment serenely.

Study	Country	Year	Number of patients heliosphere®	Early removal for intolerance	Pancreatitis Erosion Ulcer	Migration (including surgical removal )
Romney, R	France	2020	110	2%	0%	1% (0%)
Coenye	Belgium	2017	250	1,2%	0%	1,6% (0%)
Erdem, H.	Turkey	2016	75	4%	0%	0%
Palmisano, S.	Italy	2016	58	0%	0%	0%
Houissa, F	Tunisia	2014	21	1	2 ulcers	0
Masini, A	Italy	2014	85	0%	0%	0%
Lecumberri, E	Spain	2011	82	1,2%	NR	3% (0%)
Sciumé, C.	Italy	2009	50	4%	0%	0%
Giovanelli, A	Italy	2009	583	<3%	NR	NR
Romney, R	France	2009	75	0	NR	1.3% (0%)
Galvao ,N	Brazil	2009	236	0,42%	NR	0%
Hermida, C	Spain	2006	192	0,7%	NR	NR
Ramirez, DK	Dominican R.	2006	64	1,56%	0%	0%

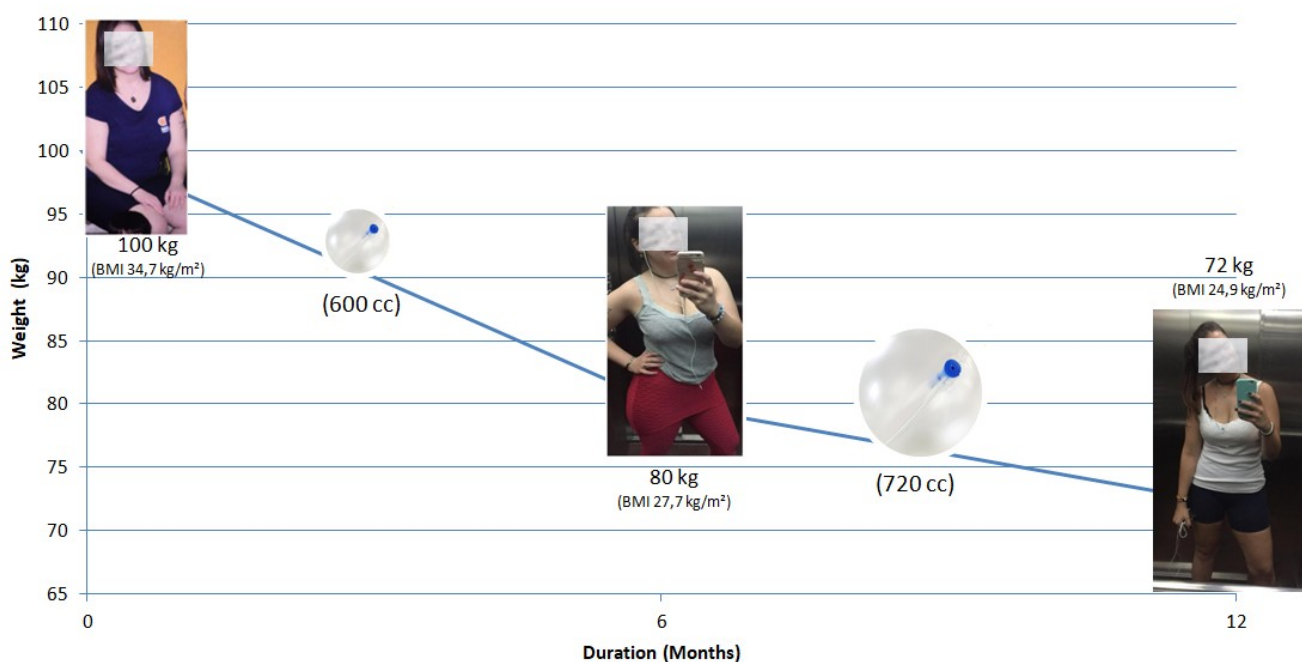
No need to be sick to loose weight

## The Perspective : Excellent Tolerance for 12 Months Sequential Treatment

Heliosphere concept enhances patients results throughout 1 year treatment with 2 balloons and only 3 endoscopies.

The method :

- Standard volume balloon (600cc) for the first 6 months period,
- Extraction at 6 months and implantation of greater volume balloon (720cc) at the same procedure,
- Extraction of the second balloon 6 months later.



### Références :

- 1 Romney (2020), Single center prospective cohort on Heliopshère Newtech (on going)
- 2 Rizwan (2017), Intra gastric balloon is still an option, but what about its efficacy. Our experience in Doha-Qatar (Poster at the 22<sup>nd</sup> World Congress Of IFSO, London, England)
- 3 Coenye (2017), Single center prospective cohort on Heliopshère Newtech (CREGG 2017)
- 4 Erdem, H., et al. (2016). "Effects of Intra gastric Balloon on Body Mass Index, Lipid Profile and Blood Glucose Regulation: A Prospective Study." *Dicle Tip Dergisi* 43(1).
- 5 Palmisano, S., et al. (2016). "Intra gastric Balloon Device: Weight Loss and Satisfaction Degree." *Obesity surgery* 26(9): 2131-2137.
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- 8 Kolesnikov (2013). Air- and Liquid-filled intra gastric balloons in treatment of obese and super obese patients (Poster at the 18<sup>nd</sup> World Congress Of IFSO, Istanbul, Turkey)
- 9 Lecumberri, E. (2011). Effectiveness and safety of air-filled balloon Heliosphere BAG® in 82 consecutive obese patients. *Obesity surgery*, 21(10), 1508-1512.
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- 16 Ramirez DK, (2006) Heliosphere Intra gastric Air Balloon: Our Initial Experience In The Dominican Republic, Abstracts Of Posters From The 11th World Congress Of IFSO, Sydney, Australia, *Obesity Surgery*; 16, 993-1031