

# Budget Impact Analysis of RefluxStop as a Treatment of Refractory Gastro-Esophageal Reflux Disease in Spain

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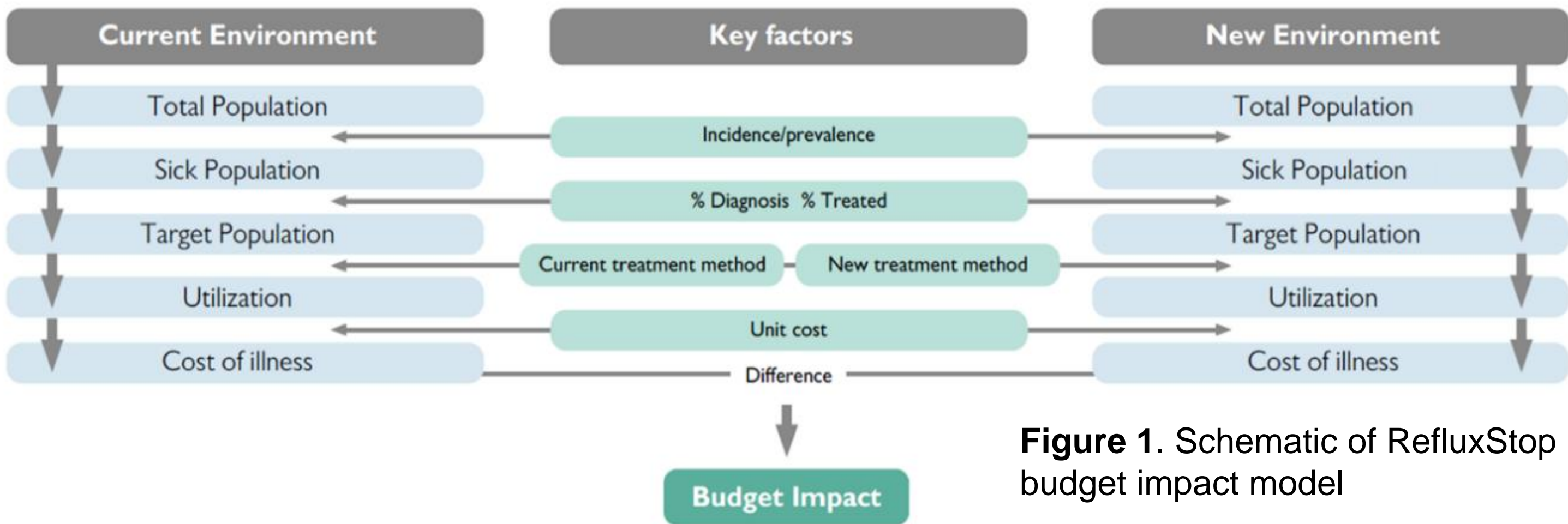
## INTRODUCTION

- Prevalence of GERD in Spain is estimated at 15%.<sup>1</sup>
  - Medical standard of care: PPIs have potential side effects with long-term use, and there is limited effectiveness in up to 40% of users.
  - Surgical standard of care: laparoscopic Nissen fundoplication is well established but can cause side effects affecting patient quality of life potentially requiring further intervention.
- RefluxStop is a new surgical treatment for GERD that represents an alternative to the established standard of care.
  - RefluxStop has demonstrated safety and effectiveness for up to 3 years or more<sup>2</sup> and is available at multiple institutions throughout Europe, including Spain (since 2023).

**OBJECTIVE:** To assess the budget impact for the Spanish national health system associated with the introduction of the RefluxStop procedure

## METHODS

- Budget impact model** developed in line with ISPOR recommendations<sup>3</sup> (Fig. 1)
  - Perspective:** Spanish national health system
  - Time horizon:** 5 years
  - Scenarios:** PPIs and Nissen—with and without RefluxStop
  - Estimates for population growth: from *Instituto Nacional de Estadística*
  - GERD incidence and prevalence, rate of anti-reflux surgery in general population: from **literature**
  - Market research and assumptions → existing and anticipated market shares of individuals needing **medical management, Nissen fundoplication, and RefluxStop**
- Costs: from **CE Markov model** adapted to Spanish settings
  - Unit costs: from literature and DRGs
  - Uncertainty** explored via **scenario analysis** – effect of **halving or doubling rates of RefluxStop uptake**



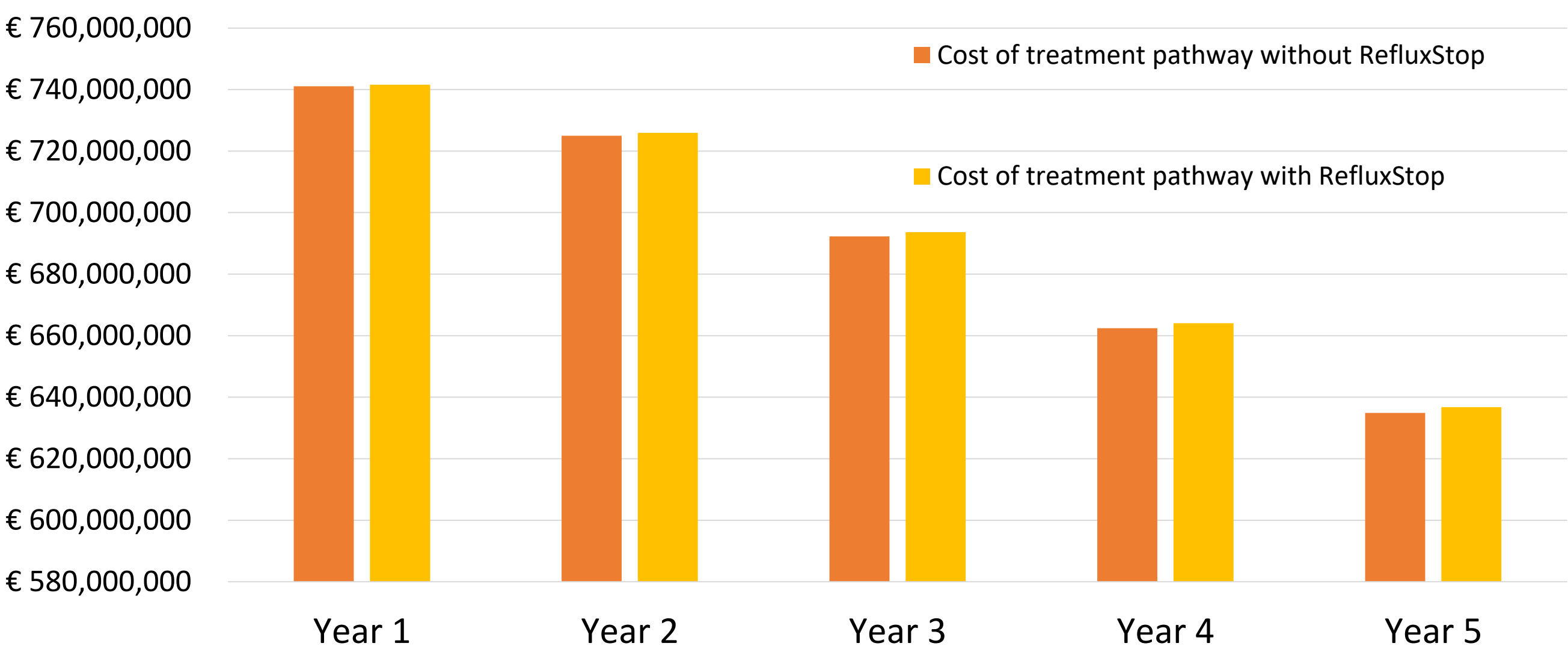
## RESULTS

**Table 1.** Market share of interventions considered in the scenarios with and without RefluxStop for the base case.

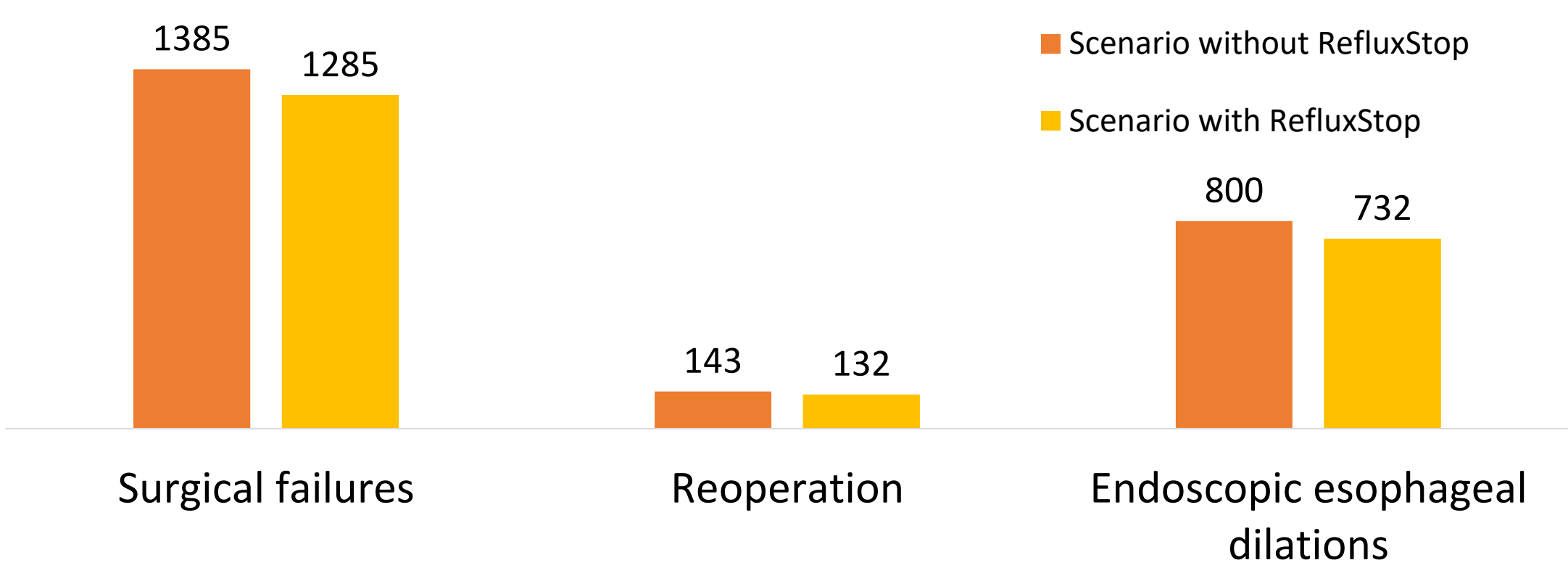
Treatment	Year 1	Year 2	Year 3	Year 4	Year 5
RefluxStop	5.1%	10.2%	15.2%	18.5%	21.8%
Nissen	94.9%	89.8%	84.8%	81.5%	78.2%

### Base-case analysis

- Budgetary impact** of RefluxStop introduction (Table 2): 1 year (€236,131), 3 years (€682,456), **5 years (€951,938)**.
- Corresponding **increase in overall annual expenditure** for GERD treatment in Spain: 1 year (0.03%); 3 years (0.10%); **5 years (0.15%)**.
- Optimistic** (doubled) and **pessimistic** (halved) RefluxStop uptake → increased expenditure: 1 year (0.13% and 0.016%); 5 years (0.3% and 0.08%), respectively.
- RefluxStop introduction associated with improved clinical outcomes: **avoided 100 surgical failures, 11 reoperations, and 68 oesophageal dilations** over 5-year horizon (Fig. 3).



**Figure 2.** Total annual costs of base-case scenarios with and without RefluxStop



**Figure 3.** Clinical outcomes of base-case scenarios with and without RefluxStop over 5y

**Table 2.** Total costs estimated in base case scenarios with and without RefluxStop and resulting budget impact

	Year 1	Year 2	Year 3	Year 4	Year 5
Eligible population	645,082	652,829	660,629	668,433	676,237
Population expected to receive RefluxStop	42	126	253	407	407
Cost of treatment pathway without RefluxStop	€735,432,300	€719,978,724	€687,837,471	€658,442,559	€631,380,506
Cost of treatment pathway with RefluxStop	€735,668,431	€720,440,393	€688,519,926	€659,261,442	€632,332,444
Nominal net budget impact	€236,131	€461,668	€682,456	€818,883	€951,938
Net budget impact as % of SNS spending for GERD treatment	0.032%	0.064%	0.099%	0.124%	0.151%

**Conclusion:** The introduction of RefluxStop, which yields a minimal budgetary impact, is likely an effective and economically acceptable surgical treatment option for the Spanish national health system.

**References**

1. Ponce J et al. Prevalence of gastro-oesophageal reflux disease in Spain and associated factors. Aliment Pharmacol Ther. 2006;23(1):175-84.

2. Harsányi L et al. Treating acid reflux without compressing the food passageway: 4-year safety and clinical outcomes with the RefluxStop device in a prospective multicenter study. Surg Endosc. 2024;38(10):6060-9.

3. Sullivan SD et al. Budget impact analysis-principles of good practice: report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force. Value Health. 2014;17(1):5-14.

**Abbreviations**

CE, cost effectiveness; DRG, diagnostic-related group; GERD, gastro-esophageal reflux disease; LNF, laparoscopic Nissen fundoplication; PPI, proton pump inhibitor; SNS, *sistema nacional de salud* (Spanish national health system).