



Medtronic

GATEKEEPER™

REFLUX REPAIR SYSTEM



A Logical Approach to GERD Treatment

GATEKEEPER™ REFLUX REPAIR SYSTEM

It's estimated that at least five to seven percent of the general population suffers from the symptoms of gastroesophageal reflux disease (GERD). The majority of these patients rely on medication to address the symptoms of GERD. While effective for many, daily medication is often costly and can require lifelong dependency. Gatekeeper is designed to address the needs of these patients without many of the risks associated with surgery.



Gatekeeper Prostheses

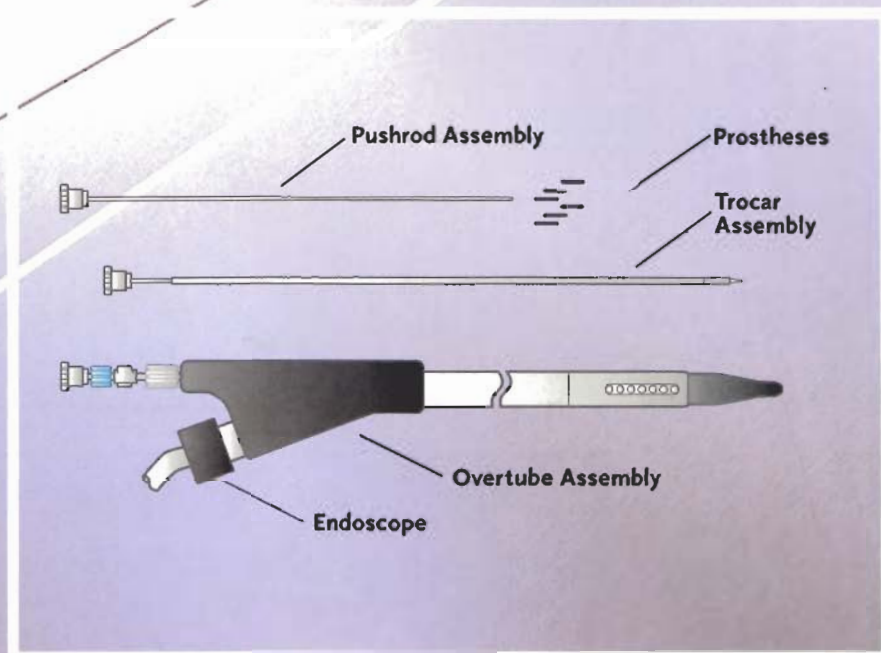
The Gatekeeper prosthesis is made of a multi-block polyacrylonitrile-based hydrogel (HYPAN) and tantalum. This material is highly biocompatible, non-carcinogenic, and non-migratory. Furthermore, it has been shown to be well-tolerated and chronically retained without significant tissue reaction. The use of HYPAN in other implantable medical devices has been well established.

Gatekeeper: A Mechanical Approach to a Mechanical Problem

Gatekeeper Therapy is intended for symptomatic relief in patients diagnosed with GERD. The product is designed to bulk the lower esophageal sphincter (LES) by implanting hydrogel prostheses. It achieves this task simply and easily, putting control of GERD in your hands.

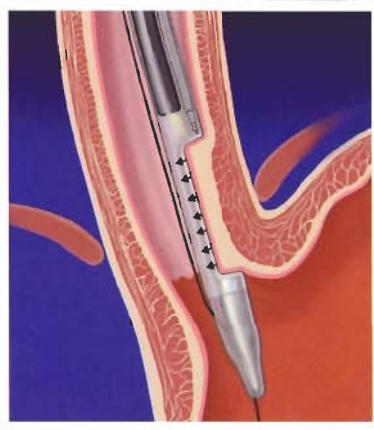
Finally, there is an endoscopic treatment option for your GERD patients that makes sense.

- Accurate placement using direct endoscopic visualisation
- Simple, reproducible technique
- Removable prostheses
- Prostheses 90% expanded at 6 hours

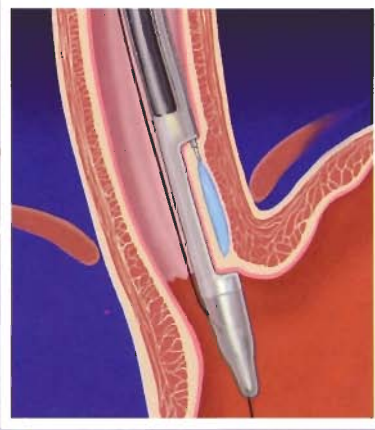


How Gatekeeper Works

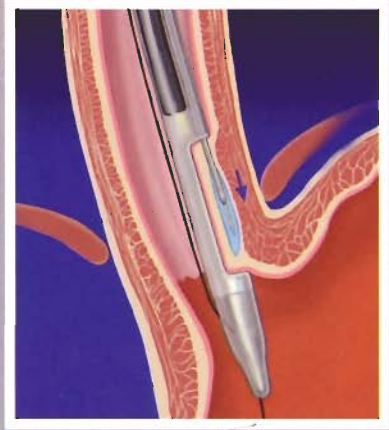
The Gatekeeper Reflux Repair System uses a controlled endoscopic delivery system to implant expandable hydrogel prostheses into the submucosa of the esophagus.



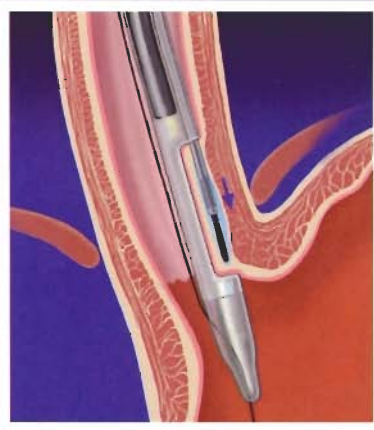
1. Esophageal tissue is stabilised in the shelf. Tissue blebs are created.



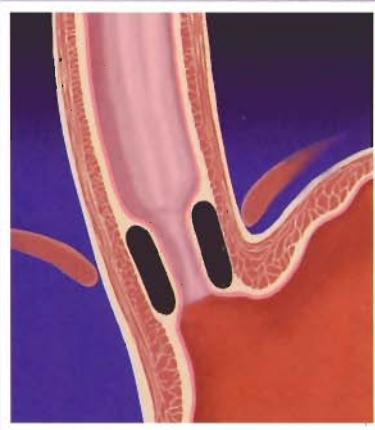
2. Saline is used to create a pocket within the submucosa.



3. Trocar assembly creates access to pocket



4. Prosthesis advanced into pocket.



5. Expanded prostheses.



Endoscopic images of four prostheses in the submucosal layer proximal to the LES (6 months post-implant)