

# No more reflux, no incisions, no more PPIs!

 **TIF**<sup>®</sup> PROCEDURE  
FOR REFLUX



[endacidreflux.com](http://endacidreflux.com)

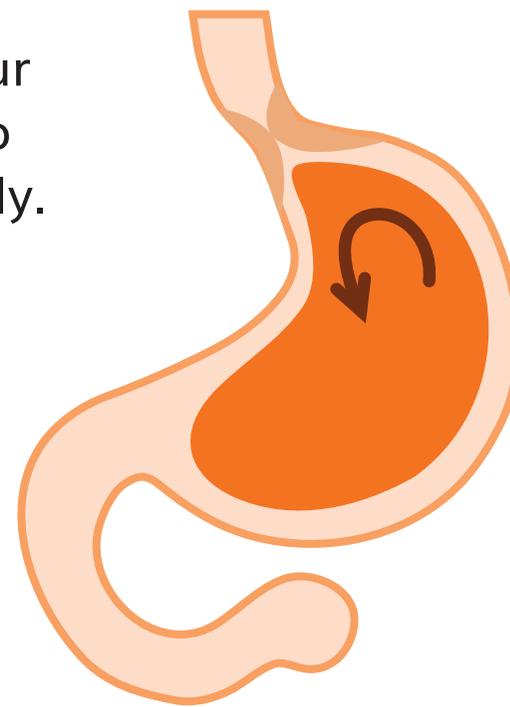
# What Is GERD?

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# GERD: Gastroesophageal Reflux Disease

GERD is when the valve that keeps your stomach contents from flowing up into your esophagus does not close properly.

- Causes damage to the esophagus
- Chronic symptoms can be very painful—even debilitating
- A progressive disease that does not resolve itself over time
- May lead to Barrett's esophagus or esophageal cancer



Healthy stomach



GERD

## What Is GERD?

**GERD is caused by a structural defect**

**Esophagus:** Passes food from the mouth to the stomach

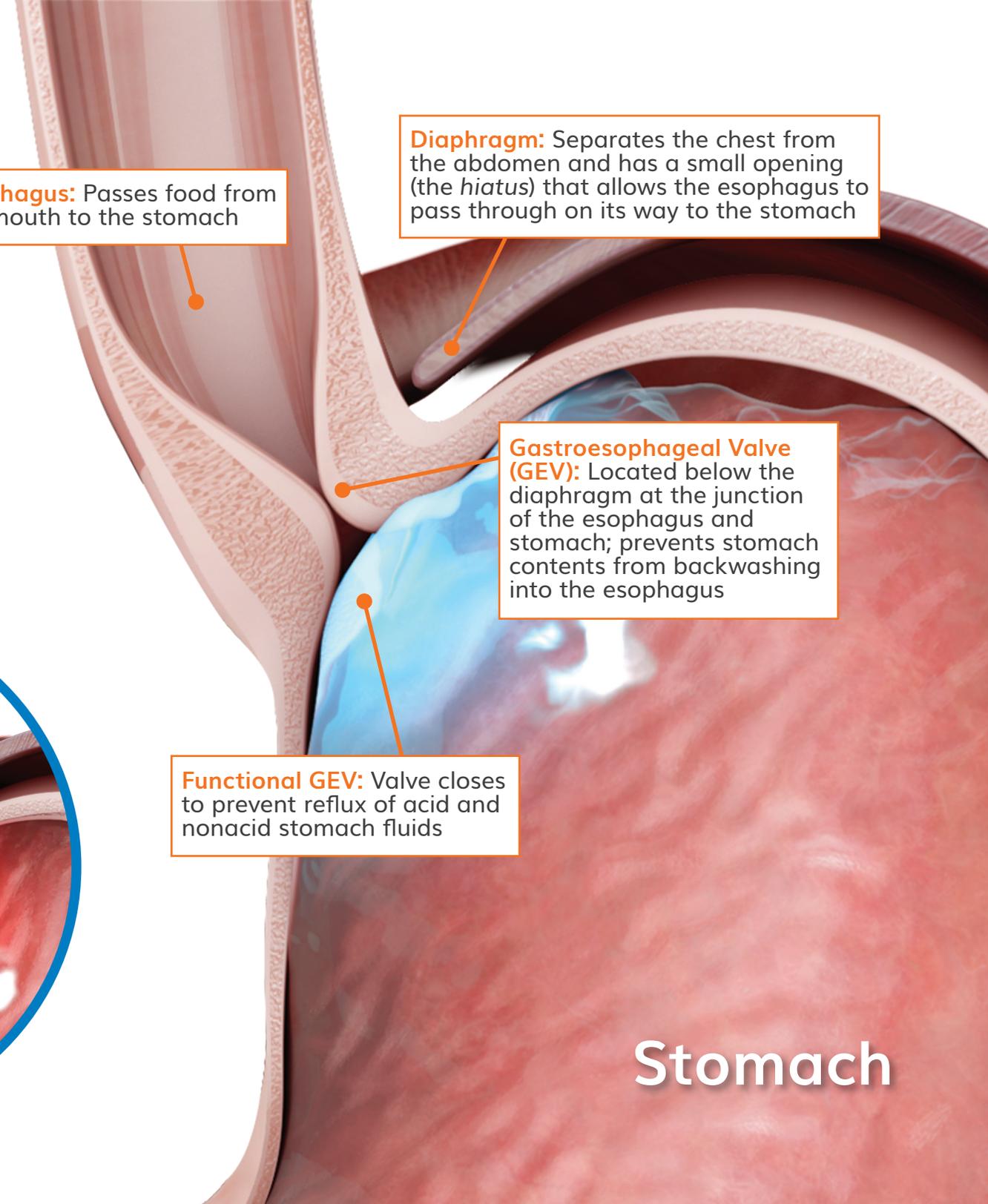
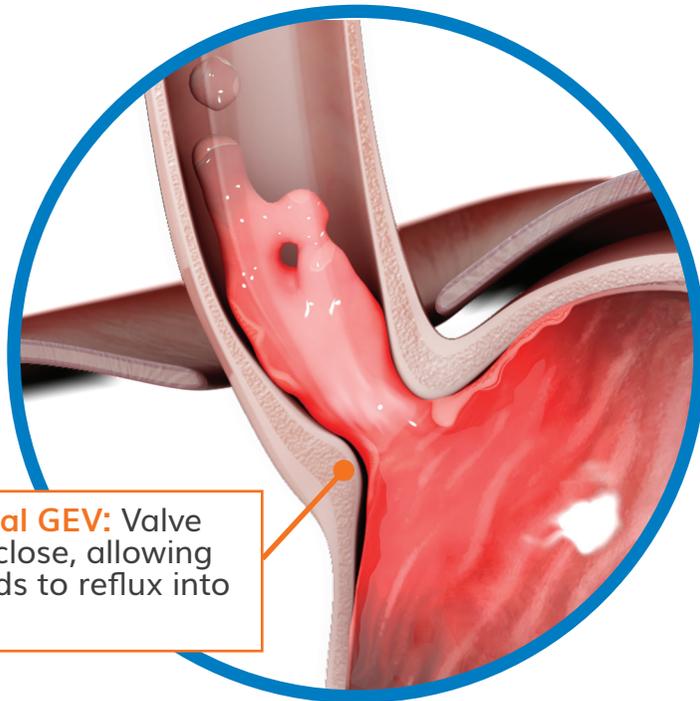
**Diaphragm:** Separates the chest from the abdomen and has a small opening (the *hiatus*) that allows the esophagus to pass through on its way to the stomach

**Gastroesophageal Valve (GEV):** Located below the diaphragm at the junction of the esophagus and stomach; prevents stomach contents from backwashing into the esophagus

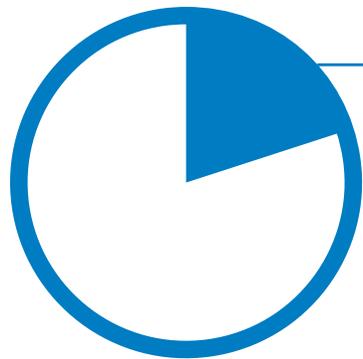
**Functional GEV:** Valve closes to prevent reflux of acid and nonacid stomach fluids

**Stomach**

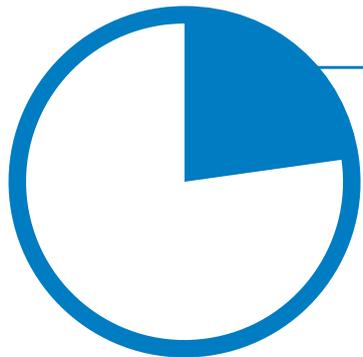
**Nonfunctional GEV:** Valve is unable to close, allowing stomach fluids to reflux into esophagus



# The good news? You're not alone.



20%  
of Americans  
suffer from  
GERD<sup>1</sup>



23%  
manage daily  
symptoms<sup>2</sup>



Up to  
40%  
of patients do  
not respond  
to medication  
treatment<sup>3</sup>

# Causes of GERD

# GERD contributing factors

There are many anatomical changes that can cause a weak gastroesophageal valve (GEV). You may have one or several factors that contribute to GERD symptoms.

## Genetics

Anatomy varies from person to person; some people naturally have weaker valves than others

## Age

As people age, musculature can weaken and cause the valve to lose its shape

## Obesity

Excess weight and overeating can cause a distortion of the anatomy

## Injury to upper chest

A sports-related injury or traumatic accident can damage the valve

# GERD Symptoms

# GERD can mean more than just heartburn

- Up to **60% of patients** have symptoms in the throat **without any significant heartburn as a symptom**<sup>4</sup>
- **75%** of patients with frequent GERD symptoms have them **at night**<sup>4</sup>
- **62%** of patients with **obstructive sleep apnea** also have GERD<sup>5</sup>

## Typical symptoms

- Heartburn
- Chest pain
- Regurgitation
- Gas/bloating
- Excessive salivation
- Trouble sleeping
- Sensitivity to some foods/liquids

## Other possible symptoms

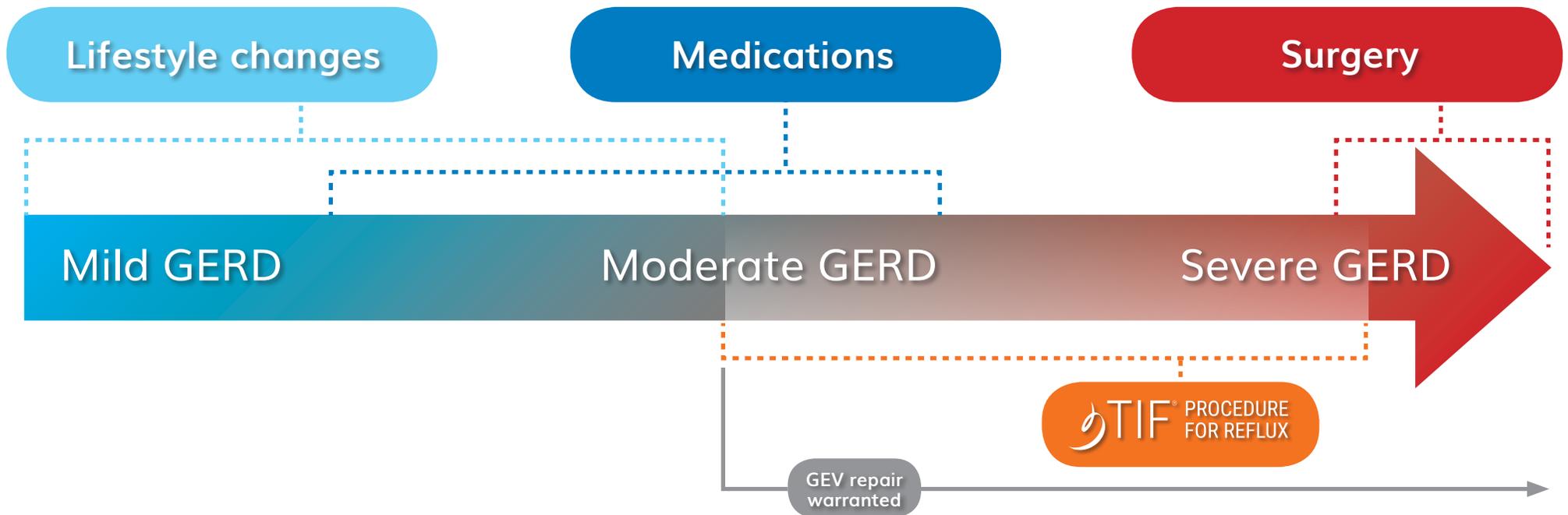
- Difficulty swallowing (dysphagia)
- Persistent cough
- Chronic sore throat
- Hoarseness/laryngitis
- Asthma or asthma-like symptoms
- Frequent swallowing/clearing of throat
- Bad breath/sour taste in the mouth
- Burning in mouth or throat
- Gum disease/dental erosions
- Ear and nose discomfort

## Hidden symptoms

- **50%** of asthmatic cough/wheezing is caused by GERD<sup>6</sup>
- **Up to 66%** of noncardiac chest pain is caused by GERD<sup>7</sup>

# GERD Treatment Options

# GERD treatment options:



## Lifestyle management & medication treatment

Patients are able to manage symptoms and maintain quality of life (65%-70% of patients)<sup>3</sup>

### GERD is a progressive disease

These symptoms are a warning to patients to seek additional evaluation:

- Increased PPI doses to control symptoms
- Breakthrough symptoms while taking PPIs
- Regurgitation
- Difficulty swallowing (dysphagia)

## The TIF procedure

Patients who need their GEV rebuilt as it is diagnosed to be the root cause of their GERD

Patients who need symptom control and to reduce medication dependence (30%-35% of patients)<sup>3</sup>

## Laparoscopic hiatal hernia repair

Patients with a hiatal hernia > 2 cm can have hernia repair and GEV rebuild in the same anesthesia session

## Traditional antireflux surgery

Patients who need a more extensive repair (0.5% of patients)<sup>3</sup>

# 65%-70% of patients manage GERD through lifestyle changes and meds<sup>3</sup>

## Treatment option 1: Lifestyle changes

- Maintain a healthy weight
- Avoid certain foods
- Don't smoke
- Avoid alcohol

## Treatment option 2: Medications

- Proton Pump Inhibitors (PPIs) like *Prilosec*<sup>®</sup> and *Nexium*<sup>®</sup> help manage GERD symptoms by suppressing acid production

Long-term medication overuse or dependence may cause:

- Dementia<sup>8</sup>
- Kidney disease<sup>9</sup>
- Stroke<sup>10</sup>
- Heart attack<sup>11</sup>
- Cardiovascular disease<sup>12</sup>
- Pneumonia<sup>13</sup>
- Intestinal bacterial and fungal infections<sup>14</sup>
- Osteoporosis fractures<sup>15</sup>

# Beyond lifestyle and meds: surgical treatment options

## Treatment option 3:

### Surgery

GERD is a progressive, chronic disease. The only way to control symptoms is to repair the esophageal valve to its natural state.

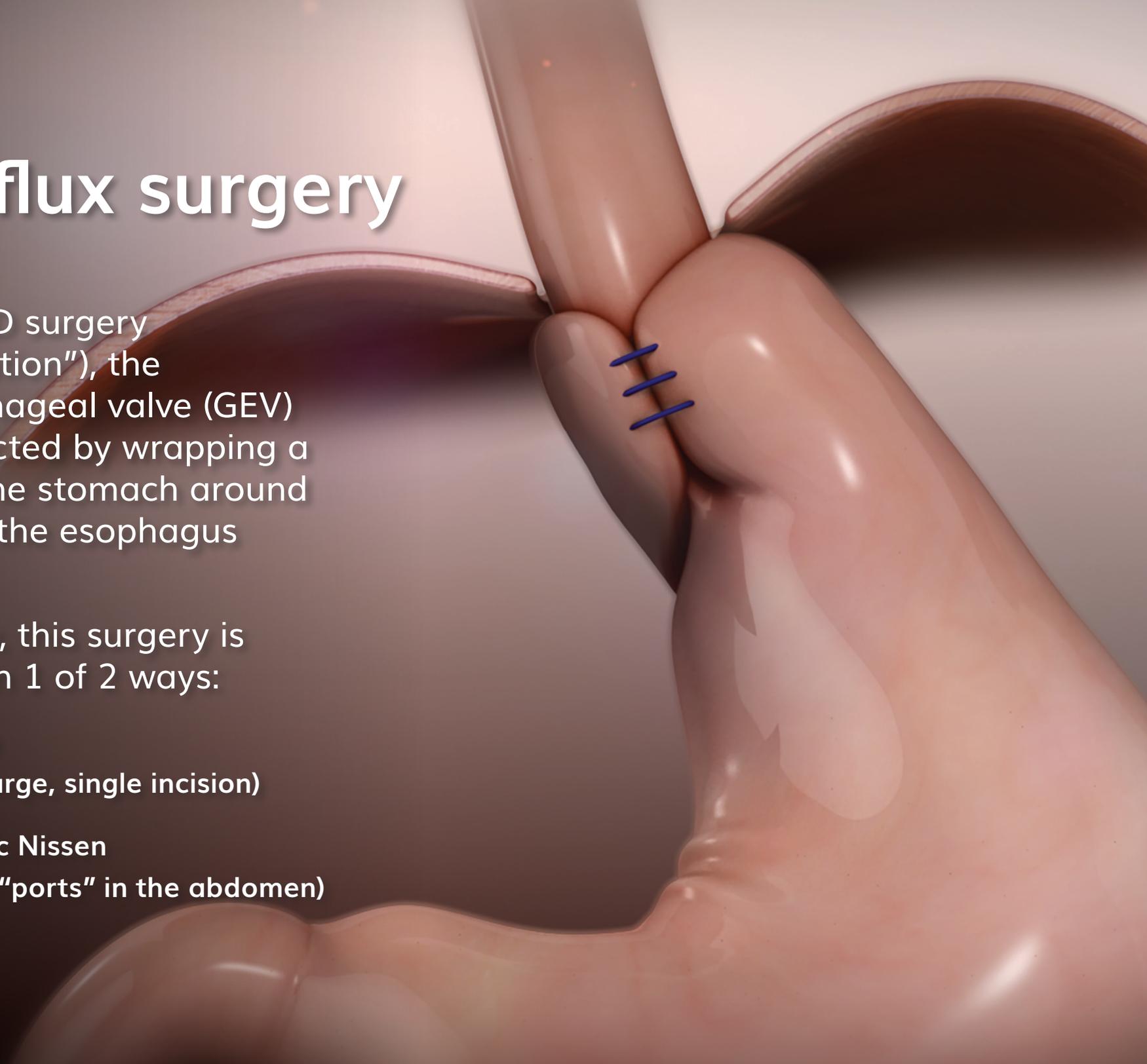
**PPIs are merely a Band-Aid, not a solution, with long-term chemical side effects.**

You may be ready for surgical treatment when you are:

- Unable to relieve symptoms with lifestyle changes and medication<sup>16</sup>
- Concerned about the long-term effects or costs associated with medication<sup>17</sup>
- You are one of the up to 40% of people who are unresponsive to PPI medication<sup>3</sup>

# Antireflux surgery

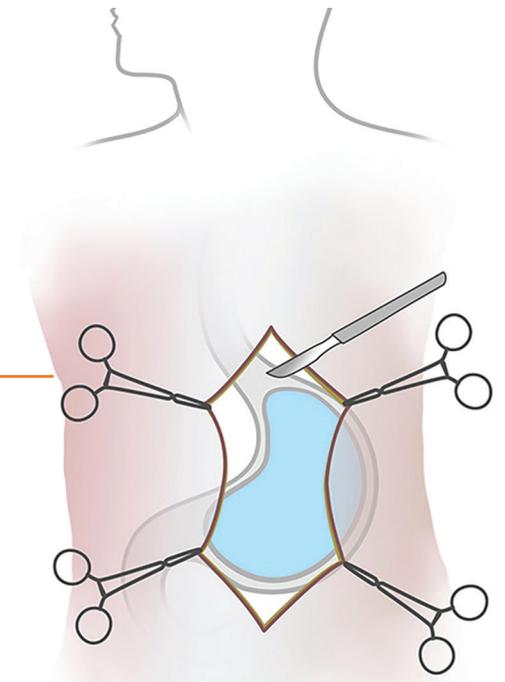
- During GERD surgery (“fundoplication”), the gastroesophageal valve (GEV) is reconstructed by wrapping a portion of the stomach around the base of the esophagus
- Traditionally, this surgery is performed in 1 of 2 ways:
  - Open Nissen  
(through a large, single incision)
  - Laparoscopic Nissen  
(using small “ports” in the abdomen)



# Traditional antireflux surgery options

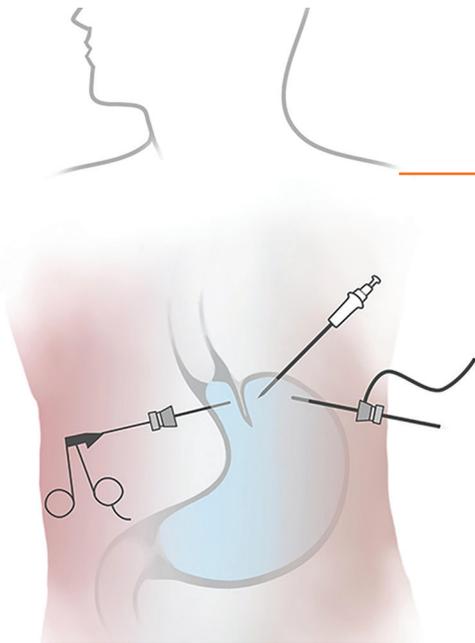
## Open Nissen Surgery

- Major surgery with large incision
- Esophagus is wrapped 360°
- Some patients cannot belch or vomit
- Long recovery (1-2 weeks)



## Laparoscopic Nissen Surgery

- Major surgery requiring several small incisions
- Can be performed on patients with any size hiatal hernia (when a part of the stomach bulges up through the diaphragm)
- The stomach is wrapped around the esophagus 360°
- Some patients cannot belch or vomit
- Long recovery (1-2 weeks)



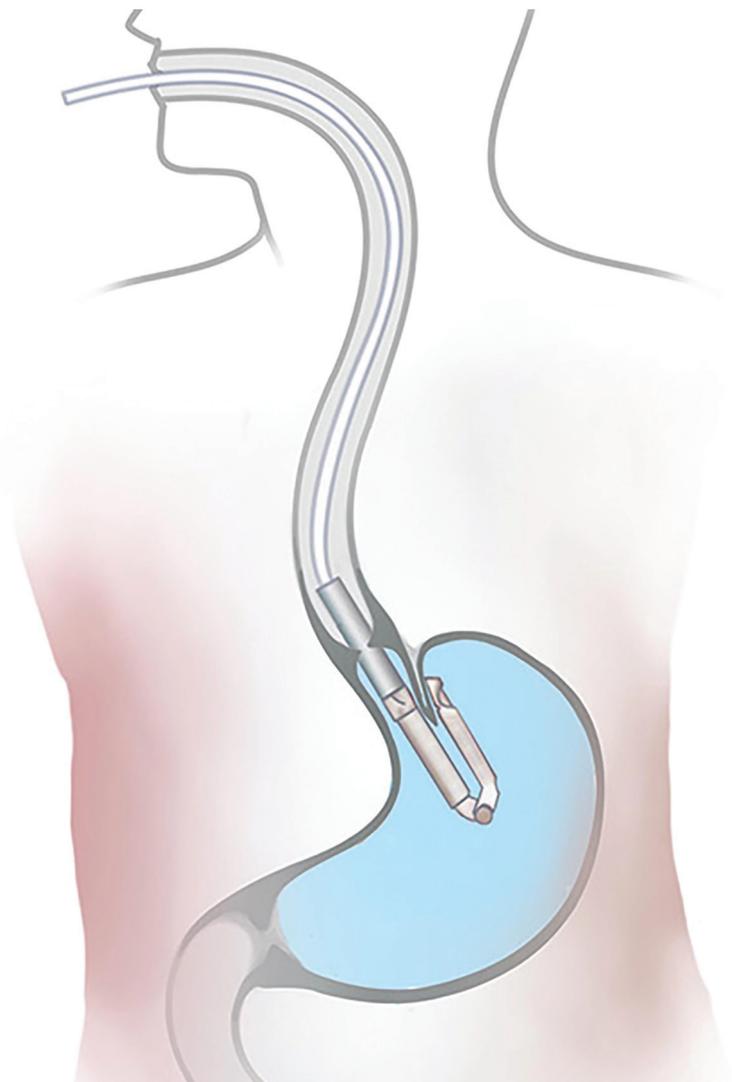
# Is there an incision-free procedure option?

**YES!**

Advancements in antireflux surgeries have evolved from a major open operation to an incision-free procedure without the negative side effects called the TIF (Transoral Incisionless Fundoplication) procedure.

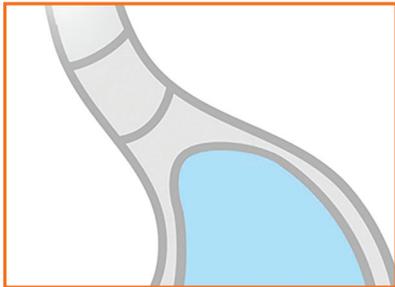
## The TIF Procedure

- Performed through the mouth = **zero incisions**
- Esophagus partially wrapped 270° to 300°
- Option for patients who do not have large hiatal hernias ( $\leq 2$  cm)
- Allows for belching and vomiting
- Short recovery—less than 1 week



# No incisions makes every body happy

## Traditional Nissen surgery

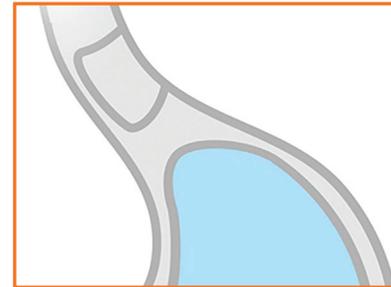


Results of a full wrapping of the esophagus. Some patients experience:

- ⊘ Difficulty swallowing
- ⊘ Increased bloating
- ⊘ Increased flatulence
- ⊘ Inability to belch
- ⊘ Inability to vomit

VS

## The TIF procedure



Results of a partial wrap of the esophagus:

- ✓ Restores the valve to its natural state
- ✓ No incisions, no cutting of body tissues
- ✓ No implants
- ✓ No negative long-term side effects
- ✓ Faster recovery time

# TIF Procedure & Benefits

# When the time is right, the TIF procedure is the natural way to go

## The TIF procedure is a lower-risk solution for patients who:

- No longer adequately respond to, or are dissatisfied with, long-term PPI use
- Experience typical or atypical symptoms of GERD
- Are concerned about the side effects of long-term PPI use

## The TIF procedure delivers relief:

- **Minimally invasive:** Fast recovery
- **Restores valve to natural state:** Maintain normal bodily functions
- **No incisions:** No scars
- **No metal implant:** No need to remove a foreign object
- **No dissection of the stomach:** No scar tissue

# The TIF procedure— why cut if you don't have to?

An anatomical diagram of the TIF procedure. It shows a cross-section of the upper abdomen and chest. The esophagus is shown as a vertical tube. The top of the stomach is folded over the lower esophagus. Blue fasteners are shown along the length of the esophagus and around the folded stomach. An orange arrow points to a 3cm distance. A large orange arc indicates a 270-degree wrap of the stomach around the esophagus.

The TIF procedure eliminates the need for tissue dissection by approaching the valve through the mouth using an endoscope.

First, the TIF procedure lengthens the esophagus. Then the top of the stomach is gently folded and partially wrapped around the lower esophagus. It is held in place with fasteners that physicians have used inside the body for decades. **No cutting needed.**

## The Benefits of TIF Procedure:

- Minimally invasive
- Fast recovery
- No incisions
- FDA cleared
- No increased flatulence
- Exemplary safety profile
- No increased bloating
- Covered by most insurance
- No metal implant
- Controls disruptive symptoms

# Proven track record of transforming lives



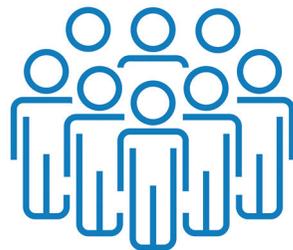
TIF patients no longer use PPIs daily<sup>18,\*</sup>



Esophagitis healed or improved one grade<sup>18,†</sup>



Significantly improved quality-of-life scores<sup>18,‡</sup>



> 22,000+ TIF procedures<sup>18</sup>



FDA cleared since 2007<sup>18</sup>

\*Across 11 studies in 568 patients reporting > 6 months PPI use. Across 3 studies in 120 patients at > 5 years 78% report no daily PPI use.

†Across 2 studies in 56 patients reporting > 36 months on follow-up endoscopy.

‡Across 10 studies in 545 patients reporting > 6 months follow-up on GERD-HRQL ( $P < .001$ ).

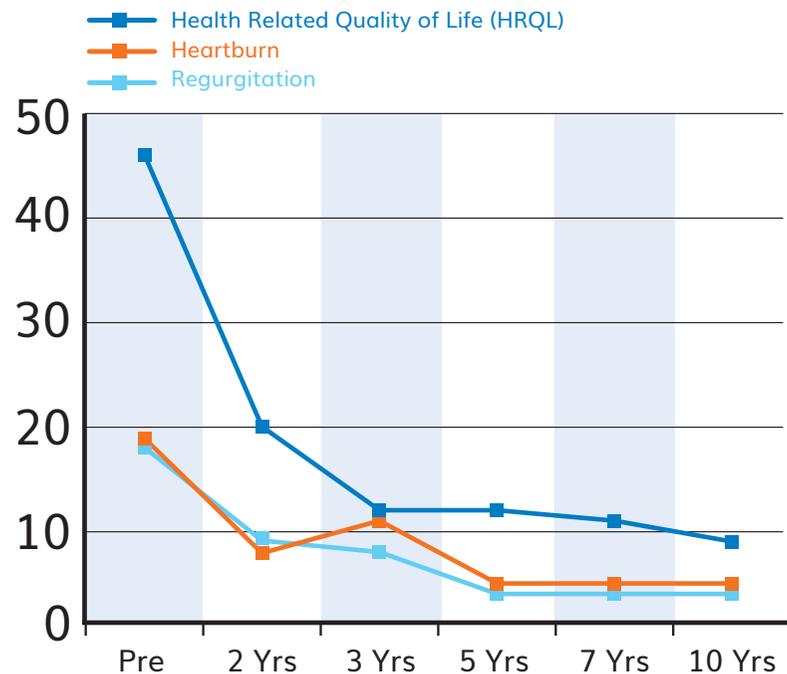
# Making the right choice

	PPI Medication <sup>19</sup>	Traditional Antireflux Surgery <sup>19</sup>	TIF Procedure <sup>18,20</sup>
Serious adverse event	24.1%	28.6%	< 0.5%
Difficulty swallowing (dysphagia)	11%	5%	< 3%
Gas bloat	28%	40%	< 3%
Flatulence	40%	57%	< 3%

**Proven safe and effective**  
 81% of patients are off daily PPIs post-TIF procedure.<sup>18,\*</sup>

\*In 11 TIF 2.0 on label studies collectively representing 568 patients where the follow-up was between 7 and 59 months, the weighted incidence percentage of patients completely off PPIs was 73.50%, and 7.91% of the patients reported occasional use of PPIs, for a total of 81.41% of the patients reporting no daily use of PPIs.

# Long-term clinical studies report the TIF procedure is safe and effective<sup>21</sup>



**Study conclusion: No troublesome, persisting procedure-related side effects reported after 10 years.**

## Results from additional clinical studies:

- In a separate randomized study comparing the results of PPIs versus the TIF procedure, 100% of patients in the PPI group opted to have the TIF procedure at the 6-month follow-up point in the study<sup>20</sup>
- Esophagitis healed in 84% of TIF patients at the 3-year follow-up<sup>18,\*</sup>
- Five years after their TIF procedure, 78% of patients were satisfied with their outcome<sup>18,†</sup>

\*In the 2 studies in 56 patients where esophagitis was assessed at  $\geq 36$  months, the median follow-up was 44 months, the weighted percentage of patients where the esophagus had completely healed was 83.94%.

†In the 2 studies in 88 patients where median follow-up was 59.5 months, 78.4% of the patients stated they were satisfied with the outcome of the procedure.

# Waiting is a losing proposition

Reflux gets worse over time and your body pays the price. With the TIF procedure, there is no reason to wait. Here are some facts you should know about esophageal cancer:

600%

Esophageal cancer (adenocarcinoma) has increased more than 600% in the past 3 decades.<sup>23</sup> It is the fastest growing cancer in the US and other Western countries.



Symptoms often occur after the cancer has spread.<sup>23</sup>



Acid reflux/GERD is a primary risk factor.<sup>23</sup>



There are NO routine or standard screenings to detect esophageal cancer in early stages.<sup>23</sup>

**Talk to your doctor about your GERD symptoms and see if the TIF procedure is right for you.**

# Indications/Contraindications Warnings/Precautions

## Indications for TIF Surgery

The TIF procedure, using the EsophyX device, may be right for you if:

- You are at least 18 years old
- You regularly experience troublesome symptoms of symptomatic chronic GERD
- You no longer respond adequately to, or are dissatisfied with, antireflux medicines
- You are concerned about the adverse long-term effects of taking proton pump inhibitors and other medicines
- You have a hiatal hernia no larger than 2 cm in size or can have a hiatal hernia repair immediately prior to the TIF procedure
- You have a Body Mass Index (BMI) less than 35

Your physician may have other criteria he or she uses to determine whether you are an appropriate candidate. Ask your physician to discuss those criteria with you.

## Contraindications for TIF procedure

The TIF procedure may not be right for you if:

- You are under 18 years old
- Your BMI is greater than 35
- You have a hiatal hernia greater than 2 cm that can't be repaired just prior to the TIF procedure
- You have a paraesophageal hiatal hernia

You have suffered from any of the following esophageal-related concerns:

- Severe inflammation of the esophagus
- Abnormal, enlarged veins in the lower part of the esophagus (varices)
- Infections or fungal disease in the esophagus
- Unusually narrow diameter of the inside of the esophagus
- Sacs or pouches (diverticula) in the wall of the esophagus
- Narrowing of the esophagus
- An obstruction or hernia next to the esophagus

You have suffered from any of the following health concerns:

- Bleeding disorder
- Chronic cough (not related to GERD)
- Limited neck mobility
- Bone spurs in the spine
- The anatomy of your esophagus would prohibit insertion of the EsophyX device
- You are unable to comply with postoperative diet recommended for appropriate healing

Your physician may have other criteria he or she uses to determine whether you are an appropriate candidate for the TIF procedure. Ask your physician to discuss the criteria, as well as any other safety concerns, with you.

You can find regulatory and labeling information by visiting [GERDHelp.com](http://GERDHelp.com).  
Take the online quiz about GERD and watch patient journey videos.

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Give us a call to see if the TIF  
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