TIF[®] 2.0 Procedure Fact Sheet



About The TIF Procedure for Reflux

- The TIF 2.0 procedure with the EsophyX[®] device uses an incisionless approach to treat the underlying anatomical cause of gastroesophageal reflux disease (GERD) — a chronic condition caused by changes in the gastroesophageal valve (GEV) that allow acid to flow back from the stomach into the esophagus.
- TIF is an acronym for Transoral Incisionless Fundoplication:
 - **Transoral** The procedure is performed from within the GI tract with the EsophyX device inserted through the patient's mouth.
 - Incisionless Using a transoral approach, abdominal incisions and internal dissection of other anatomy are not required.
 - Fundoplication The EsophyX device enables reconstruction of the anti-reflux valve according to the established principles of conventional anti-reflux surgery.
- Hiatal hernias are a common finding contributing to reflux symptoms. Hiatal hernias can be repaired (HHR) to ensure proper positioning of the stomach and esophagus below the diaphragm. This restores the angle at which the esophagus enters the stomach and the high-pressure zone which contributes to one-way GEV operation to prevent reflux.

How TIF 2.0 Procedure Works

- The TIF 2.0 procedure uses the EsophyX device to deliver SerosaFuse[®] fasteners which are used to rebuild the anti-reflux valve and restore the body's natural protection against acid reflux. Repairing the GEV allows patients to have long-term relief from GERD symptoms without dependency on medical therapy.
- When a small hiatal hernia measuring 2cm or less is present, the EsophyX device uses suction to move the GEV below the diaphragm while it's being repaired. If the hiatal hernia is larger than 2cm, a TIF procedure can be performed immediately after the hiatal hernia has been repaired laparoscopically. These procedures are performed on the same day while under general anesthesia.
- By accessing the gastroesophageal junction (GEJ) through the mouth, there are no scars with the TIF procedure, minimizing complications and recovery is rapid.
- Due to the unique approach of the TIF 2.0 procedure, most patients return to work and normal activities within a few days after the procedure, allowing them to get back to life sooner, free of the distraction and discomfort of GERD.
- While the TIF 2.0 procedure has an excellent safety profile and is less invasive than conventional laparoscopic fundoplication, it is important to note that it is still a surgical approach. There are potential risks and complications with any surgery including an endoscopic approach which include: sore throat, musculoskeletal pain, epigastric or abdominal pain and difficulty swallowing.

Understanding the Significance of TIF Procedure

- To date, the TIF 2.0 procedure has been performed in more than 20,000 patients worldwide.
- In the past 10 years, over 80 peer-reviewed papers report follow-up in over 1,300 unique patients; consistent
 outcomes following the TIF 2.0 procedure demonstrate significant clinical efficacy across a range of outcome
 measurements including symptoms, quality of life scores, cessation of PPI therapy and improvements in pH
 measurements and LES pressure. *
- Clinical studies demonstrate TIF patients rarely experience long-term side effects commonly associated with traditional antireflux surgery such as trouble swallowing (dysphagia), gas bloat syndrome and increased flatulence. *
- Four-year post-procedure clinical data from a randomized clinical trial demonstrates that 85 percent of patients undergoing the TIF 2.0 procedure experienced elimination of regurgitation and all atypical GERD symptoms; and 89 percent of patients experience healing of esophagitis, a complication of GERD. *

