

Origination Date: 10/04	Revision Date(s): 9/05, 9/06, 9/07, 9/08
Developed By: Medical Criteria Committee	

- Gatekeeper™ Reflux Repair System
- Plexiglas or polymethylmethacrylate implantation.

Information to be Submitted with Pre-Authorization Request:

None. Endoscopic procedures for the treatment and management of GERD are considered to be experimental/investigational by ODS.

References:

- Ozawa S, Yoshida M, Kumi K, et al. New endoscopic treatments for gastroesophageal reflux disease. *Ann Thorac Cardiovasc Surg.* 2005. 11(3):146-153.
- Watson TJ, Peters JH. Lower esophageal sphincter injections for the treatment of gastroesophageal reflux disease. *Thorac Surg Clin.* 2005 Aug;15(3):405-15.
- Zhi XT, Kavac SM, Park AE. Management of gastroesophageal reflux disease: medications, surgery, or endoscopic therapy? (Current status and trends). *J. Long Term Eff Med Implants.* 2005;15(4):375-88.
- Johnson DA. Enteryx implant for gastroesophageal reflux disease. *Curr Treat Options Gastroenterol.* Feb 2005;8(1):51-57.
- FDA preliminary public health notification: recall of Boston Scientific Enteryx® procedure kits and Enteryx® injector single packs for treatment of gastroesophageal reflux disease (GERD). October 14, 2005. Accessed at www.fda.gov/cdrh/safety/101405-enteryx.html.
- Yeh RW, Triadafilopoulos G. Endoscopic antireflux therapy: the Stretta procedure. *Thorac Surg Clin.* 2005 Aug;15(3):395-403.
- Ozawa S, Yoshida M, Kumai K, et al. New endoscopic treatments for gastroesophageal reflux disease. *Ann Thorac Cardiovasc Surg.* 2005 Jun;11(3):146-53.
- Hogan WJ. Clinical trials evaluating endoscopic GERD treatments: is it time for a moratorium on the clinical use of these procedures? *Am J Gastroenterol.* 2006 Mar;101(3):437-9.
- Haider M, Iqbal A, Filipi CJ. Endoluminal gastroplasty: a new treatment for gastroesophageal reflux disease. *Thorac Surg Clin.* 2005 Aug;15(3):385-94.
- Schiefke I, Zabel-Langhennig A, Neumann S, et al. Long term failure of endoscopic gastroplication (EndoCinch). *Gut.* 2005 Jun;54(6):752-8.
- Portale G, Filipi CJ, Peters JH. A current assessment of endoluminal approaches to the treatment of gastroesophageal reflux disease. *Surg Innov.* 2004 Dec;11(4):225-34.
- Physician Advisors