Advice for Patients
with ENTERYX® for
Gastroesophageal Reflux Disease

Boston Scientific Corporation has recalled all ENTERYX® Procedure Kits and ENTERYX® Single Pack Injectors, because of reports that improper injection procedures can lead to serious patient injury and death.

ENTERYX® is used to treat patients with gastroesophageal reflux disease (GERD). A physician injects the ENTERYX® liquid into the inside muscle wall of the esophagus, close to where it joins the stomach (i.e., the lower esophageal sphincter). The liquid then thickens into a sponge-like substance within the muscle where it helps the sphincter act as a barrier to stomach acids, preventing the acids from entering the esophagus and eventually the throat.

The company has received reports that in rare cases, physicians may inadvertently inject the ENTERYX® liquid into areas close to the esophagus, including other vital organs. This can result in serious health complications for the patient, including internal bleeding, reduced kidney function, and death. Even though doctors monitor patients during and immediately after the procedure to make sure they inject ENTERYX® in the right location, they may not detect some cases of improper injection right away.

Symptoms that patients may experience if ENTERYX® is improperly injected include:

- Pain in the chest or side
- Cough
- Shortness of breath
- Difficulty swallowing
- Significant weight loss
- Fever
- “Flu-like” symptoms
- Fainting
- Weakness
- Fatigue

To date, all known cases of improper injection of ENTERYX® were discovered within three weeks of the procedure in patients experiencing these symptoms.

It is important for patients to know that even when ENTERYX® is injected properly, long-term complications are still possible. In at least two cases, patients experienced some of the above symptoms up to seven weeks after their procedure, even though ENTERYX® was injected properly.

Advice for Patients

- Go to the nearest emergency room if you experience chest pain or fainting.

- If you have had the ENTERYX® procedure within the last seven weeks, contact your doctor immediately if you experience any of the following symptoms, even if you have already been treated in the emergency room:
    - Pain in chest or side
    - Shortness of breath
    - Difficulty swallowing
    - Significant weight loss
    - Cough
    - Fever
    - "Flu-like" symptoms
    - Fainting
    - Weakness
    - Fatigue

Your doctor may order a follow-up procedure such as chest x-rays, barium swallows or chest and abdominal scans to confirm or rule out improper injection of the ENTERYX® product.

- Continue to see your doctor for regularly-scheduled follow-up appointments, even if you experience no symptoms.

Your doctor has been notified of the problems associated with ENTERYX®, and has received specific information about how to monitor patients who have had this procedure. FDA will continue to monitor reported problems with ENTERYX®, and we will update this notice as more information becomes available.

FDA and Boston Scientific are working together to see that all physicians are notified of the reported problems and receive accurate, up-to-date information. Additional information on this recall is available at www.fda.gov/cdrh/safety/101405-enteryx.html.