

The following document is a copy of a
Safety Alert from **Boston Scientific**.

SAFETY ALERT

July 22, 2004

Dear Doctor/ Enteryx™ User:

I am writing to inform you that Boston Scientific has learned of a death that occurred approximately three weeks following an Enteryx™ Procedure. Upon becoming aware of this case, BSC immediately initiated an investigation. This investigation included discussions with the treating physician, the pathologist involved in the autopsy and the FDA.

The patient's treating gastroenterologist reported the following: The patient was an elderly female who was treated with a standard volume of injected Enteryx™ material under endoscopic and fluoroscopic visualization. The patient had mild retrosternal pain for two days following the procedure. The symptoms resolved spontaneously. During the following two weeks, the patient had some mild upper respiratory symptoms while on vacation, but no signs or symptoms of bleeding. The patient returned home approximately 3 weeks after the procedure, and had a syncopal episode. During the evaluation of the syncope, while in the hospital, she began having GI bleeding requiring intubation, blood transfusion and vasopressive medications. The patient became stable enough to undergo an upper endoscopy, but the source of the bleeding could not be clearly seen. Epinephrine was injected without effect. Attempts to stabilize the patient failed, and the patient died before exploratory surgery was possible.

The cause of death was believed to be hemorrhage. The pathologist reported that an autopsy indicated 2 ulcerations about one cm above the squamo-columnar junction, a fistula from the aorta to the esophagus, extensive inflammation, as well as evidence of some Enteryx™ material having been injected transmurally into the superficial layer of the aorta. This aortic injection may have led to necrosis of the aorta resulting in the fistula, which was the apparent source of the hemorrhage.

In an effort to reduce the risk of recurrence, Boston Scientific is reiterating the importance of close adherence to the Directions for Use and their guidance on appropriate injection technique and informing you of the potential patient risk associated with a transmural injection into the wall of the aorta.

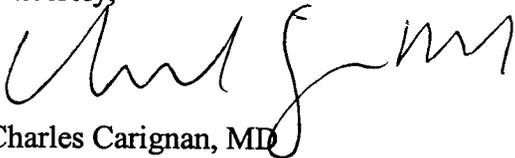
- 1. Enteryx™ solution should only be injected at or just below the squamo-columnar junction**
- 2. The needle should be inserted into the muscle of the esophagus at an antegrade angle (toward the stomach)**

3. **Fluoroscopy should always be used while the material is being injected in order to help identify a possible transmural injection.**
4. **Injection into the aortic wall may cause necrosis, leading to hemorrhage and death.**

We are working with the FDA to update the Directions for Use to further emphasize the need for proper injection technique. In addition, the Directions for Use are being updated to recommend close patient follow-up in the event of a transmural injection or suspected transmural injection, and to include as additional potential risks pleural and pericardial effusions.

If you have any additional questions or concerns, please do not hesitate to contact Gaby Baramki, MD, Associate Medical Director (508 650-8212) or Charles Carignan, MD, Medical Director (508 652-5057).

Sincerely,

A handwritten signature in black ink, appearing to read 'Charles Carignan', written in a cursive style.

Charles Carignan, MD
Medical Director