

Circulatory System Devices Panel
Questions for Discussion
EMBOL-X Aortic Filter
G990105
K022071

October 23, 2002

The EMBOL-X Aortic Filter is being reviewed under the 510(k) regulatory process using a combination of predicate devices: 1) the PercuSurge device, K003992, cleared in June 2001, and 2) CPB Arterial Line Filters. The PercuSurge device is a balloon/aspiration catheter that is indicated for containing and aspirating embolic material in saphenous vein bypass grafts (SVG's). It was agreed that the PercuSurge device (similar intended use as the EMBOL-X Aortic Filter, i.e., capture and removal of embolic debris), in combination with the CPB Arterial Line Blood Filter (similar mechanism of action, i.e., filtration), could be used as a combination predicate device for the EMBOL-X Aortic Filter. As such, the EMBOL-X Aortic Filter is being reviewed as a 510(k) with clinical data. FDA is seeking clinical input on the results of this study.

Clinical Study

1. The primary safety endpoint for this study was a composite of 7 clinical adverse events (including death, neurologic deficit (mild and severe), renal insufficiency, perioperative myocardial infarction (MI), gastrointestinal complications, and limb-threatening peripheral embolism), evaluated at hospital discharge or 30 days (whichever was shorter). The median follow-up time was 7.0 days. Some facts from the study are:
 - ?? The observed overall composite event rates were 17.1% in the EMBOL-X arm and 18.9% in the control.
 - ?? As specified in the protocol, the composite event rate for the EMBOL-X arm was shown to be equivalent (not more than 5% higher) than the control ($p < 0.001$).
 - ?? Also as specified in the protocol, a separate test for a lower event rate in the EMBOL-X arm was not statistically significant ($p = 0.37$).
 - ?? The EMBOL-X arm demonstrated a significantly higher incidence of aortic endothelial injury (9.2% vs. 2.0%, $p < 0.001$). Although these patients did not appear to have any short-term (median follow-up 7.0 days) clinical sequelae resulting from the injuries, the long-term effects are unknown.

Do these data support the safety of the EMBOL-X Intra-Aortic Filter?

2. The primary effectiveness endpoint in this trial was to demonstrate that 75% of the devices would capture at least one particle during elective CABG or single valve procedures. This was demonstrated in the study. There was no demonstrated reduction in any category of clinical adverse event in this well-controlled 1289 patient trial.
 - a. Can this method of embolic entrapment, from this study or elsewhere, be extrapolated to clinical efficacy?
 - b. Do these data support the effectiveness of the EMBOL-X Intra-Aortic Filter?
3. Do the study data support an appropriate risk/benefit profile?

Labeling

4. One aspect of the 510(k) review of a new product is the review of its labeling. The labeling must indicate which patients are appropriate for treatment, identify potential adverse events with the use of the device, and explain how the product should be used to maximize benefits and minimize adverse effects. Please address the following questions regarding product labeling.
 - a. Do the INDICATIONS FOR USE adequately define the patient population studied? For example, should the patient population receiving this device be limited to the same patient population utilized in the study? (E.g., non-emergent; patients 60 or over; first time isolated valve or CABG patients.)
 - b. Are there any other restrictions that should be placed on the patient population receiving this device?
 - c. Based on the clinical experience, should there be additional CONTRAINDICATIONS, WARNINGS and PRECAUTIONS for the use of the EMBOL-X Intra-Aortic Filter?
 - d. Should the labeling include specific study information such as 1) no reduction of clinical events were noted in a 1300 patient clinical study; and 2) the EMBOL-X device appears to increase the rate of endothelial injury.
 - e. What should the labeling include regarding the use of ultrasound both before (for assessment of the aorta) and after (monitoring of injury) the use of the device?

5. Please provide any other recommendations or comments regarding the labeling of this device.

Additional Information

6. If the data provided are not adequate to support safety and/or effectiveness, what additional data, analyses, or study would you require?