

## 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

The following 510(k) Summary of Safety and Effectiveness information is provided in accordance with the requirements of 21 CFR §807.92 and SMDA 1990.

**510(k) Number:** K022071

**Date Prepared:** July 29, 2002

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**Trade Name:** EMBOL•X® Aortic Filter

**Common Name:** Arterial Line Blood Filter

**Classification Name:** Filter, Blood, Cardiopulmonary Bypass, Arterial Line; 21 CFR §870.4260; Class II

**Device Description:** The EMBOL•X Aortic Filter device consists of three primary components: 1.) a distal heparin-coated mesh filter, mounted onto a flexible frame to form a filter basket for particulate emboli capture and retention; 2.) a locking cartridge housing for attachment to the EMBOL•X Aortic Cannula side port, permitting access to the aorta and to ensure correct orientation of the filter during use; and 3.) a proximal syringe-like plunger mechanism to deploy and withdraw the distal basket into and from the aorta, via the cannula, during surgery. The filter is introduced surgically into the aorta via the previously placed cannula, and particulates are captured and removed as blood passes through the filter basket. The filter may remain *in situ* for up to 60 minutes. The EMBOL•X Aortic Filter utilizes conventional medical grade materials and processes, and is provided packaged, labeled, and sterile, intended for single-use.

**Intended Use:** The EMBOL•X Aortic Filter is indicated for use with the EMBOL•X Aortic Cannula in cardiac surgery procedures to contain and remove particulate emboli.

**Predicate Devices:** Substantial equivalence is derived from a composite of characteristics from multiple predicate devices. The EMBOL•X Aortic Filter is substantially equivalent in intended use, clinical application, principle of operation, design and materials, sterility and biocompatibility, and performance to the Medtronic PercuSurge GuardWire Plus Temporary Occlusion and Aspiration System (K003992) and/or the Edwards Lifesciences AF-1025D/AF-1040D Duraflo (heparin treated) Arterial Blood Filter (K820044).

**Technological Characteristics:** The EMBOL•X Aortic Filter has similar intended use, design intent, principle of operation, materials, sterility and biocompatibility, accessory requirements, and labeling as that of the predicate devices. Any noted differences between the devices (specific indications for use, method of device delivery, specific physical dimensions and geometry) do not raise new types of safety or effectiveness questions, do not introduce new technological issues, and therefore do not impact the substantial equivalence of the EMBOL•X Aortic Filter.

**Non-Clinical Test Results:** The results of biocompatibility, in-vitro (bench), and pre-clinical (animal) tests demonstrate that the EMBOL•X Aortic Filter is sterile, biocompatible, meets established internal performance specifications, and satisfies the requirements of relevant external standards and applicable FDA Guidance.

**Summary of Clinical Studies:** Data to support the EMBOL•X Aortic Filter (and associated EMBOL•X Aortic Cannula) were obtained from the EMBOL•X ICEM 2000 trial. The purpose of this prospective, multi-center, 1:1 randomized, controlled equivalency study was to demonstrate the safety and effectiveness of the EMBOL•X Aortic Filter (and the associated EMBOL•X Aortic Cannula) in capturing particulate emboli during first-time non-emergent coronary artery bypass graft (CABG) or aortic/mitral valve repair/replacement procedures utilizing cardiopulmonary bypass. This study was conducted at 22 sites within the United States and Canada, and was comprised of 1289 patients, of which 645 were randomized to the EMBOL•X Aortic Filter, and 644 were randomized to control. An independent Clinical Events Committee (CEC) adjudicated the major clinical endpoints and events.

**Summary of  
Clinical Studies  
(continued):**

The primary safety measure was a composite endpoint comprised of the following post-operative clinical events, measured from the time of randomization (the operation) through hospital discharge or 30 days, whichever occurred first: Neurologic deficit (mild and severe); Renal insufficiency (with and without dialysis); Gastrointestinal (GI) complications; Perioperative Myocardial Infarction (MI); Limb-threatening peripheral embolism (Limb Ischemia); and Death. The primary effectiveness endpoint was the capture of particulate emboli by the filter (Treatment arm only) in at least 75% of the filtered patients, with particulate debris visually confirmed by light microscopy.

The patient population of this study was limited to patients undergoing first time, non-emergent Coronary Artery Bypass Grafting (CABG), aortic valve replacement or mitral valve repair or replacement only, aged 60 years and older. Of the 1289 patients studied, 927 (71.9%) were male, and 1042 (80.8%) were 65 years of age or older; 65 (5.0%) had a LVEF < 30%, and 388 (30.1%) had a prior MI. None of the demographic or medical history differences between the randomized groups achieved statistical significance ( $p < 0.05$ ).

18 of 22 enrolling centers performed peri-procedural ultrasound imaging (TEE or EPI), resulting in an analysis of a subset (910, or 70.6%) of the total enrolled patients.

The primary safety endpoint was met, with the EMBOL•X Aortic Filter arm composite event rate statistically equivalent to that of standard treatment (17.1% vs. 18.9%,  $p < 0.001$ ). In addition, differences in the stratified events between the randomized groups did not achieve statistical significance ( $p < 0.05$ ). The primary effectiveness endpoint was also met, with particulate capture demonstrated in 96.8% of all filters analyzed ( $p < 0.001$ ).

The following tables summarize the results of the ICEM trial.

**Table 1.**  
Major Adverse Events [Number (%)]

Event	Treatment (N=645)	Control (N=644)	P-Value
Death	10 (1.6)	11 (1.7)	0.82
Neurologic deficit (Stroke/TIA)	18 (2.8)	18 (2.8)	1.00
Renal insufficiency (RI)	40 (6.2)	52 (8.1)	0.19
RI (w/o dialysis)	33 (5.1)	43 (6.7)	0.23
RI (dialysis)	7 (1.1)	9 (1.4)	0.61
Myocardial infarction (MI)	67 (10.4)	64 (9.9)	0.79
Q Wave MI	21 (3.3)	18 (2.8)	0.63
CK-MB Elevation	46 (7.1)	46 (7.1)	0.99
Gastrointestinal complications (GI)	5 (0.8)	5 (0.8)	1.00
Limb ischemia	3 (0.5)	3 (0.5)	1.00
Any event	110 (17.1)	122 (18.9)	0.38

Numbers are for all randomized patients

*Death:* Death for any cause

*Stroke:* Central neurologic deficit persisting for > 24 hours

*Transient neurologic deficit (TIA):* An ischemic event of the central nervous system that causes a neurologic deficit persisting for < 24 hours

*Renal insufficiency:* Increase of serum creatinine to > 2.0 mg/dl or a 50% or greater increase over abnormal baseline prior to procedure

*Renal insufficiency (dialysis):* The new requirement for dialysis

*Q-Wave MI:* New pathological Q-Waves in 2 or more contiguous leads

*Non Q-Wave MI:* CPK > 5x normal and CK-MB > 5x above the upper limit of normal for the institution, in the absence of new Q-Waves

*Gastro-Intestinal Complications:* include GI bleeding requiring transfusion; Pancreatitis with abnormal amylase/lipase requiring NG suction therapy; Cholecystitis requiring cholecystectomy or drainage; Mesenteric ischemia requiring exploration

*Limb-threatening Peripheral Embolism:* Acute onset of diminished pulse, altered pallor (discoloration, either hypo- or hyper-), and pain as evidence of limb-threatening peripheral ischemia

**Table 2.**  
Echocardiographically Evident Endothelial Disruptions Observed through Imaging

Treatment n/N (%)	Control n/N (%)	P-Value
42/456 (9.2)	9/454 (2.0)	< 0.001

**Table 3.**  
Composite Endpoint Events Stratified by Echocardiographically Evident Endothelial Disruptions Observed through Imaging

Arm	Events in Patients With Endothelial Disruption n/N (%)	Events in Patients Without Endothelial Disruption n/N (%)	P-Value
Treatment	2/42 (4.8)	74/414 (17.9)	0.03
Control	1/9 (11.1)	81/445 (18.2)	1.0



Table 4. Particulate Capture Effectiveness

<b>Attribute</b>	<b>Result</b>
Number EMBOL•X Filters Deployed	618
Number (%) Filters Which Captured = 1 Particle	598 (96.8%)
Lower 95% Confidence Bound on Percent of Filters Which Captured = 1 Particle	95.3%

Conclusions drawn from Study

The results from the clinical investigation demonstrate that the EMBOL•X Aortic Filter, when used in patients undergoing first time, non-emergent Coronary Artery Bypass Grafting (CABG), aortic valve replacement or mitral valve repair or replacement, does not pose any additional risk to the treated patient population when compared to that of the current standard treatment of no filtration, and the Aortic Filter was effective in capturing particulates. The data demonstrate that the EMBOL•X Aortic Filter is compatible with conventional CPB procedures. It was therefore concluded that the EMBOL•X Aortic Filter is safe and effective when used as indicated in the Instructions for Use.

**Summary:** Review of the device *in vivo* and *in vitro* pre-clinical studies, combined with the results of the clinical investigation, provides valid scientific evidence and reasonable assurance that the EMBOL•X Aortic Filter is safe and effective for its intended use. Comparison of the product attributes supports the conclusion that the device is substantially equivalent to the commercially marketed predicate devices.

