

INSTRUCTIONS FOR USE

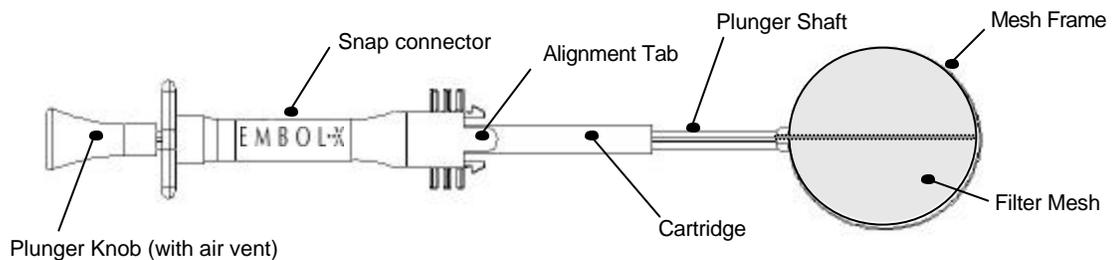
EMBOL•X

EMBOL-X AORTIC FILTER

1. DESCRIPTION

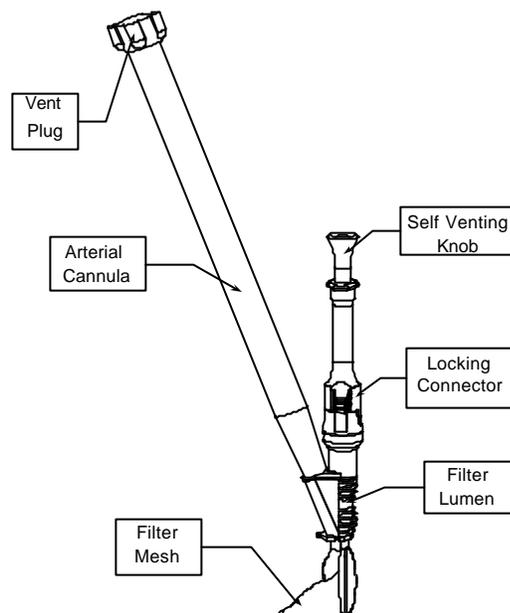
The EMBOL•X Aortic Filter consists of three primary components: a distal filter or basket assembly to capture and retain particulate emboli (positioned within the aorta); a locking cartridge for attachment through the EMBOL•X Aortic Cannula sideport and to ensure correct orientation of the filter during use; and a proximal syringe-like plunger mechanism to deliver and withdraw the basket into and from the aorta. The distal filter consists of a heparin-coated mesh filter mounted on a frame.

Diagram 1: EMBOL•X Aortic Filter



The EMBOL•X Aortic Filter is provided in a cartridge that locks into the Introducer port of the EMBOL•X Aortic Cannula in a fixed position to ensure proper orientation of the Filter when it is inserted into the aorta. The Filter is inserted through the Introducer port by depressing its syringe-like plunger mechanism. The self-venting knob allows the air in the cartridge to automatically vent when the cartridge is inserted into the cannula and contacts blood. On insertion, the Filter opens to fill the diameter of the ascending aorta. A marker band (optional) on the plunger shaft, when aligned with the Filter Cartridge handle, indicates that the Filter is exiting the Introducer port and is about to enter the aorta. The Filter is withdrawn by pulling up on the plunger.

Diagram 2: EMBOL•X Aortic Filter connected with EMBOL•X Aortic Cannula



2. INDICATIONS AND 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.

3. CONTRAINDICATIONS

The EMBOL•X Aortic Filter is contraindicated for use in patients with:

- ?? Aneurysm of the ascending aorta
- ?? Aortic trauma

4. WARNINGS

- ?? Do not manipulate or reposition the EMBOL•X Aortic Cannula or the EMBOL•X Aortic Filter shaft with the filter deployed. If the cannula must be repositioned, first retract the Filter. Failure to do so may cause injury to the aorta.
- ?? Hold the base of the Introducer port of EMBOL•X Aortic Cannula while inserting the EMBOL•X Aortic Filter. Failure to do so may cause injury to the aorta.
- ?? Do not deploy the EMBOL•X Aortic Filter if excessive resistance is felt. Attempting to deploy the EMBOL•X Aortic Filter when resistance is felt may indicate improper positioning of the cannula. Forcing deployment may cause injury to the aorta.
- ?? Failure to remove all air from the EMBOL•X Aortic Filter may result in air embolism.
- ?? The EMBOL•X Aortic Filter must be retracted and removed from the EMBOL•X Aortic Cannula Introducer port prior to routine administration of protamine for heparin reversal, since the Filter is heparin-coated. Failure to do so may result in thrombus formation on the Filter.
- ?? Do not use a single EMBOL•X Aortic Filter more than once. This may result in:
 - o Air embolism, since the porous plug on the Filter plunger will vent only once.
 - o Increased risk of thrombus formation, which may make the Filter difficult to insert or remove.
 - o Distortion of the Filter frame.
- ?? Although the EMBOL•X Aortic Cannula may be used separately in place of a standard arterial return cannula, the EMBOL•X Aortic Filter must be used in conjunction with the EMBOL•X Aortic Cannula.
- ?? Ensure that the cross-clamp is positioned at least 2.0 cm away from the EMBOL•X Aortic Cannula. Failure to do so may result in difficulty with insertion and/or removal of the Filter.
- ?? Do not use a single EMBOL•X Aortic Filter intra-aortically for more than **60** (sixty) minutes.
- ?? If resistance is met while retracting the EMBOL•X Aortic Filter into the cartridge, leave the Filter in place until the EMBOL•X Aortic Cannula can be removed with the Filter deployed, using standard decannulation techniques.

5. PRECAUTIONS

- ?? CAUTION: Federal (US) Law restricts this device to sale by or on the order of a physician.
- ?? Supplied sterile and non-pyrogenic in undamaged package. For single use only. Do not resterilize or reuse. Resterilization may cause damage to the device and subsequent patient injury.
- ?? Do not use device if the package sterile integrity appears jeopardized or is opened or damaged.
- ?? Note "Use Before" or "Use By" date prior to use. Do not use past the allowable date.
- ?? The EMBOL•X Aortic Filter and any other accompanying device should only be used in an operating room completely equipped for conventional cardiac surgery and by a surgeon trained in cardiac surgery.
- ?? Proper surgical procedures and techniques are the responsibility of the medical professional. The described instructions provided are for information purposes only. Each surgeon must evaluate the appropriateness of the procedure based on his/her own medical training, experience, type of surgical procedure, and patient condition.
- ?? Do not expose the device to organic solvents, ionizing radiation, ultraviolet light, or alcohol-based fluids. The housing may weaken or crack and subsequent use may result in patient injury.

6. OBSERVED ADVERSE EVENTS

Twelve hundred eighty-nine (1289) patients were enrolled at twenty-two (22) centers in the ICEM 2000 clinical trial for primary CABG or primary valve surgical procedures. Of these, 645 patients were randomized to the EMBOL•X Aortic Filter (Treatment), and 644 patients were randomized to not receive the Aortic Filter (Control). Major adverse events reported during the trial are shown in Table 1.

Table 1: Major Adverse Event Summary

Number (%)

Event	Treatment (N=645)	Control (N=644)
Limb ischemia	3 (0.5)	3 (0.5)
Gastrointestinal complications	5 (0.8)	5 (0.8)
Death	10 (1.6)	11 (1.7)
Neurologic deficit	18 (2.8)	18 (2.8)
Renal insufficiency	40 (6.2)	52 (8.1)
Myocardial infarction	67 (10.4)	64 (9.9)
Any event	110 (17.1)	122 (18.9)

POTENTIAL ADVERSE EVENTS

The potential adverse events associated with the use of the EMBOL•X Aortic Filter (as with other invasive cardiac surgery devices) include, but are not limited to, the following (in alphabetical order):

?? Allergic reaction	?? Gastrointestinal complications
?? Angina	?? Heart block
?? ARDS	?? Hemothorax / Pneumothorax
?? Atrial / Ventricular arrhythmia	?? Hepatic failure
?? Bleeding requiring transfusion	?? Limb ischemia
?? Cardiac arrest	?? Metabolic coma
?? Cardiac tamponade	?? Myocardial infarction
?? Coagulopathy	?? Pneumonia
?? Death	?? Prolonged ventilation
?? Delirium	?? Renal insufficiency
?? Dissection of aortic wall	?? RIND / TIA / Stroke
?? Embolism	?? Septicemia
?? Endocarditis / Pericarditis	?? Shock
?? Endothelial disruption of aortic wall	?? Sternal infection
	?? Visual impairment

7. CLINICAL STUDY

Study Design

The EMBOL•X ICEM 2000 trial was a prospective, multi-center, 1:1 randomized, controlled study 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. The study was conducted at 22 sites, and was comprised of 1289 randomized patients, of which 645 were randomized to the EMBOL•X Aortic Filter (Treatment arm) and 644 were randomized to not receive the Aortic Filter (Control).

Primary Endpoints

The primary safety hypothesis is that of equivalence between a composite perioperative complication rate for patients undergoing cardiac surgery using the EMBOL•X Aortic Filter (Treatment) as compared to the current CPB cardiac surgery practice of using no Aortic Filter (Control). The primary safety composite endpoint was 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.

Patients Studied

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; 376 (29.2%) were diabetic, 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).

Study Methods

An independent Clinical Events Committee, blinded to the treatment arm, adjudicated all major clinical events. Clinical follow-up for all treated patients extended to 30-days post-procedure or discharge, whichever occurred first. All randomized patients were included in the intent-to-treat analysis.

Study Results

173 (13.4%) of the randomized 1289 patients underwent a valve repair or replacement procedure, while 1116 (86.6%) received a CABG procedure. Partial occlusion clamps were used in 521 (40.4%) of the cases, the mean CPB and cross clamp times for Treatment (Control) were 91.6 (88.8) and 64.3 (63.3) minutes, respectively. For the Treatment patients, the EMBOL•X Aortic Filter was in-place for a mean of 20.9 minutes (range of 0-99 minutes). None of the surgical procedure differences between the randomized groups achieved statistical significance (p<0.05).

Table 2: Major Adverse Events (to 30 days)
Number (%)

Event	Treatment (N=645)	Control (N=644)	P-Value	RR (95% CI)	Difference (95% CI)
Death	10 (1.6)	11 (1.7)	0.82	0.91 (0.39 – 2.12)	-0.002 (-0.015 – 0.012)
Neurologic deficit (Stroke/TIA)	18 (2.8)	18 (2.8)	1.00	1.00 (0.52 – 1.90)	0.000 (-0.018 – 0.018)
Renal insufficiency (RI)	40 (6.2)	52 (8.1)	0.19	0.77 (0.52 – 1.14)	-0.019 (-0.047 – 0.009)
RI (w/o dialysis)	33 (5.1)	43 (6.7)	0.23	0.77 (0.49 – 1.19)	-0.016 (-0.041 – 0.010)
RI (dialysis)	7 (1.1)	9 (1.4)	0.61	0.78 (0.29 – 2.07)	-0.003 (-0.015 – 0.009)
Myocardial infarction (MI)	67 (10.4)	64 (9.9)	0.79	1.05 (0.76 – 1.45)	0.004 (-0.028 – 0.037)
Q Wave MI	21 (3.3)	18 (2.8)	0.63	1.16 (0.63 – 2.17)	0.005 (-0.014 – 0.023)
CK-MB Elevation	46 (7.1)	46 (7.1)	0.99	1.00 (0.67 – 1.48)	0.000 (-0.028 – 0.028)
Gastrointestinal complications (GI)	5 (0.8)	5 (0.8)	1.00	1.00 (0.29 – 3.43)	0.000 (-0.010 – 0.010)
Limb ischemia	3 (0.5)	3 (0.5)	1.00	1.00 (0.20 – 4.93)	0.000 (-0.007 – 0.007)
Any event	110 (17.1)	122 (18.9)	0.38	0.90 (0.71 – 1.14)	-0.019 (-0.061 – 0.023)

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

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

Table 3: Echocardiographically Evident Endothelial Disruptions Observed through Imaging

Treatment n/N (%)	Control n/N (%)	P-Value	Difference (95% CI)
42/456 (9.2)	9/454 (2.0)	< 0.001	0.072 (0.048 – 0.097)

As shown below, the presence of an echocardiographically evident endothelial disruption did not put the patient at a statistically greater risk for a composite endpoint event.

Table 4: 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	Difference (95% CI)
Treatment	2/42 (4.8)	74/414 (17.9)	0.03	-0.131 (-0.205 – -0.057)
Control	1/9 (11.1)	81/445 (18.2)	1.0	-0.071 (-0.279 – 0.138)

Table 5: Composite Endpoint Events Within Various Subgroups

Subgroup	EMBOL•X Filter n/N (%)	Control n/N (%)	P	RR (95% CI)	Difference (95% CI)
Type of Surgery					
CABG	95/556 (17.1)	104/560 (18.6)	0.52	0.92 (0.71 – 1.18)	-0.015 (-0.060 – 0.030)
Valve	15/89 (16.9)	18/84 (21.4)	0.44	0.79 (0.42 – 1.46)	-0.046 (-0.163 – 0.071)
Sex					
Male	79/470 (16.8)	90/457 (19.7)	0.26	0.85 (0.65 - 1.12)	-0.029 (-0.079 – 0.021)
Female	31/177 (17.5)	32/185 (17.3)	0.96	1.01 (0.65 - 1.59)	0.002 (-0.076 – 0.080)
Age Group					
< 65	18/130 (13.9)	19/117 (16.2)	0.60	0.85 (0.47 – 1.54)	-0.024 (-0.113 – 0.065)
65 – 69	29/160 (18.1)	32/181 (17.7)	0.91	1.03 (0.65 – 1.62)	0.004 (-0.077 – 0.086)
70 – 74	23/158 (14.6)	26/152 (17.1)	0.54	0.85 (0.51 – 1.42)	-0.025 (-0.107 – 0.056)
75 – 79	26/129 (20.2)	24/121 (19.8)	0.95	1.02 (0.62 – 1.67)	0.003 (-0.096 – 0.102)
? 80	14/68 (20.6)	21/73 (28.8)	0.26	0.72 (0.40 – 1.29)	-0.082 (-0.224 – 0.061)
? 75	40/197 (20.3)	45/194 (23.2)	0.49	0.88 (0.60 – 1.28)	-0.029 (-0.111 – 0.053)
BMI					
< 25 kg/m ²	18/162 (11.1)	30/157 (19.1)	0.05	0.58 (0.34 – 1.00)	-0.080 (-0.158 – -0.001)
25-29.9 kg/m ²	55/294 (18.7)	51/288 (17.7)	0.75	1.06 (0.75 - 1.49)	0.010 (-0.053 – 0.073)
= 30 kg/m ²	37/191 (19.4)	41/197 (20.8)	0.72	0.93 (0.63 - 1.38)	-0.014 (-0.094 – 0.065)
LVEF					
= 25%	3/30 (10.0)	10/29 (34.5)	0.02	0.29 (0.09 - 0.95)	-0.245 (-0.456 – -0.033)
> 25%	106/615 (17.2)	112/613 (18.3)	0.64	0.94 (0.74 - 1.20)	-0.010 (-0.053 – 0.032)
Plaque					
Present	12/82 (14.6)	18/93 (19.4)	0.41	0.76 (0.39 – 1.47)	-0.047 (-0.159 – 0.065)
Absent	59/350 (16.9)	57/342 (16.7)	0.95	1.01 (0.73 – 1.41)	0.002 (-0.054 – 0.058)
Not Evaluable	39/213 (18.3)	47/209 (22.5)	0.29	0.81 (0.56 – 1.19)	-0.042 (-0.119 – 0.035)
Hypertension					
Yes	87/504 (17.3)	102/483 (21.1)	0.12	0.82 (0.63 – 1.06)	-0.039 (-0.088 – 0.011)
No	23/141 (16.3)	20/161 (12.4)	0.33	1.31 (0.75 – 2.29)	0.039 (-0.040 – 0.118)
Renal Insufficiency					
Yes	6/17 (35.3)	10/16 (62.5)	0.12	0.56 (0.27 – 1.19)	-0.272 (-0.613 – 0.069)
No	104/628 (16.6)	112/628 (17.8)	0.55	0.93 (0.73 – 1.18)	-0.013 (-0.054 – 0.029)
Diabetes					
Yes	42/183 (23.0)	37/193 (19.2)	0.37	1.20 (0.81 – 1.77)	0.038 (-0.045 – 0.120)
No	68/462 (14.7)	85/451 (18.9)	0.10	0.78 (0.58 – 1.05)	-0.041 (-0.090 – 0.007)
Prior Stroke					
Yes	2/21 (9.5)	7/33 (21.2)	0.46	0.45 (0.10 – 1.96)	-0.117 (-0.321 – 0.087)
No	108/624 (17.3)	115/611 (18.8)	0.49	0.92 (0.73 – 1.17)	-0.015 (-0.058 – 0.028)
Cerebrovascular Disease					
Yes	5/30 (16.7)	14/35 (40.0)	0.04	0.42 (0.17 – 1.02)	-0.233 (-0.455 – -0.012)
No	105/617 (17.0)	108/607 (17.8)	0.72	0.96 (0.75 – 1.22)	-0.008 (-0.050 – 0.035)
Prior Stroke or Cerebrovascular Disease					
Yes	6/43 (14.0)	17/56 (30.4)	0.06	0.46 (0.20 – 1.07)	-0.164 (-0.332 – 0.004)
No	104/602 (17.3)	105/588 (17.9)	0.79	0.97 (0.76 – 1.24)	-0.006 (-0.049 – 0.037)
Peripheral Vascular Disease					
Yes	21/88 (23.9)	26/87 (29.9)	0.37	0.80 (0.49 – 1.31)	-0.060 (-0.192 – 0.071)
No	89/557 (16.0)	96/557 (17.2)	0.57	0.93 (0.71 – 1.21)	-0.013 (-0.056 – 0.031)
COPD					
Yes	19/82 (23.2)	17/87 (19.5)	0.56	1.19 (0.66 – 2.12)	0.036 (-0.087 – 0.160)
No	91/565 (16.1)	105/555 (18.9)	0.22	0.85 (0.66 – 1.10)	-0.028 (-0.073 – 0.016)
Vent. Arrhythmia					
Yes	8/41 (19.5)	11/29 (37.9)	0.09	0.51 (0.24 – 1.12)	-0.184 (-0.396 – 0.027)
No	102/606 (16.8)	111/613 (18.1)	0.56	0.93 (0.73 – 1.19)	-0.013 (-0.055 – 0.030)

Table 6: Summary of Particulate Capture Effectiveness

Attribute	Result
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%

Table 7: Captured Particulate Histology ¹
Percent (n)

Histological description (N= 623 Filter Treatment Cases) ^{1,2}	Randomized CABG and Valve (n=623)	Randomized CABG (n=538)	Randomized Valve (n=85)
Total Dissolved/No emboli	24.4 (152)	24.2 (130)	25.9 (22)
Total Filters for Histological Analysis	75.6 (471)	75.8 (408)	74.1 (63)
Fibrous Atheroma	86.6 (408)	87.0 (355)	84.1 (53)
Fibrocalcific Atheroma	3.4 (16)	1.0 (4)	19.0 (12)
Grumous atheroma / cholesterol	1.3 (6)	1.5 (6)	0 (0)
Medial tissue	0.6 (3)	0.7 (3)	0 (0)
Fibrofatty/Adventitial tissue	1.7 (8)	1.0 (4)	6.3 (4)
Platelets/Fibrin	37.8 (178)	37.0 (151)	42.9 (27)
True RBC thrombus/Clot	2.1 (10)	2.0 (8)	3.2 (2)
Dissolved (during processing) ²	21.0 (131)	20.6 (111)	23.5 (20)
No particulate emboli observed	3.4 (21)	3.5 (19)	2.4 (2)
Particulate Capture Rate per Filter	96.6 (602)	96.5 (519)	97.6 (83)

¹ Totals may not equal 100% due to multiple particulates within the same Filter.

² Filters with dissolved and 0 samples not included in percentage calculations of histologic composition.

Conclusions

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). It was therefore concluded that the EMBOL•X Aortic Filter safety profile was equivalent to that of the current standard treatment of no filtration, and the Filter was effective in capturing particulates.

8. METHOD OF USE

I. Materials Required

- ?? Container of sterile normal saline solution for wetting the filter prior to use.
- ?? EMBOL•X Aortic Cannula for vascular access to the aorta.
- ?? EMBOL•X Aortic Sizers (optional).

II. Inspection Prior to Use

Prior to opening and use, visually examine:

- ?? The package integrity. If the package sterile integrity appears to have been jeopardized, do not use.
- ?? Remove the EMBOL•X Aortic Filter from the package and inspect to ensure that it has not been damaged or has components missing. If the device appears damaged or has components missing, do not use.
- ?? The Filter's vent knob, a built in self-venting plug for exposures to any fluids. This would prevent the plug from venting air properly. The plug is only able to vent air once and will stop venting once fluids contact it. If the vent plug appears to have contacted fluids prior to Filter insertion, do not use.

III. Preparation for Use

- ?? Verify that there are no aneurysmal changes or trauma present in the ascending aorta.
- ?? Visually estimate the diameter of the ascending aorta.
- ?? If an EMBOL•X Aortic Sizer is used, choose one which most closely represents the size of the aorta. Using the Sizer, measure the outer diameter (OD) of the aorta.
- ?? Once the outer diameter has been established, estimate the wall thickness of the aorta. The inner diameter (ID) of the aorta is estimated by subtracting twice the wall thickness from the outer diameter of the aorta [ID = OD – (2x wall thickness)]. Select the appropriate sized EMBOL•X Aortic Filter based on the aortic inner diameter (refer to Table 8, below).
- ?? The Filter vent knob will vent once and will stop venting once fluid contacts it. For this reason, it is important to keep the Filter cartridge upright during preparation after submersion to ensure that saline inside the cartridge does not wet the vent knob.
- ?? Maintaining the Filter cartridge in an upright position, thoroughly moisten the EMBOL•X Aortic Filter by submerging the distal Filter end in a container of sterile saline and slowly swirling it around the container. This is intended to remove all air from the Filter material. Do not submerge the Filter plunger knob as this will prevent it from venting properly once the Filter is inserted.
- ?? Retract the EMBOL•X Aortic Filter fully into the cartridge while gently pinching the edges of the Filter between your thumb and forefinger and guiding the edges of the Filter upwards.

WARNING: Do not use a single EMBOL•X Aortic Filter more than once. This may result in:

- ?? Air embolism, since the porous plug on the Filter plunger will vent only once;
- ?? Increased risk of thrombus formation, which may make the Filter difficult to insert and remove; or
- ?? Distortion of the Filter frame.

WARNING: Failure to remove all air from the EMBOL•X Aortic Filter may result in air embolism.

Table 8: EMBOL•X Aortic Filter Sizes and Aortic Internal Diameters.

Aortic Filter Sizes	Minimum Aortic Inner Diameter (cm)	Maximum Aortic Inner Diameter (cm)
X-Small	2.2 cm	2.6 cm
Small	2.6 cm	2.9 cm
Medium	2.9 cm	3.2 cm
Large	3.2 cm	3.5 cm
X-Large	3.5 cm	4.0 cm

IV. Insertion and Deployment of the EMBOLX Aortic Filter

- ?? After CPB has been initiated and JUST PRIOR to removing the aortic cross clamp, prepare to deploy the EMBOL•X Aortic Filter.
- ?? While holding the cannula to prevent excessive force on the aorta, unlock the obturator and remove it from the EMBOL•X Aortic Cannula Introducer port. The one-way valve will prevent excessive backbleeding.
- ?? While still holding the cannula, slowly insert the EMBOL•X Aortic Filter (retracted into cartridge) into the Introducer port until an audible “click” is heard. The EMBOL•X Aortic Filter is now locked in place.
- ?? Confirm de-airing of the Filter and cartridge by looking for blood in the knob of the plunger. If blood is not visible in the knob, DO NOT DEPLOY the filter. Remove the Filter and insert a new one.
- ?? Deploy the EMBOL•X Aortic Filter by slowly pushing the plunger all the way down.
- ?? If resistance is met during deployment and the Filter will not deploy, check the marker band on the plunger shaft to view the position of the indicator line relative to the cartridge handle. If the line is still visible (e.g., not deployed past the handle), the Filter has not yet exited the Introducer port. If the line is already deployed past the handle, the Filter may be already deployed into the

aorta. Ensure that the EMBOL•X Aortic Cannula is positioned so that the Introducer port is perpendicular to the aorta prior to attempting to re-deploy the Filter. If using pledgets, place them on either side of the Cannula instead of in front of the Cannula. Ensure that the Cannula Introducer port is not exposed to the outside of the aorta due to the pledget lifting the Cannula out of the aorta. See EMBOL•X Aortic Cannula IFU for positioning requirements and techniques.

- ?? Remove the aortic cross-clamp. A partial occlusion clamp may be applied and removed while the filter in place. Remove the partial occlusion clamp prior to EMBOL•X Aortic Filter removal.
- ?? The EMBOL•X Aortic Filter may be left in place for up to 60 minutes to collect any emboli that may result from the clamping procedure or manipulation of the ascending aorta and heart during CPB surgery.

WARNING: Although the EMBOL•X Aortic Cannula may be used separately in place of a standard arterial return cannula, the EMBOL•X Aortic Filter must be used in conjunction with the EMBOL•X Aortic Cannula.

WARNING: Hold the base of the Introducer port of EMBOL•X Aortic Cannula while inserting the EMBOL•X Aortic Filter. Failure to do so may cause injury to the aorta.

WARNING: Do not deploy the EMBOL•X Aortic Filter if excessive resistance is felt. Attempting to deploy the EMBOL•X Aortic Filter when resistance is felt may indicate improper positioning of the cannula. Forcing deployment may cause injury to the aorta.

WARNING: Do not manipulate or reposition the EMBOL•X Aortic Cannula or EMBOL•X Aortic Filter shaft with the Filter deployed. If the cannula must be repositioned, first retract the Filter. Failure to do so may cause injury to the aorta.

WARNING: Do not use a single EMBOL•X Aortic Filter intra-aortically for more than **60** (sixty) minutes.

WARNING: The EMBOL•X Aortic Filter must be retracted and removed from the EMBOL•X Aortic Cannula Introducer port prior to routine administration of protamine for heparin reversal, since the Filter is heparin-coated. Failure to do so may result in thrombus formation on the Filter.

WARNING: Ensure that the cross-clamp is positioned at least 2.0 cm away from the EMBOL•X Aortic Cannula. Failure to do so may result in difficulty with insertion and/or removal of the Filter.

V. EMBOL•X Aortic Filter Removal

- ?? Hold the cannula to stabilize the device and fully retract the EMBOL•X Aortic Filter into the cartridge by retracting the plunger until it stops.
- ?? Unlock and remove the EMBOL•X Aortic Filter by pinching the locking connector tabs together and slowly sliding the Filter out of the Introducer port.

WARNING: If resistance is met while retracting the EMBOL•X Aortic Filter into the cartridge, leave the Filter in place until the EMBOL•X Aortic Cannula can be removed with the Filter deployed, using standard decannulation techniques.

9. PHYSICIAN TRAINING

As a means to augment proper technique, EMBOL•X will, upon request, provide the following training elements as needed to new centers intending to utilize the EMBOL•X Aortic Filter:

- ?? In-Service: EMBOL•X representative will review the method of use and present procedural and case review materials prior to first clinical use;
- ?? Case support: EMBOL•X representative will support the first case;
- ?? Documentation: EMBOL•X representative will provide a document reflecting the completion of in-service and/or case support to the center.

10. HOW SUPPLIED

STERILE: The device is provided STERILE and NON-PYROGENIC when in unopened, undamaged packaging. The device is sterilized by Gamma Radiation. For single use only. DO NOT resterilize. DO NOT REUSE.

CONTENTS: The EMBOL•X Aortic Filter is individually packaged.

STORAGE AND HANDLING: Store sterile packaged device in a cool, dry, dark place until ready for use. Do not expose to organic solvents, ionizing radiation, ultraviolet light, or alcohol-based fluids.

11. ADDITIONAL INFORMATION

For customer service or product information, please contact EMBOL•X, Inc. at the following address:

EMBOL•X, Inc.

645 Clyde Avenue
Mountain View, CA 94043-2208 USA
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DISCLAIMER OF WARRANTY

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This product, and the use thereof, is covered by U.S. Patent No. 5,846,260, 5,989,281, 6,007,557, 6,051,015, and other patents pending.

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Graphical Symbols for Medical Device Labeling

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