

5.2.2 Exclusion Criteria

Candidates will be excluded from the study if **any** of the following conditions are present:

1. Evidence of an acute myocardial infarction \leq 1 month before the intended treatment (defined as: Q wave MI, or non-Q wave MI with total CK elevation of CK-MB \geq twice normal in the presence of MB elevation and/or troponin level elevation (WHO definition)).
2. Aortic valve is a congenital unicuspid or bicuspid valve, or is non-calcified.
3. Mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation $>3+$).
4. Any therapeutic invasive cardiac procedure performed within 30 days of the index procedure, (or 6 months if the procedure was a drug eluting coronary stent implantation).
5. Pre-existing prosthetic heart valve in any position, prosthetic ring, or severe (greater than 3+) mitral insufficiency.
6. Blood dyscrasias as defined: leukopenia ($WBC < 3000 \text{ mm}^3$), acute anemia ($Hb < 9 \text{ mg}\%$), thrombocytopenia (platelet count $< 50,000 \text{ cells/mm}^3$), history of bleeding diathesis or coagulopathy.
7. Untreated clinically significant coronary artery disease requiring revascularization.
8. Hemodynamic instability requiring inotropic support or mechanical heart assistance.
9. Need for emergency surgery for any reason.
10. Hypertrophic cardiomyopathy with or without obstruction (HOCM).
11. Severe ventricular dysfunction with LVEF < 20 .
12. Echocardiographic evidence of intracardiac mass, thrombus or vegetation.
13. Active peptic ulcer or upper GI bleeding within the prior 3 months.
14. A known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid), or clopidogrel (Plavix), or sensitivity to contrast media, which cannot be adequately pre-medicated.
15. Native aortic annulus size $< 16\text{mm}$ or $> 24\text{mm}$ per the baseline echocardiogram as estimated by the left ventricular outflow tract (LVOT).
16. Patient has been offered surgery but has refused surgery.
17. Recent (within 6 months) cerebrovascular accident (CVA) or a transient ischemic attack (TIA).

18. Renal insufficiency (creatinine > 3.0) and/or end stage renal disease requiring chronic dialysis.
19. Life expectancy < 12 months due to non-cardiac co-morbid conditions.
20. Significant aortic disease, including abdominal aortic or thoracic aneurysm defined as maximal luminal diameter 5cm or greater; marked tortuosity (hyperacute bend), aortic arch atheroma (especially if thick [> 5 mm], protruding or ulcerated) or narrowing (especially with calcification and surface irregularities) of the abdominal or thoracic aorta, severe "unfolding" and tortuosity of the thoracic aorta (applicable for transfemoral patients only).
21. Iliofemoral vessel characteristics that would preclude safe placement of 22F or 24F introducer sheath such as severe obstructive calcification, severe tortuosity or vessels size less than 7 mm in diameter (applicable for transfemoral patients only).
22. Currently participating in an investigational drug or another device study. [Note: Trials requiring extended follow-up for products that were investigational, but have since become commercially available, are not considered investigational trials].