

5.2.1 Inclusion Criteria

Cohort A:

All candidates for Cohort A of this study must meet **all** of the following Inclusion criteria:

1. Patients must have co-morbidities such that the surgeon and cardiologist Co-PIs concur that the predicted risk of operative mortality is $\geq 15\%$ and/or a minimum STS score of 10. A candidate who does not meet the STS score criteria of ≥ 10 can be included in the study if a peer review by at least two surgeon investigators (not including the enrolling surgeon) concludes and documents that the patient's predicted risk of operative mortality is $\geq 15\%$. The surgeon's assessment of operative comorbidities not captured by the STS score must be documented in the study case report form as well as in the patient medical record.
2. Patient has senile degenerative aortic valve stenosis with echocardiographically derived criteria: mean gradient > 40 mmHg or jet velocity greater than 4.0 m/s or an initial aortic valve area (AVA) of < 0.8 cm² (indexed EOA < 0.5 cm²/m²). (Qualifying AVA baseline measurement must be within 30 days of study valve implantation procedure).
3. Patient is symptomatic from his/her aortic valve stenosis, as demonstrated by NYHA Functional Class II or greater.
4. The subject or the subject's legal representative has been informed of the nature of the study, agrees to its provisions and has provided written informed consent as approved by the Institutional Review Board (IRB) of the respective clinical site.
5. The subject and the treating physician agree that the subject will return for all required post-procedure follow-up visits.

Cohort B

All candidates for Cohort B of this study must meet # 2, 3, 4, 5 of the above criteria, **and**

6. The subject, after formal consults by a cardiologist and two cardiovascular surgeons agree that medical factors preclude operation, based on a conclusion that the probability of death or serious, irreversible morbidity exceeds the probability of meaningful improvement. Specifically, the probability of death or serious, irreversible morbidity should exceed 50%. The surgeons' consult notes shall specify the medical or anatomic factors leading to that conclusion and include a printout of the calculation of the STS score to additionally identify the risks in these patients.