

Date of study exit: ____ / ____ / ____ (DD/MMM/YYYY)

Screen Failure

- Subject did not meet I/E criteria prior to index procedure (if subject was randomized, please do not select)
- Subject did not meet I/E criteria after the Index Procedure TEE was performed and prior to the Access Sheath crossing the body
- Other Inc/Exc/Screening assessment failure; **Please Specify:** _____

Briefly describe why the subject exited: _____

No longer meets eligibility criteria (Select this if subject had an implant attempted but device was not implanted)

Withdrawn

- No Implant received at index procedure (after IMPLANT imaging, Access Sheath crossed the body)
- Subject withdrew consent
- Subject lost to follow up
- Investigator decision to withdraw subject
- Site terminated by Sponsor
- Sponsor terminated the Study
- Subject withdrew due to COVID -19 diagnosis
- Subject withdrew due to COVID -19 safety concerns
- Other; **Please Specify:** _____

Briefly describe why the subject exited: _____

Subject Death

Completed Study – Subject implanted and completed follow up through 5 years

Subject Classification

____/____/____

Site Personnel Signature

Date (DD/MMM/YYYY)