

TWIST-EFS (2024-13)

TLFs for ROP

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| Protocol Title: | Transcatheter Mitral Valve Replacement with the INNOVALVE System Trial – Early Feasibility Study |
| Protocol Number: | 2024-13, Revision B |
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# Table 2 Patient Disposition & Follow-up Visit Compliance by Interval

Enrolled Population (N=42)

| Patient Status at Follow-Up | 30 Days | 6 Months | 1 Year | 2 Years |
| --- | --- | --- | --- | --- |
| Eligible for Visit¹ | 41/42 (97.6%) | 30/42 (71.4%) | 24/42 (57.1%) | 12/42 (28.6%) |
| Visit Completed Within Window | 32/42 (76.2%) | 27/42 (64.3%) | 21/42 (50%) | 11/42 (26.2%) |
| Visit Completed Outside Window | 9/42 (21.4%) | 3/42 (7.1%) | 3/42 (7.1%) | 0/42 (0%) |
| Visit Not Performed (Reasons Below) | 0/42 (0%) | 0/42 (0%) | 0/42 (0%) | 1/42 (2.4%) |
| Pending Visit Within Window | 0/42 (0%) | 0/42 (0%) | 0/42 (0%) | 1/42 (2.4%) |
| Ineligible for Visit | 1/42 (2.4%) | 12/42 (28.6%) | 18/42 (42.9%) | 30/42 (71.4%) |
| Visit Not Due | 0/42 (0%) | 8/42 (19%) | 9/42 (21.4%) | 19/42 (45.2%) |
| Died Before Window | 1/42 (2.4%) | 4/42 (9.5%) | 8/42 (19%) | 10/42 (23.8%) |
| Withdrew Before Visit Window | 0/42 (0%) | 0/42 (0%) | 1/42 (2.4%) | 1/42 (2.4%) |
| [1] Patients are eligible if they complete the visit or their visit window is open and prior to FU visit window , they (a) are alive , (b) are not explanted, (c) did not withdraw from study, (d) are not lost to FU. | | | | |
| Visit Windows: 30 Days FU window (23-37 days), 6 FU window (166-194 days), 1 year FU window (335-390 days), 2 year FU window (680-765 days) | | | | |
| Categorical measures: n/Total N (%) | | | | |
| Source: t2\_patientdisposition.R Extract Date: 2025JUL28 Run Date (Time): 08Aug2025 (17:10) | | | | |

# Table 3 Demographics and Baseline Characteristics

Enrolled Population (N=42)

| Baseline Characteristic | Total |
| --- | --- |
| Age (Years) | 73.2 ± 10.3 (42) 76 (44, 90) |
| BMI (kg/m²) | 27.5 ± 6 (42) 27.1 (18.6, 52.7) |
| Sex at Birth         Female         Male | 16 / 42 (38.1%) 26 / 42 (61.9%) |
| NYHA Class         Class II         Class III | 11 / 42 (26.2%) 31 / 42 (73.8%) |
| LVEF (TTE)         21 - 25         26 - 30         31 - 35         36 - 40         41 - 45         46 - 50         51 - 55         56 - 60         61 - 65 | 2 / 40 (5%) 4 / 40 (10%) 2 / 40 (5%) 5 / 40 (12.5%) 9 / 40 (22.5%) 2 / 40 (5%) 5 / 40 (12.5%) 5 / 40 (12.5%) 6 / 40 (15%) |
| Stroke | 6 / 42 (14.3%) |
| Atrial Fibrillation | 28 / 42 (66.7%) |
| PCI | 13 / 42 (31%) |
| CABG | 12 / 42 (28.6%) |
| Continuous variables: Mean ± SD (n); Median (min, max) | |
| Categorical measures: n/Total N (%) | |
| Source: t3\_baselinedem.R Extract Date: 07AUG2025 Run Date (Time): 08Aug2025 (17:10) | |

# Table 4 Device Success at Exit from Or/Cath Lab (Per Device Analysis)

Enrolled Population (N=42)

| Device Outcome | Total |
| --- | --- |
| Device success¹ | 41/42 (97.6%) |
| Device deployed as intended | 41/42 (97.6%) |
| Device system successfully retrieved as intended | 41/42 (97.6%) |
| [1] Device Success: Device is deployed as intended and the delivery system is successfully retrieved as intended at the time of the patient’s exit from the cardiac catheterization laboratory. | |
| Categorical measures: n/Total N (%) | |
| Source: t4\_devicesuccess.R Extract Date: 08AUG2025 Run Date (Time): 08Aug2025 (17:10) | |

# Table 8: CEC Adjudicated Endpoints for Events up to 1 Year

Enrolled Population (N=42)

| Event | Early Events   (≤ 30 Days) | | Late Events   (> 30 days to 1 Year) | | Total Events | |
| --- | --- | --- | --- | --- | --- | --- |
| No. Events | Patients | No. Events | Patients | No. Events | Patients |
| Composite MAE | 9 | 6/42 (14.3%) | 26 | 12/41 (29.3%) | 35 | 15/42 (35.7%) |
| Death | 1 | 1/42 (2.4%) | 6 | 6/41 (14.6%) | 7 | 7/42 (16.7%) |
| Stroke | 0 | 0/42 (0.0%) | 2 | 2/41 (4.9%) | 2 | 2/42 (4.8%) |
| Bleeding¹ | 4 | 4/42 (9.5%) | 7 | 7/41 (17.1%) | 11 | 10/42 (23.8%) |
| Major Vascular Complications Requiring Surgery to Repair | 1 | 1/42 (2.4%) | 0 | 0/41 (0.0%) | 1 | 1/42 (2.4%) |
| Major Cardiac Structural Complications Requiring Surgery to Repair | 1 | 1/42 (2.4%) | 0 | 0/41 (0.0%) | 1 | 1/42 (2.4%) |
| Stage 2 or 3 Acute Kidney Injury (Including New Dialysis) | 0 | 0/42 (0.0%) | 5 | 3/41 (7.3%) | 5 | 3/42 (7.1%) |
| Myocardial Infarction or Coronary Ischemia Requiring PCI or CABG | 0 | 0/42 (0.0%) | 0 | 0/41 (0.0%) | 0 | 0/41 (0.0%) |
| Unexpected Cardiogenic Shock | 0 | 0/42 (0.0%) | 3 | 3/41 (7.3%) | 3 | 3/42 (7.1%) |
| Any Valve-Related Dysfunction, Migration, Thrombosis, or Other Complications Requiring Surgery or Repeat Interventions | 2 | 2/42 (4.8%) | 3 | 3/41 (7.3%) | 5 | 5/42 (11.9%) |
| [1] Includes fatal, life-threatening, extensive or major bleeding as defined by MVARC  Categorical measures: n/Total N (%) Source: t8\_CEC\_MAEs.R Extract Date: 2025AUG06 Run Date (Time): 08Aug2025 (17:10) | | | | | | |

# Table 11 CEC Adjudicated Heart Failure Hospitalizations and Non-elective Mitral Valve Reinterventions

Enrolled Population (N=42)

| Category | Early Events   (≤ 30 Days) | | Late Events   (> 30 Days to 1 Year) | | Total Events | |
| --- | --- | --- | --- | --- | --- | --- |
| No. Events | Patients | No. Events | Patients | No. Events | Patients |
| Heart Failure Hospitalization | 2 | 2/42 (4.8%) | 13 | 9/41 (22.0%) | 15 | 10/42 (23.8%) |
| Non-elective mitral valve re-intervention, percutaneous or surgical | 2 | 2/42 (4.8%) | 3 | 3/41 (7.3%) | 5 | 5/42 (11.9%) |
| Categorical measures: n/Total N (%) | | | | | | |
| Source: t11\_CEC\_HFH\_MVR.R Extract Date: 2025AUG06 Run Date (Time): 08Aug2025 (17:10) | | | | | | |

# Table 13 NYHA Class: Unpaired Analysis

Implanted Population (N=41)

| NYHA Class | Baseline   (N=41) | 30 Days   (N=41) | 6 Months   (N=30) | 1 Year   (N=24) |
| --- | --- | --- | --- | --- |
| Class I | - | 9/41 (22.0%) | 10/30 (33.3%) | 11/24 (45.8%) |
| Class II | 11/41 (26.8%) | 23/41 (56.1%) | 14/30 (46.7%) | 8/24 (33.3%) |
| Class III | 30/41 (73.2%) | 8/41 (19.5%) | 4/30 (13.3%) | 3/24 (12.5%) |
| Class IV | - | 1/41 ( 2.4%) | 2/30 ( 6.7%) | - |
| Categorical measures: n/Total N (%) | | | | |
| Source: t13\_NYHA.R Extract Date: 2025AUG06 Run Date (Time): 08Aug2025 (17:10) | | | | |

# Table 14 MR Grade by Core Lab TTE: Unpaired Analysis

Implanted Population (N=41)

| MR Grade | Baseline   (N=41) | Discharge   (N=41) | 30 Days   (N=41) | 6 Months   (N=30) | 1 Year   (N=24) |
| --- | --- | --- | --- | --- | --- |
| None/Trace | 0/36 (0%) | 26/37 (70.3%) | 15/36 (41.7%) | 13/30 (43.3%) | 9/19 (47.4%) |
| Mild | 0/36 (0%) | 10/37 (27%) | 18/36 (50%) | 15/30 (50%) | 9/19 (47.4%) |
| Mild-Moderate | 3/36 (8.3%) | 1/37 (2.7%) | 3/36 (8.3%) | 2/30 (6.7%) | 1/19 (5.3%) |
| Moderate-Severe | 22/36 (61.1%) | 0/37 (0%) | 0/36 (0%) | 0/30 (0%) | 0/19 (0%) |
| Severe | 11/36 (30.6%) | 0/37 (0%) | 0/36 (0%) | 0/30 (0%) | 0/19 (0%) |
| Baseline column reports cumulative MR grade, while all other columns report transvalvular MR grade | | | | | |
| Categorical measures: n/Total N (%) | | | | | |
| Source: t14\_MRgrade.R Extract Date: 2025AUG06 Run Date (Time): 08Aug2025 (17:10) | | | | | |