TWIST-EFS DSMB

Invalid Date

Table of contents

[Tables 1](#_Toc204786841)

[Table 1 Enrollment by Site 1](#_Toc204786842)

[Table 2 Patient Disposition & Follow-up Visit Compliance by Interval 1](#_Toc204786843)

[Table 3 Demographics and Baseline Characteristics 1](#_Toc204786844)

[Table 11 CEC Adjudicated Heart Failure Hospitalizations and Non-elective Mitral Valve Reinterventions 1](#_Toc204786845)

[Figures 1](#_Toc204786846)

[Figure 1 Linear Graph of Cumulative Enrollment by Month 1](#_Toc204786847)

# Tables

## Table 1 Enrollment by Site

| **Site Number** | **Site Name** | **Enrolled¹ (N=38)** | **Implanted² (N=37)** |
| --- | --- | --- | --- |
| 19 | Mayo Clinic | 8/38 (21.1%) | 8/37 (21.6%) |
| 237 | OhioHealth Research Institute | 6/38 (15.8%) | 6/37 (16.2%) |
| 238 | Vanderbilt University Medical Center | 5/38 (13.2%) | 4/37 (10.8%) |
| 383 | Piedmont Hospital, Atlanta, GA | 5/38 (13.2%) | 5/37 (13.5%) |
| 4 | Cleveland Clinic Foundation | 5/38 (13.2%) | 5/37 (13.5%) |
| 127 | Oregon Health Sciences University | 4/38 (10.5%) | 4/37 (10.8%) |
| 10 | Cedars-Sinai | 2/38 (5.3%) | 2/37 (5.4%) |
| 824 | Swedish Medical | 2/38 (5.3%) | 2/37 (5.4%) |
| 66 | University of Michigan Hospital | 1/38 (2.6%) | 1/37 (2.7%) |
| [1] Enrolled: A patient is considered enrolled if they have signed informed consent and have the study procedure attempted (defined as introduction of the investigational delivery system into the patient). | | | |
| [2] Implanted: A patient is considered implanted if they have undergone the study procedure and leave the operating room with the study valve in place. | | | |
| Categorical measures: % | | | |
| Source: t1\_enrollmentbysite.R Extract Date: 2025JUL28 Run Date (Time): 30Jul2025 (16:50) | | | |

## Table 2 Patient Disposition & Follow-up Visit Compliance by Interval

| **Patient Status at Follow-Up** | **30 Days** | **6 Months** | **1 Year** | **2 Years** |
| --- | --- | --- | --- | --- |
| Eligible for Visit | 42/42 (100%) | 33/42 (78.6%) | 32/42 (76.2%) | 20/42 (47.6%) |
| Visit Completed Within Window | 32/42 (76.2%) | 27/42 (64.3%) | 21/42 (50%) | 11/42 (26.2%) |
| Visit Completed Outside Window | 8/42 (19%) | 3/42 (7.1%) | 3/42 (7.1%) | 0/42 (0%) |
| Visit Not Performed | 2/42 (4.8%) | 12/42 (28.6%) | 18/42 (42.9%) | 31/42 (73.8%) |
| [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. | | | | |
| [2] Specify the visit window: 30 Days FU window (23-37 days), 6 FU window (166-194 days), 1 year FU window (335-390 days). | | | | |
| Categorical measures: % | | | | |
| Source: t1\_enrollmentbysite.R Extract Date: 09JUL2025 Run Date (Time): 30Jul2025 (16:50) | | | | |

## Table 3 Demographics and Baseline Characteristics

| **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: 28JUL2025 Run Date (Time): 30Jul2025 (16:50) | |

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

| **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 (%) | | | | | | |
| Source: t1\_enrollmentbysite.R Extract Date: 2025JUL28 Run Date (Time): 30Jul2025 (16:50) | | | | | | |
| **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 (%) | | | | | | |
| Source: t1\_enrollmentbysite.R Extract Date: 2025JUL28 Run Date (Time): 30Jul2025 (16:50) | | | | | | |

# Figures

## Figure 1 Linear Graph of Cumulative Enrollment by Month

