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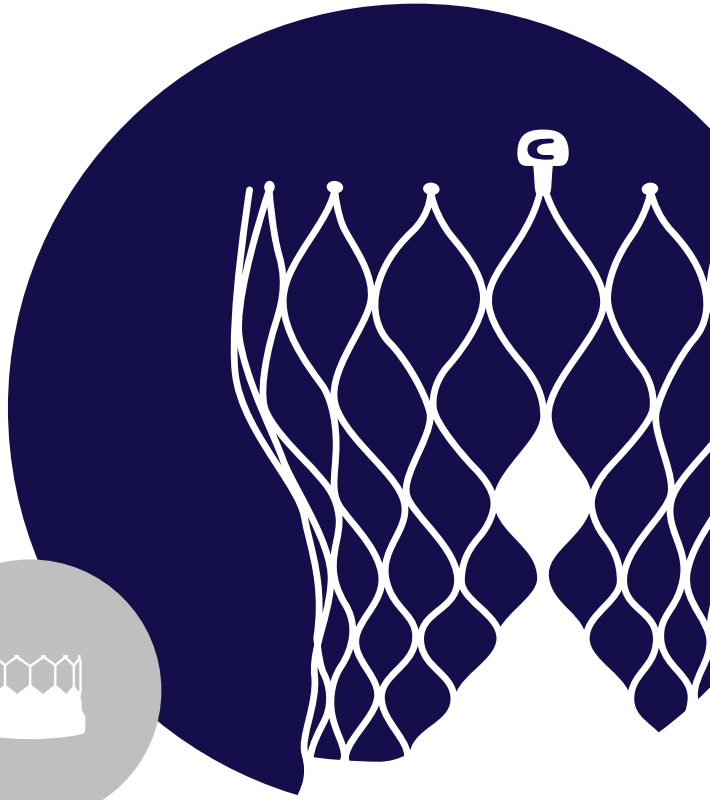
It's not TAVI, it's Evolut™.

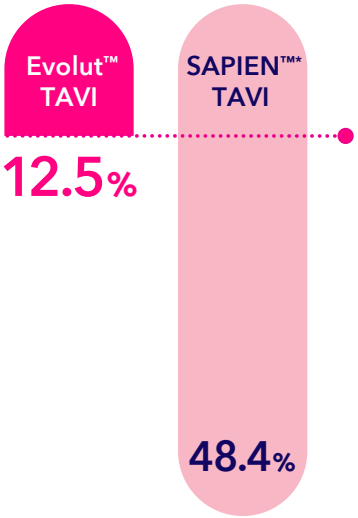
SMART Trial

2-year results



Through two years,

Evolut™ TAVI maintains superior valve performance† vs. SAPIEN™* TAVI in small annulus patients.‡[1]



Significantly less BVD† with Evolut™ TAVI

vs. SAPIEN™* TAVI in small annulus patients.‡[1]

$p < 0.001$

Sustained excellent patient outcomes through two years[1]

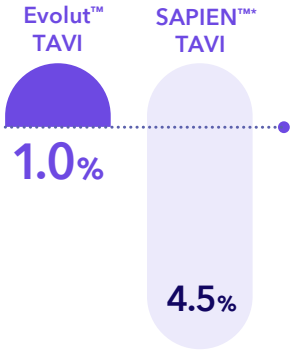
Clinical outcome composite:
All-cause mortality, disabling stroke, or heart failure rehospitalization.

Evolut™ TAVI: 17.8%
SAPIEN™* TAVI: 17.6%, p = 0.97
Hazard ratio: 1.01 (95% CI 0.71, 1.43)

Devices used: Evolut™ PRO+ 78.0%, Evolut™ PRO 17.1%, Evolut™ FX 4.3%, Evolut™ R 0.6%; SAPIEN™* 3 Ultra 80.8%, SAPIEN™* 3 19.2%

Compared to SAPIEN™* TAVI,

only Evolut™ TAVI delivers:

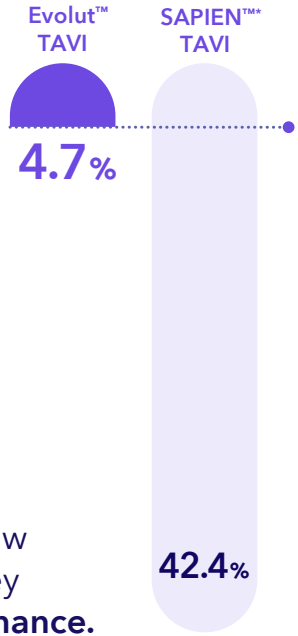


4.5x less

prosthetic valve thrombosis[§]

through two years in small annulus patients.[‡1]

p = 0.0048



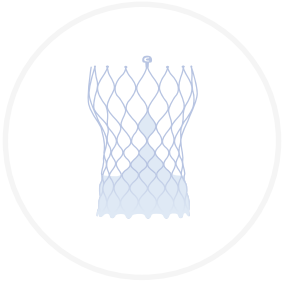
9x less

HSVD[◊]

(mean gradient ≥ 20 mmHg)

through two years in small annulus patients.[‡1]

p < 0.001



Evolut™ TAVI continues to show strong results across these key components of **valve performance.**

† Valve performance as defined as freedom from bioprosthetic valve dysfunction (BVD) through 24 months. BVD is defined as a composite including any of the following: hemodynamic structural valve dysfunction (mean gradient ≥ 20 mmHg), non-structural valve dysfunction (severe prothesis-patient mismatch or ≥ moderate aortic regurgitation), clinical thrombosis, endocarditis, and aortic valve reintervention.
‡ In patients with small annuli (area ≤ 430 mm2) in all-comers trial, consisting of majority low surgical risk participants (52.1%).
§ Prosthetic valve thrombosis as defined as a composite of clinical and sub-clinical valve thrombosis.
◊ Hemodynamic structural valve dysfunction.

1. Herrmann H, et al. SMART 2 Year Data Update. Presented at CRT; March 2025.

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