

Market insights summary

United States transcatheter heart valve device market

What's trending and new

01. Availability of novel transcatheter replacement and repair devices

- Edwards Lifesciences introduced its EVOQUE TTVI¹ device in 2024, the first of its kind to be approved in the US.
- Abbott Laboratories introduced its Navitor TAVI² device in 2023 and its TriClip TTVR³ device in 2024, which was the first of its kind to be approved in the US.
- Medtronic relaunched its Harmony TPVI⁴ device in 2023 after earlier recalls in 2022 and received premarket approval for its Evolut FX+ system for the treatment of symptomatic, severe aortic stenosis in 2024.

02. CMS reimbursement coverage for new technology and expanded indications

- TTVI and TTVR devices are currently being considered by the CMS⁵ for a national coverage determination which, if granted, will expand coverage and support volumes for these procedures.
- DASI Simulations' Precision TAVI software, which uses AI to simulate personalized TAVI procedures based on the anatomy of each patient's heart, has received FDA⁶ clearance and a CMS outpatient billing code.
- New indications—including novel valve-in-valve procedures, treatments for asymptomatic patients, and TAVI for aortic regurgitation—are increasingly being targeted to further expand the treatable patient population.

Access more insights and data in the [report](#).
[Speak to our team](#) to see how we can power your innovation.

¹TTVI = Transcatheter Tricuspid Valve Implantation

²TAVI = Transcatheter Aortic Valve Implantation

³TTVR = Transcatheter Tricuspid Valve Repair

⁴TPVI = Transcatheter Pulmonary Valve Implantation

⁵CMS = Centers for Medicare & Medicaid Services

⁶FDA = Food and Drug Administration (US)

2023 U.S. transcatheter heart valve device market snapshot

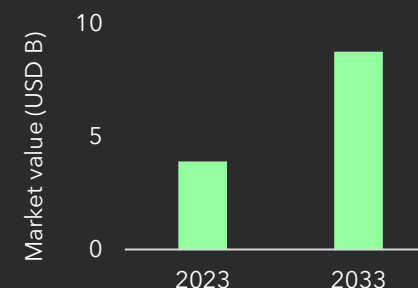
\$3.9B

Market revenue

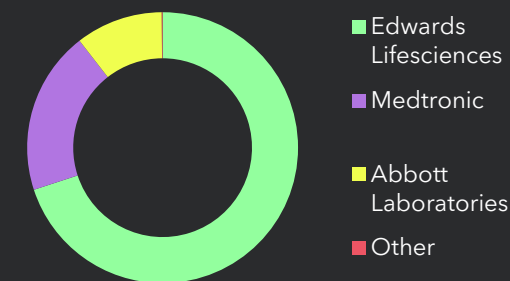
7.1%

CAGR ('19 - '33)

U.S. transcatheter heart valve device market



2023 U.S. transcatheter heart valve device competitive landscape



Edwards Lifesciences

- Edwards Lifesciences continues to lead the U.S. market for transcatheter heart valve devices, supported by its SAPIEN and EVOQUE series of replacement devices and PASCAL repair devices.
- Recent acquisitions of JenaValve and Innovalve Bio Medical will expand its product portfolio and offer new opportunities for growth.
- In 2024, Edwards Lifesciences received FDA approval of its EVOQUE TTVI device, further strengthening its position in the overall market.

Abbott Laboratories

- Abbott Laboratories remains the market leader for transcatheter repair devices due to continued uptake of its MitraClip TMVR device and recent approval of its TriClip TTVR device, the first of its kind.
- Although it has struggled to capture market share in the transcatheter replacement segment, the approval of the Navitor TAVI system in 2023 offers an opportunity for growth in an increasingly competitive market.