

# **SAPIEN 3 Transcatheter Aortic Valve Replacement Compared with Surgery Intermediate-Risk Patients: A Propensity Score Analysis**

**Vinod H. Thourani, MD**  
on behalf of The PARTNER Trial Investigators

**Edwards Lifesciences v. Boston Scientific Scimed  
IPR2017-00060, U.S. Patent 8,992,608  
Exhibit 2052**

**ACC 2016 | Chicago | April 3, 2016**

# Disclosure Statement of Financial Interest

Vinod H. Thourani, MD

Within the past 12 months, I or my spouse/partner have had an interest/arrangement or affiliation with the organization(s)

## Affiliation/Financial Relationship

- Grant/Research Support
- Consulting Fees/Honoraria
- Major Stock Shareholder/Equity

## Company

- Boston Scientific, Clariva  
Lifesciences, Medtronic
- Abbott Vascular, Edwards  
St. Jude Medical
- None

# Background

- The 3<sup>rd</sup> generation SAPIEN 3 transcatheter heart valve demonstrated improved clinical outcomes in high-risk patients at 1 year.
- The 30-day outcomes in *intermediate-risk* patients with SAPIEN 3 in PARTNER 2 were...
  - All-cause Mortality: 1.1%
  - Disabling Stroke: 1.0%
  - PVL  $\geq$  Moderate: 3.8%
- There is a paucity of longer-term data in intermediate-risk patients with SAPIEN 3 and there have been no direct comparisons with surgery in intermediate-risk patients.

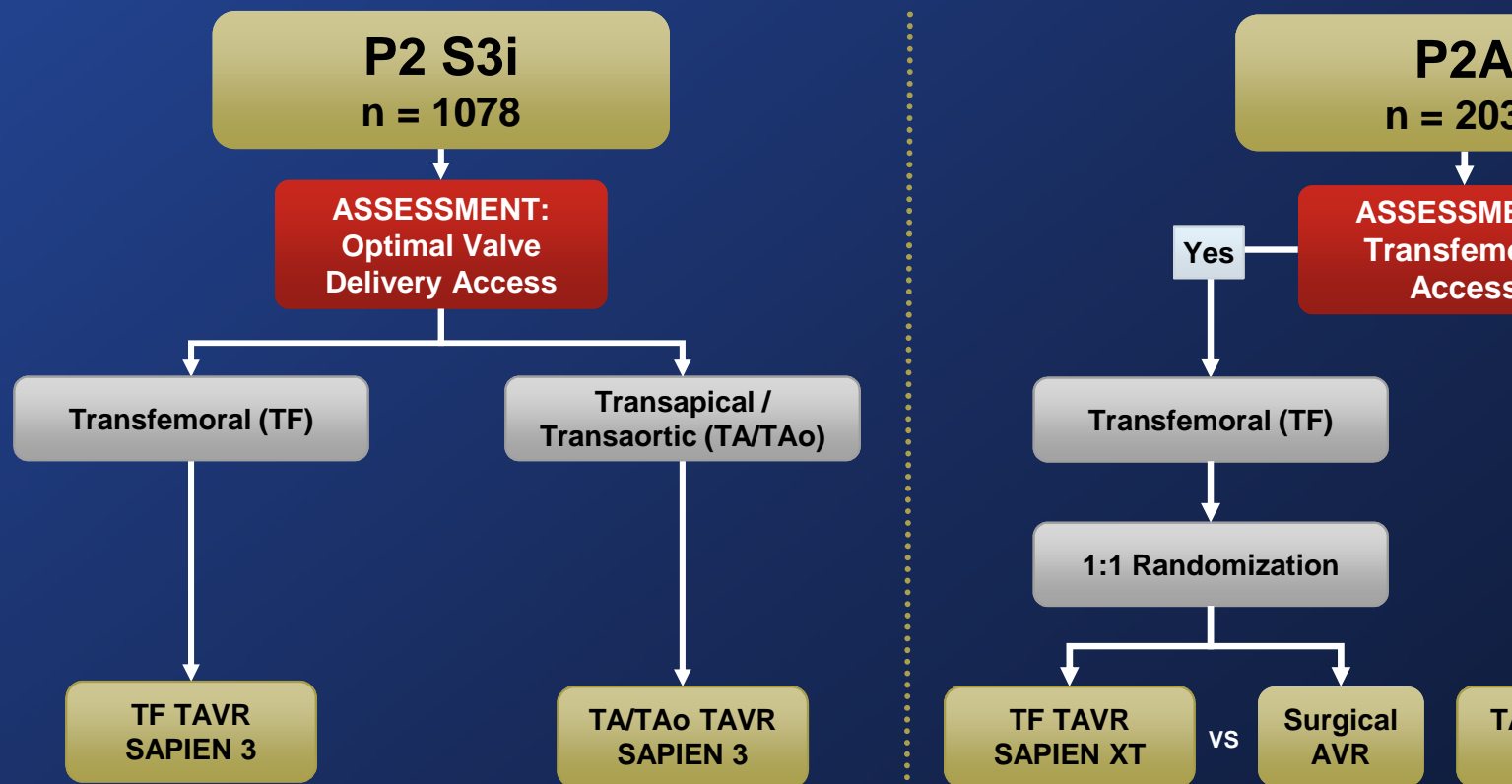
# Purpose

- To evaluate the 1-year clinical and echo out SAPIEN 3 TAVR in intermediate-risk patients
- To compare these intermediate-risk patient using SAPIEN 3 TAVR with surgery results intermediate-risk patients from the PARTNER using a rigorous *pre-specified propensity score analysis*.

# The PARTNER 2A and S3i Trials Study Design

Intermediate Risk Symptomatic Severe Aortic Stenosis

Intermediate Risk ASSESSMENT by Heart Valve Team



# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.