



# Simulation for Assessment of Coronary Obstruction Risk

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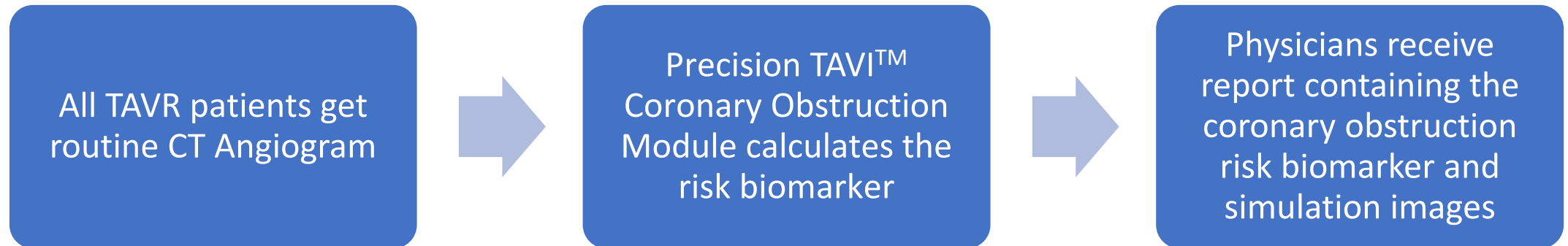
March 8, 2022

# Introduction:

**Precision TAVI™ Coronary Obstruction Module is for patients diagnosed with severe aortic stenosis (AS) and are under consideration for transcatheter aortic valve replacement (TAVR)**

- The vast majority of target patients are Medicare
- Coronary obstruction remains one of the most serious TAVR complications, and although it is rare, it is associated with high mortality
- Current tools and processes lack the predictive power to determine the risk of coronary obstruction resulting in thousands of deaths each year
- The Precision TAVI™ Coronary Obstruction Module provides a highly precise biomarker that predicts coronary obstructions in TAVR procedures and is intended to be used for pre-planning prior to hospitalization, and may be used prior to the procedure during the patient's hospitalization to inform surgeons of the risks for coronary obstruction

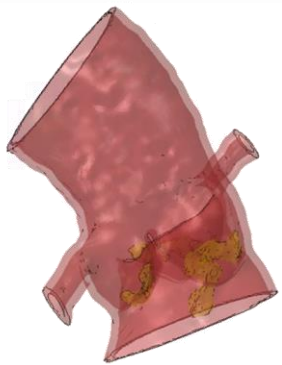
# Precision TAVI™ Coronary Obstruction Module Process Diagram



# How Does the Coronary Obstruction Module Calculate the Risk?

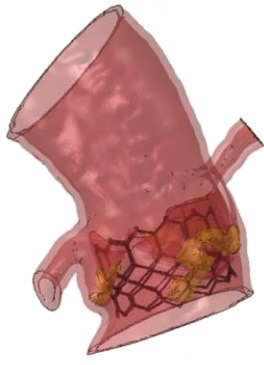
## 1. Segmentation

CT image-based 3D reconstruction of patient's aortic root



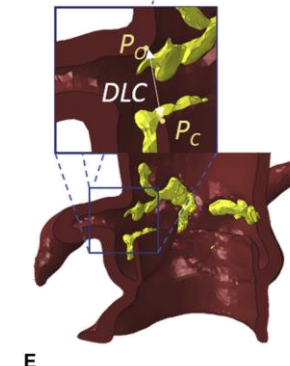
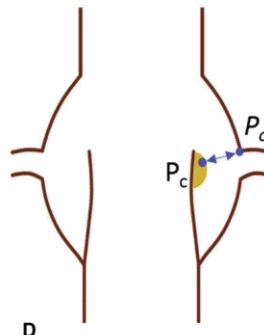
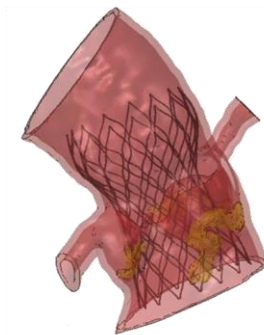
## 2. THVs Deployment Simulations

FDA approved THV deployment simulations provide intelligent decision support data to help the physicians better predict coronary obstruction



## 3. Coronary Obstruction Module

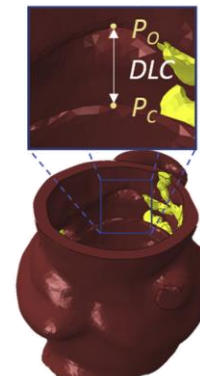
Calculates the coronary risk obstruction (DLC/d)<sup>\*,\*\*</sup> biomarker that shows the degree of coronary ostia obstruction for each THV deployment simulation scenario



## 4. Report Generation

Interactive 3D report in an HTML format contains:

- Simulation images
- **Coronary Obstruction Risk Biomarker (DLC/d)<sup>\*,\*\*</sup>**



\* Heitkemper M, Hatoum H, Azimian A, Yeats B, Dollery J, Whitson B, Rushing G, Crestanello J, Lilly SM and Dasi LP, "Modeling risk of coronary obstruction during transcatheter aortic valve replacement", *J Thorac Cardiovasc Surg.* 2020;159:829-838.e3.

\*\* Sri Krishna Sivakumar BY, Venkateshwar Polsani, Pradeep Yadav, Vinod Thourani, Lakshmi Prasad Dasi. Computational modeling of coronary obstruction (CO) in Valve-in-Valve (ViV) Transcatheter Aortic Valve Replacement (TAVR): comparison with 2-dimensional CT based risk assessment. *Transcatheter Therapeutics (TCT) Meeting 2021.* 2021.

# Precision TAVI™ Coronary Obstruction Module Results Review

## 1. Report Download

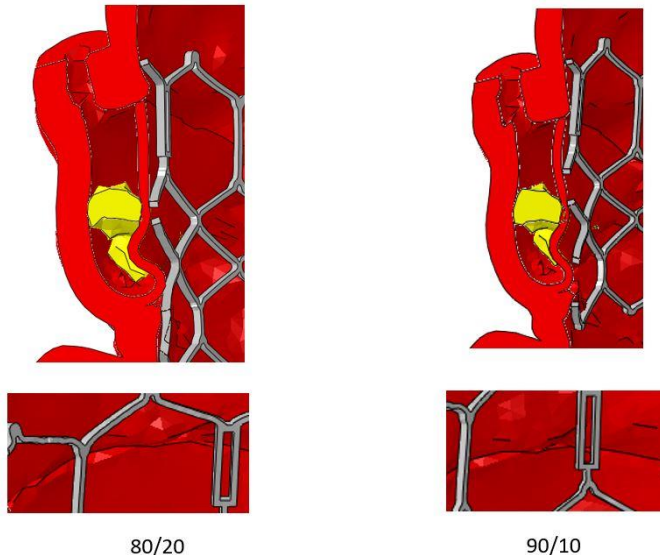
- Clinical specialists download the Precision TAVI™ Coronary Obstruction Module interactive report for review



## 2. Heart Team Results Discussion

Precision TAVI™ Coronary Obstruction Module results are discussed during hospital heart team meetings in the context of TAVR pre-planning.

- High Risk
- Blocked Sinus
- DCL=0<sup>\*,\*\*</sup>
- DCL/d = 0<sup>\*,\*\*</sup>



\* Heitkemper M, Hatoum H, Azimian A, Yeats B, Dollery J, Whitson B, Rushing G, Crestanello J, Lilly SM and Dasi LP, "Modeling risk of coronary obstruction during transcatheter aortic valve replacement", *J Thorac Cardiovasc Surg.* 2020;159:829-838.e3.

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**Thank you**

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