Abbott's TECTONIC Clinical Trial Demonstrates Strong 30-Day Outcomes And High Procedural Success For Its Investigational SonicForce™ Coronary Intravascular Lithotripsy System

- SonicForce is an investigational coronary intravascular lithotripsy (IVL) system that uses acoustic pressure waves, similar to those used to break up kidney stones, to crack calcium in coronary arteries and restore blood flow
- The system is designed to bring purposeful innovation to treating complex coronary calcium, with longer treatment lengths, more pulses and enhanced catheter deliverability
- Approval of the investigational system would further strengthen Abbott's comprehensive coronary devices portfolio, complementing its advanced imaging, lesion preparation and stent technologies

ABBOTT PARK, Ill., Nov. 1, 2026 /PRNewswire/ -- Abbott (NYSE: ABT), the global healthcare leader, announced strong 30-day results from the TECTONIC Coronary Artery Disease (CAD) Intravascular Lithotripsy (IVL) Investigational Device Exemption (IDE) Study evaluating the use of its investigational SonicForce™ Coronary IVL System, which is designed to crack calcium buildup in coronary arteries. The study met its primary safety and effectiveness endpoints, demonstrating excellent early clinical outcomes in patients with severe coronary calcification.

Results from the TECTONIC CAD IVL IDE Study were presented today at the Transcatheter Cardiovascular Therapeutics (TCT) conference in San Diego (Oct. 31-Nov. 3, 2026) and simultaneously published in the *Journal of the American College of Cardiology: Cardiovascular Interventions.*

The TECTONIC study enrolled 335 patients with severely calcified CAD across 40 U.S. sites and evaluated the investigational SonicForce Coronary IVL System in people with narrowed coronary arteries caused by calcium buildup. Key data from the trial include:

- The study met its primary safety endpoint, with a low 30-day target lesion failure rate of 0.3%.
- The study achieved its primary effectiveness endpoint, with high procedural success in 97% of patients.
- Key secondary endpoints were also met, including post-IVL stent delivery with remaining vessel blockage dropping to less than 50% for all patients assessed by core laboratory and major adverse cardiovascular events (MACE; composite of cardiac death, all myocardial infarction, target vessel revascularization) of 0.3% of patients in the as-treated population.

IVL is a minimally invasive medical procedure that uses acoustic pressure waves, similar to technology used for kidney stones, to crack hard plaque in narrowed heart vessels. In a prespecified imaging sub-study of 106 patients, optical coherence tomography (OCT) imaging identified calcium fractures within lesions following treatment with the investigational SonicForce Coronary IVL System and showed improved post-stent expansion.

"Coronary calcium remains one of the greatest challenges to achieving optimal percutaneous coronary intervention outcomes," said Eric A. Secemsky, MD, MSc, RPVI, FACC, FAHA, FSCAI, FSVM, director of vascular intervention at the Cardiovascular Institute, Beth Israel Deaconess Medical Center in Boston and co-principal investigator for the TECTONIC CAD IVL trial. "The TECTONIC CAD data suggest that Abbott's investigational SonicForce Coronary IVL System may provide physicians with a safe and effective approach to modifying severe coronary calcification prior to stenting. For operators treating increasingly complex coronary disease, this product has the potential to expand the tools available for treatment options and meaningfully improve procedural success and patient care."

"The investigational SonicForce System has the potential to expand Abbott's broad range of access-to-closure devices, strengthen our leadership in treating severely calcified coronary arteries, and reinforce our commitment to equip physicians with integrated solutions for patients at every stage of care," said Julie Tyler, senior vice president of Abbott's vascular business.

The SonicForce System approval would further expand Abbott's portfolio of technologies designed to support complex cardiovascular disease.

Frequently Asked Questions

Q: What did the TECTONIC study show?
A: The TECTONIC Coronary Artery Disease (CAD) Intravascular Lithotripsy (IVL) Investigational Device Exemption (IDE) Study met its primary safety and effectiveness endpoints, demonstrating positive results for Abbott's investigational SonicForce™ Coronary IVL System. The study enrolled 335 patients with severe coronary artery calcification across 40 U.S. sites and reported a low 30-day target lesion failure rate of 0.3% and high procedural success in 97% of patients.

Q: What is the SonicForce™ Coronary IVL System and how does it work?
A: Abbott's investigational SonicForce Coronary Intravascular Lithotripsy (IVL) System uses IVL, a technology that delivers acoustic pressure waves to crack calcium buildup within coronary arteries. Adapted from technology used to treat kidney stones, the system uses a balloon-mounted catheter to deliver acoustic pressure waves that modify calcium deposits. SonicForce Coronary IVL System is designed with features intended to support treatment of calcified lesions and delivery of up to 160 pulses at two pulses per second that helps facilitate vessel preparation.

Q: Why is this technology important for treating coronary artery disease?

A: Coronary artery disease (CAD) affects more than 20 million adults in the United States and remains the leading cause of death nationwide.[1,2,3] Calcium buildup within coronary arteries can make procedures more complex and may affect how well a stent can be delivered and expanded. By cracking calcium before stent placement, IVL can help physicians prepare the blood vessel, so that the stent has room to fully expand.

SonicForce Coronary IVL System has not been approved by the U.S. Food and Drug Administration (FDA) and is limited by federal law to investigational use.

About Abbott
Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 122,000 colleagues serve people in more than 160 countries.

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[1] Nowbar, A.N., et al., Mortality From Ischemic Heart Disease. Circ Cardiovasc Qual Outcomes, 2019. 12(6): p. e005375.

[2] Tsao, C.W., et al., Heart Disease and Stroke Statistics-2023 Update: A Report From the American Heart Association. Circulation, 2023. 147(8): p. e93-e621.

[3] Brown JC, Gerhardt TE, Kwon E. Risk factors for coronary artery disease. PubMed. Published January 23, 2023. https://www.ncbi.nlm.nih.gov/books/NBK554410/

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