Heartflow Plaque Analysis Now Supported by Scientific Statements From American College of Cardiology and American Heart Association for Personalized Management of Patients with Suspected CAD

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Reinforces Role of AI-Powered Quantitative Coronary Plaque Assessment

MOUNTAIN VIEW, Calif., Dec. 18, 2025 (GLOBE NEWSWIRE) -- Heartflow, Inc. (Heartflow) (Nasdaq: HTFL), the leader in AI technology for coronary artery disease (CAD), announced the American College of Cardiology (ACC) and the American Heart Association (AHA) published new scientific statements supporting the prognostic value of quantifying coronary plaque and reinforcing the critical role of the coronary computed tomography angiography (CTA) + Heartflow pathway in CAD patient management. The ACC's consensus recommendations, published this week in *JACC: Cardiovascular Imaging*, highlight the importance of quantitative plaque assessment and underscore the benefits of adopting AI-powered Heartflow Plaque Analysis for personalized, precision cardiac care.[1] The ACC statement elevates plaque analysis from an emerging technology to a defined clinical consideration in CAD management, outlining appropriate patient selection and best practices for interpreting and reporting.

In direct alignment with the ACC's call for rigorous quality assurance, reproducible results, and "human in the loop" analysis, Heartflow delivers a differentiated standard for clinical plaque quantification by combining AI-driven analysis with expert quality review. Heartflow Plaque Analysis is the only FDA-cleared, AI-powered plaque quantification tool with 95% agreement to the gold standard, IVUS, using blinded core lab adjudication.[2] This rigor, together with Heartflow's commitment to standardized reporting and advanced algorithmic approaches such as adaptive thresholds, reflects a level of validation and quality oversight consistent with ACC guidance.

The AHA statement, published recently in *Circulation*, reinforces plaque burden and composition as central in managing nonobstructive CAD.[3] The expert authors emphasize that patients with nonobstructive CAD should not be considered low-risk, recognizing that coronary plaque burden, extent, and composition are major determinants of outcomes. Earlier this year, a commission perspective published in *The Lancet* called for a fundamental shift in managing CAD, urging clinicians to focus on identifying and managing plaque early, before the opportunity for prevention has been lost.[4] Together, the scientific statements from ACC and AHA reinforce that broader paradigm shift toward understanding plaque burden, not just artery obstruction, in modern CAD management.

"The ACC and AHA scientific statements address an important need by providing evidence-based consensus recommendations for clinicians and imagers, solidifying coronary CTA-based quantitative plaque analysis as a powerful tool for enhanced risk stratification in patients with suspected CAD," said Ron Blankstein, M.D., writing committee member for both the ACC and AHA statements, Director of Cardiac Computed Tomography at Brigham and Women's Hospital, and Professor of Medicine and Radiology at Harvard Medical School. "These statements highlight the limitations of current methods to assess risk based on risk factors or stenosis severity alone. Integrating AI-powered technology into clinical practice using ACC and AHA's guidance can help clinicians move beyond diagnosing blockages, toward predicting and preventing major cardiovascular events."

Both the ACC and AHA scientific statements support the use of quantitative coronary plaque analysis to identify high-risk patients, enabling the immediate and appropriate initiation of preventive treatment. Heartflow Plaque Analysis addresses the need to quantify disease following visual detection of plaque, and is delivered instantly upon order to maintain seamless clinical integration and enable timely clinical decision-making.

"The ACC and AHA scientific statements signal growing consensus that plaque assessment is essential for risk stratification, prevention, and long-term CAD management. Heartflow Plaque Analysis enables more precise risk stratification for personalized, preventive treatment plans," said Campbell Rogers, M.D., F.A.C.C., Chief Medical Officer at Heartflow. "The expert guidance articulates the need for rigorous validation and standardization, which Heartflow is uniquely positioned to address, given our technology and quality systems already align with these stringent recommendations. We are energized by the opportunity to continue collaborating with clinicians as a catalyst to redefine and improve precision cardiovascular care."

The ACC and AHA's scientific statements reflect a growing body of clinical evidence further substantiating the prognostic significance of Heartflow Plaque Analysis. A retrospective analysis of symptomatic patients from a cohort of the FISH&CHIPS Study presented at the AHA Scientific Sessions 2025 provided the largest validation to date of the Heartflow Plaque Staging framework based on total plaque volume measurement as a predictor of future heart attacks or cardiovascular death.[5] The company is generating additional real-world evidence through the DECIDE registry, the largest prospective registry evaluating the clinical impact of Heartflow Plaque Analysis on medical management decisions. The DECIDE registry showed that more than 50%

of patients had their medical management changed when Plaque Analysis with Plaque Staging* was added compared to their management based on CCTA alone.[6]

About Heartflow's Technology and Research
Heartflow's technology is redefining precision cardiovascular care through clinically-proven AI and the world's largest coronary imaging dataset. Heartflow has been adopted by more than 1,400 institutions globally and continues to strengthen its commercial presence to make this cutting-edge solution more widely available to an increasingly diverse patient population. Backed by ACC/AHA guidelines and supported by more than 600 peer-reviewed publications, Heartflow has redefined how clinicians manage care for over 500,000 patients worldwide. Key benefits include:

- **Proprietary data pipeline:** Built from more than 110 million annotated CTA images, Heartflow's data foundation powers advanced AI models that deliver highly accurate, reproducible insights across diverse patient populations.
- **Extensive clinical and real-world validation:** Heartflow's AI-driven solutions have been validated through clinical evidence in over 100 studies assessing over 365,000 patients. Proven in real-world practice with reproducibility and accuracy, Heartflow's coronary CTA image acceptance rates exceed 97%.
- **Seamless clinical integration via upgraded workflow:** Heartflow delivers final quality-reviewed analyses instantly upon order, enabling clinicians to move from diagnosis to decision without delay.
- **Quality system, global security and patient-data integrity compliance:** Heartflow meets or exceeds leading international standards, including HITRUST, SOC 2 Type 2, ISO 13485, and ISO 27001.

About Heartflow, Inc.
Heartflow is transforming coronary artery disease from the world's leading cause of death into a condition that can be detected early, diagnosed accurately, and managed for life. The Heartflow One platform uses AI to turn coronary CTA images into personalized 3D models of the heart, providing clinically meaningful, actionable insights into plaque location, volume, and composition and its effect on blood flow — all without invasive procedures. Discover how we're shaping the future of cardiovascular care at heartflow.com.

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[1] Chandrashekhar Y, Blankstein R, Shaw L. et al. Quantitative Coronary Plaque Analysis in Clinical Practice: 2025 ACC Scientific Statement: A Report of the American College of Cardiology. J Am Coll Cardiol Img. doi: 10.1016/j.jcmg.2025.11.008

[2] Ihdayhid A, et al. Radiol Cardiothorac Imaging. 2024. doi: 10.1148/ryct.230312 and internal bridging study with ICC correlation between first generation and second generation Plaque Analysis algorithm.

[3] Slipczuk L, Blankstein R, Bucciarelli-Ducci C. et al. State of the art: evaluation and medical management of nonobstructive coronary artery disease in patients with chest pain: a scientific statement from the American Heart Association. Circulation. 2025;152:e443–e466. doi: 10.1161/CIR.0000000000001394

[4] Zaman, Sarah et al. The Lancet Commission on rethinking coronary artery disease: moving from ischaemia to atheroma. The Lancet. 2025;405,10486:1264-1312. Doi: 10.1016/S0140-6736(25)00055-8

[5] Fairbairn et al. AHA 2025.

[6] DECIDE Registry. Rinehart, et al., presented at SCCT 2025.
*Heartflow Plaque Analysis is an FDA-cleared device. Heartflow Plaque Staging is an investigational-only framework, and its safety and effectiveness have not been reviewed by the FDA.