Heartflow's Plaque Analysis Leading The Way: 95% Accuracy vs Invasive Imaging In Newly Published REVEALPLAQUE Study

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MOUNTAIN VIEW, Calif. – May 15, 2024 — Heartflow, Inc., a leader in non-invasive artificial intelligence (AI) heart care solutions, today announced that the data from its REVEALPLAQUE study, highlighting the accuracy of its Plaque Analysis, was published in the *European Heart Journal Cardiovascular Imaging.*

REVEALPLAQUE aimed to evaluate Heartflow's non-invasive plaque technology , an automated, deep learning-based method for identifying, characterizing, and segmenting plaque in the coronary arteries. Understanding the volume and composition of plaque allows physicians to ensure appropriate medical treatment, which could be life changing for patients.

Key Results: Heartflow Plaque Analysis is highly accurate in determining total plaque volume and plaque volume by type vs. invasive imaging (IVUS)[1]

- Total Plaque Volume vs. IVUS: 95% agreement
- Calcified Plaque Volume vs. IVUS: 95% agreement
- Non-Calcified Plaque Volume vs. IVUS: 93% agreement

Heartflow Plaque Analysis is the only FDA cleared, AI-enabled plaque quantification tool validated in a prospective, international trial against the gold standard of invasive imaging (IVUS) using blinded core lab adjudication.[1]

Heart disease is the leading cause of death for both men and women.[2] Four out of five of the deaths may be preventable with nutrition, lifestyle, and medication therapy changes for patients identified early.[3] Now with Heartflow Plaque Analysis, physicians can measure confidently and accurately, the volume by type. Ultimately, this supports patients in a technology forward way that hasn't previously been possible.

"I'm thrilled to see such an overwhelming result showcasing that CT angiography, coupled with automated AI-driven Plaque Analysis is an effective way to assess plaque burden," said Jagat Narula, M.D., Ph.D., co-principal investigator and and K. Lance Gould Distinguished University Chair of Coronary Pathophysiology at UTHealth Houston. "This is a futuristic step forward for patients and clinicians to have an accurate, non-invasive test that gives insights into their total plaque volume, and is every bit as good as the invasive reference standard. It will allow clinicians to feel more informed to deliver the best treatment recommendations possible for each patient."

The REVEALPLAQUE trial was a large, global prospective study which enrolled 258 patients across 15 sites in the U.S. and Japan. This was an independent, blinded, core lab adjudicated study to determine the accuracy of Heartflow's AI Plaque Analysis compared head-to-head with IVUS.

"Heartflow continues to be the clear market leader in developing clinically useful AI-powered tools for non-invasive diagnostic testing for coronary artery disease. What's more, we continue to support clinicians by providing an overwhelming body of clinical evidence attesting to their utility and accuracy," said Campbell Rogers, M.D., F.A.C.C., Chief Medical Officer of Heartflow. "With the addition of the REVEALPLAQUE data, we're pleased to highlight that we are the only platform that has conducted and published a head to head comparison vs. IVUS using the most rigorous approach possible. Our plaque assessment technology is highly accurate, giving clinicians confidence in the product to support their clinical decision making."

The Heartflow Plaque Analysis technology is an automated method which analyzes coronary computed tomography (CT) scans and enables clinicians to visualize, characterize, and quantify plaque. The plaque technology is based on Heartflow's proprietary deep learning-enabled algorithms, which have been trained on more than 15 million coronary CT images. This critical information is delivered seamlessly to physicians in the Heartflow platform, and when paired alongside anatomy and physiology of the patient, enhances decision-making for the clinician. Heartflow's Plaque Analysis is FDA cleared and is commercially available. Heartflow has been adopted by over 1,000 institutions globally and continues to strengthen its commercial presence to make cutting-edge solutions more widely available to an increasingly diverse patient population worldwide.

About Heartflow, Inc.

Heartflow is transforming precision coronary care with the only AI-powered non-invasive integrated heart care solution across the CCTA pathway. As the pioneer of FFR_{CT}, which is now supported by the ACC/AHA Chest Pain Guideline, Heartflow continues to advance the diagnosis and management of CAD. Heartflow's suite of non-invasive technologies includes its FFR_{CT} Analysis,

Roadmap™ Analysis and Plaque Analysis. To date, more than 500 peer-reviewed publications have validated our approach and, more importantly, our technologies have helped clinicians diagnose and manage over 250,000 patients. For more information, visit www.Heartflow.com.

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References

[1] Narula et al. Prospective Deep Learning-based Quantitative Assessment of Coronary Plaque by CT Angiography Compared with Intravascular Ultrasound EHJ 2024.

[2] CDC.org

[3] Wang et al. JAHA 2020