



Heartflow FFRCT Analysis Receives Regulatory Approval in Japan

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REDWOOD CITY, Calif. – Nov. 17, 2016 – [Heartflow Inc.](#) has announced the approval of its Heartflow® FFR_{CT} Analysis by the Japanese Ministry of Health, Labour and Welfare (MHLW). The Heartflow FFR_{CT} Analysis is the only non-invasive technology to deliver insights on both the extent of a coronary blockage and any impact the blockage has on blood flow to the heart, aiding clinicians in selecting an appropriate treatment.

Also commercially available in the United States, Europe and Canada, the innovative technology has been proven to reduce the need for invasive and costly procedures to diagnose patients suspected of having coronary artery disease. It has the potential to positively impact a significant patient population in Japan, where heart disease is the second leading cause of death and coronary artery disease accounts for approximately half of these deaths.¹

"The MHLW's approval of the Heartflow FFR_{CT} Analysis is another important milestone for Heartflow and will give physicians in Japan a new tool to determine the optimal treatment for patients with cardiovascular disease," said John H. Stevens, M.D., chairman and CEO of Heartflow. "With our commercial release in Japan, we expand our ability to help more clinicians diagnose cardiovascular disease non-invasively while reducing unnecessary invasive catheterizations and saving costs."

The Heartflow FFR_{CT} Analysis is a web-based platform that aids clinicians in diagnosing coronary artery disease, and provides personalized, actionable information to physicians to manage each patient. The technology solves millions of complex equations simulating blood flow in the coronary arteries to provide mathematically computed fractional flow reserve (FFR_{CT}) values. The result is a personalized color-coded model of the patient's coronary arteries that aids physicians in determining, vessel-by-vessel, if sufficient blood is reaching the heart.

"We are very pleased that the MHLW has approved the novel Heartflow FFR_{CT} Analysis," said Takashi Akasaka, M.D., Ph.D., Professor of Medicine, Department of Cardiovascular Medicine, Wakayama Medical University. "Having used the technology as part of clinical studies at our facility, we believe it has the potential to profoundly impact the way we care for cardiovascular patients in Japan."

About Heartflow Inc.

Heartflow, Inc. is a personalized medical technology company seeking to transform the way cardiovascular disease is diagnosed and treated. The company's Heartflow FFR_{CT} Analysis is the first available non-invasive solution that enables a physician to more accurately evaluate whether a patient has significant coronary artery disease (CAD) based on both anatomy and physiology. The novel solution, which produces a model of the patient's coronary arteries, is well positioned to become an integral part of the standard of care for patients who are at risk for CAD because of its potential to improve clinical outcomes, improve the patient experience and reduce the cost of care. The Heartflow Analysis is commercially available in the United States, Canada, Europe and Japan. For more information visit www.Heartflow.com.

1. ¹ Iso H. Changes in Coronary Heart Disease Risk Among Japanese. Circulation. 2008;118:2725-2729