

Infraredx, a Nipro Company, Announces FDA Approval of Expanded Label Claim for the Makoto™ Intravascular Imaging System

The label claim expands usage guidelines to include identification of patients and plaques at increased risk of major adverse cardiac events (MACE)

BURLINGTON, Mass., April 22, 2019 -- Infraredx, a Nipro Company, a pioneer in intravascular imaging for mapping coronary artery disease, announced today that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to expand the indications for use for its Makoto™ Intravascular Imaging System. The approval is based on the results of the landmark Lipid-Rich Plaque (LRP) Study, which demonstrated the ability of intravascular ultrasound (IVUS) and near-infrared spectroscopy (NIRS) technology to identify patients and coronary plaques at an increased risk for major adverse cardiac events (MACE).

The study, which enrolled 1,563 patients from 44 sites across the U.S. and Europe, utilized IVUS+NIRS technology to assess patient and plaque lipid core burden index (LCBI) in stable and unstable patients requiring an angiogram procedure for new or ongoing cardiac symptoms. LCBI is validated as a quantitative summary metric of the lipid core in a scanned or selected region. The system utilizes NIRS to detect lipid core plaque (LCP) and automatically displays the results via a simple, color-coded map, called a chemogram. The system automatically generates LCBI calculations and the chemogram, which displays the presence of LCP in yellow and absence in red.

Results released at the 2018 Transcatheter Cardiovascular Therapeutics (TCT) conference showed that patients with a maxLCBI_{4mm} (The maximum LCBI value of any 4mm section of a scanned or selected region) greater than 400 were at 87 percent higher risk of non-index culprit lesion related MACE than a patient with a lesser maxLCBI_{4mm}. In addition, study results found that the risk of non-index culprit lesion related MACE in a coronary segment with a maxLCBI_{4mm} greater than 400 is more than 4-fold higher than in a segment with a lesser maxLCBI_{4mm}.

“We are very proud of this new milestone that expands the indication for use of the Makoto™ Imaging System and accompanying Dualpro™ IVUS+NIRS catheter to detect both plaques and patients at high risk for dangerous cardiovascular events,” said Nozomu Fujita, President and CEO of Infraredx, a Nipro Company. “IVUS+NIRS imaging has the power to transform the imaging world as we know it and we hope that its use will help predict and prevent heart attacks.”

Ron Waksman, MD, Associate Director of the Division of Cardiology at MedStar Heart Institute, Director of Cardiovascular Research and Advanced Education at the MedStar Heart and Vascular Institute, and the Principal Investigator of the Lipid-Rich Plaque Study, said, “These expanded FDA label claims are evidence based on the NIRS imaging technology that was demonstrated in the landmark Lipid-Rich Plaque Study. The study demonstrated that NIRS imaging can identify both patients and non-culprit lesions at risk for subsequent events. These label claims are an important and exciting milestone for the technology and the physicians who have access to the NIRS technology. This carries important information for patients and physicians.”

Antonio Colombo, MD, Maria Cecilia Hospital in Cotignola (Ravenna), General Coordinator GVM Hospitals and Columbus Hospital in Milan, Italy, stated, “The Makoto Imaging System significantly advances the field of intracoronary imaging. We are already successfully employing the System at our hospital and collecting key insights from the chemogram information it provides. The information we receive from the system helps to make more personalised treatment decisions for my patients.”

Gregg W. Stone, MD, Director of Cardiovascular Research and Education at New York Presbyterian Hospital/Columbia University Medical Center and the Cardiovascular Research Foundation in NY, USA, and Principal Investigator of the ongoing PROSPECT II Study, said, “The new FDA indication for NIRS for identification of patients and plaques at increased risk of major adverse cardiac events is a landmark achievement. The emerging data that this imaging technology can identify dangerous plaques that may suddenly progress should enable development of new therapeutic approaches to improve the prognosis of these high-risk patients.”

Infraredx, a Nipro Company, launched the Makoto™ Imaging System in Japan in 2018 and will continue expansion into the US and EU markets.

About Infraredx, a Nipro Company

Infraredx, Inc., a Nipro company, is advancing the diagnosis and management of coronary artery disease by providing cardiologists with the most precise imaging tools required to predict and ultimately prevent heart attacks. Infraredx is dedicated to advancing this important field of research and conducting landmark clinical trials to transform how we view and treat heart disease. For more information about the Lipid-Rich Plaque Study, please visit <https://www.infraredx.com/lrp> and connect with Infraredx on [Twitter](#) and [LinkedIn](#).

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