

New imaging device for the detection of lipid core-containing plaques

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A new device for the detection of lipid core-containing plaques called a Catheter-based LipiScan™ Coronary Imaging System manufactured by InfraReDx has received 510(k) clearance from the U.S. Food and Drug Administration on 29 April 2008.

The LipiScan device uses near-infrared spectroscopy to identify lipid core-containing plaques of interest in the coronary arteries in patients already undergoing cardiac catheterization. Such plaques, which cannot be detected by commonly-used tests such as a treadmill examination or even coronary angiography, are suspected to be the cause of most sudden cardiac deaths and non-fatal heart attacks.

The InfraReDx LipiScan Imaging System uses infrared imaging to detect lipid core-containing plaques of interest and assess a patient's coronary artery lipid core burden index. The LipiScan Coronary Imaging System is a catheter-based device that uses laser light to detect how much fat and other substances are contained in a plaque.

Near infrared (NIR) diffuse spectroscopy is a technique based on the absorption of light in the NIR spectrum, in a specific manner, by organic molecules. NIR spectroscopy has demonstrated the ability to identify plaques with lipid pools through blood [1].

The device works by placing a catheter equipped with a fiber-optic laser into the artery. The device shines the near infrared light through the blood to the artery wall and measures the light reflected back from it, a technique called spectroscopy. The reflected wavelengths vary depending on how much fat and other substances are in the plaque in the illuminated portion of the wall.

The identification of the chemicals present is based on the differential absorption of light in the NIR spectrum by different molecules. An important feature of near-infrared light is that it can penetrate tissue and can therefore identify a tissue despite the presence of blood between the detector and the target. This is an important advantage for imaging within the human coronary artery.

The system consists of a laser light source, an automated pullback and rotation device and a small fiber-optic catheter. While the catheter is similar in size and ease of use to an intravascular ultrasound catheter, the information it provides is quite different since it is based on an optical rather than an ultrasonic signal (Fig. 1).

The NIR system obtains signals from patients that are analyzed with algorithms validated by comparison to tissue histological findings in ex-vivo coronary specimens. It is therefore possible to perform a pullback in a patient's artery and provide an image of the NIR signals which indicate the presence of lipids and other chemicals of interest. It is expected that these images, which are called Intravascular Chemograms™, will provide information for interventional cardiologists to help in the care of patients already undergoing cardiac catheterization for coronary events. The identification of the chemical composition of coronary plaques is of value to cardiologists in the selection of medical, stenting or surgical therapy for coronary lesions. The device is also expected to be of value to the pharmaceutical industry as a means to assess the effect of novel anti-atherosclerotic agents on lipid core plaque burden.

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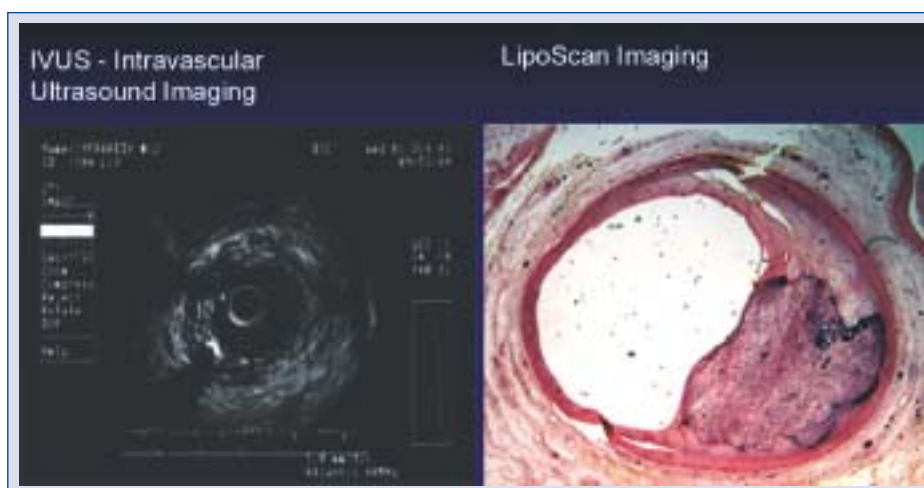


Figure 1. Comparison of intravascular to near-infrared plaque imaging.

The initial use of the InfraReDx device will be for diagnosis, which will help in prevention of a second coronary event in the approximately 2 million individuals world-wide who undergo a coronary intervention each year.

References

1. Moreno PR, Lodder RA, Purushothaman KR et al. Detection of lipid pool, thin fibrous cap, and inflammatory cells in human aortic atherosclerotic plaques by near-infrared spectroscopy. *Circulation*, 2002; 105: 923–927.