



FOR IMMEDIATE RELEASE

## **First Use in a Patient of The InfraReDx LipiScan™ Coronary Imaging System**

*Excellent results obtained with a newly cleared device to identify the lipid core (fatty) coronary plaques of interest that are associated with complications of coronary stenting*

**BURLINGTON, Mass., May 15, 2008** - InfraReDx, Inc. today announced that physicians at Beaumont Hospital in Royal Oak, Mich., have successfully used its *LipiScan™ Coronary Imaging System* in a patient undergoing a cardiac catheterization. This is the first patient in the world in whom it has been possible to assess the chemical composition of coronary artery plaques and utilize such information to assist in the management of coronary artery disease.

Dr. Daniel Schultz, Director of the FDA Center for Devices and Radiological Health, has stated, "This is the first device that can help assess the chemical make-up of coronary artery plaques and help physicians identify those plaques with lipid cores, which may be of particular concern."

Physicians at Beaumont Hospital performed the procedure on May 8, 2008 in a 70-year old male patient. The LipiScan System revealed the presence of a lipid core containing plaque not detectable by conventional diagnostic measures. This fatty plaque was located near a narrowing that required a coronary stent for the usual reasons. Because of the presence of this plaque, the physicians selected a stent that was 50 percent longer than the one that would have been used to cover the narrowing only. This longer stent covered the lipid core containing plaque and avoided placing the end of a shorter stent in the fatty plaque. Termination of a stent in a fatty plaque has been associated with clotting of the stent years after placement.

"If doctors can identify these fatty plaques, we can recommend better treatment options to patients," says Simon Dixon, M.D., director of the cardiac catheterization laboratories and co-director of cardiac research at Beaumont, Royal Oak. "This information tells us immediately what length of stent (tiny mesh "scaffold" to hold an artery open) to use and where to place it in patients with severe narrowings. Based on further research, this novel device may help determine which type of stent – bare metal or drug-eluting – is best for the patient."

The [U.S. Food and Drug Administration](#) approved The LipiScan Coronary Imaging System in late April.

### **First patient case to be presented at EuroPCR Conference this week**

The results of the first use in patients of this system will be presented by Drs. Renu Virmani, M.D. and Gregg Stone, M.D. at the [EuroPCR conference](#) taking place this week in Barcelona, Spain from May 13-16, 2008.

### **About The LipiScan Coronary Imaging System**

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. The identification of the chemical composition of coronary plaques is expected to be 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.

"The InfraReDx team is pleased that the LipiScan Coronary Imaging System has been validated in tissue samples and a clinical study and has been cleared by the FDA for use in patients. We understand the great potential of interventional cardiology and anticipate that this novel tool will assist physicians with the complex decisions they face in the management of patients with coronary artery disease," says James E. Muller, M.D., cardiologist, co-founder, President and CEO of InfraReDx, Inc.

Dr. Muller noted that the creation of this novel device was greatly aided by the support and expertise of Sanderling Ventures of San Mateo, California. "Robert McNeil, Ph.D., Chairman of the Board of InfraReDx, and Timothy Mills, Ph.D., InfraReDx Board member are managing directors of Sanderling and both have extensive experience in medical device development," said Dr. Muller. "Sanderling was a seed investor in Advanced Cardiovascular Systems, a company that pioneered development of balloon angioplasty and was acquired by Guidant. With the development of the LipiScan Coronary Imaging System, Sanderling is again contributing to a major step forward in providing a useful tool with which interventional cardiologists may improve the care of cardiac patients."

"There is a real unmet medical need to identify lipid core containing plaques of interest in the coronary arteries, which before now we could not do," says James Goldstein, M.D., an interventional cardiologist and consultant to InfraReDx. "The ability to detect lipid core containing plaques of interest may go a long way in providing information to help prevent heart attacks in the near future."

Coronary artery disease, which causes heart attacks and chest pain, is the single leading cause of death in America, according to the web site for the American Heart Association. It accounts for one of every five deaths in America.

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### **About InfraReDx, Inc.**

InfraReDx, Inc. is a science-based medical device company with expertise in near-infrared spectroscopic (NIRS) technology and its application to coronary imaging. The company,

located in Burlington, Mass., was founded in 1998 to meet the unmet medical need for detection and identification of lipid core containing plaques of interest in the coronary arteries. For more information, visit the InfraReDx website at [www.infraredx.com](http://www.infraredx.com).

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