

## Volcano Corporation Announces FDA Clearance of the Revolution™ 45 MHz IVUS Imaging Catheter -- Novel Design will Allow Use of Phased Array and Rotational Catheters on Same IVUS Console

**Rancho Cordova, CA, October 12th, 2005** -- Volcano Corporation is pleased to announce the FDA clearance of the Revolution™ 45 MHz IVUS Imaging Catheter. The Revolution™ is Volcano's newest state-of-the-art IVUS imaging catheter, incorporating a rotating 45 MHz imaging core, housed inside of a protective sheath. Volcano is the only company with FDA clearance of both a rotational IVUS catheter and a digital phased array IVUS catheter.

The Revolution Catheter has a center operating frequency of 45 MHz, making it the highest frequency intravascular catheter approved for sale in the U.S. The Revolution is built on intellectual property and technology recently licensed and acquired from Philips NV of The Netherlands. Volcano expects this imaging technology will appeal to a number of physicians who have trained using high frequency rotating IVUS imaging catheters. The Revolution also incorporates enhanced polymer transitions for improved handling and trackability, RFID chip technology for catheter data transfer, and a reinforced telescoping region for more reliable performance and reduced peri-procedural catheter failure and breakage.



**Figure 1: Schematic of Revolution™ 45 MHz IVUS Imaging Catheter**

The Revolution is designed to function on Volcano's existing IVUS imaging systems, the In-Vision Gold (IVG) family of IVUS consoles. This bi-modal capability (the ability to run either digital phased array or single element rotational catheters on the same system) will be unique in the industry - and provides IVG owners with un-matched flexibility.

### **SpinVision™: A New, Streamlined Automatic Pull-back Device**

The SpinVision Automatic Pull-Back device has been submitted to the FDA for review. It includes a new pullback device and motor drive called the SpinVision PIMr, which will enable the Revolution catheter to operate at 45 MHz on the IVG. The SpinVision pullback device will allow a full 15 cm pullback to be performed automatically. This system may also be operated in manual mode. The SpinVision uses an optical encoder to relay precise, absolute position information to the IVG console, and should enable physicians to assess lesion and stent lengths with unmatched simplicity and accuracy. The pullback device will be a reusable system and requires only a single sterile bag for each use, lowering costs and reducing waste.



**Figure 2: Photo of SpinVision PIMr Automatic Pull-Back Device**

Revolution catheters and SpinVision Pull-back devices will be on display and available for demonstration in Volcano's exhibition booth at the 17th Annual Transcatheter Cardiovascular Therapeutics (TCT) conference in Washington DC, October 17th to October 19th, 2005. Come see us at booth #314. The addition of a high frequency, sheathed rotating IVUS catheter to our product line, combined with other key advances announced yesterday - such as the release of Version 1.4 of VH IVUS - and throughout the rest of this week, demonstrate Volcano's commitment to innovation in the field of interventional imaging.

#### **Comments from Leading Interventional Cardiologists**

The Revolution product family is undergoing validation testing as a prerequisite to full market launch. Peter Fitzgerald, M.D., Ph. D., Professor of Medicine and Engineering at Stanford University commented, "The Revolution represents a second entrant into the high frequency IVUS catheter market. Having multiple companies in this space will further promote innovation and solidify the presence of valuable IVUS technology moving forward. I have had the opportunity to use and observe the Revolution catheter during its development and testing phase and am extremely impressed with the image quality, catheter handling, performance and pull-back design."

Gary S. Mintz, MD, Director, Publications and Editorial Services of the Cardiovascular Research Foundation, NY, NY, commented, "Since I was involved with a related high frequency IVUS catheter project several years ago, I am intimately familiar with the advantages and design challenges involved with bringing a catheter like this through the development and testing process. My initial impression of the Revolution 45 MHz catheter is that it should provide very high quality images and is likely to be well received by the physician community. This project reflects Volcano's focus to provide advanced products which are designed with the physician and cath lab staff in mind."

#### **Company Comments**

Scott Huennekens, CEO of Volcano Corp commented "The Revolution catheter emphasizes Volcano's commitment to innovation in the field of IVUS imaging. Our goal is to provide our physician partners with a choice in IVUS catheters -- including fast, easy-to-use phased array catheters and high frequency, single element rotational catheters -- so that they may decide which technology is most appropriate for each individual patient." He continued, "This announcement does not represent a change in direction or focus for our company. Volcano will continue to invest heavily in our digital phased array product lines, as well as our groundbreaking VH™ IVUS technology. The Revolution is just another example of our core competency in intravascular imaging and our ability to innovate and quickly make new technologies available to physicians."

## **About Volcano Corporation**

Volcano Corp. is a privately held medical device company founded in 2001. With over 475 worldwide employees, Volcano is dedicated to providing technologies leading to optimal management of coronary artery and peripheral vascular disease. Volcano products include Intravascular Ultrasound (IVUS) systems and catheters, as well as physiology guide wires. With global distribution, Volcano is a leading provider of innovative therapy-enabling and therapy-guiding technologies to the interventional cardiology and peripheral vascular fields. For more information, please visit [www.volcanocorp.com](http://www.volcanocorp.com).

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