



TERUMO INTERVENTIONAL SYSTEMS

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**FOR IMMEDIATE RELEASE**

**TERUMO TO SIMULTANEOUSLY EVALUATE MISAGO SELF-EXPANDING STENT SYSTEM IN THE UNITED STATES AND JAPAN**

*Precedent-setting Clinical Trial is Part of Harmonization by Doing Trial Pilot*

**SOMERSET, NJ** (May 12, 2010) – Terumo Medical Corporation, a U.S.-based subsidiary of Terumo Corporation, today announced it has received an investigational device exemption (IDE) conditional approval from the U.S. Food & Drug Administration (FDA) for its *Occlusive/Stenotic Peripheral Artery Revascularization Study* (OSPREY) in the U.S., which will evaluate the safety and effectiveness of the MISAGO™ Self-expanding Stent System for use in the superficial femoral artery (SFA). This marks the company's first U.S. clinical trial for a premarket approval (PMA) device. A unique feature of the clinical trial is that it will simultaneously enroll patients in the U.S. and Japan. Referred to as "Medical Device Collaborative Consultation and Review of Premarketing Applications" under the larger "Harmonization by Doing" (HBD) initiative, Terumo's trial was selected as one of two projects to pilot this approach, which is intended to shorten the gap between product approvals in these two significant world healthcare markets.

HBD is an international effort to develop global clinical trials and address regulatory barriers that may be impediments to timely device approvals. This process is a cooperative effort to move both Japan and the U.S. toward international regulatory harmonization. The HBD initiative is a pilot project launched in December 2003 that seeks regulatory convergence between FDA and MHLW-PMDA (Japan's regulatory bodies). The learning obtained in the "proof of concept" trials will assist both regulatory bodies in streamlining the clinical trial process for faster approvals in both countries, as well as promote the idea of global trials for purposes of collecting better data. In this pilot HBD approach, the products will be submitted for review and approval at the same time.

"I believe this approach to shorten the time for new product approvals between the U.S. and Japan is critical and exciting," said Takao Ohki, MD, Chairman and Professor, Department of Surgery, Jikei University School of Medicine, Division of Vascular Surgery, and the global principal investigator of the OSPREY trial. "This innovative movement could dramatically solve the current device lag issue between our countries."

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In the U.S., OSPREY is a single-arm, multi-center, non-randomized prospective clinical trial for the treatment of atherosclerotic stenoses and occlusions of the SFA. In Japan, there are two arms of the study, 50 patients receiving the MISAGO Stent and 50 patients receiving percutaneous transluminal angioplasty (PTA).

The primary endpoints of the U.S. study are:

- Primary stent patency rate at one year as confirmed by duplex ultrasound or angiography.
- Freedom from major adverse events within 30 days of the procedure, which would result in target lesion revascularization, amputation of the treated limb or death.

The study will include up to 350 patients, a maximum of 250 patients in up to 30 centers in the U.S. and 100 patients in Japan. There have already been six patients enrolled in Japan, which received regulatory approval to begin the trial last year. The first U.S. enrollments are expected in June 2010. The U.S. principal investigator is J. Fritz Angle, MD, Associate Professor of Radiology, University of Virginia.

“Peripheral vascular disease management continues to be a major clinical problem,” said Dr. Angle. “We need better tools to improve revascularization of femoral-popliteal vessels. I applaud Terumo's efforts to advance this field.”

The MISAGO Self-expanding Stent consists of a nitinol stent pre-mounted on the distal portion of a rapid-exchange delivery catheter system. The stent has three radiopaque markers located on each end of the stent to help ensure accurate placement in the lesion. The stent is currently available for sale in Europe.

“We are eager to move forward with the first harmonized clinical trial in the U.S. and Japan,” said Juichi (Jim) Takeuchi, President and CEO, Terumo Medical Corporation. “We are not only proud of the MISAGO Stent, but also of Terumo’s selection to participate in this precedent-setting international collaborative effort between regulators, industry, clinical researchers, patients, and academia. We look forward to initiating our first PMA clinical trial in the United States and to bringing innovative new interventional technology to market to improve patients’ quality of life.”

For more information, customers can contact Tamera Barry-Lawal, Terumo Project Manager, at 732.302.4955.

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### **Terumo Interventional Systems**

Terumo Interventional Systems (TIS), a strategic business unit of Terumo Medical Corporation, directly markets a full line of guidewires, catheters, introducer sheaths, guiding sheaths and embolization products for use in a multitude of different interventional procedures.

Interventional Radiologists, Interventional Neuroradiologists, Interventional Cardiologists, and Vascular Surgeons are among the medical professionals that depend upon TIS products to access and cross difficult-to-reach lesions, thereby allowing therapeutic intervention in previously unreachable vascular beds.

### **Terumo Medical Corporation**

Founded in 1972 as a Terumo Corporation subsidiary, Terumo Medical Corporation (TMC) develops, manufactures, and markets high-quality medical devices used in a broad range of applications in numerous healthcare markets. TMC manufactures a broad portfolio of needles and syringes, entry-site management products, and a line of sterile connection devices used in hospitals and blood banks worldwide.

### **Terumo Corporation**

Tokyo-based Terumo Corporation is one of the world's leading medical device manufacturers with \$3.0 billion in sales and operations in more than 160 nations. Founded in 1921, the company develops, manufactures, and distributes world-class medical devices including products for use in cardiothoracic surgery, interventional procedures, and transfusion medicine; the company also manufactures a broad array of syringe and hypodermic needle products for hospital and physician office use. Terumo contributes to society by providing valued products and services to the healthcare market and by responding to the needs of healthcare providers and the people they serve. Terumo Corporation's shares are listed on the first section of the Tokyo Stock Exchange (No. 4543, Reuters symbol <4543.T>, or Bloomberg 4543: JP) and is a component of the Nikkei 225, Japan's leading stock index.

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