



NEWS RELEASE FOR May 31, 2011 at 10:00 am EDT

FINAL PUBLISHED TRIAL DATA IN *THE LANCET* SUPPORTS SAFETY AND EFFECTIVENESS OF MICROVENTION-TERUMO'S HYDROCOIL® EMBOLIC SYSTEM FOR TREATMENT OF CEREBRAL ANEURYSMS

*International Clinical Trial Results Show Statistically Significant Angiographic Reduction in Major Recurrence Rates with the HydroCoil Embolization System*

TUSTIN, CA. – May 31, 2011 – MicroVention-Terumo, Inc., a leader in developing, manufacturing and marketing interventional neurovascular devices, announced today the final 18-month follow-up data in a landmark international study. The HydroCoil® Endovascular Aneurysm Occlusion and Packing Study (HELPS) published in *The Lancet*, showed that the HydroCoil Embolic System for treating cerebral aneurysms reduced recurrence and retreatment rates and provided improved outcomes in study patients when compared to bare platinum coils. A cerebral aneurysm is an abnormal, weakened area on the wall of a blood vessel in the brain that causes it to bulge or balloon out. If a cerebral aneurysm ruptures, it can cause a hemorrhagic stroke, a serious medical condition, which can lead to brain damage and death.

HELPS was a prospective, randomized controlled trial that compared the results from the HydroCoil system to results from bare platinum coils. The 500-patient, independently-run, multicenter, multinational 18-month trial was the first comparative adjudicated study completed since the International Subarachnoid Aneurysm Trial (ISAT) was presented in 2002. HELPS results were published in the prestigious journal, *The Lancet*, by the lead author and primary investigator, Philip White, M.D., of Western General Hospital in Edinburgh, Scotland.

“Our study shows that the non-invasive techniques for treating brain aneurysms are getting better. Hydrogel coated coils offer an improved treatment for ruptured aneurysms and coiling has a faster recovery than having to have brain surgery and come with less risk as well, which is great news for the thousands of people affected by this condition each year,” said Dr. White.

HELPS Trial results showed that the HydroCoil system, based on a microporous expandable hydrogel, proved to be a more stable solution for endovascular occlusion of aneurysms than bare platinum. The HydroCoil implant is a non-bioactive coil that combines platinum with an expanding hydrogel polymer which provides the features of greater aneurysm volume filling with biologically inert material for natural tissue proliferation.

Angiographic results from an independent core lab indicated there was a statistically significant decrease (8.6%) in major aneurysm recurrence with the HydroCoil system arm as compared to bare platinum control arm. Aneurysms in the trial ranged in size from 2 mm to 25 mm, and 84% of all aneurysms were medium and large in size.

Key results of the trial demonstrated:

- HydroCoil implants had statistically significant more stable angiographic results with a significant decrease in major remnant/recurrence rates.
- The primary composite endpoint, while neutral, showed a strong trend favoring the HydroCoil Embolic System.

- There was a very low retreatment rate: 3% HydroCoil system arm vs. 4% bare platinum control arm.
- The effect of the HydroCoil system on outcomes was superior in ruptured aneurysms: 68% HydroCoil implants vs. 50% bare platinum implants.
- The HydroCoil system had less thromboembolic complications: 5.6% vs. 10% with bare platinum<sup>1</sup>.
- HydroCoil implants resulted in a higher packing density with less coil length (reduction of 20%<sup>1</sup> as compared to bare platinum) due to its expansion properties: 63.9% for HydroCoil implants and 23.2% for bare platinum implants.
- Outcomes were superior when the targeted amounts of HydroCoil implants were achieved in aneurysms ( $\geq 50\%$  HydroCoil implant length per protocol).

“We are very pleased with the exceptional results from this landmark trial. It continues to validate findings from previous multi-center and single-center trials, which is that the HydroCoil system provides excellent results in reducing aneurysm recurrence and retreatment in a wide range of cerebral aneurysms as compared to bare platinum coils,” said Richard Cappetta, President and Chief Executive Officer of MicroVention-Terumo.

Procedural safety and efficacy results for HELPS, previously published in 2008, found that the HydroCoil system can be safely used in a wide spectrum of aneurysms with a risk profile equivalent to that of bare platinum coils<sup>1</sup>.

“MicroVention-Terumo is dedicated to clinical research and studies that focus on the science of interventional neuroendovascular surgery. Having the results of this important study published in a journal as prestigious as *The Lancet* is a real testament to the outstanding work and dedication of Dr. White and all of the HELPS collaborators,” Mr. Cappetta added.

Since the HELPS patient enrollment was completed in February 2007, MicroVention-Terumo has continued to innovate the HydroCoil line of coils, including the HydroSoft® finishing coil for filling small spaces that provides hydrogel at the neck of the aneurysm, and the HydroFrame® framing coil that provides optimal framing of the aneurysm with the clinical benefits of hydrogel.

The trial was based in the United Kingdom and managed by the Lothian Health Board with support from UK’s National Health Service. A total of 24 worldwide medical centers participated. The Core Lab that independently reviewed the results was Centre Hospitalier de l’Université de Montréal (CHUM) in Montreal, Quebec, Canada.

### **About the HydroCoil Embolization System**

The HydroCoil Embolic System is a unique non-bioactive endovascular embolization device combining the Company’s platinum microcoil technology with a proprietary hydrogel. The hydrogel polymer is a biomaterial that begins to swell after a brief period of contact with blood, giving physicians the ability to precisely control delivery of the device. Once the hydrogel swells, it provides improved filling of the aneurysm without exerting pressure onto the aneurysm wall or adjacent coils. The HydroCoil system combines the safety of platinum coils with the filling and mechanical stability of hydrogel. The HydroCoil system offers a therapeutic alternative to the current treatment choices of platinum coils and neurosurgical clipping, and is also being used clinically to treat fistula and peripheral vascular lesions.

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<sup>1</sup> White PM, Lewis SC, Nahser H, et al. **HydroCoil Endovascular Aneurysm Occlusion and Packing Study (HELPS Trial): Procedural Safety and Operator-Assessed Efficacy Results.** *AJNR Am J Neuroradiol* 2008 Feb;29 (2) 217-223

**About MicroVention-Terumo, Inc.** MicroVention-Terumo ([www.microvention.com](http://www.microvention.com)) develops innovative neuroendovascular technologies for the treatment of vascular diseases in small vessels and is committed to developing and manufacturing the highest quality products for its customers and patients. MicroVention products are sold throughout the world in 62 countries. In March 2006, MicroVention merged with Tokyo-based Terumo Corporation, an international manufacturer and provider of general hospital, cardiac, vascular and home healthcare products.

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