

## For Immediate Release

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## PATHWAY MEDICAL TECHNOLOGIES RECEIVES FDA CLEARANCE FOR JETSTREAM™ PATHWAY PV™ ATHERECTOMY SYSTEM

Next-Generation Atherectomy Device Offers Minimally Invasive Treatment for Peripheral Artery Disease; Capable of Treating Hard and Soft Plaque, Calcium, Thrombus and Fibrotic Lesions with Predictable Results

KIRKLAND, WA—September 5, 2008—Pathway Medical Technologies, Inc., an innovator of endovascular treatments for peripheral arterial disease (PAD), today announced that the U.S. Food & Drug Administration (FDA) has given the company clearance to market Jetstream<sup>TM</sup>, a peripheral atherectomy catheter designed for use in the treatment of PAD in the lower limbs. The clearance marks the company's second 510(k) clearance and the first device on the market capable of treating an entire spectrum of disease found in the PAD patient, including hard and soft plaque, calcium, thrombus and fibrotic lesions with consistent clinical results.

Pathway Medical Technologies President and CEO Tom Clement commented, "The market introduction of Jetstream<sup>TM</sup> represents a major business milestone for our organization and a dramatic new treatment option for the endovascular community in fighting PAD. We expect the device to provide interventionalists with the clinical versatility they seek, while providing patients suffering from peripheral arterial disease with more predictable outcomes. Jetstream<sup>TM</sup> is truly the next logical evolution in atherectomy."

Approximately 12 million Americans suffer from the effects of PAD and many in this rapidly expanding patient population go undiagnosed. Commonly associated with high blood pressure, diabetes, heart disease, stroke and aging, PAD causes a build-up of plaque within the arteries that limits blood flow to the extremities. PAD can lead to severe limb pain, non-healing ulcers and critical limb ischemia and, if left untreated, can lead to gangrene, amputation and even death. The most common intervention for PAD has historically included highly-invasive procedures, including bypass surgery. Unfortunately, many patients are poor surgical candidates for whom surgery can be life threatening.

Jetstream<sup>TM</sup> represents an innovative and minimally invasive solution to clear blockages in the peripheral vasculature, restoring blood flow and effectively treating PAD. Jetstream<sup>TM</sup> consists of a sterile, single-use catheter and control pod and a reusable, compact console that mounts to a standard I.V. stand. The catheter has an expandable cutting tip with rotating blades that safely debulk and preemptively remove both hard and soft plaque, as well as calcium, thrombus and fibrotic lesions. Excised tissue and thrombus are continually aspirated from the peripheral treatment site through ports in the catheter tip to a collection bag located on the console. The distal portion of the catheter also possesses infusion ports that provide continuous infusion of sterile saline during the atherectomy procedure. Active aspiration is a safety feature that minimizes the risk of distal embolization.

According to William A. Gray, M.D., director of endovascular services, Center for Interventional Vascular Therapy, New York-Presbyterian Hospital, "Clinical data suggests that Jetstream<sup>TM</sup> is quite effective at debulking and treating vascular disease in the peripheral vasculature. I have seen the efficacy of the Pathway technology first hand in several cases in Germany and look forward to treating future atherectomy candidates."

With simple set up and an ergonomic design for easy operation by trained clinicians, Jetstream<sup>TM</sup> maximizes treatment effectiveness with an average device activation time of about three and a half minutes during atherectomy treatment. For patients, Jetstream<sup>TM</sup> offers renewed hope for non-surgical candidates and the benefits of a minimally invasive treatment option, including faster recovery and decreased systemic complications.

Jetstream<sup>TM</sup> delivers several cosmetic and user interface improvements from the company's first-generation product, the Pathway PV<sup>TM</sup> Atherectomy System, which was used in the company's Pathway PVD Study, a pivotal 172 patient European multi-center clinical trial completed in Germany at three primary centers: Abteilung Angiologie in Bad Krozingen, Germany, Hamburg University Cardiovascular Center in Hamburg, Germany, Clinical and Interventional Angiology, Heart Center-University of Leipzig in Leipzig, Germany.

## About Pathway Medical Technologies, Inc.

Pathway Medical Technologies, Inc. was founded to design, market and manufacture medical devices for the treatment of arterial disease. The company's initial focus is treating peripheral arterial disease (PAD) more quickly and effectively than existing technologies. An estimated 12 million people are afflicted by PAD in the U.S. and that number is projected to grow to over 20 million during the next 10 years. The company's Jetstream<sup>TM</sup> device allows for a minimally invasive procedure designed to restore circulation in the peripheral arteries by removing both hard and soft diseased tissue. For further information, visit the company's Web site at <a href="https://www.pathwaymedical.com">www.pathwaymedical.com</a>.

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