ICU
MANAGEMENT & PRACTICE

ZOLL Acquires Assets of Coaxia, Inc. - Expands Acute Critical Care Portfolio

ZOLL Medical Corporation, a manufacturer of medical devices and related software solutions, announced today that it has purchased the assets of CoAxia™, Inc., of Maple Grove, Minn., an early revenue stage medical device company that provides catheter-based perfusion augmentation therapies to improve outcomes for patients with cerebral ischemia resulting from vasospasm, following subarachnoid hemorrhage.

The acquisition of intellectual property also includes several key patents on cerebral perfusion augmentation as well as numerous other patents relevant to other various vascular procedures.

The core application for CoAxia's catheter technology, under the trade names NeuroFlo™ and FloControl™, involves the redistribution of blood flow from the lower extremities to support brain function during ischemia. These devices also offer significant potential applications in blood flow redistribution for trauma, cardiac arrest, coronary procedures, surgical blood loss, and renal perfusion.

NeuroFlo and FloControl have regulatory clearances and reimbursement in the United States. NeuroFlo has received Humanitarian Device Exemption approval from the U.S. Food and Drug Administration (FDA) for use in patients with vasospasm following subarachnoid hemorrhage. FloControl has also received 510(k) clearance for stopping and controlling blood flow in the peripheral vasculature.

NeuroFlo and FloControl blood flow redistribution technology uses dual balloons to create temporary partial obstruction in the descending aorta. This technique causes a redistribution of cardiac output from the lower extremities to the cerebral vasculature without significantly increasing arterial blood pressure.

The acquisition of CoAxia's intellectual property offers synergy with ZOLL's acute critical care portfolio of products such as temperature management, which may reduce reperfusion injury following ischemia by also using balloon catheters. The use of temperature management in ischemic stroke patients is being studied in several clinical trials ongoing and in development.

"NeuroFlo technology has the potential to address a large portion of the population who suffer cerebral ischemia, offering a significant benefit to patients and the healthcare system," said James Palazzolo, President of ZOLL. "Our task is to continue to develop the significant body of clinical evidence started by CoAxia demonstrating the safety and efficacy of the NeuroFlo catheter and, in the end, do what is necessary for it to be a standard treatment option for hundreds of thousands of stroke patients worldwide."

Palazzolo explained that ZOLL plans to conduct a follow-up to the SENTIS (Safety and Efficacy of NeuroFlo Technology in Ischemic Stroke) clinical trial in the near future. The SENTIS trial did not achieve statistical significance in its primary efficacy end point, but achieved the trial's primary safety endpoint, as well as demonstrated numerous positive signals for both safety and efficacy using the NeuroFlo technology.

The SENTIS trial was conducted at leading stroke centers in North America and Europe to determine if this proprietary method for increasing cerebral blood flow could minimize the damage caused by ischemic stroke and improve outcomes in patients up to 14 hours after the onset of their stroke. ZOLL will work with the leading stroke centers and the US FDA to identify the next steps for the NeuroFlo technology in ischemic stroke.

Source: ZOLL Medical Corporation

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