

Japan approves Zoll's temp management system

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Singapore: Zoll Medical, a manufacturer of medical devices and related software solutions, has received Shonin approval from the Japanese Ministry of Health, Labor and Welfare (MHLW) to enter the Japanese market with its Intravascular Temperature Management (IVTM) technology. It is the first intravascular temperature management system to receive Shonin approval in Japan.

Zoll's IVTM solution will be marketed and sold by Asahi Kasei Zoll Medical, a Zoll company established in August 2012 to pursue the regulatory approval, sale, and marketing of Zoll products in Japan.

Zoll's IVTM technology was approved in Japan for fever control in neurologically injured patients. The intravascular system offers superior temperature control when compared to other cooling methods. Fever is commonly found in both neurologically injured and neurosurgical patients and is associated with poor outcomes. Specifically, moderate fever has been reported to almost double patient mortality, while extremely high fever can triple mortality. Management of the body's core temperature is

key to proper neurological function, especially for patients in neurointensive care.

Zoll's IVTM system provides cooling and warming through a balloon catheter inserted into the venous system. This provides better control of the core body temperature over surface methods by directly cooling or warming the patient's blood as it flows through the body. This catheter is connected to the Thermogard XP console, which circulates cold saline solution inside the catheter. Since the saline flows only within the catheter, no fluid is infused into the patient. Zoll offers a variety of triple-lumen catheters with placement options to handle specific patient challenges. The Zoll IVTM system is efficient, precise, and easy to use, and frees up clinical staff to attend to other patient needs.

"We are very excited to begin commercialization of IVTM in Japan and to continue to offer innovative technologies and devices for critical care to this high-growth market," said Mr James Palazzolo, president of Zoll Sunnyvale operations. "We are now preparing for a clinical trial for therapeutic hypothermia following cardiopulmonary resuscitation, a treatment having a Class 1 recommendation³ from both the American Heart Association and the Japan Resuscitation Council.