ICU
MANAGEMENT & PRACTICE

Abiomed Enrolls First Patient In Percutaneous Heart Pump Study

Abiomed, Inc., a leading provider of breakthrough heart support technologies, announced on April 1, 2013 the enrollment of the first patient in RECOVER RIGHT, an Investigational Device Exemption (IDE) study of Impella® RP (Right Peripheral).

The Impella RP is a percutaneous heart pump that is implanted through a single access site in the patient's leg and deployed through the venous system, across the right side of the heart without requiring a surgical procedure.

The RECOVER RIGHT clinical study, which received FDA IDE approval to begin in November 2012, will enroll 30 patients that present with signs of right side heart failure, require hemodynamic support, and are being treated in the catheterization lab or cardiac surgery suite.

The following two patient cohorts will be examined in the RECOVER RIGHT study:

1. Patients that develop right side heart failure within 48 hours post-left ventricular assist device (LVAD) implantation;
2. Patients that develop right side heart failure subsequent to post-cardiotomy shock within 48 hours post surgery or post myocardial infarction.

The first enrollment in the RECOVER RIGHT study was a patient who developed right ventricular dysfunction after receiving an implantable LVAD. The Impella RP was implanted at Einstein Medical Center Philadelphia under the leadership of Mark Anderson, M.D., FACS, Chair of the Division of Cardiothoracic Surgery at Einstein. The Impella RP implant was performed by Christian Witzke, M.D., Director of the Structural Heart Disease Program and Parul Patel, MD., Director of the Cardiac Catheterization Laboratory at Einstein Medical Center Philadelphia.

"This is another example of how Einstein Healthcare Network is committed to providing the best possible outcomes for patients by conducting clinical trials to assess the safety and probable benefit of innovative technologies such as the Impella RP pump," added Dr. Anderson, who is co-principal investigator of the RECOVER RIGHT study with William O'Neill, M.D., medical director of the Center for Structural Heart Disease at Henry Ford Hospital.

"The Impella RP gave this patient a level of hemodynamic support that allowed our heart failure team to treat the patient's right-sided heart failure quickly in a minimally invasively manner," said Dr. Witzke.

The Impella RP is currently the subject of an investigational device exemption (IDE) clinical study and is not currently approved for sale in the United States.

Source: Abiomed, Inc.

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