

## BiO2 Medical Begins Enrollment for the Pivotal Investigation of the Angel® Catheter

SAN ANTONIO, Feb. 19, 2015 /PRNewswire/ -- Enrollment for The Angel Catheter® Clinical Trial has begun with three patients successfully enrolled. Site Initiation Visits are underway with a goal to include up to 30 U.S. sites in this multicenter, prospective, single arm clinical investigation of the Angel® Catheter. At the successful completion of the study, BiO2 Medical will be seeking a prophylactic indication, the first for an Inferior Vena Cava (IVC) filter.

Dr. Ann Peick, Principal Investigator at Mercy Hospital in St. Louis, Missouri, the first site to enroll patients for the study commented, "We are excited in our participation in this program. I see the Angel® Catheter as a great bridging technique in trauma and acute surgical emergencies. So far the study has been very fluid and we've had wonderful access, patients and interest in participation. In our preliminary evaluation we've had very satisfactory results and no complications. At this time we have successfully inserted and retrieved two devices at Mercy Hospital."

The Angel® Catheter features the rapid and acute protection of a retrievable Nitinol IVC filter permanently attached to a multi-lumen Central Venous Catheter, which simultaneously provides Pulmonary Embolism (PE) protection and central venous access for patients at high risk of PE, a large and currently underserved group of patients. The novel design of the Angel® Catheter allows for placement directly at the patient's bedside without the need for fluoroscopy and significantly reduces the complications of traditional IVC filters by ensuring 100% removal of the IVC filter when the catheter is retrieved.

Dr. Victor Tapson, lead Principal Investigator for The Angel® Catheter Clinical Trial, stated the following, "Acute pulmonary embolism continues to be a vexing problem, particularly in high risk, ICU patients. Frequently, anticoagulant prophylaxis is contraindicated. IVC filters clearly prevent PE in the vast majority of cases.

The Angel® Catheter is an easily placed and easily retrieved IVC filter built into a multi-lumen central venous access catheter. It is intended for use in critically ill patients, essentially all of whom are at risk of acute VTE and thus, fatal PE. We are very excited about this study."

For more information on The Angel® Catheter Clinical Trial, please visit <u>clinicaltrials.gov</u> (NCT02186223). Inquiries regarding the study should be directed to Dr. Margaret Tumas, BiO2 Medical's VP of Clinical Affairs, at <u>mtumas@bio2medical.com</u>.

Source: <u>http://www.prnewswire.com/news-releases/bio2-medical-begins-enrollment-for-the-pivotal-investigation-of-the-angel-catheter-300038598.html</u>

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