

FDA clears worlds first robotic-assisted system for PCI

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Singapore: Corindus Vascular Robotics, a leading developer of precision vascular robotics, received FDA 510(k) clearance for the CorPath 200 System to be used in percutaneous coronary interventions (PCI). The technology is now approved in the US to assist interventional cardiologists in performing PCI, a procedure to restore blood flow to blocked arteries in patients with coronary artery disease (CAD).

Mr David M Handler, president and CEO, Corindus Vascular Robotics, said that, "We are pleased to have received clearance from the FDA for the world's first system designed for robotic-assisted PCI procedures. The CorPath System offers hospitals the opportunity to bring robotic-assisted technology benefits to their coronary patients and their physicians."

The CorPath PRECISE Trial, a prospective, single-arm, multi-center, study, which served as the basis for the submission of a pre-market clearance (510(k)) application to the FDA, demonstrated that robotically-assisted PCI is safe and feasible for patients. PCI was successfully completed without having to convert to manual PCI in 98.8 percent of patients and without device-related complications. The overall procedure success rate was 97.6 percent. Additionally, the trial found that robotic-assisted PCI can make the procedure safer for the interventional cardiologist by reducing the radiation exposure by 95 percent when performing the procedure with the CorPath 200 System.

The CorPath 200 System is the first and only robotic-assisted procedure to allow for controlled placement of coronary guidewires and stent/balloon catheters from an optimized interventional cockpit. The lead-lined cockpit protects the

interventional cardiologist from harmful radiation exposure and the seated position in front of monitors may provide enhanced view of the angiography screen while reducing fatigue and minimizing head, neck and back strain.

Mr Handler said that, "There has been a tremendous amount of interest in the CorPath 200 System, and we are excited to bring to market a solution that has the potential to transform the standard of care for PCI procedures. Corindus is ready to help our customers successfully implement the complete CorPath-assisted procedure program into their institutions."