FDA CLEARS FIRST ROBOTIC-ASSISTED SYSTEM FOR CORONARY ARTERY DISEASE STENT PROCEDURES

Corindus Vascular Robotics wins 510(k) clearance for CorPath® 200 System; Robotic-assisted percutaneous coronary interventions (PCI) enhances control and protects physicians from radiation

NATICK, Mass. –July 25, 2012 – Corindus Vascular Robotics, a leading developer of precision vascular robotics, today announced FDA 510(k) clearance has been granted for the CorPath 200 System to be used in performing percutaneous coronary interventions (PCI). The technology is now approved in the United States to assist interventional cardiologists in performing PCI, a procedure to restore blood flow to blocked arteries in patients with coronary artery disease (CAD).

“We are pleased to have received clearance from the FDA for the world's first system designed for robotic-assisted PCI procedures,” said David M. Handler, President and CEO of Corindus Vascular Robotics. “This is an important milestone for interventional cardiology as we take the next step in transforming the way these procedures are performed in the future. The CorPath System offers hospitals the opportunity to bring robotic-assisted technology benefits to their coronary patients and their physicians.”

“The FDA clearance of the CorPath System will truly change the way I am able to practice. As interventional cardiologists, we perform our procedures using X-ray guidance and are cognizant that throughout our careers, we will be exposed to a high amount of radiation. In the past, we have relied on heavy lead aprons to protect us from radiation, but the physical stress of wearing these aprons can lead to back pain, fatigue and orthopedic injuries,” said Joseph P. Carrozza, Jr. M.D., Chief of Cardiovascular Medicine at St. Elizabeth’s Medical Center in Boston. “Robot-assisted PCI procedures allow us to provide our patients with the highest quality of care working in an ergonomic position with robotic-assisted stent and balloon placements to restore blood flow.”

Recent data published in Catheterization and Cardiovascular Intervention journal demonstrated an interventional cardiologist’s daily exposure to radiation and the physical stresses inherent in the cath lab can lead to occupational health risks, including orthopedic problems, cataracts, and cancer. 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.

“Gaining significant experience with the CorPath 200 System, I was impressed with its performance and the precise control of the interventional devices, including manipulating the guidewire and stent and being able to move the devices precisely in increments as small as one millimeter,” said Giora Weisz, M.D., Director of
Clinical Research at the Center for Interventional Vascular Therapy at NewYork-Presbyterian Hospital/Columbia University Medical Center and Associate Professor of Medicine at Columbia University College of Physicians and Surgeons, New York. “Working with this robotic technology is very intuitive and the PRECISE trial demonstrated its applicability in today’s cath lab environment. I strongly believe robotic-assisted PCI will enhance the way we are conducting PCI, and we are looking forward to adapting it in our everyday practice.”

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.

“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,” said Handler. “Corindus is ready to help our customers successfully implement the complete CorPath-assisted procedure program into their institutions.”

About Corindus Vascular Robotics
Corindus Vascular Robotics (http://www.corindus.com) is the global technology leader in robotic-assisted percutaneous coronary interventions. The Company’s FDA cleared CorPath® 200 System is the first medical device that offers interventional cardiologists PCI procedure control from an interventional cockpit. The CorPath open-platform technology and intellectual property will enable Corindus to address other segments of the vascular market, including peripheral, neuro and structural heart applications.
Coronary Artery Disease (CAD) is the narrowing of the small blood vessels that supply blood and oxygen to the heart.

To restore blood flow, a physician may place a stent in the coronary artery to prop it open. This procedure is called percutaneous coronary interventions (PCI).

In 2011, over 950,000 PCI stent placements were conducted in the United States.

In 2010, it was recorded that CAD cost the United States a total of $108 billion due to the medical care, treatments and loss of productivity.

PCIs are typically performed in the catheterization laboratory (cath lab) using X-ray imaging.

**Occupation Hazards in the Cath Lab**

- Intervventional Cardiologists (ICs) have among the highest radiation exposure among healthcare professionals, leading to severe health problems.
- ICs may have an increased rate of brain cancer.
- Higher rate of cataracts among ICs compared to the general population.
- A 15 pound lead apron can place pressure of up to 300 pounds per square inch.
- 50% of ICs reported chronic back pain.

**The Solution: Robotic-Assisted PCI**

- PRECISE Trial 164 patients enrolled/9 sites
- RESULTS
  - Excellent Clinical Results
  - 95% radiation reduction rate for physicians

**Challenges in Contemporary PCI Procedures**

- Up to 47% of the stents implanted in patients' coronary arteries are not optimally placed.
- Factors that lead to longitudinal geographic misses in stent placements include:
  - Difficulty visualizing and measuring the lesion length
  - Accuracy of stent deployment
  - Guidewire and stent stability
  - Large volumes of X-ray contrast media used to see arteries may cause kidney damage in patients.

**Corindus CorPath® 200 System**

- First robotic-assisted PCI for CAD patients
- Radiation protected, seated cockpit
- Precise robotic movement of stent and guidewires
- Discrete control and stability of PCI devices
- Compatible with commercial stents and devices
- Potential to enhance visualization
- Measurement capabilities

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