

Siemens CorPath Vascular Robot

Overview

The CorPath Vascular Robotic System (CorPath 200 & CorPath GRX) is a remote robotic platform for interventional, percutaneous, and vascular procedures. It is comprised of an interventional cockpit control console and a bedside unit that allows for delivery and manipulation of guidewires and catheters.¹ Limiting radiation exposure and preventing orthopedic complications have been promoted as advantages of this technology. Cardiovascular interventionalists are at high-risk of radiation exposure, requiring them to wear heavy lead aprons which can result in orthopedic injuries.²

Components	Description
Interventional Cockpit	Control console, X-ray foot pedal, high resolution monitor, radiation shielded workstation
Bedside Unit	Robotic drive, single-use cassette, touchscreen, extended reach arm

Indications for Use

The CorPath Vascular Robotic System is a platform that uses anatomical measurements, with automated movements and remote approach for the maneuvering of guidewires, guide catheters, and rapid exchange catheters, to assist in operator navigation of complex anatomies in interventional percutaneous and vascular procedures.¹

Clinical Data

There are few studies supporting the CorPath Vascular Robotic System, with a sample summarized below.

- The industry funded 2013 PRECISE single arm, non-randomized, multicenter study of 164 patients with coronary artery disease was conducted with the first generation CorPath 200 System for evaluation of safety and effectiveness.³ Inclusion criteria consisted of patients with de novo stenosis of a minimum of 50% by visual estimate, 24 mm maximum length with a diameter of 2.5 to 4.0 mm which could not be covered by a singular stent placement. Clinical success was measured as <30% residual stenosis with the absence of any major adverse cardiac event (MACE). Technical success was measured as successful advancement and retraction of devices without the need to convert to a manual approach. Clinical success was 97.6%, while technical success measured at 98.8% with only 2 patients requiring conversion to manual intervention. Overall, it was noted to be a safe and effective procedure option.³
- A 2017 study reviewed the use of the CorPath GRX in patients with complex coronary disease (n=40).⁴ Physicians who had previous expertise with the first generation CorPath 200 system were included in this single arm, single center study. All participants had obstructive coronary artery disease as evidenced by >70% stenosis. Clinical success was measured as <30% residual stenosis and final Thrombolysis in Myocardial Infarction flow grade 3 after the intervention, with the absence of MACE. Technical success was measured as a successfully completed robotic assisted PCI without the need to convert to manual PCI, or unplanned manual assistance during the duration of the procedure. Technical success was noted to be 90% with failure occurring in 3 procedures, clinical success was 97.5% with failure in one patient.⁴ Additional clinical studies to support these findings are needed.

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Physician Advisor Insight

A panel of interventional cardiologists within our HealthTrust Physician Advisor Network offered the following insight with regard to the use and adoption of the Siemens CorPath Vascular Robot. While all three were familiar with the technology, none have used it.⁵

- **Benefits:** Improve optimization of stent sizing, helpful in crossing and treating chronic lesions. Decreased orthopedic strain and reduction in radiation exposure. One physician noted an opportunity for reducing operator variability in interventions and possibly improving patient outcomes.
- **Challenges:** All the physicians identified cost and return on investment as barriers to adoption. One physician noted that extensive hands-on training demonstrating at least equivalence of the technology to standard practice would be necessary to convince skilled operators that it is worth the cost.
- **Adoption:** One physician predicts a slow adoption of technology over the next 8 to 10 years, before increasing widespread use. Two physicians noted that additional positive clinical trials are needed to drive more adoption. One physician emphasized that physician/staff training and product support would need to be exceptional. The physicians felt hands on the experience was needed to better determine how usable it is for typical interventional cardiology practice on a routine basis.
- **Safety Concerns:** One physician was concerned that it may add time to start of Acute MI cases. Another physician noted the concern of losing the benefits of tactile sensation, and his ability to differentiate between “good” and “bad” resistance, versus just appearance. Another physician noted that he would like to see more clinical evidence on device safety and performance in complex anatomy.

References

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