ACHIEVE GRX Registry Summary

TITLE	A Post-Market Registry for the Evaluation of the CorPath® GRX System Effectiveness in Peripheral Vascular Interventions
SHORT TITLE:	ACHIEVE GRX Registry
DEVICE	CorPath GRX System: • The Bedside Components consist of an Extended Reach Arm, Robotic Drive and Single-use Cassette • Interventional Cockpit • Control Console
REGULATORY STATUS	The CorPath GRX was granted 510K clearance (K173288) for use in peripheral interventions on February 15, 2018, and was CE Marked effective March 07, 2018 (CE 549879).
INDICATION FOR USE	The CorPath GRX System is intended for use in the remote delivery and manipulation of guidewires and rapid exchange catheters, and remote manipulation of guide catheters during percutaneous coronary and vascular procedures.
STUDY OBJECTIVE	To collect data on the routine patterns of use, safety and effectiveness, including the clinical and technical performance of the CorPath GRX System, in the delivery and manipulation of guidewires and rapid exchange catheters and manipulation of guide catheters during peripheral vascular intervention (PVI) procedures.
STUDY DESIGN	This is a prospective, single-arm, open-label, multi-center patient registry of the CorPath GRX System to examine its performance during peripheral vascular interventions and patient outcomes through 24 hours post-procedure or hospital discharge, whichever occurs first.
CO-PRINCIPAL INVESTIGATORS	Dr. Jon George Einstein Medical Center 5501 Old York Road Philadelphia, PA 19141 Dr. John Phillips Riverside Methodist Hospital 3705 Olentangy River Rd, Suite 100 Columbus, OH 43214
SAMPLE SIZE	It is expected that up to 200 subjects shall be enrolled in the study.

EVALUATION PERIOD	Estimated date of first patient enrolled: October 2020 Anticipated enrollment period: 24 months Estimated date of last patient enrolled: October 2022
INVESTIGATIONAL SITES	It is expected that up to 10 centers (USA and International) may participate in this study.
STUDY DURATION/ FOLLOW-UP PERIOD	All subjects will be followed post-CorPath percutaneous vascular intervention through 24 hours post-procedure or hospital discharge, whichever occurs first.
SUBJECT POPULATION	Subjects with a clinical indication for Peripheral Vascular Intervention (PVI).
PATIENT GENERAL INCLUSION CRITERIA	Candidates will be included in the study only if all the following conditions are met: 1. Age ≥ 18 years. 2. Subject has a clinical indication for Peripheral Vascular Intervention (PVI). 3. Subject is deemed appropriate for robotic-assisted PVI. 4. The subject has been informed of the nature of the study, agrees to its provisions and has provided written informed consent. 5. Individual monitoring of radiation dose, using the pocket dosimeter, was initiated at start of procedure.
PATIENT GENERAL EXCLUSION CRITERIA	Candidates will be excluded from the study if any of the following conditions are present: 1. Failure/inability/unwillingness to provide informed consent. 2. The investigator determines the subject or the peripheral anatomy is not suitable for robotic-assisted PVI. 3. Women who are pregnant.
STAFF GENERAL INCLUSION CRITERIA	Staff members may participate in the study only if all the following conditions are met: 1. Interventional lab staff, including the operating physician, secondary operator, and, if applicable, ancillary staff (technician and nurse). 2. Interventional lab staff member has been informed of the nature of the study, agrees to its provisions, and has provided written informed consent.
STAFF GENERAL EXCLUSION CRITERIA	Staff members will be excluded from the study if any of the following conditions are present:

1. Failure/inability/unwillingness to provide informed consent
2. Interventional lab staff members who are undergoing medical treatment involving additional radiation exposure.
3. Interventional lab staff members who have exceeded their hospital defined dose limits for radiation anytime during their participation in the study.

PRIMARY EFFECTIVENESS ENDPOINT

Technical Success
The primary effectiveness endpoint will be defined as successful completion of the robotic-assisted endovascular procedure absent any unplanned conversion to manual for guidewire or balloon/stent catheter inability to navigate vessel anatomy.

Clinical Success
Defined as <30% residual stenosis in all CorPath GRX System treated lesions at the completion of the interventional procedure in the absence of device-related serious adverse events (SAE), either within twenty-four (24) hours of the procedure or prior to hospital discharge, whichever occurs first.

PRIMARY SAFETY ENDPOINT

The primary safety endpoint will be a composite of intra- and peri-procedural events, including target vessel rupture, clinically significant perforation or dissection, and distal embolization, within 24-hours post-procedure or hospital discharge, whichever occurs first.

SECONDARY ENDPOINTS

PVI Procedure Time
Defined as the time measured from the insertion of the guiding sheath until the removal of the guiding sheath.

Manual time
Defined as the total amount of time the procedure is completed using a manual technique.

Robotic Time
Defined as the total amount of time the procedure is completed robotically from the robotic cockpit.

Fluoroscopy Time
Total fluoroscopy utilized during the procedure as recorded by an Imaging System.

Operator Radiation Exposure
Cumulative dose the operator receives as recorded from an electronic pocket dosimeter during the procedure.

Staff Radiation Exposure
Cumulative dose the staff receives as recorded from an electronic pocket dosimeter during the procedure.

Patient Radiation Exposure
DAP (dose-area-product) and AK (air kerma) as recorded during the procedure.

Contrast Fluid Volume
Total volume of contrast (mL) used during the procedure.

STUDY SPONSOR	Corindus, Inc. 309 Waverley Oaks Road, Suite 105 Waltham, MA 02452 USA
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