SYNOPSIS

STUDY TITLE	Cardiac Cath Lab Staff Radiation Exposure During Chronic Total Occlusion PCI: CorPath®GRX vs. Manual
SHORT TITLE	SAFE-T Study
PRINCIPAL INVESTIGATOR	William Lombardi, MD (Acting) University of Washington Seattle, WA William Nicholson, MD (Emeritus) WellSpan York Hospital York, PA
STUDY SPONSOR	Corindus, Inc Waltham, MA USA
RATIONALE	The PRECISE pivotal trial showed that operators sitting at the CorPath' s shielded cockpit had a median 92.5% reduction in radiation exposure when compared to published results. To date there have been no direct randomized comparisons of patient safety and staff radiation exposure comparing robotic-assisted (CorPath GRX) CTO PCI to conventional manual CTO PCI. This study will be a randomized evaluation comparing patient outcomes and radiation exposure of Cardiac Catheterization Laboratory staff in similarly matched coronary CTO PCI procedures.
REGULATORY STATUS	The CorPath GRX System was granted 510(k) clearance (K160121) on October 27, 2016.
FDA CLEARED INDICATION FOR USE	The CorPath GRX 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	The objective of this randomized safety and observational study is to demonstrate CorPath GRX CTO PCI is safe, and that Cardiac Catheterization Laboratory staff have no additional exposure to radiation when compared to conventional manual CTO PCI procedures without added procedure time.
STUDY DESIGN	This is prospective, dual-arm, randomized, multi-center, observational study comparing patient outcomes and staff radiation exposure in CTO PCI procedures through 48 hours post procedure or hospital discharge, whichever occurs first.

SUBJECT POPULATION	Subjects >18 years of age with symptoms suggestive of ischemic heart disease, with TIMI grade 0 flow and a lesion that is thought to be present for more than 3 months.
NUMBER/LOCATION OF SITES	This safety and observational study will be conducted at up to no less than three (3) centers.
STUDY DURATION	All subjects will be followed through 48 hours post CTO PCI procedure or hospital discharge, whichever occurs first.
SAMPLE SIZE	At least 90 CTO PCI procedures (45 CorPath GRX (robotic-assisted) / 45 Manual)
EFFECTIVENESS PERFORMANCE MEASURE	**Clinical Success** Defined as successful CTO PCI revascularization with achievement of <30% residual diameter stenosis (visual estimate) within the treated segment and restoration of antegrade TIMI grade 3 flow, without in-hospital major adverse events (MAE).
SAFETY MEASURE	**In-hospital MAE** MAE that occurs within 48 hours of the CTO PCI procedure or hospital discharge, whichever occurs first.
OTHER MEASURES	**Operator Radiation Exposure** Cumulative dose the physician receives as recorded from electronic pocket dosimeter during procedure. **Staff Radiation Exposure** Cumulative dose the staff receives as recorded from electronic pocket dosimeter during procedure. **Patient Radiation Exposure** DAP (dose-area-product) and/or (AK) air kerma as recorded during the procedure **Overall Procedure Time** Defined as the time measured from the placement of the first guide catheter to last guide catheter removal. **Manual Time** Total amount of time away from the cockpit. **Actual Time at Cockpit** Defined as the time the physician operator spends *in the robotic cockpit* from first entering the cockpit to procedure end time (guide catheter removal). **Fluoroscopy Time** Total fluoroscopy (min.) utilized during the procedure as recorded by an Imaging System. **Contrast Fluid Volume** Total contrast (mL) used during the procedure.

INCLUSION CRITERIA	For a CTO PCI procedure to qualify for this study, the procedure must meet the following inclusion criteria: 1. Age ≥ 18 years; 2. One (1) CTO lesion, *successfully crossed* with conventional manual techniques; 3. The Investigator deems the procedure appropriate for robotic-assisted CTO PCI with the CorPath GRX System; 4. Individual monitoring of radiation dose, using the pocket dosimeter, was initiated at start of procedure; 5. The subject has been informed of the nature of the study, agrees to its provisions and has provided written informed consent.
EXCLUSION CRITERIA	If any of the following criteria are met, the procedure cannot be included in this study: 1. Failure/inability/unwillingness to provide informed consent, or 2. Cardiogenic Shock; or 3. Perforation which requires treatment (e.g. covered stent, coil and other embolization techniques, or pericardiocentesis). 4. More than one lesion (CTO or non-CTO) to be treated.
RANDOMIZATION	The randomization scheme will utilize random block sizes of 4 or 6. Once the investigator has determined that the procedure is eligible based on inclusion/exclusion criteria, the procedure will be randomized in a 1:1 fashion to either CorPath GRX robotic-assisted CTO PCI or conventional manual CTO PCI. To randomize the procedure, a member of the study staff will select the next sequential number from the electronic data capture (EDC) system and declare the procedure's assignment. The assignment will be logged in the EDC.
INVESTIGATIONAL DEVICE	N/A: CorPath GRX will be used with accordance to the indication cleared by FDA.