TREAT GRX STUDY SUMMARY

TITLE	An Evaluation of Performance of the CorPath® GRX System in Robotic-PCI during Acute STEMI
SHORT TITLE	TREAT GRX Study
DEVICE	CorPath® GRX System: • Bedside Unit consists of the Extended Reach Arm, Robotic Drive, and single-use Cassette. • Interventional cockpit • Control console
REGULATORY STATUS	The CorPath GRX System was granted 510(k) clearance (K160121) on October 27, 2016.
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	This study will evaluate the performance of the CorPath GRX System in Robotic Primary PCI (RPPCI) in the treatment of STEMI.
STUDY DESIGN	This is a prospective, post-market, single-arm, multi-center, observational study to evaluate the performance of the CorPath GRX System during robotic-PCI for acute ST elevation myocardial infarction (STEMI).
PRINCIPAL INVESTIGATOR	Salvatore F. Mannino, DO, MA, FACC, FSCAI Interventional Director, Short Term Mechanical Circulatory Support Program WellStar Health System 55 Whitcher St Suite 350 Marietta, GA 30060 USA
SAMPLE SIZE	Up to 100 subjects shall be enrolled in the study.
INVESTIGATIONAL SITES	A maximum of five (5) sites may participate.

EVALUATION PERIOD	Estimated date of first patient enrolled: August 2020 Anticipated enrollment period: 12 months Estimated date of last patient enrolled: August 2021
STUDY DURATION/ FOLLOW-UP PERIOD	All subjects will be followed post-CorPath GRX PCI procedure through 72-hours post-procedure or hospital discharge, whichever occurs first.
SUBJECT POPULATION	Subjects with a clinical indication of STEMI.
INCLUSION CRITERIA	Candidates will be included in the study only if all the following conditions are met: • Age ≥18 and ≤ 80 years • Patients with STEMI<12 h of symptom onset • Patient deemed appropriate for robotic-assisted PCI • The subject has been informed of the nature of the study, agrees to its provisions, and has provided written consent
EXCLUSION CRITERIA	Candidates will be excluded from the study if any of the following conditions are present: • Cardiogenic shock • Cardiac arrest • Need for manual or mechanical thrombectomy • Failure/inability/unwillingness to provide informed consent • The Investigator determines that the subject or the coronary anatomy is not suitable for robotic-assisted primary PCI treatment
PRIMARY ENDPOINT	Time from Catheterization Lab Arrival to Device Activation (CLADA) by CorPath GRX System.

SECONDARY ENDPOINTS

Freedom from MACE events
Completion of the STEMI procedure without in-hospital major adverse cardiovascular event MACE). MACE is defined as cardiac death, clinically driven target vessel revascularization (TVR) by repeat PCI, surgical bypass for any segment of the target vessel or stent thrombosis.

First Medical Contact (FMC) to device activation time
Time at which the patient was first evaluated by Emergency Medical System (EMS) or Emergency Department arrival to device activation.

Access to device activation
Time from initial sheath insertion to device activation.

Access to wire time
Defined as time measured from sheath insertion to crossing the lesion with the coronary guidewire.

Overall procedure time
Defined as the time measured from sheath insertion to removal of the last device used to treat the culprit lesion.

Fluoroscopy time
Total fluoroscopy time (min.) utilized during the procedure as recorded by the Imaging System.

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

Contrast fluid volume
Total contrast volume (mL/cc) used during the procedure.

Conversion to manual (Binary)
Conversion from robotic technique to manual technique due to inability to successfully wire lesion or deliver first device.

Technical success
Completion of the PCI procedure entirely robotically or with partial manual assistance.

Serious adverse events
All Serious Adverse Events (SAEs) from the start of the CorPath GRX procedure until the end of the study will be summarized.

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STATISTICAL ANALYSIS SERVICES	TBD