Protocol No.: R-One-20241121231

Platform Construction and Clinical Application of 5G Technology for Remote Operation of the R-One™ Robot in Percutaneous Coronary Intervention

Clinical Trial Protocol

Version No. : 1.0

Date : 2025-03-01

Name of investigated device : Vascular Interventional Navigation Control System

Model/Specification : R-One

Class III devices subject to clinical trial: Yes ☑ No ☐

Equivalent products in China : Yes ☐ No ☑

Leading institute : People's Hospital of Xinjiang Uygur Autonomous

Coordinating Investigator : Yang Yining

Sponsor : Cathbot (Shanghai) Robot Co., Ltd.

CONFIDENTIALITY STATEMENT

Protocol Revision History

Version No.	Date of Revision	Revision Description
1.0	2025-03-01	/

Protocol Abstract

Trial Name	Evaluation of the effectiveness and safety of robot-assisted percutaneous coronary interventions in cardiology using the R-OneTM vascular interventional navigation control system
Protocol No.	CATHBOT-2021-R-One
Date of Revision	1.0 / 2025-03-01
Sponsor	Cathbot (Shanghai) Robot Co., Ltd.
Test device	Vascular Interventional Navigation Control System
Test purpose	Evaluation of the Safety and Efficacy of the R-One™ Vascular Interventional Navigation Control System for Percutaneous Coronary Intervention Procedures
Study design	Prospective, multicenter, single-arm clinical study
Applied Scope of Product	Cardiology PCI procedures
Scope of Subjects Population	Patients requiring cardiology percutaneous coronary intervention
Total Number of Cases	Randomized Controlled, 60 cases
Duration of Research	October, 2024 – September, 2026 (including subject screening, enrollment and completed pre-discharge follow-up)
Primary Evaluation Indicators	**1 Clinical success rate of the surgery** 1.1 Calculation formula: Clinical success rate = number of subjects that were clinical successes ÷ number of subjects that received surgical treatment × 100%. 1.2 Definition of clinical success:

(1) The target lesion was treated with test device, and the residual stenosis in the target vessel (visual description by angiography) reduced to less than 30% after PCI and a TIMI grade of 3.

(2) No major adverse cardiovascular events (MACE) occurred in the hospital.

2 Success rate of surgical techniques

2.1 Calculation formula:

Technical success rate = number of subjects that were technical successes ÷ number of subjects received surgical treatment × 100%

2.2 Definition of technical success:

The Robot-assisted PCI procedure was successfully completed without any unplanned manual assistance or shift to manual operation.

(1) Definition of planned manual assistance:

During robotic surgery: Reposition of guidewires or stents/balloons, manual translation/rotation of guidewires or stents/balloons to guiding catheters, reposition of guiding catheters and usage of any device that is not compatible with the robotic platform.

(2) Definition of unplanned manual assistance:

Manual translation/rotation of the guidewire and/or manual translation of the stent/balloon once the guidewire has left the guiding catheter .

(3) Definition of the shift to manual operation:

Any situation during the PCI procedure that results in the shift to manual operation; number of system restart failure during robotic surgery <3.

Surgical clinical success	1. Procedure duration (from arterial sheath insertion to removal) 2. Duration of robot-assisted treatment (from robotic guidewire manipulation initiation to withdrawal from coronary vessel) 3. Radiation exposure to the patient 4. Radiation exposure to surgeons 5. Contrast dose (mL) 6. Cardiovascular disease-related deaths, perioperative and spontaneous myocardial infarction and target lesion revascularization driven by clinical symptoms - In-Hospital MACE - 30-day MACE after PCI (30±7 days)
Performance evaluation indicators	1. Evaluation of intraoperative operation, interface friendliness, and smoothness of operation by surgeons 2. Incidence rate of serious system malfunction 3. The occurrences of repairable system malfunction 4. Evaluation of Device Usability
Indicators for Safety Evaluation	Adverse events, adverse device effects and serious adverse events

Glossary of terminologies and related abbreviations

ADE	Adverse Device Effect
AE	Adverse Event
ASADE	Anticipated Serious Adverse Device Effect
BARC	Bleeding Academic Research Consortium
CA	Competent Authority
CABG	Coronary Artery Bypass Grafting
CAD	Coronary Artery Disease
CEC	Clinical Events Committee
CERC	Cardiovascular European Research Center
CK	Creattinine Kinase
DS	Diameter Stenosis
cTn	Cardiac Troponin
EC	Ethics Committee
ECG	Electrocardiogram
eCRF	Electronic Case Report Form
GCP	Good Clinical Practices
ITT	Intention To Treat
LAD	Left Anterior Descending
LCX	Left Circumflex
LBBB	Left Bundle Branch Block
MI	Myocardial Infarction
NHLBI	National Heart, Lung, and Blood Institute
PCI	Percutaneous Coronary Intervention
PTCA	Percutaneous Transluminal Coronary Angioplasty

RCA	Right Coronary Artery
RVD	Reference Vessel Diameter
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SC	Steering Committee
SCAI	Society for Cardiac Angiograph and Intervention
SOP	Standard Operating Procedure
ST	Stent Thrombosis
STEMI	ST-Elevation Myocardial Infarction
TC	Teleconference
TIMI	Thrombolysis In Myocardial Infarction
TL	Target Lesion
TLF	Target Lesion Failure
TLR	Target Lesion Revascularization
TVR	Target Vessel Revascularization
TV	Target Vessel
ULN	Upper Limit of Normal
USADE	Unanticipated Serious Adverse Device Effect
DCF	Data Clarification Form
SDV	Source Data Verification
CI	Confidence Interval
FAS	Full Analysis Set
PPS	Per Protocol Set
SS	Safety Set

HIS	Hospital Information System
NMPA	National Medical Products Administration
NYHA	New York Heart Association

Assessed Items and Follow-Up Schedule

Visiting nodes	**V1**	**V2**	**V3**	**V4**	**V5**
Time window	-15 days ～Day 0	-72 hrs. ～Day 0	Day 0	Pre-discharge	30 days ±7 days
Investigation phase / **Assessed item**	**Screening visits**		**Operation Day Visit**	**Pre-discharge Visit**	**1 month post-operative visit**
Sign the informed consent	×				
General Inclusion/Exclusion Criteria	×				
Inclusion/ exclusion angiographic criteria			×		
Demographic Information	×（1）				
Pregnancy test (if applicable)	×（2）				
Physical examination	×（3）				
Blood routine test	×（4）			×	
Echocardiography	×（5）				
12-lead ECG.		×（7）		×	
Cardiac enzyme markers		×（8）		×	
CREA	×（6）			×	
Angiography			×		
Concomitant	×	×	×	×	×

medication records					
Adverse events record	×	×	×	×	×

Notes:

1. Blood routine test includes: Red blood cells, white blood cells, hemoglobin and platelet counts, etc.
2. Concomitant medication records: is limited to records associated with adverse events.
3. V5 1 month post-operative follow-up can be carried out by phone.
4. Screening period examinations (1)-(6) accept examination results 15 days before the surgery, (5) accepts examination results within 3 days after surgery, (7)-(8) accept examination results 72 hours before the surgery, record as baseline data, and it's not required that the time of examination should be after the signing the informed consent.
5. Cardiac enzyme markers include: Creatine kinase (CK), creatine kinase isoenzyme (CKMB), troponin T or I (TnT or Tnl). If 48h postoperative CK-MB > 5 times above the upper limit of normal range or troponin > 35 times above the upper limit of normal range, the investigator should decide whether the subject need re-examination based on his symptoms; otherwise, the 48h post-operative examination of cardiac enzyme marker can be considered as the pre-discharge test and do not need other additional ones.

Table of Contents

1 Sponsor Information

1.1 Name of sponsor

People's Hospital of Xinjiang Uygur Autonomous Region

1.2 Office Address

91 Tianchi Road, Xinjiang Uygur Autonomous Region, China

1.3 Name of participate sites

Karamay Central Hospital

Luopu County People's Hospital

The First Hospital of Kashgar Prefecture

Jimusar County People's Hospital

1.4 Investigators information

	Name	Clinical Title	Institution/Affiliation	Role
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10	Shan Fuxiang	Chief Physician	Jimusar County People's Hospital	Site Investigator

2 Background information of clinical trial

2.1 Clinical Application Background

The prevalence of coronary heart disease (CHD) in China continues to rise, with 11.39 million people suffering from CHD. Cardiovascular disease is the leading cause of death among urban and rural residents in our country [1]. With the development of treatment technologies and equipment, percutaneous coronary intervention (PCI) has become the main treatment method for cardiovascular diseases. The number and complexity of PCI operations continue to increase, further increasing the burden of surgeons [2]. A large number of studies have proved that the cumulative radiation dose received by vascular interventional physicians cannot be ignored. With a large number of surgeries, the cumulative radiation dose of experienced interventional physicians is even greater [3]. Long-term low-dose radiation can lead to lens opacity, a significant increase in the incidence of brain and left head tumors, and thickening of the carotid intima associated with carotid artery stenosis [4,5]. Wearing heavy lead clothing for a long time also causes nearly 50% of cardiac interventionist to report at least one orthopedic disease [6]. Surveys show that over 84% of people believe that better occupational protection will ultimately benefit patients [6]. Therefore, robot-assisted coronary intervention surgery is one of the solutions to this inevitable trend.

Since the initial application in 2006, robot-assisted PCI has been shown to be safe and feasible in simple lesions. With advances in system technology and increased operator experience, vascular interventional robots are also beginning to be applied to complex, more “real-world” lesions, where their safety and efficacy have been further validated [7-13]. However, reducing radiation exposure for the operator is not the sole objective of vascular interventional robotics. It is also envisioned that robotic surgery can assist in decision-making, enhance the operator’s operations, further improve surgical safety and efficacy, achieve more precise treatment targeting, reduce patients' radiation exposure and contrast dose, thereby benefiting both patients and physicians. The R-One™ vascular interventional robot employs an innovative bionic twisting technology that replicates the hand movements of physicians. Through mechanical clamping and millimeter-level stepping, it delivers superior motion stability and high precision, preventing unintended displacement of instruments caused by

operator muscle tremors, fatigue, or mishandling during instrument exchanges. Robotic-assisted surgery eliminates the limitations of manual methods, such as tremors that may lead to serious complications, thereby enhancing surgical precision and safety. Simultaneously, it reduces the need for repeated manipulations and instrument repositioning, consequently lowering patients' radiation doses and contrast agent consumption [Patent No.: CN107847281B; CN106535808B]. Thanks to its unique technological design, the introduction and removal of instruments (guidewires and balloon/stent catheters) takes only one second. The R-One robotic platform can precisely and perfectly replicate hand movements, ensuring medical staff can execute procedures rapidly. Owing to its intuitive operation, the R-One platform features a swift learning curve. As early as the 2017 safety study of this device, medical personnel—without any specialized training—demonstrated that robotic-assisted PCI differed from manual PCI by merely one minute in procedure time. As part of using R-One for coronary interventions, interventional cardiologists can operate the robot via a console behind radiation-proof screens while seated almost entirely. This significantly improves ergonomic positioning and comfort for healthcare providers. The setup also enhances surgical visual feedback by enabling closer observation. The control station features a mobile radiation shield (190 cm height × 152 cm width × 118 cm depth), accommodating multiple personnel to ensure protection for the entire care team. The secure execution of interventional procedures substantially reduces stress among medical staff. Comprehensive protection against radiation exposure prevents occupational injuries, thereby contributing to improved patient care quality.

The advancement and widespread adoption of internet technology have dismantled spatial barriers in human interaction, enabling cross-regional communication and interaction. Since the inception of internet technology, the medical field has endeavored to leverage it to overcome temporal and spatial constraints. In September 2001, doctors from New York carried out the world's first attempt at remote surgery for patients on the other side of the Atlantic in Strasbourg[15]. The operation was performed using the Zeus robot, which transmitted signals through dedicated submarine optical fibers to carry out a cholecystectomy for the patient, leaving behind a surgical name named after the explorer who first crossed the Atlantic Ocean - the Lindbergh operation. Since then, several clinical studies on remote

surgery based on endoscopic surgical robot systems have explored the safety and efficacy of remote robotic surgery [16-18].

With the development of vascular interventional surgery robot technology and 5G telemedicine technology, cardiac interventional experts have begun to explore vascular interventional robot-assisted PCI surgery based on 5G remote technology. In 2020, Professor Ryan from the Frederik Meijer Heart & Vascular Institute performed PCI procedures on vascular simulators, with 20 target lesions operated on and 16 target lesions consecutively treated in the transcontinental model, in New York (206 miles, regional model) and San Francisco (3,085 miles, transcontinental model) using a remote vascular interventional robotic system (Corpath) console in Boston. System measurements revealed master-slave delays by comparing transcontinental model with regional model as follows: 121.5 ± 2.4 ms vs. 67.8 ± 0.9 ms ($p < 0.001$) in the wired mode; 162.5 ± 1.1 ms vs. 86.6 ± 0.6 ms ($p < 0.001$) in the 5G mode. Although statistically significant differences in delay existed between models, operators rated the latency as "imperceptible" in both scenarios [19].

China's vast territory leads to uneven distribution of medical resources. High-quality doctors and advanced equipment are predominantly concentrated in first-tier and provincial capital cities, while remote grassroots areas suffer from underdevelopment and scarce medical resources. This forces patients to travel long distances for treatment, increasing burdens on both patients and hospitals. Cross-regional medical access has long been a challenge in healthcare development. 5G communication technology, with its advantages of high throughput, low latency, and massive connectivity, can empower China's medical services toward mobility, remote operation, and intelligent development when integrated with robotics. This integration enables the implementation of remote surgery. Therefore, the development of 5G remote surgical robot system and its regular application can enable surgeons to be free from time and space restrictions, allowing patients to receive high-quality medical services locally. This is conducive to the balanced development of high-quality medical resources and truly makes high-quality medical services accessible to the general public.

The success of remote surgery hinges on, on the one hand, operational consistency and real-time synchronization between the master and slave systems of surgical robots; on the other hand, technical robustness, including signal stability, anti-interference capability, and high-

throughput data transmission [18]. Network latency severely impacts surgical operations; data transmission latency affects surgical operation time; latency fluctuation causes packet disordering, leading to mechanical jitter in robotic manipulators.

The device tested in this study adds a remote communication workstation and a remote control room (1 doctor console +1 remote communication workstation) on the previous generation product. By taking advantage of the 5G communication technology's flexible multi-point layout, large bandwidth, low latency and high reliability, the DSA images are transmitted to the surgical experts to achieve remote control of the robot. At the same time, through remote real-time audio and video communication, cardiac interventional surgery experts can perform robot-assisted remote PCI for patients. R-One^{TM} vascular intervention robot is embedded software with negligible end-to-end delay. After adding 5G remote robotic surgery function, risks mainly come from 5G network transmission delay, packet loss and network disconnection. The remote control module of R-One^{TM} vascular intervention robot adopts end-to-end control, remotely transmitting control signals and emergency stop signals. The operation mode of remote control remains unchanged, achieving continuous signal transmission, which has good reliability and stability. If the network condition, delay and packet loss are comprehensively evaluated before the operation and meet the clinical and technical requirements, remote surgery can be carried out. All instructions are transmitted continuously, and remote control handle instructions are updated in real time to ensure that network delay and packet loss do not exceed clinical and technical requirements. In case of abnormality, network interruption or emergency, it can switch local or local manual operation with one key.

This clinical study used the "Vascular Interventional Navigation Control System" (i.e., the experimental device) to complete the classic PCI surgery with the assistance of a remote robot, and to evaluate the safety and efficacy of this system in the treatment of cardiology.

2.2 CoA of investigational device

According to the requirements of Provisions on Medical Devices Registration Administration,

Norms on the Quality Management of Medical Devices for the Clinical Trials and other

regulations issued by the National Medical Products Administration and relavant health authorities, the product shall attained the CoA from medical device testing institutions that meet the relevant qualifications before clinical trial for registration, and its performance shall meet the safety standards of national, industry or relevant requirements.

2.3 Summary of Animal Experiments

From October 2017 to May 2018, the sponsor initiated a series of animal experiments for the Vascular Interventional Navigation Control System. The results confirmed the safety and efficacy of the system for PCI procedures. A total of 14 procedures were carried out on 3-5 months old, 62-70 kg female Landrace pigs, including the representative cardiology surgical option PCI. The experiment was designed to compare the R-One robotic approach (test group) with the gold standard manual approach (control group) in terms of implantation and evaluate the efficacy and safety with the same criteria. There were 7 procedures and 4 pigs in each group (2 acute, 2 chronic). Pathological analysis was performed after 30 days of postoperative followed up. 3 pigs died on the day of surgery. All the implantation procedures went smoothly, without any robot-related major adverse event. Efficacy was evaluated in all arteries undergone implantation, and no safety issues were observed. All chronic animals completed the 30-day follow-up smoothly and successfully. The stent patency achieved good performance during implantation and completion, with no abnormalities at the implantation position or on distal organs, indicating sound local and general tolerability. No significant lesions were found at the histological level. Both implantation methods were a success and had no difference based on the criteria of mobility, navigation, implantation accuracy, stent function (TIMI score), and stent tissue integration.

Therefore, it can be confirmed that the efficacy of stent implantation through a robotic approach is 100%. In term of safety, no significant adverse events had been reported through either the manual or robotic approach. The duration was approximately 1 minute longer, the dose of contrast increased by approximately 9 ml, the total exposure to X-ray was approximately 1 minute longer, and the cumulative X-ray dose of patient was approximately 3 mGy.cm^2 higher in R-One robotic implantation. It's possible that these results are correlated

to the learning curve of robotic implantation and is believed to improve over time through practice. The surgeons expressed that the R-One became easy and intuitive to use after a short training period, improved surgical conditions by providing comfortable sitting position and X-ray protection, and was qualified to proceed with clinical trials.

2.4 Summary of registered clinical trials

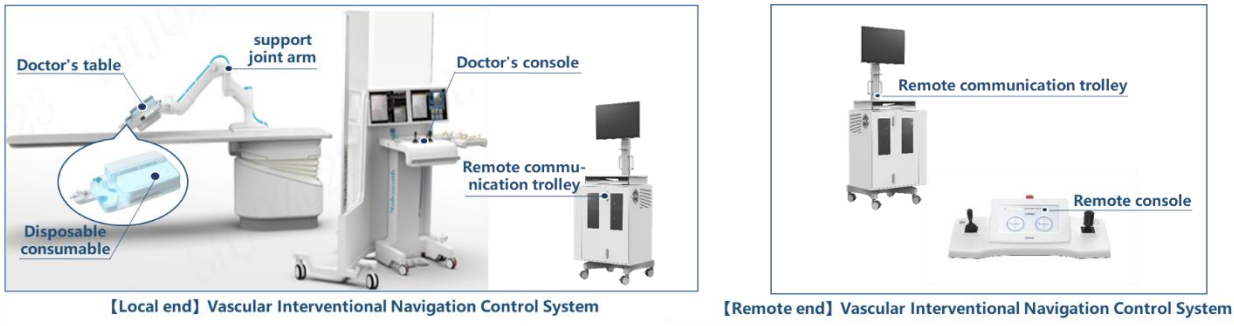
In order to verify the safety and effectiveness of "R-One vascular interventional navigation control system" for PCI surgery in cardiology department, from September 2021 to September 2022, Zhimai (Shanghai) Robotics Co., Ltd. initiated a prospective, multi-center, single-arm clinical trial. Four centers participated in the study, and a total of 145 subjects were enrolled who required cardiac PCI. The average age of all subjects was 61.92 years old, male 69.66%, female 30.34%, and average body mass index (BMI) 25.01. Among 145 subjects, 6 (4.14%) had two target lesions. The mean diameter of the target vessel was 3.14 mm, and the mean length of the target lesions was 20.07mm. Complex lesions (type B2 and C lesions) accounted for 38.41%, and the preoperative stenosis degree of the target lesion was 88.28%. The clinical success rate of the surgery and the success rate of surgical techniques were 100%. There was no in-hospital major adverse cardiovascular events (MACE), and no MACE occurred within 30 days after PCI. In the robot-assisted PCI operation stage, the radiation dose of the operator was 97.59% lower than that of the traditional manual surgery bedside operator. The performance evaluation of the device was good. No serious system failures occurred in the four clinical trial centers during the enrollment period. There were no adverse events related to the trial device and no device defects. This conclusion demonstrates the safety, efficacy and reliability of this product in assisting the treatment of PCI surgery in cardiology, meeting the clinical application requirements of PCI surgery in cardiology and providing a reasonable basis for subsequent clinical application and promotion.

3 Investigational device

3.1 Test device

The investigational device was R-One Vascular Interventional Navigation Control System developed and produced by Robocath, and was composed of a platform (instruction unit, robot, support joint arm), a consumable set (cartridge, instruction unit protective sleeve), and

a remote workstation.



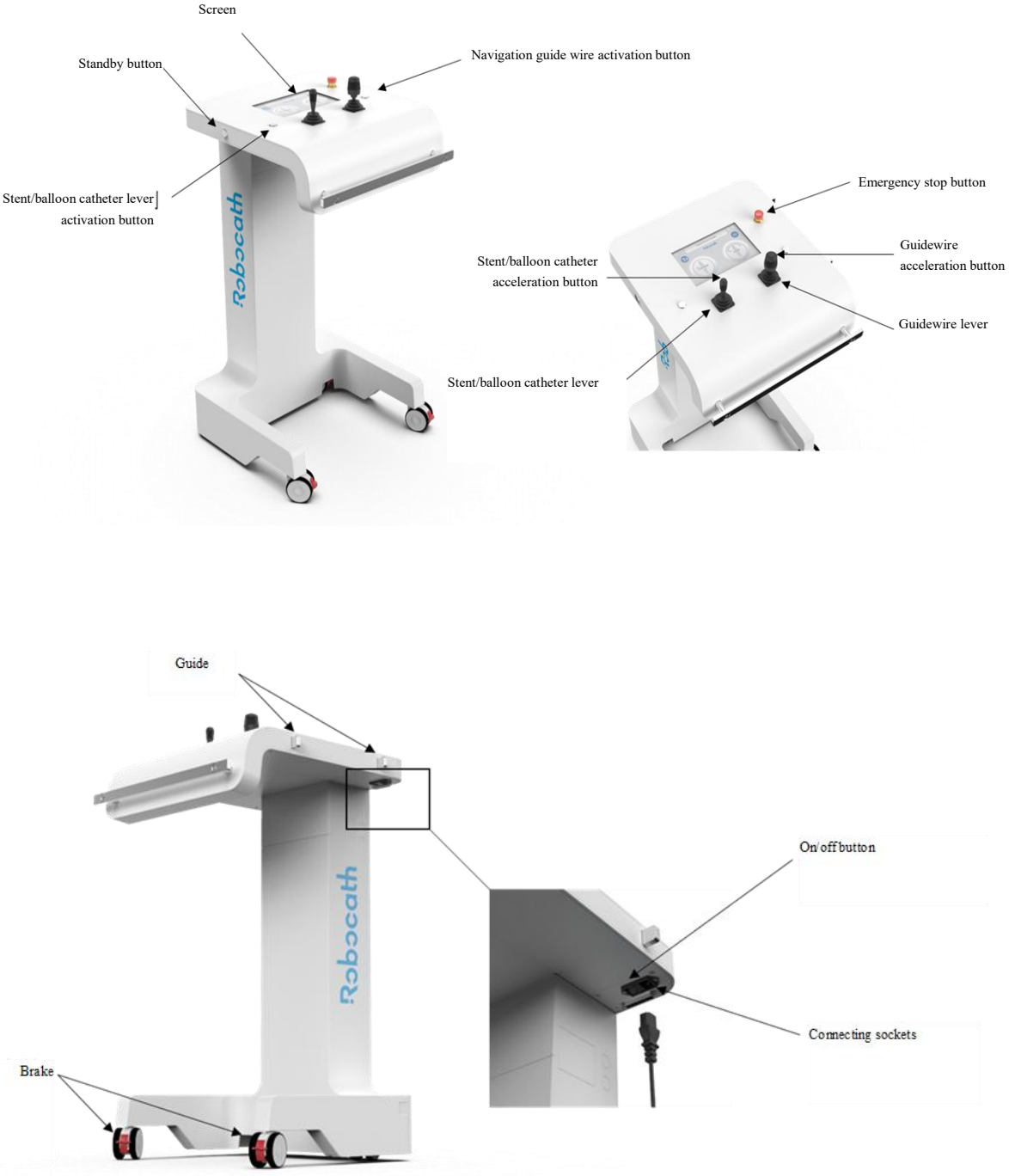
General architecture of 5G-based remote vascular interventional robot-assisted PCI surgery

3.1.1 Instruction Unit

The instruction unit is the control center of the R-One Vascular Interventional Navigation Control System and consists of a standby button, stent/balloon catheter lever activation button, navigation guidewire activation button, screen, stent/balloon catheter acceleration button, guidewire acceleration button, stent/balloon catheter lever, guidewire lever, emergency stop button, guide rail, brake, and start/shutdown button.

Name of the components		**Model & Specifications**
Instruction Unit	Standby button	R-One
	Stent/balloon catheter lever activation button	
	Navigation guide wire activation button	
	Screen	
	Stent/balloon catheter acceleration button	
	Guidewire acceleration button	
	Stent/balloon catheter lever	
	Guidewire lever	
	Emergency stop button	

	Guide	
	Brake	
	On/off button	

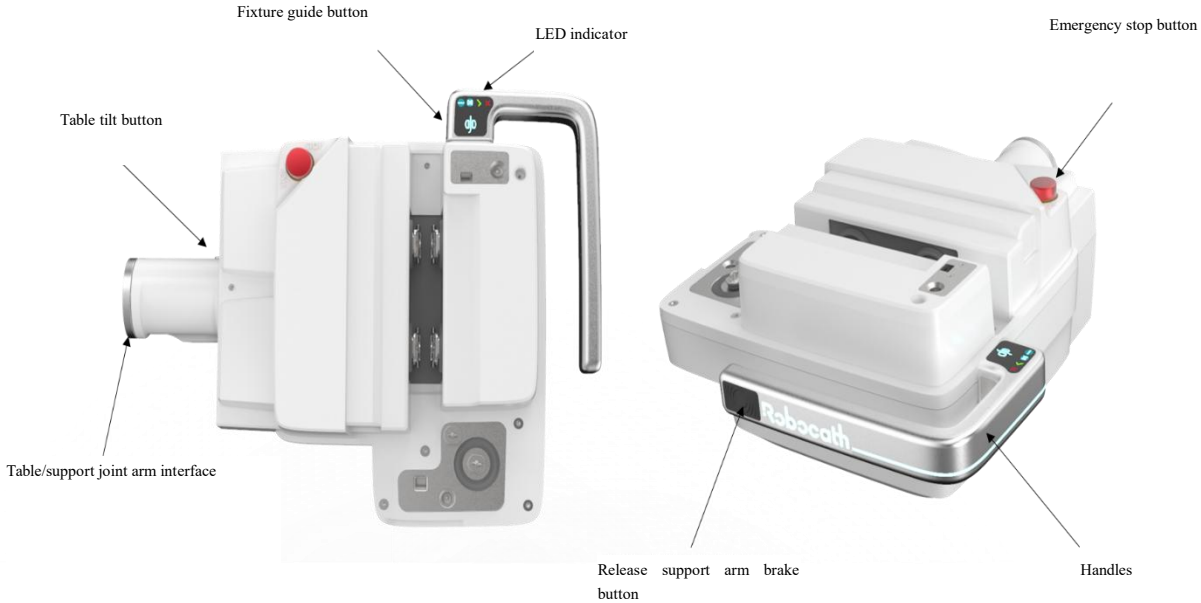


Schematic diagram of instruction unit

3.1.2 Robot

The robot consists of a table/support joint arm interface, table tilt button, fixture guide button, LED indicator, emergency stop button, release support arm brake button, and handles.

Name of the components		Model & Specifications
Robot	Table/support joint arm interface	R-One
	Table tilt button	
	Fixture guide button	
	LED indicator	
	Emergency stop button	
	Release support arm brake button	
	Handles	



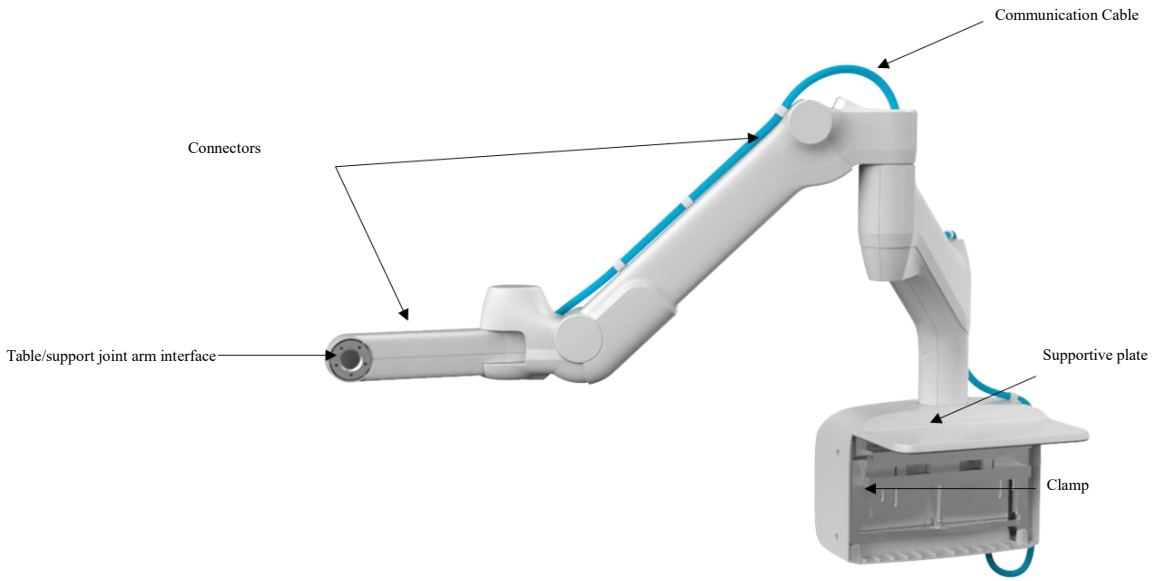
Robot schematic diagram

3.1.3 Support joint arm

The support joint arm consists of a support plate, a clamping clamp, a communication cable, a

connector, and a support joint arm/table interface.

Name of the components		Model & Specifications
Support joint arm	Supportive plate	R-One
	Clamp	
	Communication Cable	
	Connectors	
	Clamp	

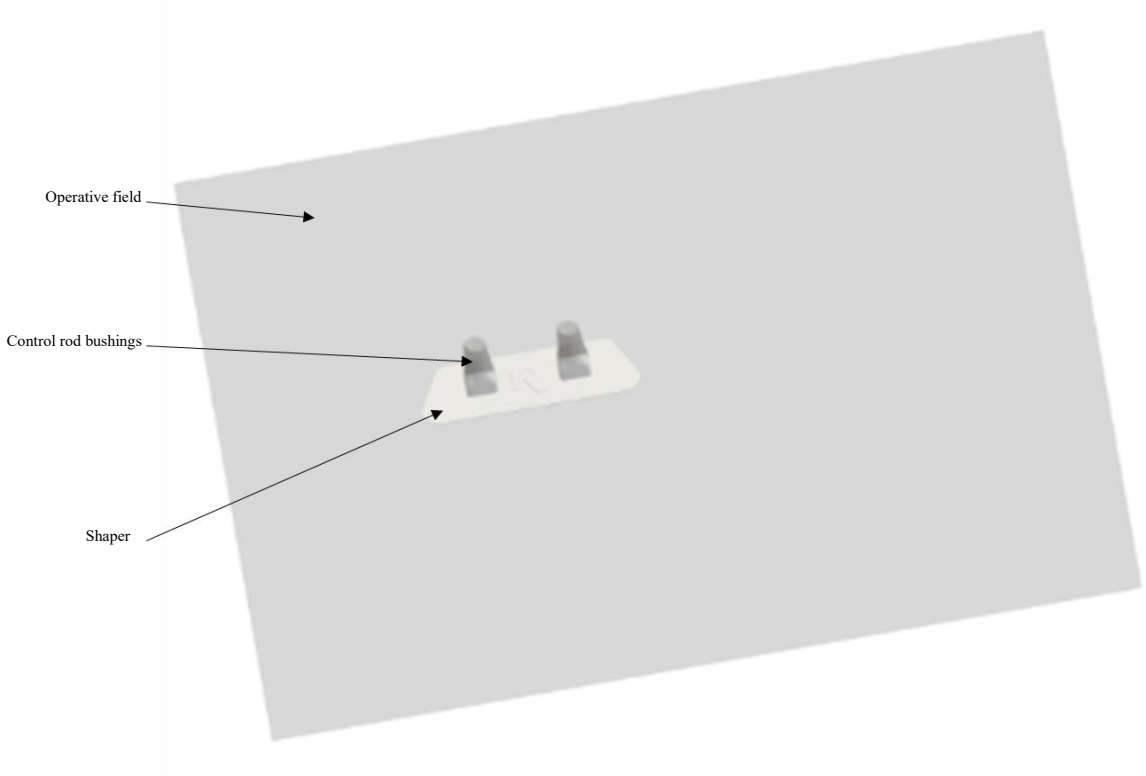


Schematic diagram of the support joint arm

3.1.4 Instruction unit protective sleeve

The instruction unit protective sleeve consists of the operative field, the lever sleeve, and the shaper.

Name of the components		Model & Specifications
Instruction unit protective sleeve	Operative field	R-One
	Control rod bushings	
	Shaper	

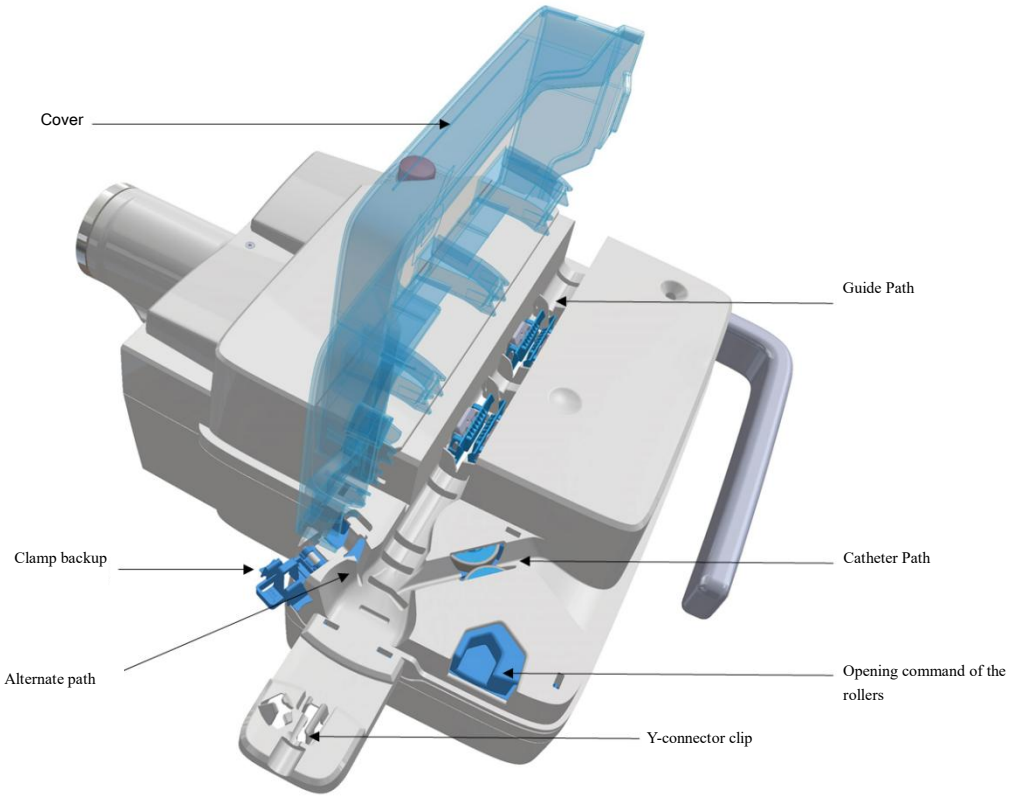


Schematic diagram of the instruction unit protective sleeve

3.1.5 Cartridge

The cartridge consists of cover, clamp backup, alternate path, guide path, wire guide slot, opening instruction of the rollers, and Y-connector clip.

Name of the components		**Model & Specifications**
Cartridge	Cover	R-One
	Clamp backup	
	Alternate path	
	Catheter Path	
	Guide Path	
	Opening command of the rollers	
	Y-connector clip	



Cartridge schematic diagram

3.1.6 Remote communication workstation

To achieve remote surgery, remote communication workstations need to be configured at all locations where remote surgery is performed. The remote control module adopts end-to-end control, remotely transmitting control signals and emergency stop signals. The operation mode of remote control remains unchanged, achieving continuous signal transmission.

The remote communication workstation of local operating room will establish the virtual surgery, and the remote communication workstation of the remote control side needs to join the virtual surgery through the invitation code to establish remote control between the two places. For the safety of remote surgery, invitation codes need to be obtained through offline communication.

After the virtual surgery is established, the two communication workstations need to incorporate the robots nearby into the operation. In this way, the two control consoles can

achieve remote control and data exchange.

The communication workstation includes an codec integrated machine to achieve video encoding and decoding. The DSA video of the local operating room can be encoded and transmitted over the network to the communication workstation of the remote control terminal. After decoding, it can be output to the display of the remote doctor's console, so that the remote doctor can receive visual feedback.

In addition, to eliminate the communication barriers for medical staff in different locations, the remote communication workstation is equipped with a multi-source video conferencing system, which enables barrier-free communication between different places. Meanwhile, this conference system also supports third-party access, enabling remote technical support and surgical guidance.

3.2 Requirements for communication networks

The remote surgery system does not limit the type of communication network, which can be 5G network, fiber optic line, wired or wireless LAN, or other better and safer networks, as long as point-to-point communication (LAN or virtual LAN) can be realized between the two places, and the network performance indicators meet the requirements of remote surgery.

3.2.1 Common network architectures

5G slice dedicated line network is currently the preferred communication network for ultra-remote surgery due to its safe, efficient and reliable network environment. However, at the same time, there is also the demand for remote surgery between multiple campuses in the same hospital, which can be realized through LAN or virtual LAN between multiple campuses for close-range remote surgeries.

3.2.2 Requirements for network performance

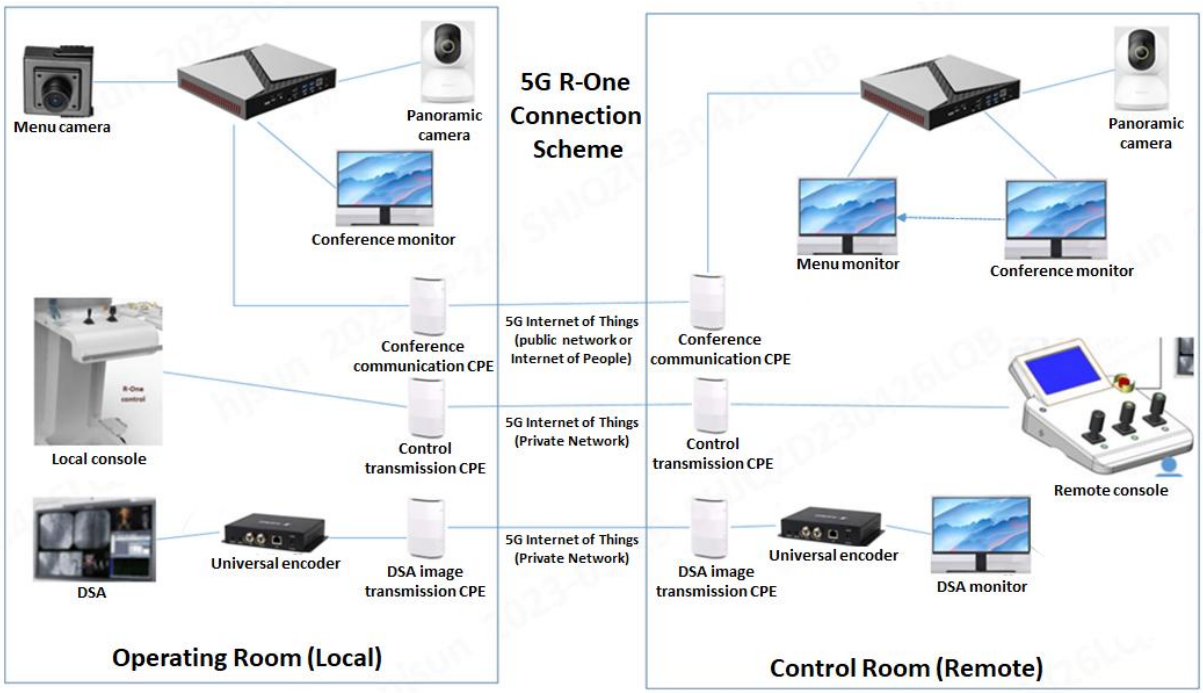
5G remote interventional surgery needs to transmit control and feedback signals between the remote end and the local end, transmitting the patient's DSA image from the operating room to the remote control end. It also needs to establish video conferencing systems in two places, so there are certain requirements for network performance.

The maximum transmission rate of the control signal is 1312 bytes per frame, with a frame rate of 4Khz and a theoretical rate of 40Mbps. The DSA signal and video conferencing use

H264 compression, with an average DSA rate of 10Mbps and an average video conferencing rate of 5Mbps.

In terms of delay, limited by the overall delay of 305ms, the network delay is limited to 55ms, the control signal delay is limited to 135ms, and the remote delay of DSA image (including image processing delay, codec delay and network delay) is limited to 170ms. The video conference system has no impact on the overall operation delay, and the general video conference delay requires 300ms.

Through the test, the 3D video transmission is unstable when the network packet loss rate is ≥0.5%. Therefore, 0.5% is set as the upper limit.



Remote surgical network communication topology based on 5G section dedicated line

Based on the above description, the system performance should comply with the provisions of the following table:

Data type	Rate requirement	Delay requirement	Reliability
Control signals	Upload and download speeds ≥40Mbps	≤135ms	≥99.999%
DSA images	Upload and download speeds ≥10Mbps	≤170ms	≥99.999%

Video conference	Upload and download speeds ≥5Mbps	≤300ms	≥99.999%

Delay < 55ms; Jitter < 30ms; RTT delay range: 80-140ms; Bandwidth: 65Mbps

3.3 Scope of Trial

- The subjects scope of the clinical trial: Patients requiring cardiovascular PCI.

4 The application, contraindications and precautions of the investigational device

4.1 Scope of application

Cardiovascular PCI.

4.2 Product Contraindications

Contraindications to the use of system have yet to been known. But it applies to the contraindications of artificial coronary angioplasty treatment.

4.3 Precautions

4.3.1 The system should only be used by interventional cardiologists who have received specific training for the use of the R-One device. Robocath only provides training related to the use of the system and is not a substitute for the necessary expertise and medical training for percutaneous coronary intervention (PCI).

4.3.2 The guidewire and/or stent/balloon catheter should not be moved through this system without x-ray examination.

4.3.3 The navigation speed of the guidewire and/or stent/balloon catheter should adapt to arterial area traversed. The rapid navigation mode can only be put into use when the guidewire and/or stent/balloon catheter is located within the guiding catheter.

4.3.4 The R-One robot platform is dedicated for use in combination with mobile radiation-proof screen and the R-One consumable kit.

4.3.5 The R-One system is only compatible with the devices shown in the table below.

Device/Equipment
0.014 inch guide wire
Rapid exchange stent/balloon catheters
Y-connector: - Super Ketch™ of Minvasys - Merit Medical's Honor ®Hemostasis Valve

4.4 Device Administration

4.4.1 Packaging label

All investigational devices are subject to strict self-inspection before they leave the factory. The product label is printed with words of "for clinical trials" and the serial number of the product, which can be used to trace the production and usage of the device.

4.4.2 Storage and transport conditions

4.4.2.1 Environmental Conditions for the R-One Robotic Platform

Transportation
-40℃-70℃ Not in wet place

Caution: System performance won't be guaranteed if conditions exceed specifications in this section

4.4.2.2 Environmental conditions for the R-One consumable kit

Transportation	Storage
-30℃-50℃ Store in a cool, dry place, and avoid light and direct sunlight	18℃-30℃ Store in a cool, dry place, and avoid light and direct sunlight

In principle, the investigational device should be protected from heavy pressure, direct sunlight and rain during transportation and be stored in a dry, cool, dust-proof room (according to the product specification).

Ordinary operation such as cleaning, disinfection, sterilization, and maintenance of the

devices should be carried out in accordance with the instructions for use and clinical specifications.

The relevant investigational devices are intended for use in this clinical trial only and shall not be used for other purposes.

4.4.3 Usage record

investigational devices must be managed by a person designated by the principal investigator, and written records of the receipt, use, and retrieval of devices must be kept.

5 Overall Design of the Clinical Trial

5.1 Study Objective

The purpose of this study is to evaluate the effectiveness and safety of the R-One™ vascular interventional navigation control system for percutaneous coronary interventions.

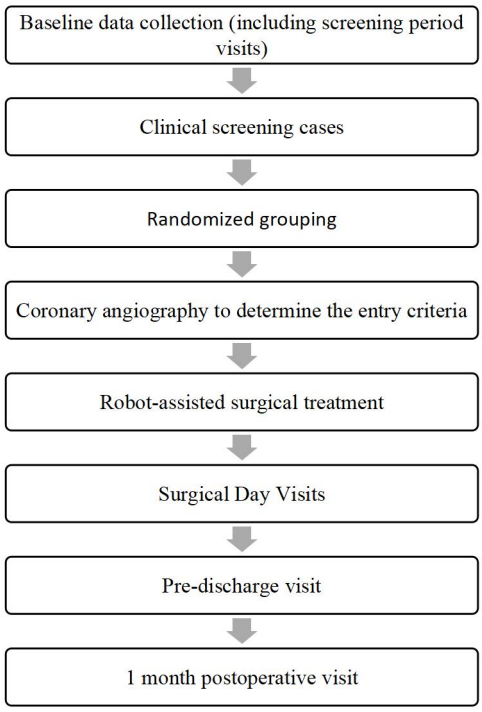
5.2 Sample size

The sample size calculation was based on the primary endpoint, i.e., the surgical success indicator. Based on the results of sample size calculation by PASS software, it was concluded that when the significance level of the statistical test was taken as unilateral 2.5% and 63 subjects were enrolled, there would be more than 90% certainty to conclude that the 5G telecontrol robot performs better PCI surgery.

5.3 Research design

A prospective, multicenter, exploratory clinical trial. Subjects who met the inclusion criteria and did not meet the exclusion criteria were enrolled into the clinical study, and the subjects are randomly grouped by using the IWRS applet (MedLand Centralized Randomization Management System). The surgeons completed the robotic-assisted surgical operation using the investigational device during cardiovascular PCI treatment. The investigator is also required to evaluate the performance of the investigational device during the procedure and

ultimately determine the safety and efficacy of its clinical application.



Data collected at the baseline and intra-operative angiography will be used as a basis for determining whether subjects are applicable for enrollment and undergo surgical treatment.

5.4 Selection of investigational methods and rationale

5.4.1 Surgical options

This clinical trial plans to enroll subjects who need to undergo percutaneous coronary intervention.

5.4.2 Endpoint selection

5.4.2.1 General Information of Vascular Interventional Robots

Since the initial application in 2006, robot-assisted PCI has been shown to be safe and feasible in simple lesions. With advances in system technology and increased operator experience, vascular interventional robots are also beginning to be applied to complex, more "real-world" lesions, where their safety and efficacy have been further validated [7-13]. However, reducing radiation exposure for the operator is not the sole objective of vascular interventional robotics. It is also envisioned that robotic surgery can assist in decision-making,

enhance the operator’s operations, further improve surgical safety and efficacy, achieve more precise treatment targeting, reduce patients' radiation exposure and contrast dose, thereby benefiting both patients and physicians. The R-One™ vascular interventional robot employs an innovative bionic twisting technology that replicates the hand movements of physicians. Through mechanical clamping and millimeter-level stepping, it delivers superior motion stability and high precision, preventing unintended displacement of instruments caused by operator muscle tremors, fatigue, or mishandling during instrument exchanges. Robotic-assisted surgery eliminates the limitations of manual methods, such as tremors that may lead to serious complications, thereby enhancing surgical precision and safety. Simultaneously, it reduces the need for repeated manipulations and instrument repositioning, consequently lowering patients' radiation doses and contrast agent consumption [Patent No.: CN107847281B; CN106535808B].

Thanks to its unique technological design, the introduction and removal of instruments (guidewires and balloon/stent catheters) takes only one second. The R-One robotic platform can precisely and perfectly replicate hand movements, ensuring medical staff can execute procedures rapidly. Owing to its intuitive operation, the R-One platform features a swift learning curve. As early as the 2017 safety study of this device, medical personnel—without any specialized training—demonstrated that robotic-assisted PCI differed from manual PCI by merely one minute in procedure time. As part of using R-One for coronary interventions, interventional cardiologists can operate the robot via a console behind radiation-proof screens while seated almost entirely. This significantly improves ergonomic positioning and comfort for healthcare providers. The setup also enhances surgical visual feedback by enabling closer observation. The control station features a mobile radiation shield (190 cm height × 152 cm width × 118 cm depth), accommodating multiple personnel to ensure protection for the entire care team. The secure execution of interventional procedures substantially reduces stress among medical staff. Comprehensive protection against radiation exposure prevents occupational injuries, thereby contributing to improved patient care quality.

The advancement and widespread adoption of internet technology have dismantled spatial barriers in human interaction, enabling cross-regional communication and interaction. Since the inception of internet technology, the medical field has endeavored to leverage it to

overcome temporal and spatial constraints. In 2020, Professor Ryan from the Frederik Meijer Heart & Vascular Institute performed PCI procedures on vascular simulators, with 20 target lesions operated on and 16 target lesions consecutively treated in the transcontinental model, in New York (206 miles, regional model) and San Francisco (3,085 miles, transcontinental model) using a remote vascular interventional robotic system (Corpath) console in Boston. System measurements revealed master-slave delays by comparing transcontinental model with regional model as follows: 121.5 ± 2.4 ms vs. 67.8 ± 0.9 ms ($p < 0.001$) in the wired mode; 162.5 ± 1.1 ms vs. 86.6 ± 0.6 ms ($p < 0.001$) in the 5G mode. Although statistically significant differences in delay existed between models, operators rated the latency as "imperceptible" in both scenarios [19].

China's vast territory leads to uneven distribution of medical resources. High-quality doctors and advanced equipment are predominantly concentrated in first-tier and provincial capital cities, while remote grassroots areas suffer from underdevelopment and scarce medical resources. This forces patients to travel long distances for treatment, increasing burdens on both patients and hospitals. Cross-regional medical access has long been a challenge in healthcare development. 5G communication technology, with its advantages of high throughput, low latency, and massive connectivity, can empower China's medical services toward mobility, remote operation, and intelligent development when integrated with robotics. This integration enables the implementation of remote surgery.

The success of remote surgery hinges on, on the one hand, operational consistency and real-time synchronization between the master and slave systems of surgical robots; on the other hand, technical robustness, including signal stability, anti-interference capability, and high-throughput data transmission [18]. Network latency severely impacts surgical operations; data transmission latency affects surgical operation time; latency fluctuation causes packet disordering, leading to mechanical jitter in robotic manipulators.

5.4.2.2 Primary endpoint

As with any medical devices, surgeons who use vascular interventional navigation control systems are challenged with learning curves.

The primary endpoints of this clinical trial are "clinical success rate" and "technical success

rate". Clinical success is defined as: 1. Target lesion was treated with the investigational device, residual stenosis of the target vessel (visual description through angiography) is less than 30% and TIMI grade 3 after PCI; 2. No in-hospital MACE; Technical success is defined as: The Robot-assisted PCI procedure was successfully completed without any unplanned manual assistance or shift to manual operation.

5.4.3 Risk observation assessment

The trial protocol requires the investigator to record all adverse events during clinical trial phases and determine the relevance and severity.

According to the *Chinese Guidelines for Percutaneous Coronary Intervention (2016)*[20], the final follow-up of this study was scheduled at 1 month after the procedure and the occurrence of adverse events was collected during the same period to meet the observation time requirement of risk infection that may result from the surgical treatment.

5.5 Subject Selection

From October 2024 to September 2026, patients with coronary artery disease requiring PCI treatment were identified by clinical screening and coronary angiography in the collaborating medical units (Lopu County People's Hospital, Karamay Central Hospital, and the First People's Hospital of Kashgar Region).

5.5.1 General Inclusion Criteria

Subjects must meet all of the following inclusion criteria:

1. 18 years of age ≤ age ≤ 80 years of age.
2. Have clinical indication(s) for PCI and need to be treated with a PCI procedure.
3. Subjects voluntarily signed an informed consent form and were willing to complete follow-up visits.

5.5.2 Angiography Inclusion Criteria

1. Visual description of target lesion diameter stenosis ≥70% (or ≥50% accompanied with

clinical evidence of myocardial ischemia within that range;

2. 2.0 mm ≤reference vessel diameter by visual description ≤ 4.0 mm.
3. Target lesion length ≤34.0 mm by visual description (If it is made up of multiple small lesions, the distance of which should not exceed 10 mm) and can be fully covered by a single stent. There are no less than 2.0 mm normal segmental vessels at the proximal and distal margins of the diseased region.
4. ≤2 target vessels to be treated, one single stent for each target lesion per target vessel, and target lesions can not be treated through stages;

5.5.3 General Exclusion Criteria

Subjects cannot meet any of the following exclusion criteria:

1. Subjects have undergone other PCI within 72 hours prior to the R-One PCI procedure;
2. Subjects have undergone PCI within 30 days prior to the R-One PCI procedure and have experienced a MACE or other serious adverse event;
3. Acute MI within one week prior to scheduled R-One PCI procedure;
4. Severe heart failure (NYHA ≥ Class III);
5. Cardiogenic shock within 48 hours prior to the PCI procedure;
6. Pregnant and lactating women, or women with plans to become pregnant during the clinical trial;
7. Subjects with allergies to aspirin, heparin, clopidogrel, contrast media, metallic materials and rapamycin;
8. Subjects with a platelet count <100 x 10^9/L or >700 x 10^9/L and a WBC count <3 x 10^9/L (e.g., thrombocytopenia, thrombocytosis, neutropenia or leukopenia);
9. Subjects with creatinine levels ≥ 177 umol/L;
10. Subjects had a stroke within 30 days prior to the planned R-One PCI procedure.
11. Subjects with an active peptic ulcer or upper gastrointestinal hemorrhage within 6 months prior to the PCI procedure.
12. Subjects with a history of massive haemorrhage or coagulation disorder, or refusal of blood transfusion within the previous 6 months.
13. Subjects are currently enrolled in another clinical study that has not yet completed the

entire follow-up period.

14. The investigators determined that the patient was not applicable for robot-assisted PCI.

5.5.4 Angiography Exclusion Criteria

1. TIMI blood flow grade of <3 for the target lesion.
2. In-stent restenosis, or the target vessel has implanted a stent previous which in close proximity to the target lesion.
3. Need other treatments (e.g., atherectomy or laser treatment) in addition to balloon angioplasty and stentoplasty.
4. Coronary anatomy deemed unsuitable for robot-assisted PCI as determined by the operator

6 Primary Evaluation Indicators

6.1 Clinical success rate of the surgery

6.1.1 Calculation formula:

Clinical success rate = number of subjects that were clinical successes ÷ number of subjects that received surgical treatment × 100%.

6.1.2 Definition of clinical surgical success:

(1) The target lesion was treated with test device, and the residual stenosis in the target vessel (visual description by angiography) reduced to less than 30% after PCI and a TIMI grade of 3.

(2) No major adverse cardiovascular events (MACE) occurred in the hospital.

6.2 Success rate of surgical techniques

6.2.1 Calculation formula:

Technical success rate = number of subjects that were technical successes ÷ number of subjects received surgical treatment × 100%

6.2.2 Definition of technical success:

(1) The Robot-assisted PCI procedure was successfully completed without any unplanned

manual assistance or shift to manual operation.

(2) Definition of unplanned manual assistance:

Manual translation/rotation of the guidewire and/or manual translation of the stent/balloon once the guidewire has left the guiding catheter

(3) Definition of the shift to manual operation:

Any situation during the PCI procedure that results in the shift to manual operation.

System restart failure during robotic surgery

(4) Definition of planned manual assistance:

During robotic surgery: Reposition of guidewires or stents/balloons, manual translation/rotation of guidewires or stents/balloons to guiding catheters, reposition of guiding catheters and usage of any device that is not compatible with the robotic platform

7 Secondary Evaluation Indicators

7.1 Procedure duration

Calculation formula: Procedure duration = arterial sheath removal time - arterial sheath insertion time.

7.2 Duration of robot-assisted treatment

Calculation formula: Robot-assisted treatment duration = time when the robot finishes moving the guidewire away from the coronary vessel - time when the robot starts manipulating the guidewire.

7.3 Radiation exposure to the patient

Evaluation Method: Measure and record dose exposure by angiography (DSA)

7.4 Radiation exposure to surgeons

Evaluation Method:

Detect radiation through radiation dosimeters. Two dosimeters will be used simultaneously during the procedure. One is placed on the operating table and the other is worn by the

surgeon to measure the radiation dose exposed to the surgeon. Both dosimeters will be calibrated once a day before use and reset to zero before each PCI procedure. Radiation readings from the dosimeter will be recorded when the first guidewire is inserted into the vessel and the last guidewire is pulled out of the vessel.

7.5 Contrast dose

Evaluation Method:

Record the contrast dose used during intra-operative angiography

7.6 MACE

Evaluation Method:

Record the in-hospital MACE of subjects

Record the MACE occurred 1 month (30±7 days) after the PCI procedure

8 Product performance indicators

8.1 Intraoperative physiological load evaluation of surgeons

Evaluation Method:

Surgeons are required to complete the Local Experienced Discomfort Questionnaire (LED scale) in time after the surgery in order to provide a retrospective evaluation of the physiological sensations during the procedure in the way of visual analog scale.

8.2 Intraoperative psychological load evaluation of surgeons

Evaluation Method:

Surgeons are required to complete the Subjective Mental Effort Questionnaire (SME scale) in time after the surgery in order to provide a retrospective evaluation of the mental feelings during the procedure in the way of visual analog scale.

8.3 Intraoperative Remote Control Performance Evaluation of surgeons

Evaluation Method:

Both remote and local surgeons are required to promptly complete postoperative subjective

assessments of intraoperative operational experience, including real-time responsiveness of remote surgical maneuvers, image quality of remote high-definition DSA (Digital Subtraction Angiography) imaging, transmission immediacy of remote DSA images, immediacy and stability of remote audio transmission, and operational flexibility of the slave-side bedside manipulator arms.

8.4 Incidence rate of serious system malfunction

Calculation formula: Incidence rate of serious system malfunction = Number of procedures with serious system malfunction during robot-assisted surgery ÷ Number of procedures in which robot-assisted surgery was performed × 100%.

Evaluation Method:

Definition of serious system malfunction: System malfunctions that occur during robot-assisted surgery that are difficult to repair in a short period of time and can have a serious impact on the surgical process or options.

8.5 The occurrences of repairable system malfunction

Evaluation Method:

Definition of repairable system malfunction: Simple malfunctions that occur during robot-assisted surgery that can be repaired by a technician or the surgical team and do not have a serious impact on the surgical process or options.

8.6 Evaluation of Device Usability

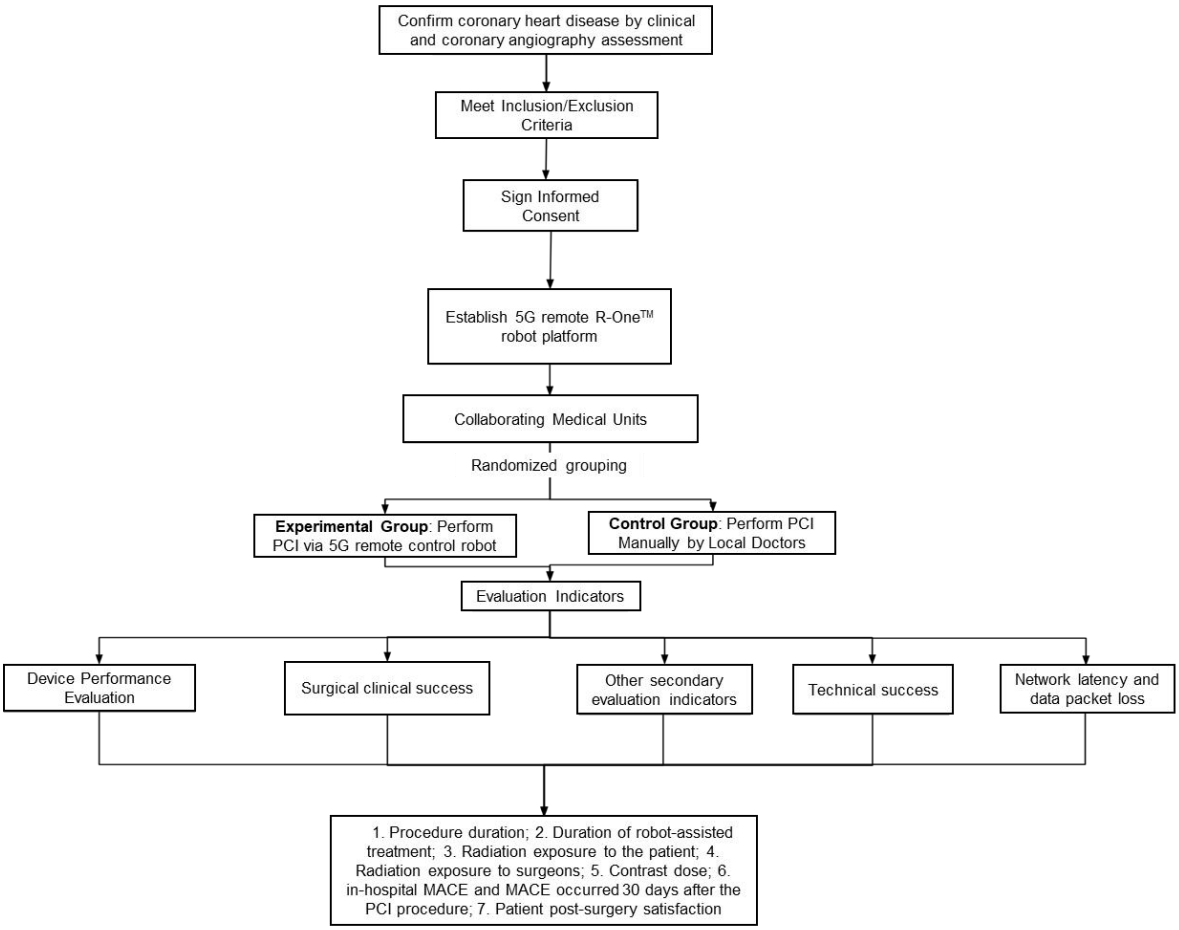
Evaluation Method:

1. Record the performance of the investigational device from preoperative preparation to the end of the procedure.
2. Investigators are required to complete the Device Performance Evaluation Form after surgery and provide a retrospectively evaluation of performance of the investigational device during the trial.

9 Indicators for Safety Evaluation

Subjects' laboratory test results collected during the screening period, operation day, pre-discharge and 1-month post-operative visit, and information of adverse events during the clinical trial, as well as investigational device-related adverse events and serious adverse events.

10 Experimental Procedure



Information of all the patients who have signed the Informed Consent Form and actually pass the screening will be registered in the screening/enrollment log sheet. If a subject is excluded from the trial, the investigator should specify the reasons for screening failure. If a subject is enrolled in the trial but does not use the investigational device, the reason should also be recorded.

All subjects enrolled in the trial will be given a corresponding enrollment number.

11 Application method of the investigational device

Subjects who meet the inclusion criteria and do not meet the exclusion criteria will be enrolled in the clinical study and the surgeon will complete the therapeutic treatment on the subject while performing the cardiology PCI procedure.

The investigational devices should be used by investigators respectively during the surgical treatment according to product instructions. Surgeons who would participate in the trial and use the study device should be independent PCI surgeons and need to be trained and supervised by the physician who completed the animal experiments using the investigational device.

12 General procedure of a surgical operation

1. Connect the power cord to the mains.
2. Load the instruction unit, ensuring that the positioning mark on the base and that on the radiation-proof screen overlap.
3. Switch on the system
4. Activate the system and simultaneously establish a master-slave connection.
5. Prepare R-One consumables kit.
6. Install the instruction unit protective sleeve.
7. Install the cartridge.
8. Install the robot.
9. Attach the Y-connector clip to the cartridge.
10. Insert the guide wire in the cartridge.
11. Navigate the guide wire through the instruction unit
12. Move the control lever and actuate the guidewire
13. Fix the guidewire
14. Insert the catheter into the cartridge
15. Navigate the catheter through the instruction unit
16. Move the control lever and actuate the catheter
17. Securing catheter
18. Simultaneous navigate the guidewire and catheter from the instruction unit

19. Place the guide wire in the alternate path as a backup
20. Place the catheter in the alternate path as a backup
21. Adjust the robot position

13 Feasibility

13.1 Analysis of subject risks and the probability of trial failure

The trial failure may be caused by the device defects occurred during operation, the investigator's failure to strictly implement the clinical trial protocol, improper operation and measurement that are against the protocol, and the high subjects drop-out rate that exceeds the expectation.

13.2 Analysis of subject benefits and probability of trial success

Since the initial application in 2006, robot-assisted PCI has been shown to be safe and feasible in simple lesions. With advances in system technology and increased operator experience, vascular interventional robots are also beginning to be applied to complex, more “real-world” lesions, where their safety and efficacy have been further validated [7-13]. However, reducing radiation exposure for the operator is not the sole objective of vascular interventional robotics. It is also envisioned that robotic surgery can assist in decision-making, enhance the operator’s operations, further improve surgical safety and efficacy, achieve more precise treatment targeting, reduce patients' radiation exposure and contrast dose, thereby benefiting both patients and physicians. The R-One™ vascular interventional robot employs an innovative bionic twisting technology that replicates the hand movements of physicians. Through mechanical clamping and millimeter-level stepping, it delivers superior motion stability and high precision, preventing unintended displacement of instruments caused by operator muscle tremors, fatigue, or mishandling during instrument exchanges. Robotic-assisted surgery eliminates the limitations of manual methods, such as tremors that may lead to serious complications, thereby enhancing surgical precision and safety. Simultaneously, it reduces the need for repeated manipulations and instrument repositioning, consequently

lowering patients' radiation doses and contrast agent consumption [Patent No.: CN107847281B; CN106535808B]. Thanks to its unique technological design, the introduction and removal of instruments (guidewires and balloon/stent catheters) takes only one second. The R-One robotic platform can precisely and perfectly replicate hand movements, ensuring medical staff can execute procedures rapidly. Owing to its intuitive operation, the R-One platform features a swift learning curve. As early as the 2017 safety study of this device, medical personnel—without any specialized training—demonstrated that robotic-assisted PCI differed from manual PCI by merely one minute in procedure time. As part of using R-One for coronary interventions, interventional cardiologists can operate the robot via a console behind radiation-proof screens while seated almost entirely. This significantly improves ergonomic positioning and comfort for healthcare providers. The setup also enhances surgical visual feedback by enabling closer observation. The control station features a mobile radiation shield (190 cm height × 152 cm width × 118 cm depth), accommodating multiple personnel to ensure protection for the entire care team. The secure execution of interventional procedures substantially reduces stress among medical staff. Comprehensive protection against radiation exposure prevents occupational injuries, thereby contributing to improved patient care quality.

5G communication technology, with its advantages of high throughput, low latency, and massive connectivity, can empower China's medical services toward mobility, remote operation, and intelligent development when integrated with robotics. This integration enables the implementation of remote surgery. Therefore, the development of 5G remote surgical robot system and its regular application can enable surgeons to be free from time and space restrictions, allowing patients to receive high-quality medical services locally. This is conducive to the balanced development of high-quality medical resources and truly makes high-quality medical services accessible to the general public.

The entire development process of this investigational device, from project planning, design and development to processing and production, has been carried out in strict accordance with industry standards and regulatory requirements, such as "Application of Medical Device Risk Management to Medical Devices", to assess the possible risk hazards and take corresponding control measures to keep the expected risks within acceptable limits as far as possible.

After the approval and consent of the Medical Ethics Committee for the protocol, the clinical trial will be carried out in compliance with the requirements of the Norms on the Quality Management of Medical Devices for the Clinical Trials, the Declaration of Helsinki and other relevant laws and regulations. The investigator should strictly follow the requirements of each protocol phase of during the clinical trial process.

Previsou animal experiments and literature studies have approved that tthere is no evidence to suggest that the investigational device may have more unanticipated adverse events or a higher risk compared to other vascular nterventional navigation control systems that are on the market or in clinical trial phase. R-One™ vascular intervention robot is embedded software with negligible end-to-end delay. After adding 5G remote robotic surgery function, risks mainly come from 5G network transmission delay, packet loss and network disconnection. The remote control module of R-One™ vascular intervention robot adopts end-to-end control, remotely transmitting control signals and emergency stop signals. The operation mode of remote control remains unchanged, achieving continuous signal transmission, which has good reliability and stability. If the network condition, delay and packet loss are comprehensively evaluated before the operation and meet the clinical and technical requirements, remote surgery can be carried out. All instructions are transmitted continuously, and remote control handle instructions are updated in real time to ensure that network delay and packet loss do not exceed clinical and technical requirements. In case of abnormality, network interruption or emergency, it can switch local or local manual operation with one key. Therefore, under strict implementation of the trial protocol, the potential benefits of using the investigational device for subjects are greater than the potential risks, and the clinical trial itself is more likely to be successful.

14 Monitoring and Quality Control of Clinical Trial

The purpose of trial monitoring is to verify that: I. The rights and health of the subjects are protected; II. The reported trial data are accurate and intact, and can be verified from the original documents; III. The trial is implemented in accordance with the protocol and in compliance with the requirements of the clinical trial regulations and relevant applicable

management procedures.

During the course of this study, the participating researchers must be uniformly trained and the entire clinical trial shall be conducted under standard operating procedures. The investigator shall record data into the CRF truthfully, detailed and carefully as per the requirements for CRF completion to ensure that the contents of the CRF are true, complete and reliable.

The sponsor will also assign inspectors to regularly visit and monitor research centre on-site to ensure that all elements in the protocol are strictly adhered to and that the study data are filled in correctly. The frequency of monitoring will be demonstrated in the monitoring plan. Monitoring may be also included contacts by correspondence or telephone, as appropriate. During monitoring visits, investigators must make time to validate data, resolve questions raised, and verify raw data for inspectors to abtain subjects records.

Definition of source data review and approval: On-site monitoring includes source document verification (SDV). SDV is the procedure of comparing data in the CRF with the source data (e.g. various laboratory test results) stored at the institutions, with the aim of verifying their accuracy. All observations and findings of the clinical trial shall be checked to ensure the reliability of data and all conclusions are drawn from original data.

General workflow of trial monitoring:

1. The CRA must notify the investigator and, if necessary, the instituional office prior to conducting on-site monitoring;
2. Each monitoring visit needs to confirm that the issues identified in the previous visit have been resolved;
3. During the monitoring process, the CRA shall communicate with the investigator in a timely manner regarding the issues identified;
4. The CRA shoud submit a written question feedback form to the investigator and, if necessary, to the institutional office;
5. The CRA shall urge the investigator to promptly address the problems identified during the monitoring until they are resolved;
6. At the end of the monitoring visit, a written monitoring visit report is submitted to the project leader.

The specific rules and requirements for the implementation of monitoring are based on the internal standard operating procedures of the sponsor/CRO company. The monitoring process shall be conducted in accordance with the relevant requirements of the clinical trial management department of the study site and in compliance with the national laws and regulations on clinical trials.

15 Ethical protection and informed consent in clinical trial

15.1 Ethical Considerations

This clinical trial is conducted in strict accordance with the requirements of the Good Clinical Practice for Medical Devices, the Declaration of Helsinki, other relevant laws and regulations, and the trial protocol. The clinical trial protocol, informed consent form and their updates and modifications are subject to the approval of the Ethics Committee before implementation. The principal investigator is responsible for reporting to the ethics committee, through the clinical trial management institutions, any modifications of the trial protocol during the course of the trial as well as severe adverse events or unexpected adverse events that may affect the safety of the subjects and actually occur during the course of the study.

15.2 Approval of Trial Protocol

This trial protocol is subject to the approval by the Medical Ethics Committee.

15.3 Informed consent process

The investigator shall obtain signed informed consent from subjects participating in the study after fully explaining the purpose, methods, expected benefits, and potential harms of the trial. For subjects who are unable to provide legal consent, written informed consent must be obtained from a legal guardian. If subjects and their legal guardians are unable to read, a public notary must be present throughout the informed consent discussion. After the subjects and guardians have verbally consented to participate in the study, the notary signs the

informed consent form, certifying that the information in the informed consent form has been accurately interpreted and understood. Investigators also need to declare that the subject can refuse to participate the study or withdraw the study any time with any reason.

If newly identified safety information is sufficient to cause a significant change in the risk/benefit evaluation, the informed consent form shall be reviewed and updated when necessary. All subjects (including patients under remedy) shall be informed about these information, and provided with a modified consent form to join in the study.

15.4 Text of Informed Consent Form

The contents of the informed consent form may vary across study sites, and only the versions that have been reviewed and approved by the principal Ethics Committee can be used at any sites.

16 Regulations for Reporting Adverse Events and Device Defects

16.1 adverse event

16.1.1 Definition of adverse events

Adverse events (AEs) refer to any adverse medical event that occurred during clinical trials, whether or not it was considered to be medical device or surgical procedure related.

All AEs that are observed during the trial must be truthfully recorded on the Adverse Event Form. The investigator shall provide targeted treatment for the AEs and follow up with the subjects until their associated symptoms disappear or become stable.

16.1.2 Determining the Severity of Adverse Events

- Mild: Does not affect daily activities;
- Moderate: Affects daily activities;
- Severe: Loses the ability to perform daily activities.

16.1.3 Determine the relationship between adverse events and investigational devices and procedures

The investigator shall assess the relationship between the adverse event and the investigational device or surgery according to the following classification criteria:

16.1.3.1 Relevance to the investigational device:

- Definitely related: There was a clear temporal logic relationship between the occurrence of adverse events and use of investigational device, and other causes could be ruled out.
- Probably related: Adverse events occurred concomitantly during the use of the investigational device, and there exist a possibility that the trial treatment caused the adverse event.
- Possibly related: Some existing evidence shows that the adverse event occurred within a reasonable time interval after use of the investigational device.
- Possibly unrelated: The adverse event did not occur within a reasonable time interval after the use of the study device.

- Unrelated: The occurrence of adverse events was related to other diseases, medications or treatments of the subjects, and did not correlate with the use of the investigational device.
- Cannot judge:

16.1.3.2 Relevance to the surgery:

- Definitely related: There was a clear temporal logical relationship between the occurrence of adverse events and the surgical operation, other causes could be excluded.
- Probably related: Adverse events occurred concomitantly during the use of the investigational device, and there exist a possibility that the trial treatment caused the adverse event.
- Possibly related: Some existing evidence shows that the adverse event occurred within a reasonable time interval after use of the investigational device.
- Possibly unrelated: The adverse event did not occur within a reasonable time interval after the use of the study device.
- Unrelated: The occurrence of the adverse event was related to other diseases, medication or treatment of the subject, and did not correlate with the surgical operation.
- Cannot judge:

16.2 Serious adverse events

16.2.1 Definition of serious adverse events

The adverse events observed during clinical trials usually include: death, life-threatening, hospitalization required or prolonged hospitalization, disability, affect the ability to work, or cause congenital deformities, etc. Medical events that have not yet resulted in death, are not yet life-threatening, or do not yet require hospitalization, may be considered as severe adverse events if they are judged by the investigator to be potentially harmful to the subjects and preventable by medication or surgical treatment.

16.2.2 Management and reporting of serious adverse events

When a severe adverse event is observed during the clinical trial, regardless of its relationship to the investigational device, the investigator shall immediately provide appropriate treatment

to the subjects and record the event in the CRF. The investigator shall also complete a Severe Adverse Event Report Form, submit a written report to the medical device management department of the clinical trial institution, and notify the sponsor in writing of the following contact information: The administrative departments for clinical trials of medical devices shall report in writing within 24 hours to the corresponding ethical committees, and the competent departments of the provincial, municipal and autonomous region Medical Products Administrations and Health Commissions where the clinical trial institutions are located. In terms of fatality, clinical trial institutions and investigators should provide the ethics committee and sponsors with all the information they need.

16.3 Anticipated Adverse Events

Anticipated adverse events are those whose occurrence can be predicted due to the subject's disease conditions, surgical procedure or study device.

16.3.1 Adverse events that may result from percutaneous coronary intervention

Adverse events that may result from general PCI surgery and anesthesia include, but are not limited to, the following[11][20][22]:

- Angina pectoris
- Myocardial infarction
- Myocardial infarction recurrence
- Acute coronary artery occlusion
- No-reflux
- Coronary artery perforation
- In-stent thrombosis
- Stent dislodgement
- Haemorrhage (Bleeding)
- Vascular complications
- Contrast-induced acute kidney injury
- Major adverse cardiovascular events (MACE) (including readmission 12 months after

surgery, angina recurrence, revascularization, in-stent thrombosis, and cardiac death)[23]

- Adverse reactions to anesthesia (headache, muscular pain and nausea)
- Allergic reaction
- Death

16.3.2 Adverse events that may result from investigational device

No clear evidence has been found that the investigational device may cause more adverse medical events than comparable products in the normal clinical settings. However, in the event of violation operation by the user, it may result in accidental injury to the user or patient.

16.4 Treatment of adverse events

When adverse events occur to subjects during the period of clinical trial, they should be treated according to the symptoms. The investigator need to evaluate the severity of the adverse event, their correlation with the investigational device and surgical procedures, put forward suggestions for further treatment, and then fill the adverse event sheet log in time.

Complications of PCI procedures (including robot-assisted PCI procedures) are usually related to surgical site, surgical approach, and intra-operative surgical proficiency. Adequate pre-operative preparation, fully understanding of anatomical variants, rational selection of surgical route, standardized surgical operation, and sound post-operative management are key to prevent and treat complications of PCI procedures.

16.4.1 Acute coronary artery occlusion

Most acute coronary occlusions occur during the operation or before leaving the catheter lab, and may also occur 24 h after the surgery. Occlusion of the major or large branches can lead to serious consequences, such as immediate blood pressure drop, decreased heart rate, and even ventricular fibrillation and ventricular arrest which may quickly cause death.

All of the above-mentioned conditions should be treated promptly or through stents implantation to restore coronary blood flow as soon as possible.

16.4.2 No-reflux

It's recommended to inject intracoronary tirofiban[24][25], calcium channel blockers[26], nitrates, nitroprusside, adenosine, apply thrombus aspiration[27]or implant IABP, which may help to prevent or mitigate no-reflow and stabilize hemodynamics. With regard to administration site, tirofiban administered via a perfusion catheter far from the coronary target lesion can better improve myocardial perfusion in patients without no-reflow compared to coronary oral administration[28].

16.4.3 Coronary artery perforation

Coronary artery perforation is a rare but very dangerous complication. When perforation occurs, a balloon with matching diameter can be used firstly at the perforation site to perform low-pressure dilatation and occlusion. It's not recommended to occlude coronary artery with large blood supply for long time, better intermittently, which is often effective for small perforations,

If the perforation is large or low-pressure balloon dilatation occlusion fails, it's recommended to implant coated stent graft at the perforation site, and suspend the use of platelet membrane glycoprotein IIb/IIIa receptor inhibitor in preparation for pericardial puncture. Monitor the activated clotting time (ACT) and apply fisetin to neutralize heparin if necessary.

If intervention fails to occlude the breach, emergency surgery should be performed.

If cardiac tamponade occurs, pericardiocentesis or pericardiotomy should be performed immediately for drainage while maintaining the stability of hemodynamics at the same time.

Coronary perforations caused by guide wires are prone to induce delayed pericardial tamponade, and need to be closely monitored. If the perforation is large, it need to be occluded with autologous fat particles or coils if necessary. Regardless of the type of the perforation, postoperative echocardiogram follow-up should be performed to prevent the occurrence of delayed pericardial tamponade.

16.4.4 Stent thrombosis

Although the incidence rate of stent thrombosis is low (0.6% within 30 d and 2.9% within 3 years)[29], its mortality rate is as high as 45%[29]. The main risk factors associated with stent

thrombosis include: （1） Patients at risk: (e.g., diabetes, renal insufficiency, cardiac insufficiency, high residual platelet reactivity, premature discontinuation of DAPT; (2) high-risk lesions: Such as type B2 or C complex coronary lesions, complete occlusions, thrombosis and small vessel diffuse lesions; (3) operation factors: Implantation of multiple stents, long stents, poor stent apposition, stent overlapping, Crush technique, small stent diameter or small internal lumen diameter, stent structural deformation, bifurcated stent, persistent postoperative slow blood flow, positive vessel remodeling, incomplete lesion coverage, or entrapment tears; (4) Stent-related factors: Allergy to stent coatings or polymers, stent-induced local vasular inflammatory reaction, stent fracture, delayed endothelialization.

Precautions of in-stent thrombosis includes: （1） Adequate preoperative and perioperative DAPT and anticoagulation, and GPI for high-risk patients or lesions after adequately evaluate the hemorrhage risks and benefits. （2） Select the appropriate intervention treatment approach. Treatments such as balloon dilation, BMS, or DES implantation should be selected based on the evaluation of the advantages and disadvantages; stent apposition need to be as good as possible, high pressure release stents (with optional post-dilatation balloons if necessary) are recommended to minimize damage to the vessels at both ends of the stent; IVUS guidance can be used for selected patients. （3） Adequate use of DAPT during the postoperative period is emphasized.

Once stent thrombosis occurs, coronary angiography should be performed immediately through recommended IVUS or OCT to clarify the cause of stent failure. Patients with high thrombus load can be treated by thrombus aspiration, and GPI continuous intravenous infusion for 48h. Balloon dilation or stents reimplantation is still the main treatment method. Intracoronary thrombolytic therapy can be applied if necessary. Platelet function should be tested to understand whether there is high residual platelet reactivity, so as to adjust antiplatelet therapy. Patients with recurrent and refractory stent thrombosis can be treated with surgical treatment if necessary.

16.4.5 Stent dislodgement

Stent dislodgement is less common and is most often seen in the following conditions: lesions that have not been adequately pre-dilated (or direct stenting), vessels have proximal tortuosity

(or the stent has been implanted), when the stent crosses a stenosis or calcified lesion with too much force and the stent pushes too hard, when stent implantation fails, and due to poor coaxiality of the stent with the guideline catheter or poor loading of the stent with the balloon, the stent dislodges when being retracted into the guide catheter. Adequate preoperative predetermination of lesion characteristics and pretreatment of lesions (e.g., pretreatment of calcified lesions by atherectomy) is an effective means to prevent stent dislodgement.

When stent dislodgement occurs and the guide wire is still in the stent lumen, a small balloon ≤1.5 mm in diameter can be delivered via the guide wire to the remote end of the stent, slightly dilate, and withdraw the stent slowly into the guiding catheter.

If the stent cannot be withdrawn into the guiding catheter due to proximal deformation, try to use a new guiding catheter with a larger OD; or use a grasper via another vascular route to capture and remove the stent.

If the above-mentioned methods do not work, the stent can be released in situ by a balloon with a diameter of 1:1 to the blood vessel delivered through the guidewire, or implant another stent and form stent-in-stent appostion Surgery can performed to remove the dislodged stent if necessary.

16.4.6 Haemorrhage (Bleeding)

Perioperative haemorrhage is a major risk factor of death and other serious adverse events[31]. Massive hemorrhage (including cerebral bleeding) may lead directly to death, and discontinuation of antithrombotic drugs after hemorrhage may also lead to thrombotic events and even death.

Precautions for hemorrhage include: All patients should be assessed for risk of bleeding before PCI (I, C), and the CRUSADE score is recommended; the radial artery route is recommended (I, A); patients with high bleeding risk (e.g., renal insufficieny, old age, history of bleeding, and low body weight), antithrombotic drugs with less bleeding risk, such as bivalirudin and sulforaphane sodium are preferred during peri-operation; adjust anticoagulant dose based on body weight during PCI ; monitor ACT to avoid over-anticoagulation.

The decision to discontinue or adjust antiplatelet and anticoagulant medications after bleeding needs to be weighed individually according to the risk of hemorrhage and recurrent ischemic

events. Hemorrhage is usually treated with general non-pharmacological hemostatic measures, such as mechanical compression to stop bleeding; record the time and dose of the last anticoagulant or thrombolytic drug, and the presence of hepatic and renal impairment; estimate the half-life of the drug; assess the source of bleeding; test the complete blood counts, coagulation indicators, fibrinogen concentration and creatinine concentration; test the antithrombotic activity of the drug when conditions permit; patients with unstable hemodynamics can be treated with intravenous rehydration and erythrocyte transfusion; treat local hemostasis with endoscopic, interventional, or surgical methods if necessary; and suspend antithrombotic drugs as soon as possible if the risk of bleeding is greater than the risk of ischemia.

If the above-mentioned methods do not work, further medication may be used. Infuse fisetin to neutralize heparin, with the dose of sulfate fisetin 1mg/80~100U heparin, and the total dose less than 50mg generally; fisetin can neutralize 60% low molecular-weight heparin (LMWH). Patients who administerred LMWH in less than 8h can inject sulfate fisetin 1mg/100U anti-Xa activity, and 0.5mg/100U anti-Xa activity can be added when there is no effect. After stopping aspirin or tigretol for 3 d and clopidogrel for 5 d, the risk of bleeding and recurrent ischemic events should be evaluated again and moderate antithrombotic therapy should be resumed at the appropriate time[32][33].

16.4.7 Vascular complications

The vascular complications are mainly related to the puncture site, and the risk factors include female, age ≥70 years, body surface area <1.6 m^2, emergency intervention, peripheral vascular diseases and perioperative application of GPI[34][35].

The major complications of femoral artery puncture and their precautions are as follows. （1）Puncture site and retroperitoneal hematoma. Small local bleeding or hematoma that is asymptomatic can be left untreated. Large hematoma, massive bleeding and decreased blood pressure should be treated with adequate pressure to stop the bleeding and transfuse appropriate amount of fluid or blood. If hypotension (with or without abdominal pain and local hematoma formation) occurs within a short period of time after PCI, retroperitoneal hemorrhage may be suspected, and ultrasound or CT should be performed if necessary, with

prompt transfuse of adequate blood. （2） Pseudoaneurysm Doppler ultrasound can provide a definitive diagnosis, and most pseudoaneurysm will be closed by applying local compression bandages and reducing lower extremity activity. Larger pseudoaneurysms that cannot be healed by compression may be treated with ultrasound-guided injection of small doses of thrombin into the aneurysm. A few require surgical treatment. （3） Arterio-venous fistula A small percentage may close on their own, or by applying local compression, but large arteriovenous fistulas often require surgical repair. （4） Arterial entrapment and/or occlusion. It can be caused by damage to the endothelium of the vessel by guide wires, catheters or plaque detachment. Precaution methods include low resistance and/or fluoroscopic pushing of guidewires and catheters.

The main complications of radial artery puncture and their precautions are as follows. （1） Postoperative radial artery occlusion: The incidence rate is less than 5%. Routine preoperative Allen test to check the traffic of radial and ulnar arteries, adequate intraoperative anticoagulation, and timely postoperative decompression can effectively prevent radial artery occlusion and hand ischemia after PCI. （2） Radial artery spasm: is more common, and the probability is increased due to inadequate anesthesia during puncture, coarse and rigid instruments, poor operation, or guidewire entering branches. When radial artery spasm occurs, it is strictly forbidden to remove the catheter by force , and need to treat by administration of 200-400ug nitroglycerin, 200-400ug verapamil, or 5mg diltiazem (repeatedly if necessary) via intraarterial sheath until the spasm is relieved before proceed with the operation. （3） Forearm hematoma: due to perforation of a small radial branch caused by hydrophilic-coated guidewire or inappropriate application of a radial artery compressor; precautions include pushing the guidewire under fluoroscopy; and radial arteriogram if there is resistance. Postoperative local compression should be aware of the puncture site. （4） Fascial gap syndrome: is rare but has serious consequences. When the rapid progression of the forearm hematoma causes increased pressure in intraosseous membrane to a certain extent, it often leads to compression of the radial and ulnar arteries and the median nerve, which in turn leads to ischemia and necrosis of the hand. Therefore, surgical treatment should be performed as soon as possible once the syndrome occurs. （5） Pseudoaneurysm the incidence rate is less than 0.01%[36], and surgical treatment is feasible if

local compression does not work.

17 Terms of trial

Prior to the study, the sponsor should sign a clinical trial agreement with the clinical trial site and the principal investigator, which will describe the financial information, responsibilities and obligations of each party participating in study.

Under the compliance of relevant laws, regulations and the provisions of the test protocol, separate agreement with each research institution can be made on specific terms according to the actual situation.

17.1 Principle of confidentiality

Investigators shall ensure patients keep anonymous and prevent any un-authorized privacy disclosure. Subjects' information on CRF or other documents submitted to sponsor could be anonymous which means to replace patient names with IDs.

Research centers and investigators shall be responsible for the confidentiality of the clinical trial protocol, the investigator's manual, the investigational device, the completed CRF, laboratory reports, study data and results, and any information relating to the study device. Research centers and investigators will only use the relevant information to fulfill the duties of the clinical trial protocol or agreements (for example, to provide the necessary explanations to potential participants of the study in order to obtain informed consent form). The above information shall not be disclosed to any third party not related to this study without the written consent of the sponsor, except in the case of inspection by a higher regulatory authority or as specifically agreed in the test protocol.

17.2 Agreement on publication of trial results

Researchers who need to use research materials independently and publish articles must comply with relevant laws and regulations. The agreement on the publish of trial results will be specified in the protocol signed by the sponsor and the research center. The sponsor has the right to obtain a manuscript or abstract of the relevant article before the researcher submits it for publication.

17.3 Insurance

In case of any investigational device-related injury, the Sponsor need to provide the treatment cost and corresponding economic compensation to the subject. Related costs may also be reimbursed by the medical device clinical trial insurance purchased by the sponsor for this trial.

Specific compensation methods and deductibles will be agreed in the test agreement and the insurance agreement.

18 Rights and responsibilities of the parties

18.1 Subjects' rights

1. The trial must firstly be approved by the ethics committee before initiation. The ethics committee approval or consent document (which includes the name of this trial protocol) shall be marked with the approval content and date of the ethics committee. This requirement applies whenever there is a subsequent amendment/change to the programme.
2. All subjects were required to understand the purpose, methods, surgical effects, and potential adverse effects of the trial, voluntarily participate in the trial, and sign a written informed consent form.
3. Subjects have the rights, as stated in the informed consent form, to withdraw from the trial at any time if they wish to do so without interfering with their normal medical treatment.
4. If a subject occurs an adverse event related to the investigational device during the study, the additional costs required will be covered by the sponsor or clinical trial insurance in accordance with the study contract.
5. The clinical trial sites shall ensure that the medical monitoring system is working properly and that subjects can contact the study physician at any time in need and receive prompt medical consultation and treatment and, if necessary, hospitalization.

6. Emphasize the responsibilities of medical personnel at all levels, pay attention to clinical observation, and ensure the safety of the subjects.
7. Adverse events in subjects should be dealt with in a timely manner, and those events related to investigational device must be followed-up until the symptoms disappear or are corrected to clinically acceptable conditions.
8. In case of serious adverse events, efforts should be mobilized for active treatment and report in writing to the ethics committee, the sponsor and the relevant health supervision and management authorities within a specified period of time.

18.2 Assume institutional and investigator responsibilities for clinical trials

Before joining in a clinical trial, a clinical trial site should evaluate the relevant resources according to the characteristics of the investigational device to decide whether to participate or not.

Clinical trial sites shall maintain proper clinical trial records and essential documents as agreed with the sponsor, including but not limited to:

(1) Clinical trial protocol and its annexes approved by the ethics committee
(2) Clinical Trial Agreements
(3) Ethical approval
(4) Investigator qualification documents
(5) Sample signature of investigator and responsibilities division form
(6) Monitoring records
(7) CRF sample form and its updates
(8) Subject screening enrollment registration form
(9) Protocol deviation records
(10) Adverse events record
(11) investigational device usage records
(12) Trial summary report
(13) Original documentation of each subject:

- Signed informed consent form
- Completed Case Report Form (CRF) and Data Clarification Form (DCF)
- Adverse event reporting documents
- Documentation of relevant laboratory test reports

Before the clinical trial, the administrative department of clinical trial for medical devices of the clinical trial sites shall cooperate with the sponsor to submit an application to the ethics committee as well as relevant documents in accordance with the regulations.

According to the needs of the clinical trial, the investigator can authorize corresponding personnel to carry out subjects enrollment, continue communication with subjects, record clinical trial data, and manage investigational device management. The investigator should train and document their authorized personnel accordingly.

The investigator shall ensure that the relevant staff involved in the trial are familiar with the principle, application range, product performance, operation method, installation requirements and technical indicators of the investigational device, understand the preclinical study data and safety data of the investigational device, and master the prevention and emergency methods that may arise from the clinical trial.

The investigator shall ensure that the investigational device is used only on subjects in the clinical trial and shall not charge any fees.

Investigators should strictly follow the clinical trial protocol and should not deviate from it or materially change it without the consent of the sponsor and the ethics committee. However, in emergency situations requiring immediate attention, such as when the subject is in immediate danger, changes may also be reported in writing afterwards.

The investigator was responsible for enrolling subjects, talking to subjects or their guardians. It is the responsibility of the investigator to explain the investigational device and the details related to the clinical trial to the subject, to inform the subject of the possible benefits and known or foreseeable risks, and to obtain signed and dated informed consent from the subject or his or her guardian.

When an investigator discovers an unanticipated adverse event related to the investigational device in a clinical trial, he or she should work with the sponsor to revise the relevant contents of the informed consent form, report to the ethics committee for review and approval in

accordance with the relevant working procedures, and have the affected subject or his or her guardian re-sign the revised informed consent form for confirmation.

The investigator is responsible for making medical decisions related to the clinical trial, and in the event of an adverse event related to the clinical trial, the clinical trial site and the investigator should ensure that adequate and timely treatment and management is provided to the subject.

If serious adverse events occur in clinical trials, the investigators should immediately take appropriate treatment measures for the subjects. Meanwhile, they should report in writing to the management department of clinical trials of medical devices in the clinical trial institutions and notify the sponsors in writing through their clinical trial institutions. The administrative departments for clinical trials of medical devices shall report in writing within 24 hours to the corresponding ethical committees, and the competent departments of the provincial, municipal and autonomous region Medical Products Administrations and Health Commissions where the clinical trial institutions are located. In terms of fatality, clinical trial institutions and investigators should provide the ethics committee and sponsors with all the information they need.

Responsibilities of investigators: investigators should record all adverse events and instrument defects found in clinical trials, analyze the causes of the events together with the sponsors, form a written analysis report, put forward opinions on continuing, suspending or terminating the trials, and submit them to the Ethical Committee for review by the management department of clinical trials of medical devices in clinical trial institutions.

Investigators should ensure that clinical trial data are accurately, completely, clearly and timely included in the case report forms. The name of the case report form shall be signed by the investigator. Any data change shall be signed by the investigator and the date shall be marked. At the same time, the original record shall be kept, and the original record shall be clearly identifiable.

Clinical trial institutions and investigators shall ensure that data, documents and records of clinical trials are true, accurate, clear and safe.

Clinical trial institutions and investigators should be monitored, audited by the sponsors and supervised by ethical committees, and provide all required records related to the trial. Clinical

trial institutions and investigators shall cooperate with the inspectors from the NMPA or Health Commission for inspection.

When clinical trial institutions and investigators find that the risks outweigh the possible benefits or that results sufficient to judge the safety and efficacy of the investigational device, and it is necessary to suspend or terminate the clinical trial, they shall notify the subjects and ensure that they receive appropriate treatment and follow-up, as well as report and provide detailed written explanations in accordance with the regulations. If necessary, report to the food and drug supervision and management department of the province, autonomous region or municipality directly under the Central Government where it is located.

At the end of the clinical trial, the investigator should ensure that the records, reports are completed. The investigator should also ensure that the quantity of investigational devices received for the trial match the quantity used, discarded or returned, and that the remaining investigational devices are properly disposed of and documented.

19 Appendices

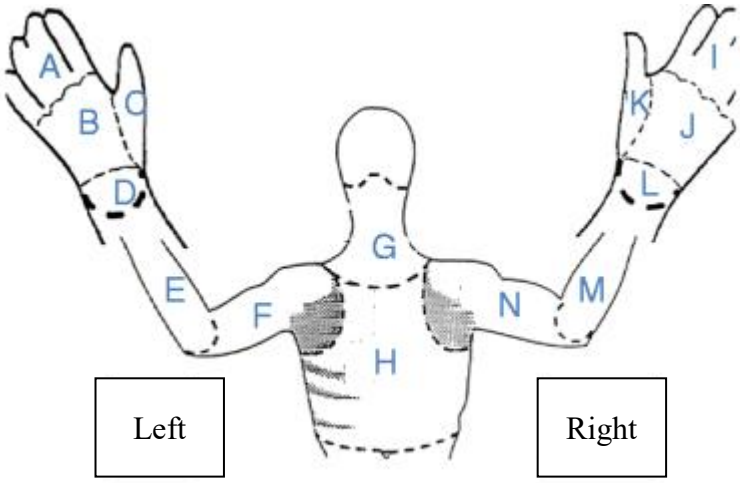
19.1 Local Discomfort Experience Scale

Subjects Screening Number:

Center No.: |__|__| |__|__|__| **Initials:** |__|__|__|__|

Enrollment number:

|__|__|__|



10	Very uncomfortable	Please (the surgeon) score the discomfort degree of the body parts indicated by the letters in the diagram after the operation:			
9					
8	Very uncomfortable				
7		A	_____	I	_____
6	Relatively uncomfortable	B	_____	J	_____
5		C	_____	K	_____
4	Some uncomfortable	D	_____	L	_____
3		E	_____	M	_____
2	Little uncomfortable	F	_____	N	_____
1		G	_____		
0	No discomfort at all.	H	_____		

Investigator (surgeon)/authorized recorder: _____

|__|__|__|__|year|__|__|months|__|__|days

19.2 Subjective Mental Load Scale

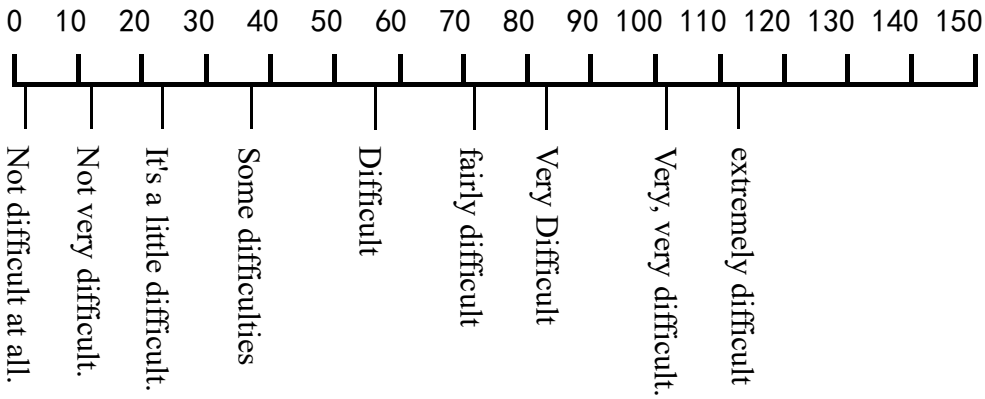
Subjects Screening Number:

Center No.: |__|__| |__|__|__| **Initials:** |__|__|__|__|

Enrollment number:

|__|__|__|

Please rate the degree of difficulty in completing this procedure based on the scale illustration and select a number on the anchor point for the final rating.



Rating: _____

Investigator (surgeon)/authorized recorder: _____

|__|__|__|__|year|__|__|months|__|__|days

19.3 Device Performance Evaluation Form

Subjects Screening Number:				
Center No.: |__|__|	|__|__|__|		**Initials:** |__|__|__|__|	
Enrollment number: |__|__|__|				
Main types of surgery:	□ Robot-assisted PCI		□ Tele-Robot-assisted PCI	
Start to move the guidewire away from the guiding catheter:	Begin time: |__|__|hours|__|__|minutes		Finished at: |__|__|hours|__|__|minutes	
Terminate the movement of guidewire from the coronary vessels.	Begin time: |__|__|hours|__|__|minutes		Finished at: |__|__|hours|__|__|minutes	
Device performance evaluation:				
Overall usage experience of the system:	□ Excellent	□ Good	□ Moderate	□ Bad
The flow performance of instruction unit:	□ Excellent	□ Good	□ Moderate	□ Bad
The visual effects of radiation-proof screen:	□ Excellent	□ Good	□ Moderate	□ Bad
The moving performance of the robotic arm	□ Excellent	□ Good	□ Moderate	□ Bad
The operating performance of the surgical device: *(If there were device replacement during the surgery, please evaluate the one with the lowest performance)*				
Cartridge:	□ Excellent	□ Good	□	□ Bad □ Not used

			Moderate		
The protective sleeve of the instruction unit:	□ Excellent	□ Good	□ Moderate	□ Bad	□ Not used
Other (_____):	□ Excellent	□ Good	□ Moderate	□ Bad	□ Not used
Other (_____):	□ Excellent	□ Good	□ Moderate	□ Bad	□ Not used
Intraoperative hemorrhage estimates: |__|__|__|__| mL				
Whether the intended purpose of robotic-assisted surgical treatment is accomplished.			□ Yes	□No	
Investigator (surgeon)/authorized recorder: _____					
|__|__|__|__|year|__|__|months|__|__|days					

19.4 System malfunction Record Form

<table>
<tr><td colspan="4">Subjects Screening Number:
Center No.: |__|__| |__|__|__| Initials: |__|__|__|__|
Enrollment number:
|__|__|__|
□ System malfunction occurred during surgery □ No system malfunction during the operation</td></tr>
<tr><td colspan="2">Occurrence Time:
|__|__|hours|__|__|minutes</td><td colspan="2">□ Serious malfunctions □ Repairable malfunction</td></tr>
<tr><td colspan="4">□ Instruction unit □ Robot □ Support joint arm
□ Mobile radiation-proof screen □ Cartridge □ Protective sleeve of the instruction unit
Location of malfunction:
Malfunction description:
Treatment measures and results: □Malfunction is resolved □Change devices □ Malfunction not repaired
□ Increase surgery duration □ Surgical option conversion
Impact on surgery: □ No visible effect</td></tr>
<tr><td colspan="2">Occurrence Time:
|__|__|hours|__|__|minutes</td><td colspan="2">□ Serious malfunctions □ Repairable malfunction</td></tr>
<tr><td colspan="4">□ Instruction unit □ Robot □ Support joint arm
□ Mobile radiation-proof screen □ Cartridge □ Protective sleeve of the instruction unit
Location of malfunction:
Malfunction description:</td></tr>
</table>

Management measures and results Impact on surgery:	□Malfunction is resolved □ No visible effect	□Change devices □ Increase surgery duration	□ Malfunction not repaired □ Surgical option conversion
Occurrence Time: |__|__|hours|__|__|minutes		□ Serious malfunctions	□ Repairable malfunction
□ Instruction unit □ Mobile radiation-proof screen Location of malfunction: Malfunction description:	□ Robot □ Cartridge		□ Support joint arm □ Protective sleeve of the instruction unit
Management measures and results Impact on surgery:	□Malfunction is resolved □ No visible effect	□Change devices □ Increase surgery duration	□ Malfunction not repaired □ Surgical option conversion
Investigator (surgeon)/authorized recorder: _____ |__|__|__|__|year|__|__|months|__|__|days			

19.5 NYHA Classification:

ILevel: Patients have heart disease, but there is no restriction on the amount of activity in their schedule. General physical activity does not cause excessive fatigue, palpitations, shortness of breath, or angina.

IILevel: Patients with heart disease have a slight restriction in physical activity and have no conscious symptoms at rest, but may experience fatigue, palpitations, shortness of breath, or angina under usual general activity.

IIILevel: Physical activity is significantly limited in patients with heart disease. Less than

usual general physical activity can cause fatigue, palpitations, shortness of breath or angina. IVLevel: Patients with heart disease are unable to engage in any physical activity, and symptoms of heart failure occur even at rest and worsen with physical activity.

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Statement of the Investigator

I hereby agree:

1. to conduct this clinical trial in strict accordance with the Declaration of Helsinki, existing laws and regulations in China, and the requirements of this trial protocol.
2. to accurately record all required data on the Case Report Form (CRF) and complete the clinical trial summary report on time.
3. The investigational device will be used only for this clinical trial, and the receipt and use of the investigational device will be recorded completely and accurately during the clinical trial, and records will be kept.
4. to allow the monitors and inspectors authorized or dispatched by the applicant and regulatory departments to audit, verify and inspect the clinical trial.
5. to strictly abide by the clinical trial contract / agreement signed by the parties.

I have read all contents of the clinical trial protocol, including the above statements, and I agree with all of the above.

Sponsor's opinions: Signature (or stamp): Date:

Investigator's Opinion: Signature Date:

Comments of clinical trial institution of medical devices:

Signature (or stamp):

Date: