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 : [Publish Date]

Name of investigated device : Vascular Interventional Navigation Control System
Model/Specification : R-One

Class III devices subject to clinical trial approval	:	Yes ☑	No ☐
Equivalent products in China	:	Yes ☐	No ☑

Leading institute	:	People's Hospital of Xinjiang Uygur Autonomous Region
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	/

Informed Consent Form for Human Biomedical Research Participants

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

Research Department: Heart & Pan-Vascular Medicine Diagnosis and Treatment Center, People's Hospital of Xinjiang Uygur Autonomous Region / Shanghai MicroPort MedBot (Group) Co., Ltd.

Principal Investigator(s): YU Xiaolin / LIN Lei

Version Number (Mandatory): 20240513

Dear [Participant Name]:

We invite you to participate in a research study. This informed consent form provides information to help you decide whether to participate. Please read it carefully. If you have any questions, please ask the researcher in charge.

We sincerely hope you will participate. This study adheres to the principles of the Declaration of Helsinki, complies with medical ethical standards, and has been reviewed and approved by the Xinjiang Uygur Autonomous Region People's Hospital Ethics Committee. Participation is voluntary, and you have the right to withdraw at any stage of the research. This will not affect your future examinations or treatment.

1. **Research Purpose:**
   Coronary heart disease (CHD) affects 11.39 million people in China and is the leading cause of death in urban and rural populations. Percutaneous Coronary Intervention (PCI) has become the primary treatment for CHD. As the number and complexity of procedures increase, so does the health burden on operators. China's vast territory leads to uneven distribution of medical resources. High-quality physicians and equipment are mainly concentrated in first-tier and provincial capital cities, while remote grassroots areas are

underdeveloped and lack resources. Patients often travel extensively for care, increasing pressure on both patients and hospitals. Many patients requiring coronary intervention miss the optimal treatment window. The safety and efficacy of robot-assisted coronary intervention procedures have been demonstrated. With the development of China's 5G telemedicine technology, cardiac intervention experts are exploring PCI procedures using vascular intervention robots based on 5G remote technology. This aims to promote equitable access to high-quality medical resources, enabling timely and effective treatment for CHD patients in remote grassroots areas, thereby improving patient quality of life and prognosis.

2. **Examination (Research) Content:**

2.1. Establish a 5G remote R-One™ vascular intervention robot platform at this hospital and partner medical units. To address the clinical need for remote vascular intervention control, high real-time and stable transmission technology will be employed to improve the immediacy and stability of remote surgical control. Real-time monitoring of communication quality and establishing an effective warning mechanism will ensure remote surgical safety. Ultra-low latency compression, low bandwidth, and high-fidelity transmission technologies will resolve technical challenges related to DSA image transmission, such as high bandwidth consumption, quality degradation and lag, enabling clear and smooth visual feedback for precise remote operation. This will further enhance the safety and efficacy of remote vascular intervention robot surgery, ensuring patient safety. This relies on the patented technology "Interventional Robot System, Operation Method, Master Device and Readable Storage Medium" (Patent No.: CN113598959B).

2.2. Validate the feasibility of the 5G remote R-One™ vascular intervention surgical robot: Through bench testing, animal experiments, and clinical trials, establish performance standards for 5G remote vascular intervention

robotic surgery, providing a basis for its widespread clinical application and standard setting.

2.3. Technology promotion and application: Following repeated validation, collaborate with partner medical units to establish standards and clinical protocols for 5G remote vascular intervention robot surgery technology and promote its clinical application.

3. **Risks and Discomforts:**

   This study involves no additional interventions. Therefore, participation will likely not expose you to risks beyond those associated with routine diagnosis and treatment. There are no additional risks associated with data collection or the disposal of biological samples. If you provide a blood sample, the blood draw process may involve the following minor risks: temporary discomfort, pain, or bruising at the needle puncture site; dizziness or fainting; and, in very rare cases, infection. If your health information is accessed by anyone outside the research team, it could potentially lead to issues with employment, insurance, or cause trouble for your family. To minimize these risks, we will maintain the confidentiality of your personal information in accordance with relevant regulations.

4. **Benefits:**

   Your participation in this study may not directly benefit you. However, the implementation of this project will promote the establishment of a 5G remote vascular intervention robot platform in Xinjiang, enabling technological benefits for the populace and technological support for Xinjiang. Patients in remote grassroots areas will be able to access treatment for major illnesses locally. It will also foster talent development in Xinjiang's CHD diagnosis and treatment field and contribute to building the 5G remote vascular intervention surgical robot platform.

5. **Costs and Compensation (Please clearly state payment arrangements during the study and compensation in case of risk):**

   There are no costs associated with participation in this research study.

You will only be responsible for the usual PCI procedure and treatment costs covered by your medical insurance. No additional fees are required.

6. **Alternative Treatments Outside This Study (Must be provided for studies involving intervention; state if no intervention involved):**
   This study **does not** involve interventional treatment.
7. **Confidentiality:**
   If you decide to participate, all information about your participation and personal data will be kept confidential. Your blood samples will be labeled with a unique study code, instead of your name. Your identity will not be disclosed, and identifiable information will not be revealed to anyone outside the research team without your permission. All research personnel are required to maintain your confidentiality. The research physician and other investigators will use your medical information for the research. This may include your name, address, phone number, medical history, and information gathered during your participation. Your records will be stored securely in locked cabinets accessible only to research personnel. To ensure the study is conducted per regulations, authorized representatives from government regulatory agencies or the Ethics Committee may review your personal data at the research site when necessary. When results of this research are published, no personally identifiable information will be disclosed.
   You may choose not to participate or withdraw from the study at any time by notifying the researcher. If you withdraw, your data will not be included in the research results, and your medical care and rights will not be affected.
   The research physician may discontinue your participation if you require other treatment, do not follow the research plan, experience a research-related injury, or for any other reason.
8. **Contact:**
   If you have any questions about the design, procedures, or results of this study, please contact us at: **Phone: 0991-8568013**. We will do our best

to answer your questions. Thank you for your and your family's trust and support! If you are an ethnic minority patient, a physician fluent in your native language will be available to address your concerns.

I (or my immediate relative) have understood the purpose, content, significance, and risks of this study and voluntarily agree to participate.

Patient Signature: _____ Date: ___/___/_____

Patient Phone: _____

Patient's Immediate Relative Signature: _____

Date: ___/___/_____

Relative Phone: _____

Legal Representative Signature: _____ Date: ___/___/_____

Representative Phone: _____

Physician (Investigator) Signature: _____ Date: ___/___/_____

Physician Phone: _____

Translating Physician Signature: _____ Date: ___/___/_____

Translator Phone: _____

(To be included in management documents if the participant belongs to an ethnic minority group)