Informed Consent Form

Protocol Name: A Prospective, Multi-center, Randomized, Open, Parallel-controlled Clinical Study of BD Pre-filled Flush Syringes

Abbreviation: BD Pre-filled Flush Syringes

Protocol No.: MDS-21FLUSHCN01

Protocol Version: V1.0

Clinical Study Institution: Beijing Hospital

Principal Investigator: Sun Chao
Address: No. 1 Dahua Road, Dongdan, Dongcheng District, Beijing
Telephone No.: 18601924876

Sponsor: BD Medical Technology (Jiangsu) Co., Ltd.

- Please read this document carefully.
- Please ask your physician all the questions you want to know about this study. If there are any statements or information that is not clear, your physician will explain them to you. Reading this informed consent form and consulting your physician may help you decide whether to participate in this study.
- If you decide to participate in this study, you must sign and date the end of this informed consent form.
- You will receive a copy of this informed consent form after signing.
- The term "you" in this informed consent form refers to the subject of the study. If you are a guardian or impartial witness for a subject in the study, please remember that "you" refers to the subject in the study.

CONTACT LIST

You may contact	Contact information	If you have any questions about...
Principal investigator **Sun Chao**	**Tel** **18601924876**	**Study tests and procedures** **Study-related injuries or emergencies** **Any study-related questions or complaints** **Withdraw from the study** **Materials you received** **Study-related conventions**
Ethics committee	**Tel** **(010)85138105**	**Rights of Study Subjects**

OTHER INFORMATION

If necessary, the sponsor may register the study information on the site http://www.ClinicalTrials.gov. No identifying information about you will be provided on the site, at most a summary of the study results will be provided. You can browse the site at any time.

FOREWORD

You are invited to participate in a study conducted at Beijing Hospital by principal investigator Sun Chao. The study is titled "A Prospective, Multi-center, Randomized, Open, Parallel-controlled Clinical Study of BD Pre-filled Flush Syringes". The purpose of this study is to compare the data obtained from BD Pre-filled Flush Syringes (manufactured by [BD Medical Technology (Jiangsu) Co., Ltd.]) to that of BD Pre-filled Flush Syringes (manufactured by [BD, USA]), to evaluate the effectiveness and safety of the BD Pre-filled Flush Syringes (manufactured by [BD Medical Technology (Jiangsu) Co., Ltd.]) for locking and flushing the end of catheter line. Your participation in this study is entirely voluntary.

For ease of distinction and understanding, in this informed consent form, "BD, USA" is an abbreviated form of the term "Becton, Dickinson and Company", which refers to the same company. You may see "Becton, Dickinson and Company" elsewhere, e.g. on the packaging of investigational devices, so please know that this is the same company.

This informed consent form includes detailed information about the study to help you decide whether to participate in this study. Please read carefully and ask any questions you may have before consenting to participate in this study.

STUDY DESCRIPTION AND PURPOSE

Study Background

Infusion is one of the necessary measures for the diagnosis and treatment of patients in the hospital. Because of the condition, some patients need to use intravenous catheters or other catheters to establish intravenous access, which is beneficial for rapid clinical administration of drugs and emergency rescue, as well as protecting patients' blood vessels and reducing the pain caused by repeated cannulation. In clinical practice, locking of venous catheter is an important part of intravenous catheters infusion technology and the key to the success of intravenous catheters indwelling. The BD Pre-filled Flush Syringes (manufactured by [BD, USA]), which are currently on the market, have a good locking effect and can effectively prevent the blockage of the peripheral intravenous catheter, thereby prolonging the use time of the intravenous catheter and reducing the pain of repeated cannulation for patients, protecting patients' blood vessels, reducing their medical costs, and also improving the efficiency of nurses.

What is the Purpose of This Study?

To compare the BD Pre-filled Flush Syringes (manufactured by [BD, USA]) and evaluate the effectiveness and safety of the BD Pre-filled Flush Syringes (manufactured by [BD Medical Technology (Jiangsu) Co., Ltd.]) for locking and flushing the end of catheter line.

What is an Investigational Medical Device?

The investigational medical devices are the BD Pre-filled Flush Syringes used in this study, which is also called investigational devices. They include a test medical device (manufactured by [BD Medical Technology (Jiangsu) Co., Ltd.]) and a control medical device (manufactured by [BD, USA]).

The test medical device is manufactured by [BD Medical Technology (Jiangsu) Co., Ltd.], which is intended to lock and flush the end of the catheter line for subjects at the intervals of different drug treatment. The product consists of barrel, plunger rod, plunger, tip cap and 0.9% sodium chloride injection solution (conforming to Chinese Pharmacopoeia and USP). The product has been tested by Shandong Institute of Medical Device and Pharmaceutical Packaging Inspection and meets the technical requirements of "Pre-filled Flush Syringes".

The control medical device is manufactured by [BD, USA], which is intended to lock and flush the end of the catheter line for subjects at the intervals of different drug treatment. The product consists of barrel, plunger rod, plunger, tip cap and 0.9% sodium chloride injection solution (conforming to USP). The product (Registration Certification No.: NMPA (J) 20163142809) are currently on the market. It has a good locking effect and can effectively prevent the blockage of the peripheral intravenous catheter, thereby prolonging the use time of the intravenous catheter and reducing the pain of repeated cannulation for patients, protecting patients' blood vessels, reducing their medical costs, and also improving the efficiency of nurses.

The investigational devices do not come into direct contact with the human body, but the 0.9% sodium chloride injection will eventually enters the body. These devices will be used on the subjects by study nurses following the steps outlined below:

1. Open the package and remove the BD Pre-filled Flush Syringes.
2. Push the plunger up (do not unscrew the white tip cap) to release the resistance between the plunger stopper and the barrel;
3. Unscrew the tip cap with aseptic technique;
4. If it is to connect the intravenous infusion system with needless infusion connector, please directly connect the needless infusion connector. If it is to connect the infusion connector that traditionally require a steel needle, please connect a safety needle that meets the requirements of the OSHA Bloodborne Pathogens Standard; (OSHA Standard, Occupational Safety and Health Standard, issued by the Occupational Safety and Health Administration [OSHA])

5. Hold the BD Pre-filled Flush Syringes upwards for priming;
6. Connect the BD Pre-filled Flush Syringes to the connector, valve or needleless system and then flush according to the relevant principles and recommendations of indwelling catheter manufacturers;
7. Discard the used BD Pre-filled Flush Syringes and any other unused portion of the solution according to the relevant principles. Do not reuse.

What Does This Study Involve?

Study Design:

This trial is a prospective, multi-center, randomized, open, parallel-controlled clinical trial. The test medical device is BD Pre-filled Flush Syringes (manufactured by [BD Medical Technology (Jiangsu) Co., Ltd.]) (specification & model: BD 10 ml PosiFlush Pre-filled Flush Syringes), and the control medical device is BD Pre-filled Flush Syringes (manufactured by [BD, USA]) (specification & model: BD 10 ml Pre-filled Flush Syringes with Standard Plunger Rod). After signing of informed consent form, all subjects who meet the inclusion criteria and do not meet the exclusion criteria are randomized into the test or control group at the ratio of 1:1. The ends of catheter lines for all subjects are flushed and/or locked by study nurses using investigational medical devices. The effectiveness and BD Pre-filled Flush Syringes shall be assessed.

During the screening period, you will be assessed by your study physician and you will be allowed to have a treatment visit for flush syringes only if you meet the inclusion criteria and do not meet any of the exclusion criteria. If you are not eligible for enrollment, you will be asked to withdraw from the study and will be considered a screening failure.

Inclusion Criteria:

1) Subjects shall be ≥ 18 years old, with no limitation on gender;

2) Hospitalized patients;

3) Subjects who are intended to require or have implanted vascular access catheter devices [include the peripheral intravenous catheter (PIVC), central venous catheters (CVC) and the peripherally inserted central catheter (PICC), etc.];

4) Subjects who are intended to require flushing the vascular access catheter with saline at the beginning, during, or end of infusion therapy; or subjects who require flushing and/or locking the vascular access catheter at the beginning, during, the end of drug therapy;

5) Subjects who can understand the purpose of the clinical trial, agree to participate in this clinical trial and voluntarily sign the informed consent form.

Exclusion Criteria:

1) Pregnant and lactating women (self-reported by the patient);

2) Subjects who are known to have blockage or recanalization of vascular access prior to this trial;

3) Subjects who are known to have uncomfortable symptoms such as redness and pain, or common complication associated with indwelling catheter such as phlebitis and infection at the localized insertion site prior to this trial.

4) Subjects who have participated in other drug or medical device clinical trials within 3 months prior to screening;

5) Other subjects that the investigator considers unsuitable for participation in this clinical trial.

After you have signed the informed consent form, you will need to work with your researchers (principal investigator, study physician, study nurse, etc.) to complete the following study procedures. Your study physician will ask about and record your medical condition, demographics, review inclusion and exclusion criteria, adverse events and concomitant medication. An adverse event is an adverse medical event that occurs during the study process, but may not be necessarily related to the treatment conducted in the study. Your study nurse will record your vital signs and flush and/or lock the end of catheter line.

Screening Period

1) Sign the informed consent form;

2) Record the demographics, including date of birth, gender, ethnicity, etc.;

3) Collect your admission diagnosis;

4) Register the screening number of subjects, and review the subject inclusion and exclusion criteria;

5) Randomization;

6) Record vital signs: Breath, blood pressure (systolic blood pressure, diastolic blood pressure), pulse, body temperature;

7) Record adverse events and severe adverse events;

8) Record concomitant medication/treatment.

Flush Syringe Treatment Period

The flush syringe treatment period is the period during which the BD Pre-filled Flush Syringes are used and operated.

1) Operation of flushing and/or locking of the end of catheter line: The study nurse will perform flushing and/or locking of the end of catheter line;

2) Effectiveness evaluation: The use of the such pre-filled flush syringes shall be evaluated by the study nurse after flushing and/or locking the end of catheter line;

3) Record adverse events (including adverse events/severe adverse events);

4) Record concomitant medication/treatment;

5) Record the device deficiency.

Follow-up (Follow-up 1 h after Flush Syringe Treatment)

1) Record adverse events (including adverse events/severe adverse events);

2) Record concomitant medication/treatment.

If you agree to participate, the researcher will also collect your medical records, treatment information, etc. to keep at the research hospital as original documents for the clinical trial.

We anticipate that approximately 126 individuals will participate in this study at Beijing Hospital. Beijing Hospital has completed the filing in the Filing Management Information System of Medical Device Clinical Trial Institution and meets the qualification requirements for medical device clinical trials. 3 hospitals in China will be selected as the study sites with a total of 378 subjects planned to participate in this study.

Randomization

If you agree to participate in this study and sign the informed consent form, you will be randomly assigned to one of the 2 study groups. Random assignment is like flipping a coin to decide which group you are assigned to, neither you nor your researcher can choose. The probability that you are assigned to any group is 50%. If you are assigned to the test group, you will be treated with the BD 10 ml PosiFlush Pre-filled Flush Syringes manufactured by BD Medical Technology (Jiangsu) Co., Ltd. and if you are assigned to the control group, you will be treated with the BD 10 ml Pre-filled Flush Syringes with Standard Plunger Rod manufactured by Becton, Dickinson and Company.

How Long Will I Be Involved in This Study?

Your participation in the trial lasts from 1-4 days. The study process includes three periods: Screening period, flush syringe treatment period, and follow-up period. The screening period is up to 3 days. Flush syringe treatment is performed next, and they may also be performed on the same day as during the screening period, after all screening period processes have been completed. Follow-up is conducted 1 hours after the end of flush syringe treatment.

Participation and Termination

Participation in this study is voluntary. You may refuse to participate or withdraw at any time during the study. Any new health information about you will not be collected after your withdrawal, but information already collected will still be used and available to others. If in the middle of the study you decide to withdraw from this study, please tell the researcher to let him/her know that you will be withdrawing from the study, informing him/her of the reason for your withdrawal.

Your investigator may terminate your participation without regard to this informed consent form if he/she believes it is best for you to stop participating in the study. Your participation in this study may also be terminated if you fail to follow the procedures described in this informed consent form. In addition, the sponsor may suspend or early terminate the study at any time.

Please note that your refusal to participate in or withdraw from the study does not necessarily mean that you wish to revoke your consent to this informed consent form. If you wish to withdraw your consent, you must inform the researcher and confirm the revocation of consent in writing.

Refusing to participate or withdrawing from the study before the end of the study period will not have any effect on your subsequent medical care. The researcher will give you appropriate medical advice and perform routine medical care.

Role of Subjects in the Study

As a study subject, your responsibilities include:

- Tell your researcher honestly about your condition/physical status (e.g., if you are a woman, whether you are pregnant or lactating);

- Inform the investigator whether you have participated or are currently participating in another clinical study within the past 3 months;
- Inform the investigator of any problems/discomfort you experience during the study;
- Cooperate strictly with the visits and procedures that your investigator arranges for you during the study.

RISK AND BENEFIT

1. Risk/Discomfort

Procedures throughout the study are standard procedures used as part of routine medical care, with minimal risk associated with the trial. In general, most treatment operations do not pose any additional potential risk to your health, safety or welfare.

However, all therapies have the potential to cause a number of adverse experiences, some of which may be unanticipated, or cause some known potential risks of BD Pre-filled Flush Syringes:

There are reports of possible transient taste and/or odor disturbance when using the control medical device BD Pre-filled Flush Syringes (manufactured by [BD, USA]). No special treatment is required to recover. No data has been reported on the test medical device because it has not yet been used.

You have the right to ask any questions related to the potential and/or known risks of this study at any time.

If you get injured in any way as a result of your participation in this study, you will receive appropriate emergency treatment or other medical treatment.

If, during the study, additional information comes to light that may affect your willingness to continue to participate in the study, you will be informed accordingly.

2. Pregnancy risk

If you are a woman and become pregnant during the study, you or your unborn child may experience some unforeseen risks. The effect of BD Pre-filled Flush Syringes on the unborn baby is unknown. You cannot participate in this study if you are pregnant.

3. Benefit

If you are using an intravenous catheter or indwelling catheter for infusion, it is often clinically necessary to flush and/or lock the catheter with a flushing solution to minimize the occurrence of blockage. The BD Pre-filled Flush Syringes have a good flushing and/or locking effect and can effectively prevent the blockage of the peripheral intravenous catheter, thereby prolonging the use time of the intravenous catheter and reducing the pain of repeated cannulation for you, and protecting your blood vessels.

BD Pre-filled Flush Syringes have been on the market for many years at home and abroad, and it has been proven that the use of BD Pre-filled Flush Syringes can improve the accuracy of drug administration, reduce the risk of drug administration and medication errors, as well as reduce the risk of microbial contamination to improve the safety and convenience of use.

Alternatives to Participating in the Study

You may choose not to participate in this study. Refusing to participate or withdrawing early from the study before the end of the study will not have any effect on your future medical care.

In addition to participating in this study, there are other alternatives available to you for flushing and/or locking the catheter based on routine clinical methods. For example, use saline or sodium heparin for positive pressure flushing and locking of the catheter to maintain the patency of IV access. It will be up to your physician to choose the appropriate method of locking catheter for you based on your own situation.

COST

This study does not require you to have a particular examination, so no free examinations are offered. In addition, the sponsor will provide you with an investigational BD Pre-filled Flush Syringe (either a test medical device or a control medical device) at no cost to you during the study that will be used by the study nurse to perform the flushing and/or locking of the catheter.

COMPENSATION

For your participation in this study, if you complete this clinical study as required (i.e., from the time of signing the informed consent form until the completion of the follow-up 1 h after the investigational medical devices have been used), you will receive RMB 100 as a financial compensation for the cost of participating in and completing this study.

STUDY-RELATED INJURY

If you incur a physical injury or illness related to this study, you will be treated as follows.

1. Responsibilities of study sites

If an injury occurs during the study, your study physician will provide you with adequate and timely treatment and management; your study physician will promptly inform you when you develop a concurrent illness that requires treatment and management.

2. Responsibilities of the sponsor

Your participation in this study is voluntary. Risks or discomforts that may occur during the study are described in this informed consent form. An injury refers to physical injury or illness that results from your participation in this study. If an injury occurs, you shall contact your investigator immediately.

In the event of your injury or death related to this study, the sponsor will be responsible for the cost of treatment, compensation, or reimbursement, excluding damages resulting from the investigator's and medical device clinical trial institution's own negligence and the subject's own disease progression.

By signing this informed consent form, you are not giving up any of your legal rights as a subject.

If a study-related injury occurs, or if you have any questions, concerns, or need to file a complaint about the study, you may contact the principal investigator, Sun Chao, at any time during the study.

If you have any questions about your rights or obligations as a study subject, you may contact: Ethics Committee.

COMPENSATION FOR RESEARCHERS

The sponsor will pay for the study sites and researchers for their work in this study.

In addition, BD Medical Technology (Jiangsu) Co., Ltd. has no other financial relationship with the principal investigator, Sun Chao.

WILL MY MEDICAL INFORMATION BE KEPT CONFIDENTIAL

TO THE EXTENT PERMITTED BY APPLICABLE LAW AND WITHOUT BREACHING CONFIDENTIALITY, THE RESEARCHERS AND CLINICAL COORDINATORS OF THIS STUDY, REPRESENTATIVES OF THE SPONSOR (CLINICAL SUPERVISORS, SPONSOR-APPOINTED AUDITORS, ETC.), THE ETHICS COMMITTEE, AND THE MANAGEMENT DEPARTMENT OF THE MEDICAL DEVICE CLINICAL TRIAL INSTITUTION AND/OR REPRESENTATIVES OF REGULATORY DEPARTMENTS (E.G., DRUG REGULATORY DEPARTMENT, HEALTH DEPARTMENT) HAVE THE RIGHT TO HAVE DIRECT ACCESS TO YOUR MEDICAL RECORDS IN ORDER TO VERIFY CLINICAL STUDY PROCEDURES AND/OR DATA. BY SIGNING THIS INFORMED CONSENT FORM, YOU AUTHORIZE PERMISSION FOR SUCH ACCESS. BY SIGNING THIS INFORMED CONSENT FORM, YOU ALSO AUTHORIZE REPRESENTATIVES OF BD MEDICAL TECHNOLOGY (JIANGSU) CO., LTD. TO PARTICIPATE IN A PART OF THE PROCEDURES OF THIS STUDY. RECORDS CONFIRMING YOUR IDENTITY WILL NOT BE MADE PUBLIC. YOUR PERSONAL INFORMATION WILL STILL BE KEPT CONFIDENTIAL EVEN IF THE STUDY RESULTS ARE PUBLISHED. IF MENTIONED, ONLY YOUR CODE NUMBER WILL BE USED.

If you want to know more about how your information is shared with the third parties, you can contact your investigator.

If you agree, you may inform your physician of your participation in this study.

Will My Information Be Used for Other or Future Studies?

Information collected from you as part of the study will not be used or distributed for other or future studies, even if the information has been de-identified (information from which personal identifiers have been removed, as defined in the *Personal Information Protection Law*).

NEW INFORMATION ON THIS STUDY

The information in this informed consent form reflects what is known about the study at the time of signing. If there is any new information during the study that may affect your willingness to continue or participate in the study, you will be informed in a timely manner.

You may keep up to date with study-related information and study progress. You may contact the principal investigator and the Ethics Committee if you have questions related to the study, or if you experience any discomfort or get any injuries during the study, or if you have questions about the rights of study subjects.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR STUDY PURPOSES

Researchers are required by law to protect the privacy of your health information, such as your date of birth, condition/diagnosis, or test results. The term "you" in this informed consent form refers to the subject of the study. Researchers can only use, create or share your health information for study purposes with your permission. This authorization for the use, creation, and sharing of health information and the informed consent form describe the activities that researchers will perform with your information.

Researchers will use your health information only in the ways described in the informed consent form and in this document. If authorization for the use and disclosure of health information is required from you as a study subject, it will be for the study purposes as described in the informed consent form and for facilitating related monitoring, regulatory, quality assurance activities, and billing and payment activities, as appropriate.

Unless you provide written permission, any information that clearly identifies you as an individual cannot be disclosed to people not associated with this study. Any data that may be published in the scientific literature will not disclose the specific identity of the study subject. Any information we obtain in connection with the study that does not clearly identify you may be used for medical or commercial purposes, including scientific research and development, clinical case studies and marketing literature.

You agree to allow this clinical trial study institution and its researchers to use and disclose information about you, including your health information in medical records, as described below:

1. What Kind of Information Can Be Generated at a Clinical Study Institution?

- Information about you that is created during the study. It may include the following:
  - Test or examination results
  - Other records of the study
- Information in your medical records that is required for the study. It may include the following:
  - Physical examination results
  - Blood tests, X-ray examinations, diagnostic or other medical procedures
  - Your medical history
  - Information that contains a personal identifier, such as your name or a number that is personally associated with you
  - The above information is sensitive personal information, if violated or illegally used, it is easy to damage your personal dignity and personal or property safety

2. Will My Name Be Removed from the Information?

- Researchers may remove your name, address, and other information that may identify you. No one can know your identity from the information.

- If information that may identify you is removed, researchers and the sponsor will use, create, and share other information as required by law. (Including use for other purposes in accordance with the law.) This informed consent form will no longer limit the ways in which the researchers can use, create, and share de-identified information.

3. Who May Use or Have Access to This Information?

- Sponsor. "Sponsor" refers to any person or company working for, with or under the sponsor.
- If this study is related to your medical care, information related to the study may or will remain permanently in your hospital, clinic, or physician's office records.
- National Medical Products Administration (NMPA)
- Government authorities of other countries
- Researchers
- Other researchers who are allowed by clinical trial institution to be shared information
- Ethics committee

4. Why is This Information Being Used and/or Provided to Others?

- To conduct study.
- To study the results.
- To ensure that the study is implemented correctly.

5. What Happens If I Decide Not to Allow the Use and Disclose of My Health Information?

- If you do not sign this informed consent form, you will not be able to participate in this study.
- There are no penalties if you choose not to participate in the study or not to authorize the use of your health information. In other words, you will not be prohibited from receiving any needed treatment and it will not have any impact on your subsequent medical care.

6. Can I View or Copy My Information?

- To maintain the integrity of the study, you will not be able to view information about you that is created or collected during the study process while the study is being conducted.
- However, you can view this information after the study is completed. At that time, you have the right to view and copy medical information collected about you during the study, provided that this information is maintained by the researchers and other entities and is subject to privacy regulations.

7. When Does My Authorization End?

- Your authorization has no end date.
- Your study data will be kept in accordance with the law. Your information will be kept at the clinical study institution for 10 years after termination or completion of the study. The Ethics Committee will keep a full record of the ethical review until 10 years after completion or termination of the study. The sponsor shall store the basic documents of clinical trial until the medical device is no longer used. This is because the information used and created during the study may be analyzed after the study is completed in accordance with relevant laws and regulations. Corresponding requirements may be implemented appropriately due to changes in laws and regulations.

8. Can I Revoke or Cancel My Authorization?

- You can cancel the authorization at any time.
- Your authorization will be effective upon signing unless you revoke it in writing. You may cancel the authorization by informing the study physician in writing.
- If you revoke your authorization, you will not be able to continue to participate in this study. We will not collect any new health information about you from the date you revoke your authorization. The information collected will not be used or provided to others.

9. Is My Health Information Protected When I Provide It to Others?

- The *Personal Information Protection Law* and other privacy protections always apply.

Authorization and Consent Statement

I have read this document (or it has been read to me). I understand that I have been invited to participate in a study. I have enough time to ask questions and these questions are answered satisfactorily.

I voluntarily agree to participate in this study.

1. I have enough time to read and understand this document and I agree to participate in the study which is titled "A Prospective, Multi-center, Randomized, Open, Parallel-controlled Clinical Study of BD Pre-filled Flush Syringes".
2. I have received the copy of informed consent form. The investigator has explained to me the nature of the research, its purpose, duration, foreseeable impacts and the activities I am expected to perform, the potential risks and benefits of the study, and alternative treatments for my condition.
3. I agree to cooperate fully with the investigator and will inform him/her of any unintended or unusual symptoms I experience.
4. I have been made aware that if any accidental injury or harm occurs as a result of my participation in this study, I will receive appropriate emergency treatment or other medical treatment. If I get injured as a result of this study, I have the right to pursue a claim through legal means.
5. I understand that this study is approved by the Ethics Committee.
6. I may withdraw at any time during the study without any discrimination or retaliation, without having to prove a reason, and without any adverse effect on my future medical care.
7. If I need other treatment, or if I don't follow the study plan, or if there are other reasonable reasons, the investigator can terminate my participation in this study.
8. I agree that the study results may be submitted to the appropriate institutions as well as to the manufacturers of the investigational devices. My name and/or contact information will not be included in any report of study results.
9. I understand that the sponsor, Ethics Committee, the management departments of the medical device clinical trial institution or representatives of the regulatory agency may wish to inspect my medical records to verify the information collected. By signing this document, I give them permission to view my records.
10. I also agree that the national regulatory agency, i.e. National Medical Products Administration, and representatives of the sponsor shall supervise the study process.
11. I agree to the use, creation and sharing of my health information for the purposes of this study.

Subject

I voluntarily agree to participate in this study.

_____

Printed name of the subject:

_____ _____

Signature of the subject Date and time (AM/PM)

_____

Contact information of the subject

If the subject is a person without capacity for civil conduct or with limited capacity for civil conduct, the written informed consent of his/her guardian shall be obtained in accordance with the law.

Guardian (if applicable)

I am the guardian of the above designated "subject" and I agree to his/her participation in this study.

_____ _____

Signature of the guardian Date and time (AM/PM)

_____

Identity of the subject's guardian or his/her relationship to the subject

_____

Reasons why the subject cannot sign the informed consent form

_____

Contact information of the guardian

If the subject lacks the ability to read or is incapable of reading, an individual unrelated to the study, who is not unfairly influenced by those involved in the study, may act as an impartial witness to read the informed consent form and other information provided to the subject and witness the informed consent.

Signature of the impartial witness (if applicable)

I am an impartial witness to the above designated "subject", and I witness the investigator explaining to the subject in detail the contents of the clinical study, including the purpose, background, process, risks and benefits, etc., and answering the questions raised by the subjects. The subject shows that he/she fully understands the contents of the informed consent form, and he/she voluntarily agrees to participate in this study.

_____	_____
Signature of the impartial witness	Date and time (AM/PM)
_____	_____
Workplace of the impartial witness	Contact information of the impartial witness

Investigator (or designee)

I have confirmed that the nature, purpose, and foreseeable effects of the study were explained to the above (printed name) _____ subject and/or his/her guardian and/or impartial witness. The subject/guardian/impartial witness agrees to confirm the subject's participation in this study by signing his/her name and date.

_____	_____
Signature of the investigator (or authorized designee)	Date and time (AM/PM)

_____

Contact information of the investigator (or authorized designee)