RESEARCH SUBJECT INFORMATION AND INFORMED CONSENT FORM

TITLE: Clinical investigation to evaluate the effectiveness of Ambu® aScope™ 4 Cysto with the aView™ 2 Advance for flexible cystoscopy

PROTOCOL NO.: CIS-023

SPONSOR: Ambu Inc. together with its affiliates (hereinafter collectively, "Ambu")

INVESTIGATOR: [Name]

SITE(S): [Name]
[Address]
[Address]

STUDY-RELATED PHONE NUMBER(S): [Phone Number(s)]

WHAT IS THIS DOCUMENT?

This document is called an informed consent form. It provides information about the study and your role if you decide to participate. This consent form describes the purpose, procedures, possible benefits and risks of the study so that you can make an informed decision. This form also explains how your medical information will be used and who may see it. This process is known as informed consent.

A person who takes part in a research study is called a research or study subject. In this consent form "you" always refers to the research subject. If you are a legally authorized representative or the parent of a minor, please remember that "you" means the research (study) subject.

You are being asked to be in a research study. Your participation in this research study is strictly voluntary, meaning that you may or may not choose to take part. The purpose of this consent form is to help you decide if you want to be in the study.

You are being asked to take part in this research study because the study doctor feels that you may meet the qualifications of the study. If you have any questions, please ask the study staff that gave you this form. You should not join this study until all of your questions are answered. If you would like to participate, you will be asked to sign this form. You will be given a copy of your consent form to keep for your records so you can refer to it while you are in this study.

WHY AM I BEING ASKED TO BE IN THIS STUDY?

You are invited to take part in this study because your doctor has recommended you have a urethral stent removed. Stent removal involves inserting a long, flexible endoscope through the urethra into

the bladder to locate and retrieve the ureteral stent. Traditionally, the endoscope used for this procedure can be used for several years, with extensive cleaning and processing between uses.

There are a variety of endoscopes that are used by doctors. A new disposable endoscope currently being used is the aScope 4 Cysto endoscope, which is made by Ambu A/S. Ambu has obtained approval from the U.S. Food and Drug Administration (FDA) for the commercial use (sale) of the aScope 4 Cysto endoscope in 2020. The aScope 4 Cysto endoscope is different from other endoscopes because it is designed to be used only once. Each time a doctor uses an aScope Cysto endoscope, they are using a brand new, sterile device. As a single-use medical device, it does not rely on cleaning between uses to prevent infection, as reusable endoscopes do.

The aScope 4 Cysto endoscope is used along with the aView 2 Advance, which processes the endoscope camera's images. Together along with other accessories and tools, the equipment is called the Ambu Cysto System.

The purpose of this study is to demonstrate the device is effective when compared to current reusable endoscopes for cystoscopic procedures. This study will also look at safety measures related to use of the device, and physician user satisfaction.

HOW LONG WILL I BE IN THIS STUDY?

This entire study is expected to last for about 9 months, from the time the first patient is enrolled until the last patient has completed their last appointment. If you agree to participate, you will be in this study for the next 10 days, approximately. The 10 days encompass the procedure and a brief phone interview approximately 7-10 days after the procedure.

HOW MANY OTHER PEOPLE WILL BE IN THIS STUDY?

This study is taking place at approximately 4 hospitals (study centers) in the United States. Approximately 102 people will participate in this study.

WHAT WILL HAPPEN IF I AGREE TO BE IN THIS STUDY?

This study does not control the type of medical care that you receive for the treatment of your medical condition. You will receive the same treatment for your medical condition as you would receive even if you were not part of this study. However, this study will control the type of endoscope that is used as part of your medical care. Approximately half of all subjects who participate in this study will receive use of the aScope 4 Cysto endoscope for their stent removal procedure. The other half of the subjects will receive use of the reusable cystoscope that is normally used at the facility. You will be put into a study group by chance (like a coin toss). You have a 1 out of 2 chance of being placed in each group. You cannot choose your study group.

Listed below is what you can expect to happen if you agree to be in this study.

1) You will be asked to sign this consent form to document that you agree to be in this study.

2) Data will be collected about you. This data includes:
   a) Basic information about you such as your date of birth, your gender, your weight and height and your ethnic and racial background;
   b) Information about your health history, physical condition and medications; this information may be updated during your time in the study.
3) During the stent removal procedure, the device will be inserted into your urethra to gain access to the bladder and the stent. If you have questions about the stent removal procedure, please ask the study staff.
4) Information will be collected from your doctor about the procedure. This information will include:
   a) Device information including the model number, lot or serial number;
   b) Information about how the device was used
   c) Information about any problems or complications that may have occurred and if they are related to your device or the procedure.
5) Information about your health status throughout your participation in this study. This information includes:
   a) Information about your pain and discomfort;
   b) Information about any problems or complications that may have occurred while the device is in use and after its use.

WHAT ARE THE STUDY PROCEDURES?

If you choose to participate in this study you are responsible to be available and agree to have all the required tests and activities done before and after the procedure, as described below. You will be expected to be available for a follow-up phone interview (as described in more detail below) after your procedure.

Before the Procedure

You will first be asked to read and sign this Informed Consent Form before any study-related procedures can be performed on you. This may be done on the day of the procedure, or earlier.

Study staff will also collect demographic data and relevant medical history. If you have other medical conditions that make it not safe for you to be in this study, then you will not be eligible to participate.

Prior to the study procedure, your doctor will examine you and ask you about your medical history to determine if you qualify for this study. There is no guarantee that you will be able to participate in this study. If you do not meet the eligibility requirements you will not be enrolled in the study. Instead your doctor will treat you based upon what is best for you.

Study Procedure

Your stent removal procedure will be performed by your doctor, following normal standard of care procedures and standard training. The doctor will use the single-use aScope Cysto endoscope or a reusable standard of care cystoscope for your endoscopy.

Following the procedure, your doctor will determine if any adverse events occurred during or immediately following the procedure.

Phone interview After the Procedure

Day 7-10: Approximately 7 days after your procedure, the study staff will contact you to ask how you have been doing following your procedure. Please note that the interview may take place at any time 7-10 days after the procedure. The interview will only take place once.

Activity	Procedure Day (Day 0)	Post-procedure (Day 7)
Informed Consent	X	
Inclusion/Exclusion Criteria	X	
Pregnancy Test (if applicable)	X	
Demographics	X	
Relevant Medical History	X	
Stent removal Procedure	X	
Adverse Event Assessment	X	X

Your doctor will treat you according to their standard practice. The phone interviews are very important to ensure all risks to you have been minimized and to help determine the safety of the device in patients with your condition. If you have any symptoms, are seen by any other doctor or are hospitalized, it is important that you call the study doctor as soon as possible after you have received treatment so that important information can be collected.

WHAT ARE THE POSSIBLE RISKS OF BEING IN THIS STUDY?

You are scheduled to have a stent removal procedure whether or not you participate in this study. The procedure will be performed the same way whether or not you participate. If you participate in this study, the doctor will use the aScope Cysto endoscope or the standard of care cystoscope for your endoscopy, both of which are cleared for use in stent removal cases by the US Food and Drug Administration. The use of the aScope 4 Cysto is not investigational; we are only collecting information on its use when your doctor uses it as he/she normally does. The study doctor will discuss the specific risks associated with the type of procedure you will have.

There may be risks or complications associated with participation in this study including those that might reasonably be expected to occur in association with the study devices and/or the stent removal procedure itself. Risks may include, but may not be limited to the following:

- Intra-procedural pain or discomfort
- Dysuria - Pain and discomfort on voiding
- Frequency
- Hematuria
- Urinary tract infections UTI

- Abdominal pain

In addition, there may be risks associated with the use of endoscopic tools used in conjunction with the cystoscope

- Urethral narrowing (strictures) due to scar tissue formation
- Inflammatory response
- Bladder perforation
- Injuries to urethral and bladder tissue from protruding tools
- Abnormal bleeding

Your doctor will discuss the risks with you. There may be risks which are unknown at this time.

WHAT ARE THE POSSIBLE BENEFITS OF BEING IN THIS STUDY?

You may or may not get any benefit from participating in this study. However, medical science and future patients may benefit from your participation.

WHAT IF NEW INFORMATION BECOMES AVAILABLE ABOUT THIS STUDY?

You will be informed in a timely manner if any new information becomes available that might change your decision to be in this study. Depending on the type of new information that becomes available, you may be asked to read and sign a new consent form if this occurs.

SPONSOR REPRESENTATIVE

If you are enrolled in this study, a representative of Ambu may:

- Provide technical expertise to the investigator on the study device and study treatment you receive
- Be aware of your data as collected for the purpose of this study

WHAT ARE MY COSTS FOR PARTICIPATING IN THIS STUDY?

All medical care provided to you for the treatment of your condition, including the devices used and your standard of care visits, procedures, and medications, will be billed to your insurance company or Medicare. If you do not have an insurance policy or Medicare coverage, these costs will be billed directly to you.

You may want to talk with your insurance company or Medicare about its payment policy for standard medical care given during a research study. If your insurance company or Medicare does not pay, you may be billed for those charges.

If you have questions about the costs related to this study, please ask your study doctor.

WHAT HAPPENS IF I AM INJURED DURING THIS STUDY?

If you believe that an injury has occurred, you should contact your doctor. Ambu has no plans to pay for any of your medical treatments. All costs related to the treatment of an injury will be billed to your insurance company, Medicare or Medicaid. If you do not have an insurance policy or Medicare or Medicaid coverage, these costs may be billed directly to you.

By agreeing to the above, you do not give up any of your legal rights which you otherwise would have as a patient.

WILL I BE PAID FOR MY PARTICIPATION IN THIS STUDY?

You will not be paid compensated for your participation in this study.

WHAT IS MY ALTERNATIVE TO PARTICIPATION IN THIS STUDY?

You do not have to participate in this research study to be treated for your medical condition. The standard reusable cystoscope can be used for your procedure. Your doctor can describe these other treatments and their associated risks and benefits to you in a manner that you can understand. Your decision not to participate in this research study will have no effect on your current treatment or any other future treatment you require.

DO I HAVE THE RIGHT TO LEAVE THIS STUDY?

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. Your regular medical care and your relationship with your doctors and the study center will not be affected.

You may leave the study by writing to the Principal Investigator at the above address. There are no consequences and no specific tests that are required prior to you leaving the study.

Your participation in this study may be stopped at any time by the study doctor or the Sponsor without your consent for any of the following reasons:

- If it is in your best interest;
- You do not consent to continue in the study;
- You do not follow the study instructions;
- Your medical condition no longer allows for participation; or
- If the study is stopped for any reason.

HOW WILL AMBU USE THE STUDY INFORMATION?

If you decide to participate in this study, Ambu including its agents and contractors will see sensitive and personal health information about you. This consent form and the Authorization to Use and Disclose Health Information describe and control how your personal information is shared and used.

Please be assured that your personal information will be held in the strictest of confidence to the extent required by applicable laws and regulations. You have the right to obtain confirmation that your personal data will be processed, including the right to access or correct personal data, within one month of the study center's receipt of your written request.

Information allowing identification of you as a particular individual will not leave the study center unless required by law or as authorized by you by signing this form.

By signing this form, you agree to allow for the collection, processing and storage of sensitive personal data, including race, ethnicity, gender, and health information necessary for the scientific research purposes of this study. Such health information includes but is not limited to your current and past medical history and treatments, study procedures and treatments. Your personal data will be collected by the study center and sent to the Sponsor and its agents or contractors for processing and indefinite ("in perpetuity") storage.

Your de-identified personal information will be used by the Sponsor to conduct this study as well as for additional purposes. These purposes include overseeing and improving the performance of its devices, new medical research, proposals for developing new medical products or procedures and other business purposes. Any reports or publications about this study or any other research will not include your name or a description of you. In addition, information received during this study will not be used to market to you. Your name will not be placed on any mailing lists or sold to anyone for marketing purposes.

By signing this form, you agree that regulatory authorities, Institutional Review Board representatives, the Sponsor and/or its representatives and contractors will be granted direct access to your original medical records for verification of clinical study procedures and/or data, without violating your confidentiality.

Ambu will keep your health information confidential in accordance with all applicable laws and regulations. The U.S. Food and Drug Administration's (FDA) regulations, as well as other applicable laws, control Ambu's work in developing and assuring the safety and quality performance of its medical devices. You agree to allow Ambu to disclose your health information to the FDA as well as to other U.S. and foreign government authorities and Institutional Review Board responsible for watching over the safety and effectiveness of medical products and therapies and the conduct of research studies.

Information from the study may also be given to the Institutional Review Board and investigators at other sites participating in the study. People from the Sponsor, the FDA as well as other regulatory authorities and the Institutional Review Board may visit the site and review your Ambu

information there to verify the procedures and data, to the extent permitted by the applicable laws and regulations.

By signing this consent form, you agree that you have freely given your informed agreement to the Sponsor's processing and storage of personal data relating to you. You also agree to allow the FDA and other governmental authorities to inspect your health information.

You may revoke approval for the study center to send your personal data to the Sponsor, but information already collected cannot and will not be deleted from the study records and may continue to be used by the Sponsor. You must request in writing to the study doctor and Sponsor that no further information be collected about you, but you will not be able to continue in the study.

If you have a question about data privacy, a concern, a complaint, or you would like to revoke permission to collect your personal data, please contact your study doctor.

AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION

By signing this consent and authorization form, I agree to permit the hospital and/or clinic and their staff(s), my doctors, and my other health care providers (together "Providers") and the study doctor and study staff (together "Researchers"), to use and disclose health information about me, including health information in my medical records, as described below, for research purposes.

The health and personal information that may be used and disclosed includes:

- All information collected related to the study as described in this consent form;
- Health information in my medical records that is relevant to the study; and
- Personal information such as your name, address, date of birth, date of study visits, and other information in my medical record.

The Health Providers and Researchers may disclose health and personal information, including your medical history before the study starts, and to obtain follow-up information even after the study has completed. The health and personal information may be disclosed to:

- To the Sponsor of the Research, Ambu, and its agents and contractors (together "Sponsor"), and any companies that may acquire Ambu or the product under study from Ambu; and
- As required by law and to representatives of government organizations, review boards (including the Institutional Review Board overseeing the study), and other persons who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research.

The Researchers may:

- Use and share my health and personal information among themselves and with other participating researchers to conduct the study;

- Disclose my health and personal information to the Sponsor for this study; and
- Disclose my health and personal information as required by law and to representatives of government organizations, review boards (including the Institutional Review Board overseeing the study), and other persons who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research.

The Sponsor may:

- Use and share my health and personal information as described in the consent form.

Once my health and personal information has been disclosed to a third party:

- There is a small risk that information about me may become known to people outside of this study;
- It may be subject to further disclosure by recipients, and federal/government privacy laws may no longer protect it from further disclosure.

Please note that:

- You do not have to sign this consent form, but if you do not, you will not be allowed to participate in the study.
- You may change your mind and revoke this consent at any time. To revoke your consent, you must write to [*name and contact information*]. However, if you revoke your consent, you will no longer be allowed to participate in the study. Also, even if you revoke your consent, the information already obtained by the Providers, Researcher, and the Sponsor may be used and disclosed as permitted by this consent form.

By signing this consent, you are authorizing the disclosure of your health information for the purposes specified in this consent. This authorization expires fifty (50) years after the date on which it is signed unless you withdraw it earlier.

WHO CAN I CALL WITH QUESTIONS, COMPLAINTS OR CONCERNS ABOUT THIS STUDY?

If you have any questions about this study or your participation, your rights as a study subject, or if you feel that a study-related injury has occurred, you should contact _____ at _____.

If you have any questions or concerns about the conduct of this study, you may also contact the Institutional Review Board that oversees this study at _____. An Institutional Review Board is a group of scientific and nonscientific individuals who review research studies with the safety and welfare of research study participants in mind.

You may ask questions about this consent form at any time. Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONSENT

My signature below means that:

1. I have read this consent form, or it has been read to me, and I acknowledge the information provided.
2. I have been given time to consider the study requirements and all my questions were answered to my satisfaction.
3. I am freely giving my informed agreement to the processing of personal data relating to me and I agree that my relevant sensitive personal information and data may be used and transferred for the purpose of this study.
4. I understand that my participation in the study is voluntary and my refusal to participate will not compromise my medical treatment. I can withdraw my consent at any time prior to and during the study, without any legal consequences and without any penalty or loss of benefits to which I am entitled. I know who to contact in the future if I decide to withdraw or if I require additional information. I understand that any information or data collected about me before I withdraw can still be used for the purposes of this research.
5. I agree to comply with the requirements of the study, follow the study staff's instructions, and to inform the study staff about my medical background, medication or other medical matters and about all medical events that occur during the course of this study.
6. My consent does not release the Sponsor from its obligations and my legal rights will not be affected.
7. I understand that I have the right to obtain confirmation regarding my personal information and data that will be processed, including the right to access or correct personal data, within one month of the receipt of my request.
8. I agree that the Sponsor, its representatives and contractors, regulatory authorities and the Institutional Review Board representatives will be granted direct access to my original medical records.
9. I have been given a signed and dated copy of this document for my records.
10. I understand that my personal doctor may be informed about my participation in this study.

_____

Subject Name (printed)

_____ _____

Signature of Subject (if no Legally Authorized Representative is used) Date of Signature

OR

_____
Printed Name of Legally Authorized Representative

_____ _____
Signature of Subject's Legally Authorized Representative Date of Signature

_____
Authority of Subject's Legally Authorized Representative or Relationship to Subject

_____
Printed Name of Person Conducting the Informed Consent Discussion

_____ _____
Signature of Person Conducting the Informed Consent Discussion Date of Signature