Utility of Esophageal Cooling Therapy for the Prevention of Thermal Injury During Atrial Fibrillation Ablation (eCool)
ICF Cover Page

This is a one page description of the study. You should review the entire consent form before deciding whether to participate in this study.

This study is voluntary: you can decide not to participate or withdraw at any time. This will not change the care you receive from your EP doctor.

Purpose of the study:

- To see if esophageal cooling using the study device limits damage to the esophagus during your ablation procedure.

Study Device

- The EnsoETM is an FDA cleared device used for temperature control but is not commonly used during ablation procedures.

This Study DOES require (and pays for) the following test:

- An upper endoscopy, which is a test to examine the lining of the esophagus, stomach, and first part of the small intestine. This is done up to 2 days after your ablation procedure.
- On rare occasion, this may cause a delay to your hospital discharge.
- This test is being done for research purposes only and is not commonly done after ablation procedures.

Study visits:

- There are no additional study visits however the research staff will collect data from your clinical visits for up to 1 year and may call you if you do not attend your routine follow up visits

Risks:

- Risks of study device: Placing the device may cause damage to your esophagus and there is a risk that the device may cause minor skin irritation if it is left in one place too long during your procedure. This is similar to the risk included when the standard of care temperature probe is inserted.

- Risks of the upper endoscopy: Common risks are sore throat and bloating. Rare risks include bleeding, damage to your GI system and allergic reaction to the sedation drugs.

Payment:

- You will receive a $100 gift card after you complete the upper endoscopy for your additional time, effort & inconvenience.

UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND
HIPAA AUTHORIZATION FORM

Protocol Title:	**Utility of Esophageal Cooling Therapy for the Prevention of Thermal Injury During Atrial Fibrillation Ablation**
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Why am I being asked to volunteer?

You are being invited to participate in a research study. Your doctor has determined that you have an irregular heart rhythm called atrial fibrillation (AF) and you are scheduled for a first-time AF ablation procedure. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to you. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do. The research team will to talk to you about the research study, and will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

Part of the standard atrial fibrillation (AF) ablation procedure involves performing ablation on a part of the heart next to the esophagus. Sometimes the heat from the

ablation in this area can also cause damage to the esophagus. Fortunately complications from this are very rare. Current techniques used during AF ablation procedures to try and reduce potential damage to the esophagus during the ablation is limited. The purpose of this study is to determine if esophageal cooling using the Attune Medical Esophageal Heat Transfer Device (EnsoETM) limits the number or seriousness of injury to the esophagus during atrial fibrillation ablation procedures. The EnsoETM is an FDA cleared device used for temperature management, but is not routinely used during atrial fibrillation ablation procedures.

How long will I be in the study? How many other people will be in the study?

If you choose to participate, you will actively be in this study for approximately 1 month, and the research staff will collect data from your clinical visits for up to 1 year. If you do not attend your routine follow up visits, the research staff may call you. About 60 subjects will be enrolled in this study at the University of Pennsylvania

What am I being asked to do?

You will be assigned to one of two treatment groups by chance (as with a flip of a coin); neither you nor your physician will be able to decide to which group you are assigned. Of the 60 participants in the study, one half will receive the study specific cooling device EnsoETM during the catheter ablation procedure and one half will receive the standard of care (standard temperature probe monitoring) during the catheter ablation procedure. Insertion of the study device will be in place of the standard temperature probe and will not add any additional time to the standard AF ablation procedure. The device will be used as indicated (for cooling) and temperature measures will be collected during the clinical ablation procedure.

All patients, regardless of the assigned group, will also undergo an esophagogastroduodenoscopy (EGD) procedure, commonly known as an upper endoscopy, which is a test to examine the lining of the esophagus, stomach, and first part of the small intestine. This procedure will be done up to2 days following the catheter ablation. This procedure is being performed for research purposes and will not be billed to your insurance. If during the EGD procedure the clinician sees something abnormal, they may take samples(biopsies) that may be billed to your insurance.

The catheter ablation procedure is being done as part of your standard of care to treat your AF. The use of the experimental cooling device and the EGD are being done solely for research purposes.

Atrial Fibrillation Ablation Procedure

Your physician has already detailed the clinical ablation procedure, including the associated risks/benefits, and you have signed a separate consent form for the clinical AF ablation. We do not anticipate that participating in this study will add any additional risks to the clinical ablation procedure that your doctor has already reviewed with you. During standard AF ablation procedures, patients undergo insertion of a temperature probe into the esophagus for monitoring while under general anesthesia. In this study, patients will be randomly selected to undergo either insertion of the standard probe or insertion of EnsoETM study device. The cooling device that we are studying has been FDA cleared, but is not currently used during routine atrial fibrillation ablation procedures.

Both the temperature probe and the EnsoETM will be removed after the procedure ends and before you wake up. The ablation procedure is otherwise not altered from standard clinical practice. After the ablation, you will be monitored in the hospital for 2-3 days as determined by your physician.

EGD Procedure

All patients that decide to participate in this study will undergo a diagnostic upper endoscopy procedure up to2 days after the ablation procedure prior to being discharged home. This procedure usually takes about 20 minutes and is performed under sedation. The EGD will be performed by a physician that specializes in gastroenterology. The EGD involves passing a camera into the esophagus to take pictures in order to evaluate if the study device is effective at preventing any inadvertent collateral injury to the esophagus from the ablation procedure. The gastroenterology and anesthesia physicians will explain the procedure and will ask you to sign a consent specific to this procedure.

Follow-up

Follow up data will be collected for one year after your ablation procedure at 4 time points (1month, 3 months, 6 months and 12 months). These are standard of care visits following an ablation procedure and participation in this study will not require any additional visits beyond what is recommended clinically by your physician. If you do not attend your routine follow up visits, the research staff may call you. In addition to the standard of care procedures and information collected by the clinical care team, the research team will also collect the following:

- Adverse event information (whether you have experienced any problems)

If you need more than one ablation to treat your AF, data from the additional ablations will be collected.

Schedule of Activities:

Study Phase	**Randomization/ Intervention Phase**		**Follow up Visit**
Visit Number	**1**	**2**	**3**
Study Days	**Day 0**	**Day 0-2**	**Day 30 -14/+30 days**
Research & Clinical Procedures			
Informed Consent	X		
Review Inclusion/Exclusion Criteria	X		
Randomization	X		
Ablation procedure (with temperature monitoring or EnsoETM device)	X		
Overnight monitoring post ablation	X		
EGD (Esophagogastroduodenoscopy)		X	
Discharge (1-2 days post ablation)		X	
Adverse Event / Unanticipated Problems Assessment	X	X	X
Data collection			
Demographics	X		
Medical History/Interim History*	X	X	X
Physical Examination*	X	X	X
NYHA	X		
Vital Signs: BP, HR, RR*	X	X	X
Height and Weight	X		
Pregnancy Test	X		
Clinical Laboratory Evaluation	X	X	
Clinical Imaging	X		
Prior/Concomitant Medications	X		X

*Interim medical history, physical exam, and vitals will be collected via chart review from routine clinical care follow up post-ablation visits that occur at approximately 3, 6 and 12 months. The research team may call you if you do not attend routine follow up clinical visits.

What are the possible risks or discomforts?

This study occurs during a cardiac ablation procedure that your doctor has scheduled for you as part of your standard of care. For subjects assigned to the control group, all procedures conducted during the ablation are standard of care and should not pose additional risks. However, for participants assigned to use of the EnsoETM device there may be additional risks. The risks are described later in this consent form. Your doctor will discuss the details of the ablation procedure and all of its associated risks with you when you review and sign the clinical

consent form. All subjects in this study will be asked to undergo an endoscopy for research purposes and there may be additional risks posed by this procedure. The risks are described later in this consent form.

Risks of EnsoETM for subjects assigned to the device treatment group

Placement of the EnsoETM device can result in or worsen esophageal tissue damage and injury, particularly in patients with known esophageal deformity or evidence of esophageal trauma. In very long procedures (i.e., longer than 8 hours), there is a risk that the device may cause minor injuries to the skin if it is left in one place. We will minimize this risk by regularly repositioning the EnsoETM during your procedure.

These risks are similar to those whom receive the standard of care temperature monitor probes inserted into the esophagus during routine clinical procedures.

Risks of EGD Procedure

This procedure is being done as part of this research study and is not standard of care for patients undergoing a cardiac ablation procedure.

In general, Diagnostic upper endoscopy procedure is a very safe test, but does have some risks associated with the procedure and with the anesthesia.

The risks associated with the procedure range from minor discomforts to significant medical problems.

The minor problems include:

1) Sore throat lasting less than 24 hours

2) Bloating and gas.

The more important risks include:

1) Bleeding (less than 3/10,000}

2) Tearing or perforation of the GI tract (less than 1/1,000)

3) Aspiration or inhaling stomach contents (less than 1/1,000).

The risks associated with anesthesia include:

1) Inflammation or bruising at the site of the IV

2) Allergic reaction (such as hives, wheezing, anaphylaxis);

3) Problems with cardiac and pulmonary function (irregular heartbeat and slowed breathing).

Although the overall risks to the procedure are quite small, occurring in less than 2/1,000 patients, there have been reports of serious, unpredicted complications that include death.

This research may also involve risks that are currently unforeseeable.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

There are no known direct benefits to the participants in this study. There may be a benefit to cooling the esophagus to reduce damage during the ablation procedure. The knowledge gained by participation in this study may benefit society as a whole in the future and potentially lead to additional studies

What other choices do I have if I do not participate?

If you do not participate in this trial, you may still receive the standard of care treatment for your condition.

Will I be paid for being in this study?

You will receive $100 for your additional time, effort & inconvenience of being in this study. Reimbursements for participation in the study will be administered using a Greenphire ClinCard, a reloadable prepaid card provided by the University of Pennsylvania. Payment will be loaded on the day of discharge after completing the EGD procedure.

Will I have to pay for anything?

You or your health insurance will be billed for the costs of medical care during this study. These tests and procedures are standard for the treatment of atrial fibrillation or are required prior to a catheter ablation procedure.

If any of the tests required by this study are not the standard of care, the Sponsor will be responsible for payment of these costs to the institution. You are still responsible for any deductibles or applicable co-pays for routine office visits, scans and blood work. Please talk to your doctor and study team about putting you in touch with a financial counselor to determine exactly what the deductible and co-pay will be for you; this is highly variable depending on your type of insurance.

What happens if I am injured or hurt during the study?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or the sponsor Attune, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by the study doctor, the study Sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The study doctor feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor, the study doctor, or the FDA has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. You should tell your researcher if you decide to stop and you will be told whether any additional tests may need to be done for your safety. Withdrawal will not interfere with your future care.

What information about me may be collected, used or shared with others

- Name, address, telephone number, date of birth.
- Social security numbers
- Medical record numbers
- Device model or serial number of the cooling device used for ablation.
- Personal and family medical history includes allergies, medications.
- Results from physical examinations includes blood pressure, heart rate, breathing rate and temperature.
- Tests such as echocardiogram transesophageal and transthoracic, CT scan/MRI or other clinical imaging will be collected if they have been performed for standard clinical care.
- Data and results from the ablation procedure

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- see if the research was done right

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The study doctor and the study team
- Other authorized personnel at Penn such as a billing representative

Who, outside of the School of Medicine, might receive my information?

- Those working under the direction of the study doctor, (e.g. under subcontracts).
- The funding sponsor and organizations supporting the sponsor

Oversight organizations

- The Food and Drug Administration
- The Office of Human Research Protections

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

The study doctor or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

Electronic Medical Records and Research Results

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any results of procedures performed as part of this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Results of research procedures performed as part of your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).

How long may the School of Medicine use or disclose my personal health information?

The duration of this authorization does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. If you stop authorization, the University of Pennsylvania may continue to use your information already collected as part of this study. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

Who can see or use my information? How will my personal information be protected?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your

name and other personal information will not be used. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the study doctor listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this combined consent and HIPAA Authorization form will be given to you.

_____	_____	
Name of Subject (Print)	Signature of Subject	Date
_____	_____	
Name of Person Obtaining Consent (Print)	Signature	Date