CONSENT FORM FOR RESEARCH

Study title: Esophageal Temperature Dynamics and Injury During Pulmonary Vein Isolation with Temperature-Controlled Very-High-Power Short-Duration Lesions Using the Novel Q-DOT Micro Ablation Catheter

Study support provided by: Biosense Webster, Inc.

Cedars-Sinai Principal Investigator: Eric D. Braunstein, MD

Study contact phone number at Cedars-Sinai: 310-248-6679

After-hours emergency contact (24 hours): Cedars-Sinai Cardiac Electrophysiology Answering Service – 310-248-6679

1. Key Information

We are asking for your consent to take part in this research study. This section provides key information about the study. The rest of this form has more detailed information.

- **Voluntary:** Taking part in this research study is your choice. You can also stop taking part at any time. You will not lose any services, benefits or rights you would normally have if you choose not to take part or stop taking part.

- **Purpose:** The purpose of this study is to compare two different ablation (destruction of tissue) strategies during catheter ablation for atrial fibrillation, and determine how these strategies affect the temperature and risk of injury to the esophagus.

- **Procedures:** The main things that will happen in this study are the planned catheter ablation for atrial fibrillation, followed by a capsule endoscopy 2-4 days after the ablation procedure in order to assess the esophagus.

- **Duration:** Taking part in this study will last about 3 months.

- **Risks:** All research studies involve some risk. Risks or discomforts from this study may be related to the capsule endoscopy, including discomfort while swallowing the capsule or rarely complications related to the capsule endoscopy such as bowel obstruction.

- **Benefits:** You are not likely to be helped from taking part in this research study. But the information learned from this study may help others in the future.

- **Alternatives:** You can choose not to take part in this study.

Please take time to read this entire form. You should ask questions before deciding whether to take part in this study. You can talk with family, friends and/or healthcare providers before you decide.

During the study, we may find out new information about this research study. We will tell you about any important changes or new findings that may impact whether you want to continue taking part in the study.

2. Purpose of the Study

We are doing this study to assess how two different ablation strategies, using two different ablation catheters during catheter ablation for paroxysmal atrial fibrillation, affect the temperature of the esophagus during ablation, and the risk of injury to the esophagus.

The U.S. Food and Drug Administration (FDA) has approved the devices used in this study as they are being used. Both devices are used routinely at Cedars-Sinai currently, and current use is based on the physician operator's preferences.

You are being asked to take part in this research study because you are undergoing catheter ablation for paroxysmal atrial fibrillation.

The study will include up to 30 people in total.

3. Main Study Procedures

This section talks about what will happen in this study. When you read this section, also read the flowchart of procedures. The flowchart is given with this consent form.

The flowchart of procedures shows a timeline of the study. It shows which study procedures are research-related and which are standard of care (routine). **Research-related procedures** are procedures done only for the research study. They would not be performed for your routine care outside of the study. **Standard of care (routine) procedures** would be performed as part of your routine care even if you did not take part in this study.

Description of main research procedures:
You will undergo catheter ablation for atrial fibrillation using the assigned ablation catheter and ablation strategy (temperature controlled very-high power, short duration or high power, short duration). Your esophageal temperature will be monitored during the procedure using a

multipolar temperature probe; esophageal temperature monitoring is routinely used during this procedure. All other aspects of the procedure will follow standard of care.

2-4 days after the ablation procedure, you will undergo a capsule endoscopy. This will involve swallowing a pill camera that will be used to take pictures of your esophagus. You will be required to return to the medical center for this test, which takes around 1-2 hours. No anesthesia is used for this test.

The study team may contact you around 90 days after the ablation procedure to assess for any issues that may have developed after the ablation procedure.

This study has 2 study groups:

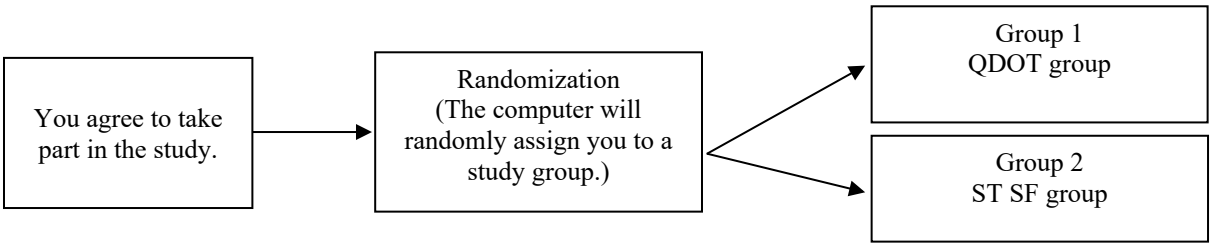
- QDOT group: This group will undergo temperature-controlled very-high power, short-duration ablation on the posterior wall of the left atrium, using the QDOT Micro ablation catheter.
- ST SF group: This group will undergo high-power, short-duration ablation on the posterior wall of the left atrium, using the ThermoCool SmartTouch SF ablation catheter.

Both the QDOT Micro and ThermoCool SmartTouch SF ablation catheters use radiofrequency (heat) energy to ablate tissue. The QDOT Micro catheter has additional thermocouples (temperature sensors) that allow it to be safely used to deliver temperature-controlled higher power and shorter duration ablation lesions. This type of ablation lesion is theoretically less deep, which may lead to equivalent heart muscle ablation with less effect on deeper surrounding tissues (such as the esophagus).

This is a randomized open-label research study.

- **Randomized**: This means that you will be put in a study group by chance (like flipping a coin). You will be randomly put in one of the above study groups. You will have an equal chance of being placed in any one of the groups described above. A computer will randomly put you in a study group. We do this because no one knows if the results in one study group are different than the other. The results could be better, the same or worse than the results in other groups. Once you are put in one group, you cannot switch to another group. You and your doctor cannot choose the group you are in.
- **Open-label:** This means you and the researchers will know what group you are in.

The chart below outlines what will happen during the study.



How long will you be in the study ?
We think you will be in this study for about 90 days. This includes the ablation procedure, the capsule endoscopy 2-4 days after the ablation, and a possible follow-up via telephone 90 days after the ablation procedure.

4. Possible Risks and Discomforts of the Main Research Procedures

This section talks about the possible risks and/or discomforts of the study procedures.

We do not anticipate additional ablation procedural risks stemming from participation in this study, as standard of care will be followed and only FDA approved medical devices will be used. Side effects and risks of standard of care procedures are not described in this consent form.

In addition to standard of care, capsule endoscopy will be performed as part of this study. Although capsule endoscopy is a very safe procedure, there is a small (1-2%) risk of capsule retention and/or bowel obstruction that could necessitate a procedure or surgery to remove the capsule. There is also a small risk of discomfort while swallowing the capsule.

Unknown Risks
There may be other risks that we cannot predict. Many complications are minor and do not last long. However, in some cases, they can be serious, long-lasting, permanent and/or fatal.

5. Common Medical Procedures Performed for Research Purposes and Risks

The procedures listed below are often part of routine care for a person with your condition. They are not experimental procedures. The procedures and their risks are research-related. This means they are being *repeated* or performed *more frequently* for this study. These common procedures and their risks should be the same as when performed outside this study.

Study Procedure	Related Risks
Medications: We will ask you about your past and current medications. Talk with the study team about any non-study medications. Non-study medications include over-the-counter drugs, supplements and vitamins.	This does not have any physical risks.
Demographic Information: We will ask you about demographics, which may include your age, gender identity, sexual orientation, race and ethnicity.	This does not have any physical risks.
Medical History Review: We will ask you about your medical and surgical history.	This does not have any physical risks.

6. Benefits From Taking Part in the Study

Taking part in this research study may or may not have direct medical benefit to you. During the ablation procedure, your esophageal temperature will be monitored more closely than usual, which could lead to a lower risk of esophageal injury. No benefit is guaranteed.

We hope the information learned from this research study will help determine the safest method of performing ablation on the posterior wall during catheter ablation for atrial fibrillation.

7. Whether Research Results Will Be Shared

The imaging procedure (esophageal capsule endoscopy) in this study is being done for research purposes. However, they will be done following standard clinical imaging techniques. The imaging results may be shared with you. They may be placed in your Cedars-Sinai medical record.

Unanticipated Incidental Findings

We will contact you using the last contact information you gave if, unexpectedly, we find results that suggest potentially clinically relevant medical information. We may suggest you talk with your treating physician about possible additional clinical testing to further evaluate the research finding. You and/or your insurance would pay for any additional testing and any related treatment.

8. Reasons Participation May Be Stopped

Your participation in this study may be stopped at any time. The researcher or the sponsor can stop your participation without your consent for any reason. Some reasons for stopping your participation include:

- The study is stopped or suspended.
- Funding for the study is reduced, stopped, or withdrawn.
- It is in your best interest.
- You do not follow the study procedures.

9. Choosing to Take Part and Other Options

Taking part in research is voluntary. You have the right to choose not to take part. You can stop taking part in this research study at any time. You can do this without any penalty or loss of benefits to which you would be entitled outside of the study. Your choice not to take part or to stop taking part will not affect the care you get at Cedars-Sinai.

If you decide to stop taking part, we will keep any data collected on you up to the time you choose to stop. Also, if you stop taking part, the study team may ask you whether you want to give further data from your routine medical care.

The study team will discuss these options and their risks and benefits with you. You may also choose to discuss these with your treating physician.

10. Confidentiality Protections

We will do our best to keep your personal information collected as part of this study private. But we cannot guarantee total privacy. We may put a copy of your research consent and authorization forms in your electronic medical record at Cedars-Sinai. Your personal information may be given out if required by law. Publications or presentations about this study at scientific meetings will not use your name and other identifiable personal information.

Organizations that may look at and/or copy your medical records for research oversight, quality assurance and data analysis include:

- Accrediting agencies (agencies that grant official certifications to educational institutions)
- Government and regulatory groups, such as the Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP)
- The Institutional Review Board (IRB), which reviews research to protect people taking part in studies
- Safety monitors, which monitors the safety of individual participants and the overall safety of the study
- Companies that sponsor the study and authorized representatives of the sponsor

Attached to this consent form is an Authorization Form. It outlines with whom your information may be shared for this research and under what circumstances.

We might share your information and/or research samples collected in this study. It might be shared with other researchers at Cedars-Sinai, other academic institutions or third-party commercial entities for future research without additional informed consent from you. Information that identifies you will be removed and will not be shared with other researchers or anyone outside of Cedars-Sinai.

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

11. Research-Related Illness or Injury

Contact your study doctor at once if you feel that you are ill or have been injured because of taking part in this study. As needed, your study doctor will treat you or refer you for treatment. If it is a medical emergency, call 911 or go to an emergency room. Promptly notify your study doctor of your situation at the phone number listed on page 1 of this consent form.

Who pays for my research-related illness or injury?
Cedars-Sinai has no plans to pay for costs associated with the treatment of research-related injury or illness. We will make every effort to seek reimbursement from your health plan. However, you will be responsible for any deductibles and copayments required under your health plan and for any claims ultimately denied by your health plan. Financial assistance may be available under Cedars-Sinai's Financial Assistance Program. If you feel that you have had a research-related injury and need financial assistance, please contact the IRB Office at 310-423-3783. You do not waive any of your legal rights by signing this form.

12. Financial Considerations

Costs of Participation
The attached flowchart lists items, drugs and services that will be billed to you and/or your insurance and those that will be covered by the Study Sponsor. Review the flowchart for details.

Standard of care procedures and the cost of the study device, implant procedure, and related items, drugs and procedures will be charged to you or your insurance company. You remain responsible for all deductibles, copays and balances under your health benefit plan.

The research staff will seek pre-authorization from your insurance company for the procedures in this study. Before any study procedures are performed, pre-authorization must be received from your insurance company. If your insurance company denies coverage, you may decline to take part in this study or you may choose to pay out of pocket. If you have questions or concerns about your insurance coverage, you should ask your health benefit plan.

Payment
You will not be paid for taking part in this research study.
Financial Interest in the Research
The principal investigator and institution have no potential financial conflict of interest with this study.

13. Contact for Questions or Problems

Please contact the investigator for questions, problems or concerns about the research. Their contact information is on page 1 of this form.

You might have feedback, questions, problems, concerns or want to obtain more information about this study. If so, you can talk with someone who is not part of this study by contacting:

Cedars-Sinai Human Research Protection Program (HRPP)
Phone: 310-423-3783
Email: ResearchConcerns@cshs.org

Website: cedars-sinai.org/research/administration/office-of-research-compliance/review-board.html

The Cedars-Sinai HRPP protects the rights and welfare of research participants.

Experimental Subject's Bill of Rights

In accordance with California Health and Safety Code 24172, any person who is required to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks to the subject reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

AUTHORIZATION FOR USE AND DISCLOSURE OF IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH

1. USE AND DISCLOSURE OF HEALTH INFORMATION

If you agree to this Authorization, you give permission to the Sponsor, Principal Investigator, other investigators and their research team described in the Consent Form for Research ("Research Team") to use or disclose your identifiable health information ("private information") for the research study titled "Esophageal Temperature Dynamics and Injury During Pulmonary Vein Isolation with Temperature-Controlled Very-High-Power Short-Duration Lesions Using the Novel Q-DOT Micro Ablation Catheter" which is described in the Consent Form for Research ("Consent Form") to which this Authorization is attached. In particular, you authorize the research team acting under the direction of the Principal Investigator to review your medical records and collect your private information from the following sources:

☒ Laboratory tests
☒ Pathology reports
☒ Imaging reports (e.g., x-rays or scans)
☐ Photographs or videos of your image
☒ Doctor/clinic records
☒ Hospital/medical records
☐ Mental health records
☐ Billing records

☒ Demographics, which may include age, gender identity, race, ethnicity, and/or sexual orientation

☐ Other tests or other types of medical information: N/a

2. WHO WILL HAVE ACCESS TO YOUR PRIVATE INFORMATION?

Your private information will be used by and/or shared with the Research Team.

In addition to the research team, if applicable, the following parties may receive your private information and inspect your records:

- The reviewing Institutional Review Boards and Cedars-Sinai offices with authority to oversee research compliance.
- U.S. government agencies, such as the Food and Drug Administration and the Department of Health and Human Services.
- Researchers at other organizations who are participating in this research study.

- The Study Sponsor, its business partners, and Cedars-Sinai's business partners for matters related to research study oversight, conduct of the research, data analysis, use of research results in product development, and payment or reimbursement.
- Representatives from regulatory agencies in other countries may join in the review of your research records, including research-related medical reports and information, with the Sponsor and/or the FDA.

Cedars-Sinai takes steps to protect your private information when sharing it with the recipients described above. Though these steps and applicable law are meant to protect your private information, there is a risk that a recipient could share your private information without your permission.

3. WHEN WILL MY AUTHORIZATION EXPIRE?

By signing this document, you authorize the use and sharing of your private information until the end of the research study and any related optional sub-study you choose to participate in.

4. REVOKING AUTHORIZATION

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, the research team may still use or disclose private information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to the Principal Investigator of the research study by writing to the Office of Research Compliance and Quality Improvement, 6500 Wilshire Blvd, Suite 1800, Los Angeles, Calif. 90048 and/or emailing to ResearchConcerns@cshs.org.

5. NOTICE OF RIGHTS AND OTHER INFORMATION

You do not have to agree to this Authorization, but if you do not agree, you may not participate in the research study. Cedars-Sinai may not condition (withhold or refuse) the provision of standard of care treatment for you on whether you agree to this Authorization.

If you agree to this Authorization, please sign on the appropriate signature line on the Signature Page. You will receive a copy of this Authorization.

Flowchart of Visits, Tests and Procedures

Legend
R = Research item/procedure done only for research purposes and their costs are covered by the study. You are not responsible for the costs of these procedures.
S = Standard of care item/procedure that is part of regular care and billed to the patient/insurance. You and your insurance company will be responsible for these costs.

Procedures	Screening Visit	Procedure
Pre-procedure office visit	S	
Catheter ablation for atrial fibrillation (S)		S
Capsule Endoscopy (R)		R

Signature Page

Consent Form for Research and Authorization for Use and Disclosure of Identifiable Health Information (Research)

If you agree to take part in this study, you should sign and date on the signature lines below. You will be given a signed and dated copy of this form. This includes the "Experimental Subject's Bill of Rights," "Authorization for Use and Disclosure of Identifiable Health Information (Research)" and any optional sub-study descriptions, when applicable.

Signature by the Participant
Main Research Study: *I agree to take part in the research study described to me during the informed consent process and described in this informed consent form. My questions have been answered to my satisfaction.*

You will be given a signed and dated copy of this form.

Participant name (please print)	Signature	Date

Authorization for Use and Disclosure of Identifiable Health Information (Research): *I hereby agree that my identifiable health information may be used and/or disclosed in accordance with the "Authorization for Use and Disclosure of Identifiable Health Information (Research)."*

Participant name (please print)	Signature	Date

Signature by the Investigator
I attest that all the elements of informed consent described in this form have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

Investigator name (please print)	Signature	Date

Signature by the Interpreter/Witness

(Signature of an interpreter is only required when enrolling a non-English-speaking subject with the assistance of an interpreter and IRB-approved "short form" consent processes. The witness may be any person who is conversant in both English and the language of the non-English-speaking subject, such as a certified hospital interpreter, study staff, a family member or other person. The witness signs the consent forms to confirm that the oral interpretation occurred.

Signature of a witness is required when an English-speaking subjects who has been determined to have capacity to consent is unable to read or physically sign the consent form, but choses to indicate via a "mark" or verbally that he/she agrees to participate. The witness signs the consent form to confirm that an oral consent process occurred and that the individual verbally consented to participate in the research.)

Interpreter/Witness name (please print)	Signature	Date