Comparative Evaluation of Optrell and Octaray Mapping Catheters for Conduction Block Confirmation and Voltage Assessment During Atrial Ablation

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- **Study Type:** Investigator-Initiated, Prospective, single-center, observational validation and workflow study
- **Site:** Shamir Medical Center, Tel Aviv University, Israel

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1. SYNOPSIS

This prospective, single-center observational study aims to compare the clinical performance, workflow efficiency, and electrophysiological metrics of two commercially available, high-density multielectrode mapping catheters (Octaray and Optrell) in patients undergoing catheter ablation for complex atrial arrhythmias.

The primary focus is to determine if the real-time vector propagation capabilities of the Optrell catheter combined with V8 software can accurately confirm conduction block across linear ablation lesions without the need for full-chamber activation remapping, which is the current standard of care. A secondary focus will pair-compare the bipolar voltage amplitude distributions recorded by both catheters, given their differing electrode sizes and spacing

2. BACKGROUND AND RATIONALE

2.1 The Clinical Challenge of Conduction Block Assessment

Catheter ablation is a cornerstone therapy for atrial fibrillation (AF) and atrial flutter. In patients with persistent AF or specific anatomical flutters, the creation of linear ablation lesions (e.g., roof line, posterior wall isolation, cavotricuspid isthmus [CTI] line, or mitral isthmus line) beyond standard Pulmonary Vein Isolation (PVI) is often clinically indicated.

A critical determinant of procedural success and long-term freedom from arrhythmia is the achievement of bidirectional conduction block across these lines. Currently, confirming this block requires time-consuming, full-chamber activation remapping using a standard high-density catheter (such as the Octaray).

2.2 The Investigational Approach

The Optrell catheter, when integrated with V8 mapping software, offers real-time visualization of electrical propagation vectors. We hypothesize that this directional vector mapping allows operators to immediately and accurately identify the presence or absence of conduction block across a linear lesion. Validating this hypothesis could eliminate the need for complete chamber remapping, significantly streamlining procedural workflow and reducing procedure times.

2.3 Voltage Amplitude Comparison Bipolar voltage amplitude is the standard metric for defining healthy myocardium versus atrial scar tissue. However, measured voltage is heavily dependent on catheter design, specifically electrode size and inter-electrode spacing. Because the Octaray and Optrell catheters differ in these physical properties, it is essential to establish how their voltage readings correlate and whether catheter-specific voltage cutoffs are necessary for accurate scar delineation.

2.4 Regulatory Status All equipment utilized in this study, including the Octaray and Optrell catheters and their associated mapping systems, are fully approved for clinical use by the FDA, CE, and AMAR (Israeli Ministry of Health) and are routinely utilized in standard practice at our institution.

3. STUDY OBJECTIVES

3.1 Primary Objective

To evaluate the diagnostic concordance and workflow efficiency of real-time vector-based assessment using the Optrell catheter (with V8 software) compared to standard full-chamber activation mapping for confirming bidirectional conduction block across atrial ablation lines.

3.2 Secondary Objectives

- To perform a paired comparison of bipolar voltage amplitude distributions in the left atrium recorded by the Optrell versus the Octaray catheter during CS pacing before and after ablation.
- To perform a paired comparison of multipolar voltage amplitude distributions in the left atrium recorded by the Optrell versus bipolar voltage with the Octaray catheter during CS pacing before and after ablation.
- To evaluate the safety profile of the dual-catheter mapping approach.
- To assess long-term clinical outcomes, specifically the 12-month freedom from recurrent atrial tachyarrhythmias (AF, atrial flutter, or atrial tachycardia).

4. STUDY ENDPOINTS

4.1 Primary Endpoints

- **Concordance:** Percentage of agreement (presence vs. absence of bidirectional block) between the Optrell real-time vector assessment and standard activation remapping on a per-line basis.
- **Workflow Efficiency:** Difference in time (in minutes) required to confirm conduction block status using the Optrell vector method versus full activation mapping.

4.2 Secondary Endpoints

- **Bipolar Voltage Correlation:** Statistical correlation and evaluation of systematic bias (limits of agreement) between the bipolar voltage amplitudes recorded by the two catheters in matched anatomical regions.
- **Multipolar Voltage Correlation:** Statistical correlation and evaluation of systematic bias (limits of agreement) between the multipolar voltage amplitudes recorded by the Optrell catheter and the bipolar voltage amplitudes recorded by the Octaray catheter in matched anatomical regions
- **Clinical Efficacy:** Freedom from any documented atrial tachyarrhythmia lasting ≥30 seconds at 1, 3, 6, 9, and 12 months.
- **Safety:** Incidence of acute procedural complications prior to hospital discharge.

5. STUDY POPULATION

The study will enroll a cohort of patients in whom the likelihood for needing ablation lines beyond PVI is high.

5.1 Inclusion Criteria

- Age ≥18 years.
- Documented persistent atrial fibrillation and/or atrial flutter.
- Undergoing a clinically indicated first-time (de novo) or redo catheter ablation where linear ablation lesion sets (e.g., posterior wall, roof line, lateral mitral line, CTI) are planned or anticipated.
- Ability to provide written informed consent.

5.2 Exclusion Criteria

- Paroxysmal or persistent AF where only standard PVI is planned.
- Mechanical mitral valve
- Presence of intracardiac thrombus or contraindication to systemic anticoagulation
- Any medical condition or anatomical contraindication that, in the investigator's judgment, precludes safe participation.
- Pregnant women
- Ability and willingness to provide written informed consent.

6. STUDY PROCEDURES

6.1 Pre-Procedural Management

1. Class I and Class III antiarrhythmic drugs will be discontinued at least 3 days prior to the procedure, with amiodarone discontinued at least 2 weeks prior when feasible. Beta blockers and Calcium channel blockers are allowed.
2. Oral anticoagulation will be maintained uninterrupted according to guideline-based practice.
3. Intracardiac thrombus will be excluded by transesophageal echocardiography, cardiac CT or intracardiac echocardiography prior to the procedure, according to institutional practice.

6.2 Intra-Procedural Workflow

The procedure will be performed under general anesthesia. Following standard venous access, transseptal puncture will be performed to access the left atrium. Systemic anticoagulation with intravenous Heparin will be administered and maintained to achieve an activated clotting time (ACT) >300 seconds.

- **Phase 1: Voltage Mapping (coronary sinus pacing)**

Following transseptal access and prior to ablation, a left atrial 3D map using TPI with left atrial voltage mapping will be performed using the Octaray catheter. The Octaray catheter will then be exchanged for the Optrell catheter, and a second high-density voltage map will be acquired on the

same 3D map (remap). A high density Mulitpolar map using parallel mapping will be performed in the same time with the Optrell catheter. All the maps need to have a fill threshold ≤3mm to allow sufficient density.

For patient in atrial fibrillation, an electrical cardioversion will be performed and mapping will be performed during coronary sinus pacing. For patient in sinus rhythm, mapping will be performed during coronary sinus pacing. For patient in atrial flutter, mapping will be performed in arrhythmia.

- **Phase 2: Ablation:**

The operator will perform PVI and any clinically indicated linear lesion sets according to standard of care using either radiofrequency or pulsed field ablation energy.

- **Phase 3: Conduction Block Assessment**

After completing the ablation phase, conduction block across lines will be assessed using both methods:

- *Optrell Vector Assessment:* Real-time evaluation of conduction vectors using the Optrell catheter and V8 software. The time to determination, from the beginning of the mapping (pacing start) to block confirmation, and the binary result (block vs. no block) will be recorded.
- *Standard Activation Mapping:* Creation of a full activation map using the Octaray catheter (often requiring pacing maneuvers) to establish the gold-standard confirmation of block. Time to determination, from the beginning of the mapping to block confirmation, and the binary result will be recorded.

6.3 Distinction Between Research Protocol and Clinical Standard of Care

It is important to emphasize that patients enrolled in this study will undergo the same clinically indicated ablation procedure and receive the same standard of care as non-participating patients. The sole distinction for research participants is the inclusion of the two additional mapping sequences: one performed prior to ablation (for the paired voltage amplitude comparison) and one performed after ablation (for the comparative conduction block assessment). Furthermore, all mapping and ablation technologies utilized during these additional research steps, including the Optrell and Octaray catheters, as well as their respective 3D mapping systems and software, are

fully approved for clinical use by the FDA, CE, and AMAR, and are routinely employed in standard clinical practice at our institution.

7. FOLLOW-UP

7.1 Acute Safety Follow-Up

Because the investigational component of this study consists solely of additional electrophysiological mapping time using commercially approved technologies within a standard-of-care procedure, an independent Data Safety Monitoring Board (DSMB) will not be established. Instead, a designated Medical Monitor will oversee safety reporting throughout the study.

The Medical Monitor will be a senior cardiologist with expertise in cardiac procedures who is not involved in the conduct of the study and has no direct role in patient enrollment, procedures, or data analysis. The Medical Monitor will independently review all reported safety events.

All acute procedural complications and safety events will be reviewed by the Medical Monitor within 72 hours of notification.

Adverse Event (AE) and Serious Adverse Event (SAE) forms will be completed by the research coordinator in collaboration with the procedural operator and documented in the study Case Report Form (CRF; Appendix C).

If serious adverse events directly attributable to the repolarization mapping protocol occur in ≥2 of the first 10 enrolled patients, study enrollment will be temporarily paused, and an ad-hoc safety review will be conducted by the Medical Monitor and study leadership to determine whether protocol modification or study termination is necessary.

Definitions

AE

An AE is any unfavorable and unintended medical occurrence in a study participant undergoing the procedure, whether or not it is considered related to the study protocol.

SAE

An SAE is any adverse event that results in one or more of the following outcomes:

- Death
- Life-threatening event
- Stroke/TIA
- Persistent or significant disability or incapacity
- Unplanned hospitalization or prolongation of hospitalization
- Any important medical event that may jeopardize the patient or require medical or surgical intervention to prevent one of the outcomes listed above

For the purposes of this study, the following procedural complications will be classified and reported as SAEs:

- Pericardial effusion or cardiac tamponade
- Stroke/TIA
- Phrenic nerve injury
- Vascular access complications requiring intervention
- Esophageal injury
- Heart failure exacerbation requiring treatment
- Prolonged hospitalization (>24 hours beyond the expected post-procedural course)
- Any other serious adverse event related to the procedure

Safety Follow-Up Period

Formal protocol-mandated safety follow-up will extend through 7 days after the procedure or until hospital discharge, whichever occurs later.

All AEs and SAEs occurring during this period will be documented in the CRF and reviewed by the Medical Monitor.

7.2 Clinical Follow-Up and Rhythm Monitoring

Patients will undergo highly structured longitudinal follow-up to monitor for clinical and subclinical arrhythmia recurrence and symptom status.

Clinic Visits:

Patients will be evaluated at the following time points after the ablation procedure:

- 1 month ±14 days
- 3 months ±30 days
- 6 months ±30 days
- 9 months ±30 days
- 12 months ±30 days

Visits at 3 and 12 months will be conducted in person, while other visits may be conducted in person or via telemedicine, depending on clinical circumstances.

During these visits, the following information will be collected:

- Symptoms suggestive of arrhythmia recurrence
- Medication use, including antiarrhythmic drugs and anticoagulation
- Interval hospitalizations or cardiovascular events
- Standard ECG documentation when available

Rhythm Monitoring:

To systematically detect symptomatic and asymptomatic arrhythmia recurrence, patients will undergo scheduled ambulatory rhythm monitoring during follow-up.

A minimum of three 48-hour Holter monitors will be performed at:

- 3 months ±30 days
- 6 months ±30 days
- 12 months ±30 days

Additional rhythm monitoring (Holter, event monitor, or ECG) may be performed at the treating physician’s discretion if symptoms suggest arrhythmia recurrence.

Recurrence of atrial arrhythmia will be defined as documented AF or atrial tachycardia lasting ≥30 seconds after the standard 2-month blanking period.

Community-Based Testing: To facilitate protocol compliance, both the 12-lead ECGs and the 24-hour Holter monitors may be performed locally at the patient's primary care clinic (Kupat Holim). The study coordinator is responsible for retrieving and analyzing these community-based reports and logging the data into the study database.

7.3 Post-Procedure Antiarrhythmic Drug Management

The use of AADs following the ablation procedure will be at the discretion of the treating electrophysiologist and managing physician, in accordance with routine clinical practice.

Continuation, initiation, or discontinuation of AAD therapy during follow-up will not be dictated by the study protocol. All AAD use will be prospectively documented, including drug type, dosing, changes, discontinuation, and replacement. This information will be incorporated into the clinical database and considered in exploratory analyses of arrhythmia recurrence.

7.4 Redo Procedures and Lesion Durability Assessment

Any documented recurrence of atrial flutter or AF will prompt consideration for a redo procedure, as clinically indicated.

If a redo procedure is performed during the 12-month follow-up period, the index protocol performed again: a left atrial 3D map using TPI with left atrial voltage mapping will be performed using the Octaray catheter. The Octaray catheter will then be exchanged for the Optrell catheter, and a second high-density voltage map will be acquired on the same 3D map (remap). A high density Mulitpolar map using parallel mapping will be performed in the same time with the Optrell catheter. All the maps need to have a fill threshold ≤3mm to allow sufficient density. For patient in atrial fibrillation, an electrical cardioversion will be performed and mapping will be performed during coronary sinus pacing. For patient in sinus rhythm, mapping will be performed during coronary sinus pacing. For patient in atrial flutter, mapping will be performed in arrhythmia.

- **Block Assessment**: Prior to delivering any new ablation, the operator must re-assess conduction block across all linear ablation lesions created during the index procedure.

Gold Standard Block Assessment: Creation of a full activation map using the Octaray catheter (often requiring pacing maneuvers) to establish the gold-standard confirmation of block. Time to determination, from the beginning of the mapping to block confirmation, and the binary result will be recorded.

Optrell Vector Assessment*:* Real-time evaluation of conduction vectors using the Optrell catheter and V8 software. The time to determination, from the beginning of the mapping (pacing start) to block confirmation, and the binary result (block vs. no block) will be recorded.

- **Data Capture:** The presence or absence of durable conduction block across each previously ablated line, as determined by the standard activation map, must be meticulously documented in a dedicated "Redo Procedure" module within the Case Report Form (CRF).
- **Treatment:** Subsequent ablation of any identified gaps or new arrhythmogenic substrates will be performed according to the operator's clinical discretion and standard of care.

For every redo procedure, a complete Redo Procedural CRF (Appendix F) will be filled.

8. STATISTICAL CONSIDERATIONS

8.1 Sample Size

A sample size of 30 patients is targeted. Because each patient will likely contribute multiple mapped regions and ablation lines (e.g., roof line, posterior wall, CTI), this will yield a robust number of paired observations for both voltage and block concordance analyses.

8.2 Efficacy Analyses

- **Concordance of Block:** Agreement between the vector-based assessment and standard activation mapping will be evaluated using absolute percentage agreement and Cohen's Kappa statistic for inter-method reliability.
- **Time to Confirmation:** The time required to confirm conduction block will be compared between the two methods using a paired t-test or Wilcoxon signed-rank test, depending on the normality of the data distribution.
- **Voltage Comparison:** Paired continuous voltage data from the Octaray and Optrell catheters will be analyzed using Pearson or Spearman correlation coefficients. Furthermore, Bland-Altman analysis will be conducted to assess for systematic bias and establish limits of agreement between the two catheter designs.
- **Clinical Outcomes:** Freedom from arrhythmia at 12 months will be analyzed using Kaplan-Meier survival estimates.

8.3 Data Management and Protocol Compliance

Protocol compliance will be strictly monitored throughout the 12-month follow-up period. Any required clinic visits, ECGs, or 24-hour Holter monitors that are missed entirely, or completed outside the designated ± 14-day window, will be documented as protocol deviations. The overall

follow-up compliance rate will be reported in the final analysis to validate the capture of the clinical efficacy endpoints.

9. ETHICAL CONSIDERATIONS

9.1 Declaration of Helsinki and IRB Approval

This study will be conducted in full compliance with the ethical principles of the Declaration of Helsinki and Good Clinical Practice (GCP) guidelines. The protocol, informed consent form, and all associated materials will be reviewed and approved by the local Institutional Review Board (IRB) / Helsinki Committee prior to patient enrollment.

9.2 Risk and Benefit Assessment

The investigational component of the study consists solely of additional electrophysiological mapping performed using clinically approved electroanatomical mapping systems and catheters during a standard-of-care AF ablation procedure.

Risks: The primary risk specific to this study is the prolongation of the procedure by approximately 15 minutes to accommodate mapping with two separate catheters. This additional mapping time is purely electrophysiological and does not involve any additional fluoroscopy (radiation) exposure. Therefore, potential risks are those inherent to standard catheter ablation procedures and include, but are not limited to:

- cardiac tamponade
- stroke or transient ischemic attack
- vascular complications
- phrenic nerve injury

Benefits: Using two high-density catheters allows for an exceptionally thorough interrogation of the ablation lines. This heightened scrutiny increases the probability of detecting micro-gaps in the ablation line that a single map might miss. Any detected gaps will be treated immediately, potentially reducing the patient's risk of future arrhythmia recurrence. Furthermore, patients will benefit from rigorous, structured follow-up care for a full year. On a broader scale, this study will help establish optimized workflows for future patients.

9.3 Informed Consent

Written informed consent will be obtained from all eligible patients prior to any study-specific procedures. Patients will be thoroughly counseled regarding the use of both catheters, the anticipated 15-minute procedural prolongation, the lack of additional radiation, and the rigorous follow-up schedule.

10. STUDY GOVERNANCE AND SAFETY OVERSIGHT

An independent Data Safety Monitoring Board will not be established for this investigator-initiated observational study due to the limited sample size and the fact that the investigational component consists solely of additional electrophysiological mapping using commercially approved technologies within a standard-of-care ablation procedure.

Safety oversight will be performed by a designated Medical Monitor, who will review all reported acute procedural complications (e.g., cardiac tamponade, stroke or transient ischemic attack, and vascular complications requiring intervention) within 72 hours of occurrence.

If two or more unexpected severe adverse events potentially attributable to the repolarization mapping protocol occur within the first ten enrolled patients, study enrollment will be temporarily paused and an ad-hoc safety review will be conducted to determine whether protocol modifications are required before enrollment resumes.

Safety events and protocol adherence will be monitored throughout the study.

Study Registration: the study will be registered in a public clinical trials registry (e.g., ClinicalTrials.gov) prior to enrollment of the first patient, in accordance with International Committee of Medical Journal Editors (ICMJE) requirements.

11. STUDY MONITORING AND DATA PROTECTION

Study Monitoring

The study will be conducted in accordance with ICH-GCP principles and applicable institutional policies. Monitoring will be performed using a risk-based approach appropriate for an investigator-initiated observational study. Monitoring activities may include on-site or remote review of study documentation.

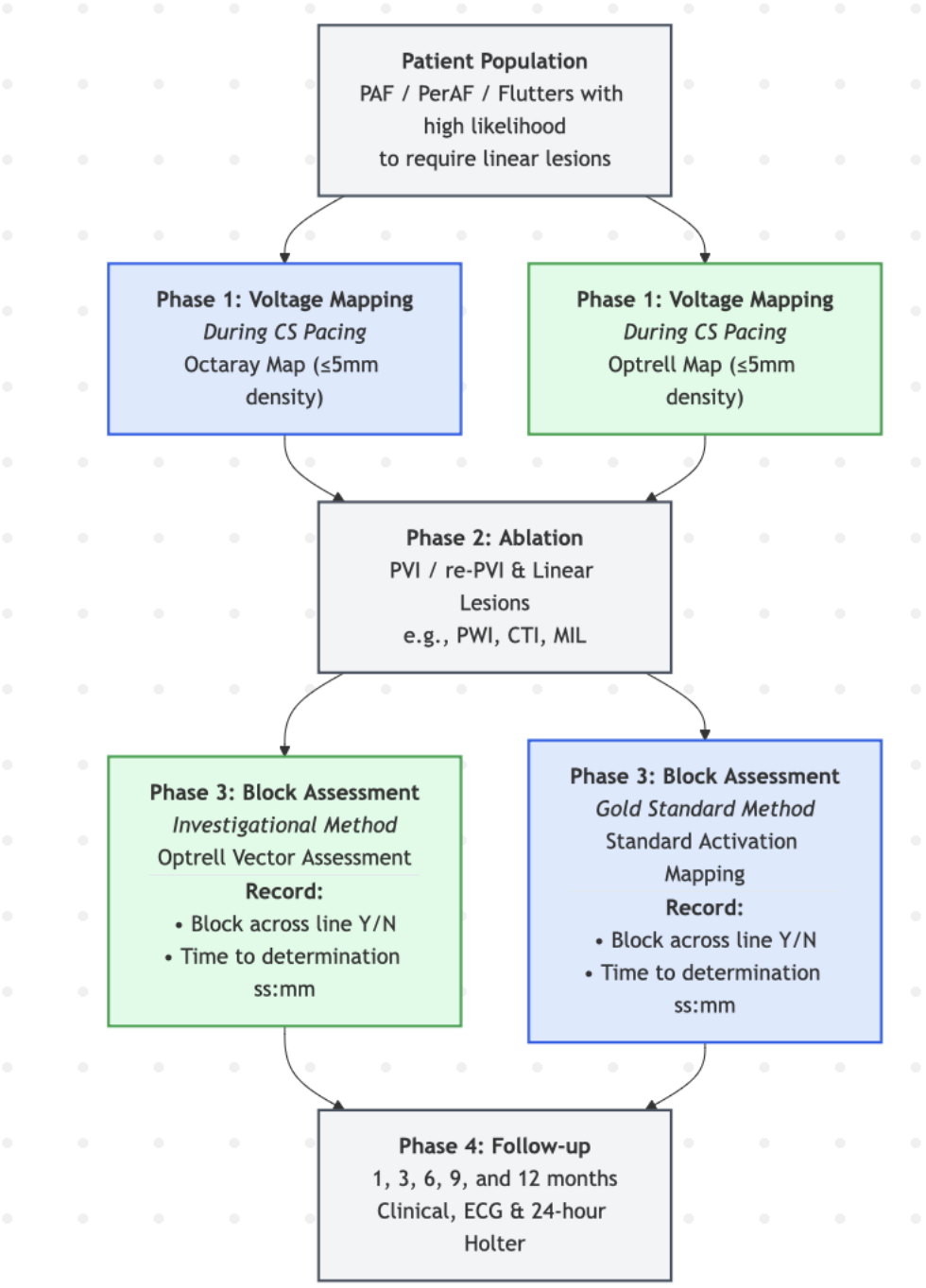
Monitoring will verify:

- IRB / Ethics Committee approval
- informed consent documentation
- patient eligibility
- accuracy of key study variables
- documentation of adverse events
- protocol compliance

Data Protection

All patient data will be collected and stored in a pseudonymized format using a unique study identification number. Directly identifiable patient information will remain securely stored at the study site and will not be transferred outside the institution. Study data will be stored in secure institutional systems and handled in accordance with applicable data protection regulations, including GDPR where applicable. Study data will be retained for at least 10 years after study completion, or longer if required by institutional or national regulations. Access to the study database will be limited to study investigators and authorized research personnel.

12. APPENDIX A - STUDY FLOWCHART



13. APPENDIX B- Schedule of Assessments

Study Activity	Screening / Pre-Procedure	Procedure Day	Post-Procedure / Discharge	1 Month	3 Months	6 Months	9 Months	12 Months
Informed consent	----------X----------							
Eligibility confirmation	X	X						
Demographics and medical history	X							
Arrhythmia Classification (PAF / PerAF / Flutter)	X							
Baseline medications	X		X	X	X	X	X	X
Standard Ablation according to protocol		X						
Procedural safety assessment		X	X					
Adverse event assessment			X	X	X	X	X	X
ECG			X	X	X	X	X	X
AAD documentation			X	X	X	X	X	X
48-hour Holter					X	X		X
Arrhythmia recurrence assessment				X	X	X	X	X
Documentation of redo ablation (if applicable)					X	X	X	X

14. Appendix C – AE / SAE Form

Field	Description / Options
Study ID	
Hopital MRN	
Event number	
Event classification	☐ AE ☐ SAE
SAE Category	
SAE type	☐ Pericardial effusion / tamponade ☐ Stroke / TIA ☐ Vascular complication requiring intervention ☐ Phrenic nerve injury ☐ Esophageal injury ☐ Heart failure exacerbation requiring treatment ☐ Prolonged hospitalization (>24h) ☐ Other (specify)
Event description	
Date of onset	
Date of resolution	
Severity	☐ Mild ☐ Moderate ☐ Severe
Seriousness criteria	☐ Death ☐ Life-threatening event ☐ Prolonged hospitalization ☐ Persistent disability ☐ Medically significant event
Relationship to procedure	☐ Related to procedure ☐ Possibly related to study mapping protocol ☐ Unrelated
Action taken	☐ Observation ☐ Medication ☐ Intervention ☐ Hospitalization ☐ Other
Outcome	☐ Resolved ☐ Ongoing ☐ Resolved with sequelae ☐ Death
Reported to Medical Mon	☐ Yes ☐ No
Date reported	
Investigator signature	

15. Appendix D – Procedural CRF

SECTION 1: DEMOGRAPHICS AND CLINICAL HISTORY/DATA

Variable	Data Entry
Date of Procedure	_____
Patient MRN	_____
Age / Gender	_____ years ☐ Male ☐ Female
Height	_____ cm
Weight	_____kg
BMI	_____kg/m^2
Type of Arrhythmia	☐ Paroxysmal AF ☐ Persistent AF ☐ Atrial Flutter : _____
Prior AF Ablation?	☐ No (De novo) ☐ Yes (Redo) :_____
Operator 1 **Operator 2**	

CHA2DS2-VASc Score

Risk Factor	Points	Check if Present
Congestive Heart Failure	1	☐
Hypertension	1	☐
Age ≥75 years	2	☐
Diabetes Mellitus	1	☐

Risk Factor	Points	Check if Present
Stroke / TIA / Thromboembolism	2	☐
Vascular Disease	1	☐
Age 65 - 74 years	1	☐
Sex Category (Female)	1	☐
TOTAL SCORE		_____ / 9

Echocardiography Parameters

Variable	Entry
Date of Echo	____ / ____ / _____
LVEF (%)	_____
LA Diameter (mm)	_____
LA Volume (ml)	_____
LA Volume Indexed (ml/m^2)	_____
RA Enlargement	☐ None ☐ Mild ☐ Moderate ☐ Severe
Mitral Regurgitation	☐ None ☐ Mild ☐ Moderate ☐ Severe

Antiarrhythmic Drug (AAD) History

(Check all currently or recently used)

☐Amiodarone ☐Flecainide ☐Propafenone ☐Dronedarone ☐Other: _____

SECTION 2: PHASE 1 - PRE-ABLATION MAPPING

(Both maps must be acquired during CS pacing or in arrhythmia if patient is in flutter, with a fill threshold 3mm)

Catheter	LA Map Completed?	Fill Threshold ≤ 3mm Achieved?	Total Number of Points
Octaray	☐Yes ☐No	☐Yes ☐No	_____ points
Optrell bipolar	☐Yes ☐No	☐Yes ☐No	_____ points
Optrell multipolar	☐Yes ☐No	☐Yes ☐No	_____ points

Catheter	RA Map Completed?	Fill Threshold ≤ 3mm Achieved?	Total Number of Points
Octaray	☐Yes ☐No	☐Yes ☐No	_____ points
Optrell bipolar	☐Yes ☐No	☐Yes ☐No	_____ points
Optrell multipolar	☐Yes ☐No	☐Yes ☐No	_____ points

SECTION 3: PHASE 2 - ABLATION DETAILS

Variable	Data Entry
Ablation Energy Used	☐RFA ☐PFA
PVI Performed?	☐Yes ☐No
PVI Successfully Achieved?	☐Yes ☐No
First Pass Isolation ?	☐Yes ☐No
Linear Lesions Created *(Check all that apply)*	☐Roof Line ☐Posterior Wall Isolation (PWI) ☐Cavotricuspid Isthmus (CTI) ☐Mitral Isthmus Line ☐Other: _____

SECTION 4: PHASE 3 - CONDUCTION BLOCK ASSESSMENT

(Complete this sub-section for EVERY linear lesion created. See Section 4b, 4c and 4d. Duplicate if necessary.)

Line Checked	☐Roof Line ☐Posterior Wall Isolation (PWI) ☐Cavotricuspid Isthmus (CTI) ☐Mitral Isthmus Line ☐Other: _____	
Ablation Energy Used	☐RFA ☐PFA	

Assessment Method	**Time to Verify Block**	**Block Confirmed?**
Optrell Vector Assessment *(time to assess block by moving the catheter across the line to review vectors)*	___ min : ___ sec	☐Yes ☐No
Octaray Activation Mapping *(time to create an activation map sufficient to determine presence or absence of block)*	___ min : ___ sec	☐Yes ☐No

Concordance for this line: ☐Yes (Methods agree) ☐No (Methods disagree)
Explain:_____

SECTION 5: ACUTE PROCEDURAL COMPLICATIONS (completed at hospital discharge)

Variable	**Data Entry**
None	☐
Pericardial Effusion / Tamponnade	☐
Stroke / TIA	☐

Variable	Data Entry
Vascular Complication requiring intervention	☐
Phrenic Nerve Injury	☐
Prolongation of Hospitalization (>24 hours beyond the expected post-procedural course)	☐
Esophageal injury	☐
Heart failure exacerbation requiring treatment	☐
Other :	_____

Form Completed By: _____ Date: _____

Investigator Signature: _____ Date: _____

SECTION 4b: PHASE 3 - CONDUCTION BLOCK ASSESSMENT

Line Checked	☐Roof Line ☐Posterior Wall Isolation (PWI) ☐Cavotricuspid Isthmus (CTI) ☐Mitral Isthmus Line ☐Other: _____	
Ablation Energy Used	☐RFA ☐PFA	

Assessment Method	**Time to Verify Block**	**Block Confirmed?**
Optrell Vector Assessment *(time to assess block by moving the catheter across the line to review vectors)*	___ min : ___ sec	☐Yes ☐No
Octaray Activation Mapping *(time to create an activation map sufficient to determine presence or absence of block)*	___ min : ___ sec	☐Yes ☐No

Concordance for this line: ☐Yes (Methods agree) ☐No (Methods disagree)
Explain:_____

SECTION 4c: PHASE 3 - CONDUCTION BLOCK ASSESSMENT

Line Checked	☐Roof Line ☐Posterior Wall Isolation (PWI) ☐Cavotricuspid Isthmus (CTI) ☐Mitral Isthmus Line ☐Other: _____	
Ablation Energy Used	☐RFA ☐PFA	

Assessment Method	**Time to Verify Block**	**Block Confirmed?**
Optrell Vector Assessment *(time to assess block by moving the catheter across the line to review vectors)*	___ min : ___ sec	☐Yes ☐No
Octaray Activation Mapping *(time to create an activation map sufficient to determine presence or absence of block)*	___ min : ___ sec	☐Yes ☐No

Concordance for this line: ☐Yes (Methods agree) ☐No (Methods disagree)
Explain:_____

SECTION 4d: PHASE 3 - CONDUCTION BLOCK ASSESSMENT

Line Checked	☐Roof Line ☐Posterior Wall Isolation (PWI) ☐Cavotricuspid Isthmus (CTI) ☐Mitral Isthmus Line ☐Other: _____	
Ablation Energy Used	☐RFA ☐PFA	

Assessment Method	**Time to Verify Block**	**Block Confirmed?**
Optrell Vector Assessment *(time to assess block by moving the catheter across the line to review vectors)*	___ min : ___ sec	☐Yes ☐No
Octaray Activation Mapping *(time to create an activation map sufficient to determine presence or absence of block)*	___ min : ___ sec	☐Yes ☐No

Concordance for this line: ☐Yes (Methods agree) ☐No (Methods disagree)
Explain:_____

16. Appendix E – Follow-Up CRF

SECTION 1: VISIT INFORMATION

Variable	Data Entry
Date of Procedure	_____
Patient MRN	_____
Follow-Up Visit	☐ 1 Mo ☐ 3 Mo ☐ 6 Mo ☐ 9 Mo ☐ 12 Mo
Visit Type	☐ In-Person ☐ Virtual (Telehealth)
Visit Date	_____
Within protocol window?	☐ Yes ☐ No (Protocol Deviation)

SECTION 2: RHYTHM STATUS & RECURRENCE

(Arrhythmia ≥ 30 sec beyond blanking period of 2 months from last procedure)

Variable	Data Entry
Documented Atrial Arrhythmia Since Last Visit?	☐Yes ☐No
Type of Arrhythmia Documented	☐AF ☐AT ☐Typical Flutter ☐Atypical Flutter
Symptomatic During Episode?	☐Yes ☐No
Date of First Recurrence	_____
Number of Episodes	☐1 ☐1-3 ☐3-5 ☐>5

SECTION 3: RHYTHM MONITORING

Variable	Data Entry
12-Lead ECG Performed?	☐ Yes (Date: _____) ☐ No
ECG Result	☐ No Arrhythmia ☐ AF ☐ AT ☐ Flutter
48-Hour Holter Performed?	☐ Yes (Date: _____) ☐ No
Testing Location	☐ Hospital Clinic ☐ Kupat Holim (Community)
Holter Result	☐ No Arrhythmia ☐ AF ☐ AT ☐ Flutter

SECTION 4: CLINICAL EVENTS SINCE LAST VISIT

Variable	Data Entry
Hospitalization	☐ Yes ☐ No
If Yes – Reason	☐ Arrhythmia ☐ Heart Failure ☐ Other CV ☐ Non-cardiac
ER Visit	☐ Yes ☐ No
DCCV Performed	☐ Yes ☐ No

SECTION 5: MEDICATION STATUS

Variable	Data Entry
Currently on AAD?	☐Yes ☐No
If Yes – AAD Used	☐Amiodarone ☐Flecainide ☐Propafenone ☐Dronedarone ☐Other : _____
AAD Change Since Last Visit	☐Started ☐Stopped ☐No Change ☐Dose Change :_____

SECTION 6: REDO PROCEDURE – see APPENDIX F REDO PROCEDURAL CRF

Variable	Data Entry
Redo Procedure	☐No ☐Yes (Date :_____)

Form Completed By: _____ Date: _____ ____

17. Appendix F – Redo Procedural CRF

SECTION 1: DEMOGRAPHICS AND CLINICAL HISTORY/DATA

Variable	Data Entry
Date of Procedure	_____
Patient MRN	_____
Age / Gender	_____ years □ Male □ Female
Height	_____ cm
Weight	_____kg
BMI	_____kg/m^2
Type of Arrhythmia	□ Paroxysmal AF □ Persistent AF □ Atrial Flutter : _____
Index Ablation	☐PVI ☐Roof Line ☐Posterior Wall Isolation (PWI) ☐Cavotricuspid Isthmus (CTI) ☐Mitral Isthmus Line ☐Other: _____
Operator 1 **Operator 2**	

CHA2DS2-VASc Score

Risk Factor	Points	Check if Present
Congestive Heart Failure	1	☐
Hypertension	1	☐
Age ≥75 years	2	☐
Diabetes Mellitus	1	☐
Stroke / TIA / Thromboembolism	2	☐
Vascular Disease	1	☐
Age 65 - 74 years	1	☐
Sex Category (Female)	1	☐
TOTAL SCORE		_____ / 9

Echocardiography Parameters

Variable	Entry
Date of Echo	____ / ____ / _____
LVEF (%)	_____
LA Diameter (mm)	_____
LA Volume (ml)	_____
LA Volume Indexed (ml/m^2)	_____
RA Enlargement	☐ None ☐ Mild ☐ Moderate ☐ Severe
Mitral Regurgitation	☐ None ☐ Mild ☐ Moderate ☐ Severe

Antiarrhythmic Drug (AAD) History

(Check all currently or recently used)

☐Amiodarone ☐Flecainide ☐Propafenone ☐Dronedarone ☐Other: _____

SECTION 2: PHASE 1 - PRE-ABLATION MAPPING

(Both maps must be acquired during CS pacing or in arrhythmia if patient is in flutter, with a fill threshold 3mm)

Catheter	**LA Map Completed?**	**Fill Threshold ≤ 3mm Achieved?**	**Total Number of Points**
Octaray	☐Yes ☐No	☐Yes ☐No	_____ points
Optrell bipolar	☐Yes ☐No	☐Yes ☐No	_____ points
Optrell multipolar	☐Yes ☐No	☐Yes ☐No	_____ points

Catheter	**RA Map Completed?**	**Fill Threshold ≤ 3mm Achieved?**	**Total Number of Points**
Octaray	☐Yes ☐No	☐Yes ☐No	_____ points
Optrell bipolar	☐Yes ☐No	☐Yes ☐No	_____ points
Optrell multipolar	☐Yes ☐No	☐Yes ☐No	_____ points

Durably Isolated PVs	☐Yes ☐No :_____

SECTION 3: PHASE 2 – PRIOR LINE CONDUCTION BLOCK ASSESSMENT

(Complete this sub-section for EVERY prior linear lesion. See Section 3b, 3c and 3d. Duplicate if necessary.)

Line Checked	☐Roof Line ☐Posterior Wall Isolation (PWI) ☐Cavotricuspid Isthmus (CTI) ☐Mitral Isthmus Line ☐Other: _____

Assessment Method	Time to Verify Block	Block Confirmed?
Optrell Vector Assessment *(time to assess block by moving the catheter across the line to review vectors)*	___ min : ___ sec	☐Yes ☐No
Octaray Activation Mapping *(time to create an activation map sufficient to determine presence or absence of block)*	___ min : ___ sec	☐Yes ☐No

Concordance for this line: ☐Yes (Methods agree) ☐No (Methods disagree)

Explain:_____

SECTION 4: PHASE 3 - ABLATION DETAILS

Variable	Data Entry
Ablation Energy Used	☐RFA ☐PFA
Redo PVI Performed?	☐Yes ☐No
PVI Successfully Achieved?	☐Yes ☐No
Linear Lesions Created *(Check all that apply)*	☐Roof Line ☐Posterior Wall Isolation (PWI) ☐Cavotricuspid Isthmus (CTI) ☐Mitral Isthmus Line ☐Other: _____

SECTION 5: PHASE 4 - CONDUCTION BLOCK ASSESSMENT

(Complete this sub-section for EVERY linear lesion created. See Section 5b, 5c and 5d. Duplicate if necessary.)

Line Checked	☐Roof Line ☐Posterior Wall Isolation (PWI) ☐Cavotricuspid Isthmus (CTI) ☐Mitral Isthmus Line ☐Other: _____
Ablation Energy Used	☐RFA ☐PFA

Assessment Method	**Time to Verify Block**	**Block Confirmed?**
Optrell Vector Assessment *(time to assess block by moving the catheter across the line to review vectors)*	___ min : ___ sec	☐Yes ☐No
Octaray Activation Mapping *(time to create an activation map sufficient to determine presence or absence of block)*	___ min : ___ sec	☐Yes ☐No

Concordance for this line: ☐Yes (Methods agree) ☐No (Methods disagree)
Explain:_____

SECTION 5: ACUTE PROCEDURAL COMPLICATIONS (completed at hospital discharge)

Variable	**Data Entry**
None	☐
Pericardial Effusion / Tamponnade	☐
Stroke / TIA	☐
Vascular Complication requiring intervention	☐

Variable	Data Entry
Phrenic Nerve Injury	☐
Prolongation of Hospitalization (>24 hours beyond the expected post-procedural course)	☐
Esophageal injury	☐
Heart failure exacerbation requiring treatment	☐
Other :	_____

Form Completed By: _____ Date: _____

Investigator Signature: _____ Date: _____

SECTION 3b: PHASE 2 - PRIOR LINE CONDUCTION BLOCK ASSESSMENT

Line Checked	☐Roof Line ☐Posterior Wall Isolation (PWI) ☐Cavotricuspid Isthmus (CTI) ☐Mitral Isthmus Line ☐Other: _____

Assessment Method	**Time to Verify Block**	**Block Confirmed?**
Optrell Vector Assessment *(time to assess block by moving the catheter across the line to review vectors)*	___ min : ___ sec	☐Yes ☐No
Octaray Activation Mapping *(time to create an activation map sufficient to determine presence or absence of block)*	___ min : ___ sec	☐Yes ☐No

Concordance for this line: ☐Yes (Methods agree) ☐No (Methods disagree)
Explain:_____

SECTION 3c: PHASE 2 - PRIOR LINE CONDUCTION BLOCK ASSESSMENT

Line Checked	☐Roof Line ☐Posterior Wall Isolation (PWI) ☐Cavotricuspid Isthmus (CTI) ☐Mitral Isthmus Line ☐Other: _____

Assessment Method	Time to Verify Block	Block Confirmed?
Optrell Vector Assessment *(time to assess block by moving the catheter across the line to review vectors)*	___ min : ___ sec	☐Yes ☐No
Octaray Activation Mapping *(time to create an activation map sufficient to determine presence or absence of block)*	___ min : ___ sec	☐Yes ☐No

Concordance for this line: ☐Yes (Methods agree) ☐No (Methods disagree)
Explain:_____

SECTION 3d: PHASE 2 - PRIOR LINE CONDUCTION BLOCK ASSESSMENT

Line Checked	☐Roof Line ☐Posterior Wall Isolation (PWI) ☐Cavotricuspid Isthmus (CTI) ☐Mitral Isthmus Line ☐Other: _____

Assessment Method	Time to Verify Block	Block Confirmed?
Optrell Vector Assessment *(time to assess block by moving the catheter across the line to review vectors)*	___ min : ___ sec	☐Yes ☐No
Octaray Activation Mapping *(time to create an activation map sufficient to determine presence or absence of block)*	___ min : ___ sec	☐Yes ☐No

Concordance for this line: ☐Yes (Methods agree) ☐No (Methods disagree)
Explain:_____

SECTION 5b: PHASE 4 - CONDUCTION BLOCK ASSESSMENT

Line Checked	☐Roof Line ☐Posterior Wall Isolation (PWI) ☐Cavotricuspid Isthmus (CTI) ☐Mitral Isthmus Line ☐Other: _____
Ablation Energy Used	☐RFA ☐PFA

Assessment Method	**Time to Verify Block**	**Block Confirmed?**
Optrell Vector Assessment *(time to assess block by moving the catheter across the line to review vectors)*	___ min : ___ sec	☐Yes ☐No
Octaray Activation Mapping *(time to create an activation map sufficient to determine presence or absence of block)*	___ min : ___ sec	☐Yes ☐No

Concordance for this line: ☐Yes (Methods agree) ☐No (Methods disagree)
Explain:_____

SECTION 5c: PHASE 4 - CONDUCTION BLOCK ASSESSMENT

Line Checked	☐Roof Line ☐Posterior Wall Isolation (PWI) ☐Cavotricuspid Isthmus (CTI) ☐Mitral Isthmus Line ☐Other: _____
Ablation Energy Used	☐RFA ☐PFA

Assessment Method	Time to Verify Block	Block Confirmed?
Optrell Vector Assessment *(time to assess block by moving the catheter across the line to review vectors)*	___ min : ___ sec	☐Yes ☐No
Octaray Activation Mapping *(time to create an activation map sufficient to determine presence or absence of block)*	___ min : ___ sec	☐Yes ☐No

Concordance for this line: ☐Yes (Methods agree) ☐No (Methods disagree)
Explain:_____

SECTION 5d: PHASE 4 - CONDUCTION BLOCK ASSESSMENT

Line Checked	☐Roof Line ☐Posterior Wall Isolation (PWI) ☐Cavotricuspid Isthmus (CTI) ☐Mitral Isthmus Line ☐Other: _____
Ablation Energy Used	☐RFA ☐PFA

Assessment Method	Time to Verify Block	Block Confirmed?
Optrell Vector Assessment *(time to assess block by moving the catheter across the line to review vectors)*	___ min : ___ sec	☐Yes ☐No
Octaray Activation Mapping *(time to create an activation map sufficient to determine presence or absence of block)*	___ min : ___ sec	☐Yes ☐No

Assessment Method	Time to Verify Block	Block Confirmed?

Concordance for this line: ☐Yes (Methods agree) ☐No (Methods disagree)
Explain:_____