	STATISTICAL ANALYSIS PLAN	FARAPULSE PersAFOne SAP V1.0 **Sponsor:** FARAPULSE **Device:** FARAPULSE ENDOCARDIAL MULTI ABLATION SYSTEM **Protocol No:** CS0607 REVISION C **ICON Project No: 5326/0006**

PersAFOne:

Feasibility Study of the FARAPULSE™ Endocardial Multi Ablation System in the Treatment of Persistent Atrial Fibrillation

Statistical Analysis Plan

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Versions	Date	Documents used	Author	Validation
Version 1.0	14/02/2023	• 1309_CS0607_PersAFOne Clinical Investigation Plan_Rev C_08Oct2019.pdf • PersAFOne_Annotated CRF_v1.3.pdf • PersAFOne_Annotated CRF_CEC.pdf • IMPACT_ CRF mapping for CSR_Point PersAFOne.xlsx • 20200619 Endpoint analysis_0603 MDT return_0603 MP return.xlsx	Najeh DAABEK	Marie-Christine REYMOND
Version 0.5	14/02/2023	• 1309_CS0607_PersAFOne Clinical Investigation Plan_Rev C_08Oct2019.pdf • PersAFOne_Annotated CRF_v1.3.pdf • PersAFOne_Annotated CRF_CEC.pdf • IMPACT_ CRF mapping for CSR_Point PersAFOne.xlsx • 20200619 Endpoint analysis_0603 MDT return_0603 MP return.xlsx	Najeh DAABEK	Marie-Christine REYMOND
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Version 0.1	27/01/2023	• 1309_CS0607_PersAFOne Clinical Investigation Plan_Rev C_08Oct2019.pdf • PersAFOne_Annotated CRF_v1.3.pdf • PersAFOne_Annotated CRF_CEC.pdf • IMPACT_ CRF mapping for CSR_Point PersAFOne.xlsx • 20200619 Endpoint analysis_0603 MDT return_0603 MP return.xlsx	Najeh DAABEK	Marie-Christine REYMOND

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SIGNATURE PAGE

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V1.0

FARAPULSE, INC

Name	Position	Date	Signature
Anitha Achyutha	Director, Clinical	Anitha Achyutha REASON: I approve this d cument 95c23c66-c1c1-496b-9e07-abfe7fb 8ad75	Anitha Achyutha 20 Feb 2023 03:08 00 UTC (Z)
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ICON CLINICAL RESEARCH SARL

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Marie-Christine REYMOND	Director of Data management and Biostatistics	Najeh Daabek REASON: I approve this d cument d0fe0951-4e46-41f5-9c58-01c89 6dec07	Najeh Daabek 14 Feb 2023 14:05 :26 UTC (Z)

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LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

AAD	Antiarrhythmic drug
ABL	Ablation
AE	Adverse event
AF	Atrial fibrillation
AFL	Atrial Flutter
CSE	Composite Safety Endpoint
CTI	Cavotricuspid isthmus
DCCV	Direct current cardioversion
ITT	Intention to treat
LA	Left atrium or left atrial
LSPV	Left superior pulmonary vein
LIPV	Left interior pulmonary vein
LCPV	Left common pulmonary vein
RIPV	Right interior pulmonary vein
RF	Radiofrequency
RMPV	Right middle pulmonary vein
RSPV	Right superior pulmonary vein
NYHA	New York Heart Association
PP	Per protocol
PT	Preferred term
PV	Pulmonary vein
SAE	Serious adverse event

SOC	System Organ system
TIA	Transient ischemic attack

1. OVERVIEW

This statistical analysis plan (SAP) describes the planned statistical analyses of the data collected during the clinical study PersAFOne.

This SAP provides additional details concerning the statistical analyses outlined in the protocol (1309_CS0607_PersAFOne Clinical Investigation Plan_Rev C_08Oct2019 dated 08Oct2019).

1.1. Study Objective

The objective of this safety and feasibility study is to assess whether the endocardial creation of electrically nonconductive lesions via PEF catheter ablation applied using the FARAPULSE Endocardial Multi Ablation System is a feasible and safe treatment for Persistent AF and associated AFL.

1.2. Study Design

This study is a prospective, multi-center, unblinded single arm safety and feasibility study.

Subjects will undergo percutaneous PEF ablation for pulmonary vein isolation and at the clinical discretion of the investigator receive PEF ablation of additional arrhythmogenic locations. Subjects will be followed at 30 days, 75 days, 6 months and 12 months for adverse events, recurrence of arrhythmia after a 90-day Blanking Period and other relevant outcome measures.

1.3. Study Plan

1.3.1. Patient's Follow-up

7 visits are scheduled:

- Visit 1: Baseline
- Visit 2: Index procedure
- Visit 3: Pre-Discharge
- Visit 4: 30-day Visit
- Visit 5: 75-day Visit and Remapping Procedure
- Visit 6: 6 Months Visit
- Visit 7: 12 Months Visit

1.3.2. Study Device use

The FARAPULSE Endocardial Multi Ablation System is comprised of the following devices:

- FARAWAVE Endocardial Ablation Catheter
- FARAFLEX Endocardial Ablation Catheter
- FARASTAR Endocardial Generator System
- FARADRIVE Deflectable Sheath.

The FARAPULSE Endocardial Multi Ablation System is indicated for the treatment of drug refractory, recurrent, symptomatic persistent atrial fibrillation.

The FARAFLEX Endocardial Ablation Catheter is used as an adjunctive device in the endocardial treatment of persistent atrial fibrillation with the following intended uses:

- Gap ablation to complete electrical isolation of the pulmonary veins,
- Focal ablation of cardiac arrhythmias, and
- Creation of ablation line between the inferior vena cava and the tricuspid valve.

1.3.3. Study Assessments

The following flowchart applies to the study:

Assessment	Baseline	Procedure	Pre-Discharge	30-Days Post-Procedure (± 7 days)	75-Days (± 15 days)	6-Month (180 ± 30 days)	12-Month (365 ± 30 days)	Unscheduled
Medical History, CHA_2DS_2-VASc	X							
AFD and Anticoagulant Medications	X		X	X	X	X	X	X
Symptoms of recurrent arrhythmia				X	X	X	X	X
History of cardioversions, ablations, hospital admissions since last visit			X	X	X	X	X	X
Pregnancy test (for females of childbearing potential)	X	X			X			
12-lead ECG	X		X	X	X	X	X	X
24-Hour Continuous ECG Monitor (e.g., Holter)						X	X	
Cardiac CT/MRI for LA and PV dimensions	X				X			
Mediastinal MRI			X[1]					
TEE or other imaging modality (to exclude left atrial thrombus)	X							
Electroanatomical Mapping		X			X			
Event Monitor readiness/compliance					X	X	X	X
NIHSS	X		X					
Neurologic exam			X[2]					
NYHA Classification	X		X	X	X	X	X	X
Fluoroscopic Examination of Diaphragm		X			X if remapped, X[3] if not	X[3]	X[3]	
Adverse Events		X	X	X	X	X	X	X

[1] At investigator's discretion
[2] If NIHSS score has increased by 2 or more points or if clinical suspicion of stroke/TIA
[3] If the Index Procedure or Remap Procedure study indicated decreased phrenic nerve function and resolution has not yet been demonstrated.

2. STATISTICAL METHODS

2.1. General Statistical Considerations

2.1.1. Time Points Definition

Baseline data is defined as the last available observation recorded before the first study device exposition for the patient.

Visit(n) data is defined as the last available observation on or before the Visit(n) time point following the first study device exposition for the patient.

2.1.2. Handling Missing Data

In order to provide unbiased and informative findings, no replacement of missing values is planned for any parameters. Analyses is performed with all available data only.

Data collected by the Investigators and reviewed by the Clinical Event Committee (CEC):

When the data are collected by the investigators and reviewed by the CEC, the analysis will be as follows:

- The data reviewed by the CEC will prevail and will be analysed with no replacement of missing data from the CEC with the data collected by the investigator

2.1.3. Descriptive Statistics in Summary Tables

- *Continuous variables* will be summarized using standard quantitative statistics: number of non-missing observations, mean, standard deviation, median, quartiles and range (minimum and maximum observed values). The number of missing observations will also be specified.
- *Categorical variables* will be summarized using classical frequency statistics: number of non-missing observations and percentages by categories. Percentages will be calculated on the number of non-missing observations and will be displayed using one decimal. The number of missing observations will also be specified.

2.1.4. Inferential Analysis

- Confidence intervals:

When applicable, bilateral asymptotic or exact confidence intervals for binomial distributions will be calculated at the 95% level.

For categorical variables, if pertinent, the 95% asymptotic confidence interval will be calculated if theoretical assumptions are verified. If this is not the case, and the corresponding proportion is 0% or 100%, then the Agresti-Coull confidence interval will be calculated instead. In all other cases, the exact confidence interval will be calculated.

- Survival analysis:

Time-to-event variables will be described over time by survival curves as per the Kaplan-Meier method together with the associated estimators, considering the upper window of the corresponding visits. The survival rate will be presented at each time point (30 days, 90 days, 180 days, 365 days) and overall.

2.1.5. Data Listings

Patient data listings will be selected data supportive of summary statistical tables, including derived/calculated data from statistical process. These data listings are performed on selected analysis sets according to the focus of the analysis and are sorted by subject number and visit. Data entry into a free field in the CRF will be described in the listings.

2.2. Sample size calculation

This investigation is the next phase of ongoing feasibility studies to allow the controlled introduction of a new cardiac ablation catheter (FARAFLEX Endocardial Ablation Catheter). This is a feasibility study with no formal hypothesis testing and therefore no required sample size. Study results will be presented using descriptive statistics. Results from this study will be used to inform and design additional clinical studies.

Forty (40) subjects at up to four sites will allow the assessment of the modified devices and the initial experience and training of investigators and study staff at a new investigational site.

2.3. Analysis Sets

2.3.1. Definition of patient populations

3 populations will be defined:

- The Enrolled population will include all subjects who provided their informed consent.
- The Safety / Intent-to-Treat (ITT) population will include all enrolled subjects except those who terminate their participation prior to the beginning of the Index Procedure.
- The Per Protocol (PP) population will include Intent-to-treat subjects for whom the Index Procedure is finished without interfering investigational device deficiency or malfunction.

The choice of reported analysis on ITT or PP populations will be driven by the purposes of the analysis.

In any case, the primary feasibility endpoint will be assessed on the ITT and PP populations.

2.3.2. Protocol Deviations

On a case-by-case basis, all protocol deviations will be reviewed and classified as “Related to COVID-19 situation (type9)” or “Not related to COVID-19 situation (type9)”.

Deviation types:

- Consentement inappropriately obtained
- Procedure not performed according to protocol/IFU
- Inclusion/Exclusion Criteria deviation
- Protocol required test not completed
- Missed Follow-up visit
- Follow-up visit performed outside of window
- Other
- Related to COVID-19 situation

2.3.1. Databases

The Remapping at 75 Days, recurrence and Additional endpoints analysis will be based on the MDT Excel file sent by sponsor, which will contain:

- Received ablation at remap"
- RF/PFA ablation at remap
- Early recurrence of atrial fibrillation (AF)
- AF status
- AF km days"
- Atrial fibrillation/ Atrial flutter / Atrial tachycardia (AF/AFL/AT) status"
- AF/AFL/AT km (days)
- Transtelephonic monitor (TTM) weeks expected
- TTM weeks received
- Number TTM transmissions
- 6-month holter
- 12-month holter
- Radiofrequency (RF) touchup

- Ablation (ABL) >90 days"
- Class I/III antiarrhythmics drug (AAD) >90 days
- Amiodarone
- Direct current cardioversion (DCCV) >90 days
- Arrhythmia-related (AF, AFL, AT) hospitalization

The Excel file sent by the Sponsor will have the same structure (in terms of variables names, labels, formats) for each analysis to ensure the continuity of the programming.

All other analysis will be done on the e-CRF clinical database.

2.4. Statistical Analyses

2.4.1. Patient Disposition and Follow-up

2.4.1.1. Patient Populations Sample Size

The number and percentage of patients included in each population and the reasons of non-inclusion in each subsequent population will be presented on the enrolled population.

The number and percentage of patients present at each visit will be presented with the study exit reasons.

A listing will be provided to present patient disposition. The following variables will be listed:

- Date of consent
- Procedure date
- Remap date
- Most recent follow-up
- Date of study exit
- Follow up time (days)

2.4.1.2. Protocol Deviations

Frequency of patients with at least one protocol deviation, as well as the total number of events, will be summarized on the ITT population, by Type of deviation in relation with COVID status.

The detail will be also presented in a listing.

2.4.2. Baseline Patient Characteristics

Descriptive statistical data will be used to draw up a recapitulation of the characteristics of the patients at the time of enrolment. It will be summarized on the ITT population.

- Demographics at baseline: Age, Gender, BMI
- Baseline Medical History : LA diameter,Time from first AF diagnosis until consent date, Patient failed at least one AAD, Class of AAD if Yes,Left Ventricular Ejection Fraction (LVEF) (%),CHA2DS2-VASc Score,Smoking, Dyslipidemia, Chronic Obstructive Pulmonary Disease, Permanent pacemaker or ICD, Unstable angina, NYHA class, Structural Heart Disease and Type(s) if yes, Cerebrovascular disease and Type, Cardiac surgery and type if yes, Diabetes, Hypertension, Hyperthyroidism,

Hypothyroidism, Myocardial infarction, Peripheral vascular disease, Pulmonary hypertension, Renal dysfunction/failure, Sleep apnea.

A listing will be provided to present previous parameter as well as: Pregnancy test, height, weight, Heart rate; Systolic and diastolic blood pressure, heart rate, Time between the most recent AF episode and the enrollment (months), Name and dose of ADD failed drug.

2.4.3. Index Procedure

Descriptive statistical data will be used to draw up a recapitulation of the intervention details at the time of the procedure.

The following data will be presented on the ITT population:

- Procedure Data: Procedure time, Farawave dwell total time, PVI ablation time, CTI (FARAFLEX) dwell time, LAPW ablation time (LAST LAPW ablation - FIRST LAPW ablation) , Fluoroscopy time, Total amount of contrast dye injected (contrast volume (cc)), Total volume of IV fluids administered (IV fluid volume (cc)), Total number of PVI applications , Number of PVI ablation/patient, Number of applications/vein, Number of LAPW applications, Total number of veins treated, Total number of veins isolated, Of the total number of veins treated, the number of veins isolated (Proportion of veins isolated), CTI acute isolation, Total number of CTI applications.

2.4.4. Remapping at 75 Days

Descriptive statistical data will be used to draw up a recapitulation of the follow-up details at 75-day Visit and Remapping Procedure.

The following data will be presented on the ITT population:

Days follow up at remap, Durable PVI, LSPV chronic isolation, LIPV chronic isolation, LCPV chronic isolation, RSPV chronic isolation, RIPV chronic isolation, RMPV chronic isolation, CTI chronic isolation, LAPW chronic isolation, Number of veins durably isolated, Number of veins with gaps.

2.4.5. 6 and 12 Months follow up

Descriptive statistical data will be used to draw up a recapitulation of the follow-up details at 6 and 12 Months follow up.

The following data will be presented on the ITT population:
TTM compliance, Holter compliance (6 month and 12 month), Freedom from AF/AFL/AT (for patient On AADs and on patient Off AADs),Freedom from AF (for patient On AADs and on patient Off AADs), Freedom from AF/AFL/AT, no DCCV>90 days, no RF, no ablation >90 days (for patient On AADs and on patient Off AADs), Freedom from AF, no DCCV>90 days, no RF, no ablation >90 days (for patient On AADs and on patient Off AADs).

2.4.6. Feasibility Analysis

The feasibility analysis will be performed on the ITT population and PP population.

2.4.6.1. Primary Feasibility Analysis

The primary feasibility analysis is the proportion of subjects that achieve Acute Procedural Success (APS) defined as the percutaneous endocardial creation of a complete, electrically isolating set of lesions around the ostia of the pulmonary veins (PVI) using the FARAPULSE Endocardial Multi Ablation System during the Index Procedure, as clinically assessed by entrance and/or exit block performed ≥ 20 minutes after the last PVI lesion is made.

2.4.6.2. Secondary Feasibility Analysis

The secondary feasibility analyses are:

- The proportion of subjects who undergo the protocol-specified 75-Day Remapping Procedure and achieve Chronic Procedural Success (CPS) defined as persistent electrical isolation of all initially ablated pulmonary veins. Chronic Procedural Success will be subdivided by Index Procedure only CPS and Reablated CPS subjects.
- The proportion of attempted subjects that achieve Acute CTI Success, defined as the creation of bi-directional electrical block across the CTI using the investigational devices.
- Durability of the CTI and/or other extra-PV lesion set(s), when applicable.

  Durability is defined as unaltered integrity of each such lesion assessed at the Remapping Procedure.
- The proportion of subjects that achieve Therapeutic Success, defined as freedom from:
  - Post-Blanking Period through assessment: occurrence of AF, AFL or AT, or ablation for AF/AFL/AT using the study device
  - At any time: ablation for AF/AFL/AT with a non-study device

  Therapeutic Success will be assessed from the end of the 90 Day Blanking Period through Months 6 and 12 and will be subdivided by on / off AADs (Atrial Fibrillation Drugs) post-Blanking Period.

2.4.7. Additional endpoints

The additional observations will be performed on the ITT population and will include:

- Proportion of subjects with early recurrence of atrial fibrillation (ERAF) by 90 days after the initial study ablation.
- Time to Therapeutic Failure
- Proportion of all ablated pulmonary veins that are isolated at the Index Procedure using the study device.
- Proportion of all ablated pulmonary veins isolated using the study device during the Index Procedure that remain isolated at the 75-day Remapping Procedure.
- The proportion of attempted subjects that achieve Chronic CTI Success, defined as persistent bi-directional electrical block across the CTI as assessed at the 75-day remapping procedure.
- The proportion of attempted subjects that achieve Chronic Focal Success, defined as persistent electrical nonconductivity of extra-PV tissue targeted for ablation in the Index Procedure, excluding the CTI

2.4.8. Safety Endpoint

Descriptive statistical data is used to analyze the Primary Safety Endpoint (PSE), the secondary safety endpoints and others analysis. The analysis is performed on the ITT populations.

The Safety endpoint will be performed on the ITT population and will include

2.4.8.1. Primary Safety Analysis

The primary safety endpoint for this study is the Composite Safety Endpoint (CSE) defined as the incidence of the following early-onset and late-onset serious adverse events (SAEs) which are device- or procedure-related, as adjudicated by the CEDMC.

Composite Safety Endpoint Definitions:

Early onset (within 30 days of an Index or Remap Procedure)

- Death
- Myocardial infarction (MI)
- Persistent diaphragmatic paralysis
- Stroke or transient ischemic attack (TIA)
- Peripheral or organ thromboembolism
- Pericarditis
- Cardiac tamponade / perforation
- Vascular access complications requiring intervention
- Heart block

Late onset (any time during follow-up through 12 months):

- Pulmonary vein (PV) stenosis (> 70% diameter reduction from baseline)
- Atrio-esophageal fistula

2.4.8.2. Secondary Safety Analysis

The proportion of subjects reporting one or more SAEs for each follow-up interval. The intervals will include the period from:

- The Primary Safety Endpoint assessed at 7 rather than 30 days
- The proportion of subjects with a device- or procedure-related SAE
- The proportion of subjects with stroke or TIA
- The proportion of subjects requiring cardioversion
- The proportion of subjects requiring an arrhythmia-related hospitalization.

2.4.8.3. Other Safety and Tolerance Analysis

Descriptive statistics is used to draw up a recapitulation of adverse event. The following data is presented on the ITT population. All AEs are reported by the System organ class (SOC) and the preferred term (PT) (according to coding MedDRA) as follows:

- Total number of Adverse Event (AE) (not including SAEs) reported, number and percentage of subjects with at least one AE reported
- Total number of Serious Adverse Event (SAE) reported, number and percentage of subjects with at least one SAE reported
- Total number of Deaths
- Total number of Device deficiency (DD) reported, number and percentage of subjects with at least one DD reported

2.4.9. Concomitant Medications

Concomitant medications will be listed on the ITT population.

2.5. Derived Criteria Calculation

If at least one of the items needed to calculate a derived criteria is missing, then the corresponding derived criteria will be considered as missing.

Patient Disposition:

- Derived criteria "Enrolled population" will be analysed as:
  IF the date of patient consent is filled in **Patient eligibility form (IE)** **THEN** "Enrolled population" = 'Yes'
  ELSE "Enrolled population" = 'No'.

- Derived criteria "ITT population" will be defined as follows:
  IF "Enrolled population" = 'Yes' in **Patient eligibility form (IE)** and the date of the Procedure is filled in **Procedural data form (PR)** **THEN** "ITT population" = 'Yes'
  ELSE "ITT population" = 'No'.

- Derived criteria "Per Protocol population PP" will be defined as follows:
  IF "ITT population" = 'Yes' **AND** Device Deficiency Number is not filled **AND** Serial # is not filled in **Device Deficiency DD Form** **THEN** Per Protocol population = 'Yes'
  ELSE Per Protocol population = 'No'.

- Derived criteria "Time of patient follow-up" will be calculated as:
  Date of study exit/withdrawal (*) in **Patient eligibility form (IE)** – date of procedure in **Procedural data form (PR)**

  *if the patient is still in the study, the last visit date will be used instead of the exit/ withdrawal one.

- Derived criteria "COVID status" will be calculated as:
  IF "Related to COVID-19 situation" =1 **OR** the term "COVID" exist in "reason for deviation" **AND** date of deviation is filled in **Protocol deviation form (PD)**, **THEN** CLASS=" COVID-19"
  ELSE IF date of deviation is filled **THEN** CLASS= "NOT COVID-19".

Baseline Patient Characteristics:

- Derived criteria "Time from first AF diagnosis until consent date (months)" will be defined as follows:
  Informed consent date – date of first documented AF diagnosis in **AF history form (AH)**.

- Derived criteria "Time between the most recent AF episode and the enrollment (months)" will be defined as follows:
  Informed consent date – date of most recent AF episode in **AF history form (AH)**.

- Derived criteria "Permanent pacemarker or ICD" will be defined as follows:
  IF Pacemaker, Implantable Cardioverter Defibrillator or Cardiac Resynchronization therapy device= 'Yes' in **Patient eligibility Form (IE)** **THEN** Permanent pacemarker or ICD='Yes'

ELSE IF Pacemaker, Implantable Cardioverter Defibrillator or Cardiac Resynchronization therapy device ='No' in **Patient eligibility Form (IE)** **THEN** Permanent pacemarker or ICD='No'

Index Procedure:

- Derived criteria "Procedure time (hours)" will be defined as follows:
  Procedure end- Procedure start in **Procedural data form (PR).**

- Derived criteria "FARAWAVE dwell time (hours)" will be defined as follows:
  SUM of [(FARAWAVE ablation catheter remove 1 – FARAWAVE ablation catheter introduction 1), (FARAWAVE ablation catheter remove n – FARAWAVE ablation catheter introduction n)] in **Procedural data form (PR)**

- Derived criteria "PVI ablation time (hours)" will be defined as follows:
  Last PVI ablation time - First PVI ablation time in **Procedural data form (AB)**

- Derived criteria "CTI (FARAFLEX) dwell time (hours)" will be defined as follows:
  SUM of [(FARAFLEX ablation catheter remove 1 – FARAFLEX ablation catheter introduction 1), (FARAFLEX ablation catheter remove n – FARAFLEX ablation catheter introduction n)] in **Procedural data form (PR)**

- Derived criteria "LAPW ablation time (hours)" will be defined as follows:
  Last LAPW ablation time - First LAPW ablation time in **Procedural data form (AB)**

- Derived criteria "Total number of PVI applications" will be defined as follows:
  SUM of [(Count (Ablation location **IN** ("Left superior", "Left inferior", "Right superior", "Right inferior", "Right middle", "Left common ostium") **OR** (Ablation location='Other" **AND** Ablation location, Other specify='LCPV'))] in **Procedural data form (AB)**

- Derived criteria "Number of LAPW applications" will be defined as follows:
  SUM of [(Count (Ablation location='Other" **AND** Ablation location, Other specify **IN** ("LA PW", "LAPW", "LEFT ATRIAL POSTERIOR WALL")] in **Procedural data form (AB)**

- Derived criteria "Total number of CTI applications" will be defined as follows:
  SUM of [(Count (Ablation location=" CTI")] in **Procedural data form (AB)**

- Derived criteria "Total number of veins treated" will be defined as follows:
  COUNT of ["left superior", "left inferior", "left common ostium", "right middle", "right superior", "right inferior"] **WHERE** isolated/Blocked in ('Yes', 'No') in **Procedural data form (PR)**

- Derived criteria "Total number of veins isolated" will be defined as follows:
  SUM of [left superior, left inferior, left common ostium, right middle, right superior, right inferior] **WHERE** isolated/Blocked = 'Yes' in **Procedural data form (PR)**

- Derived criteria "Of the total number of veins treated, the number of veins isolated (Proportion of veins isolated)" will be defined as follows:
  Derived criteria "Total number of veins isolated"/ Derived criteria "Total number of veins treated"

- Derived criteria Proportion "CTI acute isolation" will be defined as follows:
  COUNT of [CTI isolated/Blocked='Yes' /CTI Attempted='Yes'] in **Procedural data form (PR)**

Remapping at 75 Days

- Derived criteria "Days follow up at remap" will be defined as follows:
  Remapping date – Date of index procedure

- Derived criteria "Durable PVI" will be defined as follows:
  IF Left Superior Lesion durable='Yes' **AND**Left Inferior Lesion durable='Yes' **AND** Left Common Ostium Lesion durable='Yes' **AND** Right Middle Lesion durable='Yes' **AND** Right Superior Lesion durable='Yes' **AND** Right Inferior Lesion durable='Yes' **AND** CTI Lesion durable='Yes' **AND** Mitral Isthmus Lesion durable='Yes' **AND** Left Atrial Roof Line Lesion durable='Yes' **AND** Left Atrial Posterior Line Lesion durable='Yes' **AND** Other 1 Lesion durable='Yes' in **Follow-up 3D electroanatomical mapping form (RM)** **THEN** Durable PVI='Yes'
  ELSE Durable PVI='No'

- Derived criteria "LAPW chronic isolation" will be defined as follows:
  IF Anatomical Structure/Area other specification 1 **IN** ("POSTERIOR WALL" "LA POSTERIOR WALL" "LAPW" "PA WALL" "BOX POSTERIOR WALL") **AND** Other 1 Lesion durable = 'yes' **OR** Anatomical Structure/Area other specification 2 **IN** ("POSTERIOR WALL" "LA POSTERIOR WALL" "LAPW" "PA WALL" "BOX POSTERIOR WALL") **AND** Other 2 Lesion durable = ='Yes' in **Follow-up 3D electroanatomical mapping form (RM)** **THEN** LAPW chronic isolation= 'Yes'
  ELSE LAPW chronic isolation = 'No'

- Derived criteria "Number of veins durably isolated" will be defined as follows:
  SUM of [LSPV chronic isolation='Yes', LIPV chronic isolation='Yes', LCPV chronic isolation='Yes', RSPV chronic isolation='Yes', RIPV chronic isolation='Yes, RMPV chronic isolation ='Yes''] in **Follow-up 3D electroanatomical mapping form (RM)**

- Derived criteria "Number of veins with gaps" will be defined as follows:
  SUM of [LSPV chronic isolation='No', LIPV chronic isolation=' No', LCPV chronic isolation=' No', RSPV chronic isolation=' No', RIPV chronic isolation=' No', RMPV Chronic isolation = 'No'] in **Follow-up 3D electroanatomical mapping form (RM)**

6 and 12 Months follow up

- Derived criteria "TTM compliance (%) (calculated)" will be defined as follows:
  (TTM weeks received /TTM weeks expected) *100 in **MDT excel file**

- Derived criteria "Holter compliance (%) at 6 months" will be defined as follows:

IF 6mo Holter in ('AF', 'none', 'SVT') in **MDT excel file** **THEN** Holter compliance (%) at 6 months = 'Yes'

ELSE IF 6mo Holter in ('MISSING') in **MDT excel file** **THEN** Holter compliance (%) at 6 months='No'

- Derived criteria "Holter compliance (%) at 12 months" will be defined as follows:

  IF 12mo Holter in ('AF', 'none', 'SVT') in **MDT excel file** **THEN** Holter compliance (%) at 12 months = 'Yes'

  ELSE IF 12mo Holter in ('MISSING') in **MDT excel file** **THEN** Holter compliance (%) at 12 months='No'

- Derived criteria "Freedom from AF/AFL/AT" will be defined as follows:

  IF AF/AFL/AT status =0 in **MDT excel file** **THEN** Freedom from AF/AFL/AT ='Yes'

  ELSE Freedom from AF/AFL/AT ='No'

- Derived criteria "Freedom from AF/AFL/AT with Class I/III AAD >90 days" will be defined as follows:

  IF AF/AFL/AT status =0 **AND** Class I/III AAD >90 days =1 in **MDT excel file** **THEN** Freedom from AF/AFL/AT with Class I/III AAD >90 days ='Yes'

  ELSE Freedom from AF/AFL/AT with Class I/III AAD >90 days ='No'

- Derived criteria "Freedom from AF/AFL/AT without Class I/III AAD >90 days" will be defined as follows:

  IF AF/AFL/AT status =0 **AND** Class I/III AAD >90 days =0 in **MDT excel file** **THEN** Freedom from AF/AFL/AT without Class I/III AAD >90 days = 'Yes'

  ELSE Freedom from AF/AFL/AT without Class I/III AAD >90 days ='No'

- Derived criteria "Freedom from AF" will be defined as follows:

  IF AF status =0 in **MDT excel file** **THEN** Freedom from AF ='Yes'

  ELSE Freedom from AF ='No'

- Derived criteria "Freedom from AF with Class I/III AAD >90 days" will be defined as follows:

  IF AF status =0 **AND** Class I/III AAD >90 days =1 in **MDT excel file** **THEN** Freedom from AF with Class I/III AAD >90 days ='Yes'

  ELSE Freedom from AF with Class I/III AAD >90 days ='No'

- Derived criteria "Freedom from AF without Class I/III AAD >90 days" will be defined as follows:

  IF AF status =0 **AND** Class I/III AAD >90 days =0 in **MDT excel file** **THEN** Freedom from AF without Class I/III AAD >90 days ='Yes'

  ELSE Freedom from AF without Class I/III AAD >90 days ='No'

- Derived criteria "Freedom from AF/AFL/AT, no DCCV>90 days, no RF, no ablation >90 days" will be defined as follows:

IF AF/AFL/AT status =0 **AND** DCCV90D=0 **AND** RF touch up=0 **AND** ABL>90 day=0 in **MDT excel file** **THEN** Freedom from AF/AFL/AT, no DCCV>90 days, no RF, no ablation >90 days ='Yes'

ELSE Freedom from AF/AFL/AT, no DCCV>90 days, no RF, no ablation >90 days ='No'

- Derived criteria "Freedom from AF/AFL/AT, no DCCV>90 days, no RF, no ablation >90 days with Class I/III AAD >90 days" will be defined as follows:

  IF AF/AFL/AT status =0 **AND** DCCV90D=0 **AND** RF touch up=0 **AND** ABL>90 day=0 **AND** Class I/III AAD >90 days =1 in **MDT excel file** **THEN** Freedom from AF/AFL/AT, no DCCV>90 days, no RF, no ablation >90 days with Class I/III AAD >90 days='Yes'

  ELSE Freedom from AF/AFL/AT, no DCCV>90 days, no RF, no ablation >90 days with Class I/III AAD >90 days='No'

- Derived criteria "Freedom from AF/AFL/AT, no DCCV>90 days, no RF, no ablation >90 days without Class I/III AAD >90 days" will be defined as follows:

  IF AF/AFL/AT status =0 **AND** DCCV90D=0 **AND** RF touch up=0 **AND** ABL>90 day=0 **AND** Class I/III AAD >90 days =0 in **MDT excel file** **THEN** Freedom from AF/AFL/AT, no DCCV>90 days, no RF, no ablation >90 days without Class I/III AAD >90 days= 'Yes'

  ELSE Freedom from AF/AFL/AT, no DCCV>90 days, no RF, no ablation >90 days without Class I/III AAD >90 days='No'

- Derived criteria "Freedom from AF, no DCCV>90 days, no RF, no ablation >90 days" will be defined as follows:

  IF AF status =0 **AND** DCCV90D=0 **AND** RF touch up=0 **AND** ABL>90 day=0 in **MDT excel file** **THEN** Freedom from AF, no DCCV>90 days, no RF, no ablation >90 days ='Yes'

  ELSE Freedom from AF, no DCCV>90 days, no RF, no ablation >90 days ='No'

- Derived criteria "Freedom from AF, no DCCV>90 days, no RF, no ablation >90 days with Class I/III AAD >90 days" will be defined as follows:

  IF AF status =0 **AND** DCCV90D=0 **AND** RF touch up=0 **AND** ABL>90 day=0 **AND** Class I/III AAD >90 days =1 in **MDT excel file** **THEN** Freedom from AF, no DCCV>90 days, no RF, no ablation >90 days with Class I/III AAD >90 days ='Yes'

  ELSE Freedom from AF, no DCCV>90 days, no RF, no ablation >90 days with Class I/III AAD >90 days ='No'

- Derived criteria "Freedom from AF, no DCCV>90 days, no RF, no ablation >90 days without Class I/III AAD >90 days" will be defined as follows:

  IF AF status =0 **AND** DCCV90D=0 **AND** RF touch up=0 **AND** ABL>90 day=0 **AND** Class I/III AAD >90 days =0 in **MDT excel file** **THEN** Freedom from AF/AFL/AT, no DCCV>90 days, no RF, no ablation >90 days without Class I/III AAD >90 days='Yes'

  ELSE Freedom from AF/AFL/AT, no DCCV>90 days, no RF, no ablation >90 days without Class I/III AAD >90 days= 'No'

Primary feasibility endpoint

IF Ablation with study device was successful = 'Yes' in **procedural form (PR)** **THEN** APS='Yes'

ELSE IF Ablation with study device was successful = 'No' in **procedural form (PR)** THEN APS='No'

Secondary Feasibility Analysis

- Derived criteria "Chronic Procedural Success (CPS)" will be defined as follows:

  IF Has all ablation with the study device(s) been successful? ='Yes' in **Procedural data form (PR)** AND Has all ablation with the study device remain successful? ='Yes' AND Additional ablation(s) performed? ='No' in **FOLLOW UP 3D ELECTRO ANATOMICAL MAPPING form (RM)** THEN Chronic Procedural Success (CPS) ='Yes, index procedure only'

  ELSE IF Has all ablation with the study device(s) been successful? ='Yes' in **Procedural data form (PR)** AND Has all ablation with the study device remain successful? ='No' AND Any PV reconnections noted? in **= 'Yes'** AND Additional ablation(s) performed? ='Yes' in **FOLLOW UP 3D ELECTRO ANATOMICAL MAPPING form (RM)** THEN Chronic Procedural Success (CPS) ='Yes, reblated'

  ELSE IF Has all ablation with the study device(s) been successful? ='No' in **Procedural data form (PR)** THEN Chronic Procedural Success (CPS) ='No'

- Derived criteria Proportion "Acute Cavotricuspid isthmus (CTI) Success" will be defined as follows:

  COUNT IF [CTI isolated/Blocked='Yes' AND CTI Attempted='Yes'] in **Procedural data form (PR)**

- Derived criteria "Durability of CTI at remap," will be defined as follows:

  IF CTI lesion durable ='Yes' in **Follow-up 3D electroanatomical mapping form (RM) THEN** Durability of CTI at remap = 'Yes'

  ELSE IF CTI lesion durable ='No' in **Follow-up 3D electroanatomical mapping form (RM) THEN** Durability of CTI at remap = 'No'

- Derived criteria "Durability of Mitral isthmus at remap" will be defined as follows:

  IF Mitral isthmus lesion durable ='Yes' in **Follow-up 3D electroanatomical mapping form (RM) THEN** Durability of Mitral isthmus at remap = 'Yes'

  ELSE IF Mitral isthmus lesion durable ='No' in **Follow-up 3D electroanatomical mapping form (RM) THEN** Durability of Mitral isthmus at remap = 'No'

- Derived criteria "Durability of Left atrial roof line at remap" will be defined as follows:

  IF Left atrial roof line lesion durable ='Yes' in **Follow-up 3D electroanatomical mapping form (RM) THEN** Durability of Left atrial roof line at remap = 'Yes'

  ELSE IF Left atrial roof line lesion durable ='No' in **Follow-up 3D electroanatomical mapping form (RM) THEN** Durability of Left atrial roof line at remap = 'No'

- Derived criteria "Durability of Left atrial Posterior line" will be defined as follows:

  IF Left atrial Posterior line lesion durable ='Yes' in **Follow-up 3D electroanatomical mapping form (RM) THEN** Durability of Left atrial Posterior line at remap = 'Yes'

  ELSE IF Left atrial Posterior line lesion durable ='No' in **Follow-up 3D electroanatomical mapping form (RM) THEN** Durability of Left atrial Posterior line at remap = 'No'

- Derived criteria "Therapeutic Success ON/OFF AAD" will be defined as follows:

IF "AF/AFL/AT status"= 0 **AND** "RF touchup"= 0 **AND** "ABL >90 days" = 0 in **MDT excel file** **THEN** therapeutic success='Yes'

ELSE therapeutic success='No'

- Derived criteria "Therapeutic Success Off ADD" will be defined as follows:

  IF Therapeutic success =Yes' **AND** Class I/III AAD>90days=0 in **MDT excel file** **THEN** therapeutic success Off ADD ='YES'

  ELSE IF Therapeutic success ='No' **AND** Class I/III AAD>90days=0 **in** **MDT excel file** **THEN** **THEN** therapeutic success Off ADD ='NO'

- Derived criteria "Therapeutic Success On ADD" will be defined as follows:

  EIF Therapeutic success ='Yes' **AND** Class I/III AAD>90days=1 **in** **MDT excel file** **THEN** therapeutic success On ADD ='No'

  Else IF Therapeutic success ='No' **AND** Class I/III AAD>90days=1 **in** **MDT excel file** **THEN** **THEN** therapeutic success On ADD ='No'

Additional endpoints

- Derived criteria "Proportion of all ablated pulmonary veins that are isolated at the Index Procedure using the study device" will be defined as follows:

  COUNT of [(Left Superior Isolated/Blocked ='Yes', Left Inferior Isolated/Blocked='Yes', Left Common Ostium Isolated/Blocked='Yes', Right Middle Isolated/Blocked='Yes', Right Superior Isolated/Blocked='Yes', Right Inferior Isolated/Blocked='Yes')] / COUNT of [(Left Superior Isolated/Blocked in (Yes, No) , Left Inferior Isolated/Blocked in (Yes, No), Left Common Ostium Isolated/Blocked in (Yes, No), Right Middle Isolated/Blocked in (Yes, No), Right Superior Isolated/Blocked in (Yes, No), Right Inferior Isolated/Blocked in (Yes, No))] in **Procedural data form (PR)**

- Derived criteria "Proportion of all ablated pulmonary veins isolated using the study device during the Index Procedure that remain isolated at the 75-day remapping procedure" will be defined as follows:

  (Derived criteria "Total number of veins isolated" - Derived criteria "Number of veins with gaps")/ Derived criteria "Total number of veins isolated"

- Derived criteria Proportion "Chronic CTI at 75d remap" will be defined as follows:

  IF CTI lesion durable ='Yes' in **Follow-up 3D electroanatomical mapping form (RM)** **THEN** Chronic CTI at 75d remap ='Yes'

  ELSE IF CTI lesion durable ='No' in **Follow-up 3D electroanatomical mapping form (RM)** **THEN** Chronic CTI at 75d remap ='No'

- Derived criteria Proportion "LAPW chronic isolation" will be defined as follows:

  IF Anatomical Structure/Area other specification 1 **IN** ("POSTERIOR WALL" "LA POSTERIOR WALL" "LAPW" "PA WALL" "BOX POSTERIOR WALL") **AND** Other 1 Lesion durable = 'yes' **OR** Anatomical Structure/Area other specification 2 **IN** ("POSTERIOR WALL" "LA POSTERIOR WALL" "LAPW" "PA WALL" "BOX POSTERIOR WALL") **AND** Other 2 Lesion durable = ='Yes' in **Follow-up 3D electroanatomical mapping form (RM)** **THEN** LAPW chronic isolation= 'Yes'

ELSE LAPW chronic isolation = 'No'

Primary Safety endpoint

Unless otherwise indicated, all the following variables will be derived from the Adverse event adjudication form (CE)

- Derived criteria "Death" will be defined as follows:

  IF (30≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) **OR** (30≤ (EVENT DATE-≤REMAPPING DATE IN **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)**) AND PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' Death' **THEN** DEATH='Yes'

  ELSE DEATH='No'

- Derived criteria "Myocardial infarction" will be defined as follows:

  IF (30≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) **OR** (30≤ (EVENT DATE-REMAPPING DATE IN **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)**) **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' Myocardial infarction' **THEN** Myocardial infarction='Yes'.

  ELSE Myocardial infarction ='No'.

- Derived criteria "PV Stenosis" will be defined as follows:

  IF (0≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) ≤360 **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' PV Stenosis' **THEN** PV Stenosis ='Yes'.

  ELSE PV Stenosis ='No'.

- Derived criteria "Diaphragmatic Paralysis" will be defined as follows:

  IF (30≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) **OR** (30≤ (EVENT DATE-REMAPPING DATE IN **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)**) **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' Diaphragmatic Paralysis' **THEN** Diaphragmatic Paralysis ='Yes'.

  ELSE Diaphragmatic Paralysis ='No'.

- Derived criteria "AE fistula" will be defined as follows:

  IF (0≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) ≤360 **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' AE fistula' **THEN** AE fistula ='Yes'.

  ELSE AE fistula ='No'.

- Derived criteria "TIA" will be defined as follows:

  IF (30≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) **OR** (30≤ (EVENT DATE-REMAPPING DATE **IN FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)**) **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' TIA' **THEN** TIA=Yes.

  ELSE TIA='No'.

- Derived criteria "CVA" will be defined as follows:

IF (30≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) **OR** (30≤ (EVENT DATE-REMAPPING DATE IN **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)**) **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' CVA' **THEN** CVA='Yes'.
ELSE CVA='No'.

- Derived criteria "Major pericarditis" will be defined as follows:
  IF (30≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) **OR** (30≤ (EVENT DATE-REMAPPING DATE IN **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)**) **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' Major pericarditis' **THEN** Major pericarditis ='Yes'.
  ELSE Major pericarditis ='No'.

- Derived criteria "Tamponade/Perforation" will be defined as follows:
  IF (30≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) **OR** (30≤ (EVENT DATE-REMAPPING DATE IN **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)**) **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' Tamponade/Perforation' **THEN** Tamponade/Perforation ='Yes'
  ELSE Tamponade/Perforation ='No'.

- Derived criteria "Pneumothorax" will be defined as follows:
  IF (30≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) OR(30≤ (EVENT DATE-REMAPPING DATE IN **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)**) **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' Pneumothorax' **THEN** Pneumothorax ='Yes'
  ELSE Pneumothorax ='No'

- Derived criteria "Heart Block" will be defined as follows:
  IF (30≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) **OR** (30≤ (EVENT DATE-REMAPPING DATE IN **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)**) **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' Heart Block' **THEN** Heart Block ='Yes'
  ELSE Heart Block ='No'

- Derived criteria "Pulmonary Edema" will be defined as follows:
  IF (30≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) **OR** (30≤ (EVENT DATE-REMAPPING DATE IN **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)**) **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' Pulmonary Edema' **THEN** Pulmonary Edema ='Yes'
  ELSE Pulmonary Edema ='No'

- Derived criteria "New or Prolonged Hospitalization, excl. AF/AFL" will be defined as follows:
  IF (30≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) **OR** (30≤ (EVENT DATE-REMAPPING DATE IN **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)**) **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' New or Prolonged Hospitalization, excl. AF/AFL' **THEN** New or Prolonged Hospitalization, excl. AF/AFL ='Yes'
  ELSE New or Prolonged Hospitalization, excl. AF/AFL ='No'

- Derived criteria "Vascular Access Complication" will be defined as follows:
  IF (30≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) **OR** (30≤ (EVENT DATE-REMAPPING DATE IN **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)**) **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' Vascular Access Complication' **THEN** Vascular Access Complication ='Yes'
  ELSE Vascular Access Complication ='No'

- Derived criteria "Total Early and Late Onset Composite Safety Endpoint" will be defined as follows:
  IF Death=Yes **OR** Myocardial infarction =Yes **OR** PV Stenosis =Yes **OR** Diaphragmatic Paralysis =Yes **OR** AE fistula =Yes **OR** TIA =Yes **OR** CVA=Yes **OR** Major pericarditis =Yes **OR** Tamponade/Perforation =Yes **OR** Pneumothorax =Yes **OR** Heart Block =Yes **OR** Pulmonary Edema =Yes **OR** New or Prolonged Hospitalization, excl. AF/AFL =Yes **OR** Vascular Access Complication =Yes **THEN** Total Early and Late Onset Composite Safety Endpoint ='Yes'
  ELSE Total Early and Late Onset Composite Safety Endpoint ='No'

- Derived criteria "Total Early Onset Composite Safety Endpoint" will be defined as follows:
  IF Death=Yes **OR** Myocardial infarction =Yes **OR** Diaphragmatic Paralysis =Yes **OR** TIA =Yes **OR** CVA=Yes **OR** Major pericarditis =Yes **OR** Tamponade/Perforation =Yes **OR** Heart Block =Yes **OR** New or Prolonged Hospitalization, excl. AF/AFL =Yes **OR** Vascular Access Complication =Yes **THEN** Total Early Onset Composite Safety Endpoint='Yes'
  ELSE Total Early Onset Composite Safety Endpoint='No'

- Derived criteria "Total Late (any time during follow-up through 12 months)" will be defined as follows:
  IF PV Stenosis =Yes **OR** AE fistula =Yes **THEN** Total Late (any time during follow-up through 12 months) ='Yes'
  ELSE Total Late (any time during follow-up through 12 months) ='No.

<u>Secondary Safety endpoint</u>

- Derived criteria "Death 7 days" will be defined as follows:
  IF (7≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) **OR** (7≤ (EVENT DATE-REMAPPING DATE IN **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)**) **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' Death' **THEN** DEATH='Yes'
  ELSE DEATH='No'

- Derived criteria "Myocardial infarction 7 days" will be defined as follows:
  IF (7≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) **OR** (7≤ (EVENT DATE-REMAPPING DATE IN **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)**) **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' Myocardial infarction' **THEN** Myocardial infarction='Yes'.
  ELSE Myocardial infarction = 'No'.

- Derived criteria "Diaphragmatic Paralysis 7 days" will be defined as follows:

IF (7≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) **OR** (7≤ (EVENT DATE-REMAPPING DATE IN **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)**) **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' Diaphragmatic Paralysis' **THEN** Diaphragmatic Paralysis ='Yes'.

ELSE Diaphragmatic Paralysis ='No'.

- Derived criteria "TIA 7 days" will be defined as follows:

  IF (7≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) **OR** (7≤ (EVENT DATE-REMAPPING DATE IN **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)**) **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' TIA' **THEN** TIA='Yes'.

  ELSE TIA='No'.

- Derived criteria "CVA 7 days" will be defined as follows:

  IF (7≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) **OR** (7≤ (EVENT DATE-REMAPPING DATE IN **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)**) **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' CVA' **THEN** CVA='Yes'.

  ELSE CVA='No'.

- Derived criteria "Major pericarditis 7 days" will be defined as follows:

  IF (7≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) **OR** (7≤ (EVENT DATE- REMAPPING DATE IN **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)**) **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' Major pericarditis' **THEN** Major pericarditis = 'Yes'.

  ELSE Major pericarditis = 'No'.

- Derived criteria "Tamponade/Perforation 7 days" will be defined as follows:

  IF (7≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) **OR** (7≤ (EVENT DATE-REMAPPING DATE IN **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)**) **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' Tamponade/Perforation' **THEN** Tamponade/Perforation ='Yes'.

  ELSE Tamponade/Perforation = 'No'.

- Derived criteria "Pneumothorax 7 days" will be defined as follows:

  IF (7≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) OR(7≤ (EVENT DATE-REMAPPING DATE IN **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)**) **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' Pneumothorax' **THEN** Pneumothorax ='Yes'. **ELSE** Pneumothorax ='No'.

- Derived criteria "Heart Block 7 days" will be defined as follows:

  IF (7≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) **OR** (7≤ (EVENT DATE-REMAPPING DATE IN **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)**) **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' Heart Block' **THEN** Heart Block = 'Yes'.

  ELSE Heart Block = 'No'.

- Derived criteria "Pulmonary Edema 7 days" will be defined as follows:

IF (7≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) **OR** (7≤ (EVENT DATE-REMAPPING DATE IN **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)**) **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' Pulmonary Edema' **THEN** Pulmonary Edema = 'Yes'.

ELSE Pulmonary Edema = 'No'.

- Derived criteria "New or Prolonged Hospitalization, excl. AF/AFL 7 days" will be defined as follows:
  IF (7≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) **OR** (7≤ (EVENT DATE-REMAPPING DATE IN **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)**) **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' New or Prolonged Hospitalization, excl. AF/AFL' **THEN** New or Prolonged Hospitalization, excl. AF/AFL = 'Yes'.
  ELSE New or Prolonged Hospitalization, excl. AF/AFL = 'No'.

- Derived criteria "Vascular Access Complication 7 days" will be defined as follows:
  IF (7≤ (EVENT DATE-PROCEDURE DATE IN **PROCEDURAL DATA FORM (PR)**) **OR** (7≤ (EVENT DATE-REMAPPING DATE IN **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)**) **AND** PRIMARY SAFETY ENDPOINT EVENT CRITERIA=' Vascular Access Complication' **THEN** Vascular Access Complication = 'Yes'.
  ELSE Vascular Access Complication = 'No'.

- Derived criteria "Total Early Onset Composite Safety Endpoint assessed at 7 days" will be defined as follows:
  IF Death 7 days='Yes' **OR** Myocardial infarction 7 days='Yes' **OR** Diaphragmatic Paralysis 7 days='Yes' **OR** TIA 7 days='Yes' **OR** CVA 7 days='Yes' **OR** Major pericarditis 7 days='Yes' **OR** Tamponade/Perforation 7 days='Yes' **OR** Heart Block 7 days='Yes' **OR** New or Prolonged Hospitalization, excl. AF/AFL 7 days='Yes' **OR** Vascular Access Complication 7 days='Yes' **THEN** Total Early Onset Composite Safety Endpoint assessed at 7 days = 'Yes'.
  ELSE Total Early Onset Composite Safety Endpoint assessed at 7 days = 'No'.

- Derived criteria "Device-Related Serious Adverse Events (SAEs)" will be defined as follows:
  IF CEC seriousness ="Serious" **AND** CEC relationship to study Device in (Causal relationship, Probably related, Possibly related, Unlikely to be related) in adverse event adjudication form **THEN** Device-Related Serious Adverse Events (SAEs)='Yes'; **ELSE** Device-Related Serious Adverse Events (SAEs)='No'

- Derived criteria "Procedure-Related Serious Adverse Events (SAEs)" will be defined as follows:
  IF CEC relationship to study procedure in (Causal relationship, Probably related, Possibly related, Unlikely to be related) **AND** CEC seriousness ='Serious' **THEN** Procedure-Related Serious Adverse Events (SAEs)='Yes'
  ELSE IF CEC relationship to study procedure ='Not related' **AND** CEC seriousness =" Serious" **THEN** Procedure-Related Serious Adverse Events (SAEs)='No'

- Derived criteria "Cardioversion" will be defined as follows:
  IF Arrythmia-Treatment DC Cardioversion is ticked in **Arrythmia episodes form** **THEN** Cardioversion ='Yes';
  ELSE Cardioversion ='No'

- Derived criteria “Stroke after index procedure” will be defined as follows:

  IF Event name=’STROKE’ in **Adverse event form AND** Event start date ≥ Procedure date in **Procedural data Form (PR) THEN** STROKE=’Yes’

  ELSE STROKE=’No’
- Derived criteria “Transient Ischemic Attack (TIA) after index procedure” will be defined as follows:

  IF Event name=’ Transient Ischemic Attack’ in **Adverse event form AND** Event start date ≥ Procedure date in **Procedural data Form (PR) THEN** TIA=’Yes’

  ELSE TIA=’No’

- Derived criteria “Stroke after Remap procedure” will be defined as follows:

  IF Event name=’STROKE’ in **Adverse event form AND** Event start date ≥ Remap date IN **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM)** THEN STROKE=’Yes’

  ELSE STROKE=’No’
- Derived criteria “Transient Ischemic Attack (TIA) after Remap procedure” will be defined as follows:

  IF Event name=’ Transient Ischemic Attack’ in **Adverse event form AND** Event start date ≥ Remap date in **FOLLOW-UP 3D ELECTROANATOMICAL MAPPING FORM (RM) THEN** TIA=’Yes’

  ELSE TIA=’No’

- Derived criteria “Arrhythmia-related (AF, AFL, AT) hospitalization” will be defined as follows:

  IF Arrhythmia-related (AF, AFL, AT) hospitalization =’Yes’ in **MDT excel file THEN** Arrhythmia-related (AF, AFL, AT) hospitalization =’Yes’

  ELSE IF Arrhythmia-related (AF, AFL, AT) hospitalization =’No’ in **MDT excel file THEN** Arrhythmia-related (AF, AFL, AT) hospitalization =’No’

- Derived criteria “Death” will be defined as follows:

  IF SAE: Death=’Yes’ in **Adverse event form OR** Reason =’Patient death’ in **study exit form THEN** Death=’Yes’

  ELSE Death=’No’

3. STATISTICAL SOFTWARE

All statistical outputs (summary tables and data listings) will be generated using SAS® version 9.4 or further.

4. STATISTICAL TABLES, LISTINGS AND GRAPHS (TABLE OF CONTENTS)

4.1. Statistical Tables

4.1.1. Table 1. Subject enrollment per Site

		Enrolled patients	ITT patients	PP patients
		(N=XX)	(N=XX)	(N=XX)
Site #	Site Name			
XX		XX (XX%)	XX (XX%)	XX (XX%)
XX		XX (XX%)	XX (XX%)	XX (XX%)

4.1.2. Table 2. Demographics

	ITT Population N = XX	
	Mean±S.D. Median (min, max) (Q1, Q3)	[95% CI]
Age	XX±X XX (XX, XX) (XX, XX)	[XX - XX]
BMI	XX±X XX (XX, XX) (XX, XX)	[XX - XX]
	n/N (%)	[95% CI]
Male Gender	XX/XX (XX.X%)	[XX% - XX%]

Female Gender	XX/XX (XX.X%)	[XX - XX%]

4.1.3. Table 3. Baseline Medical History

	ITT Population N = XX	
	Mean±S.D. Median (min, max) (Q1, Q3)	[95% CI]
Left atrial diameter (cm)	XX±X XX (XX, XX) (XX, XX)	[XX - XX]
AF history (number of months)	XX±X XX (XX, XX) (XX, XX)	[XX - XX]
LVEF (%)	XX±X XX (XX, XX) (XX, XX)	[XX - XX]
CHA2DS2VASC	XX±X XX (XX, XX) (XX, XX)	[XX - XX]
	n/N (%)	[95% CI]
Patient that failed any AAD	XX/XX (XX.X%)	[XX% - XX%]
If Yes: Class I	XX/XX (XX.X%)	[XX% - XX%]

If Yes: Beta Blocker/Class II	XX/XX (XX.X%)	[XX% - XX%]
If Yes: Class III	XX/XX (XX.X%)	[XX% - XX%]
If Yes: Calcium Channel Blocker/Class IV	XX/XX (XX.X%)	[XX% - XX%]
Smoking	XX/XX (XX.X%)	[XX% - XX%]
Dyslipidemia	XX/XX (XX.X%)	[XX% - XX%]
COPD	XX/XX (XX.X%)	[XX% - XX%]
PPM/ICD	XX/XX (XX.X%)	[XX% - XX%]
Unstable angina	XX/XX (XX.X%)	[XX% - XX%]
NYHA Heart Failure	XX/XX (XX.X%)	[XX% - XX%]
Class I	XX/XX (XX.X%)	[XX% - XX%]
Class II	XX/XX (XX.X%)	[XX% - XX%]
Class III	XX/XX (XX.X%)	[XX% - XX%]
Class IV	XX/XX (XX.X%)	[XX% - XX%]
Any History of Structural heart disease	XX/XX (XX.X%)	[XX% - XX%]
If yes: Cardiomyopathy	XX/XX (XX.X%)	[XX% - XX%]
If yes: Coronary artery disease	XX/XX (XX.X%)	[XX% - XX%]
If yes: Aneurysm	XX/XX (XX.X%)	[XX% - XX%]
If yes: Left ventricular hypertrophy	XX/XX (XX.X%)	[XX% - XX%]
If yes: Valvular heart disease	XX/XX (XX.X%)	[XX% - XX%]
Cerebrovascular disease	XX/XX (XX.X%)	[XX% - XX%]
If yes: CVA/Stroke	XX/XX (XX.X%)	[XX% - XX%]
If yes: TIA	XX/XX (XX.X%)	[XX% - XX%]
Cardiac surgery	XX/XX (XX.X%)	[XX% - XX%]
If yes: CABG	XX/XX (XX.X%)	[XX% - XX%]
If yes: Valve	XX/XX (XX.X%)	[XX% - XX%]
Diabetes	XX/XX (XX.X%)	[XX% - XX%]

Hypertension	XX/XX (XX.X%)	[XX% - XX%]
Hyperthyroidism	XX/XX (XX.X%)	[XX% - XX%]
Hypothyroidism	XX/XX (XX.X%)	[XX% - XX%]
Myocardial infarction	XX/XX (XX.X%)	[XX% - XX%]
Peripheral vascular disease	XX/XX (XX.X%)	[XX% - XX%]
Pulmonary hypertension	XX/XX (XX.X%)	[XX% - XX%]
Renal dysfunction/failure	XX/XX (XX.X%)	[XX% - XX%]
Sleep apnea	XX/XX (XX.X%)	[XX% - XX%]

4.1.4. Table 4. Procedure

	ITT Population N = XX	
	Mean±S.D. Median (min, max) (Q1, Q3)	[95% CI]
Procedure time (hours)	XX±X XX (XX, XX) (XX, XX)	[XX - XX]
Farawave dwell time (hours)	XX±X XX (XX, XX) (XX, XX)	[XX - XX]
PVI ablation time (hours)	XX±X XX (XX, XX)	[XX - XX]

	(XX, XX)	
CTI (FARAFLEX) dwell time (hours)	XX±X XX (XX, XX) (XX, XX)	[XX - XX]
LAPW ablation time (hours)	XX±X XX (XX, XX) (XX, XX)	[XX - XX]
Fluoroscopy time (min)	XX±X XX (XX, XX) (XX, XX)	[XX - XX]
Contrast volume (cc)	XX±X XX (XX, XX) (XX, XX)	[XX - XX]
IV fluid volume (cc)	XX±X XX (XX, XX) (XX, XX)	[XX - XX]
Total number of PVI applications	XX	NA
Number of applications/patient	XX±X XX (XX, XX) (XX, XX)	[XX - XX]
Number of applications/vein	XX	NA

Number of LAPW applications	XX	NA
	N, n, n/N (%)	95% CI
Total number of veins treated	XX	NA
Total number of veins isolated	XX	NA
Of the total number of veins treated, the number of veins isolated	XX/XX (XX.X%)	[XX% - XX%]
CTI acute isolation	XX/XX (XX.X%)	[XX% - XX%]
Total number of CTI applications	XX	NA

4.1.5. Table 5. Remap at 75 Days

	ITT Population N = 25	
	Mean±S.D. Median (min, max) (Q1, Q3)	[95% CI]
Days follow up at remap	XX±X XX (XX, XX) (XX, XX)	[XX - XX]
	n/N (%)	[95% CI]
Durable PVI	XX/XX (XX.X%)	[XX% - XX%]
LSPV chronic isolation	XX/XX (XX.X%)	[XX% - XX%]
LIPV chronic isolation	XX/XX (XX.X%)	[XX% - XX%]
LCPV chronic isolation	XX/XX (XX.X%)	[XX% - XX%]
RSPV chronic isolation	XX/XX (XX.X%)	[XX% - XX%]
RIPV chronic isolation	XX/XX (XX.X%)	[XX% - XX%]
RMPV chronic isolation	XX/XX (XX.X%)	[XX% - XX%]

CTI chronic isolation	XX/XX (XX.X%)	[XX% - XX%]
LAPW chronic isolation	XX/XX (XX.X%)	[XX% - XX%]

4.1.6. Table 6. Per Remapped Veins Analysis

	Veins Remapped N = XX	
	n/N (%)	[95% CI]
Number of veins durably isolated	XX/XX (XX.X%)	[XX% - XX%]
Number of veins with gaps	XX/XX (XX.X%)	[XX% - XX%]
Missing Data	XX	NA

4.1.7. Table 7. Arrythmia Recurrence at 12 Months

	ITT Population N = XX	
	Mean±S.D. Median (min, max) (Q1, Q3)	[95% CI]
TTM compliance	XX±X XX (XX, XX) (XX, XX)	[XX - XX]
	n/N (%)	[95% CI]
Holter compliance (6 month)	XX/XX (XX.X%)	[XX% - XX%]
Freedom from AF/AFL/AT	XX/XX (XX.X%)	[XX% - XX%]
	XX/XX (XX.X%)	[XX% - XX%]
On AADs	XX/XX (XX.X%)	[XX% - XX%]

Off AADs		
Freedom from AF	XX/XX (XX.X%)	[XX% - XX%]
On AADs	XX/XX (XX.X%)	[XX% - XX%]
Off AADs	XX/XX (XX.X%)	[XX% - XX%]
Freedom from AF/AFL/AT, no DCCV>90 days, no RF, no ablation >90 days	XX/XX (XX.X%)	[XX% - XX%]
On AADs	XX/XX (XX.X%)	[XX% - XX%]
Off AADs	XX/XX (XX.X%)	[XX% - XX%]
Freedom from AF, no DCCV>90 days, no RF, no ablation >90 days	XX/XX (XX.X%)	[XX% - XX%]
On AADs	XX/XX (XX.X%)	[XX% - XX%]
Off AADs	XX/XX (XX.X%)	[XX% - XX%]

4.1.8. Table 8. Primary Safety Endpoint –Composite Safety Endpoint (CSE)

	ITT Population N = XX	
	n/N (%)	[95% CI]
Early and Late Onset Composite Safety Endpoint	XX/XX (XX.X%)	[XX% - XX%]
Total Early (within 30 days of Index or Remap Procedure)	XX/XX (XX.X%)	[XX% - XX%]
Death	XX/XX (XX.X%)	[XX% - XX%]
Myocardial infarction (MI)	XX/XX (XX.X%)	[XX% - XX%]
Persistent diaphragmatic paralysis	XX/XX	[XX% - XX%]

	(XX.X%)	
Stroke	XX/XX (XX.X%)	[XX% - XX%]
Transient ischemic attack (TIA)	XX/XX (XX.X%)	[XX% - XX%]
Peripheral or organ thromboembolism	XX/XX (XX.X%)	[XX% - XX%]
Pericarditis	XX/XX (XX.X%)	[XX% - XX%]
Cardiac tamponade / perforation	XX/XX (XX.X%)	[XX% - XX%]
Vascular access complications requiring intervention	XX/XX (XX.X%)	[XX% - XX%]
Heart block	XX/XX (XX.X%)	[XX% - XX%]
Total Late (any time during follow-up through 12 months)	XX/XX (XX.X%)	[XX% - XX%]
Pulmonary vein (PV) stenosis (> 70% diameter reduction from baseline)	XX/XX (XX.X%)	[XX% - XX%]
Atrio-esophageal fistula	XX/XX (XX.X%)	[XX% - XX%]

4.1.9. Table 9. Primary Feasibility Endpoint – Acute Procedural Success (ITT population)

	ITT Population N = XX	
	n/N (%)	[95% CI]
Acute Procedural Success*	XX/XX (XX.X%)	[XX% - XX%]

4.1.10. Table 10. Primary Feasibility Endpoint – Acute Procedural Success (PP population)

	PP Population N = XX	
	n/N (%)	[95% CI]
Acute Procedural Success*	XX/XX (XX.X%)	[XX% - XX%]

4.1.11. Table 11. Additional Endpoints

	ITT Population N = XX	
	Mean±S.D. Median (min, max) (Q1, Q3)	[95% CI]
Time to Therapeutic Failure (days)	XX±X XX (XX, XX) (XX, XX)	[XX - XX]
	n/N (%)	[95% CI]
Proportion of subjects with Early recurrence of atrial fibrillation (ERAF) by 90 days after the index procedure	XX/XX (XX.X%)	[XX% - XX%]
Proportion of all ablated pulmonary veins that are isolated at the Index Procedure using the study device	XX/XX (XX.X%)	[XX% - XX%]
Proportion of all ablated pulmonary veins isolated using the study device during the Index Procedure that remain isolated at the 75-day remapping procedure	XX/XX (XX.X%)	[XX% - XX%]

The proportion of attempted subjects that achieve Chronic CTI Success, defined as persistent bi-directional electrical block across the CTI assessed at the 75-day Remapping Procedure	XX/XX (XX.X%)	[XX% - XX%]
The proportion of attempted subjects that achieve Chronic Focal Success, defined as persistent electrical nonconductivity of all extra-PV tissue targeted for ablation in the Index Procedure, excluding the CTI	XX/XX (XX.X%)	[XX% - XX%]

4.1.12. Table 12. Secondary Safety Endpoints

	ITT Population N = XX	
	n/N (%)	[95% CI]
Primary Safety Endpoint (Early and Late Onset Composite Safety Endpoint) assessed at 7 days	XX/XX (XX.X%)	[XX% - XX%]
Total Early (within 30 days of Index or Remap Procedure)	XX/XX (XX.X%)	[XX% - XX%]
Death	XX/XX (XX.X%)	[XX% - XX%]
Myocardial infarction (MI)	XX/XX (XX.X%)	[XX% - XX%]
Persistent diaphragmatic paralysis	XX/XX (XX.X%)	[XX% - XX%]
Stroke	XX/XX (XX.X%)	[XX% - XX%]
Transient ischemic attack (TIA)	XX/XX (XX.X%)	[XX% - XX%]
Peripheral or organ thromboembolism	XX/XX (XX.X%)	[XX% - XX%]
Pericarditis	XX/XX (XX.X%)	[XX% - XX%]
Cardiac tamponade / perforation	XX/XX (XX.X%)	[XX% - XX%]
Vascular access complications requiring intervention	XX/XX (XX.X%)	[XX% - XX%]
Heart block	XX/XX (XX.X%)	[XX% - XX%]
Total Late (any time during follow-up through 12 months)	XX/XX (XX.X%)	[XX% - XX%]

Pulmonary vein (PV) stenosis (> 70% diameter reduction from baseline)	XX/XX (XX.X%)	[XX% - XX%]
Atrio-esophageal fistula	XX/XX (XX.X%)	[XX% - XX%]
Device-Related Serious Adverse Events (SAEs)	XX/XX (XX.X%)	[XX% - XX%]
Procedure-Related Serious Adverse Events (SAEs)	XX/XX (XX.X%)	[XX% - XX%]
Stroke	XX/XX (XX.X%)	[XX% - XX%]
Transient Ischemic Attack (TIA)	XX/XX (XX.X%)	[XX% - XX%]
Cardioversion	XX/XX (XX.X%)	[XX% - XX%]
Arrhythmia-related (AF, AFL, AT) hospitalization	XX/XX (XX.X%)	[XX% - XX%]

4.1.13. Table 13. Secondary Feasibility Endpoints

	ITT Population N = XX	
	n/N (%)	[95% CI]
Chronic Procedural Success (CPS)* for subjects who undergo the protocol-specified 75-Day Remapping Procedure	XX/XX (XX.X%)	[XX% - XX%]
Acute Cavotricuspid isthmus (CTI) Success**	XX/XX (XX.X%)	[XX% - XX%]
Therapeutic Success***	XX/XX (XX.X%)	[XX% - XX%]
On AADs	XX/XX (XX.X%)	[XX% - XX%]
Off AADs	XX/XX (XX.X%)	[XX% - XX%]
Durability of the CTI and/or other extra PV lesion set(s)	XX/XX (XX.X%)	[XX% - XX%]

4.1.14. Table 14. Adverse Events (AEs) (not including SAEs)

	ITT Population N = XX		
SOC Term/PT Term	Total Number of	Number of	n/N (%)

	Events	patients n	[95% CI]
ALL	XX	XX	XX/XX (XX.X%) [XX% - XX%]
SOC1	XX	XX	XX/XX (XX.X%) [XX% - XX%]
PT1	XX	XX	XX/XX (XX.X%) [XX% - XX%]
PT2	XX	XX	XX/XX (XX.X%) [XX% - XX%]
SOC2	XX	XX	XX/XX (XX.X%) [XX% - XX%]
PT3	XX	XX	XX/XX (XX.X%) [XX% - XX%]
PT4	XX	XX	XX/XX (XX.X%) [XX% - XX%]

4.1.15. Table 15. Serious Adverse Events (SAEs)

	ITT Population N = XX		
SOC Term/PT Term	Total Number of Events	Number of patients n	n/N (%) [95% CI]
ALL	XX	XX	XX/XX (XX.X%) [XX% - XX%]
SOC1	XX	XX	XX/XX (XX.X%) [XX% - XX%]
PT1	XX	XX	XX/XX (XX.X%) [XX% - XX%]
PT2	XX	XX	XX/XX (XX.X%) [XX% - XX%]
SOC2	XX	XX	XX/XX (XX.X%) [XX% - XX%]
PT3	XX	XX	XX/XX (XX.X%) [XX% - XX%]
PT4	XX	XX	XX/XX (XX.X%) [XX% - XX%]

4.1.16. Table 16. All Deaths

	ITT Population N = XX	
	n/N (%)	[95% CI]
All-cause Mortality	XX/XX (XX.X%)	[XX% - XX%]

4.1.17. Table 17. Protocol Deviations according investigator without COVID-19

	ITT Population N = XX		
Type of Deviation	Total Number of Events	Number of patients n	n/N (%) [95% CI]
Protocol Deviation Type 1	XX	XX	XX/XX (XX.X%) [XX% - XX%]
Protocol Deviation Description 1	XX	XX	XX/XX (XX.X%) [XX% - XX%]
Protocol Deviation Description n	XX	XX	XX/XX (XX.X%) [XX% - XX%]
Protocol Deviation Type n	XX	XX	XX/XX (XX.X%) [XX% - XX%]
Protocol Deviation Description 1	XX	XX	XX/XX (XX.X%) [XX% - XX%]
Protocol Deviation Description n	XX	XX	XX/XX (XX.X%) [XX% - XX%]

4.1.18. Table 18. Protocol Deviations according investigator with COVID-19

	ITT Population

	N = XX		
Type of Deviation	Total Number of Events	Number of patients n	n/N (%) [95% CI]
Protocol Deviation Type 1	XX	XX	XX/XX (XX.X%) [XX% - XX%]
Protocol Deviation Description 1	XX	XX	XX/XX (XX.X%) [XX% - XX%]
Protocol Deviation Description n	XX	XX	XX/XX (XX.X%) [XX% - XX%]
Protocol Deviation Type n	XX	XX	XX/XX (XX.X%) [XX% - XX%]
Protocol Deviation Description 1	XX	XX	XX/XX (XX.X%) [XX% - XX%]
Protocol Deviation Description n	XX	XX	XX/XX (XX.X%) [XX% - XX%]

4.1.19. Table 19. Device Deficiency Summary Table

	ITT Population N = 25
Device deficiency rate	XX/XX (XX%) [XX% - XX%]

4.2. Listings

4.2.1. Listing 1: Patients populations, reasons of non-inclusion in the different population, withdrawals and follow-up duration

4.2.2. Listing 2: Protocol deviations according the investigator

4.2.3. Listing 3: Demographics at baseline

4.2.4. Listing 4: AF History

4.2.5. Listing 5: Medical History (1/3)

4.2.6. Listing 6: Medical History (2/3)

4.2.7. Listing 7: Medical History (3/3)

4.2.8. Listing 8: Procedure data (1/4)

4.2.9. Listing 9: Procedure data (2/4)

4.2.10. Listing 10: Procedure data (3/4)

4.2.11. Listing 11: Procedure data (4/4)

4.2.12. Listing 12: Additional Ablation

4.2.13. Listing 13: Chronic Procedural Success at remap

4.2.14. Listing 14: Primary Safety endpoints

4.2.15. Listing 15: Device Deficiencies

4.2.16. Listing 16: Adverse events according CEC review

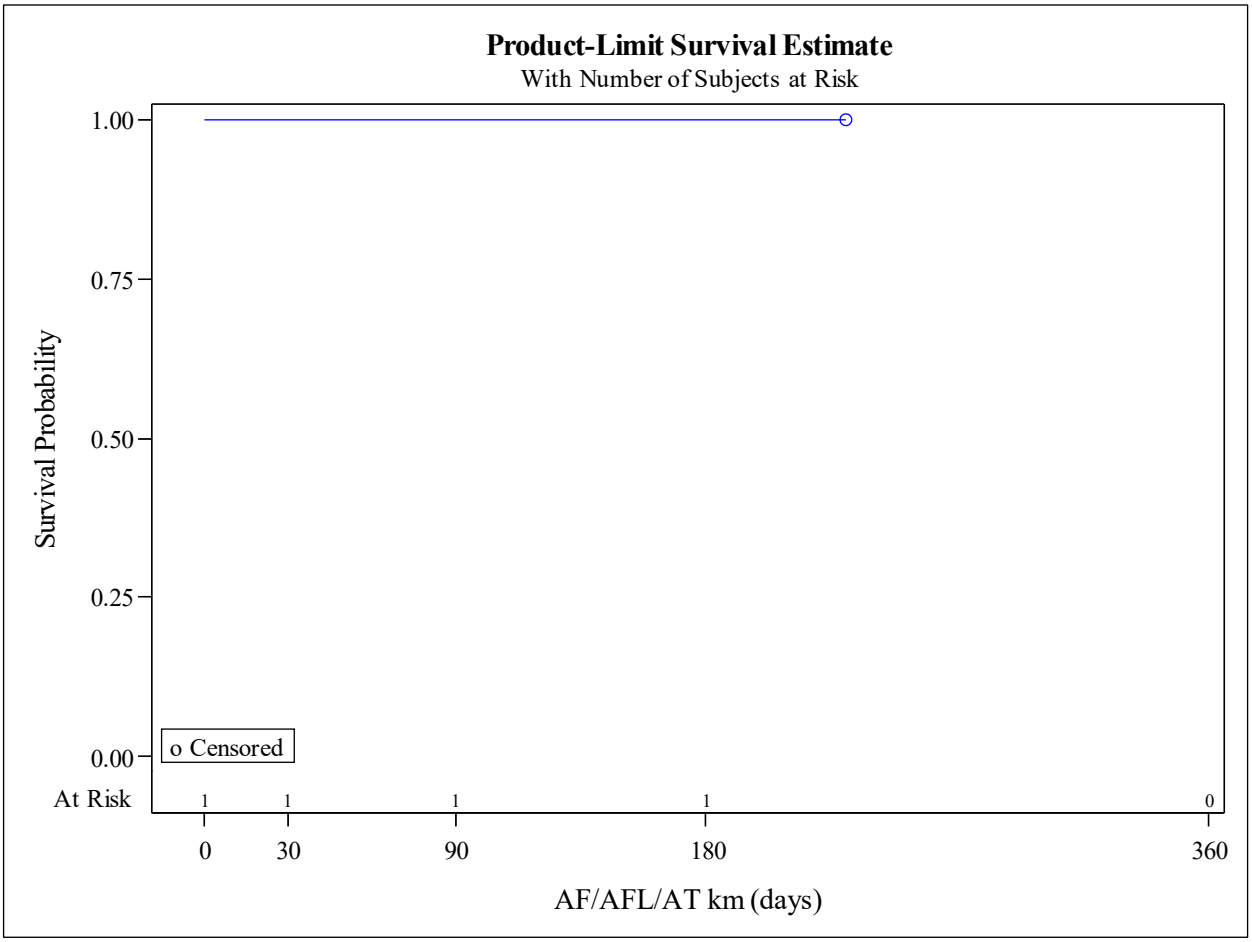
4.2.17. Listing 17: Serious adverse events according CEC review

4.2.18. Listing 18: Concomitant Medications

4.3. Graphs

4.3.1. Graph 1: Patient disposition

4.3.2. Graph 2: Freedom from AF/AFL/AT on ADDs



- **Summary table**

	Group 1 (N=XXX)
Nb of patients	XXX
Nb of patients with an event	XX (XX.X%)
Nb of patients without an event	XX (XX.X%)
Survival rate	XX %
Time to event (days)	
Median	XX
(95% CI)	(XX, XX)
25th-75th percentile	XXX – XXX
Range	X.XX - X.XX