# ABLATOR Brasil – Observational Study (Registry) of Ablation

SponsorSt Jude Medical Brasil Ltda. [redacted]

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Principal Investigator [redacted]

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# 1 Introduction

The prevalence of Atrial Fibrillation (AF) in the Western world is high and increasing, from 0.9% to 24.2% in men over 85 years of age. [12] These estimates are in line with data related to the United States, which indicates that the number of people with AF is expected to double by 2050.

AF ablation is now considered a secondary therapeutic line and can sometimes be used as primary therapy before the failure of any antiarrhythmic drug (AAD). [34] The most common approach to AF ablation is based on isolation of the Pulmonary Veins (PVI), however, several alternative approaches are being used and studied (e.g. lines, fractional complex electrograms (CFE), rotors, epicardial approach). Radio frequency (RF) is predominantly used, with 3D mapping for both anatomical and electrical mapping.

St. Jude Medical (SJM) has a broad portfolio of products that can be used during atrial fibrillation (AF) ablation and recently expanded its portfolio with the new FlexAbility ablation catheters, which have enhanced handling capability and innovative irrigation, and TactiCath, which has a contact sensor. [5]

Many studies approach the treatment of AF from a clinical perspective (see bibliography of 6-9). This registry aims to collect a large number of real cases focusing on the synergy between the various tools and investigate their impact on the effectiveness of the procedure and clinically in Brazil.

The results obtained will support the Brazilian medical society for

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recommendations of optimal techniques, evaluate overall costs, provide *feedback* for the development and creation of new tools, create data in support of randomized clinical trial designs, and provide information for choosing the appropriate tool within the various options.



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# 2 Registry Delineation

## 2.1 Purpose

The purpose of this registry is to evaluate the performance and clinical efficacy of the combination of SJM mapping and ablation products in the treatment of atrial fibrillation (AF) in Brazil.

## 2.2 Goals

- Ensure patient safety as part of after-sales surveillance.
- Evaluate the combination of SJM products during the procedures.
- Assess the learning curve with a combination of SJM products.
- Collect *feedback* from users of SJM products

## 2.3 Type of Research

Post-commercial, national, multicenter, prospective and observational single-arm.

This registry will be conducted in approximately 25 centers around Brazil, seeking to include the greatest possible regional diversity.

## 2.4 Public to be registered

All patients who have indication for ablation of atrial fibrillation and who are willing to provide a written consent form, except pregnant women, may be included in this registry.

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## 2.5 Products/Devices used

In order to ensure a minimum level of uniformity and to allow the comparison of acute and long-term efficacy as well as the efficiency of the procedure according to the technique used, a combination of 2 types of devices from the predetermined list should be used to qualify in this registry.

List of products/devices that should be used in this registration:

Combination of at least 2 devices:

- Ablation Catheter: TactiCath or FlexAbility
- Sheathed access: Agilis NxT or Swartz Braided
- Diagnostic catheter: Inquiry Afocus II DL, Optima or Reflexion Spiral

In the case of mapping, EnSite Velocity will need to be used.

Only commercially available SJM products should be used in this registration. The manuals provided should be consulted. New models that are made available in the market can be used once they are available, have ANVISA registration and approved for commercialization.



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## 3 Data collection

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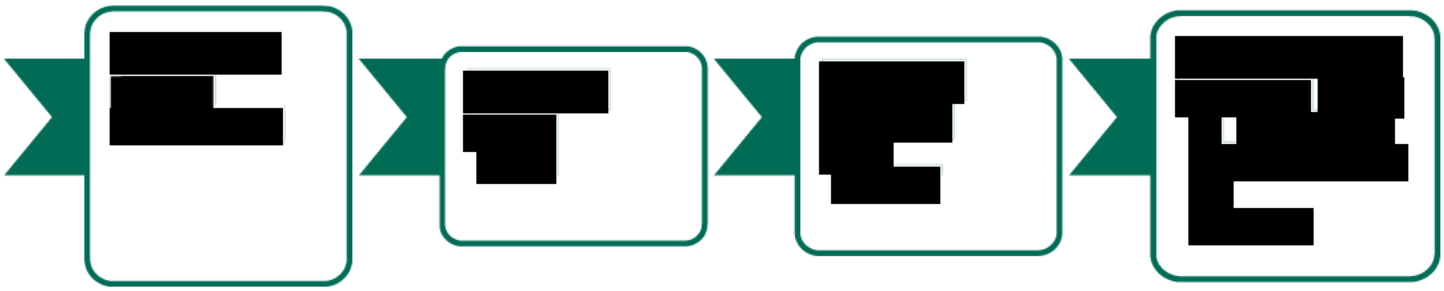

All procedures will follow the local standard of care

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3.2.1 Recruitment & Informed Consent Process

The investigator is responsible for screening for this Registry and obtainingthe Informed Consent Form (ICF) from the patient, as applicable in accordance with local regulations. Obtaining the Informed Consent Form is mandatory for all patients (or their legal representatives) prior to participation in the investigation. The process of obtaining the TCLE must comply with the latest version of the Declaration of Helsinki, ISO 14155 and all applicable regulations. The principal investigator will conduct the consent process. This process will include a verbal discussion with the patient about all aspects of the clinical investigation that are relevant to their decision to participate in the study. It is crucial that this discussion is documented (patient hospital records).

The patient will be provided with a Free and Informed Consent Form written in a language that is understandable to the patient and that has been approved by the Ethics Committee. The patient will be given sufficient time to consider participation and ask questions if necessary.

In order to avoid any kind of undue influence, or inducement of the patient to participate, the sponsor requests the investigator to sign the Informed Consent Form only after the patient has signed and dated the document and therefore has voluntarily decided to participate.

The informed consent of a patient should always be dated and signed personally by the patient and the investigator responsible for conducting the informed consent process. It is crucial that the signature of the ICF is documented in the source documents (hospital records of the patient).

One copy of the original ICF must be kept on file by the investigator and a second signed original copy is provided to the research participant (responsibility of the investigator). The patient's legal rights will not be waived, nor will they appear to be unenforced. Native non-technical language will be used, understandable to the patient. New important information that becomes available during registration will need to be

provided in writing to new and existing patients. If relevant, all affected patients should confirm

their participation in the study by providing their written informed consent.

3.2.2 Initial Data

The following information will be collected:

- Patient demographics;
- History of Atrial Fibrillation (type, frequency, duration and other arrhythmias besides AF);
- Cardiovascular history (NYHA class, AE diameter, LVEF% and grade of valvular heart disease);
- Medical history (pre-existing conditions and cardiac procedures).

3.2.3 Ablation Procedure

- Products/Devices used;
- Ablation Parameters;
- Definition of ablation success and outcome;
- *User feedback* (Combination of products chosen, product handling, ease of use in combination with other equipment);
- Number, experience and type of service;
- Definition of the standard of care (follow-up procedures and occurrences).

3.2.4 6 and 12 Months of Follow-up (+/- 30 days)

- Recurrence of atrial arrhythmias: list of atrial arrhythmias since the last visit, classification of episodes, duration of episodes (only events with evidence of source data should be recorded)

- Changes in therapy (new antiarrhythmic drug, redone procedures).

- In case of repetition of procedures, reconnections and new ablations should be documented.



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### 3.2.5 Serious cardiovascular adverse events

An adverse event should be reported in this registry when the event is considered to be of cardiovascular origin and has the potential to lead to:

-Death

- A serious deterioration of the patient's health , which may result in:
  - A life-threatening disease or condition
  - In: permanent capacity of a body structure or a bodily function;
  - Prolonged hospitalization
  - Medical orsurgical intervention to prevent life-threatening disease or injury
  - Malignant tumor
- Fetal distress, fetal death, or a congenital abnormality or defect

Planned hospitalization for a pre-existing condition is not considered a serious adverse event.

Cardiovascular serious adverse events (CAEs) include, but are not limited to, the following:

abnormal ECG, angina (chest pain), arrhythmia, fistula, complete heart block, coronary artery injury, cardiac perforation, thromboembolism, fluid overload, damage to components of the ICD or implantable pacemaker, morte, displacement of implantable defibrillator, a n d ndocarditis, exacerbation of pre-existing atrial fibrillation, heart failure, arterial hypertension, AV block, esophageal fistula, myocardial infarction, obstruction/perforation/damage of the vascular system, palpitations, cardiac effusion/tamponade, pericardial effusion without tamponade, pericarditis, pulmonary vein dissection,

pulmonary vein stenosis, pulmonary vein thrombus, complete heart block, valvular damage, or ventricular arrhythmia insufficiency requiring defibrillation.



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*Procedure for the evaluation, registration and notification of EAGs*

Cardiovascular EAGs should be reported following local regulation. All cardiovascular EAGs between patient recruitment and the end of registration must be reported to the sponsor and local Ethics Committees in accordance with local regulations.

In the event that an EAG occurs, complete and submit an Adverse Event to St. Jude Medical.

Additional information may be requested, if necessary, by Sponsor in order to report EAGs to regulatory authorities. The investigator must notify the Ethics Committee, if applicable, in accordance with national and local laws and regulations.

### 3.2.6 Death

All patient deaths that occur during this registry must be reported to SJM within 72 hours of the center becoming aware of the fact. An Adverse Events form must be completed for all deaths at all centers.

### 3.2.7 Protocol deviations

Investigators are required to adhere to the study protocol by signing the Contract to conduct the clinical trial, in accordance with applicable federal (national) or state/local laws and regulations, as well as all conditions imposed by the Ethics Committee or applicable regulatory authorities. A deviation in the protocol is used to describe situations in which the protocol was not followed. All deviations from the study protocol should be reported to the SJM.

### 3.2.8 Exclusions

Every reasonable effort should be made to keep the patient on the Registry. If a patient completes their participation in the Registry, the future management of the patient will not be



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altered by this decision, whether voluntary or not. If a patient drops out and completes participation in the Registry, document the information in the clinical exclusion form (CRF) as soon as possible.

# 4 Conduct of the Registry

## 4.1 Sponsor Responsibilities

The sponsor will:

- Propose registration to potential centers
- Train and provide center personnel with training and access to an electronic data capture platform
- Monitor data collected in the registry

## 4.2 Responsibilities of the Investigator

The principal investigator and his or her team are required to adhere to the Protocol in order to prevent patients from being exposed to excessive risks. Above all, the principal investigator must comply with the signed study contract, applicable national or local laws and regulations, and all conditions required by the Ethics Committee.

## 4.3 Monitories

Centralized monitoring will occur through routine internal data review. This monitoring is designed to identify lost and inconsistent data, outliers of data, and potential protocol deviations that may be indicative of non-compliance.

## 4.4 End of the Investigation

Sponsor reserves the right to discontinue registration at any stage by giving appropriate written notice to the investigator.

Possible reasons for early termination of the Registro by the sponsor may include, but are not limited to:



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- Sponsor decision
- Request from regulatory bodies
- Request from the Ethics Committee
- The unexpected occurrence of EAG related to a device that cannot be avoided in future cases

Registration will be terminated in accordance with applicable regulations.

### 4.5 Declaration of conformity

Registration will be carried out in accordance with the most current versions of the Declaration of the World Medical Association (WMA) of Helsinki, ISO 14155 and regional and/or national regulations.

The investigator should not begin to include patients or request informed consent from any patient before obtaining approval from the Ethics Committee and approval from the competent authority, if applicable, and written authorization from the sponsor.

If additional requirements are imposed by the Ethics Committee or the competent authority, these must be followed.

## 5 Risks and Benefits of Clinical Research

This registry will follow standard procedures of local practice, so there will be no risks or benefits associated with participating in this registry for the patient. Long-term benefits for therapy are expected based on the scientific outcome of the registry data analysis.

## 6 Statistical Considerations

This is a national, multicenter, post-marketing registry, made on the basis of observations. The purpose of this registry is to evaluate the performance and clinical efficacy of a combination of



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SJM ablation products for the treatment of individuals with Atrial Fibrillation (AF), and to collect scientific data in a real-world setting. Up to 400 patients will be enrolled in this registry. As this is a post-marketing study, the sample size adopted was not calculated, however, the selected sample size (up to 400 patients) provides an adequate estimate forthe conclusions of the study. Long-term effectiveness as well as procedure efficiency data will be compiled (see section 2.2). Descriptive statistics will be performed to compare the impact of treated medical conditions and the combination of devices used in the procedure and follow-up of clinical evolution. Statistical tests will be applied to determine clinical significance as needed.

## 7 Data Management

Investigational data will be analyzed by SJM and may be transferred to any other regulatory authority worldwide in support of market approval.

The doctor must enter the information through an electronic database within 10 days of the visit.

## 8 Document Retention

The principal investigator should keep a copy of all documents (e.g., patient consent form) that make up this registry. Records must be kept in the files of the responsible researcher for at least 15 years after notification by SJM that all investigations are complete, completed or cancelled.

If the participating physician retires, changes, or for other reasons relinquishes responsibility for maintaining the study records, custody of the data must be transferred to another person who accepts responsibility. SJM must be notified in writing of the change in custody of these records.



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## 9 Amendments

This protocol, clinical records, patient consent terms, or other patient information or registration documents should be changed as necessary throughout the registry. A justification must be included in each changed section of a document. Protocol amendments and patient consent should be informed and approved by the Ethics Committees and regulatory authorities, if necessary. The version number and date of the changes should be documented.

## 10 Publishing policy

The investigator must strictly comply with the publication agreement related to this study.

SJM is the legal owner of the entire clinical trial database. Decisions on the timing and content of the publication(s) from the Registry will be coordinated by the SJM.



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**Appendix A: Data acquisition method**

Sponsors/Investigators are required to prepare and keep up to date an adequate case history in order to record all observations and other data pertinent to the investigation about each research participant. Source documents include all the original records from which the data from the clinical records are derived. Worksheets can be provided to assist investigators in collecting clinical experimental data and ensuring the collection of all data required for the protocol. These worksheets will not be copies of the clinical records, but should contain fields not filled out for data collection not performed by the investigators routinely. All documentation regarding clinical evaluations and medical evaluations must be signed and dated by the appropriate medical team. An electronic database will be used for this study.



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