Clinical Trial Report

☐ Yearly ☐ Final

Study title:

Start date: **Date of the conclusion:**

Responsible for the report: **CPF:**

Priority: **Status:** **(including / recruitment completed / completed)**

Protocol Code and Version:

Process Number (ID): **Office hour:**

Sponsor or equivalent:

CNPJ:

Special Announcement Date (CE):

Clinical trial design

Phase:

Centers:

Technical name of the medical device:

Proposed Use:

Number of arms:

Control: Yes / No **Masking:**

Allocation:

Reason for randomization:

Comparison:

Number of follow-ups (periods):

Statistical analysis Sample: **Purpose of statistical analysis:**

n for statistical analysis:

Purpose of the clinical trial:

Primary Objective of the Clinical Trial:

Duration of follow-up: (weeks/months/years)

Study duration: (weeks/months/years)

Vulnerable Population:

☐ Children ☐ Elderly ☐ women of childbearing age ☐ indigenous community

☐ Not applicable

Description of segments:

Recruitment speed: included/month

1. **Are any patients still participating in the study?** ( ) Yes ( ) No

2. **Are there any patients still being monitored?** ( ) Yes ( ) No

2.1. If so, are these patients allocated to a protocol extension study?

( ) Yes No

3. Are there any patients being monitored for survival analysis?

( ) Try ( ) No ( ) Not applicable

4. **Is inclusion open at any center?** ( ) Yes ( ) No

5. What was the date of inclusion of the first patient in the study?

No world:

In Brazil:

6. **Is there an extension to this protocol?** ( ) Yes Specify ( ) No

6.1. **Have CEP approvals been sent for the extension of the protocol?**

( ) Try ( ) No

center	Investigator Name Principal	CPF	Yes	No

7. **Was the study's masking code broken?** ( ) Yes ( ) No ( ) Not applicable

If so, specify patient and location; describe circumstances.

8. THE NUMBER OF VOLUNTEERS IN THE CLINICAL TRIAL

	Number of volunteers in Brazil	Number of volunteers in study	Extension (when applicable)
Planned Volunteers for the Study			
Volunteers randomized/included			
Volunteers discontinued (not include the failures of screening, deaths and loss to follow-up)			
Number of deaths			
Volunteers lost to follow-up			
Volunteers in follow-up			
Completed the study			

8.1. Was there loss to follow-up?
( ) Yes ( ) No ( ) Not applicable

Specify subject number, follow-up allocation and reason for loss.

Subject number	Tracking allocation	Reason for loss

9. Justify the withdrawal of each volunteer (discontinued)

10. Indicate whether any of the items below have occurred in the study since the last report:

10.1. Serious adverse events, unexpected serious adverse events, possible, probable or definitely related to the product(s) under test, occurring in Brazil

( ) Try ( ) No

10.2. **Protocol deviations** ( ) Yes No

Specify subject number, follow-up allocation and deviation.

Investigator's name, CPF	Identification of the research center	Research center location

Identification of Research Participant	Date of occurrence of the deviation	Visit	Description of the deviation	Action taken

10.3. **Protocol Violations** Specify ( ) Try ( ) No

subject number, follow-up allocation, and deviation.

Investigator's name, CPF	Research do center identification	Research center location

Research Participant Identification	On the occurrence of the violation	Visit	Description of the breach	Action taken

10.4. **Amendments to the protocol** ( ) Try ( ) No

10.5. **Change in the location of any center?** ( ) Yes No

Describe the change, if applicable ____________________________________

10.6. **Change of principal investigator?** ( ) Try ( ) No

Describe the change, if applicable ____________________________________

11. Since the last report has there been safety information reported to the centers?

( ) Try ( ) No

11.1. **If so, has this information been reported to the CEPs?** ( ) Yes ( ) No

12. **Since the last report, has any CEP terminated or suspended approval of any** ( ) No
center participating in this study? ( ) Try

13. **Since the last report, has any CEP imposed restrictions or sanctions on any center participant in this study?** ( ) Try ( ) No

14. Have any patients sought compensation for harm caused by this study?
( ) Try ( ) No

15. Did any center receive any complaints from patients regarding the conduct of the study?
( ) Try ( ) No

16. **Was there a change of zip code at any center in this study?** ( ) Yes ( ) No

17. **Was the study terminated prematurely?** ( ) Try ( ) No

18. **Were any centers prematurely terminated from the study?** ( ) Try ( ) No

If you answered “yes” to any of questions 10 to 19, provide a detailed explanation and any relevant documentation.

Import and distribution of products intended for clinical trials

LI number	Description and Quantity of imported products	Release date

Sending the product(s) under investigation to study centers

Institution Name	Products sent to center and their respective quantities	Send date

Frequency distribution of serious adverse events Related to the medical device under investigation or procedure and Expected

Description of the Adverse Event	Clinical evolution			
	Total of research subjects Recovered	Total of research subjects evolved to Death	Total of subjects of search with Sequela	Grand total by event type

Serious adverse events Related to the medical device under investigation or procedure and Not expected

Research Subject Number or Code	Event Description	Notification number	Cause of Adverse Event	Research Center Identification (Supporting institution; Name of the center)	Clinical Evolution

Serious adverse events NOT related to the investigational medical device or procedure

number or code Research subject	Event Description	Number of notification	Cause of Adverse Event	Identification of research Center (Institution maintainer; Name of center)	Clinical Evolution

Space reserved for comments, recommendations, observations, among others made by the data monitoring committee:

Report from the monitoring committee data	Sent by	Data

Data publication data (Name of the journal, title of the work, authors, volume, series, year, pages, publisher):

Demographics of the included population (Final report):
(characteristics, severity, race, age, baseline, sex, ...)

Conclusion of results according to the sponsor*: *Description of the results, inform *p* -value and confidence intervals for each result.

Statement of responsibility

I assume, civilly and criminally, full responsibility for the veracity of the information provided here.

Data

Name:

Sponsor:

Signature: **CNPJ:**

CPF: