SÃO RAFAEL	INFORMED CONSENT FORM	Dr. ANA VERENA MENDES Medical Director CREMEB 15976

PATIENT: **SERVICE:** **DATE:**

BIRTH: **AGE:** **GENDER:** **UNIT:** **HOSPITAL. PERIOD:**

INSURANCE: **PLAN:**

- GENERAL PROCEDURES - VASCULAR INTERVENTIONAL -

I hereby state that:

DIAGNOSIS AND TREATMENT

I was duly informed, in clear and objective language by the physician, that the assessments and exams performed revealed the following diagnostic change(s) and/or hypothesis(es):

DIAGNOSIS:

And based on this diagnosis, I was recommended the following treatment/procedure:

- GENERAL PROCEDURES - VASCULAR INTERVENTIONAL -

Details or additional procedures:
NO

LATERALITY: ☐ RIGHT ☐ LEFT ☐ BILATERAL ☐ NOT APPLICABLE

DESCRIPTION OF PROCEDURE

General vascular interventional procedures are techniques that aim to treat/cure diseases that interfere with the patient's hemodynamics, performed through the intervention of the physician, who can insert an orthosis/prothesis implant to improve vascular functioning and stabilize the patient's clinical condition. They can occur through conventional and also minimally invasive practices. Performing such invasive procedures is intended to improve the health status of a patient whose hemodynamics are compromised.

Other description of procedure:
NO

EXPECTED BENEFITS

Such support measures aim at achieving better clinical stability for the patient by reducing the use of drug therapy to control blood circulation and consequently improve their quality of life.

Other expected benefits:
NO

ALTERNATIVES AND POTENTIAL CONSEQUENCES OF NOT HAVING THE PROCEDURE PERFORMED

Alternatives to treatment must be discussed together with the responsible physician, according to the clinical picture presented to prevent the worsening of the patient's clinical condition.

Additional alternatives and consequences:
NO

POTENTIAL RISKS OF THE PROCEDURE

The decision to undergo surgery/procedure in the vast majority of cases is personal and patients themselves decide whether the benefits will be in line with their goals and whether the risks and potential complications are acceptable.
This procedure has the following risks:

- Intraoperative hemorrhages
- Cardiovascular diseases
- Anesthesia-related complications
- Anaphylactic shock
- Contrast-induced nephropathy
- Perforation of heart chamber or vessels
- Burns caused by the use of electrocautery
- Sensory and/or motor disorder
- Peripheral embolization
- Lower limb ischemia requiring revascularization, resulting in a high risk of amputation
- Hematomas or pseudoaneurysms/aneurysms at the puncture site with subsequent need for ultrasound-guided compression/surgical intervention
- Infections in the surgical wound/puncture site
- Hematomas
- Recurrence of the abnormality
- Death

I was informed that the catheters and prostheses used are subjected to prior tests, but may present defects or even suffer fractures, causing adverse reactions and injuries of varying order and degrees, which may even require surgery to remove them. However, such risks are less than 1%.
I am aware that, during the performance of the proposed procedure, the physician specialized in Hemodynamics and their team will be present, and the presence of other specialists may be requested, as well as observers from the manufacturer of the equipment and material used.
I am aware that minimally invasive procedures, for technical or patient-related reasons, may be converted to more conventional techniques, partially or completely, when the initially proposed technique proves to be unfeasible or of major risk.
Complications associated with this procedure/surgery, although uncommon or rare, range from simple injuries to more complicated injuries not described herein that may require follow-up in the intensive care unit after surgery.

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I understood that this procedure/surgery is one of the treatments of choice for the current clinical condition; however, it may not be the cure for such condition. I understood that there is no absolute guarantee about the results to be obtained, regardless of the type of surgery, good surgical and anesthetic technique and efficiency of medical care.
I am aware that, during the procedure, other unpredictable situations that have not yet been diagnosed or emergencies may occur that require changes to the proposed procedure.
I am aware that there may be a need for a blood transfusion.
I was informed about the possibility of experiencing pain during and after the procedure, and about the measures adopted by the institution to manage such pain.

Additional potential risks:
NO

REHABILITATION

I was informed that, after the surgery, I will be responsible for the use of medications, for attending follow-up appointments, and that I must strictly follow the healthcare guidelines provided by the team taking care of me. Financial investment will be required in medications, transportation to appointments and personal care. I also understand that psychological and emotional aspects are factors that can have an impact on the entire recovery process.
I am aware that the post-operative rehabilitation process is important for a good result and consists of a variable period defined by my physician based on the characteristics of my diagnosis and the procedure performed. The recovery period for patients undergoing treatment is very important and varies according to individual characteristics and the treatment received, and it is up to me to strictly follow medical recommendations for better post-surgical adaptation and recovery. The responsible physician has discussed and explained the rehabilitation guidelines.

Additional rehabilitation guidelines:
NO

AUTHORIZATION OF PATIENT OR RESPONSIBLE PERSON

On my own initiative, I accept taking the above-mentioned risks and give voluntary permission/authorization for the procedure(s) to be performed as set out in this form, including the procedures necessary to try to resolve the unpredictable and/or emergency situations, which must be conducted and resolved according to the unique convenience of each event.
This authorization is given to the physician identified below, as well as their assistant(s) and/or other professional(s) selected by the physician.
I authorize [ ] Yes [ ] No filming/taking photos of the surgical site (preserving the patient's identity), as well as the dissemination of said images for scientific purposes, without any financial burden, in the present or future.
I authorize the anatomopathological examination on materials that are removed during the procedure by a pathology laboratory associated with Hospital São Rafael S.A.
I had the opportunity to have all my questions answered regarding the procedure(s), after reading and understanding all the information herein, before signing this document. I was informed about the procedure(s) and associated risks, potential alternatives to the procedure, the consequences of not having the proposed examination/treatment/procedure performed and the problems that may occur during recovery.
After understanding the explanations I received, having all my questions answered and being fully satisfied with the information received, I reserve the right to revoke this consent before the procedure(s), the subject matter of this document, is performed.
I state that I have received instructions prior to the procedure.

Salvador,_____20 _____ _____:_____(hh:min)

_____ or _____

Patient Responsible Person

In case the patient is a minor or has a legally responsible person or cannot sign this document.

Representative / Legally Responsible Person:
ID:
Relationship:

STATEMENT OF PHYSICIAN

I CONFIRM that I have explained in detail to the patient and/or their family member(s), or responsible person(s), the purpose, benefits, risks, and alternatives for the treatment(s)/procedure(s) described above, answering the questions asked by them, and clarifying that the consent that is now granted and signed may be revoked at any time before the procedure. According to my understanding, the patient or their responsible person is able to understand what was informed.

SÃO RAFAEL	**INFORMED CONSENT FORM**	**Dr. ANA VERENA MENDES** **Medical Director** **CREMEB 15976**

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Salvador,