HeartMate 3™ Registry:

Evaluating the HeartMate 3™ with Full MagLev Technology in a Post-Market Approval Setting (ELEVATE™)

Informed Consent and Authorization for Use and Disclosure of Health Information

I. INTRODUCTION

I am being asked to extend my participation in a registry which involves collection of my information relating to my HeartMate 3 (HM3) implant and related treatment and follow-up care. This consent form will provide me with what I need to know to decide if I want to take part in this registry extension, including the purpose of this registry, the information that will be collected as part of this registry, and my role and rights as a participant of this registry. If I sign this form, I am agreeing that I would like to take part in this registry extension.

I have been implanted with the HM3 Left Ventricular Assist Device. The HM3 is a Thoratec LLC, an Abbott affiliate, device which has received CE Mark approval for commercial use.

II. PURPOSE OF REGISTRY

The purpose of the HM3 ELEVATE Post-Market Registry Extension is to collect long-term information about how I do after implantation. Abbott will use the registry to track post-market use and effectiveness of the product.

This is an observational registry, which means that my information will be collected and nothing new or different will be done with my care. I will be cared for like any other HeartMate 3 patient, regardless of whether I take part in this registry.

III. COLLECTION AND USE OF MY INFORMATION

My information will be collected for 3 additional years, for a total of 5 years, while I have the HM3 pump in place. My information will be collected during my routine visits to the hospital or clinic at 36, 48 and 60 months follow-up visits. During these visits I will have routine procedures and blood tests done. I will also be asked to fill out a quality of life questionnaire and complete a walk test. My information may also be collected if I am hospitalized or have any complications.

To help keep your medical file and personal information confidential, only certain authorized people will have access to your records. These include the researchers in your hospital who are part of this study, the Sponsor, its affiliates and representatives of Abbott that perform study-related services in the United States (U.S.), Europe and other countries, the regulatory authorities and/or the ethical committees, insofar as this relates to this study. The goal of this access is to follow-up on the study progress, to verify the study data and procedures, and to ensure that the information collected for this study is accurate. Your study doctor or one of his/her colleagues will supervise the access to your personal records.

Your personal data will be key-coded using a unique patient number before they are processed with the purpose not to permit your identification, except if necessary for the purpose of the trial or for regulatory obligations. Your coded study data will be processed manually as well as by computer and analyzed during and after the study.

Your coded personal data may be transferred outside of the European Economic Area, including to the U.S., for purposes that include, without limitation, processing, monitoring, auditing and control of the study or the conduct of inspections by the relevant authorities, medical product development, additional scientific analysis of the study data and obtaining approval to use and market medical products resulting from, or related to the study. Your coded study data may be transferred to other countries where data protection laws may not be as strict as in your own country. However, Abbott has taken security measures to ensure

your identity will not be disclosed.
You have a right to access your personal data and to have any justifiable corrections made. If you wish to do so, you should request this to your study doctor.
A description of this clinical trial is available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.
By signing the Patient Informed Consent form, you authorize the Sponsor to use the information obtained during the study for scientific communications and publications in medical journals without disclosing your name and any other information that could identify you. By signing, you also agree that your General Practitioner may be informed of your participation in this study unless you specifically request not to do so.

IV. RISK AND DISCOMFORTS

There may be some inconveniences associated with the registry as well, such as completing a quality of life questionnaire or completing a walk test.

V. BENEFITS

My entry into this registry and the collection of my information for this registry may increase what is known about the HeartMate 3 LVAD device, and its use and effectiveness.

VI. ALTERNATIVES TO PARTICIPATION

If I do not want to enter this registry, the care and treatment I receive will not change. I will receive the same treatment procedures, care, and follow-up visits as a HM3 patient, regardless of my participation in this registry.

VII. COST TO PATIENT/COMPENSATION

There are no additional costs for participating in this registry, nor will any payment or compensation be due to me for taking part in this registry. Standard medical treatment will be provided to me, and my treatment, benefits, or cost/coverage of treatment will not be impacted by my participation in the registry.

VIII. RESULTS AND LIABILITY

It is understood that nothing in this informed consent shall act to waive any of my legal rights or to release, (hospital)_____, Abbott, (physician)_____, or any of their agents from liability for negligence.

IX. QUESTIONS ABOUT PARTICIPATION

I know that a copy of this form will be given to me if I agree to extend my participation in the registry.

I know that taking part in this registry is voluntary and that I am free to refuse to participate, to withdraw consent for the use or disclosure of my personally identifiable information or stop taking part in this registry at any time without penalty or prejudice to my care. If I chose to withdraw my consent for the use or disclosure of my personally identifiable information I know that I must do so in writing to my doctor. My information that has already been sent to Abbott cannot be withdrawn. If I decide to withdraw my consent, I will contact Dr. _____ in writing and let him/her know that I am withdrawing my consent.

Any important new findings that may affect my willingness to take part in this registry will be given to me, as they become available.

I know that Dr. _____ and the medical center can be reached at _____ (phone #) or _____ (address).
I know they are willing to answer any questions I or my family or authorized representative may have during the registry. I also know that I may call the Ethics Committee at _____ if I need any more information about my rights as a registry subject.

X. PARTICIPANTS' RIGHTS

You have the right to request access to, correction of, destruction of, or to block your personal information. If you would like to make a request to exercise any of your rights mentioned above, you should direct these requests to your doctor or health care provider. There may be instances where requests for access, correction, destruction, or blocking cannot be allowed. Your doctor may stop your participation in the research study at any time, without your consent, for any reason. Additionally, the sponsor may stop the study at any time.

XI. PATIENT ACKNOWLEDGMENT

The purpose of this registry, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have additional questions. I understand that certain personally identifiable information will be collected as part of this registry and will be treated confidentially according to law. The information will be disclosed outside the hospital and will be transferred to the United States.

XII. DATA PROTECTION

The EU General Data Protection Regulation ("GDPR") applies since 25 May 2018. The GDPR amends and updates the rights you have in relation to your personal data, and what companies that process your personal data are permitted and required to do.

If you decide to take part in this study, your study doctor will collect personal data from you and/or your medical records. Personal data is defined as any information that identifies you or information from which you could be identified, and may include information such as your name, identification numbers, medical insurance numbers, your health information, and other information that may individually identify you. The GDPR emphasizes that all patient health information, such as the patient's weight, height, age, medical condition, treatment, dates of treatment, etc., are also considered personal data, even if it is hard to identify the patient with this information. If you decide to take part in this study, your medical records and personal data will be kept confidential to the extent allowed by European and local law.

For use in this clinical study your personal data will be key-coded using a unique patient number before it is processed so that only your hospital treating doctors and nurses can identify you. Only this key-coded personal data will be referred to below, when we talk about "personal data". To safeguard your rights The Sponsor will use the minimum amount of personally-identifiable information possible. Your names, identification numbers or medical insurance number will never be collected as part of this study.

If you decide to participate in the study, your personal data may be processed for the following reasons:

- Where there is a public interest to do so, such as for scientific research purposes; or
- Where it is necessary to protect one's vital interests, such as in relation to the provision of medical care.

The study Sponsor and others who work with the study, regulatory agencies, EC and Sponsor's representatives may inspect your medical records. Trained Sponsor representatives may assist doctors during the implant of the study device and help with technical support during the follow up study visits.

Your personal data may be used by the Sponsor in the following ways:

- To analyze and make conclusions about the study, make scientific presentations
- For reporting undesirable events to government health agencies
- For processing, monitoring, auditing and control of the study or the conduct of inspections by the relevant authorities
- To conduct new medical research study, to reanalyze the study results in the future or to combine your information with information from other studies

- To develop new medical products and procedures, and other product-development related activities
- To assist with submitting insurance claims and processing reimbursements requests
- For regulatory submissions for product approvals to government regulatory agencies (including those in other countries)

While using data in the above-mentioned ways, the Sponsor may give study data to its affiliated companies in the U.S. or other countries outside the European Economic Area ("EEA"), which do not offer the same level of data protection as required by the EEA. The Sponsor may also share the data with its research or business partners or companies it hires to provide study-related services. In order to safeguard your personal data, we will only make such transfers on the basis of (i) a decision of the European Commission that permits this, (ii) the EU-U.S. Privacy Shield or the Swiss-U.S. Privacy Shield, or (iii) subject to approved Standard Contractual Clauses to transfer your personal data from the EU to other countries, such as the United States.

Your personal data will be processed manually as well as by computer and analyzed during and after the study.
Information received during the study will not be used for any mailing lists or sold to anyone for marketing purposes.

With your signature at the bottom of this patient information and informed consent form, you permit the sponsor to use anonymized information obtained in the context of this study for scientific communications and publications in medical journals. Anonymized means without revealing your name or any other information which could be used to identify you. With your signature, you also consent to your primary care physician being informed of your participation in this study, unless you have expressly stated that you do not wish this.

Abbott will act as the data controller for this study. This means that Abbott is responsible for looking after your information and using it properly. Abbott will keep key-coded data about you for twenty five (25) years after the study has finished. After that the data will be deleted, unless this is opposed by legal retention obligations of the Sponsor.

A description of this clinical study will be available on https://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search the Web site at any time.

What rights do you have in relation to your personal data?
The GDPR requires the individual rights be provided to you in relation to your personal data. However, as a medical device company Abbott has a legitimate interest in using information relating to your health, when you agree to take part in a research study. Your rights to access, change, or move your information may be limited, as Abbott need to manage your information in specific ways in order for the research to be reliable and accurate.

The following rights in principle are available to you in relation to Abbott's processing of your personal data:
The right to request access, change or deletion of any personal data that Abbott holds about you;
The right to lodge a complaint with your national data protection supervisory authority or to receive compensation for any damage you suffer.

What happens if you don't provide us with your personal data? – Your personal data is needed for clinical research, to seek regulatory approval, for study reports or scientific presentations, or for future research. Any failure to provide such personal data will mean that you are unable to participate in the study. If you

choose not to participate in this clinical study, your personal data will not be collected or processed as part of this study.

Data Protection Officer ("DPO") – If you have any queries in relation to the processing of your personal data please contact your study doctor. If you wish to raise a complaint on how Abbott has handled your personal data, you can contact Abbott's Data Protection Officer ("DPO") who will investigate the matter. You can reach Abbott's EU DPO by email at eu_dpo@abbott.com or by post by heading your correspondence "EU DPO" and posting it to the following addresses:

Abbott GmbH & Co. KG
Max-Planck-Ring 2
65205 Wiesbaden
Germany

Abbott Labs Ltd
c/o Abbott House
Vanwall Business Park
Maidenhead
SL6 4XE
U.K.

Abbott AG
Neuhofstrassee 23
P.O. Box CH-6341 Baar
Switzerland

Data Protection Consent
I have read this consent form and agree to participate in this registry. I consent to the disclosure of my personal data to Abbott and the use of my personally identifiable information in the registry, as described within this consent form. I consent to the transfer of my data to Abbott and affiliates, with the understanding that I may withdraw my authorization to disclose my personally identifiable information at any time. I have been told that I will be given a signed copy of this consent form.

PATIENT:

_____
NAME (please print)

_____ _____
Signature Date

NAME OF THE PERSON OBTAINING CONSENT:

_____
NAME (please print)

_____ _____
Signature Date

If the participant is unable to give consent:
I have read and understood the patient information of above mentioned research study and all my questions have been answered. I agree that above mentioned patient agrees to participate in this study.

_____
Participant's Legal Representative NAME (please print)

_____ _____
Signature Date