PATIENT DATA RELEASE FORM
CoreValve Evolut R FORWARD study

INFORMATION SHEET

Dear patient,

You are invited to participate in a registry carried out by Medtronic Bakken Research Center BV entitled "***Corevalve Evolut R FORWARD***" (hereafter named FORWARD study).

Being in this study is voluntary. Before you decide to participate in this study, it is important that you understand why the study is done and what it will involve. Please read this form carefully and ask your doctor any questions you may have. If you decide to participate, you will sign and date the last page of this form for consent.

This study is a prospective, multi-center observational study for patients with aortic valve stenosis who are suitable for the Medtronic CoreValve™ Evolut R™ system (hereafter named Evolut R system). The Evolut R system is CE marked and is approved for use for standard care in patients who have severe aortic stenosis.

PURPOSE OF THE STUDY:

The purpose of this study is to document the clinical and device performance outcomes of the Evolut R system used in routine hospital practice.

You, and about 1000 other patients, worldwide, are invited to take part in this study. During this study, you will benefit from a medical follow-up and be treated as appropriate for your medical condition as if you were not participating in the study. The information obtained from your participation in this study may provide valuable information to assist future patients.

USE OF PERSONAL DATA/CONFIDENTIALITY:
Your participation in this study is entirely confidential.

While participating in this study, the following personal data will be collected: ,

- Identifying data (name, age, data on your ethnic origins).
- Medical and health data from your medical records.
- Information related to your condition (physical and neurological) and treatment.
- Information from your procedures, such as;
    - Multi-Slice Computed Tomography (MSCT) scan: an exam that uses X-ray to evaluate the anatomy of your heart and arteries.
    - Transthoracic echocardiogram (TTE): an exam that uses sound waves to take pictures of your heart and measure the degree of narrowing of your aortic valve; a probe is placed on the outside of your chest.
    - Electrocardiogram (ECG): an exam that records electrical impulses of your heart; patches are placed on the outside of your chest.
    - A physical and neurological (brain) exam where you will be asked to answer a series of questions. This exam will take approximately 15 minutes.

      (hereinafter called "personal data")

For this study, you will be seen at baseline (starting point), the day of your implant, prior to your discharge from the hospital and for follow-up visits at one month and after 1, 2 and 3 years and potentially up to 5 years after the implant. Your study doctor will schedule these visits with you.

Your personal data will be processed at all times in accordance with applicable legal requirements.

In general only the study doctor and/or nurse as well as the study monitor who acts on behalf of Medtronic have direct access to your personal data in your patient file. Furthermore it may happen, that members of the ethical committee and representatives of national, European or other international public authorities are granted direct access to your personal data in order to comply with legal requirements.

If necessary due to local laws, your personal data may also be transferred to public authorities, which are located in your country, in a member state of the European Economic Area but maybe also in a country where the European Directive on Data Protection does not apply.
< NOTE: The last sentence is only applicable to the patients who are located in Europe. If this template will be used for clinical studies outside Europe, this sentence needs to be adjusted according to the local law and needs local Legal approval>.

For conducting the study your personal data will be transferred to and processed by Medtronic (meaning the Medtronic Bakken Research Center BV. as well as all affiliates of this group of companies) or a third party designated by Medtronic - **but solely in a key coded form** -.
< NOTE: The last sentence is only applicable to the patients who are located in Europe. If this template will be used for clinical studies outside Europe, this sentence needs to be adjusted according to the local law and needs local Legal approval>.
This means that your data will be transferred to Medtronic or a third party designated by Medtronic which is located in your country, in a member state of the European Economic Area but maybe also in the United States or another country where the European Directive on Data Protection does not apply.

Medtronic may also use your personal data for additional purposes such as overseeing and improving the performance of its device, new medical research, developing new medical products or procedures, and other business purposes.

You are entitled to access the personal data collected about you and to have inaccuracies corrected.

Any published information including reports and articles about the study will not include your name or any information that could personally identify you. Information received during the study will not be used to market to you; your name will not be placed on any mailing lists or sold to anyone for marketing purposes.

You may change your mind and take back this permission to continue collecting your personal data at any time. To take back this permission, you will need to write to [insert name and contact information]. However, if you take back this permission, you will no longer be a participant in the study. All of your personal data that was already collected will still be used. [Add this for Europe: ,unless you object and ask for deletion of the data.]

[Use for outside Europe:
Even after your participation in the study ends, your health information cannot be removed from the study data and Authorized Personnel may continue to use and disclose the personal data they obtained during the study as described in this consent form.]

If you agree upon, your personal physician will be informed about your participation in the study.

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SIGNATURE SHEET

I have read the patient information of this study and my physician has answered all my questions regarding the study.

I had sufficient time to consider my participation into this study, I am aware that participation into this study is completely voluntary, and I agree to follow the instructions from the study doctor.

I realize that I may decide to refuse participation or stop participation at any time without penalty and without affecting the quality of my health care or the relationship with my physician.

I understand and agree that personal data about me will be collected and used for the purpose of the study. For conducting the study these data will be transferred to and processed by Medtronic or third parties designated by Medtronic as described in the section “use of personal data/confidentiality”.

I understand and agree that representatives from Medtronic, regulatory authorities and the Ethics Committee representatives will be granted direct access to my medical records.

I understand and agree that the physician(s)/hospital will release the relevant personal information about me for the purpose of this study.

I understand that I am entitled to access the personal information collected about me and to have inaccuracies corrected.

I agree to participate voluntarily in and comply with this study.
I understand that I will receive a dated and signed copy of the Patient Informed Consent Form.

You may agree or disagree that your personal physician is informed on your participation in this study.
Please, check one option below indicating your choice:

! must be checked by patient

☐ I agree that my personal physician is informed about my participation in this study.
☐ I disagree that my personal physician is informed about my participation in this study.

Patient:

Name	Signature **! must be written by patient**	Date (dd MMM yyyy) **! must be written by patient**

Study doctor or designated person by study doctor:

! Only study doctors officially trained and authorized on the delegated task list are allowed to sign off

I have conducted the informed consent discussion.

Name	Signature	Date (dd MMM yyyy)

If patient is **unable to read**:

I have attended the entire informed consent discussion. I attest that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the. Informed consent was freely given by the patient.

Impartial Witness:

Name	Signature **! must be written by Impartial Witness**	Date (dd MMM yyyy) **! must be written by Impartial Witness**