Patient Information and Declaration of Consent for the Use of the BIOTRONIK Home Monitoring® Service and ReportShare

Dear Patient,

Please ask your physician to explain any wording or information that you do not clearly understand in this Patient Information and Declaration of Consent form.

You have received a BIOTRONIK (BIOTRONIK SE & Co. KG, Woermannkehre 1, 12359 Berlin, Germany) pacemaker, defibrillator, or implantable cardiac monitor as a result of your cardiac condition. This device is capable of analyzing your heart's rhythm and sensing abnormal heart rhythms on a regular basis. Your implanted device also saves information regarding its functional capacity as well as your heart rhythm. In addition, pacemakers and defibrillators are also able to treat any abnormal rhythms if necessary. Regular follow-ups are necessary to check the proper function of your implanted device. At these follow-ups, a programmer and a programming head are used to painlessly communicate with your implanted device, conduct tests, and retrieve and print out information that has been stored in the device over a period of time. If necessary, setting changes may be made to your implanted device.

You have been implanted with a pacemaker, defibrillator, or implantable cardiac monitor which – in addition to its basic functions – is able to monitor certain functional parameters and your heart rhythm remotely. This remote monitoring function is called BIOTRONIK Home Monitoring®. Using a special device called CardioMessenger® that you receive from your physician, your implanted device can automatically transmit certain information it has stored via the cellular telephone network. This data is transmitted either daily or when certain events occur, as previously specified by your physician. In certain cases an additional transmission of data can be triggered by your physician via the BIOTRONIK Home Monitoring Service Center.
BIOTRONIK Home Monitoring may be used to replace some routine in-clinic follow-up sessions. The system may also help your physician better evaluate your health status and/or the technical status of the implanted device at times between your regularly scheduled in-clinic visits. Early detection of certain events due to information transmitted via BIOTRONIK Home Monitoring could also result in additional in-clinic follow-ups at the direction of your physician.

With BIOTRONIK Home Monitoring, medical and technical data is sent from the implanted device to the CardioMessenger. This data is then forwarded to the BIOTRONIK Home Monitoring Service Center via the cellular telephone network, where the data is automatically processed and displayed in a concise report. Subsequently, the physician who monitors your implanted device can review this data from the Home Monitoring Service Center website. In the event of medical abnormalities, the physician can also be notified. Once the data reaches the physician, the information transmitted via BIOTRONIK Home Monitoring Service enables your physician to better monitor your heart rhythm and the functional capacity of your pacemaker, defibrillator, or implantable cardiac monitor without waiting for the next routine follow-up, which could be scheduled weeks or even months into the future. Data is sent to the Home Monitoring Service Center in an encrypted form. The data is not permanently stored in the CardioMessenger. Confidentiality of your data is maintained at all times. The type and frequency of data transmitted will be determined by your physician and may depend upon your unique medical condition. Finally, not all data regarding your implanted device will be transmitted automatically on a daily basis.

Please note the following important information:

- The attending physician can only evaluate your data and contact you, if necessary, during consultation hours.

- The attending physician will use the information solely to support your treatment.

- Using BIOTRONIK Home Monitoring, your physician can prolong the time intervals between in-person follow-ups considerably (up to one year).

- If follow-ups are required for other medical reasons, they must take place. Please consult your physician on this matter.

- In particular, the BIOTRONIK Home Monitoring Service is not an emergency information system. In the event of an emergency or in case of any type of medical complaints, you should immediately seek medical care and go to the available medical facilities.

Use of the BIOTRONIK Home Monitoring Service is subject to the following conditions:

- The functional capacity of the BIOTRONIK Home Monitoring Service depends on the cellular telephone network coverage in the area where you reside as well as on the flawless operation of the information processing components and other participants. Neither BIOTRONIK nor the attending physician can be held responsible for missing coverage, disturbances regarding the cellular telephone network, or data transmission and processing.

- The functionality of the CardioMessenger will be explained to you by your physician. The availability of data is dependent on the proper functioning and operation of the CardioMessenger. BIOTRONIK cannot be held responsible for improper handling of the device.

- Your BIOTRONIK Home Monitoring data is only displayed to your physician with a working Internet connection. BIOTRONIK cannot be held responsible for any problems with your physician's Internet access. In addition, BIOTRONIK is not liable for any disturbances with the transmission of notifications in the event of medical abnormalities.

- The medical handling of the BIOTRONIK Home Monitoring data sent to your physician is subject to his or her professional responsibility and cannot be attributed to BIOTRONIK.

In addition to the data obtained via Home Monitoring, cardiological and technical data of your pacemaker, defibrillator, or implantable cardiac monitor can be retrieved using the programmer during the follow-ups with your attending physician and transmitted to the BIOTRONIK Home Monitoring Service Center. This feature is called ReportShare. The process described for data transmission, storage, protection, and retrieval from the Home Monitoring Service Center applies to the same extent to the use of ReportShare. Confidentiality of your data stored on the programmer will be ensured by your attending physician/clinic.

This information is an explanatory note for the functional requirements of the BIOTRONIK Home Monitoring Service and the ReportShare feature. The medical personnel in charge of your care will explain this general information as it relates to your personal situation.

I declare that the function, the functional limitations, and the requirements for use of the BIOTRONIK Home Monitoring® Service and the ReportShare feature have been clearly explained to me and that any and all questions that I have asked were answered in a satisfactory manner.

I would like to take advantage of the BIOTRONIK ReportShare system and the BIOTRONIK Home Monitoring Service. I obligate myself to take good care of the CardioMessenger which was given to me. My physician can decide at any time to end BIOTRONIK Home Monitoring or ReportShare or both systems.

I am aware that I can terminate my participation in BIOTRONIK Home Monitoring and/or ReportShare at any time. For this purpose I only have to revoke this declaration of consent with my physician. An oral revocation is sufficient. I understand that my physician cannot use the respective services for diagnosis and assessment any more after I revoked this declaration.

Remarks:

Created on _____ in two copies, one of which was handed over to the patient.

_____ _____

Name of Patient Name of Physician

_____ _____

Date and Signature of Patient Date and Signature of Physician

_____

Signature of Legal Representative (if required)